6. Health and intellectual property rights

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1. THE INTERNATIONAL REGULATION OF IP

Intellectual property (IP) plays a significant, and often controversial, role in the health sector.[1] This book addresses global health law and in that regard is looking at health and IP regulation from the worldwide perspective, rather than from the perspective of a single national or regional territory. Before getting into the specifics of particular forms of IP and their role in the protection and promotion of health, it is important to provide some background into how the international regulation of IP is organized.[2]

As a general organizing principle, IP rights are granted and applied in respect to individual national territories.[3] There is no existing mechanism for the grant of an internationally applied and governed IP right. Each form of IP is granted and implemented at the national level. This organizing principle is essential to understanding how the international IP system functions.

There are, however, long-established treaties that prescribe substantive and procedural rules that obligate national governments to apply certain

[1] Healthcare involves the provision of a wide array of goods and services to individual patients and communities. Healthcare goods include pharmaceutical products, such as therapeutics, vaccines and diagnostics; as well as medical devices such as diagnostic and testing equipment, surgical equipment and supplies, implants and basic healthcare products. Enterprises that produce and supply these goods rely on machinery and equipment that is often specific to the healthcare sector. Healthcare also involves individual professional service providers (including doctors and nurses) that market services directly or indirectly through intermediaries such as hospitals and clinics.

[2] A more detailed explanation of intellectual property and its regulation, including international aspects, can be found in Frederick M. Abbott, Thomas Cottier and Francis Gurry, *International Intellectual Property in an Integrated World Economy* (3rd edn, Aspen Publishers 2015).

[3] Abbott, Cottier and Gurry (n 1) at 80–97. The European Union is somewhat exceptional in this regard as some forms of IP are "regional", but this is largely based on the idea of the EU as a constitutionally integrated region.

standards of protection. The Paris Convention for the Protection of Industrial Property, which covers patents, trademarks, tradenames and unfair competition, dates back to 1883,[4] and the Berne Convention on Literary and Artistic Works, which covers copyright, dates back to 1886.[5] These were two of the first broadly-adopted international economic agreements. More recently, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) entered into force on 1 January 1995,[6] and prescribes minimum substantive standards of protection and enforcement for the main forms of IP. The TRIPS Agreement also introduced a trade-based dispute settlement mechanism that can be used to pressure WTO Member countries to comply with their obligations.

From the perspective of the health sector, the entry into force of the TRIPS Agreement was a significant milestone.[7] The agreement required (subject to transition periods) WTO Members to extend patent protection to all fields of technology, which included healthcare technologies such as pharmaceuticals, and this subject matter had previously been excluded from patentability by many countries. The TRIPS Agreement also introduced the concept of protecting pharmaceutical regulatory data at the multilateral rule-making level, and this likewise had a substantial impact on the global health sector. Later in this chapter we will explore the tension between the IP standards mandated by the TRIPS Agreement and demands for affordable access to medicines.

In addition to broadly-adopted multilateral IP treaties, the past several decades have witnessed a proliferation of bilateral, regional and plurilateral agreements that address IP in ways that are relevant to the health sector. These trade and investment agreements, sometimes referred to as

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[4] Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979). Source: www.wipo.int.

[5] Berne Convention for the Protection of Literary and Artistic Works (as amended on September 28, 1979). Source: www.wipo.int.

[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Apr. 15, 1994, in World Trade Organization, *The Legal Texts: The Results Of The Uruguay Round Of Multilateral Trade Negotiations* 321 (1999).

[7] See generally, ICTSD-UNCTAD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, last updated 1 June 2005, available at https://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

'preferential trade agreements' or PTAs,[8] often include obligations to protect IP in ways that supplement the standards of the TRIPS Agreement and generally limit the exercise of national discretion or flexibility.[9] These are typically referred to as 'TRIPS-plus' standards. TRIPS flexibilities and efforts to limit them are discussed in greater detail later in this chapter.

The Paris and Berne Conventions, and the TRIPS Agreement, address substantive and enforcement standards, and provide some rules regarding acquisition and maintenance of IP. There is another type of international agreement or treaty that facilitate the acquisition of IP rights at the national level. The most important of these from a global health perspective are the Patent Cooperation Treaty (PCT),[10] facilitating filing of patent applications, and the Madrid Agreement and Protocol (Madrid System),[11] facilitating the acquisition of trademark rights, each administered by the World Intellectual Property Organization (WIPO).

In addition to these formal treaties or international agreements, there are various types of working arrangements among national IP offices, including patent offices, that involve sharing responsibilities and that may also facilitate the review of applications and grant of IP rights. The Patent Prosecution Highway (PPH) is one such arrangement that involves mutual recognition of the results of patent examinations among participating patent offices.[12]

International agreements regarding IP are intended to enlarge the geographical scope of right-holder interests by facilitating their ability to secure rights in multiple and diverse jurisdictions, as well as to harmonize or approximate standards at some level. As with other international economic agreements, there is thought to be a benefit to facilitating protection at the international level through efficiencies, including efficiencies gained through requiring IP applicants to comply with a similar

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[8] Such agreements go under a variety of names, including bilateral investment treaties (BITs), free-trade agreements (FTAs), economic partnership agreements (EPAs), trade and investment agreements (TIAs) and so forth.

[9] See Frederick Abbott, 'Trade in medicines' in R. Smith et al (eds), *Trade and Health: Building a National Strategy* (WHO 2015) 117–40, available at SSRN: https://ssrn.com/abstract=2659277.

[10] See WIPO, PCT – The International Patent System, at http://www.wipo.int/pct/en/, done 19 June 1970, as amended.

[11] See WIPO, Madrid – The International Trademark System, at http://www.wipo.int/madrid/en/, Madrid Agreement, done April 14, 1891, as amended; Madrid Protocol, done 27 June 1989, as amended.

[12] See, e.g., WIPO, PCT-Patent Prosecution Highway Pilot (PCT-PPH), http://www.wipo.int/pct/en/filing/pct_pph.html.

set of requirements and meet a similar set of standards. It is probably correct that international IP agreements are a more efficient means of providing IP protection on a global basis than entirely separate national processes and rules.

On the other side of the equation, international IP agreements reduce the discretion afforded to national authorities to make judgments about the social benefits and costs of IP in general and in specific cases. A national government may recognize that agreeing to international standards for IP will have a potential negative impact in terms of the public health budget, but conclude that agreement to these standards is on the whole beneficial to the country because of positive effects in other areas. This puts public health authorities in a difficult situation. A negative impact on the public health budget may not be offset by positive impact of an agreement in other areas (for example, in manufacturing).

We revert later in the chapter to some specifics about how international negotiations on trade and investment agreements address IP in ways that have an impact on public health.

