

**HUMANITARIAN &
DEVELOPMENT
PROGRAMME**

PATENTS AND ACCESS TO MEDICINES: Blocks are political and not legal

**By
Céline GRILLON**

HARM REDUCTION, HIV AND HEPATITIS C ADVOCACY ADVISER, MÉDECINS DU MONDE

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« GLOBAL HEALTH » THINK TANK



The issue of pharmaceutical patents and access to essential medicines continues to fuel debates in the field of global health. It indicates a rivalry between health policies aimed at accessing quality and low-cost medicines; and on the other hand, trade policies aimed at fostering economic growth and income of industrial health goods. The tension between these two objectives - and, above all, the lack of effective political support for the former - led the Secretary General of the United Nations to mandate a high-level working group (i.e. people recognised as experts in the field) to reflect on the disagreement that results from this rivalry. The report of this working group, published in September 2016, recommends - amongst other things - making full use of the international legal regime so that it improves access to medicines.

CREATION OF A GLOBAL LEGAL SYSTEM FOR INTELLECTUAL PROPERTY

In 1994, the creation of the World Trade Organization (WTO) was accompanied by the signing of several international treaties, including the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This agreement contains the international standards of intellectual property rules. It imposes, in particular, the standards for the patentability of all inventions, whilst countries were previously free to grant patents to certain types of inventions and for the duration of their choice.

Thus, India - like other countries - deemed for a long time that pharmaceuticals could only be patented for the manufacturing processes of medicines and not for medicines themselves, as they were considered too essential to the public interest to be monopolised. The scheme has encouraged the Indian industry to find new ways to synthesise medicines to circumvent patent protection, which has helped to strengthen India's generic drug industry, now one of the most successful.

The TRIPS agreement, the result of intense lobbying by industrialised countries (United States, the European Union and Japan) on developing countries, now obligates WTO member states to issue patents on pharmaceutical products and processes. These patents allow the holder to prohibit the manufacture, use, sale and importation of the patented object or object obtained by the patented process for a period of twenty years from the date of filing of the patent application.

COMPULSORY LICENSES, A TOOL FOR PUBLIC HEALTH

The agreement allows, however, some flexibility in the application of these rules. Governments may, under certain conditions, use or permit a competitor to use the patented invention (an object or process) without the consent of the patent owner. The conditions governing this right of public power, commonly known as compulsory licensing, include protection of the owner of the patent by granting them royalties if an invention is used, or being able to negotiate with the patent holder (this rule does not apply in a national emergency and other emergencies, or in public use for non-commercial purposes).

This flexibility has been given so that governments can mitigate any potential abuse by patent holders and put public interest first, including protecting health by ensuring that people have access to essential medicines. This was recalled in 2001 by the WTO members who adopted a 'Doha Declaration on the TRIPS Agreement and Public Health'¹, which states:

"4. 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 in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- a. (...)*
- b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."*²

In the field of public health, compulsory licensing therefore enables governments to improve access to patented medicines that the patent holder may otherwise make difficult by, for example, supplying insufficient quantities, or at too high a price.

As the TRIPS agreement limits compulsory licensing primarily to supply to the domestic market, the export of medicines produced under the agreement may be restricted. This

¹ This statement follows the trial known as the "Pretoria trial" during which 39 major pharmaceutical companies sued the South African state for authorizing the importation of generic treatments against AIDS. The laboratories finally abandoned their complaint following the strong international mobilization of civil society. Cf. MSF, Pretoria: chronicle of a bad trial, 29 April 2002 <http://www.msf.fr/actualite/articles/pretoria-chronique-mauvais-proces>

² 4 and 5 of the 'Declaration on the Agreement on TRIPS and Public Health' adopted on 14 November 2001

is a problem for countries that have insufficient pharmaceutical production capabilities, and which depend on imports. To overcome this problem, on 30th August 2003, the WTO agreed terms that allows the issue of compulsory licenses specifically for export; but this process is so complex that it has only been used once³. However, TRIPS was formally amended in January 2016 to incorporate this process, following ratification by two thirds of the WTO members. Several countries, notably India, have called for a critical review of this process and consideration on how to find a more efficient alternative⁴. The high-level working group directed by the Secretary-General of the United Nations also recommends that this decision be reviewed to find a solution for the effective export of pharmaceutical products produced under compulsory licensing⁵.

