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Global Governance

Anyone who thought a decade ago that implementing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would settle international debates once and for all on the wisdom of increasing global intellectual property right standards was sorely mistaken. In the early years of the 21st century, arguments about intellectual property rights (IPRs) have become increasingly strident and contentious. Radical commentators and strong economic interests reside on both sides of the chasm between highly protective and harmonized international standards, on the one hand, and strict limitations on the scope of proprietary rights, on the other. This divide seems only to grow wider over time as new and more controversial IPR-related issues—such as a human right to good health, free access to knowledge, and the need for widespread diffusion of environmentally sound technologies—enter the global policy arena. Intellectual property developers, particularly in the United States and European Union, push their governments to globally extend and defend their rights, while consumer groups, public health advocates, and nongovernmental organizations (NGOs) fight back with proposals to relax or eliminate those rights.

This chapter describes how we got to this state of affairs. The discussion is largely historical and institutional and focuses on the evolution of the global IPR regime, starting with the TRIPS Agreement, highlighting the so-called TRIPS-Plus provisions of recent preferential trade agreements, and working through to the considerable pushback by various groups. While touching on these issues as well, fundamental economic concepts are deferred to later chapters that focus on particular national policies or sectoral controversies.

TRIPS Finishes Its Test Ride

The TRIPS Agreement was adopted as Annex 1C of the single undertaking establishing the World Trade Organization (WTO) in 1995.[1] It is easily the most comprehensive international agreement ever reached regarding government standards and actions in the realm of intellectual property. Further, by being subject to the WTO's dispute resolution mechanism it is the only multilateral accord on IPRs that can be enforced through legal action and trade sanctions.[2] As such, TRIPS is the bulwark of the international IPR regime and the basis on which most national legal IPR systems are built.

Before turning to specifics, some central principles must be understood about IPRs and TRIPS in order to appreciate the ongoing controversies surrounding them. First, intellectual property rights, or rather the standards and policies defining them, are commercial regulations applying to all firms and institutions wishing to use them. They are fundamentally different from tariffs, trade subsidies, and other elements of trade regulation that arise at national borders. Trade restrictions are almost uniformly recognized as inefficient, inequitable, costly, and tending to reduce welfare in both the importing and exporting countries. Their mutual reduction or removal can be counted on to raise well-being and efficiency in all trading partners, even if it redistributes income within countries. Indeed, the fundamental economic justification for the WTO agreements on reducing border measures is to achieve globally beneficial policy changes that might not be attainable for countries dealing with solely domestic political economy interests.

In contrast, there is no uniform standard of economic optimality in the case of IPRs. When a country expands the scope of patent or copyright protection, it favors current and potential rights holders but reduces the direct access of consumers and makes imitative competition more difficult. These short-run costs may be offset by long-term gains in dynamic competition, though that outcome depends on many disparate circumstances. Even this fundamental tradeoff depends on a country's national income levels, technological development, output mix, social preferences, and even demographic factors. Put simply, countries do not have universal preferences over IPRs, and an agreement to raise standards everywhere may raise or reduce well-being in different trading partners.

Second, although TRIPS is a multilateral agreement, the precise specification of how IPRs are protected remains the province of individual countries. Indeed, a core principle is that WTO members can implement TRIPS according to their own legal systems and practices (Article 1). It has always

1. This section draws on Maskus (2012c).

2. Note, however, that the agreement includes a moratorium on so-called nonviolation complaints, by which one country can allege that another has deprived it of anticipated benefits by virtue of a separate action that does not violate TRIPS. This moratorium existed for five years, was extended in 1999, and remains in place today.

been the case that patents, copyrights, trademarks, and other IPRs exist as national rights, not international rights. A few examples illustrate the point. A company may register a patent or trademark in the United States but must also register it in all other countries or jurisdictions where it desires protection. Definitions of what is protectable subject matter can vary sharply across countries. Copyrights generally do not require registration formalities, but there are different national limitations on the scope and duration of protection. Some countries permit rights holders to exclude reimportation of their goods, while others do not.

That rights are nationally rather than internationally held (at least to date) has been true throughout the history of IPR regulation and cross-border agreements. The TRIPS Agreement does not change that. Rather, it mandates that WTO member nations establish and enforce a set of minimum legal standards in their IPR systems. These minimum requirements frequently have prompted significant legislative and administrative changes in particular member countries, especially the developing and least developed countries. However, they leave considerable room for variations in precise standards, limitations, and exceptions—the so-called TRIPS flexibilities that remain widely discussed in public debates. Thus, for example, WTO parties have the right to employ measures needed to protect public health and nutrition and to pursue the public interest in sectors that are deemed critical to social and technological development (Article 8.1). TRIPS, therefore, hardly settles the issue of how strongly rights holders should be protected. Indeed, in some cases it focuses attention on how to use its proffered flexibilities for social development or industrial policy purposes.

While this point is crucial, it should not be overemphasized. Thus, the third point to keep in mind is that, flexibilities aside, TRIPS both markedly raises the average level of IPR protection in the world and holds countries more accountable for their laws and enforcement regimes. In that regard, it is highly unlikely that the minimum standards required in the agreement would have been voluntarily adopted in the bulk of developing countries had they been left to their own devices. While quantitative assessments of the net impact of TRIPS are extremely difficult to make, on qualitative grounds it seems evident that the primary beneficiaries are major intellectual property developers, which reside overwhelmingly in the wealthy postindustrial economies and, to a lesser extent, the emerging industrialized countries.

It is often claimed that developing economies were willing to accept this arrangement in return for the prospect of improved market access abroad in such areas as agricultural and primary commodities and textiles and apparel (Maskus 2000a, Sell 2003, Stiglitz and Charlton 2005). Another motivation was the expectation that implementing TRIPS standards would encourage expanded flows of international investment and technology (Maskus 2004a). To date, neither of these anticipated gains appears to have been realized significantly, except for liberalization of textiles and apparel trade. Regarding technology transfer, the review in chapter 2 suggests that higher IPR standards

are prompting more cross-border transactions with the middle-income and emerging-market countries, but there seems little to show in the least developed countries in this regard. At the same time, authorities in countries adopting stronger IPR laws recognize the potential restrictions those laws impose on public health systems, agricultural supports, and other areas of social concern. It is little wonder that TRIPS remains controversial.

Major Requirements

Numerous published treatments extensively describe the details of TRIPS, a task that does not need to be repeated here.[3] However, it is worth noting the primary standards and obligations it sets out for all WTO members, since many of these are at the core of ongoing international controversies.

A major requirement is that as WTO members change their IPR laws they do so on a completely nondiscriminatory basis. Both national treatment and most favored nation (MFN) are basic principles of TRIPS, subject to minor exceptions based on provisions in prior international intellectual property conventions (Articles 3 and 4).[4] The MFN plank had not existed in prior international conventions. It requires that any country adopting more extensive protection for intellectual property than is set out in TRIPS in favor of any one country must immediately and unconditionally apply the stronger rules to entities of other WTO partners. The idea is to avoid the discriminatory application of IPRs from becoming a barrier to trade and investment. Note, however, that this principle means in particular that developing countries adopting TRIPS-Plus standards in the context of a bilateral trade agreement do not do so on a preferential basis. Rather, the intellectual property provisions of bilateral agreements necessarily ratchet up protection for all comers. This feature, which has not been widely appreciated in the literature, establishes a bias over time toward more rigorous IPRs in a broader set of countries, moving the baseline up from TRIPS. It is discussed more fully in the section later in this chapter on preferential trade agreements.

Patents

TRIPS includes several notable minimum standards with respect to patents. First, patent protection must endure for at least 20 years from the application date, making TRIPS the first international agreement requiring a minimum duration period. Second, patents must be made available for both products

3. The WTO itself offers a good overview at www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed on June 1, 2012). Readers can find the full text, while UNCTAD-ICTSD (2005) offers an extensive discussion. See also Maskus (2000a), World Bank (2001), Watal (2001), Deere (2009), and several chapters in both Cottier and Mavroidis (2003) and Maskus and Reichman (2005a).

4. However, these exceptions do not apply to agreements made at the WIPO, which is discussed later in this chapter.

and processes. The relevance is that, prior to the agreement, many countries had offered protection only to processes for making pharmaceuticals and chemicals, which are far easier to invent around than the compositions of the products themselves. Third, all fields of technology must be eligible for patents, without discrimination in duration or scope. Significant exceptions exist here: Countries may exclude from patentability inventions that, if used domestically, might damage public order or morality, pose a threat to human, animal, or plant health, or seriously harm the environment.[5] They also can exclude diagnostic, therapeutic, and surgical methods for treatment of humans and animals. Further, countries may refuse patents for animals and plants other than microorganisms and methods of biological reproduction, except for microbiological processes.[6]

Plant Variety Rights

Relatively few developing countries had a legal system for defining and protecting plant variety rights prior to TRIPS, which requires some means of registration and protection, an entirely new obligation in international commercial regulation. Countries were obliged to implement either a sui generis system of protection, patents for new plant varieties, or both.[7] In adopting the former, nations had available as models the provisions of the International Union for the Protection of New Varieties of Plants (UPOV) treaties.[8]

There are two relevant versions of the UPOV treaties, stemming from the dates when they were revised. Under UPOV 1978, countries could choose to recognize the so-called farmers' privilege, which permits farmers to retain seeds for their own use and to exchange them under noncommercial circumstances, and the "breeders' exemption," which allows rival plant breeders to use existing varieties in their experimentation without license or compensation. The provisions in UPOV 1991 disallowed the exchange of seeds and required that breeders gain authorization of rights holders for use of their varieties. Most developing countries have implemented legal systems based on the earlier version, even though UPOV 1978 is no longer open for accession. Others have acceded to UPOV 1991 with its more rigorous provisions, sometimes in the context of negotiating a free trade agreement (FTA) with the United States or the European Union.

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5. The authority to limit protection in order to sustain public health and nutrition and to pursue policies promoting socioeconomic and technological development actually applies to all forms of IPRs (Article 8).

6. The language on patenting of life is in Article 27.3(b), which has proved both confusing and controversial.

7. This requirement exists also in Article 27.3(b), showing that some negotiators saw a strong connection between patents and plant varieties.

8. UPOV is the French acronym by which the agency is best known.

Copyrights

The TRIPS Agreement incorporates by reference the substantive obligations of the Berne Convention, thereby extending its rules to all WTO members. That convention essentially defines copyrightable subject matter, describes the exclusive rights inherent in copyright (including moral rights of authors and artists), indicates minimum time periods of protection, and sets out certain principles under which free use of copyrighted materials may be allowed. Thus, for example, TRIPS now obliges nations to respect copyrights for a period covering the life of an author plus 50 years or, where no author is identified (as in the case of many corporate creations) for 50 years. Member states are free to adopt longer periods, as many have done.

Moving beyond the Berne Convention, TRIPS introduces additional obligations. For example, it requires the extension of copyright to computer programs as literary expressions and to compilations of data where their accumulation and arrangement can be considered intellectual creations. While these are important new rights, note that the agreement does not require patent protection for software, as is provided in the United States, nor does it obligate governments to erect patent-like, sui generis protection for databases, as exists in the European Union. It also requires that rights holders be permitted to exclude copyrighted movies and computer programs from rental markets. Finally, TRIPS defines rights of artists to prevent recording and broadcasting of their performances, of music producers to prevent direct or indirect reproduction of phonograms, and of broadcasters to prevent recording or rebroadcasts of their products, such as television programs.

Despite these additional rights, TRIPS falls short of dealing effectively with issues of copyright protection in the digital age, which were largely unknown at the time it was negotiated. A particular problem emerging later was unauthorized downloading and file sharing. Thus, the music, film, and proprietary software industries have worked tirelessly in the intervening period to expand and sharpen such rights, while opposition has been raised by certain NGOs and university and public libraries.

Trademarks and Geographical Indications

The trademark provisions in TRIPS are largely uncontroversial and essentially incorporate basic practices in major developed economies that combat misleading or fraudulent use of registered marks, logos, symbols, and the like. One difficult element in some developing nations has been implementation of laws protecting well-known trademarks, such as Intel Inside and Chanel No. 5, which are often copied by local imitators but are familiar to consumers and firms in relevant sectors. Countries must prevent these marks from unauthorized use on dissimilar products as well. The definition of what is well known is not entirely clear, and no definition was given in TRIPS, leading to some variability in legal standards and enforcement.

More controversial was the introduction into TRIPS of protection for geographical indications, which identify a product as being produced (at least partially) in a particular region, and where some quality attribute of the good is associated with that location. Obvious examples are Burgundy wines, Scotch whiskey, and Parma hams. WTO members are required to establish procedures permitting owners of geographical indications to prevent misleading or unfair use of their place names and to preclude registration of geographical indications that attach to products that do not originate in the territory indicated. At the insistence of the European Union, a stronger set of requirements was put in place to protect geographical indications for wines and spirits, though prior use in good faith remains permissible under some circumstances. Notably, TRIPS calls for additional negotiations to establish an international registry and notification system of wines and spirits. Such registration among members that adopt it would amount to a list of geographical indications that must be protected (Fink and Maskus 2006). These negotiations are now under way as a component of the Doha Round. They form a key component of the IPR deliberations, as discussed below.

Trade Secrets and Confidential Test Data

Although there are no precise substantive obligations with respect to trade secrets or confidential business information, TRIPS does require members to permit firms to take legal measures to prevent their disclosure through means that are contrary to honest practices. In practice, this has meant implementing laws that defined such unfair practices and established judicial procedures for adjudicating disputes about whether means of unauthorized disclosure were within the law. TRIPS is otherwise silent on the extent of this obligation.

