Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law

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ACRONYMS & ABBREVIATIONS

ANDA	Abbreviated New Drug Application
ATF	Bureau of Alcohol, Tobacco and Firearms
AVA	American Viticultural Area
CAFC	Court of Appeals for the Federal Circuit
CAFTA	Central American Free Trade Agreement, includes USA, Costa Rica, Guatemala, Dominican Republic, Nicaragua, Honduras and El Salvador
COLA	Certificate of Label Approval
EU	European Union
FDA	U.S. Food and Drug Administration
FTAs	Free Trade Agreements
GATT	General Agreement on Tariffs and Trade
ICTSD	International Centre for Trade and Sustainable Development
IPRs	Intellectual Property Rights
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTB	Alcohol and Tobacco Tax and Trade Bureau
UNCTAD	United Nations Conference on Trade and Development
USTR	United States Trade Representative
WTO	World Trade Organization

FOREWORD

Intellectual Property Rights (IPRs) have never been more economically and politically important or controversial than they are today. They are frequently mentioned in discussions and debates on diverse topics such as public health, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, and the entertainment and media industries. In a knowledge-based economy, there is no doubt that a better understanding of IPRs is indispensable to informed policy making in all areas of human development.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth in general remains limited and inconclusive. Conflicting views also persist on the impact of IPRs on development prospects. Some argue that in a modern economy, the standards laid down in the World Trade Organization's Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, thus inducing innovation, technology transfer and private investment flows. Others counter that intellectual property, especially some of its elements, such as the patent regime, will adversely affect the pursuit of sustainable development strategies for instance by raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers. While TRIPS has established substantive minimum standards of protection and enforcement of IPRs, recent regional and bilateral free trade agreements (hereinafter "FTAs") include IPR commitments that go beyond these TRIPS standards. The FTAs require significant changes in the domestic legislation of participating countries.

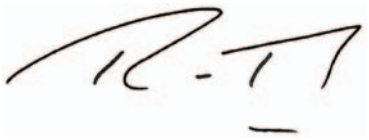
It is urgent, therefore, to ask the questions: how best can the developing countries use intellectual property tools to advance their development strategy? What are the key concerns surrounding the issues of IPRs for developing countries? What are the specific difficulties they face in intellectual property negotiations? Is intellectual property directly relevant to sustainable development and to the achievement of agreed international development goals? Do developing countries have the capacity, especially the least-developed among them, to formulate their negotiating positions and become well-informed negotiating partners? These are essential questions that policy-makers need to address in order to design intellectual property laws and policies that best meet the needs of their people, as well as to negotiate their positions effectively in the future.

It is to address some of these questions that the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development was launched in July 2001. One central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries – including decision makers, negotiators but also the private sector and civil society – who will be able to define their own sustainable human development objectives in the field of intellectual property and effectively advance them at the national and international levels.

The present paper on *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law* is a part of the efforts of the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development to contribute to a better understanding of issues relating to the implementation of intellectual property provisions arising from FTAs and their impact on both developed and developing countries.

This paper examines, from a public interest perspective, recent regional and bilateral FTAs concluded by the United States. The analysis is provided against the background of U.S. domestic laws and policies, as specified through U.S. case law and statutory provisions.

We hope you will find this study a useful contribution to the debate on IPRs and sustainable development.



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EXECUTIVE SUMMARY

This paper is being published by UNCTAD-ICTSD as a part of its Issues Paper Series. It examines recent bilateral and regional free trade agreements (hereinafter "FTAs") from the perspective of United States law and policies. It analyses crucial and sensitive issues in these agreements in light of U.S. regulatory and case law experiences.

During the past several years, the United States has concluded a substantial number of bilateral and regional free trade agreements (hereinafter "FTAs"), largely with developing countries. Each of those FTAs includes substantial commitments in the field of intellectual property rights (IPRs) and related regulatory matters. These commitments exceed those required by the TRIPS Agreement which establishes minimum substantive standards of protection and enforcement for all WTO Members.

There is a relatively consistent view among economists studying intellectual property rights that the interests of countries with respect to standards of protection varies depending upon the level of development and other characteristics of the country adopting such protection. The TRIPS Agreement provides some flexibility to WTO Members with respect to the level of protection, allowing developing countries a measure of leeway. Since there has been little enthusiasm at the WTO for raising standards of IPRs protection above that mandated by TRIPS, the United States has shifted its attention to other fora to accomplish its objective of securing greater levels of IPRs-based rents or royalties. The U.S. FTA policy weakly takes into account developmental interests. In some areas, such as the protection of pharmaceutical patent holders, U.S. policy threatens to cause harm to the interests of comparatively poor populations.

IPRs and related regulatory standards deemed appropriate for the United States may not be appropriate for developing countries. Even so, within the United States the law establishes a particular balance between the interests of IPRs holders and consumers. Most U.S. IPRs rules are formulated in terms of general principles, with limitations and exceptions to them. The FTAs negotiated by the United States largely reflect the general rules of application, though not in all cases. What the FTAs do not adequately reflect is the interplay between rule, limitation and exception that establishes the balance. This is of special importance in areas such as public health regulation where incomplete familiarity with the flexibility inherent in the U.S. system may lead its trading partners to conclude that restrictive implementation of the FTAs is required. Differences in the capacity of the United States and many developing countries to create and manage legal infrastructure may lead to a disparity in the way FTA rules are implemented.

In the negotiating process, developing countries should carefully consider whether the capacity of their domestic legal and regulatory system will permit them to balance interests as does the United States. It is probably unwise to accept commitments that will strain domestic capacity and which may lead to the application of rules in a more restrictive manner than the agreements require. If commitments are accepted, developing countries should pay careful attention to implementing them in a way which properly reflects the domestic public interest.

In conclusion, this study suggests that it is not only the public in developing countries that encounters risk from these FTAs. The U.S. public faces similar risks. The USTR assures the United States Congress that the agreements do not tie the hands of the domestic legislator. This is a position perhaps comfortably asserted within the more powerful of the parties to

an FTA. Yet it is almost inevitable that when Congress considers changing domestic law, arguments will be made by industry groups that to do so may violate America's international obligations and damage the national interest. Congress may choose to ignore U.S. international obligations, but it would be surprising if Congress were not at least somewhat reluctant to do so. The United States is increasingly bound by a set of highly restrictive intellectual property and regulatory commitments that may not over time be seen to be consistent with the American public interest.

1 INTRODUCTION

During the past several years the United States has concluded a substantial number of bilateral and regional free trade agreements (hereinafter "FTAs"), largely with developing countries.[1] Each of those FTAs includes substantial commitments in the field of intellectual property rights and related regulatory matters. The United States is exporting high levels of intellectual property rights protection. These levels of protection exceed those required by the TRIPS Agreement which establishes minimum substantive standards of protection and enforcement for all WTO Members.

There is a relatively consistent view among economists studying intellectual property rights that the interests of countries with respect to standards of protection varies depending upon the level of development and other characteristics of the country adopting such protection.[2] The TRIPS Agreement provides some flexibility to WTO Members with respect to the level of protection, allowing developing countries a measure of leeway.[3] Because there has been little enthusiasm at the WTO for raising standards of IPRs protection above that mandated by TRIPS, the United States has shifted its attention to other fora to accomplish its objective of securing greater levels of IPRs-based rents or royalties. U.S. FTA policy only weakly takes into account developmental interests. In some areas, such as the protection of pharmaceutical patent holders, U.S. policy threatens to cause harm to the interests of comparatively poor populations.[4]

The intellectual property rights chapters of the FTAs set forth obligations to provide protection for various subject matter, including expressive works (protected by copyright), trademarks, geographical indications, inventions (protected by patents) and data (protected by marketing exclusivity rules). These obligations are in most, but not all, cases consistent with the general level of IPRs protection required by U.S. federal law,[5] which law is more favorable to right holders than the TRIPS Agreement. In a number of cases, the exceptions in the FTAs are narrower than those allowed by the TRIPS Agreement. The problems potentially created for developing countries by the adoption of these IPRs provisions in fields such as public health have been widely noted.[6]

Differences in the capacity of the United States and many developing countries to create and manage legal infrastructure may lead to a disparity in the way FTA rules are implemented. The United States already has in place a sophisticated system of checks and balances to offset the general intellectual property and regulatory standards which are reflected in the FTAs. Historically, the internal law of the United States has reflected a careful balance between the interests of intellectual property rights holders and the general public.[7] While over the past two decades the balance may have shifted in favor of IPRs holders, nonetheless, U.S. law continues to reflect a balance. Some of that balance is constitutionally mandated.[8] Some is codified in legislation and regulation, and some arises out of court interpretation.

