

10 TRIPS+ provisions

TRIPS imposes a minimum standard of protection of intellectual property, however it does not prevent countries from adopting extra protections. Such provisions are often referred to as TRIPS-plus (TRIPS+). Many countries have national laws that encompass TRIPS+ provisions, as a consequence of technical assistance provided by international agencies such as WIPO or by other countries promoting high levels of protection, of pressure from these countries, pressure, lobbying or litigation by multinational pharmaceutical corporations, through accession to the WTO or due to the signing of bilateral or regional trade agreements. This factsheet identifies the most frequent types of TRIPS+ provisions one can find in national laws and free trade agreements.

Expansion of the scope of patentability

According to the TRIPS agreement, “patents shall be available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step and is capable of industrial application” (art. 27.1). This provision leaves WTO Member states some invaluable flexibility in the way they apply this definition as well as the option to exclude materials from patentability under some circumstances (art. 27.3). In contrast, trade agreements or some national laws tend to expand patentability criteria and limit general exclusions in several ways. This leads to an increase in the number of patents issued and creates additional barriers to generic access.

One important expansion involves granting patents on new uses of known substances (a.k.a. second indications, second medical uses, Swiss-type claims), new forms of known substances, and fixed dose combinations of known drugs.

The proliferation of patents is also fueled by the suppression of some of the exceptions to patentability (on plants, animals, methods for treatment, surgical methods, diagnostics, etc.). For instance, pressing forward in the march of relaxing patentability standards, the US FTA with Oman introduces the patentability of “new methods for treatment of particular medical conditions” even though the TRIPS Agreement specifically allows for the exclusion of methods of treatment from patenting.

In addition to TRIPS+ provisions affecting the scope of patentability, patent offices often

tend to grant patents without applying strict patentability criteria and instead interpreting novelty and inventiveness in a very lax and broad way which leads to the multiplication of weak and frivolous patents and unjustified monopoly situations.

Restrictions on oppositions to patents

National laws or trade agreements often place restrictions on patent opposition mechanisms. In particular some countries exclude pre-grant oppositions, that is, oppositions during the examination process before the patent is granted. This is very relevant in the field of health, where social stakes are high as pre-grant oppositions can prevent the establishment of undue monopolies that will otherwise prevent the use of generic products. In an increasing number of countries, people living with HIV, health groups and other public interest groups have filed multiple patent oppositions with key successes. (see factsheet on patent oppositions).¹ Post-grant opposition systems in most countries do not have suspensive effect i.e. the patent remains in force during the opposition proceedings. Some countries also only allow third party observation systems allowing information to be submitted to the patent office without providing any active role for an opponent to argue the case or provide replies to claims of patent applicants.

It is also often the case that the window to introduce pre-grant or post-grant oppositions is very short: too short to realistically allow opposition that develop complex technical and legal arguments to be developed.

1. See for instance the patent opposition database: [<https://www.patentoppositions.org>].

Other obstacles can include the fact that the opposition may have to be filled through a court action only, when in many countries it can be done directly to the patent office. Countries also place restrictions on those who can file oppositions at times and may not allow public interest groups to oppose patents.

These limitations are unfortunate as opposition actions can be of great help for patent offices in fulfilling their duty to grant high quality patents that reward genuine inventions.

Extension of the duration of patent protection

The negotiations of the TRIPS Agreement ultimately led to the institution of an international standard of patent protection of 20 years from the date of filing (art. 33). In many countries this led to a significant increase in the period of monopoly. The rationale for the new consensus, was, in particular, taking into account the fact that the patent granting process necessarily takes time, to ensure a period that would be long enough for patent holders.

However, since the TRIPS agreement was concluded many bilateral or regional trade agreements require that governments allow extension of patent protection beyond the 20-year period. The arguments used to support this extension is generally to compensate for excessive delays either in the examination process of patent application or in the process to grant marketing approval to medicines, and that have to be compensated.

This of course delays the introduction of affordable generic medicines. There can be several reasons for the time taken in granting patents or giving marketing approval including delays by the patent applicant. Patent examination and the granting of marketing authorization should be performed properly, in depth and not be rushed. Moreover, nothing can justify that extra income be extracted from developing countries by prolonging monopolies, especially as pharmaceutical companies already make so much profit during each year that they enjoy the monopoly and considering that monopolies have a strong impact on prices which in turn limit access of patients to new and essential health products.

Restrictions on parallel imports

Parallel import allows nationals to buy a patented good from outside of their country, for instance patented medicines that are sold at a cheaper price abroad. Parallel importation is the importation a patented product without the consent of the patent-holder. It is based on the

legal notion of “exhaustion of rights” according to which a right owner is correctly and definitively remunerated once the product is put on a market. As the right owner has exhausted his/her intellectual property rights on the commercial exploitation of the good through the act of selling the product, s/he cannot prevent the circulation of patented goods put lawfully on the market. The regime of exhaustion of rights can be international, regional or national. Under a regime of national exhaustion of rights, once the right owner has put the product on the national market, s/he loses control on how it is resold on this market. However, s/he (or somebody s/he has authorized) can oppose importation of patented product from abroad. In the case of an international exhaustion of right, once the product is put on the market somewhere in world, the patent holder loses the authority to prevent importation from any place in the world. In the case of a regional regime of exhaustion, the product can only be purchased from a country in the region. Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members have this right, stating that each Member is free to establish its own regime (international, regional or national) for such exhaustion without challenge.

