Project document

The Problems of Intellectual Property in Latin America and How to Address Them

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Abstract

Defining appropriate Intellectual Property (IP) policy is a key industrial and social policy matter for Latin American governments. The IP interests of countries in Latin America may differ substantially from comparable interests in the United States, Europe and Asia, and IP interests among Latin American countries may differ. Many Latin American countries have a strong tradition of creative works covered by copyright, such as authorship of books, music and paintings. Most Latin American countries do not have a tradition of developing new chemical entities in the pharmaceutical sector, and patent rights are held almost exclusively by European, Japanese and US firms. Protection of trademarks and related "identifiers" is generally necessary for business, regardless of geographic location.

Conceptually, Latin American countries may have interests in stronger IP protection for artists and authors, weaker IP protection for pharmaceutical enterprises, and shared business interests in the protection of trademarks. In all cases, education, research and other public access interests should be promoted. The specific tailoring of IP laws to suit the national interest is the "norm" in the United States and Europe, where the laws are constantly being readjusted.

I. IPRs and Trade Agreements

a. Multilateral Trade: The TRIPS Agreement

There are different forms of trade agreement that regulate IP matters. The principal multilateral trade agreement in the IP field is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"). The second most important set of trade agreements that regulate IP are regional and bilateral agreements in the form of Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs) that have been negotiated by the United States and European Union.[1]

The TRIPS Agreement entered into force on January 1, 1995. A limited number of TRIPS Agreement obligations arose for developing countries on January 1, 1996 (mainly national and most favored nation treatment). On January 1, 2000, TRIPS Agreement obligations became generally applicable to developing countries, with some important exceptions, particularly relating to pharmaceutical products. On January 1, 2005, developing countries were required —if they had not previously done so— to implement pharmaceutical product patent protection. Separate TRIPS Agreement transition rules apply to "least developed countries" (LDCs). Haiti is the only LDC in Latin America, and this paper will not address LDCs in any detail.

The United States is pursuing a policy of negotiating FTAs requiring IP protection substantially stronger than that required by the WTO TRIPS Agreement in all fields of protection, but especially in regard to strengthening protection for the "originator" pharmaceutical industry and copyright industries. FTAs with the United States have entered into force for Mexico

[1] There is another set of multilateral agreements regulating IP, administered under the auspices of the World Intellectual Property Organization (WIPO), including the Paris Convention on the Protection of Industrial Property and the Berne Convention on the Protection of Literary and Artistic Works, but these WIPO-administered agreements are not considered "trade" agreements. The organizers requested this paper to address the subject of trade agreements and IP, and so discussion of the WIPO-administered agreements is limited.

(NAFTA), Chile, Central America (CAFTA-DR),[2] and have been signed with Colombia, Panama and Peru. The European Union is in the process of negotiation an EPA with Caribbean countries.

The TRIPS Agreement fundamentally altered the international IP landscape.[3] It broadly extended the scope of patent subject matter coverage (including to nutrition and health-related products), established a common 20-year term of protection and established limits on exceptions. Copyright and trademark substantive changes brought about by the TRIPS Agreement were not as dramatic. The TRIPS Agreement also addressed geographical indications, industrial designs, protection of integrated circuits and trade secrets. The Agreement included multilateral rules on the protection of regulatory data regarding new chemical entities in pharmaceutical and agricultural sectors against "unfair commercial use" (TRIPS Agreement, art. 39.3).

The TRIPS Agreement also introduced enforcement obligations, that is, obligations to provide adequate and effective IP protection, including some specific requirements regarding procedural and substantive enforcement matters. Disputes between countries (referred to as "Members") under the TRIPS Agreement are subject to dispute settlement at WTO, raising the possibility of enforcement through trade sanctions. Implementation of the TRIPS Agreement by individual Members is subject to periodic review by TRIPS Council, but bringing enforcement actions for alleged noncompliance is in the hands of individual Members.

b. TRIPS Agreement Flexibilities

The TRIPS Agreement incorporates a broad range of "flexibilities", and the importance of these flexibilities was explicitly reaffirmed for the field of public health in the "Doha Declaration on the TRIPS Agreement and Public Health" adopted on November 14, 2001. The right of Members to use the flexibilities in the TRIPS Agreement was also recognized by the WTO Appellate Body in the so-called *India-Mailbox* case. Nonetheless, Latin American countries have not taken full advantage of these flexibilities.