A more precise, and decidedly more controversial, obligation was to state (Article 39.3) that member governments had to protect confidential data submitted in the process of gaining marketing approval for pharmaceuticals and agricultural chemicals against unfair disclosure, or at least ensure that the data could not be used unfairly for commercial purposes. This provision refers largely to test data from expensive clinical trials, which many governments require be submitted for marketing approval. The notion is that such data should be protected for some period of time in order to give the originator firms a lead-time advantage over generic firms, which could otherwise use the data in demonstrating quickly and cheaply that their drug versions are therapeutically equivalent. However, the agreement does not mention a minimum period of protection, leaving governments free to decide what it should be in their own legislation. This issue has been at the center of debates over TRIPS-Plus provisions in free trade areas.

Enforcement Obligations

One of the unique features of TRIPS in comparison with other components of the WTO agreements is that it set out an expectation that IPR owners have the ability to enforce their rights through an administrative and judicial system. IPRs are privately held and it is generally up to their owners to enforce them through litigation, though customs agents and police are often involved in raids against counterfeit and pirate operations. The enforcement procedures must permit effective action against infringement and include remedies to prevent and deter infringing activity, including criminal sanctions in the case of willful counterfeiting and piracy on a commercial scale. However, TRIPS does not define the meaning of "effective" in this context, nor does it require countries to erect legislative and enforcement procedures that go beyond their general procedures for law enforcement. This latter issue was central in the US-China dispute over copyrights, discussed later in this chapter.

Among its enforcement provisions, TRIPS calls for government agencies to have the authority (if not the obligation) to issue injunctions, order fines and monetary damages, destroy or dispose of infringing commodities and production equipment, and employ provisional measures to address infringement in a timely manner. There also need to be special border measures—again, the first time such a requirement has appeared in a multilateral agreement—that allow customs authorities, upon the request of rights holders who present sufficient evidence of infringement, to prevent exports of suspected goods and ensure that imported counterfeit products are not released into general circulation. Some safeguards exist to discourage rights holders from engaging in abuses of these enforcement measures so that they do not become illegitimate barriers to trade.

Limitations to Rights: The "TRIPS Flexibilities"

While setting out these general standards and expectations in support of IPRs, the TRIPS Agreement also recognized the importance of striking a balance between the scope of private rights and the need for user access. This discussion offers a brief overview of the general limitations and exceptions described in the agreement, while deferring to later sections an analysis of their importance.

Exhaustion and Parallel Imports

The exhaustion doctrine is a legal principle setting out the circumstances under which the rights of an IPR owner to prevent further distribution of a good are exhausted (Maskus 2000b, Ganslandt and Maskus 2008).[9] For the vast majority of goods these rights are exhausted upon first sale within a country. If a consumer purchases a car or a book, it is his or hers to sell to others. The

9. The issue is complex both in legal and economic terms and will be analyzed in chapter 4.

exception arises with respect to digital products: When someone downloads a movie or computer program the transaction is generally a licensing agreement that prevents resale or other distribution by the consumer.

Exhaustion becomes an international trade issue because IPRs are nationally defined and a country may choose to prevent reimportation of goods that were legitimately placed on the market in another country by the rights holder or its licensees, such as production affiliates and distributors. Such reimported goods are referred to in the economics literature as parallel imports because they are transacted in a parallel distribution channel, without the authorization of the rights owner. In the United States, for example, it is illegal to import, beyond certain de minimis exceptions for personal use, products that are protected by US patents, design patents, and copyrights, though goods protected solely by trademarks are generally open to parallel trade. Thus, the US policy is to ensure free circulation of protected goods within its territory by virtue of the first-sale doctrine, but to prevent competition from parallel imports. This is an example of national exhaustion. The European Union pursues a policy of regional exhaustion, permitting free parallel importation among its members but preventing it from outside the region. Still other countries follow an international exhaustion policy, where distribution rights are eliminated on first sale anywhere in the world and parallel imports are legal. There is considerable variation across countries and forms of intellectual property in this regard.

The TRIPS Agreement essentially states in Article 6 that determination of the exhaustion regime is up to individual governments and there is no obligation to permit or prevent parallel imports, so long as the system meets the dictates of national treatment and the MFN principle. In the early years after TRIPS was introduced there was considerable discussion about the legal meaning of Article 6, but the consensus since the Doha Declaration is that it permits national choice in this matter.[10] Thus, WTO members are free to pursue their own laws governing parallel trade. Again, this has been a key issue with respect to TRIPS-Plus provisions in US FTAs.

Compulsory Licenses and Unauthorized Use

Developed countries for a long time have featured in their law provisions for permitting unauthorized uses of patented technologies. In one form, such uses are permitted as limitations on patent rights to encourage competition. A prominent example is the "Bolar" exemption (or early working exception)—part of the US Drug Price Competition and Patent Term Restoration Act passed in 1984—under which generic drug companies can use protected formulations during the patent term in order to achieve rapid marketing approval upon expiration of the patent. Another is the research exception, which permits others

10. The Doha Declaration is discussed below.

to experiment on a patented product or process in order to invent around protected inventions and bring new innovations to the marketplace faster.

In a second form, firms may be subject to compulsory licenses or nonvoluntary licenses. Nonvoluntary licenses may be issued for a variety of reasons (Reichman and Hazensahl 2003). Governments can claim the need to use patented information for public and noncommercial purposes on grounds of national security, a public health emergency, or even the need to develop a vital economic sector. Thus, the government may wish to have multiple producers of a key medicine during a public health emergency. A prominent example happened in 2001 when, in the wake of the 9/11 terrorist attacks, the United States ordered the Bayer Company to reduce its price and expand supply of ciprofloxacin, a treatment for the symptoms of anthrax poisoning, or else share its production rights with designated producers. Governments may issue a public-use license for critical technologies that offer national security benefits or address other public goods.

Governments may also compel the owners of patents or copyrights to share some or all of their rights with third parties, generally in return for compensatory royalties. Most commonly, antitrust authorities may compel a firm with a dominant technology to license its use to other firms as part of a competition order. For example, in 1998 the US Department of Justice, concerned about the potential anticompetitive effects of a merger between Monsanto and DeKalb Genetics, ordered the former to license its patented corn germplasm to over 150 seed companies to encourage development of transgenically improved hybrid varieties.[11]

The TRIPS Agreement has a general exceptions clause (Article 30) that permits governments to recognize limited exceptions to exclusive rights so long as they "...do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." In practice, many developing countries have interpreted Article 30 as a broad approval to extend legal limitations on patent rights.

Regarding compulsory licenses, TRIPS does not restrict the purposes for which they may be awarded. However, it does have extensive language (Article 31) setting out conditions that need to be met when issuing them. Among other elements, these conditions are that reasonable but unsuccessful efforts have been made to license the technology, that the use will be temporary and cease when the conditions supporting it no longer exist, that the license is nonexclusive (and, in particular, remains available for use by the patent owner), and that adequate remuneration is paid based on the economic value of the compulsory license. Article 31 also provides scope for compulsory licenses

11. See "Justice Department Approves Monsanto's Acquisition of DeKalb Genetics Corporation: Divestiture of Transformation Technology Rights and Licensing of Corn Germplasm Implemented," US Department of Justice press release, November 30, 1998, www.usdoj.gov/atr/public/press_releases/1998/2103.htm (accessed on June 1, 2012).

so that a dependent patent (one that requires access to the initial patented technology to work) may be exploited and to remedy anticompetitive licensing practices by rights holders. The most controversial provision is Article 31(f), which states that a compulsory license can be authorized only for production and sale aimed predominantly at the domestic market. This provision made it impossible for small countries with little domestic production capacity to access medicines produced under compulsory licenses elsewhere, a problem discussed in the next section.

A survey of implementation laws in 49 developing countries found that virtually all had adopted provisions for issuing compulsory licenses (Musungu and Oh 2006). However, the reasons for their use varied considerably. Most of the countries established that the failure of a rights owner to work the patent by providing adequate domestic supply within three or four years was sufficient grounds, as was the need to invigorate a dependent patent. Somewhat fewer explicitly recognized public interest, national security, and public health grounds. Fewer than half listed the need to remedy anticompetitive practices or the failure of domestic firms to obtain licenses under reasonable terms.

Anticompetitive Practices

A third general area limiting the scope of actions that rights holders may take is the ability of governments to employ antitrust actions to discipline abusive practices in licensing intellectual property (Article 40). The logic is that anticompetitive and abusive actions by firms can restrict trade or diminish prospects for technology transfer. While three potentially abusive practices were listed in the provision, the list is not exhaustive and countries are free to deploy their own competition rules within their legal systems. Since the implementation of TRIPS, a large number of developing countries have adopted antimonopoly laws with provisions aimed at licensing abuses or IPR-oriented restraints of competition.[12]

Copyrights and Fair Use

In its traditional conception, a copyright is literally the legal ability of authors or composers, or the entity to which they assign the right, such as a publishing company, to prevent others from making or distributing copies of their original works. Over time copyrights were extended to performers, broadcasters, owners of satellite transmissions, software developers, and producers of digital products and databases. However, the scope of copyrights was limited by permitting nations to enact limitations and exceptions (L&Es), subject to principles listed in the Berne Convention. In essence, this doctrine permits countries to adopt L&Es to the exclusive rights of content developers and

12. Chapter 5 discusses economic aspects of compulsory licensing and the nexus between IPRs and competition policy.

owners so long as those provisions do not interfere with the normal commercial exploitation of the rights and do not unreasonably prejudice the rights owners' legitimate interests. Examples include reproducing works by libraries for preservation purposes and supporting free access by persons with disabilities, such as the sight-impaired (Okediji 2006, Deere 2008).

Copyrights are further narrowed by the doctrine of fair use, which excuses from infringement liability certain unauthorized uses, lying outside legislated L&Es, of protected material. Prominent examples include making limited copies for personal use, using short quotations for criticism and reviews, allowing the press to make copies necessary for the reporting of events, and permitting teachers to use extracts of copyrighted works for educational purposes. This list is by no means exhaustive.

In fact, the TRIPS Agreement, by incorporating these broad exceptions through its reference to the Berne Convention, permits considerable latitude to countries in narrowing the legal reach of copyrights. For example, while TRIPS requires that computer programs be protected by copyrights at a minimum, it is silent on the issue of whether program code may be decompiled for purposes of reverse engineering and promoting interoperability. It also permits governments, through the Berne Convention Appendix, under certain circumstances to issue compulsory licenses for copying imported products to promote access to works published abroad.

Perhaps most significantly, TRIPS does not address limitations on copyright protection for digital products, such as recorded music, movies, and e-books, presumably because it was negotiated before the internet made such goods easily downloadable and available on file-sharing services. This thorny issue was addressed in two further treaties negotiated at the World Intellectual Property Organization (WIPO), as discussed below, but remains highly controversial. Many developing countries have yet to define their available L&Es in this regard.

The Doha Declaration and the TRIPS Waiver for Public Health

It did not take long after TRIPS was adopted for interested parties to argue that its provisions may have unduly raised roadblocks against the ability of developing countries to promote widespread and inexpensive access to patented medicines, some of which could prove essential in dealing with endemic diseases.[13] Specifically, the obligation to provide patents for new drugs and biotechnological treatments injected new or broader exclusive rights into many developing countries. This raised the prospect of higher drug prices, as pharmaceutical companies would enjoy long periods of exclusive production and distribution rights free from generic competition. This prospect was compounded by the limits placed on the ability of countries to promote

13. The extensive and complex linkages between intellectual property protection and public health provision are discussed in chapter 5.

early generic competition through compulsory licensing or other means. Government-use licenses are not of much help if the authorities are unwilling to invoke an emergency and if no domestic entity is capable of producing the drugs. Most starkly, TRIPS Article 31(f) ruled that a compulsory license could be ordered only for products that would be made substantially for the domestic market. This provision effectively eliminated the possibility of issuing such a license to import production from generic firms abroad. In combination with an obligation to protect confidential test data and the ambiguity surrounding the scope for parallel importation, it seemed that governments would find it extremely difficult to gain low-cost access to new medicines.

The essential and much debated question posed by this dilemma was whether commercial WTO rules governing trade, investment, and regulation would trump the perceived needs of individual countries to pursue public health goals. This conflict was brought into early sharp relief by the dispute between South African representatives of the global pharmaceutical companies and that country's government, which passed legislation in 1997 to deal with the burgeoning population of HIV/AIDS patients. Under the Medicines Act of that year the government adopted measures to reduce drug prices through compulsory licensing, generic substitution, and parallel importing. The US government made concerted representations to the South African authorities to encourage withdrawal of the legislation. That government refused, despite threats of trade sanctions and a listing on the Special 301 Watch List, and ultimately the United States backed down, recognizing that these legal provisions were in compliance with TRIPS.

In the wake of such concerns, WTO members met in November 2001 to launch the Doha Round of trade negotiations. A critical outcome was the Doha Declaration on the TRIPS Agreement and Public Health, which affirms that "...the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health." It therefore confirmed that countries could take advantage of TRIPS safeguards and provisions to attain health goals, including enhanced access to medicines in poor countries.[14] In particular, it referenced the ability of countries to grant compulsory licenses and the rights to determine what constitutes a national health emergency and establish a regime of exhaustion of IPRs. The declaration also extended the TRIPS implementation period for the least developed countries from 2006 to 2016, though only as regards drug patents and marketing rights and test-data protection. Thus, the Doha Declaration clarified that poor countries were permitted to find ways to ensure access to patented medicines, even as TRIPS attempts to preserve the role of patents in incentivizing R&D in the industry.

