Trade Note

February 7, 2005

The World Bank Group
www.worldbank.org

International Trade Department

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Trade Note 20

Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements

Introduction

Over the past few years, the United States has pursued an increasing number of bilateral and regional free trade agreements (FTAs) in different parts of the world (see Table 1). This has marked a considerable shift in US international trade diplomacy. While the US 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.

A central element of the recent set of bilateral FTAs is the establishment of strong rules for the protection of intellectual property rights (IPRs). This is a key offensive market access interest of the United States—supported by private sector constituents for whom the export of intangible assets is commercially gainful. Indeed, the Trade Promotion Authority, under which these agreements were negotiated, explicitly states as a negotiating objective to promote intellectual property rules that "… *reflect a standard of protection similar to that found in United States law*."[1] US trading partners generally have more defensive negotiating interests in intellectual property, but are willing to commit to stronger intellectual property rules as a quid pro quo for concessions in other areas—most notably, preferential access to US markets for agricultural and manufactured goods.

Table 1. Recent U.S. Free Trade Agreements

FTA signed and approved by US Congress	FTA signed, but not yet approved by US Congress	FTAs currently being negotiated
Vietnam (2001)[2]	DR-CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua)	Andean countries (Colombia, Ecuador, Peru)
Jordan (2001)	Bahrain	Thailand
Singapore (2003)		Panama
Chile (2003)		Southern African Customs Union
Morocco (2004)		Free Trade Area of the Americas
Australia (2004)		

This note offers an overview of the main elements, in which recent US FTAs go beyond multilateral standards on intellectual property. 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 US FTAs go beyond TRIPS standards?

The IPRs chapters of recent US FTAs include provisions on all types of intellectual property instruments and the mechanisms available to administer and enforce exclusive rights. While a detailed review of all these elements is beyond the scope of this short paper, Table 2 outlines key areas in

which recently signed US bilateral trade agreements go beyond standards found in the Agreement on Trade-Related Intellectual Property Rights (TRIPS). Even though the detailed provisions differ from agreement to agreement, there are certain common elements.

Protection of patents and pharmaceutical test data

As in TRIPS, all bilateral FTAs provide for a patent term of 20 years. However, they additionally require the extension of the patent term for delays caused by regulatory approval processes, such as obtaining approval for marketing a new drug. Moreover, some agreements call for patent term extensions when delays in the granting of the patent itself occur.

Three agreements (US-Australia, US-Morocco, US-Bahrain) extend the scope of patentability by mandating that patents 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 US-Morocco, which explicitly mandates the provision of patent protection for life forms. Others do not exempt plants and animals from patentability, which is a flexibility provided for under TRIPS. The weakest agreement is the one with the Dominican Republic and six Central American countries (US-DR-CAFTA), which only calls for 'reasonable efforts' to provide for patentability of plants.[3]

In the area of medicines, the bilateral agreements contain a number of provisions that limit the ability of governments to introduce competition from generic producers. First, to override the market exclusivity of patent holders, governments need to 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 (US-Vietnam, US-Jordan, US-Singapore, and US-Australia) limit the use of compulsory licensing to emergency situations, anti-trust remedies, and cases of public non-commercial use.[4]

Second, to effectively make use of compulsory licenses, generic drug manufacturers need to 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 (US-Vietnam and US-Jordan) prevent marketing approval of a generic drug during the patent term without the consent of the patent holder—an issue on which TRIPS does not impose any 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 only requires test data to be protected against "unfair commercial use". By contrast, most of the bilateral agreements explicitly mandate test data exclusivity, as provided for under US law. Once a company has submitted original test data, no competing manufacturer is allowed to rely on these data for a period of five years to request marketing approval for its own drug.[5] The new compilation of comparable test data by competing manufacturers may take several years and may be prohibitively expensive. Thus, test data exclusivity may pose a second obstacle for governments to effectively use compulsory licensing.

Several of the bilateral agreements go further on data exclusivity. When pharmaceutical companies seek marketing approval for previously unapproved uses of already registered drugs, regulatory authorities typically require the submission of 'new' clinical information. The agreements with Morocco and Bahrain provide for an additional 3 year data exclusivity period triggered by such new clinical information. Drugs benefiting from this type of marketing exclusivity do not only include new 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 granting marketing approval for the same product at home. The intellectual property chapter of the US-Singapore Agreement mandates, in this case, 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 for seeking own marketing approval at home.

