International Agreements on Intellectual Property Rights: TRIPS and Beyond

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Abstract

In this chapter the author argues that in recent years the world has seen the most significant increases in global protection of intellectual property rights (IPRs) in history. This shift has been the outcome of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization, additional treaties reached at the World Intellectual Property Organization, and, especially, in elevated standards negotiated in preferential trade agreements (PTAs). He discusses the primary standards and expectations in TRIPS, which introduced numerous novelties into global IPRs agreements and has transformed protection regimes in emerging and developing countries. He also reviews remaining policy space and important cases of dispute resolution involving TRIPS issues, noting the clarifications in law and precedents those disputes raised. However, TRIPS alone failed to address important new technological issues, such as copyright protection for digital goods on the internet, nor did it meet the needs of the global pharmaceutical and biotechnology industries. Thus, recent PTAs negotiated by the United States and the European Union have added stronger standards through a process commonly called "TRIPS-Plus". This progression continues in current multilateral PTAs, such as the Trans-Pacific Partnership.

Introduction[1]

The period since 1995 has seen the greatest expansion of global protection for intellectual property rights (IPRs) in history. This fundamental policy shift covers multiple dimensions, including bringing most of the world comprehensively into a more harmonized system, extending legal standards and enforcement expectations across virtually all areas of intellectual property, and tightly linking such regulations to international trade and investment policy. It is no exaggeration to state that IPRs have been elevated from an obscure bit of backwater regulatory policy to the top rank of international structural concerns. Policymakers in nearly all countries now posit that effectively protecting IPRs is a *sine qua non* for promoting economic growth and a shift toward more innovative economies.

This major regime change is the outcome of several international policy initiatives, beginning with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a foundational component of the World Trade Organization (WTO). Policy emphasis on international protection of IPRs quickly migrated to other international organizations, particularly the World Intellectual Property Organization (WIPO) and, especially, to regional trade agreements negotiated chiefly by the United States and the European Union. On the strength of such accords, rights holders generally enjoy stronger and more harmonized global protection for their patents, copyrights, and trademarks.

These changes are the focus of this chapter. The next section describes the primary elements of TRIPS and how it has transformed protection in the developing world. The third section addresses the importance of preferential trade agreements (PTAs) in pushing the protective agenda forward. A final concluding section briefly mentions the mixed empirical

evidence on how effective the new global regime seems to be in encouraging innovation and trade in technology, key objectives of such agreements.

TRIPS and the WTO

The TRIPS Agreement, adopted as Annex 1C of the single undertaking establishing the World Trade Organization, is the most important global accord on IPRs for three reasons. First, it is by far the most comprehensive agreement ever reached regarding policy standards and government responsibilities in this realm. Second, because membership in the WTO is virtually universal it establishes minimum protection norms on a global scale. Third, because TRIPS is covered by 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] TRIPS is therefore the bulwark of the international regime and the basis on which most national legal systems are constructed.

Before considering specific elements of TRIPS, two basic principles about IPRs as regulatory devices should be clarified. First, the standards and policies defining the scope of intellectual property rights are commercial regulations applying to all entities using them. They differ considerably from tariffs and other elements of border trade regulations. Such restrictions are widely recognized as inefficient and costly. Their reduction or removal generally increases welfare in all trading partners, even if it redistributes income within countries. In contrast, there is no clear standard of optimality in the case of IPRs. A country that broadens its patent or copyright protection may generate gains in technology transfer and innovation but may also suffer losses in access and higher-cost imitation. Even this trade-off depends on numerous socioeconomic factors, including national income levels and technological development. Countries vary widely in their attitudes toward IPRs and an agreement to raise standards globally may benefit some trading partners and harm others.

Second, although TRIPS is a multilateral agreement, countries retain considerable ability to determine the precise specifications by which IPRs are protected according to their own legal systems and practices. Patents, copyrights, trademarks and other provisions are *national* rights, not *international* rights. Definitions of patentable subject matter vary across countries, as do limitations on patent scope. There are different national limitations and exceptions (L&Es) on the scope of copyrights. Some countries bar unauthorized re-importation of goods protected by IPRs, while others do not.