2. SPECIFIC FORMS OF IP

Intellectual property is a defined set of intangibles that is afforded legal protection in the form of rights granted to holders.[13] Intellectual property (IP) is typically referred to by the form of legal protection, mainly patent, trademark, copyright, design right, trade secret, geographical indication and plant variety protection. These forms are referred to as 'intellectual property rights' or IPRs. Certain healthcare products, such as pharmaceuticals and biologic medicines, are granted regulatory protection that may be referred to as a form of IP. The following sections of this chapter introduce key characteristics of the various forms of IP.

2.1 Patents

IP in the form of the 'patent' is traditionally used to promote innovation by providing a monetary reward to an inventor of a new product or process.[14] Patents afford their owners with rights to prevent others from making, using, offering for sale, selling and importing for these purposes patented

[13] See generally, Abbott, Cottier and Gurry (n 1).

[14] A more detailed explanation of intellectual property and its regulation, including international aspects, can be found in Abbott, Cottier and Gurry (n 1).

products, or from using patented processes (and including to import products made by such processes).[15] The minimum term of the patent is 20 years from the date the application is filed. However, in some countries (including the United States and EU member states), the patent term may be extended to take into account the duration of the drug regulatory approval process.[16] The right to exclude third parties from the market is often referred to colloquially as the 'patent monopoly'. Regarding pharmaceuticals, while a patent owner indeed holds a monopoly with respect to the specific compound or biologic substance that he or she invented, this does not necessarily translate into a dominant position in a particular therapeutic class. The extent to which a patent owner controls the market and can exert pricing power will depend upon factors such as the uniqueness of the drug and the availability of effective substitutes.

Pharmaceutical products are of three main types. First, there are medicines that are natural products, such as herbs, that may be processed into different forms (such as powders or liquids), but that largely retain their characteristics as used by patients. Second, there are medicines that are products of synthetic organic chemistry, or chemical compounds, that generally involve the combination of basic elements (such as carbon, hydrogen, nitrogen, phosphorus, oxygen and sulfur) into intermediate compounds, and finally into active pharmaceutical ingredients (APIs). The efficacy of a pharmaceutical compound is not dictated solely by the relative volume of elements in a compound mixture, but also by the molecular structure of the compound (e.g., the way that the molecules are attached to each other). APIs often take the form of a salt or crystalline structure which is combined with 'excipients' such as sugar to create a finished pharmaceutical product in a form that can be placed in a capsule or formed into a tablet and ingested, or liquefied for infusion, or otherwise made deliverable (e.g. through a transdermal patch) to the patient. Third, there are medicines that are biological materials that are produced by replicating cells whose DNA structures typically have been modified from those found in nature. These 'biologics' are replicated under tightly controlled conditions, and are typically infused.

A vaccine is a type of pharmaceutical product that is intended to act as a prophylactic against disease. Vaccines generally involve use of weakened forms of microbes, but are becoming increasingly sophisticated

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[15] See, e.g., WTO TRIPS Agreement, art. 28.

[16] See, e.g., for the EU, Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

through manipulation of DNA in virus samples and through other mechanisms. Vaccines or processes that are used in creating vaccines are the subject of patents.

Patents cover inventions. The decision whether a claimed invention should be awarded a patent is made by examining whether the subject matter meets certain patentability criteria. To constitute a patentable invention, the subject matter must be 'new' or 'novel', meaning it has not been anticipated by prior art. This first criterion seeks to assure that a person is not granted a patent on something that was previously invented. Next, an invention must involve an 'inventive step' (or be non-obvious), meaning that a person reasonably skilled in the art practised by the invention would not have found it an obvious improvement from the existing art. This criterion seeks to prevent the award of patents for insignificant changes to existing technologies by requiring that there be a certain distance between the old and new. Third, the claimed invention must be useful. This criterion has become more important in recent years as new technologies have made it possible to develop or identify new subject matter without knowing what it might be used for. Fourth, the inventor must describe the invention sufficiently to enable others to practice it without undue experimentation. One of the main objectives of the patent system is to introduce information to the public so that it will be free to use once the patent has expired, and to allow it to be studied during the term of the patent. In terms of subject matter, patentable inventions may be products or processes, and each of these categories is subject to its own definitional complexities. For example, routes of administration and even the dosage of a pharmaceutical product may be considered patentable as a 'process' or 'method'. Finally, there are certain types of discoveries that typically are not considered patentable subject matter. These include materials as found in nature, natural phenomenon and abstract principles. As illustration, the US Supreme Court recently decided that genetic material as found in nature, and its corresponding DNA sequences, are not patentable subject matter.[17] We will subsequently discuss how these criteria and subject matter limitations are relevant in the pharmaceutical sector.

Applications for the patenting of pharmaceutical inventions require review by examiners at patent offices with sufficient knowledge in the

[17] *Association for Molecular Pathology v. Myriad Genetics*, No. 12-398 (569 U.S. ___ June 13, 2013).

corresponding areas to be able to properly assess the applications. Even with relatively sophisticated knowledge, given the time pressures and the fact that an application claiming a new pharmaceutical compound or biologic material by definition has not been seen before, examiners face daunting challenges. The examiner must determine whether prior art or earlier disclosure anticipates the invention. The examiner must also determine whether the claimed invention involves a sufficient inventive step over the prior art so as to merit the granting of a patent. The assessment of inventive step is at least somewhat subjective as it asked the question whether a person of ordinary skill in the art would have found the claimed invention obvious considering the prior art.

Pharmaceutical products are complex chemical or biological structures, and the chemical and biological sciences reflected in patent applications is correspondingly complex. For example, it is not uncommon for a pharmaceutical patent to refer to the combination of chemicals from different groups that may literally entail millions of potential compounds. The owner of such a patent may apply for additional patents on specific combinations derived from previously claimed groups (i.e., selection patents) asserting that such specific combinations have unique properties.

It is easier for a pharmaceutical company to modify an existing compound to add some property that may be useful for patients, such as an extended release formula, than to create a new therapeutic class of drugs. Modifying the delivery mechanism or the dosage of a known substance involves substantially less risk than R&D on new types of drugs because there is a substantial amount of information available regarding the known substance, such as its toxicity profile. The question from a public policy standpoint is whether we should encourage companies to invest in minor modifications which may be profitable and may provide some benefit to patients when this is likely to divert R&D resources away from more fundamental inquiries. Moreover, when pharmaceutical companies develop minor modifications they typically engage in marketing practices that are intended to transition physicians and patients from older forms to newer forms in order to maintain profit margins. These practices raise questions regarding the way in which healthcare budgets are spent, whether publicly or privately.

Should patents be granted on minor variations of existing compounds if there is no evidence that the variations generate different patient outcomes (i.e., enhance efficacy)? The government of India imposed such a requirement with respect to new forms of known substances (Section 3(d) of the India Patents Act, 2005 Amendments) and was sharply

criticized by the originator pharmaceutical industry, the US government and others favoring easily granted patents.[18]

No one suggests that minor improvements to pharmaceutical products should not be made. The question is whether patents should be granted on these minor improvements, and whether advertising and promotion budget should be expended to transition physicians and patients to more expensive versions that remain (or are newly) protected by patent.

