Intellectual Property and the WTO

By Carsten Fink¹

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I. Introduction

One of the most significant developments of the Uruguay Round of Trade Negotiations (1986-94) was the inclusion of intellectual property rights (IPRs) issues on the agenda of the multilateral trading system. The resulting Agreement on Trade-Related Intellectual Property Rights (TRIPS) is one of three pillar agreements, setting out the legal framework in which the World Trade Organization (WTO) has operated since the end of the Uruguay Round.²

For the multilateral trading system, TRIPS marked the departure from narrow negotiations on border measures such as tariffs and quotas toward the establishment of multilateral rules for trade-affecting measures beyond borders. This move reflected underlying trends in international commerce. Due to the growth of trade in knowledge and information-intensive goods, the economic implications of imitation, copying, and counterfeiting had in many industries become at least as relevant for international commerce as conventional border restrictions to trade.

Yet the TRIPS negotiations on intellectual property were marked by significant North-South differences. Developed countries, which host the world’s largest intellectual property-producing industries, were the key advocates for comprehensive minimum standards of protection and enforcement of IPRs. By contrast, many developing countries, which see themselves mostly as a consumer of intellectual property, felt that stronger standards of protection would serve to limit access to new technologies and products, thereby undermining poor countries’ development prospects. Not surprisingly, the TRIPS Agreement remains one of the most controversial agreements of the WTO.

This short paper seeks to provide an introduction to the main instruments used to protect intellectual property (Section II), the key economic trade-offs of stronger IPRs (Section III), the basic provisions of the TRIPS Agreement (Section IV), and recent TRIPS developments affecting access to medicines in developing countries (Section V). The paper draws heavily from Primo Braga, Fink, and Sepulveda (2000), Fink and Primo Braga (2001), and Fink (2003). A more extensive treatment of many issues raised here can be found in these papers, as well as in Maskus (2000) and World Bank (2001).

¹ Senior Economist, World Bank Institute, World Bank Office in Geneva. Comments from Philip English, Roumeen Islam, Gianni Zanini, and an anonymous reviewer are gratefully acknowledged. The views expressed here are personal and should not be attributed to the World Bank.

² The other two pillar agreements are the Multilateral Agreement on Trade in Goods and the General Agreement on Trade in Services (GATS).
II. What are intellectual property rights?

Intellectual property broadly refers to creations which result from intellectual activity in the industrial, scientific, literary, and artistic fields. Over the course of history, different legal instruments for protecting intellectual property have emerged. These instruments differ in their subject matter, extent of protection, and field of application, reflecting society’s objective to balance the interests of creators and consumers for different types of intellectual works. Table 1 provides an overview of the different IPRs instruments.

*Patents* are legal titles granting the owner the exclusive right to make commercial use of an invention. To qualify for patent protection, inventions must be new, non-obvious, and commercially applicable. The term of protection is usually limited to 20 years, after which the invention moves into public domain. The patent system is one of the oldest and most traditional forms of IPRs protection. Almost all manufacturing industries make use of the patent system to protect inventions from being copied by competing firms. Since the early 1980s, patents have also been granted for agricultural biotechnology products and processes and for certain aspects of computer software.

As an adjunct to the patent system, some countries have introduced *utility models* (or petty patents). The novelty criteria for utility models are less stringent and are typically granted for small, incremental innovations. Their term of protection is far shorter than for “regular” invention patents (typically four to seven years). Similarly, *industrial designs* protect the ornamental features of consumer goods such as shoes or cars. To be eligible for protection, designs must be original or new. They are generally conferred for a period of five to fifteen years.

*Trademarks* are words, signs, or symbols that identify a certain product or company. They seek to offer consumers the assurance of purchasing what they intend to purchase. Trademarks can endure virtually indefinitely provided they remain in use. Almost all industries use trademarks to identify their goods and services. The use of trademarks has turned out to be of high significance in certain consumer goods industries, such as clothing and watches. Similar to trademarks, *geographical indications* identify a product (e.g., wine or olive oil) with a certain city or region.