Although IPRs are nationally determined, TRIPS does mandate that WTO member nations establish and enforce a set of minimum legal standards, including in such untraditional areas as computer software and geographical indications. These requirements have prompted policy changes in many nations, especially in the developing world. Nonetheless, there remain numerous so-called 'TRIPS flexibilities' that remain widely discussed in public debates. For example, WTO members may deploy measures needed to protect public health and to pursue the public interest in sectors deemed critical to social and technological development.

Such flexibilities notwithstanding, TRIPS markedly raises the average level of protection in the world and holds countries more accountable.[3] In that context, it is unlikely that many of its stipulations would have been voluntarily adopted in the bulk of developing countries, given their continuing status as importers of intellectual property.[4] Many developing countries were willing to accede to TRIPS in return for improved market access for their exports and the expectation that it would raise inflows of investment and technology.[5]

Major Requirements of TRIPS[6]

TRIPS requires WTO members to have IPRs laws and procedures that are non-discriminatory, applying both the national treatment and most-favored nation (MFN) principles,

subject to minor exceptions. Under MFN, any country adopting stronger protection for intellectual property must immediately and unconditionally apply those new standards to entities of all WTO partners. This principle applies to so-called 'TRIPS-Plus' standards countries may adopt through a preferential trade agreement, making such protection available beyond the PTA members alone.[7] This feature means that recent PTAs have ratcheted upward the protection of IPRs globally.

Copyrights

The TRIPS Agreement expanded the scope of copyright protection for authors, composers, and other creative interests, and introduced new protected subject matter. For example, it requires countries to offer copyrights, at a minimum, for a period covering the life of an author or creator plus fifty years, or, where no author is identified, for fifty years. WTO members are free to adopt longer protection, as many have done. For example, the basic period in the United States is life of the author plus 70 years, or 120 years from creation for works developed for hire or made anonymously.

TRIPS introduced significant new global standards beyond duration. For example, it requires that computer programs be copyrighted as literary expressions. It also mandates that compilations of data be protected where their accumulation and arrangement can be considered intellectual creations. However, the Agreement does not require that new software be patented, as in the United States and the EU.[8] Neither does it obligate governments to provide patent-like protection for databases, as exists in the EU. TRIPS does require that copyright owners be permitted to exclude films and computer programs from rental markets. Finally, TRIPS clarifies that artists may prevent recording and broadcasting of their performances, music producers may

deny reproduction of recorded works, and broadcasters may deter unauthorized use of their works, such as television programs.

Despite these changes, TRIPS failed to deal effectively with issues of copyright protection in the digital age, which largely arrived after 1995. Thus, the music, film, game, and software industries have worked tirelessly in the intervening period to expand and sharpen their rights to limit unauthorized downloading and file-sharing, both in national legislation and as a component of PTAs. Opposition to expanding such rights has been raised by certain civil-society groups and university and public libraries.

Patents

TRIPS ushered in several notable minimum standards regarding patent protection. First, patents must be awarded for at least 20 years, making TRIPS the first international agreement with a minimum patent length. Second, patents must be available for both products and processes, addressing the long-standing problem that many developing economies had only offered the latter for pharmaceuticals and chemicals. Third, all fields of technology must be eligible for protection, with exceptions for inventions that may harm public order, threaten human, animal, or plant health, or seriously harm the environment. Countries may also exclude surgical, diagnostic, and therapeutic treatments and may refuse patents for plants and animals other than microorganisms and for methods of biological reproduction, except for microbiological processes. These provisions on patenting life (Article 27.3(b)) remain controversial even after more than two decades of application.

Trademarks and Geographical Indications

The trademark provisions in TRIPS essentially incorporate legal practices, found in the major developed economies, to address misleading or fraudulent use of registered marks. One

challenge in some developing nations has been to implement laws protecting well-known international trademarks, even without local registration. What makes a mark well-known is sometimes vague, leading currently to variability in protection standards.

More controversial was the TRIPS requirement that geographical indications (GIs) be protected. These devices identify a good, such as Bordeaux wines or Gruyere cheese, as being produced in a particular region, where some quality attribute of the product is associated with that location.[9] WTO members are required to establish procedures permitting owners of GIs to prevent misleading or unfair use of their place names. The EU demanded that a stronger set of requirements be put into place for wines and spirits, though prior use in good faith remains permissible under some circumstances.