The patent examiner also needs to determine whether the claimed invention is 'useful'. Application of this criterion has become more challenging as advances in science made it relatively easy for researchers to develop new compounds or biologic materials without any good idea what might be done with them.

Assuming that 'something' might be done with a new compound or biologic material, courts have differed over how much that something should entail. Should the applicant for a patent on a new pharmaceutical compound be required to demonstrate that it will be useful in treating a disease in humans, or should it be enough to demonstrate that the compound generates biological activity in an animal? Originator pharmaceutical companies typically argue that usefulness should be a very low threshold criterion, and that even a 'scintilla' of usefulness justifies the grant of a patent because this is necessary to stimulate investment in completing the development of a drug. In other words, without a protected position, the company will not be secure in making additional financial investment.

Should we grant patents to inventors of new chemical compounds or biological materials before the applicant knows whether these compounds or materials have a beneficial therapeutic effect? A patent by preventing third parties from using protected subject matter places a compound or material 'off-limits' during its 20 plus year term. Do we want to limit experimentation with a promising compound or biological material to only the company that created it? What if that company decides against pursuing R&D? What if that company can generate thousands of compounds and wall off entire areas of potential research? When in the process of inventive activity should we step in and grant an exclusive right?

Some public health advocates have argued that low utility thresholds discourage competition in innovation by excluding potential researchers

[18] See Frederick M. Abbott, *The Judgment in* Novartis v. India*: What the Supreme Court of India Said*, Inside Views, Intellectual Property Watch, April 4, 2013. Available at SSRN: https://ssrn.com/abstract=2250494.

at an early stage, allowing originators to lock up promising avenues of scientific investigation.

There is no obviously correct answer to the question where along the spectrum of invention a patent should be granted. Under the terms of the WTO TRIPS Agreement, governments are largely free to determine where along the spectrum of demonstrating utility they want to grant patents. In the absence of certainty regarding where is the best point for grant, allowing different governments to follow different policies may help to identify what the optimal approach is.

In some countries there is a legislatively-created 'link' between the marketing approval process of the drug regulatory authority (DRA) and the patent system, such that in one way or another an application for DRA approval for marketing (such as to introduce a generic version of a previously approved product) triggers notification to a patent owner and engages the possibility for that patent owner to block regulatory approval during the term of the patent. This so-called 'linkage' is a controversial practice because the functions performed by the DRA (e.g., assessing quality, safety and efficacy) are not directly related to the question whether a pharmaceutical compound is patentable or whether a patent would be infringed by a newly approved product. In addition, because the legal systems in some countries make it easy for patent owners to obtain preliminary injunctions that may be difficult to successfully challenge, a disproportionate burden is placed on generic producers in bringing their products to market. Linkage favors the patent owner, and originator pharmaceutical companies lobby to incorporate linkage requirements in bilateral and regional trade agreements (discussed later in this chapter).

2.2 Regulatory Exclusivity

Legislation in a substantial number of countries provides that the pharmaceutical company that first registers a new product for commercial sale is entitled to a period of 'market exclusivity' during which other companies are precluded from registering the same (or substantially similar) products.[19] Unlike patents which are granted with respect to innovation, the grant of market exclusivity is mainly in recognition of investments in demonstrating the safety and efficacy of new drugs through clinical trials and so forth. There are important distinctions

[19] See, e.g., explanation of the EU market exclusivity mechanism in European Commission Competition Directorate, Pharmaceutical Sector Inquiry Final Report, at 124–28, adopted 8 July 2009.

between patents and regulatory market exclusivity. A patent may typically be challenged on grounds that the patented product did not genuinely satisfy the criteria of patentability when the patent was granted. Patents may be, and often are, invalidated. Regulatory exclusivity is based on DRA approval of the product. Traditionally, such regulatory approval was rarely subject to third-party challenge and the legal frameworks under which such challenges could be made were undeveloped, certainly as compared with the mechanisms for challenging patents.[20] With the increasing importance of regulatory exclusivity in the biologics sector and the large amounts of money at stake, there is increasing attention paid to mechanisms for challenging the decisions of DRAs, even though these avenues are only beginning to be explored.[21] It remains that regulatory marketing exclusivity based on approval of a new drug is more secure from a legal standpoint than patent exclusivity, and this accounts for the substantial attention that is paid to this form of exclusivity in trade and investment agreement negotiations.

Regulatory market exclusivity is not something that would be thought of as a traditional form of IP. It rewards investment and work, but not creativity (though neither do trademarks). The WTO TRIPS Agreement in its Article 39.3 requires governments to provide parties that submit regulatory data regarding new chemical entities for which there has been significant investment protection against 'unfair commercial use'. It does not mandate regulatory market exclusivity, thus permitting other means of protection against unfair exploitation. Some governments, however, regard regulatory market exclusivity as a requirement of Article 39.3, and this has led to significant international controversy. More recently, some governments have begun to grant regulatory market exclusivity to new biologic products with terms that exceed those that have been granted with respect to chemical products.[22] The WTO TRIPS Agreement does not seem to address regulatory data with respect to biologics. Article 39.3

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[20] The DRA might decide to revoke an approval on some ground, such as that a drug is substantially more dangerous than thought at the time of initial approval, and this would have the effect of eliminating the exclusivity. But, that would be more or less superfluous since the drug could not be marketed by anyone.

[21] See, e.g. Kurt R. Karst, *A Hole in One? Eagle Sues FDA Over BENDEKA Orphan Drug Exclusivity in Depomed-like Lawsuit*, FDA Law Blog, April 28, 2016, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/04/a-hole-in-one-eagle-sues-fda-over-bendeka-orphan-drug-exclusivity-in-depomed-like-lawsuit.html.

[22] See, e.g., for the United States the 12 year term of biologics market exclusivity found in 42 U.S. Code § 262(k)(7).

expressly refers only to new chemical entities.[23] This increases pressure from the originator biologics industry to push for new standards in international trade and investment negotiations. We will discuss further how this factors into international trade negotiations regarding intellectual property.

2.3 Trademarks

IP covers a substantially wider ground than the promotion of innovation. IP in the form of the 'trademarks' or 'brand names' associate healthcare products or services with their producers or providers. These identifiers are important to consumers and to the business of healthcare. Trademarks are signs or symbols that are used on goods or services in commerce and that serve to distinguish the products of one enterprise from another.[24] In common parlance, trademarks are often referred to as 'brands' or 'brand names'. Trademarks are generally considered signifiers of the reputation of the provider of goods and services. In other words, they reflect the accumulated goodwill of the enterprise. The quality and effectiveness of health products, including pharmaceuticals, is important to all stakeholders in the healthcare chain, and especially consumers. Clinics, hospitals, doctors, pharmacists and patients often have preferences for products identified by particular trademarks, and those preferences naturally have a value to the trademark owners.