The agreements with Australia, Bahrain, and the DR-CAFTA countries are still more far reaching on the cross-border application of data exclusivity. 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 whether to allow the parallel importation of pharmaceutical products that have been placed on the market in foreign markets. Parallel importation can be a means of putting downward pressure on pharmaceutical prices, if products are sold more cheaply abroad. The TRIPS Agreement affords WTO members flexibility in determining whether to permit parallel importation of patented drugs.[6] By contrast, the agreements with Australia, Morocco, and 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? This Declaration—issued at the WTO Ministerial Meeting in Doha, Qatar in 2001—recognized the gravity of the public health problems afflicting many developing countries and least developing countries. Among other things, it reaffirmed the right of WTO members to use the flexibilities of TRIPS in the area of compulsory licensing and parallel importation to "… *promote access to medicines for all*."[7] Moreover, in August 2003, WTO members created a special mechanism under the TRIPS Agreement that allows countries with insufficient manufacturing capacity to effectively use compulsory licenses by importing generic drugs (see Fink, 2003). Technically, the Doha Declaration and the August 2003 Decision by WTO members do not address questions of marketing approval during the patent term and test data exclusivity. However, the provisions of the FTAs in these areas can still be seen as being 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 US-DR-CAFTA, US-Morocco and US-Bahrain agreements, the respective governments shared understandings that the intellectual property chapters do not affect their ability to "… *take necessary measures to protect public health by promoting medicines for all […].*"[8] In a recent letter to a Member of the US Congress on the US-Morocco FTA, the General Counsel of the United States Trade Representative (USTR) further clarified:

> "*[…], 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.'*"[9]

At the same time, the US Government does not view the side letters as creating any kind of exemption that would allow parties to the FTAs to ignore obligations in the agreements' intellectual property chapters.[10] The side letters merely signal the signing governments' belief that the intellectual property rules of the FTAs will not interfere with the protection of public health.[11]

Copyright protection

TRIPS requires copyright to be protected for the life of the author plus 50 years. Except for the

agreements with Vietnam and Jordan, the bilateral FTAs 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 only came to prominence with advances in information and communication technologies that greatly facilitated the copying of any literary or artistic work in digital form. The US Digital Millennium Copyright Act of 1998 strengthened standards on circumventing technologies designed to prevent unauthorized copying of digital content. These 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 (ISPs) when copyright infringing content is distributed through their servers and networks. Again, these provisions are based on standards found in the US Digital Millennium Copyright Act.

In copyright infringement cases, all bilateral FTAs—except for the US-Vietnam Agreement—place the burden of proof on the defending party to show that works are in the public domain. TRIPS does not have any obligation on this question. The FTAs thus strengthen the position of copyright holders, as artistic and literary works should generally be considered as protected—unless they obviously belong to 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 CDs—that have been lawfully sold in foreign markets. Some countries, for example New Zealand, have permitted parallel importation of certain copyrighted products as a way to stimulate price competition. By contrast, the 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 existing 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.*"[12]

The agreements with Vietnam, Jordan, and Australia 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' IPRs chapters with inherent institutional constraints, such as limited budgetary or human resources. The agreements with Singapore, Chile, Morocco, DR-CAFTA, and Bahrain go further in spelling out that resource constraints cannot be invoked as an excuse for not complying with the agreements' specific enforcement obligations.[13] 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 only requires these measures 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 IPRs infringement. For example, TRIPS only requires the imposition of fines adequate to compensate IPRs 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 IPRs holders. TRIPS only mandates criminal procedures 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 infringement acts 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.

Table 2. Intellectual Property Provisions of Recent U.S. bilateral and FTAs that go beyond TRIPS standards[a]

	US-Vietnam	US-Jordan	US-Singapore	US-Chile	US-Morocco	US-Australia	US-DR-CAFTA	US-Bahrain
Protection of patents and pharmaceutical test data								
Patent term	Extension given for delays caused by regulatory approval process.		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 US-Chile) or 2 years after a request for examination (3 years for US-Chile).					
Second-use patents	No specific provision.				Obligation to provide patents for new uses of known products.		No specific provision.	Same as US-Australia.
Patenting of life forms	Certain plants and animals may not be excluded from patentability.[14]	No general exclusion of plants and animals from patentability.[15]			Explicit obligation to provide patent protection for plants and animals.	Exclusions *only* allowed for moral, health and safety reasons.	'Reasonable efforts' have to be undertaken to provide for patentability of plants.[16]	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.		Same as US-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.	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 US 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.[17]	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.		TRIPS standards apply.	
Side letters on public health?	No	No	No	No	Yes	No	Yes	Yes

[a]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 US-DR-CAFTA and US-Morocco agreements well as Roffe (2004) on the US-Chile Agreement. As explained in

Table 2. Intellectual Property Provisions of Recent US bilateral FTAs that go beyond TRIPS standards (continued)

	US-Vietnam	US-Jordan	US-Singapore	US-Chile	US-Morocco	US-Australia	US-DR-CAFTA	US-Bahrain
Copyright protection								
Term of copyright protection	Same as TRIPS if determined by life of author, 75-100 years otherwise.	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. Civil liability in case of willful infringement. Criminal liability in case of willful infringement for commercial purposes. Exempted are nonprofit libraries, archives, educations 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.[18]					
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.[13]	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.[13]			No specific provision.	Same as US-Chile.	Same as US-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 US-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 case 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).			

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. As illustrated in Table 3, six of the bilateral agreements have separate chapters on investment. The US-Bahrain and US-Jordan FTAs do not have such chapters, but the respective governments have negotiated bilateral investment treaties (BITs) with similar provisions.[19] As no multilateral agreement on investment exists at the WTO or elsewhere, these bilateral investment rules break new ground.

