

## Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements

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Over the past few years, the United States has pursued bilateral and regional free trade agreements (FTAs) in different parts of the world (table 1). This has marked a considerable shift in U.S. international trade diplomacy. While the U.S. Government entered into regional trade agreements in the past—notably in the case of the North American Free Trade Agreement (NAFTA)—it relied mostly on the multilateral trading system to advance the progressive opening of world markets and to create legally enforceable trading rules.<sup>1</sup>

Prominent in the recent set of bilateral FTAs are strong rules for the protection of intellectual property rights (IPRs), a key market access interest of the United States—supported by private sector constituents who derive significant revenues from exports of intangible assets. Indeed, the trade promotion authority, under which these agreements were negotiated aims explicitly to promote intellectual property rules that “reflect a standard of protection similar to that found in United States law.”<sup>2</sup> U.S. trading partners generally have more defensive negotiating interests in intellectual property, but they are willing to commit to stronger intellectual property rules as a quid pro quo for concessions in other areas—notably preferential access to U.S. markets for agricultural and manufactured goods.

This note offers an overview of key elements of recent U.S. FTAs that go beyond multilateral standards on intellectual property as set forth in the Agreement

**Table 1. Recent U.S. free trade agreements**

Signed and approved by U.S. Congress	Signed but not yet approved by U.S.	Under negotiation
Vietnam (2001) <sup>a</sup>	Bahrain	Andean countries (Bolivia, Colombia, Ecuador, Peru)
Jordan (2001)		Thailand
Singapore (2003)		Panama
Chile (2003)		Southern African Customs Union
Morocco (2004)		Free Trade Area of the Americas
Australia (2004)		
DR-CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua) (2005)		

a. The U.S. bilateral agreement with Vietnam is not a free trade agreement, but a bilateral agreement intended to establish normal trade relations under U.S. trade law. It is included in this note for purposes of comparison. The United States has signed similar agreements with other countries, such as Cambodia and Laos.

on Trade-Related Aspects Intellectual Property Rights (TRIPS). It also offers a perspective on the intellectual property bargain in trade agreements, outlines key economic and social implications from the adoption of new intellectual property standards, and discusses several lessons learned.

### **Where do U.S. FTAs go beyond the TRIPS standards?**

The IPR chapters of recent U.S. FTAs include provisions that affect all types of intellectual property instruments and the mechanisms available to administer and enforce exclusive rights. Although the detailed provisions differ from agreement to agreement, there are certain common obligations which go beyond the TRIPS standards (table 2).

#### ***Protection of patents and pharmaceutical test data***

As in TRIPS, all of the FTAs listed in table 1 provide for a patent term of 20 years. However, they also require that the patent term be extended in the event of delays caused by regulatory approval processes, such as obtaining approval for marketing a new drug. In addition some agreements call for extensions for delays in the granting of the patent itself.

Three agreements (U.S.–Australia, U.S.–Morocco, U.S.–Bahrain) extend the scope of patentability by mandating that patents must be available for new uses of known products. All bilateral agreements go beyond TRIPS in enhancing patent protection for plants and animals. The strongest agreement in this regard is U.S.–Morocco, which explicitly mandates patent protection for life forms. Others do not exempt plants and animals from patentability, an option provided under TRIPS. The weakest agreement is the one with the Dominican Republic and six Central American countries (U.S.–DR–CAFTA), which simply calls for “reasonable efforts” to provide for patentability of plants.<sup>3</sup>

In the area of medicines, the bilateral agreements contain provisions that limit the ability of governments to introduce competition from generic producers. First, to override the market exclusivity of patent holders, governments must grant so-called compulsory licenses to generic manufacturers. TRIPS allows the use of compulsory licenses without specifying the grounds for issuing them. Four of the bilateral agreements (with Australia, Jordan, Singapore, and Vietnam) limit the use of compulsory licensing to emergency situations, antitrust remedies, and cases of public noncommercial use.<sup>4</sup>

Second, to make effective use of compulsory licenses, generic drug manufacturers must be able to obtain regulatory permission to enter the market. Provisions in the bilateral agreements impose an obstacle in this respect. All but two agreements (those with Jordan and Vietnam) prohibit the signatories from approving the marketing of a generic drug during the patent term without the consent of the patent holder—an issue on which TRIPS imposes no obligation. In

other words, compulsory licenses may become ineffective in introducing competition from generic drug makers.