At the multilateral level, there are a number of agreements important in regard to trademarks. These are the TRIPS Agreement and Paris Convention that together prescribe substantive rules regarding the types of 'identifiers' that may serve as trademarks, the exclusive rights of trademark owners and some basic rules about how trademark rights may be secured. These are supplemented by a multilateral registration system administered by WIPO referred to as the Madrid System (which involves a combination of the Madrid Agreement and Madrid Protocol).[25] The Madrid System enables a trademark owner to secure protection in a substantial number of countries through a single application in a Madrid country, although this ultimately results in the registration of independent

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[23] Article 39.3 provides in relevant part: 'Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize *new chemical entities*, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use' (Italics added).

[24] See, e.g., WTO TRIPS Agreement, art. 15.

[25] WIPO, Madrid System (n 11).

trademarks in each country. There is no 'international trademark' (although there is a European Union trademark).

As trademarks are a ubiquitous part of modern commerce, the basic concept should require little further elaboration. A few points about trademarks with specific reference to the pharmaceutical sector are worth mention. First, 'brand' names such as Lipitor for Pfizer's atorvastatin calcium are distinct from the International Nonproprietary Name or INN that is typically referred to as the 'generic' name for the relevant pharmaceutical product. The INN is proposed by the originator of a new drug, and thereafter subject to an approval process within WHO.[26] When a new drug is first introduced by a pharmaceutical company holding a patent and/or regulatory market exclusivity, the trademark or brand name will usually be better known by the public, and perhaps the medical profession, than the INN or generic name. When the drug goes off-patent and is no longer protected by regulatory market exclusivity, pharmaceutical companies other than the originator may not use the originator's brand name, and may select a different trademark or brand name for the same pharmaceutical product. They will also refer to it by its INN or generic name.

When countries or regions have adopted 'generic substitution' laws applicable to their pharmacy dispensing system, the pharmacist either must (mandatory generic substitution) or may (discretionary generic substitution) provide the patient who has received a prescription with the non-originator branded version of the drug if it is less expensive than the branded version.[27] Since physicians and patients may be most familiar with the originator brand when it goes off-patent, the pharmacist must be aware that despite a prescription stating a brand name, substituting a generic version is mandatory or permissible, depending on the local rule. Sometimes, mandatory generic substitution rules allow a physician to 'expressly override' the general rule by using terminology such as 'no substitution permitted'. Otherwise, force of habit among physicians might negate the potential benefits of generic substitution.

Another important aspect of trademarks is that the type of signs or symbols that may be protected include colors and shapes. The tablet or capsule form and color of a pharmaceutical product is theoretically protected by trademark, although this aspect is controversial and not the

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[26] WHO, Essential Medicines and Health Products, Guidance on INN, http://www.who.int/medicines/services/inn/innguidance/en/, accessed 5 February 2017.

[27] See, e.g., William H. Shrank, et al., 'State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid' (2010) 29(7) *Health Affairs* 1383–90.

subject of uniformity among national laws. Consider, for example, that a particular originator blood pressure medication may be in the form of a small round pink tablet. Individual patients who are using that medication may readily identify their daily prescribed dosage by looking for a small pink tablet. If a generic producer is required to select a different color and tablet size, this could become quite confusing to patients, particularly the elderly, and the risk of dosing errors would increase.

A common rule in trademark law is that trademark protection does not extend to subject matter that is 'functional'. The protection of function is in the realm of other forms of IP, such as patent and trade secret. Colors and shapes are functional when used by patients, nurses, etc. to identify the appropriate prescribed drug. As a policy matter, it does not appear that trademark law should provide protection to a particular company for the color or shape of a medication.[28]

2.4 Copyright

Copyright protects the expression (in any form) of authors and artists against unauthorized reproduction and distribution. Copyright may seem an unlikely candidate for raising issues with respect to health products, including pharmaceuticals. As with other forms of IP, however, copyright can foster tension between its function of protecting the interests of creators, on one hand, and the interests of the public in access to health products, on the other.

For example, pharmaceutical product producers are typically required to include brochures regarding appropriate use and risk factors along with their medicines, and if a generic producer or other competitor copies that form of 'literature', this might be a violation of copyright. This issue is of concern in countries where drug regulatory authorities, for example the US FDA, specifically approve information brochures which generally may not be modified without further FDA approval.[29] Because a generic company must include the same product information as the originator copyright, at least in theory, might effectively block the entry of generic products. However, copyright does not protect 'function', and informational brochures accompanying pharmaceutical products serve an important function. That function would not appear deserving of copyright protection. As a policy matter, it would seem that copyright should not

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[28] See *Qualitex Co. v. Jacobson Products Co., Inc*, 514 U.S. 159 (1995).

[29] See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and *PLIVA v. Mensing*, 131 S.Ct. 2567 (2011).

prevent the reproduction of pharmaceutical brochures, but this does not prevent claims to the contrary.

Copyright has an industrial function as it has become the default mechanism for protecting computer software. The typical pharmaceutical manufacturing plant makes use of a wide range of computer software products that may, for example, control production processes, monitor quality control testing, track inventory, etc. Copyright protects the creators of that software. In low income countries lack of resources to purchase expensive computer software can place a burden on those attempting to initiate pharmaceutical manufacturing.

Copyright in research materials allows publishers to support their activities. At the same time, it may affect access to research materials. For example, concerns are expressed about the high cost of journals devoted to scientific research. In response, efforts toward creating 'open source' publication outlets for scientific literature have proliferated.[30]

Copyright has a fairly long duration; pursuant to the TRIPS Agreement at least 50 years following the death of the author or artist. That long duration benefits the author or artist by extending the period in which income may be earned from sales, but at the same time potentially limits access to the material.

Copyright, like trademark, can be used to protect certain types of designs and color combinations. Questions arise in copyright law regarding whether protection should extend to product packaging, drug colors and shapes, and other potentially functional subject matter.

2.5 Trade Secret

Trade secret laws protect commercially valuable information that is not publicly available in its precise form that its owner has taken reasonable steps to protect against third-party misappropriation. Trade secret can cover production processes, customer lists, formulas for chemicals and food products, and a wide range of other subject matter that has commercial value. In principle, trade secret protection can last indefinitely, i.e. as long as the relevant information remains secret. Countries take different approaches to the legal requirements for establishing trade secret violations. But, even during the early days of the TRIPS Agreement negotiations it appeared that virtually all countries had a trade secret law of one type or another. The unauthorized taking

[30] 'Open source' written material is typically protected by copyright, but through a type of licence that provides free access to the material, subject to different types of licence conditions (e.g., a requirement to identify the author).

of a trade secret is a form of 'unfair competition'. The TRIPS Agreement, in Article 39.1–2, requires WTO members to provide trade secret protection.

