Jorge Mario Martínez-Piva
Editor

Knowledge Generation and Protection

Intellectual Property, Innovation and Economic Development

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Foreword

This book is the English version of the text published by the Economic Commission for Latin America and the Caribbean in April 2008 and entitled *Generación y protección del conocimiento: propiedad intelectual, innovación y desarrollo económico.*[1]

Since then, the year that has passed has been fraught with uncertainty but has also brought signs of hope.

Indeed, the past year was marked by the outbreak of the deepest and most pervasive financial and economic crisis since the Great Depression of 1929, a crisis generated in the United States but whose negative repercussions have spread at a phenomenal rate throughout the planet. The impact of this crisis on the peoples of Latin America and the Caribbean will undermine the region's prospects for economic growth, employment, and poverty alleviation.

This was the year in which United States citizens elected Barack Obama as their President, a clear sign of new hope. This hope was tangible at the Fifth Summit of the Americas, held in 2009 in Port of Spain, which marked a turning point in the relations between the countries that make up this hemisphere. The open posture of the United States and that country's readiness to listen rather than to impose any particular position and its willingness to engage in dialogue on an equal footing were positive signs. Moreover, it was generally admitted that there is not just one model for advancing successfully toward development.

Both of these developments are of great significance, bearing in mind that negotiations are now taking place with a view to the signing of free trade agreements between the United States and various Latin American countries. Intellectual property is known to be one of the most crucial and controversial issues in the negotiation of these treaties.

Knowledge is a major engine of economic growth in today's world and will play an increasingly vital role in ensuring the prosperity and well-being of nations. How can developing nations obtain access to, and ownership of, accumulated knowledge? What are the first steps to be taken on the long path toward the construction of the very bases of knowledge generation in the pursuit of higher levels of development?

[1] LC/MEX/G.12.

These are some of the questions that ECLAC has been considering in its study of intellectual property and knowledge generation for growth. The numerous workshops and seminars held by the Commission attest to its concern for these topics, which are also dealt with in the background document for the 19th Ibero-American Summit of Heads of State and Government, to be held in Portugal during 2009.

ECLAC wishes to take this opportunity to express publicly its deep appreciation to the Canadian International Development Agency for the support and collaboration that it has provided over the years to ECLAC in this area, which is so crucial for the development of Latin America.

Alicia Barcena
Executive Secretary of ECLAC

Preface

Technological change is increasingly the path by which countries leave their peripheral condition. A profound understanding of the dynamics and contemporary mechanisms for the circulation, dissemination, and access to knowledge is therefore imperative.

The capacity to generate research, create knowledge, adapt to it, and transform it into new technologies is fundamental to the wealth of the developed nations, and largely explains their economic growth. In this regard, analysis and debate about how to generate knowledge and technological innovation is a subject of major importance for the developing countries.

The way in which economies create and use knowledge and innovation is increasingly relevant. It requires efficient national innovation systems in constant renewal to strengthen the innovative capacities of less developed countries and thus create opportunities for convergence with the developed countries. These systems must be sufficiently versatile in their use of all the available tools, among them, the incentives and flexibilities of intellectual property laws. In national innovation systems, the weight of intellectual property is always on the increase, especially in open economies with a strong external sector. It is therefore necessary to take advantage of the opportunities that these rules offer and use their versatility to promote national innovation policies and adapt them to the type of innovation to be promoted.

Since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into force in 1995 the architecture of intellectual property rights has become more and more complex. The protection mechanism for intellectual property, in its diverse forms, shows two important elements: on the one hand, it is a mechanism of appropriation of income that generates monopolistic or quasi-monopolistic gains for those who hold it, and on the other hand, there is an economic incentive to research since it offers inventors repayments for the investments made until their innovation becomes a market product. Nevertheless, there is concern that the intellectual property of innovations work more as incentives for the protection of rents than incentives for innovation, which is contrary to the desired effect.

Three intersecting subjects with diverse emphases are studied in this book. First, whether strengthening protection of intellectual property stimulates or hinders technological learning and innovation in developing countries. The second subject treats

the way in which knowledge is generated and how it is transformed into useful technology for markets, that is to say, how national innovation systems work. The final topic is the role of public policy as an instrument for innovation and for regulation of intellectual property.

The political economy of the systems of intellectual property involves the interests of powerful groups related to the chemical and pharmaceutical industries, biotechnology, software, and entertainment. These groups have endorsed free trade agreements promoted by the United States, which have been signed by several Latin American countries. Both factors have strengthened the rules of intellectual property in the agreements, which have been monitored ever more jealously by the United States.

If Latin American countries seek to develop a dynamic competitiveness based on knowledge and innovation in a context of rigorous intellectual property rights like the present one, they will have to take a leap forward in their science and technology policies to generate processes and products of greater value added, move up in the technological scale, and improve workers' income. In short, active public policies in science and technology are required to take advantage of the increasing worldwide market and to open paths for long-term development.

ECLAC, Mexico City, Mexico Jorge Mario Martínez-Piva

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I am also grateful to the authors of the different chapters that appear in this book: Mario Cimoli, Álvaro Díaz, and Annalisa Primi, who were colleagues at ECLAC at the time of contributing to the book; as well as invited experts Jorge Amigo Castañeda, Jorge Cabrera, Gabriela Dutrénit, María Fabiana Jorge, Andrés Moncayo, César Morales, Pedro Roffe, and Daniel Villavicencio. My appreciation also to my colleagues and experts who made valuable comments on earlier versions of this work, specially to João Carlos Ferraz, Director of the Division of Production, Productivity and Management at the time of preparation of this volume. This publication is also the result of the technical and administrative support of Cristina Gil Escribano, de Marie-Laure Maertens, Monica Rangel, and Samuel Romanowsky to whom I am very grateful.

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Introduction

"For to him who has will more be given, and he will have abundance; but from him who has not, even what he has will be taken away." (Matthew 13, 12). This controversial Biblical text illustrates what Economics Nobel Prize Winner Gunnar Myrdal, called the principle of circular and cumulative causation. According to this principle, growth and economic development take place through interrelations among variables which tend to create an accumulative process, which, if this involves variables that promote development, strengthen it, and give it impetus, but if not they promote its stagnation. The concept is useful in understanding the importance of knowledge and technological capabilities in economic development.

Knowledge incorporated as a proportion of the total value of a product is increasing by the day in all sectors. The capacity to generate knowledge, appropriate it, and transform it into new technologies lies at the root of the wealth of the most developed nations and largely explains their economic growth.

Development researchers agree that technical change, the introduction of new products and processes, the capacity to respond and to open up new market niches are determining factors in the patterns of growth and development of economies. In a context of growing trade openness and therefore of increasing exposure to international competition, response capacity is a determining factor for economic success.

The relationship between the technological capability and the capacity to compete successfully in global markets further explains countries' development potential. The richest nations transform their production systems into more intricate, interlinked, and technology-intensive frameworks. These are the nations that invest more in generation of knowledge and technology, which in turn transforms into greater capacities for technological progress and international competition, that is to say, they live a virtuous circular and cumulative causation process.

This process of accumulation of technical capabilities tends to advance in parallel with a process of change of international rules on the appropriation of the income generated by innovations and the protection of their property over third parties. Intellectual property laws strengthen the means whereby the most developed nations generate large part of their wealth, for they constitute a system that regulates and protects income stemming from innovations while at the same time limiting competition.

If the evolution of production systems toward more complex structures determines the processes of convergence between regions and countries, then Mario Cimoli and Annalisa Primi appear to be right by affirming in this book that technical change seems increasingly to be the road for transition from a condition on the periphery to a position of leadership in the world's economies. Hence a deep understanding of the dynamics and contemporary mechanisms of the circulation and dissemination of and access to knowledge is an urgent task.

The aim of this book is, on the one hand, to go more deeply into the analysis of the interrelations between generation, access to and dissemination of knowledge, and technological innovation as the foundations of economic development and, on the other hand, to analyze their international regulations. That is, it delves further into the study of the linkage between innovation processes, mechanisms for protection of intellectual property rights, and economic development.

Three themes run across the book with different emphases. The first refers to the increase in protection of intellectual property and whether this is in detriment to or encourages technological learning and innovation in the developing countries. The second is the way in which knowledge is generated and how it is transformed into useful technology for the market, that is to say, the functioning of national innovation systems. The third is the role of public policy as an instrument of innovation and as an instrument of regulation of intellectual property.

Since the rules for protection of intellectual property embrace a wide variety of subjects and their recent evolution suggests that the protected subject matters will increase over time, it was not possible to cover all the topics protected under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Instead, we chose relevant topics that serve the object of the book, divided into four thematic areas.

Part I is an analytical approach to the topic of intellectual property rights from an economic rather than juridical point of view, as is usually the case. Two articles analyze intellectual property rights as mechanisms for appropriation of income and incentives for research, and the recent evolution of the patents system until such patents become assets in themselves.

Intellectual property as a form of protection of innovation shows two important aspects: it is a mechanism of income appropriation that generates monopolistic or quasi-monopolistic earnings for the holders, but it is also an economic incentive to research by compensating the innovator for the investments made until the innovation becomes a market product. Economic analysis shows that this mechanism, although conceived to encourage innovation, can stand as a barrier to the entry of other innovators and as an instrument to preserve monopolies, resulting more as an obstacle than as an incentive to innovation.

The recent evolution and transformation undergone by the system of protection of intellectual property are illustrated by an analysis of patents. Conceived as a mechanism of ex post appropriation of income, patents have become assets in themselves whose value tends to lose its linkage to a certain extent from the innovations that sustain them, becoming "liquid" assets with their own value in terms of expectations on their value and their "liquidity" in the corporate transactions market.

In the new markets, patents take on a value irrespective of their direct industrial application. Thus, they increasingly act as decisive assets in the settling of legal disputes and play an important role in mergers and acquisitions between corporations, influencing market structure, and the organizational hierarchy. Patents respond more to defensive and competitive conducts. Thus, their rationale is being displaced toward markets that operate under different logics and incentives. In the knowledge markets, the value of future bets and the search for *exhrante* income become determining factors for seeking protection by means of patents.

Another contribution addresses the linkage between innovation processes – How is knowledge generated and what public policies promote it? – and the mechanism for protection of intellectual property. In this regard, it analyzes two economic policies closely linked to local economic development and to the processes of protection of intellectual property: local endogenous development and the attraction of foreign direct investment.

The second part of the book addresses the topic of intellectual property within the purview of recent bilateral trade agreements and multilateral treaties on the subject and analyzes how the trade agreements between the United States and Latin American countries have strengthened protection of intellectual property.

The architecture of intellectual property rights has become complex, especially following the entry into force of TRIPS in 1995. Intellectual property rights currently constitute an essential chapter in bilateral and regional trade negotiations. The recent agreements concluded by the European Union and the United States include specific chapters on the subject, which in many cases broaden the rights and obligations of TRIPS, for which reason they are considered TRIPS Plus.

Moreover, harmonization exercises with regard to intellectual property are being explored in different fora, such as the World Intellectual Property Organization and specialized fora on rights and instruments of access to genetic resources, their conservation and the equitable share of benefits, such as the Convention on Biological Diversity and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

For over two decades, the United States has shown constant concern over protection of intellectual property, which has recently been accentuated. At the domestic level, this country has increased its protection standards and has continued to monitor observance of intellectual property rights internationally and has gone as far as considering, through the Trade Act, the possibility of imposing trade sanctions on countries that systematically breach the US intellectual property rights holders.

It should be recalled that the United States was the promoter of the first multilateral industrial property protection treaty (Paris Convention of 1883) and played a preponderant role in including the topic in the Uruguay Round, which culminated in the creation of TRIPS. NAFTA (North American Free Trade Agreement) was the first post-TRIPS agreement with stricter provisions on the issue, characteristics which were followed in other bilateral agreements.

The Free Trade Agreement between Chile and the United States includes a chapter on intellectual property, following the guidelines set down by prior free trade agreements signed by the United States, and has served as a model for agreements

this country has negotiated with other countries of the region (DR-CAFTA and those signed with Colombia, Panama, and Peru). Likewise, the pattern of the chapter on intellectual property is reproduced and expanded in subsequent agreements, as was the case of the agreements between the United States and Australia, Bahrain, Morocco, and Oman. For this reason a study was made of the central aspects of the most recent bilateral agreements signed by the United States, taking the Agreement with Chile as a model.

The second part includes analyses of feasible spaces for the Latin American countries to develop their public policies on science and technology. A common matter in this part is that the impact of the intellectual property rights agreed on depends on the public policies implemented *before and after* their entry into effect. The authors develop the view that a new generation of public policies and post-neoliberal or post-Washington-consensus regulations could obtain important benefits and minimize the negative impacts of trade agreements. The trade agreements with the United States are not incompatible with an increase in the public sector's presence in social policies, the expansion of public policies in innovation and technological development, an increase in economic regulations in consumer rights, competition, workers' rights, and environmental protection. Furthermore, the agreements do not stand in the way of integration of the Latin American subcontinent in a perspective of *open regionalism.*

The third part includes articles on particularly sensitive topics for developing countries: access to medicines and protection of biological diversity, living organisms, and traditional knowledge. The debate on intellectual property is based on broad considerations regarding the role of these rights in the dissemination of innovations and knowledge as agents of development. Many discussions revolve around the consequences that stringent intellectual property rights have in the use of technology and access to basic instruments of education (data bases and software, among others) and health care. Until not very long ago many countries exempted pharmaceutical and food products from the possibility of being patented. Recent trade agreements include them in the chapter on intellectual property. The effect of these agreements on access to medicines is analyzed in this third part.

In recent years the discussion on intellectual property has linked the topic to the environmental agendas. Most of the authors and organizations that discuss it consider the effects that intellectual property rights could have on biodiversity and indigenous and rural communities. The arguments range from the danger of fostering bio-piracy on resources and traditional knowledge, to restrictions on farmer keeping and exchanging seeds of protected varieties, including the implications of genetically altered organisms.

As a result of the establishment of an international legal framework by the Convention on Biological Diversity and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, insistence has been placed on the existence of a conflict between certain trends oriented to the strengthening of intellectual property rights and the objectives of conserving, utilizing biodiversity in a sustainable manner and equitably sharing the benefits derived from the use of genetic resources. One chapter in this book studies whether the implementation of

TRIPS leaves room for appropriate synergies between trade obligations with regard to intellectual property rights and those of international environmental treaties.

Also examined are the situation and prospects of intellectual protection of living organisms. This is a complex topic on which there are markedly different positions between developed and developing countries, companies linked to genetic engineering, universities and academic bodies, and development agencies. The interests of the holders of the technologies to commercially develop altered organisms tend to differ from the interests of those who possess the biodiversity. This conflict is analyzed in the light of the evolution of international law and its consequences for the development and protection of living organisms.

The fourth and final part of the book is devoted to the policy of innovation and protection of intellectual property in Mexico. The information may be useful not only for this country but also for the rest of the countries of Latin America. Mexico is the only Latin American country that is a member of the OECD and has a rich history of industrial policy, science and technology policy, and trade openness. This chapter analyzes the policy of protection of intellectual policy and the actions of the Mexican State to strengthen innovation capacities and companies' adaptation to the process of international integration initiated over a decade ago.

Mexico's science and technology policies began to change in the early 1990s, when the country entered international markets. The change was marked by the transition from the supply-side approach based on support for science toward a market approach oriented to fostering private-sector innovation. As of 2000 this change intensified and in recent years an innovation policy has clearly emerged which includes a series of instruments, following international experiences (Brazil, Chile, and the Organisation for Economic Cooperation and Development, OECD).

The results, however, have not been those expected so far, as the intensity of research and development (currently 0.4% of GDP) has not increased since the 1990s, low private-sector participation in overall spending on research persists, the country's competitive position dropped from 33 in 2000 to 56 in 2004 (according to the International Institute for Management Development), and in general the innovative behavior of the stakeholders is poor. Many academics, industrialists, and members of civil society perceive that no substantial changes have taken place in the field, nor in national technological capabilities.

Theoretical discussion of the approaches to and premises of Mexico's science, technology, and innovation policies is enriched by an empirical performance analysis of some of the instruments employed. The source of information corresponds to national statistics on such instruments and the national innovation survey.

Another contribution studies the evolution of Mexico's industrial and technological development policies during the import substitution period, the transition that began in the 1980s and the period of trade liberalization. In regard to the latter period, it sets forth the main characteristics of the general scheme to foster industrial and technological development and analyzes the functioning of the institutions, programs, and mechanisms implemented as of the amendments to the Law on Science and Technology.

This part ends with a review of the functioning of the Mexican Industrial Property Institute (IMPI by its Spanish acronym) and its work in the registration, protection, and promotion of intellectual property. IMPI has created novel programs such as patenting centers in various cities of the country, and the creation of a portal on patents in the public domain that provides access to technical information contained in patent documents (requests for patents published and patents granted), including information on patenting costs and plans for creating funds to support small and medium-sized enterprises under these headings.

By way of conclusion, the main findings and suggestions of the studies are collected. The topics currently under discussion are identified, as are the countries' technological and innovation capacities and they are linked to sustainable economic growth and well-being. The linkage between the forms of protection of intellectual property and promotion of innovation is also pointed out, identifying possible lessons for the developing countries.

ECLAC coordinated the different articles collected in this book within the framework of a program of creation of trade capacities which had the financial support of the Canadian International Development Agency. It is hoped that this book will be a useful contribution to informed debate on increasingly important issues for economic development and that it will serve the designers of economic, trade, and innovation policy in shaping a joint development agenda.

Part I
Intellectual Property Today: Appropriability, Innovation and Public Policy

Chapter 1
Intellectual Property and Development: An Interpretation of the (*NEW*) Markets for Knowledge

Mario Cimoli and Annalisa Primi

1.1 Introduction

Patenting activity has intensified in the last few decades. Year after year, patent offices receive a growing number of applications and grant more patents. This growth is registered on a global scale, and despite the fact that the leading economies in technological capacities are those that show the greatest growth, the activity has also intensified in emerging economies and developing countries.[1] However, certain stability persists in terms of dominant stakeholders. Today, the United States, Germany, and Japan account for 80% of the patents issued by the United States Patent and Trademark Office (USPTO),[2] which, together with the offices of the European Union and Japan, continues to be the world's most important patent office.

However, considering the total number of patents granted in the United States to non-residents we note that in the 1960s the three main countries were Germany, England, and France, which accounted for 58.8% of total patents issued to non-residents, whereas in 2003 the three main stakeholders became Japan, Germany, and the Chinese province of Taiwan, which together possess 67.3% of that total. Now, if we consider the cumulative share of the five countries with the largest number of patents issued, the degree of concentration goes from 73.8 to 75.5%, and England, Switzerland, and Canada yield their places to Japan, the Chinese province of Taiwan, and the Republic of Korea. This "overtaking" is not alien to the structural changes experienced by these countries, which in the last few decades have radically transformed their production structures by intensifying their specialization

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in knowledge-intensive sectors (Amsden, 1989; Wade, 1990; Jomo, 1997; Cimoli et al., 2005). The combination of – active and selective – industrial, technological, and trade policies supporting the industrial sector and the gradual opening up to foreign trade as the productive sectors achieved international competitiveness have generated technological, and productive capacities, explaining the intensification of patenting activity. This responds to a logic in which the production system, once transformed into a generator and disseminator of knowledge, needs patents to appropriate the income stemming from innovative effort. Moreover, it also responds to the most recent pressures in world trade forums in favor of increasing homogeneous standards of intellectual property protection.

What is in fact happening is a reconfiguration of the stakeholders aspiring to participate in the markets for technology and knowledge that exert pressure on the dominant positions of traditional players. The emergence of new players – notably the countries of Southeast Asia, China, India, Brazil, and South Africa – which aim or could aim to develop on the basis of technology and engineering-intensive sectors, and the growing integration of economies, nourish the debate on international protection of intellectual property from different perspectives. Understanding the changes in patenting dynamics is a determining factor in proposing strategies for convergence and development in the contemporary context.

The current debate on intellectual property protection takes place in a scenario of open economies in which changes in scientific and technological patterns pose challenges to those systems, both in terms of their capacity to guarantee appropriability and in terms of their function to encourage or discourage innovation. With the new technological paradigms, new sectors with diverse returns and logics emerge; in these paradigms many advances derive from multiple complementarities and innovation is more and more incremental. In this context, the intensification of patenting, the new institutional framework for intellectual property management, the stance of the United States jurisprudence in favor of protection of intellectual property, the marginalization of multilateralism, the proliferation of trade agreements, and the conditioned and not always proactive attitude of the developing countries bring about a situation in which the role of systems for the protection of intellectual property has been completely reconfigured.

The logic and rationale for patenting have changed. In addition to the traditional concept of patents as mechanisms for appropriability of income stemming from investment in research and development, and as incentives for efficiency in the technology markets, there are new dynamics from which the new markets for knowledge derive. Among them we can identify, first of all, the market for science, in which universities and research institutes patent innovations deriving from basic and experimental research. Second, we can recognize what we call "the liquid and derivative markets for knowledge," in which the traditional concept of patents as mechanisms for appropriability is overcome. Patents are reconfigured as strategic assets of companies' competitive strategies. Patents are "monetized" and their benefits no longer depend on the temporary monopoly of the innovation alone, but can derive, for example, from the strengthening of negotiating power among corporations, or from

the (potential) future appropriability of oligopolistic rents generated by other companies, when the patent or group of patents become determining factors for the production of some good or tangible service in the future. The logic of patenting seems thus to become unlinked from the immediate incorporation of knowledge (of the "intangible") into "tangible" production, thus generating new markets and new challenges. How do the developing countries and those of Latin America in particular participate in those markets? What effect can that reconfiguration of markets for knowledge have on the creation of endogenous technological capacities and on convergence over the long term?

In order to answer these questions, this chapter presents an interpretation of the knowledge markets which goes beyond the traditional view of patents. First of all, it makes a brief review of the role of intellectual property rights in general, and of patents in particular, as mechanisms of appropriability; second, it outlines the main characteristics of the changes in the management and in the institutional framework of intellectual property systems throughout the world. Third, it analyzes the rationale and functioning of the markets for technology and the markets for knowledge. Then, the chapter examines the relationship between participation in those markets, the production structure specialization, and the dynamics of patenting from the perspective of the developing countries in general and the Latin American countries in particular. The conclusions highlight that understanding the new dynamics that nourish the patenting game and the factors that determine the (potential) participation in or exclusion from the markets for knowledge is a task that cannot be postponed when it comes to proposing long-term development strategies based on innovation that goes beyond rhetoric and good intentions.

1.2 Intellectual Property, Appropriability, and Enforcement

Intellectual property regimes include the set of rules, regulations, procedures, and institutions regulating appropriability, transfer, access, and right to use knowledge and "intangibles."[3] Intellectual property rights confer an exclusive and – in certain cases, such as patents and copyright – temporary right on the use and transfer of technologies and knowledge.[4] Thus, patents create temporary monopolies on knowledge which respond, in principle, to the tension between the need to guarantee appropriability of innovation efforts as "intangible" which, in their absence, could be easily appropriated by competitors, and the need to favor the disclosure of knowledge and innovations owing to the multiplier effect of innovation in the whole economic system (Machlup, 1958; Kitch, 1977; Besen and Raskind, 1991; Besen, 1998, among others). However, there is a certain gap between the theory and the functioning of the system. The relationship between innovation and patents is neither determinist nor linear, and the discussion on the appropriability of knowledge and its effects on the rate and direction of technical change continues to be open in the economic literature (Machlup and Penrose, 1950; Arrow, 1962; Scherer, 1977; Dosi, 1982; David, 1993; Heller and Eisenberg, 1998; Mazzoleni and Nelson, 1998).[5]

First of all, patents are not the only mechanism for the appropriability of income stemming from innovation. The pioneering empirical studies on the propensity to patent of innovations are those of Scherer (1965 and 1983) and Mansfield (1986). In these, and in subsequent studies – despite the different definitions of propensity to patent, which in general measures the percentage of innovations in which patents are applied for – we can appreciate different rates of propensity to patent according to sectors, generally the textile sector is the one with the lowest propensity and the pharmaceutical is the one with the highest rate. In general, these asymmetries depend on corporate appropriability strategies, which vary in terms of the value assigned to the dissemination of information to competitors and users (Horstman et al., 1985; Levin et al., 1987; Harter, 1993; Arundel et al., 1995; Harabi, 1995; Arundel and Kabla, 1998). Besides patents, companies can also protect their innovations by means of industrial secret, temporary advantages stemming from placing the innovation on the market with substantial anticipation over competitors, and complementary manufacturing capacities, among others.

Levin et al. (1987) and Cohen et al. (2000) analyze the set of mechanisms that firms use to guarantee the appropriability of returns deriving from innovations. In addition to the notable differences between sectors, to the characteristics of the innovation process, and to the market structure, corporations use different combinations of mechanisms for appropriability. According to Cohen et al. (2000), whose study is based on a survey applied to around 1,500 research and development laboratories of manufacturing firms in the United States, patents are extremely relevant only in certain sectors, particularly pharmaceuticals.[6] The authors find that on an average, patents are effective for 34% of product innovations, whereas industrial secret is effective for 51%, temporary advantages for 53%, sales capacities and complementary services for 43%, and complementary manufacturing capacities for 46% of product innovations.[7] Furthermore, patents play a relatively more important role in the appropriability strategies of larger corporations. Considering the case of appropriability mechanisms of large firms, the importance of patents increases considerably, for these turn out to be effective in 41.5% of product innovations, showing an effectiveness similar to that of complementary manufacturing capacities, both in sales and services and in manufacturing companies. However, industrial secret and temporary advantages continue to be the most used appropriability mechanisms, for they are considered effective in more than 51% of cases.

These dynamics are not exclusive to firms in the United States. In an analysis based on data from innovation surveys in Germany, Belgium, Denmark, the Netherlands, Ireland, Luxembourg, and Norway, Arundel (2001) shows that most companies consider industrial secret a more effective appropriability mechanism than patents. Similar studies have recently begun to be made in Latin American countries. López and Orlicki (2006) show that in Brazil – the only country of the region for which information is available based on innovation surveys on legal and strategic appropriability mechanisms – industrial trademarks are the mechanism preferred by companies, since 21.8% of firms use them, whereas only 8.3% use industrial secret, 7.4% patents, 1.9% temporary advantages, and 1.4% the complexity of the industrial design. The preference for trademarks, common in the various

countries of the region, reflects the type of generally adapting innovation and the productive specialization of these countries, rather than a strategic management of different appropriability mechanisms, as happens in the most developed countries.

Second, intellectual property rights confer the right to appropriability, but they do not guarantee the effective appropriability. The existence and legal recognition of these rights do not automatically translate into effective capacity to guarantee control over the intangibles and to the generation of de facto monopolies over innovations. Patents confer the right to defend the monopoly or the privilege conferred through legal action and, as Shapiro (2003) and Lemely and Shapiro (2005) noted they can be defined as "probabilistic" rights. Effective appropriability is a function of the capacity and will of the holder to exercise its own right (enforcement capacities). The costs of lawsuits, the competence of lawyers' teams, the negotiating power, and the capacity to monitor the market and the competitors are factors that have a bearing on the possibility that legal ownership translates into effective appropriability. It is necessary for the patent holder to have the capacity (and the will) to exercise the right conferred by the title so that the patent can fulfill its theoretical dual function of appropriability mechanism and circulation of knowledge. In a study on patenting behavior of small and medium-sized enterprises in the United States, Koen (1991) points out that the majority of these enterprises know when their intellectual property rights are being breached, but that 55% of them do not institute any kind of legal proceedings in their defense due to the high costs and the protracted length of legal disputes.

At the same time, the possibility of incurring in litigations might affect companies' innovative behavior by influencing decisions on investment in research and development in certain technological trajectories. In markets in which dominant stakeholders exist by virtue of oligopolistic or monopolistic positions derived from temporary advantages from entry or accumulated production and technological capacities, patents may discourage the entry of new stakeholders and restrict competition. A number of studies explore this aspect. Lerner (1995) shows that small and medium-sized enterprises tend to reduce investment in research and development in technological areas and sectors where the probability of being the object of a lawsuit for patent infringement by big corporations is high. Lanjouw and Lerner (2001) observe that large corporations use preliminary injunction to discourage the research and development activities of smaller companies.[8] The preliminary injunction can result in the legal decision to prevent both parties from using the patents object of the dispute and suspend production of the goods and services involved. These are costs that smaller, highly specialized firms find it difficult to bear. For the large firms, on the other hand, such costs are relatively minor, so they can invoke the judicial injunction in a strategic manner.

In sum, agents' technological, production and legal capacities, firms' size, and sectoral specialization have a bearing on the use of patents. Recognizing that patents are only one of the appropriability mechanisms used by enterprises and considering the increase in patenting activities leads one to question what are the new dynamics, rationales, and interests that make companies applying for and obtaining an increasing number of patents. In effect, the changes in the management and institutional

framework of intellectual property, together with new technological paradigms have contributed, in a determining manner in the last few decades, to altering the scope and function of patents in companies' competitive strategies.

1.3 The Reconfiguration of Intellectual Property Systems

The transformation of intellectual property systems has gone hand in hand with the different phases of development of modern economies.[9] From regulations of national scope, during the beginning of industrial development and the "inward" stage of development of the industrial takeoff of the countries of first industrialization, intellectual property systems have evolved toward regimes of supranational scope. This transformation has taken place as foreign trade and interaction among countries have become more necessary, closer, and more frequent, and the entrepreneurial and production structure has gradually become more articulated and diversified, increasing the focus on know-how, technical information, knowledge, and the consequent value of its appropriability.[10]

However, beyond the transformation deriving by the change in social and production systems and pushed by the new technological paradigms, as of the 1980s we have seen radical changes in the management of intellectual property. Such changes have occurred in the context of growing trade integration and as a result of the transition to a system of open economies and have aimed, in general terms, at the strengthening and alignment of intellectual property rights on an international scale. In this regard, two major transformations can be identified:

1) The changes in the institutional framework and strengthening of protection of intellectual property in the United States, which have originated the changes in the rest of the countries in various ways. Broadly speaking, the reconfiguration of the system of intellectual property in the United States as of the 1980s is characterized by a) expansion of the patentable frontier (Hunt, 2001); b) predominance of a legal stance oriented to strengthening of protection of intellectual property;[11] and c) the transition from a model of open science to one that is more proprietary and oriented to commercialization (Dasgupta and David, 1994).
2) The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the inclusion of intellectual property in bilateral trade negotiations. Intellectual property became a central element in trade negotiations, first multilateral and then bilateral, as part of a strategy of support to firms' competitiveness, whose dominant position can be eroded by the lack of uniform intellectual property protection systems in global markets. Although recent bilateral agreements tend to reduce the spaces for intellectual property management for the developing countries, the latter have not pushed strategic intellectual property management by including the topic in a broader industrial and technological development strategy; the use of the flexibilities provided by TRIPS has been scarce, not to say almost non-existent. Instead, the countries have favored the search for preferential access to market for the products in which they possess comparative advantages, thus bringing about a situation

in which they easily yield to the new provisions on intellectual property in exchange for concessions in the markets for traditional exports. The changes in the intellectual property protection regimes in contexts of obvious asymmetries between north and south pose challenges to the creation of scientific, technological, and production capacities, their costs, time frames, and viability, and as regards the role played in that process by intellectual property mechanisms (Fink and Reichenmiler, 2005; Abbot, 2006, 2006, Moncayo, 2006, among others).

1.4 Transactions in the Markets for Technology

The idea of markets for technology has been explicitly explored in the economic literature in a relatively recent period (Eaton and Kortum, 1996; Arora, Fosfuri and Gambardella, 2001). According to the definition proposed by Arora, Fosfuri, and Gambardella (2001), when the knowledge necessary for production (know-how) or the right to use it is separated from the product or service which embodies it, a line of demarcation emerges between the market for "tangibles" and the market for the technology necessary to the production. This concept of the markets for technology assigns a determining role to intellectual property rights, especially to patents, since they represent the basic institutional infrastructure for their functioning.

In this framework, patents define the conditions of use and transfer of knowledge, allowing specialization according to comparative advantages, and maximization of the system's efficiency. Patents guarantee the appropriability of the innovative effort by technology providers and represent the mechanism through which the profitability of the innovation is captured. In this regard, the market is assumed to be composed by a set of firms with different comparative advantages, some specialized in technology and the provision of intermediate technological inputs, but without productive and market-access capacities, and others with complementary manufacturing capacities that enable them to use the patented technologies to carry out the production processes and incorporate the technology into products or processes and reach the consumers' market. Patents would thus act as an incentive for "efficiency" in the technology markets, favoring specialization and the division of labor in keeping with comparative advantages (Arora, Fosfuri, and Gambardella, 2001).

In the markets for technology, the ultimate aim of intellectual property protection is to incorporate the patented innovation into present or future tangible production. That is, the value and the market itself arise because there are firms specialized in the provision of "technology" and firms that demand for their production processes and their end products and services. In this context, innovation is generated and disseminated according to a "soft" and continuous process in which there is a series of companies that, starting from an existing pool of knowledge, carry out research and development activities, patent scientific and technological advances, and have the dual possibility of incorporating them into production, or license them in exchange for royalties to another company that will devote itself to production and commercialization of the good or service in question. This approach presents an interesting

framework for describing the dynamics of specialization and the division of labor in the generation, production, and transfer of some technologies. Nevertheless, over the last few decades, entrepreneurial behavior has undergone transformations that escape that logic and give rise to new markets for knowledge in which the rationale of patenting turns out to be completely reconfigured.

1.5 Liquidity and Derivatives in the Markets for Knowledge

A number of studies show the growing importance of patents and the increase in the use of technology licenses in terms of transfers, acquisitions, and cross-licensing among companies (Grindley and Teece, 1997; Thurow, 1997; Granstrand, 1999; Guellec, Martínez, and Sheenan, 2004).[12] At the same time, transactions in intangible goods and services have grown constantly starting from the 1980s. International payments for royalties and licenses as a share of total world imports tripled from the mid-1980s to 2002 (Cimoli, Coriat, and Primi, 2006). However, the importance of markets for technology and the increase in worldwide transactions of intangible goods explain only some of the dynamics related to the recent explosion in patenting and new trends in firms' strategies.

In fact, according to us, patents are becoming progressively unlinked from tangible production. Changes in the patent regime and in firms' behavior have generated markets in which the value of patents is increasingly independent from their direct or indirect incorporation into current production. Patents play new roles and respond to logics that differ from the traditional view of appropriability mechanisms of income deriving from innovation. Their value derives increasingly from future expectations, that is, (i) from the possibility that the patented innovation becomes a determining factor for production or for a set of future patents; (ii) depending on the role that the patent itself may have in the hierarchical repositioning among companies, in technology transfers agreements, in settlement of legal disputes; and (iii) in the case of patent portfolios and patent pools, in terms of the value and relevance of other patents.

Three markets coexist in this scenario, which operate under particular logics and incentives and in which patents play different roles: 1) the market for technology, in which patents guarantee the appropriability and allow the specialization and the division of labor between technology producers and users; 2) the market for science, in which universities and research institutes patent innovations derived from basic and experimental research and development activities, and 3) the liquid and derivative markets for knowledge, in which patents are reconfigured as strategic assets in companies' competitive strategies. Figure 1.1 presents a taxonomy of this reconfiguration of the markets for knowledge.

In this reconfiguration of the markets for knowledge, the dynamics of the markets for technology persists. Companies invest human, financial resources, and time in research and development, and they seek to protect the investment by means of patents and to generate rents through the direct sale of products, processes, or

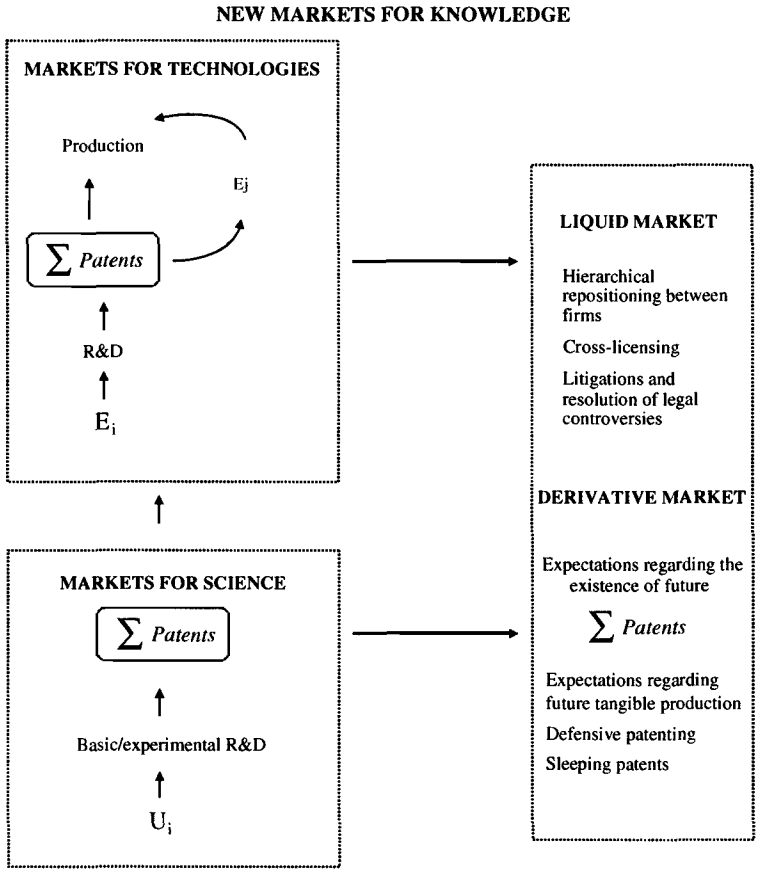


Fig. 1.1 New markets for knowledge. Source: Prepared by the authors
Note: In the market for science U_i represents the university or series of universities, and Σpatents represents the patent or series of patents applied for by the universities. In the market for technology, E_i represents the firm or the group of firms carrying out research and development activities (R&D); E_j represents the firm or the group of firms that use the innovations patented by other firms, and Σpatents represents the set of patents applied for by companies (which may be based on the patents generated in the previous market for science). The series of patents (Σpatents) in addition to characterizing the dynamics of the markets for technology and science, nourish the dynamics of the liquid and derivative markets for knowledge.

services that incorporate the innovation or through the license of the patented innovation to other companies which incorporate the technological advances in their processes or products.

However, the transactions in this market explain only one part of current patent dynamics. The study by Cohen, Nelson, and Walsh (2000) shows that companies can receive additional benefits (whether monetary or not) from their patents than those deriving from the appropriability of innovation rents, which result from

direct sales of the good, product, or service that incorporates the technology, or from technology licensing. Indeed, companies also patent to block the entry of competitors into markets, to increase their negotiating power in cross-licensing agreements, and to protect themselves from lawsuits on intellectual property infringements. In our view, the changes in the institutional framework and in the management of intellectual property regimes and the new technological paradigms contribute to generate additional spaces and markets for knowledge that are even more unlinked from tangible production. The current scenario has become more complex due to a series of transactions in which patents operate under different incentives, logics, and institutional frameworks favoring the exponential growth of patenting.

The extension of patentable subject matter and of the range of parties eligible as patents' holders derived from the changes in intellectual property systems has altered the traditional conception of open science, giving rise to incentives for the creation of a market for science in which the universities apply for and obtain patents relative to innovations stemming from basic and experimental research and development activities. Thus, a "prior" market to that of technology has emerged, to which companies must recur when they need innovations deriving from the research patented by the universities.

The adoption of the Bayh-Dole Act in the United States in 1981 represents an important institutional change in this regard (Jaffe, 2000; Mowery et al., 2004). This act regulates the granting and transfer of patent rights to the parties that develop federally funded inventions, that is to say, it regulates the protection of intellectual property relative to research activities developed mainly by universities and research centers.[13]

After the Bayh-Dole Act, patenting activity in United States universities has intensified. According to Mowery and Sampat (2005), the share of patents issued to universities in relation to the total of those issued to residents in the USPTO has grown from 1% in the 1960s to 3.5% in the early 1990s. According to the USPTO data, in 1990 the universities received 1,182 patents, whereas in 2003 they received 3,259. That year, the number of patents issued to local universities represented 4.5% of the total of invention patents granted to companies. In just over a decade, the number of patents issued annually to universities has tripled. The phenomenon of universities' patenting is not limited to the United States; universities are the holders of 2.4% of applications for patents presented to the European Patents Office (EPO) between 2001 and 2003 (OECD, Patent Database, 2006).

In the market for science, universities (and some technology-based companies) carry out basic and experimental research and development activities and patent the advances obtained without these necessarily being incorporated into the production of goods and services. Formerly, the scientific advances made by the research and development laboratories of universities contributed to the pool of knowledge available to the production agents, and the filter for access to that knowledge, mainly derived from companies' technological and productive capacities, from firms' routines, from the tacit component of knowledge, and from the capacities for decoding the technical knowledge embodied in companies.

The market for science reconfigures the setting in which companies operate and introduces intellectual property in a phase prior to that of the markets for technology, thus reshaping the spaces for action and the incentives for firms and the universities themselves. This market differs from the market for technology basically according to the category of intellectual property holders and to the patent subject–matter, i.e., innovations derived from basic and experimental research developed by public research laboratories and universities. The introduction of the Bayh-Dole Act and the increase in the number of patents applied for and obtained by universities pose challenges to the model of open science and nourish the discussion on proprietary science and its potential effects on long-term technological dynamism (Rai, 2001; Dasgupta and David, 1994; Mowery et al., 2004). In short, the market for science, by standing as an ex-ante market with respect to the market for technology, introduces an initial degree of complexity to the functioning of the contemporary markets for knowledge.

However, on analyzing the behavior of firms and universities, the current scenario takes on an even greater degree of complexity. In the new technological paradigms – characterized by innovation processes which are increasingly intensive in interrelations between companies and networks, and cumulative in nature, in which scientific and technological advances multiply and, consequently, the patents on which subsequent innovations are based – the rationale of patenting changes. Firms patent to reduce the probability that their counterparts will reinforce their position in cross-licensing agreements and to increase their own negotiating power. Companies carry out defensive patenting strategies and build patent portfolios, with sleeping and blocking patents. According to a survey on the value and use of invention patents in European firms based on the cases of Germany, France, England, Italy, the Netherlands, and Spain, the share of inactive patents – i.e., sleeping and blocking patents – varies between 18% in small enterprises and 40% in large corporations and universities (Cesaroni and Giuri, 2005).

In this regard, it may be stated that a liquid market for knowledge emerges; patenting responds to companies' strategies that go beyond the need to protect the innovation. Patents become a liquid asset in the portfolios of the companies that use them, for example, to increase their negotiating power vis-à-vis other companies, to increase their value and reputation, and to facilitate settlement of legal disputes.

The attribute of "liquidity" of patents derives from the fact that these markets and their transactions are disentangled from the incorporation of the patented innovation into tangible production. In this regard, the patent as such acquires value, even if it cannot be incorporated into the current production of a company; its value depends and is a function of other patents of the company, or the patents of other firms that need it, of the value of the patents portfolio, or the importance it may acquire in a cross-licensing agreement.

Patents are "liquid" in the sense that they constitute assets that are exchangeable among firms, without the counterparts necessarily having the scientific and technological capacities to incorporate the respective innovations into production. In fact, a market is liquid when there is facility of circulation of the assets exchanged. Patents are liquid because they lose the density and weight of the technological

component and can circulate fluidly in the market without necessarily having to be embodied in some end product or service; these dynamics characterize transactions in the technology markets. The liquid market for knowledge takes place in a different context in which the strategic utilization of patents prevails. In that market, the rationale behind patenting is different; companies tend to increase the number of patents' applications since their value increasingly depends on that of other patents.[14]

The decision to patent innovations, even those that have no direct and immediate industrial application, has been compared in the literature to the purchase of lottery tickets (Scherer, 2001; Lemely and Shapiro, 2005). Even though the probability of winning is very low, the reward in playing is sufficiently high to encourage agents to bear the costs of patenting. In fact, the current scenario is even more complex than that of the lottery, since the probability of "winning" and the prize associated with the patent are uncertain. In this regard, it may be affirmed that a market for knowledge emerges, in which patenting is a function of expectations relative to the uncertain potential future value of patents. In that market, companies patent for various reasons independently to the incorporation of the patented innovation in tangible production. Thus, patents are obtained in order to raise entry barriers to potential competitors, ensure a share of possible income derived from subsequent discoveries related to incremental evolutions of the innovation or because of the possibility of including the patent at a particular time in a patent pool, among other reasons.

These markets may be defined as "derivative" markets for knowledge. This category of markets is extremely peculiar, since no transactions take place between companies. The transactions correspond to the firms' decisions to patent their innovations, without having the willingness to license them. Thus a "derivative" market is created, in which patents do not circulate among companies but remain in their portfolios waiting for their future potential value.[15] That market includes sleeping patents, those that block the entry of new stakeholders or competitors (blocking patents), and those stemming from the expectation of their inclusion in future transactions in other markets (technology, science, and liquid markets).

The expectation of the (potential) future value of the patent, the threat of the fact that competitors might obtain the patent, and the possibility that its value does not depend on protected innovation, but on the value of additional patents of the company itself or others, encourage aggressive patenting strategies. So this gives rise to "derivative" markets in which the decision to patent is based on expectations, depending on firms' risk aversion or propensity.

The scenario, in which these markets coexist, explains the exponential growth in patenting, even though the distribution of the value of patents is skewed. Despite some sectoral and specific tendencies in some industrial sectors, in general there is a very limited series of significant patents of high value, followed by a whole series of patents of lesser value, which acquire value in terms of future expectations of profitability, as an instrument for defending a dominant position and as a mechanism for barrier to entry of other players in a particular paradigm or technological trajectory. In the chemical industry, for example, it is a common strategy to patent

advances and incremental innovations around the patent that protects the main innovation in order to reduce the probability of competitors entering that research space. In the electronics sector, companies build up portfolios of a wide range of patents to defend their dominant positions and raise barriers to the entry of new competitors. In those reconfigured markets for knowledge, firms and universities patent not so much to appropriate the income derived from their innovating efforts, but to increase the possibility of appropriating, today or in the future, a share of the oligopolistic rents stemming from the present or future research and development efforts of other stakeholders (Levin et al., 1987; Cohen et al., 2000).

Corporate strategies do not follow linear patterns in innovation nor in the search and management of profitability. The effect of the exponential growth in patenting and the favorable attitude of the courts toward raising protection standards might have perverse effects in the markets for knowledge, in which an excess of patents can become a barrier to the entry of new actors in specific technological development trajectories. This is the case of the patent thicket, a situation in which a series of intellectual property rights on complementary technological components coexist and overlap, subjecting the interested parties to the obligation to obtain licenses or establish agreements with several intellectual property rights holders when they wish to market new technologies based on those technological components (Shapiro, 2001). According to Llobet (2003), in contexts of cumulative inventions, excessive protection and legal rulings in favor of intellectual property rights holders in lawsuits for patent violation can inhibit companies' research and development efforts.

Hence, markets for knowledge turn out to be conflicting scenarios in which costs and barriers to entry of new players, the costs of potential violations of patent rights, legal defense costs, and those associated with the decisions are extremely high. In the hierarchies of entrepreneurial networks, companies' position is increasingly determined in terms of the patents portfolio, with the consequent pressure toward market concentration and strengthening of dominant positions. At the same time, there are spaces so that new stakeholders impose themselves as leaders in certain technological sub-trajectories as a result of strategic use of intellectual property. Nevertheless, the institutional capacity to guarantee the appropriability of income derived from intangibles continues to be crucial, especially in the new technological paradigms.

1.6 Participation and Exclusion in the Markets for Knowledge

Intellectual property regimes represent a key controversial issue in current economies. The intensification of patenting activity, the new and diverse forms in which firms use patents, the new technological paradigms, the context of open economies, the growing global integration of economies, institutional modifications in intellectual property systems, and the coexistence of diverse markets for technology and knowledge reconfigure the rationales and the leeway for action of

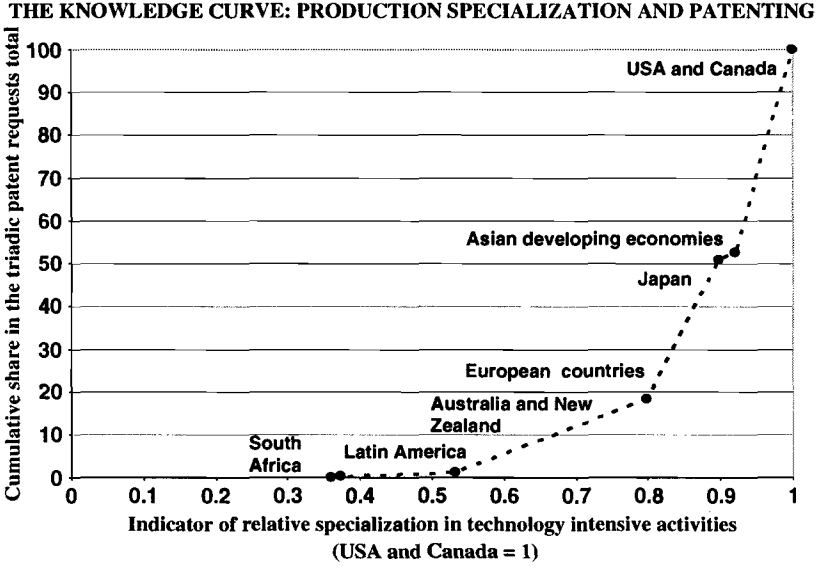
companies and governments. The management of intellectual property systems and an understanding of their relationship with the creation of scientific and technological capabilities is an urgent challenge for the countries of Latin America and the developing countries in general.

A parallel can be drawn between the "North-South" asymmetry in the dynamics of patenting and the "North-South" asymmetry in the technological intensity of the production structures and patterns of specialization. That is, the countries' participation in the dynamics of world patenting and its changes is not alien to the dynamics of production structures and the processes of technical change. The industrialized countries are specialized in knowledge- and technology-intensive activities and sectors and invest more resources in research and development activities; it therefore comes as no surprise that they are also leaders in the number of patents applied for and granted. The developing countries, on the other hand, are specialized in traditional sectors that are more intensive in labor and natural resources, invest scant resources in research and development, and their patenting activity is less intense (Aboites and Cimoli, 2002; Cimoli, 2005; Montobbio, 2006). The geographical concentration of the patents applied for and granted (see Table 1.1) corresponds to the concentration of research and development activities. The United States and Canada

Table 1.1 Geographical concentration of main USPTO patent holders. Evolution 1963–2003

	1963	1973	1983 (%)	1993	2003
Quota of patents issued to the three main stakeholders	90.5 (United States, Germany, UK)	83.7 (United States, Germany, Japan)	82.9 (United States, Japan, Germany)	83 (United States, Japan, Germany)	83.8 (United States, Japan, Germany)
Quota of patents issued to the three main stakeholders without the United States	58.8 (Germany, UK, France)	59.1 (Germany, Japan, UK)	67.5 (Japan, Germany, UK)	67.9 (Japan, Germany, France)	67.3 (Japan, Germany, Chinese Province of Taiwan)
Quota of patents issued to the five main stakeholders without the United States	73.8 (Germany, UK, France, Switzerland, Canada)	74.5 (Germany, Japan, UK, France, Canada)	79.7 (Japan, Germany, UK, France, Switzerland)	80 (Japan, Germany, France, UK, Canada)	75.5 (Japan, Germany, Chinese Province of Taiwan, Republic of Korea, France)

Source: Prepared by the authors based on data from USPTO, Technology Monitoring Division Report, Utility Patents Report.



Source: Prepared by the authors on the basis of OECD Patent Database, 2005, OECD STAN Database and PADI.

Chart 1.1 The knowledge curve: production specialization and patenting
Note: In the abscissas we measure the indicator of relative specialization in technology-intensive activities based on United States and Canada = 1. The relative specialization indicator for geographical areas is calculated as a simple average of countries. The emerging economies of Asia include India, Republic of Korea, and Singapore. The European countries are Finland, France, Ireland, Israel, Norway, Sweden, and the U.K. For Latin America, Argentina, Brazil, Chile, and Mexico are considered. The ordinates measure the accumulated share of triadic patents applications.

carry out 41.9% of world spending on research and development, the European Union 28.2%, Asia 27.3%, Latin America and the Caribbean only 1.3%, Oceania 1.1%, and Africa 0.2% (RICYT, 2004).

The asymmetry in patenting reflects profound structural differences among countries. Chart 1.1 orders the countries in terms of their production specialization and the intensity of their patenting activity. A "knowledge curve" is built in which 19 countries are ordered, grouped into seven geographical areas, according to their relative technological specialization and their patenting activity. The United States and Canada are considered the technological frontier on account of their participation in knowledge-intensive sectors in the total manufacturing value added. In terms of relative specialization in technology-intensive sectors they are followed for by the Republic of Korea, India, and Singapore,[16] then Japan, the European countries, Australia and New Zealand, and finally, Latin America, and South Africa.

If we order the countries by the relative technological intensity of the manufacturing industry, the "knowledge curve" shows that those with a production structure similar to that of the technological frontier (Japan and the European countries)

are also those that have the largest share of patents applications. In the United States, Japan and the European countries there is a relationship between their knowledge-intensive production structure and their relatively more intense patenting activities. In other words, the economies in which the knowledge-intensive sectors contribute to generating a significant share of the total manufacturing value added, patent more. The exceptions to this tendency are the emerging Asian countries, the Republic of Korea and Singapore in particular, where the process of structural change and transition toward more knowledge-intensive productive frameworks is recent. Therefore, the dynamics of patenting, however much it may have accelerated, continues to be residual. This leads us to reflect on the temporary dynamics of technical and structural changes and companies' competitive behavior in terms of patenting.

The dynamics of patenting derives from production specialization; the creation of production and technological capabilities is a long-term process influenced by path-dependent dynamics and by sectoral and temporary public-policy choices. In the past 30 years, the Republic of Korea and Singapore have intensified their specialization in technology-intensive sectors. In the 1970s, engineering-intensive sectors generated 10% of the industrial value added in the Republic of Korea; in 2000 they generated 63%, surpassing the United States. Singapore is a similar case in point: those sectors' quota has risen from 34 to 65% over the same period. At the same time, these countries invest considerable resources in research and development (2.8 and 1.9% of GDP, respectively, on an average, between 1996 and 2002). In parallel, these countries have notably intensified their patenting activity.

The introduction and use of the intellectual property protection system go hand in hand with the creation of industrial productive capabilities. Specialization in knowledge-intensive sectors, technological development, and investment efforts in research and development favor technical change, increase the absorption capacity of the production structure, and lead to generate a structure that demands more knowledge. Hence, the intensification of patenting emerges as those capacities are developed and built. When certain technological capacities have been accumulated, the production system requires a patents system and can benefit from it.

How to achieve convergence and the development of technological capabilities, that is, how to move on the knowledge curve in contexts characterized by high levels and standards of intellectual property protection, remains an open question. Understanding the dynamics of patenting in the current context is the first step in that direction.

The patents game is increasingly costly in terms of the necessary human and financial resources needed to convert the "probabilistic" right conferred by the patent into an effective right and in terms of the necessary time to carry out research and development activities, create a patentable innovation, and obtain the correspondent intellectual property right. The firms that possess a certain accumulated level of technological capacities are the ones that dominate the scenario. In the current reconfiguration of markets for knowledge, the game is, in our view, increasingly competitive among companies, posing serious challenges to designing development strategies based on knowledge and innovation.

In the countries of the technological frontier, especially the United States, the discussion on intellectual property follows a double track. Foreign policy defends the raising of standards of protection for intellectual property rights. It aims at the standardization of those rights, since the weakness of protection and the asymmetry between the systems of the developed countries and those of the developing ones is viewed as a systemic failure which prevents the knowledge dissemination and technical progress derived from trade liberalization. Investing in research and development and trading knowledge in a context of scarce protection of intellectual property is a risk that few are prepared to take. In the internal debate, on the one hand, pressure groups, large corporations from sectors such as pharmaceuticals and chemicals, and jurisprudence, which advocate growing standards of protection and, on the other, academics and the members of organizations of civil society, which express concern over the proliferation of patenting and their potential adverse effect on the capacity to innovate of the economic system in the long term.

In Latin America, the inclusion of intellectual property issues in trade negotiations has raised the topic in political discussions. The discussion is mainly characterized by the paradox of adopting favorable positions on trade liberalization in tangible sectors and, at the same time, promoting the adoption of protection measures in the area of intellectual property and intangibles. The stances are varied, but in general a lack of strategic perspective prevails on the role that intellectual property in general, and patents in particular, can play in the development and construction of endogenous technological capabilities.

At international level, in both multilateral and bilateral negotiations, the debate is characterized by a double standard in which there is a push for free trade in goods and services and a pressure to increase protection of intellectual property and "intangibles." These circumstances redefine the scenario and policy spaces in which less developed and developing countries have to define their strategies toward convergence, thus posing new challenges for catching up strategies. In this context, recognizing that the rationale for patenting is moving away from the traditional markets for technologies and heading to the new markets for science and the liquid and derivative ones, in which transactions and the role of patents are completely new and uncertain, is the first step in proposing a pragmatic development agenda capable of going beyond good intentions and declarations.

1.7 Conclusions

Almost all Latin American countries aim toward a development based on knowledge, at least in plans and declarations. Innovation, science, and technology policies have begun to appear again in politically correct discourses. However, the search and need for access to markets in traditional sectors lead to cede on potential dynamic advantages in intellectual property. In general, marginal stances prevail which advocate for "adding value" in the natural resources-intensive sectors, rather than for selective policies of creation of new sectors. In the discourse on intellectual property rights, attention to the development of the legal and institutional infrastructure

prevails over the concern for generating productive and technological capacities that could benefit from the regulations themselves. The modernization of patents offices, institutional reforms, design of public-policy instruments of support for the protection of intellectual property are current topics in political debates. Nevertheless, these efforts could become sterile unless they are accompanied by a deep understanding of the effects of the new dynamics of patenting on the construction of production and technological capacities and on the need to implement policies to support the technical and structural change.

Lack of strategic vision and short-term demands can come into conflict with learning processes and the development of scientific and technological capacities, which are localized and are built up gradually in a continuous process of trial, error, and feedback (Atkinson and Stiglitz, 1969). Prioritizing traditional sectors with comparative advantages in the present without considering the strategic relevance of capacity building in more knowledge-intensive sectors, the effects of spillover and linkage these may have on the economy and the role played by intellectual property protection systems in that process may turn out to be a short-sighted strategy that does not sufficiently value knowledge and technology management.

Firms use patents not only as incentives and mechanisms for appropriability of innovation but also as strategic assets for the generation and maintenance of dominant positions. Transactions in the technology markets – basically patent licenses – are but one of the components of the (new) markets for knowledge. Nowadays there is a former market, the science market, in which new players (universities) patent innovations stemming from basic research and basic development which were previously not classified as patentable material.

At the same time, additional markets are also created in which patents acquire the role of strategic asset, beyond the effective utilization of protected innovation in present or future tangible production. On the one hand, patents become a determining asset in redefining companies' strategic and hierarchical position and increasing their negotiating power. Patents become "liquid" assets, easily transacted between companies, which make it possible to settle legal disputes and facilitate cross-licensing agreements.

As in a competitive game, expectations on the value of a patent and the possibility of combining patents of little or no value in patent pools or patent portfolios encourage companies to develop aggressive patenting strategies. Thus, a "derivative" market for knowledge emerges, in which, in contrast to other markets, companies apply for patents for the explicit purpose of not using them in transactions with other companies. In that market, patents possess a value in themselves, based on a series of future expectations, whether by means of their inclusion in a patent pool, in the possible importance of the patented innovation for future incremental innovations, or in the desire to block the entry of new competitors. Patents act as a signal, without the need for them to circulate among companies. In this market, the theoretical balance between the two basic functions of patents, those of protection and appropriability versus the disclosure of knowledge, fades away. Patents lose their traditional attribute of a mechanism to facilitate the disclosure of knowledge (disclosure function) and remain sleeping, block the entry of other players (blocking), or

simply increase the value of the company by indicating its (potential) technological capacities.

In this type of scenario, clearly the Latin American countries and the developing countries in general are residual actors. However, once the firms in developing countries acquire the technological capacities to enter those markets, they will operate under the same logics, will use mechanisms of appropriability in a strategic manner, and will play in the various markets – the technology, science, liquid and derivatives markets – the same as their competitors in the most advanced countries. Therefore, in the current discourse on intellectual property and development it is important to recognize that the present dynamics show completely novel traits. It is fundamental to refocus the debate in the countries of the region, leaving behind the conventional view of patents. Recognizing the existence of the different markets for knowledge and understanding the variety of functions and roles performed by patents in company strategies is essential (i) in understanding how the region could enter the new global knowledge game and (ii) in formulating public policies to support industrial development and innovation beyond the rhetoric.

Notes

1. Several studies analyze this increase in patenting activities. See Kortum and Lerner (1997); Hall (2004); Guellec, Martínez, and Sheehan (2004), Montobbio (2006), among others.
2. In the 1960s, the degree of concentration – the percentage of patents issued to the three main countries – was 90%. The analysis of patterns of application and issuance of patents in the USPTO prevents capturing the intensity and dynamics of the phenomenon in the different national offices and can lead to underestimating their activity. Nevertheless, since the USPTO is the major office worldwide, its activity is a reliable indicator for studying the phenomenon in a global and comparative perspective. In order to avoid the bias toward the United States stemming from USPTO data, the analysis of patenting dynamics in the other countries considers the total of patents applied for or issued only to non-residents.
3. These systems define a set of rights that are interlinked in different legal regimes of vast scope, which range from patents on inventions, copyright on original forms of expression (such as artistic and literary productions) and the marks protecting the symbols that identify goods and services, among others.
4. Since their origin, the intellectual property protection systems are associated with the creation and recognition of privileges. The etymological root of the term patent derives from the Latin *litterae patente*, "manifesto" or "open letter," a document that publicly declared the granting of a special privilege. The guilds in the Middle Ages used in order to concede exclusive rights may be considered as an embryonic system of protection of intellectual property. The first law on patents goes back to the Republic of Venice in 1474. The British statute of 1623 eliminated all monopolies and privileges, exclusively recognizing the monopolies created by the first inventor of manufacturing methods in the field. For an analysis of the historical evolution of protection systems for intellectual property, see David (1993) and Drahos (1999).
5. The discussion on intellectual property is an old debate. Plant (1934) puts forward a skeptical position as to the need for a system of protection of intellectual property. Kitch (1977) underscores the importance of patents as an incentive for investment in research and development. The debate on the duration and optimum scope of patents is also extensive. See, among others, Gilbert and Shapiro (1990), Klemperer (1990) and Lerner (1994). For a review of patents as indicators of economic phenomena, see Grilliches (1990).

6. The peculiarity of the pharmaceutical sector in the use of patents is a topic widely debated in the literature (see Mansfield, 1986; Levin et al., 1987; Mazzucato and Dosi, 2006, among others).
7. The authors show that patents and legal instruments are also the least effective instruments for guaranteeing appropriability of process innovations, a case in which industrial secret appears as the most adequate instrument for appropriability.
8. The study analyzes 252 lawsuits in courts of the European Union between January 1990 and June 1991.
9. See Machlup and Penrose (1950); David (1993) and Moncayo (2006), among others.
10. The 1883 Paris Convention on protection of industrial property and the 1886 Berne Convention, which regulates protection of original forms of expression, such as artistic and literary works, represent the first stages of the internationalization of intellectual property rights. Those two conventions were followed, always with an approach of international protection, by the 1891 Madrid agreement on industrial marks and the 1925 The Hague agreement on industrial design. In 1893 the Office for the Protection of Intellectual Property (BIRPI) was created, an antecedent of the World Intellectual Property Office, established in 1967, under whose administration today are various international treaties for the protection of intellectual property.
11. See the studies by Adelman (1987); Merges (1992); Mazzoleni and Nelson (1998); Jaffe (2000); Hall and Ziedonis (2001); Cohen and Lemely (2001); Gallini (2002); Bessen and Hunt (2004); Hall (2003); Graham and Mowery (2003).
12. Grindley and Teece (1997) underscore the growing use of technology licenses by large corporations such as IBM, Hewlett-Packard, and AT&T during the nineties decade.
13. Assessing the consequences of the Bayh-Dole Act goes beyond the scope of the present study, but it is interesting to highlight that one section – 204 indicates that the right to patent and the faculty of transferring the right to utilization in an exclusive manner applies only if the product or service incorporating the invention or the process carried out through the invention is manufactured principally in the United States. Section 204 introduces a preferential mechanism for the local manufacturing industry and corresponds to a utilization strategy of the instrument to protect domestic industry at international level. This reflects one of the asymmetries in the management of intellectual property between countries on the technological frontier and the developing countries (Cimoli, Coriat, and Primi, 2006).
14. The identification of that potential market for patents and the change in attitude of agents and courts in favor of raising protection standards for intellectual property contribute to explaining the exponential increase in patenting activities in recent decades.
15. In the financial derivative markets parties acquire the right to buy or sell a particular asset at a particular price at a particular future moment, as is the case of options contracts, or to purchase or sale an asset at a future date at a pre-established price, as in the case of futures contracts. In those markets, present costs and obligations are assumed according to future expectations. It is in this sense that the "derivative" market for knowledge is defined.
16. In fact, the weight of technology-intensive sectors in the total manufacturing value added of Korea and Singapore is higher than that of the United States. However, the values of the indicator of relative specialization are calculated as simple averages, and the inclusion of India reduces the indicator to a value below the unit. In any event, the group of emerging Asian countries is the one that possesses the most similar productive structure to that of the frontier.

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Chapter 2
Protection of Intellectual Property Rights, Innovation, and Development

Jorge Mario Martínez-Piva

2.1 Introduction

Knowledge embedded as a proportion of the total value of a product grows by the day in all sectors. Technological development is not only present in industrial goods but also in agricultural processes and in services.

Capabilities for research, creation, and appropriation of knowledge and its transformation into new technologies form part of the foundations of wealth in the most developed nations and largely explain their economic growth. In this regard, analysis and debate on how to generate knowledge, technological innovation, and development is a topic of utmost importance for the developing countries.

As of the entry into effect of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, the architecture of Intellectual Property Rights (IPR) has gradually become more complex. TRIPS has been promoted mainly by the most developed nations, and bilateral trade agreements have progressively incorporated diverse complementary rules, some of them known as TRIPS Plus for extending intellectual property beyond the original TRIPS.

The mechanisms for intellectual property protection – patents, trademarks, geographical indications, copyright, breeder rights, etc. – present two important aspects: on the one hand, they are forms of appropriation of income that generate monopolistic or quasi-monopolistic gains for their holders and, on the other, they are financial incentives for research inasmuch as they remunerate the innovator for the investments carried out until succeeding in turn their innovations into market products. Both aspects are examined in this chapter.

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Economic analysis shows that if not correctly formulated, IPR protection mechanisms can become a barrier to the entry of other innovators and an instrument to preserve monopolies, resulting in a further obstacle rather than as an incentive for research and for economic development.

Finally, two economic phenomena are analyzed which are closely linked to economic development and to intellectual property protection mechanisms: local endogenous development and attraction of Foreign Direct Investment (FDI).

2.2 Innovation and Endogenous Development

The concept of decreasing returns is a pillar of economic theory since its founding by David Ricardo. It refers to the fact that the rate of return on investment and the growth rate of the per capita product are normally decreasing functions of the level of per capita capital stock. The logic of this argument is simple: initially, when the per capita capital stock increases, per capita production will rise at a proportional rate, but if the capital stock continues to grow, there will be a point as of which per capita returns will have declining rates.

This argument leads to the conclusion that among countries with different endowments of per capita capital and therefore different productivity and income, the country with the lowest capital/labor ratio will be the one that obtains the highest productivity and income growth rates. Therefore, the countries with the least income should show a tendency to converge with the rents of the countries with the highest income.

By this reasoning, as Romer (1986) indicated that initial conditions or current distortions should not have long-term effect on the level of production and consumption. However, according to Romer, the evidence does not back up the conclusions of the principle of decreasing returns. Madison (cited by Romer, 1986) shows that the countries that have had the highest productivity indices since 1700 have achieved increasing and not decreasing rates of productivity. On the other hand, it has been proved that the most developed countries benefit more from periods of growth and suffer less the periods of crisis of the external economy than the developing countries (Reynolds, 1983, cited by Romer, 1986).

Two assumptions make the analysis of convergence among countries predict different results from those shown by the evidence: the first is that technological change is exogenous to the growth process of and the second is that the same technology is available all over the world. The assumption is, then, that there is free access to the technology on the market and therefore, investment decisions in one country are determined by the relative prices of the factors of production, technology being a given factor, that is, exogenous. According to this approach, changes, improvements, and technological leaps are external to countries, which take them for their investments (Lucas, 1988; Romer, 1986).

Although it is true that investment rates in rich countries are higher than in poor countries, the variation between them is not so high as to explain the difference in

growth. The assumption that the level of available technology is the same for all countries has been identified as the key to the error.

To model the fact that developed countries maintain higher growth rates than less developed ones –which is indicated by the empirical evidence– it would be necessary for each investment unit in capital to increase not only the stock of physical capital but also the level of technology for all companies. This redefines the relationship between technology and the rest of the economic variables, since investments in capital or labor have external effects on it. The latter is therefore neither constant nor the same for all countries. Long-term growth would be determined mainly by the accumulation of knowledge – know-how, knowing how to use technology, knowing how to improve technology, all of which is self-reinforcing – in the agents that maximize benefits by constantly introducing improvements. The most important part of this is that knowledge accumulates and grows, so that if we look on production as a function of knowledge, in addition to other functions, it will have growing returns.

The statement by Romer, Lucas, Rebelo, and others has given rise to a great deal of literature on this topic, whose essence is expressed in the following equation:

$$Y = AK,$$

where Y is national production, A represents diverse factors affecting technology, and K includes human capital and physical capital.

Through K, knowledge and technological development become endogenous. The current study of economic development necessarily includes analysis of the interrelation between the factors of endogenous growth, that is to say, how human capital, physical capital, and other factors that influence technology have a bearing on growth. In this regard, protection of IPR, that is, the economic incentives for innovation and the exclusion of competitors, is an element of growing importance for countries' economic development.

2.3 Local Endogenous Development and Innovation

The study of local development indicates that all regions possess cultural, historical, physical, and institutional characteristics that represent their own development potential (Vázquez and Garofoli, 1995). The regions possess knowledge, techniques, preferences, etc., which are the fruits of their own historical legacy. Over time, communities develop their own culture, beliefs, and values which impregnate all their activities, including economic ones. For the theory of local development, these aspects endow each community and region with a potential of resources which also constitute their development potential.

Analyses of local development consider three aspects, on which potential of development is largely based: a *specific know-how*, which has evolved from forms of accumulation of agricultural surpluses to craft and subsequently industrial production; *local production linkages*, which generate and encourage productive specialization, strengthening local know-how; and *entrepreneurial capacity* itself.

The latter is usually pointed to as the decisive element for promoting local development (Vázquez, 1988).

Local economic development occurs in delimited geographical areas where there is a critical mass of micro and small enterprises vertically or horizontally integrated in specific production processes (Vázquez, 1988). Such characteristics give the region organic interdependence to which other enterprises and the public administration provide complementary services, creating a homogeneous, specialized, and integrated economic and social framework.

In addition to these elements are those characteristic of endogenous development, i.e., making knowledge endogenous – through the variables of human and technological capital – such as forms of generation of value, improvements in productivity, and in local production processes. Since the analysis of local development explicitly incorporates the knowledge variable, we talk of local endogenous development.

In the developing countries, much the same as in many developed countries, the majority of enterprises are small and their market objective is strictly local or national, and therefore improvements in the living standards of the population require the modernization and improvement of these small enterprises' productivity and growth. In recent years, the Latin American countries, as many developing countries around the world, have opted for a model of development based on the promotion of exports and the attraction of FDI, which in principle has relegated local endogenous development to second place.

This model has implied new priorities, new institutions, capabilities, organization of resources, etc. Governments have promoted exports – some small enterprises have successfully benefited from this model – and the attraction of foreign investment. The model has also implied processes of accumulation of knowledge, capacities, and resources more linked to the international economy. Today's economy is increasingly knowledge based, a determining factor of productivity. The contribution of knowledge-intensive sectors to the world economy's value added and employment is growing continuously, and innovations have become a decisive element in competitiveness. The logic of development based on exports and attraction of FDI leads to competing internationally, and rewards the firms which at the time of opening up national markets already had sufficient maturity to produce with international standards.[1]

However, by means of policies and strategies that act on the necessary basic levels of development, the local production can also be promoted so contributing to national development (Alburquerque, 1997). In a context of open economies in which the technological component and knowledge are increasingly relevant to firms' competitiveness, it is essential to design local endogenous development strategies that promote the use of knowledge, the use of useful innovations, and improve productivity rates.

The developing countries that have opted for full integration into the world economy face the challenge of designing and implementing policies of technological innovation as an essential part of the model they should follow.

Four levels have been identified in which public policy should act to promote local endogenous development (Alburquerque, 1997):

Macroeconomic level, to assure the necessary conditions of stability for economic accumulation and reproduction.

Microeconomic level, in which the production units improve their techniques and their entrepreneurial management, and the necessary technological changes are made.

Mesoeconomic level, in which institutions create and maintain the innovative setting so that companies grow and multiply.

Meta level, in which a generalized commitment to investment, risk, and growth derived from the capacity for community development and strategic concerted agreement take place. In a local economy that is articulated or aims to articulate its production, it is essential that the actors participate in the intentionality and they bet on development. Given that all are part of the same production environment, quality, effort, and growth affect its setting, which is why the level of concerted agreement for development becomes essential.