Third, obtaining marketing approval for drugs requires the submission of test data on a drug's safety and efficacy to regulatory authorities. Such data is protected by separate legal instruments that differ from country to country. The TRIPS agreement requires only that test data be protected against "unfair commercial use." By contrast, most of the bilateral agreements mandate exclusivity of test data, as under U.S. law. Once a company has submitted original test data, no competing manufacturer may rely on those data for a period of five years to support a request for approval for its own drug.<sup>5</sup> The compilation of new test data by competing manufacturers may take several years and be prohibitively expensive. For that reason, test-data exclusivity may pose a second obstacle for governments to make effective use of compulsory licensing.

Several of the bilateral agreements go further on data exclusivity. When pharmaceutical companies seek marketing approval for previously unapproved uses of drugs already registered, regulatory authorities typically require the submission of "new" clinical information. The agreements with Morocco and Bahrain provide for an additional three years of data exclusivity whenever new clinical information is presented. Drugs benefiting from this type of marketing exclusivity include not only newly patented products, but also older generic products for which the patents have expired (though generic competition for previously approved uses of such drugs would remain unaffected).

Sometimes drug regulatory authorities recognize the marketing-approval decisions of foreign regulators in making decisions to approve the same product at home. The intellectual property chapter of the U.S.–Singapore Agreement mandates, in this regard, that foreign data exclusivity also applies at home. In other words, no competing manufacturer is allowed to rely on the test data submitted to a *foreign* regulator when seeking marketing approval at home.

The agreements with Australia, Bahrain, and the DR-CAFTA countries reach even farther. Even if regulatory authorities do not recognize foreign marketing approvals, competing manufacturers are prevented from using test data submitted to a drug regulatory agency in another territory. In other words, test-data exclusivity applies automatically in all FTA jurisdictions once a company submits test data to a drug regulator in one territory—even outside the FTA area.

A fourth aspect of intellectual property regulations affecting the supply of medicines is the permissibility of parallel importation of pharmaceutical products that have been placed on the market in foreign countries. Parallel importation can be a means of exerting downward pressure on prices of pharmaceuticals that are sold more cheaply abroad. The TRIPS agreement affords World Trade Organization (WTO) members flexibility in determining whether to permit parallel importation of patented drugs.<sup>6</sup> By contrast, the U.S. agreements with Australia, Morocco, and

**Table 2. Intellectual property provisions of recent U.S. bilateral and FTAs that go beyond**

	U.S.–Vietnam	U.S.–Jordan	U.S.–Singapore	U.S.–Chile	U.S.–Morocco	U.S.–Australia	U.S.–DR–CAFTA	U.S.–Bahrain
Protection of patents and pharmaceutical test data								
Patent term	Extension given for delays caused by regulatory approval process. In addition, extension given when a delay in the granting of the patent exceeds 4 years from the filing of the application (5 years for U.S.–Chile) or 2 years after a request for examination (3 years for U.S.–Chile).							
Second-use patents	No specific provision.							
Patenting of life forms	Certain plants and animals may not be excluded from patentability. <sup>a</sup>	No general exclusion of plants and animals from patentability. <sup>b</sup>			Obligation to provide patents for new uses of known products. Explicit obligation to provide patent protection for plants and animals.	Exclusions only allowed for moral, health and safety reasons.	No specific provision. Reasonable efforts have to be undertaken to provide for patentability of plants. <sup>c</sup>	Same as U.S.–Australia. Explicit obligation to provide patent protection for plants, but animals can be excluded.
Compulsory licenses	Compulsory licenses limited to national emergencies, as antitrust remedy, and for public non-commercial use.		TRIPS standards apply.	TRIPS standards apply.		Same as U.S.–Singapore.		TRIPS standards apply.
Linkage between patent status and drug marketing approval	No specific provision.	Patent owner must be notified when marketing approval is sought during the patent term.	Marketing approval of a generic drug is prohibited during the patent term, unless authorized by the patent owner. In addition, the patent holder must be notified of the identity of the generic company requesting marketing approval.					
Test data protection for pharmaceutical products	Data exclusivity for a "reasonable" period, normally not less than 5 years.	TRIPS standards apply. In addition, length of protection should be the same as in the originator's country.	Data exclusivity for 5 years. In addition, where drug regulators rely on foreign marketing approvals, data exclusivity applies automatically at home.	Data exclusivity for 5 years. Additional 3 year data exclusivity triggered by "new clinical information".	Data exclusivity for 5 years. Additional 3 year data exclusivity triggered by "new clinical information".	Data exclusivity for 5 years. In addition, data exclusivity applies in all FTA member countries, once first obtained in another territory. In the case of U.S. Bahrain, additional 3 year data exclusivity triggered by "new clinical information" (with equivalent provisions on cross-border application).		
Parallel imports of patented products	No specific provision. <sup>d</sup>	TRIPS standards apply.	Patent holders may limit parallel imports of pharmaceutical products through licensing contracts.	TRIPS standards apply.	Patent holders may limit parallel imports through licensing contracts.	Patent holders may limit parallel imports through licensing contracts.		TRIPS standards apply.
Side letters on public health?	No	No	No	No	Yes	No	Yes	Yes

