Chapter 5

Intellectual Property and Access to Medicines and Vaccines

5.1 Introduction

Intellectual property (IP) and patents have become one of the most debated issues on access to medicines since the creation of the World Trade Organization (WTO) and the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Patents are by no means the only barriers to access to life-saving medicines, but they can play a significant or even determining role. During the term of patent protection, the patent holder's ability to decide on prices, in the absence of competition, can result in the medicine being unaffordable to the majority of people living in developing countries.

This chapter aims, in its first part, to introduce key aspects of access to medicines and intellectual property. The second part describes and defines some of the basic terms and concepts of the relatively new area of pharmaceutical policy, the trade-related aspects of intellectual property rights that regulate the research, development and supply of medicines and health technologies in general.

5.2 The WTO TRIPS Agreement

The World Trade Organization (WTO) is an international organisation of (currently) 164 Member States dealing with the rules of trade and providing the institutional framework for the conduct of trade relations among its members. On joining the WTO, members adhere to several agreements, and of these the Agreement on

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Trade-Related Aspects of Intellectual Property Rights (TRIPS) certainly has the greatest impact on the pharmaceutical sector.

The TRIPS Agreement establishes minimum standards for the protection and enforcement of a set of intellectual property rights that WTO Members are required to implement through national legislation. The TRIPS Agreement was adopted and came into force in 1995, but countries could benefit from different transition periods according to their economic development and the protection that they had granted to intellectual property until then. Before the TRIPS Agreement, patent issues were treated differently in each country and countries had different approaches to patent (and other types of intellectual property) protection to cater for their different needs.

5.3 What Is a Patent?

A patent is a title granted by the public authorities conferring temporary monopoly for the exploitation of an invention. It provides the patent holder a negative right; that is, the right to prevent others from using, making, selling, importing or marketing the patented invention during the term of the patent, without the permission or consent of the patent holder.

5.3.1 *There Is No Global or International Patent*

An important concept related to patent rights is **territoriality**. What this means is that the rights over a patented invention have a limited geographic coverage. In many cases, patents are granted by national patent offices, governed by the patent legislation in force in the country. The territorial reach of the patent right in such cases is national, i.e. the patent-holder of a patent granted by the patent office of Country A, will not have patent rights in Country B, unless a patent has also been similarly granted in Country B.

In some cases, there may be a regional patent office; in which case, a patent granted by the regional patent office may be recognised in the countries that are members of the regional patent agreement, subject to different conditions and procedures. For example, the European Patent Office may grant an EPO patent, which is recognised by all parties of the European Patent Convention. In this case, such a patent is regarded as a ‘bundle of nationally enforceable’ rights; that is to say, the rights accruing to the patent will have to be individually enforced in each member country.

The African Intellectual Property Organization, which is better known as OAPI (derived from the acronym of its name in French: *Organisation Africaine de la Propriété Intellectuelle*), is a regional patent organisation that acts as the common patent authority for the 16 OAPI Member States (i.e. Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Cote d’Ivoire, Equatorial

Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo). The unique feature of the OAPI patent regime is that a patent granted by OAPI will automatically apply in each of the OAPI Member States. OAPI thus functions as the national patent office for all its Member States, receiving applications and granting patents. While an application may be filed with the relevant national administration in a Member State, OAPI is the body responsible for the granting of the patent. Once granted, the rights accruing to a patent are independent of national rights, defined under the provisions of the Bangui Agreement but also subject to the national legislation, if any, of the Member States. In contrast, the African Regional Intellectual Property Organization (ARIPO) permits filing of one patent application (designating the countries in which protection is sought) at the Industrial Patent Office of any contracting state or directly with ARIPO but does not have automatic national effect in its Member States. The 16 Member States of ARIPO (Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe) may reject patents granted by ARIPO within 6 months of receipt of the notification, on the basis that they are contrary to national legislation or that they do not comply with the provisions of the Harare Protocol on patents, marks, models and designs (Shashikant, 2014).

