

Public health protection in patent laws: selected provisions

Countries that are members of the World Trade Organization (WTO) have to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). The TRIPS Agreement has to a large extent harmonized the standards for the protection of intellectual property rights, including patents. For developing countries, generally, the TRIPS Agreement has increased the level of intellectual property protection; for example, WTO Member countries cannot exempt pharmaceuticals from patent protection (as a number of countries did, before TRIPS came into force). The introduction of these higher TRIPS standards has delayed the marketing of generic versions of new medicines and, thus, the competition they entail; in several developing countries prices of new medicines have remained high for a longer time. This could result in reduced access to those medicines.

In 2001, all WTO members adopted the Doha Declaration on TRIPS and Public Health (or the Doha Declaration) which states that the TRIPS Agreement, “can and should be interpreted and implemented in a manner supportive of WTO members’ rights to protect public health and, in particular, to promote access to medicines for all”. Thus, the TRIPS Agreement does contain some flexibility and some safeguards, which can be used to mitigate potential negative impact on access to medicines. However, they can only be used when incorporated in the national legislation. Therefore, it is crucial to appropriately reflect these flexibilities and safeguards in the national law. This briefing note highlights some of the key issues from a public health perspective that countries may wish to take into account when drafting or revising their intellectual property laws.

However, this note does not – and cannot – provide a complete overview of all provisions

that affect public health. Nor does it purport to be a guide that enables the drafting of intellectual property laws. It merely draws attention to some of the main issues that health officials may wish to raise or verify during the process of drafting or revising such laws.

Box 1: Use a three-pronged strategy

There are three overarching strategies that can be used to protect access to medicines:

- (1) provide adequate safeguards in the domestic law
 - ⊙ incorporate all TRIPS-compliant safeguards
 - ⊙ make sure the safeguards are workable and user-friendly
- (2) exercise exemptions and flexibilities wisely
 - ⊙ use the “2021” and “2033” exemptions for least developed countries (LDCs) if applicable
 - ⊙ avoid “evergreening” and allow for patent oppositions
- (3) avoid “TRIPS-plus” provisions, including in the trade secret or unfair competition law

Since these strategies effectively complement each other, countries may wish to use them in combination.

1. Provide adequate safeguards

Incorporate multiple safeguards

From a public health perspective, it is of utmost importance that the national legislation contains multiple safeguards. This section briefly explains

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some of the key safeguards and provides examples of legal provisions.ⁱ

- ⦿ A “Bolar” provision (or regulatory review exception) allows testing and regulatory approval of generic versions of a medicine, before the patents related to it expire. In the absence of this provision, generic manufacturers may only be able to start the time-consuming process of testing and registering their products after the end of the patent term; this can delay the actual marketing of generics to up to two years after patent expiry. By allowing these preparations to take place before patents expire, a “Bolar” provision creates conditions that allow generic manufacturers to start marketing their product immediately upon expiry of relevant patents. Example 1 shows sample wording.

Example 1: “Bolar” provision

Section: Rights conferred by patent

It is not an infringement of a patent for any person to import, make, construct, use or sell the patented invention solely for purposes reasonably related to the development and submission of information required under any law in [Country name] or of any other country that regulates the manufacture, construction, use or sale of any product.

Other useful exceptions preventing interpretations for infringement of patents include research, experimental use and private non-commercial use.

- ⦿ *Parallel importation* refers to importation, without the consent of the patent holder, of a patented product that is marketed in any other country. In other words, parallel importation allows for importation of the patented product from a third country where it is sold at a lower price. Parallel importation works most effectively when countries adopt an “international exhaustion” regime, thus allowing the imports of patented products marketed anywhere in the world. Like a “Bolar” provision, parallel importation is usually incorporated in the section of the law that deals with exceptions to the rights conferred by a patent (see Example 2).

ⁱ Legal provisions in this note are shown by way of example; they would need to be adapted to fit the national legal context.

Example 2: Parallel importation

Section: Rights conferred by patent

The rights under the patent shall not extend:

....

to acts in respect of a product which has been put on the market in any territory or country by the owner of the patent or with his consent.