A common element of the recent US FTA 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 raises, for example, the question of whether granting a compulsory license is 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. However, the US-Vietnam FTA and the two BITs with Bahrain and Jordan do not have a comparable safeguard. Thus, as an example, if Vietnam 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 investor-to-state dispute settlement—going beyond the more traditional state-to-state dispute settlement procedures included in trade agreements. An exception is the investment chapter of the US-Australia FTA, which only allows for the possibility that investor-to-state dispute settlement procedures 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 economists apply to mercantilist trade bargaining does not straightforwardly extend 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 to make a stronger case for import lib-

Table 3. Intellectual property rights and investment disciplines

	US-Jordan, US-Bahrain	**US-Vietnam**	**US-Singapore, US-Chile, US-Morocco, US-DR-CAFTA**	**US-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

eralization: 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.[20] 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 US markets for agricultural and manufactured goods is of a preferential nature. These preferences are time-bound because they will be eroded once the US reduces remaining tariffs and quotas on a non-discriminatory basis in the current or future multilateral trading rounds (or signs additional FTAs). By contrast, a commitment to stronger IPRs rules is permanent and likely to be implemented on a non-preferential 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) treatment of IPRs holders.[21] 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 well-understood, 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 FTAs in the area of intellectual property is a difficult task. First of all, this requires an understanding of the changes in laws and regulations required by obligations in the FTAs that do not already reflect actual 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—re-examine from time to time existing policies and sometimes decide to change course.[22] Certainly, if policy changes were not conceivable, 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 and goes beyond the scope of this note. Still, 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 IPRs 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, affecting the nature of 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 falls 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 over-riding 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.[23]

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 or 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 case of copyright infringement could diminish the rights of consumers and the general public (CIPR, 2002).

Such concerns have also been voiced in the United States itself, not only by consumer rights advocates and academic institutions, but also by computer manufacturers and communications service providers that distribute copyrighted works. For example, specific amendments to the Digital Millennium Copyright Act have been proposed that would permit the circumvention of technological protection measures if such action does not result in an infringement of a copyrighted work.[24] 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, or online databases would be limited if access to such tools is 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 away financial and human resources from other development priorities.

Lessons learned

As indicated in Table 1, the United States is in the process of negotiating FTAs with additional—mostly developing—countries, and new negotiations are likely to be launched in the foreseeable future. Given the importance of intellectual property as a market access interest for the US, it will likely be difficult for US trading partners to avoid negotiating new IPRs rules. What are the lessons learned 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). To varying degrees of success, US trading partners were able to advance their own, mostly defensive interests. Of particular importance is the preservation of flexibilities to protect public health. Indeed, the US 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 […] ."[25]

Second, the intellectual property chapters of the eight FTAs mostly reflect proposals put forward by the US. It may be possible to change the negotiating dynamics in future FTAs, if US trading partners put forward 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 new intellectual property rules intend to fix.[26]

Finally, countries need to carefully assess the economic and social effects of tightened IPRs 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] See the Bipartisan Trade Promotion Authority Act of 2002, available at http://www.tpa.gov.

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

[3] At the same time, the US-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 to first make efforts to obtain a voluntary license from the patent holder, although this requirement can be waived in emergency situations or for public non-commercial 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 non-discriminatory.

[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 US 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 US-Chile and US-DR-CAFTA agreements have similar language to 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] 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."

[15] In the case of US-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.

[16] 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 al-

ready provides patent protection for plants, accession to UPOV 1991 is not a requirement.

[17] The question of intellectual property rights exhaustion, which determines the permissibility of parallel importation, is not addressed in the US-Vietnam Agreement.

[18] In the case of US-Morocco, a side letter specifies the form in which notifications in case of alleged copyright infringement must be made.

[19] These bilateral investment treaties entered into force in 2001 (US-Bahrain) and 2003 (US-Jordan). See http://www.tcc.mac.doc.gov for the text of these treaties.

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

[21] 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 therefore needs to bring its intellectual property system in compliance with the TRIPS Agreement.

[22] For example, Australia removed parallel import restrictions for CDs in 1998. The European Union (EU) considered in 1999 to free parallel importation of trademarked goods from countries outside the EU, but in the end decided to maintain its existing regime. In 2004, legislation to allow parallel importation of prescription drugs into the United States has been extensively debated in the US Congress, although no decision has been taken as of October 2004.

[23] Least developed countries are not required to protect pharmaceutical patents until 2016, with a possibility of a further extension (see Fink, 2003).

[24] See the proposed Digital Media Consumers' Rights Act, introduced in the US 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).

[25] See the Bipartisan Trade Promotion Authority Act of 2002, available at http://www.tpa.gov.

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

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This Trade Note was written by Carsten Fink, Senior Economist at the World Bank Institute and Patrick Reichenmiller, Consultant to the World Bank. Comments by Frederick Abbott, Carlos Braga, Jean-Christophe Maur, Richard Newfarmer, Lorenzo Pupillo, Pedro Roffe, Philip Schuler, Rudolf Van Puymbroeck, as well as James Mendenhall and other staff from the Office of the USTR are gratefully acknowledged. This Trade Note can be downloaded at http://www.worldbank.org/trade.