5.3.2 *The Patent Cooperation Treaty*

The Patent Cooperation Treaty (PCT) adopted in 1970 is one of the treaties administered by the World Intellectual Property Organization (WIPO) with more than 150 contracting states. PCT makes it possible to seek patent protection for an invention simultaneously in many countries by filing a single ‘international’ patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent offices in what is called the ‘national phase’.¹

After ‘international’ patent application is filed in the patent office of a PCT member state or in the International Bureau of WIPO, a search and examination is then conducted on that application by a patent office of a PCT member state that is recognised as a PCT International Search and Examination Authority. The ‘international’ patent application can be filed within a period of 12 months from the first filing of the corresponding patent application in any state that is party to the Paris Convention. The International Search Authority to which the application is transmitted then conducts a prior art search based on published documents and issues a written opinion and an international search report on whether the application meets generally the criteria of patentability based on the prior art search, without any assessment of the application against national legal standards on the thresholds of

¹ WIPO, PCT FAQs, <https://www.wipo.int/pct/en/faqs/faqs.html>.

patentability criteria. The application and the written opinion and the search report are then published within a period of 18 months from the first filing of the application in any country. The applicant then has the option to request a supplementary search by another patent office recognised as an International Search Authority. The applicant also the option to request a supplementary international examination to analyse the patentability of the application, usually based on an amended version of the application. These requests can be made within a period of 22 months from the initial application. The International Preliminary Report on Patentability or the Supplementary International Search Report is issued within 22 months. Following this, the applicant can decide on whether to pursue national phase prosecution of the patent application and the request the same to the respective national offices within a period of 30 months from the initial application.

The national patent offices are not bound by the international search and examination report but may rely on it in course of their own search and examination. However, this also allows patent offices that produce the international search and examination report in their capacity as International Search Authority (ISA) to influence the national examination of that application in a developing country.² Indeed, as explained by the WIPO Secretariat, one advantage of the PCT system is that ‘... the search and examination work of patent offices can be considerably reduced or virtually eliminated ...’³ (Syam, 2019).

The bilateral and regional free trade agreements promoted by the United States and the European Union (EU), typically introduce an obligation for developing countries to join PCT. According to Syam (2019), ‘while a large number of developing countries have acceded to the PCT, the system is predominantly used by applicants from a few countries. Many developing countries that have joined the PCT system lack capacity in conducting substantive examination, though they have witnessed significant increase in the number of patent applications filed in their countries through the PCT route’.

5.3.3 *Validity of Patents*

The fact that a patent has been granted by a patent office does not mean that this is the final say on the matter. A granted patent can sometimes be partly or completely invalidated, for a number of reasons. For example, if on closer scrutiny, it is found that the patent does not meet one or more of the patentability criteria (as set out in the national patent law); it may be possible to challenge its validity.

Patent laws may also have provisions that exclude certain kinds of inventions: common examples are therapeutic or surgical methods. Patent laws may also

² See Peter Drahos, ‘Trust Me: Patent Offices in Developing Countries’, *American Journal of Law & Medicine*, vol. 34 (2008), pp. 151–174.

³ Available from <http://www.wipo.int/pct/en/treaty/about.html>.

exclude the patenting of inventions when their commercialisation is prohibited because the invention would be contrary to *ordre public* or morality. Patents granted in the excluded fields would also be invalid.

Even where a patent has been properly granted, the patent holder must maintain the patent by paying the required maintenance fees to the patent office. When the fees are not paid, the patent will lapse and therefore will no longer be valid.

5.3.4 Minimum Standards of Patent Protection

The minimum standards that the TRIPS Agreement requires for the protection of patent rights include the following:

- All WTO members have to provide patent protection for ‘inventions’, in all fields of technology. In the case of pharmaceuticals, WTO members have to grant patents to any invention of pharmaceutical product or process.
- WTO members shall apply the patentability criteria of novelty, inventive step (non-obviousness), and industrial application (utility). However, there is room for individual countries to determine the actual definition and application of these criteria.
- The fact that the TRIPS Agreement does not define novelty, inventive step and industrial applicability leaves countries significant room for manoeuvre; therefore, patentability requirements represent the principal and most important flexibility allowed by the Agreement to protect public health and access to medicines (Velásquez, 2015). ‘Politicians and legislators have broad room for manoeuvre to give legal effect to those flexibilities’ (Arias, 2014).
- The TRIPS Agreement also requires a minimum term of protection for patent rights of 20 years from the date of filing the application. Thus, WTO members cannot now have a shorter duration of patent protection than the minimum required 20 years.