2.4 National Innovation Systems

The concept of National Innovation System (NIS) refers to the network of institutions and organizations in the production structure and in social institutions that import, develop, and disseminate new technologies or knowledge. This concept incorporates the knowledge element in the function of production and places innovation and the learning process at the center of analysis. An NIS seeks to understand how knowledge is generated, how it is disseminated, and how it becomes transformed into technology.

The ways in which each society produces knowledge are diverse and complex. Every system depends on factors that change slowly (culture, technological path, systems of governance). NISs are no exception. For this reason it is said that they are systems of actors, interactions, and structural conditions that produce knowledge, disseminate it, and eventually incorporate it into useful technology for the market.

Edquist (2004) and Chaminade (2005) indicate that NISs are made up of two elements: (a) the so-called components, and (b) the relationship between them, as occurs in any system. In the components it is common to distinguish between organizations (firms, universities, public research centers, NGOs, etc.) and institutions (rules, routines, laws, etc.). It is precisely the relationships between the components of the system, that is, between organizations and institutions, which define the functioning of an NIS.

Placing emphasis on a single element of the NIS (intellectual property rights, public or private research, public incentives, etc.) does not make much sense. What is decisive is the system as a whole to ensure that the region or the country has the

capacity to generate knowledge (through the organizations), transmit it (through the relations among organizations), and develop it (by organizations and institutions).

From the point of view of local endogenous development, the analysis of innovation systems explains the manner in which a region generates and incorporates knowledge into its production. It thus contributes information on how to build up the functioning of the system by means of public policies in order to generate more knowledge, increase productivity, and improve the capacity to incorporate knowledge into local production.

2.4.1 Determining factors for innovation processes

A number of studies have analyzed the factors at play in innovation processes, that is, the activities related to the creation, dissemination, and development of technological innovations, without so far reaching consensus on the determining factors (Liu and White, 2001; Johnson and Jacobsson, 2003; Rickne, 2000).

Every country or region can have determining factors depending on the series and functioning of its organizations and institutions and therefore, each system tends to be unique and unrepeatable. Even so, any country or region that strives to identify the said factors must base itself on the yardstick that the system's main function and the object of study is the innovation process: development, dissemination, and use (exploitation) of the innovations.

As Edquist (2004) states, almost certainly any satisfactory explanation of innovation processes will find multiple causes – reinforcing one another – and therefore should specify the relative importance of each one of them. In any case, the exercise should be pragmatic: identifying the important activities that have a bearing on the innovation process. Thus action areas can be identified for public policy on science and technology (see Box 2.1).

Box 2.1 Determining factors of innovation systems

1. Availability of Research and Development (R&D) centers that produce new knowledge, especially in the areas of engineering, medicine, and natural sciences.
2. Creation of competences or capabilities (availability of education and training, creation of human capital, production, and reproduction of skills).
3. Creation of markets for new products.
4. Exacting demand for the quality of new products.
5. Creation and evolution of the necessary organizations for the development of new fields of innovation, i.e., improvement of entrepreneurial capacity to create new enterprises and diversify existing ones.

6. Relations through the market and other mechanisms, including interactive learning processes among organizations participating in the innovation process.
7. Creation and renewal of institutions – i.e., intellectual property laws, fiscal incentives, environmental and security regulations, practices of investment in research and development, etc. – which influence organizations and processes.
8. Incubation activities with access to adequate facilities, administrative support, etc.
9. Financing for innovative processes and other activities that facilitate the marketing and adoption of knowledge.
10. Availability of relevant consultancy services for innovation processes, i.e., technology transfer, commercial information, legal advice.

Source: Prepared by the author based on Edquist (2004).

2.4.2 National innovation systems in Latin America

Regardless of the indicator used to analyze and compare the NISs of developing countries to those of the developed ones, there are major quantitative differences (number of patents registered per year, relative weight of expenditure on research and development in GDP, number of people working on research projects, etc.) and qualitative ones (types of patents, relevance of their use, etc.), which places the developing countries at a serious disadvantage in competing and promoting policies of technological convergence and innovation.

Although the data for measuring and rating NISs may not be very solid in the sense that they do not necessarily reflect the countries' innovating capacities – i.e., number of patents registered or number of scientists in the universities – this section presents the most commonly accepted indicators.

One initial fact is the innovation index designed by Warner (2000), which is based on replies from company executives by means of surveys on sources and results of innovating processes, evaluation of the quality of scientific research institutions, higher education, teaching of mathematics and sciences, and incentives for innovation.

The index is on a scale of −2 to +2 (close to −2 means low innovation and close to 2 supposes greater innovation). The average for Latin America is −0.99. On an average the industrialized countries have an index of 0.89 and the countries with the highest indexes are the United States and Finland with 2.02, which shows that the Latin American lag is very significant and of concern if compared with the average of the countries of Southeast Asia (−0.25) or with South Korea, whose index is 0.33. For countries such as Costa Rica and El Salvador, the index is −0.21 and −1.35, whereas larger countries such as Mexico, Brazil, and Argentina show indexes of −-0.76, −0.52, and −0.95, respectively.

Table 2.1 Latin America and selected countries patent registration – PCT*

Country/region	Patents registered per year			
	2002	2003	2004	2005
Europe (EPO)	42,447	43,205	44,010	47,239
United States	41,294	41,026	43,342	46,019
Japan	14,063	17,414	20,263	24,815
Republic of Korea	2520	2949	3556	4685
Brazil	201	219	279	280
Mexico	132	131	118	140
Colombia	36	24	22	23
Argentina	9	15	11	21
Cuba	11	20	18	11

Source: WIPO, Statistics Division, 2005 Yearly Review of the PCT.
*Patent Cooperation Treaty (PCT), WIPO.

If we analyze production of innovation based on patents registered, we also find a great difference between the Latin American region and other regions of the world (see Table 2.1). It should be noted that in the entire Latin America region, including Mexico and Brazil, where the indicator is higher, it is the transnational corporations (not residents) that concentrate the largest number of patents (see Chart 2.1).

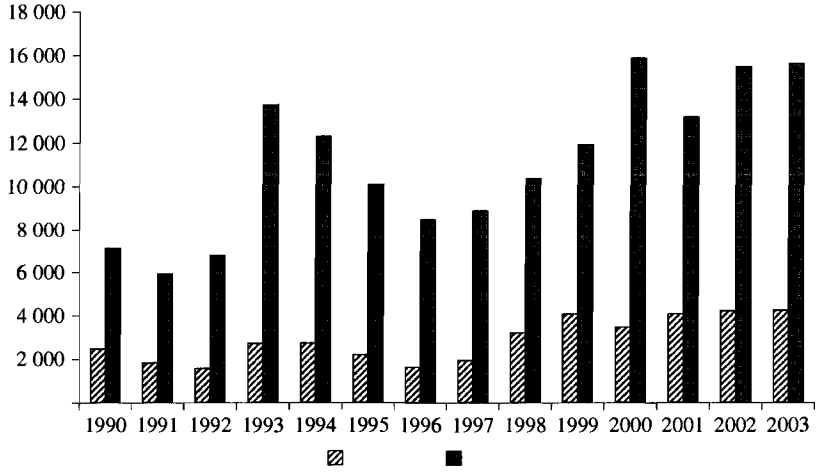

Chart 2.1 Latin America: patents registration BY Category.
Source: Prepared by the author based on RICYT (2004)

Spending on science and technology as a percentage of GDP also indicates that the Latin American countries are a long way from investing the proportions that countries such as the United States invest under this heading (2.67% of GDP as against Nicaragua's 0.14% and El Salvador's 0.84%). Interestingly, countries like Brazil, Costa Rica, and Cuba make more investment in science and technology in

relation to GDP than countries like Spain, but with mediocre results in production of marketable knowledge (measured by the number of patents). This fact is relevant as regards the type of relations between the organizations and the institutions that constitute their national innovation systems.

Finally, it is important to underline two characteristic elements of protection of innovations in Latin America which make it difficult to measure innovation capacity: (a) most innovations are incremental and adaptive (important to the economy and firms, but not patentable) and (b) the most often used mechanisms of protection for inventions are industrial secret and trademarks.

Whichever the indicator used to analyze investment and development of innovations in Latin America, the region suffers a considerable lag in comparison with other regions of the world, which is evident with respect to the developed countries, but also to other developing countries, such as those of East Asia. Latin America has made considerable progress in its absolute indicators, but in relative terms it is increasingly far removed from its competitors.

2.4.3 Characteristics of NISs in Latin America

According to Melo (2001), NISs in Latin America are "open," which means that their sources and principal agents of innovation are foreign technology flows and that foreign economic actors – especially transnational firms– are the main agents of domestic innovation processes. This is illustrated by the ownership of locally registered patents, which largely belong to foreign corporations in the region, 84.4% (see Chart 2.1). Similarly, the growing share of technological industries in the region's industrial exports is contributed by transnational firms.

Foreign technology flows through three main channels: (1) foreign direct investment; (2) imports of capital goods and intermediate goods; and (3) transfer by means of purchase of technology not incorporated into goods, but in the form of patents, licenses, and technical assistance, among others.

This characteristic of Latin American NISs brings to mind that in terms of innovation policy there is a need to improve the transfer channels from foreign to national agents. If a country or region does not have high levels of investment in research and development, it should seek the capacity to absorb the knowledge generated in other places, adapt it to its needs, and develop it. An example of a country without research capacity some decades ago which turned into an innovator is Republic of Korea. Other countries of East Asia are attempting to improve their NIS by following Korea's model.

Another characteristic of Latin American NISs is their heterogeneity, which means that the differences within the region may be greater than with regard to other countries. Depending on the indicator used, the differences between countries such as Uruguay, Cuba, or Brazil compared to others such as Bolivia, Peru, or Nicaragua are greater than the differences the former countries have with more developed countries. It has been calculated that 73% of Latin America's researchers are concentrated in Brazil, Argentina, and Mexico.

Finally, another characteristic of Latin American NISs is the role of private firms in the innovation process. Unlike the majority of the developed countries, where innovative efforts are concentrated in the private sector, in Latin America they are concentrated in the public sector. In the 1990 s decade, 60% of spending on science and technology was carried out by the public sector as against less than 30% by the business sector. It is also significant to point out that the links and therefore the flows of knowledge between firms and research institutions – including universities – are weak. This shows that the relations between the centers that concentrate research and the firms in charge of applying and marketing innovations are not effective.

It should also be highlighted that Latin America has a low coefficient of patent generation with respect to its investment in research, but its production of scientific articles is considerable (see Álvaro Díaz in this book, in Chapter 5). Mexico's National Researchers' System uses the publication of scientific articles as an indicator of scientific production and instead of other type of innovative product (i.e., patents or utility models). Many university systems in the region reward scientific publication, not patent registration. Many companies use forms other than patents (industrial secret, utility model and, in software, copyright) as forms of protection of intellectual property. The number of scientific articles reflects significant efforts in the Latin American region, which should work to connect such efforts to technological development. Thus, it is not a matter of lacking "innovative culture," but rather that the scarce use of patents is basically the result of the type and scope of their innovative activities and protection models.

These characteristics common to the Latin American NISs serve as a guide for the work every country should do to analyze and strengthen their respective systems. The relations between the organizations and institutions that make up NISs are different in each country and it is therefore important for each one to draw up national research and development plans by identifying the most appropriate public policies.

2.4.4 Public innovation policies

The developing countries' lag as regards the processes of creation, dissemination and use of the developed countries' innovations should be the object of concern and should give rise to public policies to close the gap. Innovation promotion policies should be understood as part of the development policies of a country or region. Just as development improves the living standards of the population of poor countries, public innovation policies should be a strategy to attain levels of creation, dissemination, and use of the knowledge of the most developed countries (catching up strategy).

> The role of productive policies is to help create the conditions for developing the innovation process, in the widest sense, and advance in the complementarity of the production structure (. . .) in contrast to the developed world, innovation in the developing countries is frequently

> more related to the process of adopting and adapting new technologies or forms of marketing than to creating new technologies or processes. In the developing countries, therefore, innovation (defined in the broadest sense) is basically related to investment, but since the "discovery" is not fully appropriable, due to the impossibility of patenting it, the appearance of new activities or processes is less than socially optimal (Machinea and Vera, 2006).

Carlota Pérez (1992) identifies several levels in which Government can act to boost the competitive restructuring of knowledge and technology-generating agencies and institutions. An initial level is the elimination of obstacles, hindrances, and mechanisms inherited from former systems. A second level is supplying facilitating resources in the form of financing, human resources, and infrastructure. A third level is the promotion and guidance of the technological change. This last level is related to systemic competitiveness and the forming of an NIS as such. At present, firms do not compete alone, but find support from the synergies created by NISs.

> In some developing countries there might be sufficiently strong economic groups to attempt to compete alone, but most enterprises in most of the countries would find it difficult to act in an isolated manner. The two necessary conditions –synergy and dynamic evolution– would most likely be attained on the basis of the establishment of a powerful 'national innovation system'[2] (Pérez, 1992).

Public policies to promote technological change and innovation processes should act on the three levels identified, but it is in the third where Governments can be more proactive, specifically in two major areas: (1) policies aimed at modifying market incentives and (2) those aimed at providing public goods (Melo, 2001).

In general, policies aimed at modifying market incentives have to do with fiscal and financial measures. The first of these include public financing for research projects, joint projects between public and private sectors, and use of public-sector procurement to induce innovation. The second are credit policies, risk capital policies, and others.

In regard to policies directed at supplying public goods, Melo (2001) highlights five policies (1) policies aimed at the dissemination of technology (particularly important for countries that do not create technology but adapt it); (2) policies aimed at the development of human resources; (3) direct production of scientific and technological knowledge by means of government financed research and development in public universities and research institutes; (4) initiatives in which the government plays a special role in organization and convening, such as promotion and creation of clusters of innovating companies; and (5) policies related to regulations and the setting of standards.

Each of these policies in which the public sector can be proactive has given rise to debates and analysis which are not addressed in this chapter. Institutional functioning, internal political relations, and the interaction between State and market adopt different forms in each country. In this regard, the preeminence of one policy over others should be appraised depending on the case.

2.5 Protection of Intellectual Property Rights (IPR)

The analysis of NISs includes intellectual property as an important institution. In some cases, intellectual property can be a powerful incentive for innovation, but in others, such as adoption of technology, the use of foreign technology, and the catching up processes can be an obstacle, although not always. Over and above this distinction, however, what must be kept in mind is that the weight of intellectual property in NISs is increasing by the day.

Innovation is costly, uncertain, and generates externalities, since the appropriation of its results tends to be incomplete and is easily appropriable by agents that have not invested in it. Although uncertainty – the success or failure of a research project or the usefulness of its results – is always present, the public sector can promote mechanisms to reduce it by means of the right incentives.

The private sector also intervenes in innovating activities and profit is its main motivation. Since innovating activities are essential for creating new technologies, which create more productivity, competitiveness, and growth, it is of prime interest that the greatest number of private and public agents become involved in them.

In order to increase the supply of knowledge and innovations it is necessary to provide private agents with the appropriate incentives so that they can cope with the high costs, the uncertainty, and the incomplete appropriability of knowledge implicit in the results of the research. Such an incentive is monopolistic power over the invention to ensure returns on the investment and encourage the risk of undertaking subsequent innovations. In view of the imperfect nature of the appropriability of knowledge and related technical inventions, monopolistic power can only be exercised by means of an adequate institutional framework.

The institutional mechanisms of monopolistic power over innovations are diverse, but the most common are the secret, commercial mechanisms, and intellectual property rights (IPR).

The secret is a mechanism based on asymmetric information in favor of the creator of a product or technology. It is based on non-disclosure of the invention, not even before the authority, which guarantees de facto monopolistic power of the proprietor over the invention. The main risk for the proprietor is that if its formula is discovered it will be left without protection.

Commercial mechanisms are based on firms' own attributes – leadership, prestige, tradition, cultural or historical legacy, productive capacity, market knowledge, distribution, logistics, etc. – in competing with producers of similar goods. Thus, such firms can benefit more from the intrinsic or aggregate value of the good than from the value of its use. Their market edge helps them to remain as productive leaders and innovators.

IPR "the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields (...). Intellectual property law aims at safeguarding creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the use made of those productions" (WIPO, 2004). Thus, IPR grant appropriability to goods which the latter do not possess. In this manner, economic attributes of appropriability are assigned to knowledge and

innovation through a legal institution. Unprotected goods are subject to open competition with similar goods whose quality and price determine their demand. But when a good receives legal intellectual protection it acquires a category similar to a non-replaceable good, for its production becomes an exclusive right of the holder (Box 2.2).

2.6 Local Endogenous Development and Geographical Indications

As has been explained above, every region possesses specific knowledge, local production linkages, and its own entrepreneurial capacity. Historically, this has given rise to its own techniques, preferences, etc., all of which constitutes human resources, institutional, and production potential, which is also regions' potential for development.

The regions with a critical mass of micro and small enterprises vertically or horizontally integrated in specific production processes for which they have generated certain knowledge, production methods, and organic interdependence are living a process of local endogenous development.

In many cases, local endogenous development creates products whose prestige and specific qualities are socially recognized and related to their geographical origin. Such products can be protected from the competition of "similar" products of different origin. This type of protection, like the rest of IPR, is a method of appropriation of extraordinary income generated in this case by prestige, local know-how, and geographical location.

Geographical indications and protected designation of origin are mechanisms of protection of local production that can be used to promote agricultural or traditional craft production and stimulate its variety, protect producers from imitators, and provide certainty to consumers regarding the quality and origin of the product.

This form of protection is regulated by the TRIPS agreements of the World Trade Organization (WTO) (Annex 1C of the Morocco Agreement whereby the WTO is established, signed in Marrakech on April 15 1994). Attempts to legislate these mechanisms date back to the end of the nineteenth century at the Paris Convention for the Protection of Industrial Property, signed on March 20, 1883 and revised and amended on repeated occasions. In WIPO, appellation of origin is protected by the Lisbon Agreement.[3]

At present, effective protection of geographical indications differs among the regions, that of the European Union being the most effective.

Box 2.2 Mechanisms for protection of intellectual property

The types of protection of the international juridical system for IPR are the following (WIPO):

a) *Inventions (patents).* A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. It is the most widespread and consolidated mechanism worldwide. This category includes utility models, which are exclusive rights granted to the holders of inventions and which prevent commercial use to third parties without authorization for a limited period. It has differences in form with regard to patents, but its content is similar, which is why they are also called "petty patents" or "innovation patents."
b) *Trademark.* A distinctive sign which identifies certain goods or services as those produced or provided by a specific person or enterprise.
c) *Industrial design.* The ornamental or aesthetic aspect of an article. The design may consist of three-dimensional features, such as the shape or surface of an article, or two-dimensional features, such as patterns, lines, or color.
d) *Copyright.* The right granted to creators to protect their literary and artistic works.
e) *Geographical indications.* A sign used on goods that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin.

In addition to these mechanisms there are new figures created by free trade agreements. DR-CAFTA (Free Trade Agreement between the United Status, the Dominican Republic and Central America) includes recognition of rights of deposit of microorganisms, the agreement on the distribution of program-carrying satellite signals, the international convention for the protection of New Varieties of Plants (UPOV),[4] domain names on the Internet, and copyright-related rights.
Source: Prepared by the author with WIPO and DR-CAFTA data.

2.6.1 Protected Designation of Origin in the European Context

Within the framework of its agricultural policy, in 1992 the European Union created the quality-control systems *Protected Designation of Origin (PDO), Protected Geographical Indication (PGI),* and *Traditional Specialty Guaranteed (TSG)* to promote and protect certain agro-food products (EEC Regulation No. 2081/1992), thus unifying the standards in France, Italy, and Spain under the name *Appellation d'Origine Contrôlée* (AOC) – the first created by the *Institut National des Appellations d'Origine* in 1935 – the *Denominazione di Origine Controllata* (DOC), and *Denominación de Origen* (DO).

The European Union distinguishes between Protected Designation of Origin and Protected Geographical Indication. In the former "all the productive processes (production, processing and preparation) must be carried out with recognized and proven specific knowledge," whereas in the latter the link with the geographical milieu is manifested in "at least one stage in the productive process" (Art 2. Regulations (EEC) No. 2081/1992).

The procedure for registering Protected Designation of Origin and Protected Geographical Indications is under the tutelage of the European Commission. The application for registration is done first before local governments, which process it before the Commission. The latter grants the designation after compliance with the requirements of the case and the non-objection of the other members of the European Union. One of the requirements is forming a group of producers and an inspection agency, which can be a public entity, generally the ministry of agro-food resources, with the participation of organized farmers.

In view of the lack of similar protection structures in other regions, the European Union recently initiated registration of Protected Designation of Origin and Protected Geographical Indications of third countries (Regulation EC No. 510/2006), whose products would thus be protected in the territory of the European Union.

2.6.2 Geographical Indications: Advantages and Risks

Geographical indications can create advantages for the protected regions and sectors, but they also involve risks. Common advantages and risks are summarized below:

2.6.2.1 Advantages

The European experience shows that the regions to which designation of origin have been authorized have succeeded in "...harmonizing productive efficiency in 'traditional' activities with technological innovation and growth of firms and employment." (Quintar and Gatto, 1992).

The successful cases show the development of networks of producers who combine cooperation and competition. In a simple representation of game theory, the creation of these networks is possible when the producers assume that the cost of competing is greater than that of cooperating.

The designation of origin creates singular income for local producers of particular products by assigning them exclusivity of origin with the regulatory requirements (climatic conditions, type of product, process, and ingredients, among others).

The designation of origin implies making the characteristics of the product homogeneous, as well as its subjection to quality and hygiene standards which in the long term make it more distinctive. Monopoly in conditions of association enables farmers to have a certain control over the sale price, which increases their benefits. Although this monopoly may on principle seem to be disadvantageous for

consumers, in fact it can be a benefit as long as the rise in price reflects an increase in product quality. Another advantage for consumers is the certainty that they are purchasing the product with particular characteristics and an increase in the variety of goods at their disposition.

Monopolistic rents and the dynamics of protection of the designation of origin – farmers' associations, strict quality controls, increasing production standards, etc. – can generate endogenous innovative processes.

Designation of origin contributes to improving farmers' competitive and innovative capacities, which motivate the transformation of local productive systems, stimulating the forming of a territorial culture (Silva, 2005). This transformation does not involve the substitution of forms and techniques of production, but their appraisal and the introduction of innovative production processes which make local tradition compatible with the competitive environment. The advantage of combining micro ambits (local farmers) with macro settings (external competitiveness) is based on an endogenous vision of development, in which public–private association is a necessary element for promoting development.

2.6.2.2 Risks

The adoption of geographical indications in regions where the distribution of the means of production and technological capacities is very uneven can give rise to greater concentration of wealth. In this regard it is interesting to study the case of agave tequila in Mexico (see Box 2.3).

Box 2.3 Economic and social consequences of protection of Agave Tequila in Mexico

The *Denominación de Origen Tequila* (DOT), instituted in 1974 and currently regulated by Mexican Standard NOM-006-SCFI-2005, is Mexico's oldest. This protection was gradually expanded in agreements signed by Mexico with the United States, the European Union, Canada and Japan, the main markets for this beverage.

The appellation covers the entire state of Jalisco (124 municipalities) and municipalities of Nayarit (8), Michoacán (29), Guanajuato (6), and Tamaulipas (11). This concentration is explained by the Jalisco origin of Tequila in the municipality of the same name, as well as by the concentration of plantations of tequilana Weber blue agave, which cover approximately 90% of all the DOT in the said region.

The economic effects of DOT have been contradictory. On the one hand, thanks to public policies of protection for private initiative, the value of overall production of this beverage (without distinguishing sales categories or terms) rose in the last decade to reach the record of 2,240 million pesos in 2004

(SAGARPA). This result evidenced not so much the increase in production of the beverage in liters, which actually fluctuated, but the final sale price (see Chart 2.2)

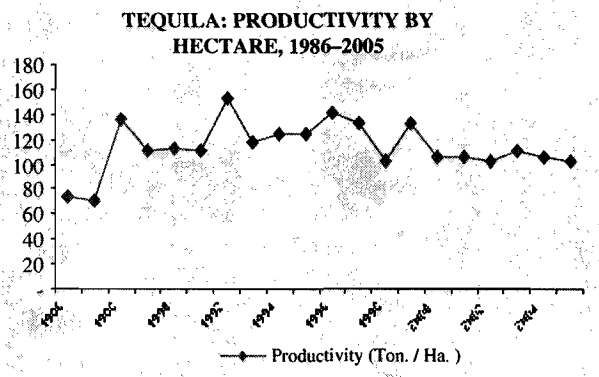

Chart 2.2

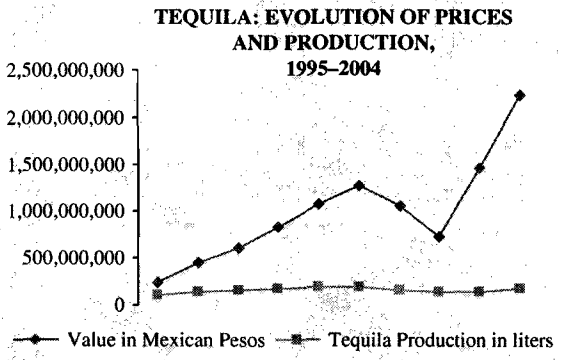

Chart 2.3

Some authors attribute these results to the increase in the competitiveness of the tequila industry, but this is not reflected in certain key indicators of the production chain. In fact, the production of tequilana blue agave, the raw material of tequila, has been constant over time (see Graph 2.3). Likewise, the average quantity of agave plants used to distill one liter of tequila and the proportion of labor (agricultural workers) in total production have gradually decreased (see Charts 2.4. and 2.5), which has an effective social impact in terms of demand for inputs and employment. In addition, the marked fluctuation in the price of agave due to lack of coordination between *agaveros* (agave producers) and industries.

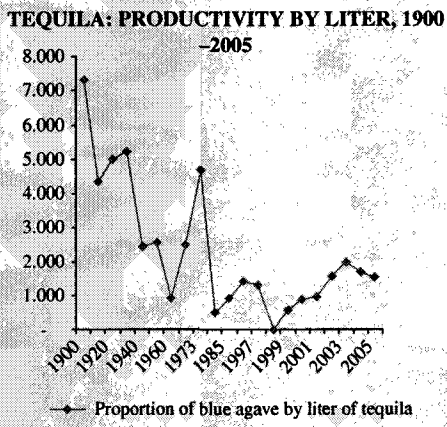

Chart 2.4

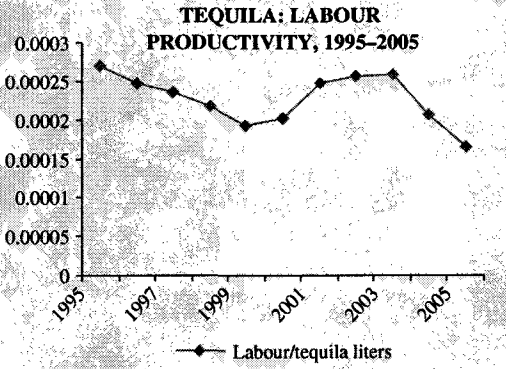

Chart 2.5

This fluctuation led to the so-called Agave War of 1996 due to oversupply which sank the price of agave to 0.75 pesos per kilo and ruined farmers. In 1999 scarcity raised the price to 14 pesos a kilo and this time it was the industries who suffered the consequences.

At present, three producers (Cuervo, Sauza, and Herradura) concentrate almost 60% of production and have plans for self-supply, which has resulted in agave planting being deconcentrated from the original region toward others with agave at a lower price. There is no doubt that the dispute between *agaveros* and *tequileros*, and unequal power relations in the industry do not favor the region's harmonious development, despite the industry's considerable growth.

Source: Prepared by the author with data from Consejo Regulador del Tequila (CRT), SAGARPA, Llamas, Jorge (1999).

Geographical indication should be defended from its possible infringers – producers from other areas, producers who violate the standards and characteristics of the product – in search of the benefits of public recognition and price of the original product. This defense has costs which can be very high. In cases in which protection benefits a small group of farmers of medium or small size, the costs can exceed the benefits and discourage regional productive organization.

One threat against successful geographical indications is unfair competition from farmers alien to the area delimited by the designation of origin, who, given a product's reputation, find incentives in its illegal production. The consequences of unfair competition, in addition to the direct loss of income caused to the legitimate producers and the costs of litigation, harm the quality and good name of the product. The cost of preventing such competition is a disincentive for the creation of geographical indications. Effective public mechanisms to minimize this risk are essential.

Finally, it is important to bear in mind that the knowledge underpinning geographical indications is in the public domain, and therefore its appropriation is not regulated, much less prohibited. In this regard, geographical indications should be considered one of various measures of protection of traditional knowledge. This opens the possibility of other IPR, such as distinctive signs, trademarks, or technical ideas on how to make some products, regulating the matter in a overlapping manner (Rangnekar, 2004).

2.6.3 Endogenous development policies based on local innovation

Endogenous local development policies based on regional characteristics and on the assessment of their capabilities identify a strategy that would make it possible to integrate local production with the national and international spatial locations (UNDP/ILO/UNOPS/EUR, 2002). Following Bianchi's (1992) view, two areas of action can be differentiated in public policies for intellectual protection of industrial production: a macro level which defines entitlements and a micro level that defines capabilities.[5]

It is on this latter level that intellectual protection faces the greatest difficulties in Latin America. In contrast to European enterprises with well-defined institutional ambits, Latin America's production units face problems derived from an insufficient educational, research, and production structure and the inability to enforce existing legislation. Another difference is that the competitiveness of small European firms is based on structures of cooperation, as is the case with the Italian industrial districts and the Spanish and French clusters, which are absent in Latin America's tradition. Nor should one underestimate the importance of the macro level in which entitlements are defined. Suffice it to recall that few Latin American countries regulate geographical indications.

Public policy can help to create favorable conditions for the emergence of local endogenous development activities. On a macro level (Bianchi, 1996), the Government can provide the legal framework to facilitate the organization of producers' networks in certain regions and regulate the creation, registration, and protection of geographical indications.

Local know-how, supported by protection granted by trademarks and geographical indications, can be strengthened and evolve toward greater diversification and product reassessment. Financial policies – access to credit – and policies of support for innovation – science, technology, education, etc.– are fundamental in making local processes gradually incorporate useful innovations.

Local innovation arises as a result of traditional knowledge and its application to production. Local innovative processes can receive impetus from the demand side (demand for greater quality standards, regulations, and specifications) and from the supply side (improvements by firms to processes or products). In both cases, the elements described in Box 2.1 structure a supply of services that has proved to be very useful in introducing innovations into local productive systems.

Another important element is the dynamics of forming capital stock. As illustrated by the case of Turrialba cheese in Costa Rica, local identity and capital stock, in addition to being the result of its own geographical and historical factors, are also built up constantly in spaces of concerted agreement and trust among the stakeholders. These spaces can also be built or promoted by public policies (see Box 2.4).

Box 2.4 Turrialba Cheese (Costa Rica)

The case of Turrialba Cheese of Costa Rica serves to analyze current limitations of small-scale and informal production in contrast to organized and legally protected production. This cheese is produced in the vicinity of the Turrialba Volcano, in the district of Santa Cruz de Turrialba. The dairy production involves around 175 production units, basically of two types:

a) Family operated firms with informal production (60%), on a small scale, lacking of strict standards of hygiene, without registration of trademark or marketing structure, which limits the marketing of their products. In the year 2000, some of them formed the *Asociación de Productores Agropecuarios de Santa Cruz de Turrialba* (ASOPROA).
b) Agroindustrial mini-plants organized in general as cooperatives (some 25). Their origin goes back to 1989 through the Program of Rural Cheese makers promoted by public entities and international cooperation (Cascante, 2003). Now they have more competitive technology which enables them

to produce, in addition to the cheese, sour cream, pasteurized cheeses, and butters. Moreover, by operating in the formal sector, they benefit from trademarks and registers.

With regard to production strategy, whereas family operated firms tend to carry out "backward" vertical integration, since they are the producers of the milk they use for cheese production, the mini-plants have specialized in processing by means of "forward" integration, including the stages of transport and marketing. Cascante (2003) remarks that one of the elements that the development of these rural agroindustry mini-plants has achieved is the forming of a capital stock manifested in the "capacity for transmission of information through the conglomerate."

Despite the advantages of formal enterprises, these suffer inconveniences similar to those of the family-operated firms, among them the lack of industrial protection regulations and *unfair competition*. The latter takes place within and outside the organization and is harmful to consumers, which is explained by the lack of process regulation, characteristics, and price margins so that the product has protection based on geographical indication.

In 2002 a second association of dairy producers was created in Turrialba: the *Asociación de Miniplantas de Turrialba* (ASOPLUT), which has made it possible to broaden the positive effects of association in the region.

Recently, ASOPROA took steps to obtain the designation of origin for Turrialba Cheeses at the Ministry of Agriculture and Livestock (MAG). Administrative procedures are in place since new regulations for Law 7978 (Law on Trademarks and Other Distinctive Signs) have been recently put in place (2007). In parallel, the creation of a Cheese Expo-Fair has been promoted, an annual event for marketing and publicity for the product (Cascante, 2003).

Source: Prepared by the author with data from Cascante (2003).

2.7 Foreign Direct Investment (FDI)

The determination showed by the majority of the developing countries to attract FDI indicates their high expectations in its contribution to development. As Paus (2005) points out, on the macroeconomic level FDI is expected to generate greater investment, employment, and fiscal revenues. On the microeconomic level, spillovers in technology, marketing, and good business practices are expected. Faced with the regional weakness in capital formation, it is expected that these investments

will replace the lack of national investment and thus cover the cost of the modernization of equipment and machinery necessary to compete in the international market.

Latin American economic performance shows weak capital formation which has not grown significantly in the last 15 years, remaining well below the 25% minimum that the United Nations Conference on Trade and Development (UNCTAD) indicates as necessary for maintaining a process of sustained growth in the less developed countries (UNCTAD, 2003).

With regard to innovation, it has traditionally been maintained that NISs are based on the mobilization and development of a country or region's endogenous economic potential. However, a number of authors (Asheim and Vang, 2006) indicate that, due to limitations with regard to capital, training, formal education, and industrial knowledge, the developing countries often depend on exogenous sources of capital, technology, and knowledge.

Transnational corporations have always been a controversial source of capital, knowledge, and technology. Although FDI can be a source of financial capital that replaces the lack of domestic savings, increases local competition, and links local producers in some cases, it is also true that frequently its localization in particular countries is only a cost-reduction strategy. In such cases, its presence does not entail technology transfer nor support for or linkage to local firms or to training and research centers.

The possibility that a hosting economy can take advantage of FDI and embark on endogenous innovating processes furthered initially by exogenous sources depends on a number of factors. Absorption capability and the national strategy to link transnational corporations to the local productive system require special attention. In both cases the types of protection for knowledge – patents, utility models, industrial secrets, among others – are determining factors for transfer of knowledge and technology.

2.7.1 Absorption Capabilities

In order for a developing region to initiate a process of systematic generation of knowledge and technological improvements by taking advantage of foreign investment, initially there is a need to develop capabilities for absorption of knowledge and technology.

Absorption capabilities are routines, habits, skills etc., that allow a company or its regional environment to benefit from the knowledge and information of the setting in which it finds itself, process them, and apply them so as to upgrade its capabilities.

For authors such as Cohen and Levinthal (1990), absorption capability is a function of original domestic knowledge – prior to the arrival of any foreign investment – and of the institutional context. The latter refers to the way in which the capital stock transmits and disseminates the knowledge contributed by a foreign company (spillovers) and the manner in which organizations support and promote this dissemination.

The capability of a region to make the best use of the knowledge developed in other regions by foreign firms will largely depend on prior and continuous investment in human capital (ongoing training, curricular improvements, etc.). But it will also depend on the interaction between the transnational corporations and their environment: suppliers, universities, other transnational corporations, research foundations, etc.

Although to a large extent they existed prior to the arrival of foreign investment, absorption capabilities can also be created and reinforced with the passing of time. However, it is also true that the rules with regard to appropriability of knowledge and technique are currently more restrictive than a few decades ago due to the regulations on intellectual property. For this reason, authors such as Chang (2002) indicate that by means of their stringent rules on intellectual property, the developed countries have kicked away the ladder they themselves went up, thus avoiding latecomers.

Moreover, the circumstances of the international market and investment attraction policies have changed a great deal over the past two decades. Until the early 1980 s, Latin America applied import-substitution policies which discouraged innovative FDI. In many cases FDI was viewed as a counterproductive competitor as regards local industry, which is why it was often faced with restrictions and adverse regulations. In many cases, restrictions on imports of inputs did not permit the development of competitive industries at international level, and therefore the transnational corporations located in Latin America did not generally develop their export potential and remained as suppliers for the domestic market. By contrast, countries such as Korea and Hong Kong attracted FDI whose main purpose was achieving competitive prices in order to export. The circumstances enabled such countries to obtain certain performance conditions from those corporations, such as linkage to local firms, and activities to facilitate technology transfer, among others. Now it is very difficult to do the same due to the strong competition to attract FDI, so the host countries lack the negotiating muscle to obtain specific conducts to facilitate the transfer of knowledge and technology.

For the above-mentioned reasons, the potential of FDI to transfer technological capabilities largely depends on domestic factors in the hosting economy that facilitate its absorption. Although IPR restrict certain activities that would facilitate that absorption, they also offer opportunities that countries should study and incorporate into their national innovation plans, i.e., greater disclosure of patent contents, expired patent data banks, exceptions to intellectual property rules for academic research centers, etc.

2.7.2 National Strategy of Linkage to Transnational Corporations

Whatever the reason for which transnational corporations choose a particular region for their operations, the greater or lesser transfer of knowledge and technology they spill over will depend on the local strategy for linkage to them.

Direct or indirect spillovers by transnational corporations tend to be scarce (Narula and Marín, 2005; Fosfuri et al., 2001) and, in many cases, these firms have explicit policies to reduce knowledge spillovers. Nevertheless, for many developing countries, basing a technological development strategy exclusively on endogenous capabilities can be a sentence for the strategy itself. Therefore, in many cases national innovation strategies go through a stage of attraction of FDI and linkage mechanisms to obtain the greatest contribution to national development.

Strategies for linkage to transnational enterprises tend to require the following elements:

a) **Absorption capability of local firms**
This element is fundamental and depends on the capabilities developed before the arrival of transnational corporations. However, as has been explained, absorption capabilities can be strengthened by means of specific actions: investment in physical and human capital, movement of employees and professionals between firms, and access to the international market and to high-quality inputs. The potential spillovers of transnational corporations will only be taken advantage of if local firms are capable of absorbing them. This is also true for institutons other than companies: universities, research centers, and others.

b) **Public programs that promote production linkages**
The arriving of transnational corporations in a region does not automatically lead to the search for local suppliers or to local companies seeking to link themselves to them. Public programs that provide incentives and offer resources, generate personal contacts, etc., have proved useful for creating links between companies. One example is the Program Costa Rica Provides,[6] which promotes production linkages between multinationals and small and medium-sized local firms. Its objective is to support the latter so that they become suppliers of the former. Among its actions are keeping a national register of local suppliers, lobbying, and making contact with multinational corporations and following up on the linkages achieved.
When they set up their business in some country, transnational corporations already have international suppliers that comply with their quality standards and extended services. Some local firms should begin by finding the niches in which they can supply transnational corporations and show that they can do so with identical or higher standards than their competitors. Local firms will often require certifications, substantial improvements in their productive processes, human capital, new knowledge, and significant investment for which public programs can be important allies.

c) **Quality local teaching institutions with the capacity to adapt**
Human capital with the skills required by transnational corporations is an important factor in their investing decisions. But once the investment has been made, the country's capacity to upgrade the skills and knowledge of its human capital can determine increases in the value chain of the firm itself.
In some sectors, especially those linked to leading-edge technologies, changes in the market and in technique tend to occur with increasing rapidity, which means that labor and educational programs must adapt quickly.

The quality of training and teaching institutions and research centers is crucial for a region to be able to offer increasingly sophisticated links to transnational corporations. Such links in turn raise the company's exit costs, which can result in greater links.

Laboratories can offer quality services, especially to local firms, so that they improve their products and services, as well as certifications and research programs suited to their needs.

The costs of graduating professionals and technicians whose knowledge and skills respond to the state of the art in their field are high for the developing countries. But it is a question of a long-term goal so as to take growing advantage of potential FDI transfers.

d) **Infrastructure**

Some requirements that local firms have to comply with in order to link themselves to transnational corporations have their limits in national infrastructure: laboratories with sophisticated services, energy services, transport, telecommunications, hazardous wastes treatment, etc. Some of these services can be provided by the private sector, but if the latter is struggling to modernize, the assistance could come from the public sector as the main provider of infrastructure for development.

2.8 Final Considerations

As a development strategy, putting emphasis on local know-how and its production relations (linkages) is a means of support for endogenous processes of strengthening entrepreneurial capabilities and useful local knowledge.

Local endogenous development is a way to promote the market based on local knowledge and also to encourage continuous improvement of processes and products. In a market in which knowledge incorporated into tradable goods is increasing, the generation and incorporation of domestic knowledge and its useful incorporation into the market becomes important.

In the current context, the rules regulating trade and industrial property pose challenges for small-scale producers and for strategies to promote local development. Restrictions on copying and technological adaptation also curb the capacity for technological absorption and make it difficult to take technological leaps to reach the most advanced countries. Other than this, mechanisms to protect local knowledge have been used little in Latin America and therefore their potential value is difficult to assess. Equally important but not much studied is the entry into new areas of protection of knowledge that could suit the countries of the region, for example, forms of protection of collective knowledge, mechanisms for access to the protection of that knowledge, etc.

Local endogenous development is one of the many public-policy options for supporting existing knowledge and strengthening its development. Equally important can be a strategy of selective attraction of FDI, complemented by national efforts of support for the capacity of its utilization: absorption of its advantages and production linkages.

The way in which a country or region creates or uses knowledge and innovations is highly relevant in the current context. There is a need for a national innovation system which is constantly reinforced in order to boost local innovative capabilities. These systems should use all the available tools, among them the incentives of intellectual property rules. As part of national innovation systems, the weight of standards of protection of intellectual property is ever greater, especially in open economies with a strong weight of foreign trade. It is therefore essential to seek the opportunities that these rules offer, use their flexibility for the promotion of national innovation policies, and adapt them to the local reality one wishes to protect.

Notes

1. These processes have led to the largest firms being rewarded, which is why in countries such as Costa Rica, which has successfully entered international trade currents – exports rose from 21.7% of GDP in 1985 to 47.4% of GDP in 2005 – distribution of wealth has worsened, measured on the Gini index, from 0.3512 (1985) to 0.4567 (2004) (INEC, National Survey on Household Income and Expenditure, 2004).
2. Author's own translation into English.
3. Its members are Algeria, Bulgaria, Burkina Faso, Congo, Costa Rica, Cuba, Czech Republic, France, Gabon, Georgia, Haiti, Hungary, Israel, Italy, Mexico, Moldova, Peru, Portugal, Republic of Korea, Serbia and Montenegro (before their division), Slovakia, Togo, and Tunis.
4. UPOV (Union for the Protection of New Varieties of Plants). Agreement on protection of intellectual property of the process of plant improvement to encourage the creation of new plant varieties (WIPO).
5. According to Bianchi (1996), "the macro level defines the entitlements of those who can take part in the game, creates the regulatory system governing the behaviour of the stakeholders and sanctions 'evaders' and the abuses of those who occupy dominant positions" (...) "The micro level defines the capabilities of the stakeholders in the economic arena, which means that micro policies include not only local firms, but also educational institutions, infrastructure, etc."
6. See web site: www.crprovee.com

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Part II
The Frontier of Trade Negotiations

Chapter 3
The Flexibility of TRIPS and Its Possible Erosion in Bilateral, Multilateral, and Regional Negotiations

Andrés Moncayo von Hase

3.1 Introduction

The architecture of intellectual property rights has become increasingly complex, especially since the entry into force of the 1995 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) reached during the Uruguay Round of GATT which ended in the establishment of the World Trade Organization (WTO).

Certain important issues have arisen over time, such as the need to establish an adequate interaction between intellectual property rights and public health needs expressed in the Doha Declaration of November 14, 2001. Likewise, at present, intellectual property rights constitute an essential aspect of bilateral and regional trade negotiations, to the extent that trade agreements signed recently by the European Union and the United States with various countries include chapters on the matter, many of which expand the rights and obligations provided for in TRIPS. In addition to this are the exercises in alignment of patent laws in the World Intellectual Property Organization (WIPO) and the negotiations and instruments on access to genetic resources, their conservation, and the fair and equitable benefit sharing at the Convention on Biological Diversity and the Treaty on Plant Genetic Resources for Food and Agriculture in effect since mid-2004. All of this poses the challenge to the developing countries of adopting the complex framework of intellectual property as a tool for their development objectives and not as an end in itself. Currently there is a sort of permanently open negotiations agenda in this field.

Some of the issues that have been the object of discussion in various bilateral and multilateral forums will be dealt with in this chapter, namely (1) patentability,

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(2) patents and public health, (3) undisclosed test or other data, and (4) exhaustion of rights and parallel imports. Many recently signed trade agreements, especially bilateral ones, tend to limit and fade the flexibility margin of TRIPS. Below we will cover the aforementioned issues and the international negotiations taking place around them, considering the possible impacts at national and regional levels.

3.2 Patentable Subject Matter

3.2.1 Introduction

Article 27 of the TRIPS Agreement, under the title "Patentable Subject Matter," evinces the importance and growing weight of immaterial goods in the economy and in companies' strategies, particularly in the most developed economies.

This provision sets a broad standard of patentability based on non-discrimination, in terms of the technology or the place from where it originates and specifies the specific cases and grounds for which the Members may exclude certain developments of patentability.

Article 27 states

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.[1] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70, and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.
2. Members may exclude from patentability any inventions, of which the prevention within their territory of commercial exploitation is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed 4 years after the date of entry into force of the WTO Agreement.

3.2.2 The Non-discrimination Principle

Paragraph 1 of Article 27 enshrines as a basic principle that patents shall be available for any inventions, whether products or processes in all fields of technology, without discrimination as to the place of invention and the field of technology, provided that they are new, involve an inventive step, and are capable of industrial application.

On interpreting the notion of "non-discrimination" in the case of "Canada Patent Protection of Pharmaceutical Products" contemplated in Article 27.1, the Special Group instituted in the sphere of the dispute settlement mechanism of WTO, within the framework of TRIPS, in some way advised to avoid the use of the term "discrimination" in the cases in which other more precise standards should be available. Thus, certain TRIPS provisions referring to discrimination – such as national treatment (Article 3) and that of most favoured nation (Article 4) – were drafted in a more precise manner without alluding to the concept of "discrimination," which has a potentially broader interpretation than any other specific definition and pejorative connotations in the sense of unjustified imposition of differentially disadvantageous treatment (*de jure* discrimination). Discrimination may be due to an ostensibly identical treatment but which, due to existing differences in circumstances, has differentially disadvantageous effects, which at times is called "*de facto* discrimination." In view of the "infinite complexity" of the term, the Special Group deemed it advisable to dispense with it when possible, or interpret it cautiously, in order not to give it more precision than that which is intrinsic in this concept.[2]

The Special Group recalled that diverse panels of the General Agreement on Tariffs and Trade (GATT) and the WTO had been dispatched as regards de notion of *de jure* and *de facto* discrimination. These recommendations have analyzed measures that were in conflict with various rules of GATT or WTO and have tended to prohibit various forms of discrimination. However, as the Appellate Body has emphasized on repeated occasions, the said recommendations have been based on the questioned legal text, in such a way that it is not possible to treat them as concrete applications of a general concept of "discrimination." Therefore, the Special Group decided to dispense with any prior general definition of such a concept and opted definitively for first analyzing the issues debated in the case and defining the concept of discrimination only to the extent that it were necessary.

It is interesting that the Special Group established particular guidelines and clarifications on the principle of non-discrimination in Article 27.1 on the measures that Members may adopt under Articles 7 and 8 and the *"limited"* exceptions to the rights of patent holders in Article 30 of TRIPS.[3] In this regard, the Panel states that "it is not true that Article 27 requires all Article 30 exceptions to be applied to all products. Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas."

From this reasoning one can infer that a national policy based on Articles 7 (promotion of technology transfer) and 8 (public health and nutrition and needs) can

result in exceptions in good faith for rights that could have effect on specific products. What is to be avoided with the principle of non-discrimination of Article 27.1 is that the public authorities succumb to domestic pressures so deliberately *"limit exceptions to areas where right holders tend to be foreign producers."*[4]

3.2.3 The Concept of Invention Under TRIPS and Positive and Negative Conditions of Patentability: The Case of Computer Programs

The TRIPS Agreement does not define the concept of invention. It does, however, stipulate that patents be granted to *any product or invention process*, as long as they are *new*, involve *an inventive step*, and are susceptible to *industrial application.* Nor are these three requirements defined, which means that their interpretation and application remains in the Members' judgement.

Some Members have established in their laws a general definition to the concept of invention (although this practice is tending to disappear) and others distinguish the invention of the discovery itself. Thus, inventions are associated with human creations that transform matter or energy for its utilization by man.[5] Other regulations, such as those of the United States and Canada, conceptually characterize the "patentable subject matter" by providing for the possibility of patenting *"any new and useful process, machine, manufacture, or composition of matter."*

Aside from these differences, national laws in general define the essential legal components of the invention in accordance with the three requirements for patentability specified in Article 27.1 of TRIPS. Obviously, the pertinence of the patents will depend on how the Members define and interpret the so-called conditions or positive requirements for patenting, that is, novelty, inventive step, and industrial application. A lax interpretation of such conditions can result in the granting of trivial patents which will not benefit society by blocking new research and not generating genuine incentives for research and development.

In any event, the fact that TRIPS has not legally defined the notion of invention, nor specified the scope and content of the positive requirements or purpose of patentability, has conferred on the Members a margin for action to continue with a practice prior to TRIPS, which consists of establishing "negative conditions of patentability." In fact, the current patent laws are not limited to establishing the positive and objective conditions of patentability of inventions, but set forth the cases in which legislators consider a priori that the invention does not exist.

Now, it is worth asking how the right of defining "negative conditions of patenting" combines with the principle of non-discrimination set down in paragraph 1 of Article 27, which prescribes that patents may be obtained and their rights enjoyed without discrimination with regard to the field and the technology. Can a national legislator, for example, decide that computing programs are not a "technology" or do not constitute a patentable invention?

Contemporary practice shows that many WTO Members are unwilling to interpret that the principle of non-discrimination of Article 27.1 entails the obligation to

recognize the patentability of computer programs. Thus, for example, the European Patent Convention does not consider computer programs inventions "as such" (Articles 52.2 and 3), although the European Patent Office (EPO) has been increasingly inclined to interpret the said provision in a restrictive manner by accepting patents for programs that display a "technical effect." This would be the closest intermediate position to the traditional public perception of what a patent means and seeks to protect. The most extreme position is that of the United States and Japan, which tend to protect computer programs and their effects, not necessarily technical, by extending patent protection to business methods (Lind-Edlund, 2003).

In any event, beyond possible interpretations, the legislative practice of WTO Members in general has not expressed the legal conviction that Article 27.1 obliges them to authorize patents for computer programs. Thus, for example, France's national legislation prohibits them, although this country is a Member of the European Patent Convention which has granted numerous patents to computer programs that have the effect of a national patent (Le Tourneau, 2003).

To be sure, in the current state of affairs, and without prejudice to the obligation of granting computer programs protection under copyright regulations, the Members have the right to define the legal concept of invention and the negative conditions of patentability in order to open or close the path to patenting computer programs, without reaching the extreme of denying them protection for the sole reason that they are inventions of an computer nature, or come from that industry.

3.2.4 Patenting Exclusions in TRIPS

3.2.4.1 *Ordre Public*, Environment and Health

Paragraphs 2 and 3 of Article 27 contain the patenting exclusions permitted to the Members of WTO. The first permits excluding the patentability of inventions whose commercial exploitation in the territory of the interested Members should be prevented to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment. The exercise of this right is subject to the exclusion not being made merely because the exploitation of the patent is prohibited by national legislation.

Thus, Members can deny patentability, for example, for food and pharmaceuticals which in their view are harmful to health. This provision is also important for genetically modified organisms, whose use has been criticized by sectors of civil society in many countries owing to the dangers they can entail for the preservation of the environment and biodiversity by transferring genes to the microorganisms present in the soil, genetic recombination, and the appearance of new pests and diseases. However, it is also true that many of them have contributed to the development of agriculture without it being possible to determine the specific damage they could cause.

In any case, the legal importance of this provision should not be underestimated, for it could be a link to the Convention on Biological Diversity (CBD) into force since 1993. CBD puts forward the following objectives: (i) conservation of biological diversity, (ii) sustainable use of its components and organisms, and (iii) fair and equitable sharing of the benefits arising out the utilization of genetic resources. In few words, it could be said that Members have the right to exclude inventions from patenting (e.g., genetically modified organisms) contrary to the objectives of CBD. All of this without ignoring the practical difficulties that could stem from applying exclusions of this nature to biotechnological inventions, as many national laws consider that the objective of patents is to encourage innovation, reserving for other branches of law, such as environmental law, to consider the risks and remedies to avoid them, including of course, prohibiting the exploitation, or marketing of the patented invention.[6]

3.2.4.2 The Right to Prohibit Diagnostic, Therapeutic, and Surgical Methods

Article 27.3(a) of TRIPS confers the right on Members to also exclude from patents *"diagnostic, therapeutic and surgical methods for the treatment of persons or animals."*

This exclusion, together with the absence of greater specifications on the difference between invention and mere "discovery," makes it possible to infer that there could be discrepancies on the level of protection that Members can grant to what is known as second use of substances or known products. This is particularly important for the pharmaceutical industry. Thus, bearing in mind that Article 27.1 makes it mandatory to grant patents for products or procedures, it says nothing, by contrast, about their uses. The same occurs with Article 28, which refers to exclusive rights that Members are obliged to recognize for patents' holders of "products" and "procedures."

In such a regulatory context, it is logical for differences to appear among Members. Some of them have not used the right to exclude from patentability diagnostic or therapeutic methods, stipulated in Article 27.3.a). Canada, for example, admits the patentability of diagnostic methods. The United States admits, in addition to patents on therapeutic methods, those of second pharmaceutical indication as *"method of use."* This means that in "discoveries" or "inventions" of a method to cure sicknesses with known substances, the method itself may be patented.

The situation in the field of the European Patent Convention is more complex, for it does not consider methods for treatment of the human or animal body as inventions susceptible to industrial application. It only admits one exception for pharmaceutical patents, limited to the first therapeutic indication. However, the European Patent Office (EPO) has admitted patents of second use or pharmaceutical indications indirectly by means of the "Swiss formula," that is to say, as a claim for a procedure in the form of *"Use of X in the manufacture of a medicine for the treatment of Y."*

Others understand that the claim for a new use of a product or a known substance is equivalent to a therapeutic method that Members of WTO can exclude from patenting. If patents protect inventions, finding a new application of a known product would be comparable to a discovery not susceptible of patentability. This is the direction taken by the Andean Community, whose Common Intellectual Property Regime (Decision 486) establishes in Article 21 that *"products or processes already patented and included in the state of the art (...) will not be the subject of new patents on the mere ground of having been put to a use different from that originally contemplated by the initial patent."*[7]

Argentina's patent law only recognizes this type of titles for products and processes, but says nothing about the patenting of new or second use of known substances or products, on which diverging opinions exist. Chilean laws, on the other hand, expressly provide for them.

As a consequence of the flexibility or lack of express regulation for second uses of products, known substances, or compounds, the solutions vary among countries, whether industrialized or developing. This means that under TRIPS, Members are free to adopt any of the stances provided for according to considerations based on protection of public health, the level of economic development, or the need to encourage innovation. These differences among legislations seem to take advantage of the flexibility of TRIPS and the Doha Declaration on TRIPS and Public Health of November 14, 2001.

3.2.4.3 The Process of Review of Paragraph (b) of Article 27

This provision authorizes Members to exclude the following from patentability:

> *b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

i) *The process of gathering information.* In its meeting of December 1988, the TRIPS Council agreed to begin the anticipated process of review through the gathering of information from the Members which should inform how they were applying Article 27.3 (b) in their jurisdictions. There was agreement in this regard, but not on how the process of review of Article 27.3 should be carried out. Countries such as India, Brazil, Egypt, and the Philippines sustained that the process of review to be carried out by the TRIPS Council should be substantial. The United States proposed revoking all exclusions permitted in the provision. The European Union initially insisted on changes, but finally accepted that it was not necessary to undertake a process of review and reform, but that it was sufficient to carry out the informative process on implementation of the article in question.

At present, it seems to be an emerging tendency or consensus toward leaving the article as it is. For developing countries, it would be a way to maintain the delicate

balance of interests in an area characterized by major differences between the Members of WTO. Developed countries, particularly the United States, have taken steps to reduce the margin of flexibility provided for in Article 27.3 (b) in their bilateral and regional trade agreements, which stipulate adherence to the International Convention for the Protection of New Plant Varieties (UPOV, 1991) and to the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1980), demanding also a future commitment of the Parties to make efforts to provide patent protection for plants. In general, the developed countries have begun to place emphasis on the exercise of harmonization of patent right undertaken several years ago by WIPO.

ii) *Positions on patenting of plants and animals.* There was a clearly favorable position for broad patent protection for inventions related to animals and plants, which may be summarize as follows:
   - Inventions relative to animals and plants should receive patent protection, in the same way as inventions in other fields, in order to promote private sector investments in innovation activities that contribute to solving problems in areas such as agriculture, nutrition, health, and environment in all countries (Japan and Switzerland).
   - To that end, it is necessary to have international regulations to protect inventions in animals and plants and not depend on national regulations (Singapore).
   - Patents facilitate technology transfer and dissemination of the state of the art and provide an incentive to the private sector to establish contract licensing, thus avoiding confidentiality (Australia).
   - The requirements of disclosure and the control conferred on patent holders can facilitate the implementation of laws designed to protect public morality, health, and the environment (Switzerland) (Table 3.1).

Against these positions, various developing countries expressed their concern for the growing tendency of developed countries to grant patents to different forms of life due to the negative impact this could have on development, food security, culture, and morality (India), namely

- The granting of patents for plants may have a strong impact on access, cost, reuse, and exchange of seeds among farmers, displace traditional varieties, and affect biodiversity (Kenya).
- The granting of excessively broad patents that do not satisfy patentability requirements has a negative impact on genetic material, traditional knowledge, and the cost associated with revocation of the said patents, while at the same time encourages "biopiracy."
- Another cause for concern is that international agreements mainly protect the interests of innovators, unlike those of countries and communities that contribute the genetic material and traditional knowledge that serve as the basis for innovations, for which reason agreements should be "rebalanced" in order to render more efficient the principles of CBD relative to prior consent and equitable benefit sharing.[9]

Table 3.1 TRIPS council: process of gathering information under Article 27.3 information on 25 Members of WTO[8]

Illustrative list of questions (patent systems)	Yes	No	Did not answer
Is there any basis for denying a patent on an invention consisting of an entire plant or animal?	17	6	
Does the patent regime exclude entire plants or animals as inventions?	2	13	8
Is it possible to obtain a patent claim that:			
Is not limited to a specific animal/plant variety?	13	5	5
Is expressly limited to one plant or animal variety?	9	11	3
Is expressly limited to a group of plants or animals?	5	17	1
Is it possible to obtain a patent on a microorganism?	23		
Is it possible to obtain a patent on an essentially biological process?	5	17	1
Is it possible to obtain a patent for matter identical to that found in nature?	1	17	6
Does the national law contemplate a "*sui generis*" protection?	22	2	2
The form adopted conforms to UPOV 1978 or 1991	17	5	2
	(UPOV 91)	(UPOV 78)	
Is prior authorization from the right holder necessary in the following cases?			
For research to develop new varieties?		22	2
To commercially exploit a variety different from the protected one, but sharing its essential characteristics?	13	8	3
Can a farmer harvest seeds from his planting of a protected variety legitimately obtained, store it, and replant it in his plantation?	1	20	3
If prior authorization is not required, are there mechanisms for remuneration to the right holder?	7	12	5

Source: Prepared by the author with WTO data.

In this context, the suggestions made in the discussions on the review of Article 27.3 (b) were the following:

- Exceptions to patentability authorized by Article 27.3 (b) are unnecessary and protection should be granted to all inventions relative to plants and animals (United States).
- The provision should be kept as it is (Australia), without diminishing the level of protection (Japan). The rule provides a balance by preserving Members' right to decide whether they exclude plants and animals from patenting according to their own needs and interests. There should only be a

process of assessment of the implementation of the rule at the national level (Japan).

- Article 27.3 (b) should be made more precise to prohibit patentability of all forms of life, especially plants and animals, microorganisms and their parts, including genes and natural processes that plants, animals, and other living organisms produce (India). Some followers of this position suggested that the rule be modified in accordance with the general exceptions and those linked to security in other WTO agreements (Kenya). It was proposed to modify the article in such a way that it prohibits patenting of inventions based on traditional knowledge and of those that violate Article 15 of CBD, which recognizes the sovereign right of States over their natural resources (India). It was also suggested that the obligation of the developing countries to implement Article 27.3 (b) should have a term of 5 years after the review process has been concluded (Kenya on behalf of the African Group).
- There were also proposals on the requirement of disclosure and dissemination of genetic material and traditional knowledge used in inventions.

iii) *Scope of the exceptions to patentability in Article 27.3 (b).* First of all, it was emphasized that the absence of definitions for the terms "plants," "animals," "microorganisms," and others specified in this provision gave rise to doubts as regard the scope of patenting (Brazil).

With regard to the definition of the terms "plants" and "animals," it was suggested that the parts of plants and animals that are excluded from patentability should be clarified (India), and there should also be a prohibition on patenting of cells, lines of cells, genes, and genomas (Kenya).

With regard to microorganisms, it was stated that there are no scientific reasons for distinguishing between plants and animals, on the one hand, and microorganisms, on the other. Both should be excluded from patentability on account of being living matter, which can be discovered, not invented (Kenya). It was also expressed that there is no scientific consensus on the meaning of the term "microorganism" (Brazil). For example, it has been questioned whether cell lines, enzymes, plasmids, and genes qualify as microorganisms (Brazil).

In response to these positions from developing countries, various developed countries expressed that the distinctions contained in Article 27.3 (b) are in keeping with the generally accepted scientific classification of organisms (Switzerland) and that the practice of classifying life forms into plants, animals, and microorganisms is widely accepted in international agreements, including CBD (Japan). It was maintained that the fact that TRIPS does not define the term "microorganism" only reflects that it has not been defined by patent experts in other fora such as the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the meetings of experts on biotechnological inventions at the headquarters of WIPO between the years 1984 and 1988. A document prepared by the United States patent office, Japan and Europe (EPO) stress that none of the laws administered by them contains a formal definition of the

term "microorganism." The administrative patent guidelines do not define either, and only identify specific microorganisms in a non-exhaustive list of organisms that can be included within such a term. As the EPO has noted, it would not be very practical to adopt a definition subject to frequent updates due to the rapid evolution of knowledge in microbiology. Therefore, if the definition was not made before, it would not be wise for the TRIPS Council to do so now.

In regard to the actions that should be adopted in WTO on treatment of microorganisms, the following opinions were expressed:

- Microorganisms and other living or biological organisms should be excluded from patentability (Kenya).
- The scope of the term "microorganism" should be clarified to exclude cell lines, enzymes, plasmids, cosmics, and genes (Kenya).
- Members may determine and apply the term individually in their own national jurisdictions in accordance with Article 1.1 of the Budapest Treaty, without trying to define it. Since the subject is a complex one, its interpretation should be left to patent offices and experts (Korea).
- The subject should be left to national policies so that they decide whether microorganisms are patentable (India).
- It is important to know the path taken by each Member within the framework of its own legal provisions in order to have a collective understanding of the terms under discussion (Australia).

Regarding microbiological and non-biological processes, the concern was voiced that Article 27.3 (b) should incorporate specific patenting obligations, but that it should not propose any definition (India). It was suggested that the artificial distinction between essentially biological processes, on the one hand, and microbiological and non-biological processes, on the other hand, be suppressed and both processes be given the same treatment (Kenya) or that the distinction be clarified (Brazil).

iv) *Conditions of patentability in Article 27.1 and inventions relative to plants and animals.* In the review process there were discussions about the manner in which novelty requirements, inventive step (not obvious), and industrial application (utility) are applied in microorganisms, microbiological processes, and other inventions related to plants or animals that may be patentable under national laws. In this regard, emphasis was placed on the lack of clear definitions of the notion of "invention" and the scope of patentable microorganisms, microbiological processes, and non-biological processes (India). Thus it was expressed that the national patent offices are the ones which should define these questions (Venezuela), although leaving them to the sole discretion of the Members could cause inconveniences (India).

One of those inconveniences would be laxity in the appreciation of requirements for novelty, inventive activity, and industrial application, which would question the credibility of the system (Brazil).

During the discussions the problem of the distinction between discoveries and inventions also arose, in particular the requirements to satisfy the test of inventive step or non-obviousness. It was stated that by stipulating that microorganisms and microbiological processes are patentable, TRIPS violates a basic premise of patent law which establishes that discoveries, in contrast to inventions, are not patentable (Kenya on behalf of the African Group).

The response to this approach was that life forms in their natural state do not satisfy the criterion of patentability of TRIPS. However, phenomena that occur naturally such as chemical substances and microorganisms that have been artificially isolated from their natural environment can indeed constitute inventions. When the patent subject matter involves sufficient human intervention, such as isolation or purification, and turns out to be matter whose existence was unknown until then, it can be considered a patentable invention (Japan, Switzerland, United States and Malaysia). To meet the criterion of patentability, plants, animals, or microorganisms and other genetic resources should be altered by the hand of man and produced by means of technical processes (Japan, European Union, United States, and Switzerland).

As regards the requirement of novelty, it was mentioned that some Members define it in such a way that they do not recognize information that is available to the public and that is used and transmitted orally beyond their jurisdictions (India and Kenya). Thus, much traditional knowledge becomes the object of patents without benefiting the communities that develop and transmit it.

It was also sustained that it was not clear whether certain patents of microorganisms adequately satisfy the requirement of industrial application, bearing in mind that its usefulness is doubtful even for the applicant himself (Brazil). Furthermore, in relation to patents involving genetic sequences, some Members demand describing its function and others do not (Pakistan).

In the face of these concerns, it was argued that the system provides for remedies such as opposition or revocation of the patent (Switzerland). The concern expressed by some developing countries is that such processes are very costly, especially those which do not admit opposition prior to the granting of the patent (India).

v) *Sui generis* protection for plant varieties: Regarding this point, developed countries held that plant varieties should be protected since this makes it possible to develop new technological solutions in the field of agriculture. The progress on the subject includes the development of new crops with greater productivity and resistance to pests and diseases (Japan and United States).

A group of developing countries voiced its concern over the adverse impact that protection of plant varieties can have on food security and the development of rural communities whose traditional knowledge has produced common varieties, including many valuable ones for medicine and biodiversity (Kenya). Concern was also

expressed that protection systems should hinder cooperation between neighboring farmers, a frequent situation in many developing countries (India).

In any case, some Members expressed that Article 27.3 (b) provides Members with flexibility to interpret the meaning of *sui generis* protection of plant varieties and that therefore, their status should not be modified (Brazil, Egypt, Malaysia, Mexico, Peru, and Venezuela). Some proposed to leave Article 27.3 (b) as it is, adding some clarifications on the meaning of "effective protection" (Brazil). The following points were proposed:

- Making reference to the UPOV Convention (European Union).
- Including a footnote after the phrase relative to the protection of plant varieties, stating that any system of *sui generis* protection of plant varieties can establish (1) protection for innovations of indigenous communities and local farmers in developing countries that are consistent with CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture, in force since June 29, 2004; (2) continuation of traditional agricultural practices that include the right to retain and exchange seeds and to sell farmers' crops; and (3) prevention of anticompetitive practices.

The Members also held discussions as to whether there is a criterion to judge the effectiveness of a *sui generis* system. The United States maintained that there was and that it was already being applied in other areas of real and intangible property. This consists of the following: (1) defining the nature of the protective subject matter; (2) providing a clear difference between the protected subject matter and the excluded matter; (3) determining who is entitled to request protection; (4) clearly expressing the circumstances under which rights exist and limitations appear; (5) specifying the term of the rights and the circumstances that determine their loss, expiry, and extension; and 6) identifying legal actions and proceedings to guarantee observance of rights.

The opposite position was expressed by India, which maintained that TRIPS had no criterion whatsoever to judge the effectiveness of *sui generis* systems.

Nor was there agreement on the subject matter to be protected by the *sui generis* system. To be effective, the system should include the whole of the plant kingdom (Uruguay). By contrast, some countries expressed that Article 27.3 (b) refers only to a *sui generis* system, without specifying details of the plant varieties to be protected (Peru). It was also emphasized that some farmers' privileges have been left to national legislators (Switzerland). In response to this, it was argued that farmers' privileges should not be limited to keeping and reusing (plantation) of the subject matter of protection within their plantations (Kenya).

There were also discrepancies regarding the term of rights. One stance assigned them 20 years from the date of granting to prevent the marketing of the protected matter or the preparations for this by third parties without authorization of the patent holder. The term of protection of new varieties of trees and wines should be 25 years as their development and marketing need more time (United States). Counter to this

opinion, other delegations considered that a *sui generis* system does not require a term of protection similar to that of patents, as Article 27.3 (b) does not specify it. Effective *sui generis* methods of protection such as UPOV admit a different duration (India).

vi) *UPOV: a system of "sui generis" protection effective under Article 27.3 (b)?* The Members also analyzed whether the protection of plant varieties by means of the UPOV regulations could be considered effective *sui generis* protection in the light of Article 27.3 (b) of TRIPS. In this regard, it was said that

1) TRIPS does not compel Members to follow the UPOV model of protection, but the latter satisfies the requirement of effectiveness of Article 27.3 (b) (Switzerland, Japan, United States, Uruguay, and the European Union).
2) The UPOV system is the most suitable for favoring and stimulating the development of new varieties in all the WTO Member (United States).
3) With regard to the concerns about the impact of UPOV on the right of farmers and plant breeders in developing countries, the flexibility of the system for satisfying national needs, such as the exception that protects farmers, was underscored.
4) Some delegations recognized the difficulties of creating and managing *sui generis* systems to protect plant varieties, but they maintained that the quickest and most effective way of implementing Article 27.3 (b) was to depend on systems of protection of varieties aligned flexibly to satisfy special national needs (European Union).

In answer to these opinions, other countries considered:

1) Article 27.1 (b) should not make any reference to UPOV, nor commit Members to use that system (Norway), although it is admitted that this is an important reference (Brazil). The Members can choose between other models of protection, such as that of the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (Brazil, India, and Zambia).
2) Incorporation of references to UPOV could alter the delicate balance of Article 27.3 (b) (Brazil).
3) There is no authorized interpretation as to whether UPOV satisfies the requirements of Article 27.3 (b) (India and Thailand).
4) UPOV is based on the protection of plant breeder in industrialized countries, not on the needs of the developing countries, despite the fact that UPOV 1978 recognizes farmers' privilege to replant stored seeds from previous harvests (India).

Finally, different points of view were expressed on the value and merit of the various Conventions of UPOV in the light of Article 27.3 (b). An important group of developed countries expressed that UPOV 1991 establishes a suitable balance

of interests, rights, and obligations. Emphasis was placed on the fact that this instrument does not permit Members to limit the varieties to be protected. This means that the new varieties not included in UPOV 1978 are included in the 1991 Convention. It was stressed that a growing number of States had adhered to UPOV 1991 and many others that signed UPOV 1978 were in the process of adhering (Switzerland).

In view of this, some developing countries stressed that although it is true that the number of Member States of UPOV 1991 had increased, a significant number of developing countries refuse to sign it to preserve the flexibility of UPOV 1978.[10] In this regard, it was underscored that UPOV 1978 allows farmers to store, exchange and, to a certain extent, sell seeds of protected varieties, whereas UPOV 1991 transforms those rights into privileges and exceptions, whose exercise will depend on the discretion of the governments that will only be able to permit the use of seeds by the farmer on his own plantations, subject to "reasonable restrictions" and bearing in mind the "legitimate interests" of the plant breeder. UPOV 1991 only allows the use of seeds in the same plantation. This would affect the food security of many communities in developing countries that depend on the storage, sharing, and replanting of seeds from former harvests (Kenya). The prospect of now having to pay royalties to be able to carry out these activities affects small farmers (Brazil). It was also held that UPOV 1991 only limits the right to sell or market the seed of the protected variety in the territory of the contracting Party, which constitutes an upsetting of the balance established by Article 6 of TRIPS, which allows States to choose the exhaustion of rights regime they prefer (Brazil).[11]

The debate at WTO on the scope of the notion of patentable subject matter and the exceptions to patentability has been extended to the deliberations of the Committee on Patent Rights regarding the Draft Substantive Patent Law Treaty of WIPO, whose purpose is to harmonize the substantive principles of patent law. In the absence of consensus, some developed countries, specially the United States and those of the European Union, have advanced by signing free trade agreements with developing countries that extend patent protection beyond the standards provided for in TRIPS. That is, the flexibility of TRIPS has gradually been eroded.

3.3 Patents and Public Health

On account of the public health crisis of the mid-1990s in South Africa and the difficulties in guaranteeing access to essential medicines for the majority of the population, the developing countries began to put forward the question of the relationship between patents and access to medicines in different international fora, beginning by the World Health Organization (WHO).