However, some national laws or some trade agreements require countries to set a national or regional regime of exhaustion of right and therefore prevents or limits parallel import. Countries that allow international exhaustion but require that the drug is put on the international market only by the patent holder also limit their access: indeed often drugs can be put on the market in other countries by a licensee of the patent holder or even a licensee under a compulsory license.

Limitations on the use of compulsory licensing

The TRIPS agreement leaves WTO member states free to decide of the reasons why they want to use compulsory licensing, as the Doha declaration reiterated in 2001: “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (§ 5.b).

However, many national laws restrict the use of compulsory licensing, often mentioning only a limited number of grounds that authorize it. Often the grounds for CL is limited to no or insufficient use of the patent after a delay – of 3 years after the granting of a patent or 4 years after filing of the application as provided in the Paris convention in cases where there is a “failure

to work or insufficient working" (Art. 5.A(4)) or to cases of national emergency. Too often national laws do not include and list important grounds such as: public non-commercial use, case of abuses of right and to remedy anti-competitive practices, prohibitive prices of medicines and when national needs are not met due to quantity or quality issues or support to key economic, social or technological development.

In some countries there is no possibility for national institutions like patent offices or ministries of health to grant compulsory licences through an administrative act and the only option is through a court; this can make the process quite cumbersome. In other countries only parties in a position to use the patent can introduce a request for a compulsory license, which excludes civil society organizations which have no industrial or commercial capacities. In some countries an appeal against the compulsory license results in its suspension till the appeal is decided. Some countries require prior negotiations with the patent holder in all cases even though the TRIPS Agreement provides that these negotiations are not required in cases of national emergency, extreme urgency, public non-commercial use or where the compulsory license is issued to remedy anti-competitive practices. In countries that implement data exclusivity there can be additional limits on compulsory licenses (see below).

Bilateral and regional trade agreements can also result in such limits being placed on the use of compulsory licenses.

Data exclusivity

To obtain marketing approval for a new product, pharmaceutical companies must submit data proving the absence of toxicity and the effectiveness of the product to drug regulatory authorities. Such data is referred to as "registration data" or "marketing approval data" and results from tests and clinical trials on animals and human beings. When a company wants to market a generic version of a pharmaceutical product already on the market, the regulatory authorities usually do not ask it to undertake the same clinical trials (which would be unethical); they often ask the company to provide the results of bioequivalence and bio-availability tests proving that the product is chemically equivalent and has the same action in the human body as the brand-name product. The authorities rely on published evidence and/or the data on toxicity and effectiveness provided for the marketing of the first product to be registered to authorize the generic versions. Data exclusivity establishes a marketing monopoly as it prevents drug regulators from

relying on the information provided to get marketing authorization in the originator dossier (in the country or in another country) to approve the generic version requiring instead that competitors conduct new clinical trials or stay off the market for a certain period of time.

The results of the clinical trial become of exclusive use to the first company and can result in delayed generic access even where a drug comes off-patent. Such data exclusivity, without a waiver provision, can also render the granting of compulsory licensing useless as even if a generic version of the product is legally produced or imported through compulsory licensing, it will not be possible to put it on the market. Even old products, unpatented products can benefit from a monopoly under this provision, as long as they have not already been marketed before.

Data exclusivity has been adopted in the wealthiest countries and is largely spread in other countries through trade agreements.

Patent Linkage

Trade agreements often require the establishment of a procedural link between the granting of marketing approval and patent protection. They require drug regulatory authorities to refuse to grant marketing approval to third parties when it concerns generic versions of products that are protected by a patent. This leads public health institutions to ensure the protection of private rights of companies, when according to patent law if there is a suspicion of infringement it is up to the patent holder to pursue legal action. They also, in some cases impose requirements on the regulatory authorities to inform patent holders of the identity of third parties applying for marketing approvals during the patent term. Drug regulators do not have the resources or expertise to determine if a medicine is actually protected by a patent or whether that patent is justified and end up relying entirely on information provided by patent holders that can be incorrect or misleading.

"Trade secrets" protection

Trade secret is an issue that was on purpose not defined and regulated by the WTO and the TRIPS agreement. Article 39.2 of the TRIPS Agreement requires countries to put in place provisions to protect information from being disclosed to, acquired by, or used by others without the consent of their owner in a manner contrary to honest commercial practices (provided that the information concerned is secret, has commercial value and there have been reasonable attempts to keep it secret). But it does not specify what

these provisions might be, does not use the term “trade secrets”, and left the freedom to member states to decide how they wanted to protect undisclosed information with commercial value from acts contrary to honest commercial practices were concerned.