Comments:

- ⦿ If the name of the country concerned replaces the words “any territory or country”, it means parallel importation is not allowed; this is known as national exhaustion. If the name of a region replaces the words “any territory or country”, it means parallel imports are only allowed from the countries in that region; this is known as regional exhaustion. In other words a country must follow the “international exhaustion” rule and allow parallel imports from any country in the world to make full use of this flexibility.
- ⦿ A broader version of parallel importation would refer to “acts in respect of products which have been lawfully put on the market in any territory or country”ⁱⁱ.
- ⦿ A *compulsory license* is a license, issued by a competent public authority, to use a patented invention without the authorization of the patent holder. A compulsory license can be used to authorize the import, production and sale of a generic version of a patented product before relevant patents expire.
- ⦿ A *government use authorization* (or compulsory license for public non-commercial use) can be considered as a special case of compulsory licensing, i.e. it is a compulsory license that the government issues for its own purposes, for instance to ensure the availability of medicines in public health facilities. The TRIPS Agreement allows countries to issue compulsory licenses (including government use authorizations), and leaves countries free to decide the grounds, or reasons, for issuing a compulsory license. Some examples of useful grounds for compulsory licenses and government use authorizations can be found in Example 3.

ⁱⁱ See reference 5

Example 3: Grounds for government use/ compulsory license

Section: Exploitation by government/non-voluntary licenses where:

the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
.....

the invention is not available in sufficient quantities or quality or at reasonable prices in [country name];

Comment: It is not a good idea to refer to predetermined reasonable prices, since this raises complicated questions regarding who should determine this and when.

Note: Other important grounds relate to cases of anticompetitive practices by the patent holder and situations of emergency or extreme urgency.

- ⦿ *A Compulsory License exclusively or predominantly for export* was provided for in the 2003 World Trade Organization General Council Decision on Paragraph 6 of the Doha Declaration. This allowed a manufacturing country to export generic versions of patented pharmaceutical products to a country with little or no manufacturing capacity of its own under a compulsory license issued primarily for the purposes of export. This Decision was also reflected in the first ever amendment to the TRIPS Agreement in the form of Article 31*bis*. As of January 2017, this amendment to the TRIPS Agreement is in effect.

It is also important to consider carefully who should have the authority to issue compulsory licenses, including compulsory licenses for public non-commercial use. In some countries, this is the responsibility of the minister under whose responsibility the patent office falls. For example, in Thailand, the Director-General of the Department of Intellectual Property has the authority to grant compulsory licenses, while a government use authorization may be issued by “any ministry, bureau or department of the government”.ⁱⁱⁱ Similarly, in the United States, any department of the federal government can use or authorize “government use” of a patent. In Ecuador, while the Ecuadorian

ⁱⁱⁱ Section 51, Patent Act B.E.2522 (1979) as amended by Patent Act (No2) B.E.2535 (1992) and Patent Act (No3) B.E.2542 (1999), Thailand

Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, is designated as the competent authority to grant compulsory licenses on patents for medicines, it is required to do so in coordination with the Ministry of Public Health.^{iv}

Some countries have stated specific timeframes in their law or regulations to ensure that compulsory licensing procedures will be completed and decisions taken in a timely manner. For example, in India, the patent law specifies that a “reasonable period” for negotiations to obtain a licence from the patentee that are required to precede a compulsory license application should not ordinarily exceed a period of six months.^v In Ecuador, the drug regulator is required to take the necessary steps for granting registration to medicines produced or imported under the compulsory licensing regime, within a maximum of 30 days from when the application for registration is filed.^{vi}

Moreover, since few countries are completely self-sufficient with regard to pharmaceuticals, it is important that the law allows the implementation of compulsory licenses and government use authorizations through importation. Laws of countries with manufacturing capacity should also allow for export of medicines produced under a compulsory license exclusively or predominantly for such purposes in line with Article 31*bis* of the TRIPS Agreement as discussed above.