**Table 2. Intellectual property provisions of recent U.S. bilateral and FTAs that go beyond TRIPS standards (continued)**

	U.S.–Vietnam	U.S.–Jordan	U.S.–Singapore	U.S.–Chile	U.S.–Morocco	U.S.–Australia	U.S.–DR-CAFTA	U.S.–Bahrain
Copyright protection								
Term of copyright protection	Same as TRIPS if determined by life of author, 75–100 years	Same as TRIPS	Life of author plus 70 years. If decided on a basis other than the life of the author, the term is 70 years from the publication or creation of the work.					
Technological protection measures	No specific provision.	'Adequate' protection and 'effective' remedies against acts of circumvention. Ban on circumvention devices.	'Adequate' protection against acts of circumvention. Ban on circumvention devices. Criminal liability in case of willful infringement for commercial purposes. Exempted are nonprofit libraries, archives, educational institutions, as well as acts related to reverse engineering, troubleshooting, protection of minors, computer or network security, and lawfully authorized government activities.					
Liability of Internet service providers	No specific provision.		Limited liability of Internet service providers on the condition that they block infringing content upon notification by the copyright holder. <sup>e</sup>					
Burden of proof in case of copyright infringement	No specific provision.	Burden of proof placed on the defending party to show that works are in the public domain. However, copyright owners still have to prove infringement.						
Parallel importation of copyrighted works	No specific provision <sup>e</sup>	Copyright holder has right to block parallel imports.	TRIPS standards apply.	Copyright holder has right to block parallel imports.				TRIPS standards apply.
Enforcement of intellectual property rights								
Institutional flexibility in IPRs enforcement	No specific provision.		Resource constraints cannot be invoked as an excuse for not complying with specific enforcement obligations. <sup>e</sup>				No specific provision.	Same as U.S.–Chile. Same as U.S.–Singapore.
Border measures	Apply to imported and exported goods.	Scope of border measures not specifically defined.	Apply to imported, exported, and transiting goods.				Apply only to imported goods (similar to TRIPS).	Same as U.S.–Chile.
Civil and administrative procedures			Obligation to fine infringers of copyright and trademark rights irrespective of the injury suffered by rights holders.					
Criminal procedures and remedies	Similar to TRIPS.	Scope of criminal procedures and remedies not specifically defined.	Similar to TRIPS. In addition, criminal procedures apply in cases of willful infringements, not only for a financial gain.	Similar to TRIPS. In addition, criminal procedures apply in cases of willful infringements, not only for a financial gain, and specifically for knowing trafficking in counterfeit labels affixed to certain copyrighted works (e.g., CDs, software).				

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**Table 2. Intellectual property provisions of recent U.S. bilateral and FTAs that go beyond TRIPS standards**

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(Continued)

*Source:* This overview table is based on the texts of the FTAs, available at <http://www.ustr.gov>, and legal analyses by Abbott (2004) on the U.S.–DR-CAFTA and U.S.–Morocco agreements and Roffe (2004) on the U.S.–Chile Agreement.