*Copyright* protects original works of authorship. Copyright protection differs from patent protection in that copyright solely protects the expression of an intellectual creation, whereas the ideas or methods advanced in the title can be freely copied. Copyright protection typically lasts for the life of the author plus 50 to 70 years. It is applicable to literary, artistic, and scientific works. During the past decade, copyright protection has also developed as the main form of protection for computer software. Rights related to copyright—often referred to as *neighboring rights*—are accorded to phonogram producers, performers, and broadcasting organizations. Limits to exclusive copyrights and neighboring rights exist in certain “fair use” exemptions, such as educational or library use or for purposes of criticism and scholarship.
Besides these traditional forms of IPRs, ongoing technological change and the unique characteristics of certain industries and products have led to additional, so-called sui generis forms of protection. *Layout designs for integrated circuits* protect producers of semiconductors. Protection is limited to the design of an integrated circuit and does not restrict reverse engineering of a semiconductor. In this regard, protection of layout designs is similar to copyright. However, the term of protection is shorter than under copyright—typically ten years. Title holders have the right to prevent unauthorized reproduction, importation, sale or other distribution of the layout design for commercial purposes. *Exclusive rights to test data* submitted to regulatory agencies have been granted in the pharmaceutical and chemical industries. Companies that first submit these data can prevent competing firms from using the same data to obtain own marketing approval.

*Plant breeders’ rights* (PBRs) protect new plant varieties that are distinct from existing varieties, uniform, and stable. Exclusive rights, in principle, include the sale and distribution of the propagating materials for a minimum of 15 years. Exclusive rights are typically subject to two general exemptions: the “research exemption,” which permits the use of a protected variety as a basis for the development of a new variety; and the “farmers’ privilege,” which gives farmers the right to re-use seeds obtained from their own harvests. With the advent of biotechnology, however, many breeders in industrial countries are increasingly using the regular patent system for protecting agricultural products and processes. Breeders enjoying patent protection can not only prevent their competitors from using their protected material for breeding purposes, but also prevent farmers from reusing harvested seed.

Finally, the protection of *trade secrets* is part of many countries’ IPRs systems. Trade-secret protection differs from other forms of protection in that it does not grant an explicit title to the creator of an original work. Instead, it protects businesses from the unauthorized disclosure or use of confidential information. Such confidential information includes inventions not yet at the patenting stage, ways of organizing business, client lists, purchasing specifications, and so on. In agriculture, breeders rely on trade secrets to protect hybrid plant varieties, if they can be kept secret. Copying through reverse-engineering does not infringe trade-secret laws. In essence, all industries possessing secret business information rely on trade-secret protection to safeguard their intangible assets.

These legal instruments are just one of the pieces that form a national system of intellectual property protection. Also crucial to the system’s overall effectiveness are the institutions administering these instruments, the mechanisms available for enforcing IPRs, and the rules regarding the treatment of non-nationals.

The administration of IPRs is most significant in the area of patents, industrial designs, trademarks, and plant breeders’ rights. To obtain protection for these types of intellectual property, applicants have to submit their intellectual creations to a national IPRs office, which examines their eligibility for protection. Copyright and neighboring rights
protection typically applies automatically upon creation of the intellectual work, although for evidentiary purposes authors may choose to register their works at copyright offices.

The enforcement of intellectual property rights relies on a country’s judicial system. Title holders fight infringement of their exclusive rights in front of courts. To immediately stop infringing activities, they can request seizures or preliminary injunctions. If the claim of infringement is verified by trial, courts can demand the payment of punitive charges to the infringed title holder (or secret holder in the case of trade secrets).

IPRs are created by national laws and therefore apply at the level of each jurisdiction, independent of such rights granted elsewhere. Accordingly, nations must reach accommodation as their residents seek protection for their intellectual works abroad. Numerous international treaties to promote cooperation among states in the protection of intellectual property have been negotiated over the last 100 years (see Table 1). These treaties are administered by a specialized agency of the United Nations—the World Intellectual Property Organization (WIPO). They typically require their signatories to follow national treatment in the protection of IPRs (equal treatment of nationals and non-nationals) and facilitate the registration of intellectual property titles in foreign jurisdictions. But for the most part they do not promote harmonized standards of protection.

III. The economics of intellectual property protection

Why do governments extend legal protection to intellectual property? One can broadly classify the various forms of IPRs into two categories: IPRs that stimulate inventive and creative activities (patents, utility models, industrial designs, copyright, plant breeders’ rights and layout designs for integrated circuits) and IPRs that offer information to consumers (trademarks and geographical indications). IPRs in both categories seek to address certain failures of private markets to provide for an efficient allocation of resources.

