

05

TRIPS Obligations and TRIPS Flexibilities on Patents

The World Trade Organization (WTO) is an international body that regulates trade between countries that are member States of the organization (currently 164). It is based on several agreements signed by all WTO members that legally bind them to adopt and implement legal and policy actions at the national level. These agreements can be enforced through the WTO Dispute Settlement Body – a mechanism for members to complain, obtain arbitration and possibly sanctions against other members. Among these is the Agreement on Trade Related Aspects of Intellectual Property Rights or the TRIPS Agreement. The TRIPS Agreement requires all WTO countries to establish a specified level of intellectual property protection through national (or regional) laws – all countries had to change their law to comply to this. While the TRIPS Agreement covers several forms of intellectual property (copyright, trademark, designs, geographical indications, patents), this factsheet will focus on the provisions of the TRIPS Agreement as they relate to patents and pharmaceuticals.

TRIPS Obligations on Patents

Patents are granted on inventions. In relation to patents, TRIPS requires WTO members to implement several obligations including:

- 1** Patents must be available for products or processes as long as they meet the patentability criteria. They must be available in all fields of technology which means that, unlike patent laws in some countries before they had to comply with TRIPS, pharmaceuticals cannot be exempted from patent protection. Some countries also used to deny patents for products or processes invented in other countries or if they were only imported and not locally manufactured. Under TRIPS such restrictions can no longer be included in a WTO member country's patent law. This is referred to as **patentable subject matter**. However under the TRIPS Agreement itself, not all products and processes are patentable (see below: exclusions from patentable subject matter)
- 2** Patents must be granted where a product or process is new, involve an inventive step (or non-obvious) and capable of industrial application (or useful). This is referred to as **patentability criteria**. The TRIPS Agreement does not however define what these terms mean and this constitutes a key flexibility based on which patents on key medicines that can lead to reject patentability in some cases (see below: Strict Patentability Criteria)
- 3** A granted patent will allow the patent holder to prevent any other person from (a) making; (b) using; (c) selling; (d) offering for sale and (e) importing a patented product without the permission of the patent holder for a certain period of time. These are known as **patent rights** and can be subject to certain limitations (see below: Limited Exceptions on Patent Rights).
- 4** A patent must be granted for 20 years. This is known as the **patent term**.
- 5** The TRIPS Agreement recognizes that countries can allow persons other than a patent holder to use, make or import a patented product. Referred to as 'other use without authorisation' in Article 31 of TRIPS,

this is more commonly known as **compulsory licenses (CLs)**. The TRIPS Agreement imposes several obligations in how countries can exercise their rights to issue CLs including requirements for prior negotiations with patent holders, providing remuneration to patent holders, providing for appeals and more (see factsheet on CLs)

6 Violation of patent rights is known as **infringement**. TRIPS requires that countries provide patent holders with avenues to enforce their patents through courts where they believe there has been an infringement. This is known as **enforcement**. It also requires countries to give their courts certain powers in such cases such as to hear the case without the party present, to prevent or stop the infringement and to award damages in such cases.

7 TRIPS also requires that countries provide patent holders with the ability to stop the import of products that violate their patents through customs authorities. These are known as **border measures**.

8 These obligations of the TRIPS Agreement were not immediately applicable to all countries. Developed countries had to comply by 1996. Developing countries had to comply by 2000 or 2005 (in case they did not recognise patents in certain fields before TRIPS came into force). Least Developed Countries have till 2021 to comply with TRIPS and till 2033 to comply with TRIPS obligations on patent and data protection for pharmaceutical products. These are known as **transition periods**.

TRIPS flexibilities

In the field of health, the products and processes that are required to be patented under the TRIPS Agreement include health technologies like medicines. It is interesting to note that until early 1990s, approximately 50 developing countries either excluded medicines from patentability or provided shorter periods of protection or operated conditions which restricted patent holders' rights. In 1995 after the WTO was established and the TRIPS Agreement signed as part of the WTO, the CEO of the US MNC Pfizer confirmed that, *"the current GATT victory, which established provisions for intellectual property, resulted in part from the hard-fought efforts of the US government and US businesses, including Pfizer, over the past three decades. We've been in it from the beginning, taking a leadership role."* Indeed, one of the key impacts of the TRIPS Agreement has in fact been in the area of pharmaceuticals.