As illustration, Brazil introduced pharmaceutical product patent protection in 1996, including wide-ranging "pipeline" protection,[4] despite the option to wait until January 1, 2005 (in contrast to India which took advantage of the 10-year transition). Brazil's local pharmaceuticals industry underwent a dramatic "negative transformation", suffering the loss of almost all active pharmaceutical ingredient (API) production capacity, and the country has coped with a tremendous negative balance of trade in the pharmaceutical sector.[5] India, by contrast, developed a world leading pharmaceutical export industry. Today, Brazil is actively seeking to reverse the adverse impact of early introduction of pharmaceutical product patents, at great cost.

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2 Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua (CAFTA) and the Dominican Republic (DR). Costa Rica has not yet brought the CAFTA into force.

3 A detailed description of the negotiating history of each article, and analysis, of the TRIPS Agreement is at UNCTAD-ICTSD RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005)(Cambridge), available online at http://www.iprsoline.org

4 Brazil not only accepted to provide pharmaceutical product protection from 1996 onward, it also accepted to grant patents for products that had not previously been introduced onto the Brazilian market, even if patents for those products should not ordinarily have been available. There is presently intensive study and concern in Brazil regarding exactly why this policy was adopted, and a number of commentators do not accept the constitutionality of this action.

5 See, e.g., Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health, (J. Bermudez & M.A. Oliveria eds. 2004), and particularly chapters 7-9.

Despite recognition of the importance of flexibilities in the Doha Declaration on the TRIPS Agreement and Public Health, some Latin American countries have not implemented public health-related flexibilities in national law.[6]

Compulsory licensing legislation serves multiple purposes, including facilitating price negotiations with patent holders, allowing authorization of generic imports, and allowing authorization of local production. Brazil has used the threat of compulsory licensing as a lever in price negotiations with multinational companies, and recently issued a compulsory license on a key HIV-AIDS treatment (Efavirenz). Brazil intends to use this license first to import from India, and later to produce the medicine domestically.[7]

New WTO TRIPS Agreement rules enabling more effective use of compulsory licensing should be implemented in national law. National legislation should be amended to take advantage of the WTO Decision of August 30, 2003 and the Protocol of Amendment permitting predominant exports under compulsory license. The impact of the January 1, 2005 transition in India will increase demands for mechanisms to reduce pharmaceutical costs. Mechanisms such as regional pooled procurement may be important to making effective use of the Decision and Amendment.[8] Model implementing legislation and notifications for the Decision and Amendment, prepared for the World Bank, are available online.[9]

c. Latin America and Offensive IP Interests

Latin American countries also have "offensive" interests in TRIPS-related IP protection. Trademarks (including certification and collective marks), as well as geographical indications, are used to identify goods and services for consumers, and may have a substantial positive effects in international trade. Interesting current examples of the effective use of collective trademarks include employment of "Juan Valdez" and "Café de Colombia" for Colombian coffee. Participation in multilateral trademark registration agreements (i.e., the Madrid Agreement and Protocol) may assist local companies by increasing efficiencies in the process of obtaining trademark registrations in a number of countries. Participation in these multilateral agreements may be resisted by local trademark attorneys because they reduce local fees. Similarly, creating an Internet-based trademark registration system can provide major cost-saving benefit for small businesses.

The TRIPS Agreement makes the national treatment and most-favored-nation treatment (MFN) principles applicable to covered forms of IP protection. Such protection is a "two-way"

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6 The World Health Organization and Pan-American Health Organization (PAHO) have prepared comparative tables regarding implementation practices. See, e.g., Maria Auxiliadora Oliveira, Jorge Antonio Zepeda Bermudez, Gabriela Costa Chaves, & Germán Velásquez, Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? BULLETIN OF THE WORLD HEALTH ORGANIZATION 2004; 82:815-821.

7 See Frederick M. Abbott & Jerome H. Reichman, Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union, Study for the European Parliament, Directorate General External Policies of the Union, June 2007.