Plant Variety Rights (PVRs)

TRIPS requires countries to provide developers of qualified new plant varieties exclusive rights to control use of their propagating material (primarily seeds) and harvested products. Such rights are important for seed companies and developers of agro-biotechnological inventions. They were relatively rare in developing countries prior to TRIPS and the international obligation to register and protect PVRs was new.

Countries were obliged to implement either a *sui generis* system of protection, patents for new plant varieties, or both. Regarding the former, developing nations could model their laws on provisions of two versions of the UPOV Treaty.[10] Under UPOV 1978, countries could implement the farmers' privilege, which permits farmers to retain seeds for their own use and to exchange them outside normal commerce, and the breeders' exemption, which allows developers to experiment with protected varieties without the need for a license. The UPOV 1991 Treaty disallowed this non-commercial exchange of seeds and required breeders to gain authorization

for experimenting with protected varieties. The majority of developing countries implemented PVRs systems based on the earlier version, which is no longer open for accession. Others formally joined UPOV 1991, adopting its more rigorous provisions, often in the context of negotiating a PTA with the United States or the EU.

Trade Secrets and Confidential Test Data

TRIPS sets out no substantive obligations regarding trade secrets or confidential business information. It does, however, require governments to let firms take legal measures to prevent their disclosure through dishonest means. Thus, countries had to enact laws that define unfair practices and to establish judicial processes to determine whether methods of unauthorized disclosure were legal.

Far more controversial was the obligation (Article 39.3) that member governments protect confidential testing data, submitted to achieve marketing approval for pharmaceuticals and agricultural chemicals, against disclosure and ensure that the data could not be used unfairly for commercial purposes. Thus, TRIPS certifies that clinical trials data should be protected for some period of time in order to give originator firms a lead-time advantage over generic rivals. However, the agreement does not stipulate a minimum period of protection, leaving authorities free to legislate their own duration. This issue has featured prominently in debates over TRIPS-plus provisions in PTAs.

Enforcement Expectations

TRIPS states that there must be an administrative and judicial system permitting IPRs owners to enforce their rights effectively against suspected infringement. The enforcement procedures must include remedies to prevent and deter infringing activity, including fines, disposal of infringing products, and criminal penalties in the case of willful counterfeiting and

piracy on a commercial level. However, TRIPS does not define 'effective' enforcement, nor does it require countries to establish processes that go beyond their general framework for law enforcement.

There also need to be measures to address infringement at the border, permitting customs authorities to prevent exports of suspect goods and ensure that imported counterfeit products are not released into the market. Some safeguards are stipulated to avoid abuses that could turn such measures into illegitimate barriers to trade. TRIPS is the first international agreement to set out expectations for national enforcement of IPRs.

Residual Policy Space

The TRIPS Agreement undoubtedly ushered in stronger global standards and expectations concerning IPRs protection. However, it also attempted to reach a balance between the needs of private rights holders and the importance of sustaining access for users of new products and technologies, whether to support competition or facilitate acquisition of public goods. This sub-section briefly discusses the primary flexibilities permitted in the agreement in order to understand the policy space remaining for member countries.[11]

One key element is the treatment of *exhaustion and parallel imports*. A country's exhaustion doctrine establishes conditions under which a rights holder loses the ability to prevent further distribution of a good.[12] For physical commodities, these rights are typically exhausted upon domestic first sale. Digital products are the exception, for when someone legally acquires a movie or computer program, the transaction is a licensing agreement that prevents resale by the consumer.

Exhaustion is an international trade issue because IPRs are national in scope, and a country may choose to bar parallel imports (i.e., imports outside the authorized distribution

channel) of goods that were legitimately placed on the market in another country. In the United States, for example, it is generally illegal to import for commercial distribution products that are protected by US patents, designs, and copyrights, a policy of national exhaustion.[13] The EU follows regional exhaustion, permitting free parallel trade among its members but preventing it from outside the single market area. Many developing countries follow international exhaustion, where distribution rights end upon first sale anywhere in the world.

The TRIPS Agreement states (Article 6) that this policy choice is up to individual governments and there is no obligation to permit or prevent parallel trade. After an initial period of debate about the meaning of this provision, a consensus now exists that WTO members are free to regulate parallel trade as they see fit.