Despite these modifications, the problem with Article 31(f) remained: Poor countries with limited or no production capacity could not benefit

14. See World Health Organization, "The Doha Declaration on the TRIPS Agreement and Public Health," www.who.int/medicines/areas/policy/doha_declaration/en/index.html (accessed on June 1, 2012).

from granting a compulsory license on a patented drug. In Paragraph 6 of the Doha Declaration, the TRIPS Council was instructed to find a solution to this problem. On August 30, 2003, a General Council decision was announced to waive Article 31(f) under certain circumstances and thereby permit countries with production capacity to export drugs made under compulsory license to those without manufacturing capability. This waiver was converted into a formal amendment to the TRIPS Agreement in December 2005.

To implement the waiver, the developed countries agreed not to take advantage of its importation provision, while it is implicit that developing countries with sufficient production capacity remain bound by 31(f). Thus, it applies only to small and poor nations with limited manufacturing potential. Several countries, led by Canada in 2007, have passed legislation permitting their generic drug companies to export under the provision if so asked, subject to certain safeguards. It should be noted that the circumstances under which the waiver may be invoked are complex and some observers consider them to constitute a remaining barrier to access. To date just one country has availed itself of the procedure. In July 2007, Rwanda announced it would import 260,000 packs of Apo-Triavir, a generic version of a patented AIDS drug produced in Canada by the generic firm Apotex. The license was issued for two years and exclusively for use in the Rwandan market.[15]

This TRIPS waiver is by no means the only international attempt to deal with the problems patents may pose for access to medicines. A broader approach has emerged from the World Health Organization following a major investigative report (WHO 2006). An Intergovernmental Working Group was established to make recommendations, and in 2008 the World Health Assembly adopted a global strategy and plan of action on public health, innovation, and intellectual property (WHO 2008).

Dispute Settlement under TRIPS

As a fundamental component of the WTO agreements, TRIPS is fully subject to the dispute settlement procedures of that body. Indeed, by January 2012, 25 disputes involving TRIPS rules or TRIPS enforcement had been notified to the dispute resolution body, though panels were formed in just a subset of those cases.[16] It is interesting to note that the United States appeared as complainant in 17 of these suits and the respondent in four. The European Communities was the complainant in seven cases and respondent in five. Among other respondents, Canada appeared twice, individual members of the European Union six times, and developing countries eight times. Among these respon-

15. International Center for Trade and Sustainable Development, "Rwanda Tests Public Health Waiver," *News and Analysis* 11, no. 6, October 2007, www.ictsd.net/i/news/bridges/4095 (accessed on June 1, 2012).

16. For an index of dispute issues, see www.wto.int/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#trips (accessed on June 1, 2012).

dent developing countries were Argentina, Brazil, China, India, and Pakistan, while Brazil filed one case against the United States, and India and Brazil filed one case against the European Union. Six of the seven most recent disputes have involved a developed country on one side and a developing country on the other. Thus, so far this litigation has taken place largely among major developed economies, but the development orientation is changing toward a more North-South context.

While each of these cases bears interest, just seven are summarized here in order to conserve space. These disputes are described because they illuminate important points with respect to TRIPS obligations and the associated economic or commercial issues.[17]

US-Brazil: Patent Working Requirements

In 2000, the United States requested consultations with Brazil regarding Article 68 of Brazil's industrial property law, adopted in 1997. Under that provision, Brazil established a local "working requirement" that firms needed to satisfy in order to enjoy exclusive patent rights. Brazil defined a failure to work as either not manufacturing the patented product or not making full use of the patented process in that country within a certain time period. Not meeting this requirement would subject the patent to a possible compulsory license. The United States argued that this provision required local production, rather than importation, to satisfy legal working needs and that this was inconsistent with Articles 27 and 28 of TRIPS. Indeed, Article 27 states that patent rights shall be "...enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced." Brazil countered that its law complies with TRIPS, while NGOs painted the dispute as another instance of US trade authorities attempting to limit the scope of compulsory licensing in medicines.

A dispute panel was set up in early 2001, but in July of that year the two parties reached a settlement and the United States withdrew the complaint. In particular, Brazil promised not to grant a compulsory license against a US-held patent, based on inadequate domestic production, without engaging in prior consultations with the US government. The latter recognized that Brazil had never invoked its industrial property law to issue such a license and therefore saw little risk of future use. Furthermore, Brazil agreed to suspend its counter dispute against the United States regarding sections of the US patent law that, in essence, require that if a small firm or nonprofit organization licenses its

17. As any trade scholar can attest, it is impossible to describe fully the legal findings and implications of such complex decisions in brief summaries, which are offered here as one nonlawyer's basic interpretation. Interested readers should consult the case documents and legal analysis directly to get a full understanding.

patented technology it must be to an entity that will manufacture the associated products "substantially in the United States."[18]

This case demonstrated that many countries have explicit or implicit production-based working requirements and also discriminate between domestic and international interests, despite the language in TRIPS Article 27. As a result, this US-Brazilian resolution in effect permits developing countries to define working requirements as they wish.

European Communities—Canada: Regulatory Review Exception

In 1997, the European Communities (EC) requested consultations with Canada over terms of its Patent Act as they applied to pharmaceuticals. In particular, the European Communities challenged two provisions that it alleged were inconsistent with the exclusive rights of patent owners during the full term of protection. First, under the regulatory review exception the Canadian law permitted potential generic competitors to use the drug, without authorization of the patent owner, in order to demonstrate that their versions were effective and safe and thereby gain official marketing-rights approval upon expiry of the patent term. Second, it allowed generic firms to produce and stockpile quantities of patented drugs so that they could be sold immediately when the patent expired. A dispute panel was formed in 1999 and reported its findings a year later. In brief, it found that the regulatory review exception is acceptable under TRIPS as a general exemption meeting the terms of Article 30. However, it also ruled that the stockpiling exception was an inappropriate use of the product during the patent term and ordered its dissolution. Canada implemented this recommendation in 2000.

This case is noteworthy for its clarification that experimental use by rival firms during the patent term for purposes of marketing approval was not inconsistent with TRIPS, so long as it did not support production or stockpiling in marketable quantities. The regulatory review exception is an important means by which generic firms can achieve rapid approval and is widely in place in developing nations.

European Communities—United States: Copyright Exceptions

In 1999, the European Communities challenged Section 110(5) of the US Copyright Act. That provision has two exceptions to the law requiring that bars, restaurants, and retail establishments procure authorization, through licensing, to amplify and display copyrighted material for the benefit of their patrons. The so-called business exemption permitted small establishments (those under a certain square footage) to play radio and television broadcasts without authorization and without paying a fee. The accompanying "home-

18. Provisions of this kind apply, for example, to university-owned patents on technologies developed using federal grants as set out in the Bayh-Dole Act.

style exemption" allowed small restaurants and retailers the same exception if they used equipment like that found in private homes, rather than commercial equipment.

The European Communities took exception to these limitations, noting in particular that the business exemption applied to most US restaurants and bars and to nearly half the retail stores in the country. The dispute settlement panel found in 2000 that the business exemption was inconsistent with TRIPS Article 13 and constituted a practice that interfered with normal exploitation of copyrighted works and unreasonably prejudiced the owners' interests, as set out in the Berne Convention. In effect, the exception applied to too large a swath of US businesses and could not be construed to be a minor limitation on the economic value of copyrights. However, the homestyle exemption was found to be acceptable because it is a significantly limited provision.

There followed a series of meetings in which the United States claimed to be working with Congress toward legislative implementation of the panel recommendations, and the European Communities (and Australia as an interested party) expressed frustration with the slow progress of that process. In 2003, the main parties reached a temporary resolution of the dispute in which the United States agreed to pay the European Communities $3.3 million as compensation for lost royalties of European music and television rights holders over 1996–98. In fact, this was the first instance of monetary compensation being paid as a resolution of a WTO dispute. However, as of early 2012 the United States still had not adopted new legislation to change its Copyright Act in compliance with the dispute settlement ruling.

United States and Australia—European Communities: Registration of Geographical Indications

In 1999, the United States requested consultations with the European Communities over its legal registration procedures as regards geographical indications. This request was followed in 2003 by a similar inquiry from Australia. These countries complained that EC Regulation 2081/92, as amended, and its administrative and enforcement procedures, discriminated against non-EU nationals and therefore violated the national treatment and MFN requirements of both the 1994 General Agreement on Tariffs and Trade (GATT) and TRIPS. A WTO panel was established in early 2004, with several countries reserving third-party rights in the case.

The panel ruled in favor of the basic claims made by the complainants. Specifically, the EC rule was found not to provide national treatment to other WTO member rights holders. First, the regulation made geographical indication registration in the European Union contingent on the home government of the applicant adopting a protection system identical to that in the European Union and providing reciprocal protection to geographical indication holders from the European Communities. Second, it mandated that firms from outside the European Union apply for geographical indication protec-

tion through their own governments and that the authorities in those home countries have inspection systems like those in EU members. This provision thereby denied identical access procedures to non-nationals that existed for EU firms and raised an additional hurdle to protection. The panel otherwise sided with the European Communities, specifically in finding that its practice of registering geographical indications, even where they may conflict with prior trademarks or cause confusion for consumers, was an acceptable limitation on trademark rights. The panel report was adopted in 2005. In response, the European Union implemented a new regulation in March 2006 that it claimed complied with the panel's recommendations. However, the United States and Australia argued that the new rule is not in full compliance and continue to press the case.

Ecuador–European Communities: Bananas

It is important to note the unique situation raised in a dispute over a non-TRIPS issue, the EC banana import regime. The dispute over the European Union's banana trade restrictions is one of the most famous in dispute settlement annals and has been widely discussed. Specifically, in 1999 a WTO panel found that the import regime favored producers in the African-Caribbean-Pacific (ACP) nations in ways that violated several GATT rules. The European Communities made only token attempts to reform the system. Ecuador requested that a panel be established in 2007 to assess the compliance with prior recommendations of the dispute settlement body regarding changes in the EC banana import regime. The new panel found again that by giving ACP producers a duty-free tariff-rate quota while charging a tariff on non-ACP bananas, the system was in violation of several GATT rules. Moreover, the applied tariff remained higher than the bound rate set in the tariff rate quota.

Less well known is that in May 2000, Ecuador, one of the complainants (along with Guatemala, Honduras, Mexico, and the United States) in the case (EC-Bananas III [DS 27]), requested and was granted the authority to suspend trade obligations with respect to the European Union in the amount of $202 million. Among the particulars of this suspension were certain copyrights for EU performers and producers of recorded music and broadcasts, geographical indications, and industrial designs. To date Ecuador has not implemented this retaliation but the authorization remains in place. The possibility is significant in economic terms, for it addresses a particular imbalance facing smaller countries proposing to retaliate against illegal trade restrictions in larger nations. Ecuador's market likely is too small for the country to damage the European Union's interests by simply raising tariffs. In contrast, the discriminatory suspension of copyrights and geographical indicators could permit significant copying of EC-owned IPRs, and perhaps a considerable expansion of regional trade in these legal copies, which would present a greater market access problem for the affected EC firms. Further, Ecuador saw that it could

request retaliation in music, geographical indicators, and industrial designs, areas of particular export concern for the European Communities.[19]

US-China: Enforcement of Intellectual Property Rights

In 2007, the United States lodged a dispute with China over four aspects of its enforcement system. The first complaint was that thresholds in Chinese law for meting out criminal penalties were too high in cases of trademark counterfeiting and copyright piracy. Second was that the scope of acts infringing copyrights and subject to criminal procedures was too narrow to be effective. Third was that goods confiscated by customs were not disposed of outside commercial channels, but rather could be auctioned after removal of fake labels. A final complaint was that China denied copyright protection to books, films, and musical recordings that were not approved for local distribution, leaving them vulnerable to copying.

US authorities argued that the weak criminal thresholds were inconsistent with TRIPS Article 41.1, which calls for procedures sufficient to permit effective action against infringement, and Article 61, calling for criminal penalties against willful trademark infringement and copyright piracy on a commercial scale. A specific concern here was that unauthorized copying of digital products on a commercial scale was not subject to criminal penalties, even if distribution of those products was. The practice of releasing seized goods into commerce allegedly violated TRIPS Articles 41 and 59, giving judicial officials the authority to order their destruction outside distribution channels. The practice of denying copyright protection to foreign creative works subject to pre-review for distribution, and those not permitted to be distributed, was thought to run counter to the national treatment principle, obligations under the Berne Convention, and Article 14.1 on the rights of performers and phonogram producers.

The Panel Report was circulated in early 2009 and was a mixed finding. It agreed with the United States that the procedures barring copyright protection for creative works not approved for legitimate sale violated TRIPS obligations. Specifically, the first sentence of China's copyright law at the time stated: "Works the publication and distribution of which are prohibited by law shall not be protected by this law." Moreover, while auctioning infringing items seized at customs was not necessarily a violation, releasing goods into circulation after removal of an infringing trademark was found inconsistent with TRIPS Article 46. In 2010, China issued new regulations to comply with these rulings.

However, on the larger point, that criminal sanctions were inadequately available to be an effective remedy to willful counterfeiting and piracy, the

19. Similar retaliation authorizations involving suspending TRIPS concessions were awarded to Brazil in its dispute over US cotton subsidies (DS 267) and to Antigua in its dispute with the United States over measures restricting cross-border gambling and betting services (DS 285).

panel demurred. It found that the United States had not demonstrated that China's procedures were inconsistent with the language of Article 61: "Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale." In essence, the ruling implies that if one country wishes to complain about another's enforcement thresholds it must give real evidence of economic damages. Thus, the importance of this case is its affirmation that the definition of what constitute effective enforcement measures is largely a matter of national sovereignty, subject to a complainant's demonstration that those measures fail to deter infringement on a commercial scale, a term left undefined.