8 Proposals are discussed by Abbott and Reichman, id.

9 Frederick M. Abbott and Rudolf V. Van Puymbroeck, Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, World Bank Working Paper No. 61 (2005). <http://www-wds.worldbank.org/external/default/WDSContent Server/WDSP/IB/2005/08/30/ 000012009_20050830130225/Rendered/PDF/334260rev0pub.pdf>.

street with a country's trading partners, so adoption of new standards must be approached with caution. For example, increasing protection for geographical indications (GIs) will provide substantial benefits to European Union exporters which may have an impact on local Latin American markets and producers. Whether to extend the range of products protected by GIs, or to strength GIs protection, is a complex economic question for many developing countries.

d. Flexibilities Cover IP Broadly

Implementation of TRIPS flexibilities affects the public interest in education, research, communications and business operations, as well as in the fields of nutrition and public health. It is important to take advantage of "fair use" doctrines with respect to works under copyright and trademark, as well as to protect the "public domain". Maintaining relatively open Internet access is fundamental to modern education and research. Preventing unauthorized downloading of MP3 music files is only a small portion of copyright interests.

Critical new "public interest" issues arise in connection with adoption and implementation of the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT). Implementation requires careful balancing of the interests of copyright holders with the interests of the public in open access to information on the Internet.[10]

In fact, TRIPS Agreement flexibilities exist across the full spectrum of IP law. Carefully drafted and balanced IP legislation may substantially advance development goals and the public interest.[11]

[10] Resources regarding copyright law are available through various multilateral organizations, including WIPO and UNESCO. For technical assistance with respect to copyright law, the Glushko-Samuelson Intellectual Property Clinic at American University College of Law in Washington, DC, and its Faculty Director, Peter Jaszi, are excellent resources.

[11] See UNCTAD-ICTSD TRIPS and Development Resource Book, supra. Models and research tools are also available from sources such as South Centre (e.g., the work of Prof. Carlos Correa).

II. Other IPRs-Related Mattters

a. Competition and IP

Competition law is an important control mechanism for exclusive IP rights, and its application is authorized by the TRIPS Agreement.[12] But enforcement of competition law tends to be resource intensive.

Competition law promotes market access and price competition, while patents and other forms of IP grant rights to exclude from the market, restricting competition. The policies promoted by competition law and IP may appear to be contradictory. However, if IP promotes innovation and the creation of new and better products, the entry of these products onto the market should stimulate competition with older products. In this sense, IP rights may promote competition, even while exercising an exclusionary effect. The complex problem is establishing the proper balance between the exclusionary rights granted to IP holders and the interests of the wide public in open markets and price competition.[13] A broad range of information regarding, as well as assistance on development and implementation of, competition law is available through UNCTAD's Competition Law and Policy Division,[14] including specifically for selected Latin America countries through the program on Competition and Consumer Protection Policies for Latin America (COMPAL).[15]

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12 See, e.g., Frederick M. Abbott, Are the Competition Rules in the WTO TRIPS Agreement Adequate?, 7 J. INT'L ECON. L. 687 (2004)(Oxford).

13 For description and analysis of TRIPS Agreement provisions addressing competition, see UNCTAD/ICTSD Resource Book on TRIPS and Development, Chapter 29, supra. See also presentation by this author at the WIPO Open Forum on the draft Substantive Patent Law Treaty (SPLT) on Patent Licensing, Competition Law and the draft Substantive Patent Law Treaty (attached as Annex A).

14 Information at http://www.unctad.org/Templates/StartPage.asp?intItemID=2239&lang=1.

15 Information at http://www.unctad.org/Templates/Page.asp?intItemID=4115&lang=1.

b. Technical Assistance and Training of Judges

Although Latin America has long history of scholarly work in field of intellectual property, judicial systems and education in this area are not typically strong. Involvement of multilateral institutions and/or technical consultants may be useful, but care must be taken to properly identify the national interest.

The World Intellectual Property Organization (WIPO) has substantial expertise in the implementation of international IP commitments, but has been criticized for proposing overly protective legislation. One important objective of the WIPO Development Agenda now under negotiation in Geneva is to mandate provision of more balanced technical advice, such as by providing options to members requesting technical assistance.