A second critical element is the freedom of governments to issue *compulsory licenses* so that domestic firms may use patented technologies without authorization by the rights owners. Authorities in developed countries have long retained the right to permit such unauthorized uses, whether to encourage competition through early working and research exceptions, to discipline anti-competitive behavior by firms with technological dominance, or to ensure government use for public and non-commercial purposes.[14]

The TRIPS Agreement has a general exceptions clause (Article 30), permitting governments to sustain exceptions to exclusive rights so long as they do not unreasonably conflict with the legitimate interests of the patent owner, or unreasonably interfere with her ability to exploit a patent. Many developing countries interpret Article 30 as a broad platform on which to establish limitations on the private exercise of patent rights, including through compulsory licenses.

TRIPS also has extensive language (Article 31) setting out conditions under which governments may award non-voluntary licenses to third parties. These provisions essentially require that reasonable efforts have been made to license the technology in the market, but without success, that the government-authorized use will be temporary, that the license is non-exclusive, and that adequate compensation is paid. TRIPS also permits compulsory licenses of dependent patents and as remedies for anti-competitive licensing practices by patent owners.

The most controversial TRIPS provision in this context is Article 31.f, which states that a compulsory license may only be authorized for production and sale aimed predominantly at the domestic market. This provision was entered at the request of countries with multinational companies seeking to maximize the international profitability of exploiting their patents, for it precludes competition from non-voluntary licensees in global markets. However, the rule was quickly recognized as problematic, for it eliminated the possibility that small countries, with little domestic production capacity, could issue compulsory import licenses in medicines. This difficulty was addressed in 2005 through adoption of an Amendment to TRIPS under which other countries could authorize exports of essential medicines to poor countries lacking such production capacity under compulsory import licenses.[15]

A survey of 49 developing countries found that virtually all had adopted provisions for issuing compulsory licenses by the early 2000s.[16] Most of these laws 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 to compel licensing. A smaller number recognized that such licenses could be issued on grounds of the public interest, national security, and public health. Fewer than half listed the need to remedy anti-competitive practices or the failure of domestic firms to acquire production rights.

A third factor is the ability to issues *limitations and exception (L&Es) on the scope of copyrights*. The reach of copyrights has long been limited by permissible L&Es, such as the fair-use doctrine sustained in the United States. Thus, TRIPS permits countries to adopt L&Es on exclusive copyrights under certain conditions. Examples include making limited personal copies, permitting teachers to use portions of copyrighted works for educational purposes, allowing libraries to reproduce works for preservation purposes, and supporting free access by persons with disabilities, such as the sight-impaired.[17] Such provisions vary widely across nations.

The TRIPS Agreement permits considerable latitude to countries in setting their L&Es on copyrights. For example, while TRIPS requires that computer programs be protected by copyrights at a minimum, it does not address whether program code may be copied and decompiled for purposes of reverse engineering and interoperability. It also permits governments, under certain circumstances, to issue compulsory licenses for copying imported works published abroad.[18]

Dispute Settlement

By the end of 2017, 37 disputes involving TRIPS rules or enforcement had been notified to the WTO dispute settlement body, though panels were formed in just a subset of those cases.[19] While each case is interesting, only five are mentioned briefly here in order to conserve space. These cases illuminate important points with respect to TRIPS obligations.

First, in 1997 Brazil established a local 'working requirement' that firms had to meet to sustain exclusive patent rights. This law required either manufacturing the patented product locally or making full use of the patented process within a certain time period. Failure to comply would subject the patent to a possible compulsory license. In 2000, the United States

complained that requiring local production, rather than importation, to satisfy access needs was inconsistent with TRIPS. Brazil countered that its law complied with the Agreement. In July of 2001 the parties reached a settlement and the United States withdrew the complaint. Brazil promised not to grant a compulsory license against an American-held patent, based on inadequate domestic production, without engaging in prior consultations with the US government. This case suggests that countries may have production-based working requirements, despite the language in TRIPS Article 27.

Second, in 1997 the European Community (EC) challenged two provisions of Canada's Patent Act as they applied to pharmaceuticals. Under its regulatory review exception, the Canadian law permitted generic competitors to use the drug, without authorization, to demonstrate that their versions were effective and safe, thereby gaining marketing approval upon patent expiration. The law also allowed generic firms to produce and stockpile quantities of patented drugs so that they could be sold immediately upon expiration. The dispute panel found that the regulatory review exception is acceptable under TRIPS but the stockpiling exception was an inappropriate use of the product during the patent term. This case clarified that experimental use during the patent term was acceptable, so long as it did not support stockpiling in marketable quantities. Such exceptions are important means by which generic firms can gain rapid entry, and are widely in place in developing nations.