*Notes:* a. Specifically, the agreement foresees that “[t]he exclusions for plant and animal varieties (as defined in Article 1 of UPOV Convention 1991) shall not apply to plant or animal inventions that could encompass more than one variety.”

b. In the case of U.S.–Chile, the agreement does not explicitly oblige protection of life forms under the patent system, but mandates “reasonable efforts” to develop legislation related to patent protection for plants within four years from entry into force of the agreement.

c. In addition, member countries are required to accede to the International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention 1991) by 2006 (2007 for Costa Rica; 2010 for Nicaragua). However, if a member country already provides patent protection for plants, accession to UPOV 1991 is not a requirement.

d. The question of intellectual property rights exhaustion, which determines the permissibility of parallel importation, is not addressed in the U.S.–Vietnam agreement.

e. In the case of U.S.–Morocco, a side letter specifies the form in which notifications in case of alleged copyright infringement must be made.

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Singapore allow patent holders to prevent parallel importation through contractual means.

Are the provisions on marketing approval during the patent term, test-data exclusivity, and parallel importation at odds with the Doha Declaration on TRIPS and Public Health? That declaration—issued at the WTO ministerial meeting in Doha, Qatar, in 2001—recognized the gravity of the public health problems besetting many developing and least developing countries. Among other things, it reaffirmed the right of WTO members to use the flexibilities of TRIPS in the realm of compulsory licensing and parallel importation to “promote access to medicines for all.”<sup>6</sup> Moreover, in August 2003, WTO members created a special mechanism under the TRIPS agreement that allows countries with insufficient manufacturing capacity to make effective use of compulsory licenses by importing generic drugs (Fink 2005). Technically, the Doha Declaration and the August 2003 decision do not address test-data exclusivity or marketing approval during the patent term. However, the relevant provisions of the FTAs appear to be at odds with the spirit of these multilateral accords, to the extent that they preclude the effective use of compulsory licenses.

In side letters to the agreements involving Bahrain, Morocco, and the DR-CAFTA countries, the respective governments shared understandings that the intellectual property chapters did not affect their ability to “take necessary measures to protect public health by promoting medicines for all.”<sup>8</sup> In a recent letter to a

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member of the U.S. Congress on the U.S.–Morocco FTA, the general counsel of the United States Trade Representative (USTR) provided further clarification:

“If circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the FTA would not stand in the way....

As stated in the side letter, the letter constitutes a formal agreement between the Parties. It is, thus, a significant part of the interpretive context for this agreement and not merely rhetorical. According to Article 31 of the Vienna Convention on the Law of Treaties, which reflects customary rules of treaty interpretation in international law, the terms of a treaty must be interpreted “in their context,” and that “context” includes “any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty.”<sup>9</sup>

At the same time, the U.S. government does not view the side letters as creating an exemption that would allow parties to the FTAs to ignore obligations in the agreements’ intellectual property chapters.<sup>10</sup> The side letters merely signal the belief of the signing governments that the intellectual property rules of the FTAs will not interfere with the protection of public health.<sup>11</sup>

### ***Copyright protection***

TRIPS requires that copyright be protected for the life of the author plus 50 years. Except for the agreements with Jordan and Vietnam, the bilateral FTAs of the United States extend this term by an additional 20 years.

Most bilateral FTAs include obligations against circumventing so-called technological protection measures—devices and software developed to prevent unauthorized copying of digital works. This issue is not covered under TRIPS. It came to prominence only with advances in information and communication technologies that greatly facilitated the copying of literary or artistic works in digital form. The U.S. Digital Millennium Copyright Act of 1998 strengthened standards on circumventing technologies designed to prevent unauthorized copying of digital content. Those standards found their way to varying degrees into seven of the bilateral agreements. Related provisions in six of the FTAs define the liability of internet service providers when infringing content is distributed through their servers and networks. Again, these provisions are based on standards found in the U.S. Digital Millennium Copyright Act.

In copyright infringement cases, all of the bilateral agreements—except for the one with Vietnam—place the burden of proof on the defending party to show that

works are in the public domain. TRIPS does not impose any such obligation. The FTAs thus strengthen the position of copyright holders, as artistic and literary works should generally be considered protected—unless they obviously belong in the public domain.