*Patents, copyright and related rights*

IPRs in the first category resolve inefficiencies in markets for information and knowledge. As opposed to, say, an automobile, information and knowledge can be copied easily once it has been put on the market. This characteristic is inherent in what economists refer to as ‘public goods’. As the name suggests, public goods are usually not provided by private markets. Profit-oriented firms have little incentive to invest in the production of public goods, as third parties can free ride on the good once it is first produced. In the specific case of information and knowledge, if creators of intellectual works cannot protect themselves against imitation and copying, they do not have an incentive to engage in inventive or creative activities, as they cannot recoup any expenditure incurred in the process of creating new information and knowledge.
Patents and copyrights offer a solution around this dilemma, as they prevent free-riding on intellectual assets by third parties and thereby create an incentive to invest in research and development (R&D) and related activities. Because the fruits of inventive and creative activities—in the form of new technologies and new products—push the productivity frontiers of firms in an economy, patents and related instruments are often seen as important policy tools to promote economic growth.

At the same time, IPRs in this first category are considered as only “second best” instruments of economic policy. This is because the exclusive rights of patents and copyrights confer market power in the supply of the protected good to the title holder, which poses a cost to society in that firms can charge prices above marginal production costs. In theory, governments can adjust the length and breadth of protection such as to maximize the net benefit that accrues to society from new knowledge and literary and artistic creations, while taking into account the distortion that arises from imperfectly competitive markets. In practice, such a welfare maximization exercise is complicated by the fact that the societal value of new intellectual creations is typically not known in advance and different sectors may require different levels of protection. Actual patent and copyright regimes are typically the outcome of history, rules of thumb, and the influence of vested interests.

Even though patents and copyright are only considered second-best, policymakers see these instruments as superior to government-funded research and artistic creation, as decisions about inventive and creative activities are decentralized and market driven. Government bureaucrats are only imperfectly informed about society’s technology needs, whereas such information is conveyed by market signals. Notwithstanding these considerations, the public sector in middle and high income countries does finance and conduct R&D in areas ignored or neglected by private markets. In particular, this is the case for basic scientific research and areas of technology to which societies attach special importance despite the lack of private demand (for example, aerospace, defense, or neglected diseases).

Patents and copyrights also impact on the diffusion of new knowledge and information. On the one hand, patent and copyright protection has a negative effect on diffusion to the extent that third parties are prevented from using proprietary knowledge. For example, some commentators argue that companies with strong intellectual property portfolios in the electronics and biotechnology industry may stifle follow-on research, as competing innovators cannot—or only at a high cost—access key technologies and fundamental research tools.

At the same time, IPRs can play a positive role in diffusion. Patents are granted in exchange for the publication of the patent claim. In return for temporary exclusive rights, inventors have an incentive to disclose knowledge to the public that might otherwise remain secret. Although other agents may not directly copy the original claim until the patent expires, they can use the information in the patent to further develop innovations and to apply for patents on their own. Moreover, an IPRs title defines a legal tool on which the trade and licensing of a technology can be based. Protection can facilitate
technology disclosure in anticipation of outsourcing, licensing, and joint-venture arrangements. The IPRs system can thus reduce transaction costs and help create markets for information and knowledge.

Governments and academics have long thought to assess how effective the patent system really is in promoting industrial innovation and technology diffusion. In 1958, an economist named Fritz Machlup conducted an investigation on behalf of the United States Congress into the functioning of America’s patent system and concluded:

“If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.”

The effectiveness of the patent system remains a controversial topic to date. Few academics would disagree that the patent system has been a stimulus to innovation over the past decade. At the same time, few academics would say with confidence that today’s patent system strikes the optimum balance between innovation incentives and competitive access to new products and technologies.

**Trademarks and geographic indications**

Trademarks and geographic indications resolve inefficiencies that result from a mismatch of information between buyers and sellers on certain attributes of goods and services. Nobel prize-winning economist George Akerlof first pointed out that markets may fail when consumers have less information about the quality of goods than producers.

Uncertainty about quality will make consumers reluctant to pay for high quality goods, eroding incentives for companies to invest in quality. Trademarks can help reduce—though not completely eliminate—this uncertainty. They identify a product with its producer and his reputation for quality, generated through repeat purchases and word of mouth. Trademarks thus create an incentive for firms to invest in maintaining and improving the quality of their products. Trademarks can be considered as first-best tools of economic policy, in the sense that they do not confer any direct market power and can co-exist with competitive markets. The presence of a trademark does not restrict imitation or copying of protected goods as long as they are sold under a different brand name.