Have user-friendly procedures

While it is of utmost importance that the above-mentioned safeguards are incorporated in the national legislation, this is not enough. It is equally important to ensure that the safeguards – especially the provisions regarding compulsory licensing and government use – are workable in practice.

- ⦿ *Appeal not to suspend compulsory license.* Countries may wish to specify in their national law that an appeal against the grant of a compulsory license cannot suspend its execution (see Example 4). Otherwise, appeals may be able to prevent or delay the implementation

^{iv} Article 2, Executive Decree No. 118 on Declaration of Public Interest Regarding Access to Medicines for Human Use, October 23, 2009, Ecuador

^v Explanation, Section 84(6) India Patents Act 1970

^{vi} Article 3, Executive Decree No. 118 on Declaration of Public Interest Regarding Access to Medicines for Human Use, October 23, 2009, Ecuador



of a compulsory license as long as a (judicial) review is pending—which can take several months or years. Even when the decision to grant a compulsory license is upheld, such lengthy delays would create significant disincentives for the use of compulsory licensing, could undermine the purpose of the compulsory license, and could have serious public health implications. Thus, from a public health perspective it is preferable to ensure that an appeal cannot suspend the execution of a compulsory license.

Meanwhile, if it was eventually found that the issuing of a compulsory license was not justified, the patent holder can be compensated financially.

Example 4: Appeal not to suspend compulsory license

Section: Exploitation by government/non-voluntary licenses

An appeal shall not stay or suspend the execution of the compulsory license.

Some patent laws explicitly state that in case of a government use authorization, the patent holder can only contest the amount of compensation (see Example 4); this is explicitly allowed by TRIPS Article 44.2 (see Box 2), and implemented in, for example, the United States of America.^{vii}

Box 2: Article 44.2 of TRIPS

Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

2. Exercise exemptions and flexibilities wisely

There are a number of other clauses that countries may wish to incorporate in their national laws.

vii See reference 4

- The “2021 and 2033 transition periods” or “LDC exemptions”: Under the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, WTO Member States that are least developed countries enjoy two transition periods. The first is the transition period to apply the TRIPS Agreement by 2021 under which LDCs are not required to implement TRIPS (except Articles 3, 4 and 5) until 1 July 2021.^{viii} The second is the right to postpone the granting and/or enforcement of patents and data protection for pharmaceuticals until 1 January 2033.^{ix} Additionally, transition period obligations that may be applicable to some LDCs to set up mailboxes and provide exclusive marketing rights to pharmaceutical products are also waived till 2033.^x This gives least developed countries more time to finetune their intellectual property regime as well as patent and data protection for pharmaceuticals according to their needs.

The pharmaceutical exemption can be incorporated in the law under matter excluded from patent protection (see Example 5) or as a standalone clause. The former approach has been taken by Uganda while the latter approach has been adopted by Cambodia (see reference 12).

Example 5: “LDC exemption”

Section: Matter excluded from patent protection
The following shall be excluded from patent protection:

...pharmaceutical products and processes until 1 January 2033.

- An “anti-evergreening” clause. “Evergreening” is an informal term that is often used to describe patenting strategies that are intended to extend patent protection over the same compound. Evergreening can occur in a number of ways but typically arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or on reformulations of the original compound that have no incremental therapeutic value, but which are nevertheless deemed patentable under some patent laws.

viii See WTO Document IP/C/64.

ix See WTO Document IP/C/73

x See WTO Document WT/L/971

For instance, patenting of a similar but different dosage form (such as capsules rather than tablets), or patenting of salts, esters, or crystals (polymorphs) of the same product.^{xi}

According to the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), evergreening occurs in almost all jurisdictions. For example, in the United States, upon expiry of the original patent on the antidepressant paroxetine, the patent holder applied for – and obtained – 10 additional patents. These covered paroxetine hydrochloride hemihydrate, new uses and different forms of paroxetine hydrochloride, and formulation patents. These additional patents delayed the marketing of a generic version for more than five years.^{xii}

In 2005, India was the first country to incorporate a provision in its law that specifically aimed at preventing the grant of “evergreening” patents (see Box 3). This provision – or a simplified equivalent – can be used to prevent the issuing of unnecessary or frivolous “evergreening” patents. In April 2008, Philippines amended its Intellectual Property Code; the amendment introduced a similar “anti-evergreening” clause.^{xiii} In 2016, Indonesia amended its patent law to also include restrictions on evergreening.^{xiv} An

Box 3: “Anti-evergreening” clause in India’s Patents Act

The following are not inventions within the meaning of this Act, - [...]