As in the case of pharmaceutical products, TRIPS does not mandate any rule on the permissibility of parallel imports of copyrighted works—such as books or musical Compact Disks (CDs)—that have been lawfully sold in foreign markets. Some countries, such as New Zealand, have permitted parallel importation of certain copyrighted products as a way to stimulate price competition. By contrast, the U.S. bilateral agreements with Jordan and Morocco give copyright holders the right to block parallel importation.

### **Enforcement of intellectual property rights**

The TRIPS agreement—for the first time in an international agreement on intellectual property—introduced detailed obligations on the enforcement of IPRs. Certainly, without judicial enforcement of intellectual property laws, rules on patents, copyright, and other forms of protection could be seriously undermined. However, recognizing the institutional limitations of the institutions in many developing countries, TRIPS does not create any obligation “with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.”<sup>12</sup>

The agreements with Australia, Jordan, and Vietnam do not explicitly allow for the same institutional flexibility. In these cases, it may therefore be difficult to defend derogations from the specific enforcement provisions of the agreements’ IPR chapters with inherent institutional constraints, such as limited budgetary or human resources. The agreements with Bahrain, Chile, Morocco, Singapore, and the DR-CAFTA countries go further, spelling out that resource constraints cannot be invoked as an excuse for not complying with the agreements’ specific enforcement obligations.<sup>13</sup> Indeed, some of the specific enforcement requirements of the FTAs seem to create additional institutional obligations. For example, as in the case of TRIPS, the FTAs require customs authorities to stop trade in counterfeit and pirated goods. But TRIPS requires such measures only for imported goods, whereas most FTAs mandate border measures for imported and exported goods and, in some cases, even transiting goods.

Finally, the enforcement rules of the bilateral agreements mandate a stronger deterrent against IPR infringement. For example, TRIPS requires only the imposition of fines adequate to compensate IPR holders for the monetary damages they suffered. In the case of copyright piracy and trademark counterfeiting, all of the FTAs require the imposition of fines irrespective of the injury suffered by IPR holders. TRIPS mandates criminal procedures only in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Many FTAs go beyond this broad standard

and define more explicitly the scope of acts of infringement subject to criminal procedures—including, for example, copyright piracy with a significant aggregate monetary value, but not necessarily for financial gain. Thus, certain forms of end-user piracy may be considered a criminal offense.

### *Intellectual property rights and investment rules*

In addition to the rules contained in the intellectual property chapters of the FTAs, IPRs are subject to separate investment disciplines. Six of the bilateral agreements have separate chapters on investment (table 2). The U.S.–Bahrain and U.S.–Jordan FTAs do not have one, but the respective governments have negotiated bilateral investment treaties (BITs) with similar provisions.<sup>14</sup> As no multilateral agreement on investment exists at the WTO or elsewhere, these bilateral investment rules break new ground.

A common element of the investment chapters and BITs is that intellectual property rights are explicitly listed in the definition of what is considered an investment. Thus, the agreements' specific investment disciplines apply, in principle, to government measures affecting the intellectual property portfolios of foreign investors. This, for example, raises the question of whether granting a compulsory license could be considered an act of expropriation. Five of the FTA investment chapters explicitly remove compulsory licenses from the scope of expropriation, as long as such licenses comply with the obligations of the TRIPS agreement and the intellectual property chapter of the respective FTA. But the U.S.–Vietnam FTA and the two BITs with Bahrain and Jordan lack a comparable safeguard. Thus, if Vietnam, for example were to issue a compulsory license in case of a national emergency, could the patent holder challenge such a decision as an act of investment expropriation?