The conflicts between safeguarding access to medicines and international obligations derived from the WTO Agreements raised two important questions. The first is the conviction that the combination of competition in generic pharmaceuticals

and the ability to recur to the safeguards of TRIPS (e.g., compulsory licenses) had a pro-competitive effect on the price of medicines, as was evidenced by the reduction of more than 95% of the annual indicative price of the triple antiretroviral therapy from 10,000 dollars in 1996 to 140 dollars in 2003. This reality was confirmed when Brazil embarked on negotiations after announcing its intention to impose a compulsory license on the "antiretroviral patents" of two important transnational laboratories (Velázquez, Correa and Balasubramanian, 2004). A consequence of this announcement was a significant reduction in the prices of these medicines in Brazil without actually imposing compulsory licenses. One precedent that contributed to the idea of reconciling access to medicines and patent rights was the speed with which Canada and the United States considered issuing compulsory licenses to bring down the price of *cirpofloxacin* faced with the fear of dissemination of anthrax after September 11, 2001 (Velásquez et al, 2004).

This background paved the way for the Declaration on the TRIPS Agreement and Public Health adopted in Doha on November 14, 2001 ("Doha Declaration").[12]

As a consequence of the mandate conferred in paragraph 6 of the Doha Declaration to the Council for TRIPS, and after almost 2 years of negotiations, the Members of WTO agreed on a solution to the problems that could be faced by the countries with insufficient or non-existent capacity to manufacture the products protected by patents upon issuing compulsory licenses.

Thus, on August 30, 2003 the General Council adopted the Decision on *"Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health"* (WT/L/540), a mechanism known as the "Paragraph 6 Solution."

In the negotiations that resulted in the Doha Declaration it was made clear that the countries with little or no capacity for the manufacturing of generics drugs that recurred to compulsory licenses would obtain very little advantage. Indeed, two requirements of Article 31 of TRIPS that regulate the conditions to grant compulsory licenses raised a number of problems, in the Members' view, for the effective use of the system by the Members with no capacity to produce medicines, namely:

1) *Subparagraph f)* which permits use of the patent without authorization from the owner *"predominantly for the supply of the domestic market of the Member authorizing such use."*
2) *Subparagraph h)* which establishes that *"the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."*

If strictly applied, the first of these requirements would make it difficult to import the product needed by the country issuing the compulsory license ("importing country"), since if the latter has to acquire the product from a foreign manufacturer of generics other than the patent owner, the foreign manufacturer would need to obtain a compulsory license in his own country ("exporting country") if the product in question were protected there by a patent, and also this latter compulsory license

could only be granted in the exporting country *"predominantly for the supply of the domestic market"* of that Member [Article 31 (f) of TRIPS].

Following the above example, subparagraph h) of Article 31 of TRIPS demands paying remuneration to the patent owner. This would cause a double payment for, according to subparagraph f), "adequate remuneration" should be paid in the exporting country and in the importing country, which would cancel out the purpose of acquiring the product at a lower price. To provide for this eventuality, the so-called Paragraph 6 Solution authorizes exemption of the obligations established in subparagraphs f) and h). This means that only the beneficiary of the license of the exporting country should remunerate the patent owner, making the commitment to export only the amount of products requested by the importing country. The solution provides for a special procedure to prevent re-exportation of the product from the importing country to third countries, and a mechanism of notifications to ensure control of the circulation of the products, among other safeguards.

Box 3.2 describes the main characteristics of the Paragraph 6 Solution applicable only to pharmaceutical products, as this concept is defined in the above-mentioned Decision of the General Council.

Paragraph 11 of the Decision establishes that the Paragraph 6 Solution, including exemptions, will be invalidated once an amendment to replace these TRIPS provisions enters into effect. It also establishes that the TRIPS Council will begin preparatory work for this amendment at the latest by the end of 2003, for adoption within the following 6 months (June 2004).

This has not yet occurred. In recent meetings of the TRIPS Council, Members have put forward diverging positions on implementation of the amendment. In the meeting held on July 19, 2004 it was decided to postpone the conclusion of the work until the end of March 2005, an aim that has not been complied with, either.

Recent free trade agreements signed by the United States with developing countries contain provisions contrary to the Paragraph 6 Solution, or can at least hinder its implementation. An example is the provisions that make it mandatory to recognize data exclusivity for pharmaceutical, chemical, and agrochemical companies before the regulatory authorities of the States that demand prior authorization to market this type of products. As will be seen, this makes it more difficult to issue compulsory licenses, since to obtain authorization to sell a product subject to prior authorization, the licensee must have the patent owner consent to use the data of the product registration and thus, exercise the powers provided for in the compulsory license. Unless the member States of these recent agreements make the legal adjustments to facilitate an orderly and transparent interaction and reconciliation between data protection and the Paragraph 6 Solution, the application of the provision runs the risk of being obstructed, if not annulled.

In view of this tendency, it can be important for developing countries that could need the Paragraph 6 Solution to ensure that the Decision of the General Council that adopted it be embodied into the TRIPS Agreement, with a reference, if possible, to its supremacy over any other international agreement having a contrary effect (Abbott, 2004).[13]

Box 3.2 Paragraph 6 Solution

	Guidelines for the Paragraph 6 Solution
Pharmaceutical product	Any patented product or product manufactured through a patented process needed to address the public health problems. Includes active ingredients necessary for its manufacture and diagnostic kits needed for its use
Importing member	Any least-developed country and any other Member that has made a notification to the TRIPS Council of its intention to use the system as an importer. Such a Member may notify at any time that it will use the system in whole or in a limited way (e.g., the system may be used for national emergencies or in cases of public non-commercial use)
Exporting member	Any Member that uses the system to produce pharmaceutical products and export them to an eligible importing Member
Waiver	Article 31 (f) of TRIPS is temporarily suspended. It demands that what is produced with a compulsory license should predominantly be for the supply of the domestic market in order to allow the exporting country to produce and export to meet the needs of the importing member. The requirement of "adequate remuneration" (Article 31 (h) of TRIPS must be fulfilled only in the jurisdiction of the exporting Member. Therefore, its application is suspended in the importing country.
Implementation	The importing Member should notify the TRIPS Council of the following information: Name and quantities of the product needed. Proof that it is a less advanced country or that it does not have the capacity to manufacture. Confirmation that a compulsory license has been or will be granted. The exporting Member should grant a compulsory license under the following conditions: a) Only the amount required by the importing Member can be produced; b) Products manufactured under license should be clearly identified with special packing, color, and shape; c) Before shipping the products to the importing Member, the licensee should publish the amount and characteristics of the product on its Internet site; and d) The exporting Member should notify the TRIPS Council that it issued a compulsory license.
Re-exportation (trade diversion)	To ensure that the products imported under the system are used exclusively for the public health purposes provided for, the importing Member shall take reasonable measures to prevent re-exportation. The measures should be proportional to its administrative capacity.

Source: Prepared by the author.

3.4 Protection of Undisclosed Information Against Unfair Competition

Article 39.1 of TRIPS provides that by guaranteeing effective protection against unfair competition in accordance with Article 10 bis of the Paris Convention (1967), the Members will protect undisclosed information consistent with paragraph 2 and the data that have been submitted to governments or to official agencies, in line with paragraph 3.

Paragraph 2 clarifies and broadens protection against acts of unfair competition or dishonest use to which Article 10 bis of the Paris Convention alludes and describes a series of features of the information to be protected. Whereas Article 10 bis of the Paris Convention describes acts that involve confusion and mislead for consumers, Article 39.2 of the TRIPS Agreement specifies the subject matter to be protected (the confidential information) and expands the list of behaviors and dishonest uses such as breach of contract, breach of confidence, and inducement to breach and includes the acquisition of undisclosed information by third parties who knew or were grossly negligent in failing to know that such practices were involved in the acquisition.

Paragraph 3 of Article 39 is the one that has given rise to the most problems among Members, and its implementation has generated wide debate due to the repercussions that the protection of data has on public health. It has been the object of consultations between the United States and Argentina, as the former considers that the latter does not guarantee adequate protection for data, without reaching any agreement so far (WT/DS196 of July 5, 2001). The field of protection of data used to obtain health registration or government approval has been extended and specified in various recently signed free trade agreements between the United States and several developing countries. Such agreements recognize exclusivity of data submitted by pharmaceutical, chemical, and agrochemical companies before regulatory authorities of the States in which prior authorization is required in order to market those products in their territories. This provision has established a link between the undisclosed information and the patents regime, even though it does not always entail data on innovative products. The recent generation of free trade agreements protects the exclusivity of data relative to "new products," understanding by such those that are presented for the first time in a country for their registration and approval. In other words, the information and data submitted to regulatory authority may be protected with respect to a product that is protected by a patent and those relative to an old product (not covered by any patent), which is considered new since it is the first time that authorization is requested for its marketing.

Thus, the protection of data is no longer warranted only by unfair competition but, aside from it being a patented product or not, its registration gives rise to the obligation of the State to recognize exclusivity and control to whomever has requested the first authorization in the country for 5 years for pharmaceutical products and 10 years for chemical and agrochemical products.

The main interest behind this type of protection is to preserve the confidentiality and economic value of the data and tests that have been necessary to obtain the first approval of the product. Simply put, it can be said that a new drug must undergo a long, complex process of selection, tests, and development in order to prove its effectiveness and minimize collateral effects. After a series of computer-simulated initial tests, laboratories have to carry out pre-clinical research so as to then make experiments in animals and finally make tests in humans. This process demands considerable effort and investment. In practice, the enormous financial resources and the time demanded by the collection and generation of the data necessary for approval of a new drug creates in itself a very high market barrier which is difficult for manufacturers of generics drugs to cross. And it is precisely this barrier that is at the center of the debate on to what extent the exclusivity of the data affects the balance and market position among research and development pharmaceutical companies and those devoted to the production of generics drugs (Pugatch, 2004)

The exclusivity term of data was an initiative by the United States and other developed countries at the Uruguay Round, which did not prosper. It is now advancing through the bilateral and regional free trade agreements. The effect is that the authorities could not base themselves on prior registration to approve pharmaceutical, chemical, and agrochemical products for 5 years since their first approval in the first case, and for 10 years in the case of chemical and agrochemical products, unless the applicants obtain the consent of the patent owner of first authorization. This could delay the entry of new competitors into the market and even exclude the competition's products with inevitable consequences on prices of medicines (Correa, 2004).

Another effect of this provision is that Members will not be able to register generic pharmaceuticals for non-commercial use in public hospitals (Abbott, 2004).

Added to this is the extension of the patent term to compensate for unjustified delays incurred in the procedure to approve marketing of the product.

In the same way as the FTA between the United States and Chile, DR-CAFTA[14] does not mention the "unfair commercial use," which is the main condition for determining whether an act is permitted or prohibited according to Article 39.3 of TRIPS. The agreement also contains the prohibition on authorizing the marketing of pharmaceutical products for 5 years and agrochemicals for 10 years without the consent of the holder of the previous approval [Article 15.10.1(a)].

DR-CAFTA extends the scope of this obligation by providing that a third party (a producer of generic drugs) will not be able for 5 or 10 years, depending on the case, to base its request for authorization to market a product in a prior approval granted in another country or on information relative to the security and effectiveness previously issued to obtain approval in the territory of another country. It will only be able to do so with the consent of the holder of the authorization in the other territory, otherwise, it will have to wait for the above-mentioned exclusivity terms to expire.

If they spread, these new provisions should be smoothed out and regulated in greater detail in the light of national law, regardless of whether they are included in free trade agreements, for if the latter do not annul the stipulations of TRIPS,

it may be considered that they are implementing the obligations stemming from Article 39.3 of this agreement through the principle of freedom of methods for their application provided for in Article 1.1. In other words, countries may and it would be advisable for them to adopt internal measures to make the data exclusivity regime compatible with that of compulsory licenses, "Paragraph 6 Solution" of the Doha Declaration and the right of defense of the competition to achieve an adequate balance between protection of immaterial goods and access to health.

3.5 Exhaustion of Rights and Parallel Imports

It is well known that the territorial nature of intellectual property laws can lead to use the exclusive rights recognized to patent holders (or to owners of other intellectual property rights) to prevent the free circulation of products within a territory or between countries in detriment to free trade. This is why for a long time courts of various industrialized countries developed the principle of "exhaustion of intellectual property rights" to limit abuse of exclusive rights on the part of patent holders and other owners of diverse intellectual property rights. This principle establishes that intellectual property rights cannot be invoked once the right holder has placed the protected good on the market or authorized a third party (licensee, distributor) to do so, since the right holder could have had economic benefits.

This principle was later used and developed by the European Court of Justice since the mid-1960s to reconcile protection of intellectual property with the free circulation of goods and services in the community area. The Court considered that the sale made by the holder of an exclusive intellectual property right, or by a third party authorized by him in one of the Member States of the European Community exhausted the intellectual property rights in the countries where parallel protection had been obtained. It was considered that otherwise, markets would be at the mercy of the distribution policies of patent holders, with the consequent damage to trade flows between the member states and the harm to the consumers, who would thus see their free choice restricted by being deprived of healthy price competition of products protected by any intellectual property right.

Article 6 of TRIPS leaves it up to the Members to adopt the systems of exhaustion of rights they consider advisable by simply providing that for the effects of dispute settlement, subject to the provisions of Articles 3 (national treatment) and 4 (most favoured nation), use will not be made of any provision of the present Agreement in relation to the issue of exhaustion of intellectual property rights.

This means that this principle could be applied on the basis of "territory" (national or territorial exhaustion), in which case, the first sale of the patented product in country A only exhausts the rights in that territory. The holder of a patent in A may then invoke its exclusive rights of importation in A to prevent importation of the product if its sale was made in country B. This principle may be also applied on a "regional" basis. This being so, the sale in the territory of a country that is a member of a free trade area, customs union or common market, exhausts the rights

in the other member States. That is to say, after the first legal sale of the product, the holder "exhausts" his right to control successive re-sales in the regional market. However, the holder of a intellectual property right can invoke his exclusive rights to halt the importation of a product he himself put on the market in a non-member country of the free trade zone, customs union or common market. And finally, the exhaustion can be of "international" nature, which means that the first sale made in any country "exhausts" the rights of the holder to control successive re-sales and distribution of the protected product.

Adoption of any system is of great significance, for on that will depend the legality of so-called "parallel imports." This type of operations involves the importation of one product into a country (State A) where such a product is patented, coming from another country (State B), where the product was placed in the market by the holder himself, or by a third party with his consent. It will thus depend on the system of each country, whether the holder can invoke his exclusive right to block imports from another country. We talk about parallel trade or imports because the "parallel importer," although selling genuine products, trade them on the sidelines of the official distribution network established by the patent holder. In other words, it can be said that the activity of the free or non-authorized reseller consists in acquiring genuine products in markets where their price is lower due to greater competition or exchange differences, in order subsequently to resell it at higher prices where the holder of the patent or the manufacturer, distributor or licensee generally operates, favored by a territorial exclusivity right.

In any event, TRIPS assumes a neutral position on the system of exhaustion of rights by clarifying in two footnotes that: i) the Members are not obliged to apply the so-called border measures to prevent parallel imports (note, Article 51), and ii) that the right of importation is subject to Article 6 (that is, to the system of exhaustion that the Member has implemented in its national legislation) (note 6 of Article 28). Freedom to determine the system of exhaustion that is most suitable for the Members was reaffirmed by the Doha Declaration on TRIPS and Public Health.

The Paragraph 6 Solution (described in Section 3.3, see Box 2.2) would seem to reaffirm the idea that exhaustion does not occur with any licit sale of the product, but only as long as the first sale has been made by the patent holder or by a third party authorized by him. This is so because in order to export to the importing Member, the holder of a compulsory license should recur to the mechanism of product notification and identification established in Paragraph 6 Solution and should adopt measures to avoid its re-exportation. That is, should the sale be made by the holder of a compulsory license, there will be no exhaustion of rights. On the contrary, exportation of the product will be done by means of a sort of *ad hoc* distribution network and specially authorized through the procedure provided for in the Paragraph 6 Solution to the effect of satisfying a specific need of the importing Member.[15]

Developed countries are inclined to adopt territorial exhaustion with regard to patents. The possibility of blocking parallel imports makes it possible to adapt product prices to market elasticity and thus repay research and development costs incurred by the patent holder. The defenders of parallel imports (who are opposed to

territorial exhaustion) argue that such imports do not stand in the way of maximizing earnings, but only reduce the margin, which will benefit consumers. The question is, knowing as of what moment the holder of a patent can estimate that his level of earnings is no longer sufficient and that it is not worth continuing to distribute the product in a particular market. Such a product would be removed from the market when the marginal cost of production is higher than the profits it generates.

3.6 Conclusions

Many developing countries initially imagined that TRIPS would set a ceiling of standards and demands for intellectual property rights. Reality has surpassed this illusion, for various recent bilateral and regional free trade agreements between developing and developed countries, mainly the United States and the European Union, provide higher and more demanding protection standards than those of TRIPS. The new agreements significantly reduce the margins of flexibility of TRIPS with regard to patentable subject matter, its exceptions, access to compulsory licensing, access to medicines by consumers, and access to generic drugs markets by firms located in developing countries.

Recent trade agreements move away from the principles of flexibility and from the need to prevent intellectual property from standing as an obstacle for guaranteeing full access to medicines set forth in the Doha Declaration on TRIPS and Public Health.

The tendency to protect test data relative to chemical, agrochemical, and pharmaceutical products in last generation free trade agreements, besides going well beyond the standard of protection stipulated by TRIPS, poses new and highly complex problems. Unless appropriate national regulations are established, undisclosed test data may raise the cost of the process of approval of pharmaceutical, chemical, and agrochemical products. It can also make it more difficult, if not impossible, to authorize compulsory licenses which TRIPS admits under certain conditions.

Nor do multilateral systems prevent the erosion of that flexibility in all cases. One example is the solution agreed on by the United States and Argentina, whereby the latter country substantially reduced the scope of the exception of exhaustion of rights provided for in its patent law, even though the topic is alien to the dispute settlement system provided for in TRIPS.

Consequently, the diversity of bilateral, regional, and multilateral trade agreements overlapped or seeking to coexist and containing regulations on intellectual property, has opened an ongoing agenda of international negotiations which obliges the developing countries to place emphasis on effective interaction of the different levels and regulatory scenarios and their different objectives.

Finally, this determines that from now on, national legislations on the matter take note of this objective and of the need to fill the spaces and inconsistencies derived from the multiple objectives and standards of protection of diverse international rules.

Notes

1. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.
2. Section 7.94 of the Report of the Special Group *"Canada-Protection by means of Patents for Pharmaceutical Products"*, WT/DS114/R, of 17 March 2000.
3. Article 30 of TRIPS establishes that *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*
4. Section 7.92 of the Report of the Special Group in the Canada-Pharmaceutical Products case.
5. Argentine patents law No. 24.481 (Article 4, paragraph a) which in this aspect, has followed the Spanish invention patents' law of 1986.
6. Cfr. decision T 356/93, *Plant Genetic Systems*, paragraph 17.3 of the Chamber of Resources of the European Patent Convention.
7. *The Court of Justice of the Andean Community* has made a statement in this regard. It has declared the non-compliance by the Republic of Ecuador and Peru with the prohibition on granting patents for second uses prohibited by Article 16 of the former Common Intellectual Property Regime (Decision 344) conceived in identical terms to the current Article 21 of the current Decision 486 and has called upon both countries to desist in such non-compliance and invalidate the corresponding patents. In both cases it involved a second use patent relative to the product *"Pirazolopirimidones for the treatment of impotence"*, PROCESO 34-AI-2001 OF 21/08/2002 and PROCESO 89-AI-2000 of 28/09/2001, respectively. See rulings in www.comunidadandina.org.
8. Explanatory list of questions to the Members: WTO document IP/C/W/122 and IP/C/W/126, Information from 25 Members in WTO document: IP/C/125 and Add1-24: Australia, Bulgaria, Canada, Czech Republic, European Community and Member States, Hong Kong, China, Hungary, Iceland, Japan, Korea, Lithuania, Moldova, Morocco, New Zealand, Norway, Poland, Rumania, Slovenia, South Africa, Switzerland, Thailand, United States, and Zambia.
9. See Note from the WTO Secretariat which summarizes the positions regarding the relationship between the TRIPS Agreement and the CBD, IP/C/W/368, 8 August 2002 (www.wto.int.)
10. To June 30, 2004, 25 States were members of UPOV 1978 and 28 had signed UPOV 1991; only two remain adhered to the 1961 version (modified by the 1972 act), UPOV Publication No. 437 (E).
11. For further details on the process of review of Article 27.3(b) and the issues linked to the relation between TRIPS and CBD, see Notes of the Secretariat IP/C/W/369 and IP/C/W/368, of 8 August 2002.
12. WT/MIN(01)/DEC/2 of November 20, 2001 (www.wto.int)
13. See the discussions on the decision relative to the Paragraph 6 Solution and the form the TRIPS amendment should take in the document of the session of the TRIPS Council of July 19, 2004 (IP/C/M/44).
14. United States Free Trade Agreement with the Dominican Republic, Honduras, Nicaragua, El Salvador, Costa Rica, and Guatemala.
15. There are views to the effect that the Paragraph 6 Solution limits the margin of freedom with regard to exhaustion recognized in Article 6 of TRIPS and in the Doha Declaration, since the whole system implicitly presupposes the existence of territorial exhaustion (González Perini, Lowenstein and Wegbrait, 2004).

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Chapter 4
Intellectual Property and the New Generation of Free Trade Agreements: The Agreement Between Chile and the United States of America

Pedro Roffe

4.1 Introduction

The Free Trade Agreement between Chile and the United States (hereinafter the FTA or the Agreement), signed in 2003 and in force since January 1, 2004, marks an important stage in the new generation of bilateral trade agreements. The incorporation of a chapter on intellectual property, following the format of previous agreements signed by the United States, has served as a model for subsequent negotiations particularly with Latin American countries (DR-CAFTA, Colombia, Panama, and Peru).

For the United States, the protection of intellectual property has been a constant concern. At the domestic level it has increased protection standards and systematically monitors their enforcement internationally through *Special Report 301*, which includes a list of countries that, in the view of the trade authority of that country, are not up to their international commitments on the subject. The said report is part of the Trade Act, and the list is the step that precedes the imposition of trade sanctions on the countries that infringe the rights of United States patent holders. The United States was the promoter of the first treaty on industrial property at the end of 19th century (Paris Convention of 1883) and has played a preponderant role in raising levels of protection, especially since the Uruguay Round and then with the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). NAFTA was the first post-TRIPS agreement with a Latin American country including robust provisions on the matter. This intent of the United States is also articulated in the protracted negotiations for a Free Trade Agreement for the Americas, whose

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chapter on intellectual property resembles the model that this country has followed in various bilateral agreements.

The purpose of this chapter is to analyze the central aspects of these agreements, taking the agreement between Chile and the United States as a reference and comparing with other free trade agreements negotiated by the United States, particularly with Latin American countries.

4.2 Objectives of the Agreement: The Preamble

The aims of the Agreement with Chile on intellectual property are set forth in the Preamble to Chapter 17, which states that its main objective is "to reduce distortions and impediments to trade between the Parties." This objective would be fulfilled by ensuring that the "measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" by means, among others, of greater efficiency and transparency in the administration of the system.

The purpose of transparency is detailed in the body of the Agreement. "Each Party shall ensure that all laws, regulations, and procedures concerning the protection or enforcement of intellectual property rights, and all final judicial decisions and administrative rulings of general applicability pertaining to the enforcement of such rights, shall be in writing and shall be published or where such publication is not practicable, made publicly available, in a national language in such a manner as to enable the other Party and right holders to become acquainted with them, with the object of making the protection and enforcement of intellectual property rights transparent. Nothing in this paragraph shall require a Party to disclose confidential information the disclosure of which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private" (Article 17.1.12).

The provision on transparency is similar to that of TRIPS (Article 63). The FTA clarifies in a footnote that the requirement of publication may be met by simply making available a written document to the public via the Internet. The principle of transparency is generally accepted in international law. In the context of international trade, the transparency of national legislation on intellectual property serves the objective of making foreign economic operators familiar with domestic regulations, thus making international transactions more predictable.

The Preamble also stresses that the Agreement builds on the foundations of the international architecture of intellectual property agreements, reaffirming, among others, "the rights and obligations set forth in the TRIPS Agreement."

The Preamble makes further explicit reference to the principles established in the Doha Declaration on TRIPS and Public Health.[1] The Declaration, among others, confirms that "... the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health (...) and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all" also "reaffirms the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Another clause of the Preamble is similar to the general objectives of Article 7 of TRIPS by underscoring that the protection and enforcement of intellectual property rights is a "... fundamental principle of this Chapter that helps promote technological innovation as well as the transfer and dissemination of technology to the mutual advantage of technology producers and users, and that encourages the development of social and economic well-being."

The Preamble acknowledges the importance of public and private investment and the role of the business community in research, innovation, and transfer of technology.

The Agreement includes two other objectives. The first refers to anticompetitive practices that can be associated with intellectual property rights, without deviating from similar principles in the TRIPS Agreement, leaving the Parties free to legislate in this regard. DR-CAFTA and the recent agreements between the United States and, respectively, Colombia, Panama, and Peru contain identical provisions. The second objective refers to bilateral technical cooperation, which can be useful in fulfilling obligations between parties with different degrees of development.

In the case of DR-CAFTA, the agreement links technical cooperation to the Committee for the Creation of Trade-Related Capabilities, a committee instituted by the agreement itself. The FTAs signed with Colombia and Peru make no direct reference to technical cooperation, but include a novel section on promotion of innovation and technological development to encourage public and private partnerships and initiatives in the area of intellectual property.

The FTAs address in detail the entry into force of its provisions and the necessary amendments to be made to domestic legislation. As of its entry into force and as a matter of general principle, each Party, in the case of Chile, will give effect to the provisions on intellectual property rights of the Agreement, including their adherence to various international treaties administered by the World Intellectual Property Organization (WIPO). A report of February 2006 by the Advisory Industrial Group to the US Trade Representative (USTR) on intellectual property emphasizes the need not only to strictly monitor the implementation of free trade agreements but also to ensure that before its entry into effect, the other Party has fully implemented its obligations.[2]

4.3 General Principles

4.3.1 Minimum Standards

The first provision of Chapter 17 of the FTA with Chile reiterates the principle of minimum standards, a pillar of the system established by TRIPS. This provision is reproduced in an almost identical manner in all the free trade agreements in the region. The FTA states "[e]ach Party shall give effect to the provisions of this Chapter and may, but shall not be obliged to, implement in its domestic law more extensive protection than is required by this Chapter, provided that such protection does not contravene the provisions of this Chapter" (17.1.1).

The provision is similar to that of Article 1 of TRIPS, but does not include the important qualification that the Members may establish the method they consider

most adequate to apply the provisions of the Agreement within their own legal system and practice. The following should be stressed in relation to this general principle:

a) The requirement to implement international agreements is implicit in the obligation to perform it in good faith ("*pacta sunt servanda*"), an obligation recognized in the Vienna Convention on the Law of Treaties (VCLT)[3] and by customary international law. The Agreement points out that each Party shall "give effect to the provisions" of the Agreement, reiterating the basic international legal obligation.
b) The FTA reaffirms the minimum standards principle that the Parties may, but need not, adopt more extensive protection of IP than is required by the FTA. In fact, the FTA goes beyond the minimum standards provided in TRIPS. This by itself is perfectly consistent with TRIPS, which left members with the freedom of adopting higher standards of protection, precisely on grounds of the minimum standard principle.
c) However, as pointed out, the FTA does not make reference to the "freedom of implementation method" recognized under TRIPS. In TRIPS each WTO Member decides whether it will adopt specific statutes or administrative rules for its implementation, or instead rely on the text of the Agreement as if it was part of national law. More importantly, TRIPS authorizes each Member to implement the rules in the manner it deems most appropriate, provided that implementation is in accord with the terms of the agreement.
d) In light of the non-derogation principle, discussed subsequently, it must be considered whether the Parties retain the "freedom of implementation" principle referred to above. One simple explanation for the omission in the FTA of this important principle of TRIPS is that the FTA sets forth specific modalities for the implementation of some of its provisions, without much freedom for the Parties to decide on its method of implementation. In other words, the freedom of implementation recognized by TRIPS is constrained but not removed from the agreement.

4.3.2 The Non-derogation Clause and the International Architecture of Intellectual Property

An important principle of the FTA with Chile that governs the way it should be interpreted states that

> Nothing in this Chapter concerning intellectual property rights shall derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO).[4] (17.1.5).

This is the first time that the principle of non-derogation appears in a trade agreement signed by the United States. It is not in NAFTA or in the agreements with Jordan, Singapore, and Australia, but it is found in DR-CAFTA[5] and in the recent

agreements signed with Colombia, Panama, and Peru, although using different terminology. One consequence of this principle is its extension to all matters relative to intellectual property and not only Parts I to IV of the TRIPS Agreement (general provisions and basic principles, rules relative to the existence, scope and exercise of intellectual property rights, observance of intellectual property and acquisition and maintenance of related *inter parties* procedures).

The principle also extends to "rights" and not only to "obligations," to the multilateral intellectual property agreements agreed on or administered by WIPO, in addition to the TRIPS Agreement, and points to the non-derogation of any right or obligation of one Party with respect to the other stemming from those international agreements. Unless otherwise provided for in the FTA, the non-derogation principle should permit the Parties to preserve all rights and obligations referred to in the TRIPS Agreement in present and future conventions concluded or administered under the auspices of WIPO to which both the United States and Chile are Parties. Thus, for example, limitations provided under the TRIPS Agreement on the granting of compulsory licenses, not explicitly referred to in the FTA, are preserved, consistent with other provisions of the Agreement. The reaffirmation that compulsory licensing is preserved is the reference made to Article 31, TRIPS, in the FTA Chapter on investment.

4.3.3 The Principles of National Treatment and Most Favored Nation

National treatment (NT) has been a guiding principle of the international trading legal system, including the General Agreement on Tariffs and Trade of 1947 (GATT, 1947) and the TRIPS Agreement. This is also one of the basic aspects of the treaties administered by WIPO since the 1883 Paris Convention for the Protection of Industrial Property. According to the FTA, this principle guarantees non-discrimination between Chilean and US nationals with regard to intellectual property. In TRIPS, the principle of national treatment has exceptions which are incorporated into the Agreement (Roffe, 2004).

The principle of Most Favored Nation (MFN) applies to third parties that are Members of WTO. Its validity in the Agreement is a consequence of the principle of non-derogation discussed earlier. In general, application of the principle of MFN to the protection of intellectual property rights is an innovation in the multilateral context. TRIPS provides for the immediate and unconditional extension to nationals of all WTO Members of any advantage, favor, privilege, or immunity granted by a Member to nationals of any country.

The TRIPS Agreement recognizes exceptions to the MFN principle. One of these exceptions relates to any advantage, favor, privilege, or immunity deriving from international agreements related to the protection of intellectual property rights entered into force prior to the entry into force of the Agreement establishing the WTO.[6] Two additional conditions should be met in this case: the said agreement

shall be notified to the WTO[7] and shall not constitute "an arbitrary or unjustifiable discrimination against nationals of other Members."[8]

The clear meaning of this principle is that any advantage, favor, privilege, or immunity accorded by a WTO Member to nationals of any other country (not necessarily a WTO Member), after January 1, 1995, needs to be immediately and unconditionally extended to nationals of any other WTO Member.

In brief, as a result of the MFN – a "cornerstone" principle of the international trading system – the advantages, favors, privileges, or immunities contemplated in the FTA between Chile and the United States will be accorded "immediately and unconditionally," in the terms prescribed in the TRIPS Agreement, to nationals of all other WTO Members. This general conclusion applies to other trade agreements signed by the United States, including DR-CAFTA and those signed more recently with Colombia, Panama, and Peru.

4.4 Substantive Intellectual Property Standards

4.4.1 Introduction

The FTA with Chile deals with certain intellectual property disciplines, setting standards of protection generally higher than those in the TRIPS Agreement. The following sections describe their main features. For other intellectual property disciplines not dealt with explicitly in the FTA, the standards of the TRIPS Agreement as well as other international instruments in which both Parties are Members would prevail. For instance, the FTA is silent on industrial designs, as well as on layout designs of integrated circuits covered in the TRIPS Agreement. On these issues and in light of the principle of non-derogation, discussed above, the standards of TRIPS prevail. Furthermore, the FTA, – as well as the other trade agreements signed by the United States with countries of the Americas – not only sets higher standards of protection than in TRIPS but also governs disciplines not covered at all by the latter, e.g., domain names, protection against circumvention of effective technological protection measures, and limitations on liability of Internet service providers (ISPs).

4.4.2 Patents and Regulated Products

4.4.2.1 Patents

Compared to TRIPS, the FTA section on patents is relatively brief. However, an important section on regulated products (pharmaceuticals and chemicals) complements it. The section on patents deals mainly with issues of patentability, limited exceptions, plant protection, derogation, and delays in their granting. The limited, but significant, treatment of patents in the FTA is explained by the fact that on matters not dealt with, the principles and standards of the TRIPS Agreement govern the relationship of the Parties.

On the exhaustion of patent rights, the FTA is silent, leaving the Parties the freedom to adopt the most appropriate system. The Chilean law on implementation of

the Agreement opts for international exhaustion of rights. On its part, the Unites States has traditionally advocated for a national exhaustion regime and in its bilateral agreements signed with Singapore, Australia, and Morocco the possibility of parallel imports may at least be restricted by contract. DR-CAFTA and the recent agreements with Colombia, Panama, and Peru follow the model of the FTA with Chile.

On the important issue of patentability, the FTA practically reproduces a parallel provision in the TRIPS Agreement (Article 27.1) and even incorporates into the main text its footnote. But, compared to TRIPS, the FTA does not fully reproduce the relevant TRIPS provision, by omitting the reference that patents shall be available and patent rights be enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.

The FTA contains the overriding requirement that patents shall be available for all types of product and process inventions. It prohibits distinctions about the field of technology to which the invention belongs. In addition, the FTA with Chile does not explicitly obligate Parties to protect the "second use" of a product.

Any patent application must satisfy the basic criteria of novelty, inventive step, and industrial applicability, without altering the criteria already explicit in TRIPS. The FTA, as in the case of TRIPS, does not define what an "invention" is; it only specifies the requirements that an invention should meet to be patentable. This leaves Parties considerable freedom to determine what should be deemed an invention and, if they so desire, to exclude from patentability any substance which exists in nature as being a mere "discovery" and not an "invention." The FTA also did not define, unlike in DR-CAFTA, the meaning of "industrial application." DR-CAFTA, importing concepts from US law, specifies that "Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility." The agreements signed between United States and Colombia, Panama, and Peru, respectively, adopt a similar approach.

The FTA with Chile qualifies that novelty or inventive step is not affected by authorized public disclosure or derived from the patent applicant, provided it occurred within 12 months prior to the filing of the patent application. This approach is common to DR-CAFTA and to the agreements signed with Colombia, Panama, and Peru.

One of the controversial provisions of the free trade agreements is the protection of life forms. In this regard, the FTAs introduce different rules to those of TRIPS. Some countries provide patent protection for all kinds of plants regardless of their method of reproduction, while others (e.g., Republic of Korea) protect under patents only those plants that are asexually reproduced.

The FTA with Chile does not contain an explicit obligation to protect plants under the patent system. But, it provides for a "best effort" clause in order for each Party to undertake reasonable efforts, through a transparent and participatory process, to develop and propose legislation – within 4 years from the entry into force of the Agreement – to make available patent protection for plants which are new, involve an inventive step, and are capable of industrial application. This provision

does not contain any limitation on the type of plants that should be protected under the patent system (sexually and/or asexually reproduced). According to this obligation that in practice applies only to Chile, the latter is not obliged to consider plants as a patentable subject matter, but to engage in a process to legislate to that effect. Similar provisions are contemplated under DR-CAFTA. Nevertheless, in the latter agreement any Party that does not provide patent protection for plants by the date of entry into force of the Agreement shall undertake all reasonable efforts to make such patent protection available. In addition, according to the same agreement, any Party that provides patent protection for plants and animals as of, or after, the date of entry into force of the Agreement shall maintain such protection. This latest approach is followed in the FTAs signed by the United States with Colombia, Panama, and Peru.

Patents confer an "exclusive" right, that is, the right to prevent others from using the invention, without the authorization of the patent holder. The market power conferred by patents and the benefits the patent owner may obtain constitute one of the essential elements of patent grants. However, the conferred rights are not absolute. Under most patent laws, such rights may not be exercised over certain acts performed by third parties. This means that under certain specified circumstances, there may be exceptions to the exclusive rights.

Exceptions can be invoked by third parties at any time during the term of the patent as a defense against alleged infringements. The FTAs allow the establishment of exceptions to patent rights, but imposes conditions on such exceptions. As in the case of TRIPS, exceptions to patent rights are subject to three conditions: the exception must be "limited"; the exception should "not unreasonably conflict with the normal exploitation" of the patent; and the exception should "not unreasonably prejudice the legitimate interests" of the right holder and of third parties. This provision is reproduced generally in subsequent free trade agreements, including DR-CAFTA.

Article 17.9.4 of the FTA with Chile makes it possible to invoke the "Bolar exception" (so called for the name of the laboratory that set the precedent) or "regulatory exception" under the following circumstances: "If a Party permits the use by a third party of the subject matter of a subsisting patent to support an application for marketing approval or sanitary permit of a pharmaceutical product, the Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of the Party other than for purposes related to meeting requirements for marketing approval or the sanitary permit, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for issuing marketing approval or sanitary permits in the exporting Party."

The purpose of the Bolar exception is to accelerate the introduction of generic medicines into the market, as soon as the term of protection of the patent of an original drug expires. Otherwise, the generic producer would have to wait until the patent expires to begin considering the production of a copy of the original product and just then ask for the approval of the drug by the health authorities. This would amount to a de facto extension of the patent term, as the

competing drugs would have to wait for a number of years to make it into the market.

In this matter the Agreement provides for two situations. One allows a third Party to use the subject matter of a patent for purposes of obtaining the sanitary permit or marketing approval of a pharmaceutical product. The other allows the third Party to use the subject matter of a patent when the product will be exported, but only to meet requirements for issuing marketing approval or sanitary permits in the exporting Party. The Bolar exception is reproduced in similar terms in DR-CAFTA[9] and in the agreements signed with Colombia, Panama, and Peru.

Among its selected patent provisions, the FTA with Chile deals with revocation or cancellation of patents: "A Party may revoke or cancel a patent only when grounds exist that would have justified a refusal to grant the patent." (Article 17.9.5).

Apparently, the only grounds for revocation or cancellation of a patent would be that the invention protected by the patent was not new, was obvious, or not useful. A footnote clarifies that fraud in obtaining the patent may also be cause for revocation. One should ask if these are the only causes for revocation or the Parties would be allowed to establish different grounds for such cancellation, such as inequitable conduct or misrepresentation. In fact, other trade agreements have been more explicit and have broadened the causes for revocation recognized in the FTA. For instance, the DR-CAFTA[10] and the United States Agreement with Peru allow for these other two causes of revocation.

Another aspect of the FTA with Chile, common to free trade agreements signed by the United States, such as with DR-CAFTA[11] , is the provision for the extension of patent terms to compensate for unjustified delays during the granting process.[12]

The Agreement also provides for extension of the patent term to compensate for "unreasonable curtailment of the patent term as a result of the marketing approval process." However, the FTA with Chile does not define what "unreasonable" is leaving each Party to determine this term. These provisions on the extension of the patent terms are reproduced in DR-CAFTA and the original agreements signed with Colombia, Panama, and Peru. It is appropriate to note that in the case of Peru and with respect to pharmaceutical products these provisions have been amended with the view of introducing some flexibility in their implementation.[13]

4.4.2.2 Regulated Products

This is one of the most controversial aspects of the free trade agreements. They refer mainly to the protection and possible use of undisclosed information concerning the safety and efficacy of pharmaceutical and agricultural chemical products, which utilize a new chemical entity. Since NAFTA negotiations, the United States has been interested in introducing in its trade agreements special provisions for data exclusivity related to agricultural chemical and pharmaceutical products. In NAFTA, the provisions apply to "undisclosed test or other data" necessary to determine safety and efficacy of "products that utilize new chemical entities" when the generation of these data "involves considerable effort." No person other than the one that has submitted the data may rely on such data to support an application for the marketing

approval of the product concerned, during a reasonable period of time, of no less than 5 in the first case and 10 years in the second.

The United States has not followed the same approach on protection of undisclosed information with its different trade partners (Box 4.1).

The Agreement with Chile states, for example: "If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public" (Article 17.10.1).

In the absence of such provision, it has been a practice that information concerning safety and efficacy of products subject to marketing approval or sanitary permit is normally submitted by the first applicant for such an authorization or permit. Subsequent applicants regarding the same or similar products will benefit from the information submitted by the first applicant and the competent authorities will base their decision for granting the marketing approval or the sanitary permit on the undisclosed information provided by that first applicant.

The purpose of the FTA provision is precisely to avoid such a practice and to oblige any person who applies for marketing approval or sanitary permit to submit to the competent authority, its own confidential information related to the safety and efficacy regarding the pharmaceutical and agro-chemical products which utilize a new chemical entity for which marketing approval or sanitary permit is requested. These provisions have been the subject of criticism for their possible impact on access to generic medicines whose prices are in principle largely lower than those of the original product. As a result of these criticisms the recent FTA with Peru includes a number of safeguard mechanisms.[14]

Box 4.1 Regulated products in recent trade agreements signed by the United States

The free trade agreement with Jordan (Article 4.22.) requires the protection of undisclosed test or other data submitted to obtain marketing approval for agricultural chemical and pharmaceutical products that utilize new chemical entities, the origination of which "involves a considerable effort." There

is no reference to prohibiting the use of such information for a market approval application in favor of a third Party. The agreement provides that new chemical entities could allow new uses for products, for which purpose protection will be extended for 3 years. In cases in which the non-disclosed information is supported by an approval in another country, Jordan will protect it from unfair use for at least the same period.

The Singapore agreement (Article 16.8.1) goes a step further by recognizing that "[I]f a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product." Note that the protection is not limited to products with new chemical entities.

The agreement with Australia contains a set of complex provisions which differentiate between pharmaceutical and agricultural chemical products. The agreement provides that "[i]f a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided such information, to market a same or similar product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years from the date of marketing approval in the Party." (Article 17.10.1(a))

For agricultural chemical products the agreement states that "[i]f a Party requires, as a condition of approving the marketing of a new agricultural chemical product, including certain new uses of the same product, the submission of undisclosed test or other data concerning safety or efficacy of that product, the Party shall not permit third persons, without the consent of the person who provided such information, to market a same or similar product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for ten years from the date of the marketing approval of the new agricultural chemical product in the Party." (Article 10.10.1(b)).

The agreement with Australia defines a new product as ". . .one that does not contain a chemical entity that has been previously approved in the Party" (Article 17.10.1(d)). The agreement also contains provisions on the protection of "new clinical information (other than related to bioequivalency)" and "evidence of prior approval of the product in another territory which is essential to the approval of the pharmaceutical product." (Article 17.10.2).

The DR-CAFTA provides for the following:

1 (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least 5 years for pharmaceutical products and 10 years for agricultural chemical products from the date of approval in the Party.

(b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least 5 years for pharmaceutical products and 10 years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seeks approval in the territory of the Party within 5 years after obtaining marketing approval in the other territory.

(c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.

(d) For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article.

2 Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was

> previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.

Under the regulated product provisions, the FTA with Chile establishes a more detailed regulation than that to be found in TRIPS and NAFTA, and for this reason it has been taken as a model for subsequent free trade agreements signed by the United States. DR-CAFTA establishes more extensive rules on regulated products, covering aspects not dealt with in the Agreement with Chile, such as confirmation of sanitary permits obtained in the other country and extended terms to validate those permits (see Box 4.1). Following the criticisms referred earlier these provisions on regulated products, in the case of pharmaceutical products, have been revised in the recent approved FTA between the United States and Peru.[15]

The FTA with respect to regulated products includes three additional important obligations to the Parties about pharmaceutical products, which are subject to a patent: (a) as noted earlier, an extension of the patent term to be available to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process; (b) the identity of any third Party requesting marketing approval of a patented pharmaceutical product shall be available to the patent owner, during the term of the patent; and (c) a Party shall not grant "marketing approval" to any third Party prior to the expiration of the patent term, unless by "consent or acquiescence" of the patent owner. In fact, this means an extension of the protection afforded to the patent owner, which goes beyond the TRIPS Agreement. This "linkage" between market approvals and the consent or acquiescence of the patentee creates a number of ambiguities and might bring into question, among others, the ability to actually exercise the flexibilities in TRIPS, such as the granting of compulsory licenses to facilitate access to medicines.[16] The bilateral trade agreements signed by the United States with Australia, DR-CAFTA, Jordan, and Singapore do not differentiate between "marketing approval" and "sanitary permit" as in the case of the FTA.[17] The most serious aspect of this linkage relates to extending to the sanitary authorities obligations on the existence and validity of patents that fall normally under the portfolio of other agencies.

In DR-CAFTA, this "linkage" is made more explicit and even includes references to market approvals "in another country" – an extension not provided for in the FTA with Chile. The linkage provision is made less stringent in the FTA with Peru.[18]

4.4.3 Copyright and Related Rights

4.4.3.1 Copyright

The FTA with Chile is the first signed by the United States in which copyright is treated separately from the related rights. The United States agreements with Singapore and Morocco and DR-CAFTA treat the subject as a whole, reflecting the legal philosophy of the United States and the preferences of its industry.

The DR-CAFTA model is not reproduced in the agreements with Peru and Colombia, which follow the approach used with Chile.

On protectable subject matter, the FTA with Chile does not innovate with respect to the Berne Convention or the TRIPS Agreement. Thus, the FTA applies to literary and artistic works, as understood by the Berne Convention, including computer programs and compilations of data in accordance with TRIPS and the WIPO Copyright Treaty of 1996 (WCT).

The Agreement with Chile provides further that authors "...have the right to authorize or prohibit all reproductions of their works, in any manner or form, permanent or temporary (including temporary storage in electronic form)" (Article 17.5.1).

This reproduction right builds upon the Berne Convention which establishes a right of reproduction of the author's work "in any manner or form," and on the Agreed Statement concerning Article 1(4) of the WCT, which provides that the right of reproduction set in Berne "fully appl(ies) in the digital environment, in particular to the use of works in digital form." Though the Agreed Statement adds that the storage of a protected work in digital form in an electronic medium constitutes a reproduction, it says nothing about temporary copies, such as those made in the RAM memory of a computer, an issue that was extensively discussed during the negotiations of the WCT, but did not make it into the final text. Here the FTA go beyond Berne and the WCT in that they make clear that temporary copies in electronic form are subject to the right of reproduction. But, the FTA with Chile, in a footnote to the main text, allows for the application of specific exceptions and limitations in the digital environment:

> For works other than computer software, and other subject matter, such exceptions and limitations may include temporary acts of reproduction which are transient or incidental and an integral and essential part of a technological process and whose sole purpose is to enable (a) a lawful transmission in a network between third parties by an intermediary; or (b) a lawful use of a work or other subject matter to be made; and which have no independent economic significance. (Note to Article 17.7.3)

Because of the fundamental importance of temporary copies in the digital environment, the explicit possibility of exempting temporary copies from the right of reproduction, subject to the traditional "three-step test,"[19] may be important at the moment of devising appropriate intellectual property policies. The rapid evolution of emerging technologies in this field explains the need for the creation of exceptions for temporary copies. For instance, the United States has dealt with this issue

by creating limited exceptions, such as allowing the making of copies for machine maintenance or repair of a computer, or by exempting small copies incidental to web casting called buffer copies. Therefore, other temporary copies, besides those explicitly exempted, must follow the fair use test of Section 107 of the US Copyright Act. The European Union, on the other hand, has included a broad exception in its Directive[20] with a similar wording to the quoted footnote in the FTA.

Neither DR-CAFTA nor the agreements signed by the United States with Australia, Singapore, Morocco, and Jordan have a provision similar to that of the FTA with Chile on exception of temporary copies to the right of reproduction.

The FTA deals with the right of communication to the public, in the same terms as the WCT. Therefore, this right covers all kinds of works communicated to the public by wire or wireless means, without prejudice to related Berne Convention provisions. This broad right of communication is not fully covered by TRIPS.

However, the FTA with Chile establishes that authors have the right to authorize or prohibit the communication to the public of their works in such a way that Members of the public may access these works from a place and at a time individually chosen by them (Article 17.5.2). This means that the Parties should recognize an exclusive right for interactive, on-demand communications. This provision does not include private communications such as electronic mails with contents protected by copyright.

With regard to the right of distribution, the Chilean FTA practically reproduces the provision of WCT but omits the exhaustion of rights provided for therein, which prescribes that: "Nothing in this Treaty shall affect the freedom of Contracting Parties to determine the conditions, if any, under which the exhaustion of the right in paragraph (1) applies after the first sale or other transfer of ownership of the original or a copy of the work with the authorization of the author."

However, Parties are free to determine whether they will apply a national or international regime of exhaustion of rights. This conclusion is based, among others, on the application of the non-derogation principle, discussed above. While Chile in its FTA implementing legislation, together with establishing the right of distribution, provided for a system of international exhaustion of rights, the United States has traditionally applied a national exhaustion regime.

The distribution right in the FTA with Chile applies only to fixed copies that can be put into circulation as tangible objects. It does not provide for the distribution of electronic copies. Some have argued that limitations to the right of distribution, such as the doctrine of exhaustion or the first sale doctrine, do not apply to the digital transmission of lawful electronic copies, because the sender would always retain a copy of the work. One may ask whether the Parties, under the FTA, still have leeway to apply limitations to the distribution right for electronic copies, when together with sending an electronic copy, the sender deletes or destroys the original copy in the computer. This could be considered a transfer of ownership altogether, the same as selling a book in the analogue world. It seems that because this particular provision and its footnote are limited to the distribution right (limited to tangible objects), Parties could provide for a digital first sale.

Consistent with the Berne Convention ("countries of the Union may grant a term of protection in excess of those provided" in the Treaty), the FTA extends copyright by 20 years for most works, to life of the author plus 70 years – up from the life of the author plus 50 years after death term of protection set in TRIPS for the majority of works. In cases where the term of protection of a work is calculated on a basis other than the life's span of a natural person, such as those whose author is a legal entity, the term was set at a minimum of 70 years from the end of the calendar year of the first authorized publication of the work, or failing such authorized publication within 50 years from the creation of the work, at a minimum of 70 years from the end of the calendar year of the creation of the work. In general, United States' industry welcomed the approach taken in the FTA with Chile and subsequently by DR-CAFTA, Colombia, Panama, and Peru.

For photographic works, the general rule for most countries is still the 25-year protection from the making of the work, provided for in the Berne Convention. Parties to the WCT agreed to modify the Berne/TRIPS standard by stating that they would "not apply the provisions of Article 7(4) of the Berne Convention." Therefore, the term of protection of photographic works went from 25 years from the making of the work to life of the author plus 50 years, which is the general rule in the Berne Convention. The FTA with Chile, in the same way as DR-CAFTA and those signed with Colombia, Panama, and Peru, extended protection on the term established in WCT by 20 years. Hence, photographic works are protected by the general 70-year rule. While the United States already protected this type of work by the standard in the FTA, Chile protected them only for the life of the author plus 50 years.

4.4.3.2 Related Rights

As for the duration of rights, in a similar provision to the one on the copyright, performers and producers of phonograms are granted a minimum of 70 years from the end of the calendar year of the first authorized publication of the work, or failing such authorized publication, within 50 years from the fixation of the performance or phonogram, a minimum of 70 years from the end of the calendar year of the fixation of the performance or phonogram. This provision applies when the terms are to be calculated on a basis other than the life of a natural person. This would normally be the case of collective works, works commissioned in the United States, and computer and cinematographic works in Chile. These terms are identical in DR-CAFTA and in the agreements signed with Colombia, Panama, and Peru.

The fact that related rights are treated separately from copyright does not mean that there are no similarities between them. Indeed, for the right of reproduction and the right of distribution (making available to the public) they are treated in the same manner for authors, performers, and producers of phonograms. With regard to the rights of reproduction and distribution for performers and producers, the wording is drawn from WIPO Performances and Phonograms Treaty of 1996 (WPPT).

As regard the right of communication to the public,[21] the standard in the FTA with Chile is the same as for copyright, as discussed above. Together with

establishing the right of communication of fixed performances[22] or phonograms[23], including the interactive on-demand communications, the FTA preserves some exceptions and limitations authorized under previous treaties. Parties are allowed to provide for exemptions for "radio broadcasting or communication to the public of performances or phonograms through analogue communications and free over-the-air broadcasting, and the exceptions or limitations to this right for such activities shall be a matter of domestic law. Each Party may adopt exceptions and limitations, including compulsory licenses, to the right to authorize or prohibit the broadcasting or communication to the public or performances or phonograms in respect of other non interactive transmissions in accordance with Article 17.7(3). Such compulsory licenses shall not prejudice the right of the performer or producer of a phonogram to obtain equitable remuneration." (Article 17.6.5 (b)).

Less explicitly than in DR-CAFTA or the agreement between the United States and Australia, the FTA with Chile reduces the asymmetries between copyright and related rights. Prior to the implementation of the FTA in December 2003, Chile's Copyright Law provided that when the interest of an author in a phonogram conflicted with the interest of the producer of the phonogram, regarding the public performance of the phonogram, the author would always prevail over the producer. After the implementation law was enacted, this was amended in order to remove such hierarchy.

The FTA, in what again seems to be a bridge between copyright and related rights, provides for freedom of contract with respect to economic or patrimonial rights, as opposed to moral rights. It also states that the licensee and the employer in the case of commissioned works will be able to fully exercise the same rights as the original creator of the work (licensor or employee).[24]

However, despite the apparent freedom to contract and the general rule that the employer can freely exercise such rights, the Agreement adds that the Parties may establish "which contracts of employment underlying the creation of works or phonograms shall, in the absence of a written agreement, result in a transfer of economic rights by operation of law; *and reasonable limits to the provisions ... to protect the interests of the original right holders, taking into account the legitimate interests of the transferees.*" (Author's emphasis).

The FTA with Chile permits limitations and exceptions to rights when their use does not conflict with a normal exploitation of the work, performance, or phonogram and do not unreasonably prejudice the legitimate interests of the right holder, similar to the "three-step rule" established in TRIPS (Article 13), the Berne Convention (Article 9.2), WCT (Article 19), and WPPT (Article 16).

With regard to the exceptions and limitations in the digital environment, the FTA reproduces the Agreed Statements to Articles 10 and 16 of WCT and WPPT, but goes further by explicitly allowing temporary copies which are transient or incidental and an integral and essential part of the technological process and whose sole purpose is to enable a lawful transmission in a network between third parties by an intermediary or the licit use of a work or other protected subject matter that has no independent economic significance.

The FTA confirms that government use of computer software should take place as duly authorized. To that end, the Parties shall issue appropriate legal instruments to actively regulate the acquisition and management of software for government use. Such measures may take the form of procedures for the preparation and maintenance of inventories of software present on agencies' computers and inventories of software licenses. DR-CAFTA and the FTA with Peru contain similar provisions.

4.4.3.3 Evasion of Effective Technological Measures and Information on Rights Management

The FTA with Chile provides for very strict rules against the circumvention of technological protection measures (TPMs) used by authors, performers, and producers of phonograms or any protected material to protect their works, performances, and phonograms, protected by copyright and related rights.[25]

The provisions on TPMs go beyond the WIPO treaties of 1996, which only state that Parties "shall provide adequate legal protection and legal remedies" against the circumvention of TPMs, leaving it to each Party to decide the way in which it will implement the provisions and whether it will apply civil and/or criminal sanctions to infringers. In a key provision, Parties are committed to

> provide that any person who knowingly circumvents without authorization of the right holder or law consistent with this Agreement any effective technological measure that controls access to a protected work, performance, or phonogram shall be civilly liable and, in appropriate circumstances, shall be criminally liable, or said conduct shall be considered an aggravating circumstance of another offence. No Party is required to impose civil or criminal liability for a person who circumvents any effective technological measure that protects any of the exclusive rights of copyright or related rights in a protected work, but does not control access to such work (Article 17.7.5).

Very limited exemptions to the FTA detailed provisions – aimed at providing adequate legal protection and effective legal remedies to fight against circumvention of effective technological measures – are permitted for cases such as reverse engineering to achieve interoperability between computer programs; analyzing and identifying flaws of encryption technologies; preventing access of minors to inappropriate online content; correcting security of a computer; disabling a capability to collect and disseminate personal information; lawful activities of government employees; and, access to works by non-profit libraries, archives, or educational institutions for the purpose of making acquisition decisions.

The provisions on TPM have a 5-year term for application in Chile, one of the longest term allowed by the FTA in its transitional provisions. In DR-CAFTA the terms for the implementation of the TPM vary according to the countries, but the average is of 3 years.

The FTAs also protect Rights Management Information (RMI)[26] in terms similar to those in the WIPO treaties of 1996 (WCT and the WPPT). The difference is that it provides for civil sanctions and for criminal sanctions when the prohibited acts are done willfully and for commercial advantage.

4.4.4 Protection of Satellite Signals

The FTA with Chile binds the Parties to ratify a number of international treaties of the so-called international architecture of intellectual property. In this respect the FTA obliges the Parties to ratify before January 1, 2009, the Convention relating to the Distribution of Program-Carrying Signals Transmitted by Satellite, agreed in Brussels on May 21, 1974 (the Brussels Convention)[27] , which entered into force on August 25, 1979. In the case of the DR-CAFTA it stipulates the same obligation to be complied with before January 1, 2008. This obligation is stricter in subsequent free trade agreements. In those of Colombia and Peru, for example, adherence must coincide with the entry into force of the agreements.

The Brussels Convention provides that each contracting Party shall take adequate measures to prevent the unauthorized distribution in or from its territory of any program-carrying signal transmitted by satellite. The said Convention (Article 8) permits specific reservations to Members, under special circumstances, which are not excluded from the FTAs.

In addition to the obligation to become a Party to the Brussels Convention and the obligations deriving from that treaty, the FTAs provide for further complementary-related enforcement obligations: first, acts such as the manufacture, assembly, modification, import, export, sale, lease, or distribution of a tangible or intangible device or system may be considered either a civil or a criminal offence if the person concerned knows that the principal function of the device or the system is solely to assist in decoding an encrypted program-carrying satellite signal without being duly authorized. The knowledge of the principal function of the device or system may be demonstrated through reasonable evidence, taking into account the facts and circumstances surrounding the alleged illegal act. Also the wilful reception or further distribution of an encrypted-program-carrying satellite signal knowing that it has been decoded without the authorization of the lawful distributor shall be considered either a civil or a criminal offence.

In the case of DR-CAFTA[28] and the FTA with Peru, the infringement is assumed to be a criminal offence and do not allow, optionally, for civil or criminal offences as in the FTA with Chile.

4.5 Identification Signs: Marks and Geographical Indications

4.5.1 Trademarks

Because of both Parties particular interest in this category of protection, the provisions on trademarks were thoroughly discussed during the FTA negotiations with Chile. Great emphasis was given in the discussions to certification and collective marks and to the different trademark systems in place in Chile and the United States. Difficulties did arise in the negotiations with respect to geographical indications (GIs), because in the United States geographical indications are generally protected under trademark law.

According to the FTA, trademarks shall include collective, certification, and sound marks and may include geographical indications and scent marks. This means that there are at least three categories of marks that should be protected, namely collective, certification, and sound marks. But, there are two further categories of signs for which protection as a trademark is not mandatory, i.e., geographical indications and scent marks. This is a TRIPS-plus and even NAFTA-plus standard because the protection of certification marks is not mandatory under those agreements. In the recent United States agreement with Australia, protection for collective and certification marks is also mandatory and geographical indications are eligible for protection as a mark. Sound and scent marks are not included in this latter agreement. However, the United States agreements with Jordan, Singapore, DR-CAFTA, and Peru have a similar provision to the FTA with Chile. In the latter FTA, certification marks do not need to be recognized as a separate category of trademark, but the sign as such should be protected as an ordinary trademark.

Consistent with TRIPS, the FTA with Chile provides that the trademark owner shall have the exclusive right to prevent others, without his consent, from using in the course of trade identical or similar signs. Nevertheless, there are two important differences when compared with the TRIPS Agreement.

First, trademark owners shall have the right to prevent third parties without their consent, from using in the course of trade identical or similar signs, "... including subsequent geographical indications..." This addition makes sense, as geographical indications are capable of constituting a trademark, according to the FTA. Second, the right of the titleholder is not only extended to products or services which are identical or similar to those for which the trademark is registered but also extended to goods or services "... that are related to those goods or services in respect of which the trademark is registered, where such use would result in a likelihood of confusion." Likelihood of confusion is a matter to be determined by the domestic trademark law.[29]

No parallel provision to that in the TRIPS Agreement on the minimum duration of a trademark and its renewal is found in the FTA. This is not the case in the agreements of the United States with Australia, Morocco, and DR-CAFTA[30], which provide for a minimum of 10 years instead of 7 years as provided for in TRIPS. This is also the case of the recent agreements signed with Colombia, Panama, and Peru.

Reportedly, an additional issue discussed during the negotiations was the prohibition of the requirement to record trademark licenses to establish the validity of such a license. While both TRIPS and the FTA with Chile say nothing about recording of trademark licenses, a provision of this nature is found in the trade agreements of the United States with Australia, Jordan, Morocco, and Singapore and FTAs with Colombia, Panama, and Peru.

The FTA with Chile contains a number of provisions about the trademark registration system to establish basic formal requirements affecting decisions and notifications; modernize the registration system by using electronic means; and encourage the use of the International Classification contained in the Nice Agreement. No similar provisions are found under the NAFTA or in the United States agreements with Jordan and Singapore, but they do appear in the agreements with Australia and

DR-CAFTA[31]. The substance of the obligations regarding the registration of trademarks contained in the FTA is already included in the enforcement provisions of the TRIPS Agreement; however, the latter provisions are less burdensome and more flexibly drafted than those in the FTA.

According to the FTA with Chile, in cases where the full implementation of the obligations requires a Party to amend its domestic legislation or additional financial resources, those amendments and additional resources should be in force or available as soon as practicable, as in the case of the trademarks provisions of the FTA and in no event later than 2 years from the date of entry into force of the bilateral agreement.

4.5.2 Special Protection for Well-Known Trademarks

As in TRIPS, the level of protection for well-known trademarks is the same as that provided under the Paris Convention for the Protection of Industrial Property (1967), but covering both products and services. In the FTA with Chile non-registered well-known marks also benefit from such protection against dilution. A similar provision is found in the United States agreements with DR-CAFTA, Jordan, Singapore, Morocco, and Australia and more recently in the FTAs signed with Colombia, Panama, and Peru.

The FTAs also go beyond the TRIPS Agreement in various respects when providing for additional measures of protection of well-known trademarks. They provide that according to the respective domestic legislation, Parties shall provide for appropriate measures to prohibit or cancel the registration of a trademark, identical or similar to a well-known trademark, if the use of that trademark by the registrant applicant: a) is likely to cause confusion; or b) to cause mistakes; or c) to deceive; or d) risk associating the mark with the owner of the well-know trademark; or e) constitutes unfair exploitation of the reputation of the trademark.

4.5.3 Geographical Indications

Although Chile and the United States have advocated similar positions and submitted joint proposals on geographical indications in the WTO, some differences remain between both countries over the scope and the means of protection available for geographical indications. The United States protects geographical indications by means of collective marks. The Agreement tries to accommodate both forms.

Besides the framework of protection under the section on geographical indications, to protect their own indications, Chile and the United States agreed to follow the same approach as provided for under the NAFTA and protect them as distinctive products. Thus, Chapter Three of the FTA dealing with "National Treatment and Market Access for Goods" governs particular geographical indications such as Bourbon Whiskey of the United States and Chilean *Pisco*. One superficial reading

of this mutual obligation is that recognition of specific geographical indications in the Market Access Chapter instead of listing the same specific indications in the Intellectual Property Rights Chapter is to ensure that listed geographical indications will be granted only market access, respectively, to the United States and Chile. However, the provisions of the Market Access Chapter go beyond access and provide a strong protection to the listed geographic terms. In fact, besides allowing for the importation of the listed products, the Parties committed themselves to ban the sale of the unauthorized products bearing those geographical indications within their territories.

As to the definition of "geographical indications," the FTAs adopt the one provided in TRIPS. Nevertheless, a second sentence was added to the relevant provisions of the FTAs which broaden the TRIPS concept to allow the protection of geographical indications under the trademark system. This extends the possibility that a trademark – in the approach followed by the United States, which includes collective and certification marks – could be protected as a geographical indication. In doing so, part of the definition of trademarks has been included by providing that

> ...Any sign or combination of signs (such as words, including geographical and personal names, letters, numerals, figurative elements, and colors) in any form whatsoever shall be eligible for protection or recognition as a geographical indication (Article 17.4.1, Chile FTA).

The new given definition is extremely broad and might produce some unexpected consequences. Any WTO Member could request, for example, Chile or the United States, according to the most favored nation principle, to extend protection to signs or combination of signs as geographical indications. While the trademark elements added to the geographical indication definition might broaden the scope of denominations protected via GIs, this may be at the expense of indiscriminate filing and registration of geographical indications. Because the standard of protection for geographical indications in TRIPS is rather objective, in the sense that the good must have originated in a certain territory and a given characteristic of the good must be attributable to that origin, it could be assumed that the registration should be more or less automatic. Yet geographical indications protected through trademarks must still be subject to the distinctiveness or secondary meaning test, because they are essentially descriptive terms (i.e., non-inherently distinctive).

A new distinction concerning the legal means that each Party should provide to the other to protect geographical indications was introduced in the FTA with Chile.[32] The latter shall provide the legal means to identify and protect geographical indications of "United States persons" that meet the criteria contained in the common definition. However, the United States shall provide the legal means to identify and protect Chilean geographical indications that meet the criteria contained in the common definition. The difference lays in the use of the concept "person" contained in the obligation by Chile. Because the United States protects geographical indications through a system of collective and certification trademarks, the owners of the those

indications are usually legal persons. For all purposes, the FTA defines "person"[33] as "a natural person or an enterprise." On the contrary, Chile protects its geographical indications through specific laws and regulations, and technically, the owner is the Chilean State because – at least in the wine and spirit sectors – they are created through Presidential Supreme Decrees.[34] Thus, for purposes of the geographical indications provisions, a footnote states that – besides natural persons and enterprises – "persons of a Party shall also mean government agencies" which means that in the case of Chile (and eventually the United States), government agencies may file for geographical indications on behalf of the Chilean State.

Due to these considerations, a special provision was included in the FTA for those geographical indications related to wines and spirits. It means Chile shall provide to geographical indications of the United States the same recognition as Chile accords to wines and spirits under the Chilean regime. This provision might be considered redundant because of the national treatment principle in the Agreement. The United States shall provide to Chilean geographical indications the same recognition as it grants to wines and spirits under the Certificate of Label Approval system as administered by the United States Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau or any successor agencies, notwithstanding the provisions of the US Trademark Act.

Other provisions of the FTAs are intended to simplify the formalities of registration and protection of geographical indications; provide publicity and transparency of the relevant regulations; and establish opposition procedures and guidelines regarding the processing of application or petitions and special grounds for refusing protection by favoring pre-existing trademarks.

Excluding the special measures on wines and spirits in the case of Chile, the provisions on geographical indications are similar in subsequent agreements, e.g., DR-CAFTA, Colombia, Panama, and Peru.

4.6 Enforcement and Settlement of Disputes

Measures related to the enforcement of rights and obligations are key components of trade agreements. The existence of a dispute settlement mechanism also provides guarantees to the Parties that the problems that may arise due to the implementation and enforcement of commitments will be resolved in an orderly manner. In the FTAs, as in the WTO system, the respective Intellectual Property Rights Chapters have specific enforcement rules, and in a separate chapter there is an FTA mechanism for the settlement of all disputes related to the agreements. This model is followed in all subsequent FTAs subscribed by the United States including DR-CAFTA and the agreements with Colombia, Panama, and Peru.

The enforcement provisions of the FTAs present the same structure as the TRIPS Agreement. Accordingly, they contain provisions on General Obligations, Civil and Administrative Procedures, Provisional Measures, Border Measures, and Criminal Procedures. For the United States, probably the most relevant achievement in this

area has been to make mandatory many of the discretionary remedies included under TRIPS. The important novelty of the FTAs, as far as TRIPS and the WIPO Internet Treaties are concerned, is that it provides for "Limitations on Liability of Internet Service Providers."

The FTA with respect to civil and administrative procedures and measures provides that each Party shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right (Article 17.11.7).

This was practically transcribed from TRIPS (Article 42) with the difference that the FTA prescribes that civil procedures shall be applied to present and future intellectual property rights that are recognized by the legislations of both countries.

The FTAs complement TRIPS (Article 50.2) in the sense that provisional measures *inaudita altera parte* (without hearing the other Party) must be acted upon expeditiously in accordance with judicial procedural rules of each Party. It seems also that the FTAs allow authorities to request evidence from the applicant only when the infringement of the right is imminent, not when it is already being infringed, as provided in TRIPS (Article 50.3). What the FTAs add to TRIPS is that reasonable security or equivalent assurance must be in an amount sufficient; not only to protect the defendant and to prevent abuses but also not to unreasonably deter recourse to such procedure.

With regard to border measures, the FTAs go beyond TRIPS particularly in one aspect. The latter provides for border measures, including *ex officio* actions, only for the importation of counterfeit trademarks or pirated goods. The application of border measures to goods being exported and to goods in transit is optional. The FTAs are TRIPS-plus in the sense that they provide for *ex officio* measures for goods being imported, as well as for those destined for export or moving in transit.

As in TRIPS, the FTAs provide for criminal measures at least for cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. But they go beyond TRIPS by broadening the scope of what is considered a willful infringement on a commercial scale for two specific situations that probably had in mind copyright infringement in the digital environment. The first, in the case of the FTA with Chile, relates to the obligation of the Parties to ensure that "willful infringement of copyright and related rights for a commercial advantage or financial gain, is subject to criminal procedures and penalties." This provision seems to disregard the quantitative "commercial scale" requirement in TRIPS and replaces it with the notion of a "commercial advantage or financial gain" element, which focus more on the purpose of the infringement, even if it is not made at a commercial scale.

The second is the establishment of rules on limitation of responsibility for Internet service providers (ISP). The FTA provides for detailed rules on the limitation of responsibility for Internet service providers (ISPs). These provisions are based on the United States Copyright Act. In the case of Chile, the issue was extensively discussed during the negotiations, mainly because of its novelty in intellectual property negotiations. Initially it was to be incorporated in the FTA as a side letter, but finally it was included in the Intellectual Property Chapter itself. No such provisions can be found in NAFTA or in the trade agreement signed with Jordan.

The FTA provides specific and detailed rules on liability of and limitation of the liability of services providers for infringing content that is transmitted or stored in their networks when they perform certain functions, such as hosting, caching, or linking.

4.6.1 The Dispute Settlement Mechanism

Under the WTO system the dispute settlement mechanism is based on the principle that any Member can challenge trade measures taken by any other Member, so that even those countries that are economically weak can challenge the more economically powerful trade partners. However, the practical application of this important principle is not necessarily straightforward.

The need for dispute settlement arises whenever a Party considers that benefits accruing to it under commitments in a trade agreement are being impaired through measures taken by the other Party. Since the free trade agreements are based on the idea of reciprocal and mutually advantageous economic benefits through trade liberalization, it is the principal objective of a dispute settlement to reinstall, as quickly as possible, a situation in which each Party can fully enjoy the benefits it is entitled to under the agreement.

The United States has long advocated greater transparency in the WTO dispute settlement system. According to that perspective, experience shows that the dispute settlement body recommendations and rulings can affect large segments of civil society. Furthermore, the increase in WTO Membership has given rise to a larger number of governments and their citizens being interested in its recommendations and rulings. Yet civil society and non-Party Members have been unable even to observe the arguments or proceedings resulting in those recommendations and rulings.

The dispute settlement mechanism of the FTAs applys to almost all the different matters covered by the agreements, except, in the case of Chile, for some provisions related to Competition Policy, Designated Monopolies, and State Enterprises (Chapter 16). In addition, some special proceedings are included for financial services, environment, and labor issues, where technical consultations are established.

The dispute settlement mechanism under the FTAs includes namely consultations, good offices, conciliation, and mediation and the establishment of an Arbitration Panel. For the latter, the FTA with Chile obliges the Parties to establish and maintain, within 6 months after the entry into force of the Agreement, a roster of at least 20 individuals who are willing and able to serve as panelists in the various disputes that could arise, appointed by mutual agreement of the Parties. Six of these Members shall be non-Party nationals. The roster remains in effect for a minimum of 3 years and panelists may be reappointed.

Finally, the dispute settlement mechanism applies broadly to disputes related to the avoidance or settlement of all disputes between the Parties regarding the interpretation or application of the Agreement; whenever a Party considers that a

measure adopted by the other Party is inconsistent with the obligations of the FTA or the Party has failed to carry out its obligations; and, whenever a Party considers that a measure of the other Party causes nullification or impairment.