Advertising-intensive consumer products, or so called status goods, constitute a special group within products bearing trademarks. For these types of goods, the mere use or display of a particular branded product confers prestige on their owners, apart from any utility derived from their function and physical characteristic. Since in this case the brand name plays a central role in firms’ product differentiation strategies, it is no surprise to find that owners of well-known brands often register up to 40 or more

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3 See Machlup (1958).
different trademarks to deter competing firms from entering their ‘brand space.’ Market research reports regularly put the value of well-known brands at billions of dollars. For instance, the Mercedes brand is estimated to be worth about 22 billion dollars (see Fink and Smarzynska, 2002). Status value is also associated with certain agricultural products protected by geographic indications, such as sparkling wine from the French Champagne region or ham from the Italian city of Parma.

In the case of status goods, brands can confer substantial market power to producers. In contrast to patents and copyrights, however, market power is not created by trademark ownership per se, but rather by heavy investments in marketing and sales promotion. In addition, firms with valuable brands may not necessarily generate ‘supernormal’ profits. Even though prices may be above marginal production costs, firms have to bear the costs of fixed market investments. Typically, the resulting market structure for many status goods industries can be characterized as monopolistically competitive: firms have a monopoly within their brand space, but have to compete with the brands of close substitute products.

The welfare consequences of status value associated with certain goods are complex and few generalizations can be made. For example, status value may stem from exclusive consumption, or, in other words, from the fact that only a selected group of consumers enjoys them. This interdependency between consumers inside and outside the exclusive group suggests that firms’ marketing activities can make some consumers better off and others worse off (Grossman and Shapiro, 1988).

**IPRs in open economies**

If one moves from a closed economy to an open economy, additional considerations arise. Consider the case of a small economy, in which most intellectual property titles are owned by foreign residents. This economy may be better off by weak standards of protection, if this leads to lower prices for goods and technology and the global incentives for the creation of new products and technologies are not much reduced (Deardorff, 1992). To put it differently, if a hypothetical small economy with little intellectual property ownership introduced patent rights from one day to another, the main effect would be a transfer of rents to foreign title holders, with little benefit to the local economy. At the same time, if a small country has special technological needs not present in other countries, such as drugs to fight country-specific diseases, it has a stronger incentive to protect foreign intellectual property (Diwan and Rodrik, 1991).

An additional consideration is that IPRs are likely to affect the international diffusion of new technologies. On the one hand, one might argue that countries that host few creative industries may benefit from weak IPRs protection, as it would allow them to imitate foreign technologies and thus build technological capacity. For example, India abolished in the early 1970s patent protection for pharmaceutical products and subsequently experienced rapid growth of the domestic pharmaceutical industry (Fink, 2001). On the other hand, it is not always possible to imitate a technology without the participation of
the firm that originally developed it. In these cases, countries have an incentive to protect IPRs to provide incentives for technology transfer to foreign intellectual property holders.

International technology transfer occurs through a variety of channels: trade, foreign investment, and international licensing. Economists have recently attempted to empirically link the extent of trade, investment, and licensing activities to the degree of intellectual property protection in developing countries. While measurement problems are inherent in any such assessment, several empirical patterns have been established. First, international trade flows generally seem to respond positively to the degree of IPRs protection and more so in the case of middle income countries than low income countries. However, this effect is surprisingly absent in the case of high technology products. One explanation is that high technology products may be more difficult to imitate than other products. Another is that high technology companies may choose to invest in countries with stronger protection rather than export to these countries.

Second, and confirming the last point, firm-level studies suggest that intellectual property policies do affect the extent and nature of investments undertaken by multinational enterprises. At the same time, relative to other factors determining foreign investment decisions, IPRs seem to be of relatively minor importance. To illustrate, China has attracted vast amounts of foreign investment, even though multinational companies and foreign governments regularly complain about weak intellectual property enforcement in the country. Finally, the cross-border licensing of technology is found to respond positively to the degree of IPRs protection in the destination country. This is not surprising, given the central importance legal protection for firm-to-firm technology transactions. At the same time, little is known about how the formal transfer of IPRs affects knowledge diffusion and productivity growth in the receiving countries.

IV. The TRIPS Agreement

The TRIPS Agreement is a multilateral WTO agreement and, as such, applicable to all 147 members of the WTO. It is also binding for every country that accedes to the WTO. The Agreement’s general obligations require countries to apply the principles of national treatment (same treatment of foreign title holders and domestic title holders) and most favored nation treatment (same treatment of foreign title holders regardless of their country of origin).

Unlike most other international agreements on intellectual property, TRIPS sets minimum standards of protection with respect to all forms of intellectual property: copyright, trademarks and service marks, geographical indications, industrial designs, patents, layout designs of integrated circuits, and trade secrets. In respect of each of

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5 Fink and Maskus (2004) review the empirical literature on the linkages between IPRs and trade, investment, and licensing decisions in greater detail. Note that most of the arguments on the open economy effects of IPRs presented here apply mainly to patents, copyrights and related forms of protection.