Trade secret protection may cover similar subject matter to patents. Since trade secret protection may last indefinitely, why would an inventor seek a patent which requires disclosure and has a limited term of 20 years, rather than keep the invention secret? The answer is straightforward. Trade secret law does not prevent 'reverse engineering' of a product or process. Most products, once they are put on the market, can be reverse engineered, though of course how long that takes and how costly the engineering endeavor will be varies depending on the complexity of the invention. In the pharmaceutical sector, a chemical combination that may have taken a decade to develop into a finished product typically can be reverse engineered in a matter of months at a relatively modest cost. Trade secret does not prevent that reverse engineering effort.[31]

Trade secrets can extend to lists of suppliers, customers, production processes and other matters. Even when a patent has disclosed a new chemical compound or biologic material there may well be trade secret information regarding how to produce that chemical compound or biologic material that is not disclosed and that may require substantial investment to reproduce. Typically, the licence of a pharmaceutical patent will include 'know-how' that is protected by trade secret. When a company loses patent protection it may yet maintain commercial secrets that would substantially aid a third party in producing the same product.

If the producer of a health product, including a pharmaceutical product, can keep valuable information secret, it generally will try to do that. This is the situation with respect to clinical trial data in many countries. When applying for regulatory approval, an originator will submit detailed information regarding the structure and results of its clinical trials, but these will not be made public as they are regarded as 'proprietary'. This has the negative consequences of limiting independent analysis of clinical trial results and may increase the risk that adverse effects will not be detected in the same way as would be the case if

[31] If the pharmaceutical originator did not secure a patent, once it put the product on the market a follow-on generic producer could quickly introduce a competing product without having expended the R&D costs. There would be limited incentive for expending large amounts to research and develop new products.

clinical trial data is made publicly available.[32] This is another subject of long-standing debate regarding the cost and benefits of IP protection in the health sector.

There has been a recent trend in some high-income countries toward criminalization of trade secret misappropriation. Though in principle this may seem like a good idea in terms of inhibiting undesirable conduct, from a business standpoint the threat of criminal prosecution can be quite chilling, and this may even discourage lawful and important technological research.

Protection of data submitted for regulatory purposes is considered a subset of trade secret protection by the TRIPS Agreement under the rubric 'Protection of Undisclosed Information'. This form of protection was discussed previously, and is revisited in the following discussion of preferential trade agreements.

2.6 Competition Law

Competition law is not a form of IP protection.[33] It rather serves as a balancing mechanism that can restrain excesses that might otherwise result from the overprotection or misuse of IP. Intellectual property protection typically provides its holder or owner with a right to prevent others from entering the market, usually but not always for a limited term. The right to exclude is inherently anti-competitive. Self-evidently, an IP owner that can prevent a third party from entering the market is blocking competition.

The inherent anti-competitive side of IP is counterbalanced by the role of IP in promoting innovation (as in patent) and in protecting consumer interests in the integrity of the market (as in trademark). If a patent encourages innovation, and a new product introduces competition with existing products, this is inherently pro-competitive. In this regard, there are both pro- and anti-competitive sides to IP. The role of competition law is to maintain the balance that the legislature seeks to establish when it adopts IP protection.

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[32] See, e.g., Jerome H. Reichman, 'Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach' (2009) 13(1) *Marquette Intellect Prop Law Rev*. 1–68.

[33] See generally Frederick M. Abbott, Sean M. Flynn, Carlos M. Correa, Jonathan Michael Berger,and Natasha Nayak, *UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries, United Nations Development Program* (ed. F. M. Abbott) (2014), available at SSRN: https://ssrn.com/abstract=2439416.

The WTO TRIPS Agreement expressly acknowledges the balancing role of competition law, so a discussion finds its proper place among IP issues. The TRIPS Agreement does not prescribe substantive rules regarding competition law. It basically states that WTO Members acknowledge the right of governments to use competition law to restrain potential excesses.

Competition law is increasingly used by enforcement authorities as a means to constrain excessive pharmaceutical prices that are burdening public health budgets around the world. By excluding directly competitive products from the market, patents and regulatory market exclusivity facilitate these excessive pharmaceutical prices, and competition law must balance the innovation-promoting aspects of exclusivity with the impact on the public in terms of prices.

Competition law (or antitrust law in the US vernacular) is a large and complex field. There is no overarching international agreement about competition law that establishes substantive rules. This does not mean that application of competition law is without limits or general procedural requirements, as these matters are addressed by public international law in respect, for example, to limiting principles with respect to the exercise of jurisdiction.

2.7 Exhaustion of Rights and Parallel Imports

Another important aspect of IP law concerns its role in so-called 'parallel import' or 'parallel trade' in medicines. This involves a complex set of IP issues revolving around the concept of 'exhaustion of rights'. The concept of exhaustion applies to all forms of IP. It refers to the point at which the IP holder no longer may control the disposition of a product embodying the IP.

A patent, trademark or copyright gives its owner the right to prevent unauthorized third parties from first placing a good on the market. However, when the subject product has been placed on the market, or 'first sold', exhaustion doctrine provides that the purchaser may resell or transfer the product to someone else without the permission of the right owner. So, for example, the owner of a patent on an invention can prevent third parties from making, using or selling the invention covered by the patent. But, once the patent owner sells the patented product, the buyer is not prevented from reselling or transferring it. In the United States this is referred to as the 'first sale rule'.

The main issue that is relevant to international trade in pharmaceutical or other healthcare products is the geographic scope of the exhaustion

rule. Each country may adopt a rule of 'national', 'regional' or 'international' exhaustion. Under a national exhaustion rule, a product that is sold within the country can be resold and transferred within the national territory without restriction, but products first placed on the market abroad may not be imported without the permission of the right owner. If a country adopts international exhaustion, a product placed on the market anywhere in the world is free from further control by the IP right owner and may be imported by a third party without the consent of the IP right owner. Under regional exhaustion, such as currently adopted by the European Union, a product placed on the market anywhere within the region exhausts the IP right-owner's authority to block trade within the region, but still allows the IP right owner to prevent imports from outside the region. Thus, for the EU, placing a patented good on the market in Germany exhausts the owner's right to block imports into France based on a corresponding 'parallel' patent, but placing a patented good on the market in Thailand does not prevent the right owner from blocking imports from Thailand into Germany or France.

When international exhaustion is recognized, the procurers of pharmaceuticals within a country can look for and import the least expensive version of the same IP-protected pharmaceuticals wherever they may be first sold in the world. Lower-priced imports naturally have a beneficial effect for consumers within the importing country. If there is only national exhaustion, sellers of pharmaceutical products have more limited competition.

There is no international rule mandating that countries must adopt the same rule of exhaustion with respect to the different forms of IP. In fact, in a substantial number of countries different exhaustion rules (i.e., national, regional or international) apply to different forms.

We discuss in the next section some of the international controversy that exhaustion doctrine has provoked.

3. THE UNEASY INTERFACE BETWEEN IP, TRADE REGULATION AND HEALTH

3.1 The Multilateral Side

One of the major motivating factors behind negotiation of the TRIPS Agreement that began in the 1980s was the interest of the originator pharmaceutical industry in the United States, Europe and Japan. The problem from the industrialized industry standpoint was that generics producers in developing countries like Argentina, Brazil and India were

manufacturing substantial quantities of products that were under patent in the United States without acknowledging the patents, paying royalties or otherwise compensating the industrialized country industry for its R&D.[34] In fact, when the TRIPS Agreement was negotiated many countries did not provide patent protection for pharmaceutical products.