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

xi See reference 6

xii See reference 6.

xiii In fact, it introduced it twice; once under “non-patentable inventions” and once under “inventive step”. See Section 5, Universally Accessible Cheaper and Quality Medicines Act of 2008 (Republic Act No. 9502), Philippines

xiv Article 3(f), Indonesia Patent Law, 2016

alternative approach would be to incorporate an “anti-evergreening” provision in the section of the law that deals with patentability criteria, notably inventiveness. In 2012, Argentina issued regulations for the examination of pharmaceutical patent applications that detail how new forms of existing medicines may not meet the patentability criteria.^{xv}

Further, most patent laws exempt methods of treatment from patent protection. Commonly found language is shown in Example 6. Other useful exemptions include discoveries and “new uses of a known substance or product”.

Example 6: Exempt methods of treatment

Section: Matter excluded from patent protection

The following shall be excluded from patent protection:

...

methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body.

- *Allow patent oppositions.* In some developing countries, public interest groups have effectively used provisions allowing the filing of patent oppositions to challenge patent applications or granted patents on critical medicines. Particularly in overburdened and under-resourced patent offices in developing countries, such oppositions can assist patent examiners with scientific and technical documents in ensuring that high-quality patents are granted. Some countries provide for either pre- or post- grant oppositions while some provide both. It is important to provide a broad standing for those who can file oppositions so that it is not restricted only to competitors but may include public interest groups as well. Under Indonesia’s 2016 amendments to its patent law, any person may file objections on a published patent application.^{xvi} Some laws that do provide for oppositions provide a limited window for such filings which may render the opportunity to oppose ineffective. Under India’s patent law on the other hand, a pre-grant patent opposition can be filed any time before the grant of a patent.^{xvii}

xv Joint Resolution No. 118/20012, 546/2012 and 107/2012 of May 2, 2012, of the Ministry of Industry, Ministry of Health and the National Industrial Property Institute (INPI), approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions, Argentina

xvi Article 49, Indonesia Patent Law, 2016

xvii Section 25, India Patents Act 1970

3. Avoid trips-plus measures

- Avoid *patent term extensions*. Patent term extensions are provisions to extend the duration of a patent beyond the 20 years required by TRIPS, for instance in order to compensate for delays in granting the patent or in registering a pharmaceutical product with a drug regulator. An example is shown below (Example 7). The TRIPS Agreement contains no obligation to grant such extensions.

Example 7: Patent term extensions

Section: Duration

In the event a patent is granted more than four years after the filing date, the term of protection of that patent shall be automatically extended so as to compensate for any period of time in excess of four years from the filing date.

Comment: This is “TRIPS-plus”; it is not required by TRIPS.

- Avoid *criminal sanctions*. Another key question is whether or not the law should provide for criminal sanctions in case of patent infringement. It can be very difficult to assess whether or not a patent is valid and has been infringed (especially for process patents and for certain “evergreening” patents (see above)). Thus, generic suppliers or public health authorities may inadvertently infringe a patent. In such cases, infringement proceedings may be warranted, but criminal sanctions would appear to be too harsh. Moreover, threats/fear of criminal prosecution could unduly deter authorities and others from supplying and using generic medicines that in fact do not infringe any patent rights. From the perspective of public health and protecting access to medicines, it is therefore preferable not to allow for criminal sanctions in case of patent infringement.

It is worth noting that TRIPS does not require countries to provide for criminal sanctions in case of patent infringement. The relevant TRIPS Article (Article 61) states “Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. ... Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial

scale” (emphasis added). For instance, in Canada, the United Kingdom and United States, patent infringement is not subject to criminal sanctions; only civil remedies are available.