Although the minimum duration required by the TRIPS Agreement is 20 years, a report from I-MAK, analyses the 12 best-selling drugs in the United States and reveals that drug makers file a large number of patent applications to extend their

Table 5.1 Examples of drugs with multiple patents granted

Product	Company	Conditions treated	No. patents granted	Years of protection
Humira	ABBVIE	Arthritis	132	39
Rituxan	BIOGEN	Cancer	94	47
Revlimid	CELGENE	M. Myeloma	96	40
Enbrel	AMGEN	Arthritis	41	39
Herceptin	ROCHE	Cancer	108	48

Source: I-MAK ‘Overpatented, Overpriced’, Nov. 2018

monopolies far beyond the 20 years of protection intended under patent law. Some examples are shown in Table 5.1 (I-MAK, 2018).

However, the TRIPS Agreement did not impose a uniform international law or uniform legal requirements. It contains provisions that allow for a degree of flexibility and some room for countries to accommodate their own patent and intellectual property systems according to their developmental needs. Thus, WTO Members are still able to determine how certain aspects of patent protection may be applied or implemented at the national level, in accordance with the social and economic welfare of the country.

Article 7 of the TRIPS Agreement, which spells out the ‘Objectives’ of the Agreement, provides that protection of intellectual property rights: ‘should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare’. In addition, WTO Members are allowed to ‘adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development ...’, as stated in Article 8, which lays down the Principles of the TRIPS Agreement (WTO, 1994).

These two provisions, together with the Preamble of the TRIPS Agreement, reflect the fundamental tenet that intellectual property rights protection should be regarded as a public policy tool; that is to say, the protection of such rights should be balanced against other public interests to achieve public policy goals.

5.3.5 *Patents on Pharmaceutical Products*

The conventional rationale for patent protection can be explained as follows: by conferring a temporary or time-limited monopoly, patents allow the inventor/producer to recover the costs of investment in research and development, and also to earn a profit in the production and sale of the invention. This is in return for making publicly available the knowledge about the invention, so that further research and development, and subsequent innovations, can be stimulated. Therefore, patent protection can be seen as a bargain struck by society with the patent holder, based on the premise that without patent protection there would be insufficient incentive for innovation. It is also based on the assumption that consumers would be better off in the long term because the short-term cost of having to pay higher prices will be offset by the creation of new inventions thanks to additional research and development.

However, questions arise as to whether these assumptions are always borne out in practice. In the area of public health and patents on pharmaceuticals, these questions have been particularly persistent.

In the case of pharmaceuticals, it is argued that patents are crucial for pharmaceutical innovation, and that without patent protection, there would be no financial incentive to fund the costs of discovery and development of new medicines. It is true

that patent protection has provided an important incentive mechanism to drive research and development in the pharmaceutical industry. Yet it is also true that patented medicines are normally priced well above production costs to obtain significant profits after paying marketing costs that frequently surpass those of research and development (Washington Post, 2015). In some developing countries, the high price of certain medicines means that patients in these countries will not have access to treatment.

Developing countries account for a very small fraction of the global pharmaceutical market (USA, EU and Japan accounted in 2018 for 89.3% of world pharmaceutical sales) and the generation of income to fund more research and development is not dependent on the profits derived from their markets (EFPIA, 2018). Indeed, the patent protection system has provided little incentive for research and development of new medicines needed for diseases afflicting developing countries (Pedrique et al., 2013). This highlights some of the difficulties in relying solely on patent protection as the incentive system and on the private sector to develop essential medicines. The WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) was tasked with analysing these issues, amongst others. In its Report, CIPRH stated that ‘because market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing countries is small and uncertain, the incentive effect of IPRs may be limited or non-existent’ (WHO, 2006). Thus, there is a need for other incentives and financial mechanisms to be put in place, which is what the WHO Global Strategy and plan of action (GSPOA) on Public Health, Innovation and Intellectual Property refers to in the WHA Resolution 61.21.

Another concern relates to the subject matter and number of patents that are granted to provide protection for pharmaceutical products. While only a small number of new chemical entities are approved annually, many patent applications for the protection of pharmaceutical products are submitted. For example, the number of new molecular entities (NMEs) approved by the US Food and Drug Administration has drastically declined since the mid-1990s (from 53 in 1996 to 22 in 2016) (Nature Reviews Drug Discovery, 2019). Patent applications for pharmaceuticals are not filed merely on the newly discovered chemical molecule or compound. Patents have increasingly been filed and often granted on variants of a pharmaceutical product, such as salts and other derivatives of the molecule and the specific formulation or dosage form of the medicine. Even so-called ‘incremental’ modifications of existing products, including slight modifications or trivial features such as the form, colour and inert ingredients, have been claimed and obtained patent protection in some countries. Patents have also been granted on the combinations of a known medicine with other known medicines. The granting of these various patents means that a particular pharmaceutical product may be protected during many years although the patent on the chemical molecule on which it is based has expired.