Developing countries may not have such checks and balances in place and may be limited in the technical capacity to implement such checks and balances effectively.[9] Unless developing countries are effectively enabled to legislate appropriate checks and balances, they may find themselves with substantially stricter intellectual property and related regulatory systems than the United States. The critical lesson for developing countries accepting IPRs commitments in FTAs with the United States is that U.S. IPRs law is replete with exceptions to the general rules, in many cases elaborated in considerable detail. If developing countries accept obligations in the FTAs, they must also be prepared to implement a significant level of exceptions so as to create a reasonable balance within their own law. If they do not implement these exceptions, they will find themselves not only with TRIPS-plus levels of IPRs protection, but also with U.S.-plus levels of IPRs protection.

This key lesson presents a substantial dilemma for developing countries. The IPRs and related regulatory system in place in the United States is complex, difficult to develop and implement, and costly to maintain. Many developing countries have yet to implement basic TRIPS standards in a way that the United States considers adequate. It is difficult to understand the purpose of imposing even more rigorous and complex undertakings on developing countries in these circumstances. It appears that developing countries which enter into these FTA commitments may immediately be in default of their obligations, and remain so. As such, they will be vulnerable to trade- related claims by the United States and its industry groups.

2 FTAs IN THE DOMESTIC LAW OF THE UNITED STATES

In the U.S. constitutional system, the President (i.e., the executive) is responsible for negotiating international agreements.[10] However, Congress has the authority to regulate commerce with foreign nations (i.e., trade) and must approve trade agreements prior to ratification by the President.[11] It typically does so under a so-called "fast-track" procedure pursuant to which Congress has agreed to forgo conditioning its approval of the agreements on amendment to the negotiated and signed texts (i.e., it agrees to vote "yes" or "no" on the signed and submitted text), in exchange for commitment by the President to consult with Congress during the negotiation process.[12] As a practical matter, the commitment by Congress to vote a trade agreement up or down without demanding amendment is, at least in substantial part, illusory. Members of Congress regularly demand new concessions from countries that have negotiated trade agreements with the United States during the approval process, and the President (through USTR) makes post-signature demands which are typically incorporated in side letters or understandings.[13]

Extensions by Congress of trade negotiating authority to the President include express statements of objectives.[14] These statements include negotiating objectives with respect to intellectual property rights. As stated in the Trade Act of 2002 (which established negotiating authority through June 1, 2005, extendable (and extended) through June 30, 2007:

> *"(4) INTELLECTUAL PROPERTY.— The principal negotiating objectives of the United States regarding trade-related intellectual property are—*
>
> *(A) to further promote adequate and effective protection of intellectual property rights, including through --*
>
> *(i)(I) ensuring accelerated and full implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights … particularly with respect to meeting enforcement obligations under that agreement; and (II) ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law;*
>
> *(ii) providing strong protection for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property;*
>
> *(iii) preventing or eliminating discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;*
>
> *(iv) ensuring that standards of protection and enforcement keep pace with technological developments, and in particular ensuring that rightholders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works; and*
>
> *(v) providing strong enforcement of intellectual property rights, including through accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms;*
>
> *(B) to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection; and*
>
> *(C) to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001."*

The President has delegated authority to negotiate trade agreements to the United States Trade Representative (USTR), a Cabinet-level official who acts in consultation with other federal agencies.[15] The extent to which USTR is fulfilling the negotiating objectives laid out by Congress is considered in the final section of this paper.

Under the U.S. Constitution, treaties and other international agreements may be "self-executing" in domestic law.[16] Whether an international agreement is self-executing depends on its terms and context. When the provisions of an international agreement are self-executing, they do not require additional implementing legislation to have effect in national law, and they may be directly relied on by private parties in the courts as a source of law.[17] Congress approves the FTAs in legislation which also implements the agreements in domestic law to the extent deemed appropriate. Congress has made a practice of expressly denying self-executing effect to the FTAs in its implementing legislation.[18] Section 102 of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act is typical of the provisions denying self-executing effect:

"SEC. 102. RELATIONSHIP OF THE AGREEMENT TO UNITED STATES AND STATE LAW.

(a) RELATIONSHIP OF AGREEMENT TO UNITED STATES LAW.—

(1) UNITED STATES LAW TO PREVAIL IN CONFLICT. — No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect.

(2) CONSTRUCTION.—Nothing in this Act shall be construed—

(A) to amend or modify any law of the United States, or

(B) to limit any authority conferred under any law of the United States,

unless specifically provided for in this Act.

(b) RELATIONSHIP OF AGREEMENT TO STATE LAW.—

(1) LEGAL CHALLENGE.—No State law, or the application thereof, may be declared invalid as to any person or circumstance on the ground that the provision or application is inconsistent with the Agreement, except in an action brought by the United States for the purpose of declaring such law or application invalid.

(2) DEFINITION OF STATE LAW.—For purposes of this subsection, the term ''State law'' includes—

(A) any law of a political subdivision of a State; and

(B) any State law regulating or taxing the business of insurance.

(C) EFFECT OF AGREEMENT WITH RESPECT TO PRIVATE REMEDIES.—No person other than the United States—

(1) shall have any cause of action or defense under the Agreement or by virtue of congressional approval thereof; or

(2) may challenge, in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, any State, or any political subdivision of a State, on the ground that such action or inaction is inconsistent with the Agreement."[19]

Based on this type of implementing legislation, the FTAs do not change existing federal law unless specifically mandated by Congress. An individual may not directly invoke the provisions of an FTA in a court of the United States. To the extent that FTAs may impose obligations on the United States that are inconsistent with existing

federal law, this is not relevant for domestic legal purposes (even if the United States may incur international legal liability).[20]

U.S. practice with respect to the treatment of international agreements in domestic law is not unusual. Many countries do not directly apply treaties in domestic law, requiring implementing legislation to give them local effect.[21] The European Court of Justice has denied direct effect to the WTO Agreement in EU law.[22] It is nonetheless useful for developing countries to be aware that a provision in an FTA negotiated with the United States does not automatically become the domestic law of the United States.

For developed countries and regions, allowing international trade agreements to have direct effect may facilitate the process of integration by allowing private operators to challenge government conduct inconsistent with the agreements.[23] Developing countries must recognize that directly effective international agreements allow private operators to challenge pre-existing legislation that is inconsistent with them. If a government wants to control the terms of implementation of the agreement, it must be prepared to adopt implementing changes to domestic law that are consistent with the agreement. Also, for developing countries, allowing direct effect presents risks because large multinational companies often have substantially greater access to legal resources than even the national government. Governments may find themselves faced with court challenges based on international agreements which are given direct or self-executing effect.[24] Even though governments may also be challenged on the basis of ordinary domestic legislation, the terms of domestic law typically will not have been negotiated with a foreign government.

USTR has expressly advised Congress that it may adopt subsequent legislation inconsistent with the terms of an FTA.[25] USTR has advised Congress that decisions of dispute settlement panels under the FTAs do not affect U.S. federal law unless those decisions are expressly given effect by the Congress.[26]

This is consistent with U.S. constitutional practice. Congress may adopt legislation inconsistent with prior international agreements.[27] This is referred to as the "last in time" rule; meaning that the later-adopted of a statute or international agreement will govern. Also, the terms of the FTAs do not strictly obligate the parties to implement the decisions of dispute settlement panels. They may instead elect to offer compensation.[28] In any case, most countries will not give direct effect to the decisions of dispute settlement panels of FTAs (or, for that matter, of the WTO (including the Appellate Body)). In order to give domestic effect to a dispute settlement decision, government implementing action is required.

The legislatures of U.S. FTA partners whose constitutions allow subsequent domestic legislation to conflict with the terms of an international agreement (i.e., those which do not follow a so-called "monist" approach), may also legislate inconsistently with the terms of the FTA.[29] In doing so, they may breach an international obligation to the United States. Because of the large imbalance in effective political and economic power between the United States and its FTA partners, countries other than the United States may find the breach of such obligations problematic. The economy of the United States is significantly dependent on only a few foreign countries, meaning that the United States can afford to strain its political and economic relations with almost all other countries. For many smaller and developing country economies, denial of access to the U.S. market would create very serious adverse effects. Therefore, it is likely that the legislatures of most U.S. FTA partners will be significantly more reluctant to legislate inconsistently with an FTA than the U.S. Congress.

3 SUBSTANTIVE PROVISIONS

Each of the IPRs chapters of the FTAs differs. These differences arise from a number of factors. The United States was insistent that Australia and Singapore, as high income countries, accept greater restrictions on compulsory licensing than other FTA partners. Chile was more successful in maintaining flexibilities than were the CAFTA countries.[30] This may have been due to more powerful local interest groups within Chile, such as local pharmaceutical manufacturers, which placed pressure on government negotiators. Also, the objectives of the United States have become more ambitious over time. The more recent agreements with Central America-DR, Bahrain and Morocco are highly restrictive.