As noted, the FTAs mechanisms include non-violation complaints as a component of the dispute settlement mechanism. In the WTO system, the difference between violation and non-violation remedies is that, under former, the competitive relationship is upset through the violation by one Member of a WTO obligation, whereas under the second situation, this competitive relationship is upset through "WTO-consistent" action on the part of one Member, rendering the results of certain market access concessions made by that Member less beneficial for other Members. It is considered a valid cause of action if a Member by some purely domestic measure frustrates the legitimate expectations of other Members as to the competitive advantages their products can draw from a negotiated tariff concession. However, such legitimate expectations may not be invoked if the complainant could "anticipate," at the time of negotiating the concession, the possible adoption of future domestic measures by the respondent that would cancel out the complainant's competitive advantage resulting from the negotiated concession. This requirement ensures that non-violation complaints are actually used in case of the frustration of legitimate expectations and not merely on grounds of a negative economic development. This distinction and rationale for non-violation complaints extend to the case of the FTAs.

In the FTA, there are exclusions in the case of intellectual property rights to non-violation complaint cases; therefore, non-violation situations could be the source of differences between the parties and give rise to a dispute following the general principles outlined above. However, the automatic application of non-violation complaints to intellectual property cases is not so obvious. In TRIPS, it was recognized that this was a subject deserving further consideration and transitional arrangements were devised to that effect. In the Council for TRIPS this continues to be an outstanding question. The FTAs have gone no doubt beyond the present state of affairs in the TRIPS Agreement making countries parties to those agreements potential subjects of unforeseeable situations that according to the other Party might frustrate its legitimate expectations. This, according to some views, could make countries more vulnerable to pressures regarding the use and modalities of implementation of the flexibilities allowed in international agreements[35] (South Centre/CIEL, 2004).

4.7 Conclusions

The TRIPS Agreement signaled a major change in international economic relations. For the first time intellectual property entered in full into the international trading regime[36]. This, in a way, reflected the approach of the United States that since the Trade Act of 1974 established in its commercial relations a link between trade and adequate protection of intellectual property. The reasons for including intellectual property rights in the framework of the multilateral trading system during the Uruguay Round of Multilateral Trade Negotiations that concluded with the

creation of the WTO are complex. The attempt was originally resisted by a number of developing countries which advanced reservations, among others, on social interest grounds, about subjecting, for example, inventions related to public health and nutrition to strict patenting rules under a new trading regime.

While TRIPS introduces minimum standards of protection, albeit with some flexibilities, recent trends suggest a more complex picture characterized as a TRIPS-plus phenomenon. It has elicited concerns as it goes beyond the minimum standards of TRIPS by seeking to harmonize intellectual property regimes in developing countries with those of economically and technologically more advanced countries. This harmonization trend is being encouraged in bilateral, regional, and new multilateral initiatives. The concerns advanced by some developing countries relate to the curtailment of their policy space in an important area of their economic development. In brief, the perception by many is that TRIPS-plus requirements will inhibit countries from using fully the flexibilities implicit in the TRIPS Agreement and to resort to industrial policies with laxer systems of intellectual property protection, which were followed in the past by developed countries and until recently by newly industrialized countries (e.g., cases of Republic of Korea and Chinese province of Taiwan).

The TRIPS-plus phenomenon responds to the view that the Agreement is considered as not adequately reflecting the highest standards of intellectual property protection needed to promote global trade and to respond to the requirements of the digital age. As a result, in recent years, the United States has followed a clear and explicit bilateral trade policy going beyond the TRIPS Agreement by including TRIPS-plus provisions in its free trade agreements post-NAFTA, which was, by the way, concluded almost in parallel with the Uruguay Round Negotiations. This bilateral agenda has included issues raised, with minor degrees of success, by the United States in various international fora, namely the extension of coverage of copyright, trademark, and patents protection; the need to ratify and enforce certain intellectual property-related treaties; patent protection for life forms; limitations in granting compulsory licenses on patents; specific implementation of TRIPS provisions in areas such as undisclosed information; rules concerning the exhaustion of intellectual property rights; and strengthened rules on enforcement. Recent trade agreements of the European Free Trade Association (EFTA) and the European Union with Latin American countries (Chile and Mexico) include provisions that oblige the parties to provide effective protection to intellectual property according to the highest standards, including effective means of enforcement. The bilateral agenda of the United States has proven to be more ambitious compared to that from Europe. However, recent initiatives from the European Union predict a more vigorous agenda on intellectual property matters particularly with respect to the enforcement of intellectual property rights.

Closer study of the FTA with Chile is a stimulating incursion into this TRIPS-plus world. At this stage, it is difficult to assess the overall impact of the intellectual property rights provisions of the FTA and even more to extrapolate results of such evaluation to other countries. The FTA is comprehensive treaty, which in Chile's perception, together with a broad network of trade agreements with a multifarious

group of trade partners, constitutes a dynamic feature of its economic policy geared at the promotion of exports of services and products. Thus, the impact of these agreements cannot be assessed in isolation of these considerations.

One tentative conclusion that one can derive from the FTA with Chile is that the level of its intellectual property rights protection and enforcement provisions are less stringent than those negotiated by the United States – simultaneously – with Singapore and subsequently with DR-CAFTA, Australia, Bahrain, and Morocco; however, it includes a number of key provisions that constitute important precedents for incorporation in future bilateral and multilateral agreements.

The provisions dealing with pharmaceutical products have elicited a number of criticisms. In this regard, it should be noted that the expanded protection of pharmaceutical products is in some respects conditioned to the Ministerial Declaration of the Doha Round on TRIPS and Public Health of November 14, 2001, which is expressly mentioned in the Preamble to Chapter 17 of the FTA with Chile. The DR-CAFTA agreement has included a letter of understanding to specify the relationship between intellectual property and access to health. The Preamble of the Agreement with Chile is innovative in comparison with other agreements signed recently by the United States. The relationship between the Preamble and the general principles of the Agreement, such as the non-derogation clause and provisions on pharmaceutical products, is at least ambiguous and leave room for creative implementation. As noted in this chapter, the recent agreement signed by the United States with Peru has introduced important changes to the provisions on pharmaceutical products amending, among others, the linkage between sanitary and marketing approval with the validity of a patent, linkage that does prevail in the Agreement with Chile and DR-CAFTA.

Among the areas not covered in the FTAs signed by Latin American countries is the granting of compulsory licenses to allow for the use of the subject matter of a patent. In this area, as well as in others not covered by the FTAs, the latter do not innovate with respect, for example, to the provisions of the TRIPS Agreement.

The trade agreements do not address the whole gamut of intellectual property issues. For example, a number of developing countries have claimed that international intellectual property regimes fail to account adequately for the protection of traditional knowledge, but free trade agreements do not provide guidelines and do not innovate with respect to current debates in WTO and WIPO.

At the same time, the free trade agreements signed by Latin American countries do not address either the issue of the exhaustion of intellectual property rights in areas such as patents and trademarks. In this respect, the Doha Declaration on the TRIPS Agreement and Public Health of November 14, 2001, reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility by leaving each Member free to establish its own exhaustion regime. The United States Free Trade Agreement with Australia, however, allows for the possibility that in the case of patents, the patent owner may contractually restrict the importation of patented products that it has placed on the market. Free trade agreements with Latin American countries leave Parties with the full flexibility contemplated in TRIPS.

Finally, as underlined in this chapter, the recent bilateral agreements promoted by the United States add an unchartered page in the history of intellectual property rights. TRIPS has been one important event in this history but not the concluding one.

Notes

1. See text of Declaration at http://www.wto.org/spanish/thewto_s/minist_s/min01_s/mindecl_trips_s.htm
2. The Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), with respect to the FTA recently signed with Peru, stated "ITAC 15 urges the US not only to monitor very closely the implementation by Peru (and other FTA partners) of their FTA obligations but also to ensure that Peru and other FTA partners have in place, before the entry into force of the FTAs, national legislation that faithfully reflects their FTA obligations. . . .IFAC-15 commends the US for working with FTA partners to secure fully-compliant national legislation before each agreement enters into force. ITAC-15 considers it essential that, if need be, entry into force be postponed until full compliance is achieved." Cited by P. Roffe (2006), *Intellectual property provisions in bilateral and regional trade agreements: the challenges of implementation,* CIEL.
3. See Article 26 of the Vienna Convention on the Law of Treaties.
4. Twenty-three agreements have been concluded or administered under the auspices of WIPO with regard to Intellectual Property. See the text of these agreements at http://www.wipo.int/treaties/es/index.html
5. The reference in DR-CAFTA to agreements concluded or administered by WIPO is limited to those where both parties are members (see Article 15.1.6).
6. The TRIPS Agreement entered into force on January 1, 1995.
7. The 41 notifications made so far by different WTO Members regarding Article 4(d) of the TRIPS Agreement are available at the WTO web site http://www.wto.org/english/tratop_e/TRIPS_e/intel7_e.htm
8. For some of the notifications made so far under Article 4(d) of the TRIPS Agreement, see UNCTAD/ICTSD Resource Book, Part One, Chapter 1.4.
9. See Article 15.9.5.
10. Article 15.9.4, CAFTA: "Without prejudice to Article 5.A(3) of the Paris Convention for the Protection of Industrial Property (1967), each Party shall provide that a patent may be revoked or cancelled only on grounds that would have justified a refusal to grant the patent. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, cancelling, or holding a patent unenforceable." The US industry reacted to this provision in the following terms: "CAFTA restricts, in Article 15.9.4, the grounds for the revocation of a patent to those limited to the patentability of the invention. Notwithstanding that IFAC-3 is disappointed that it does not require CAFTA countries to also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking, cancelling or holding a patent unenforceable, it urges the U.S. Government to work with the CAFTA governments in the implementation of this provision to ensure that it is consistent with U.S. practice. For example, the possibility of preventing enforcement of a patent due to actions that are found to constitute inequitable conduct should be limited to acts that are material to the patentability of the invention. Since CAFTA countries are already members of the Paris Convention, IFAC-3 notes that the reference to the obligations contained in Article 5.A (3) of the Paris Convention does not add or detract from the obligation contained in the FTA Article 15.9.4." See IFAC-3-CAFTA.
11. See Article 15.9.6 (a).
12. This provision has its origins in the US Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), which together with granting an extension of the patent

term for administrative delays in the FDA, awarded extensions for delays during the granting of the patent.

13. See Pedro Roffe and David Vivas, "A Shift in Intellectual Property Policies in US FTAs?", *Bridges,* Geneva, Year 11, 5, August (2007).
14. Ibid.
15. See Roffe & Vivas, op. cit.
16. Correa, 2004.
17. In fact, there are two provisions in the FTA dealing with regulated products. The first provision (Article 17.10.1) states that the protection is awarded to undisclosed information for the grant or marketing approvals or sanitary permits. The second provision (Article 17.10.2) establishes the relation between regulated products and patents referring exclusively to "marketing approvals." A logical interpretation should lead to the conclusion that the parties probably meant different things in the use of the terms "marketing approval" and "sanitary permits." One expression of this might be the interpretation that if a Party grants only sanitary permits (i.e., to certify the safety and efficacy of the product), the provisions of Article 17.10.2 (that refers to marketing approval) would not apply to that Party. However, as stated in this study, the provisions of the FTA in this area derive from Article 39, TRIPS, and these refer only to marketing approvals.
18. See Roffe & Vivas, op. cit.
19. The so-called three-step test allows Parties to "confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder". See Article 13, TRIPS.
20. See Article 5 of Directive 2001/29/EC of the European Parliament and of the Council of May 22, 2001, on the harmonization of certain aspects of copyright and related rights in the information society.
21. According to the FTA "Communication to the public of a performance or a phonogram means the transmission to the public by any medium, otherwise than by broadcasting, of sounds of a performance or the sounds or the representations of sounds fixed in a phonogram. For the purposes of Article 17.6(5) 'communication to the public' includes making the sounds or representations of sounds fixed in a phonogram audible to the public."
22. Under Article 17.6.8(c) of the FTA: Fixation means the embodiment of sounds, or of the representations thereof, from which they can be perceived, reproduced, or communicated through a device.
23. Phonogram means, according to the FTA, the fixation of the sounds of a performance or of other sounds, or of a representation of sounds, other than in the form of a fixation incorporated in a cinematographic or other audiovisual work.
24. For the relevant equivalent provision in DR-CAFTA, see Article 15.5.6.
25. According to the FTA: An "effective technological measure" is any technology, device, or component which in the normal course of operation, controls access to a work, performance, or phonogram or other protected subject matter, or protects copyright or other related rights which cannot be evaded accidentally.
26. According to Article 17.7.6 (b), FTA, Rights management information means: "information which identifies a work, performance, or phonogram; the author of the work, the performer of the performance, or the producer of the phonogram; or the owner of any right in the work, performance, or phonogram; information about the terms and conditions of the use of the work, performance, or phonogram; and any numbers or codes that represent such information, when any of these items is attached to a copy of the work, performance, or phonogram or appears in conjunction with the communication or making available of a work, performance, or phonogram to the public. Nothing in paragraph 6(a) requires the owner of any right in the work, performance, or phonogram to attach rights management information to copies of the owner's work, performance, or phonogram or to cause rights management information to appear in connection with a communication of the work, performance, or phonogram to the public." In the case of DR-CAFTA, see equivalent Article 15.5.8 (c).

27. In no other bilateral trade treaty recently negotiated by Chile (with Mexico, EFTA, EU, or Korea), there exists a similar obligation to become member of the Brussels Convention.
28. See Article 15.8.
29. Footnote 4, FTA.
30. See Article 15.2.9 of DR-CAFTA.
31. Article 15.2.6, CAFTA.
32. Articles 17.4.2 and 17.4.3, FTA. These two provisions are not found in CAFTA or the US–Morocco FTA
33. Article 2.1, FTA, on general definitions.
34. See Article 27 of Chile's Law 18.455, which "Sets Rules on Production, Elaboration, and Commercialisation of Ethylic Alcohols, Ethylic Beverages and Vinegars." Article 27: "The President of the Republic, by supreme decree issued through the Ministry of Agriculture, may establish vine-producing zones and denominations of origin for wines and spirits in certain areas of the country, where conditions of weather, soil, varieties of grapes, cultural and oenological practices are homogeneous" (non-official translation).
35. South Centre/CIEL, 2004. The report acknowledges that "Nonetheless, these bilateral agreements establish some limitations for non-violation complaints that must be taken into account. In the United States-Chile FTA, for instance, benefits expected under the intellectual property chapter cannot be invoked with respect to measures taken under the general exceptions provisions. That is, measures taken under Article XX of GATT 1947 (along with its interpretive notes, into the agreements *mutatis mutandis*) cannot be challenged on the basis of annulment or impairment of benefits expected under the intellectual property provisions."
36. Previous to the TRIPS Agreement, there were references to intellectual property rights in the GATT-1947. For instance, Article IX deals with Marks of Origin; both Article XII on Restrictions to Safeguard Balance of Payments and Article XVIII on Governmental Assistance to Economic Development state that Parties may not apply restrictions which would prevent compliance with patent, trade mark, copyright, or similar procedures. Finally, Article XX, which provides for general exceptions, allows for exceptions necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to the protection of patents, trade marks and copyrights, and the prevention of deceptive practices.

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Chapter 5
Free Trade Agreements and Intellectual Property: Impacts and Challenges

Álvaro Díaz

5.1 Introduction

A decade after having adhered to the agreement of the World Trade Organization (WTO) concerning Trade-Related Aspects of Intellectual Property Rights (TRIPS), 10 countries of Latin America and the Caribbean have signed free trade agreements (FTA) with the United States, which contain extensive chapters on intellectual property which go beyond the TRIPS Agreement of 1994.

The agreements have given rise to heated debate in all the signatory countries. In Costa Rica, the country with the longest democratic tradition on the continent, DR-CAFTA was subject of strong controversy and therefore, the Legislative Assembly agreed in September 2007 to carry out a referendum which was won by the government by a short margin. In the United States the process was not easy either. DR-CAFTA was approved by only one vote, and the defeat of the Republican Party in the 2006 parliamentary election – and the current recession in the United States – postponed for an uncertain future the agreements with Colombia and Panama.[1]

If these obstacles are overcome, almost the entire Pacific coast of Latin America will have FTA's with the United States. Including Mexico, this means 11 countries of the region which represent almost 30% of the subcontinental territory and 45% of the population and of the regional GDP.

Nevertheless, the free trade agreement wave has ended for the foreseeable future. The Colombia and Panama FTA's are stalled in Congress. In the case of Ecuador, the negotiations were first interrupted in 2006 by the Bush Government and then suspended by President Rafael Correa.[2] Most importantly this FTA wave failed to incorporate Brazil and Argentina, for it is clear that neither of them will sign agreements with the United States which include public purchases and intellectual

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property if the United States does not substantially reduce agricultural subsidies. Brazil and Argentina worked for a multilateral solution in the Doha Round, but its collapse in 2008 increased the uncertainty on these matters.

The ten Latin American countries that negotiated trade agreements with the Bush Government had very focalized goals: consolidate, diversify and increase exports and also promote foreign direct investment. In exchange they had to accept the strengthening of intellectual property rights, the opening of public purchases to foreign firms and the reduction of regulations for short and long term capital movements.

Evidently, the FTA's will intensify the opening and export-led orientation of these Latin American economies. The governments of the region commissioned studies that estimated the effects of tariff reduction on growth and concluded that although the effects were positive, they were rather small. No studies were commissioned about the economic impact of intellectual property. Although there is consensus that there will be significant economic consequences, the scarcity of statistical data, uncertainty on implementation methods of the FTA's obligations and the possible formulation of new public policies make it impossible to make reliable estimates.

In this context, there are two viewpoints. On the one hand, the orthodox view assures that the agreements can have transitory costs but their benefits will be greater, provided that the contracted obligations are fully applied and complemented with new reforms and deregulation to strengthen the free market. On the other, the heterodox view maintains that the agreements entail risks for macroeconomic stability, can generate regressive social effects and affect some branches of production, which may not be compensated by expansion of exports, nor by greater foreign investment, if any.

This chapter follows the second view, emphasizing that the consequences of the agreements will depend on the flexibilities achieved in their implementation and on the public policies put into effect *before and after* their entry into force. In this regard, the present world economic crisis which begun in the United States will probably favour a pos Washington consensus for a new balance between markets and state, between private and social control, even in the intellectual property arena. The recent G-20 April 2009 London Agreement is an example. This could inspire a new generation of public policies and regulations that maximize benefits from the free trade agreements and minimize their negative impact.

This could seem deceptive because it is common to establish a causal relation between the FTA's, the strengthening of the market and the reduction of the State. However, the agreements with the United States are not incompatible with greater public-sector activity in social policies, the expansion of public policies in innovation and technological development, the development of sound regulations in public utility services, the progress of legislation and the competition agencies, as well as the strengthening of consumer rights, labor rights and environmental protection. Furthermore, the agreements do not hinder the political autonomy of the countries in international affairs, as occurred when Mexico and Chile opposed the United

Nations' intervention in Iraq. Nor do they stand in the way of the integration of the subcontinent in a perspective of *open regionalism*, which we hope will be the next generation of agreements.

This perspective can also be applied to intellectual property rights (IPR). To be sure, one should start by recognizing that the agreements broaden and strengthen IPR by generating important consequences for the dynamics of technological innovation, as well as consumption of products intensive in information and communication technologies (ICT). They will also have a powerful impact on the agricultural and pharmaceutical sectors.

The IPR strengthening commitments should be fully implemented toward the year 2010. There will inevitably be postponements, but even so, they will bring about a rapid institutional and regulatory change. To understand its scope, there is no doubt that the text of trade agreements is a starting point for analyzing the possible impacts of IPRs. This, however, is not sufficient. First of all, because despite their technical and legal complexity, free trade agreements are "incomplete contracts," that is, they make numerous explicit obligations but leave gaps and ambiguities that can only be filled with laws, regulations, and the jurisprudence of each country. Second, because other public policies related to technological innovation, competition, consumer rights, health, education, and social protection will determine the final balance between IPR protection and social access to knowledge and goods like pharmaceuticals.

One possible scenario is a strict implementation of free trade agreements causing an overprotection of IPRs, which could be combined with weak public policies in innovation, health, competition, consumer rights, and others. The result will be inevitable. There will be negative impacts in the population's access to health and in the competitiveness of small-scale agricultural production, also hindering the dynamics of local innovation and increasing the inequality of access to knowledge and information.

Another scenario is a flexible implementation of free trade agreements, creating a more adequate balance between the holders of intellectual property rights and the general interests of society, which could be combined with a new very active generation of public policies with regard to innovation, health, competition, and consumer rights. In this context, the negative impacts could be minimized and more favorable conditions for a growth path with equity could even be created.

To meet these challenges, this chapter addresses two major issues. Section 5.2 analyzes the possible impacts of free trade agreements focusing on technological innovation and the digital economy.[3] Section 5.3 makes recommendations for a new treatment of IPRs to encourage creation and innovation, spread the transfer of knowledge on a large scale, and maximize the dissemination of its benefits. To end this chapter, Section 5.4 summarizes the main challenges faced by the Latin American countries that ratified the FTA's: the building of a new treatment for intellectual property and the encouragement of a new generation of post-Washington consensus public policies.

5.2 Impacts of Free Trade Agreements

5.2.1 Innovation

Free trade agreements devote little space to patents and most of the provisions regulate patents only for pharmaceutical and agrochemical products. There are three main changes: first, although they do not impose obligations, they open the doors to an expansion of patentable subject matter, specially in business methods, software, and the patenting of plants[4]; second, they strengthen enforcement of intellectual property with administrative, civil, and criminal proceedings; and third, they make it mandatory to compensate during the term of the patent for administrative delays of more than 5 years, which in practice is not an excessive obligation.

Nevertheless, the free trade agreements have numerous ambiguities and gaps. Countries are not strictly compelled to broaden patentable subject matter and could oppose patenting business methods, software, and plants.[5] Furthermore, the free trade agreements do not define the "height" or innovation level to assess patentable innovations, nor do they provide conditions for compulsory licenses and parallel imports. Therefore the countries keep a margin of freedom to fill these gaps with their laws and technological innovation policies.

But none of this is guaranteed. The political economy of implementation of the agreements shows that there are countries that could further harden the provisions of the free trade agreements. Therefore, it is necessary to reach national consensuses in order to effectively take advantage of the gaps in patent regulation and promote a new generation of technological innovation policies.

5.2.1.1 Technological Innovation and Patents

Will the strengthening of the patents regime lead to more local innovation and will it encourage the registration of patents by national private entities and universities? For some, the unequivocal answer is affirmative under the assumption that weak intellectual property rights do not allow Latin American firms to assure the appropriability of high-risk investments in innovation, causing an under-investment in research and development (R&D). Hence, it is believed that the strengthening of IPRs will stimulate technological innovation and logically increase national patent applications.

This is a reductionist approach that leads to erroneous conclusions of diagnosis and appropriate public policy design.

It is well known that technological change in Latin American countries mostly depends on capital goods imports. The 10 countries that ratified the FTA's have a small and asymmetric scientific and technological infrastructure shown by the fact that for every million dollars' invested in science and technology, there is an output of four times more scientific articles than patents. Moreover, investment in R&D is low and has little private participation. Patent registration has very slow growth rate and foreign companies represent 90% of total patent applications. Table 5.1 summarizes the reality in these matters and shows that the 10 countries that signed

Table 5.1 Indicators 2000–2004 OECD-Latin America and the Caribbean[6] (5-year averages at 2000 prices)

Regions and countries	Population (millions)	GDP (billions of dollars)	R&D (millions of dollars)	R&D as % of GDP	Scientific articles	Application for patents	Application for patents USPTO
	−1	−2	−3	(3/2)	−4	−5	−6
OECD	910	25,091	622,706	2.50	533,267	754,835	310,672
LAC	522	2,007	11,222	0.60	17,575	5,496	702
Brazil	180	623	6,177	1.00	7,918	3,403	246
Mexico	102	592	2,395	0.40	3,492	505	181
Argentina	38	270	1,131	0.40	3,066	753	119
10 Countries with FTA	122	287	840	0.29	1,954	491	88
Chile	16	81	499	0.60	1,370	318	34
Colombia	44	88	161	0.20	334	68	21
Costa Rica	4	17	52	0.30	88	28	9
El Salvador	7	14	11	0.10	2	9	2
Honduras	7	6	3	0.00	11	9	2
Nicaragua	5	4	2	0.00	8	6	1
Panama	3	12	44	0.40	45	10	6
Peru	27	56	58	0.10	88	28	9
Dominican Republic	9	9	10	0.10	8	15	4
Rest of LAC	83	234	680	0.29	1,138	338	72
Venezuela	25	114	384	0.30	533	87	36
Cuba	11	30	181	0.60	262	148	11
Uruguay	3	19	44	0.20	165	42	8
Bolivia	9	9	24	0.30	32	16	1
Ecuador	13	17	14	0.10	30	11	7
Guatemala	12	20	10	0.10	14	9	2
Jamaica	3	8	5	0.10	49	10	3
Trinidad and Tobago	1	9	11	0.10	46	4	3
Paraguay	6	8	7	0.10	7	11	1
FTA10/LAC (%)	23.3	14.3	7.5		11,1	8,9	12,5
FTA11/LAC (%)	42.9	43.8	28.8		30,1	18,1	38,3

Source: ECLAC, WIPO, USPTO, UNESCO, RICYT, Statistics of National Patent Offices.

agreements with the United States represent 23.3% of the population and 14.3% of GDP, but only 11.1% of scientific articles and 8.9% of national applications for patents in Latin America.

The above-mentioned asymmetries have deepened over time. In the 1994–2004 period, the growth rate of foreign patent applications doubled the national one.[7] At the same time, the scientific articles–patents coefficient increased from 1.3 in 1994 to 4 in 2004.

Nevertheless, the above has not hindered technological change driven mainly by capital goods imports with embedded technology, exports, and foreign investments which lead to new product and process technologies, the diffusion of information and telecommunications technologies, and also new management methods in business. Although most advanced companies carry out little research and development in the conventional sense, it is also true that they devote significant efforts to imitative, adaptive, and incremental innovations. This explains the asymmetry between very low private R&D and the high levels of adaptive and imitative innovation. This is consistent with empirical studies that have concluded that innovation occurs in most industries despite the shortage of patents (Arundel and Kabla, 1998; Cohen, Goto, Nagata, Nelson, and Walsh, 2003).

But why Latin American firms invest so little in R&D and consequently have such low levels of patent registration? Historical comparison shows that low levels of IP protection is not the fundamental cause. The American, Chinese, German, and Japanese historical experiences show that these countries substantially increased R&D and patent registration *before* the strengthening of IPR's.

There are other sources of explanation. One of them is that innovative Latin American firms that potentially could submit a patent application are inhibited by the risks of litigation whose costs generally exceed the expected benefits and are quite superior to the initial R&D investment. This is particularly discouraging for innovative small and medium-sized enterprises (SMEs) which lack funds to back these kinds of risks. However, innovative firms have other alternative strategies to deal with problems of appropriability: industrial secret, market-lead time, vendor lock-in techniques that generate customer dependency because of high switching costs, among others practices (Levin et al. 1987).

Furthermore, the conditions of appropriability vary among sectors. In the chemical and pharmaceutical sectors patents are very important because of high sunken costs of R&D that contrasts with low imitation and reproduction costs. As regards financial services, retail trade, and Internet services, the costs of innovation are relatively low, but the advantage of being first is very important. In such cases, free-rider problems and waiting games are lesser problems, which reduce the importance of patents.

For the Latin American countries that have trade agreements with the United States, a significant part of their R&D – often not computed as such – is linked to national resources research: adaptation of species, mining exploration and prospecting, biomass studies, identification of ecosystems, and combating forestry and agricultural pests. These activities attract public resources, generate scientific articles, and require continuous innovation in science and technologies methodologies

and techniques, but they can hardly obtain invention patents because they will be mostly classified as discoveries. Moreover, only a few countries authorize patents for genes, plants, and animals. In this cases, industrial secret will generally be the preferred technique.

Finally, it should be borne in mind that in these countries public science and technology policies are concentrated on promoting technology transfer toward small enterprises and on supporting scientific research in universities.[8] This is necessary, but is definitely insufficient to encourage private efforts in research and development.

5.2.1.2 Lessons from the Mexican Experience

The Mexican experience after NAFTA indicates that rigid application of the FTA obligations does not necessarily encourage local innovation subject to protection by intellectual property. Between 1995 and 2005 registration of Mexican patents dropped 12%, whereas that of foreign patents doubled, despite the fact that spending on R&D increased from 0.2 to 0.4% of GDP, a coefficient nevertheless five times lower than the OECD average (Chart 5.1).[9]

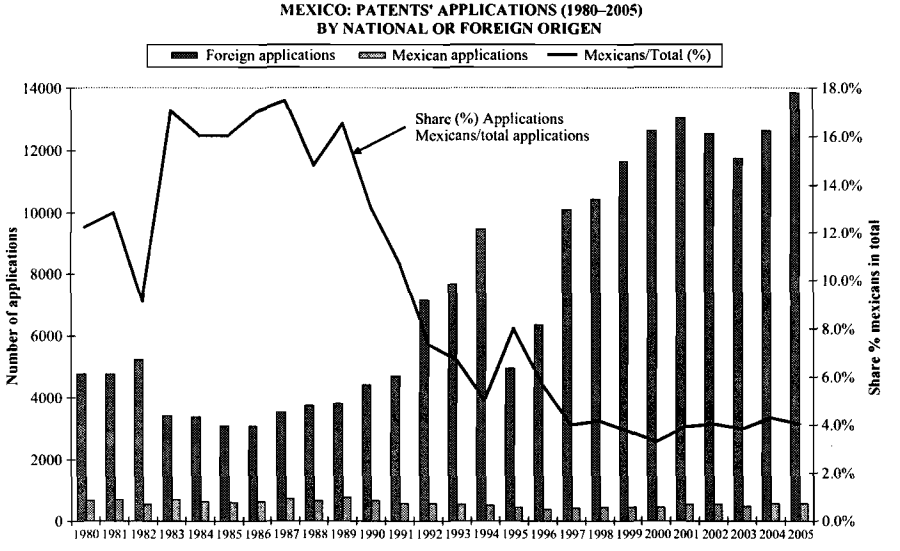

Chart 5.1 Mexico: patent applications according to origin national or foreign, 1980–2005. Source: Díaz (2007).

This poor performance in patents also extends to models of utility and industrial designs, which contrasts with the notable increase in scientific articles classified in the Science Index. Between 1990 and 2004 Mexico almost quadrupled annual production of scientific articles with a higher performance than the Latin American average.

What were the causes of this post-NAFTA drop in national patent registration in the Mexican Intellectual Property Institute (IMPI)? As it is known, Mexico was deeply integrated into the North American economy as a result of the NAFTA agreement. Although between 1994 and 2004 GDP only increased by 30%, exports and imports tripled, while foreign investment grew rapidly. This brought an economic and a social restructuring marked by the emergence of new industries and the decline of others.

Facilitated by a stricter intellectual property regime and by the Mexican adherence to the Patent Cooperation Treaty (PCT),[10] the entry of foreign investment generated an increase of foreign patent applications, particularly in the automotive, electro-electronic, machine tool, chemical, pharmaceutical, and agro industrial sectors. This speed-up in foreign patent applications crowded out local innovators, especially where the industrial restructuring was most intense. This can be explained because foreign patents give rise to monopolistic rights and increased the costs and risks of litigation for local innovators (Jones, 1995; Kortum, 1993; Reinganum, 1983).

The Mexican Government did not respond with a strong Science and Technology Strategy. Between 1994 and 2004 Mexican R&D only rose from 0.2 to 0.4% of GDP and private participation did not exceed 30% of total spending under this heading, far from the average of the developed countries. Also, the increase in R&D spending was concentrated in universities and scientific–technological research centers, which explains the 160% increase in scientific articles.

This situation can change, but it will not be easy. Mexican scientists and technologists can use the growing number of registered patents to develop incremental innovations (Romer, 1990; Aghion and Howitt, 1992), but this can be insufficient to compensate for litigation costs and for the sunk costs of generating new knowledge as a technological opportunity (Evenson, 1993; Evenson and Kislev, 1976; Kortum, 1996; Segerstrom, 1998). Moreover, the innovative dynamism of various Mexican industries does not usually require competitive strategies based on patents, but on the alternatives above described.

5.2.1.3 Importance of Research and Development

The evidence indicates that there is a clear association between R&D spending and patenting rate, as illustrated in Chart 5.2 which considers a sample of 44 countries for the period 2000–2004. A Cobb–Douglas function is used, $P = I\&D^{\beta}\alpha.$, in which P is applications for patents, $I\&D$ the spending on R&D in constant US dollars of 2000, and β is the elasticity which links both. The regression yields a correlation coefficient of 0.92, which is statistically sound. β patents–R&D elasticity is 0.93. A similar correlation was observed when the dependent variables are patent applications in the United States Patent and Trademark Office (USPTO).

Even when the correlation between spending on R&D and patents has been widely documented, controversial aspects persist. Trajtenberg (2002) and Griliches (1990) find that although patents are clearly proportional to R&D in cross-section studies, in a more dynamic perspective, decreasing returns appear. In a dynamic

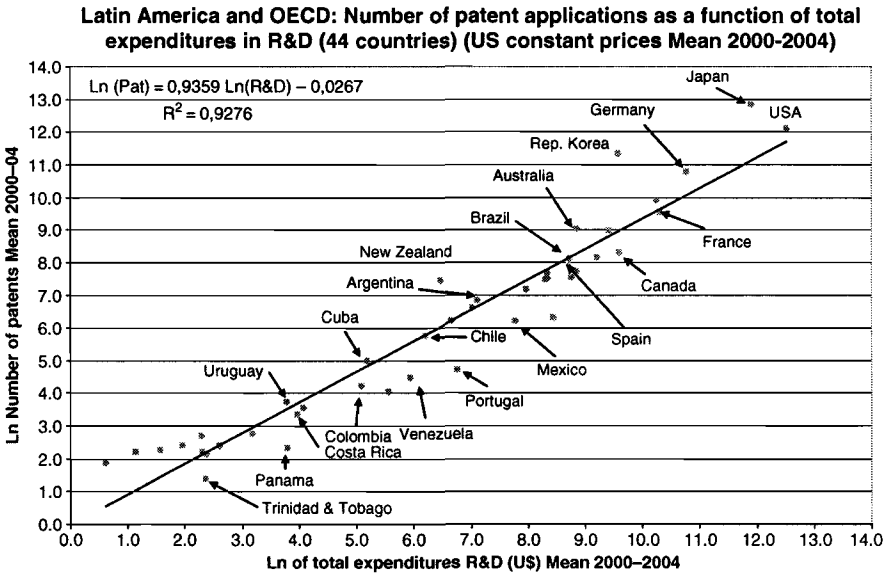

Chart 5.2 Latin America and OECD: Number of patent applications in relation to spending on R&D (44 countries) (Dollars at constant prices, average 2000–2004). Source: Díaz (2007).

panel study, Bosch and others (2005) find a high correlation between both variables. For developed countries there is a unitary elasticity consistent with the hypothesis of constant but not increasing returns, *whereas in developing countries they find low elasticity, which is consistent with decreasing returns and at the same time with significantly lower patent return rates than the developed countries.* The authors explain these differences in elasticity by institutional factors (education, property rights, and quality of innovation systems).

The experience of developed countries and the most recent of India, China, and Brazil indicate that the expansion of private and public R&D *precedes* the strengthening of IPRs. For almost a century, the United States had a "weak" intellectual property regime which facilitated the absorption of foreign technological knowledge without paying for the corresponding licenses. As United States innovation and investments abroad sped up, so did the tendency toward the strengthening of intellectual property rights.

The Latin American export economies are mostly based on learning systems that rely in knowledge and technology import and dissemination. The "weakness" of industrial property regimes in Latin America facilitated imitation, adaptation, and integration of technologies. In this context, do these countries require a significant strengthening of the patents system? The answer is no, for stronger IP rights will not encourage per se an increase in national R&D efforts and national patents applications. On the contrary, it could hinder technological development by increasing the cost of imitative, adaptive, and incremental innovation.

Therefore, Latin American countries need to develop efficient private–public collaboration for promoting and disseminating new knowledge and state-of-the-art technologies. This is the key for spurring new waves of innovation. The increase of IPR must be balanced with the strengthening of national science, technology, and innovation capacities. In this context, the most coherent path is to take advantage of the flexibilities stipulated by TRIPS and the trade agreements, in order to design appropriate regulations and policies.

Only a long-term effort that efficiently increases public spending or subsidies in science, and technology research in universities, public institutions, and private firms may positively impact local innovation. This is not an easy task and there are many policy challenges, but we should not create unreasonable expectations: although innovation should there be no immediate increase in patent applications or private participation in R&D, except when a big Hi-Tec firm decides to invest in a small country like Costa Rica. For countries like Chile, Peru, and Colombia, the Mexican experience shows that the FTA's can generate crowding-out effects that can de-incentivize local patent applications. Also firms conduct R&D for learning and adaptive innovation or invest in fields where patents are not the right instrument of protection, so they will rarely produces patentable products. And although it is possible that universities and science and technology laboratories emerge as sources of intellectual property titles, it is best not to create illusions in relation to patents. The United States experience indicates that few universities have enough critical mass to obtain a significant output in patents.

5.2.2 Copyright in the Digital Economy[11]

The FTA's will also have a strong impact on the emerging digital economies of the region. If the provisions are fully applied, the conditions of dissemination of computers and Internet will change, because middle- and low-income access to software and other digital goods has been achieved through piracy (with commercial purposes) and illegitimate copies distribution (without commercial purposes). In theory, low-income users will be affected by the higher costs of access to software and digital contents protected by intellectual property or by electronic encryption, although this should not prevent them from having continued access to open code software and free contents.

Latin American and Caribbean countries should be very careful in the copyright provisions implementation. An excessive strengthening of digital property rights without the enforcement of exceptions and limitations to copyright set forth in international treaties such as the Berne Convention will not only restrain the dissemination of ICTs but also encourage digital piracy and promote the illegal economy.

Despite the socioeconomic importance of software and digital contents, Latin American and the Caribbean countries paid less attention to the copyright sections of the FTA's than those of patents and medicines. Three factors influenced this behavior. First, governments had little knowledge of the digital economy complexities.

Second, the software and digital-contents industry was small and had little capability in putting forward its own strategic interests. And third, the United States software and multimedia industries have an important influence in the region. The result was an asymmetric behavior: a great deal of concern in issues such as drugs and patents, but fairly little preoccupation for access to software and digital contents which have an increasing influence in the region.

5.2.2.1 The Dissemination of ICTs in Latin America and the Caribbean

The development of the Latin American and Caribbean countries has been increasingly influenced by the digital revolution in the last 10 years. To 2005, the Economic Commission for Latin America and the Caribbean (ECLAC) estimated that in the ten LAC countries that signed FTA's with the United States there were almost 19 million fixed phone lines, 52 million mobile telephones, 33 million computers, and 20 million Internet users. The growth rate of fixed lines was low during the period 2000–2005 but notable in the other categories, especially in Internet. Chile heads the tendency of broadband penetration, followed by Costa Rica and Colombia (Table 5.2).

Despite their lag with respect to the developed countries and the persistence of access gaps, a growing number of Latin American firms, consumers, and public institutions are using ICTs more and more. The development of the telecommunications infrastructure and the dissemination of computers have been accompanied by a mass expansion of software, music, videos, and digitalized contents through Internet. For most of the 1990s, the dissemination of digital contents mainly took place via CD and DVD. In the last 5 years, it has been increasingly by Internet.

Although the countries that have signed trade agreements with the United States are not characterized – with the exception of Costa Rica – as exporters of ICT goods and services, they have developed important telecommunications and information technologies services sectors. Furthermore, all the countries register the expansion of a sector that offers wide and growing diversity of contents and services via Internet.

However, the ten LAC countries appear to be entering a difficult stage in the continuing expansion of digital access. The urban high-income markets are beginning to reach their saturation point and the challenge now is to reach low-income urban and rural social population with higher infrastructure costs and less purchasing power. This will translate into a slower expansion until new wireless technologies are more competitive and competition invigorates the natural inertia of incumbent firms. In this context, public policies can facilitate and act as a catalyst in the process.

5.2.2.2 The Obsolescence of the Old Copyright Regime

Digital products and networks are proliferating in Latin America and the Caribbean. This produces a progressive obsolesce of the 19th century legal regime of copyright protection adapted for printed matter. As it is known, all digital contents can be copied, stored, reproduced, and distributed through the Internet any number of

Table 5.2 ICT expansion in Latin America, 2000–2005

Countries	Fixed telephones			Mobile telephones			Computers			Internet users		
	2000	2005	Var. (%)	2000	2005	Var. (%)	2000	2005	Var. (%)	2000	2005	Var. (%)
Costa Rica	899	1,389	55	212	1,101	419	600	950	58	228	1,111	387
El Salvador	625	972	56	744	2,412	224	120	401	234	70	628	797
Guatemala	677	1,132	67	857	3,168	270	130	267	105	80	1,039	1,199
Honduras	299	494	65	155	1,282	727	70	121	73	55	242	340
Nicaragua	164	221	35	90	1,119	1143	120	231	93	50	826	1,552
Dominican Republic	894	895	0	705	3,623	414	198	728	268	327	985	201
Panama	429	440	3	410	1,352	230	105	1,352	1188	90	487	441
Peru	1,717	2,251	31	1,274	5,583	338	1,050	4,113	292	800	3,638	355
Colombia	7,193	7,767	8	2,257	21,850	868	2,257	21,850	868	878	6,004	584
Chile	3,303	3,436	4	3,402	10,570	211	1,420	3,000	111	2,537	4,623	82
Subtotal	16,200	18,997	17	10,106	52,060	415	6,070	33,013	444	5,115	19,583	283
Latin America and the Caribbean	65,549	96,864	48	62,385	236,916	280	24,523	56,165	129	19,673	80,072	307
Share of Latin America and the Caribbean (%)	25	20	−21	16	22	36	25	59	137	26	24	−6

Source: ITU and ECLAC estimates.

times, all with identical quality. This poses a basic economic problem: while the creation and production of an original work require considerable investments, the marginal cost of reproduction is almost 0. This is why it is conventionally stated that with no technological protection measures (i.e., encrypting) and/or enforcement of copyright, the social benefit of an original work would be greater than the private benefit and there would be no incentives to creators and inventors.

For the United States Government, Latin America and the Caribbean are subcontinents where digital piracy predominates. For several years, the Business Software Alliance (BSA) publishes annual statistical reports on software "piracy," which are used by the United States Trade Representative (USTR) to ground its complaints. According to a BSA report for 2007, 65% of computers in Latin America had "pirate" software, equivalent to 4.123 billion dollars losses, less than half the United States figures. But the BSA report has some important flaws such as not considering the difference between a software copy for personal use – which can be legitimate – and piracy as such.[12] Other similar reports from associations representing the music industry or the audiovisual industry have equally unclear methodologies and sources, which creates considerable doubts about their objectivity.[13] However, although the economic and social magnitude of the piracy and illegitimate distribution phenomenon can be discussed, there is no doubt that its importance grew significantly in the last decade and this implies that changes have to be made in the national copyright regimes which were born in the 19th century.

5.2.2.3 The Debate on the New Copyright Regime

Free trade agreements strengthen the protection of copyright like never before. They expand the protected subject matter to ephemeral copies and interactive digital radio broadcast, increase the duration of protection from 50 to 70 years, increase the scope of technological protection of digital contents, and strengthen their enforcement by means of judicial and administrative proceedings.

The principal question that LAC countries face is how to apply the TRIPS and Berne copyright exceptions and limitations provisions that are accepted by the free trade agreements. The Bush Administration answer for reducing exceptions and limitations seems very simple: digital technologies and Internet facilitate illegal reproduction, making it increasingly difficult to delimit the above-mentioned limits and exceptions. The answer to this difficulty in access and content control should be to limit the right to obtain digital copies of the works for private, non-commercial purposes, and restrict non-commercial reproduction of works by educational establishments, research centers, and libraries, since there is a risk of deviation toward illegitimate copies.

LAC countries must consider international experience in this field. If copyright regulation changes are applied without considering the TRIPS and Berne multilateral international treaties, there could be a negative alteration of the carefully crafted balances shaped during the 20th century. In particular, they could restrict the rules of the game which made it possible to expand the digital economy over the past 20 years.

In this context, LAC countries should carefully craft the exceptions to copyright, such as the "fair use" right to copy for personal purposes or the reproduction of material for educational and scientific–technological research purposes, all established in the Berne Convention and in the 1996 agreements of the World Intellectual Property Organization (WIPO). Particular attention should be brought on the limits and exceptions of copyright of *temporary copies* (temporary electronic storage) and the legal scope and exceptions of the so-called Effective Technological Protection Measures (TPMs) used to prevent, through encrypting or devices, unauthorized access to software and contents.[14]

Although the free trade agreements allow flexible application, LAC governments face a strong external and internal pressure to considerably increase protection of copyright. This could lead to a rigid implementation of the obligations incurred, restricting the exceptions and limitations to copyright, facilitating indiscriminate application of TPMs, could in practice annul the provisions of the Berne Convention, the TRIPS Agreement, and WIPO. This could make piracy difficult, but at the same time it could increase the social costs of access to information and knowledge, limit competition, and hinder innovation and creation.

5.2.2.4 The Consequences on the Digital Gap

There are two views on the possible impacts of an increase of intellectual property in the digital world in LAC countries. One is that experience shows that it is very difficult to achieve full efficiency in copyright enforcement and that the TPMs have not curbed the proliferation of illegal copies. This means business as usual: enforcement will be possible for high-income groups and formal firms market, but piracy and illegal dissemination of software and contents will continue to predominate in low-income groups and the small informal business. The battleground will be the middle class and the formal small firms.

Another view is that the combination of increased IP enforcement and greater efficiency of technological protection measures will reduce piracy and increase the appropriation capacity of software and content producing companies by means of compulsory payment for authorized copies. This process will take time but in the end it could reduce the extension of illegal markets and unauthorized copy distribution. However, it will exclude small business and medium- and low-income sectors access, which can be partially compensated by strategies of market discrimination, where versions of lower quality of software can be freely accessed or sold at a lower price. At the same time, the reduction in piracy will create better conditions for the development of markets for free and open source software (FOSS), which offers popular platforms and programs such as Linux and Open Office. Nevertheless, the network economies involved will only make this alternative possible insofar as public sectors and educational establishments adopt strategies of growing use of FOSS-type software.

In this scenario, the case of digital contents is different because it is very difficult to discriminate markets by means of reduced versions of an original work, thus running the risk of large segments of the population not having access to knowledge and the cultural heritage of humanity. Hence, to ensure mass access to knowledge

and information proactive public policies will be required – for example, digitalization of contents and dissemination by public libraries- which can be complemented by voluntary options such as creative commons.

This scenario can also generate an enrichment of competitive strategies for software and proprietary contents. It is known that software firms distribute free copies and then sell originals of higher quality or with more functions. Other firms have established a relationship of alliance and competition with free and open source software companies (Lerner and Tirole, 2005), because they can offer complementary services and goods in proprietary market segments. Proprietary contents firms, for their part, also resort to the distribution of free copies as part of their business strategy (Varian, 2005). They can distribute free copies of some songs with the aim that consumers buy the whole CD or to assure attendance at concerts and sales of T-shirts or other similar goods. These trends are becoming generalized and are bringing about deep-seated changes in the contents industries that are beginning to be assimilated in LAC countries. But business innovation is always accompanied with some form of uncompetitive behavior, which demands a greater role for competition policies. LAC countries need to accelerate institutional learning in this field.

In any case, a careful and balanced legislation is necessary and should be complemented with an explicit public policy agenda oriented toward social access to digital contents. This is one of the challenges of the information and knowledge society.

5.2.2.5 The Consequences on Innovation and Creation

Current thinking is that the strengthening of intellectual property rights will encourage creation, thus fostering the development of cultural industries. But creativity is not only determined by private control of contents, but also determined by a set of factors such as the capacity of each author to become inspired by using, reusing, mixing, combining, and even copying contents that are already in the cultural and scientific heritage of humanity. Creation produces new knowledge but it also requires inputs of pre-existing knowledge. This is why intellectual property ensures appropriability to encourage creation but it also considers regulations that assure social dissemination. Excess protection of intellectual property rights can restrict mass access to a nation's cultural heritage and thus discourage creation and innovation.

LAC governments must consider that it is not proven that more intellectual property protection necessarily translates into more creation and innovation. In a critique of the Digital Millennium Copyright Act of the United States, a group of economists calculated that at a discount rate of 7%, an increase from 50 to 70 years in copyright protection has trivial effects and its yield will not be higher than 0.33% of the present value of the first 50 years of protection. It has also been discussed whether such broad protection terms make any sense without paying renewal rates for rights. In fact, only a small proportion of works has a significant market for such long periods (70 years after the author's death). In the United States, between 1883 and 1964, when renewal was compulsory, only 11% of works had an application for renewal of

the 28-year period. Landes and Posner (2003) note that of more than 10,000 books published in 1930, less than 200 were being printed in 2001.

Excess protection of intellectual property can bring about a contrary effect to the one pursued. Without laws that restore the balance between protection of intellectual property rights and free access to knowledge and culture, creators and innovators could live in a jungle of restrictions and litigation threats that could curb the development of cultural industries.

5.2.2.6 New Roles for the Public Sector

Free trade agreements contain a set of obligations aimed at strengthening intellectual property rights in the digital world. In their implementation, governments should take care to preserve the flexibilities permitted by the multilateral agreements of Berne and WIPO, with the aim of not overprotecting intellectual property rights, since this could have negative effects on social access and innovation. At the same time, this brings about the need to move forward toward a new generation of public policies aimed at providing high-quality education, promoting universal access to knowledge, and fostering innovation and creation.

It should be stressed that the expansion of the digital economy in Latin America and the Caribbean opens up singular opportunities for production and distribution of digital public goods on a mass scale. On the one hand, there is an important development of the so-called *electronic government*, that is, the growing use of digital technology by government agencies to capture, process, produce, and distribute information and public, free knowledge through Internet. On the other hand, a similar process is occurring in universities, research centers, non-governmental organizations, and international organizations, which are rapidly expanding the supply of public, free contents through Internet. At the same time, new digital industries have emerged – providers of Internet access and search engines – where the business is built on the basis of access to information on a mass scale. In this context, public policies should promote their development, applying criteria and intellectual property legislation in a coherent manner.

All of this expands the public domain and makes room for innovation in public policies, which come to light in projects such as the digitalization of the cultural heritage, the placement of growing volumes of public information on the Internet, and the expansion of information in public libraries. As these processes become generalized and the private sector develops similar initiatives, the increase in intellectual property protection will be harmonized with the objectives of digital inclusion and the promotion of innovation and creation.

5.3 Challenges of Implementation and Economic Policy

The accumulated experience in the LAC countries with free trade agreements with the United States show that the main challenges comes with the legislative and regulatory implementation. The experience indicates that the process is neither easy nor straightforward, because the FTA are incomplete contracts with many silences

and ambiguities The implementation process is a struggle among local interests which was augmented by the Bush Administration decision to fully influence the configuration of laws and regulations in each of the region's 10 signatory countries.

The agreements can be divided into three stages: negotiation, short-term application, and medium-term implementation. The process will be exhausted formally in 2010–2012 when all stipulated obligations are to be fulfilled, but it could go beyond that.

The negotiation stage ends with the signing of the agreement by governments. The short-term application stage begins with parliamentary ratification of the agreement and culminates with its entry into effect. The medium-term implementation stage includes the ratification of international agreements and the parliament approval of more complex rules and regulations that implement FTA obligations (see Fig. 5.1).

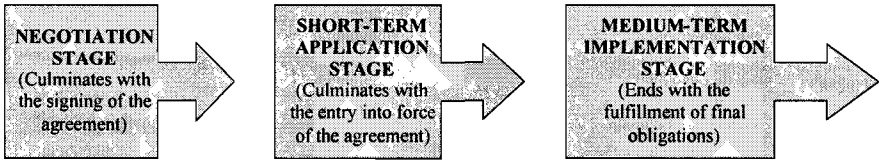

Fig. 5.1 Agreements' stages
Source: Prepared by the author.

Each stage is marked by an intense political economy which comes to light with the crafting of new laws and regulations that implement the free trade agreements and that also expresses itself with the development of public policies such as health and competition policies, which can limit or expand the scope of the FTA intellectual property provisions.

Intellectual property is a complex combination of international agreements, laws, and regulations that affects patents, copyright, and other categories. So, there is not one but various political economies which determine different implementation paths. For example, in patents for pharmaceutical products there is a well-defined polarization: on the one hand, health ministries, generic industries, and non-governmental organizations; and on the other hand, the brand name pharmaceutical industry and the United States government. In copyright the interests of national and foreign industries tend to coincide in increasing enforcement, whereas education ministries, libraries and Internet Services Providers (ISP) emphasize the need for access to information and knowledge.

The ambiguities and silences of free trade agreements are the object of sharp controversy in *short-term* implementation. The United States Government has instruments of pressure such as delaying the entry into effect of the agreement to ensure that its *immediate* implementation is in accordance with its interests. This was harshly manifested in the cases of Guatemala, Honduras, El Salvador, and Nicaragua.[15] The same did not occur with Chile, partly because as a non-permanent member of the United Nations Security Council it opposed the intervention in Iraq and the Bush Administration faced high political costs if it held back on the free

trade agreement as a form of retaliation. Nevertheless, between 2003 and 2008 Chile was subject of an increase pressure by the Bush Administration and was placed on the "Special Watch List" of USTR's Special 301 Report (2006), 16 years after having kept Chile on the "Watch List."

In this context, LAC countries that signed trade agreements with the United States face a triple challenge. First, develop a new set of intellectual property laws and regulations that maintain a balance between incentives to innovation and access to knowledge and the protection of human health. Second, develop a *complementary agenda* or a set of public policies and legislation in innovation, education, competition, and consumer rights. And, last but not least, building an institutional framework that facilitates *Coordination within government. This is crucial.* Intellectual property cannot be an exclusive matter for the agencies in charge of its protection. It is also a matter of concern for other government agencies in charge of health, innovation, and science and technology. Equally important is developing an institutional framework that facilitates expression of the interests of intellectual property holders and of the consumers and users of goods and services protected by intellectual property.

A new positive agenda for the next decade should be considered that should at least include the following recommendations.

5.3.1 A National Commission on Intellectual Property

In view of the complexity of the subject matters involved, it is essential for countries to devise strategies that integrate intellectual property into policies for innovation, competition, health, and access to knowledge and information. It is therefore recommendable, to set up a national commissions on intellectual property with representatives of the sectors involved, including international experts. This commission should issue recommendations based on the commitments of the trade agreements, the stipulations of TRIPS and WIPO, and on considerations related to policies for innovation and productive development, education, health, competition, and consumer rights.

The more open and informed the debate on legislation for implementation and the impetus of the complementary agenda, the greater the opportunities to establish a balanced legislation. The recommendations of these commissions will not substitute the decisions of national congresses, but will help build consensuses on the most desirable legislation for implementation. If several countries set up similar commissions, the possibilities for cooperation will grow considerably.

5.3.2 Link the Innovation Policy to Intellectual Property

The strengthening of the intellectual property regime should be accompanied by a leap forward in science, technology, and innovation policies. This is essential to advance toward economies whose competitiveness is increasingly based on knowledge and innovation. World experience indicates that the protection

of intellectual property is not a sufficient incentive to promote innovation, and overprotection discourages it.

5.3.2.1 Recommendations on Patent Regulation

Patents can encourage innovation, provided that its application is adequately delimited. Trade agreements are ambiguous on the matter. On the one hand, they state that they accept TRIPS, which establishes exceptions to intellectual property rights, but on the other hand they impose some shortcuts and they establish that governments should make efforts to patent plants, but do not compel them.

First recommendation: governments should not accept patents for software, plants and animals, business methods, and second use. In such cases, patents are not the most appropriate instrument for promoting innovation because they can hinder the protection of intellectual property of subsequent innovators or small and medium firms that make incremental innovations.

This does not imply leaving invention and creation unprotected. Software, for instance, is already protected by industrial secret and copyright. Plants have UPOV protection and it is reasonable to permit patents of isolated DNA sequences with industrial application,[16] although not complete genomes, which accounts for the cases of transgenic plants.[17] On the other hand, second use patents favor the foreign pharmaceutical industry but nothing prevents countries from invoking the TRIPS clause that allows rejecting them, which could be reinforced by the exclusion of patentability of surgical methods.[18]

Second recommendation: although the free trade agreements uphold the TRIPS criterion of a 20-year term of a patent from the time of application, the countries can carefully regulate aspects not considered in bilateral and multilateral agreements, but which have as much economic importance as the duration of protection. Indeed, the definition of the requirements of novelty and the scope of a patent constitute a relatively unexplored dimension of regulations on industrial property.

Furthermore, experience shows that regulations on intellectual property rights based on technological and industrial policy can be established. In fact, if the purpose were to foster original and radical innovations, the regulations should increase novelty requirements and broaden scope claims, although this will expand the monopolistic power of the first innovators and discourage subsequent innovations of third parties. This will favor patenting by foreign firms but will discourage that of national entities.

In this context, what would be the most appropriate system for developing countries with low R&D spending and low patentability rate? Although at first it could seem more adequate, a system that favors patents with greater scope and less novelty requirements could end up discouraging imitative innovation because it would increase litigations risks postponing the entry of imitators into the market (Gallini, 2002). This could discourage R&D efforts, especially in small and medium firms.

One solution could be to rigorously delimit a patent's claim scope sphere, in such a way that it favors the development of subsequent innovations that adapt technologies to a product or process other than that originally patented. At the same

time, they can establish more or less demanding novelty requirements that could be specific according to major areas of technique.[19] For example, in patent applications associated with life sciences additional conditions can be required to prove that it is not a question of a discovery. In the chemical and pharmaceutical areas second use patents can be rejected, since neither the free trade agreements nor the TRIPS Agreement have obligations in this regard. In any event, a balanced approach is required with regard to novelty and scope in order to maintain incentives for patenting of national innovations.

Third recommendation: the countries that recently signed a trade agreement with the United States should pay special attention to the application of intellectual property in life sciences and natural resources. All of them have abundant and diverse natural resources and genetic patrimony. It is in this area that the largest and most competitive companies tend to concentrate, as well as most of the scientific and technological personnel of universities, where full importance is placed on the exclusion from patentability of plants and animals, the establishment of rigorous novelty requirements, the delimiting of patent claim spheres, the promotion of the use of protection of plant varieties – considering exceptions for plant breeders and small agricultural production – as well as the promotion of geographical indications.

5.3.2.2 Promotion of the Use of Patents

Technological innovation policies should remove unnecessary obstacles to protect results of R&D. This implies four recommendations.

i) *Use intellectual property to strengthen the results of R&D+I financed with public funds.* Every R&D public financing scheme should promote the use of intellectual property rights, particularly in R&D projects oriented toward innovation developed by companies and/or universities. In this context, intellectual property does not run counter to the objectives of dissemination and transfer of technology, since public technological centers and universities can use a broad, flexible system of licenses that allows dissemination of the new technologies on a mass scale without the risk of undue appropriation by third parties. In innovation projects whose results are subject to private appropriation, the use of patents or other forms of intellectual protection should also be promoted. This will favor subsequent innovations carried out by the private sector.

ii) *Incorporate applications and registers for patents and other forms of intellectual property as an additional criterion for academic evaluation in universities and technological centers.*There is already a certain amount of accumulated experience to incorporate this system of incentives into existing ones. This, however, requires careful criteria which, for example, draw a distinction between patent applications and registers.

iii) *Further a massive and rapid process of training of scientific personnel in innovation management and intellectual property.* In the 10 countries that have signed agreements with the United States there are more than 175,000 researchers and tens of thousands of innovating entrepreneurs who require rapid

training in use of intellectual property in business, particularly in processes, utility models, industrial design, circuit layout, and plant varieties. The scarce culture and experience in this field points up public innovation policy.

iv) *Promote technological transfer entities specializing in intellectual property linked to universities and technological scientific centers.* These entities should put together multidisciplinary teams to identify business opportunities derived from research programs of universities and technological scientific centers. Experience indicates that there is a need to attain scale and scope to diversify the risk, but there should also be a policy that assures long-term sustainability based on results. This policy should consider regional and international best practices.

5.3.3 Copyright and Digital Economy

The countries with trade agreements with the United States should use the exceptions and limitations to copyright and adequately regulate legal protection of technological protection measures (TPMs), so that it is consistent with consumer rights and with the facilities for innovation and creation.

5.3.3.1 Treatment of Exceptions and Limitations

The countries can use the flexibilities in exceptions and limitations stipulated in the Berne Convention and ratified by the TRIPS Agreement. Applying these criteria can balance access to knowledge and culture with the interests of intellectual property rights holders.[20]

Exceptions and limitations apply to official texts, personal use, use of works for purposes of science, technology, and education, reproduction in libraries and archives for storage and replacement, unorganized facts and data, quotes, daily news and press information, political and legal speeches, works for radio broadcasting, ephemeral recordings, reproduction and adaptation of computer source codes for purposes of interoperability and control of monopolistic abuse.

In the ratification of Articles 1-21 of the Berne Convention, the signatories issued Agreed Statement concerning Article 1(4) of the WIPO Copyright Treaty (WCT, 1996) which states "The reproduction right, as set out in Article 9 of the Berne Convention, and the exceptions permitted there under, fully apply in the digital environment, in particular to the use of works in digital form. It is understood that the storage of a protected work in digital form in an electronic medium constitutes a reproduction within the meaning of Article 9 of the Berne Convention."

In this context, it is worth considering the following recommendations on limitations and exceptions on copyright in the digital environment.

First, *ensure the right to a copy for personal use*, which includes the family and, in some national legislations, the circle of close friends. This is a limitation accepted by all the developed countries, which should be kept adequately delimiting its application.[21]

Second, *maintain reproduction rights for educational purposes*, an exception provided for in Article 10(2) of the Berne Convention, which includes distance education related to execution and reproduction rights and distribution to the public.

Third, *the press should maintain reproduction rights for articles on political, religious, and scientific topics.*This includes maintaining the right to quote, guaranteeing freedom of expression, criticism, and information.

Fourth, *maintain the exception on ephemeral recordings.* This would enable radio broadcasting companies to conserve the content in official archives, which is current practice in contracts with rights management companies.

Fifth, *maintain and reinforce the role of libraries.* Libraries should be important subjects of the exceptions and limitations due to their purpose of collecting, preserving, and disseminating knowledge, a basic function of educational institutions. It will be necessary to eliminate ambiguities in many legislations by discouraging the presence of mass photocopying centers and reinforcing the work of reproduction for libraries' legitimate uses, among them ensuring reproduction for purposes of storage and replacement.

Sixth, *ensure access for disabled people.*

Seventh, *allow copies of software to ensure interoperability.* In the process of ensuring interoperability between software programs, copies can be obtained in order to modify these programs. This is a basic condition for promoting competition and encouraging efficiency and the development of innovative companies.

5.3.3.2 Appropriate Treatment of Technological Protection Measures (TPMs)

It will be necessary to achieve a balance between enforcement of effective technological protection measures (TPMs) and respect for consumer rights and the need to grant facilities to innovation and creation (Villaroel, 2005). TPMs are necessary to protect intellectual property rights in the digital era, but by transferring access regulation to works protected from the public domain to the private (Okediji and Prosser, 2005), copyright exceptions and limitations provided for in the Berne Convention and the TRIPS Agreement and that were not modified by recent free trade agreements could be reduced (Okediji and Prosser, 2005). To preserve the original purpose of TPMs, avoid monopolistic abuses and ensure consumer rights, the following initiatives should be considered.

First, establish the compulsory requirement of information on TPMs, a condition so that the user and the consumer identify the TPM of the case and know where and how to recur in order to obtain authorization to do without it with legitimate ends.

*Second, assure the obligation of providing interested parties with means to legally elude TPMs.*Consumers and users should have the necessary information and means to benefit from the exception when merited. It should be provided that failure to comply with this obligation will be the object of legal complaint by means of class-action suits and that this will give rise to indemnity obligations.

Third, prohibit the application of TPMs for certain categories of users. It is necessary to establish express prohibitions of TPMs that control access or copy for libraries, educational institutions, researchers, and the disabled.

And fourth, competition policy should consider the risk of monopolistic abuse of TPMs. It should be sanctioned under the competition laws and the corresponding authorities should be endowed with the means to apply sanctions against those who use TPMs for purposes other than those provided for.

5.3.4 Competition Policy and Consumer Rights

In most of the Latin American countries, particularly those that have signed trade agreements with the United States, there is a notable asymmetry between intellectual property legislation and the lag of institutions for the defense of competition, especially the areas related to intellectual property. This demands an effort to create a new institutional framework with appropriate laws and the capacity to implement them. The following measures could be taken in this regard:

First, legislate and ensure budget resources to set up strong, autonomous, and modern antimonopoly Commissions. This also involves creating economic inspector's offices with ample technical capacity, legal force, endowed with broad investigation powers, as well as their own budget and independence of action. It is necessary to ensure that the inspector's offices and commissions rapidly develop capacities to investigate, analyze, and take decisions in cases in which there is monopolistic abuse through the use of intellectual property rights.

Second, promote regional cooperation to foster quick learning in competition policy and its relations with intellectual property. All the countries are promoting laws or reviewing their competition legislation. The TRIPS Agreement and trade agreements establish criteria to assure national treatment, transparency, due process, but they do not specify guidelines on situations in which monopolistic abuse exists based on the use of an intellectual property right. To that end, the countries have considerable freedom to establish an institutional framework that responds to their needs according to the best world practices and joint regional learning.

Third, promote open and democratic debate on competition policy and intellectual property to identify guidelines and best practices for control of monopolistic abuses in cases where there are intellectual property rights. The document of the Federal Trade Commission and the Department of Justice of the United States, as well as the resolutions of the Competition Commission of the European Union are important precedents. Likewise, Canada, Australia, and Japan have shown similar efforts. "Guide" documents on antimonopoly legislation and intellectual property rights can be prepared by means of regional cooperation and the assistance of multilateral technical agencies.

And fourth, strengthen and train consumer associations, particularly those related to intellectual property-intensive goods and services. This will probably require that national laws adopt figures such as class-action suits.

5.3.5 Patents and Medicines

The free trade agreements with the United States contain provisions that broaden protection for medicines and agrochemical products protected by patents or undisclosed information, but here too there is room for a flexible implementation aimed at reducing the terms of entry of generic medicines into the market. In this regard, some countries have greater freedom of action than others, but the Democrat-Republican agreement of May 2007 contains provisions that should make the traditional position of the USTR more flexible.

5.3.5.1 Strengthening the System of Compulsory Licenses and Parallel Imports

Compulsory licenses and parallel imports were not the subject matter of the 10 trade agreements with the United States but they are stipulated by the TRIPS agreement.[22] Thus, the Central American countries and those of the Andean Community do not need to modify their law to authorize them.[23] Chile had the possibility of strengthening its system and did so. Its 1991 legislation only permitted compulsory licenses against monopolistic conducts. Its new law broadens the grounds to reasons of public health, national security or national emergency, non-commercial public use, as well as exploitation of later patents that could not be exploited without infringement of an earlier patent.

Since 1994 only one Latin American country has used the compulsory license. We refer to Brazil in April 2007, when it applied this mechanism for the medicine Efavirenz made by Merck Sharp & Dohme, used for treatment against HIV–AIDS. This measure will make it possible to manufacture or purchase generic versions of the medicine at low cost, establishing the payment of a moderate royalty to the American company. Although it is a rarely used mechanism, there is evidence that the mere threat of using it brings about the desired results. To that end, the presence of strong health institutions and transparent and flexible administrative procedures are essential in order to avoid judicial proceedings that would hinder its use. However, for the countries without the capacity to produce medicines, compulsory licenses are not sufficient to ensure enough imports, for they can be the object of restrictions established in TRIPS, which has given rise to intense discussions in the Doha Round.

Nor do the trade agreements consider parallel imports, so the TRIPS provisions continue to be valid, although problematical. In cases in which a country without productive capacity issues a compulsory license for monopolistic conduct, TRIPS

(Article 31.31.k) establishes that the latter can import from third countries. When a country without productive capacity issues an obligatory license for reasons of national emergency or public security, it could import the medicines from a third country with productive capacity, but TRIPS (Article 31.31.f) imposes restrictions for that country. This can be overcome by means of laws or regulations that explicitly permit exporting to countries that have legally established a compulsory license, as well as by agreements that combine compulsory licenses for patents and parallel imports.[24]

5.3.5.2 Adaptation of Administrative Procedures in Pharmaceutical Patents

The administrative procedures for granting or rejecting pharmaceutical patents are a central component of regulations on industrial property. The following recommendations are made in this regard:

First, conserve or implement formal objections, allowing third parties to challenge the degree of inventiveness, novelty, or industrial application of patent applications. This would facilitate the work of industrial property offices that face problems of asymmetry of information due to budget shortages.

Second, regulate compensation of patent duration due exclusively to administrative delays. The trade agreements with the United States provide for compensating pharmaceutical patent terms when their processing exceeds 5 years not counting the applicant's delays. This seems reasonable, provided there is an application from the holder[25] that is only valid for pharmaceutical patents for human use and that the time consumed by objections from third parties is not counted as administrative delay. Since no yardstick was established to count the compensation time, maximum compensation terms could be established similar to the provisions of the Hatch-Waxman Act in the United States.

Third, define clear compensation procedures due to administrative delays in sanitary permits. In the trade agreements this provision is only in force for pharmaceutical products and therefore agrochemicals, foods, and medical devices can be excluded. Nor are strict deadlines established, which grants flexibility of implementation to each country. In this regard, the yardstick of speed of granting of sanitary permits should be subordinated to public health considerations. Therefore extensive terms or powers to expand the established terms are recommendable.

Fourth, specify the legal definitions of "undisclosed information" and "new chemical entity" (NCE). All the countries agreed to protect undisclosed information for 5 years for pharmaceutical products and 10 years for agrochemicals.[26] Although the language of the agreements differ, they contain at least three flexibilities: (i) the concept of NCE should be limited to new active ingredients not registered or marketed; (ii) "undisclosed information" should be limited to clinical or field test data that were the object

of reasonable measures to keep them reserved and that are not known by experts in the area; and (iii) protection should be eliminated in case of granting of a compulsory license or when the product has not been marketed in the national territory in a period of 12 months, an essential condition for the effectiveness of compulsory licenses.

Even though DR-CAFTA, Peru, Colombia, and Panama accepted that the 5 years' protection should be counted as of the time the NCE was registered in their territories and not in countries such as the United States, they could incorporate greater flexibilities into their legislations, such as demanding that the first registration of a drug in the world has a period of no more than 12 months to be registered in their territories.[27] Furthermore, if the agreement between Republicans and Democrats communicated in May 2007 by USTR becomes effective and which establishes that "in certain circumstances" the protection period for test data in developing countries that have signed an free trade agreement with the United States "shall not exceed the period in which that protection is available in the United States," which is coupled with a provision that encourages greater speed in approval of marketing permits. Although the specific proposals that USTR will make have yet to be seen, and this is valid only for Colombia, Panama, and Peru, there is no doubt that in the long run the rest of the countries will be able to incorporate these flexibilities into their national legislations.[28]

Fifth, delimit terms of validity of patent protection with criteria similar to those of the United States,[29] where the effective period of validity of pharmaceutical patents, including possible compensations for delays in approval of the product, cannot be longer that 14 years after approval.

Sixth, sanitary approval requirements should not delay the entry of generic medicines into the market. It should be ensured that these initiate the procedure to obtain sanitary approval, even though they cannot market it because the patented product continues to be protected. This is equivalent to application of the Bolar exemption provided for in US legislation.

5.3.6 Institutional Framework and Intellectual Property

The strengthening of intellectual property requires a process of institutional modernization. It is critical to develop strong and independent antimonopoly commissions with the capacity to act in cases where intellectual property rights are involved. It is necessary to strengthen legislation for consumer protection and foster consumer associations. At the same time, there is a need to improve transparency of procedures in intellectual and industrial property offices, as well as entities in charge of sanitary supervision, establishing regulations to avoid their capture by interest groups. This involves new challenges that did not seem important in the times prior to the free trade agreements, when intellectual property systems had low standards. The free trade agreements and their implementation will establish new regulations, but that

will require modern, vigorous, independent, transparent, and effective institutions. The recommendations are

First, modernize intellectual property agencies which should be autonomous public services with representative directorates. The governments and parliaments face a problem with this type of public entities, since they run the risk of being controlled by corporate interests such as lawyer's offices specializing in the field. It is therefore advisable to establish directorates of experts in economics, law, and engineering, representatives of intellectual property associations, and consumers. It is a question of creating a transparent vigilance mechanism that is regularly informed by the agency's director and technicians.

Second, assure quality management and periodic independent assessments. The procedures and criteria used by industrial and/or intellectual property agencies are not usually codified in regulations or procedure manuals. The dynamics of assessment and granting of patents and other categories of intellectual property are deeply influenced by the idiosyncrasy of institutions that are not very transparent to the public and the government, which favors corruption. This is a chronic problem in developed countries and there is frequently uncertainty with regard to the novelty requirements demanded, the sphere of protection granted, administrative procedures effectively carried out, the rules applied to ensure that applicants for a patent turn over the complete technical information necessary so that someone knowledgeable about the subject can reproduce it, and the subject matter that will remain as a trade secret. All of this needs to be regulated and clarified by means of written rules available to the public, for which purpose an active policy of cooperation with international and regional entities is necessary. Moving forward in these matters will reduce arbitrariness, give greater certainty, and limit corruption (Green and Scotchmer, 1993). At the same time and as has occurred in the United States, there should be periodic assessments by government entities in charge of public innovation policies and by the authorities in charge of competition policies.