From the standpoint of the pharmaceutical industry, the TRIPS Agreement that entered into force on 1 January 1995, accomplished the major objective of requiring that pharmaceutical product subject matter be subject to patent protection, that patents would have a minimum duration of 20 years from the filing date, that submissions of regulatory data would be protected and that countries would be required to maintain civil enforcement mechanisms that would permit the enforcement of rights. In addition, the rules that were prescribed would be enforceable within the framework of the new WTO Dispute Settlement Understanding (DSU), that included the establishment of the Appellate Body to supplement the former GATT panels, and permitted enforcement through withdrawal of 'cross-concessions'.[35] This meant that the failure by a developing country to provide adequate patent protection could be remedied by withdrawal of market access for agricultural products or similar products of export interest to that developing country.

When the TRIPS Agreement was adopted in the mid-1990s many public health advocates viewed extending the requirements of patenting pharmaceuticals and protecting regulatory data as contrary to the interests of developing countries because these countries did not have funds to invest in pharmaceutical innovation. Virtually all patents and regulatory exclusivity grants for pharmaceuticals were owned by developed country multinational originator companies. If new drugs were to be protected in developing countries by patents owned by foreign corporations, and if affordable generic copies would not be available, pharmaceutical budgets would be strained and access to medicines diminished.

The TRIPS Agreement provides that governments have flexibility in the way they implement their IP laws, and are not subject to a uniform

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[34] Frederick M. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework' (1989) 22(4) *Vanderbilt Journal of Transnational Law* 689, 1989, available at SSRN: https://ssrn.com/abstract=1918346.

[35] Frederick M. Abbott, *Cross-Retaliation in TRIPS: Options for Developing Countries*, ICTSD Programme on Dispute Settlement and Legal Aspects of International Trade, Issue Paper No. 8, April 2009, available at SSRN: https://ssrn.com/abstract=1415802 or http://dx.doi.org/10.2139/ssrn.1415802.

approach. It leaves some play in the joints or 'flexibility' for developing (and developed) countries to adopt standards that can help avoid or mitigate excessive protection, for example in respect to patents and regulatory data. There was a transition arrangement that allowed countries like India to delay for up to ten years the introduction of pharmaceutical product patent protection.[36] There are rules provided for the compulsory licensing of patents that essentially allow such licences to be issued for any reason, and facilitate the grant of licences in urgent circumstances and for government use. There is a 'limited exception' that can be used to address matters like research, though with potentially broader application. The Agreement makes clear that countries can adopt international exhaustion of patent (and other IP) rights. The provision on regulatory data protection does not require the grant of exclusive marketing rights. These flexibilities are generally viewed by public health advocates as a positive aspect of the TRIPS Agreement.

In an early case, the WTO Appellate Body confirmed the inherently flexible nature of the TRIPS Agreement and noted that while governments (in this case India) were required to provide sound mechanisms to implement their obligations, they were not obligated to follow an approach that industrialized countries or their industries thought best.[37] In subsequent decisions involving the TRIPS Agreement, panels and the Appellate Body have not deviated from the fundamental principle that each WTO Member has the right to implement the rules in a manner compatible with their own legal system and practice.

Perhaps the most important decision under the WTO DSU with respect to public health was taken by a panel in the *Canada-Generic Pharmaceuticals* case.[38] Here the European Union sought to force Canada to change legislation that allowed the early working of patents by generic producers for purposes of seeking regulatory approval prior to the expiration of patent terms (a so-called 'Bolar exception'). Regarding the regulatory review exception at issue in the dispute, the panel held that

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[36] There was a more significant extension for least developed countries, though because of the small paying markets in these countries this would not have had great economic significance.

[37] *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Report of the Appellate Body, AB-1997-5, WT/DS50/AB/R, 19 Dec. 1997.

[38] *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R 17 March 2000.

Canada's legislation was sufficiently limited that it fell within the scope of Article 30 of the TRIPS Agreement that authorizes governments to establish limited exceptions to patents. Important from a long-term perspective, the panel said that Article 27.1 of the TRIPS Agreement, a key provision that precludes governments from discriminating against particular fields of technology, does not prevent them from treating different patent subject matter differently when there are legitimate reasons for doing so. For example, there may be good reasons why a government may decide to treat nuclear energy and computer software patents differently because the subject matter performs substantially different functions and may not be assessed using the same criterion. Likewise, there may be legitimate reasons in a variety of settings for treating pharmaceutical patents differently from other patents.

Up until now, the WTO dispute settlement system has been empathetic to the concerns of developing countries in terms of implementation and enforcement of IP when there may be an impact on public health. As this chapter is written, there are claims from certain tobacco growing countries that 'plain packaging' legislation implemented by Australia is depriving them of their trademark rights. The main issue is under TRIPS Agreement Article 20, and asks whether Australia's decision to require plain packaging is an 'unjustifiable' encumbrance on trademark use, which it certainly is not. There is little doubt from a substantive trademark law standpoint that the claims of the tobacco industry being championed by a few tobacco exporting countries do not stand up under trademark law. But, without a decision yet from the WTO panel, which might then be followed by an appeal to the Appellate Body, it is difficult to know whether the health-empathetic approach of the dispute settlement system will be continued.

A major public health related set of developments at the WTO grew out of efforts by the originator pharmaceutical industry to prevent the government of South Africa from implementing 1997 legislation that would, among other things, have expressly authorized international exhaustion of patents for pharmaceutical products. The originator industry and certain supporting governments alleged that the legislation was inconsistent with South Africa's obligations under the TRIPS Agreement, which was plainly not the case. Ultimately, the industry backed down in the face of a large international NGO protest movement, and the basic inadequacy of its legal arguments. But, this was not before very substantial damage was done to the reputation of the industry, and along with that the WTO and the TRIPS Agreement itself.

Notably, in 2017 the Supreme Court of the United States adopted a rule of international exhaustion of patents for that country,[39] again confirming that the adoption of international exhaustion is permitted by international rules. The pharmaceutical originator industry strongly opposed adoption of international exhaustion of patents in amicus briefs to the Supreme Court, essentially arguing that measures that reduce their profitability will interfere with their R&D mission. Public health advocates observed that the logical consequence of that argument is that no effort should be made to control pharmaceutical prices.

In large measure as a response to the case in South Africa, in November 2001 WTO Ministers adopted the Doha Declaration on the TRIPS Agreement and Public Health that confirmed the flexibilities available under the TRIPS Agreement, and the right of governments to interpret the agreement in a manner that supported access to medicines 'for all'.[40] This was a very important moment for those concerned with assuring that patents and other forms of IP would not stand as an obstacle to the promotion and protection of public health. References to the Doha Declaration have been incorporated in a substantial number of subsequent international agreements and resolutions of international organizations.