Nonetheless, the IPRs chapters of the FTAs are more notable for their similarities than their differences. In this paper, illustrative provisions are used from the various FTAs without in each case comparing the cited provisions to others that were negotiated (and may be different). However, there are several sources that compare the IPRs provisions in each of the FTAs and which may be consulted.[31]

3.1 Patents

3.1.1 Patent term extension

The FTAs generally require an extension of the patent term for pharmaceutical products (or other products) to "compensate" for unreasonable curtailment of the patent term based on regulatory review procedures. For example, the U.S. - Bahrain FTA provides:

> *"15.9(6) (b) With respect to any pharmaceutical product that is covered by a patent:*
>
> *(i) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of the product in that Party; and*
>
> *(ii) where a Party approves the marketing of a new pharmaceutical product on the basis of information concerning the safety or efficacy of a same or a similar product in another territory, such as evidence of prior marketing approval, the Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term in the Party as a result of the marketing approval process in the other territory and in the Party.*
>
> *For purposes of this paragraph,* **effective patent term** *means the period from the date of approval of the product until the original expiration date of the patent."*

The U.S. Patent Act (at 35 USC §156) provides for extension of the patent term with respect to drugs that undergo regulatory approval at the U.S. Food and Drug Administration (FDA). This provision is complex and subject to a substantial number of conditions and qualifications.[32] The regulatory review is divided into two phases: (1) the phase during which the drug is subject to clinical testing (which is dated from authorization to test by the FDA) (the "testing" phase) and (2) the phase during which the FDA evaluates the test (and other) data (the "approval" phase). One half of the period of the testing phase plus the approval phase are subject to compensation (35 USC §156 (c) & (g)). In no event may the duration of the extension exceed five years (35 USC §156(g)(6)(A)). The total period of effective patent protection may not exceed 14 years (the original patent term, shortened by the regulatory review period, plus the extension) (35 USC §156(c)(3)). There are a substantial number of additional conditions, including a limitation to the first commercial marketing of the product.

The provision of the FTA is not qualified by reference to "one half" of the testing phase of the regulatory review period, nor is a five-year limitation (or total 14 year period) implied or even suggested. A legislator outside the United

States who is unfamiliar with the U.S. statutory scheme would not likely assume that the FTA provision is based on a provision of U.S. law which is so highly qualified.[33] That legislator might logically assume that compensation is intended to take place strictly reflecting the period of regulatory review.

Another common provision of the FTAs requires an extension of the patent term for unreasonable delay in the granting of a patent, and fixes a maximum term from the date of filing or request for examination to trigger the extension. For example, the U.S.-Morocco FTA provides at Article 15.9:

> *"7. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays."*

The U.S. Patent Act provides (at 35 USC §154) for extension of the patent term based on delay of the Patent Office, generally more than three years from the filing of the application. Unlike the extension based on drug regulatory approval, the extension based on delay of the Patent Office applies to all fields of technology. However, there are several important exceptions to the general rule of extension.[34] Thus, for example, if an interference is declared under 35 USC 135(a) and a proceeding is held to determine the rightful claimant to a patent among competing claimants, the interference period is excluded from the processing time (as are appeals from decisions of the patent examiner). Likewise delays based on national security review are excluded.

The FTA provision does not refer to the exceptions adopted in the United States. And, because the FTA provision expressly excludes delays based on actions of the patent applicant, an inference might logically be drawn that any delays based on events other than those of the patent applicant may not be excluded. Yet, the U.S. Patent Act incorporates additional exclusions.

Provisions which extend the term of patents are especially important to developing countries in fields such as pharmaceuticals and agricultural chemicals where each additional year of protection may have a significant effect on the national health care and agriculture budget.

3.1.2 Regulatory review exception

The FTAs commonly restate Article 30 of the TRIPS Agreement and separately incorporate a specific provision with respect to the regulatory review exception. The regulatory review exception in the U.S.-Morocco FTA provides at Article 15.9:

> *"6. Consistent with paragraph 3 [restatement of Article 30], if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating information to meet requirements for approval to market the product, and if the Party permits exportation, the Party shall provide that the product shall only be exported outside its territory for purposes of meeting marketing approval requirements of that Party."*

The regulatory review exception of the U.S. Patent Act, 35 USC§ 271(e), is framed more broadly. It provides:

> *"(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or*

> *import into the United States a patented invention (other than a new animal drug or veterinary biological product…) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."*

This provision refers to uses of the patented invention reasonably related to the development and submission of information under a law which regulates "the manufacture, use, or sale of drugs...". The language of the US regulatory review exception is significantly broader than the language of the FTA provision which refers only to generating information to meet requirements "for approval to market the product". This difference is quite significant when analyzed in the context of recent US Supreme Court jurisprudence.

In *Merck v. Integra Lifesciences*, 125 S. Ct. 2372 (decided June 13, 2005),[35] the U.S. Supreme Court interpreted 35 USC§ 271(e) to allow the use of patented inventions for the purpose of conducting research with respect to drugs as to which there is some reasonable prospect that an application to the FDA may be submitted, regardless whether an application is, in fact, eventually submitted or successful. The relevant research may be conducted at the pre-clinical trial phase. The Supreme Court made clear that the regulatory review exception is not limited to the development by generic producers of information necessary to show bioequivalence in the abbreviated new drug application (ANDA) process. It said, among other things:

> *"Properly construed, §271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law.' §271(e)(1).*
>
> *For similar reasons, the use of a patented compound in experiments that are not themselves included in a 'submission of information' to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the 'development and submission of information' to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA." 125 S. Ct. at 2383*

The exception broadly allows third-party use of patented technology for research and experimentation toward the development of new drugs. In reaching this decision the Supreme Court overruled a highly restrictive interpretation of the regulatory review exception adopted by the Court of Appeals for the Federal Circuit (CAFC) in the same case.[36]

In 2002, the CAFC rendered a dramatically restrictive interpretation of the common law "experimental use exception" in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). It restricted experimental use to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" (citing *Embrex v. Service Engineering*, 216 F.3d 1343 (Fed. Cir. 2000). It observed that universities are in the business of providing education and that as a consequence their activities are conducted with a commercial aim. For that reason, research activities conducted by universities do not generally fall under an experimental use exception. *Madey*, 307 F.3d at 1362. The common law "experimental use exception" interpreted by the CAFC in *Madey* is different than the statutory "regulatory review exception" interpreted by the Supreme Court in *Merck v. Integra*. For all intents and purposes, however, the Supreme Court has in the field of drug research and development

created a broad experimental use exception which takes precedence over the narrow CAFC interpretation. The CAFC has consistently elevated the interests of patent holders above those of consumers and third-party users of technology. And, it is the jurisprudence of the CAFC which the United States is typically seeking to incorporate in the FTAs.

It is only with some difficulty that the language of the U.S.-Morocco FTA regarding the permissible scope of the regulatory review exception can be construed to generally allow experimentation using patented inventions for the development of new drugs. It could be argued that the Supreme Court decision contravenes the provision of the FTAs. The United States might argue that the restated Article 30 exception allows sufficient additional scope to encompass the Supreme Court decision. This would go against the customary rule of interpretation that when a general provision has been qualified by a more specific provision, the terms of the specific provision will govern. While it is doubtful that any party to an FTA with the United States will choose to challenge the Supreme Court interpretation, it is interesting to consider whether USTR would have shown the same restraint if, for example, the courts of Morocco had so broadly construed the regulatory review exception.

It is also of interest that the US statutory regulatory review exception interpreted by the Supreme Court in *Merck v. Integra* applies only to drugs. This means that the United States has accepted that Article 27.1 of the TRIPS Agreement allows it to differentiate between fields of technology in the application of exceptions to the exclusive rights of patent holders.

While not all U.S. FTA partners have significant research and development capacity, for those that do, recognizing the broad scope of the exception granted for pharmaceutical R&D in the United States is very important because it means that a similar exception should be recognized within their own jurisdiction. Moreover, the aggressive U.S. Supreme Court approach to exceptions should signal other countries that the language of the FTAs can be interpreted in a way that allows considerable flexibility in how the domestic medicines regulatory approval system can be operated.

3.1.3 Patent-regulatory approval linkage

In most countries, in order for a drug to be placed on the market it must be approved and registered by local public health regulatory authorities. When a "new" drug application is first submitted by its "originator" in a country with the capacity to undertake a sophisticated evaluation,[37] the application will include information concerning clinical trials designed to demonstrate the safety and efficacy of the drug. There are at least two situations in which less comprehensive information is presented in drug approval applications. First, countries with less sophisticated capacity for the evaluation of drug applications may rely on the fact of approval in another country as the basis for determining the safety and efficacy of the originator's product. So, for example, after the U.S. Food and Drug Administration has approved a new drug, public health authorities in developing countries may decide to accept the FDA's approval as the basis for their own approval. Second, when generic producers are preparing to enter the market with the same drug as the initially approved originator drug, typically they are required only to demonstrate the "bioequivalence" of their product with the originator's product. The originator will have already demonstrated that the drug is safe and effective. For the public health authorities it is only a matter of ascertaining that the generic producer intends to provide the same thing. Requiring the generic producer to repeat clinical tests of safety and efficacy would be a waste of time and money, and it would be unethical. A portion of the patients in a clinical study typically receive a placebo and do not benefit during the course of the study.