The training of judges is essential if IP interests are to be properly balanced. Without proper training, the tendency of local judges is to accept IP-right holder claims without close examination.

There is no easy mechanism for obtaining a balanced training program for judges deciding IP cases. In some countries, such as Brazil, local industry associations are funding training by selected IP experts. Seminars for judges can be conducted by local IP law professors and other experts. Much of the funding available for training judges is directed toward promoting stronger enforcement of IPRs. The US Department of State, for example, is providing substantial funding for training of judges, but this is explicitly directed to enhancing enforcement and criminal prosecution for IPRs violations.

Latin American governments are encouraged to developing and implement IPRs judiciary training programs based on local interests so as to achieve an appropriate balance between the interests of IPRs holders and society more broadly.

III. Regional and Bilateral Agreements Regulating IP

There is a major current trend in the negotiation of trade agreements affecting all fields of regulatory interest.[16] This is the negotiation and conclusion of bilateral and regional trade agreements. In specific regard to IP and Latin America, the trend of negotiation of Free Trade Agreements (FTAs) with United States and/or Economic Partnership Agreements (EPAs) with EU is of special importance.

IP Chapters are a major focus of the negotiations for both the United States and EU. Major “drivers” for the United States are the copyright industries (music and film) and the "originator" pharmaceutical industry. The EU drivers include the copyright and food product (geographical indications-dependent) industries.

a. US FTAs and IP

US IP demands are typically presented in the form of "template" over which negotiating options are very limited. IP Chapters are effectively presented on a "take it or leave it" basis, as a condition to completing FTA negotiations. Conclusion of the FTA is usually followed by intensive intervention by USTR (and US industry) in the national implementation process as a pre-condition to bringing the FTA into force. The implementation phase may be even more difficult than the treaty negotiation because USTR's demands may exceed those explicitly enumerated in FTA, and because these implementation negotiations tend to be “non-transparent”.

The major controversy surrounding the IP Chapters in US-negotiated FTAs has focused on pharmaceutical-related provisions, including patents and marketing exclusivity requirements. Though country-to-country results vary, the U.S. template has included:

- Extending the scope of patent protection to cover new uses of known compounds, and plants (and, on occasion) animals;

[16] See Frederick M. Abbott, A New Dominant Trade Species Emerges: Is bilateralism a threat?, 10 J. INT’L ECON. L., forthcoming 2007 (Oxford).

- Providing patent term extensions to offset regulatory delay;
- Limiting the scope of permissible exceptions to patent rights;
- Providing fixed periods of marketing exclusivity for a broad class of previously unapproved products, based on submission of regulatory data, or reliance on foreign marketing approval or foreign submission of regulatory data;
- Prohibiting the effective granting of marketing approval by the health regulatory authority during the patent term without the consent or acquiescence of patent holders ("linkage");
- Authorizing nonviolation nullification or impairment dispute settlement claims, and;
- Prohibiting parallel importation (in some cases).

These provisions strengthen the position of originator-patent holder pharmaceutical enterprises on national markets, and may impose substantial obstacles to the introduction of generic pharmaceutical products.

One major concern with several of the foregoing restrictive measures is that they could effectively preclude use of compulsory licensing because they contain no provision expressly for exceptions in such cases. All (or virtually all) countries require a medicine to be approved and registered by the public health authority before distribution on the market. Prior to recent developments, discussed below, the provisions of the FTAs for patent linkage made no provision for registration of generic products produced under compulsory licenses, while otherwise requiring the consent of the patent holder for marketing approval. In response to objections from NGOs and members of Congress, USTR appended "side letters" to the FTAs intended to give the appearance of addressing this problem. But USTR refused to acknowledge that these attachments resulted in any exception to the express terms of the agreements.[17]

The Democratic Party majority in the US Congress recently negotiated modification of pharmaceutical-related provisions in the FTAs with the Executive Branch (USTR),[18] requiring changes to sign but not yet ratified agreements with Colombia, Panama and Peru. The proposed changes include limiting the grant of marketing exclusivity in some cases to a period contemporaneous with that obtained in the United States; eliminating provision for patent term extension based on approval delay; eliminating the express linkage between patents and marketing approval; and incorporating express provision for use of compulsory licensing notwithstanding existing marketing exclusivity.