6 The Agreement makes reference to several of the conventions listed in Table 1, requiring WTO members to adhere to certain principles of these conventions.
these areas of intellectual property, the Agreement defines the main elements of protection, namely, the subject-matter to be protected, the rights to be conferred, and permissible exception to those rights.

For the first time in an international agreement on intellectual property, TRIPS addresses the enforcement of IPRs by establishing basic measures designed to ensure that legal remedies will be available to title holders to defend their rights. The approach taken by the Agreement is to set general standards on, among other things, enforcement procedures, the treatment of evidence, injunctive relief, damages, and provisional and border measures.

In principle, the provisions of TRIPS became applicable to all signatories by the beginning of 1996 and are binding to each WTO member. However, developing countries and economies in transition were entitled to a four-year transition period except for obligations pertaining to national and MFN treatment. Developing countries were also entitled to an additional five-year transitional period for product patents in fields of technology that were not protected at the date of application of the Agreement. For pharmaceuticals and agricultural chemicals, however, developing countries have had to accept applications for product patents and grant exclusive marketing rights for five years or until the patent is granted or rejected, whichever is shorter. Least-developed countries were entitled to a 10-year transitional period to comply with the obligations of the Agreement (again, except for national and MFN treatment), which can be extended upon request.

Many developing countries (e.g., Mexico, South Korea) strengthened their intellectual property regimes before the coming into force of the TRIPS Agreement, such that no or only few adjustments were necessary to comply with its provisions. For others (e.g., Brazil, India) certain changes to intellectual property laws have been made since 1996, as these countries have faced the end of the transition periods outlined above.

TRIPS has made disputes between WTO members with respect to the Agreement’s obligations subject to the WTO’s integrated dispute settlement procedures. WTO disputes are always state-to-state disputes. In other words, disputes are not about individual IPRs infringement cases, but are about disagreements between governments on whether a country’s laws and regulations meet the TRIPS requirements. In case a WTO member is found to violate its obligations, complaining governments obtain the right to impose trade sanctions in the form of punitive tariffs. Since 1996, there have indeed been more than 20 TRIPS-related disputes between WTO members. Interestingly, only a minority share of these disputes involved a defendant from a developing country. Most disputes are between developed country members, specifically between the United States and countries of the European Union.

Finally, negotiations during the Uruguay Round left several issues unresolved. For example, the Agreement calls for the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits. Moreover, some members would like to see the higher level of protection for geographic indications
currently granted to wines and spirits applied to other products as well. Little progress has been made on both these issues, however. This reflects to a large degree divisions between the European Communities, the trading block that hosts the largest number of geographical indications, and so-called new world producers (e.g., Argentina, Australia, Chile, the United States), which prefer relatively weaker levels of protection. During the TRIPS negotiations, which focused mostly on wines and spirits, most developing countries showed little interest in establishing strong provisions on geographical indications. Since then, a few developing countries (e.g., Bulgaria, Hungary, Sri Lanka) have taken a more pro-active stance, supporting the demands of the European Union.

A second area of unresolved rule-making concerns the patentability of biotechnology inventions. Currently, TRIPS foresees patent protection for microorganisms and non-biological and microbiological processes, but allows for the exclusion of patent coverage for plants and animals as well as essentially biological processes for the production of plants and animals. The Agreement calls for a review of these provisions. Moreover, some WTO members have linked discussions in this area to clarifying the relationship between TRIPS and the Convention on Biodiversity, as well as to establishing disciplines on the protection of traditional knowledge and folklore. However, little progress has been made on any of these issues.

Economic benefits and costs of TRIPS

As mentioned at the outset, the signing of TRIPS has generated much controversy about its economic implications for developing countries. Proponents of the Agreement have argued that stronger IPRs will stimulate creative industries in developing countries and promote foreign direct investment, with an overall positive development outcome. Opponents of TRIPS have claimed that the Agreement will forestall developing countries’ access to new technologies, lead to higher prices and rent transfers from poor to rich countries, and impose high implementation costs in resource-constrained environments. As always, the truth lies somewhere in between these two polar views.

Developing countries indeed host inventive and creative industries that stand to benefit from stronger IPRs. However, these industries can mostly be found in middle income countries, rather than low income countries. The empirical evidence discussed above on the link between FDI and IPRs, suggests that the mere strengthening of an intellectual property regime is unlikely to result in a dramatic increase in inflows of foreign investment. At the same time, past reform experiences suggest that stronger IPRs can positively impact on domestic enterprise development and foreign investment, if they are complemented by improvements in other aspects of the investment climate.⁷ By signaling a country’s commitment to internationally binding rules, TRIPS can make a positive contribution in this regard—though it is difficult to assess the quantitative importance of this contribution.