The originator of a new drug often also holds a patent on the drug. However, many countries permit parties other than the patent holder/ originator to register a drug during the term of the patent so that these other parties are

prepared to promptly place the drug on the market when the patent expires.[38] Some countries, such as the United States, have established legislative and regulatory linkages between the patent system and the public health regulatory system.

Designing a system which prevents the effective marketing approval of a medicine during the term of a patent without significantly impairing the ability of generic producers to place drugs on the market at the end of the patent term has proven exceedingly difficult. One of the principal reasons is that patents on drugs are not difficult to secure. Even in the United States and European Union, where patent offices employ significant numbers of highly trained technical staff, patents that are subject to challenge are often found to be invalid.[39] They should not have been granted. However, the staff at the public health regulatory office responsible for marketing approval of medicines typically will not be in a position to evaluate whether a patent is valid. The health regulatory staff must in effect rely on the determination made by the patent office. Both "good patents" and "bad patents" become obstacles to the marketing approval of generic drugs. This problem can be particularly acute in countries where there is no effective examination of patent applications.

Allowing the patent holder to block the effective marketing approval of a drug enhances its capacity to prevent third-party sales by setting an additional obstacle in the path of those sales. Recognizing that patents may not have been granted on solid grounds, the United States employs a complex linkage mechanism by which patent holders may prevent the early market entry of generic drugs. Pharmaceutical patent holders list their patents on the "Orange Book" of the FDA.[40] When a generic producer submits an abbreviated new drug application (ANDA) to the FDA it must certify whether there is a patent covering the drug[41] and whether it is seeking to market the drug before the expiration of the patent term. The generic producer may indicate that it does not consider a patent to be valid and that it intends to market the drug as soon as the FDA approves its application.[42] The patent holder is notified and provided a window of opportunity to initiate litigation in the federal courts to block market entry. If the patent holder initiates litigation, there is an automatic stay (30 months) of the effectiveness of any registration until the court has made a determination about the validity of the patent (which may be sooner than 30 months).[43] This system includes an element designed to encourage generic producers to seek early entry of their products onto the market (including by challenging the validity of patents). The first party that successfully applies for approval of a generic version of an originator product is granted a 180-day period of generic marketing exclusivity.[44]

In 2002, the U.S. Federal Trade Commission issued a report concluding that the FDA Orange Book system was subject to a substantial amount of abuse by patent holders.[45] Among other problems, originators were found to have filed highly suspect patent applications in order to prevent the marketing of generic drugs. In addition, the system permitted more than one patent holder challenge to the ANDA, leading to a succession of automatic 30 months stays. As a consequence of this report, the rules of the FDA were amended, *inter alia*, to prevent successive stays,[46] and a consent decree was imposed on a major pharmaceutical company to prevent further abuses of the Orange Book list.[47]

The FTAs generally require parties to implement measures in their pharmaceutical marketing approval process to prevent the approval of generic products from becoming effective during the term of a patent, without the consent or acquiescence of the patent holder. The U.S.-Morocco FTA, for example, provides at Article 15.10:

> *"4. With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior*

marketing approval by persons other than the person that previously submitted such information, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner,

(b) if it allows applications to be made to market a product during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product."

The FTA provision refers to the adoption of "measures in its marketing approval process to prevent … other persons from marketing a product covered by a patent during the term of that patent". This obligation is stated in a way that does not appear to contemplate a system which requires the patent holder to affirmatively intervene to prevent effective marketing approval. Yet, since the U.S. marketing approval system requires affirmative patent holder intervention this must be contemplated as a permitted method for implementing the obligation, and this mechanism of patent holder intervention is contemplated by subparagraph (b). Even so, for most developing countries the adoption of a system such as that used in the United States will place a considerable strain on the legal and regulatory system. That is, the courts will be faced with lawsuits and demands for injunction initiated by patent holders to prevent market entry. If the patent office does not perform substantive examination of applications, there are likely to be even more "bad patents" listed on a public health regulatory ledger than on the U.S. FDA Orange Book. There is, in fact, a significant likelihood that in order to minimize legal and administrative burdens, public health regulatory authorities in developing countries will accept at face value that patents are valid and block the effective registration and market entry of generic drugs.

There are two main points. First, the language of the FTA permits but does not spell out the conditions and qualifications that are part of the U.S. regulatory system. The U.S. system may not be "in conflict" with the language of the FTA, but unless one is familiar with the way the U.S. system works it would be very difficult to understand the arrangement. Second, it will be very difficult for many developing countries to adopt and/or implement a system modeled on that of the United States because of the legal complexity. A developing country is more likely to adopt a simplified procedure which puts greater power in the hands of the patent holder. This will avoid potential conflicts with U.S. trade enforcement authorities.

3.1.4 Compulsory transfer of trade secret

The U.S.-Australia and U.S.-Singapore FTAs limit the grounds on which compulsory licenses may be granted and incorporate TRIPS-plus conditions. Compulsory licensing may only be authorized to remedy anticompetitive practices or in cases of public noncommercial use, national emergency or circumstances of extreme urgency. With respect to public noncommercial use and national emergency/urgency, three conditions are added. One is that:

"(iii) the Party shall not require the patent owner to transfer undisclosed information or technical 'know how' related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph."

The U.S. federal government has broad powers to take private property for public use,[48] subject to the payment of just compensation as provided by the Takings Clause of the Fifth Amendment to the Constitution.[49] The President may authorize takings by executive order pursuant to his constitutional power as

the executive and commander-in-chief of the armed forces,[50] and the Congress may legislate such takings.[51] While the federal Trade Secrets Act criminalizes unauthorized disclosure by government employees of confidential business data,[52] this does not apply when agency disclosures are made pursuant to law. The Food, Drug and Cosmetic Act (FDCA) also contains a prohibition against taking personal advantage of or revealing trade secrets, but this would not preclude a government taking order directed to a patent holder, nor would it appear to preclude the FDA's use of information in implementing government use of a patent.[53] Although there is no specific federal statute authorizing the President to take undisclosed information or technical know-how from a private party, in a national emergency the President would be constitutionally empowered to take such property. It defies common sense to suggest that if the nation were faced with an imminent threat of serious disease outbreak, and the federal government determined that it was necessary to produce a patented pharmaceutical, that it could not and would not also order and compel the transfer of trade secret information to enable such production.

The disconnect between the U.S. government behavior and legal rhetoric with respect to authorization of government use of pharmaceutical patents and data was illustrated in 2001 when Secretary of Health Thompson threatened to issue a compulsory license on Bayer's Cipro patent,[54] and in 2005 when Secretary of Health Leavitt stated before Congress that the United States could not tolerate a situation in which Tamiflu was not produced within the United States, because in a pandemic situation foreign suppliers could not be relied upon.[55] The comment by Leavitt was inconsistent with the position the United States took against Brazil in initiating a dispute settlement action at the WTO on the basis of Brazil's compulsory licensing statute because, with respect to Roche and Tamiflu, the U.S. government was effectively compelling the foreign patent holder to produce within the United States as a condition of maintaining patent exclusivity.[56] As the United States confronted the potential for an avian flu pandemic, it was made explicit that the government was prepared to take whatever steps it considered necessary and appropriate to protect the U.S. population, and it is inconceivable that these steps would not extend to taking and/or making use of proprietary Roche production process information as the situation warranted.

3.1.5 Parallel importation of patented products

Several of the FTAs obligate the parties to allow patent holders to block parallel imports of patented products. The legal formula allows the parties to condition the right to block such imports on a contract-based restriction. Article 15.9 of the U.S.-Morocco FTA, for example, provides:

> *"4. Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.10 [10:] A Party may limit application of this paragraph to cases where the patent owner has placed restrictions on importation by contract or other means."*

In 2001, the U.S. Court of Appeals for the Federal Circuit decided in *Jazz Photo v. ITC*, 264 F.3d 1094 (Fed. Cir. 2001) that U.S. patent holders have the right to block importation of goods first sold abroad under parallel patent. Prior to this holding, the preponderant weight of court decision in the United States allowed such parallel imports, at least where the patent holder had not expressly restricted such imports by contract.[57] The CAFC, in effect, announced a new rule against parallel imports of patented products.[58] This remains the current rule as of 2006, so that the provision of the FTA requiring parties to allow the blocking of parallel imports of patented products is consistent with the current U.S. rule.