Third, in 1999 the EC challenged Section 110(5) of the US Copyright Act. That provision contains a 'business exemption', permitting small bars and restaurants to play radio and television broadcasts freely and without authorization. An accompanying 'homestyle exemption' allowed the same uncompensated use if establishments used equipment like that found in private homes. The EC argued that the business exemption applied to the majority of

US restaurants and bars, and to nearly half the retail stores in the country, and therefore interfered with the legitimate exploitation of copyrights. In 2000, the panel found that the business exemption violated TRIPS because it was not a minor limitation on the economic value of copyrights. However, the homestyle exemption was found to be acceptable. The United States has yet to amend the law in light of this ruling; rather, it paid the EC $3.3 million as compensation for lost royalties of European music and television rights-holders. This was the first instance of monetary compensation being paid as a resolution of a WTO dispute.

In a fourth case, in 1999 the United States, later joined by Australia, requested consultations with the EC over its registration procedures with respect to geographical indications (GIs). These countries complained that certain regulations and administrative procedures discriminated against firms outside the EU, violating the national treatment and MFN requirements of TRIPS. The ensuing WTO panel in 2005 ruled substantively for the complainants, finding that the procedures did not provide national treatment, primarily because they made GI registration dependent on the domestic government of the applicant adopting a protection system identical and reciprocal to that in the EU. The European Union adopted a new regulation in 2006 that it claimed complied with the ruling, but the United States and Australia argued that it did not reach full compliance and continue to press the case.

A final case was the United States dispute with China regarding aspects of its IPRs protection and enforcement, launched in 2007. The United States charged that China's criminal penalties against trademark counterfeiting and copyright piracy were an ineffective deterrent and that the customs authorities were failing to dispose seized goods properly outside commercial channels. Separately the US argued that the denial of copyrights in China to works that were not approved for local distribution was inconsistent with TRIPS. The WTO panel report essentially

split these claims. The criminal penalty thresholds were found not to be a TRIPS violation, largely because the agreement is not prescriptive in that regard, but the public auctioning of seized goods was inappropriate. Further, China's denial of copyright protection to works not approved for distribution was found to be inconsistent with TRIPS. In 2010 China revised its copyright law and customs regulations to comply with these rulings.

The panel's findings in US-China essentially affirmed that countries retain sovereignty over the scope of penalties associated with enforcing IPRs, so long as procedures are consistent with the overall legal framework. However, authorities cannot unreasonably interfere with the market opportunities of IPRs owners, nor can they use other forms of regulation, such as censorship, to deny copyright protection.

The Role of Preferential Trade Agreements and the TRIPS-Plus Agenda

Despite the comprehensive nature of TRIPS, it did not take long after its introduction for major producers of intellectual property to realize that it failed to achieve a number of their objectives.

WIPO Copyright Treaties

An initial example was that the copyright provisions of the agreement did not anticipate the subsequent emergence of the internet and how it would facilitate the unauthorized use of software and other forms of digital content. Thus, not long after the WTO's foundation this issue was addressed initially by the negotiation of two treaties at the World Intellectual Property Organization (WIPO). These were the WIPO Copyright Treaty (WCT) and the WIPO Performance and Phonograms Treaty (WPPT), both aimed at setting a framework for securing digital copyrights. These treaties have attracted widespread adherence around the world, in part

because the United States and the EU demand such accession by partners in the PTAs they negotiate.

Briefly, 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 and that protection must be provided against circumvention of technological methods used by rights owners to prevent digital copying and retransmission. It also requires that countries have effective remedies against removing or disabling the systems deployed to manage. The WPPT recognized the right of performers and publishers of music and other digital products to authorize recordings of their performances and communication of those recordings and published works over the internet or other channels. These entities were given rights to compensation for the use of their works.

Thus, these WIPO accords set out broad obligations to deal with the problems inherent in trading digital products and services, including unauthorized downloading and circumvention of digital-rights management. As such, they have improved the framework for trading digital content among member nations. However, many countries have taken advantage of the limitations and exceptions they permit, consistent with the earlier discussion of general copyrights. Both treaties also state that nations may select their own policy toward exhaustion of copyrights in software, databases, recordings and other digital products, so that markets may remain open to parallel imports even through electronic means.