Third, full autonomy of health, environmental, and plant health agencies. The entities responsible for approval and regulation of medicines and agrochemicals protect public goods, whereas intellectual property agencies assign property rights in the matter. It is therefore a question of different purposes and functions. In this regard, it is not recommendable to apply the USTR proposal in the sense that sanitary agencies should perform administrative functions of vigilance of intellectual property rights. Even though it may be a question of one same drug, the types of analysis carried out in each of these agencies have completely different technical grounds and purposes. This does not exempt the sanitary agencies from the duty to be fully transparent and communicate the relevant information to the public so that the interested parties exercise their rights. If some owner of a patent considers that his rights have been or could be harmed, he can avail himself of

the courts to institute civil and even penal proceedings, including stopgap measures.

5.4 Conclusions: Toward a New Deal

The recent free trade agreements between Latin American countries and the United States have embarked on a process of transformation of intellectual property regimes, giving rise to public policy challenges that demand to be addressed in a systemic manner in order to create a new balance between incentives for innovation and creation with the social interest of maximizing dissemination of knowledge and benefiting consumers. The free trade agreements have established an agenda for legislation and regulations on intellectual property and this poses the challenge of assuring a flexible implementation that minimizes negative effects and assures the interests of developing countries. At the same time a process of institutional modernization of intellectual property agencies is required. But more important is the promotion of a complementary agenda in the fields of education, health, innovation, competition, and consumer rights.

This raises the need to build a new deal that includes the following public policies:

1) Take measures to lower piracy, understood as reproduction and illegal distribution of copies for commercial purposes, without confusing it with digital copies for personal use, a practice that millions of Latin Americans carry out daily and which should not be prevented, so as not to affect rights established by Conventions such as Berne and WIPO. To that end judicial proceedings should be streamlined and strengthened, at the same time assuring respect for due process.
2) Expand the system of public libraries, the national network of infocenters and the supply of digital public information for citizens, as well as encourage the use of the growing open code platforms, on which China, Japan, India, Germany, and Brazil are betting.
3) Assure health protection and not allow, through exaggerated protection of intellectual property, increased prices of medicines or public action to be hindered in the face of sanitary emergencies and natural disasters. Therefore, the new laws should strengthen systems of compulsory licenses, authorize parallel imports, and establish other rules to avoid overprotection of intellectual property.
4) Strengthen systems of competition and consumer rights, particularly in matters in which intellectual property rights are involved. The complaints against Microsoft in the United States and Europe, in connection with its product Internet Explorer, are a clear indication of where the world is moving toward with regard to prevention of monopolistic abuses. The experience of the developed countries on the matter should be studied and rapidly assimilated.
5) Promote a new generation of public policies in order to advance toward economies that are more intensive in knowledge, innovation, and learning

capacity. This involves increasing available budgets for scientific and technological funds and programs that increase the national effort in R&D and increase technology transfers to small and medium firms, also encouraging mass training of world-class professionals and the development of high-quality learning systems for life.

Laws and regulations express an architecture of private and social interests. This also happens with intellectual property. The agreements contain many provisions, but they constitute "incomplete contracts." Although it is true that the 10 Latin American countries undertook important commitments in signing trade agreements with the United States, it is also true that they keep ample room for maneuver to adapt the intellectual property regime to their own needs, and at the same time they can promote a complementary agenda aimed at strengthening their innovation systems and ensuring a path of growth with equity.

This requires that all the stakeholders participate and express their interests and aspirations. The debate should incorporate the whole range of voices of civil society and companies. The case of Costa Rica is a significant democratic experience, but the referendum of September 2007 was to approve or not the DR-CAFTA already signed by that country's government. The subsequent challenge – which is faced by the other nine countries – is to ensure a democratic and transparent debate on the implementation legislation and the complementary agenda.

In short, the new intellectual property regime should be based on a new deal for the 21st century, which should translate into regulations and the balanced play of stakeholders. Incentives for creators and innovators should be counterbalanced by provisions that assure maximum dissemination of knowledge, protection of human health, sanctions for monopolistic abuse, and a policy that promotes innovation and creation as sources of economic and social development.

Notes

1. The bipartite agreement between Republicans and Democrats also included new labor and environmental clauses and incorporated some flexibilities in pharmaceutical patents and undisclosed information, which until this date are only valid for Peru.
2. The wave of agreements made room for Uruguay and the United States to sign one on investment and services in December 2006, which could be expanded with chapters on public purchases and intellectual property, although its scope would be lesser than the rest. Uruguay is deeply integrated to Brazil and Argentina, and its leeway is less. A recent joint declaration by Presidents Lula and Tabaré Vázquez admits the possibility of a United States–Uruguay agreement, but the latter will remain within MERCOSUR. This could also be Paraguay's course in the future.
3. The impact on the agricultural economy and the pharmaceutical market is extensively covered in book A. Díaz (2008) "América Latina y el Caribe: la propiedad intellectual después de los tratados de libre comercio", Libro de la CEPAL, N° 94, February, Santiago de Chile.
4. El Salvador agreed to maintain plant patents; Nicaragua adopted them in the implementation law and Chile rejected them, but opted for patenting isolated genetic sequences that could be applied industrially.

5. Chile decided not to patent plants or business methods, and its new Intellectual Property Law upholds the criterion that patents must have "industrial application", thereby excluding "stand alone" software patents. Nicaragua and El Salvador, for their part, decided to legally permit plant patents. However, both countries still have margins of freedom on how they will apply that legislation.
6. The Caribbean countries for which information is unavailable are Antigua and Barbuda, Bahamas, Barbuda, Belize, Dominica, Granada, Haiti, Guyana, Suriname, Saint Lucia, Saint Kitts and Nevis, and Saint Vincent and the Grenadines. These countries have a population of 11.6 million inhabitants (2.2% of the regional total) and a GDP of 18 billion dollars (0.9% of the regional total).
7. Among the 10 countries mentioned, Chile represents more than 50% of foreign applications.
8. At the same time, the predominant system of academic evaluation encourages researchers to publish articles, not to register patents or other intellectual property titles.
9. The above means that R&D-patents elasticity was negative for the 1994–2004 decade, which would seem to contradict studies that estimate a unitary elasticity (Jaffe and Trajtenberg, 2002; Griliches, 1990). The Mexican experience of that decade does not corroborate the study by Aghion and Howitt (1998) which shows constant returns for R&D taken as a percentage of GDP. However, it could be consistent with approaches that suggest decreasing returns in patents in relation to R&D spending.
10. The PCT unifies patent application procedures in the signatory countries with the presentation, before the receiving office (in Mexico's case, the IMPI) of the international "PCT" application, which avoids red tape in each country, lowering costs and encouraging patenting in countries other than that of the applicant's residence.
11. Copyright and related rights are valid for "all productions in the literary, scientific and artistic fields, whichever the means or form of expression." Both rights are protected equally because authors, artists, performers, producers, radio broadcasters, and others are essential elements of the cultural industries.
12. Business Software Alliance (BSA) and International Data Corporation (IDC), September 2008. It should be noted that BSA has not revealed its sources and methodology. An article in The Economist "Software piracy: BSA or just BS?" of May 19, 2005 points out that BSA's methodology calculates losses based on an estimate of the stock of computers and its annual increase, the amount of software estimated per PC, and sales of legitimate software. The difference between legitimate software sold and the increase in the stock of total software existing is assumed to be "pirate" software. To estimate sales losses, the difference is multiplied by the market price of the legitimate software without considerations of price and income elasticity, which strongly overestimates losses.
13. When Chile began negotiation of the trade agreement with the United States, BSA declared that Chile had 51% piracy. Twelve months later, at the end of the negotiation, it inexplicably declared that the figure was 63%.
14. TPMs are devices or components that restrict unauthorized access to subject matter protected by copyright and related rights, as well as other contents not necessarily protected. There are two types of TPMs: those that control access and those that ensure reproduction rights (anti-copy).
15. Something similar occurred in the agreement with Morocco which was signed in March 2004, but did not enter into force until the country complied with USTR demands in January 2006.
16. It is advisable to sign the Patent Cooperation Treaty (PCT), which only regulates procedures, not substantive matters, and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1980).
17. El Salvador is the only country which before the agreement with the United States already permitted plant patents but also established exclusions.
18. Other exclusions are a) discoveries, scientific theories, and mathematical methods; b) systems, methods, principles and economic, financial, commercial, business plans or plans of simple verification, and monitoring; and c) those referring to purely mental or intellectual activities, or games.

19. For example, the criteria applied in life sciences can require additional conditions to prove that it is not a question of a discovery, in contrast to what occurs in other areas of technique.
20. This involves paying attention to the provisions of the TRIPS Agreement and Berne Convention with regard to the "three criteria rule", ratified by WIPO, the European Union and the Free Trade Agreements. In TRIPS (Article 13) this rule states that "Members shall confine limitations or exceptions to exclusive rights to (i) certain special cases which (ii) do not conflict with a normal exploitation of the work and (iii) do not unreasonably prejudice the legitimate interests of the right holder" (Berne talks of authors). The rule applies to all categories of the Berne Convention. The criterion of "certain special cases" implies that these should be clearly defined, although it is not necessary to identify all possible situations. The concept of "normal exploitation of the work" should be delimited so as not to overestimate the relevant market. Finally, the concept of "unreasonably prejudice" should be considered in relation to the reasonable benefits of the intellectual property right holder.
21. Okediji and Prosser (2005) put forward cases in which the digital copy for personal use has gray areas: For example, reproduction for personal use could imply placing (the work) on a web page for personal use, which could be accessed by third parties, thus canceling the personal nature of the reproduction. Furthermore, placing protected material on a web page could affect exclusive distribution and communication rights. The sending of audiovisual material to private computer terminals affects the right of public performance insofar as the work can be accessed by persons alien to the immediate circle. Therefore, the copy for personal use will depend on the nature of the work and how it is accessed.
22. Compulsory licenses appeared in the Statute of Monopolies of the United Kingdom of 1623, but their consolidation in the sphere of intellectual property took place with the Paris Union Convention of 20 March 1883, whose Article 5.A.2 permitted them to prevent patent abuse. Canada is the country with the greatest tradition and inclination in the use of compulsory licenses to guarantee medicines at affordable prices.
23. The Central American Convention for the Protection of Industrial Property of 1998 (Guatemala, El Salvador, Nicaragua, Honduras, and Costa Rica) contains regulations on compulsory licenses that are consistent with the TRIPS Agreement. Decision 486 of the Andean Pact, incorporated in the laws of Colombia and Peru includes grounds for unjustified non-exploitation of patents.
24. See Abbott and Ball (2002).
25. See Roffe P. (2004).
26. Upon expiry of exclusivity, the information is not released into the public domain, but other applicants can base themselves on it if their product is proved to be equivalent.
27. Thus the Free Trade Agreement would be complied with and situations would be avoided in which an NCE, having exhausted its protection of undisclosed information in country A where the generic equivalent already exists, obtains 5 years in country B only because it had not been registered there. Thus country A could only export patented, non-generic products to country B, which would hinder free trade. By establishing a term of 6–12 months, this scenario is substantively delimited.
28. "Bipartisan Agreement on Trade Policy: Intellectual Property Provisions", May 2007, Office of the United States Trade Representative (www.ustr.gov).
29. Title 35 U.S.C. § 156(3).

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Part III
Intellectual Property Rights in the Agenda of the Developing Countries

Chapter 6
Intellectual Property Rights in the Agenda of the Developing Countries. Intellectual Property Laws and Access to Medicines

María Fabiana Jorge

6.1 Introduction

Agreements on intellectual property rights, and especially bilateral agreements signed by the United States in recent years, have led to increased levels of intellectual property protection where each new agreement sets higher standards than the previous one. Until a little over 10 years ago, several countries did not grant patents for pharmaceuticals and foods.[1] The Agreement on Trade Related Aspects of Intellectual Property (TRIPS) was the first global intellectual property agreement. It was concluded after almost 8 years of negotiations and marked a substantial change in the protection of intellectual property and access to medicines.

The Uruguay Round of the General Agreement on Tariffs and Trade (GATT), which included TRIPS, was concluded in December 1994. Since then, 20 year monopolies were granted for patents, including for pharmaceuticals. Indeed, Article 27 specifically states that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

Although trade agreements have traditionally sought to open markets, by eliminating barriers to entry and thus increasing competition and benefiting consumers who as a result can have access to more affordable products, intellectual property agreements do the opposite. Instead of removing barriers to entry, they create them through the granting of patents; instead of increasing competition, they eliminate it during the term of the patent (20 years); instead of benefiting consumers with lower prices, the monopolies created by the patents result in higher prices, including pharmaceuticals, thus undermining access to affordable medicines.

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All this was done for the purpose of promoting investment and innovation in developing countries, although it is questionable if either goal was achieved, due to higher levels of protection. In fact, after Chile passed a new Industrial Property law during the 1990s, investments in the pharmaceutical field did not increase. On the contrary, international pharmaceutical companies closed manufacturing plants and only kept marketing offices open.[2] Furthermore, a report from an Association of Southeast Asian Nations (ASEAN) workshop states that after the introduction of patents for pharmaceuticals, the experience of countries such as Chile, Colombia, and other Andean countries shows that foreign direct investment (FDI) did not increase. There was no new investment, and various laboratories were closed down, since many foreign companies decided to import their products, thus substantially increasing the trade deficit in the region.[3]

The adoption of the TRIPS Agreement, which has become the standard for the protection of intellectual property rights for all Member States of the World Trade Organization (WTO), has had an enormous impact throughout the world. In some cases it has introduced stricter levels of protection than those in effect in many developed countries at the time the Agreement was signed, including the most jealous defenders of Intellectual Property Rights (IPR). With regard to patent terms, for example, in the United States the patent term was 17 years from the date of the granting of the patent, but after the adoption of TRIPS, it was extended to 20 years from the date of filing of the application.

Although it is true that innovation is expensive and discovering new medicines is a risky and expensive business that has to be adequately paid for in order to provide incentives to innovators and to foster research and development, the question here is whether bilateral intellectual property agreements are striking the necessary balance between protecting the rights of inventors and those of consumers. Is the current agreement balanced? Where are bilateral trade agreements going? Who is promoting these agreements? What are the key provisions? What is their impact on consumers?

This chapter seeks to respond to those questions by providing an overview of what has happened in the past 12 years in the area of intellectual property rights, specifically with regard to pharmaceutical patents, and to reflect on the kind of system that would make sense for Latin America so as to strike a balance between promoting innovation while protecting patients' rights to access to life-saving medicines.

6.2 Main Provisions of the TRIPS Agreement

As mentioned above, the TRIPS Agreement has become the standard for the protection of intellectual property rights for the member countries of the WTO. Although Article 1.1 of the Agreement states that "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement," some developed nations claim that the TRIPS Agreement grants the minimum level of IP protection. Furthermore, some developed countries have pressured developing

countries not to avail themselves of the flexibilities provided in the agreement and since the adoption of TRIPS to adopt higher levels of protection than those that were agreed upon.[4] As we will see later, this is consistent with the strategy of negotiating new bilateral agreements that take the standards set in the TRIPS Agreement as the basis to build on and establish higher levels of intellectual property protection.

For this analysis the TRIPS provisions have been divided into two groups: (a) those that seek to strengthen the rights of patent holders and (b) those that aim to protect consumers and/or foster technology transfer.

6.2.1 Strengthening the Rights of Patent Holders

6.2.1.1 Patent Term

The length of the patent term entailed a significant gain for the brand name pharmaceutical industry, since with this agreement all members of the WTO agreed to grant 20 year patent protection as of the filing date. As mentioned above, even in the United States the patent term had to be extended, since at the time the agreement was signed, patents were protected for 17 years from the date they were granted.

6.2.1.2 Patentable Subject Matter

Article 27 of the TRIPS Agreement defines patentable subject-matter and specifies those inventions that can be excluded from patentability if a government desires to do so, in the following manner: "patents shall be made available for any inventions whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Furthermore, the definition contains three important specifications: patents shall be valid "without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced." These specifications are significant because the developed nations wanted to make sure that countries would not discriminate against the place of invention, that its field of technology would not be exempted, and that countries would not be forced to manufacture the products in specific countries. Medicines are very light products, easy, and inexpensive to ship, and countries negotiating the agreement wanted to ensure that they would be able to have full access to all markets where they could export their products from a few distribution points in the world. This would allow innovative name companies to reduce costs, increase exports and sales, and control markets by restricting competition for 20 years.

More important still, the evolution of trade agreements from TRIPS to the negotiation of bilateral Free Trade Agreements (FTAs) promoted by the United States shows the gradual expansion of the scope of patentable subject matter. In fact, many of them have eliminated the exclusions established in Article 27 of TRIPS.

The second paragraph has been less controversial and, in general, recent FTAs maintain the provision stating that members may exclude inventions to

protect *l'ordre public* or morality from patentability, although the reference relative to "avoiding serious prejudice to the environment" has been dropped from recent FTAs.

Finally, Article 27.3 is where the FTAs are making the biggest difference. It states that Members may exclude from patentability (i) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals and (ii) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

Although the list of exceptions is very clear, there have been strong lobbying efforts –in many cases successful– to eliminate or at least to start eliminating them. The effects of this change on pharmaceuticals, especially as regards biotechnology, are quite significant.

6.2.1.3 Rights Conferred

Article 28 introduces an important provision by establishing that patents may be granted for "products" or "processes." Before the signing of the TRIPS Agreement, some countries only patented the process of manufacturing medicines, so that if someone obtained the same product through a different process, the patent did not protect the patent owner from competition over the final product. Thus, Article 28 was an important gain for the innovative name pharmaceutical industry.

The protection afforded by this article goes further by preventing "third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing [that product] for these purposes." This has serious implications since, for instance, a company in a country where the patent has not expired would be prohibited from manufacturing the product for export to a country where the patent has already expired.

Finally, the article reaffirms that only the patent holder has the right to transfer the patent by succession and to terminate licensing contracts. Clearly this article concentrates a great deal of power on the patent owner.

6.2.1.4 National Treatment

Article 3 of TRIPS establishes that "[e]ach Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits..."

Article 4 ("Most-Favored Nation Treatment") follows the same reasoning by establishing that "[w]ith regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a Member to the nations of any other country shall be accorded immediately and unconditionally to the nationals

of all other Members." Although they list some exceptions, Articles 3 and 4 seek to ensure that there will be no discrimination against foreign companies and that any concession granted to any Member must be automatically extended to any other Member State of the WTO.

Article 4 has additional implications for bilateral FTAs. Although these are negotiated between two countries, whatever is agreed upon with regard to intellectual property has to be extended to all WTO members. Therefore, to a certain extent, this article acts as a trigger for the harmonization of new intellectual property standards. For this reason, many question the effectiveness of these bilateral agreements, given that they entail additional concessions to almost 150 countries, although the negotiating countries receive reciprocal benefits only from each other, unless other countries also decide to grant such concessions, which they are not being forced to do.

6.2.2 Protecting Consumers and Fostering the Transfer of Technology

Article 7 of the TRIPS Agreement states that "[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

It is therefore clear that this agreement seeks to achieve three objectives: (1) to promote innovation and foster the transfer of technology; (2) to strike a balance between the rights of patent holders and those of consumers; and (3) to strike a balance between rights and obligations. Unfortunately, new trade agreements upset the balance by increasing the protection that is granted to patent holders, while at the same time eroding or even eliminating those provisions that sought to ensure benefits for society and which could have expedited access to innovations.

Article 8 of TRIPS describes the key principles that should guide IP protection under the terms of the agreement. As in the section regarding the objectives, this article reveals that those negotiating the agreement sought to ensure a balanced system, by stating that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition..."

The second paragraph introduces a key concept that for the most part has been omitted in either the implementation of laws or in subsequent bilateral trade agreements, with the exception of the FTA signed between Chile and the United States and DR-CAFTA (Free Trade Agreement between the United States, the Dominican Republic and the five Central American countries) as well as the FTA with Colombia and Peru, which followed the Chilean example, and that refers to the fact that governments can implement measures to prevent the abuse of IP rights by patent holders. In fact, Article 8.2 of the TRIPS Agreement specifically states that, "[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by

right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

6.2.2.1 Conditions on Patent Applicants

Article 29 of TRIPS establishes the basic conditions for the granting of a patent: "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."

Although at first glance this article seems to be quite basic, in recent FTAs there has been a deliberate effort on the part of the United States to limit disclosure requirements. For example, the reference to the "best mode" has been dropped in many agreements since DR-CAFTA, with the exception of the FTAs negotiated by the United States with Peru and Colombia, where Colombia requested that it be included. As we will see in more detail later on, the weakening of such requirements – which are not necessarily considered to be burdensome to start with – can have extremely negative consequences in the area of access to affordable medicines and with regard to the transfer of technology, one of the key objectives of the TRIPS Agreement.

As part of the effort to reach a balanced agreement, the TRIPS included flexible clauses that give countries some leeway so that they can respond to the needs of their citizens. Such clauses are related to Paralel imports of medicines (exhaustion of IPR) and permit imports from any country where they are marketed in accordance with patent laws. For instance, if a patent holder sells a medicine that is patented in countries A and B (respecting the commitments of the TRIPS Agreement), but at a higher price in country A, the latter could import the medicine that has been put in the market by the patent holder in country B without infringing on any patent rights.

Alternatively, a country could adopt the regime of national exhaustion of intellectual property rights, so that even if drugs are cheaper in other countries where intellectual property rights are respected, country A could not import the medicines (at lower prices) from country B. In other words, the international exhaustion of IPR is a flexibility that can provide a government with an additional tool to ensure access to affordable medicines. Some bilateral agreements, such as Australia–United States, prevent this flexibility.

6.2.2.2 Exceptions to Rights Conferred

Before addressing the issue of compulsory licensing, Article 30 of TRIPS makes reference to "Exceptions to Rights Conferred": "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not excessively endanger normal use of the patent and do not unreasonably cause damage to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties."

6.2.2.3 Other Use Without Authorization of the Right Holder

Much has been written about Article 31 of TRIPS on compulsory licensing, so this paper will only address the issue very briefly. This is undoubtedly one of the key flexibilities of the TRIPS Agreement, as it allows governments to issue compulsory licensing under certain circumstances and after considerable and unproductive efforts were made to obtain authorization from the right holder on commercial conditions and reasonable terms. In any event, the patent holder must be adequately remunerated for the use of his/her invention, taking into account the economic value of the authorization.

One condition for the use of this tool is that its scope and duration must be limited to the purpose that justifies the compulsory license, which should end once its cause is extinguished. In addition, use of a patented invention shall be non-exclusive, non-assignable, and shall be authorized mainly to supply the domestic market (this limitation was the subject of extensive negotiations that resulted in the Doha Declaration on the TRIPS Agreement and Public Health of November 2001, and the amendment to the TRIPS Agreement with the incorporation of Article 31 bis at the end of 2005). This issue will be addressed in more detail with regard to the Doha Declaration.

6.2.2.4 Transition Periods

Article 65 of TRIPS provides for specific transition periods for countries according to their stages of development to enable them to modify their laws and regulations in order to comply with the commitments entered into. All signatory countries had 1 year to implement them; the developing countries were granted four additional years; countries undergoing transformations from a centrally planned economy into a free market economy had four additional years; and those countries that did not have patent protection for products for some areas of technology could further postpone their implementation for a period of five additional years. In addition, Article 66 granted least-developed nations a transition period of 10 years which the Doha Declaration on the TRIPS Agreement and Public Health (paragraph 7) extended until 2016 for pharmaceutical patents (paragraph 7).

Although Articles 65 and 66 are very important to compensate for the major adjustments that the implementation of TRIPS entailed for many countries, interest groups and some developed countries have consistently pressured governments to give up this and other flexibilities, as it will be described in more detail further on.

6.3 The Doha Declaration on TRIPS and Public Health

The Doha Declaration on the TRIPS Agreement and Public Health was the result of a great deal of concern and frustration, especially from developing nations, which mostly regarded TRIPS as the result of an enormous effort to protect intellectual property rights, with potentially serious economic and social costs in the area of

access to medicines. After they signed it, they found to their surprise that some developed countries, under pressure from powerful interest groups, were not willing to fully respect it, but only to implement the provisions that best suited their interests.

Indeed, soon after the agreement was signed, some developed countries were only interested in implementing some of the provisions and started lobbying and pressuring other signatory countries to "unilaterally" forgo some of the flexibilities. Several countries such as Argentina, Brazil, and South Africa were among those that faced the most pressure. On June 14, 1995, only 6 months after the TRIPS Agreement was signed, Mickey Kantor, then United States Trade Representative (USTR), sent a letter to Domingo Cavallo, Minister of Economy of Argentina, in which he raised his concerns regarding indications that the Argentine government was considering a multi-year transition period (under the TRIPS Agreement Argentina was granted a period of transition of 10 years) and that it would "allow onerous clauses on compulsory licensing and provisions that would explicitly permit Paralel imports," two flexibilities expressly included in the TRIPS Agreement. The letter also stated that "we have received no indication that Argentina will address the issues of pipeline protection and test data exclusivity." In that regard, it is important to note that during the negotiation of the TRIPS Agreement, there were discussions as to whether there should be a period of exclusivity and whether pipeline protection should be granted, but both were excluded from the agreement, since Article 39.3 of TRIPS only refers to protection of undisclosed information but does not establish any exclusivity period.

Argentina, like many other countries, is under constant pressure, especially from the United States, to implement "TRIPS Plus" provisions; that is, stricter intellectual property standards than those adopted in the TRIPS Agreement. The pressure built up until January 15, 1997, when the Office of the USTR sanctioned the country under the Special 301 Review.[5] In a press release issued at the time, USTR argued that Argentina would not be granting patent protection for pharmaceutical products until 2000 (Argentina finally gave up half of the transition period that it had been granted due to US pressures) and was not granting an exclusivity period for test data. The sanctions entailed the elimination of 50% of the General System of Preferences for Argentine imports to the United States.

While the cases of pressures kept mounting, the HIV/AIDS crisis was steadily spreading. In a meeting organized in 2001 by the World Health Organization (WHO) and the World Trade Organization (WTO), representatives of associations of pharmaceutical companies from Argentina and Mexico demanded that the flexibilities of the TRIPS Agreement be respected. During the second half of that year, the TRIPS Council held a number of meetings that resulted in the Doha Declaration on the TRIPS Agreement and Public Health, signed on November 14, 2001.

Under normal circumstances, this declaration would not have been necessary since, for the most part, it just restates some of the clauses that were part of the TRIPS Agreement regarding the right of Member States of the WTO to avail themselves of certain flexibilities in the implementation of their IPR obligations. The only real addition made at Doha was to address the restrictions of Article 31.f of TRIPS

(that compulsory licensing should be authorized predominantly for the supply of the domestic market of the Member authorizing such use).

The Doha Declaration specifically states that countries "agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

In addition, the Doha Declaration states that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted, that each country has the right to determine what constitutes a national emergency, and that each member has the right to establish its own regime for the exhaustion of intellectual property rights.

In December 2005, an agreement was finally reached with regard to amending the TRIPS Agreement to allow compulsory licensing for countries that do not have medicine manufacturing capacity and need to import them from another country.[6] The negotiations for this amendment were long and complex and not without criticism from non-governmental organizations which considered the process for allowing trade in compulsory-license medicines burdensome.[7]

6.4 The Era of Bilateral Agreements on Intellectual Property

The impact of TRIPS should not be underestimated. Not only did it establish high standards for intellectual property protection, it also opened the door to other agreements that set higher standards of protection. As mentioned above, until the adoption of TRIPS, many countries did not grant patents for pharmaceuticals, as these are considered to be an essential good for life. With the signing of TRIPS, the concept of monopolies on pharmaceuticals was globally accepted as necessary to provide enough incentives to foster innovation. Some interest groups became aware of the benefits of trade agreements as instruments to change countries' laws, thus ensuring control of their respective markets, and what may be called the "Era of Bilateral Free Trade Agreements on Intellectual Property" was born.

Although bilateral agreements have been signed between many different countries, the most far-reaching in the area of intellectual property rights are the ones signed by the United States. Indeed, with the exception of a few agreements such as EFTA (European Free Trade Association)-Chile agreement, which has specific provisions on the protection of undisclosed information and general paragraphs on patent extensions, the IP section and the articles in most agreements are very broad and focus on areas such as observance and cooperation on intellectual property rights and refer to the need to comply with the obligations under the TRIPS Agreement.[8]

From the US perspective, intellectual property continues to be an area where American industry has strong leadership and is very competitive. This, coupled

with the lobbying efforts of the innovating brand name industry, has turned the intellectual property chapters into a priority in bilateral FTAs.

Such agreements have a dual purpose. The immediate one is to obtain additional access and control over the trading partner's market, whereas the more far-reaching purpose is to set precedents for future agreements, as USTR has acknowledged in public statements. On May 8, 2003, for example, Ralph F. Ives, III, Assistant Secretary of USTR for Asia, the Pacific and Asia-Pacific Economic Cooperation (APEC), spoke before the House Energy and Commerce Subcommittee on Commerce, Trade and Consumer Protection, where he said the following:

> Also, in the FTAA, the United States is seeking to negotiate a state-of-the-art agreement. While some countries negotiate free-trade agreements that exclude important areas of trade such as services and E-commerce, the United States seeks to negotiate the kind of ambitious and far-reaching commitments that one would expect to see in a 21st century free-trade agreement. *To accomplish this, the U.S. is using bilateral FTAs as model to break new ground and set new higher standards.* (Our emphasis).

Furthermore, speaking before the Senate Finance Committee's Subcommittee on International Trade on May 13, 2003, Peter F. Allgeier, Deputy US Trade Representative stated that "the United States has relatively unique interests in protecting the intellectual property of its world-class entertainment, software, biotechnology, and pharmaceutical industries. In the Chile FTA, we have set very high standards of protection in these areas and we are seeking to do the same with our CAFTA partners." In fact, the bilateral agreements negotiated by the United States after the US–Chile FTA include increasing levels of intellectual property protection.

Therefore, there is a clear strategy to use these agreements as steps to gradually increase intellectual property standards. We should not make the mistake of thinking that the TRIPS Agreement is all there is. On the contrary, there are many different fronts that are operating simultaneously, including regional negotiations such as the one to create the Free Trade Area of the Americas (if the FTAA moves forward, there will be a great deal of pressure to harmonize intellectual property standards at the highest levels of protection that have been set in various bilateral agreements that have already been signed in the region); in global negotiations such as the Doha Development Round (although at the moment these negotiations seem to be stalled), ongoing harmonization efforts at the World Intellectual Property Organization (WIPO),[9] and among developed nations.[10]

6.5 Trade Promotion Authority (TPA)

The United States Congress has the power "to regulate Commerce with foreign Nations".[11] However, in order to avoid a protracted and difficult process whereby Congress introduces changes to what has already been negotiated by the Executive, Congress has granted "fast track" authority, to the USTR, giving it the power to

conduct trade negotiations, thus only reserving the right to vote up or down on an agreement. These "fast track authorizations" are granted for limited periods of time. In 2002, while Chile and Singapore were negotiating free-trade agreements with the United States, Congress granted such authority to President Bush under the "Trade Promotion Authority" section of the Trade Act of 2002.

Under the leadership of Senators Edward Kennedy and Diane Feinstein and with the support of various groups concerned about access to medicines, the Senate unanimously approved the inclusion of the Kennedy–Feinstein Amendment, according to which in negotiations entered into under this mandate, the USTR must respect the Doha Declaration on the TRIPS Agreement and Public Health. Thus, under the TPA mandate, the USTR cannot negotiate bilateral agreements that restrict the flexibilities of the TRIPS Agreement.

The Kennedy–Feinstein Amendment was supported by both political parties. In fact, during the debate on this amendment, Senator Grassley (R-IA), Chairman of the Senate Finance Committee, which has oversight of trade negotiations, said that "this amendment makes an important contribution to the underlying trade promotion authority bill," and added "During the WTO ministerial at Doha, the members of the organization adopted a political declaration that highlights the provisions in the TRIPS agreement that provide members with the flexibility to address public emergencies, such as the epidemics of HIV, tuberculosis, and malaria. The objectives on intellectual property, which are part of this bill, were drafted before completion of the Doha ministerial meeting. Senator Kennedy's amendment updates these objectives to take into account the important declaration on public health made at the Doha meeting. It is a good addition to the bill. I am pleased to accept it."[12]

Senator Baucus (D-MT), the ranking Democrat of the Committee, also stated that "the amendment recognizes the special declaration concerning public health that was adopted last November in Doha. The special declaration provided assurance to poor countries facing the immense challenges of dealing with public health emergencies caused by pandemics of infectious diseases like HIV/AIDS, that measures necessary to address such crises in these countries can be accommodated by the WTO TRIPS Agreement, the Agreement on Trade-Related Aspects of Intellectual Property Rights".[13]

Nevertheless, a review of recent bilateral agreements negotiated by the United States shows that USTR negotiators have not followed this mandate. As a result, in February 2005 Senator Kennedy issued a clarification to the congressional record on this clause in which he stated the following:[14]

> [...] Our amendment made it a principal objective of the United States to respect the Doha Declaration in all trade negotiations. Regrettably, in several trade agreements since then, the administration has refused to fulfill this obligation.
>
> [...] Our amendment to the Trade Promotion Authority Act reinforces the Doha Declaration. The Bush administration should be using it to negotiate trade agreements that allow urgently needed access to medicines. Instead, the administration has used trade agreements to promote the interests of the pharmaceutical industry at the expense of access to drugs in developing nations.

Again and again, the administration has defied the Doha Declaration and imposed unjustified restrictions on the availability of patented drugs. It has done so in trade agreements with Australia, Jordan, Morocco, Singapore and other nations. In these agreements, the Bush administration has undermined the very core of the Doha Declaration. Now it is trying to do so in the Central American Free Trade Agreement."

6.6 Key Provisions of Bilateral FTAs

The key provisions of bilateral agreements that affect pharmaceuticals can be classified into two main groups: (A) provisions that favor patent holders and (B) provisions that protect consumers.

Although this chapter is focused mostly on Latin America, in this section we are including references to other agreements as some provisions first established in agreements outside the region have set precedents that have been included later on in FTAs negotiated in the Americas.

6.6.1 Provisions Favoring Patent Holders

The following are provisions that favor the rights of patent holders: (a) patent extensions for delays incurred by regulatory agencies, (b) patent extensions for delays in the patent office, (c) test data protection, (d) linkage (link between patent status and marketing authorization), (e) elimination or reduction of the restrictions on patentable subject–matter, (f) elimination of the requirement to disclose the best mode for carrying out an invention, and (g) harmonization.

6.6.1.1 Patent Extensions for Delays Incurred by Regulatory Agencies

Any analysis of this issue must take into consideration that the TRIPS Agreement does not establish patent extensions, so any provision extending the term of a patent is clearly TRIPS Plus. In addition, there are several issues that must be looked at (i) which are the patents subject to extensions, (ii) whether any limits are set for the extensions, (iii) whether there is a minimum period of delay of the health authority to grant an extension, (iv) whether delays incurred by the patent holder could be taken into account in granting an extension, and (v) whether the granting of extensions in one country that was used as a reference for granting a patent in another country means that another country should also grant such extensions.

Given the complexity of the issue, below is a more detailed analysis of each of these points:

(i) *Which are the patents subject to the extensions?* According to one of the negotiating objectives of the TPA passed by the US Congress, negotiations in the area of intellectual property rights must "reflect a standard of protection similar to that found in United States law." Nevertheless, it seems that US negotiators

have been picking which aspects of the law to follow and which ones to ignore. For instance, under US law, patent extensions due to delays in the regulatory approval process (FDA) are only granted for new chemical entities (NCE).[15] Nevertheless, all recent FTAs fail to include this limitation, thus opening the door to extending patents to cover a broader range.

(ii) *Whether any limits are set for the extensions.* Under US law there are very specific and clear limits on the period that a patent may be extended. For instance, an extension cannot be longer than 5 years, and the total effective patent term (EPT), which is the period from the date of marketing approval of the product until the original expiration of the patent, cannot go beyond 14 years.[16] Therefore, if a drug enters the market in the 8th year of the patent and is granted a 5 year extension (its maximum) the total effective patent term would be 17 years. Nevertheless, under US law (due to the fact that the EPT cannot be more than 14 years), 3 of the 5 years of the extension would be automatically eliminated. All these limitations to protect consumers are not being included in the FTAs, even though they are part of US law so that extensions in the FTAs can be interpreted as being unlimited.

(iii) *Whether there is a minimum period of time to trigger an extension.* The language of the FTAs does not specify a time to request patent extensions during health approval of a medicine (there are in cases of delays in the approval of a patent in the office of intellectual property; see below).

(iv) *Whether delays incurred by the patent holder could be taken into account as part of the delay to justify authorization of extensions.* Any country negotiating patent extension provisions should ensure that delays that resulted from actions attributable to the patent holder are not eligible for patent extensions. This sort of language has been generally included in FTAs for the delays occurred in granting a patent, but not for those that occurred during the marketing approval process. Such limitations should be included in both cases.

(v) *Whether the granting of extensions in a country that was used as a reference for granting a patent in another country means that the second country should also grant such extensions.* This language is serious cause for concern, since a delay in a reference country may not have affected at all the registration in the other country and yet nonetheless, based on this language, it would be granted an extension. This was included in the US–Bahrain FTA (Art. 14.8.7.).

6.6.1.2 Patent Extensions for Delays in the Patent Office

Although the TRIPS Agreement only requires a period of patent protection of 20 years from the filing date, all recent FTAs negotiated by the United States since the US–Singapore and the US–Chile FTAs include extensions for delays in the granting of a patent.

The language in most of these agreements is similar, although the periods of delay that trigger a request for an extension varies depending on the country. For instance, the FTAs signed with Singapore, Australia, Morocco, Bahrain, and Oman establish that an unreasonable delay shall at least include a delay in the issuance of a

patent of more than 4 years from the date of filing of the application in the territory of the Party, or 2 years after a request for examination of the application, whichever is later.

In the FTAs signed with Chile, Peru, and Colombia, as well as the DR-CAFTA, the trigger periods are 5 and 3 years instead of 4 and 2, respectively. There is a simple reason for this. Although the language proposed by the United States to Chile also had 4 and 2 years, the Chilean intellectual property team set a good precedent for the Americas. The FTA with Chile includes several examples of well negotiated provisions. During the renegotiation of the FTA with Peru and Colombia in 2007 the requirement of patent extensions was eliminated just for pharmaceuticals.

Finally, all FTAs from Singapore onward include similar language stating that the two trigger periods to request an extension of the patent may be granted, provided that the periods of time attributable to the actions of the patent applicant need not be included in the determination of such delays.

6.6.1.3 Test Data Exclusivity

This is one of the most complex issues included in the FTAs and one which has serious consequences. The level of detail and the sophistication of the language that has been included in the latest agreements reveal the growing problem for access to medicines.

From a broader perspective, establishing exclusivity periods for test data protection is no doubt part of TRIPS Plus, even though some interest groups have argued that this is an obligation derived from Article 39.3 of the TRIPS Agreement. However, that article does not in any way establish an exclusivity period, but only states that "Members, when requiring, as condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed tests or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use ..."

Data exclusivity periods entail a number of restrictions on access to medicines. For instance, if a government decides to issue compulsory licenses, its effectiveness may be hindered if the data for the drug are protected by an exclusivity period. Furthermore, it has been argued that several pharmaceutical companies have weak pipelines, and therefore they may want to extend their existing monopolies on their current bestselling drugs for as long as possible, even beyond the patent term, in order to keep their revenues up.

(i) *"At least" 5 years.* In addition, there is the concern that once a country has accepted the concept of a period of exclusivity (different from TRIPS) it is only a matter of time until there is an effort to increase the period of exclusivity. For instance, in Europe the average data exclusivity period was 6 years. However, in 2004 the EU passed Directive 2004/27/EC, extending exclusivity to 10 years, with the possibility of an additional year for new indications. [17] In Canada, the exclusivity period of 5 years was extended to 8 years in October

2006.[18] Furthermore, all recent bilateral trade agreements establish a period of exclusivity of "at least" 5 years, thus opening the door to longer periods in the future. This is another example of the language proposed by the United States where it can be argued that USTR negotiators are going beyond US law requirements. Indeed, under US law, data exclusivity for new chemical entities is granted for 5 years, and not 1 day more. Nevertheless, USTR negotiators have ensured that countries agree to an open-ended exclusivity period with a minimum of 5 years.

(ii) *Subject matter protected by exclusivity periods.* This is a key issue that concerns what exactly can be protected and where there are significant differences between several recent bilateral trade agreements.

The text proposed by the Office of the USTR does not follow US law, where the 5 years of protection is only granted for new chemical entities. Nevertheless, the language of some recent FTAs goes beyond that. The broadening of the scope of pharmaceutical products eligible for such exclusivity or monopoly would have a direct impact on the timing of the entry of generic competition into the market. Chile was the only country that actually made sure that this protection would be granted only for new chemical entities, even though the original US proposal included much more ambitious language. Unfortunately, other agreements negotiated later on, including the DR-CAFTA, failed to use this very important precedent.

(iii) *Same or similar.* An additional and very serious problem results from the inclusion of the words "same or similar." Several recent FTAs establish that "the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market the same product or a similar one..."[19] The implications of this text are dangerous, since it basically establishes that if a period of exclusivity is granted, no generic version could be authorized for the whole therapeutic class of drugs related to the one that was granted the exclusivity. This goes beyond what is in effect in the United States and has serious consequences for access to affordable medicines. Furthermore, by prohibiting the approval of same or similar drugs, the approval of generic versions of biotechnology drugs would be banned which would have a very negative effect on access to medicines since these are the most expensive drugs.

(iv) *Consecutive periods of exclusivity.* This is one of the most regressive data exclusivity provisions from the point of view of developing nations and access to medicines, since it basically entails that the period of protection in a developing country could be twice as long as the protection granted in a developed country, or even more. The Central American countries (DR-CAFTA), Peru, and Colombia (in the case of the last two countries the grace period was modified in the 2007 renegotiation) accepted the granting of a 5 year grace period for brand name companies to register a product in a country once the other Party has registered (in this case the United States). The period of "at least" 5 years of data exclusivity goes into effect from the moment of registration,

and thus the CAFTA countries, the Dominican Republic, Peru, and Colombia could be actually granting brand name companies 10 or even more years of data exclusivity, when US consumers would only need to wait for 5 years to have access to more affordable medicines.

What normally occurs is that brand name companies first register the data in developed countries where their earnings are higher. For instance, most companies register their drugs first in the United States, given that, according to IMS (Information on Pharmaceutical Markets),[20] this is where about 50% of global pharmaceutical sales occur. However, small countries such as Guatemala or El Salvador may not be a high priority for pharmaceutical companies in terms of sales, so a company is likely to register its products there later on. In practice, this means that people in those Central American countries would be unable to have access to the drugs they need for longer periods of time than the citizens of developed nations.

In Jordan, the first country that accepted the consecutive application of data protection periods in a bilateral FTA, domestic generic companies are reluctant to take the risk of bringing a product to market, even if that product has not yet been registered in Jordan, because the brand name company could suddenly decide to enter the local market, thus banning the generic company from selling the drug for 5 years and therefore ruining the investment that had been made to bring the product to market. Hence, this provision is very regressive for those that have limited resources.

Finally, another element to look for with regard to the consecutive application of the protection is whether protection could go even beyond 10 years. DR-CAFTA states that a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within 5 years after obtaining marketing approval in the other territory. It is important to note that the text says that a Party "may require" but therefore, it may also not require it and leave the registration of the data in the country open ended. This could have terrible consequences for consumers whose access to more affordable medicines may be indefinitely delayed. This is also a negative provision for domestic pharmaceutical companies and as a result for the economy of these nations.

(v) *Period for registration of confidential information.* Although Chile accepted the granting of data exclusivity for pharmaceuticals for "at least 5 years," it rejected the consecutive terms proposed. The amendments to the Industrial Property Law passed by the Chilean Congress following the approval of the FTA set limits on the grace period provided to brand name companies to register their data in the country, after which they lose such rights. Thus, Chile granted a 12-month grace period to register data in Chile after the data is first registered elsewhere. If the holder fails to register its product within that timeframe it loses the right to do so later on.[21]

This was a positive and creative provision, as it provides an incentive for pharmaceutical companies to register their products in Chile soon after their first registration in another country, thus providing consumers with

expeditious access to medicines and also avoiding unnecessary delays in the introduction of generic competition in the market.

Some DR-CAFTA countries and others argued that the consecutive application of the periods of protection was positive, since it set a clear limit on how long a company could actually take to register a medicine in their countries. However, Central American consumers have a disadvantage with respect to consumers in developed countries that will have access to cheaper and equally effective medicines much earlier.

Chile's legislation provides that data exclusivity will be lost if a pharmaceutical product has not been traded in Chile for a period of 12 months since its registration in the country.

(vi) *Data exclusivity can go beyond the patent term.* Another very regressive step is the fact that several of these agreements, including the FTAs negotiated with Peru, Colombia, Oman, Bahrain, Morocco, Singapore, and Australia, establish that the period of exclusivity for the protection of test data could go beyond the term of the patent. Indeed, recent FTAs have included language that specifically states that "when a product is subject to a system of marketing approval pursuant to paragraph 1 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 in the event that the patent protection terminates on a date earlier than the end of protection specified in paragraph 1.".[22]

Many believe that the issue of data exclusivity is not very serious because it entails a period of 5 years, whereas the period for patents is 20, thus it would not affect consumers because the monopoly granted by a patent remains in force. This is not so, given that the protection of data can be requested for products that are no longer under patent. Furthermore, countries that have accepted to grant three more years of exclusivity for new clinical information preventing the approval of any "same or similar" products would block all same or similar products approved before. It is important to underline that each new 3-year period will block the generic competition for the original product, as well as any other similar product, so that it is possible that a patent may expire before market exclusivity does.

(vii) *"Require" or "permit".* A troubling addition was recently made to the language of some FTAs, such as those that the United States negotiated with Bahrain, Oman, Peru, and Colombia (the word "permit" was eliminated in 2007 with regard to Peru and Colombia with the renegotiation of the FTA), with regard to regulated products (test data) which specifically states that "If the Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning safety and efficacy..."[23] This text could allow a company to submit information and request protection for said information, even though it is not required to demonstrate the safety and efficacy of the product. This could potentially result in delaying new research and therefore innovation as well as the approval of some generic drugs.

(viii) *Eliminating the word "undisclosed".* Another negative development from the point of view of access to medicines is the language regarding protected information. While the US–Australia FTA protects "undisclosed tests or data concerning the safety or efficacy of products," the wording of more recent FTAs, such as the ones signed with Bahrain, Oman, Peru, and Colombia is broader, as it refers to "the submission of information concerning safety and efficacy of the product." The word "undisclosed" was reintroduced in the FTA with Peru and Colombia with the 2007 renegotiation.

There are two significant differences. First, the term "undisclosed," as related to data, was dropped. By not including the word "undisclosed," the information that could be protected by a period of exclusivity is much broader and could include information that is already in the public domain. Second, the replacement of the words "test or data" with "information" again broadens the scope of protection, which could delay generic competition and thus hinder consumers' access to more affordable medicines.

Unfortunately, this is consistent with the most recent USTR Annual 301 Review published of April 28, 2006, where the USTR states that a number of countries do not provide adequate protection against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking approval for their products, thus widening the scope of the data that they are seeking to protect.

(ix) *Additional 3 years for new clinical information.* Another negative development for consumers is the fact that some FTAs, such as the ones negotiated with Morocco, Bahrain, and Oman, include an additional 3-year protection period for new clinical information submitted in support of the marketing approval process.

6.6.1.4 Linkage (Between the Health Registration Office and the Patents Office)

The linkage between marketing approval and patent status is a complex issue, since it is related to several other issues, including evergreen patents, improper filing of patents (frivolous lawsuits), and the misuse or abuse of patents by right holders. According to this regulation, in the United States and Canada, no generic drug can be approved until any claim of alleged patent infringement is decided in court or for a certain period of time (30 months in the United States and 24 in Canada), whichever comes first. In the United States, once a patent has been granted, a company can register it in the Orange Book at the Food and Drug Administration (FDA), but not every patent can be registered in the Orange Book. The only patents that can be listed are those that claim to be (1) a drug substance (active ingredient); (2) a drug product (formulation and composition); and (3) a method of use.

Recent bilateral agreements include the linkage provision, which is not part of the TRIPS Agreement and which is being questioned in the United States even by members of the US Congress, as it has opened the door to a number of abuses by patent holders.[24] In addition, there are serious doubts as to whether the linkage is

in compliance with Article 27.1 of the TRIPS Agreement, which specifically states that patents shall be available without discrimination in the field of technology. The linkage clearly applies only to pharmaceuticals, so it could be argued that it actually discriminates based on the field of technology and therefore is inconsistent with the TRIPS Agreement.

The way it is being included in agreements goes significantly beyond US law. For instance, in the United States, when a patent holder is notified by the FDA that a generic company is applying for a drug covered by a patent, the patent holder has 45 days to file a lawsuit against the generic applicant or the FDA could authorize the generic applicant. In addition, while in the United States only a limited number of patents may receive this protection, the language of this provision in the FTAs is so broad that it would actually cover most if not all patents. In fact, in the 2006 Special 301 submission of PhRMA[25] to the USTR regarding the 301 Annual Review, the association criticizes Mexico, which adopted linkage provisions through a presidential decree in September 2003, due to the fact that the linkage protection is only granted for active substances or ingredients.

Finally, it is important to highlight that this provision shifts the responsibility for protecting private property from its owner to the government, thus putting an additional burden on the latter, which must assign resources to the implementation and enforcement of this provision. It is interesting to note that a report from the Department of Health and Human Services (HHS) on drug imports stated that "it is outside the scope of HHS' responsibility, expertise and jurisdiction to protect intellectual property rights."[26] Why is it that going to the courts to solve a patent dispute may not be enough for patent holders?

6.6.1.5 Elimination of Requirements Regarding Disclosure of the Best Mode to Reproduce an Invention

Under US law, a patent applicant must disclose what is known as the "best mode" to reproduce an invention so that after the patent expires, society can benefit from the knowledge of that invention.

Such information is essential for the reproduction of biotech drugs after a patent expires. These drugs are the most expensive on the market – the cost ranges from a few thousand dollars a year to more than a hundred thousand.[27] The USTR argues that it is not necessary to include the "best mode" requirement in the text of the FTAs, since many countries do not have such requirements. Yet at the same time the USTR is including linkage provisions, even though most countries do not have this type of regulations. Therefore, the same rationale could be used to argue that the linkage provision should not be included in the FTAs. The only consistent element in all of these provisions is that all of them seek to favor the rights of patent holders at the expense of consumers, thus upsetting the carefully crafted balance achieved in the United States with the Drug Price Competition and Patent Term Restoration Act of 1984, best known as the Hatch-Waxman Act, between the need to foster competition from generic drugs and the maintenance of incentives to invest in the research and development of new drugs.

6.6.1.6 Harmonization

There are three harmonization efforts under way, one within the framework of the World Intellectual Property Organization (WIPO), the second one led by the US Patents and Trademarks Office (USPTO), along with its counterparts in Australia, Canada, the European Union, and Japan, and the third within NAFTA. Indeed, during a public hearing held in the US House of Representatives, John Melle, Assistant Secretary for North-American Affairs at the USTR, said that a review of NAFTA has been launched to "identify more ambitious disciplines than our more recent regional FTAs that could be candidates for incorporation into the NAFTA."[28] The USTR is currently accepting proposals from United States industry regarding which provisions should be included. Considering that intellectual property is one of the top priorities of the United States in the negotiation of FTAs, it is expected that the USTR will seek to include IP provisions.

Furthermore, the US–Australia FTA specifically states that "each Party shall endeavor to participate in international patent harmonization efforts, including WIPO for dealing with reform and development of the international patent system."[29]

6.6.1.7 Restriction of the Flexibilities of the TRIPS Agreement

As mentioned above, the TRIPS Agreement includes some flexibilities for the implementation of intellectual property provisions, some of which are key to ensuring access to medicines, such as the use of compulsory licensing, Paralel imports, and restrictions on patentable subject matter. Unfortunately, several of the FTAs have limited these flexibilities, despite the fact that the Trade Promotion Authority specifically states that the new agreements negotiated by the USTR under this authority must respect such flexibilities. (Trade Act of 2002, Title XXI, Section 2101 (b) 4C).

6.6.1.8 Elimination of the Restrictions on Patentable Subject Matter

Article 27.3 of the TRIPS Agreement states that "Members may also exclude from patentability:

i) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
ii) Plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. . ."

Nevertheless, the Office of the USTR proposes the inclusion of language in the FTAs that seek to limit these provisions. In the case of patentable subject–matter, the USTR included language that seeks the elimination of these restrictions in the FTAs with Chile, Peru, and Colombia, as well as the countries in DR-CAFTA, stating

that the Parties will undertake all reasonable efforts to make the patenting of plants available. Other FTAs go further, like the Jordan-US FTA, which does not include the patenting of plants and animals as one of the potential restrictions to patentable subject matter.

6.6.2 Provisions to Protect Consumers

These provisions include (a) Bolar, (b) compulsory licensing, (c) Paralel imports, (d) revocation, (e) measures to prevent abuse of rights by intellectual property holders, (f) opposition proceedings to the granting of a patent; and (g) side letters.

The provisions listed in this section are among those that contribute to ensuring access to affordable drugs. However, the language included in several of the recent FTAs with regard to these clauses tends to favor in several cases the rights of patent holders, leaving consumers less protected.

6.6.2.1 Bolar

This provision allows the pre-registration of a generic drug so that during the time that the patent is in force a generic applicant can conduct all the necessary testing and make the submissions to the regulatory offices to obtain the pre-approval of the medicine. This allows a generic company to enter the market immediately after a patent expires. The absence of a Bolar-type provision entails a de facto extension of the patent term beyond 20 years.

The adoption of the Bolar provision in the United States has been one of the most successful chapters in ensuring access to medicines. The text of the law is very clear: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (...) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development of information under a Federal law which regulates the manufacture, uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[30]

Despite its importance, in the trade agreements the USTR has chosen to water down the language of certain US laws by not requiring the inclusion of Bolar, but rather only allowing it if a government decides to adopt it. Some may consider that this is enough, but the countries that have concluded negotiations have discovered that once the negotiating process ends, new negotiations start on the implementation of the provisions that are in the text of an agreement. It is essential that the language be very clear and leaves no room for different options or for any future attempts to eliminate them.

A report from the United States International Trade Commission regarding the US–Australia FTA states that, "U.S. industry and government trade officials are

especially concerned that the Australian Government may allow domestic drug producers to conduct trials and produce generic equivalents of patented pharmaceuticals prior to the expiration of the patent holders' right to legally sold drugs. This would permit domestic producers' drugs to obtain Australian regulatory marketing approval in advance of patent expiration so that generic equivalents could be sold immediately after the patent had expired."[31]

As the report shows, countries negotiating this type of agreement should not simply agree on a text that may either allow or ban its implementation. Countries should demand unequivocal language, as under US law.

6.6.2.2 Compulsory Licensing

Although compulsory-licensing provisions are at the heart of the flexibilities available under the TRIPS Agreement, some of the bilateral FTAs negotiated by the United States such as those with Jordan, Singapore, and Australia seriously limit the use of compulsory licensing, directly contradicting the TPA mandate to respect the Doha Declaration on the TRIPS Agreement and Public Health.

6.6.2.3 Parallel Imports

Under Article 6 of the TRIPS Agreement, countries could decide whether to opt for the national or the international exhaustion of intellectual property rights. The USTR has proposed and in some cases succeeded in including language that eliminates this clause by banning imports of legally sold patented drugs in international markets. The agreements that include such restrictions are the FTAs negotiated by the United States with Singapore, Australia, and Morocco. The United States also proposed similar language in other agreements, such as in the FTA with Chile, but was rejected on the grounds that the TPA mandate supports countries' right to avail themselves of the flexibilities of the TRIPS Agreement. It is important that countries make sure that such flexibilities are fully respected in free-trade agreements.

6.6.2.4 Revocation of Patents

Most FTAs state that a patent may be revoked only on the grounds that would have justified a refusal to grant the patent and also in the case of fraud, misrepresentation, or inequitable conduct. Nevertheless, none of the recent FTAs include the possibility of revoking a patent if the granting of a compulsory license has not remedied the lack of exploitation of the patent. This provision was included in NAFTA and would be an important option for other developing nations.

6.6.2.5 Measures to Prevent Abuse of Rights by Intellectual Property Holders

Article 8.2 of the TRIPS Agreement specifically states that "appropriate measures, provided that they are consistent with the provisions of this Agreement, may be

needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

This article is very important, since monopolies may be abused by right holders. Nevertheless, most recent FTAs do not include language of this type. There are a few exceptions, such as the US–Chile FTA, which included it at the request of the latter, as well as DR-CAFTA, the US–Peru FTA and the US–Colombia FTA, which followed the Chilean example, and Vietnam. All the other agreements are silent with regard to patent abuse. In the case of Australia, an amendment was added to the United States Free Trade Agreement Implementation Bill 2004 with provisions penalizing patent holders that abuse their rights. Among other things, the amendment requires patent holders to issue a certificate when they seek to use the courts to block cheaper generic drugs from entering the market which must attest that the legal action has been commenced in good faith, has reasonable prospects for success, and will be conducted without unreasonable delay. If the certificate is false or misleading, or if any undertakings given under the certificate are subsequently broken, the patent holders could be liable to a civil penalty of up to $10 million for each contravention. This provision has been strongly rejected by PhRMA, which is seeking its elimination.

6.6.2.6 Opposition Proceedings to the Granting of a Patent

There is growing concern regarding the quality of the patents granted. In fact, the Federal Trade Commission (FTC) in the United States devoted a section of its 2003 report entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy"[32] to the problem of questionable patents. Specifically, the report states that "[a] poor quality or questionable patent is one that is likely invalid or contains claims that are likely overly broad. Hearings participants raised concerns about the number of questionable patents issued. Such patents can block competition [...] and harm innovation in several ways."[33]

Therefore, it is very important to devise a mechanism to ensure that only legitimate patents are granted. Different countries have chosen different ways to do so. Some, like India, have pre- and post-granting opposition proceedings. Other countries have one of the two. In the case of recent bilateral agreements, the United States has proposed language that would only allow post-granting opposition proceedings. Not having the opportunity to challenge a patent during the application process poses a problem, since it would only leave the option of resorting to costly litigation after a patent had been granted, in addition to the harm to consumers.

6.6.2.7 Side Letters

Given governments' and civil society's increasing concern over the impact of these agreements on access to affordable medicines, recent FTAs including those with Singapore, the DR-CAFTA countries, Morocco, Australia, Bahrain, Oman, Peru, and Colombia (the letters in the Peru and Colombia FTAs were incorporated into

the main text after the renegotiation of 2007) include side letters that seek to allay concerns by stating in broad terms that the obligations of the intellectual property chapters do not affect the ability of the Parties to take necessary measures to protect public health. However, in many cases the side letters are restrictive, since the language seems to limit governments to act in the case of certain specific diseases and epidemics, as well as in circumstances of extreme urgency or national emergency (CAFTA, 2004).

It is important to note that these letters fail to accomplish their intended objective, since their legal standing is unclear, for they are not part of the text of the agreement.

USTR has failed to clarify the exact interpretation of side letters. Therefore, countries that accept higher intellectual property standards because they believe that the letters provide a safeguard are taking a very high risk.

6.7 Concerns of US Members of Congress Regarding IPR Agreements

Although the USTR has pressured other countries to adopt higher levels of intellectual property protection, other areas of the US government are very concerned with this trend. There have been a number of letters from Members of Congress to the USTR which are very critical of some of the TRIPS Plus provisions sought by the United States.

The US generic industry, which supports a balance between innovation and access, is also concerned about the language that is being included in these agreements, since they are setting new intellectual property standards that go even beyond US law and may undermine the balance achieved in the Hatch-Waxman Act.

6.8 The Role of Political Authorities in the Bilateral Agreements

Negotiations in the area of intellectual property rights are very costly with regard to access to medicines, where the impact will be increasingly felt as time goes by. It is imperative that before engaging in this type of negotiations governments be aware of the potential cost to public health. If the decision is made to move forward, there are two key elements to ensure a fair and beneficial negotiation: a negotiating team with the necessary expertise in the area of IP and leaders willing to leave the negotiating table if it becomes clear that it is not possible to reach a compromise that would not undermine public health and access to medicines. One element without the other would make it harder to strike a balance between promoting innovation and ensuring access to affordable medicines.

6.9 Conclusions

The TRIPS Agreement marked the adoption of new standards of intellectual property protection, when members of the WTO attempted to reach a balance between

the rights of patent holders and those of consumers. The proliferation of bilateral agreements signed by the United States has gradually established precedents that are changing the IP laws in different countries, which may eventually result in new IP standards following regional or global patent harmonization efforts. Unfortunately, recent FTAs have failed to reach the necessary balance by increasing the rights of patent holders at the expense of consumers. In fact, many of these FTAs go beyond US law, thus potentially upsetting the balance between access and innovation sought by the Hatch-Waxman Act. This trend is cause for legitimate concern.

Multilateral negotiations are likely to provide a better framework to balance the interests of all countries than bilateral negotiations between unequal trading partners. As they engage in these negotiations, countries must bear in mind that in order to promote innovation, is it is also necessary to have a healthy competition policy. Some developed countries have been reluctant to negotiate the elimination of agricultural subsidies in bilateral agreements, arguing that such negotiations should be conducted at the global level. Perhaps it is time that developing countries do the same with intellectual property issues, so that they are no longer negotiated bilaterally, but rather at the multilateral level.

Finally, after this chapter was submitted for publication, on May 10, 2007, the Ways and Means Committee of the House of Representatives of the United Status Congress announced that it had reached agreement with the Office of the Trade Representative (USTR) whereby a number of clauses negotiated in the free-trade agreements with Peru and Panama were amended. Such changes would also apply to Colombia if this country grants certain guarantees to the US Congress regarding reduction of violence and violations of the human rights of union leaders in that country.

As indicated in the announcement, this new two-party policy represents a fundamental change in United States trade policy and touches areas such as labor rights and environment, and other new ones such as access to generic medicines. Regarding the latter, the changes would be as follows:

First, an amendment is made to the clause on data exclusivity (the period during which a generic company cannot use the test data of an innovating company) in order to allow earlier entry of generic medicines by eliminating the consecutive terms of protection (the previous text established 5 years as of registration in the country, granting in addition a grace period for the said registration of up to 5 further years since registration in the United States). Therefore the period would be limited to 5 years which would run concurrently from the granting of the first protection.

Second, an exception is included whereby if a government grants a compulsory license, the exclusive rights would not block effective use of the said license.

Third, the requirement of linkage (link between the patent and the marketing permit) is eliminated.

Fourth, the requirement of granting extensions to patents of a pharmaceutical product is eliminated, even though the establishment of an expeditious process for patent approval and its marketing permit is required.

Nevertheless it should be noted that the texts and final amendments to these agreements continue to be negotiated and therefore it is necessary to wait before making definitive analyses of the same.

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Chapter 7
Intellectual Property Rights and Biological Diversity: Considerations for Latin America

Jorge Cabrera Medaglia

7.1 Introduction

The legal and institutional transformations that have accompanied free trade agreements in such important areas as competitiveness, industrial development, public health, education, food security, environment and Intellectual Property Rights (IPRs) are the subject of intense discussions in various national and international forums.[1] In relation to IPRs and the environment, and due to the emergence of an international body of laws within the framework of the Convention on Biological Diversity (CBD) and of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, emphasis has been placed on the existence of a conflict between certain tendencies oriented toward the strengthening of IPRs and the objectives of conserving, using biodiversity sustainably and equitably distributing the benefits derived from the use of genetic resources. Although we consider that certain forms of intellectual property can have negative effects, this chapter assumes that there is sufficient room for maneuver to create synergies between trade obligations in the matter and environmental treaties.

The debate on IPRs is based on certain considerations regarding their role in the dissemination of innovation and knowledge as factors of development. The discussion centers on the consequences that the strengthening of IPRs could have on technological development, access to basic instruments for education (databases, software, among others), health (i.e., medicines), and biodiversity. It is no surprise that the environmental topic should now be added to linkage of the subject to development (since the mid-1960s) and trade agendas.[2]

Most researchers on the topic (in reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights; TRIPS, specifically Article 27.3.b) analyze

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and anticipate the effects of IPRs on biodiversity and indigenous and farmer communities. The arguments range from the risk of fostering biopiracy of resources and traditional knowledge, to the prohibition on farmers to keep and exchange seeds of protected varieties, including the possible consequences of genetically modified organisms on the environment (Downes, 1999).

7.2 Biodiversity and Intellectual Property Rights: Synergies and Opportunities. International Forums

In regard to international instruments, it is essential to consider at least the following. 1) the Convention on Biological Diversity (CBD), the resolutions on intellectual property and biodiversity of the Conference of the Parties and the possible implications of the negotiation under way of an international regime on access to genetic resources and sharing of benefits; 2) the International Treaty of the Food and Agriculture Organization (FAO) on Plant Genetic Resources for Food and Agriculture, particularly its provisions on access to genetic resources (Articles 10–14), farmers' rights (Article 9) and the impossibility of recognizing IPR for materials in the "received form" of the multilateral system of access (Article 12.1.d); and 3) the debate in the World Trade Organization (WTO) and the TRIPS Agreement in the light of the Doha Declaration (subparagraph 19) and the technical aspects studied by the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO).

7.2.1 The Convention on Biological Diversity

The progress in living organisms exploration techniques and the economic potential of biotechnology have given rise to a new consideration of the "hidden" value of genetic and biochemical resources. Thus, the biological wealth of tropical countries and the associated traditional knowledge have emerged as a new economic, scientific, and technological frontier.

According to the CBD, whose provisions will be analyzed in detail further ahead, there is the obligation for access to these resources and knowledge to comply with the following requirements:

a) Prior obtaining of the informed consent of the State and other holders of knowledge or the biological, genetic, and biochemical resource (PIC).
b) Agreement on the distribution of benefits derived from access to biodiversity and associated traditional knowledge, including the terms of access.
c) Conservation of biodiversity and creation of national capacities to give value added to each country's natural resources.

In accordance with the Charter of the United Nations and the principles of international law, the CBD reaffirms the sovereignty of States over their natural resources

(Article 3), which entails the power to exploit and regulate their access to such resources and, subject the provisions of the CBD and to national legislation, the fair and equitable benefit sharing among the diverse actors (Arts. 15, 16, and 19). The objectives of the CBD are conservation of biological diversity, sustainable use of its elements, the fair and equitable share of the benefits derived from genetic resources, among other means by the appropriate transfer of the pertinent technologies and appropriate financing. These provisions should be complemented with those of Article 15 of the same convention (Access to Genetic Resources).

Article 15 recognizes the authority of governments, in keeping with their national legislation, to control and facilitate access to their genetic resources (subparagraph 1), provided that their use is environmentally sound and no restrictions contrary to the objectives of the Convention are imposed (subparagraph 2).

Access is subject to prior informed consent of the Contracting Party, unless the latter provides otherwise, and it will be carried out in mutually agreed conditions (subparagraphs 4 and 5).

Finally, each country may take legislative, administrative, or political measures in accordance with Articles 16 and 19 to share fairly and equitably the results of research and development activities and the benefits derived from commercial and other use with the Party contributing such resources. This sharing will be carried out in mutually agreed conditions.

Access to genetic resources is complemented with Articles 16 and 19 of the CBD. When negotiating it, the developing countries invoked the wealth of their genetic resources to include rules that would allow them to acquire technology. However, most of that technology is now in the hands of large private corporations, whereas the provisions of new trade agreements tend not to compensate for contributions of the raw material (genetic resources) and local communities for the improvement of crops, animals, pest control, and natural medicine, all of which is the subject of concern. The stance of the developing countries was initially rejected by various developed countries, which sought a "more classic" convention referring to topics on conservation and use of biodiversity. In the process the guidelines on IPR that had gained importance in the Uruguay Round of GATT and the North American Free Trade Agreement (NAFTA) emerged.

Article 19 (biotechnology management and sharing of its benefits) is in line with Article 15, but restricts its scope to biotechnological research (subparagraph 1), reiterating the power of the Parties to adopt practicable measures to promote fair and equitable conditions for access to the results and benefits of biotechnologies based on genetic resources.

The most controversial article is 16 (Access and transfer of technology). At its origin is the common concern of the developing countries since the 1970s of putting forward the potential of their biological resources to benefit from transfer of technology, a position that would subsequently take on major importance due to the development of biotechnology, which is now at the center of the dispute because its property is essentially in private hands.

The developing countries' access to technology will be assured or facilitated in fair conditions and in the most favorable terms, including the preferential conditions

that are established by common agreement and, whenever necessary, through the financial mechanism of Articles 20 and 21.

Discussion of this issue was conflictive, with a clear "North-South" nuance and references to the obligations derived from IPRs. According to Article 16 it was determined that in the case of technology protected by patents and other IPRs, its access and transfer will take such rights into account. Article 16 permits each Contracting Party to take the legislative, administrative, or policy measures to assure, particularly to the developing countries that contribute those genetic resources, access to the technology that uses such material and the transfer of that technology, in mutually agreed conditions, including the technology protected by patents and other intellectual property rights. Paragraph 5 of this article recognizes that patents and other IPRs can influence application of the Convention and that the Parties will cooperate in this regard in accordance with their own laws and international law to ensure that those rights support the objectives of the same.

Article 8 provides that the contracting Parties, insofar as possible, will respect, preserve, and maintain the knowledge, innovations, and practices of local and indigenous communities that involve traditional lifestyles that are pertinent for the conservation and sustainable use of biological diversity and will promote their broader application with the approval and participation of those who possess such knowledge, ensuring that the benefits are equitably shared.

Other important articles are 10, subparagraph c (protect and encourage the customary use of biological resources in accordance with traditional cultural practices compatible with conservation or sustainable use), 17, subparagraph 2 (exchange of information on traditional and autochthonous knowledge), and 18, subparagraph 4 (fostering and developing cooperation methods for the development of technologies, including traditional and autochthonous ones).

7.2.1.1 Resolutions of the Conferences of the Parties of the Convention on Biological Diversity

Decision III-5 of the Third Conference of the Parties of the CBD (access to genetic resources) requested the Executive Secretary to cooperate with WTO to explore links between Article 15 of the Convention and the TRIPS Agreement. Decision III-17 resolved that more research was required to determine such links on the points relative to technology transfer, conservation and sustainable use of biodiversity, fair and equitable sharing of benefits, and protection of traditional knowledge. The Fourth Conference (Bratislava, 1999) emphasized the need to ensure consistency between the provisions of CBD and TRIPS to reconcile concerns over biodiversity and protection of IPRs (IV-15). Decision V-26 of the Fifth Conference (Kenya, 2000) requests WIPO and the International Union for the Protection of New Varieties of Plants (UPOV) to consider the provisions of CBD, including the repercussions of IPRs on the conservation and sustainable use of biological diversity and in particular the value of traditional knowledge. Later on it invited WTO to take into account that TRIPS and CBD are related and called upon it to explore that relationship more in-depth. Resolution VI/24/C 1, "The role of intellectual property rights

in the implementation of distribution of benefits agreements," invites the governments and the Parties to promote the disclosure of the origin of genetic resources in IPR applications when the protected subject matter consists of genetic resources or makes use of them. Numeral 2 makes the same invitation in relation to associated traditional knowledge. At the Seventh Conference of the Parties, Decision VII/19 requested the Working Group on ABS to identify the aspects relative to the disclosure of the origin of genetic resources and associated traditional knowledge in IPR applications, including those relative to the certificate of origin/source/legal provenance. It also requested WIPO and UNCTAD to prepare studies on disclosure of origin in IPR applications, based on a list of topics to be addressed.

7.2.1.2 Negotiation of an International Regime and Its Implications for IPRs

In the CBD negotiations, the developing countries strove to include the sharing of benefits derived from the use of genetic resources as an objective of the Convention. Although the convention included these nations' positions, little has been done to put them into practice. The Working Group on ABS concluded its work in October 2000 in Bonn with the document "Bonn Guides on Access to Genetic Resources and Distribution of Benefits," approved by the Sixth Conference of the Parties, held in The Hague in 2002.[3] Such guidelines were welcomed by the developed countries and companies with interests in these resources, but some developing countries considered them insufficient on account of being of voluntary compliance and paying little attention to the measures to be taken by the developed countries to fulfill their obligations, especially administrative, policy, and legislative measures for sharing benefits.

In a parallel manner the Group of Like-Minded Megadiverse Countries (GAPMA) was formed through the Cancún Declaration in January 2002 (see www.megadiverse.com).[4]

At the Johannesburg Summit on Sustainable Development, GAPMA scored a victory point by furthering the establishment of an international regime that effectively promotes and safeguards fair and equitable distribution of benefits, a resolution embodied in paragraph 42, subparagraph O, of the Johannesburg Action Plan. In its resolution 57-260 of December 20, 2002, the United Nations General Assembly invited the Conference of the Parties to take the necessary measures in relation to the commitment of the Summit to negotiate the said regime.

Decision VII/19 of the Seventh Conference of the Parties resolves that one of the elements of the International Regime shall be an international certificate of origin/source/legal acquisition of genetic resources and associated traditional knowledge. Point E (Measures of user countries) establishes the need to address the disclosure of origin as a mechanism to support compliance with access legislation, prior informed consent and mutually agreed terms. Point 6 requires the Working Group for Access to Genetic Resources to analyze the feasibility, cost, and practicality of the certificate of origin.

Decision VII/19 agrees to call once again the Working Group on Access to Genetic Resources and Distribution of Benefits so that ". . .in collaboration with the

Working Group of Article 8, subparagraph J, on traditional knowledge, and ensuring the participation of indigenous peoples and communities, non-governmental organizations, industry and academic and intergovernmental institutions, it elaborate and negotiate an international regime of access to genetic resources and sharing of benefits in order to adopt an instrument or instruments to effectively implement the provisions of Article 15 and 8, subparagraph J, and the three objectives of the Convention."