The changes, when made, should certainly represent an improvement over the current situation. However, it must be noted that additional obligations have been proposed to reduce the magnitude of the changes. Patents and marketing exclusivity are to be expressly de-linked, but signatories will be obligated to provide transparent and expeditious mechanisms for initiating patent infringement litigation. Direct patent term extension will be eliminated, but obligations will be added to ensure expeditious processing of applications for patents and marketing approval. While marketing exclusivity obligations may be limited in some cases to periods contemporaneous with those running in the United States, the basic requirement of marketing exclusivity remains a substantial TRIPS-plus obligation. As of the date when this paper was presented, USTR and Congress had not yet finalized the proposed new "template", and details in this area are critical to assessing the potential effect of the proposals (i.e., the "devil in the details").

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[17] Carsten Fink & Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent Us Free Trade Agreements, World Bank Trade Note No. 20, 2005, at 3, 10 Nn.10, 11.

[18] See, e.g., USTR, Bipartisan Agreement on Trade Policy: Intellectual Property, May 2007, Trade Facts, available at <http://www.ustr.gov>.

b. Best Practices in Implementation

In terms of "best practices" on implementation, note that U.S. law on the subjects addressed by the pharmaceutical-related provisions of the FTAs contains numerous conditions and qualifications, so that a principle of "absolute" or "unconditional" implementation should be rejected.[19] And, it is critical to note that US law in the field of patents, including with respect to those covering pharmaceuticals, is continuously being re-adjusted. Just during past two years, the US Supreme Court has overturned three key elements of patent law underlying USTR's "strong protection" policy as reflected in the FTAs:

- Merck v. Integra Lifesciences, 125 S. Ct. 2372 (2005), opened up a broad research exemption specifically in the pharmaceutical sector;
- E-Bay v. MercExchange, 126 Sup. Ct. 1837 (2006), eliminated the automatic award of injunction for patent infringement, moving to a "four factor" balancing of equities test;
- KSR v. Teleflex, 127 Sup. Ct. 1727 (2007), tightened the standards for demonstrating "inventive step" by requiring consideration of prior art regardless of a specific "teaching, suggestion or motivation" for the claimed invention.

In the specific context of the pharmaceutical sector, "best practices" on implementation should take into account a number of elements:

- Even if "new uses" of known compounds are patentable, a great deal of discretion remains regarding the potential scope of patentability (e.g., patenting of "dosages", "modes of administration", and "patient populations" are stretching the meaning of "second medical indication" subject matter);
- Critical issues surround protection of "polymorphs" (i.e., molecules with same chemical composition but different arrangement of structure). The inventive step test should approach the patentability of polymorphs very cautiously to avoid "evergreening". This result is implied by KSR v. Teleflex, referred to above;
- "Linkage" (i.e., blocking of health authority registration on the basis of patents), a core problem of prior FTAs, should no longer be required for Colombia, Panama and Peru based on renegotiated texts. It is essential that these countries take advantage of the greater flexibility in their national legislation. Countries that previously accepted linkage obligations (e.g., CAFTA-DR and Chile) should attempt to "claw back" this obligation from the United States. In other words, they should seek to newly negotiate greater flexibility at least to the extent found in the renegotiated texts with Colombia, Panama and Peru.
- With respect to pharmaceutical marketing exclusivity requirements, some important problems should be resolved by new terms in the Colombia, Panama and Peru agreements. The duration of marketing exclusivity should, at least in some case, be limited to the term granted in the United States. It should be made clear that exceptions to marketing exclusivity should be available to protect public health. Again, CAFTA-DR and Chile should attempt to "claw back" obligations in these

[19] See generally Frederick M. Abbott Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law, UNCTAD - ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 12, Feb. 2006.

areas that they previously accepted. In all events, exceptions should be incorporated in national law.

- Chile addressed the potential late filing for regulatory approval by placing a one-year limitation on the right to file for approval within Chile following regulatory approval abroad, and by requiring the subject product to be placed on the market in Chile within one year following its registration there. USTR consequently placed Chile on its Special 301 Priority Watch List. This seems wholly disproportionate to Chile's reasonable measures.