OTHER FLEXIBILITIES AVAILABLE TO MEMBER STATES

Other TRIPS flexibilities include further scope for interpretation left by TRIPS to the participating members, which allow the latter to build a fairly balanced national patent legislation between the private rights of patent holders and public interest.

This concerns in particular the definition of criteria for patentability, which essentially means the conditions to be met by innovations in order to claim a patent. TRIPS states that countries may exclude certain inventions from patentability, as well as certain fields of work⁶. In order to obtain a patent, inventions must be new, involve a creative step (i.e. not be obvious to a person specialised in the technological field concerned), and have potential for industrial application. Countries are free to state their interpretation of these conditions in their national laws. Hence, the Indian law requires that the new forms of medicines which already exist do have an added therapeutic benefit to satisfy the conditions of the creative step. In this way, it prohibits the practice of 'ever-greening', the process of making slight modifications to drugs and patenting them; thus artificially prolonging the monopolies of drugs whose patents are going expire⁷.

³ Médecins Sans Frontières, « Neither expeditious, nor a solution: The WTO August 30th decision is unworkable », 2006.

https://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf

⁴ India's intervention before the TRIPS Council on 28 October 2014 <http://www.keionline.org/node/2114>

⁵ *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*, September 2016, p. 27. <http://www.unsgaccessmeds.org/final-report/>

⁶ This is the case for inventions that, if exploited, would call into question public order or morality (including the health and life of humans, animals, plants or the environment); diagnostic, therapeutic and surgical methods as well as plants and animals (other than micro-organisms), and importantly, biological processes for the production of plants or animals, other than non-biological and microbiological processes.

⁷ Médecins Sans Frontières 'Novartis, Patents and Indian Law', 2012. <http://www.msf.fr/press/videos/novartis-brevets-et-loi-indienne>

Countries may support the rigorous application of these rules by ensuring a transparent and adversarial process of investigating and granting patents, as well as allowing for opposition. The latter consist of allowing those interested (competitors or representatives of civil society) to produce reasons for rejecting the application and/or revocation of the patent during the investigation of the application, and/or after the grant of the patent. Unfortunately, most countries have not or have only partially implemented adequate procedures.

In addition, TRIPS allows governments to provide - under certain conditions - limited exceptions to the rights of the patent, such as permitting the use of the patented invention in research and bioequivalence studies on expiry of the patent. It also limits the scope of the rights of the patent by allowing countries to resort to parallel imports (i.e. the purchase of a patented product on a market other than the domestic market where it would be sold cheaper, for example).

Finally, a transitional period has been granted to countries classified by the United Nations as Least Developed Countries (LDCs)⁸, during which they are not required to meet TRIPS obligations. Initially planned until 2005, it has been extended several times and now runs until 1st July 2021 (and until 2033 for pharmaceutical products). However, many LDCs do not benefit from this exemption and have already introduced intellectual property policies on medicines, sometimes even more extensive than TRIPS, such as countries of the African Regional Intellectual Property Organization.

IN PRACTICE

In practice, the implementation of TRIPS flexibilities to improve access to medicines has been limited by the economic and political pressures of pharmaceutical companies⁹, and of some countries such as the United States, Switzerland and the European Union. The most recent example is the efforts by the US and Swiss administrations to discourage Colombia from compulsory licensing of Imatinib, an anti-cancer drug¹⁰.