New trade agreements request countries implement protections specifically on “trade secrets”. This is a way for multinational companies to obtain new rights and has been high on their lobbying agenda over the past few years. The objective of MNCs is to be able to qualify as “trade secret” any information they want to be able to refuse to disclose. In the field of health and medicines this can concern hidden side effects, overstated health benefits, blockage of access to clinical trial information that would help develop a counter expertise in civil society and among health professionals, etc.²

New laws on trade secrets are also a means to create new grounds to attack competitors, employees, whistle-blowers, public institutions, governments for releasing or using information that they consider should not be made public or used by others. Law setting a broad and unspecific definition of trade secret, qualifying it at intellectual property (when undisclosed commercial information were until now not considered as such in most countries across the world) make it possible for large commercial companies to be very aggressive towards other actors that do not necessarily have the means to defend themselves (employees, doctors, small enterprises, etc.). It may even serve the purpose of companies’ actions against governments through *Investor-state dispute settlement (ISDS)* made possible by trade agreements (see below).

2. See for instance Health Action International statement during the negotiation of the EU directive in 2016: [<http://haiweb.org/wp-content/uploads/2016/04/Statement-on-Trade-Secrets-Directive-Vote.pdf>].

3. See for instance MSF letter concerning the Regional Comprehensive Economic Partnership (RCEP) investment chapter : [https://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Letter_RCEPInvestmentLetterForNegotiators_ENG_2017.pdf].

Investment chapters and ISDS

Many trade agreements and bilateral investment treaties (BITs) contain investment rules that threaten access to affordable medicines. Indeed these chapters contain provisions allowing multinational pharmaceutical corporations to challenge any domestic regulation or judicial decision they claim impedes their investments and the profits deriving from investments. As intellectual property assets are considered in these agreements as investment, multinational companies can argue that any policy or administrative decision resting on the use of TRIPS flexibilities to protect public health and ensure access to generic medicines is contrary to their investments.

Such provisions can be used by pharmaceutical companies to sue governments in international arbitration tribunals under the controversial investor-state dispute settlement (ISDS) mechanisms that are established under these agreements. These ISDS tribunals are *private tribunals* outside of the domestic court system; they do not meet standards of transparency or due process, and rarely take into consideration issues such as the right to health.

In the field of medicines several examples have shown the extremely dangerous impact of these investments rules forcing governments to reverse policy decisions or if they decide to face the arbitration pay millions in legal fees.³ Taking advantage of the arbitration tribunal established by the investment chapter of the North American Free Trade Agreement (NAFTA), in 2013, Eli Lilly launched a \$500 million claim against the Government of Canada. The pharmaceutical company challenged the decision by a Canadian court to invalidate secondary patents on drugs used to treat mental illness. Although the Canadian government finally won the case, its costs and legal fees in defending the case amounted to 15 million dollars of which Eli Lilly was directed to pay only 5 million dollars. In 2016, Gilead Sciences threatened to use investment rights and ISDS provisions under the US-Ukraine BIT against the Ukrainian government over the registration of a generic version of the hepatitis C medicine sofosbuvir. The damage claim exceeded US\$ 800 million. Gilead withdrew the case only after the government of Ukraine cancelled the generic registration. The same year, Novartis threatened to resort to international investment arbitration established by the Swiss-Colombian bilateral investment treaty (BIT), signed in 2006, to discourage Colombia’s government from issuing a compulsory license to allow generic competition on the leukaemia drug imatinib.

READING MATERIAL

→ The Need to Avoid “TRIPS-Plus” Patent Clauses in Trade Agreements, Martin Khor, The South Centre, March 2017. Available at: [https://www.southcentre.int/wp-content/uploads/2017/03/PB37_The-Need-to-Avoid-%E2%80%9CTRIPS-Plus%E2%80%9D-Patent-Clauses-in-Trade-Agreements_EN.pdf].

→ Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements, The South Centre, Carlos M. Correa, February 2017. Available at: [https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf].

→ Mercosur-EU Free Trade Agreement: Impact analysis of TRIPS-plus measures proposed by the EU on public purchases and domestic production of HIV and Hepatitis C medicines in Brazil, Gabriela Costa Chaves, Walter Britto Gaspar, Marcela Fogaça, September 2017. Available at: [<http://www.ensp.fiocruz.br/portal-ensp/informe/site/arquivos/anexos/01abfe4ae54f0d6efd743fe6eeab259bdb702.PDF>].

→ Global Summit On IP And Access Discusses Impact Of TRIPS-Plus Measures On Public Health, Catherine Saez, January 2018. Available at: [<https://www.ip-watch.org/2018/01/17/global-summit-ip-access-discusses-impact-trips-plus-measures-public-health>].