Brazil–European Communities and India–European Communities: Transshipment of Generic Medicines

In May 2010, India and Brazil requested consultations with the European Communities and the Netherlands in relation to repeated seizures of generic drugs originating in India and en route to Brazil and other locations. In 2008 and 2009, authorities had seized a number of such transshipments while in European harbors or airports on the grounds that they violated local patents, even though the drugs were not patented in the origin and destination countries. For example, in December 2008 authorities impounded a shipment of a generic version of the hypertension drug Losartan, bound for Brazil, for 36 days before returning it to India where it was made.[20] The drug was not on patent in either country but was in the Netherlands. Some shipments were held for as long as eight months at the request of the patent-owning pharmaceutical companies, including Novartis and Eli Lilly, according to an Indian complaint.[21] Canada, China, Ecuador, Turkey, and Japan also joined the consultations as interested generic-drug exporters or importers.

The question here is whether products that temporarily appear in a country, though bound for another destination and therefore no clear threat to domestic patent rights, should be considered infringing in the transshipment location. If this practice is sustained in law it would mean that shippers would have to avoid sending otherwise legal products through locations where they would infringe local rights, thereby increasing trade costs. Moreover, it offers patent owners an unusual means of slowing or reducing generic competition in destination markets. The Brazilian government argued that such a standard would violate WTO disciplines on freedom of transit (GATT Article V) and

20. International Center for Trade and Sustainable Development, "Brazil, India Challenge Generic Drug Detentions," *BRIDGES Weekly*, May 12, 2010, www.ictsd.org/i/news/bridgesweekly/75730 (accessed on June 1, 2012).

21. Jennifer M. Freedman, "India, Brazil Complain at WTO over Generic Drug Seizures by European Union," Bloomberg, May 12, 2010, www.bloomberg.com/news/2010-05-12/india-brazil-complain-at-wto-over-generic-drug-seizures-by-european-union.html (accessed on June 1, 2012).

asked for modification in the policy. Regulation 1383/2003, the EC provision on which this authority to seize transshipments suspected of infringing IPRs rests, remains in place. After consultations failed to resolve the matter, Brazil and India asked in September 2010 that a WTO panel be assembled. Consultations proved unnecessary because European officials expressed a willingness to modify the regime and the case was resolved.

Continuing TRIPS Issues and Intellectual Property Rights in the Doha Round

Although TRIPS has been in place for over 15 years, it remains subject to potential revisions. The agreement itself left some issues open for subsequent analysis by the TRIPS Council at the WTO and ultimate renegotiation by member states. Other elements have emerged that are the subject of intense debate regarding their inclusion in the Doha Round. A brief overview is provided here, with more substantive analysis of major items in chapters 4 and 5.

Technology Transfer Mandate

One of the selling points that prompted developing countries to adhere to TRIPS during its negotiation was the promise of greater technology transfer, which is seen by many as central to achieving gains from IPR reforms. This notion was in part an implicit bargain, with many policy authorities in developed nations and independent observers noting the enhanced prospects of technology flows to reforming countries (Maskus 2000a). It was also explicit, with a number of TRIPS provisions mentioning technology transfer. Article 7, for example, lists as a basic objective of TRIPS "...the promotion of technological innovation and...the transfer and dissemination of technology...." Most directly, Article 66.2 requires that developed members provide incentives to their enterprises and institutions to encourage and promote technology transfer to the least developed countries.

The TRIPS Council monitors the implementation of this mandate through inspection of periodic reports submitted by authorities in developed nations about such incentives. Several analysts have read some of these reports and commented on the nature and effectiveness of the policies (Maskus 2004a, Moon 2008). In most cases they find little evidence that new incentives have been put into place or that procedures are effective at encouraging technology transfer to the least developed countries. Indeed, representatives of these countries are frustrated at the lack of progress in achieving inward technology transfer in the period since TRIPS was agreed upon.[22] This ineffectiveness is unsurprising because the economic characteristics of least-developed-country markets generally do not attract private technology flows. Nonetheless, figuring

22. Statements by delegations to the WIPO High-Level Forum on Intellectual Property for the Least Developed Countries, Geneva, July 2009.

out how to make Article 66.2 more effective via enhanced actions by developed members remains a priority item for the least developed countries.

Geographical Indications

As noted earlier, TRIPS recognizes geographical indications as globally protectable subject matter. In general terms, geographical indications are names or words identifying products that were made (at least partially) in a specific geographic region and where some element of the quality or reputation of the product is attributed to that region. Such products could be wines, spirits, beverages and food products, textiles and clothing with artisanal designs or weaving patterns, and other goods for which regional characteristics matter. WTO members must provide means for geographical indication owners to prevent others from making false or misleading claims about the origin of their goods. However, the particular means by which this protection is offered is at each country's discretion. Thus, for example, geographical indications are protected in the United States largely as trademarks, collective marks, and certification marks, such as "California almonds," rather than through a special regime. Also used in various countries are elements of consumer protection law and common law.

In negotiating TRIPS, the European Union succeeded in achieving stronger protection for wines and spirits. In essence, where firms were not already using names such as "Champagne" or "Scotch whiskey" in good faith for an extended period prior to TRIPS, countries must prevent such use, even if accompanied by qualifiers such as "kind" or "imitation." That is, misuse must be prevented even if it does not confuse consumers. This carved out an exception for the established wine industries in countries such as the United States and Australia, but raised a barrier to the use of such names by new labels anywhere. However, the European Union saw this TRIPS solution as insufficient protection for geographical indications in wines and spirits. Therefore, inserted in Article 23.4 is a mandate for additional negotiations within the TRIPS Council over the establishment of a multilateral system of registration and notification of geographical indications in this industry.

This requirement now forms one element of ongoing negotiations in the Doha Round over geographical indications. The EU position is that TRIPS should be amended to say that a product entered into the multilateral register would enjoy a legal presumption that the name must be protected in all members unless it is a generic term or does not fit the definition of a geographical indication. Specifically, registration with the WTO Secretariat would constitute prima facie evidence that the name fits the TRIPS definition of a geographical indication and this fact must be taken into account when the reviewing country decides whether to accept the application and how to protect it. Opponents, led by the United States, Australia, Argentina, Chile, Canada, and other "new world" wine-producing nations, argue that there is no need to amend TRIPS. Rather, the TRIPS Council could establish a voluntary

registration system and only those countries that join the system would be obliged to consult the database when considering a geographical indication registration.

The second element relates to proposals to extend the higher level of protection beyond wines and spirits to other products. This campaign is led by the European Union and Switzerland, for the extension gives them greater leverage in pushing for the registry on wines and spirits. Numerous developing countries, including India, Indonesia, Brazil, China, Thailand, Turkey, and the African Group, have joined the campaign. They believe that their producers of location-based food products and designs can gain greater global marketing reach and earn additional economic value through registration and protection of geographical indications.[23] The United States and other countries focused more on trademark-based approaches resist such extensions. Note the interesting fact that in this case the debate over IPRs is not between North and South but rather mixes countries at differing income levels.

Disclosure of Origin of Genetic Resources in Patent Applications

One of the most perplexing components of TRIPS is Article 27.3(b), which relates to intellectual property protection for life forms. This provision permits countries to exclude from patentability plants and animals and "essentially" biological processes for producing them (i.e., biological reproduction techniques). However, this exclusion does not apply to microorganisms or microbiological processes and nonbiological processes of production. The intent was to make biotechnological inventions widely available for patenting. Further, even if newly bred or bioengineered seeds are excluded from patents they must be protected with some effective sui generis system, such as plant variety rights.

Article 27.3(b) reflected an awkward compromise between the needs of biotechnology producers—still an emerging industry but with increasing global reach—and those who are uncomfortable with the idea of firms owning private rights to life forms. It also struck a balance between the interests of innovative firms in agricultural life sciences such as Monsanto and authorities in developing countries wishing to preserve the ability of farmers to keep and exchange seeds. However, the language on life patents is so vague that there has been considerable confusion in interpreting its meaning as countries implement new patent regimes (Deere 2009). Moreover, commercial interests found it unsatisfying. Accordingly, negotiators included a provision for review of this article within four years of the passage of TRIPS.

In that review it quickly became evident that Article 27.3(b) raises difficult issues regarding its consistency with the United Nations Convention on Biological Diversity (CBD). In particular, the CBD states that countries have sovereign rights over the genetic resources, including plants and animals,

23. The economic tradeoffs in protecting geographical indications are analyzed in chapter 4.

found in their jurisdictions. States can, therefore, regulate the extraction of such resources for use in any capacity, including scientific and industrial activities that may generate patentable inventions. Further, the CBD posits that extracting firms and institutions should achieve prior informed consent with the owners of such resources (typically national governments) and ensure that benefits from their use are shared with those owners or citizens.[24]

TRIPS is silent on all these issues, requiring only that microbiological inventions be patented and plant varieties protected, with no requirements for prior informed consent or benefit sharing. In principle, then, a foreign firm or university could take plant material from a developing country, use it to develop new biogenetic processes and medicinal products, and patent these inventions wherever it wants, without sharing the benefits. That would block inventors in the originator nation from developing competing products based on their own formulations and from exporting to those markets. It could even be possible for the foreign entity to patent the products in the country where the resources originate, if permitted by the patent law, and enforce those patents against similar medicinal uses that may have existed in a village's traditional practices for a long time. Apocalyptic anecdotes along these lines quickly prompted NGOs and others to encourage developing countries to adopt laws governing the use of genetic resources and traditional knowledge, with provisions for prior consent and benefit sharing. Among others, China, Peru, and India have implemented extensive legislation in this regard.

In the face of such concerns, WTO members in the Doha Declaration called for the TRIPS Council to consider the relationship between TRIPS and the CBD, along with means of protecting traditional knowledge and folklore.[25] Over time this consideration evolved into proposals by some countries to negotiate a change in TRIPS that would mandate a particularly contentious rule: Patent applications must include statements identifying the sources of genetic materials on which the inventions are based. Positions taken to date are far apart, reflecting the controversial aspects of this issue. At one extreme are a group of countries, including the United States, Australia, Japan, Canada, and South Korea, that argue there is no inconsistency between TRIPS and the CBD and that both agreements can be implemented at the national level without conflict. In particular, they claim that proper recourse to existing patent application protocols will ensure that invalid patents are not issued, thereby safeguarding the prior knowledge of others (which must be in written form, another contentious issue). Further, these patent rules do not prevent applicants from engaging in prior informed consent and benefit sharing. Many developing countries are skeptical in light of the voluntary nature of this

24. See chapter 5 for a more detailed discussion of the CBD.

25. See WTO Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship between the TRIPS Agreement and the Convention on Biodiversity*, IP/C/W/368/Rev.1, February 8, 2006.

mechanism and the well-known problems with the quality of patents issued in the United States (Jaffe and Lerner 2004, Maskus 2006a).

At the other extreme are countries that see inherent conflicts between TRIPS and the CBD on two primary grounds. The first is that TRIPS offers scope for appropriation and ownership of genetic materials without recognizing the sovereignty of countries over their use. The second is that TRIPS does not require prior informed consent or benefit sharing. Countries in this camp, including the African Group, the group of least developed countries, and Bolivia, argue that Article 27.3(b) should be amended to state that life forms and inventions from genetic materials cannot be patented.

Other countries are arrayed between these poles, with most developing countries taking the view that while there may be no inherent inconsistency between TRIPS and the CBD, the global patent system needs to be reformulated to make sure that both agreements are respected in practice. From this logic flows the proposal for disclosure in patent applications of source and country of origin of any biological resources or traditional knowledge involved, as advocated by the Andean Community, Brazil, China, India, the Philippines, and many other developing countries, along with Switzerland and Norway among developed nations. These proposals would also require patent applicants to demonstrate that they had achieved prior informed consent from appropriate authorities and entered into fair and equitable benefit-sharing arrangements. These procedures would apply also to international applications through the Patent Cooperation Treaty at the WIPO.

Little progress has been made on these complex negotiating issues. The United States and Japan, for example, seem unyielding in their opposition to a disclosure requirement, arguing that this would become a fourth condition of patentability and overturn centuries of legal tradition. Their commercial and innovative interests, including some universities, are concerned that such a requirement would destroy a valuable trade secret, which is confidential information about the location of materials.

In 2008, the European Communities and Switzerland joined forces with many developing countries to push for incorporating both the geographical indication provisions and the disclosure requirement into formal revisions of TRIPS at the Doha Round.[26] This reflects an alliance of cross-issue interests that may be sufficiently broad and powerful to overcome the opposition of other major countries.

The World Intellectual Property Organization Does Its Part

Despite the fundamental importance of TRIPS as part of the WTO agreements, functional responsibility for overseeing the international IPR system is largely invested in the WIPO, a specialized UN agency. The WIPO Secretariat

26. WTO, Trade Negotiations Committee, *Draft Modalities for TRIPS-Related Issues*, TN/C/W/52, July 19, 2008.

supports the operation of multiple international treaties and agreements on aspects of intellectual property. These range from the foundational Berne Convention (literary and artistic works) and Paris Convention (industrial property) to specialized international registration agreements such as the Patent Cooperation Treaty and the Madrid Protocol (trademarks). It also facilitates negotiations among WIPO member states on revisions to these treaties for the purposes of setting norms and achieving efficiencies in the global use of IPRs. Finally, WIPO staff actively undertake capacity building in developing countries in order to improve the legal and administrative features of those countries' intellectual property regimes.