7.2.1.3 Current Status of the Negotiations of the International Regime

The Eighth Conference of the Parties to CBD met in Curitiba, Brazil, to analyze the topic of the international regime. Although most of the deliberations solved aspects of procedure, a few important topics were agreed on.

Decision VIII/4 resolved to transmit the Annex (the results of the Granada meeting) to the Working Group on Access to Genetic Resources and Benefit Sharing (ABS) at its fifth meeting so that, in accordance with Decision VII/19, it continues the preparation of an international regime, including the following topics:

i) The results of the Technical Expert Group on the certificate of origin/source/legal provenance.
ii) The progress report on analysis of gaps and the matrix.
iii) Other contributions submitted by the Parties related to the subject matter of the Working Group.

The elements of the Annex, under the title "Fair and equitable distribution of benefits," include the disclosure of origin or source in IPR applications that make use or consist of genetic resources and traditional knowledge, including evidence of abidance by the law of the supplying country as regards prior informed consent and benefit sharing.

The paragraph on measures to support compliance with prior agreed consent and Mutually Agreed Terms of the Parties reaffirms that the disclosure of origin in IPR applications is an element of the terms of reference of the Annex to Decision VII/19 D for the preparation of the international regime. It is recognized that the topic has been discussed in WIPO and WTO and the relevant forums are invited to address (or continue) the topic of disclosure of origin in IPR applications, considering the need to ensure that the work supports the objectives of CBD. The Executive Secretary is required to renew his accreditation as an observer before the Council of TRIPS.

In conclusion the following provisions of CBD are relevant to IPRs:

i) Respect for national sovereignty over biodiversity (genetic resources).
ii) Prevention of so-called biopiracy and support for the countries' efforts to establish a system of access to genetic resources that includes the obligation to obtain prior informed consent and fair and equitable benefit sharing.
iii) Protection of traditional knowledge.
iv) Conservation and sustainable use of biodiversity in general.

7.2.2 *The Treaty on Plant Genetic Resources for Food and Agriculture*[5]

The International Undertaking on Plant Genetic Resources was adopted by FAO in 1983. Its objective is to "ensure that plant genetic resources of economic or social interest, particularly for agriculture, are explored, preserved, assessed and made available for improvement and scientific purposes." It declares that plant genetic resources have free access and are part of the Mankind Heritage, but include in one same category elite lines and improved varieties, the latter protected by IPRs. Due to the potential conflict of this category, eight nations, most of them developed, expressed their reserve. Certain developing countries, for their part, questioned the principle of free access and the absence of benefit sharing. This gave rise to the negotiation and approval of clarifications regarding the scope of the Undertaking on the part of FAO. Resolution 4-89 ("the Agreed Interpretation") established that the rights of new plant varieties established by UPOV were not incompatible with the Undertaking and provided that the States should impose minimum restrictions on the free exchange of materials. Finally, the Free Interpretation clarified that the term "free access" did not mean free of cost and that the benefits under the Undertaking were part of a reciprocal system. That same year and as a counterpart to recognition of the rights of new plant varieties, Resolution 5-89 (Farmers' Rights) was adopted. It was stated that throughout history innumerable generations of farmers had conserved, improved, and made available plant genetic resources without their contribution having been recognized. Thus the concept of farmers' rights came into being, those "who arise from the past, present, and future contribution of farmers in the conservation, improvement and availability of plant genetic resources." Such rights are attributed to the international community as trustee for the benefit of present and future generations of farmers.

In 1991, Resolution 3-91 of the FAO Conference recognized that the concept of Mankind Heritage was subject to the sovereignty of States over their plant genetic resources and stipulated that their conditions of access required subsequent clarification, that farmers' improved stock and material for improvement would be available at the discretion of their creators during the development time, and that farmers' rights would be implemented by means of an international fund which had not been constituted.

It is worth mentioning Resolution 7-93, which was issued in response to the signing of CBD, in particular to Resolution No 3 of the Nairobi Act, which established the need to resolve, within the framework of FAO, access to collections *ex situ* not covered by CBD and the issue of farmers' rights. Resolution 7-93 requested the Director General of FAO to organize a Negotiations Forum among the governments to make the Undertaking with CBD compatible,[6] consider access to plant genetic resources on mutually agreed terms, including *ex situ* collections, and the manner in which to put farmers' rights into practice. Since then, the Commission on Genetic Resources of FAO had been reviewing the Undertaking until the International Treaty on Plant Genetic Resources for Food and Agriculture was concluded.[7] The central topics of this treaty are access to genetic resources, farmers' rights, the possibility of

authorizing IPRs on the materials of the Multilateral System, relations between the treaty and other international agreements, especially TRIPS, and the list of species to be considered.

The disputes on farmers' rights centered on their own definition, whether as an abstract concept (proposed by some developed countries) or as a specific right to be carried out. It was agreed that the responsibility of making them a reality was the responsibility of national governments. Each Party, according to its own legislation, should adopt the following measures: protect traditional knowledge related to plant genetic resources and guarantee the right to participate equitably in benefit sharing and decision making. None of the above would limit other rights of farmers to conserve, use, exchange, and sell crop resources conserved in their farms (Article 9) in accordance to national laws and as appropriate.[8]

With regard to access to genetic resources and benefit sharing, a Multilateral System was created for the species included (some 35 crops and 29 forage species listed in Annex 1) to be "efficacious, effective and transparent to facilitate access to plant genetic resources for food and agriculture and share in a fair and equitable manner the benefits derived from the use of such resources" (Article 10). The Multilateral System should include all the resources in Annex I which are under the Administration and Control of the Contracting Parties and are in the public domain (Article 11). Access will be carried out under the conditions indicated in Article 12 and the sharing of benefits includes exchange of information, access to technology and its transfer, promotion of the capacity and distribution of monetary benefits derived from commercialization (Article 13). When the product incorporates material whose access is protected by the Multilateral System, the beneficiary should pay an "equitable" part to the International Fund, except when the product is at the unrestricted disposal of other persons for research and subsequent improvement, in which case the receiver should be encouraged to make such a payment. In other words, if the product is protected by a patent, payment will be compulsory; if it is protected by plant breeders' rights or lacking any kind of rights, payment will be voluntary.[9] The amount, form, and type of payment should be defined by the Governing Body of the Treaty in accordance with commercial practice (Article 13).

The receivers shall not claim any IPR or of any other type that limit facilitated access to plant genetic resources for food and agriculture or their parts or genetic components in accordance with the Multilateral System (Article 12).

To date, the Commission on Genetic Resources, acting as an Interim Body of the FAO Treaty, has the draft of the Material Transfer Agreement with the standard provisions governing the transfer of genetic resources by means of the Multilateral Access System.

In conclusion, the main provisions of the Treaty on biodiversity are the following:

a) Restrictions on the authorization of IPRs on the material received as such by the Multilateral System. Nevertheless, restrictions should be incorporated into the Material Transfer Agreement, and therefore its drafting escapes the norms of intellectual property.

b) Recognition of the right of farmers to reuse, exchange, or sell protected seeds and to protect traditional varieties by means of a system of exclusive rights similar to those of IPRs.
c) Compatibility of the Treaty with the protection of plant varieties in keeping with UPOV.
d) Support for conservation, sustainable use, and fair and equitable sharing of the benefits derived from access in accordance with the objectives of the FAO Treaty (Article 1).

7.2.3 Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore[10]

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore of WIPO was established in October 2000 as a forum for dialogue on the relationship between intellectual property and traditional knowledge, genetic resources, and traditional cultural expressions.[11] At the session of the General Assembly of WIPO in 2005 it was decided to extend the mandate of the Committee 2 years, including the possible drafting of legally binding instruments. One of the topics the Committee continues to consider is disclosure of origin in patent applications and protection of traditional knowledge. The Committee has met on nine occasions.[12]

To date, WIPO's main work in genetic resources and traditional knowledge is the following:

7.2.3.1 Genetic Resources

i) Diverse analyses and creation of a database on IPR clauses in the agreements on access to genetic resources and benefit-sharing, including agreements on transfer of materials and model clauses, which are at the draft stage.
ii) With regard to access to genetic resources, WIPO has prepared a number of studies on the clauses relative to IPRs in the agreements on access to genetic resources and benefit sharing, including agreements on transfer of materials and model clauses. A database on public examples has also been created, with emphasis on IPR clauses. Likewise, draft guidelines on IPR clauses in agreements on access and benefit sharing have been prepared.
iii) Similarly, in accordance with Decision VI/24 of COP, WIPO was invited to prepare a study on disclosure of origin in patent applications which should include, among other aspects, (a) the genetic resources used in inventions; b) the country of origin of the genetic resources used in inventions; c) the associated traditional knowledge, innovations, and practices used in inventions; d) the source of associated traditional knowledge; and e) evidence of prior informed consent. This Technical Study of the requirements of disclosure of

origin in patent applications was submitted to the Seventh COP in Malaysia and received by the COP with appreciation (Decision VII/19/E). Furthermore, the Seventh COP requested WIPO to prepare a new technical study that would include examining and addressing, as appropriate, aspects relative to the relationship between access to genetic resources and disclosure of origin in patent applications, including the following aspects, among others:

1) Options of models for disclosure requirements.
2) Suggestions for application procedures for IPRs in relation to disclosure.
3) Incentive options for applicants.
4) Identification of the implications of requirements for disclosure in treaties administered by WIPO.
5) Aspects of intellectual property originated by the draft certificate of origin/source/legal provenance.

WIPO prepared the technical document "Study of the issues relative to the interrelation between access to genetic resources and requirements of disclosure of origin in applications for intellectual property rights" (WO/GA/32/8) at the request of the COP.

iv) Together with UNCTAD and the Secretariat of CBD, WIPO prepared a study on the role of IPRs in connection with technology transfer (February, 2006).
v) Despite the abundant information generated by WIPO and the exchange of opinions and positions in the sessions of the Committee, these debates have not translated into initiatives for national or international legal amendments on disclosure of origin in IPR applications.[13] Some countries have questioned whether WIPO and not WTO should be the entity in charge of processing this topic, doubting that its steps would lead to specific normative advances.
vi) In the reviews of the Substantive Treaty on Law of Patents, disclosure of origin has been discussed. Pursuant to the mandate of the 2005 General Assembly a process of two sessions of the Standing Committee on Law of Patents was established, one formal and another informal, to analyze the proposals.[14] The topic is also under discussion in the Patent Cooperation Treaty.

7.2.3.2 Traditional Knowledge

In relation to protection of traditional knowledge, WIPO has prepared a number of documents on positive and defensive measures of protection and other activities such as the following:[15]

i) Systematic study and clarification of the legal options for the protection of traditional knowledge.
ii) Analysis of cases of the use of IPR to protect traditional knowledge, as well as the establishment of *sui generis* protection systems.
iii) Case studies and analysis of practical experiences.

iv) Draft of the Tool Kit to document traditional knowledge associated with genetic resources.
v) Gradual recognition of traditional knowledge in patent systems by means of patent examiners, mechanisms to ensure better understanding of traditional knowledge as a previous art by means of links with databases and incorporation of traditional knowledge in the minimum novelty search standards by the authorities of the Patent Cooperation Treaty.
vi) Draft policy objectives and fundamental principles in connection with traditional knowledge. These provisions are considered compatible with CBD, although their scope is broader than that of traditional knowledge related to biodiversity. Such provisions are particularly important for establishing national rules.[16]

7.2.4 Principal Positions in WTO

7.2.4.1 Important Rules of TRIPS and Discussions of WTO

The TRIPS Agreement negotiated during the Uruguay Round of GATT establishes in Article 27 the obligation of the Member States to confer protection by means of patents in all fields of technology without any discrimination whatsoever.[17]

Patent rights can be obtained and enjoyed without discrimination as to the place of invention, the field of technology, or whether the products are imported or manufactured in the country.

Members can exclude from patentability any inventions whose commercial exploitation in their territory should be prevented to protect *ordre public* or morality, the health or life of persons or animals, preserve plants, and avoid serious damage to the environment, provided that such exclusion is not done merely because the exploitation is prohibited by their legislation.

Without an appropriate set of exceptions and limitations, this general provision would entail, for instance, the need for the member countries to grant protection to modern biotechnological inventions. Nevertheless, due to the discrepancy regarding the scope of protection of inventions related to plants and animals, Article 27.3.b of the Agreement provides the following:

"Members may also exclude from patentability:

a) ...
b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

According to the TRIPS Agreement, there are three options for protecting plant varieties: system of patents, *sui generis* system, or a combination thereof. This last

option was probably drafted considering the United States 1930 Plant Patents Act. The best-known *sui generis* system is that of UPOV, which imposes less onerous requirements for receiving the certificate of plant breeder,[18] but also greater limitations and exceptions and the rights conferred have less scope than patents. UPOV has 1978 and 1991 versions. The countries that have not ratified the Convention can only accede to the 1991 version. However, TRIPS does not require member countries to enact laws based on UPOV, although Article 27.3.b was negotiated with knowledge of its provisions on the *sui generis* system, which is not mentioned either by the international treaties referred to by the TRIPS Agreement.[19]

So countries may establish their own *sui generis* systems on condition that they are "effective." But their conditions and implications for being in keeping with WTO's multilateral system has no univocal answer. Other than recognition that a *sui generis* system should be based on its "own nature," there are no other guidelines.

Article 30[20] provides for limited exceptions to the exclusive rights conferred by the patent on condition that they do not unjustifiably endanger normal exploitation of the patent or cause unjustified harm to the legitimate interests of its holder. The most generalized exception is acts carried out for purposes of research or teaching, which is common in most legislations.

The TRIPS Agreement regulates in detail Enforcement of Intellectual Property Rights, including norms of proceedings and civil and administrative recourses in the face of infringement of rights, evidence, judicial orders, losses, seizures, provisional measures, border measures, penal sanctions, and others.

Should some country fail to comply with the provisions of the Agreement, there is the recourse of the dispute-settlement process pursuant to the WTO provisions. This proceeding, to which recourse has been taken frequently, makes it possible to impose trade sanctions on countries that do not respect IPRs and to use access to markets to compel the adoption of legal changes in accordance with the TRIPS Agreement.

In view of the implications of some changes, transitory terms were established for application of the Agreement: developed countries, 1 year as of the entry into force of the Agreement, that is, January 1996; developing countries, 5 years as of the same date; and less advanced countries, 11 years with the right to extension to amend their legislation. To provide protection by means of patents to technological sectors that did not have them, 10 years.

7.2.4.2 The Concept of the *Sui Generis* System

As has been stated, the only clarifications to the *sui generis* system are the special characteristic of the system and that it should be effective. Few analyses have been carried out regarding the requirements of this mechanism.[21]

Leskien and Flitner (1997) interpret that such conditions mean:

i) Protection of all plant varieties
ii) Exclusion of third parties from use of the protected material, unless remuneration is involved.

iii) Respect for the principles of National Treatment and Most Favored Nation.
iv) The existence of procedures for the enforcement of rights.

The *sui generis* system can depart from the requirements of UPOV in any of its versions and add provisions on protection of farmers' rights, that is, on landraces, whose requirements vary according to whether it is a question of benefit sharing for use of genetic material or of authorizing instruments such as the certificate of origin; and it should modify the requirements and rights granted to the holders of varieties and therefore the actions that require authorization.

Leskien and Flitner propose a different *sui generis* scheme from that of UPOV with more precise definitions on material that can be protected, protection requirements, inclusion of elements such as certificate of origin and value of crop and use, sphere of protection (acts that require authorization or remuneration to the holder), duration of rights, "interface" with other IPRs and registers, funds, and benefit-sharing mechanisms.

Although the provisions of *sui generis* systems should have been reviewed in the Council of TRIPS I 1999, the Members limited themselves to compiling information on its compliance by the countries.[22] The developing countries had until January 1, 2000 to enact the respective laws, unless the alternative chosen was patentability of plant varieties, in which case the term was extended until 2005.

7.2.4.3 The Doha Round: Link Between TRIPS and CBD

The Doha Declaration that inaugurated the WTO Round of Trade Negotiations under way recommended to the Council of TRIPS to examine the relationship between this agreement and CBD, protection of traditional knowledge and folklore, and the new matters submitted by the Members based on the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement, taking the dimension of development fully into consideration.

One measure suggested to achieve a synergic relationship between CBD and intellectual property systems (particularly TRIPS) was disclosure of origin of genetic resources or associated traditional knowledge in IPR applications, especially patents. This request has been put forward for various years in CBD, WTO, WIPO and in numerous forums and reports.[23]

Disclosure of origin in IPR applications based on the Doha Declaration has been discussed in WTO. The main positions of the countries or groups of countries can be summarized as follows:[24]

The African Group proposed to eliminate patents on life forms in the framework of the TRIPS Agreement and include disclosure of origin in IPR applications.

The United States, to a certain extent with the support of Japan, was opposed to including disclosure of origin in patents since it considered that this would not solve the problems stemming from undue appropriation of genetic resources and traditional knowledge and would give rise to uncertainty and practical problems in IPR systems. Both countries proposed improving the quality of the patent granting process, creating databases and other mechanisms to eliminate problems associated

with "bad patents," using existing systems of nullity and revocation, etc. They did not consider that there was conflict between TRIPS and CBD and, to avoid undue appropriation, proposed strengthening access laws and the use of contracts.

Switzerland proposed modifying the Patents Cooperation Treaty since it considered the requirements for disclosure of origin formal and not substantive, together with its regulations for permitting (not obliging) countries to include disclosure of origin of genetic resources in IPR applications based directly on such resources.

The so-called "Friends of disclosure" (Brazil, China, Cuba, Dominican Republic, Ecuador, India, Kenya, Pakistan, Peru, Thailand, Venezuela, Zambia, and Zimbabwe), with occasional support of other countries, maintained that TRIPS and CBD should mutually support one another.[25] They suggested amending the TRIPS Agreement and argued that patenting of biological resources could encourage biopiracy and undue appropriation to the detriment of national sovereignty recognized by CBD. They pointed out that TRIPS did not contain elements that assure prior informed knowledge of the holders of biological material used in patented inventions nor did it permit the countries of origin to claim benefit sharing (Box 7.1). They therefore requested inclusion of the obligations to (i) disclose the source and the country of origin of biological resources and the traditional knowledge used in patent applications; (ii) evidence prior informed consent in accordance with national laws, and (iii) prove the fair and equitable sharing of benefits obtained according to national regimes.

Box 7.1 Disclosure of Origin in Intellectual Property Rights

Although the idea of disclosure of origin/evidence of prior informed consent/evidence of benefit sharing has mainly been discussed within the framework of the patents system, it is also applicable to plant varieties and their respective approval processes.

The objectives of the proposal are:

1. Transparency: Permit national authorities that authorize access to genetic resources to track their use in patent applications and titles.
2. Compliance with conditions of access: Permit compliance to be tracked with prior informed consent and the conditions under which access was granted.
3. Determination of previous art: Permit a better analysis of novelty and inventive step by Patent Offices.
4. Relationship between the TRIPS Agreement and CBD: Prevent conflicts between TRIPS and CBD and support the implementation of both.
5. Biopiracy: Control biopiracy or undue appropriation of genetic resources or traditional knowledge through the granting of "bad patents."

In the case of plant varieties, the 1991 UPOV Convention establishes that the requirements for granting or canceling new plant variety rights should not be diverted from those provided for. It specifically indicates that the rights of plant breeders should not be subject to additional conditions (Article 5), provided that national formalities and payment of rates have been complied with. Rights will not be annulled for reasons other than those indicated in Articles 21 and 22. UPOV is not opposed to disclosure that facilitates examination, as long as it is not considered an additional protection requirement.

The article provides for its own subjection to countries' formalities. Therefore, stipulating disclosure of origin as a non-substantive formal requirement is legally possible. If not submitted, the application will not be processed. The second aspect to be considered is false disclosure of origin. The countries that demand the requirement have opted for one of the following solutions: cancellation of the patent (India, Brazil, the Andean Community) and penal, administrative, or civil sanctions outside patent law (Norway, Denmark, Belgium, Sweden, and other of the European Union). Third, it is important to consider the particularities of origin of plant varieties and the extent to which the legality of access to material of domestic or foreign origin would be safeguarded, the latter being the most probable in the case of imported materials.

In this regard, the Report of the Commission on Intellectual Property Rights stated that "the countries should provide in their legislation for compulsory disclosure in patent applications of the geographical origin of the genetic resources from which the invention derives."

Source: Girsberger (2004) and own preparation.

The European Union accepts addressing the topic in WTO, although it considers WIPO the most appropriate forum. However, its proposal on disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications submitted to the WIPO Committee (November 16, 2004) includes compulsory requirement to disclose the country of origin or source from which physical access was obtained; the invention should be directly based on genetic resources; the requirement would apply to traditional knowledge, a concept that requires greater study; of the patent applicant does not submit the information despite having been granted the possibility, the application will not be processed; if the information is incorrect or incomplete, effective, proportional, and dissuasive sanctions outside patent law should be provided for; a notification procedure should be introduced by Patent Offices to CBD's Information Exchange Mechanism to inform the country of origin of the respective application. The European Union appears to be ready to discuss obligatory disclosure of origin in patent applications, provided that there is a direct relation between the invention and the genetic resource. The consequences of not respecting it will be regulated outside the patents system.

Norway does not consider that there is any contradiction between TRIPS and CBD and has indicated its preference for national actions, but prefers to discuss disclosure in WTO, although possibly with more limited language consistent with its own national regulations (which demand evidence of previously informed knowledge, but not of benefit sharing).

The Hong Kong Ministerial Meeting did not include a negotiation proposal despite the insistence of India, Brazil, and Peru, but took note of the work of the TRIPS Council in accordance with paragraph 19 of the Doha Declaration and agreed that the work would continue on the basis of this paragraph and the progress made to date. Furthermore, in accordance with paragraph 39, relative to implementation aspects, it was decided to address the relationship between the TRIPS Agreement and CBD with the participation of the Deputy Director of WTO.[26]

Finally, toward the end of May, six countries, among them India, Brazil, and Peru, submitted a proposal for changes to TRIPS to support disclosure of origin by means of the incorporation of Article 29 bis,[27] the main provisions of which are

i) Establish a relationship of reciprocal support between CBD and TRIPS.
ii) Include biological resources and associated traditional knowledge.
iii) Disclosure of origin in applications for patents developed with biological resources or associated traditional knowledge.
iv) Disclosure of country or source supplying the resources or the knowledge and provide evidence of compliance with requirements applicable in the supplying country on prior informed consent and fair and equitable sharing of benefits derived from use of the resources or associated traditional knowledge.
v) The Parties may require the applicant to complement or correct the information described above if the latter had knowledge of new information.
vi) The Members should publish the information disclosed together with the application or granting of the patent. The same is provided for in the case of information supplied to complement or correct the information initially disclosed.
vii) The Parties should prevent the processing of the patent or its granting, revoke it, or declare it non-executable when the applicant has not complied with disclosure obligations or has supplied false or fraudulent information.

7.2.4.4 Disclosure of Origin and Free Trade Agreements

The implications of free trade agreements signed by numerous countries with the United States and the European Union and their provisions on IPRs should also be considered. The most controversial case is the Free Trade Agreement between Central America, the Dominican Republic, and the United States (DR-CAFTA), which has been said to establish a limitation with regard to disclosure of origin. The language of DR-CAFTA comes from the United States law, in which each Party establishes that disclosure of a claimed invention should be considered sufficiently clear and complete if it provides information that allows the invention to be repeated or used by a person skilled in the art, without undue experimentation, to the date

of submission (Article 15.9.9). The doubt that arises is whether the text prevents requesting further information at the time of disclosing the patent. No mention is made of the obligation to indicate the best mode of carrying out the invention, as required by many national laws.

7.3 Relations Between Intellectual Property and Biodiversity

CBD reaffirms countries' sovereign right over their natural resources, which is firmly rooted in international law. At the same time it establishes the objective of fair and equitable sharing of benefits resulting from the use of biological, genetic, and biochemical resources. None of these aspects is considered by the Intellectual Property System. Thus, many have seen a conflict between the intellectual property system (especially due to its extensions to living matter) and CBD. If such a conflict exists, its topic is of a high political and emotional expression.

Application of intellectual property to biodiversity entails the topic of protection of living matter or, as it has been called, the "patentability of life."[28] The controversy, which arose with special force in the 1990s, presented the following points (Dutfield, 2002):

1) The moral implications of treating inventions relative to plants, animals, microorganisms, their components such as genes, gene sequences, proteins, cells, etc., as property.
2) The way in which such property endangers basic considerations of patent law such as novelty, inventive level, description of the invention, exhaustion of rights, and, in some cases, elimination of the distinction between invention and discovery.
3) The possibility that basic research and commercialization may be discouraged by broad claims of patents involving biotechnological research instruments and due to the conflicts between patents.
4) The possibility that IPRs on life forms support so-called biopiracy, that is, the appropriation of genetic material and traditional knowledge without the consent of the countries and communities and indigenous peoples or without adequate benefit sharing.
5) The way in which IPRs can hinder or limit farmers' rights to keep, reuse, exchange, and sell seeds and other propagation material conserved on their farms.

For a more in-depth understanding of the implications of the debate, a few central points are considered below.

7.3.1 Intellectual Property Rights and Discoveries/Inventions

IPRs exclude third parties from use of inventions that are new, possess an inventive step, and have industrial application, which excludes discoveries. Genetic and biological resources in their natural state are not subject to protection by means of

IPRs. Therefore, to talk about privatization of biodiversity by means of patents for living matter is inexact. An altered biological entity fulfills protection requirements for patents without affecting sovereign right over the original entity. However, the types and interpretation that biotechnology patents have been acquiring in developed nations, especially the United States, appear to erase the difference between invention and discovery.

Nor is the situation clear regarding unmodified living substances. In the United States and the European Union protection can be given to the holders of unmodified genes and microorganisms, provided that they are isolated from their environment, their existence has not been known, and their usefulness has been determined. With this interpretation, the distinction becomes thinner and thus the claims for appropriation of matter existing in nature increase.

As Correa (1999) states, "In the United States, according to the principles developed for chemical patents, an isolated and purified form of a natural product is patentable. The requirement of 'new' does nor mean 'preexisting' but 'novel' in relation to the state of the art, so the unknown but natural existence of a product cannot exclude it from patentable subject matter. As a result of this interpretation, the dividing line between discoveries and inventions is very thin in the United States. (...) This principle and the approach described above have made it possible for the patenting of cells and genes, among other substances, to be preexisting or modified. In the United States, for instance, genes produced by mutagenesis or genetic engineering techniques, and even those whose natural existence was previously unknown, are patentable. The usual in these cases is that claims refer to an isolated DNA sequence, DNA constructions and new derived transformed plants, although they also often include natural sequences of DNA without limitations."

One case of a claim per se is that of the glyphosate-resistant synthetase gene, which protects from the action of herbicides. Here is the text of one of the pertinent claims. "A DNA sequence of less than 5 kb with a structural gene that codifies glyphosate-tolerant 5-enolpyruvyl-3-phosphoshikimate synthase" (Correa, 1999).

In relation to plants it should be considered that patents can be applied to a wide variety of biological material and procedures, among them:

- Isolated DNA sequences that codify for certain proteins
- Isolated or purified proteins
- Seeds
- Plant cells and plants
- Plant varieties, including parental lines
- Processes to genetically modify plants
- Processes to obtain hybrids

In January 2000, the United States Appeals Court ruled that patents for sexually reproduced varieties of plants were valid and rejected the argument that plant breeding rights were only appropriate to protect new varieties. In Europe the situation has been rather confusing, even though recently the "Enlarged Board of Appeal" of the European Patents Office accepted the patentability of claims on more than one variety. This provision is consistent with the adoption by the Administrative

Council of the Office of new "implementation rules" (June 16, 1999), which reflect the provisions of the European Patents Directive, which are accepted with supplementary means of interpretation. It would definitely seem that acceptance of patent protection for plant varieties largely depends on "lawyers' verbal skills" (Llewelyn, 2000).

The development of genomics also gives rise to controversy. Genomics (the study of species' genes and their interaction) is one of the most powerful tools for research and development of agricultural and pharmaceutical products. "Access to and control of complex genomic information is now perceived as the cornerstone for the future development of transgenic plants, and the leaders of the agroindustrial genetic complex have entered a race for being the first to identify – and hopefully own – the genes involved in the regulation of commercially interesting traits and their interactions" (Correa, 1999). The advances of structural (gene mapping and sequencing), functional (identification of the function of genes, when, how, and what genes act together to generate a characteristic) genes and bioinformatics (management and analysis of data resulting from genetic sequences) are another source of controversy due to the possibility that its access and utilization are controlled by IPRs. The cost and capabilities required can increase the lag and dependence of the developing countries.[29]

In regard to this topic, protection of databases is important. However, the WIPO Treaty on copyright and the developments in different legislations and legislations of regional blocs, such as the European Union, only establish database appropriation rights, not the data in themselves. In other words, genomics information can be stored and consulted at a price, but this does not establish rights over sequences and genes, unless they are subject to independent patents.

7.3.2 Sovereignty over Genetic Resources

Whereas the sovereignty of States refers to genetic resources (including biochemical ones), application of IPRs to modifications that meet the basic requirements of protection will not affect rights over unmodified living matter. But if the definition of sovereignty includes synthesized or derivative products (i.e., the Common Access Regime of the Andean Pact), these become the object of IPRs, which could create a conflict due to the extension of the concept of sovereignty beyond genetic resources (Article 2 of CBD). It is probably necessary to distinguish derivative products (such as biochemical resources) subject to the access regime of those that consist of final or synthesized products (see Glowka, 1998). In any event, the latter could well be the object of negotiations for benefit sharing, in the case of products based on genetic and biochemical resources.

7.3.3 Protection of Microorganisms; Definition of Essentially Biological and Microbiological Processes[30]

The obligation to protect microorganisms can be conflictive due to the lack of definition of the "microorganism" concept, so in certain nations a broad interpretation

makes it possible to protect sub-cellular material such as genes, genetic sequences, and plasmids. According to the European Patents Office, the term "microorganism" includes not only bacteria and yeasts but also fungi, algae, cells, protozoans, plasmids, and viruses.

However, countries can decide to protect only modified microorganisms (Brazilian law on industrial property), interpret the concept in a restricted manner (excluding genes and genetic sequences), or limit the scope of the patent to a specific use of the product, which would be compatible with TRIPS.

The TRIPS Agreement stipulates protection of microorganisms but does not mention genes or genetic sequences, at the same time as it admits granting patents in all areas of technology, which would seem to permit protection of the latter. The thesis would seem to uphold that DNA is only a chemical structure. For example, there would be no legal problem on patenting DNA sequences produced in laboratories, which are different from natural ones and some sections of the molecule would have been eliminated in the process. There are arguments against this. For example, the elimination of junk DNA is obvious to an "expert in the art" for the techniques of isolation and purification of DNA are common use. Patents for genes and genetic sequences should be analyzed first from the point of view of the impossibility of granting them if the product does not have a known function[31] And second, the option of protecting sequences, that is, parts of genes, entails a dangerous fragmentation of the patentable subject matter which can increase the number of holders whose permits are necessary, if not for research, then to place a product on the market, with the negative consequences for research and development.[32]

Finally, defining and setting the limits on essentially biological processes, microbiological, and non-microbiological (chemical, etc.) ones are not easy to do, especially in biotechnology, nor do uniform solutions exist in the world.

It is not altogether clear how far the theory that propounds the impossibility of patenting recipes from nature (Gollin, 1994) is being transgressed by new legal interpretations and rules and whether these affect national sovereignty.

7.3.4 Patented Traits Present in Natural Form

It is advisable to consider the effects of intellectual property systems on biological resources. If a patented trait (the gene and the protein for which it codifies) is manifested in natural form and it is possible to incorporate it into plants by conventional improvement methods, there would be a not altogether clear interface between the patent holder and the traditional improver (Correa, 1999). Barton (1997a) states that in this case the patent holder is protected against use of the gene by another biotechnologist but leave third parties free to use and improve organisms that naturally contain the gene.

Although it is not a similar antecedent, it is worth citing the lawsuit of the Monsanto Company against the Canadian farmer Percy Schmeiser, sued for using soy resistant to glyphosate. Schmeiser argued in his defense that his crops were contaminated with transgenic soy from neighboring crops, by accidental spillage

or carried by the wind, and he never used it intentionally, even though he had it in his possession. The Court ruled in favor of Monsanto under the argument that Schmeiser lacked the right to use the gene protected by patent law without authorization, even if it was naturally deposited on his land. The effects of this jurisprudence (now under appeal) on the farmer's civil responsibility in fields with transgenic and non-transgenic crops have yet to be seen, but they could entail major risks for those who, even without using genetically altered varieties, could be subject to costly and long judicial proceedings (Louwars and Minderhoud, 2001).

7.3.5 Effects on Traditional Uses

There is concern over patents that cover an active component of a plant traditionally used by local or indigenous communities. The effect of such protection could restrict the possibility of peoples to export the plant to the country that protects it, even for different or unrelated medicinal uses. This issue has become more relevant due to complaints that the patents system is a mechanism for appropriation of traditional knowledge and genetic resources without fair and equitable benefit-sharing and without informed consent. The above has been denounced as biopiracy on resources and knowledge, as in the cases of neem, curcuma, quinoa, Mexican bean, ayahuasca, nuna bean and yacon. In these and other hypotheses, preexisting biological resources with minor modifications and broadly disclosed traditional knowledge (which would cancel out the novelty of the invention, at least in theory) have been the basis for applying for IPRs without meeting the requirements of inventive level and without the prior informed consent of the peoples, communities, or countries. Some of these patents have been revoked, thus accepting that they should never have been granted. In other cases it has been argued that IPRs have been used to appropriate genetic material under the custody of international agricultural research centers, as has been denounced against 147 IPR applications on plants. In one third of the cases the materials were obtained from other countries without evidence of improvement and another 16 involve germplasm under custody, to which no protection should be granted (IDRC, 1994).

7.3.6 Functional Patents

Functional patents, those that cover all possible means of solving a problem (Correa, 1999), such as granted to Agracetus, which excludes third parties from any genetic manipulation of cotton and soy, or patents on the use of BT technology,[33] which hinder practically any process involving the use of this substance, have given rise to problems for agricultural research, one of the ends that IPRs should contribute to attaining.

In order to limit the pernicious effects of functional patents, the International Plant Genetic Resources Institute (IPGRI, 1999) proposes, among others:

i) Antimonopoly laws.
ii) That the burden of proof on the functioning of claims should fall on the patent applicant and not on its challengers.
iii) Rigorously apply the requirements of inventive level and industrial application.
iv) Establish mechanisms that balance the claims of initial and subsequent innovators.
v) Limit or prohibit the use of functional claims.

7.3.7 IPRs and Traditional Practices of Reuse and Exchange of Seeds

Article 10 of CBD promotes customary practices of use of biological resources, one of which is keeping seeds for reuse and sale. When it has not been possible to protect this practice by technical means (as in the case of hybrids which, although they can be reused, lose their vigor), efforts have been made to restrict it by legal means, especially through patents, plant breeding rights and contracts. Protection prevents seeds from being reused, a practice considered essential by some to conserve biodiversity and the way of life of farmers themselves, and therefore its restriction should be seen as an infringement of Article 10 c and the principles of CBD.

Some reports and decisions of United Nations agencies warn of the possible implications of these tendencies, indicating risks and impacts on human rights and development (UNDP, Report on Human Development, 1999). In August 2000, the Sub-commission for the Protection of Minorities of the Commission on Human Rights adopted a Resolution on Intellectual Property Rights and Human Rights that points to current or potential conflicts such as obstacles in the application of IPRs for technology transfer to developing countries; the consequences of IPRs on genetically modified organisms and the basic right to food security; reduction of communities' control over their genetic resources, their cultural values and the possibilities of biopiracy; and restrictions on access to patented medicines and their implications on the basic right to health. The Resolution requests WTO to take human rights into consideration during the TRIPS negotiations.

7.3.8 IPRs and Genetic Erosion

A concern for those related to genetic improvement, agricultural production, and food security is the conservation of plant and animal genetic resources as a reserve for creating new varieties, seeds, and crops. Plant genetic resources have been defined as essential for agricultural development, increasing production, alleviating poverty, and promoting economic growth (Cooper et al., 1994). The phenomenon of genetic erosion has therefore been denounced as a threat to food security. Recent trends regarding protection of plants and animals by means of patents and new plant variety rights could reduce genetic diversity. This would occur when modern and homogeneous varieties (the homogeneity and stability of varieties is a requirement for obtaining their protection), on being used massively by farmers, would displace

local varieties (much more diverse) and create dependence on a narrow genetic base (Cooper et al., 1994). This dependence and homogeneity entails a risk for crops because of their susceptibility to pests and diseases.

Genetic erosion is a significant threat for agricultural production, but its relationship with the requirements of IPR has not been demonstrated. The causes of loss of genetic diversity and the threats to agricultural diversity in general are varied and complex, and it is difficult to isolate the behavior of a specific factor such as the one mentioned and assign it a general consequence. Several studies on activities and processes affecting diversity in general and agricultural diversity in particular do not mention IPRs at all (Dutfield, 2000).

In spite of this, one should consider Reid's stance,[34] who points out a strong connection between IPRs and the direction of agricultural scientific research, which ultimately has a bearing on agrobiodiversity. Reid maintains that whereas IPRs on varieties and plants foster the development of agricultural research aimed at uniform, homogeneous crops, they discourage research on agroecological conditions, which are more adapted to local needs and conditions.

While IPRs foster the development of seeds and varieties with wide demand to recover costs, companies will seek to focus their research on high-value crops and develop varieties that can be cultivated as much as possible. This entails the dissemination of highly homogeneous commercial varieties to be distributed and commercialized. Critics point to the tendency of IPRs to indirectly create systems of mono-cultivation, the consequence of which will be a reduction in biological diversity.

Other factors play more important roles in this problem. According to a study submitted by the Secretariat of CBD to the Third Conference of the Parties in 1996, among the policies that can foster the use of new varieties and the loss of local varieties are credits, subsidies, and other forms of governmental agricultural extension, policies and programs of international agencies and donors, control of corporations over research, distribution of pesticides and agrobiotechnologies, marketing and research, and development policies of transnationals enterprises.

It is difficult to argue that IPRs give rise to perverse incentives to develop technologies that reduce biological diversity (creating genetic erosion and increasing the use of chemicals, among others). Nonetheless, a document issued by the Secretariat of CBD[35] identifies the following categories of impacts of IPRs on the objectives of the Convention:

a) Impact on the traditional knowledge, innovations, and practices of local and indigenous communities.
b) Impact on indirect incentives that affect conservation and sustainable use.
c) Impact on benefit-sharing through the development of technologies that use genetic resources.
d) Impact on transfer of or access to technological and scientific information.
e) Impact of IPRs on mechanisms of exchange of information established in the Convention.

7.3.9 IPRs and Benefit-Sharing

IPR systems have not considered benefit-sharing derived from the use of traditional knowledge or biological resources incorporated into or used by the resulting innovations. Actually it is a question of two approaches that are different rather than contradictory. In any event, the question on the possibility of using IPRs to protect biodiversity remains and can be made as long as IPRs create value for biodiversity by allowing the use of genetic and biochemical resources in biotechnological research.

"It is important to understand that intellectual property rights create value because they provide a protected market for products generated by biodiversity. Pharmaceuticals, cosmetics and similar indirectly create value due to the incorporation of the raw materials of biodiversity (Lesser, 1991). This notwithstanding, it is worth asking whether IPRs are appropriated to claim that value. The answer is negative, for IPRs are not conceived to protect non-marketable materials (Lesser, 1991), in addition to other theoretical and practical inconveniences. Nevertheless, if these rights are accompanied by benefit-sharing agreements they could have a positive impact on distribution.

Some maintain that IPRs could indirectly provide more value to traditional knowledge and to genetic and biological resources if patents were authorized for products based on biological resources, especially in the area of biotechnology, or if it were possible at least to use the different types of intellectual property to protect that knowledge, innovations, and practices when IPRs involve agreements on benefit-sharing.

7.4 Conclusions

Intellectual property rights are linked to national and international policies and legislations related to sustainable development, conservation, and fair and equitable distribution of the benefits derived from the use of genetic resources. It is necessary for the modifications to IPR systems, including those stipulated in free trade agreements, to consider the implications that such rights will have on these issues.

Diverse points of contact make it necessary to proceed in this way, particularly those relative to the manner of synergic implementation of IPR systems and the obligations established in agreements such as the Convention on Biological Diversity, the FAO International Treaty, and the discussions of the Intergovernmental Committee of WIPO. Mechanisms such as disclosure of origin and the design of juridical systems for protection of traditional knowledge, among others, should be explored and, if appropriated, implemented to address the questions on the compatibility of IPRs with other development objectives.

Only through proper consideration of these needs and the search for synergies will it be possible to incorporate the new obligations assumed with regard to IPRs into the processes of sustainable development, which entail the conservation and use of biodiversity and protection of traditional knowledge.

Notes

1. Among other forums, the Council of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), Committee on Trade and Environment of that Organization, Convention on Biological Diversity, and World Intellectual Property Organization (WIPO).
2. See ICTSD-UNCTAD (2003) and Commission on Intellectual Property Rights (2002) on the implications of IPRs on development, biodiversity, and food security. Both documents provide detailed and objective analyses of the implications and tendencies of IPRs on agriculture and access to genetic resources, traditional knowledge, and benefit sharing.
3. The Bonn Guides establish that the Parties with users of genetic resources should consider measures to support compliance with the prior informed consent of the Party providing the same and the mutually agreed terms under which access takes place. These measures include: fostering disclosure of the country of origin of the resources and of the traditional knowledge in IPR applications.
4. Although the language of the Summit refers to benefit sharing, the meeting of the Working Programme of the Convention (Montreal, March 2003) recommended that the Working Group consider, at its second meeting, the process, nature, sphere, elements, and types of an international regime of access to genetic resources and benefit sharing.
5. On the evolution of and activities carried out by the Commission on Genetic Resources, see Mekour (2002) (www.fao/ag/cgrfa) and Cooper (2002).
6. Decision II-7 of the Second Conference of the Parties in 1995 had already recognized the distinctive characteristics of Agricultural Genetic Resources.
7. The Treaty entered into effect on 29 July 2004 with ratification No. 50.
8. The Preamble stipulates that the rights recognized by the Treaty to conserve, use, exchange, and sell seeds and other propagation material conserved in farms is fundamental to the validity of farmers' rights.
9. On principle, for even if the product is patented, broad exceptions could be applied with regard to research. And if it is not, access to the material could be restricted by means of contracts.
10. Other aspects related to disclosure of origin are also discussed in the Standing Committee on the Law of Patents (Substantive Treaty on Law of Patents) and in the Working Group for the Reform of the Patent Cooperation Treaty, both of WIPO.
11. See other details at www.wipo.int/tk/en/igc/
12. At its last session, the Committee limited itself to taking note of the documents and proposals for decision that it reviewed, without taking any substantive decision with regard to the topics of genetic resources and intellectual property, traditional knowledge, and folklore.
13. The European Union's proposal on disclosure of origin for genetic resources and associated traditional knowledge in patent applications (November 16, 2004) includes compulsory requirement to reveal country of origin or source in patent applications, valid for national, regional, and international applications; the applicant must declare the country of origin or the source to which the inventor had physical access; the invention must be based directly on genetic resources; the requirement would apply to traditional knowledge, a concept that requires further study; not process applications that are not accompanied by the required information; provide for effective, proportional, and dissuasive sanctions, outside patent rights, for those who turn in incorrect or incomplete information; notification procedure in charge of the Patent Offices to advise the country of origin of the respective application.
14. India has proposed that the Committee on Genetic Resources should meet with the Committee on Law of Patents.
15. Cfr. WIPO, "Intellectual Property and Traditional Knowledge", Booklet No 2.
16. The Committee has developed a draft of objectives and principles on traditional cultural expressions or Folklore, which can be part of protection of traditional knowledge in the broad sense of the word. The Committee distinguishes protection in the strict sense (traditional knowledge) and broad sense (traditional cultural expressions).

17. The forum for dealing with topics related to intellectual property had traditionally been WIPO. Nevertheless, due to its lack of effective dispute settlement mechanisms, GATT was considered the most viable alternative for changing the forum for negotiations and establishing minimum standards. As a result of the negotiation of the Substantive Patent Law Treaty (SPLT), WIPO has once again been supported as the main regulator on the matter. See Correa and Mussungu (2002).
18. Basically it is required that the variety be homogenous, stable, new, different (in the commercial sense), and have a denomination.
19. UPOV is considered neither necessary nor sufficient to comply with such a provision because a) it is not required by Article 27.3.b and b) it is not sufficient, since the mandate of TRIPS requires as different system from that of UPOV1991. For example, the granting of National Treatment only to UPOV members (based on the principle of reciprocity) would be in violation of TRIPS. Furthermore, UPOV permits initial protection of a limited amount of varieties, whereas TRIPS includes them all.
20. In a case taken before WTO, the Panel concluded that any exception that substantially reduces the holder's rights would be inconsistent with Article 30 of WTO. This implies that even in the case of patents as a means of solution for the case of varieties, the exceptions of the Right of New Plant Varieties could be incompatible with Article 30 of the TRIPS Agreement (case of the Canadian Patents Law of 2000).
21. Although the TRIPS Agreement does not mention the rights of plant breeders, in one case brought before WTO the Appeals Panel, on analyzing Section 211 of the 1998 United States Omnibus Act, expressed that the *sui generis* rights of Article 27.3.b were a form of intellectual property admitted by TRIPS.
22. At the time of the review there were significant divergences regarding its scope. For the developed countries, the system should center on implementation aspects. Most of the developing countries advocated a substantive review that would conclude in amendments to the text. See the documents submitted by the countries and those prepared by the TRIPS Council at www.wto.org and at International Center for Trade and Sustainable Development, www.ictsd.org.
23. On technical and legal aspects concerning disclosure of origin, see WIPO (2005); Sarnoff, Joshua and Correa (2006); Rojas et al. (2005); Sarnoff (2006); Ho (2003); and Hoare (2006).
24. For an analysis of the proposals submitted until February 2006, see "The relationship between the TRIPS Agreement and the Convention on Biological Diversity." Summary of issues raised and points made. Note by the Secretariat. *Document IP/C/W//368/*Rev.1, February 2006, and *IP Quarterly Update*, South Centre and CIEL, First Quarter, 2006.
25. The main promoters of these proposals are the Group of African countries by means of the document entitled "Taking Forward the Review of Article 27.3.b of the TRIPS Agreement" and a Group of Developing Countries, some of the megadiverse, headed by Brazil and India (plus Bolivia, Cuba, Ecuador, Dominican Republic, Peru, Thailand, and Venezuela). See http://docsonline.wto.org/DDFDocuments. Although the proposals differ in language and certain legal considerations, in general they seek to introduce the requirement of disclosure of origin and proof of legality of access in the patents system. See a summary in *IP/C/W/273/*Rev., February 2003. In early 2004 some developing countries submitted a Check List of the issues that should be discussed, which has been useful in orienting the discussions.
26. The Deputy Director has initiated negotiations on the basis of a document that contains 11 questions to be answered by the Members.
27. WT/GC/W/564, May 31, 2006.
28. The WIPO questionnaire WIPO/GRTKF/IC/1/ of April 6, 2001, which compiles information from various countries on practices of protection of biotechnological inventions, cites as topics of interest: the possibility of patenting or not plants and animals if they meet the basic requirements; extension of denial to do so (plants and animals per se, varieties, breeds, etc); protection of new uses of biological material, of microorganisms, and microbiological processes, including those isolated from essentially biological and genetic sequence processes, even those identical to the ones existing in nature, etc.

29. This research does not deal with the ethical, legal, and economic implications of disclosure of the human genoma in February 2001 by two research teams and published in *Nature* magazine. This topic and the appropriability of the results by means of IPR are of major interest for plant genomics. The description of the Arabidopsis genoma and the works under way on corn and rice makes it likely that there will also be debate in this field.
30. According to Tansey (1999), the expressions of Article 27 of TRIPS subject to interpretation are plants, animals, microorganisms, essentially biological, non-biological, microbiological procedures, plant varieties, efficacious, and *sui generis*.
31. In the case of human genes, fragments, without known use, are called "expressed sequence tags." As Bergel (1997) states, "Granting patents on these DNA fragments, that is to say, monopolizing in their inventors almost all the subsequent technical advances (complete sequence of DNA, products that codify and uses of these products) would contravene the basic principle that the scope of protection of a patent should be proportional to the contribution of the invention to the state of the art.
32. In 2000, 355,000 sequences were patented, an increase of 5,000% over 1990. It is likely that the trend will increase.
33. Technology for creating transgenic plants that express the gene of the Bacillus Turingensis or BT, which allows these to eliminate, by the expression of a substance, pests such as lepidoptera.
34. Cited by Dutfield (2000).
35. Secretariat of the Convention on Biological Diversity (UNEP/CBD/COP/3/22).

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Chapter 8
Intellectual Property in Living Organisms. Current Situation, Trends and Challenges

César Morales

8.1 Introduction

This chapter analyzes and studies the situation and perspectives of intellectual property protection of living organisms from the standpoint of the interests of the development countries in general and the Latin American region specially. It is a rather complex issue on which there are considerably different positions between the developed and the developing countries, companies linked to genetic engineering, universities, research centers, and development agencies.

The complexities are not new, but have deepened with the advances in genetic engineering and recombinant DNA techniques, which have made the production of transgenic organisms a reality and increased the value of genetic sequences of plants, animals, bacteria, and fungi with characteristics of commercial value.

The very definition of living organisms is accompanied by difficulties and the need to specify. Although it would seem obvious that all organisms are living by definition, in viruses this is not always so. These acellular entities, of major importance for the production of plant and animal transgenic organisms, are on the border between living beings and what is defined as inert and are, moreover, of great importance for the production of plant and animal transgenic organisms.[1] This fact can have important implications from the viewpoint of intellectual protection.

Viruses are sub-microscopic entities capable of feeding themselves, growing, reproducing themselves, and dying, by parasitizing a cell and using its genetic material. Without them they cannot carry out any of these functions and can crystallize like minerals, remaining inert for indefinite periods.[2]

Added to the above is the fact that scientific development has succeeded in artificially producing organisms which nature would never have been able to produce and

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which combine their genetic material with parts of completely alien and unrelated organisms, such as plants, animals, bacteria, fungi, and viruses.

The difficulty in managing the economic aspect of these advances lies in the fact that the interests of those who possess the technologies to commercially develop these modified organisms do not coincide with those of the countries that have the necessary biodiversity to develop them, that is, plants, animals, and other organisms with commercially desirable characteristics. This has given rise to conflicts of interest and opposed points of view.

The different regulatory frameworks add a little more complexity to the existing picture. In force at multilateral level are the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the Convention on Biological Diversity (CBD), which coexist with the *sui generis* systems of diverse countries within the framework of the International Convention for the Protection of New Varieties of Plants, which is administered by the International Union for the Protection of New Varieties (UPOV), as well as different autonomous national laws.

There is a major controversy regarding the possibility of patenting living organisms. This goes back many years, but the scenario has undoubtedly been complicated by the development of genetic engineering and the possibility of industrially developing products based on the use of modified living organisms.

World Trade Organization (WTO), through the TRIPS Agreement, has put forward criteria on the possibility of granting intellectual protection to biotechnological innovations. According to Article 27.3(b) of TRIPS, plants and animals other than microorganisms are patentable subject–matter, as are essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, TRIPS also stipulates that Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof and that such provisions shall be reviewed 4 years after the date of entry into force of the WTO Agreement.

Article 27.3(b) is one of the most controversial in the TRIPS Agreement since on the one hand it describes patentable subject–matter, and on the other hand, it obliges Members to protect microorganisms and certain biological processes. The above reflects the strong conflict of interests between developed countries desiring to obtain protection for their biotechnological innovations, the differences between various countries on the scope of protection, and the concern of the developing countries about patents on life forms (UNCTAD-ICTSD, 2005).

8.2 Protection and Regulatory Frameworks: Some Conceptual Aspects

8.2.1 Intellectual Property Protection

The types of protection applicable to living organisms or parts of them are the following: technical protection, industrial secret, patents, and plant breeders' rights.

8.2.1.1 Technical Protection

This type has to do with the nature of the process or product and is assigned when it is impossible, very difficult or very costly to copy the innovation. The degree of protection, that is, how difficult it would be to imitate the product or process, depends on to the extent that the innovation is incorporated into the product. There are two cases in point:

(i) When it is impossible to recover the innovation as of the product or process and
(ii) when the innovation is fully recoverable as of the product of process.

Between the two cases there are infinite possibilities. Hybrid seeds[3] correspond to the first case, since their characteristics cannot be reproduced in the offspring, which cannot even be obtained in many cases. Among the industrial crops reproduced on the basis of hybrids are corn, sunflower, and sorghum. The opposite case is that of the new varieties of autogamous plants,[4] whose technical protection is impossible or very limited, as it is possible to obtain "copies" from their seed. It is said that in this case the seed completely "embodies" the innovation. Autogamous plants cultivated industrially are soy, wheat, oats, and barley.

8.2.1.2 Industrial Secret

This type of protection is associated with seeds of hybrids and with processes that confer desirable characteristics on commercial plants. It is used a step prior to an application for a patent or to recognition of the producer of new plant varieties. In contrast to other types of intellectual protection, the industrial secret does not confer exclusive rights and is not conditioned to registers, or to proof of novelty or inventive step.

8.2.1.3 Patents

Patents can be granted to processes and products such as new varieties of hybrid plants, transgenic plants, processes to endow them with desired characteristics, vaccines, agricultural machinery. In such cases it is necessary to demonstrate that the invention is novel and meets the requirements of inventive step and industrial application, a concept that includes uses in agriculture. There are differences among countries on the patentability of microorganisms, cell lines, genes, and genetic sequences and on the importance assigned to the product or process used.

8.2.1.4 Utility Models

This modality can be applied to the holders of rights on equipment and agricultural machinery, their parts and pieces, including their configuration or external

design. In general, their requirements and duration are less than those demanded for patents.

8.2.1.5 Plant Breeders' Rights

Cover the plant varieties resulting from plant breeding, as long as they meet the requirements of novelty and are distinguishable, stable, and uniform. The requirement of novelty means that the new variety should not have been commercialized or offered for sale by the plant breeder in the country of application. It is also demanded that one or more of its characteristics should be clearly distinguishable from other commonly known ones. It has likewise been established that new varieties should maintain their characteristics and essential traits stable in time after repeated propagations.

8.2.2 International Regulation

8.2.2.1 Paris Convention for the Protection of Industrial Property

It was signed in 1883 and has been the object of various revisions. It applies to patents, trademarks, geographical indications, industrial designs and models, and unfair competition.

8.2.2.2 Patent Cooperation Treaty (PCT)

It facilitates the application for and registration of patents abroad for the signatory countries.

8.2.2.3 International Convention for the Protection of New Varieties of Plants (UPOV)

It was signed in 1961 and was amended in 1978 and 1991. It establishes the criteria for protecting plant varieties by means of "plant breeders' rights." The 1991 amendments stipulate strengthening the rights of plant breeders over the multiplication, commercialization, exportation, and importation of the material to be propagated, including improvements to the potential protection of all genres and species of plants. These provisions were incorporated into the European Union's Plant Varieties Law in 1995.

UPOV also introduced the concept of "essentially derived varieties" to allow plant breeders to control the use of random mutations. Understood as such are varieties "it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety" (UNCTAD–ICTSD, 2005).

Thus the rights of plant breeders who would otherwise lose the value of their intellectual property in a short time are protected (as would often occur when a plant breeder made "cosmetic" changes to a previous variety without paying for it).

Other UPOV stipulations recognize the right of farmers to keep seeds for the next sowing cycle without the need to ask permission and that "small farmers" are exempt from payment of royalties and may keep particular varieties for 7 years.

Despite these flexibilities, the 1991 UPOV revision brought the regime of plant breeders' rights closer to that of patents. The Convention extends the coverage of intellectual property rights to imports, exports, and harvested crops; broadens the duration of plant breeders' rights, aligning them with that of patents; restricts free access to protected varieties (although it maintains it for purposes of reproduction of new varieties); and extends plant breeders' rights to all varieties considered "essentially derived" from the protected variety, limiting the use of new varieties that are developed. Although the new norms allow using protected varieties for research purposes, any improvement obtained should show significant changes in the phenotype. Otherwise, the variety is not considered "new" and will continue to be the property of the first plant breeder. Furthermore, the right to use formerly permitted, such as the accumulation and reproduction of varieties protected in "gene banks" aimed at preserving genetic diversity, is restricted. Finally, farmers' privilege of keeping seeds for later sowing seasons is eliminated.

8.2.2.4 Madrid Agreement

Deals with repression with illegitimate use of indications in products.

8.2.2.5 TRIPS

This agreement stems from an agreement signed at the Uruguay Round in April 1994. It provides minimum standards of protection in practically all aspects of intellectual property (patents, copyright, trademarks, industrial designs, geographical indications, integrated circuits, and business secrets). According to the transitory articles, the developing countries had 5 years as of January 1, 1995 (until January 1, 2000) to implement them. The period was extended to 11 years for the less developed countries. For products which at the time of signing the agreement were not patentable, the term was extended until January 1, 2005.

The TRIPS Agreement also provides new rules for patents on pharmaceutical and biotechnological products, extends their protection to 20 years, eliminates or limits the requirement of local exploitation of inventions, and strengthens the mechanisms for enforcement of rights (IICA, 2000). TRIPS is an expansion on a world scale of the criteria adopted in the 1980s, especially in the United States, to have more vigorous and uniform laws to protect inventions.

Despite the agreements, important differences among the Members persist, even among the developed countries with respect to plants and animals and the processes

to produce them. Thus, for example, the member countries of the European Patents Convention do not recognize patents on plant varieties. To save this situation, the TRIPS Agreement recognizes the authority of WTO Members to exclude from patents plants and animals that are not microorganisms and essentially biological processes for the production of plants or animals.

In any event, the countries should take the necessary measures to protect plant varieties by means of patents, *sui generis* systems, or a combination thereof. According to this provision and in the absence of greater accuracy, animals and plants as such, animal breeds and species of plants and animals may be excluded from patents.

Although TRIPS does not make it compulsory to adopt a regime identical to that of UPOV or adhere to it, many countries have established the obligation to protect plant varieties in accordance with plant breeders' rights and adhesion to UPOV. DR-CAFTA includes the obligation to sign UPOV 1991, thus forgoing each country's option to create its own *sui generis* system. Other developing countries, by contrast, are discussing *sui generis* regimes different from those of UPOV.

In sum, intellectual property protection may be obtained on innovations, whether plants, parts of the latter or new varieties. This is possible according to the regimes set forth below:

i) *Plant breeders' rights.* Applicable to new plant varieties (UPOV).
ii) *Invention patents.* Applicable to plants or parts thereof, that is, cells, genes, seeds, procedures for the transformation of plants and transformation vectors and, in some countries, to plant varieties and hybrids (TRIPS).

In regard to the second point, European norms do not consider patentable plant varieties, animal breeds, and essentially biological plant or animal breeding procedures since they are independent from human technical intervention. However, they admit that the patentability of inventions that coincide with products from nature when they have been obtained through technical procedures is feasible. Thus, "biological material isolated from its natural environment and produced by means of a technical procedure could be the object of an invention, even when it already existed previously in a natural state" (UNCTAD–ICTSD, 2005; IICA 2000).

Thus, it is possible to patent DNA sequences, microorganisms, and other beings the same as those pre-existent in nature. What is important is that said inventions should be structurally or morphologically identical to a product from nature, have been isolated from their natural environment, or produced by some technical procedure, which guarantees the possibility of industrial production. Accordingly, the fact that the biological matter is in its natural state does not hinder its patentability (requirement of novelty), but its invention may be obvious (lack of inventive activity) or lack industrial application.

Box 8.1 summarizes the main characteristics of the regimes of UPOV and the Paris Convention.

Box 8.1 Protection of biological materials: plant breeders' rights and patents

Regime	UPOV	Paris Convention
Rights	Plant breeders' rights	Patents
Material that can be protected	Plant varieties	Plant varieties, plants, or parts of plants such as seeds, cells, and genes. In some countries (United States), genes produced by means of genetic engineering can be patented
Protection requirements	a) Novelty: that the variety has not been sold in the country where protection is requested in 1 and 4 years in other countries b) Singularity c) Homogeneity d) Stability	a) Novelty: no prior publication or execution of the invention anywhere in the world b) Singularity c) Homogeneity d) Stability e) Inventive activity
Materialization	Applicable to existing varieties	That the invention can be carried out according to the pertinent description
Exceptions to exclusive rights	Exception of the plant breeder, who permits use of the protected variety for subsequent development	Depending on countries, exceptions are admitted for scientific research
Duration	20–25 years	20 years
Territoriality	Only in the country where the right was obtained	Only in the country where protection was obtained (and in the countries affiliated to PCT if the interested country is a member)
Accumulation	It is possible to accumulate plant breeder's rights and patents on the same variety. Such is the case of transgenics	Use of plant material as a source of germplasm is not permitted for other developments

Source: Correa, C. (1999), "Normativa Nacional, Regional e Internacional sobre Propiedad Intelectual, su aplicación en los INIAS del Cono Sur."

8.3 Patents and Innovation

The relationship between the forms of protection of innovations has been under discussion for a long time. The granting of monopolies by means of intellectual property rights for a specific number of years is associated with fair retribution to

the innovator for the investment made, until the innovation in question is out on the market.

In most cases, especially in cutting-edge technology, investments to create an innovation are very considerable. Added to the expenses deriving from basic research are others no less considerable to finance the tests (test data) demanded by the respective authority so that the product circulates in the market.

These demands are greater for pharmaceuticals, food products, and substances with the risk of significantly affecting the environment. Finally there are the expenses derived from the waiting time for approval of the product by the consumer. It is estimated that the average total time is 10–16 years for new varieties of plants and medicines. In view of the amount of the investments, it comes as no surprise that the largest and most solvent companies present the most applications for patents.

It is estimated that putting a new drug on the market entails a cost of around 400 million dollars. In view of the high investments at play, companies in the pharmaceutical–biotechnological sector are under pressure to improve their productivity and the rate of introduction of new products into the market. It is estimated that to achieve 10% growth in earnings from sales, a new drug needs to be introduced into the market every 6 months. At present, despite the advances in the matter, the major companies launch a new drug onto the market every 27 months on an average. One reason for these long periods is the time demanded by the tests to which drugs and biotechnological products must be subjected, especially as regards their effects on health, side effects, and effects on the environment.

The costs and time frames of agricultural biotechnological products are similar. Discovering a new gene can cost several million dollars, but inserting it in a germplasm costs only some 200,000 dollars, depending on the crop (Lichtenberg, 2000). These are costs prior to crop tests for their approval by government agencies (in the United States this involves the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, and others).

It is estimated that the costs of preparing the basic background material for biological tests for the effects on human health, on other organisms, and toxicity reach almost 2 million dollars. The respective spending for chemical pesticides is higher. In addition to this there are other costs which increase the figure to almost double. The Monsanto Company estimates that the costs of preparing information required by tests on insect-resistant transgenic maize reaches some 3.8 million dollars (Lichtenberg, 2000, Appendix A).

At present there is an enormous quantity of patents registered in the offices of all countries and in the specialized international agencies, and this tendency is accelerating. In the United States, since the creation of the Patents Office (USPTO), to date more than six million patents have been granted, more than half of them since 1988, and there are applications for a similar number or more. Except in the case of the green revolution, which gave rise to innovations that were defined as public goods, important scientific discoveries have always brought new technologies that significantly increase the number of applications. However, the increase in patents and applications in the field of genetics since the last decade, especially as of the end of the human genome project, has no comparable precedents.

This context redefines the long-standing controversy on the relationship between protection of intellectual property rights and innovation. On the one hand there are those who maintain that protection by means of patents is a basic condition to assure the generation of innovations and, on the other hand, those who affirm that patents tend rather to raise barriers to the entry of other innovators and induce companies to move for speculative reasons.[5] Nonetheless, it tends to be accepted that patenting is a "proxy" of innovation.

In regard to the proportion of patents that reach the market incorporated in products, there are few studies due to the difficulties in following their route. In any case, although the existence of important sectoral differences can be presumed,[6] the well-known consulting firm Ernst & Young estimates that no more than 10% of patents on biotechnological innovations are finally incorporated into commercial products. Follow-up on the matter by the Patent and License Exchange coincides with the above estimate (Platt, 2001).

The fact that 90% of the patents obtained do not reach the market incorporated in products suggests that there are hidden factors that have a bearing on patenting activity and that there is a need for appropriate mechanisms so that more patents finally reach the market.

With regard to the first point, it is possible that many patent registers have no other purpose than to block the entry of other innovators. As for the second, the development of an explicit secondary market for patent transactions could help transform more patents into marketable innovations. In market terms, there is a high lack of liquidity in the "primary market" for patents as a consequence of the risk and uncertainty these entail.

8.4 Barriers to Entry

Initially conceived to encourage innovation, the patents mechanism tends to turn into an instrument for preservation of monopolies obtained thus and into barriers to entry for other innovators. In fact, protection of innovation ensures exclusivity for the patent holders and collection of royalties and licenses for their use. According to WIPO and other agencies, in the mid-1990s half of the royalties and license payments favored large United States' corporations and around 70% of them corresponded to transactions between their own subsidiaries and other related companies. According to UNDP's 2000 Human Development Report, 85% of advanced technology patents are in the hands of the major conglomerates.[7]

The resources generated by intellectual property rights are of such magnitude and have such growth dynamics that the regulatory framework is seen by some as more appropriate for protecting this source of earnings than for encouraging innovation. It is estimated that in 1990 total earnings from royalties and licenses for the use of patents brought in 15 billion dollars for their owners. In just 8 years this figure increased to 100 billion dollars and it was estimated that in 2005 it would reach 5 trillion dollars (Mooney, 2000).

Another barrier to the entry of new stakeholders, especially smaller ones, is the high costs of lawsuits on patents due to the complexity and specialization they entail. In 1999 alone 8,200 proceedings were instituted on the matter in the United States, a figure 10 times higher than 4 years before. This profusion of litigation suggests that the regulatory framework, rather than encouraging innovation, encourages the interests of large corporations and dissuades smaller firms, institutions, universities, and innovators without large amounts of resources.

Control by the large corporations over almost the entirety of innovations in cutting-edge technology makes it more difficult for new agents to enter the innovation process. Only three large conglomerates of private companies linked to the Human Genome Project have made three million patent applications on parts of genes, DNA, and cell lines from 2000 to date. The complexity of the applications and their enormous number make it very difficult for patent offices to assess their pertinence and they relegate the right for their applications to be processed to third parties.

Genetic codification of biological barriers is added to these barriers. The first generation of these technologies, known as Terminator, consists of a protein that kills the seed embryo once the seed has fulfilled its productive cycle. Thus its reuse is prevented in new sowing seasons, obliging the farmer to acquire them for each cycle. More recent technologies codify the seed's sensitivity to particular agrochemicals that sterilize it externally or make it lose its commercial properties.[8]

Paradoxically, these innovations can lose importance as mechanisms to ensure complete appropriation of their benefits. Satellite technology for the control of agricultural activities has reached a level of sophistication such that it can make it less costly for biotechnological and transformation companies to ensure through production contracts with farmers the use of the anticipated technological inputs (seeds and agrochemicals) for the time agreed and in the required form. In this way it will be possible to control reuse of seeds without authorization from the supplying companies and demand the use and application of particular pesticides and treatments.

8.5 Application and Granting of Patents

8.5.1 Background

In 1873 the United States Patents and Trademarks Office (USPTO) granted patent No. 141,172 to Louis Pasteur for yeast free of disease germs, considering it a manufacture. It was subsequently decided not to continue along that line, with some exceptions (a breed of bacteria in 1977). The criterion that prevailed was considering that living organisms were not patentable because they were regarded as products of nature, or because they were not subject to sufficient written description, as demanded by the patents system. This excluded bacteria and fungi that produced antibiotics, for which reason prior to 1980 most patents were granted to processes,

mainly those that used bacteria to treat wastewater or produce chemical substances, antibiotics, etc.

In 1930 the United States Congress approved the Plant Patent Act, which permitted protection for asexually reproduced plants with the exclusive right to propagate the plant for 17 years (Solleiro et al., 1996). To date the USPTO has granted around 6,000 patents for plant holders, mainly fruit trees, flowers, ornamental trees, grapes, and other horticultural species.

In 1961 the International Convention for the Protection of New Varieties of Plants (UPOV) was signed in Paris. It has been submitted to three revisions, the last one in 1991.

In 1970 the United States introduced an adapted version of the UPOV System of Plant Breeders' Rights into its legislation to protect new sexually reproduced varieties of plants.

In Europe, after the signing of UPOV, several countries recognized protection titles for new plant varieties. Nevertheless, in 1973 the European Patent Convention in Munich excluded the patenting of plant varieties and the essentially biological procedures for their production (Correa, 2002).

In 1977 the first patent on a breed of bacteria was granted in the United States, but it was not until 1980 that the first major changes were made to intellectual property regulations.

In 1972 microbiologist Chakrabarty filed a patent application for 36 claims related to the invention of a genetically designed bacterium of the *Pseudomonas* species, capable of degrading the multiple components of crude petroleum. The application was rejected, but Chakrabarty appealed, and on June 16, 1980, the United States Supreme Court decided in a historic ruling that the said bacterium was a "manufacture" or "composition of matter" which met the criteria of novelty (inexistent as such in nature and not obvious for science at the time) was derived from an inventive step (it had been produced in a laboratory by transfer of plasmids) and met the requirement of usefulness (its purpose was to use it in oil spill clean-up work).

The ruling included the following phrase: patents can be granted "to anything under the sun that is made by man." Thus the objection to patents on living beings for the simple fact of being living was eliminated. The Budapest Treaty (1977, in force since 1980) establishes as a requirement for patent applications on microorganisms the deposit of cultures in well-known collections to that effect.

This decision marked an important change on the subject and led to modifications of the regulatory framework for Intellectual Property Rights in the United States. The perception of deterioration of the United States' comparative advantages in the technology-intensive industry brought about significant changes in forms of protection of intellectual property rights (Hunt, 1999).

The loss of competitiveness was attributed to the fact that the system was geared to basic research, was weak, and rather inefficient in producing results for firms, whereas the results of research were easily appropriable by competitors due to lack of protection (Coriat and Orsi, 2001).

One important modification was the one that habilitated universities and scientific teams to patent their innovations, including those financed with public resources. As of that time the innovative activities of the main universities were significantly unleashed, giving rise in the process to small biotechnological companies made up of scientific personnel from the same universities. Subsequently, most of these firms were acquired by large corporations in the field through mergers and acquisitions.

In 1985 the Board of Patents Appeals and Interferences granted Kenneth Hibbert the first utility patent for a plant that could be sexually propagated and genetically manipulated: a variety of maize enriched with Tryptophan of the firm Molecular Genetics & Development. Utility patents protect not only the plant but also parts of it, the seeds and genes, so they justify multiple claims according to applications of the innovation in different products, processes, and species. Two years later it was the turn of an inferior animal: a polyploid oyster.

In 1988 Harvard University obtained a patent on a genetically modified mouse, precursor of a transgenic breed, carrier of a human oncogene that makes it susceptible to developing tumors. After heated debate, on April 12, 1988, it was granted patent No. 4,736,866. The year before, the Commissioner of Patents had established that the United States could concede patents to "multicellular non-human living organisms, including animals, which do not occur in nature. There have been hundreds of applications to patent transgenic animals but very few have been granted."

In 1990 the United States Supreme Court admitted the patent rights of the University of California regarding a line of cells that could be cultivated in vitro against the pretensions of Mr. Moore (Moore v. University of California).

In 1991 and 1992 the United States National Institutes of Health applied for patents for thousands of DNA segments with unknown function, obtained as copies by reverse-transcription of RNAm. The long dispute on patenting of DNA and genes was beginning.

Since that time and together with the impressive advances in decoding the human genome, the debate on the protection of intellectual property has become enormously complicated. Novelty and inventive step, discovery, and invention become more diffuse factors as progress is made on increasingly complex ground.[9] Thus, for example, in 1991 Dr. Craig Venter presented patent applications to USPTO for 337 partial human gene sequences. In 1992 the application was extended to 2,700 new fragments which due to the manner of obtainment were called expressed sequence tags (EST).

These applications gave rise to an intense debate which still has not concluded. Many biologists were directly opposed to these intentions because they could curb basic research and technology transfer in very promising spheres of genetics. For different reasons, associations of biotechnological companies also requested that data on sequences of the National Institutes of Health (NIH) should be made publicly available (Iañez, 2001). In 1997 the USPTO admitted that under certain conditions, ESTs were patentable. The first was granted to Incyte Pharmaceuticals on October 6, 1998. However, new applications and the rather unclear conditions of authorization have further kindled the debate.

Faced with this panorama, the Biotechnological Industries Organization (BIO) requested the intervention of USPTO to clarify the issue and distinguish between applications for patents for EST with sufficient utility and EST with rather unclear utility. In 1998 USPTO issued some provisional guidelines that led to establishing the definitive provisions ("Revised Utility Examination Guidelines") in December 1999. These indicate that the invention "should have a specific and substantial utility" that "excludes 'unimportant,' 'insubstantial,' or 'unspecific' utilities."

From then on the situation has become increasingly complex, for unforeseen problems appear which have led some specialists to maintain that there is a gap between advances in sciences and intellectual property regulations.