In these circumstances, the criteria applied to examine and grant pharmaceutical patents are extremely relevant for public health policies and not only a matter of concern for patent and industrial policy. Policy makers in the public health area, as well as patent examiners, should be aware that decisions relating to the granting of a patent can directly and unduly affect the health and lives of people.

5.3.6 Patents and Access to Essential Medicines

The HIV/AIDS pandemic and the urgent need to make treatment available for the 14.6 million people in need of treatment (at the end of 2018) continue to bring the question of the affordability of antiretroviral (ARV) medicines to the forefront of international attention (UNAIDS, 2019).

When ARVs were first introduced, the cost of treatment per person was over US\$ 10,000 a year (about US\$ 30 a day). This cost put ARVs out of reach for the vast majority of HIV patients in developing countries, where more than 3 billion people live on less than US\$ 2 a day.⁴ Introduction of competition has resulted in significant reductions in the prices of ARVs. Since then, there has been an increasing reliance on low-cost generic ARV therapy as a strategy for treating more patients; today the annual first line treatment per person is available at less than US\$ 100.

HIV/AIDS was one of the detonating factors of the controversy on patents and access to medicines. Affordability of treatment for other diseases affecting millions of people, such as hepatitis C, malaria, diabetes, cancer, tuberculosis or cardiovascular diseases is also now part of the debate.

5.4 The Doha Declaration on the TRIPS Agreement and Public Health

Although the TRIPS Agreement has introduced a multilateral framework with minimum binding standards for the protection of intellectual property rights, there still exists flexibility within the provisions of the Agreement that permits countries to determine how intellectual property rules should be interpreted and applied to make them more consistent with their national public interest and priorities. However, some governments have been unsure of how that flexibility would be interpreted and how far their rights to use it would be respected.

Although TRIPS affords some discretion about how its obligations are interpreted and implemented by national governments, developing countries have faced obstacles when they sought to use measures to promote access to affordable medicines. For example, when the South African Medicines and Related Substances Act was amended in 1997 to enable parallel importation, the provision was challenged by 39 pharmaceutical companies and the South African Pharmaceutical Manufacturers' Association (PMA) before the Supreme Court of South Africa. The pharmaceutical companies eventually withdrew their legal suit because of a strong reaction from international organisations (notably WHO) and civil society. In another case, the United States challenged the legality of the Brazilian legislation that authorises the grant of compulsory licences in cases where the patent holder has

⁴DO Something.org. '11 Facts About Global Poverty'. <https://www.dosomething.org/us/facts/11-facts-about-global-poverty>.

not ‘worked’ their invention locally (i.e. to manufacture the patented product in the country). The US Government initiated a complaint under the WTO dispute settlement system against Brazil but later withdrew its complaint in 2001.

Other examples are referred to in the report of the United Nations Secretary-General’s (UN SG) High-Level Panel on Access to Medicines such as Thailand’s 2006 decision to import generic versions of the antiretroviral medicine efavirenz from India under compulsory licence (UNHLP, 2016). This decision was met with hostility from the manufacturer, Merck, and the United States Government, which questioned the legality of the compulsory licence and pressed Thailand to rescind its decision. Thailand’s subsequent decision to issue two further compulsory licences in 2007 for lopinavir/ritonavir and clopidogrel also resulted in retaliatory measures. Abbott withdrew from the Thai market all medicines awaiting registration in the country. The European Trade Commissioner wrote to the Thailand Government criticising its use of compulsory licences as ‘detrimental’ to medical innovation, noting that such approaches could lead to Thailand’s isolation from the global biotechnology investment community and urging negotiations (UNHLP, 2016).