The U.S. Congress recently had before it a bill (with strong bipartisan support) which would have authorized the parallel importation of patented pharmaceuticals from OECD countries as a means to take advantage of lower prices in those countries.[59] Such congressional efforts are likely to continue. Should Congress adopt legislation that would authorize parallel importation of patented pharmaceutical products, U.S. law would then contravene the provision in the FTAs requiring that patent holders be able to block parallel imports. USTR expressly advised that Congress has the authority to adopt subsequent legislation inconsistent with the terms of the FTAs and that a dispute settlement panel cannot force the United States to revise its law. The USTR web site stated with respect to the U.S.-Australia FTA:

> *"Does the U.S.-Australia FTA prevent Congress from passing drug re-importation legislation?*
>
> *No. The FTA reflects current law in the United States. Nothing in this FTA or any other trade agreement prevents Congress from changing U.S. law in the future. Even if a dispute settlement panel found the U.S. acted inconsistently with the FTA, it could not require Congress to amend the law. Importantly, provisions in the FTA protecting patent holders' rights only apply to products under patent. This provision would have no impact on importation of non-patented (generic) prescription drugs."*[60]

This statement by USTR is technically correct because, as noted earlier, the United States follows a last-in-time rule with respect to the relationship between domestic law and international agreements. However, two points are in order. First, the United States would be placing itself in breach of its international obligations as a consequence of changing its rules inconsistently with an FTA, presumably requiring offsetting compensation or concessions by the United States. Second, it is curious that USTR does not first recommend negotiating with U.S. trading partners to amend the terms of the agreements prior to breaching obligations.

Finally, it should be noted that in late 2005, Congress adopted legislation prohibiting USTR from negotiating provisions in FTAs that would block parallel imports of patented products.[61]

3.2 Copyright

3.2.1 Exclusive rights and exceptions

The U.S. Copyright Act (17 USC §§ 101, et seq.) is a complex system of rules and exceptions to them. While the holder of a copyright is generally able to prevent the reproduction of an expressive work, there are a number of circumstances under which others are authorized to make use of that work. In a limited number of situations, remuneration is mandated.

Section 106 of the Copyright Act sets out the exclusive rights of the copyright holder.[62] These rights are expressly qualified by sections 107 through 122. Section 107, by way of illustration, prescribes rights of "fair use":

> *"Limitations on exclusive rights: Fair use Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include--*
>
> *(1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;*
>
> *(2) the nature of the copyrighted work;*
>
> *(3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and*

(4) the effect of the use upon the potential market for or value of the copyrighted work.

The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors."

The WTO TRIPS Agreement accounts for the exceptions by incorporation of the articles of the Berne Convention which provide for them (Article 9.1, TRIPS Agreement incorporating Articles 1-21, Berne Convention, including Articles 9-10bis), and by inclusion of a TRIPS-specific exceptions provision (Article 13, TRIPS Agreement).

The FTAs incorporate an exception provision comparable to that of Article 13 of the TRIPS Agreement, extending its explicit application to performances and phonograms.[63] Moreover, because the parties to the FTAs acknowledge the continuing application of the Berne Convention, the exceptions of that Convention are incorporated, notwithstanding the lack of explicit references.[64]

Because the parties are generally enabled to adopt the exceptions permitted under the TRIPS Agreement and Berne Convention, the FTAs do not prevent developing countries from following the US lead with respect to the breadth of exceptions they choose to adopt. The question is whether developing countries will have the institutional capacity and political will to do this.

3.2.2 Parallel importation of copyrighted works

The question whether parallel importation of copyrighted works into the United States may be prevented by copyright holders has been left open by the Supreme Court. In 1998, the Supreme Court in *Quality King v. L'Anza*, 523 U.S. 135 (1998) addressed a closely related issue. It decided that copyrighted works first sold in the United States, and then exported, could not be blocked from importation by the U.S. copyright holder. The first sale in the United States had exhausted the copyright holder's exclusive right to control distribution, and the copyright holder did not reacquire exclusive rights by virtue of the export. The decision was based on the Court's interpretation of statutory language in the Copyright Act (Sections 106, 109 and 602). The Court acknowledged that it was not addressing the situation in which a copyrighted work is first placed on the market outside the United States, and then imported into the United States. This would be the typical "parallel import" situation. The Court expressed skepticism that businesses should be able to use intellectual property rights to charge different prices in different world markets. However, when it revisits the parallel imports question in copyright, the Court's decision is likely to be based on statutory language of the Copyright Act, rather than on its policy perspective. It is not possible to predict what the Supreme Court will do.

Certain FTAs prohibit the parallel importation of copyrighted works. For example, the U.S.-Morocco Agreement provides at Article 15:

"2. Each Party shall provide to authors, performers, and producers of phonograms the right to authorize or prohibit the importation into that Party's territory of copies of the work, performance, or phonogram, including where the copies were made outside that Party's territory with the authorization of the author, performer or producer of the phonogram."

The FTA, by requiring parties to prevent parallel importation of copyrighted works, have internationally bound the United States to a particular interpretation of the Copyright Act prior to a determination by the Supreme Court regarding the proper interpretation of the Act. It is of interest that in its *Quality King* decision, the Court held that several executive trade agreements with Caribbean countries (which prohibited parallel trade in copyrighted works) could not influence the Court's interpretation of the Copyright Act.

3.3 Geographical Indications

3.3.1 Conflicts between trademarks and geographical indications

In the United States, protection for geographical indications is generally accomplished through registration of certification or collective trademarks. Registration as a certification or collective mark is available for all classes of goods. However, the United States maintains an additional system that allows for the protection of geographical indications for wines and spirits. This system is administered by the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury (TTB). The registration system is established pursuant to the Federal Alcohol Administration Act (27USC §201, et seq.), which is supplemented by Chapter 27 of the Code of Federal Regulations (27 CFR §1.1, et seq.).[65]

The FTAs require that applications for registration of geographical indications be rejected if they conflict with an existing trademark or trademark application. For example, Article 15.4 of the U.S.-Morocco FTA provides:

> *"Relationship to Trademarks*
>
> *2. Each Party shall provide that each of the following shall be a ground for refusing protection or recognition of a geographical indication:*
>
> *(a) the geographical indication is likely to be confusingly similar to a trademark that is the subject of a good-faith pending application or registration; and*
>
> *(b) the geographical indication is confusingly similar to a pre-existing trademark, the rights to which have been acquired in the territory of the Party through use in good faith."*

However, the U.S. system for the registration and protection of the name of viticultural areas which are used as identifiers for wines does not require that applications for registration be rejected if a name is confusingly similar to a registered trademark. In Sociedad Anonima Vina Santa Rita v. Department of Treasury, 193 F. Supp. 2d 6 (DDC 2001), the Federal District Court for the District of Columbia decided that recognition by the TTB (then the ATF) of an American viticultural area (AVA) designation/identifier which would be used as the basis for certificate of label approval (COLA) did not violate the Lanham Act. It further noted that the holder of a trademark which considered that use of the AVA identifier on a label violated its trademark rights could bring a private trademark-based cause of action against the alleged infringer. The court said:

> *"Of course, it is entirely possible or, indeed, likely that wineries will eventually produce labels bearing the Santa Rita Hills AVA designation. If Plaintiff concludes that any of those labels infringes on its trademark, Plaintiff is fully entitled to bring suit under the Lanham Act against the entity that has developed the label. In other words, the ATF's approval of the Santa Rita Hills AVA does not affect Plaintiff's right to pursue trademark claims against individual wineries if and when those wineries use labels that infringe or dilute Plaintiff's mark." 193 F Supp. 2d, at 38.*[66]

3.4 Enforcement

3.4.1 Publication of written judicial opinions

A discrepancy between U.S. law and practice and the terms of the FTAs lies in the area of the publication requirement. The typical FTA includes a provision such as Article 15.11(1) of the U.S.-Morocco FTA:

> *"ARTICLE 15.11: ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS*
>
> *General Obligations*
>
> *1. Further to Article 18.1 (Publication), each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property*

rights shall be in writing and shall state any relevant findings of fact and the reasoning or the legal basis on which the decisions or rulings are based. Each Party shall provide that such decisions or rulings shall be published[16] or, where publication is not practicable, otherwise made available to the public in a national language in such a manner as to enable governments and right holders to become acquainted with them. [Footnote 16] For greater certainty, a Party may satisfy the requirement for publication by making the decision or ruling available to the public on the Internet."

Article 63.1 of the TRIPS Agreement also includes a publication requirement that is applicable to "final judicial decisions pertaining to the subject matter of the agreement". The FTA provision adds the requirement that the decisions be in writing and state relevant findings of fact and the reasoning or legal basis of the decision.

The federal judiciary of the United States makes a routine practice of not publishing opinions.[67] The vast majority of federal appellate court decisions are unpublished.[68] While a substantial number of unpublished opinions are available on the Internet, not all such opinions are available. Moreover, the opinions are not consolidated on readily searchable web sites.[69] The U.S. Federal Rules of Civil Procedure permit federal district court judges to orally announce their judgments in open court.[70] There is no requirement that the parties or public be provided with a written opinion setting forth reasoning. State courts follow similar rules and practices.[71]

As a matter of policy, it may be laudable for the United States to encourage the writing and publication of reasoned opinions by foreign judiciaries. However, since this is neither the uniform law nor the practice of U.S. courts, it is imposing an obligation on foreign legal systems which it does not itself accept and which may involve a significant financial and administrative burden, particularly for developing countries.