Check unfair competition and trade secret provisions

In avoiding TRIPS-plus provisions, in addition to the provisions that relate to patents, it is also important to review the provisions on trade secrets and/or unfair competition; trade secrets are considered to cover commercially valuable information such as production methods, business plans, clientele, etc. and are protected as long as they remain secret. Such protection takes different forms depending on the legal system in a country and can either be part of an integrated intellectual property law, or form a separate law or act as seen in the boxes below.

Certain “TRIPS-plus” provisions, notably data exclusivity, may figure here.

Data exclusivity prevents the regulatory authorities, for a specified period, from relying on data (e.g. the results of clinical trials) provided by an originator, in order to grant marketing approval to a generic equivalent. Data exclusivity can delay generic market entry, even when a medicine is not patented.^{xviii}

Data exclusivity is not required by the TRIPS Agreement, and is unlikely to benefit developing countries. It should not be confused with data protection, which is a TRIPS-requirement under Article 39.3 which requires WTO Members to protect undisclosed data on new chemical entities in the pharmaceutical or agrochemical sectors that is submitted to government regulators to obtain marketing approval.

TRIPS-plus provisions on data exclusivity go beyond TRIPS requirements and often features in free trade agreement negotiations. This can include fixed terms of data exclusivity, data exclusivity for new uses or new forms of new chemical entities or for older chemical entities previously approved abroad (but being approved for the first time in the country in question), data exclusivity for biological medicines or data exclusivity based on data not submitted to the government regulator but that is submitted abroad.

^{xviii} For more information, see: Briefing note: Data exclusivity and other “TRIPS-plus” measures. WHO SEARO and WPRO, 2017.

In effect such requirements may delay registration of generic pharmaceutical products.

Box 4 illustrates data protection, while Box 5 illustrates data exclusivity.

Where the law has a preamble or a section stating its objectives, this should refer to protecting innovation; and preferably also mention the need to take into account public interest and interest of technology-users to have access to knowledge, inventions and creations. This is important, since Courts may draw on the preamble and/or objectives when interpreting the law.

Obviously there are many more issues and details that merit attention and that can have implications for public health. These include a considerable number of procedural matters. Examples include, but are not limited to, the clauses dealing with disclosure standards, invalidation, restoration and the provision of information on foreign patent applications on the same invention (see also references 1 and 2). These and other provisions should be appropriately worded and reflected in the national legislation to ensure protection of the public health interest.

Box 4: Data protection clause in the Andean Community Decision No. 486 establishing the common industrial property regime

Title: TITLE XVI UNFAIR COMPETITION IN CONNECTION WITH INDUSTRIAL PROPERTY

Article 266. Where Member countries demand, as a condition of marketing approval for pharmaceutical products or agricultural chemicals that make use of new chemical compounds, the submission of undisclosed test or other data the production of which has entailed a considerable effort, they shall protect those data against any unfair commercial use. Member countries shall, in addition, protect those data against any disclosure, except where it is necessary for the protection of the public, or unless action is taken to guarantee the protection of the data against any improper commercial use. The Member countries may take necessary action to guarantee the protection provided for in this Article.

Comment: This is TRIPS-compliant language providing for data protection.

Box 5: Data exclusivity clause in Jordan's Trade Secrets and Unfair Competition Law

Article 8: If an official party stipulated, for approving the marketing of pharmaceuticals, or agrochemical products in which new chemical materials are used, the submission of secret formulae or any data attained through considerable efforts, such party should observe the following:

A. The protection of such data from the unclassified commercial use, through preventing any other person who did not obtain the applicant approval from depending thereon for marketing his pharmaceuticals and products except after 5 years as of the date of the applicant obtaining any approval for marketing his products.

Comment: This language is "TRIPS-plus" providing for data exclusivity as it prevents registration of generic medicines for a period of time (5 years); it is not required by TRIPS – NB: TRIPS-plus – to be avoided.

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