⁷ See the review by Fink and Maskus (2004).
Turning to the costs of TRIPS, it is first important to point out that the Agreement did not require to extend IPRs protection to products and technologies already invented. Information and knowledge that were in the public domain at the time the Agreement came into force will continue to be in the public domain. The implementation of the Agreement will therefore not lead to actual prices rises of existing products and related rent transfers, because IPRs protection will only apply to new products and technologies entering the market.\(^8\) Still, as the market share of newly protected products and technologies increases over time, prices above marginal production costs and associated rent transfer are a cause for concern—especially in the case of pharmaceutical products, as will be further explained in the next section.

As for the implementation of the Agreement, a number of commentators have argued that TRIPS poses significant institutional and financial challenges for developing countries. For example, based on figures from World Bank assistance projects, Finger and Schuler (1999) put the cost of upgrading intellectual property laws and enforcement in Mexico at $30 million. For many resource constrained governments in poor countries, implementation costs of this magnitude would likely impose a significant burden on public sector budgets and draw away resources available for other development priorities.

At the same time, it can be questioned whether the $30 million figure from Mexico is a realistic estimate of TRIPS-related implementation costs. The underlying World Bank project in Mexico was not aimed at implementing the TRIPS Agreement (the project was completed before the coming into force of TRIPS) and mostly consisted of activities not directly mandate by TRIPS, such as staff training, computerization of the patent and trademark office, and the creation of a specialized intellectual property court. Indeed, it is important to point out that the institutional obligations of TRIPS accommodate the weaker institutional capacities of developing countries. For example, while TRIPS does set certain principles on rights enforcement, it does not require members to make available more resources to the enforcement of IPRs than the enforcement of law in general. Similarly, in the area of rights administration, TRIPS only requires that IPRs are administered such as to avoid “unwarranted delays” in the grant or registration of an IPR.

More burdensome institutional obligations are more likely to emerge from other sources. The United States has in recent years negotiated bilateral free trade agreements (FTAs) with a number of developing countries that include intellectual property obligations beyond what is required under TRIPS.\(^9\) In particular, these FTAs require governments to put in place more stringent measures for the enforcement of IPRs and remove some of the institutional flexibility embedded in TRIPS. Similar obligations may be placed on countries that are currently negotiating accession to the WTO (e.g., Ukraine and Russia). Even though TRIPS is the primary WTO benchmark on IPRs, existing members of the

\(^8\) The World Bank (2001) presents estimates of rent transfers associated with the TRIPS Agreement. However, they should be regarded as hypothetical and interpreted with caution, as they do not account of the non protection of existing subject matter.

\(^9\) These countries include Bahrain, Chile, Costa Rica, El Salvador, Dominican Republic, Guatemala, Honduras, Jordan, Morocco, Nicaragua, Vietnam, and Singapore. See Fink and Reichenmiller (2004).
WTO have demanded in the past so-called WTO-plus commitments as a condition of entry into the WTO. These WTO-plus commitments can take the form of additional obligations on IPRs enforcement.

Importance of flexibilities

Although the TRIPS Agreement lays the foundation toward higher standards of protection for intellectual property rights on a global scale, it leaves its signatories with important flexibilities in designing national IPRs regimes. It is important for governments to carefully consider alternative ways of implementing provisions in the TRIPS Agreement that only set a broad standard of protection and choose the options that are most suited to domestic needs.

For example, the criteria used for determining the novelty, non-obviousness, and usefulness of patentable inventions can be defined differently across countries. Thus, a WTO member may deny patent protection for, say, business methods that are frequently claimed to involve only a minor inventive step. TRIPS also does not require countries to extend patent protection to computer software as well as plants or animals.

Countries are free to override the exclusive rights of patents by granting so-called compulsory licenses (government authorizations to use a patent without the patent holder’s consent). TRIPS only requires that compulsory licenses be considered on their individual merits and that compensation be paid to rights holders.

In the area of copyright, TRIPS allows for important leeway in defining fair use exemptions to strike a balance between the interests of copyright producers and the interests of the general public.

TRIPS does not address the question of so-called parallel trade. In some jurisdictions, IPRs holders have the right to block the importation of products that they have placed for sale in a foreign market. In other jurisdictions, IPRs holders do not have such a right and parallel imports can be an important means of creating price competition for products such as books, CDs, or pharmaceuticals. Under TRIPS, countries are free to allow or disallow parallel importation.