There are two fundamental differences between the WIPO accords and the TRIPS Agreement. First, adherence to a WIPO treaty is voluntary and not all countries join, while WTO membership is nearly universal. Second, WIPO treaties are not directly subject to binding dispute resolution, as are the provisions of TRIPS.[27] In this context, the WIPO is a convenient location for developing new international agreements that establish or modify norms in areas not covered by TRIPS. The most prominent examples are the two treaties adopted to deal with issues of digital copyrights and the internet: the WIPO Copyright Treaty (WCT) and the WIPO Performance and Phonograms Treaty (WPPT), both adopted in December 1996. As of October 2011, the WPPT had 87 contracting parties and was in force in 77 of them. The WCT had 88 contracting parties, with 79 having put it into their laws. The United States adopted both into law in 2002.

The essential reason that some countries saw it important to negotiate these treaties in the wake of TRIPS is that the latter simply did not come to grips with complex issues of digital content and the emerging power of the internet. It says little about fair use of digital goods and technologies. Nor does it anticipate the possibility that users might defeat copyrights through circumvention of technological means of deterring copying or file sharing. In short, changes in digital technologies quickly overwhelmed TRIPS in the copyright arena.

Thus, the WCT states that authors of copyrighted works have exclusive rights to authorize the communication to the public of those works by wire or wireless means, including in ways that permit time shifting by users. It also clarifies that temporary copies (i.e., screen downloads) are subject to the reproduction right. Further, the WCT states that "Contracting parties shall provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors in connection with the exercise of their rights under this Treaty or the Berne Convention and that restrict acts, in respect of their works, which are not authorized by the

27. These statements are not quite accurate in that the Berne Convention and Paris Convention are both incorporated by reference into TRIPS. Thus, a violation of their provisions by even a nonmember of the conventions could be construed as a derogation from TRIPS.

authors concerned or permitted by law."[28] The treaty also requires effective remedies against removing or altering such means of managing digital rights as electronic click-on licenses and identifying information. These remedies may be civil or both civil and criminal.

For its part, the WPPT extended to performers the right to authorize the fixation (recording) of their performances in any manner or form and the communication of those recordings to the public by wire or wireless means. Publishers of music and other digital products are given the same communication right. Both performers and publishers are entitled to compensation from the use of their works in broadcasts or other communication to the public (e.g., in bars and restaurants). The treaty also contains language ordering remedies against circumvention of technological measures and alteration of digital rights management information. It is worth noting that the WPPT clarified that the minimum period of protection of phonograms would be 50 years from the date issued, consistent with the duration of protection for films under the Berne Convention.

Thus, these treaties recognized that circumvention of technical solutions in digital goods and the acts of copying for use at other times and places were becoming significant problems from the standpoint of copyright industries. Accordingly, they set out broad obligations to deal with these difficulties, leaving precise solutions to contracting parties. In fact, countries have taken different approaches, particularly as the ability to copy and the power of the internet have expanded. For their part, many developing countries have not signed or implemented the WCT and WPPT and are, therefore, not bound by them. Some countries that have implemented the agreements have taken advantage of the limitations and exceptions they permit. Specifically, the WCT and WPPT leave discretion to national authorities to define acceptable limits on copyright under terms of the Berne Convention. Both treaties also state that countries may select their own regimes as regards exhaustion of copyrights in software, databases, recordings, and other digital products, so that markets may stay open to parallel imports.

A further set of WIPO negotiations has been the lengthy attempt, spearheaded by the United States, European Union, and Japan, to develop a Substantive Patent Law Treaty. The first rounds in 2000 considered standards governing conditions under which patents would be granted, including definitions of prior art, novelty and nonobviousness (the inventive step), the meaning of an invention's commercial utility, claim drafting, and other requirements. Later discussions were to focus on basic legal procedures, such as the need for a system in which patent grants could be challenged after they are issued and disclosure requirements for patents based on genetic resources. These negotiations made little progress and have become moribund since 2005 at least as far as most WIPO members are concerned. In that year strong concerns were raised by a number of countries about whether the harmonization of patent

28. Article 11, WIPO Copyright Treaty.

law would hamstring their abilities to use differentiated patent standards as a tool for economic development.

When TRIPS Is Not Enough

The provisions in TRIPS and the WIPO treaties describe the current balance struck in multilateral negotiations between the exclusive rights of innovators and rights holders and the access needs of followers and users. Some observers find that situation to be, in fact, highly imbalanced in favor of IPR owners. They argue that the level of private rights in the global regime should be scaled back or, at a minimum, that developing countries should be held only to the barest minimum standards (Stiglitz and Charlton 2005, Ruse-Khan 2009). Others argue that the balance seems reasonable and the global standards should be given time to find an equilibrium (Maskus 2000a, Commission on Intellectual Property Rights 2002). An interesting variation is that global policy might improve if developing countries were left to experiment with varying use of TRIPS flexibilities (Maskus and Reichman 2005b, Reichman 2009).

Clearly, however, there are areas of minimum international protection norms that are seen as inadequate by major producers of intellectual property. Patents can be denied on eligibility grounds and overturned by compulsory licenses. In some countries test data may not be protected from disclosure for very long. Governments may permit parallel imports, greatly diminishing the ability of rights holders to segment markets. TRIPS and the WIPO treaties leave considerable room for establishing legal exceptions from copyright. Strong anticircumvention procedures in the United States or Europe are of little use when they cannot be applied extraterritorially in countries with weak copyrights or enforcement.

Unsurprisingly, therefore, the United States and the European Free Trade Association (EFTA) early in the last decade, and later the European Union, chose to focus attention on expanding the scope of IPRs beyond TRIPS. This was possible by negotiating stronger standards in bilateral preferential trade agreements and FTAs. This policy is commonly known as demanding "TRIPS-Plus" standards and is a central plank of the US and European FTA strategies. The remainder of this section focuses on US practice, while the EU policy is described briefly after that.

United States

Practically speaking, the TRIPS-Plus strategy means the following. First, for IPRs that are not negotiated within a particular FTA, the relevant TRIPS minimum standards pertain as a baseline level of protection. Next, the FTA may adopt standards and expectations that exceed those of TRIPS. Finally, newer areas of IPRs that were not covered by TRIPS may be subject to negotiations in FTAs, an especially prevalent issue in the digital age.

It is important to point out that the United States has negotiated IPRs in FTAs under the principle of national treatment, meaning that rights owners and applicants from all countries are treated no less favorably than their domestic counterparts. While FTAs generally do not mention MFN status, this principle also applies because TRIPS requires any intellectual property regulations to be nondiscriminatory. No GATT Article 23–like exception permits differential treatment of nationals from different countries. Accordingly, stronger IPRs that are reached in bilateral agreements must be extended immediately and unconditionally to registrants of intellectual property from all WTO contracting parties. Thus, while particular standards vary across FTAs, the trading partner involved must offer those terms to third parties. In terms of the underlying US strategy, this is an important means of ratcheting up global standards of protection for IPRs.

The US policy preference for TRIPS-Plus derives its authority from formally adopted negotiating objectives. The Trade Act of 2002 restored trade promotion authority to the executive branch but also set out an extensive list of negotiating priorities.[29] One such priority is to ensure the "accelerated and full implementation" of the TRIPS Agreement, particularly with respect to its enforcement obligations. Another is to ensure that the IPR provisions of FTAs "...reflect a standard of protection similar to that found in US law." A third is to provide strong protection for new and emerging technologies and products embodying intellectual property. A fourth is to ensure that standards keep pace with technological developments, especially in the area of digital copyrights, providing rights holders the "...legal and technological means to control the use of their works through the Internet...and to prevent the unauthorized use of their works."

Main Elements of TRIPS-Plus

These four objectives encapsulate the nature of recent and current US negotiations on IPRs on a bilateral and multilateral basis. Put simply, the priorities are greater enforcement, exportation of US laws, upgraded standards abroad, and technological protection of digital content. Indeed, the so-called TRIPS-Plus Agenda has evolved over time, reflecting both stronger US interests in expanding protection and the perceived need to upgrade and develop standards as technologies change. For example, the draft article covering IPRs in the US-Israel FTA, agreed upon in 1985, reads as follows:

> ARTICLE 14 [INTELLECTUAL PROPERTY]
>
> The Parties reaffirm their obligations under bilateral and multilateral agreements relating to intellectual property rights, including industrial property rights, in effect between the Parties. Accordingly, nationals and companies of

29. The text of this act (Public Law 107-210) is available at www.bilaterals.org/IMG/pdf/TPAA_2002.pdf (accessed on July 14, 2012).

> each Party shall continue to be accorded national and most favored nation treatment with respect to obtaining, maintaining and enforcing patents of invention, with respect to obtaining and enforcing copyrights, and with respect to rights in trademarks, service marks, trade names, trade labels, and industrial property of all kinds.

Nine years later, when NAFTA came into force in 1994, the chapter on IPRs simply anticipated TRIPS. Indeed, the language of many provisions in TRIPS comes from the corresponding provisions in NAFTA. Accordingly, NAFTA embodies similar IPR standards and flexibilities, leaving much up to national discretion. In particular, NAFTA Chapter 17, Article 1709.3 is virtually identical to TRIPS Article 27.3(b) on patents for organisms and plant variety rights.

The US-Chile FTA enacted in 2004 has somewhat stronger requirements, particularly in the areas of patents and trade secrets, but generally relies on TRIPS as its baseline. However, in FTAs with Jordan, Morocco, Singapore, Australia, and members of the Central American Free Trade Agreement–Dominican Republic (CAFTA-DR), the United States pushed for increasingly protective standards. The TRIPS-Plus objectives were particularly evident in reaching the IPR chapter in the Jordan-US FTA, sometimes called the "gold standard" agreement among trade diplomats and strong intellectual property advocates in the United States.[30] Table 3.1 encapsulates the TRIPS-Plus regulations reached in that early agreement.

Despite the enthusiasm for the Jordan-US agreement provisions, TRIPS-Plus requirements have become even more rigorous over time. One way to see this is to note that the Jordan-US FTA Article 4 on IPRs comprised five pages and 29 paragraphs, while the CAFTA-DR (ratified in the United States in 2005) Chapter 15 on IPRs covered 29 pages (excluding country-specific provisions) and 94 paragraphs with extensive subclauses. Much of this expansion reflected the perceived need to spell out explicit protection terms for rights in digital goods and enforcement expectations. Other recent FTAs are similarly detailed in this context.

The current primary elements of TRIPS-Plus requirements are described below.[31] Table 3.2 indicates the status of these issues in seven recent FTAs.[32]

The United States prefers that countries provide extensions to patent coverage and scope in several ways. One way is to narrow the exclusions from patentability and, in particular, to extend eligibility to life forms, including genetic sequences and biotechnological research tools. Plant varieties are another area in which eligibility for patents could be provided, though in some FTAs the partner countries have been asked to join or ratify UPOV 1991,

30. Author's conversation with officials at the US Department of Commerce, February 2005.

31. See Fink and Reichenmiller (2005), Roffe and Spennemann (2006), Maskus (2006b), and Wunsch-Vincent (2003).

32. Readers should note that there are some variations in these provisions across FTAs and each should be consulted for precise details.

Table 3.1 TRIPS-Plus provisions in the Jordan-US free trade agreement (2001)

Area	Provision
Copyrights	Jordan to adopt the provisions of the WIPO Copyright Treaty and the WIPO Performance and Phonograms Treaty.
	No parallel importation.
	Civil and criminal remedies for circumvention and for use of circumvention equipment.
Patents	No per se exclusion of biological processes and genetically modified life forms.
	Compulsory licenses only for national emergencies, public noncommercial use, and anticompetitive behavior.
	Importation satisfies working requirements.
Plant variety rights	Jordan to adopt provisions of the International Union for the Protection of New Varieties of Plants 1991 treaty.
Test data	Regarding marketing approval in pharmaceuticals and agricultural chemicals, protection against unfair commercial use.
	If approval is based on tests submitted to another country, protection period must be at least for the same period as in that location.
Patent term	Term extensions must be available to compensate for unreasonable delays in marketing approval of pharmaceuticals and agricultural chemicals.
Second-use patents	Protection awarded for new uses of existing chemical entities.
Enforcement	Border enforcement and actions against criminal copyright piracy and trademark counterfeiting may be taken by officials at their volition.
	Defines willful copyright piracy on a commercial scale.

TRIPS = Agreement on Trade-Related Aspects of Intellectual Property Rights; WIPO = World Intellectual Property Organization

which permits limited exceptions to the breeder's exclusive rights, including private and noncommercial use of seeds by farmers.[33] As noted in table 3.2, in five of seven cases the bilateral agreement includes a commitment by the US trading partner or partners to implement patent protection for higher-order

33. It is interesting that CAFTA-DR contains a footnote making this limitation explicit and also stating that there is no conflict between UPOV 1991 requirements and provisions of the CBD. See the text at www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf (accessed on June 1, 2012).