Nowhere has the conflict between trade and health been as apparent as in the case of the HIV epidemic. However, while the TRIPS Agreement was being negotiated, developing countries and LDCs were able to obtain some safeguards also known as **TRIPS flexibilities** that allow countries to balance between private interests and public interest. In order to use these safeguards and flexibilities, countries need to include these in their own laws. When the use of flexibilities became necessary to many developing countries in order to access HIV medicines in the context of an epidemic that was out of control, it has proven difficult to do so, because of (legal, political, economic) threats by MNCs or developed countries. In 1999, the South African government tried to include and use flexibilities in its medicines law and was sued by 39 pharmaceutical companies. The global outrage over the case eventually led to the signing of the Doha Declaration on TRIPS and Public Health in 2001 which stated that "the (TRIPS) 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."**

What the Doha Declaration highlighted was that countries could use safeguards in the TRIPS Agreement, also known as TRIPS flexibilities to ensure access to medicines. In doing so it specifically highlighted three key flexibilities i.e. compulsory licenses, parallel imports and transition periods for LDCs. It also led to the adoption of an additional flexibility

i.e. compulsory licenses for exports. However, contrary to popular perception and attempts by pharmaceutical MNCs to argue otherwise, there are several TRIPS flexibilities in addition to these that are available to WTO members that they can use to ensure access to affordable health technologies. These include:

1 Exclusions from patentable subject matter: The TRIPS Agreement itself provides that certain products and processes can be excluded from patentability such as on grounds of public order and morality. Additionally countries can exclude plants and animals from patents which can prevent patents on plants with medicinal properties. They can also exclude patents on diagnostic, therapeutic and surgical methods which for instance would prevent a surgeon from patenting a new way to make an incision during a surgery. Although not specifically mentioned in TRIPS, countries also exclude discoveries from patents; for instance, in some countries human genes related to Her-2 positive breast cancer have been patented preventing access to affordable diagnostics for women. An exclusion of discoveries from patents could have a huge impact on patients' capacity to access medicines or diagnostics.

2 Strict patentability criteria: The TRIPS Agreement does not define what new, inventive step or industrial applicability means; whether a country decides to apply these standards strictly or not determines how many patents that country would have to deal with. For instance in applying the criteria of "new", a country that does not grant patents on a product or process if information on it has been published anywhere in the world will have less patents than a country that only looks for prior information published within the country. Similarly strict standards can be included for determining inventive step and industrial application. Developing countries can also use strict standards of patentability to prevent evergreening and ensure that only truly innovative medicines and not new uses or new forms of old medicines get patented in their countries. New forms and new uses of existing products can thus be excluded from patents. This would prevent an old drug previously used to treat cancer from being patented for its use in HIV as happened in the case of zidovudine in some countries or minor and obvious changes to an existing drug or combinations of existing drugs from being patented. (See factsheet on evergreening).

3 Patent Oppositions: Oppositions filed before the grant of a patent (pre-grant oppositions) or after the grant of a patent (post-grant oppositions) are critical processes aimed at assisting the Patent Office with all available information on the product or process on which a patent application is filed. In several developing 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)

4 Limited exceptions to patent rights: TRIPS recognises that countries may provide limited exceptions to patent rights under Article 30; while these exceptions are not specified, there have been several long established exceptions in the patent laws of countries including exceptions for Private and Non-commercial Use; Research/Experimental/Scientific Use exception; Prior Use exception; Pharmacy exception; Exhaustion exception(s); Regulatory Review exception; Medical practitioner exception; Teaching exceptions, etc. Two of the most often discussed exceptions are:

(A) Regulatory Review or Bolar Exception: When a generic company wants to sell its medicine on the market, it has to register it with the country's drug regulator and has to prove the safety and efficacy of its medicine. This process can take a long time and if generic companies were to start the process of registering their medicine only after a patent expires, is revoked or a compulsory licence is issued, then in effect the patent holder's monopoly would continue while the generic company gets their medicine registered. To ensure that the generic medicine can enter the market as soon as possible, many countries have the "bolar" exception in their law allowing generic companies to complete the registration process while the patent is in force. This means that their making the generic version for providing samples and registering the medicine is not considered to be infringement of the patent.