- A key issue is defining products that may be considered "new" from the standpoint of benefiting from marketing exclusivity. CAFTA-DR, for example, defines "new product" as "one that does not contain a chemical entity that has been previously approved in the territory of the Party." This definition might require protection for molecules "old" in other countries (i.e., no universal standard of novelty). This problem may be cured for Colombia, Panama and Peru if the US marketing exclusivity period becomes the benchmark because the US FDA strictly limits the type of molecules that are considered new and different for marketing exclusivity purposes. It should be made clear that "chemical entity" covers the range of polymorphs and other variations of the "same drug" so that additional periods of marketing exclusivity cannot be tacked on.

- Another problem under existing texts is the "extraterritorial" effect of US (or other foreign) submissions of regulatory data (or approval) against which reliance is precluded, notwithstanding the lack of submission in the country where approval is sought. This is not included in Chile's FTA, but it is found in CAFTA-DR. Generic producers may be blocked from obtaining marketing approval despite the absence of regulatory data submitted to the host national authority. The new template may address this problem for Colombia, Panama and Peru.

c. European Union Economic Partnership Agreements

In contrast to the United States, EU EPA demands focus on geographical indications and "enforcement". In the enforcement section of its IP chapters, the EU is essentially attempting to transpose the EU Intellectual Property Enforcement Directive into the law of EPA countries.

The EU nominally stays away from imposing in its EPAs additional IP limitations that may affect public health, but this stated policy of avoidance is somewhat illusory. The IP chapters include obligations to join or apply the Patent Cooperation Treaty (PCT). This will likely increase the number of patent filings in countries that previously were not parties, and establish an effective 30-month priority period during which patent applicants can decide whether to proceed on their applications (making it very problematic for potential competitors to enter the market during that period).

Latin American governments should exercise great caution in assessing the enforcement provisions proposed by the EU. To give two examples:

- One enforcement provision of a draft EPA proposed by the Commission requires that competent judicial authorities, "even before the commencement of proceedings on the merits of the case", on the basis of "reasonably available evidence to support [an IP rightholder's] claims" … may "order prompt and effective provisional measures"… including "the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or

distribution of these goods". Such a provision, with a low evidentiary standard and lacking a temporal limitation, may have a strong chilling impact on producers of generic medicines who are threatened with seizure of products and production equipment on the basis of "reasonably available evidence" in advance of a determination as to the validity of the evidence. The seizures could last for an extended duration and cripple the business without any meaningful judicial process. While similar, this provision goes well beyond the requirements of the TRIPS Agreement with respect to available enforcement measures, and lacks several express safeguards.

- Article 4 of the EU Enforcement Directive, replicated in draft EPAs, provides that:" Member States shall recognise as persons entitled to seek application of the measures, procedures and remedies referred to in this chapter: … (d) professional defence bodies which are regularly recognised as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law." This Enforcement Directive obligation may, for example, provide pharmaceutical sector industry groups with a right to initiate legal claims against generic producers seeking entry into the national market.

There are various other enforcement provisions in the draft EPAs strongly favoring the interests of IP right holders, including provisions relating to obtaining evidence and the calculation of damage awards. The provisions do not contain correspondingly strong protections for those accused of infringement, or for the general public.

d. The Context of Implementation

It is of considerable importance that national legislation be evaluated in the specific context of the judicial and administrative processes used in the implementing country. These processes vary a great deal, including among Latin American countries. In addition, it is very important that all of the agencies with regulatory authority over the subject matter be included in the implementing process (for example, the public health authority must be included in discussions affecting access to medicines).

IV. Addressing the Future

There is no easy way for Latin American governments to counter demands from the United States and EU in trade negotiations for stronger protection for IP. Already the IP chapters of the FTAs and EPAs are generally disfavored by Latin American governments and local industry. The government typically does not need persuading that the IP chapter is a “net negative” from the standpoint of local pharmaceutical producers, or that it will otherwise impose substantial administrative costs. The terms of the IP chapters have been accepted to enable conclusion of the trade agreements “as a whole”, which presumably are assessed by governments to provide "net benefits" to the countries involved based on concessions obtained in other areas, such as trade in textiles or agricultural products.