Table 3.2 Comparison of TRIPS-Plus elements in selected US free trade agreements

Agreement	Date in force	Patent eligibility	Pharmaceutical term extension	Pharmaceutical second use	Generic ban	Working requirements
Jordan	December 2001	Life	Yes	Yes	Notification	Imports
Chile	January 2004	Life	Yes	No	Yes	TRIPS
Singapore	January 2004	Life	Yes	No	Yes	TRIPS
Australia	January 2005	Life	Yes	Yes	Yes	Imports
CAFTA-DR	2005–09[a]	TRIPS	Yes	No	Yes	TRIPS
Morocco	January 2006	Life	Yes	Yes	Yes	TRIPS
Peru	Signed April 2006	TRIPS	Yes	No	Yes[b]	TRIPS

Agreement	C license	Test data	Plant varieties	Parallel trade	Copyright term
Jordan	Restricted	Equal	UPOV 1991	No	TRIPS
Chile	TRIPS	5 + 10	Patents	TRIPS	Life + 70, 70
Singapore	Restricted	5 + 10	UPOV 1991	TRIPS	Life + 70, 70
Australia	Restricted	5 + 10	Patents	No (patents)	Life + 70, 70
CAFTA-DR	TRIPS	5 + 10	UPOV 1991; commit to patents	TRIPS	Life + 70, 70
Morocco	TRIPS	5 + 10	Patents	No (patents)	Life + 70, 70
Peru	TRIPS	5 + 10	Patents	TRIPS	Life + 70, 70

Agreement	Software	Digital copyrights	Anticircumvention	Exceptions
Jordan	TRIPS	WCT, WPPT	Yes	TRIPS
Chile	TRIPS	WCT, WPPT	Yes	Limited[c]
Singapore	TRIPS	WCT, WPPT	Yes	Limited
Australia	TRIPS	WCT, WPPT	Yes	Limited
CAFTA-DR	TRIPS	WCT, WPPT	Yes	Limited[c]
Morocco	TRIPS	WCT, WPPT	Yes	Limited
Peru	TRIPS	WCT, WPPT	Yes	TRIPS

CAFTA-DR = Central American Free Trade Agreement–Dominican Republic; TRIPS = Agreement on Trade-Related Aspects of Intellectual Property Rights; UPOV = International Union for the Protection of New Varieties of Plants; WCT = World Intellectual Property Organization Copyright Treaty; WPPT = World Intellectual Property Organization Performance and Phonograms Treaty

a. CAFTA-DR was signed into law in the United States in 2005 and was implemented in other member countries at various times between 2006 and 2009.
b. Peru must prevent generic entry but offer entrants the chance to oppose validity of the patent in force.
c. Chile and members of CAFTA-DR have greater flexibility than those in other "limited" free trade agreements to permit copyright exceptions in software decompilation, research, education, and government use.

life forms, going beyond the requirement in TRIPS Article 27.3(b). The exceptions are CAFTA-DR and the Peru Trade Promotion Agreement, which was signed in 2006 and went into force on February 1, 2009. As for plant varieties, in four cases the partner agreed to implement plant and animal patents over some period of time, while members of CAFTA-DR are committed to using best efforts to implement plant patents.[34]

Other areas in which patents could be provided are computer software and business methods (typically as embodied in computer programs). One way in which the policy of extending patents to new areas is encouraged in recent FTAs is to adopt the broad US definition of industrial application (a basic requirement for patentability), also called the utility standard in US law. This broad definition permits patenting of business methods (that do not pass the narrower "industrial applicability" test in the European Union) and experimental inventions with limited use in industry, such as research tools. Still, as noted in table 3.2, none of the FTAs explicitly mandates patents in computer programs, leaving countries with the TRIPS standard (copyrights) as the default option.

A second issue is to provide patent-term extensions for drugs and agricultural chemicals in cases where health authorities issued marketing approvals with undue delays and, therefore, reduced effective patent duration. As seen in table 3.2, this provision exists in all the FTAs. Another is for authorities to grant "second-use patents," or protection to known drugs that are shown to be effective in treating indications beyond that in the initial claims. Such patents can effectively extend patent protection for chemical entities beyond their original applications. This provision exists in three of the seven FTAs. Yet another is to limit experimental use of patented materials and also to restrict their use by potential generic firms in preparation for entry as patents expire.

Perhaps most significant is the demand that health authorities ban the registration of any generic drugs during the lifetime of a patent. Specifically, this so-called linkage rule would preclude approval of any generic entry until the drug regulatory authority could certify that no patent would be violated by it. Table 3.2 shows that in the case of Jordan the requirement is solely that the patent owner be notified of the identity of any firm asking for marketing approval of a generic during the patent term. This provision was upgraded to a linkage-rule ban on generic entry in the agreements with Chile, Morocco, Singapore, Central America and the Dominican Republic, and Peru. In the Peruvian case, however, a safeguard for the health authorities was carved out: Generic entry must be disallowed but the patent regime must offer a means for the potential entrants to challenge the validity of the original patents.

Turning to two final patent issues, Jordan agreed in its early FTA to define "working" to include the act of importation by the patent holder. However, the other FTAs are silent on this subject, leaving its scope rather ambiguous, as in TRIPS. And in three cases the agreements further limit the ability of govern-

34. These practices were already in Australian law.

ment authorities to issue compulsory licenses beyond the restrictions set out in TRIPS. This is perhaps unsurprising in the cases of Singapore and Australia, which have strong ownership rights in IPRs.

As for protecting against unfair use of confidential test data, the United States has succeeded in exporting its legal standard of five years for pharmaceutical products and 10 years for agricultural chemicals in all cases. Jordan agreed to a standard of protecting the data for a period at least equal to that of the country in which an applicant has achieved marketing approval and has submitted the information from that process to Jordan for certification. The periods adopted generally begin from the date on which the original applicant, which submitted the data, is granted marketing approval. This provision means that exclusive marketing rights exist in such circumstances, even if a patent is not granted. It also can effectively extend patent rights in cases where they are granted, if marketing approval comes late in the patent period.

There is also some variation in the FTAs as regards the permissibility of parallel imports. Jordan agreed to make such imports illegal in copyright-protected goods, while Australia and Morocco did so for patented products. Australia remains open to parallel imports in copyrighted goods. The remaining FTAs, however, do not discuss the issue and leave the discretion offered by TRIPS in place.

Turning to copyrights, the United States has consistently negotiated a term of protection of life plus 70 years for authors and composers and 70 years for works of corporate or institutional authorship, with these dates beginning upon first publication. In the United States itself these standards are life plus 70 years in the first case and 120 years after creation or 95 years after publication, whichever comes first, in the second case. Thus, while the FTAs come up short of the current US standards, they exceed the TRIPS protection periods of life plus 50 years for authors and composers and 50 years for works of corporate or institutional authorship. As for digital copyrights, the basic level of protection arises from the WIPO treaties, which each FTA partner is required to ratify. In particular, each country must enact laws against circumvention of technological access controls and other means of digital rights management. The treaties also call for protection for performers and broadcasters, while the FTAs also set out expectations for protection of authorized satellite signals, both within and across national boundaries. The latter expectation is to be accomplished through specific guidelines in the FTAs and adherence to the Brussels Convention of 1974.[35]

With respect to limitations and exceptions to copyrights, the United States negotiated some restrictions relative to TRIPS in five of seven cases. The exceptions are Jordan, where its early FTA essentially preceded the policy emphasis on this issue, and Peru.

35. See *Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite,* www.wipo.int/treaties/en/ip/brussels (accessed on June 1, 2012). As of early 2011, this convention had 35 contracting parties, not including some of the US FTA partners discussed here.

The Peruvian case is interesting in its own right. Alone among the small developing countries negotiating an FTA with the United States, Peru achieved a number of significant exceptions from the strong TRIPS-Plus program. For example, Lima did not agree to a formal provision on second-use patents, while there are no restrictions on its ability to issue compulsory licenses except those in TRIPS. The country remains open to parallel imports and has perhaps the most permissive language among these FTAs regarding fair use and L&Es in copyrights. Most significantly, it is the only FTA with the United States to explicitly affirm that, at least with regard to test data and market approvals in pharmaceuticals, nothing precludes Peru from taking advantage of the WTO Doha Declaration on TRIPS and Public Health or any TRIPS waivers and amendments enacted to support that declaration. It is no accident that Peru took this stance. The country had access to advisors and NGO analysts who sharply disapproved of the TRIPS-Plus approach. More broadly, Peru's approach reflects to some degree a groundswell of opposition to strong TRIPS-Plus standards in bilateral trade agreements, as discussed in the following section.

Even more important were evolving political conditions in the United States. By 2006 concerns had been raised within the US government about the implications of the strategy for development and public health prospects in poorer trading partners (Correa 2006, Roffe and Spennemann 2006). Indeed, in March 2007, 11 members of Congress sent a letter to US Trade Representative (USTR) Susan Schwab arguing that provisions in recent FTAs regarding data exclusivity, patent extensions, compulsory licensing, and other factors were inconsistent with the Doha Declaration on Public Health and urging that these agreements be revised to achieve adherence.[36]

There followed in May 2007 a bipartisan agreement between the Bush administration and Democratic congressional leaders to scale back some of the TRIPS-Plus provisions in medicines in FTAs then under negotiation. For example, the agreement softened the requirement for extended patent terms associated with regulatory delays, substituting an exhortation for making best efforts to approve patents and authorize marketing in an expeditious fashion. US policy would no longer demand that medical authorities link marketing approval of generics solely to a drug's patent status. The agreement also established that countries may take exception to the requirement for test-data protection in cases where it might compromise public health. Finally, the agreement affirmed that provisions of US FTAs should not be interpreted to deny countries the ability to take measures to protect public health, including ensuring access to medicines. These latter provisions effectively recognized

36. The letter is posted at www.twnside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.030705.htm (accessed on June 1, 2012).

that FTA partners should have the authority to grant compulsory licenses in cases of public need.[37]

Note that this agreement applies only to the FTAs with Colombia, Panama, and Peru. However, it is likely to serve as the basis for intellectual property chapters in preferential agreements reached by the United States going forward. At the same time, the USTR continues to face pressure from the US business community to seek strong intellectual property protection, leaving the office in a delicate balancing position. For example, the United States is currently negotiating with eight Asia-Pacific trading partners to establish a Trans-Pacific Partnership (TPP) agreement. The USTR released a white paper in September 2011 describing a new strategic initiative, Trade Enhancing Access to Medicines (TEAM), that is supposed to enhance access to both innovative and generic medicines in the TPP region. Its central feature is an "access window" that would require innovators to bring their patented medicines to market within an agreed time period, or else face expedited generic entry. The notion is that originator drugs will come to market more quickly, which should have therapeutic benefits. The USTR also claims that the initiative will increase legal certainty for producers of generic medicines, largely by making it clearer when patents will expire. However, the white paper did not indicate how long the access window would be open, a question presumably subject to negotiation. The TEAM also puts considerable emphasis on reducing trade in counterfeit medicines through customs and criminal enforcement within the TPP.

It remains to be seen whether this initiative will go beyond the talking stage and, if adopted by the TPP, will actually improve access to generic medicines. The US position in pharmaceuticals still retains such TRIPS-Plus elements as test-data protection and patent-term extensions for those innovators who operate within the window. Representatives of access-oriented NGOs, such as Médecins Sans Frontières, were quick to criticize the initiative as simply a way to bring high-cost patented drugs to market faster without addressing the affordability question.[38] As an economic matter this judgment seems premature, since the access window has the potential to accelerate competition among both innovators and generic producers to some degree.

The European Free Trade Association and the European Union

The remaining members of the EFTA (Norway, Switzerland, Iceland, and Liechtenstein) have pursued similar TRIPS-Plus provisions in their FTAs with Chile (signed in 2003), Lebanon (2004) and Tunisia (2004).[39] Thus, for ex-

37. See Fink (2008) and Roffe and Vivas-Eugui (2007) for details. The agreement is described at www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf (accessed on June 1, 2012).

38. "USTR White Paper on Trade in Medicines Raises Questions," *Intellectual Property Watch*, September 14, 2011.

39. See Abbott (2004) and Roffe and Spennemann (2006).

ample, data exclusivity is required for five years in Chile and Tunisia and six years in Lebanon, though it can be waived in the latter two cases if adequate compensation is paid to the data developer. Otherwise, the FTAs reached by EFTA with developing countries are largely based on TRIPS, supplemented by an expectation that the partner country accede to the WCT and WPPT.

Like the United States, the European Union is an enthusiastic proponent of bilateral trade agreements and has struck 18 of them with developing countries in the Middle East, North Africa, Eastern Europe, and elsewhere, with numerous others under deliberation (Horn, Mavroidis, and Sapir 2010). A major priority is to expand international protection of selected European geographical indications. As noted above, the European Union spearheads attempts at the WTO to establish a multilateral register for geographical indications and to extend the protection of wines and spirits to other agricultural products. In its bilateral and regional trade agenda, however, the European Union pushes for greater protection.

In general, place names may be protected by trademarks or explicit geographical indications, depending on the legal practice of partner nations. However, in the case of wines and spirits the European Union asks for recognition of selected geographical indications that is equivalent to its own high levels. In its agreements with significant wine-making and spirits-producing nations, including Australia in 1994 (this accord preceded TRIPS), Chile (2002), Mexico (1997), and South Africa (1999), the European Union negotiated such equivalence (Vivas-Eugui and Spennemann 2006).[40] In particular, these texts call for each partner country to protect geographical indications at a level that follows the systems in the countries where the products originate. Thus, countries must overturn and deny the use of trademarks that incorporate or mimic EU geographical indications and must phase out over a period of time the use of generic geographical terms such as "champagne" or "port."[41] In contrast, TRIPS permits continued good-faith use of generic names and trademarks that are similar to geographical indications if they had already been on the market.

Further, EU partners must provide protection on a reciprocal basis, in essence requiring automatic registration of EU-certified geographical indications rather than an examination process consistent with TRIPS. These nations also must reserve use of the listed names exclusively for the products origi-

40. Somewhat less restrictive rules apply to an agreement with Mexico covering spirits.

41. In September 2010, a new bilateral wine agreement went into effect ensuring protection of EU-registered geographical indications and traditional expressions in Australian wines sold domestically and exported anywhere. Australian wine producers agreed to phase out use of such seemingly generic names as champagne, port, and sherry, along with some traditional expressions, such as Amontillado and Claret. However, they get to retain use of certain quality indicators (unrelated to location), such as tawny, cream, and vintage. The agreement reflects a delicate balance of interests among producers. See "EU-Australia wine trade agreement enters into force," press release, Brussels, August 31, 2010, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1078 (accessed on June 1, 2012).

nating in the partner countries where they were originally registered. Finally, countries must protect "traditional expressions" associated with the production of wines and spirits, such as eiswein, tawny, grand cru, and reservas. These are not geographical indications because they are not attached to particular locations, but serve to offer exclusive rights to products made with those processes or achieving certain colors or other attributes.