The rules and practice of the U.S. federal judiciary may be inconsistent with Article 63.1 of the TRIPS Agreement. That inconsistency is exacerbated by the terms of the FTA which expand on the TRIPS Agreement obligation.

3.4.2 Damages calculation

The provisions of the FTAs regarding calculation of damages for infringement of IPRs set forth a methodology. For example, Article 15.11 of the U.S. Morocco FTA provides:

"(6)(b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, inter alia, the value of the infringed-on good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder."

The standard of "suggested retail price" is used in only one of the many U.S. statutes regulating intellectual property, that is, the prohibition in the Tariff Act of 1930 against the importation of goods bearing an infringing trademark.[72] U.S. courts generally have substantial discretion in determining the basis for establishing the level of damages in cases of infringement. In a trademark infringement suit, the trademark holder is ordinarily required to prove its "actual damages" which would be based on the market price of its goods. The "suggested retail price" of a good or service will be the "market price" in only a limited number of cases. The Copyright Act also uses the measure of "actual damages", providing:

"(b) Actual damages and profits. The copyright owner is entitled to recover the actual damages suffered by him or her as a result of the infringement, and any profits of the infringer that are attributable to the infringement and are not taken into account in computing the actual damages. In establishing the infringer's profits, the copyright owner is required to present proof only of the infringer's gross revenue, and the infringer is required to prove his or her

deductible expenses and the elements of profit attributable to factors other than the copyrighted work." 17 USC §504

A U.S. court might allow a trademark, copyright or patent holder to base its claim for remedies in an infringement action on the suggested retail price of its goods if there was no reasonable way to prove the actual selling price of the goods in the market. However, because the suggested retail price is a hypothetical price this would not be a first option.

The use of "suggested retail price" as the basis for calculating damages is also problematic because it suggests that the IPRs holder receives the "retail" price for its goods or services. In many cases, the IPRs holder will sell to intermediaries such as wholesalers and distributors and will receive a price substantially discounted from the suggested retail price, even assuming that the suggested retail price represents the price paid by the consuming public. The IPRs holder's "actual damages" should instead be based on the price it receives from the intermediaries.

The FTA provision does not limit courts solely to the consideration of "suggested retail price" in the calculation of damages. However, it requires the courts to take this measure into account when presented by the right holder. In doing so, it implies that using the basis of "suggested retail price" is a "safe harbor" under the FTA which can be used to avoid trade disputes.[73]

4 FTAs AND U.S. NEGOTIATING OBJECTIVES

As noted at the outset of this paper, Congress has identified objectives with respect to negotiations on intellectual property in international trade agreements. These include "ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law" and "to respect the Declaration on the TRIPS Agreement and Public Health".

The FTAs largely reflect U.S. IPRs standards. In that regard, it might be said that the IPRs rules in the FTAs reflect standards "similar" to those of the United States. However, in some cases, such as the regulatory review exception, the FTA standard appears more protective of IPR holder interests than current U.S. law. In some others, such as the rule on parallel trade in copyrighted works, the FTAs pre-judge a determination yet to be made by the Supreme Court. In still others, such as restricting the use of confidential data in national emergencies, the FTAs impose obligations which would never as a practical matter be enforced within the United States. At the very least, from a public health standpoint, a rule depriving the U.S. government of the ability to effectively address a national public-health emergency is a terrible idea.

The Doha Declaration on the TRIPS Agreement and Public Health was adopted to address specific developing country concerns that the TRIPS Agreement was being used by certain developed countries and their industry groups to prevent important reforms of health-care legislation and to restrict access to medicines.[74] In particular, the Doha Declaration was a response to actions by the United States and European Union threatening South Africa with trade sanctions for legislation implementing its 1996 public health policy, coupled with a lawsuit by 39 pharmaceutical companies. The WTO dispute settlement action against Brazil based on its compulsory licensing legislation provided further impetus for the Declaration.

Paragraph 4 of the Doha Declaration affirms the right of governments to use to the full the flexibilities of the TRIPS Agreement. The patent and data protection provisions of the FTAs, for example, eliminate such flexibilities; e.g., governments are required to grant patents with respect to new medical indications and must apply strict market exclusivity rules with respect to submissions of data, neither of which are required by the TRIPS Agreement. Paragraph 5(d) of the Declaration recognizes the right of Members to establish their own policies with respect to exhaustion of rights and parallel importation. A number of FTAs restrict parallel importation, eliminating national discretion as a matter of international law. Paragraph 5(b) of the Declaration on Public Health acknowledges that the TRIPS Agreement does not limit the grounds on which compulsory licenses may be issued. A number of FTAs restrict those grounds.

The argument has been made that because the TRIPS Agreement permits WTO Members to adopt higher levels of protection than the minimum, and because the Doha Declaration does not literally require Members to take advantage of flexibilities, restrictions in the FTAs do not technically violate the Declaration.[75] In other words, it is argued, nothing in the Doha Declaration prevents a government from abandoning the Declaration's confirmation of sovereign rights.

It is difficult, however, to reconcile this argument with the essential object and purpose of the Declaration which "reaffirm[s] the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose" (Paragraph 4).[76] That object and purpose, as reflected in the terms of the Declaration, is to assure that the TRIPS Agreement is "interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The bilateral and regional agreements negotiated with developing countries restrict or eliminate TRIPS Agreement flexibilities

reaffirmed in the Declaration. Congress ultimately approves and implements the FTAs and implicitly makes a determination as to whether its negotiating objectives have been met. Even if an FTA is inconsistent with the Doha Declaration, Congress is not prevented from legislating inconsistently with its own prior mandate.[77] Nevertheless, if its statement of negotiating objectives is anything more than window dressing, and if U.S. undertakings at the WTO are serious, more detailed consideration should be given to how the FTAs affect access to medicines and other critical healthcare issues in developing countries, as a counterweight to the consideration currently given to the interests of the major pharmaceutical producers.

5 SUMMARY AND CONCLUSIONS

U.S. law reflects a balance between the interests of IPRs holders and consumers. Most U.S. IPRs rules are formulated in terms of general principles and exceptions to them. The FTAs negotiated by the United States largely reflect the general rules of application, though not in all cases. What the FTAs do not adequately reflect is the interplay between rule and exception that establishes the balance. This is of special importance in areas such as public health regulation where incomplete familiarity with the flexibility inherent in the U.S. system may lead its trading partners to conclude that restrictive implementation of the FTAs is required.

In the negotiating process, developing countries should carefully consider whether the capacity of their domestic legal and regulatory system will permit them to balance interests as does the United States. It is probably unwise to accept commitments that will strain domestic capacity and which may lead to the application of rules in a more restrictive manner than the agreements require. If commitments are accepted, developing countries should pay careful attention to implementing the agreements in a way which properly reflects the domestic public interest.

It is not only the public in developing countries which faces risk from these FTAs. So also the U.S. public faces risk. USTR assures Congress that the agreements do not tie the hands of the domestic legislator. That is a position perhaps comfortably taken by the more powerful of the parties to an FTA. Yet it is almost inevitable that when Congress considers changing domestic law, arguments will be made by industry groups that to do so may violate America's international obligations and damage the national interest. Congress may choose to ignore U.S. international obligations, but it would be surprising if Congress were not at least somewhat reluctant to do so. The United States is increasingly bound by a set of highly restrictive intellectual property and regulatory commitments that may not over time be seen to be consistent with the American public interest.

ENDNOTES

1 *See* discussion and analysis of the phenomenon in Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317, 348-58 (2005) and Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS* and *Variable Geometry for the Preservation of Multilateralism*, 8 J. Int'l Econ. L. 77, 88-98 (2005).; Peter Drahos, *Developing Countries and International Intellectual Property Standards-Setting,* 5 J. World Intell. Prop. 765 (2002); Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements* (World Bank Trade Note No. 20, 2005); World Bank, Global Economic Prospects 2005, ch. 5, at 98-110.

2 *See generally See* Keith Maskus, Intellectual Property Rights in the Global Economy (Inst. for Int'l Econ., 2000), Intellectual Property and Development (C. Fink and K. Maskus eds. 2005)(Oxford U. Press) and Keith Maskus & Jerome Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. Int'l Econ. L. 279, 314-16 (2004).

3 *See generally* UNCTAD-ICTSD, TRIPS and Development Resource Book (2005)(Cambridge U. Press).

4 *See* British Comm'n on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, ch. 2, Health (Sept. 2002) and Abbott, *Toward a New Era*, *supra* note 1, at 94-95 (discussing impact assessments undertaking to date).

5 Because Congress is generally required to approve the terms of FTAs, U.S. trade negotiators exercise some care to avoid direct conflicts with existing U.S. federal law.