In early 2016, the Ministry of Health of Colombia adopted resolution 2475, declaring that access to imatinib, a medicine that appears on the WHO Essential Medicines List, was of ‘public interest’ for the treatment of leukaemia. The resolution was a legal step necessary for the subsequent issuance of a compulsory licence. Letters sent to the co-chair of the UN SG report on Access to Medicines chronicle attempts by various domestic and foreign parties to dissuade the Colombian Government from issuing a compulsory licence as allowed by the TRIPS Agreement and the Doha Declaration.

Paragraph 4 of the Doha Declaration provides important guidance on the interpretation and implementation of the TRIPS Agreement, setting out the basic principle as follows:

*We agree that the TRIPS Agreement **does not and should not** prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement **can and should be** interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose. (Emphasis added.) (WTO, 2001)*

5.5 What Are the TRIPS Flexibilities?

The resolution (WHA49.14) on ‘Revised Drug Strategy’ requested the WHO Director-General to undertake a study on the impact of the WTO, and particularly the TRIPS agreement, on access to health. This study was entrusted to the WHO Drugs Action Programme (DAP). In November 1997, the DAP published the study ‘Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement’, commonly known in the WHO as the ‘red book’ on the TRIPS Agreement (Velásquez & Boulet, 1997, p. 58).

The WHO ‘red book’ speaks about ‘margins of freedom’⁵ (Velásquez & Boulet, 1997, p. 34). Subsequently, in March 2001, the WHO adopted the term ‘safeguards’ in a widely distributed document available in the six WHO official languages (WHO, 2001). In June 2001, the European Commission talks about ‘a sufficiently wide margin of discretion’ regarding the implementation of the TRIPS Agreement (European Commission, 2001, p. 1). A few months later, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health referred to ‘the provisions of the TRIPS Agreement that provide flexibility’.⁶ It is only in June 2002 that WHO referred to TRIPS ‘flexibilities’, in a paper analysing the implications of the Doha declaration, authored by Carlos Correa (WHO, 2002, p. 13) (emphasis added).

The Doha Declaration confirmed that the TRIPS Agreement permits governments to consider and implement a range of options that take public health into account, when formulating intellectual property laws and policy, at national and regional levels. It specifically referred to several aspects of flexibility within the TRIPS Agreement, including the right to grant compulsory licences and to permit parallel importation. This means that countries cannot be prevented from taking certain measures that limit exclusive patent rights, where the interests of public health and the need to ensure access to affordable medicines so require.

The main public health-related flexibilities available under the TRIPS Agreement are briefly described below.

5.5.1 *Criteria for Patentability*

A patent is granted when the application satisfies the criteria for patentability, as laid down in the national (or regional) patent legislation. According to Article 27 of the TRIPS Agreement (WTO, 1994) all national legislations must require a patent application to satisfy the three-fold criteria of:

- **novelty** – the invention must be new, in that it does not form part of the current state of the art in the particular technical field or technology; the state of the art comprises everything that before the application date has been available to the public, nationally or internationally, through its description, utilisation or any other way.
- **inventive step (non-obviousness)** – the invention must not be evident for a ‘person skilled in the art’ (a person trained and experienced in the particular field or technology) in the light of the current state of art; and
- **industrial applicability** (utility) – the invention must be capable of being manufactured or otherwise industrially used, since the aim of the patent law is to protect technical solutions to a given problem, not abstract knowledge.

⁵Emphasis added.

⁶WTO. ‘Doha declaration on the TRIPS Agreement and Public health’, WT/MIN(01)/DEC/W/2, p. 1. Emphasis added.

The way in which the patentability criteria are applied has changed over time and across countries, depending on how governments have determined the appropriate balance of public and private interests. Although the WTO TRIPS Agreement sets out the patentability criteria, it does not provide specific directions or definitions for how these criteria should be interpreted or applied at national level. Hence, WTO members retain the ability to define and apply the criteria, as it best suits the public interest. In this context the definition and interpretation of the three criteria for patentability are probably the most important flexibility contained in the TRIPS Agreement (Correa, 2007; Velásquez, 2015).

5.5.2 *Compulsory Licences*

The patent holder is free to exploit the patent-protected invention or to authorise another person to exploit it. However, when reasons of public interest or the need to correct anticompetitive practices justify it, the government may allow a third party to use the invention, without the patent holder's consent, under a compulsory licence. The patent holder is therefore forced to tolerate the exploitation of his invention by a third person or by the government itself. In these cases, the public interest in ensuring broader access to the patented invention is deemed more important than the private interest of the patent holder in fully exploiting his exclusive rights. Compulsory licences thus permit third parties to use an invention, without the patent holder's consent. For example, where particular medicines are patent protected and priced out of reach of the local population, local pharmaceutical companies may obtain compulsory licences to produce generic versions of patented medicines, or to import generic versions of medicines from foreign manufacturers. There have been 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995 (Son & Lee, 2018).