The year of the turning-point in this process was 1980, when USPTO granted around 60,000 patents. In 2001 the figure rose to 166,000. Since its independence as a country over 200 years ago, the United States has recognized more than six million patents, and the number of unanswered applications is very high. On genetic materials alone there are more than three million pending applications.

8.5.2 Regulatory Levels and Frameworks

Patents can be applied for and obtained at national, regional, and international level. For the first level there are the specialized national offices, for the second the regional authority (e.g., the European Patent Office), and for the third the International Patent Cooperation Treaty (PCT) administered by WIPO, under which valid patents can be registered in all the signatory countries.

Patents do not grant the same rights in all countries, for each one has its own law. For the same reason, authorizations may have different coverage, so that comparisons with information from different countries and systems entail difficulties.

USPTO, the European Patent Office (EPO), and the Japan Patent Office (JPO) are the ones that receive the most applications and authorize the largest number of patents. The agents that apply for and obtain patents are usually classified into companies, individuals and government, nationals, and foreigners. It is also possible for patents registered abroad to be applied for by the head office in some cases and by subsidiaries in others.

8.5.3 Patenting Trends

According to available data, applications for patents grew from 2.3 million in 1994 to more than 8 million in 2001 and more than 12 million in 2004 throughout the world. Applications under the Patent Cooperation Treaty show a similar growth rate, from just over 1.1 million to 5 million during the period.

As for the fields in which patents are applied for, there are some differences between USPTO and EPO. According to the international classification, in USPTO

17% of applications fall under the category "Human Needs," which include foods, food production, and transgenics. In EPO the most important category is chemicals and metallurgy, although not much more than others.

A research project with USPTO information for the past 10 years shows that the United States is the most active country, since between 1980 and 2000 the number of patents authorized more than doubled, and between 2000 and 2004 these grew 60%.

Although the innovating agents that patent the most are individuals and national firms, as well as governments, foreigners are the most dynamic.

Japan, Germany, the United Kingdom, France, and Canada are the most active countries within the United States, the country that concentrates the most foreign patents. One outstanding fact is the high concentration of patenting activities in few countries. Japan is the country that patents the most in the United States, for it holds 452,737 patents, more than four times the number of the United Kingdom (101,330) and almost 20 times more than the Chinese province of Taiwan (24,646).

Latin America and the Caribbean are in a very marginal position. Mexico is in first place with position 24th in the world and 1,907 patents. Fairly far behind is Brazil (place 28th with 1,263 patents), Argentina (32nd place with 904 patents), and Venezuela (36th with 557 patents).

At the corporate level, IBM of the United States occupies first place, followed by Canon and Toshiba of Japan and Samsung of the Republic of Korea.

The most dynamic fields for patenting in the United States are biotechnology and molecular microbiology, pharmaceuticals and compounds, electronics, and optic systems (Box 8.2). In the field of biotechnology, transgenics and associated processes, genes, and gene sequences are outstanding.

Box 8.2 Main patenting agents

Biotechnology	Agricultural biotechnology
Dow Chemical	Monsanto Group (5.9% of total patents)
Basf	Dupont Pioneer Group (0.2%)
Ciba Geigy	Singenta (13.8%)
Monsanto	Aventis (15.7%)
United States Government	Universities under contract with the above-mentioned groups and on their own account (56%)
Universities and Foundations	
Researchers	

Source: Prepared by the author from USPTO databases.

In transgenics and advanced biotechnology applications on plants, research with USPTO data indicated that so far, 4,609 patents have been obtained, of which 902

Table 8.1 United States: patents obtained on transgenics and new plant varieties

Category	No. of patents
Total	4,609
Higher cultivable plants, seed plants, or parts of plants (angiosperms and gymnosperms)	902
Maize	783
Soy	501
Pathogen-resistant transgenics	423
Transgenics with male sterility	336
Insect-resistant transgenics	316
Brassica (Canola)	187
Herbicide-resistant transgenics	176
Tobacco	173
Rice	117
Potatoes	103
Wheat	95
Cotton	89
Herbicide-resistant maize	82
Sunflower	76
Beans	27
Marrow, Zucchini	22
Cucumber	21
Others	180

Source: Prepared by the author from USPTO databases.

correspond to higher cultivable plants, seed plants, or parts of plants (Angiosperms and gymnosperms); 501 patents for transgenic soy; 423 for pathogen-resistant transgenics; and 336 for transgenics with male sterility (see Table 8.1).

With regard to genes and gene sequences, the ranking is as follows:

a) United States Government
b) University of California
c) Smith Kline Beecham Incyte Pharmaceuticals Inc.

8.6 The Challenges

Latin America and the Caribbean as well as many other developing countries possess an enormous biodiversity and its native inhabitants have for centuries developed knowledge and learning on how to utilize that enormous wealth in a sustainable manner. One hectare of Latin America's tropical forest possesses more biodiversity than the entire European continent. Thanks to the work of the original peoples of the region, humanity has foods such as maize and potatoes, among many others. The region also has an important base of scientists and technicians in agricultural innovation, but it benefits little from their knowledge. Conservative estimates indicate that in Latin America and the Caribbean more than 150 million people live in the rural area, and a significant part of them in conditions of poverty and indigence.

The major challenges for the region in terms of intellectual property and innovation fall within this general picture. The consolidation of the new regulatory frameworks of TRIPS can increase the gap between developing and developed countries, unless the former take the necessary measures to reinforce their scientific development and protect their heritage and their creations simultaneously.

The linkage of these agreements with the free trade agreements points up the need for the countries to articulate their efforts to co-ordinate both aspects, particularly biodiversity.

The region has an important amount of scientific advances without intellectual protection. Many of them have been generated in institutes and public universities with the involvement of private parties. In view of the investments made and their capabilities, it is a question of subject–matters that can and should be addressed from a public-policy perspective.

Innovative efforts in the field of scientific and technological development require economic scales that the region itself can provide, for instance in agriculture and in the protection and utilization of biodiversity, where a critical mass of qualified scientists is available, whose coordination could be the object of multinational efforts.

In this regard, public policy should consider elements such as the following:

1) Creation of a regulatory framework that favors care and sustainable use of biodiversity and recognition and protection of the traditional learning and knowledge of indigenous peoples and peasants. This involves making national laws compatible with agreements between countries on biodiversity, the fight against biopiracy, and norms on bioprospecting contracts.
2) National and regional innovation policies that make possible the sustainable use of the region's capabilities, protection of locally generated knowledge, adoption of new technologies with regard to biodiversity and the environment, and the entry of new national innovators. In keeping with the above, establish regulatory measures to prevent monopolistic or almost monopolistic control of knowledge.
3) In line with the above, establish measures to neutralize or at least counter the control of complete productive chains via genetic coding of seeds and the exclusion of small farmers.

Notes

1. Organisms are considered transgenic when they are the result of genetic manipulation whose genome combines genetic materials of other organisms with which they have no sexual affinity. With current techniques, a transgenic carries its own genetic material and others from viruses and bacteria, from plants, and/or animals.
2. Viruses' position on the border between the living and the inert poses the problem of their origin. For many scientists viruses would be the first beings in the evolution between inert and living, effectively combining the functions of replication, transcription, and translation. They would thus be the least evolved organisms (es.wikipedia.org/wiki/Virus).

3. Hybrids are produced from plants that reproduce by cross-pollination between to sexually different individuals. In this case, the seed can only be used for a certain time, for subsequently it loses its commercial characteristics. They are plants that have biological or technical protection. Farmers must buy the seeds for every crop.
4. Crops with autogamous plants correspond to those that reproduce by self-fertilization and in which hybridizing is commercially impossible. In this case the seed can be used for more than one cultivation period and it is therefore not possible to count on protection on the basis of the biology of the plant or on technical protection.
5. The first line of argument includes academic media and large corporations and the second, some recent papers by Cimoli (2002) and Katz (2005).
6. In pharmaceutical chemistry it is estimated that between 30 and 60% of patented innovations can become marketable products.
7. *Human Development Report and Globalization* (2000), Sustainable Development Topics, Number 2, UNDP, page 39: "...only ten countries accounted for 84% of world spending on research and development, and they controlled 95% of United States patents in the last two decades. Moreover, more than 80% of patents granted in developing countries belong to residents of industrialized countries."
8. Novartis recently patented a technology of this type which uses a derivative of aspirin to control the growth of seeds and plant characteristics.
9. Patent law rejects the patentability of discoveries. The reason is that discoveries do not involve a technical contribution and are not the product of human ingenuity, which are characteristics of the concept of invention. Nevertheless, as highlighted by the Communication from the Administrative Council of the European Patent Office of July 1, 1999, the importance of biotechnological inventions is ever greater. Since the 1980s more than 15,000 applications for biotechnological patents have been deposited in the European Patent Office, of which 1,500 are for transgenic plants, 600 for transgenic animals, and 2,000 for DNA sequences. Some 3,000 have been granted.

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Part IV
Technological and Innovation Policy in Mexico

Chapter 9
Premises and Instruments of Innovation Policy: A Reflection from the Mexican Case

Gabriela Dutrénit

9.1 Introduction

There is growing consensus that a close relationship between science, technology, innovation, and growth exists; the creation and dissemination of knowledge are basic factors of innovation, sustainable economic growth, and the well-being of nations. This idea has already been highlighted by Solow (1957), who suggested that basic science is a determining factor of economic progress.

There are, however, different approaches to the premises of the most appropriate science, technology, and innovation policies (STIP), the aims they should follow, the actors that should participate in their definition, what institutions will put them into practice, and the desirable relationships between science, technology, economics, and society.

In Mexico's case, STIP have been changing since the early 1990s, from a supply-side approach of support for science to one oriented toward promoting innovation of the private sector in market conditions. The change has intensified in recent years, shaping the emergence of an innovation policy, which is made up of a combination of instruments gathered from other experiences, such as those of Brazil, Chile, and the OECD.

However, spending on research and development (R&D) has not increased since the 1990s (currently 0.4% of GDP), the private sector's share of total spending on R&D continues to be reduced, the country's competitive position dropped from 33rd place in 2000 to 56th in 2004 (according to the International Institute for Management Development) and, in general, the innovative behavior of the players is limited. Many stakeholders in academia, industry, and civil society perceive that there have been no substantial changes in innovation capacity or in national technological capabilities as a whole. In fact, there are many aspects to reflect on and discuss before arriving at a clear STIP.

This chapter aims to contribute to this discussion with two objectives in mind: first, to examine the premises of the design of STIP, particularly innovation policy, of

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the different agents in Mexico, and second, to discuss the design of the combination of instruments according to the systemic approach. The method combines theoretical discussion of the STIP premises with empirical analysis of the results from some of the instruments used. The sources of information are national statistics on the matter and the National Innovation Survey.

Section 9.2 discusses some of the STIP premises and argues the need to focus them in a perspective of innovation system; Section 9.3 analyzes the scope and instruments of innovation policies, as part of the STIP; Section 9.4 presents different opinions of Mexican agents on STIP; Section 9.5 studies the characteristics of national technological capabilities and the results of certain instruments of innovation policy; and Section 9.6 presents a few reflections.

9.2 The Science, Technology, and Innovation Policy From a Perspective of Innovation System

The perception on the process of innovation and its interaction with science and technology has been shifting. There are at least five generations of innovation models with implications for STIP (Rothwell, 1994). Moreover, it is possible to see the evolution of the policies following the conceptions on the innovation model.

The Linear Model, in its Technology Push version of the fifties, assigned a central role in development and innovation activities to the supply of science and technology. According to this model, STIP should basically be oriented to investment in science. In the 1960s the Demand Pull Model emerged, in which the market and clients were the source of new ideas, so that STIP should be oriented mainly toward identifying client needs and development activities. The Coupling Model (or interactive model) of science, technology, and market followed in the 1970s and 1980s, which defines a set of sequential stages, which nonetheless interact among themselves. In this model, STIP should stimulate both technology supply and market needs. In the 1980s the discussion on the Integrated Model was introduced, in which the functional stages are parallel and highly integrated. In the 1990s the emphasis on the Model of Integration of Systems and Networks, which is an evolution of the Integrated Model, became generalized. In this model basic research ceases to be an exogenous transmitted knowledge to become closely related to economic and technological factors in "nodes of a network" for the creation of wider knowledge. Consequently, STIP should focus on balancing technology supply and market needs, fostering the creation of networks.

The experiences of successful STIP suggest that countries' progress is closely associated with constant capacity building in science and technology to lay the foundations for knowledge-based development. Modern approaches of STIP have overcome the linear model of innovation and tend to adopt a frame of reference closer to the model of integration of systems and networks and new forms of production of knowledge in order to reach (1) a balance between supply of and demand for science and technology oriented to innovation, addressing economic and social needs, and (2) the development of networks between agents.

Since knowledge is produced today in a context of application by means of multidisciplinary configurations, teamwork, and social responsibility, the idea has

emerged that STIP should orient science and technology toward the solution of economic and social problems (Velho, 2005; Casas, 2005). For this it is necessary to place STIP within a perspective of national innovation system (NIS).

Given that NIS is a system of players, interactions, and structural conditions (see Fig. 9.1), STIP should be oriented to improving the performance of the system as a whole and not to solving possible market failures, for systems depend on factors that change slowly (culture, technological path, governance systems) (Laredo and Mustar, 2001; Smith, 2000).

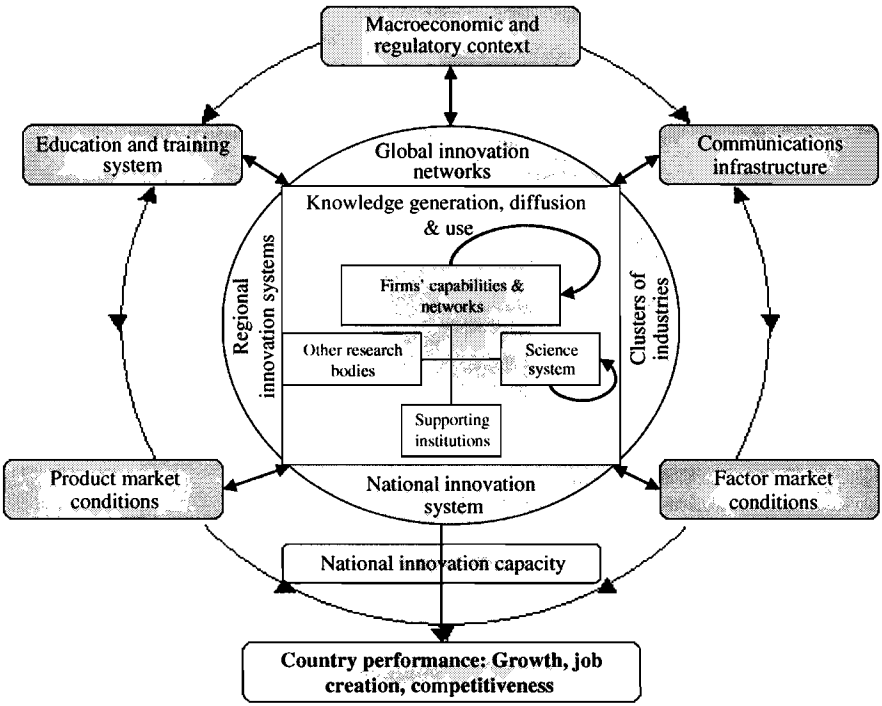


Fig. 9.1 Dimensions related to National Innovation Systems. Source: OECD (1998)

The literature highlights the following objectives of a modern STIP (Laredo and Mustar, 2001; EC, 2003; Georghiou, 2004):

a) Identify national specificities, weaknesses, and strengths of the NIS to design ad hoc science, technology, and innovation policies.
b) Design a set of mixed, sustained, and co-ordinated policies between the different levels of government.
c) Design long-term policies based on consensuses, association, and commitment among the key actors. Only long-term policies have cumulative effects and bring about changes in the behavior of the agents.
d) Support scientific development to generate knowledge, develop expertise, and consolidate the training of human resources in science and technology.

e) Promote close relations between the scientific community and other agents of the NIS to efficiently apply the knowledge generated to national needs.
f) Combine direct and indirect innovation policy instruments. The direct instruments should combine demand side policies (of innovative products to encourage companies to develop R&D and stimulate the country's leading innovation markets) and supply-side policies (to transfer resources and innovation capabilities to companies from the government and related agents, universities, research centers) and instruments of support when the conditions of the milieu – human resources, scientific base, regulatory framework, and policy coordination – are critical.
g) STIP involves different levels of government: local, regional, and national. The up-down relations of politics tend to be incapable of linking themselves to regional/local diversity. It is increasingly evident that in the regions and localities networks among companies, clients, suppliers, universities, and other agents involved in innovation activities are created. The relations within these networks are strongly influenced by the regional/local economic, political, social, and cultural setting. It is therefore necessary to combine up-down policies with down-up policies stemming from the regions and localities.
h) Support initiatives for the development of clusters with infrastructure, education, training, risk capital, spaces for consensus-seeking, etc. Cluster relations tend to be down-up, and informal communication and networks play a central role.
i) Use the functions of government to facilitate and spark changes in agents' behavior and promote collective actions and learning processes instead of subsidizing the development of previously selected companies and technologies.
j) Strike a balance between investment in the development of national technological capabilities of high and medium intensity of knowledge and activities based on local knowledge and systems.

STIP studies show that policies are adaptations to the context in two ways: (i) imitation of and inspiration from policies implemented in other countries, and (ii) own diagnoses of the problems and absorption of other countries' experiences (Sanz, 2005). There is increasing consensus regarding the fact that STIPs should be long term and should be based on the association and the commitment of the key stakeholders in order to have cumulative effects and bring about changes in behavior.

9.3 Innovation Policy: Objective and Instruments

Innovation policy is related to that of science and technology, but has its own objectives. The objectives of science and technology policy are to expand the borders of knowledge, train human resources, and contribute to meeting social needs (environment, health, etc.) and to economic growth.

The main objective of innovation policy is applying knowledge to the development of new products, processes, and services. The innovative capacity of companies depends on the economic setting and the NIS. Innovation policies seek to remedy the deficiencies of companies or of the context in which they operate with the objective of increasing the rate and the success of the introduction of products, processes, and services (EC, 2003). In this regard, innovation policies are also oriented toward supporting the creation and dissemination of knowledge (strengthening NIS) and stimulating company spending on R&D. To this end they seek to ensure that companies recognize that investment in R&D will give them sustained returns. Private R&D and innovation are in turn linked to economic growth and an increase in productivity. Here innovation policy is decisive in improving the dynamics of NIS, but is not limited to promoting R&D, it includes innovation activities related to organization, marketing, etc. (Malkin, 2005).[1]

Innovation policy is related to other economic policies (competition, industrial, labor, financial market, e-commerce, investment, educational). A set of direct and indirect instruments of innovation policy can be identified to increase the rate and the success of the introduction of new products, processes, and services. Most of the instruments are direct and are grouped as shown in Box 9.1 (EC, 2003).

Box 9.1 Direct instruments of innovation policy

Supply-side policies

- Oriented to transferring resources and capabilities for innovation to firms from the government and related agents (universities, research centers, etc.)
- Force of support when the conditions of the setting (human resources, scientific base, regulatory framework) and policy coordination are critical conditions.

Demand-side policies

- Oriented to increasing demand for innovating products and thus to increasing firms' incentives to develop R&D.
- Seek to stimulate leading markets in the country's innovating activity that can direct the changes required.

In relation to the context in which companies and institutions operate, the literature identifies four types of deficiencies and the most common innovation policy instruments to overcome them (Metcalfe and Georghiou, 1998; EC, 2003). Such deficiencies usually entail resources, incentives, capabilities, and opportunities.

Deficiency of resources means that sufficient resources for carrying out R&D are unavailable without public funds. This situation comes about particularly in academic research, private R&D in conditions of considerable uncertainty and in

cases in which social returns demand an investment that the private sector cannot or is unwilling to carry out. With regard to incentives, the deficiencies refer to the fact that research institutions or the market do not provide the incentives for socially desirable behavior (e.g., academia-company linkage). The deficiency in capabilities occurs when organizations lack the key capabilities to innovate (e.g., abilities to develop business plans or access risk capital). Finally, the deficiency of opportunities refers to situations in which there is difficulty in creating innovation opportunities. This deficiency is one of the main justifications of public science.

Box 9.2 lists a set of policy instruments and the deficiencies they contribute to overcoming. As may be seen, each instrument deals with specific deficiencies and can contribute to overcoming one or more, although it can also have a contradictory influence, positive in some and negative in others. Therefore innovation policies should foresee measures to counteract negative effects.

Box 9.2 Innovation policy instrumentsand deficiencies dealt with

Supply-side measures	Resources	Incentives	Capabilities	Opportunities
Support for basic research				
Support for public research aimed at productive sector				
Support for training and the mobility of researchers				
Donations, subsidies, supports and prizes for industrial R&D				
Tax incentives for R&D				
Initial financing for risk capital				
Co-localization measures				
Support for information and intermediation between agents				
Measures for the creation of networks				
Demand for new goods or services				
Systemic policies				

Source: Based on EC (2003) and Georghiou (2004).

The design and implementation of innovation policies to induce greater spending on R&D and thus expand the rate of introduction of new products and processes into the market is part of the agenda of policy designers in almost all countries (Teubal, 2002; Bartzokas and Teubal, 2001).

Progress has been made at international level in the building and use of a set of indicators to measure innovation capacity, such as 1) generation of knowledge (public-sector R&D, researchers in the public sector, basic research and scientific publications); 2) Science/industry links (private financing of public research,

scientific publications cited in patents); 3) industrial innovation (private R&D as percentage of GDP, private researchers for every 10,000 employees, number of patents [triadic] proportion of innovating companies [Oslo Manual]), and 4) organizational investment (information and communication, training, value chains). Efforts are being made in Mexico to gather and systematize information in line with these indicators.

The evidence from successful countries suggests that innovation policies should have characteristics such as the following:

1) Combine demand-side and supply-side policies to increase spending on R&D and improve competitiveness. Excessive emphasis on only one aspect could turn out to be useless or counterproductive.
2) Adopt an innovation system perspective.
3) Involve and co-ordinate different levels of government: local, regional, and national.
4) Assure sustained investments to create technological capabilities in companies and reinforce certain areas of knowledge in universities and research centers.

Argentina, Brazil, and Chile have some successful experiences of innovation, but lack the NIS approach and continue to have difficulties in creating links among agents (Chudnovsky, Niosi, and Bercovich, 2000; Vonortas, 2002; Furtado et al., 1999; Velho, 2005; Mani, 2004). Mani (2004) argues that the fine-tuning of financial instruments for R&D is not enough and should be complemented with non-fiscal instruments, particularly human resources training policies. The success of such instruments depends, among other factors, on the existence of a sufficient number of technicians with capabilities that can be incorporated into R&D activities. A more systematic and thorough evaluation is needed, and greater documentation of the experiences.

9.4 Different Perceptions on the Innovation Model and the Approach to Science, Technology, and Innovation Policy in Mexico

The evidence shows that in Mexico there is a certain degree of consensus among agents on various premises of STIP. Box 9.3 shows these and adds the divergences.[2]

Box 9.3 Perceptions on the stip approach in Mexico

Premises agreed on

- Need for a macroeconomic context that is stable and favors public intervention in science, technology, and innovation (STI).

- STI contribute to social development and to the building of a knowledge-based society
- Importance of scientific research to increase society's cultural heritage, train human resources (generation of talent), and generate knowledge for technological development and innovation.
- Need to articulate science, technology, and innovation policy with a balance that solves any redistributive conflicts that may arise.
- Interactivity as the hub of policies and creation of links among disciplines and fields of knowledge, between areas of knowledge, sectors and state and regional problems, between local/regional and national policies), concurrence of stakeholders and creation of networks to build and orient science, technology and innovation capabilities.
- Approach to solve economic and social problems.

Other points in the agreement

- Reach long-term agreements among the three major actors (government, academia, and business sector) to influence who takes the decisions in public policies and budgets.
- Ensure the participation of different sectors of society, considering that financing comes from citizens and therefore there should be accountability.
- Since there are different actors involved in the conception of STIP, mechanisms are needed so that universities, firms, national institutes, public research centers, regional science and technology councils, scientific communities, associations of producers, public officials and other stakeholders set forth their objectives, interests, and demands for knowledge. There should be multidirectional communication mechanisms among the same and participation of the stakeholders in discussing STIP follow-up and evaluation mechanisms.
- Advance toward a society based on knowledge that solves priority socioeconomic problems and ensures greater social access and transfer of knowledge to improve the quality of life of the population. Since economic and social problems demand the conjunction of several disciplines, the approach of the solutions should be multidisciplinary.
- Distinguish between generation of knowledge and "innovative application of knowledge," which entails building bridges between science and technology. There is a need to train human resources to bring about the required change.
- Make an agreed-on diagnosis of national scientific and technological capabilities and a proposal to the political parties that take different scenarios into account. Consider the existence of different traditions, rhythms and logics in the production of knowledge among disciplines, research groups, and other stakeholders (universities, public research centers, etc.).
- Identify sectors and areas in which international technological leadership can be exercised and support them with new careers and research centers

- Place STIP within a strategy of consistent national development and in an NIS perspective, where learning plays a central role. Analyze systemic relations between STIPs and other systems (financial markets, labor markets, fiscal policy, etc.) and design a comprehensive policy that links the policies (STIP, industrial, competition, labor, etc.).
- Scientific and technological development requires financial resources, and it is therefore necessary to assure sustained investments.
- STIP involves different levels of government: local, regional, and national. The up-down dimension of the policy cannot include regional/local diversity. It is necessary to combine it with down-up policies stemming from the regions and localities.
- Policy design responds to a structure of bodies that legislate and organs responsible for the design. The different stakeholders should participate but not replace existing structures.

Diverging opinions

- On political will on the topic of science and technology.
  - As an argument in favor of the existence of political will the approval of the science and technology law by a congress with diversity of opinions was mentioned.
  - As an argument against, it was stated that there was neither clarity on the role of science and technology in development nor policy articulation.
- To what extent there are structural conditions to take a leap in technological, economic, and social development.
  - Arguments in favor: a regulatory framework has been created, the scientific and technological community has grown, there is macro stability, there is a certain political stability and the interest rate has dropped.
  - Arguments against: loss of competitiveness as a country (drop to place number 56–60 in the IMD) and lack of articulation among the three major actors (government, academia, and business sector) in policy design.
- With regard to the adequate institutional framework to formulate these policies, the options appear to be: continue with CONACYT, create a Ministry of Science and Technology, or separate decisions on science and technology on one hand, and innovation on the other hand. Nor is there any agreement on whether an integrated STIP should be defined or a specific policy for each one of these activities has to be designed.
- It is not clear how investment in science and technology can have a bearing on better living conditions. There is no agreement on the way of

identifying basic economic and social needs/problems, or mechanisms to orient science in terms of the kind of country that is desired.

- What rationale should prevail: one that is economic and business oriented, or a social one? In this regard, there is no agreement on the main policy model: academic, economic, or social oriented. There is a perception that emphasis was placed on the first since the 1970s; emphasis on the second in the last decade and that little attention has been paid to the third.
- Which should be the functions of government: some consider that these are facilitating and acting as a catalyst for the changes in behavior of the actors; others that they are to chose and subsidize company development and specific technologies.

Source: Foro Consultivo Científico y Tecnológico (2005).

The differences of opinion come from different theoretical–conceptual frameworks on the model of innovation, the relationship between STIP and economic and social development, and the outline of activity (academia, industry, and government) and institutions ascribed to diverse political positions. Beyond the differences, it is necessary to build consensuses in key aspects to achieve a more harmonious implementation of the policies.

9.5 Toward an Assessment of Innovation Policy in Mexico

9.5.1 Evidence of National Technological Capabilities

Over time, economic growth is the result of the interaction among a set of incentives – related to each country's institutional framework – and its domestic capabilities. Domestic technological capabilities include the ability to make effective use of knowledge to produce goods and services satisfying social needs.

Table 9.1 summarizes some indicators of the technological capabilities of four Latin American countries, including Mexico. It introduces information on the Republic of Korea as a point of comparison.

The information indicates that Latin America's endowment of human resources in the 1980s was fairly low in comparison with the Republic of Korea's, even though spending on education as a percentage of Gross Domestic Product (GDP) and the net rate of enrolment in secondary and tertiary education were not much smaller. This suggests that the Latin American countries have made an important effort to develop their human capital in recent decades, but that the results in terms of quality have not been as significant as those of the Republic of Korea. This result suggests that there are institutional aspects of the organization of educational activities that could explain these results. First, the indicator for Expenditure in Experimental Research and Development (EERD, or GIDE for its Spanish acronym) shows very low values in most of the countries, which evince that the Latin American countries' efforts in

Table 9.1 Indicators of national technological capabilities in some Latin American countries

	Republic of Korea	Argentina	Brazil	Chile	Mexico
A. Economic performance					
1. GDP billions of dollars (2003)[a]	605.7	126.7	492.2	72.1	620
2. Per capita GDP dollars (2003)[a]	12,638	3,300	2,757	4,548	6,008
3. Competitiveness ranking[a]					
- 2000	29	42	38	30	33
- 2004	35	59	53	26	56
B. Human capital					
1. Central government spending on education (% GDP)[b]					
- 1980	3.5 (1990)	1.9	0.7	4.1	3.1
- 2001	3.6	4.6	4	3.9	5.1
2. Net enrolment rate (%)[b]					
- Primary (1990)	104	94	86	88	100
- Primary (2002)	101	108	97	89	101
- Secondary (1990)	86	66.5 (1985)[c]	15	55	46
- Secondary (2002)	89	81	72	75	60
- Post-secondary education (1980)[c]	–	22.2	12	10.8	14.9
- Post-secondary education (1998)[c]	–	–	12.6	31.4	17.6
3. Students in post-secondary education in sciences, mathematics and engineering, percentage of total students in post-secondary education (1994–1997)[b]	34	30	23	43	31

Table 9.1 (continued)

	Republic of Korea	Argentina	Brazil	Chile	Mexico
C. Efforts in science and technology					
1. Patents granted to residents per million inhabitants, 2002[b]	490	4	0	2	1
2. EERD[d]					
- 1996	2.6	0.42	0.77	0.58	0.41
- 2001	2.91	0.42	0.87	0.57	0.4
3. EERD by source of funding[d]					
- Government (2002)	25.4	70.2	60.2 (2000)	50.5 (2003)	55.5
- Business (2002)	72.2	24.3	38.2 (2000)	35.2 (2003)	34.7
- Others (2002)	2.4	5.5	1.6	14.3 (2003)	9.8
4. Researchers in R&D per million inhabitants[d]			−2000		
- 1996	2,193	651	–	358	215
- 2001	2,880	684	323	419	434
			−2,00		
5. PhDs in sciences and engineering obtained by foreigners in the United States by citizenship of origin, 2001[e]	862	69	141	–	205

[a]IMD (2004); [b]UNDP (2004); [c]ECLAC (2003); [d]CONACYT (2005); UNESCO (2004), and OECD (2004a); [e]OECD (2004b). Data on researchers in R&D and EERD for the Republic of Korea were taken from the World Bank (2004).

Notes: The net enrolment rate corresponds to school-age children with respect to the total population of that age. Rates that exceed 100% in the table reflect discrepancies of information for both categories.

Patents granted were calculated on the basis of information on patents granted to residents in WIPO (2004).

EERD, expenditure on experimental research and development.

science and technology are still weak. Brazil shows the highest level of EERD (double that of most Latin American countries), but lower than the Republic of Korea. Second, the EERD by financing source shows that the greatest effort is that of governments, whereas firms do not show a high level of commitment to R&D activities. By contrast, Korean firms contribute with a significant percentage of EERD. Third, there are important differences between Latin America and the Republic of Korea with regard to number of researchers and human resources involved in science and technology activities.

This evidence suggests that Mexico and other Latin American countries have made efforts to increase their domestic technological capabilities through the training of human resources, but the resulting educational quality is still poor. In contrast, efforts in science and technology fall way behind international standards. Both factors contribute to explaining the slow evolution and weakness of technological capabilities in recent decades.

9.5.2 Some Characteristics of R&D Activity and Innovation of Mexican Firms

The 2001 National Innovation Survey (1999–2000 data) showed that 33% of firms operating in Mexico are innovative, that is, they introduced new products or processes into the market during the period. Some 47.5% of innovating firms stated that they carried out R&D activities.

Innovating firms follow strategies similar to those of latecomer countries, that is, they carry out R&D to differentiate technologies and products, mainly on the basis of machinery and equipment. Their strategies include creation of technology for their own use, although they also make great efforts to adapt and assimilate. Chart 9.1 shows firms' main strategies.

Three indicators are used at international level to obtain an approximate measurement of innovation inputs: intensity of R&D, intensity of spending on innovation, and technological intensity. Table 9.2 presents the levels of these indicators in Mexico, which show that a) spending on R&D is not high, the firms that carry out R&D spend an average of 0.7% of their sales on this item (in Spain they spend 1.8%); b) the companies that carry out R&D tend to make greater efforts in innovation; and c) a high percentage of spending on innovation refers to machinery and equipment, which is an international tendency.

Firms combine internal and external sources of knowledge. The internal sources are important, but the more intense the R&D activities, the greater the use of external sources. However, there is little cooperation for innovation with universities and public research centers, which reflects deficient articulation of the Mexican NIS.

In terms of the results of innovation activities, new products represent 16.2% of sales in firms that carry out R&D, a slightly greater percentage than the companies that do not carry it out (see Chart 9.2).

This differentiated behavior is greater when we consider the degree of novelty of innovations. Chart 9.3 shows that the majority of innovations introduced by all of the

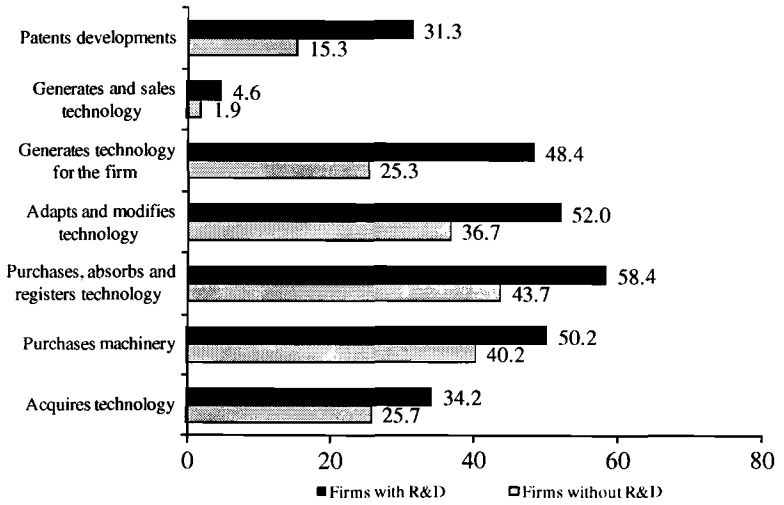


Chart 9.1 Focus of the technological strategy of innovating firms. Source: Encuesta Nacional de Innovación (2001)

Table 9.2 Indicators of inputs for innovation activities

	Innovators with R&D	Innovators without R&D	Innovators in Spain
Intensity of R&D	0.7	0	1.8
Intensity of spending on innovation	3.4	2.2	2.4
Technological intensity	30.8	0	33.4

Source: National Innovation Survey (2001).

firms analyzed are only novel for the firms themselves or for the country. But among the firms that carry out R&D, a much higher percentage of innovations translate into new products in the international market in relation to the firms that do not carry out R&D, 27.4 and 14.5%, respectively. This means that R&D activities are associated with better innovative results, sales of new products represent a higher percentage of firms' sales, and these tend to introduce a larger amount of novel products into the international market.

9.5.3 Assessment of Instruments of Innovation Policy

Over the last few years an innovation policy has been integrated, which in 2005 translated into a structured set of instruments which address different deficiencies, as described in Box 9.2 (resources, incentives, capabilities, and opportunities). Its

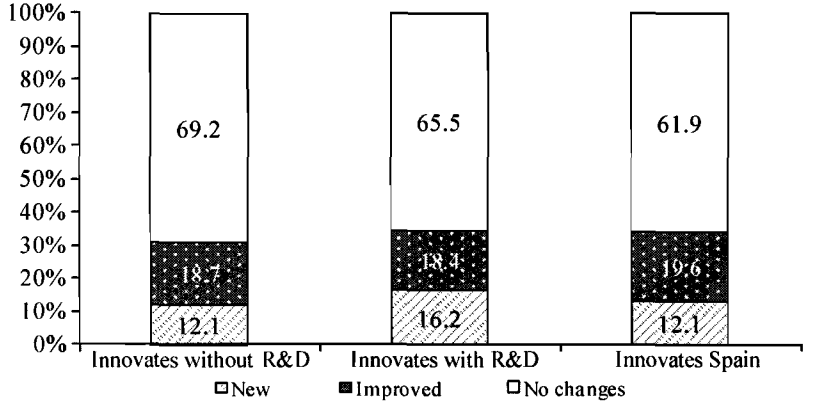
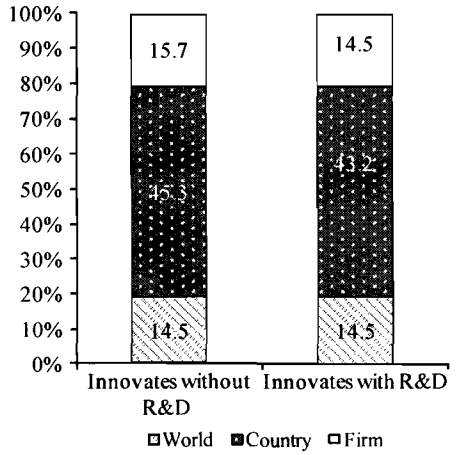


Chart 9.2 Results of innovative activity: percentage of new products in sales. Source: Encuesta Nacional de Innovación (2001)

Chart 9.3 Results of innovative activity: novelty of innovations. Source: Encuesta Nacional de Innovación (2001)



implementation has been slow and many of the instruments were not implemented until the end of the 2000–2006 six-year presidential term.

9.5.3.1 Combination of Innovation Policy Instruments

Most of the instruments are supply side, that is, they are oriented to transferring to companies the necessary resources and capabilities for innovation from the government and related agents (universities, research centers, etc.). They have been designed as supports when the conditions of the setting (human resources, scientific base, regulatory framework) and policy coordination are critical conditions. The

instruments and the deficiencies they address are shown in Table 9.3. A detailed description is included in the work by Daniel Villavicencio in this book.

There are three major articulators of innovation policy with different degrees of maturity: a) CONACYT[3] funds, b) fiscal incentives, and c) AVANCE[4].

The CONACYT funds are defined in the Science and Technology Law under the regime of trust fund. They allow the Council to interact with State ministries, state governments, federal entities, academic and scientific institutions, and private enterprises. There are three types of funds: a) sectoral, b) joint, and c) institutional.

The Sectoral Funds are trust funds that the Federal Public Administration and CONACYT constitute to allocate resources to scientific research and technological development.

The Joint Funds[5] are supports for state and municipal government to scientific and technological development by means of a trust fund made up of contributions from the State or Municipal Government and the federal government through CONACYT. Their objective is to empower the state and municipal governments to allocate resources to scientific research and technological development in order to solve strategic problems identified by the State itself; promote the development and consolidation of the scientific and technological capabilities of the states/municipalities; and channel resources to help the state's comprehensive development. There are currently 29 co-ordinated state joint funds and one municipal one. An evaluation of their performance is presented further ahead.

The Institutional Funds support the development of quality scientific research, the training of professionals with a high academic level at all grades (with emphasis on strategic areas and new, emerging and lagging fields) and the consolidation of international-level interdisciplinary research groups that promote national scientific development.

Fiscal Incentives for R&D are a program of federal fiscal benefits for taxpayers who invest in R&D in order to develop new products, materials, or processes. The objective is to reinforce the spending and annual investment made by the firms on projects carried out or in process to develop new products, processes, or services. The incentives, in force as of 2001, consist of tax credits of 30% of the spending and investment under this heading and in training of specialized personnel essential for the attainment of the previously established objectives. This instrument is aimed at remedying deficiencies in resources and incentives and is evaluated further on in this chapter.

Finally, the AVANCE (High Value Added in Business with Knowledge and Entrepreneurs by it Spanish acronym) subprogram, assigned to the Program for Promotion of Innovation and Technological Development, whose objectives are to promote the creation of organizations with high value added based on scientific and technological knowledge and design and implement and operate seed risk capital schemes for the financing of technology. It is made up of three instruments: the first is "Last Mile," designed to convert mature scientific and technological developments into investment prospects that give rise to high value added businesses or new lines of business. The second is the "CONACYT-NAFIN Entrepreneurs Program" to support capital investment by firms that develop new high value added

Table 9.3 Innovation policy instruments in Mexico and deficiencies dealt with

Policy measures	Instruments in Mexico	Resources	Incentives	Capabilities	Opportunities	Year started
Supports for basic research	SEP-CONACYT basic science fund					Continuation of supports for basic research from previous administrations, from 2002 in this form
Support for oriented research	Various sectoral and joint funds					2002
Support for training and the mobility of researchers	Doctors and specialists to industry					Competitive Grant Process 2005[a]
	Young talents					At the design stage
	Avance-business schools					Competitive Grant Process only in 2003
Donations, subsidies, supports and prizes for industrial R&D.	Avance-last mile					May 2003, call 2004-1
	Avance-CONACYT-NAFIN guarantee fund					November 2004
	Economy fund					2002
	ADIAT and PNT prizes					Continuation from previous administration
	Innovation consortia					2004
Fiscal incentives for R&D	Fiscal incentives for research and technological development					2001
Initial financing for risk capital	AVANCE-Funds to promote innovation (seed capital)					At the design stage
	Avance-CONACYT-NAFIN Entrepreneurs program					April 2004
Support for information and intermediation among agents (services, AVANCE tools)	Real options					January 2005
	Customs firm					2003
	Industrial and intellectual property					2004
Measures for the creation of networks	Network of talents for innovation (promotion measures)					2005

Source: Author's analysis of the PLASC data.
[a]Competitive Grant Process refers to a yearly process called in Spanish "convocatorias".

lines of business based on scientific and technological knowledge at the commercial development stage. The third is the "CONACYT-NAFIN Guarantee Fund," which facilitates access to lines of credit by means of guarantees and preferential financing to companies that develop new lines of business.

Furthermore, the instrument "Innovation promotion funds (seed capital)" is linked to the AVANCE subprogram with seed capital funds for incipient businesses and firms based on the exploitation of scientific discoveries or technological developments. As a whole, the AVANCE subprogram mainly addresses deficiencies of resources and incentives.

An assessment of the impact of some instruments on the increase in private R&D should measure inputs, products, and behavior of additionality. There is evidence that certain supports, particularly those associated with the program of collaboration in R&D, do not necessarily generate additional contributions from the firms on the resources received (Georghiou, 2002). In Mexico this is especially important for tax incentives, sectoral funds, joint funds and consortia, but a study of additionality is not the object of this chapter.

9.5.3.2 Analysis of Joint Funds and Fiscal Incentives[6]

These instruments were designed and implemented from the beginning of the 2000–2006 administration so they have a certain maturity and it is now possible to evaluate some results.

i) *The joint funds.* Table 9.4 shows the evolution of the total amount allocated to the joint funds. Charts 9.4, 9.5 and 9.6 show the results of the 1,425 projects approved and financed in 111 competitive grant processes during the period 2002–2005.

Table 9.4 Evolution of joint funds (millions of current dollars)

	2002	2003	2004	2005
Joint funds	19.4	20.2	18.7	27.3

Source: Prepared by the author based on official CONACYT data on the financial situation of the funds.

An analysis of the information shows that

- the state funds in operations and the total amount allocated to financing projects have grown constantly;
- projects have been aimed at scientific research and technological development;
- the knowledge areas with the highest percentage of projects approved are engineering and industry (22.6%), biotechnology and agricultural sciences (20.3%), and social sciences and economy (16.2%);

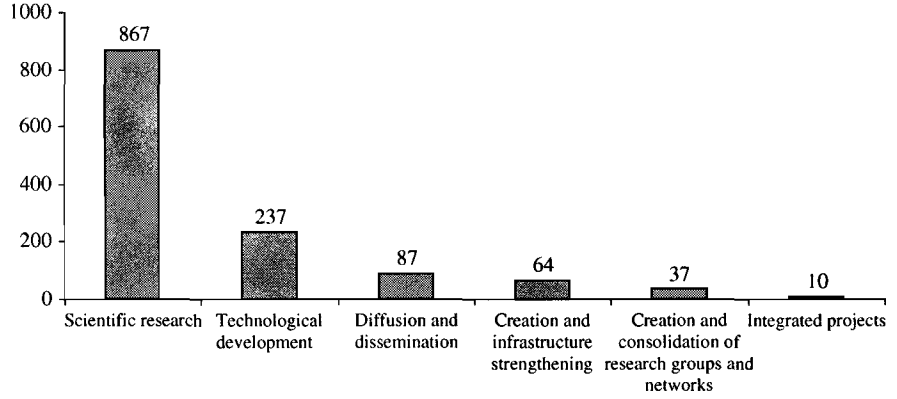


Chart 9.4 Types of joint funds, 2002–2005 (projects). Source: Prepared by the author based on official CONACYT data on the joint funds

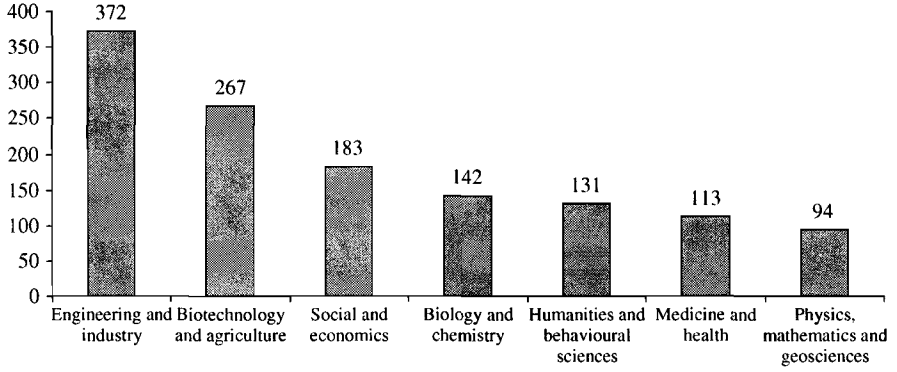


Chart 9.5 Supports by areas of knowledge (projects). Source: Prepared by the author based on official CONACYT data on the joint funds

- although the joint funds are oriented toward applied research (82%), a smaller percentage of the projects can be classified as technological development (14.5%) and basic science (3.5%);
- the institutions benefited are mainly state higher education institutions (66%), the CONACYT research centers (16%), and, to a lesser extent, firms (9.6%);
- the bias toward state universities contributes to greater decentralization of federal resources allocated to science and technology.

ii) *Fiscal incentives.* This instrument was one of the most successful of the 2001–2006 administration. Between 2001 and 2005 both the amount of fiscal incentives authorized and the firms benefited increased. The universe of firms that carry out R&D in Mexico is made up of micro, small, medium, and large enterprises in different sectors of activity. This heterogeneity is reflected in fiscal incentives, as can be seen in Tables 9.5 and 9.6.

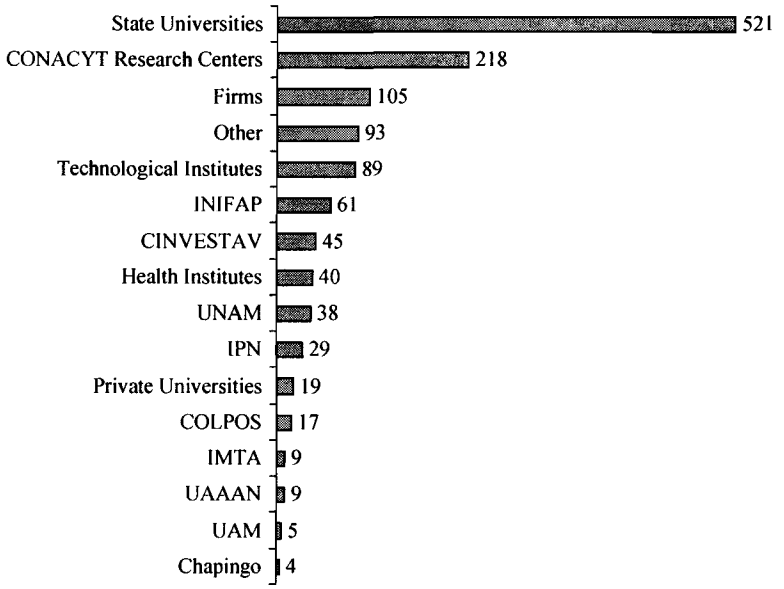


Chart 9.6 Sponsored institutions (projects). Source: Prepared by the author based on official CONACYT data on the joint funds

Table 9.5 Evolution of the amount of fiscal incentives (millions of current dollars)

	2001	2002	2003	2004	2005
Amount	37.8	45.1	45.5	90.9	272.7

Source: Prepared by the author based on official CONACYT data.

Table 9.6 Evolution of the projects submitted by firm size (millions of current dollars)

Firm size	2001	2002	2003	2004	2005
Large	31.5	52.5	63.5	85.4	124.9
Medium	22.7	29.3	29.4	38.5	52.4
Small	5.3	9.9	12.8	12.8	21.7
Micro	2.3	5.4	3.2	9.5	15.6

Source: Prepared by the author based on official CONACYT data.

Firms of all sizes have submitted projects with an increase in micro and small ones. A more detailed analysis at firm level shows that of the 621 firms benefited during the period, 327 applied for incentives for the first time in 2005. Moreover, the majority of the incentives were concentrated in few companies. As shown in Table 9.7, of the 505 firms benefited up to 2004, 26 obtained 54% of the incentives granted throughout the period. Outstanding among them are automotive companies

Table 9.7 Fiscal incentives of the main firms, 2001–2004 (thousands of dollars)

Firm name	Amount					Total amount (%)
	2001	2002	2003	2004	2001–2004	
Volkswagen de México, S. A. de C. V.	0	0	0	1,390	14,117	6.44
Controladora General Motors de México, S. A. de C. V.	2,679	2,247	3,578	4,490	12,995	5.93
Delphi Automotive Systems, S. A de C. V.	0	2,818	4,431	3,677	10,927	4.98
Hewlett Packard de México, S. A. de C. V.	2,690	1,876	2,047	2,811	9,424	4.3
Nemak, S. A.	1,789	1,730	1,558	1,514	6,591	3.01
Vitro S. A. de C. V., several	1,909	1,761	1,025	1,478	6,172	2.81
Du Pont México, S. A. de C. V.	2,240	2,084	669	1,043	6,036	2.75
Tip de México, S. de R. L. de C. V.	0	0	640	3,399	4,039	1.84
Tubos de Acero de México, S. A.	386	3,198	443	0	4,027	1.84
Hylsa, S, A. de C. V.	988	926	1,219	451	3,584	1.63
Phi México, S. A. de C. V.	0	1,103	1,050	1,272	3,425	1.56
Daimler Chrysler de México, S. A. de C. V.	0	0	0	3,238	3,238	1.48
Centro de Ingeniería Avanzada en Turbomáquinas, S. de R. L. C. V.	1,100	0	929	1,068	3,096	1.41
Alestra, S. de R. L. de C. V.	2,863	151	35	0	3,048	1.39
Sigma Alimentos several, S. A. de C. V.	615	960	547	826	2,948	1.34
Ford Motor Company, S. A. de C. V.	0	0	0	2,607	2,607	1.19
Centro de Investigación de Polímeros, S. A. de C. V.	0	874	950	761	2,585	1.18
Galvak, S. A. de C. V.	233	56	652	1,590	2,532	1.15
Investigación de Tecnología Avanzada, S. A. de C. V.	398	274	98	1,660	2,430	1.11
Mabe México, S. de R. L. de C. V.	0	0	1,695	715	2,410	1.1
Toyota Motor Manufacturing de Baja California, S. de R. L. de C. V.	0	0	0	2,326	2,326	1.06
Metalsa, S. de R. L.	0	847	372	1,086	2,305	1.05
Transmisiones y Equipos Mecánicos, S. A. de C. V.	339	499	537	890	2,265	1.03
Laboratorios Silanes, S. A. de C. V.	564	0	699	911	2,174	0.99
Ganaderos Productores de Leche pura, S. A. de C. V.	0	709	878	585	2,172	0.99
Probiomed, S. A. de C. V.	650	513	504	196	1,863	0.85

Source: Prepared by the author based on official CONACYT data.

Table 9.8 Reported spending on research (millions of dollars)

Firm size	2001	2002	2003	2004
Micro	4.0	3.6	2.7	9.0
Small	9.5	22.3	29.6	39.3
Medium	49.0	175.4	104.4	115.0
Large	4.0	3.6	2.7	9.0

Source: Esteva Maraboto (2005).

Table 9.9 Project size (dollars)

Incentive applied for	Number of projects
More than 1 million dollars	35
Between 100,000 and 1 million dollars	347
Between 10,000 and 100,000 dollars	938
Less than 10,000 dollars	286

Source: Esteva Maraboto (2005).

and companies with Mexican capital that carry out R&D activities (Vitro, Nemak, Hylsa, Metalsa, Probiomed, etc.).

In parallel to the duplication of the number of firms benefiting from fiscal incentives, reported spending on R&D has quadrupled (see Table 9.8). This evolution can be partly explained by the firms' increase in spending in the 4 years (General Motors; Hewlett Packard; Investigación de Tecnología Avanzada, Galvak, Metalsa) and partly by the inclusion of new firms with high expenditures (Volkswagen, Tip de México; Daimler Chrysler; Sigma, Ford Motor Co., etc.).

As appreciated in Table 9.9, the average value of the projects is small, since the majority of them report spending between 10,000 and 100,000 dollars, and there are only 35 projects with spending above 1 million dollar.

The innovations reported are technological applications based on packages of existing knowledge (customizing), identification and development of opportunities to improve costs or quality, development of improvements, design adaptation of elements for local supply, and development of systems and other back-up instruments to improve business administration.

In general terms, fiscal incentives reveal certain characteristics: firms of all sizes have received them, although one third were applied for by large companies. The number of firms that have obtained fiscal incentives by their R&D spending has increased, which shows greater dissemination of the instrument. However, only 26 firms received 54% of the benefits, among them various subsidiaries of multinational corporations explain a high percentage of the incentives granted. Furthermore, the average value of the projects is small, for most of them reported spending of between 10,000 and 100,000 dollars. Finally, the low average amount of the projects and the objectives and nature of the innovations generated seem to indicate that R&D is aimed more at bringing about incremental improvements than new products or processes.

The projects have different objectives, from disperse and random actions for improvement by individuals or temporary groups, professionals or technicians dedicated to other functions who carry out isolated tasks to seek improvements, product of factory engineering groups with time and resources assigned to research, to groups dedicated to R&D in an exclusive or preferential manner. This result is consistent with the data reported by the National Innovation Survey on the formality of R&D activities and the personnel dedicated to these activities. Only 64% of the companies that carry out R&D have a laboratory, and many firms do not report personnel dedicated to these activities.

The high share of automotive assembly plants in the total of fiscal incentives assigned is noteworthy, since they do not have a tradition of carrying out R&D activities in Mexico. A more detailed study of this instrument is required in order to evaluate to what extent the incentives have supported spending on R&D, and basically experimentation, instead of development, which entails identifying the activities reported by the beneficiaries.

9.6 Final Reflections

International experience shows that innovation policies are important in improving the dynamism of national innovation systems and countries' competitiveness in products with high value added. But success appears to depend on the combination of instruments on the demand and supply sides sustained over the long term.

A number of studies have documented that Mexico, like various Latin American countries, is weak in the design of the STIP. Although some policies applied over the last few decades have resulted in the creation of an infrastructure of human capital research and development, the same cannot be said about companies' technological behavior. Due to the macroeconomic turbulence that these countries have confronted in recent decades, firms have developed a defensive behavior that has negatively affected the option to invest with a long-term outlook.

Mexico has a great deal to do so that STI contribute to economic development. International evidence shows that sustained policies are needed in order to advance. In view of the differences in opinions on different aspects of STIP, it is necessary to encourage the necessary consensus to guarantee the design and implementation of a sustainable strategy over the long term.

An initial approximation to the analysis of STIP in the 2000–2006 administration suggests that beyond the efforts made, design and implementation weaknesses persist:

1) A long-term approach based on the consensus and commitment of the key players is lacking, which counteracts the cumulative effects and the expected change in the behavior of the agents.
2) Certain changes in the instruments employed in the period gave rise to confusion among the players, which does not contribute to altering their behavior.

3) A systematic and sustained NIS approach is lacking. STIP has been more geared to solving market failures than to solving those of the system as a whole.
4) Different conceptions on the innovation model persist, and many policy makers seem to assume the old idea of the linear model.
5) Beyond decentralization efforts, an up-down approach persists which is imposed on the down-up proposals that emerge from the regions.

The study of innovation policy showed that

1) The approach to the STIP until the end of the 1980s was basically supply side. An innovation policy was gradually designed in the 2000–2006 administration.
2) Combining demand and supply innovation policies has been lacking. The measures continue to be basically direct on the supply side. Various novel instruments have begun to be implemented or have been designed but not implemented, which weakens STIP as a whole.
3) Policy instruments in Mexico tend to be changed every 6 years by the incoming government, which hinders cumulative effects to change the behavior of the agents. It is likely that this practice will be maintained.
4) The design of the innovation policy has been articulated around three instruments with different degrees of maturity: a) the CONACYT funds, b) the fiscal incentives, and 3) AVANCE.
5) This chapter studied the joint funds and the fiscal incentives. Significant progress can be observed in the impact of these instruments. The joint funds have increased substantially and have contributed to greater decentralization of the resources allocated to science and technology. The number of enterprises using fiscal incentives has also increased. The literature points up that there are firms that become captives of this type of instruments, which makes it necessary to measure the additionality to have a clearer evaluation of their impact.

The STIP is not sufficient to induce sustained growth in the industrial sector. It is necessary to articulate it with industrial policies oriented to productive development (Péres, 1997; Katz, 2000) and with competition policies designed to change the conditions in which different types of firms compete (Tavares and Tineo, 1999). Furthermore, there is a need to design and implement a combination of horizontal and vertical policies that integrate the down-up-down dimension of activities. In other words, there is a need for joint, sustained, and co-ordinated policies between the different levels of government and long-term strategies, consensuses, association, and commitment of the key stakeholders.

Notes

1. OECD and EC focus on innovation policies instead of STIP. In the case of developing countries, which have limited scientific and technological capabilities, it seems that is more appropriate to focus on STIP.

2. Foro Consultivo Científico y Tecnológico (2005).
3. CONACYT is the Spanish acronym form the Mexican National Commission of Science and Technology (www.conacyt.gob.mx).
4. AVANCE is the Spanish acronym for the program High Value Added in Business with Knowledge and Entrepreneurs.
5. In Spanish, Fondos Mixtos (FOMIX)
6. See Dutrénit et al. (2006) for a detailed study of the 2000–2006 science and technology program in Mexico.

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Chapter 10
Recent Changes in Science and Technology Policy in Mexico: Innovation Incentives

Daniel Villavicencio

10.1 Introduction

In the current context of trade liberalization we can see the development and co-existence of novel processes and dynamics which suggest new ways of designing and implementing policies to foster firm production and innovation. For instance, trademark exploitation (franchises) and production methods for durable goods for personal and domestic use (apparel, footwear, domestic appliances, and even cars) reinforce the tendency toward worldwide standardization. Moreover, there is a trend toward economic specialization in regions and countries. Production processes have gradually been segmented into links in worldwide production chains in regions, which has promoted specialization in firms manufacturing parts and components and product assembly. The subsidiaries of multinational corporations and national companies participate in this trend in different ways, irrespective of size.

At world level, we see the forming of clusters and chains of production with particular forms of coordination and hierarchical relations, which depend on the complexity of the components manufactured or assembled, on knowledge and human capital and on the capacity of companies to obtain the inputs and services necessary to create value and keep up the productivity standards demanded by the global chain.

The national and regional offer of intellectual capital, services to production and to trade, incentives to productivity and innovation, as well as political and macroeconomic stability determine the attraction for investment and the establishment of links in global production chains.

The regulatory action of the State by means of public policy programs must contribute to creating room for companies to take advantage of the opportunities and counteract the negative effects of the trade opening. To what extent have the

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industrial and technological development policies in effect in Mexico contributed to creating supports in keeping with productivity, innovation, and competitive needs within the framework of global market dynamics and transnational chains of production and creation of value?

The purpose of this chapter is to analyze transformations in the design and execution of industrial and technological policy in recent years in Mexico as of the different programs implemented by CONACYT and other institutions.[1]

Section 10.2 contains a general reflection on the changes in industrial and technological policies (hereinafter ITP) at world level. Section 10.3 includes a brief outline of the evolution and distinctive features of the policies to promote industrial development in Mexico. Section 10.4 presents the main characteristics of the general pattern and functioning of institutions, programs, and mechanisms implemented in the last few years in Mexico based on certain amendments to the Science and Technology Law and on program design.

10.2 The New Premises of Industrial and Technological Policy

This section introduces the main transformations in the conception and design of industrial and technological policy (ITP) on the argument that the world scenario characterized by globalization has particular effects on industrial sectors and regions, so that the design of the new ITPs responds to the demands of the "current technical–economic paradigm" (Freeman and Pérez, 1988). This paradigm compels firms to increase their productivity and competitiveness based on new technological and organizational competences, greater use of knowledge and new institutional links.

Another important aspect is the role of public policy in the promotion of companies', sectors', regions', and even countries' innovation. In this regard and from the perspective of the evolving economy, Edquist (2002) states that public policy does not mean solving market "failures," but market "problems." This idea is closely linked to the neo-institutionalist approach, which highlights the function of institutions as a framework for company operations and relations in the market.

The point to underscore is the role of the State and public policy in the design and implementation of market regulation mechanisms. Under the premise of the rationale and limited action of stakeholders in the market, it is clear that the attainment of companies' objectives and interests is possible in the space established by the interests and actions of the other stakeholders. Tensions and conflicts between them are settled within the framework of the laws governing trade, investment, labor markets, intellectual property, etc.

Now, the market is built by the action of firms and other institutions at the macro, meso, and micro levels. Those actions in turn give rise to new specific forms of cooperation, but also to tensions (competition, for example) which must be settled by the laws, programs, and related public institutions (problem-solving policy).

The third aspect is the prevailing concept of the meaning and dimensions of innovation. Innovation is a process of knowledge creation based on existing knowledge,

exploration, and exploitation of new opportunities. It requires learning processes and acquisition of cumulative technological, productive, and organizational capabilities which result in better and/or new processes and products in the market (Dosi et al., 1988). In these processes, companies develop capabilities to articulate their internal technological and organizational experiences, both individual and collective, with those obtained in their interaction with the environment (Villavicencio and Arvanitis, 1994).

Innovation occurs in firms, not in an isolated manner, but in interaction with other firms or public and private Research and Development (R&D) agencies and universities. Moreover, the ideas of where, how, and when to innovate not only come from entrepreneurs, engineers, and researchers from R&D laboratories but also come from interaction with suppliers, clients, and even from the actions of competitors.

The creation of technological knowledge has increasing, varied time-frames and processes and is distributed among more and more stakeholders, and therefore the forms of interaction between these and the speed of circulation of knowledge become central aspects of innovation. Therefore, production chains, sectoral clusters, and innovation networks take on importance to the extent that they offer less costly knowledge dissemination mechanisms, becoming collective stakeholders that foster co-operative innovation.

The learning of new technological capabilities, the acquisition and capitalization of knowledge, and the capacity to translate it into new processes and products have been the central element of firms' innovation strategies since the end of the 1980s. The learning process and the use of knowledge are linked to the size and financial capacity of firms, as well as to the characteristics of the sectors in which these operate, including the immediate (regional) institutional setting (Malerba, 2003).

Thus, technological knowledge demands firms to develop innovation strategies that integrate commercialization, services, organizational changes, use of patents, and others (Nyholm et al., 2002).

For many years technology was conceived as a "material" good (machines and techniques) available on the market for all companies. Thus, industrial and technological strategies were basically conceived as fund distributors to acquire "material" technology and thus increase firms' economic performance. These policies, which we can call "sole-instrument" (Lipsey, 1998), did not distinguish sectoral dynamics and firm characteristics, namely size, market, products, technological intensity of productive processes, organizational and technological capacity (Villavicencio, 1993).

Nowadays, ITP design and decision makers assign an important role to technology due largely to the thrust and dissemination of microelectronics, new materials, and information and communication technologies, which have shown a growing capacity to overcome company productivity and adaptability to markets since the 1980s. The introduction of these technologies has been accompanied by substantial changes in organization of labor and of the firm as a whole.

Toward the end of the 1980s a combination of approaches and conceptual proposals on the content of the new technologies appeared. Research projects during

those years underscored that technology was more than a strictly technical "material" artifact, for it included intangible and organizational aspects relative to the use of information, the appropriation of knowledge, and interaction and cooperation with multiple agents. This expansion of the concept made it possible to clarify two issues:

1) It is not enough to acquire technological goods to increase productivity or economic performance, but to acquire the information necessary to use them, develop operational abilities, implement mechanisms for the dissemination of knowledge, etc.
2) Firms are social institutions with economic ends; they are the product of relations and rules built by individuals possessing diverse backgrounds and purposes. They are also heterogeneous entities with different capabilities to acquire and use technology, and they therefore take advantage of market opportunities through different strategies.

Such considerations form part of the OECD (1994, 1996) recommendations for the design of countries' industrial and technological policies. Recent studies place emphasis on an important change of conception and implementation of these policies on the basis of the characteristics of real economic stakeholders, considering their different productive capacities, technological competences, market strategies, etc. (Niosi and Bellon, 1995; Eliasson, 1998; Archibugi and Iammarino, 2003; Laredo and Mustar, 2001).

This change is also reflected in the types of financing of technological development and innovation, which used to be extended as loans and direct credits for firm projects. Without abandoning these types completely, financing today is granted indirectly as tax deductions or scholarships to professionals for research stays that make it possible for firms to have highly qualified personnel available at low cost.[2]

Another type is the promotion and joint financing of research and innovation networks, such as jointly sponsored projects or with risk capital for R&D in association with universities and basic and applied research laboratories (Amitav, 1990; Bellandi, 1992; Arvanitis, 1996). This type makes it possible to save on costs, especially for companies without the financial capacity and infrastructure required by R&D projects. For academic and research institutions, association with companies enables them to obtain resources for research and productive expansion of innovations and even obtain the respective patents.

The promotion of co-operative innovation networks has been accompanied by the strengthening of intellectual property instruments (licensing, patents, etc.), especially as concerns emerging technologies, with the object of assuring protection of knowledge, appropriation of its benefits, and control of its dissemination.

The redefinition of ITPs in the last decade involves public and private institutions in the design of objectives, mechanisms, and instruments; distribution of resources and financing; and even evaluation of results. The purpose of these new policies is to support firms in acquiring and improving technologies (hard and soft), increase R&D activities, and take the opportunities to innovate (Metcalfe

and Georghiou, 1998). In this regard, policies are not only aimed at redefining the framework for solving market problems but to take advantage of opportunities (opportunity-creating policy) generated by technology, dissemination and appropriation of knowledge, etc. (Edquist, 2002).

10.3 Heritage and Evolution of Industrial and Technological Policies in Mexico

Mexico's industrial policy has been linked to the import substitution model which prevailed for over 40 years. This model brought with it a combination of features that forged the heritage of industrial and technological development and of firms' actions, features which the current globalization and technological competitiveness have obliged to modify substantially. We can distinguish at least two stages in the alternative industrialization model. The first, from the fifties to the end of the 1960s, was characterized by stable economic growth; the second, as of the 1980s decade, imposed limits on the model and began a transition to the mid-1990s. As of that time a new regulatory framework began to be put in place, in which technology, innovation, and the markets' global-regional dynamics acquired an essential role for the economic performance of enterprises and the country as a whole.

However, it was not until the first years of this decade when more horizontal and selective policies were adopted which fostered innovation, favoring private joint financing and cooperation with academic institutions and public R&D centers.

10.3.1 Period of Import Substitution

The first stage in the import substitution period was characterized by attraction of foreign capital to boost national industrialization. It was a period when large transnational corporations' investment in the most dynamic sectors (engineering, chemical and pharmaceutical, automotive, and household appliances) predominated. For some authors, the strategy during this stage was simply to welcome any investment aimed at manufacturing goods in the country (Halty-Carrère, 1986).

More selective industrial policies were established in the 1970s, favoring investment of domestic capital with laws for the protection of strategic industries and stricter regulation of foreign investment and technology transfer. It was a defensive strategy to reduce the economic influence of foreign corporations and strengthen domestic industrial groups to create jobs and new markets, make more efficient use of natural resources, etc. Nonetheless, the protection mechanisms, price instability, and the shortage of inputs did not favor an improvement in technological capabilities, much less the strategies of entrepreneurial innovation.

Box 10.1 summarizes the general characteristics of the context, the industrial policy of the times, and companies' behavior. The distinctive trait is companies' lack of interest in technological development in a context of relative economic growth and growing demand for low-cost, standardized products. Entrepreneurial actions

were oriented to establishing political agreements with the elites in power with the aim of obtaining spaces for free play to obtain earnings to the detriment of their productive and technological capacities (Tirado, 1994; Luna, 1995; Mújica, 1997; Pérez, 1996; Alba, 1997).

Box 10.1 ITP during the period of import substitution, 1950s–1970s

General context	*Economic stability and relative growth* – Industrialization dominated by strategies of multinational corporations – Almost exclusive use of public resources by large domestic enterprises – Deficient industrial infrastructure – High cost of R&D – Little dissemination of technological information
Characteristics of firms' behavior	*Save cost of factors and increase productive capacity* – Little vertical integration, few chains of production – Dependence on suppliers of foreign equipment and technology – Adaptive learning and reverse engineering with high costs – Copies of products and process improvements, lack of innovation
Institutional actors of industrial policy and of science and technology	*Lack of coordination among instruments, agents, and services of technological and industrial development* – Diverse public institutions contribute to policy formulation (SPP, SECOFI, NAFIN, SEP, CONACYT[a]) which operate in an isolated manner and repeat patterns
General policy objectives	*Increase in infrastructure for productive capacities and employment* – Effort to increase and improve human resources – Financial support projects for large firms' technological development projects
Instruments types of financing	*Programs to finance infrastructure and productive capacity projects* – Export information services – Subsidies, trust funds, direct credits under guarantees that only large firms can comply with – Public financing, exclusively

Characteristics of policy operation	*Vertical and direct policies* – Offer of supports for short-term projects – No quality evaluation of results – Red tape in procedures and selection – Nature of firms, sectors, and regions not discriminated
Implications for firms' learning and innovation capacities	*Firms are passive and not very receptive* – It is hoped that policies will replace firms' shortcomings – Some firms succeed in improving their productive capacity – Technological dependence on foreign suppliers is not overcome – Innovation is sporadic and only in large firms – Few firms benefit from the policies

Source: Prepared on the basis of Villavicencio (2000).
[a]For their Spanish acronyms: SPP, Secretariat of Programming and Budget; SECOFI, Secretariat of Trade and Industrial Development; NAFIN, development banking institution (Nacional Financiera); SEP, Secretariat of Education; CONACYT, National Commission of Science and Technology

Prominent in Mexican industrial policy is the creation of public institutions which, at times repeating inherited objectives, granted subsidies and direct financing to short-term projects aimed at job creation, almost the only objective of industrial policy. Finally, it should be noted that the supply of services and public benefits was only useful to large companies that were capable of meeting the guarantees and conditions to obtain and reimburse the financing (Villavicencio, 2000).

10.3.2 Transition Period as of the 1980s

The second period, the transition, initiated in the early 1980s, was characterized by a set of structural problems associated with the energy crisis of the 1970s, its late impact on the Mexican economy, and by the obstacles inherited from the previous model, which became evident in the face of the new world trends. The structural problems were reflected by high costs deriving from inefficient production and marketing of goods (transportation and communications problems), monopolistic positions in some sectors, protectionist barriers to international trade, and little pressure to raise productivity and competitiveness, which was reflected by few incentives for innovation.

In the second half of the 1980s changes began to be introduced into the regulatory framework of the economy in general and trade, industry, and services in particular,

which were expressed in opening up to international trade, liberalization of foreign investment, elimination of state subsidies, promotion of exports, and policies to increase the productivity of national industries.

A notable change during this period, which was prolonged into the mid-nineties, was the role assigned to the technological dimension of productive processes by means of policies and programs to promote a culture of quality and technology and encourage technological modernization. The rules for public financing for scientific and technological activities were reformed, a new industrial property law was enacted and specialized agencies for the certification and metrology of productive processes were created.

Box 10.2 summarizes the general characteristics of the period and shows that despite the changes in the general conception of ITPs and the problem of technological modernization of firms, institutional inertias from the preceding period prevailed, with after effects on instruments and objectives, as well as on the behavior of firms.