6 See note 1, supra, and Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Arrangements (QUNO Occasional Paper No. 14, Apr. 2004), available at http://www.geneva.quno.info, and; Carlos Correa, Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines, 36 Case W. Res. J. Int'l L. 79 (2004). See also, various NGO papers cited in Abbott, Medicines Decision, supra note 1, at footnote 234.

7 The Hatch-Waxman Act, which is the legislative basis for the system under which generic medicines are authorized for marketing by the U.S. FDA (discussed *infra*), illustrates the balance between protecting the rights of patent holders and promoting the introduction of competitive non-patented generic medicines onto the market.

8 The Constitution authorizes Congress: "To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries" (art. 1, §8, cl. 8, U.S. Const.). This clause restricts copyrights and patents to a limited term. The Supreme Court has interpreted "Authors" to impose a requirement of creativity for the grant of copyright protection. *See Feist Publications, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 361 (1991).

9 Theoretically, the FTAs could spell out in greater detail exceptions to general rules, effectively mandating an equivalency among intellectual property systems. However, the creation of a more elaborate system of exceptions would be contrary to the preservation of flexibility in the establishment of intellectual property policy. Reflecting the object and purpose of the Doha Declaration, the objective of developing countries should be to preserve regulatory flexibility, not restrict it.

10 Art. II, §2, U.S. Const. See generally, Stefan A. Riesenfeld and Frederick M. Abbott, *The Scope of U.S. Senate Control over the Conclusion and Operation of Treaties*, in Parliamentary Participation in the Making and Operation of Treaties (S. Riesenfeld & F. Abbott eds. 1994) (Martínus Nijhoff), also available at 67 Chi.-Kent. L. Rev. 571 (1991).

11 Under the U.S. Constitution, the Senate has the express authority to approve the ratification of treaties by two thirds majority vote (Art. II, §2, U.S. Const.), although many international agreements are nevertheless subject to congressional approval. Because Congress has the express authority to regulate commerce with foreign nations (i.e., trade) (Art. I, §8, U.S. Const.), trade agreements are generally subject to congressional approval (i.e., by a majority vote of the Senate and the House of Representatives), rather than Senate approval.

12 *See* Trade Act of 2002, Public Law 107–210, 107th Congress, Pub. L. 107–210—Aug. 6, 2002 116 Stat. 933, at §§2101, et. seq., and particularly §2105.

13 See, e.g., *Bush Secures CAFTA Vote in Last Hours with Renewed Textile Pledge*, Inside U.S. Trade, July 29, 2005 (World Trade Online).

14 *Supra* note 12, at §2102(b).

15 *See* http://www.ustr.gov, "Mission of the USTR" page.

16 *See* Riesenfeld & Abbott, *supra* note 10, at p. 265.

17 The existence of a private cause of action depends on the rule of the agreement being sufficiently precise to be applied by the courts in a concrete case or controversy.

18 *See* Riesenfeld & Abbott, *supra* note 10, text at note 271, tracing the practice to congressional approval of the GATT Tokyo Round Agreements, and the U.S.-Israel and U.S.-Canada FTAs.

19 Dominican Republic-Central America-United States Free Trade Agreement Implementation Act, Pub. L. 109-53, 109th Cong., 1st Sess. (2005).

20 The United States does follow a doctrine of consistent interpretation pursuant to which courts will endeavor to interpret domestic law consistently with international agreements, where this is possible.

21 *See* country reports in Riesenfeld and Abbott, *supra* note 10.

22 *See* TRIPS and Development Resource Book, *supra* note 3, at p. 34-35.

23 Frederick M. Abbott, *Regional Integration Mechanisms in the Law of the United States: Starting Over*, 1 Indiana J. Global L. Stud. 155 (1993).

24 The South Africa Pharmaceuticals Case changed this author's view regarding the desirability of giving international trade agreements self-executing or direct effect in developing countries. Even though it is doubtful that the TRIPS Agreement is directly effective in the law of South Africa, the pharmaceutical companies challenged the Medicines and Related Substances Control Amendments Act of 1997, *inter alia*, on the basis of alleged TRIPS-inconsistencies.

25 *See* text at note 60, *infra*.

26 *Id.*

27 *See* Riesenfeld & Abbott, *supra* note 10, at p. 264. Although not expressly decided by the courts, this rule may not apply with respect to *jus cogens* norms established by international agreement.

28 *See, e.g.,* art. 19.11, US-Bahrain FTA.

29 They may also refuse to give direct effect to the decisions of dispute settlement panels

30 For a comprehensive analysis of the US-Chile FTA, *see* Pedro Roffe, Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement (Quaker International Affairs Programme, Ottawa, TRIPS Issues Paper No. 4, 2004).

31 The World Bank has compiled tables of intellectual-property-rights-related provisions in the various bilateral agreements. *See* Fink & Reichenmiller, *supra* note 1. A number of NGOs have also compiled tables showing the TRIPS-plus provisions adopted on an agreement-by-agreement basis. *See, e.g.*, Oxfam Briefing Note, Undermining Access to Medicines: Comparison of Five US FTAs (June 2004), *available at* <http://www.oxfamamerica.org/pdfs/fta_comparison.pdf>; CPTech, Table of Selected Provisions Related to Healthcare in the Free Trade Agreement Texts That Have Been Made Public [as of Apr. 6, 2005], *available at* <http://www.cptech.org/ip/health/trade>; *see also* MSF Briefing Note, Access to Medicines at Risk Across the Globe: What to Watch out for in Free Trade Agreements with the United States (May 2004), *available at* <http://www.accessmed-msf.org>.

32 *See* the description of the process furnished by the FDA Center for Drug Evaluation and Research, Frequently Asked Questions on the Patent Term Restoration Program, available at http://www.fda.gov/cder/about/smallbiz/patent_term.htm.

33 The United States presumably would argue that the United States does "make available an extension of the patent term to compensate", even if it does so in a qualified way.

34 U.S.C§154(b)(1)(B) provides:

"Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3) (C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued."

35 Available at http://www.supremecourtus.gov.

36 *Integra Lifesciences I v. Merck*, 331 F.3d 860 (Fed. Cir., 2003).

37 The first party which obtains regulatory approval to place a new drug on the market is known as the "originator"

38 This "regulatory review exception" to the rights otherwise granted a patent holder to exclude others from making, using, selling, offering for sale or importing the drug was approved by the WTO dispute settlement panel in the *Canada-Generic Pharmaceuticals* case, Canada-Patent Protection of Pharmaceutical Products a WT/DS114/R, 17 March 2000.

39 *See* Kimberly A. Moore, *Judges, Juries, and Patent Cases - An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 392 (2002).

40 Such patents relate to approved drugs and uses and to drugs and uses pending FDA approval. *See Warner-Lambert v. Apotek*, 316 F.3d 1348 (Fed. Cir. 2003).

41 The Federal Food, Drug, and Cosmetic Act, 21 U.S.C §355(a),

42 The Federal Food, Drug, and Cosmetic Act provides:

" (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)--

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted;" (21 U.S.C §355(b)).

43 The Federal Food, Drug, and Cosmetic Act, 21 U.S.C §355(c)(3), provides:

"(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or

supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed-

(I) if the judgment of the district court is appealed, the approval shall be made effective on--

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii). In such an action, each of the parties shall reasonably cooperate in expediting the action."

44 21 U.S.C. §355(j)(5)(B)(iv)(I) and see, e.g., Teva Pharmaceuticals v. FDA, US Dist. Ct. DC, Civ. Act. No. 04-1416 (RBW), opinion filed Dec. 23, 2004, US-DIST-CT, FD&C-RPTR ¶38,779.

45 U.S. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

46 Food and Drug Administration Order, published at 68 FR 36676, June 18, 2003. Technical amendments, 69 FR 11309, March 10, 2004. 30-Month Stays on ANDA Approvals Final Rule Issued.

47 *Bristol-Myers Will Settle Antitrust Charges by U.S., Agrees to 10-Year Ban on Patent Practices*, NY Times, March 8, 2003, at B2.

48 *See generally Kelo v. City of New London*, No. 04-108, slip opinion, decided June 23, 2005, the United States Supreme Court.

49 "[N] or shall private property be taken for public use, without just compensation." U. S. Const., Amdt. 5.

50 Articles 1.1 and 2.1, U.S. Constitution.

51 *See Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984).

52 In *McDonnell Douglas v. U.S. Air Force*, 375 F.3d 1182 (CADC 2004), the District of Colombia Court of Appeals noted:

"The Trade Secrets Act provides a criminal penalty for anyone who: publishes, divulges, discloses, or makes known in any manner or extent not authorized by law any information coming to him in the course of his employment or official duties ... which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount, or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation or association.