Questions like this may be important, as these investment agreements provide for direct dispute settlement between investor and state, going beyond the more

**Table 3. Intellectual property rights and investment disciplines**

	U.S.–Jordan, U.S.–Bahrain	U.S.–Vietnam	U.S.–Singapore, U.S.–Chile,	U.S.–Australia
FTA chapter or previous BIT?	Previous BIT	Separate FTA chapter on investment		
Expropriation	No explicit exemption.		Compulsory license and revocation/limitation of intellectual property right not considered expropriation, if in compliance with multilateral and bilateral trade rules.	
Investor-state dispute settlement	Investors have recourse to investor-state arbitration procedures.			No recourse to investor-state arbitration

*Source:* This overview table is based on the text of the relevant investment chapters and BITs, available at <http://www.ustr.gov> and <http://www.tcc.mac.doc.gov>.

traditional state-to-state dispute settlement procedures in most trade agreements. An exception is the investment chapter of the U.S.–Australia FTA, which allows only for the possibility that investor-to-state dispute settlement procedures might be negotiated in future. Investor-to-state dispute settlement may be more attractive to foreign investors, who can seek arbitration awards for uncompensated expropriation. By contrast, state-to-state dispute settlement can typically authorize only the imposition of punitive trade sanctions.

Notwithstanding these considerations, the reach of investment agreements into the intellectual property domain is still untested and remains in many ways legally uncertain (Correa 2004).

### **A good bargain?**

Whether an FTA's package of commitments produces net welfare gains to all parties is an empirical question. However, FTAs with stronger rules on intellectual property complicate an assessment of economic benefits and costs—for three reasons.

First, the traditional logic that economists apply to mercantilist trade bargaining does not extend straightforwardly to intellectual property. While reduced import protection is seen as a concession by trade negotiators, it is generally regarded as a welfare-enhancing policy change by trade economists. Nonetheless, economists have supported mercantilist bargaining, as it helps governments make a stronger case for import liberalization: exporters that gain from improved access to foreign markets can become a political counterweight to firms that would lose out from more intense import competition.

From an economic perspective, IPRs are different. Put simply, they imply a trade-off between incentives for innovation and competitive access to new technologies.<sup>15</sup> To balance these trade-offs, governments limit the length and scope of the market exclusivity conferred by IPRs, according to national policy objectives. In particular, there is no assurance that stronger intellectual property rules will always be welfare-enhancing, and the direction and size of the welfare effect will depend on a country's level of economic development. While there is undoubtedly a market-access dimension to IPRs, subjecting standards of protection to mercantilist bargaining cannot be viewed in the same light as subjecting import barriers to such bargaining.

Second, improved access to U.S. markets for agricultural and manufactured goods is of a preferential nature. Preferences are time-bound, because they will be eroded once the United States reduces remaining tariffs and quotas on a nondiscriminatory basis in the current or future multilateral trading rounds (or once it signs additional FTAs). By contrast, a commitment to stronger IPR rules is permanent and likely to be implemented on a nonpreferential basis. Even if preferential treatment in the area of IPRs were technically feasible, it would likely be inconsistent with the TRIPS agreement, which mandates most-favored-nation (MFN) treat-

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ment of IPRs holders.<sup>16</sup> In contrast to the WTO's agreements on trade in goods and trade in services, the TRIPS agreement does not provide for an exception to the MFN principle for FTAs.

Third, it is inherently difficult to quantify the implications of changing intellectual property standards, let alone to compare them in monetary values to the gains derived from improved market access abroad. As will be explained further below, certain effects of stronger IPRs are conceptually not well-understood. But even where they are, the direction and size of net welfare changes depend on future developments that are difficult to predict—such as the nature of future innovations and their relevance to the country concerned.

### **Economic and social implications**

As just pointed out, evaluating the social and economic implications of the U.S. FTAs in the area of intellectual property is a difficult task. First of all, it requires an understanding of the changes in laws and regulations required by obligations in the FTAs that do not reflect current legal practice in the countries concerned. For example, both Morocco and the United States had legislation in place prohibiting parallel imports of pharmaceutical products before they signed the FTA. To be sure, trade agreements are still relevant even if they do not require changes in laws, because they make it difficult for countries to change their minds and amend laws. Indeed, in the specific case of parallel importation many countries—including the United States—reexamine from time to time existing policies, sometimes deciding to change course.<sup>17</sup> Certainly, if policy changes were inconceivable, there would be no need to lock policy into trade agreements.

A full economic assessment of the new intellectual property obligations in the FTAs would require in-depth study in each of the affected countries, an effort that far exceeds the scope of this note. Still, we may ask, what are some of the general benefits and costs that may come with the new intellectual property standards outlined above?