The impact of these agreements on pharmaceutical prices and availability must be closely monitored, and adjustments to public health programs made to offset any adverse effects on less advantaged individuals.

The trend toward adoption of FTAs and EPAs might be reversed by a Latin American region-wide decision to move trade negotiations back to the multilateral setting (i.e., the WTO), where developing countries had negotiated more successfully in recent years. But, a decision to reinvigorate the WTO does not appear to be on the immediate horizon.

Annex

Annex 1

Patent Licensing, Competition Law and the draft Substantive Patent Law Treaty

1. Patent licensing may enhance the development of new technologies and making them available to the public.
    a. Patent licensing may facilitate access by researchers to third-party technologies and facilitate experimentation with a view toward commercialization or public use;[1]
    b. Patent licensing may facilitate movement of new technologies from the research phase to the commercialization phase as small and medium enterprises out-license inventions to more highly capitalized enterprises;
    c. Patent licensing may provide a means for enterprises to negotiate the "patent thicket" so as to overcome obstacles to incremental innovation;
        i. In areas such as standards-setting, sharing of patented technologies may be necessary to maintenance of competitive markets
    d. Patent licensing may facilitate joint research and development, accelerating technology development and spreading risk;
    e. Patent licensing may facilitate partitioning of R & D and production functions, allowing production at most efficient locations without corollary investments in R & D.
2. Patent licensing is a tool for the transfer of technology between developed and developing countries.
    a. Positive welfare effects dependent on validity of underlying patent. Licensing and payment of royalties on technology otherwise in the public domain is unjustified social expense;
    b. "Securitization" of invention encourages sharing of information based on rent or royalty stream expectation;
    c. Forms of enterprise combination and licensing arrangements highly variable – parent-subsidiary, joint venture, independent entities, etc.
    d. Extent to which patent licensing generates improvement to local technology capacity is context specific
        i. Patent licensing may take place in closely-guarded intracorporate setting which may limit local diffusion, or may take place in open setting (e.g., to university research institution) which may encourage diffusion
        ii. Associated "know-how" licensing affects level of technology transfer
        iii. Restrictive licensing terms may substantially affect economic and social value of patent license to transferee country
3. Patent licensing is subject to anticompetitive abuse.

[1] Note that U.S. Supreme Court in Merck v. Integra Lifesciences, 125 S. Ct. 2372 (decided June 13, 2005), dramatically expanded scope of permissible non-infringing uses of patented pharmaceutical technologies during drug research and development phase, reducing need for licensing prior to market entry.

a. "Patent pools" into which enterprises combine their technologies may be used to create prohibitive market entry barriers, facilitating cartelization of markets

b. Restrictive third-party licensing terms (e.g., exclusive grantbacks) may be used to foreclose emergence of competitors

c. Patent licensing terms can be used to leverage market power, such as through product tying arrangements and block licensing

d. Patent licensing agreements may include terms generally disfavored in competition law, such as fixing of resale prices, restricting output and dividing territories among horizontal competitors

e. No-challenge clauses in patent licenses encourage unearned surplus payments to holders of invalid patents

f. Patent licensing agreements merit particular scrutiny in the context of licensors holding dominant position on the relevant market

4. Control of anticompetitive patent licensing is a generally accepted practice among states

a. The WTO TRIPS Agreement includes provisions which recognize that intellectual property rights may be abused, that authorize Members to regulate anticompetitive licensing practices and that encourage cooperation in enforcement (e.g., Articles 8.2, 31(k)-(l), 40).[2] Concern with anticompetitive patent licensing is reflected in the original International Trade Organization Charter.

b. Paris Convention recognizes abuse of patents as grounds for compulsory licensing (Article 5A(2))

c. Developed country regulation specifically addresses anticompetitive patent licensing arrangements

i. See, e.g., U.S. Department of Justice/Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995). Also, the Supreme Court has ruled that patent misuse is an equitable defense to the enforcement of patents (e.g., in the case of certain product tying arrangements). See also U.S. Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003)

ii. See, e.g., European Commission Regulation No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements and Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C/ 101/02)

iii. See, e.g., Fair Trade Commission of Japan (FTCJ), Antimonopoly Act Guidelines Concerning Joint Research and Development, 20 April 1993

d. Developing countries address anticompetitive patent licensing through regulation and court decision

i. See, e.g., Andean Community, Decision 291, Article 14

[2] See Frederick M. Abbott, Are the Competition Rules in the WTO TRIPS Agreement Adequate?, 7 J. INT'L ECON. L. 685 (2005 Oxford).