The Doha Declaration also dealt in a preliminary way with a narrow issue regarding the circumstances under which compulsory licenses could be issued to address shortfalls of medicines outside the country of production (the Article 31(f) problem). This led to a further two years of negotiations which culminated in the adoption of a waiver on 30 August

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[39] *Impression Products v. Lexmark International*, U.S. Sup. Ct., No. 15–1189, May 30, 2017. See Frederick Abbott, 'US Supreme Court Adopts International Exhaustion for Patents: Paving the way for parallel imports to exert downward pressure on domestic pharmaceutical (and other) prices', *IP-Watch*, 31 May 2017, https://www.ip-watch.org/2017/05/31/us-supreme-court-adopts-international-exhaustion-patents-paving-way-parallel-imports-exert-downward-pressure-domestic-pharmaceutical-prices/; and 'US Supreme Court Adopts International Exhaustion Of Patents (Part II): Addressing the New Competitive Landscape', *IP-Watch*, 8 June 2017, https://www.ip-watch.org/2017/06/08/us-supreme-court-adopts-international-exhaustion-patents-part-ii-addressing-new-competitive-landscape/.

[40] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469, available at SSRN: https://ssrn.com/abstract=1493725.

2003,[41] and ultimately to the first formal amendment of the TRIPS Agreement in December 2005, which only recently has been brought into force as Article 31bis of the TRIPS Agreement as a consequence of a sufficient number of ratifications having been secured. Whether Article 31bis is optimally designed is a subject of debate—some argue that it is too complex or burdensome to be used effectively.[42] But, when it was negotiated it was not understood as the solution to the world's problems surrounding access to affordable healthcare, rather a tailored solution to an issue that might arise under the TRIPS Agreement. It should not be viewed as a substitute for comprehensive pharmaceutical sector reform. The reformulation of that single clause in the compulsory licensing provision of the TRIPS Agreement cannot realistically bear that burden.

Providing universal access to medicines for the world's population will require a combination of policy approaches involving finance, production and distribution mechanisms, and a rethinking of the way that R&D efforts are encouraged and rewarded. While the patent system may encourage innovation by offering financial reward to the creators of new pharmaceutical products, the reward is paid from the prices charged to patients (whether directly or indirectly through government or private insurance budgets). This skews access toward those with the most capacity to pay, and without government intervention to control pricing tends toward excessive rent-seeking through higher prices, as well as overconsumption of drugs. This does not mean that patents or other forms of regulatory exclusivity are inherently bad for public health. Patents and regulatory exclusivity are tools to promote certain objectives. What it means is that the use of these tools must be regulated in the interests of affordability and access, and that alternative tools should also be used where appropriate. These alternative tools include direct government subsidy and prizes, ideally with financial contributions made from a wide range of countries taking into account capacity to pay.

The WTO is not the only multilateral organization whose rules and decisions are significant with respect to public health. The UN body directly charged with overseeing the development of international IP

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[41] Frederick M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 *American Journal of International Law* 317–58, available at SSRN: https://ssrn.com/abstract=763224.

[42] Frederick M. Abbott and Jerome H. Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' (2007) 10 *Journal of International Economic Law* 921–87, available at SSRN: https://ssrn.com/abstract=1025593.

rules, WIPO, plays a role in providing technical advice to developing countries in respect to how best to implement IP laws.[43] There has been some controversy regarding who the providers of advice are, and whether they are appropriately taking into account the public health implications of their work. There has been a strong push by developing country members in particular toward a more public health oriented approach by and at WIPO. But, notwithstanding a substantial amount of controversy in and around the organization, WIPO has not played a major role in the IP and health dialogue. While there has been the conclusion of a treaty that will obligate access in favor of sight-impaired individuals to copyright protected works, there has not been any other significant international agreement at WIPO affecting public health since the TRIPS Agreement was adopted at WTO.

The World Health Organization (WHO) has seen a great deal of interest in IP law, and patents in particular. Although the WHO played almost no role during the TRIPS Agreement negotiations, various divisions within the WHO shortly after TRIPS Agreement adoption began to address how the potential disruptive effects of the new rules on public health interests could be addressed. The WHO has provided continuing guidance to its member countries regarding interpretation and implementation of IP law.[44] Debates concerning the role of IP in innovation and access to medicines has played a significant role in negotiation of the Framework for Pandemic Influenza Preparedness (PIP).[45] WHO members also look to ways for facilitating financing of R&D on new medicines and vaccines that do not rely on high pharmaceutical prices based on patent protection. The idea of 'delinking' the R&D element from the production and distribution elements in the pharmaceutical sector is a significant focus of attention.[46] The idea is to seek ways of financing

[43] See Abbott, Cottier and Gurry (n 1) at 290–93.

[44] See, e.g., WHO, Information on Technical and Financial Cooperation Programmes Carried Out by the World Health Organization Relevant to the Implementation of the TRIPS Agreement and Public Health, WTO TRIPS Council Doc. IP/C/W/516/Add.1, 15 October 2008.

[45] Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits, WHA64.5, Agenda item 13.1, 24 May 2011, World Health Organization (WHO) 2011, available at http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf.

[46] See, e.g., Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination, Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, World Health Organization (WHO), April 2012, available at http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

R&D through alternative mechanisms, which may well include patents, but to separately authorize the production of resulting medicines without the grant of monopoly rights. This is an important and interesting puzzle in that pharmaceutical R&D is expensive—though indeed how expensive is the subject of much debate—and the predominant patent model has successfully aggregated R&D. It is a question whether some other form of funding model, whether government subsidy, prizes, continuing royalties, or others, would similarly provide adequate funding.

The role of international organizations in respect to IP and health extends beyond the WTO, WIPO and WHO. The UN Secretary General appointed in 2015 a High Level Panel on Access to Medicines which issued a report with recommendations on potential future directions.[47] It remains to be seen whether the UN General Assembly will further take up these recommendations, or how other institutions may rely on the recommendations of the report.

3.2 Preferential Trade Agreements (PTAs)

The most intense debates concerning the interface between IP rules and public health has taken place in the context of negotiation, conclusion and implementation of bilateral, regional and plurilateral preferential trade agreements (PTAs).[48] These agreements go under various designations. For the United States, most are labeled 'free trade agreements' or FTAs, for the European Union most are identified as 'Economic Partnership Agreements' or EPAs. But, these types of agreements are not limited to US or EU endeavors. Many countries negotiate such agreements without US or EU participation, though few devote similar attention to the pharmaceutical sector, IP or health more generally.

The United States began a push to negotiate FTAs during the GATT Uruguay Round negotiations as it pursued the North American Free Trade Agreement (NAFTA) with Canada and Mexico. One of the US objectives was to demonstrate that unless other countries were willing to make concessions at the GATT, the US could pursue a narrower set of

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[47] Report of the United Nations Secretary General's High-Level Panel on Access to Medicines, Promoting access to innovation and health technologies, September 2016.