Preferential Trade Agreements

From the standpoint of digital content providers these WIPO treaties did not go far enough to meet their evolving needs in a dynamic technological market. That many countries chose to adopt weak provisions (or not enforce stronger rules) disciplining circumvention of

digital copyrights and unauthorized file-sharing was a major frustration for content providers. Other intellectual property concerns remained dissatisfied with the flexible elements of TRIPS itself, such as the ability to exclude certain technologies from patent eligibility, the unclear obligations for test-data protection, and the near absence of substantive provisions for addressing trade secrets.

As a consequence, both the United States and the European Union soon adopted the strategy of expanding the scope of IPRs beyond TRIPS through negotiating stronger standards in bilateral and multilateral PTAs. This focus on demanding “TRIPS-Plus” standards is a central priority of American and European trade policy, albeit with somewhat different emphases. US policy strives to raise standards primarily in the areas of pharmaceuticals, biotechnology, and digital copyrights, while the EU adds protection of geographical indications.[20]

Thus, for example, in recent US-negotiated PTAs a key demand has been to provide patent-term extensions for drugs and agricultural chemicals in cases where health authorities issued marketing approvals with undue delays. Another is for authorities to grant "second use patents", or protection for existing drugs that are shown to be effective in treating indications beyond the initial claims. Yet another is to limit experimental use of patented materials and also to restrict their use by generic firms in preparation for entry as patents expire.

A major change compared to TRIPS is the requirement in some PTAs that local health authorities ban the registration of any generic drugs during the lifetime of a patent. This “linkage rule” precludes approval of any generic medicine until the regulatory authority can certify that no patent would be violated by it. Strong provisions of this type ban generic entry without linkage notifications in the US agreements with Chile, Morocco, Singapore, South Korea, and others.

Regarding protections against unfair use of confidential test data, the United States successfully negotiated the adoption of its own legal standard of five years for pharmaceutical products and ten years for agricultural chemicals in all recent PTAs. These periods begin from the date at 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.

Turning to copyrights, the United States has consistently negotiated a term of protection of life plus 70 years for authors and 70 years for works of institutional authorship. These terms exceed the TRIPS protection periods of life plus 50 years and 50 years, respectively. As for digital copyrights, the basic level of protection arises from the WIPO treaties, which each PTA partners is required to ratify. Thus, in addition to protecting performers, publishers, and broadcasters from unauthorized copying, partners must enact laws against circumvention of technological access controls and digital rights management. Some PTAs with the United States also feature TRIPS-Plus restrictions on the ability to deploy particular L&Es in copyrights. More recent agreements have added language on protection of satellite broadcasts, the responsibilities of internet service providers, and additional scope for civil and criminal penalties for infringing digital copyrights.

That PTAs have become the preferred method for raising global IPRs standards may be seen from reading the intellectual-property chapters in succeeding agreements over time. In the early US-Israel FTA there was just a single paragraph committing both sides to act without discrimination. Each succeeding agreement reached increasingly complex and lengthy chapters, which may be illustrated by the US-Korea Free Trade Agreement, which entered into force in

2012. Chapter 18, covering IPRs, stretches over 35 pages and 12 substantive articles, covering nearly all elements of standards, administration, and enforcement expectations.

Even more expansive was the language on IPRs agreed in the Trans-Pacific Partnership (TPP), the massive PTA negotiated among 12 countries of the Asia-Pacific region, across a mix of developed and developing economies. This agreement, as originally negotiated, would have extended the US model for protecting intellectual property to a large swath of the global economy. The draft text added numerous substantive requirements going well beyond TRIPS and existing US-led PTAs. For example, it called for patent eligibility for plants, animals, medical therapies, and surgical procedures, and clarified the need for issuing second-use patents and delaying generic entry. The IPRs chapter also introduced a period of protection for confidential test data in new forms of drugs, called biologics. It further harmonized minimum protection periods for copyrights, placed limits on fair-use provisions, and issued strong expectations for administrative and criminal enforcement. The TPP also brought in an expectation that countries add criminal penalties to willful violation of confidential business information, or trade secrets, a novel concept in global IPRs agreements.