Compulsory licenses have been issued in developing as well as developed countries. For instance, in July 2017, the German Federal Court announced that it had affirmed the decision of the Federal Patent Court the previous year to issue a compulsory license for the HIV drug raltegravir (marketed as Isentress) (Teschemacher, 2018). Thailand issued a compulsory licence for efavirenz, an HIV/AIDS drug, and in January 2007 issued another two compulsory licences for a heart-disease medicine and for another HIV/AIDS medicine. In May 2007, Brazil also issued a compulsory licence for efavirenz.

5.5.3 *Government Use*

Most patent laws allow the government (or authorised agents of the government) to use privately owned patents for public, non-commercial purposes, without the consent of the patent holder. The right of the government to use a patent for public and

non-commercial use is often framed in broad terms in national laws and very often the process is procedurally much simpler. In other words, it allows for the government use of patents to be ‘fast-tracked’, which is of importance when life-saving medicines are required urgently. There is only an obligation to inform the patent holder of the proposed use of the patent, or promptly after such use. Government use permits the public sector’s production or the importation of generics, for instance, for use in public hospitals (see Box 5.1).

Box 5.1: Examples of Government Use

In October 2003, Malaysia allowed the import of generic didanosine, zidovudine and the lamivudine+zidovudine combination from India, to supply its public hospitals, under the government use provision in its Patent Law. In 2004, Indonesia authorised government use of patents to enable local production of nevirapine and lamivudine. In September 2017 Malaysia issued a ‘government use’ licence for sofosbuvir to treat hepatitis C.

5.5.4 *Parallel Imports*

Patented products that have been legitimately put on the market of the exporting country may be imported into a country without the consent of the patent holder under the principle of exhaustion of rights. This principle means that the rights holder’s control over the pharmaceutical product ceases when the said product is placed in the market for the first time. Since some patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of patented products from countries where they are sold at lower prices. For example, where the national law provides for it, there can be export of a patented medicine from Country A (where it is sold at a lower price) for sale in Country B, subject to the drug regulatory requirements of Country B. ‘Developing countries were keen to clarify in the Doha Declaration, the Members’ right to adopt an international principle of exhaustion of rights’ (Correa, 2016).

5.5.5 *Exceptions to Patent Rights*

All national patent laws have provisions relating to exceptions to the exclusive rights granted by a patent (not to be confused with the exceptions to patentability), although the scope and content of these provisions vary from country to country. Exceptions to the exclusive rights granted by patents are justified on the grounds that in certain circumstances limited exercise of the patent rights is required to achieve public policy purposes of encouraging innovation, promoting education and protecting other public interests. In the context of public health, exceptions to patent rights may be extremely important in facilitating the transfer and diffusion of

technologies and in facilitating the production of generic medicines. National legislation may include different types of exceptions to patent rights; the most important among them being exceptions granted for research and the so called ‘early working’ exception. The ‘early working’ exception (also known as the ‘Bolar’ exception) permits the production of samples of a patented medicine for the purposes of testing and approval before the end of the patent term, to enable speedy introduction of a generic product once a patent expires.

5.5.6 Flexibility in Test Data Protection

The TRIPS Agreement (WTO, 1994, Article 39.3) requires WTO Members to protect test data against unfair competition, which does not create exclusive rights. A correct interpretation and implementation of that provision avoids the burden of creating a ‘data exclusivity’ problematic layer of protection in addition to patent rights on pharmaceuticals. In effect, WTO Members are not obligated under Article 39.3 to confer exclusive rights on the originator marketing approval data (Correa, 2016, p. 62).

5.5.7 Avoidance of TRIPS-Plus Provisions and Policies, Including Extension of Patent Term, Data Exclusivity, Second-Use Patents, Border Measures

TRIPS-plus provisions in free trade agreements (FTAs) (or resulting from accession to WTO) may negatively affect access to medicines. Negotiators of these agreements need timely and evidence-based information to avoid, as far as possible, provisions of this kind that may reduce the accessibility and affordability of medicines through the extension (beyond 20 years) of the term of a patent, exclusive rights in respect of the results of clinical trials (data exclusivity), overbroad border measures (e.g. covering medicines in transit) and other measures affecting market dynamics (see Sect. 5.7 of this book).