[48] See Frederick M. Abbott, 'The Evolution of Public-Health Provisions in Preferential Trade and Investment Agreements of the United States' in P. Roffe and X. Seuba (eds), *Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals, Global Perspectives for the IP System*, CEIPI-ICTSD, Issue No. 4, 2017, pp. 45–63.

countries and reach the results it wished to achieve. In terms of the TRIPS Agreement, the NAFTA IP Chapter is rather similar to what became the WTO TRIPS Agreement. This was the first time the US had incorporated regulatory data protection in an international agreement, and the result in the NAFTA is in fact a bit stronger than the result it achieved in TRIPS.[49]

From the originator pharmaceutical industry standpoint the TRIPS Agreement is 'incomplete'. The flexibilities unnecessarily weaken the potential originator market protection in developing countries and soften the hoped-for restraints on developing country pharmaceutical industries. But, following the difficult experience of the pharmaceutical industry in South Africa, and subsequent adoption of the Doha Declaration, it was clear to the United States pharmaceutical industry and US trade negotiators that strengthening protection for the industry at the WTO was unfeasible, at least for the near to medium term. Attention was shifted almost exclusively to negotiating bilateral and regional agreements where stronger protections could be obtained. This resulted in a template requiring a minimum five-year term of market exclusivity for pharmaceutical products, and an obligation to link regulatory approval and patents. A number of other more modest matters such as possibilities for patent term extension and narrowing of the limited exception were incorporated.

Of particular note was the incorporation from NAFTA onward of investor to state dispute settlement (ISDS) mechanisms that appear to incorporate IP, including patents, as protected forms of investment subject to claims of unlawful taking. While these ISDS provisions include an exception for compulsory patent licences issued consistently with the TRIPS Agreement, this leaves open the possibility of ISDS claims contending that a compulsory licence was issued inconsistently with the TRIPS Agreement. Success on an ISDS claim may result in the award of monetary damages, and not an order for revising legislation. But, for example in a claim initiated by Eli Lilly against the government of Canada under the NAFTA investment chapter, the pharmaceutical company demanded $500 million in damages for invalidation of two patents based on alleged misinterpretation of the utility doctrine in patent

[49] Specifically, the NAFTA regulatory data provision includes a presumptive five-year period of market exclusivity as the mechanism for accomplishing protection, although it is not a fixed-term obligation. Art. 1711: Trade Secrets, NAFTA.

law. The arbitral tribunal ruled against the pharmaceutical company.[50] Several months later, in an unrelated case, the Supreme Court of Canada modified the utility doctrine that had been the subject of the Eli Lilly dispute to make it harder to invalidate pharmaceutical patents.[51] The claim by Eli Lilly was widely perceived as an attack on the sovereignty of the Canadian court system, and accelerated a trend among governments toward precluding or limiting ISDS in other PTA negotiations. It remains unclear how long this movement will last, or how effective it will be.

The decision by the Trump Administration in early 2017 to withdraw US signature of the Trans Pacific Partnership Agreement (TPP) has created a great deal of uncertainty regarding the posture of the United States in future PTA negotiations. The provision of the TPP that would have obligated its 12 countries to provide a minimum eight years' market exclusivity for newly approved biological pharmaceutical products (biologics) was, if not the most controversial matter in the negotiations, among the top few. The US biologics industry group strongly opposed the eight-year term, arguing that the US should have demanded the 12 years required under US law. Paradoxically, the Obama Administration was pushing domestically to reduce the term to seven years. In its early months, the Trump Administration has provided mixed signals regarding its posture in this area. On one hand, it has voiced dissatisfaction with foreign protection of IP, while on the other hand there have been strong statements by the President demanding lower pharmaceutical prices. What this means for international IP policy with respect to pharmaceuticals is not clear.

3.3 The Limits of Economic Analysis

Defining the optimal domestic and foreign policy with respect to patents and other forms of IP, and the best outcome from a public health standpoint, would naturally be made easier if there was some way to robustly predict what the effect of stronger and weaker protection of IP is. Regrettably, tracing back to the seminal economics work of Fritz

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[50] *Eli Lilly v. Canada*, Final Award of the Arbitral Tribunal, Case No. UNCT/14/2, 16 March 2017. For case documents, see http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng.

[51] *AstraZeneca v. Apotex*, Sup Ct. Canada, 2017 SCC 36, decided 30 June 2017.

Machlup in the 1950s,[52] it is exceedingly difficult to draw correlations between IP and innovation.

On the static side, we know that providing exclusive rights to a particular seller of a drug product enables it to charge a higher price than in a freely competitive market where competitors could introduce the same product. The extent of pricing power depends on the demand for the product, and whether there are substitutes available, even if imperfect ones. With that said, it is easy enough to see that there is a correlation between the grant of patents on pharmaceutical products and the prices that are charged for them. Reducing the strength of patent protection results in lower prices. This much we know.

In a circumstance such as the HIV-AIDS pandemic as it stood in the late 1990s and early 2000s, it was evident that allowing patent owners to charge prices beyond the means of the vast majority of individuals who needed treatment was in essence a death sentence. A judgment in favor of restricting patent protection was not difficult to reach, even if this meant that funding available for future research on HIV-AID vaccines and treatments might be diminished. It would be no good to tell millions of people dying from a terrible disease that patents would improve the lot of future generations. This can well be viewed within the lens of human rights, though one hardly needs to be a human rights expert to reach the appropriate conclusion.

The pharmaceutical originator industry argues that strong patent protection is essential for future research and development, and that weakening patent protection means that society will be without vaccines and treatments that are needed. This does not, however, tell us what the optimum duration of a patent is, whether unfettered pricing power is necessary to achieve desirable ends, whether alternatives to patent protection might work just as well, or better, and so on. Economists cannot tell us with any certainty how to design the optimal patent system because there are too many external variables that influence invention. In a low-income country, granting strong patent protection may have no influence at all in generating investment in pharmaceutical R&D if neither trained scientists nor adequate infrastructure are present. In a high-income country, the pharmaceutical industry is affected by the general state of the economy, alternative avenues for investment, whether

[52] Fritz Machlup, An Economic Review of the Patent System, Subcomm. on Patents, Trademarks and Copyrights, of the Senate Committee on the Judiciary, 85th Congress, 2d Sess. (1956).

the government is financing basic research, whether or not prices are controlled, and other factors.[53]

The fundamental objective of global public health is to provide universal healthcare, including universal access to medicines. Intellectual property, and especially patents, is part of the toolkit for achieving that objective. It is clear, however, that use of the IP toolkit needs to be situated within a broader regulatory environment that takes into consideration factors outside of IP, including making the results of R&D accessible and affordable.

[53] One may want to discern whether adding a year of patent protection and keeping generic drugs off the market generates sufficient additional innovation to justify the burdens on the public health system. If a pharmaceutical company has earned $10 billion on a drug for which $1.5 billion was spent in R&D, does providing an incremental $10 billion result in sufficient R&D improvement to offset financial demand on patients? And, from whose perspective or lens do we make the analysis?