ii. Abuse of patent is common grounds in developing country patent legislation for grant of compulsory license.

iii. As a general proposition, developing countries have a lower level of competition law enforcement capacity than the OECD countries. Competition law enforcement tends to be fact intensive, complex and expensive.

e. Proposals from leading experts on competition law for international antitrust regulation routinely address anticompetitive patent licensing practices, see International Antitrust Working Group (W. Fikentscher, et al.), Draft International Antitrust Code, at Article 6: Restraints in Connection with Intellectual Property Rights.[3]

f. Trend of regulation in OECD is to evaluate patent licensing restrictions under "rule of reason" approach and to limit inquiry where market share of parties is below defined threshold. Nonetheless, certain per se (or hardcore) prohibitions remain (e.g., in EU, against exclusive grantbacks).

i. Specific doctrinal issues are continuously re-examined. For example, U.S. Supreme Court currently considering presumption of patent-based market power in context of tying arrangements (Illinois Tool Works v. Independent Ink, No. 04-1329)

g. Current regulatory approach of OECD competition law authorities is not necessarily the best approach for developing countries which tend to have lower levels of enforcement capacity.

h. Developing countries may benefit from greater use of per se rules and other positive prohibitions such as characterized EU competition and technology law until 2004.[4]

i. Developing countries are more likely to be patented-technology importers than exporters

ii. Developing country markets are generally more susceptible to market power concentration among dominant enterprises than developed country markets

i. Competition law risk assessment should account for these factors

5. Rules regarding anticompetitive aspects of patent licensing are within the reasonable potential subject matter scope of a Substantive Patent Law Treaty. Such rules might take a positive form, prescribing certain types of conduct or establishing presumptions regarding certain types of conduct. Such rules might take a negative form, making clear that governments are permitted to regulate anticompetitive licensing practices notwithstanding positive obligations regarding the grant of patents. Such rules might include illustrative list of potentially anticompetitive licensing practices.

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[3] Reprinted in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION (eds. F. Abbott & D. Gerber 1997)(Kluwer), at Appendix 2. See also, Wolfgang Fikentscher, The Draft International Antitrust Code (DIAC) in the context of international technological integration, id. at 211.

[4] See elaboration in F. Abbott, supra note 2.

a. The negotiating history of the GATT Uruguay Round and subsequent efforts within the WTO to establish mandatory positive competition rules suggest obstacles to that approach in the context of SPLT negotiations.

   i. In TRIPS Agreement Art. 40, listing of anticompetitive licensing conditions is illustrative of subject matter that may be addressed, not prohibited as mandatory positive obligation

   ii. WTO Trade and Competition Working Group manifested disagreement on limited set of positive rules, with differences between governments at all levels of development.

b. Approaches to regulation of competition tend to vary over time within the same jurisdiction as industrial policy considerations shift. This may argue in favor of preserving regulatory flexibility.

c. Industrial policy considerations of developed and developing countries with respect to application of competition law to patent licensing may differ. Developing countries at different stages of development may also maintain differing industrial policy interests.

d. A negative approach would permit maintenance of regulatory flexibility. For example:

   "Nothing in this [SPLT] shall prevent or hinder a member state from prescribing or enforcing measures to address patent licensing conditions or practices determined to be anticompetitive. Such measures, which may be preventive and remedial, may be enforceable by private and government action, and may include civil damages and criminal penalties."

   Note that the foregoing does not address patent misuse in general because the subject matter of this presentation concerns patent licensing. However, it is reasonable to assume that additional negative provision should be included in SPLT to permit maintenance of regulatory flexibility regarding patent abuse in other contexts, such as abuse of patents by dominant enterprises.

e. A combination approach might negatively preserve regulatory flexibility and positively list potentially anticompetitive practices, along the lines of the WTO TRIPS Agreement.

   i. An SPLT provision might also address enhanced enforcement cooperation and capacity-building