5.5.8 Mitigating Implementation or Effects of TRIPS-Plus Provisions

If TRIPS-plus provisions have been accepted, however, there is a range of conditions and safeguards that may be introduced to limit the possible negative impact of such provisions, such as exceptions to data exclusivity (for instance, when a compulsory license has been granted) and limitations to the scope and length of patent term extensions.

5.5.9 Exemption for LDCs

Least developed countries (LDCs) need not grant patents for pharmaceuticals at least until 2033 (WTO, 2001). To use this policy space, some LDCs that provide for the grant of such patents would need to review their legislation or to adopt other measures to protect the government and private parties from infringement claims. They should also preserve that policy space in negotiations of free trade and other international agreements.

5.5.10 Pre- and Post-patent Grant Opposition

Procedures before many patent offices, including the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO), provide for the possibility for third parties to contribute to the examination process through ‘observations’ or ‘oppositions’ whether before or after the grant of a patent, or both. The correct implementation of these procedures helps to improve the quality of patents granted and to avoid the creation of unjustified market barriers.

5.5.11 Use of Competition Law to Address the Misuse of Patents

Competition law may be applied to correct market distortions created through the abuse of intellectual property rights. There are national precedents that may provide useful examples of best practices (UNDP, 2014). Guidelines for the competent authorities on intellectual property and competition law may be developed to facilitate the intervention of such authorities when needed to address anti-competitive practices.

5.5.12 Disclosure Requirement, Particularly for Biologics

The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. Deficient disclosure may unjustifiably extend the coverage of a patent and prevent legitimate acts by third parties. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.

5.5.13 *Flexibilities in Enforcement of IP*

Measures to enforce IP – such as reversal of the burden of proof, determination of damages, border measures – if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. However, there is room to design such measures in a manner that is fair and equitable to all parties engaged in administrative or judicial procedures regarding IP.

5.6 The Paragraph 6 Problem and Its Solution

The so-called ‘Paragraph 6’ mechanism of the Doha Declaration, as implemented by the WTO Decision of 30 August 2003, was a mandate of the WTO Ministerial Conference in Doha (2001) to solve, in an ‘ad hoc’ manner, a problem that affected the poorest countries.

What was (is) the problem? In paragraph (f) of Article 31 of the TRIPS Agreement, it is stated that a compulsory license ‘shall be authorized predominantly for the supply of the domestic market’ (WTO, 1994). This limits the volume of medicines that can be exported when their production has been enabled by a compulsory license. Such provisions affect mainly those countries that lack the manufacturing capacity to produce medicines, such as the least developed countries. This is the reason why Paragraph 6 of the Doha Declaration gives a mandate to find an ‘expeditious solution’ to this problem (Velásquez, 2017, p. 7; WTO, 2001).

The WTO Members first agreed on a temporary solution with the General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. On 6 December 2005, WTO Members agreed to convert the waiver into a permanent solution, which would take the form of an amendment to the TRIPS Agreement. The amendment only came into force on 23 January 2017, when two-thirds of the WTO Members ratified it, although the scheduled deadline to formally accept the amendment was originally fixed for 1 December 2007. The ‘solution’ requested by the Doha Declaration took more than 10 years to be incorporated into the WTO rules.

The decision on Paragraph 6 contains several cumbersome conditions to ensure that beneficiary countries can import generic medicines. In 15 years only one country, Rwanda has used it once, with an importation of antiretroviral medicines from Canada. The manager of the Canadian generic firm stated after the exportation that the system was so complicated that his firm had no intention of using it again (South Centre, 2011).

One of the recommendations of the UN Secretary-General’s High-Level Panel on Access to Medicines state that ‘WTO Member States should review the decision in Paragraph 6 to find a solution that would allow for a quick and convenient export of pharmaceutical products produced under a compulsory license. WTO Member States should, as appropriate, adopt an exception and a permanent reform of the TRIPS Agreement’ (UNHLP, 2016, p. 27).

5.7 Impact of ‘TRIPS-Plus’ and ‘TRIPS Extra’ Provisions

Several bilateral and multilateral international trade and investment agreements require countries to adopt TRIPS-plus or TRIPS extra measures. Such provisions are known as ‘TRIPS-plus’.