Thus, the TPP, had the United States not famously withdrawn from it early in the Trump Administration, would have institutionalized a set of standards considerably elevated from global norms. It remains to be seen how much of this expansion may remain as the other 11 countries decide whether to ratify a modified agreement, but the draft TPP set a baseline that is likely to sustain stronger protection, even without US participation.

Concluding Remarks

When negotiated, the TRIPS Agreement was, and remains, the most comprehensive global agreement covering standards of protection and enforcement norms in IPRs. Numerous

developing and emerging nations implemented significant legal reforms over time, according to the allowable transition periods.[21] At the same time, developed economies have continued to advance their own standards, particularly in the areas of digital protection, medical and biological patents, GIs, and trade secrets. Further, recent bilateral and regional PTAs with successively stronger IPRs chapters have ratcheted global protection upward. Together, these changes, despite the policy flexibilities inherent in TRIPS, have strongly increased the global scope of protection for patents, copyrights, and related rights.

Whether this new global regime has achieved an appropriate balance between incentives for innovation and licensing on the one hand, and the needs for access to new goods and information on the other, remains an open question. A positive note is that there is solid empirical evidence that this regime is encouraging the formal transfer of new technologies to emerging countries through enhanced trade and investment in high-technology sectors.[22] Further, innovation seems to be growing in major emerging economies that have introduced markedly stronger patent laws, as measured by the development of new products, additional R&D investments, and foreign patenting.[23] And the introduction of domestic patents is correlated with more rapid introduction of new global pharmaceuticals into developing markets.[24] In this sense, TRIPS and the broader system seem to be improving the global landscape for technology transactions and the use of information.

However, there are reasons to remain cautious about the overall impacts of these policy shifts. First, there is little evidence to date that technology transfers, even through outsourcing within supply chains, are increasing to the poorest developing economies. It appears that reforming IPRs protection by itself is not particularly effective in connecting such countries to the global technological structure. Second, there is no indication that innovative enterprises in

the advanced or emerging economies are investing more in products and technologies that would meet the specific needs of consumers and patients in poor countries. This is particularly unfortunate, for the development of such incentives was touted as a key reason for developing economies to support TRIPS in the first place. Put briefly, stronger international patent protection is not sufficient to overcome other market difficulties that may prevent such innovation and technology diffusion.

Perhaps most importantly, stronger IPRs raise fundamental, and as yet unanswered, concerns about the ability of governments and international organizations to procure needed public goods at reasonable cost.[25] Private property rights in information do not seem to be an adequate global solution to such problems as procuring and distributing essential medicines, transferring green technologies, or diffusing scientific knowledge into the developing world. In this sense, the international system remains controversial and subject to further revisions.

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[1] This chapter draws in part on material in Keith E. Maskus, *Private Rights and Public Problems: the Global Economics of Intellectual Property in the 21st Century*, Peterson Institute for International Economics, Washington DC, 2012.

[2]Interestingly, TRIPS included a moratorium on so-called 'non-violation complaints', which effectively remains in place.

[3] Maskus, supra note 1, reviews various measures of increased protection around the world.

[4] This argument is developed in Gene M. Grossman and Edwin L.-C. Lai, 'International Protection of Intellectual Property', *American Economic Review* 94(5), 2004, 1635-1653.

[5] See Maskus, supra note 1, Joseph E. Stiglitz and Andrew Charlton, *Fair Trade for All: How Trade Can Promote Development*, Oxford University Press, 2005, and Keith E. Maskus, *Encouraging International Technology Transfer*, International Center for Trade and Sustainable Development, Geneva, Issue Paper 7, 2004.

[6] There are numerous detailed descriptions in the literature. An extensive discussion is in International Center for Trade and Sustainable Development, *Resource Book on TRIPS and Development*, Geneva, 2005. See also Maskus, supra note 1, and Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, Oxford University Press, 2009.

[7] For descriptions of the TRIPS-Plus process within PTAs, see Carsten Fink and Patrick Reichenmiller, *Tightening TRIPS: the Intellectual Property Provisions of Recent U.S. Free Trade Agreements*, Washington DC: World Bank Trade Note 20, 2005, and Pedro Roffe and Christoph Spennemann, 'The Impact of FTAs on Public Health Policies and TRIPS Flexibilities,' *International Journal of Intellectual Property Management* 1(1–2), 2006, 75–93.