A commitment to stronger intellectual property protection may send a welcoming signal to foreign investors, contributing to a country's increased participation in international commerce. The empirical evidence on this question is mixed, however. Fink and Maskus (2004) review studies undertaken to gauge the link between the strength of intellectual property protection and the attraction of foreign direct investment flows. They conclude that countries that strengthen their IPR regime are unlikely to experience a sudden boost in inflows of foreign investment. Other factors account for most of the variation across countries in the activity of multinational enterprises. At the same time, the empirical evidence does point to a positive role of IPRs in stimulating cross-border licensing activity, which affects formal technology transfers.

Moving on to sector-specific implications, the role of patent protection in the pharmaceutical industry is conceptually well-understood. Patents create an incentive to invest in pharmaceutical research and development (R&D), but the market exclusivity they confer leads to prices above marginal production costs—as illustrated by sharp price drops when patents expire and generic competition emerges. The benefits and costs associated with protecting pharmaceutical patents differ from country to country. Among other things, they depend on the relevance of drug discoveries to national disease patterns, the purchasing power of patients, and the availability of health insurance programs that cover drug expenses. As already pointed out, insufficient flexibility in overriding drug patents can have a detrimental impact on the protection of public health. The need for such flexibility has not been widespread so far, as generic sources for most medicines have still been available. However, it is likely to become more important in the future, as the implementation of TRIPS obligations will lead newly invented drugs to be protected by patents in most developing countries that host generic pharmaceutical industries.<sup>18</sup>

The benefits and costs of stronger and new copyright protection standards are less clear cut. Most countries have industries that rely on copyright protection and that may benefit from strengthened protection. And new technologies that greatly facilitate the copying of digital works pose challenges that policymakers need to address. At the same time, copyright laws have historically sought to strike a balance between the interests of copyright producers and the interests of the general public. So-called fair-use exemptions allow the copying of protected works for educational and research purposes. There are concerns that new rules on the term of protection, technological protection measures, the liability of Internet services providers, and the burden of proof in cases of copyright infringement could diminish the rights of consumers and the general public (CIPR 2002).

Such concerns have been voiced from within the United States, not only by consumer rights advocates and academic institutions, but also by computer manufacturers and communications service providers that distribute copyrighted works. For example, proposed amendments to the Digital Millennium Copyright Act would permit the circumvention of technological protection measures if it did not result in an infringement of a copyrighted work.<sup>19</sup> Ensuring fair use of copyrighted material seems particularly important for accessing educational material. The opportunities and gains from the use of digital libraries, Internet-based distance-learning programs, and online databases would be limited if access to such tools were unaffordable or otherwise restricted by copyright law.

Finally, strengthening the enforcement of intellectual property rights can be a costly exercise—both in terms of budgetary outlays and the employment of skilled personnel. For developing countries that face many institutional deficiencies, a critical question is whether stronger enforcement of IPRs would draw financial and

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human resources from other development priorities.

### Lessons learned

The United States continues to negotiate FTAs, mostly with developing countries (see table 2), and still other negotiations are likely to be launched. Given the importance of intellectual property to the United States, it will be difficult for U.S. trading partners to avoid negotiating new IPR rules. What lessons can they learn from the recently signed agreements?

First, while there are common elements in the eight intellectual property chapters discussed here, there are also important differences (see table 2). With varying degrees of success, U.S. trading partners were able to advance their own, generally defensive interests. Of particular importance is the preservation of flexibilities to protect public health. Indeed, the United States is obligated by its own trade promotion authority “to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha.”<sup>20</sup>

Second, the intellectual property chapters of the eight FTAs discussed here mostly reflect proposals put forward by the United States. It may be possible to change the negotiating dynamics in future FTAs, if U.S. trading partners put forward their own proposals on new intellectual property rules and related incentive mechanisms. These may pertain to policy areas in which developing countries have offensive interests, such as the protection of biodiversity and traditional knowledge. But they may also consist of alternative mechanisms of addressing the problems that new intellectual property rules are intended to fix.<sup>21</sup>

Finally, countries need to carefully assess the economic and social effects of tightened IPR standards, ideally before new agreements are negotiated. As pointed out above, these effects are multifaceted and depend on country-specific circumstances. An assessment should therefore involve consultations with relevant ministries, the private sector, consumer groups, and other stakeholders.