Other than geographical indication protection, earlier EU agreements were restrained on TRIPS-Plus issues, generally listing an expectation that partner countries would offer nondiscriminatory access to intellectual property protection and would uphold TRIPS, UPOV 1978 or 1991, WCT, WPPT, and a selection of other international conventions. Recently, however, EU negotiators have sought considerably greater protection in pharmaceuticals, particularly as regards confidential test data. This shift in emphasis comes despite the preference of the European Parliament not to do so, as stated in the European Parliament Resolution of July 12, 2007, on the TRIPS Agreement and access to medicines. This document (paragraph 11) calls on the European Council "to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licenses, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries."[42]

A shift toward broadly preferring TRIPS-Plus measures may be seen in several EU FTAs with developing countries. Thus, agreements with Jordan, Tunisia, Morocco, Mexico, Bangladesh, South Korea, Egypt, Algeria, Lebanon, and Syria require partners to join the WCT, WPPT, UPOV 1991, and the Budapest Treaty, which is a WIPO-administered agreement on procedures for depositing microorganisms in anticipation of patent applications.[43] The South African agreement requires patents in biotechnological inventions. Similar requirements were entered into the draft FTA between the European Union and the Association of Southeast Asian Nations (ASEAN), along with patent-term extensions and data exclusivity. However, those talks were halted in March 2009 and the European Union moved deeper into bilateral negotiations with individual ASEAN nations.[44] In early 2011, the EU Parliament approved an FTA with South Korea that calls for both patent extensions to

42. TRIPS Agreement and access to medicines, July 12, 2007, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:175E:0591:0594:EN:PDF (accessed on July 14, 2012).

43. This agreement permits patent applicants to deposit examples of microorganisms with one of several internationally recognized agencies rather than in every country where they wish to gain protection.

44. EU Trade, European Commission, Overview of FTA and Other Trade Negotiations, June 26, 2012, http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_118238.pdf (accessed on June 1, 2012).

compensate for regulatory delays in approval of new drugs and 10-year data exclusivity protection.

It is worth noting that the European Union has had less success in achieving TRIPS-Plus standards in its ongoing negotiations with India on a bilateral FTA. India has agreed to strong protection for geographical indications and, indeed, prefers to extend it to agricultural products. However, it has not agreed to patent-term extensions or protection of test data, though the European Union inserted such provisions into draft texts.[45] Nor has India concurred on adopting terms of UPOV 1991 regarding rights in plant varieties. Neither has it been willing to give up its rules for disclosure of origin of genetic resources for patent eligibility. India has refused to negotiate on accepting the EU sui generis protection system for databases and the draft text has copyright protection terms shorter than those in Europe. No agreement has been reached on requirements for protecting against circumvention of technological measures and digital rights management in copyrighted products or transmissions.

Trade Preferences and Bilateral Investment Treaties

The United States and the European Union also tie their trade preferences and bilateral investment treaties to IPRs. Thus, effective intellectual property protection is expected of developing countries hoping to benefit from trade preferences in the US market. For example, Colombia and Peru are beneficiaries of the US Generalized System of Preferences and the Andean Trade Preference Act (ATPA), which was recently replaced by the Andean Trade Promotion and Drug Eradication Act. All of these laws impose high standards for IPRs.[46] As for bilateral investment treaties, the United States generally includes language treating IPRs as equivalent to other forms of property owned by investors in partner countries.[47] Thus, investors may use those rights as they wish under all legal provisions and the nondiscrimination requirements essential to bilateral investment treaties.

45. "EU-India FTA Negotiations," draft text as of February 24, 2009, www.bilaterals.org/IMG/pdf/EU-India-Texts_Goods_SPS_IPR_feb2009.pdf (accessed on June 1, 2012). See also Correa (2006).

46. "Colombia: A Country where Formalities Matter, " *Managing Intellectual Property*, September 2004, www.managingip.com/Search-Results.html?Home=true&Keywords=colombia+formalities+matter. In 2004, the Pharmaceutical Research and Manufacturers of America petitioned the USTR to remove Peru from the list of ATPA beneficiaries because of its "nullification of patents" and failure to provide effective data exclusivity (Mayne 2005, 9).

47. In Maskus (2012b) I offer an extensive analysis of the treatment of IPRs in bilateral investment treaties and other investment agreements.

A Powerful Pushback

The TRIPS Agreement was adopted in 1995 and quickly encountered critical reviews. An important early commentary by the United Nations Conference on Trade and Development (UNCTAD) pointed out that IPR laws and standards were traditionally national in scope and naturally varied by level of economic development and per capita income (UNCTAD 1996). It called on developing countries to take advantage of the limitations and flexibilities retained in TRIPS. An influential report from experts assembled by the UK government reinforced this view (Commission on Intellectual Property Rights 2002). It was highly skeptical of the potential for TRIPS standards to promote economic development and encouraged developing countries to undertake the minimum required implementation. A few years later an influential scholarly piece looked deeply at TRIPS and suggested a moratorium on additional global standard setting so that poor nations could adopt suitable policies (Maskus and Reichman 2005b). That paper was the first to encourage developing countries to experiment with newer and more competitive regulations than those in TRIPS. Carolyn Deere (2009) provides a critical review of how key developing countries chose to implement TRIPS and related standards, along with the technical and political problems they faced.

These commentaries are rather mild in comparison to the torrent of sharp criticisms aimed at what some see as a strongly protective global IPR regime (Stiglitz and Charlton 2005, Netanel 2009). Even harsher comments have been aimed at the TRIPS-Plus strategies pursued by the United States and the European Union. Indeed, it seems that opposition by health professionals in partner countries, NGOs, and members of the US Congress raised enough concerns that the USTR now implicitly deemphasizes this aspect of its regional trade policy.

Although there are many specific issues, in broad sweep there are several primary complaints about the newly globalized regime. First, despite the wiggle room left in TRIPS variously described as flexibilities or limitations and exceptions, the fact that it set higher minimum IPR standards, and that these are binding commitments under WTO rules, struck many observers as an inappropriate claim on national sovereignty. This one-size-fits-all mentality is unusual in global commercial regulation and unlikely to be optimal for many countries. Further, it was seen as unbalanced because the minimum standards were largely taken from US and EU laws and practices. Those countries had few significant reforms to make, while most developing countries were obliged to adopt substantially more protective IPRs than they had in place.

Second, while the idea that a more globalized regime could benefit developing countries is enshrined in the TRIPS text, it is far from a self-evident proposition as a matter of economic or social policy. That agreement, and especially the TRIPS-Plus mandates in FTAs, energized complaints that the evolving regime simply did not pay sufficient attention to the policy needs of developing countries, especially the poorest among them. To many, the system

seems heavily imbalanced in favor of rights holders, who remain located overwhelmingly in a small number of advanced economies.

Third, as noted in the prior chapter, governments in many developing economies do not see material evidence of the primary benefit claimed by TRIPS advocates: a flowering of inward technology transfer and a consequent rise in productivity.

Fourth, the new rules seem to usher in an intermediate-run increase in market power in drugs, agricultural technologies, software, and other key inputs without a clear promise of long-run economic or social gains.

Finally, the evolving system paid attention to the exclusive rights of private knowledge developers without sufficient regard to the implications for global public goods provision. A policy backlash was inevitable.

At the official level the most important element of this pushback is the WIPO Development Agenda. For decades the WIPO had the single aim of facilitating international protection of intellectual property, essentially without regard for the implications of more rigorous standards on economic development and national social objectives. In the face of growing doubts, Brazil and Argentina in 2004 advanced opening statements at the WIPO about the need for the agency, in both its policy work and negotiations, to pay closer attention to the relationships between IPRs and development. Those two countries quickly grew into a group of 15 nations making up the "Friends of Development." Since 2004 this group and other developing-country delegations at the WIPO have put forward comprehensive proposals to push the institution toward advocating and facilitating a flexible approach to IPRs that takes development issues into account. These ideas encompass widely varying elements, including a treaty to ensure free access to knowledge generated by publicly funded research, government policies to encourage technology transfer to poor countries, freedom to limit the scope of drug patents in pursuit of public health objectives, means to diminish the digital divide between rich and poor countries in access to the internet, and rules providing for recognized limitations and exceptions on the scope of copyrights in digital goods.

If adopted, a number of these proposals would radically change the global IPR landscape. Unsurprisingly, they have been opposed by major developed countries. For example, an access-to-knowledge treaty encounters resistance from the United States, European Union, and other countries that generate basic knowledge, often at high public cost. Also unacceptable to US and EU policymakers are a WIPO policy supporting unrestrained compulsory licensing in medicines, particularly in middle-income countries, and a global endorsement of free access to digital goods under a definition of international L&Es. Thus, during subsequent years the scope of the Development Agenda deliberations was significantly reduced. However, in 2008 the WIPO created a Committee on Development and Intellectual Property to rejuvenate the process and facilitate further negotiations, which are ongoing.

A detailed description of remaining proposals would take up too much space in this chapter, but a brief discussion is informative. The first cluster

of proposals relates to the WIPO's technical assistance and capacity-building efforts. Originally, proponents saw these efforts as a way to push the WIPO away from its high-protection approach toward encouraging poor countries to fully adopt TRIPS flexibilities. Under pressure from US negotiators, however, the emphasis shifted toward a "demand-driven and transparent" program of technical assistance, putting the burden on client countries to ask for specific help. Still, current language recognizes that poor countries have distinctive needs in the IPR area and that the WIPO's advice should depend on the level of national development. Particularly notable is that the WIPO would "promote measures that will help countries deal with IP-related anti-competitive practices...in order to better understand the interface between intellectual property rights and competition policies."[48] This emphasis would be new for any technical assistance, not just that of the WIPO. Further, member states would be assisted in making national IPR institutions more efficient and achieving a "fair balance between intellectual-property protection and the public interest."[49] If these objectives were fully emphasized, the WIPO's technical assistance would be completely reformulated in terms of the importance of development-sensitive IPR policy.

The second grouping is about norm setting, policy flexibilities, and the public domain. Here, the primary language remains vague, referring to the need for member-driven consideration of norms, a balance of costs and benefits, and the importance of preserving the public domain. The vision is so broad that little progress toward specifics has been made, despite wide-ranging deliberations.

A third cluster addresses technology transfer, information technologies, and access to knowledge, the areas of greatest emphasis by the original *demandeurs* of the Development Agenda. Here the original language is the most diluted, leaving little suggestion that a multilateral agreement on open access to knowledge might emerge. Rather, delegations suggest exploring means of using "intellectual-related policies and initiatives to promote the transfer and dissemination of technology."[50] Developed nations are also exhorted to "urge their research and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries."[51] While important, these and other provisions actually stop short of the language on technology transfer found in Articles 7 and 66.2 of TRIPS. Thus, the Development Agenda seems unlikely to generate much global policy reform

48. See "The 45 Adopted Recommendations under the WIPO Development Agenda," Cluster A, paragraph 7, available at www.wipo.int/ip-development/en/agenda/recommendations.html (accessed on July 15, 2012).

49. Ibid., paragraph 10.

50. Ibid., Cluster C, paragraph 25.

51. Ibid., Cluster C, paragraph 26.

on access to information, differential charges and terms for using research results, or other key aspects of technology diffusion.

The remaining areas focus on the need for institutional improvements in understanding IPRs. One recommendation calls on the WIPO "...to undertake new studies of the economic, social and cultural impact of the use of intellectual property systems" in member states.[52] In response, the WIPO has established an office of economic analysis, which should help achieve this objective. Another suggests that the WIPO enhance the ability of civil society organizations to participate in its activities. Like the parallel process at the WTO, this will be a task that the secretariat might find challenging.

As a practical matter, the WIPO's Committee on Development and Intellectual Property is charged with overseeing the implementation of recommendations from discussions leading to the 2007 Development Agenda. In principle, implementation of certain aspects of the agenda could engender important and beneficial reforms in the priorities of a narrowly focused and insular agency (De Beer 2009). It could also provide an extended forum where governments can officially recognize that IPRs have significant impacts on development and therefore view it as important to integrate them into development and social policies. Confirmation that national authorities retain space for adopting policies that, while remaining within the broad framework of recognized IPRs, may be tailored to local needs could help reestablish confidence in the global system. The Development Agenda could also mobilize more resources to pay for technical assistance and improvements of institutions in poor countries to allow them to benefit more from reforms in their own IPR systems.

Nevertheless, there is a risk of potentially damaging, if unintended, consequences. First, if the Development Agenda were to result in a sharp revision of the global IPR regime that markedly diminished TRIPS standards, for example, technology-intensive multinational firms might pull back from their increasing engagement with developing countries. Second, technology-intensive firms view the global IPR regime as a means of reducing the speed at which their technologies are learned by competitors, expanding their market power and lead times. These firms have an important influence on policy strategies taken by the United States, European Union, Japan, and other developed economies. If those countries were to sign on to a WIPO Development Agenda with teeth they would surely view it as a concession and ask for some kind of compensation. Elements of this possibility are already evident in the difficulty of achieving agreement at the WTO Doha Round on disclosure requirements on the sources of genetic materials and in the ongoing standoff regarding technology transfer mandates in climate change negotiations. A more practical manifestation may be the new emphasis now being placed on strict international procedures for enforcing IPRs in international commerce, as noted in the next section.