18 U.S.C. § 1905. Although the proprietor of commercial information does not have a private right of action to enforce § 1905, it may seek review of an agency action that violates the Trade Secrets Act on the ground it is 'contrary to law,' per § 10 of the Administrative Procedure Act, 5 U.S.C. §702. Chrysler Corp. v. Brown, 441 U.S. 281, 317, 60 L. Ed. 2d 208, 99 S. Ct. 1705 (1979); Widnall, 57 F.3d at 1164." 375 F.3d 1182, 1186 at n. 1.

53 The prohibited acts under 21 U.S.C. §331 (of the FDCA) include:

"(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act [*21 USCS §§ 301* et seq.], any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708 or 721 [*21 USCS § 344*, *348*, *350a*, *350c*, *355*, *360*, *360b*, *360c*, *360d*, *360e*, *360f*, *360h*, *360i*, *360j*, 360eee, 360eee-1, 360eee-2, *374*, *379*, or *379e*], concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) [*21 USCS § 346a(i)(2)*] or any regulation issued under that section.[.] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee."

This statutory provision is directed to information obtained by the FDA under its statutory authority and would not apply to information otherwise acquired by the federal government from a patent holder. To the extent the federal government intended to use information already in the possession of the FDA, the provision expressly refers to "us[e] by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department". This language does not appear to encompass federal government use of data for its own manufacturing and supply requirements because such use would not involve personal gain, and the provision does not appear to preclude employees of the FDA from making use of data for public purposes.

54 *See discussion in* Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469, 485 (2002).

55 U.S. Representative Joe Barton (R-Tx) Holds a Hearing on Pandemic Flu Preparedness, House Energy And Commerce Committee, FDCH Political Transcripts, Nov. 8, 2005, exchange between HHS Sec'y Michael Leavitt and Representative Tom Allen, Lexis-Nexis News database.

"LEAVITT: Mr. Allen, let me just make clear that, in a pandemic situation, I think all those who have modeled and studied it believe that you'll get what's produced domestically.

That's one of the reasons we have pushed so hard for Roche to develop domestic manufacturing capacity, which they have agreed to do and are in the process of developing.

LEAVITT: I don't believe that will be an issue in a pandemic, because I think people who have it within their borders will keep it.

ALLEN: That may well be if it's global and not concentrated in one country or another.

Back when we had the anthrax scare here and Cipro was the available drug to treat it, Secretary Thompson said -- essentially threatened the compulsory licensing. Would you be prepared to do the same?

And now I grant you -- what you said before -- I grant you the manufacturing process is long and difficult and complicated, but would you be prepared to issue a compulsory license if Roche failed to provide an adequate authority to expand production here?

LEAVITT: I do not contemplate that being a circumstance that would present itself. It is important, however, that people of this country know we will do everything necessary to protect them."

56 *Id.*

57 *See, e.g.*, Frederick M. Abbott, *Political Economy of the U.S. Parallel Trade Experience: Toward a More*

Thoughtful Policy, 3 World Trade Forum 177 (Thomas Cottier and Petros Mavroidis eds. 2003) (University of Michigan Press). See also cases cited in *Fuji Photo v. Jazz Photo,* (DNJ 2003), 249 F. Supp. 2d 434, 449-50, discussed in note 58 following.

58 The federal district court that assessed damages subsequent to the decision by the CAFC noted that the appellate court decision on the parallel imports issue addressed subject matter that previously had been left open by the Supreme Court. An early Supreme Court decision, *Boesch v. Graff*, 133 U.S. 697 (1890), is distinguished because it dealt with products which were placed on the market in a foreign country without the consent of the patent holder (under a prior user's right exception). See Fuji Photo v. Jazz Photo, (DNJ 2003) 249 F. Supp. 2d 434, 449-50. *See also, e.g.*, *Margreth Barrett, A Fond Farewell to Parallel Imports of Patented Goods: The U.S. and the Rule of International Exhaustion*, in EIPR 2002, 571 ff.

59 S. 2328, 108th Cong., 2d Sess, provided:

'' Section 27, (h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

60 U.S.-Australia Free Trade Agreement -- Questions and Answers About Pharmaceuticals, July 8, 2004, available at http://www.ustr.gov/Document_Library/Fact_Sheets/2004/U.S.-Australia_Free_Trade_Agreement_--_Questions_Answers_About_Pharmaceuticals.html.

61 Science, State, Justice, Commerce, and Related Agencies Appropriations Act, 2006 Pub. L. 109-108, Nov. 22, 2005, at §631.

62 17 U.S.C § 106. "Exclusive rights in copyrighted works

Subject to sections 107 through 122, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following:

(1) to reproduce the copyrighted work in copies or phonorecords;

(2) to prepare derivative works based upon the copyrighted work;

(3) to distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending;

(4) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and motion pictures and other audiovisual works, to perform the copyrighted work publicly;

(5) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and pictorial, graphic, or sculptural works, including the individual images of a motion picture or other audiovisual work, to display the copyrighted work publicly; and

(6) in the case of sound recordings, to perform the copyrighted work publicly by means of a digital audio transmission."

63 *See, e.g.*, art. 15.5(10)(a), CAFTA.

64 *Id.*, art. 15.1(7).

65 The FTAs require that applications for the recognition of geographical indications be processed with a minimum of formalities. For example, Article 15.3 of the U.S.-Morocco FTA provides:

1. If a Party provides the means to apply for protection or petition for recognition of geographical indications, it shall:

(a) accept those applications and petitions without requiring intercession by a Party on behalf of its nationals;

(b) process those applications or petitions, as relevant, with a minimum of formalities.

Defining a "minimum of formalities" is a subjective exercise. Some areas of regulation are inherently more complex than others, and require a greater scope of inquiry. Nonetheless, it is reasonable to ask whether the regulatory scheme applicable to the registration of foreign geographical indications set out in Chapter 27 of the Code of Federal Regulations represents a minimum set of requirements.The provision setting out the requirement for a petition for foreign designations is not itself complicated,

but likewise does not elaborate the details required for an approved application. By way of contrast, the requirements for approval of U.S. designations are set out in detail, suggesting that similar but unspecified details are required from foreign applicants. *Compare* 27 CFR§12.3 with 27 CFR§4.25.

66 In summarizing its decision, the court says:

"In short, contrary to Plaintiff's argument that the ATF's decision conflicts with the requirements of the Lanham Act, the Court finds that the ATF has proceeded in a manner in which the Lanham Act and the FAA are effectively reconciled. Specifically, while the Lanham Act affords Plaintiff certain rights and causes of action with respect to the use of its marks, the ATF's decision to approve the Santa Rita Hills AVA does not impede those rights. If a winery ultimately uses a label in a manner that infringes on Plaintiff's trademark, Plaintiff may bring suit to enforce its trademark notwithstanding the ATF's prior approval of the AVA." 193 F. Supp. 2d, at 43.

67 *See generally* Penelope Pether, *Inequitable Injunctions: The Scandal of Private Judging in the U.S. Courts*, 56 Stan. L. Rev. 1435 (2004).

68 According to Pether:

"Let me look first at the rates of unpublication in appellate courts. As I have noted supra, in 2000 the rate of unpublication in the Federal Courts of Appeals ran at 79.8%, with the Fourth Circuit having the highest rate at 90.5% and the Seventh the lowest, at 56.5%, up significantly from the First Circuit's lowest tally for 1999 of 45.5%. Only a tiny number of states do not institutionalize unpublication of judicial opinions. Many state appellate courts designate a majority of their opinions as 'not selected for official publication.'

Trial courts and appellate courts both federal and state also 'unpublish' a high proportion of their decisions. At the federal district court level, 'Nationwide, over 260,000 civil cases were filed in the federal district courts during fiscal [year] 1999 ... . Each year only a few of the federal district court decisions are designated for publication by each district court judge.' In the Federal District Court for the District of Colorado, for example, 'one judge published 36 opinions and another published only one. On average, the federal district judges each choose approximately four to six opinions per year to be published.'" Id. at 1471-72. [Footnotes omitted]

69 *Id.,* at 1467-68.

70 Rule 52(a), Federal Rules of Civil Procedure.

71 Pether, *supra* note 67, at Appendix.

72 19 USCS §1526 (f)(2) "For the first such seizure, the fine shall be not more than the value that the merchandise would have had if it were genuine, according to the manufacturer's suggested retail price, determined under regulations promulgated by the Secretary."

73 IPRs holders, similarly, are not obligated to present damage requests on the basis of "suggested retail price". They may present requests on the basis of other "legitimate measures" of value. The courts are required to consider those alternative valuations.

74 See Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469 (2002).

75 *See, e.g.,* Mickey Kantor, *U.S. Free Trade Agreements and the Public Health*, manuscript transmitted to the WHO Commission on Intellectual Property Rights, Innovation and Public Health, July 25, 2005, available at http://www.who.int/intellectualproperty/submissions/en/index.html.

76 The Doha Declaration is best characterized as an agreement by WTO Members on interpretation of the TRIPS Agreement.

77 In effect, Congress is amending prior law.

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