For countries which use it, mandatory licensing has resulted in significant price reductions or made generic drugs available, thus making the savings needed to substantially improve access to life-saving HIV therapies (Brazil, Thailand, and Indonesia), or more recently against certain cancers (India). Paradoxically, in 2001 the United States government itself used the threat of compulsory licensing to acquire a

⁸ <http://www.un.org/fr/globalissues/ldc/>

⁹ The pharmaceutical company 'Abbott' announced in the press that it would no longer sell its health products on the Thai market after Thailand gave several mandatory licensing conditions for some antiretroviral drugs, one of which was patented By Abbott. A major international outcry forced the laboratory to reverse this decision.

¹⁰ Knowledge Ecology International, <http://keionline.org/colombia>

price reduction for ciprofloxacin (in order to keep stocks of this anthrax antidote with views of a possible attack).

The use of this tool is on a diverse scale, with the main influences appearing to be those of economic power and the ability to withstand pressures. The same applies to other flexibilities. With the Indian law adhering to its strict interpretation of patentability criteria, it has since been the subject of litigation, being taken to the Supreme Court¹¹ by that the pharmaceutical company Novartis, and being regularly subject to diplomatic pressures¹².

TRIPS flexibilities have also been attacked on ideological grounds. The war on compulsory licensing has been so severe that many governments no longer consider using this tool. This is particularly the case in France, even after this tool made it possible to reinstate medicinal products in French common law on patents in 1968¹³.

The European Union (which allows parallel imports under its single market) is further proof of the political imbalance against the use of TRIPS flexibilities. Since the early 2000s, the United States and Japan have imposed new standards for the protection of intellectual property, involving their implementation in the framework of the negotiation of bilateral or regional trade agreements. These new standards are called TRIPS+, as they are more restrictive than TRIPS and may limit the use of flexibilities¹⁴.

Since the adoption of TRIPS, economic pressure relating to drug prices has continued to increase, now causing restrictions for access, high-income countries included. In the United States and within the European Union, new voices are mounting against the rise in prices. The Organization for Economic Co-operation and Development (OECD) recently released a report calling for a new approach to rising drug prices.

The effective use of TRIPS flexibilities - including compulsory licensing as a sanction for the misuse of patents by their holders - offers concrete opportunities for re-equilibrating in favour of public health. The Secretary-General's High-Level Panel on Access to Medicines created a report that recommends countries to commit at the highest level to the letter of the Doha Declaration on the TRIPS Agreement and Public Health by 'using all TRIPS flexibilities (including compulsory licensing), and ensuring that trade agreements do not restrict the possibility'. This is a major political issue. ■

¹¹ Act Up-Paris, Communications Group 'Novartis bid rejected by the Supreme Court of India: Relief for the sick and the activists from around the world', 2013, <http://www.actupparis.org/spip.php?article5139>

¹² Médecins Sans Frontières, 2015, <https://www.msfaccess.org/about-us/media-room/press-releases/msf-launches-global-campaign-urging-india-protect-access>

¹³ Maurice Cassier, 'Pharmaceutical Patents and Public Health in France: Opposition and Specific Drug Appropriation Devices, 1791 and 2004', *Business and History*, 2004/2 (No. 36)

¹⁴ Gaëlle Krikorian, 'Access to medicines compromised by bilateral IP policies', *Transversales - Science and Culture*, 2005 http://grit-transversales.org/article.php3?id_article=129

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« GLOBAL HEALTH » THINK TANK

Directed by Nathalie ERNOULT and Dr. Anne SÉNÉQUIER
ernoult@iris-france.org – senequier@iris-france.org

A Think Tank under the

HUMANITARIAN & DEVELOPMENT PROGRAMME

Directed by Michel MAIETTA, Senior Research Fellow at IRIS
maietta@iris-france.org

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INSTITUT DE RELATIONS INTERNATIONALES ET STRATÉGIQUES
2 bis rue Mercoeur
75011 PARIS / France

T. + 33 (0) 1 53 27 60 60
contact@iris-france.org
@InstitutIRIS

www.iris-france.org