Additional flexibilities exist in many other areas of TRIPS. As already pointed out, bilateral FTAs or WTO-plus commitments in accession agreements may reduce these flexibilities. It is important for governments to carefully assess whether the benefits of “TRIPS-plus” standards outweigh their costs and defend their interests in the course of trade negotiations.

V. TRIPS and access to medicines

In few other sectors is the role of patents as important—and as controversial—as in the pharmaceutical industry. Research-based pharmaceutical companies invest heavily in the
development of new drugs, which is a risky and lengthy process. At the same time, new chemical entities can easily be imitated by competing firms—unless these chemical entities are protected by patent rights.

The extent to which innovative drug companies have pricing power depends critically on the therapeutic efficacy of a new medicine and the availability of substitute products that compete with this medicine. For some drugs, the pricing power can be substantial. This is revealed when drug patents expire and competing producers—so-called generics companies—enter the market. For example, the wholesale price of Pfizer’s blockbuster drug Prozac fell from $240 to less than $5 per bottle within six months after patent expiry in the United States in 2001.10

The TRIPS Agreement requires WTO members to protect patents without discrimination as to the field of technology, which means that countries are obliged to grant 20-year patent protection for pharmaceutical products and processes. This represents a significant shift in a number of developing countries such as Brazil, India, and Thailand that previously allowed generics producers to freely copy medicines protected by patents in other countries. Those medicines—including many important drugs classified by the WHO as essential medicines—will continue to be available generically at competitive prices. However, the share of patented drugs that will be introduced to developing country markets is likely to increase from 2005 onwards. Even though TRIPS came into force in 1996, it usually takes 8-10 years from the grant of the patent for a new medicine to be introduced to the market.11 Indeed, in some developing countries (e.g., Brazil), some pharmaceutical products patented between 1996 and 2005 have already been marketed.

This shift in global pharmaceutical patent rules has raised concerns that greater pricing power by pharmaceutical companies would adversely affect access to medicines in poor countries. These concerns were brought to the fore by the spreading HIV/AIDS pandemic in large parts of the developing world. Treatments in the form of antiretroviral drugs became available in the second half of the 1990s, but initially these drugs were priced at levels unaffordable to poor people and health systems in the developing world. However, the introduction of generic versions of these drugs—marketed by developing country producers in which these drugs were note patent protected—contributed to a steep price decline, starting in 2000 (see Figure 1).

Responding to concerns that the TRIPS patent rules could undermine access to medicines in poor countries, members of the WTO issued a Declaration at the Ministerial Meeting in Doha, Qatar in 2001. In this Declaration, WTO Members agreed that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.” It reaffirms the right of governments to use compulsory licenses to

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10 As reported by Frontline documentary “The other drug war”, June 19, 2003.

11 In addition, in 2005, those developing countries (e.g., India) that opted for the transitional exclusive marketing rights arrangement (see previous section) will need to grant patents to applications submitted during the transition period.
override the exclusive rights conferred by patents. Moreover, for least-developed countries, it delayed the implementation of TRIPS with respect to pharmaceutical products until 2016 (with the possibility of further extensions).

In the future, granting a compulsory license to a local producer may emerge as an effective strategy to promote generic competition in developing countries that have the capacity to manufacture pharmaceuticals. For example, well-developed pharmaceutical industries can be found in Brazil, China, India, or Thailand. Yet many other developing countries—especially the least developed countries in Africa—do not possess pharmaceutical manufacturing capabilities. These countries can effectively use the compulsory licensing option only if they are allowed to import generic drugs. Yet there was legal uncertainty in the original TRIPS Agreement whether such importation would be allowed if the drug is patented in the exporting country. The ‘Doha Declaration’ acknowledged the difficulties countries with insufficient or no manufacturing capacity face in effectively using the compulsory licensing mechanism and called for negotiations “... to find an expeditious solution to this problem.”

After almost two years of negotiations, WTO Members decided in 2003 on a mechanism that creates a framework for the importation of generic drugs produced under a compulsory license. This mechanism includes several safeguards intended to minimize the risk that drugs destined for poor countries leak in to rich countries’ pharmaceutical markets. While the 2003 Decision still needs to be formally integrated into the TRIPS Agreement, several developing and developed country WTO members have initiated legislative changes that would allow for the export of generic drugs under terms consistent with the Decision.