Box 10.2 ITP in the transition period from the 1980s to the mid-1990s

General context	*Contraction of markets and increase in international competition* – Need to modify production structures – Economic and financial crises (1982, 1987, 1994) – High mortality of firms – Shortage of public resources – Deficient industrial infrastructure and scarce R&D – Increase in investment in *maquiladora* industry
Characteristics of firms' behavior	*Optimize resources, technological modernization, and search for productive efficiency* – Little vertical integration, few chains of production – Lack of liquidity and investment – Dependence on suppliers of foreign equipment and technology – Adaptive learning and reverse engineering – Improvements in products and processes to remain in the market and little innovation

Institutional actors of industrial policy and of Science and Technology	*Lack of coordination among instruments, agents, and services for technological and industrial development* – Science and technology policies under CONACYT supervision compete with those of other agencies (SECOFI, NAFIN, BANCOMEXT[a]) – Decentralized agents emerge to promote links between public and private actors
General policy objectives	*Promotion of firms' technological modernization* – Continuation of many objectives of the previous period – Creation of infrastructure and services for metrology and certification – Efforts to increase the participation of private agents in technological development – Financing to obtain technological information, access export markets, training
Instruments types of financing	*Programs to finance projects for infrastructure and productive capacity* – New rules for direct and indirect public financing – Predominance of public financing – Information services for exporting, finding suppliers, metrology, technological training – Subsidies, trust funds, funds for risk projects – Deregulation to encourage private financing
Characteristics of policy operation	*Reconversion policies* – Aim of simplifying procedures – Lack of evaluation of result quality and of institutional coordination – Promotion of the participation of private agents and of links between universities and companies – SMEs receive more attention, priority sectors are identified

Implications for companies' learning and innovation capacities	*Competition obliges firms to seek competitiveness strategies* – Credits and technological modernization instruments enable some companies to improve their technological infrastructure – Some companies carry out R&D to improve products and processes – Some domestic firms (large and medium) succeed in being innovative – Networks of firms emerge to externalize technological development

Source: Prepared on the basis of Casalet et al. (1995) and Villavicencio D. (2000).
[a]Acronyms as indicated in Box 10.1. BANCOMEXT, Bank of Foreign Trade.

There have been few studies on the action of entrepreneurs and business institutions such as chambers and their role in the construction of relations with the State favorable to the country's industrialization. Several authors coincide on pointing out the importance of the political links between business organizations and the successive governments (Story, 1990). For Mújica (1997), for example, business chamber acted historically as support and corporate negotiation in the building of the State, which had an influence on the unequal development of economic sectors. Attention to entrepreneurial demands used to occur under circumstantial pressures, which did not favor the development of a competitive industry, either.

Thus, while public institutions in charge of designing and implementing ITP were modernizing, companies and business chambers kept up old habits of eminently political interlocution with the State, with a lack of demands for instruments in keeping with the process of productive and industrial restructuring of the period. The very supply of ITP instruments and entrepreneurial proposals was limited to demands to reduce costs of raw materials, services, taxes, etc.

10.3.3 The Period of Opening

It was not until the second half of the 1990 that a new framework for the design of industrial and technological policy was introduced, which coincided with a currency depreciation crisis and a deep but brief recession.

The patterns of monopolistic behavior and technological autarchy of many companies, inherited from the import-substitution model, were combined with lack of

liquidity, increase in debts and, for the same reason, lack of investment, increase in the costs of foreign technology and services to production. At the same time, a period of accelerated competition not only in high technology and value added goods but also in products from traditional sectors and mature technology with countries with lower labor costs such as those of south-east Asia and China. The mortality of small and medium-sized enterprises (SMEs) increased and many large domestic firms were obliged to reduce their supply of products and establish agreements and strategic alliances with foreign firms in order to survive and remain in the domestic market.[3]

The process experienced by the industrial sector during the first half of the 1990s constitutes, in our view, the reference point for the modernization of ITPs. Many institutions restructured their policies, seeking greater coordination with other agencies and trying to avoid overlapping of objectives and instruments. The main aspect of the new policies is based on the need to increase productivity and the quality and competitiveness of firms to satisfy the domestic market faced with foreign competitors and to increase firms' exports.

Another important feature of the new ITPs is the promotion of association and cooperation among firms in order to integrate the smallest and weakest into sectoral chains to avoid the reduction of the productive plant and employment. Sub-contracting exchanges, programs of technological incubators and programs of university-company linkage received more attention with the aim of saving firms' specific costs such as those associated with technological development and investment in machinery. The implementation of ITPs tended to decentralize, regional and sectoral agencies were created, promoted by state governments, and regional institutions emerged that relied on public financing, but with autonomy to design and implement entrepreneurial promotion programs, especially SMEs.

Entrepreneurial agencies, for their part, began to show greater interest in taking part in the conception of ITP. In some cases, business chambers acted as regional consultative bodies and co-operated with public institutions to design and operate programs of their interest. Box 10.3 summarizes the main aspects of this period.

Box 10.3 Description of ITP in the period of opening 1995–2000

General context	*Unstable macroeconomic scenario and shortage of financial resources* – Increase in demand and adaptation of foreign technology with competitiveness in mind – Macroeconomic stability – Industrial structure dominated by strategies of large multinational and domestic firms – Insufficient domestic R&D

Characteristics of firm behavior	*Efforts to improve production processes, quality and economies of scale, and learning oriented to increasing productivity* – Lack of liquidity – Technological modernization processes and productive efficiency – Strategic alliances and chains of production – Tendency to specialization in products – Proliferation of the "*maquiladora*" companies scheme in many sectors – Some innovations of products and processes
Institutional actors of industrial policy and of Science and Technology	*Emergence of public and private bridge institutions* – CONACYT acquires the status of institution for the promotion of Science and Technology policies – Creation of regional and sectoral agencies that implement support programs for science and technology on the initiative of local governments
General objectives of the policies	*Promotion of technological capacities, productivity, and quality. Continuation of objectives of the previous period* – High-risk and shared-risk project financing – Financing at regional level – Financing for the integration of chains of production and exports – Promotion of incubators, development of suppliers, productive associations
Instruments types of financing	*Programs to finance technological development programs and innovation* – Trust funds, public funds for risk projects – Information for technological exports, suppliers, certification, metrology, technological training – Scarce private financing for technological development
Policy operation characteristics	*More inducive horizontal policies* – Creation of quantitative assessment mechanisms – Insufficient institutional coordination – Simplification of procedures

	– Promotion of cooperation and networks – Search for profitable projects and incentives to innovation projects – SMEs receive more attention
Results and implications for the capacities of firm learning and innovation	*Some firms active, others defensive* – Firms try to maintain market positions through prices (niches) and in some cases through technological advantages – Firms' technological capabilities are used to substitute machinery and equipment due to the difficulty in accessing foreign technological markets – High costs of access to information and to technological knowledge – Many firms use their innovation potential for marketing activities – Innovation networks (firms, institutions, etc.) are weak

Source: Prepared on the basis of Casalet (2000) and Villavicencio (2001).

10.4 Recent Changes in Science and Technology Policy in Mexico and the New Programs to Foster Innovation

The entry into force of Mexico's free trade agreements with countries of North America, Latin America, the European Union, and others since the mid-1990s coincided with the process of macroeconomic and financial stabilization, conditions which favored greater certainty for domestic and foreign investment, savings, trade, and productive activities in general.

At the same time, these changes allowed a greater presence of global corporations in the domestic market, which altered the conditions of competition through the introduction of greater technological and innovation capacities. In some sectors there were mergers and acquisitions of national firms by foreign competitors (chemical industry, for example). In others, processes of productive specialization were introduced and some firms became suppliers of parts and components in global chains of production, such as the automotive and electronics industries. In the commodity production sectors there was a high firm mortality rate due to international competition.

In 2000 there was a change of government which, among other things, promoted legal reforms and created instruments for the country's scientific and technological development (Casalet, 2005). Among the most important changes were the

Science and Technology Law (2002), the Organic Law of CONACYT, and the Special Program for Science and Technology (PECYT by its Spanish acronym). PECYT establishes three objectives: (1) adopt a policy of State in science and technology; (2) increase the country's scientific and technological capacity, and (3) raise competitiveness and firms' innovative spirit.

PECYT's strategies to attain its objectives are the following:

1) Structure the National Science and Technology System.
2) Adapt the Organic Law of CONACYT so that it satisfies the attributions assigned to it by the Law for the Promotion of Scientific and Technological Research (LFICyT by its Spanish acronym).
3) Promote areas of strategic knowledge for the country's development.
4) Decentralize scientific and technological activities.
5) Increase the scientific–technological culture of Mexican society.
6) Increase the national budget for scientific and technological activities.
7) Increase the middle- and high-level technical personnel and scientific and technological personnel with postgraduate studies.
8) Promote basic scientific and technological research and the strengthening of applied and technological research.
9) Expand the national scientific and technological infrastructure, including basic, middle, and higher education.
10) Strengthen international cooperation in science and technology.
11) Increase private investment in research and development.
12) Promote technological management in firms.
13) Promote the incorporation of high-level scientific–technological personnel in firms.
14) Strengthen infrastructure aimed at supporting firms' competitiveness and innovation.

In contrast to previous programs, PECYT tresses the need to foster innovation, bring supply and demand for science and technology closer, and induce greater participation of the private sector in financing and innovation activities, including SMEs. Decentralization of programs and resources and assessment of performance and operation of the instruments[4] also constitute substantial changes in this regard. Private strategies underscore an increase in infrastructure, the education of human resources, and inter-institutional cooperation by means of basic and applied research networks and consortia.

PECYT identifies strategic areas of promotion of research from a sectoral perspective. These areas are related, on the one hand, to leading-edge technology and, on the other hand, to aspects that concern national development: informatics, computer science, biotechnology, communications, materials, construction, petrochemicals, manufacturing processes, natural resources (maritime and land), water problems, technology transfer, and health.

PECYT gave rise to a set of new programs that came to light as of 2001 with the participation of other government agencies.[5] These are

1) institutional funds administered by CONACYT such as Risk Capital, AVANCE (High Value Added in Business with Knowledge and Entrepreneurs by its Spanish acronym), and Fiscal Incentives,[6] among others;
2) sectoral funds with financing shared with CONACYT, State ministries, and other parastate agencies;
3) international cooperation funds (NSF, EU, etc.); and
4) Joint Funds for shared financing with state governments.

In contrast to previous periods, when many government agencies related to strategic areas (energy, natural resources, health, etc.) established their own scientific and technological development programs in parallel with CONACYT, the PECYT funds were an effort to establish public policy coordination mechanisms in strategic sectors.

Below we will analyze the characteristics of some of these programs in order to interpret the nature of the institutional changes in relation to policy strategies and the new realities of the national economy.

10.4.1 The Sectoral Funds

In concert with other public agencies, CONACYT has created 17 sectoral funds to foster applied research and technological development. All of them have been implemented with resources from CONACYT and federal agencies related to the sector in question. Some were created for the first time and others are improved versions of earlier programs.

Each fund convokes a yearly competitive process and establishes areas of demand or sectoral priorities for research projects. The projects selected receive financing for the acquisition of machinery and equipment, improvement of infrastructure, thesis scholarships for graduate and postgraduate studies, travel expenses and per diems, and operating costs of the project itself (research assistants, logistics, surveys, laboratory tests, etc.). Depending on the characteristics of the areas, some funds favor support for research group projects, including inter-institutional groups, to foster co-operative research and generate more knowledge.

The amounts of resources for projects have varied from year to year depending on availability. One important aspect is that in projects proposed by enterprises, these should contribute at least the same amount as the resources requested with the intention of increasing the productive sector's share of spending on R&D and applied research. Table 10.1 lists the existing sectoral funds, they date they were launched and the number of convocations issued to December 2007.

10.4.2 The Joint Funds

The Joint Funds (Fondos Mixtos, FOMIX by its Spanish acronym) are jointly administered by CONACYT and state government agencies to decentralize the

Table 10.1 List of the convocations of the sectoral funds

Sectoral funds	Year begun	Number of competitive processes to the end of 2007
Sectoral Research Fund for Airport Development and Air Navigation ASA-CONACYT	2003	5
Sectoral Fund for Research and Technical Development in Energy CFE-CONACYT	2004	4
Sectoral Research and Development Fund on Water CNA-CONACYT	2004	4
Sectoral Fund for Research, Development and Technical Innovation in Forestry CONAFOR-CONACYT	2002	9
Fund for Scientific and Technological Development for the Promotion of Production and Financing of Housing and Growth of the Housing Sector, CONAFOVI-CONACYT	2002	4
Sectoral Science and Technology Fund for Economic Development ECONOMÍA-CONACYT	2002	6
Sectoral Research and Development Fund INMUJERES-CONACYT	2003	2
Sectoral Fund for Research in Agriculture, Livestock, Aquaculture, Agrobiotechnology and Plant Genetic Resources SAGARPA-CONACYT	2002	5
Sectoral Research Fund for Social Development SEDESOL-CONACYT	2002	4
Research and Development Fund SEGOB-CONACYT	2004	2
Sectoral Fund for Research and Development in Naval Sciences SEMAR-CONACYT	2002	5
Sectoral Environmental Research Fund SEMARNAT-CONACYT	2002	3
Sectoral Research Fund for Education SEP-CONACYT (2002-to date); initially Competition for Support for Basic Research Projects (2001) and before "Competition for Support for Research Projects 1999-2000"	2002	10
Sectoral Fund for Research in Health and Social Security SSA/IMSS/ISSSTE-CONACYT	2003	10

Source: Prepared by the author based on information from www.conacyt.mx.

financing of scientific and technological development. The first 16 FOMIX were set up in 2001 and 9 more in 2002. By December 2005, 28 state FOMIX had been created, plus 1 municipal (in Ciudad Juárez, Chihuahua).

The states' contribution has varied according to the agreements and especially the capacity of the federative entities to finance scientific and technological development activities. Some entities contribute the same amount as CONACYT and others that contribute half or less.

In the majority of cases, CONACYT's counterpart is represented by the State Science and Technology Council of each state. When there is no similar agency, Joint Funds are administered by the State Economic Development Secretariat or the Education Secretariat.

According to the structure of the FOMIX, there are priority areas, although these do not appear systematically in each yearly competitive granting process. In some Joint Funds' competitive processes have been opened for more specific areas. Table 10.2 shows the number of projects approved by area and year.

Table 10.2 Projects supported by Joint Funds in areas of demand

	Number of projects approved					
Area	2001	2002	2003	2004	2005	Total
Total	44	286	484	369	346	1,529
Agricultural food chain	10	54	66	53	60	243
Health	4	37	33	40	33	147
Social and educational development	15	59	95	96	46	311
Urban and rural development	4	26	25	24	35	114
Industrial development	8	46	126	112	64	356
Environment and natural resources	3	64	139	44	108	358
Issuance of competitive processes	*1*	*19*	*23*	*18*	*24*	*85*

Source: Prepared by the author based on documents that appear in www.conacyt.mx

As can be seen in Table 10.2, the number of projects supported in 2003 was higher than in other years. This is because the issuance competitive grant process and project approval lasts an average of 5 months and because there are Joint Funds that issue two competitive processes a year and others that issue them less often according to available resources. The larger number of project approvals in 2003 is due to the conjunction of various factors: a) greater availability of resources in some federative entities in 2003,[7] b) greater number of competitive grant processes issued in late 2002 which were added to those of 2003, and c) accumulation of applications by researchers, companies, and other agencies as the Joint Funds took root.

Table 10.3 also shows that the greater proportion of projects supported corresponds to the areas of environment, industrial development, and social and educational development. This situation is partly due to the fact that these three areas have appeared in the competitive grant process of all the Joint Funds every year. Moreover, the number of projects approved in these areas reflects the capability of applied research, the interest of the communities of scientists and technologists in them, and firms' participation in industrial development.

In addition to the areas of demand, there are five types that specify the kinds of projects to support and the results desired. Thus the majority correspond to projects of type A, which groups together more than half of the projects, followed by type B, which refers to technological development (see Table 10.3).

The project approval rate in 2002 was 39.3%, that is, for every 10 projects almost 4 were approved; in 2003, the rate was 42% and in 2004, 39.7%. Thus, the conclusion can be drawn from Table 10.3 that there is an appreciable supply of applied

Table 10.3 Projects approved by type in the Joint Funds

Type	Number of projects approved			
	2002	2003	2004	Total
Total	330	484	377	1,191
a) Scientific research	270	200	223	693
b) Technological development	29	101	88	218
c) Creation and consolidation of research groups and networks	4	13	18	35
d) Creation and strengthening of infrastructure	17	32	15	64
e) Dissemination and information activities	6	50	33	89
Various modalities	4	–	–	–
Not available	–	88	–	88

Source: Prepared by the author based on information from www.conacyt.mx

research projects, as every year approximately 1,000 applications are turned in. This situation contrasts with the 1990s, when the programs were administered by centralized federal agencies.

Most of the competitive grant processes present specific demands depending on real and potential users, so the expected results are ones that have an impact on the entity's needs or problems. Projects last an average of 2 years, and therefore some research projects from the first competitive grant process have just concluded or are about to conclude. However, CONACYT has not so far presented an estimate of the qualitative impact of the results or their benefits in terms of social and economic development.

10.4.3 The Science and Technology Sectoral Fund for Economic Development

The aim of this fund is to promote R&D and innovation in the production sector by means of resources for firm projects. Firms proposing projects must contribute a sum of economic resources equal to those requested, not necessarily of domestic capital, so the subsidiaries of transnational corporations can also compete.

There are three types of firm projects: a) innovation and technological development; b) creation and consolidation of R&D groups; and c) creation and strengthening of the firm's or the industrial sector's technological infrastructure.[8] More than 80% of the projects approved to date are type "i" followed by type "iii" (about 15%).

According to the information available on the CONACYT web page, in the first 3 years of the Fund's operation 177 projects were sponsored, one third of the total of applications (see Table 10.4). In terms of national industry and the total number of

Table 10.4 Projects approved in the convocations

Year	Projects requested	Projects approved	Percentage approval
2002	295	56	19
2003	209 (129)[a]	63	48.4
2004	209	58	27.8
Total	703	177	

Source: Prepared by the author based on documents that appear in www.conacyt.mx

[a]That year the modality of pre-proposals was used, with only 129 projects viable for assessment being selected. This is why the percentage approval appears greater, since it is calculated on 129 and not 209.

existing firms, these data are not very significant. However, if we consider that over the past 20 or 30 years new products and new technologies came mainly from abroad and that few domestic companies developed R&D, we can conclude that the sectoral fund tends to modify the patterns of technological development and innovation in the country, not only because of the very nature of the projects it finances but also because it fosters private investment in R&D.

Since it was set up, the Fund has encouraged industrial firms to create or improve their technological capabilities, to develop prototypes, and to provide the domestic market with new processes and products. In this regard, every year specific areas have been convoked, taking into account their economic and technological dynamism and, above all, the possible substitution of inputs, the generation of qualified jobs and the capacity to insert firms in chains of production with high value added. Box 10.4 lists the industrial areas that have appeared in competitive grant processes. As may be seen, there is a certain continuity from 1 year to the next in particular areas, such as the automotive and auto parts, electric and electronic, food, and pharmaceutical industries, which appear in all the competitive grant processes.

If we take into account all the periods that issued competitive grant processes and the continuity of the areas of the sectoral fund, the projects of the automotive and auto parts and electrical and electronic sectors are the ones that have received most approvals, which reflects their technological dynamism, which since the signing of NAFTA[9] have been a pillar of the growth of domestic manufacturing production, especially in the industrial areas of the north and center of the country.

As an interpretation of the way in which the fund is contributing to favoring innovation dynamics in the country, we can prepare a classification of the projects in four categories that enable us to understand the state of development of firms' productive and technological capacities in relation to their innovation strategies. Thus, there are projects to improve the R&D infrastructure to develop prototypes, to create R&D centers, and to improve or carry out new products and productive processes.

Box 10.4 Continuity of the areas of demand of the sectoral fund

Industrial area or of demand of competitive grant processes	*2002*	*2003*	*2004*	*2005*	*2006*
Food industry (processed foods)					
Automotive and auto parts industry					
Construction industry					
Pharmaceutical industry					
Machine tool industry					
Chemical and petrochemical industry					
Leather and footwear industry					
Textile industry					
Information and communication technologies (ICTs)					
Biotechnology					
Electrical and electronics industry					
Aeronautics and aerospace					
Nanotechnology: applied to materials, electronics, health, among others				*	
Advanced materials: ceramics, compounds, polymers, etc.				*	
Products for design and advanced manufacture				*	
Electronics and telecommunications: devices, sensors, circuit design, etc.				*	
Information technologies: information systems, biometrics, simulation, informatics security, embedded software, etc.				*	
Biotechnology environmental, food and health.				*	

Source: Prepared by the author based on documents that appear in www.conacyt.mx
*Areas of knowledge created in the 2005 competitive grant process

From the point of view of firms' technological learning paths and their relation to the competitiveness strategies, it may be said that the more knowledge is accumulated, the more complex the productive and organizational routines tend to be. In this regard, the firms that find themselves in the initial phases of a specific path

or with technologies that have received little dissemination in the market devote themselves to improving processes and products. In the stages that follow, firms are engaged in developing prototypes for new products, create infrastructure and even R&D centers which operate as autonomous business units capable of providing technological knowledge to other companies of the industrial group or sell R&D projects to external companies.[10]

Table 10.5 shows the projects approved per year according to the above classification. It can be seen that the largest proportion of projects is in the category of new or improved processes and products, which in the 5 years reviewed exceeds 40% of the projects approved followed by the category of prototypes, which represents more than one third. By contrast, projects to create R&D centers or improve infrastructure account for the lowest proportion.

Two hypotheses can be put forward regarding the last aspect a) that many firms have sufficient R&D infrastructure, and therefore they do not require financing for improving it or creating centers and b) that many firms do not have R&D centers or departments because they lack the financial, organizational, and human resource capacity.

The second hypothesis seems more plausible, since until the mid-1990s, the industrial sector was experiencing a process of productive and organizational restructuring in which many firms disappeared, others became specialized and others established relations of subcontracting or strategic alliances. Some had to make their production processes more efficient and modernize their technology to meet needs such as quality, price, and quick market response and, in cases such as the chemical and pharmaceutical industries, adapt to pollution reduction standards. This process of forced modernization in the first years of the trade opening, which meant putting finances on a sound footing, correcting errors, improving productive efficiency, and reducing production costs had to use productive and technological capabilities accumulated during the period of import substitution, to the detriment of their use to develop competitiveness strategies based on R&D and innovation.

Some authors maintain that in the 1990s there was a loss of technological capabilities due to the trade opening and the productive restructuring (Katz, 2000). But these factors could merely evidence the obsolescence of the accumulated capabilities, as global productivity and competitiveness patterns had changed considerably through the introduction of new technologies, new materials, and new uses of technological knowledge. In this process, some companies in technologically dynamic sectors kept up their competitive positions due to their capacity to enter global productive chains.

Table 10.6 shows the distribution of projects approved by the Fund in 2003[11] in relation to industrial sectors and the taxonomy used. It is worth noting that half of the projects are for new or improved processes and products and that only the automotive, electrical and electronics, and pharmaceutical sectors develop projects to create or strengthen R&D infrastructure. We can also see that most of the projects aimed at developing prototypes are from the automotive, electrical, and electronics sectors.

Table 10.5 Taxonomy of projects approved

Categories	Competitive grant process 2002		Competitive grant process 2003		Competitive grant process 2004		Competitive grant process 2005		Competitive grant process 2006	
	Projects	%	Projects	%	Projects	%	Projects	%	Projects	%
Total	56	100	63	100	58	100	74	100	33	100
Infrastructure for R&D	4	7.1	7	11.1	8	13.8	9	12.2	--	--
New or better products and processes	26	46.4	30	47.6	29	50.0	35	47.3	14	42.4
Creation of R&D centers	3	5.4	7	11.1	3	5.2	14	18.9	9	27.3
Prototypes	23	41.1	19	30.2	18	31.0	16	21.6	10	30.3

Source: Prepared by the author based on documents that appear in www.conacyt.mx

Table 10.6 Classification of projects by industrial sector (competitive grant process 2003)

	R&D Infrastructure		New products and processes		Creation of R&D centers		Prototypes		
	Projects	%	Projects	%	Projects	%	Projects	%	Total
Total	7	100	30	100	7	100	19	100	63
Aeronautics and aerospace			1	3.3					1
Biotechnology			5	16.7			1	5.3	6
Electrical and electronics industry	3	42.9	4	13.3			4	21.1	11
Food industry			5	16.7	2	28.6	1	5.3	8
Automotive and auto parts industry	3	42.9	9	30.0	5	71.4	7	36.8	24
Pharmaceutical industry	1	14.3	1	3.3			1	5.3	3
Other areas			3	10.0			3	15.8	6
Information and communication technologies (ICTs)			2	6.7			2	10.5	4

Source: Prepared by the author based on information that appears in: www.conacyt.mx

The above can be explained by the importance that these sectors have taken on in industry and the national economy as a result of the signing of NAFTA. In fact, during the 1990s there were major investments by foreign corporations in these sectors in order to increase the number of plants producing parts and components and final assembly on the country's northern border. The investments coincide with the strategies of many transnational corporations to articulate global productive chains, setting up plants in Mexican territory and forming networks of local suppliers.

However, participation by firms in the global chains of transnational or Mexican automotive, electrical, and electronics industries (large or SMEs) implies using and maintaining global standards of manufacture, logistics, and exchange of pieces and parts, as well as responding swiftly to the constant changes in product and equipment design. On account of the type of projects it supports, the sectoral fund makes it possible to complement firms' strategies in applied research and technological development in the most technologically dynamic sectors such as the electronics and auto parts industries.

NAFTA and the growing trade with the United States and Canada have boosted the development of trade, services, infrastructure, and qualified labor platforms in the large industrial population centers on the country's northern border, thus assuring a favorable territory for production needs. The result has been the forming of spaces for learning and institutional dynamics that represent settings with conditions and opportunities to raise the competitiveness of high technology sectors (Villavicencio and Casalet, 2005).

So far no information is available on the effects of the sectoral fund's supports on firms' technological learning capabilities, the strength of R&D centers, and the impact of new and improved products on the domestic market. However, the Fund enables firms in technologically dynamic sectors to carry out adaptation and innovation activities and thus respond to the demands for competitiveness of global chains of production and for trade exchanges within the framework of NAFTA. In this regard, the Fund contributes to the country's technological development by combining public and private investment.

10.5 By Way of Conclusion

This chapter has made a brief description of the main changes in the country's industrial and technological policies, as well as their effects on firms' behavior, with emphasis on the period that began with the trade liberalization and the signing of NAFTA.

We have seen how, as of the 2001–2006 administration, institutional changes were introduced that laid new foundations for the design and implementation of programs. In contrast to the models applied until the end of the 1990s, characterized by a heterogeneous supply of instruments lacking coordination, the policies of the last period tend to be more horizontal, decentralized and autonomous, for they seek, among other aspects:

1) Greater coordination between CONACYT and other government agencies.
2) Greater participation by the productive sector in the supply of programs and in the use of resources for R&D and innovation.
3) Greater sectoral orientation of applied research.
4) Greater regional orientation of the instruments.
5) Creation of infrastructure for technological development and R&D.
6) Incentives to co-operative forms of carrying out applied research and technological development through the financing of networks, consortia, and university-firm linkage.

The process of implementation and evaluation of the results of public policies requires long terms, especially in policies that aim to be innovative in design and implementation. The current policies reveal interesting quantitative results (for instance, the growth of projects approved) and have fostered growing participation by enterprises and academic institutions in the Joint and Sectoral Funds, thus fulfilling the assignment of meeting the demands of the various stakeholders, bearing in mind the specificity of regions, areas, and priority areas.

However, it is still early to assess the performance and the impact of instruments on firms' innovation capacity or the quality of applied research carried out by universities and public research centers. Many projects financed by the sectoral and Joint Funds are only just about to conclude, and in many cases, the results expected correspond to prototypes or generic knowledge that will require the design of instruments for their validation and dissemination.

Today's policies should set their sights on complementary objectives, take advantage of sectoral specialization and the technological and productive advantages inherited from the period of productive restructuring and foster the development of innovation areas in the "windows of opportunity" opened by emerging technologies. Furthermore, instruments and incentives should be combined in order to increase the technological capabilities of the greatest number of capabilities in all sectors of production and services, but also to select "winners" capable of expanding the technological frontier in strategic sectors.

One decisive condition for obtaining positive results over the medium and long terms is to maintain the country's macroeconomic stability to guarantee the positive results of policies and programs. Otherwise, financial or political crises could prevent not only implementing the policies altogether (Cimoli, 2005) but also taking advantage of technological opportunities and consolidating firms catching-up and innovation strategies.

Notes

1. Here we show information consulted at www.conacyt.mx
2. See the comparative study of programs implemented by different countries in Europe and Latin America in Casalet et al. (1995).
3. A study of the transformations during this period can be found in the compilation by Cimoli (2001) on the Mexican Innovation System.

4. Article 52, section IV, subparagraph b) of the Decree for the Expenditures Budget of the Federation for each Fiscal Year provides that "Programs subject to rules of operation shall present the evaluation of results of each program to the Budget and Public Accounts Committee of the Chamber, to the Ministry and to the Public Administration no later than 30 September, so that the results are considered in the process of analysis and approval of the Expenditures Budget of the Federation for the following fiscal year."
5. Programs in effect for more than 30 years, such as those for training of human resources, are maintained.
6. Reformed version of a program initiated in the mid-1990s.
7. The total amount approved for projects in 2003 was almost double that of 2002. See www.conacyt.mx
8. These modalities existed until 2005, the year in which it appears as "i" Firm association schemes for technological innovation, and what was previously considered as "ii" and "iii" were merged.
9. The North American Free Trade Agreement (Canada, United States, and Mexico) entered into effect in 1994.
10. Roussel et al. (1991) make an interesting analysis of the evolution of R&D activities in the last few decades and observes a process of diversification of units or departments.
11. The data for 2002 and 2004 reflect a similar distribution.

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Chapter 11
Scientific and Technological Policy in Mexico and Intellectual Property

Jorge Amigo Castañeda

11.1 Introduction

Before addressing the topic of scientific and technological policy in Mexico and its relation to intellectual property, it is important to review some aspects that have contributed to the establishment and evolution of what we know today as the "intellectual property system."

These facts make it easier to understand why industrial property is currently considered as an essential ingredient of countries' economic, industrial, technological, and intellectual development and growth.

The first known instance of "intellectual property" took place in the 15th century, in 1421 in Florence, when the State granted architect Filippo Brunelleschi a temporary privilege to make exclusive use for 3 years of a design of a barge to transport marble to Florence Cathedral, at that time under construction (IMPI, 1997).

Thus, intellectual property is not a recently created right, but has been the basis for the generation of knowledge, instruments, artistic creations, methods, and processes that have given rise to innovations and technical solutions to diverse problems and the benefits of which are reflected in better living standards in communities.

This is why many countries have adopted schemes and institutions to foster knowledge of the implications of the use of the intellectual property system.

Examples of this are the intellectual property and technology transfer units of some of the world's most prestigious universities. These units carry out various activities, among them analysis of technical information on patents in order to provide advisory assistance to those responsible for research projects; identification of latent needs to develop projects to meet those needs; identification of the portfolio of industrial property assets to be protected; steps taken before the authorities for the protection of such assets; and negotiation of technology transfer licenses or contracts.

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Mexico has not remained on the sidelines of these schemes. Since its establishment in 1993, the Mexican Industrial Property Institute (IMPI) has worked closely with public and private universities and research centers, as well as with national and foreign public agencies to make known the existence of the Institute and the means of accessing the system of protection offered by the Law on Industrial Property.

Going back to the historical antecedent mentioned above, by recognizing Brunelleschi's effort to solve the problem of transporting marble to Florence Cathedral, inventive activity was stimulated in the rest of his community to provide solutions to existing problems. But recognition and authorization of the exclusive period of use granted by the State demand in exchange documented information on the problem in question. The technical information contained in patents documents is an endless source of new knowledge that will serve as the groundwork for the development of new inventions.

Moreover, when the inventions or the products and services derived from them reach the consumer or end user they will need an image and a distinctive name or trademark. These names or marks are added to the portfolio of industrial property assets on which technological development relies and contribute to providing greater protection and legal certainty to the holders.

So far we have used the terms intellectual property and industrial property indistinctly, but the latter is one of the two major branches of the former. The other is copyright.

The authority in charge of registering copyright in Mexico is the National Copyright Institute, an agency that is answerable to the Ministry of Public Education; the authority in charge of registration and protection of industrial property is IMPI.

11.2 Universe of Intellectual Property

The juridical concepts overseen by IMPI are grouped into two sections: inventions and distinctive signs. The former include patents, utility models, industrial designs (which are in turn divided into industrial blueprints and industrial models), layout designs of integrated circuits, and industrial secrets. The latter include trademarks, collective marks, trade names and notices, and denominations of origin.

So, what is understood by industrial property?

Briefly, industrial property consists of a set of exclusive rights that the State grants to the creators of new products, procedures, or designs that will be offered on the market and will be accompanied by indications of a commercial nature to facilitate their identification to the consumer or user faced with products from competitors. These rights allow the holders to exploit industrially or commercially their inventions or distinctive signs exclusively for a particular period.

Protection by the system of industrial property is limited to the territory of the country in which the application for registration was filed. This responds to the fact that each industrial property office has its own regulatory framework that typifies the

juridical concepts of protection, the term of the rights, and the applicable procedures of examination and opinion.

The time frame for marks, notices, and trade names in Mexico is 10 years as of the date of presentation of the application, extendable for periods of 10 years, successively.

The term for inventions, which is also counted as of the date of filing of the application, changes depending on the concepts protected and is not extendable. Thus, the protection period for patents and industrial designs is 20 and 15 years, respectively, whereas the period for utility models and layout designs for integrated circuits is 10 years.[1]

The legal protection afforded by the Law on Industrial Property through IMPI contributes to promoting investment in scientific and technological research and development activities that can have a bearing on our country's economic growth.

OECD studies show that investment in science and technology makes itself felt by up to 25% in the growth of the developing countries and at least by 50% in the developed countries.

Spending on science and technology in Mexico in 2003 reached 0.39% of GDP, a proportion that is considered insufficient. It is worth mentioning, furthermore, that more than half of the investment in scientific and technological activities is financed by the government.

11.2.1 Investment in Science and Technology

Evidence of the importance of investing in research and scientific development activities is the impact these have on productivity. It is estimated that productivity can increase 0.17% for each percentage point that investment increases in research and development activities in developing countries.

Another indicator that complements the above statement is the annual average growth rate of spending on research and development, which it estimated should be 18% to reach the level of self-sufficiency. This indicator did not rise above 3% in the 2000–2004 period.

Investment in research and development in Mexico has increased very little in comparison with other countries since 1970. In Brazil, whose development is similar to Mexico's, it grew five times, whereas in Mexico it only grew two times. (Table 11.1).

Another angle of appreciation of this item is the quantity of patent applications by the nationals of these countries in their respective industrial property offices. The Korean Intellectual Property Office (KIPO) received 139,198 patent applications in 2004, of which 75.6% corresponded to Korean applicants (105,198) (KIPO, 2005), whereas IMPI received 13,194 patent applications, only 4% (565) of which corresponded to Mexican applicants in the same period (IMPI, 2006).

Investment in research and development also has a direct relation to countries' competitiveness and the per capita income of their populations.

Table 11.1 Investment in research and development

Country	Growth of investment	Patent applications by nationals (2004)
Republic of Korea	9.6 times	105,198
Spain	6.5 times	2,864
Brazil	5 times	3,098[a]
Mexico	2 times	565

Source: Prepared by the author based on official information.
[a]Data to 2002.

A study of these variables in eight countries, among them Mexico, clearly shows that the more the investment made in scientific and technological research activities, the better the competitive position and the greater the per capita income that can be attained.

11.2.2 Investment in Research and Development

The United States invests almost 2.69% of GDP in scientific and technological activities, which enables it to occupy first place in competitiveness and obtain a per capita income of around 37,000 dollars. In Mexico, where investment in scientific and technological activities barely reaches 0.39% of GDP, per capita income is less than 6,000 dollars and the country is in 41st place in competitiveness.[2]

The participation of the above-mentioned countries in the international patent application mechanism through the Patent Cooperation Treaty (PCT) shows a similar situation. The United States is also the country that presents the largest quantity of international PCT applications (more than 42,000), whereas Mexico only presents 0.10%.[3]

In the case of the United States there seems to be a direct relation between investment in scientific and technological activities, utilization of the PCT mechanism and its competitive position as a nation.

We can see, then, that investment in science and technology, with the consequent development of innovations in products and processes, leads to protection of intellectual property rights not only in the country of origin but also in others, giving rise to competitive advantages and consolidating the market position of innovating companies.

In Mexico's case, strong impetus has been given in recent years to the National Researchers' System (SNI), which increased the base of researchers registered in the period 1995–2003 by 73.6%. This has resulted in an increase of 98.3% in the publication of scientific and technological articles. However, patent applications by Mexicans registered only an 8.3% variation during the period.

This is due to the fact that the National Researchers' System favors the publication of scientific articles over the filing of patent applications for the results of research carried out (see Table 11.2). Moreover, it is much simpler for researchers to publish articles than undertake the process to obtain a patent, around 4 years, the

Table 11.2 Scientific production in Mexico

Year	Researchers (SNI)	Articles	Patent applications by Mexicans
Total	Does not apply	39,001	4,105
1995	5,868	2,916	432
1996	6,969	3,282	386
1997	6,278	3,587	420
1998	6,742	4,057	453
1999	7,252	4,531	455
2000	7,466	4,633	431
2001	8,018	4,999	534
2002	9,200	5,213	526
2003	10,189	5,783	468

Source: IMPI (2005).

standard time for the study and report on patent applications at international level and in Mexico.

It is important to mention that the publication of the advances of research can endanger protection of the results that may be obtained, since the advances are incorporated into what is known as the "state of the art," which harms the requirement of novelty of a possible invention.

As mentioned earlier, patent applications by Mexicans presented for study before IMPI barely reached 4% of the total in the 2004 fiscal year (IMPI, 2005).

An interesting fact that can be seen in Chart 11.1 is that patent applications from abroad increased gradually following Mexico's accession to the PCT, which entered into effect on 1 January 1995.

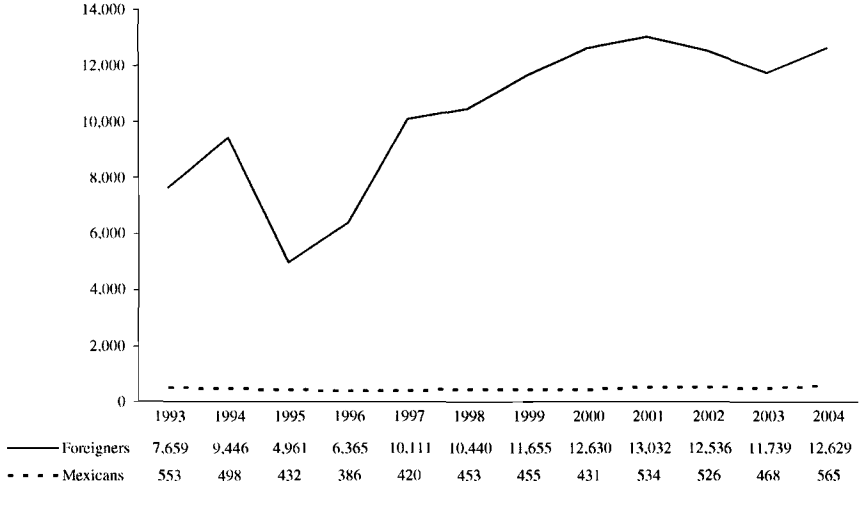

Chart 11.1 Patent applications filed before IMPI Mexicans-foreigners
Source: IMPI (2005).

Nevertheless, it should be mentioned that although patent applications by Mexicans have not increased significantly, their relative share of the total of applications received has diminished due to the constant increase in foreign applications.

In 1970, Mexico and the Republic of Korea had similar levels of investment in science and technology, competitiveness, and per capita income; in 1984 both countries had a similar number of patents granted by USPTO (Chart 11.2).

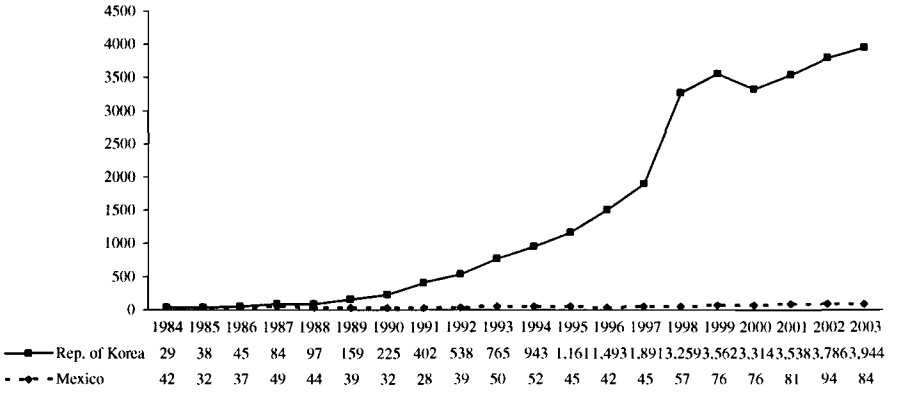

Chart 11.2 Patents granted by USPTO comparison Mexico-Republic of Korea
Source: IMPI (2005).

The gap between the two began to widen during the second half of the 1980s until it became very wide in 2003. While Mexico doubled its investment in science and technology, the patents granted to Mexicans by USPTO rose by 100%. In the Republic of Korea, by contrast, investment in science and technology increased almost 10 times, while the patents granted to Koreans by USPTO registered an increase of 13,500%.

These data reinforce earlier statements to the effect that investment in scientific and technological research has a direct bearing on industrial property and therefore, on nations' competitiveness.

The consequence of patents on the economy and industrial development of countries can also be appreciated by relating it to the labor force. This gives an idea of the innovating effort of the productive plant and its technological level.

On analyzing the trend in Mexico, Latin America, and the Caribbean during the period 1960–2000, it is noteworthy that Mexico has registered a decreasing patent rate per million workers, in contrast to the rest of Latin America and the Caribbean, which, as of 1970, are above Mexico (Chart 11.3).[4]

The Republic of Korea once again stands out when comparing it directly with the rest of the countries of East Asia and Mexico, Latin America, and the Caribbean.

In the 1970s, Mexico, Latin America, the Caribbean, and the countries of East Asia were above the Republic of Korea, a situation that was reverted as of the period 1990–1994, when the Republic of Korea reached almost 20 patents per million

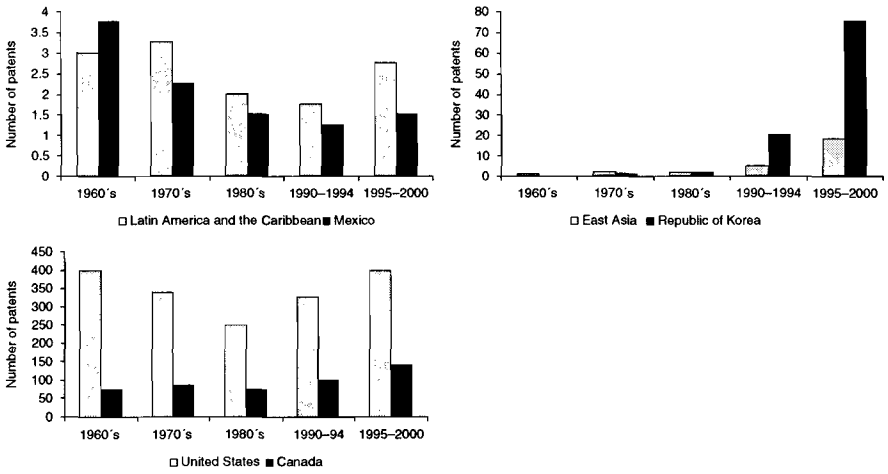

Chart 11.3 Number of patents per million workers, 1960–2000
Source: Lederman, Maloney and Serven (2005).

workers, whereas Mexico, Latin America, and the Caribbean registered an average of almost three patents per million workers.

By the period 1995–2000 this gap had widened significantly, for the Republic of Korea exceeded 70 patents per million workers, whereas Mexico, Latin America, and the Caribbean barely reached 4.5 per million workers.

The 2005 General Report on the Status of Science and Technology of the National Science and Technology Council (CONACYT) documents that 55% of investment in science and technology in Mexico is made directly by the State, whereas the remaining 45% comes from private initiative (CONACYT, 2005).

In this regard, the five main Mexican patent holders for the period 2002–2005 are public institutions. The first three contribute 76.9, 72.5, and 55.5%, in that order. It should be mentioned that in the 3 years under study, the Mexican Petroleum Institute remained in first position with more than double the number of patents than the institution or enterprise that occupies second place (IMPI, 2005) (see Table 11.3).

If we analyze the five main countries holding patents in Mexico for fiscal year 2004 (Germany, United States, France, Japan, United Kingdom and Switzerland), we can see that no government institutions feature in any of them (IMPI, 2005) (see Table 11.4). The majority are private enterprises that protect their technological innovations in industries such as electronics, chemicals, and pharmaceuticals.

It should be noted that five of the six countries included in Table 11.4 focus particularly on research and protection of chemical and pharmaceutical innovations and developments, while Japan is oriented toward the electronic field.

Table 11.3 Main Mexican holders of patents granted by IMPI, 2002–2004

Mexico 2002	
Instituto Mexicano del Petróleo	17
Universidad Nacional Autónoma de México	7
Grupo Bimbo, S. A. de C. V.	6
Universidad Autónoma Metropolitana	6
Comercial Acros Whirlpool, S. A. de C. V.	3
Mexico 2003	
Instituto Mexicano del Petróleo	19
Universidad Nacional Autónoma de México	7
Grupo Bimbo, S. A. de C. V.	6
Servicios Condumex, S. A. de C. V.	5
Universidad Autónoma Metropolitana	3
Mexico 2004	
Instituto Mexicano del Petróleo	19
Grupo PI Mabe, S. A. de C. V.	8
Helvex, S. A. de C. V.	6
Instituto de Investigaciones Eléctricas	6
Servicios Condumex, S. A. de C. V.	6

Source: IMPI (2005).

Table 11.4 Main holders of patents granted by IMPI in 2004 by country of origin

Germany		United States	
BASF Corporation	97	The Procter & Gamble Company	184
Bayer, Inc.	95	Kimberly Clark Worldwide, Inc.	140
Aventis Pharma, S.A.	49	Pfizer Inc.	97
Boehringer Ingelheim International GMBH	28	E.I. Du Pont de Nemours and Company, Inc.	65
Merck & Co., Inc.	16	Qualcomm, Inc.	57
France		*Japan*	
Thomson Consumer Electronics, Inc.	107	Matsushita Electric Industrial Co., Ltd.	28
L'Oréal	56	Sony Corporation	19
SANOFI-SYNTHELABO	30	Mitsubishi Denki Kabushiki Kaisha	13
Aventis Pharma, S.A.	28	Alps Electric Co., Ltd.	9
LES Laboratoires Servier	16	Shionogi & Co., Ltd	9
United Kingdom		*Switzerland*	
Glaxo Group Limited	14	F. Hoffman-La Roche AG	51
Smithkline Beecham PLC	11	CIBA Specialty Chemicals Holding Inc.	47
Switched Reluctance Drives Limited	7	Société des Produits Nestlé S.A.	28
AstraZeneca UK Limited	5	Novartis AG	18
BP Chemicals Limited	5	Tetra Laval Holdings & Finance S.A.	14

Source: Prepared by the author with IMPI information.

Having taken a quick look at the factors that have a bearing on countries' technological development and competitiveness and their relation to industrial property, we will briefly analyze some projects that are being developed in IMPI in order

to contribute to building a culture of respect and protection for industrial property rights and thus promote the incorporation of this discipline into Mexico's scientific and technological policy through educational and research and development institutions.

First of all, emphasis should be placed on the hard work carried out by IMPI with higher education and public and private research institutions to educate and train human resources in the field of industrial property. The result has been the creation of "Patenting Centers," the object of which is to act as advisory and/or promotion units within their respective institutions in order to identify projects that are subject to not only protection but also commercialization by means of the licensing or transfer of the industrial property rights acquired.

11.2.3 Creation of Patenting Centers

To date, IMPI has set up 12 patenting centers in institutions carrying out scientific and technological research activities. Most of them are in institutions in the states of the country, so in addition to their substantive advisory work, they have become extensions of IMPI in promoting and disseminating the advantages and benefits of the industrial property system.

Under this scheme, IMPI acquires the commitment to train the group of advisors who will be in charge of the patenting center, while the host institution contributes the infrastructure for its functioning and operation. Likewise, IMPI provides access to the technical information databases on patents, consultation of which is essential for advisory assistance.

In order to foster applications for patents by Mexicans, the Industrial Property Law provides for a 50% discount on the corresponding rates and on the search for technical information on patents carried out by IMPI's Technological Information Center. This discount only applies for independent inventors, micro entrepreneurs, research centers, and Mexican higher education institutions.

IMPI has also developed training programs and schemes on topics related to industrial property, such as the annual program of courses given weekly on its premises, as well as the participation of the Institute's officers in conferences, workshops, diploma courses, and seminars organized by diverse public and private institutions.

Since IMPI's participation in this type of activities increases year by year (716 in 2004 and 866 in 2005) (IMPI, 2005 and 2006), the need has arisen to provide schemes for formal education. To that end the creation of an Academy of Intellectual Property is under study, which would be in charge of the design of study plans in the formal education system for users of the industrial property system (lawyers, technologists, entrepreneurs, researchers, etc.), and well as for personnel from the institute itself. The academy would also undertake research projects and/or studies in diverse topics in this discipline.

The idea has been studied to situate the academy as a higher education institution within Mexico's National Education System so that it imparts updating and continuous education programs at the postgraduate level by means of diploma courses and organizes congresses with the possibility of teaching master's degree courses and doctorates in industrial property in the future.

The establishment of the academy would be in three stages, listed in Box 11.1.

Box 11.1 Stages of the project for the creation of the academy of intellectual property in Mexico

First stage: project design (fiscal year 2006)

1) Feasibility study
   a) Background
   b) Rationale
2) Conceptual framework
3) Academic structure – administrative
4) Functioning of academic life
5) Regulatory framework and academic policy guidelines
6) Administrative structure
7) Inputs for its operation
8) Financing
   c) Operative
   d) Infrastructure
   e) Scholarships program
   f) Faculty
   g) Experts' visits
9) Work program 2006: launching of the IMPI Academy
10) Start of operations

Second stage: implementation of the project (fiscal years 2007–2009)

1) Building of curriculum
2) Hiring of academic-administrative staff
3) Training of staff in teaching and public-speaking skills
4) Registration of accreditation and certification processes
5) Building of the premises
6) Start of operations on the new premises
7) Definition of lines of research

Third stage: evaluation of the project (fiscal year 2010)

1) Evaluation of study programs
2) Evaluation of user satisfaction
3) Evaluation of administrative processes

Source: Prepared by the author with IMPI information.

11.2.4 Public Domain Patents Portal

With the aim of promoting the technological modernization of enterprises, especially small and medium ones, IMPI developed in conjunction with the Under Ministry for Small and Medium Enterprises of the Ministry of Economy and the Mexico-United States Foundation for Science (FUMEC), a Public Domain Patents Portal with access to technical information contained in patent documents (published patent applications and patents granted).

The ultimate aim of this portal is for companies to consult it and take advantage of the available technological alternatives for their incorporation into existing productive processes or as the groundwork for the creation and development of technological innovations.

The portal would place at the disposal of interested parties a large quantity of patent documents from different parts the world that did not request protection in our country or that are no longer protected and are therefore free to use in Mexico.

The information ranges from traditional technological sectors to new fields of knowledge such as biotechnology, nanotechnology, mecatronics, pharmaceuticals, genetic engineering.

The portal is designed with a technological alert system in the form of traffic lights for easy understanding (see Fig. 11.1).

The red light indicates technologies protected in Mexico with the possibility of their being licensed by their patent holders. The amber light means technologies that can be used in Mexico. And the green light indicates technologies that are not protected in Mexico and can therefore be used freely.

The portal is made up of the following sections: search, FAQs, discussion forums, sites of interest, and support for companies.

A search can be carried out in different ways:

a) simple, in which terms are located in English, French, and Spanish;
b) classified, using the International Patents Classification, which is made up of eight sections;
c) advanced, in which words in English or French and the logic operators are used; and
d) localization in fields of the catalogue card, i.e., by biographical data.

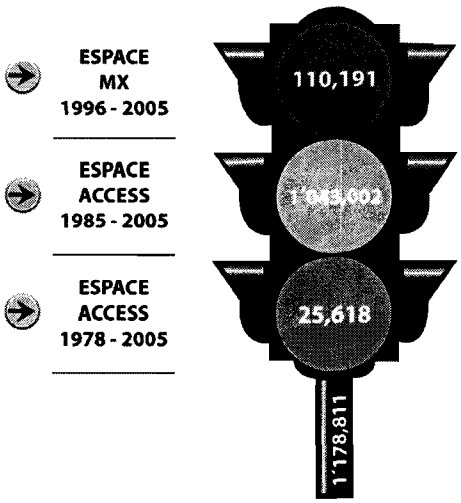

Fig. 11.1 Technological alert traffic lights.
Source: Public Domain Patents Portal

Source: Public Domain Patents Portal.

In this portal SMEs have a point of liaison with general topics of interest to users. The sites of interest section offer direct links to other industrial property offices in the world and to international agencies. The area of support to companies is a link to national institutions that offer support to SMEs, inventors, researchers, and other users.

In its 12 years of existence IMPI has identified a number of obstacles that hinder micro entrepreneurs, researchers, independent inventors, higher education institutions, and research centers in using the industrial property system to protect their technological developments.

One of them is the investment required for filing applications for protection and/or registration of innovations. Earlier we informed of the discount offered to foster the filing of applications by Mexicans. But the investment needed for the filing of applications through the Patent Cooperation Treaty (PCT) amounts to several thousand dollars, an investment that most inventors and micro entrepreneurs are unable to make.

This is why IMPI has been studying various options with CONACYT and other agencies to assess the legal and financial viability of creating a support fund for projects with possibilities of commercial success that need to be protected in Mexico and abroad through PCT.

One concern that arises at the time of requesting protection for inventions is that of remuneration of the people involved in their development.

This is a problem whose solution depends on the labor contracts that researchers may have signed with the institution responsible. If the contract does not establish any remuneration as regards royalties derived from exploitation of the invention, the

researcher(s) involved will not have access to any additional financial benefit to the salary they earn.

One possible solution to this problem in the case of researchers who are members of CONACYT's National Researchers' System (SNI)[5] would be for the SNI to privilege the filing of patent applications and their obtainment over the publication of scientific articles, which, as has been mentioned, can put the novelty of the invention at risk.

For researchers who do not form part of SNI a remuneration scheme could be established in terms of the profits derived from commercialization of the invention.

However, the solution to this issue does not depend directly on IMPI, but on other agencies or organizations in the public and private sectors.

In addition to the areas in which IMPI is working, other projects are summarized below by way of final notes.

a) *Electronic payments portal.* In order to facilitate and streamline the filing of applications for protection and/or registration of inventions and distinctive signs, the corresponding payments can be made through a Portal as of 19 September 2006. This is in keeping with the strategies and specifications for the development of Electronic Government established by the 2001–2006 administration.

Although this is a major step forward for the simplification of the procedures that users must follow to request protection of their industrial property rights, the project is only just in its first phase. It is foreseen that future phases will facilitate the presentation of applications for distinctive signs and inventions electronically. These phases will be made known during the course of 2007.

Use of the portal's services does not entail additional costs for users. The only requirement is registration, which is carried out only once to have access 24 h a day 365 days a year throughout the country, being subject to the policies of the affiliated banks. Attendance online will make it possible to adequately select the current items and rates, including calculations for the payment of annual installments on patents.

Similarly, IMPI's internal management systems, accounting and treasury systems are empowered to interact with the portal, thus guaranteeing the continuity of operations and simplifying processes within IMPI.

In order to guarantee the security and confidentiality of users' operations, the payments portal is endowed with security and encrypting elements validated by certifying entities recognized worldwide. Likewise, the service complies with the current guidelines regarding protection of personal data in accordance with the Federal Law on Transparency and Access to Information.

This does not mean that the portal will be the only means of access to services. IMPI will maintain the services payment scheme by means of the use of printed formats to cater to users who do not have electronic media and also as a contingency in the face of failure of online services.

b) *Archive storage.* Due to the fact that IMPI's physical archives grow by the day, the construction of a building has been provided for with the necessary facilities for their proper handling, control, storage, and conservation.
c) *Technological Information Center.* Construction has been foreseen for a new building for IMPI's Technological Information Center, whose functions are essential for the promotion and dissemination of the information contained in patent documents. Currently it has more than 25 million documents that require storage, control, reproduction, and consultation. The present installations are insufficient. Hence more suitable installations have been provided for.

It is hoped that the points addressed in this document will be useful for understanding the relationship between scientific and technological policy and industrial property, and consequently, with nations' competitiveness and economic well-being.

At IMPI we work with the conviction of the importance of the institution and industrial property for Mexico's economic, technological, and industrial development, and we are working daily to disseminate and promote the use and integration of the industrial property system into the national science and technology policy and its linkage to the productive sectors.

Notes

1. Law on Industrial Property, "Amendment of 26 January 2004."
2. International Institute of Management Development.
3. WIPO Statistics – PCT Statistical Indicators Report, 2005.
4. Lederman, Maloney and Serven (2005).
5. The National Researchers' System was created in 1984 to recognize and encourage the work of persons devoted to producing scientific knowledge and technology. The recognition grants the appointment of national researcher and corresponding financial incentives.

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General Conclusions: The Challenges for Development

This book is made up of 11 academically solid chapters, based on relevant empirical sources and on contributions by experts in the field of economic and political decision making. By way of conclusion we recall the main findings and recommendations for the developing countries and identify the topics currently under discussion regarding countries' technical and innovation capabilities in relation to sustainable economic growth and well-being and the links between forms of protection of intellectual property and the promotion of innovation.

Since the late 1980s, the Latin American countries in general and the smallest ones in particular have sought actively to enter the world economy's main tendencies by opening up their economies, looking for new trading partners, and attracting foreign direct investment.

The rates and strategies for entry are diverse, but the first step taken by all the countries was unilateral trade liberalization based on tariff-reduction programs. The second step was participation in the multilateral negotiations of the Uruguay Round and accession to the General Agreement on Tariffs and Trade (GATT). The third step was the negotiation and signing of bilateral and regional trade agreements (Martínez-Piva and Padilla, 2007).

All of this has resulted in a new development model whose strategy is to attract foreign investment helping to complement investment needs, so that external markets boost growth through the demand for domestic products and so that the supply of new products stimulates production and technology transfer.

The signing of free trade agreements with the United States is a natural step of the trade policy adopted by various countries of Latin America, among them those of Central America, Chile, Colombia, Dominican Republic Mexico, Panama, and Peru. These countries assign a central role to foreign investment and international trade in their development model, in which the United States is a very significant trading partner and an important source of foreign investment.

Prior to the signing of the free trade agreements, a large part of the Central American and Andean exports to the United States benefited from diverse preferential-treatment schemes whose unilateral nature gave rise to uncertainty as to their renewal (Pacheco and Valerio, 2007). These and other considerations led to the negotiation and signing of free trade agreements that eliminate the uncertainty, but include strict intellectual property rules.

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Despite the dynamic growth of exports in some of the countries of Latin America and their diversification toward manufactures – especially Central America, the Caribbean, and Mexico – including those of high and medium technology, the value added of exports continues to be low on account of their considerable dependence on imported intermediate inputs. Thus, the growth of exports has been accompanied by an increase in imports, particularly in technology-based industries such as electronics, whose inputs are largely imported. This gap highlights the need to create productive links between the manufacturing export industry and the rest of the local economy (Martínez-Piva and Padilla, 2007).

The current productive specialization of most of the Latin American countries, like the majority of the developing countries, concentrates on links in the global value chain that are less knowledge intensive, such as assembly and large-scale manufacture. This type of integration, characterized by the temporary importation of intermediate goods for their subsequent exportation, is limited as regards the development of technological capabilities. This means that in order to raise productivity, improve workers' income and achieve dynamic competitiveness, it is necessary to have public policies that promote escalation on the production value chain.

In their contribution, Cimoli and Primi show a parallel between "North-South" asymmetry in patenting activities and technological capabilities, and the "North-South" asymmetry in technological intensity of production structures and patterns of specialization. Although patenting is not the only indicator of countries' technological capability, its dynamics reflects the structural differences between them. The industrialized countries have production structures that are more specialized in activities and sectors that are knowledge and technology intensive, and invest more resources in research and development, so it is not surprising that they are leaders in the number, diversity, and rate of patents applied for and granted.

If the technological capabilities of the developing countries determine their condition on the periphery, their transition toward a position of leadership in the international market makes it necessary to emphasize the policies on diffusion and access to knowledge, innovation, and creation of technology. Trade policies and policies to reinforce intellectual property rights do not in themselves make it possible to move toward economies capable of escalating on the national production value chain.

Free trade has favored a dynamic rate of technological change in the developing countries, but it is furthered by imports of capital goods with different degrees of technological intensity. This has determined that most of the advanced national companies undertake little research in the conventional sense, although they take pains to imitate and develop adaptive and incremental innovations. In view of their dependence on imports of capital goods with incorporated technology and their lack of significant advanced scientific and technological infrastructure, it will be difficult for developing countries to take the path of innovation without previously implementing the appropriate policies.

Mexico signed the North American Free Trade Agreement and created the Mexican Industrial Property Institute in 1993. This Institute has made important efforts to promote patenting and the use of its stock of information to strengthen

innovation in that country. Paradoxically, the register of Mexican patents dropped 12%, whereas that of foreign patents doubled between 1995 and 2005, even though spending on scientific and technological activities also doubled during the period. Spending on research and development in Mexico rose from 0.2 to 0.4% as a percentage of GDP, but it continues to be very low in comparison with the United States, which invests almost 2.69% of GDP under this heading. The coefficient of investment in science and technology in Mexico is five times lower than the OECD average.

The rest of Latin America is not doing much better. The countries that invest the most in research and development fail to reach 1% of GDP: Brazil (0.99%) and Chile (0.57%). The region as a whole registers an average level of around 0.5% of GDP, which definitely does not contribute to reducing the technological gap with the developed countries: in the United States, for instance, this indicator has remained at around 2.5% of GDP for several years (Lugones, 2007).

1 Trips Plus

For the majority of the Latin American countries, the United States is their most important trading partner. This country has pushed for trade agreements with market access rules and processes that are convenient for its partners, but at the same time it has obtained their consent to adopt stricter and more comprehensive intellectual property regulations. This is largely explained by the political economy of the United States' trade negotiations, which are encouraged by powerful interest groups that support trade agreements as long as they include the strengthening of intellectual property rights. The signing of trade agreements with the United States entails the obligation to adopt stricter intellectual property rules than those of TRIPS Agreement.

Prior to the free trade agreements recently signed by the United States and the European Union with developing countries, the latter assumed that TRIPS was the ceiling as regards standards and demands concerning observance of intellectual property rights. Nevertheless, most of these agreements, mainly those signed with the United States and the European Union, establish stricter standards, which is why they have rightly been called TRIPS Plus. The new rules reduce TRIPS' margins of flexibility in patentable subject matter and its corresponding exceptions, compulsory licensing, access to medicines by consumers, and access to generic pharmaceuticals by companies in developing countries (see Andrés Moncayo's contribution in this volume).

In other areas the demands for protection have also gone beyond the demands of TRIPS; such is the case of protection of undisclosed test data relative to agrochemicals and pharmaceutical products in latest-generation free trade agreements. This poses additional problems, since unless adequate regulation is provided for at the national level, the exclusivity of undisclosed test data can make the process of approval of pharmaceutical or agrochemical products more costly, and can – in the

absence of adequate national regulations – make it more difficult, if not impossible, to grant the compulsory licenses provided for in the TRIPS Agreement.

The concerns voiced by the developing countries refer mainly to the reduction in leeway for the exercise of public policies in important areas for economic development and social well-being. Many hold the view that the TRIPS Plus requirements will prevent countries from recurring to the flexibilities of TRIPS and implementing industrial policies with laxer intellectual property rights, as the developed countries themselves and newly industrialized countries such as the Republic of Korea and the Chinese province of Taiwan utilized to strengthen their technological capabilities (see the contribution by Pedro Roffe).

In the face of these inconveniences, new trade negotiations would be expected to strike a balance between intellectual property regimes, earnings expectations by corporate patent holders and greater access to external markets by the developing countries. But even more important than the above-mentioned balance should be expectations for expansion and the type of growth hoped for over the long term. In this regard, many people are right when they state that the economic success of trade agreements lies in the complementary agendas of public-policy combinations that help make the most of the opportunities afforded by such agreements.

Public policies must now adjust to the obligations acquired under the new trade agreements, but this does not stand in the way of legislating on important issues for the Latin American countries and most of the developing countries. Such issues are linked to the sectors that have significant weight in the economy: agriculture, medicines and health, biological diversity, and the creative industries in general. It is equally important not to be limited to a static analysis of traditionally important sectors, but to promote new sectors, which will certainly have increasing knowledge-intensive components.

In the area of medicines it is very important for the countries to update their intellectual property and health laws, in such a way as to regulate, make transparent, and streamline procedures related to consumer rights. In this regard there is a pending task regarding use of the Bolar clause, granting of compulsory licenses, regulation of parallel imports, and revocation of patents. It is important to bear in mind that compulsory licensing, although it is little used, the mere threat of its use can prove positive. At the same time, work should be undertaken in prevention of intellectual property rights abuses by their holders, in the creation or improvement of competition regulations and practices and opposition proceedings to the granting of a patent. It is no less important to analyze and regulate the possibilities of special clauses in order to take measures to protect public health (see contribution by Fabiana Jorge).

Just as health and medicines are matters of public interest, so is agriculture for the protection of biodiversity. In Latin America and the Caribbean more than 150 million people live in the rural milieu and many of them are poor. At the same time, rural areas are the depositories of an enormous biodiversity and traditional knowledge. There should therefore be a legal framework and public policies that favor the care and sustainable utilization of the region's biodiversity and recognition and protection of traditional know-how and knowledge. This involves addressing issues

such as the relationship between national laws and international agreements on biodiversity, the fight against bio-piracy, and standards for contracts on bio-prospecting (see César Morales' contribution).

National laws should regulate sustainable development and in particular conservation, sustainable use and fair and equitable distribution of the benefits derived from the use of their biodiversity, including genetic resources and protection of traditional knowledge. This opens up leeway to make intellectual property regimes compatible with the stipulations of international treaties, such as the Convention on Biological Diversity and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Resources such as disclosure of origin and the design of standards for protection of traditional knowledge, among others, should be explored and implemented to bring intellectual property rights into line with other development objectives (see the contribution by Jorge Cabrera).

In addition to protection of traditional sectors and their major development potential, it is important to promote new, knowledge-intensive sectors. There is consensus in the Latin American region that the main challenge is building economies that are more intensive in knowledge, innovation, and learning capacity. In order for the strengthening of intellectual property regulations to contribute to and not hinder progress in this direction, there is a need for careful implementation and the development of a complementary agenda focusing on innovation, diffusion of knowledge, competition, and consumer rights.

2 The Importance of Research, Development, and Innovation

The capacity to generate research, create knowledge, and translate it into new technologies is the basis for the wealth of the most developed nations and goes a long way toward explaining their economic growth. Equally important is the capacity to appropriate themselves of the rents generated by research and technology, but in order to arrive at this state it is necessary to go through previous processes of innovation, considering that rigorous intellectual property rules do not in themselves encourage innovation.

The regime of protection of intellectual property rights stimulates the creation of production capacities once the industry has developed its own technological capabilities in the highest links in the value chain. Specialization in knowledge-intensive sectors favors technical change, increases the absorption capacity of the production sector, and demands more knowledge in a typical process of cumulative circular causation. It is as of the time when certain technological capabilities have accumulated that the productive system requires a regime of intellectual property rights and benefits from it (see contribution by Mario Cimoli and Annalisa Primi).

The experience of the developed countries and more recently that of India, China, and Brazil shows that the expansion of research and development activities preceded the strengthening of intellectual property rights. Many countries, like the United States, had for a long time "weak" intellectual property regimes that

facilitated the absorption of foreign technological knowledge without paying for the corresponding licenses. As these countries' innovation dynamics expanded and their investments abroad grew, the tendency toward the strengthening of intellectual property rights increased (see the contribution by Álvaro Díaz).

Since a rigorous intellectual property rights regime will not in itself encourage research and development and, on the contrary, could even hinder technological innovation, in that it could hamper and raise the cost of imitative, adaptive and incremental innovation, efforts should concentrate on science and technology public policies that counteract such stumbling blocks.

In the intellectual property regimes considered TRIPS Plus, the room for maneuver for implementing science and technology policies has been reduced. Some provisions lengthen patents' years of protection, restrict the use of pharmaceutical and agrochemical products' undisclosed test data, prohibit reverse engineering, broaden patentable subject-matter, and reduce access to the same for research purposes. A new science and technology policy for developing countries should maximize the flexibilities of TRIPS and other international agreements.

In short, the future of the Latin American nations that have signed free trade agreements with the United States will be defined by the public policies they design after ratification of the respective agreements. Such policies will build up their economic development.

These policies should design a balanced system of institutions in which at the same time as an increase in protection of intellectual property rights, the available flexibilities are used, protection of competition and consumer rights are strengthened, access to information and knowledge are developed, and science and technology policies oriented toward innovation and technological learning are promoted. In his contribution, Álvaro Díaz points out that the developing countries that have signed agreements with TRIPS Plus rules face a threefold challenge:

First, implementing intellectual property legislation which complies with the provisions of the trade agreements, but which also uses all possible flexibilities to achieve a balance between incentives to innovation and facilities for access to knowledge and the cultural heritage, which protects human health and provides access at reasonable cost to the goods and services protected by intellectual property.

Second, developing a complementary agenda that reinforces public policies and enacts laws favorable to innovation, education, competition policy, and consumer rights.

Third, considering intellectual property as a field of public policy that requires solving coordination faults within governments. Intellectual property rights are not the exclusive competence of the agencies in charge of their protection. They should also be a matter of concern to ministries of health, innovation, and science and technology. It is equally important to develop an institutional framework that facilitates expression of interests, both for the holders of intellectual property rights and for consumers or users of goods protected by such rights. This involves a balanced system of public institutions, transparent and legally endorsed.

The processes of trade opening can give rise to a significant expansion of international trade and foreign direct investment. In some cases, such as Central America,

the process led to a change in the export structure, from raw materials to manufactures, mainly in apparel and, in recent years, high technological intensity industries such as electronics and medical equipment. However, the indicators for efforts and technological results leave much to be desired, which shows that the trade opening, although accompanied in some cases by export-promotion and investment-attraction programs, has not favored the development of local technological capabilities.

The efforts of the Latin American countries, especially those that have recently signed trade agreements with the United States, are weak in science, technology, and innovation policies. Overcoming this problem does not occupy an important place in most countries' agenda, and the financial and human resources of existing programs are insufficient.

The above shows that the pending domestic tasks are major ones, irrespective of whether or not trade rules have strengthened intellectual property standards. The basic efforts – public spending on education, spending on research and development, use of licenses, among others – are insufficient and, as expected, the results – number of patents, number of scientific publications, economic internationalisation pattern, etc. – are poor.

Due to the trade strategy of many Latin American countries, it is very important to establish a positive relationship between international trade, foreign direct investment, and technological change. The trade strategy under way is an opportunity to encourage technological learning by means of activities related to exportation and importation and with interaction with foreign subsidiaries. For this to happen the countries have to be capable of absorbing the new technologies, which in turn demands specific technological capabilities of acquisition and use of the technological knowledge thus transferred. The capacity to absorb technology is developed in long processes of human capital formation, investments in process and product innovation, and linkage to external sources of technology (Martínez-Piva and Padilla, 2007). This opens up a wide field for countries' public policies, not for policies directly related to intellectual property, but for the creation of capacities that will subsequently demand intellectual property rights.

Finally, in industrial policy there are also spaces that the countries can occupy. In many cases, export products and related production processes, even in industrial sectors considered of medium and high technology, tend to remain unlinked from the development of local technological capabilities. This happens especially in the *maquiladora* industry, where in general such firms participate in parts of the value chain that are not knowledge intensive. In the case of high-technology exports, their success is not based on a solid domestic industrial and technological structure, but on the productive strategies of transnational corporations.

The experience of Ireland, Republic of Korea, Singapore, and others shows that orientation toward external markets has the potential of creating virtuous circles of development of technological capabilities. In this regard, ECLAC (Martínez-Piva and Padilla, 2007) has pointed to three central elements on which public policy can focus:

First of all, capital formation at all levels, especially in knowledge-intensive activities, such as design and research and development, that is, university and

postgraduate education. Also, there should be more on-the-job training due to its advantage of rapid adaptation to new technologies in accordance with the specific knowledge demanded by firms. This is independent of basic education coverage, whose insufficiency continues to be enormous in most Latin American countries.

Second, there is a need to develop and strengthen innovation systems, which is a complex task. One of the first steps is to strengthen public institutions and organizations in charge of the formulation, implementation, and coordination of science, technology and innovation policy. Likewise, resources should be allocated to the strengthening and interaction of the other components of the system by increasing research and development activities in universities, research centers, and in the private sector itself.

Third, even though it may appear obvious, it is necessary to design and execute policies related to the trade opening, such as promoting exports with higher value added, attracting transnational corporations that offer greater technological and economic spillovers, programs to strengthen the capacities of local firms so that they supply the transnationals corporations established in the country, and initiatives to strengthen links between transnationals corporations, universities, and local research centers, among others.

In the relationship between international trade, TRIPS Plus rules and economic development, not everything centers on intellectual property. Many actions can be undertaken on the sidelines with direct effects on technological and innovation capabilities. The combination and balance of public policy measures that may be taken will be determining factors in intensifying a particular development path or in surpassing it with economic structures based on knowledge and greater technological capacity.

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