While TRIPS-plus and TRIPS extra provisions that have been enacted unilaterally (i.e. where a country has adopted TRIPS-plus or TRIPS extra provisions on its own) may be changed where they are deemed to be inconsistent with the national public health interest, TRIPS-plus obligations entered into under bilateral and other agreements are not as easily reversed without costs. In exchange for the promise of greater access to developed country markets, a number of developing countries have accepted such TRIPS-plus or TRIPS extra obligations. These provisions have raised questions regarding their potential to compromise the use of the TRIPS flexibilities for public health purposes and for promoting innovation with respect to diseases that disproportionately affect developing country populations. The proliferation of bilateral and regional free trade agreements has increased concerns about the impact of trade agreements on access to medicines.

The World Health Assembly, in 2004, passed a resolution urging Member States to ‘take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference’ (WHO, 2004). The need to consider the Doha Declaration and the public health-oriented flexibilities while subscribing trade agreements has been further reiterated by World Health Assembly resolutions. Similarly, the United Nations Secretary-General’s High-Level Panel on Access to Medicines (2016) recommended that: ‘Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available’ (UNHLP, 2016, p. 28).

Some key examples of TRIPS-plus and TRIPS extra provisions are described next.

5.7.1 *Extension of Patent Protection Beyond the TRIPS Minimum*

The TRIPS Agreement requires a minimum patent term of 20 years from the date of filing. This patent term has been extended by provisions in certain bilateral trade agreements to compensate patent holders for any ‘unreasonable delays’ in the granting of the patent or unreasonable curtailment of the patent term because of the

marketing approval process. No such requirement exists under the TRIPS Agreement.

5.7.2 Restrictions on the Use of Compulsory Licences

A few free trade agreements include provisions that restrict use of compulsory licences to cases of emergencies, public non-commercial use or to remedy anti-competitive practices. Such limitations are contrary to the broad discretion governments have in the granting of compulsory licences, as affirmed by the Doha Declaration.

5.7.3 Data Exclusivity

Provisions in several bilateral agreements prohibit the use of test data submitted by originator companies for obtaining marketing approval of a product to facilitate the marketing approval of the generic versions of the originator product for a certain period. Several bilateral trade agreements require a 5-year period during which such data exclusivity will prevent drug regulatory authorities from relying on submitted test data to approve generic entrants. Data exclusivity is not a requirement of the TRIPS Agreement and creates a potential barrier for generic entrants, even when there is no patent on the product. Data exclusivity may also prevent effective use of a compulsory license, in that it may not be possible to obtain marketing approval for a medicine produced or imported under compulsory licence. Furthermore, should generic manufacturers decide to produce such data, it would result in economic waste and in unethical repetition of tests for which the outcomes are already known.

5.7.4 Marketing Approval and Patent Term Linkage

Several bilateral trade agreements have included provisions that prevent national drug regulatory authorities from granting marketing approval for generic pharmaceutical products without 'consent or acquiescence' of the patent holder, when there is a relevant patent in force. This 'linkage' between the patent protection and marketing approval may prevent approvals for generic products during the lifetime of a patent, whereas the TRIPS Agreement permits generic producers to seek regulatory approval during the life of a patent without conditions. Additionally, it obliges an already overloaded national drug authority to undertake a job beyond its field of expertise and competence. In addition, commonly there are many 'secondary' patents in relation to a single drug, which may be unduly used to prevent generic competition, even when the patent on the active ingredient has expired.

5.8 Conclusions

Notwithstanding the Doha Declaration and Article 31bis of the TRIPS Agreement, there remain major challenges in the future scenario for access to medicines. Their success in securing effective access to medicines in developing countries – depends on how countries will implement intellectual property rules to optimise the TRIPS flexibilities in their national laws and whether the necessary policy decisions and measures will be taken. Major challenges for access to medicines in the context of intellectual property rights and trade agreements still exist.

Many developing countries have yet to incorporate the full range of the TRIPS flexibilities within their national laws. There may be several reasons for this delay. First, there may be a need for specific legal expertise to craft and formulate patent laws and regulations that can consider the needs and concerns of developing countries. Second, governments may be subject to pressure from the industry or other governments not to incorporate such flexibilities.

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