As pointed out above, most medicines in developing countries have been free of patents, such that there has been little need to issue compulsory licenses. More recently, however, several developing and least developed countries have issued compulsory licenses on selected antiretroviral drugs, including Malaysia, Mozambique, Zambia, and Zimbabwe.12 In addition, the threat of permitting the production of competing generic medicines has led pharmaceutical companies to offer the drugs at cheaper prices themselves. This was arguably the case when some in the United States Government advocated the grant of a compulsory license on the patented drug Ciprofloxacin during the 2001 anthrax crisis. Similarly, the pharmaceutical company Roche offered a 40 percent price reduction on its AIDS drug Viracept to Brazil, after the Government publicly announced in 2001 that it would issue a compulsory license to a local laboratory (Fink, 2003).

VI. Summary of key messages

This short paper offered an introduction to the main instruments used to protect intellectual property, the key economic trade-offs of stronger IPRs, the basic provisions

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of the TRIPS Agreement, and recent TRIPS developments affecting access to medicines in developing countries. The key messages can be summarized as follows:

- Intellectual property rights protect creations which result from intellectual activity in the industrial, scientific, literary, and artistic fields. IPRs instruments encompass patents, copyrights and neighboring rights, trademarks, geographic indications, layout designs for integrated circuits, plant breeders’ rights, and trade secrets.

- IPRs seek to resolve certain failures of private markets. Patents, copyrights and related forms of protection aim at stimulating inventive and creative activities. Trademarks and geographic indications offer information about the origin of goods to consumers.

- For developing countries, stronger IPRs bring about benefits in terms of increased trade, foreign direct investment and technology transfer. However, these benefits mainly accrue to middle income countries and the size of benefits depends on complementary policy reforms, notably improvements in other aspects of the investment climate.

- The main cost of stronger patents, copyrights, and related rights is the market power conveyed to IPRs holders, leading to prices above marginal production costs for the duration of protection. For small developing economies with little inventive and creative capacity, stronger IPRs may lead to rent transfers to foreign title holders.

- The TRIPS Agreement is the most important international agreement for the protection of intellectual property. It is binding to all members of the WTO and enforceable through the WTO’s dispute settlement system. It sets minimum standards of protection for all IPRs instruments, but also leaves governments important flexibilities to design IPRs regimes to suit domestic needs.

- Stronger pharmaceutical patent rights required by TRIPS have raised concerns that greater pricing power by pharmaceutical companies would adversely affect access to medicines in poor countries. To address these concerns WTO members have reaffirmed the right of governments to use compulsory licenses to override the exclusive rights conferred by patents. In addition, a special importing mechanism was created in 2003 that allows developing countries with insufficient pharmaceutical manufacturing capabilities to import generic drugs.
References


Table 1: IPRs: Instruments, Subject Matter, Fields of Application, and Related International Agreements

<table>
<thead>
<tr>
<th>Type of IPR</th>
<th>Instruments of Protection</th>
<th>Subject Matter</th>
<th>Main Fields of Application</th>
<th>Major International Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrial designs</td>
<td>Ornamental designs</td>
<td></td>
<td>Manufacturing, clothing, automobiles, electronics, etc.</td>
<td>Hague Agreement (1925), Locarno Agreement (1979), TRIPS</td>
</tr>
<tr>
<td>Trademarks</td>
<td>Signs or symbols to identify goods and services</td>
<td>All industries</td>
<td></td>
<td>Madrid Agreement (1891), Nice Agreement (1957), Vienna Agreement (1973), TRIPS</td>
</tr>
<tr>
<td>Geographical indications</td>
<td>Product names related to a specific region or country</td>
<td>Agricultural products, foodstuffs, etc.</td>
<td></td>
<td>Lisbon Agreement (1958), TRIPS</td>
</tr>
<tr>
<td>Sui generis protection</td>
<td>Plant breeders’ rights</td>
<td>New, stable homogenous, distinguishable plant varieties</td>
<td>Agriculture and food industry</td>
<td>Convention of new Varieties of Plants (UPOV, 1961), TRIPS</td>
</tr>
<tr>
<td>Trade secrets</td>
<td>Secret business information</td>
<td>All industries</td>
<td></td>
<td>TRIPS</td>
</tr>
</tbody>
</table>

Note: All international treaties except TRIPS and the Universal Copyright Convention are administered by the World Intellectual Property Organization. Years shown refer to the year in which an agreement was first adopted.

Source: Primo Braga et al. (2000).
Figure 1: Originator and Generic Drug Prices for a Sample ARV Triple-Combination

Notes: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.