

WAIVER OF IP RIGHTS IN THE EYE OF THE COVID-19 PANDEMIC

The World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations and it has currently about 150 members. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹ is an international legal agreement between all the member nations of the World Trade Organization that sets the minimum standards which member countries must implement to protect intellectual property rights.

TRIPS contains certain flexibilities that allows a degree of freedom for countries to accommodate their own intellectual property systems and thus allow members to formulate national legislation to ensure a proper balance between the goal of providing incentives for innovation and the public's interest.

Article 30 defines that Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The three main areas of flexibility, mainly contained in Article 31, concern parallel importation², research exception³ and compulsory licensing⁴.

A patent grants a negative right, thus the right to exclude others from certain conduct such as making, using, offering for sale, selling, and importing of the claimed invention. Waiving a patent, or any intellectual property right, would mean that the owner of the right will not be able to enforce the right against infringers and will not be able to charge a royalty or license fee for the use of the right.

In the context of public health, the use of TRIPS flexibilities is an important tool to assist countries to fulfil their human rights obligation to provide access to essential medicines. The most used flexibility being compulsory licenses. These must however be used with care and as a general rule, to grant such licence should only be if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher authority.

Is it possible to waive IP rights in view of the minimum requirements set by TRIPS for protection of IP Rights?

It is indeed possible. The 2007 amendment of TRIPS by including Article 31 *bis* addressed some of the shortcomings of the existing flexibilities around compulsory licenses and was a consequence of a waiver decision by the Ministerial Conference of the WTO⁵.

¹ https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

² **Parallel import means** that the **patented** or trademarked goods are purchased in a foreign market and resold in the domestic market. If parallel importation is not allowed it **means** that the IP holder can prevent the **importation** of the protected goods where the intellectual property right is held

³ R&D of a protected right (as opposed to commercial) exploitation is used. For example, the right to technical trials in support of a regulatory product registration of a pharmaceutical or agri product

⁴ Compulsory licensing is when a government allows use of patent right without the consent of the patent owner - TRIPS allow for this with the caveat that the compulsory license must be subject to conditions aimed at protecting the legitimate interests of the right holder

⁵ Allowing countries to export drugs manufactured under compulsory licensing to countries that lacked the manufacturing ability

In terms of Article III subsection 2 of the Marrakesh Agreement establishing the WTO (the “WTO Agreement”), the WTO shall provide the forum for negotiations among its members concerning their multilateral trade relations in matters dealt with under the agreements in the Annexes to this Agreement, such as the TRIPS agreement.

The WTO may also provide a forum for further negotiations among its members concerning their multilateral trade relations, and a framework for the implementation of the results of such negotiations, as may be decided by the Ministerial Conference of the WTO.

In terms of Article IX.3 of WTO Agreement it is provided that in “exceptional circumstances”, the Ministerial Conference of the WTO may waive an obligation imposed on a WTO member by... “*any other multilateral trade agreement.*” The WTO Agreement sets out the requirements in detail which include the submission of a request to various international Councils including the TRIPS Council. A waiver may only be granted when there is justification what the “exceptional circumstances” are as well as setting out terms and conditions that shall govern the working of the waiver. The waiver should also not be unlimited and be set for a time frame subject to review by the Ministerial Conference if granted for more than a year.

There have been various formal TRIPS Council meetings discussing the waiver requests received in response to COVID-19, the most recent, the author is aware of being the 23 February 2021 meeting. It is reported that members were unable to reach a decision.

The patent waiver controversy, i.e., whether patent rights should take precedence over providing affordable medicines for people afflicted by a deadly disease is not new. We faced the same with access to HIV/AIDS drugs two decades ago.

The argument for the waiver of IP right is that the only effective response to COVID-19 pandemic requires rapid and easy access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients. The normal TRIPS flexibility, such as compulsory licenses will not affect this, as it is time consuming and expensive. As such the only quick and efficient option that will bring about quick relief, is to rely on the instrument of waiver of IP rights. Whether it is necessary to waive all forms of IP rights for as far as the IP right relates to the prevention, containment or treatment of COVID-19 remains questionable.

There has been reluctance to date (according to the TRIPS Council reports) from developed countries to waive IP rights. The recent announcement of the USA that it intends to support the patent waiver for vaccines may just tip the scale in favour of the waiver applications serving before the TRIPS Council. A waiver must be supported by three-quarters of the members of the WTO for it to be effective⁶.

Waivers can be granted on a country by country basis⁷. Just like HIV/AIDS was considered an emergency in 2001 to avail flexibilities under the TRIPS Agreement, even more so we expect the COVID-19 pandemic that is a world-wide crisis. Exactly what the terms and conditions of the waiver would be remains to be seen, that it is eminent is clear. It is suspected that parallel imports would be allowed and that countries with manufacturing and distribution facilities, like the USA, would provide

⁶ See WTO Agreement - Decision-Making Procedures under Articles IX and XII

⁷ Articles IX.3 and IX.4 of the WTO agreement

a temporary waiver of enforcement of IP rights to enable free manufacturing and supply of Covid-19 vaccines without fearing infringement of pharmaceutical companies IP Rights. It is however not necessary for a world-wide waiver to apply. The application made by India and South Africa may thus be heard on its own merits.

The question is however more fundamental than whether to waive or not. It is whether the waiver of IP Rights would in fact alleviate the burden of access to effective and affordable medicines and vaccines?. Is it really necessary and what would the consequence be for future research and development in the pharmaceutical industry? Does Article 31bis⁸ of TRIPS not already allow sufficient flexibility?

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⁸ https://www.wto.org/english/docs_e/legal_e/31bis_trips_04c_e.htm