### Notes

1. Comments by Federick Abbott, Carlos Braga, Jean-Christophe Maur, Richard Newfarmer, Lorenzo Pupillo, Pedro Roffe, Philip Schuler, Rudolf Van Puymbroek, as well as James Medenhall and other staff from the Office of the USTR are gratefully acknowledged.

2. See the Bipartisan Trade Promotion Authority Act of 2002, available at <http://www.tpa.gov>.

3. At the same time, the U.S.–DR–CAFTA Agreement requires countries that already provide patent protection for plants to maintain such protection.

4. The TRIPS provisions on compulsory licensing require a government first to make efforts to obtain a voluntary license from the patent holder, although this requirement may be waived in emergency situations or for public noncommercial use. The obligations of bilateral agreements are similar or identical in this respect.

5. In the case of agrochemical products, most of the bilateral agreements require data exclusivity for 10 years.

6. The permissibility of parallel importation is governed by rules on the exhaustion of patents. A system of international exhaustion is associated with free parallel trade, while patent holders can restrict parallel importation if patent rights exhaust only nationally. TRIPS Article 6 does not mandate a particular exhaustion regime, as long as its application is nondiscriminatory.

7. See paragraph 4 of the Doha Declaration on TRIPS and Public Health, available at <http://www.wto.org>.

8. The side letters also clarify that the intellectual property chapters of the FTAs do not prevent the effective utilization of the August 2003 decision by WTO members described in the text.

9. See the letter from USTR General Counsel John K. Veroneau to Congressman Levin dated July 19, 2004, available at Inside U.S. Trade.

10. As clarified by USTR staff in correspondence with World Bank staff.

11. The agreements with DR-CAFTA, Chile, Australia, and Jordan contain provisions affirming the rights and obligations of member countries under the TRIPS agreement. To some extent, these provisions may be interpreted as preserving the flexibilities of the TRIPS agreement. However, the value of these non-derogation clauses in bilateral disputes is legally uncertain (Abbott 2004).

12. See Article 41.5 of the TRIPS Agreement, available at <http://www.wto.org>.

13. The U.S.-Chile and U.S.-DR-CAFTA agreements have language similar to that of the TRIPS agreement, acknowledging that no obligation is created regarding the distribution of law enforcement resources. But the fact that resource constraints may not be invoked as an excuse for not meeting the agreements' specific enforcement obligations appears to significantly weaken this flexibility.

14. These bilateral investment treaties entered into force in 2001 (U.S.-Bahrain) and 2003 (U.S.-Jordan).

15. From an economic perspective, trademarks and geographical indications are different intellectual property instruments. They primarily seek to remedy asymmetries of information between buyers and sellers of goods and do not entail a trade-off between innovation and competitive access. See Fink and Maskus (2004).

16. It is worth noting that Vietnam is not a member of the WTO and therefore not bound by the TRIPS disciplines. However, Vietnam is in the process of acceding to the WTO and must therefore bring its intellectual property system into compliance with the TRIPS Agreement.

17. For example, Australia removed parallel import restrictions for CDs in 1998. The European Union considered in 1999 to free parallel importation of trademarked goods from countries outside the Union, but in the end decided to maintain its existing regime. Legislation to allow parallel importation of prescription drugs into the United States has been extensively debated in the U.S. Congress, but no decision has been taken as of October 2005.

18. Least developed countries are not required to protect pharmaceutical patents until 2016, with a possibility of a further extension (see Fink 2005).

19. See the proposed Digital Media Consumers' Rights Act, introduced in the U.S. House of Representatives (<http://www.house.gov/boucher/internet.htm>). Companies supporting the proposed legislation include computer manufacturers such as Gateway and Sun Microsystems; component manufacturers such as Intel; and telecommunications companies such as Verizon, Qwest, and BellSouth. For a full list, see <http://www.house.gov/boucher/docs/107supporters.htm>.

20. See the Bipartisan Trade Promotion Authority Act of 2002, available at <http://www.tpa.gov>.

21. For example, in the area of data protection, instruments other than data exclusivity exist to protect test data against unfair commercial use (CIPR 2002).

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