(B) Research/experimental/scientific use Exception: Scientists and researchers often continue researching a medicine even after it is patented and put on the market. To allow them to do this without the threat of legal proceedings by patent holders, developing countries have a research exemption to allow the use of patented medicines for the purposes of research.

5 Parallel Imports: Companies often charge different prices for the same patented medicine in different countries. At times the price difference can be significant. They can also be much lower if supplied under a voluntary license or a compulsory license in another country. In such cases it would be cheaper for a country to import the patented medicine than to buy it at the price charged in the local market. In legal terms parallel import 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. The principle of national exhaustion of rights means that the right owner, once s/he has put the product on the national market, 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 case of international exhaustion of right, once the product is put on the market somewhere in world, the patent holder loses the authority to prevent parallel importation – that is importation from any place in the world. Thus, under an international exhaustion rule the import of cheaper priced patented medicines from anywhere in the world is possible. With a national exhaustion on the contrary the right holder can prevent the importation of cheaper brand name product from other countries. The TRIPS Agreement leaves each government free to decide what rule of exhaustion they want: national, regional (if there is a commercial agreement between countries) or international.

6 Compulsory Licenses: Governments can allow generic production of a patented medicine by issuing compulsory licenses. TRIPS recognizes the right of Members to authorize the use of a patent by third parties (compulsory licences) or for public non-commercial purposes (government use licence) without the authorization of the patent owner. The grounds for such use of patents are not limited but they are defined by the national law (see factsheet on compulsory licensing). The national law or regulation sets the conditions and remuneration paid to the right holder. In the field of medicines, this can allow the production or importation of affordable generic medicines. This mechanism has been used extensively by developing countries to ensure access to medicines for HIV, hepatitis C and cancer. TRIPS does not limit the grounds on which CLs can be granted but does specify several conditions that have to be met. Through a recent amendment, the TRIPS Agreement also recognizes compulsory licenses for export to countries that have little or no manufacturing capacity provided that several procedural requirements are met including reporting to the TRIPS Council. This mechanism has however proven very difficult and cumbersome to use and several developing countries have asked for a review of this system.

There are several other flexibilities in the TRIPS Agreement including transition periods for LDCs and enforcement-related flexibilities. The full use of TRIPS flexibilities is central to the achievement of the Sustainable Development Goals (finding specific mention in Goal 3b),¹ the WHO’s Global Action Plan for the Prevention and Control of Non-Communicable Diseases² and its Global Health Sector Strategy on Viral Hepatitis.³ In 2016, the UN Secretary General’s High Level Panel on Access to Medicines found that that governments are duty bound to “protect the rights of their citizens by using TRIPS flexibilities.”⁴ Developing countries and LDCs should accordingly commit to including and fully using these flexibilities to ensure access to medicines for all who need them.

READING MATERIAL

- Integrating Public Health Concerns into Patent Legislation in Developing Countries (Carlos Correa), 2000, [<http://apps.who.int/medicinedocs/en/d/Jh2963e>].
- The Doha Declaration On The TRIPS Agreement and Public Health 2001, [<http://www.who.int/medicines/areas/policy/tripshealth.pdf>].
- UNAIDS, UNDP, WHO, Using TRIPS flexibilities to improve access to HIV treatment, 2011, [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf].

1. [<http://daccess-ods.un.org/access.nsf/GetFile?OpenAgent&DS=A/RES/70/1&Lang=E&Type=DOC>].

2. [http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1].

3. [<http://apps.who.int/iris/bitstream/10665/246177/1/WHO-HIV-2016.06-eng.pdf?ua=1>].

4. [<https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/1/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>].