52. Ibid., Cluster D, paragraph 35.

In any event, the Development Agenda is certainly viewed with suspicion. In December 2010, a US ambassador was quoted as saying that a strong development focus at the WIPO would be destructive. "If we get to a system where the protections of patents are abrogated in the name of development, then we certainly will kill that organization."[53]

The New Enforcement Emphasis

A final element of emerging governance moves in the opposite direction. Whatever their legal provisions, implementation of TRIPS and the WIPO treaties has not prevented the rapid global expansion of trademark counterfeiting and copyright piracy. There is irony here, for the original justification for bringing IPRs into the system of global trading rules was precisely to reduce these problems. Of course, the major contributing factor is simply the extremely low cost of copying trademarks and logos, duplicating compact disks, and downloading and sharing songs and movies.[54] Digital technology has moved well beyond anything anticipated by the framers of the TRIPS Agreement.

Not surprisingly, fashion designers, cosmetics companies, pharmaceutical enterprises, and distributors of music, movies, and digital publications find the existing system grossly inadequate for their needs and have pushed for a stronger solution. The primary outcome is the Anti-Counterfeiting Trade Agreement (ACTA), negotiated by a subset of mostly high-income WTO members. Specifically, in April 2011, after three years of negotiations, the governments of Australia, Canada, Japan, South Korea, Morocco, New Zealand, Singapore, and the United States signed the agreement. The agreement was opened for signatures by participants and any other WTO member for a two-year signature period on May 1, 2011, with the European Union (and 22 EU states) signing in January 2012. Mexico and Switzerland, which were participants in the negotiations, along with five EU states, had not signed it as of March 2012. ACTA will take effect in the ratifying nations when six participants have ratified it into law, though no country had done so as of this writing.

ACTA aims to establish an international framework for more effectively addressing counterfeiting and piracy through cooperation by authorities, greater investments in enforcement, and elevated administrative procedures and civil and criminal penalties against counterfeiting and internet copyright piracy. The intent is for these governments to cooperate on policies to enhance international enforcement of IPRs, including infringements in digital technologies, without creating barriers to legitimate trade and digital commerce. ACTA builds on the basic enforcement language in TRIPS, adding stronger

53. "US Ambassador: Over-Focus on Development Will Kill WIPO," *Intellectual Property Watch*, December 17, 2010.

54. The economics of enforcement are addressed in chapter 4.

language in a number of areas, taken largely from legal procedures in the United States and European Union. Some of these areas are left to the discretion of signatories, while others create additional enforcement obligations.

Because ACTA calls for significantly expanded enforcement norms in comparison with TRIPS, it has attracted much criticism. Listed next are the major provisions of the agreement that have prompted considerable opposition from civil society, open-information advocates, consumer groups, and governments in a number of developing nations. First, parties must provide for criminal procedures and penalties at least in cases of willful trademark counterfeiting or piracy of copyright or related rights on a commercial scale.[55] The "related rights" language applies essentially to the rights of audiovisual producers. Acts carried out on a commercial scale are defined as "...at least those carried out as commercial activities for direct or indirect economic or commercial advantage." New here is the concept of "direct or indirect" advantage. Opponents argue that this provision could be applied widely to activities that have no underlying commercial intent, marking an expansive interpretation of criminal enforcement. Criminal procedures are to be applied also for willful importation of labels and packaging that infringe trademarks. Consistent with TRIPS, penalties available for criminal infringement must include prison terms and monetary fines sufficient for deterrence. However, judicial authorities may also order asset seizures commensurate with damages, a new element in international agreements on IPR enforcement.

Second, ACTA contains far more expansive language than TRIPS on the definition of damages that may be awarded. For example, TRIPS Article 45 permits damages "...adequate to compensate for the injury the right holder has suffered...." ACTA repeats this language but adds: "In determining the amount of damages for infringement of intellectual property rights, a Party's judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price." The agreement also calls for authorities to set preestablished damage presumptions for computing damages. Further provisions expand the amount of information that authorities may demand from alleged infringers and obligations to destroy infringing goods and materials and equipment used to make them. Finally, authorities are permitted to act expeditiously against suspected infringement without hearing from the accused parties.

Third, the scope of border measures against suspected counterfeit goods is expanded from TRIPS. For example, on their own authority customs offices may notify rights holders of the entry of suspected infringing goods into a country. Further, authorities may act against in-transit goods suspected of infringement, permitting seizures at the border of goods destined for other markets. Thus,

55. Countries may exclude infringement of patents and trade secrets from civil and criminal measures in the agreement. Requiring their inclusion would have run counter to US law, however the European Union wanted to retain them.

rights holders anywhere can request action in any participant country's port against suspected counterfeit goods en route to another location. Opponents of ACTA paint this as a significant gap through which rights holders can harass producers of legitimate goods and force them to ship through higher-cost channels. A major concern arose when earlier versions of the text suggested that patent-infringing generic pharmaceuticals could be seized and destroyed while in transshipment. However, the final ACTA text clarifies that patents and trade secrets are not covered by its rules on border measures.[56] In a nod to the European Union, border measures need not apply within a customs union or against legitimate goods placed into a market and subject to parallel trade.

The newest elements pertain to enforcement of digital copyrights, toward which ACTA sets out an expansive approach. Thus, civil and criminal penalties must apply to infringement of copyrights and related rights, including over the internet and other networks, a provision that extends to means of permitting widespread distribution (e.g., file sharing). In so doing, a party may permit its authorities to order online service providers to disclose information to rights holders to let them identify infringers. Next, countries must protect against unauthorized circumvention of technological protection against infringement and against efforts to remove or change information regarding electronic rights management. The procedures for these purposes need to be "adequate legal protection and effective legal remedies," but need not be criminal, and countries may sustain certain limitations and exceptions on behalf of legitimate copyright use.

Negotiators recognized that expanding enforcement of digital copyrights would raise hackles. Thus language is included to ensure that measures taken to deter copyright infringement and the circumvention of electronic rights management are implemented in a way that prevents barriers to legitimate online activity and preserves the country's legal conditions with respect to freedom of expression, fair process, and privacy. As noted below, this inclusion has neither reassured critics nor forestalled controversy.

Lastly, the agreement calls for extensive information gathering, data sharing, and transparency in publishing rules and procedures. It also calls for capacity-building and technical assistance to move countries toward best practices. Further exhortations exist for transparency and building public awareness of the costs of counterfeiting and piracy.

As noted above, ACTA will enter into force as soon as six countries ratify it. A primary feature is that other WTO members are invited to join ACTA upon negotiation of the terms of accession. This open membership provision is clearly designed to spread these enforcement practices more widely into developing and transition economies, where much of the infringement originates.

It is obvious why the countries that negotiated ACTA are interested in stronger enforcement. The volumes of counterfeit trade, digital copying, and

56. Recall the earlier discussion of the Brazilian and Indian complaints against the European Union on transshipment of generic medicines.

internet piracy are astounding and negatively affect the profits and employment of high-technology and entertainment firms in developed nations, although by how much is difficult to ascertain. Furthermore, a consequential share of counterfeit goods entering international trade is reckoned to be adulterated and low quality, whether of medicines, food products, machinery, automobile parts, or other critical inputs. These products can be dangerous and should be excluded from markets. Low-quality goods also present companies under whose misappropriated trademarks they are sold considerable challenges in sustaining reputations and retaining consumer loyalty. Finally, it is also thought that organized crime and terrorist groups engage heavily in counterfeit trade, providing another reason to combat it.[57] Few people dispute the importance of these problems.

Nevertheless, ACTA has raised concerns among a number of consumer groups, advocates of access to digital information, and those concerned with free expression and privacy. There are several primary objections. First, ACTA may invite trademark owners to enlist the help of customs authorities to seize and delay shipments of generic goods, especially medicines, to the extent that they may be depicted as counterfeit.[58] To be sure, generics and counterfeits are not the same thing but this distinction is sometimes lost. More fundamentally, a product may not infringe IPRs in the origin or destination market but the authority to seize in-transit goods offers rights holders a means of controlling international competition. Despite the exclusion of patents from the agreement's scope, activists are concerned about the potential for pharmaceutical companies to use ACTA to harass generic drug shipments.

Second, ACTA provides judicial and customs authorities considerable room to act against infringement on their own volition and instructs them to share information about suspected infringement with rights holders. In that sense it represents a shift in emphasis from private enforcement of IPRs—the long-standing tradition—to public enforcement at taxpayer cost.

Third, stiff objections arise with respect to enforcement of digital copyrights. Governments may opt in their own laws to make online service providers liable in some degree for third-party infringement. ACTA says that signatories shall provide authority to act against circumvention and protect electronic rights management, and may choose to oblige online service providers to reveal information about subscriber behavior. These procedures already exist in US law under terms of the Digital Millennium Copyright Act, which might serve as the standard toward which national laws migrate.[59] Similarly, it may encourage countries to adopt policies to cut off internet access after a certain number of infractions, a provision that already exists in the laws of France

57. For vivid descriptions, see Naim (2006) and Phillips (2005).

58. "Anti-counterfeiting trade agreement could endanger lives of people needing affordable medicines," Oxfam International, July 11, 2010.

59. See remarks by Michael Geist in "Europe Learns the Truth(s) about ACTA," *Intellectual Property Watch*, April 7, 2010.

and other developed nations (see chapter 4). Critics see such policies as significant restrictions on privacy and freedom of expression. Still, the final text shies away from requiring that stringent disclosure obligations be placed on online service providers and permits countries to shield them from liability. Further, it permits nations to establish some limitations and exceptions on the scope of measures used to deter circumvention of technological locks and electronic rights management.

Fourth, fundamental concerns are raised by certain developing countries that are concerned that these stronger enforcement measures threaten to supplant the basic language in TRIPS. Arguably, ACTA overturns a key element of the WTO Panel ruling on IPR enforcement in US-China by changing the definition of "commercial scale" infringement to an act that generates any direct or indirect commercial advantage. The WTO determination was that it meant a particular level of activity.[60] If ACTA indeed becomes an agreement with widespread membership, whether through accessions or extension of its provisions through preferential trade agreements, it could displace TRIPS altogether in key areas, despite not having been negotiated in a multilateral forum. In any event, it is another channel for ratcheting up global IPR protection.

A final set of concerns relates to the negotiation process and constitutionality. One of the remarkable features of ACTA is that it was negotiated in complete secrecy, leaving considerable room for controversy to swirl among those suspicious of strongly elevated enforcement practices (Yu 2011). Under Executive Order 12958, the United States asserted confidentiality for ACTA, arguing that unauthorized disclosure of negotiating information would be a threat to national security, surely a novelty in trade agreements.[61] The secrecy meant that interested observers had to speculate about its provisions as they were negotiated, often leading to heated claims, such as that electronic devices of international travelers could be seized at airports, without legal recourse.[62] More fundamentally, while industry interests were surely represented through their influence on trade negotiators, little opportunity was afforded consumer groups or public interest representatives to participate and hold negotiators accountable.

Regarding constitutionality, some US legal scholars argue that ACTA, as a trade agreement, is required to undergo the Senate supermajority approval process that applies to most negotiated treaties (Flynn 2011). The Obama administration, however, argues that it can be implemented by an executive order because none of the agreement's provisions is inconsistent with US law. This difference of opinion may well result in constitutional litigation.

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60. "TRIPS Council Discusses Efficacy of ACTA, Public Health Amendment," *Intellectual Property Watch*, October 29, 2010.

61. This innovation is set to continue, as ongoing negotiations of the Trans-Pacific Partnership Trade Agreement operate under the same rules.

62. "Digital Copyright: It's All Wrong," *Sydney Morning Herald*, June 10, 2008.

Similar concerns exist in other countries that participated in the negotiations. The Mexican Senate voted in 2011 not to implement the law, though the country's executive branch asserts the right to do so on its authority. A report issued by the European Parliament questioned whether certain key provisions of ACTA were consistent with the national laws of several members.[63] In February 2012, the European Commission referred ACTA to the European Court of Justice for an opinion on its consistency with EU provisions on privacy and freedom of expression as regards internet copyrights. In the wake of these concerns, no EU member has moved to implement ACTA, while some, such as Poland, have determined not to. Indeed, on July 4, 2012, the European Parliament voted overwhelmingly to reject ACTA.[64] This rejection raises considerable doubts that the agreement will be ratified by the requisite six countries.

Thus, despite the enthusiasm of its industry backers ACTA faces a tough road in becoming international law. Ironically, this may be a case where secrecy backfired on those who advocated it. So much opposition was raised in the absence of information that the agreement became highly controversial, if not toxic. As a result, the final text was stripped of much of its earlier and strongly protectionist provisions, making it largely consistent with existing national provisions, except for some digital copyright issues that may end up blocking its adoption.

Summary

The years since the WTO was founded have seen the sharpest expansion of protection for IPRs in history, both in terms of the scope of standards and the breadth of coverage across countries. These fundamental reforms, coming first in TRIPS and the WIPO and now proliferating in FTAs and investment treaties, are both extensive and ongoing. Additional areas, such as geographical indications, access to genetic resources, and protection for traditional knowledge, may erect new protection systems altogether. The system is far from static.

The emerging world IPR regime also remains intensely controversial for many reasons. Many societies see the evolving system as imbalanced in favor of intellectual property owners in the developed nations, threatening the viability of imitative firms in poor countries. Civil society groups raise deep concerns about the ethics of gene patents and the terms of access to innovative medicines, green technologies, and new plant varieties. Libraries around the world are worried about their access to copyrighted scientific and educational material. And still many innovator firms find the system too weak for their needs, so they push for higher standards and tighter enforcement mechanisms. This tug of war will continue, as will be discussed in the ensuing chapters.

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63. European Parliament, Directorate General for External Policies, Policy Department, *The Anti-Counterfeiting Trade Act (ACTA): An Assessment*, 2011.

64. "European Parliament Rejection Puts ACTA Future in Doubt," *Intellectual Property Watch*, July 4, 2012.