India and SA request waiver of Trips Agreement for Covid-19 treatment

By Tim Ball

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South Africa and India are seeking a waiver of the global agreement on IP rights to enable access to Covid-19 treatments, but more would need to be done in SA on a practical level to make this effective

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The World Trade Organisation (WTO) recently reported that India and South Africa had requested a waiver of certain provisions of the Trips Agreement, for the prevention, containment and treatment of Covid-19.

The Trips Agreement (more fully, the Agreement on Trade-Related Aspects of Intellectual Property Rights) is an international agreement setting out minimum standards for the regulation of intellectual property (IP) rights.

The purpose of the waiver is to ensure that certain IP rights contemplated in the Trips Agreement do not prevent countries from accessing affordable medical products such as vaccines and medicines needed to combat Covid-19.

India and SA have particularly asked the WTO General Council to pass a resolution including a statement that "the obligations of members to implement or apply Sections 1, 4, 5 and 7 of Part II of the Trips Agreement or to enforce these Sections under Part III of the Trips Agreement, shall be waived in relation to prevention, containment or treatment of Covid-

19, for [X] years from the decision of the general council".

The requested waiver is broad, covering the entire sections relating to copyrights (Section 1), industrial designs (Section 4), patents (Section 5), and protection of undisclosed information (Section 7). Particular concerns raised in South Africa's General Statement on Covid-19 to the Trips council meeting of 30 July 2020 include:

IP barriers go beyond patents, and often flexibilities in other IP such as industrial designs, copyright and trade secrets are often less understood and implemented nationally.

Developing country members may face legal, technical and institutional challenges in using Trips flexibilities. This is especially true for countries that have never utilised flexibilities such as compulsory licences (i.e. licences to use the subject matter of a patent without the authorisation of the right holder).

Limitations

When an exporting country is producing under a compulsory licence for export, the mechanism of Article 31bis of the Trips Agreement would be applicable. However, the mechanism is neither expeditious nor workable. Also, implementation of the Article 31bis mechanism at a national level is rather limited or may not achieve its intended objectives. Further, some countries have opted out of using this system as importers, which may pose a challenge to access.

Although the Trips Agreement allows member states to place various limitations on IP rights to protect public health and deal with emergencies, there are serious arguments that it unduly restricts their ability to deal with public health emergencies. The interface between IP rights and access to medicines will always be fraught when state-enforced exclusion is the mechanism for realising the public benefit ideals of the IP system. This is even more the case in the international context, where exclusion in a given jurisdiction may have only the most tenuous link to the broader public interest justifications of promoting innovation contemplated by IP theorists.

The Trips Agreement does not deal in detail with exceptions to copyright and industrial design protection - providing only briefly for limitations or exceptions in Article 13 (for copyright) and Article 26.2 (for industrial designs). This is probably because these forms of protection are generally regarded as not monopolising concepts, but as protecting only expressions of these concepts. However, it may well be argued that there is a legitimate case for allowing unauthorised use in emergency situations, where "designing around" these types of protections may waste time and resources.

With regard to undisclosed information, Article 39.3 of Section 7 of the Trips Agreement requires member states to protect confidential data submitted to medicines regulatory authorities from "unfair commercial use" and to protect it from disclosure. While the protection against disclosure has a public interest exception, the protection against unfair commercial use does not have any such limitation. Although there is some debate about it, there is a widely-held view that the protection against unfair commercial use requires member states to provide for regulatory data exclusivity (i.e. precluding generic competitors from registering products based on the submissions of an earlier applicant) for a defined period. This would prevent the quick registration of generic medicines for new diseases.

Data exclusivity

In the South African context, however, domestic law does not provide for data exclusivity in relation to medicines, and has for many years allowed registration of a generic medicine at any time on the basis of bioequivalence with an existing registered medicine. (Of course, cynics have argued that delays at the previous Medicines Control Council, and more recently at the South African Health Products Regulatory Authority, have resulted in de facto data exclusivity, simply as result of regulatory delay.) A waiver of the relevant provisions of the TRIPS Agreement would therefore not affect the South African position in this regard (other than to regularise existing law for purposes of Covid-19 treatments, if it is indeed non-compliant).

Nevertheless, the problem raised in South Africa's General Statement regarding access via importation is significant. Article

31 of the Trips Agreement provides in some detail for member states to permit use of patented inventions without authorisation from the patent holder. However, Article 31(f) provides that such use "shall be authorised predominantly for the supply of the domestic market of the member authorising such use". The limited exception to this provision provided by Article 31bis is no solution to the generalised problem of emergency cases, as it is limited to supply to least-developed countries. In the globalised modern world, a significant portion of the supply of medicines in most countries - even highly developed countries - is met by importation. Accordingly, in the absence of the patent holder's consent, emergency supply by importation is thus effectively precluded, by prohibiting the manufacturing member state from authorising production for exportation.

It is worth noting that the South African Government has a history of making high-level gestures on public health-based limitations on IP rights, while very little has been done at a practical level to improve access to medicines. South African national law remains significantly more restrictive than permitted under the Trips Agreement. In particular, the following should be remembered:

- In 1997, government amended the Medicines and Related Substances Control Act, 1965 to introduce section 15C, allowing the minister of health to prescribe conditions for the supply of more affordable medicines in certain circumstances to protect the health of the public, particularly permitting the minister to permit parallel importation of patented medicines. This amendment was challenged in litigation brought by a group of more than 40 pharmaceutical manufacturers, but the pharmaceutical manufacturers eventually withdrew their case in 2001 - leaving section 15C intact. However, we are not aware of any reliance on section 15C by the Government in the approximately 20 years since; and
- In 2018, government announced a new IP policy, the bulk of which is aimed at addressing IP issues affecting public health. However, two years on, there is no sign of amendments to any IP legislation to achieve the public health objectives of the 2018 IP Policy.

This latter point is particularly significant, since South African national law will in any event have to be amended if the South African Government is to make use of the requested Trips Agreement waiver.

ABOUT THE AUTHOR

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