[8] These jurisdictions vary markedly in this regard. The EU essentially requires that computer programs be implemented in order to effect a useful outcome within a tangible product to be protected, while the United States permits utility to be found within the program itself.

[9] For further analysis see Carsten Fink and Keith E. Maskus, 'The Debate on Geographical Indications at the WTO', in Richard Newfarmer, ed., *Trade, Doha and Development: A Window into the Issues*, The World Bank, 2006, 197–207.

[10] UPOV stands for the French acronym of the International Union for the Protection of Varieties of Plants.

[11] Further analysis may be found in Carolyn Deere, supra note 6, International Center for Trade and Sustainable Development, supra note 6, and several chapters in Keith E. Maskus and Jerome H. Reichman, eds. *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge University Press, 2005.

[12] See Mattias Ganslandt and Keith E. Maskus, 'Intellectual Property Rights, Parallel Imports and Strategic Behavior', in Keith E. Maskus, ed., *Intellectual Property, Growth and Trade*, Elsevier-North Holland, Amsterdam, 2008.

[13] Recent decisions by the US Supreme Court suggest that national exhaustion may no longer hold for patented goods (*Impression Products, Inc. v. Lexmark International, Inc.*, 2017) and copyrighted textbooks (*Kirtsaeng v. John Wiley and Sons*, 2013). However, the full reach of these rulings remains unclear.

[14] For fuller analysis see Jerome H. Reichman and Catherine Hazensahl, *Non-Voluntary Licenses of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of Practice in Canada and the United States*, International Center for Trade and Sustainable Development, 2003.

[15] This amendment has rarely been used, for reasons that are not altogether clear. See Maskus, supra note 1.

[16] Sisule Musungu, Sisule and Cecilia Oh. *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* World Health Organization Study on Intellectual Property Rights, Innovation and Public Health, Geneva, 2006.

[17] See Ruth L. Okediji, *The International Copyright System: Limitations, Exceptions and Public-Interest Considerations for Developing Countries*. International Center for Trade and Sustainable Development, Geneva, Issue Paper 15, 2006, and also Deere, supra note 12.

[18] Despite its complex structure, many WTO participants did not see TRIPS as a finished agreement and there were subsequent calls for its revision within the Doha Round. Key issues included clarification of Article 27.3(b) on patenting of life forms, an international registry of GIs, disclosure of origin of genetic resources in patent applications, and the meaning of Article 66.2 (mandating affirmative actions of developed countries to encourage technology transfer to least-developed countries). For further discussion see Maskus, supra note 1.

[19] See 'Disputes by Agreement' at www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm. Maskus, supra note 1, offers fuller analysis of these disputes.

[20] Roffe and Spenneman, supra note 7, is an early analysis of TRIPS-Plus measures in pharmaceuticals. Maskus, supra note 1, details the American approach while a comprehensive discussion of the EU strategy may be found in the chapters of Josef Drexl, H. Grosse Ruse Khan, and S. Nadde-Phlix, edss, *EU Bilateral Trade Agreements and Intellectual Property: for Better or Worse?* Springer-Verlag, Heidelberg, 2013.

[21] Many of the poorest economies have yet to come into compliance in particular ways.

[22] See the review in Maskus, supra note 1. Recent papers with such findings include Lee Branstetter, Raymond Fisman, C. Fritz Foley, and Kamal Saggi, 'Does Intellectual Property Rights Reform Spur Industrial Development?' *Journal of International Economics* 83(1), 2011, 27-36 and Olena Ivus, 'Do Stronger Patent Rights Raise High-Tech Exports to the Developing World?' *Journal of International Economics* 81(1), 2010, 38-47.

[23] See Yi Qian, 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Protection, 1978-2002,' *Review of Economics and Statistics* 89(3), 2007, 436-453 and Yonmin Chen and Thitima Puttitanun, 'Intellectual Property Rights and Innovation in Developing Countries', *Journal of Development Economics* 78(2), 2005, 474-493, and Branstetter, et al, supra note 23.

[24] See Margaret K. Kyle and Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS*, National Bureau of Economic Research, Working Paper 20799, 2014, Cambridge MA.

[25] See various chapters in Maskus and Reichman, supra note 12.