

**Council for Trade-Related Aspects of
Intellectual Property Rights**

Original: English

INTELLECTUAL PROPERTY AND PUBLIC INTEREST:

**BEYOND ACCESS TO MEDICINES AND MEDICAL TECHNOLOGIES TOWARDS A MORE
HOLISTIC APPROACH TO TRIPS FLEXIBILITIES**

COMMUNICATION FROM SOUTH AFRICA

1 INTRODUCTION

1. A main focus at the WTO has been how to facilitate access to medicines in the context of the Doha Declaration on TRIPS and Public Health. The amendment of the TRIPS Agreement entered into force in 2017. In the usual way, the term 'TRIPS flexibilities' has been emphasised in the context of access to medicines and medical technology through compulsory licenses or government use and even in that context remains under-utilized.

2. The High-Level Panel Report on Access to Medicine observes that: "...WTO Members retained important public health flexibilities that can be used to adapt their intellectual property law, policies and practices to meet human rights and public health objectives. These include the ability to determine patentability criteria, issue compulsory licences, authorise parallel importation, apply general exceptions and employ competition laws to limit and remedy the abuse of intellectual property rights in domestic legislation."¹ In this regard, there are still a significant number of countries that do not make full use of available flexibilities under the TRIPS Agreement.

2 TOWARDS AN INTEGRATED APPROACH TO TRIPS FLEXIBILITIES

3. The use of TRIPS flexibilities to address a public health concern is usually seen as a matter concerning patents. However, the COVID-19 pandemic requires a more integrated approach to TRIPS flexibilities that include other various types of intellectual property (IP) rights including copyrights, industrial designs and trade secrets. The use of TRIPS flexibilities in other areas of intellectual property, beyond patents, is less understood at the national level. In fact, in other fields of IP, national IP laws may not even provide for sufficient flexibilities to address issues of access. A variety of IP rights are relevant in the fight against COVID-19.

4. The COVID-19 crisis created the need to produce essential equipment and medical supplies, there is a growing need to be able to manufacture essential medical devices such as masks, ventilators and other personal protective equipment. As the debate over COVID-19 moves beyond medical issues, the nature of the pandemic requires non-medical approaches to detect, diagnose and trace the coronavirus. Studies have found that levels of neutralizing antibodies against SARS-CoV-2 remain high for a few weeks after infection, but then typically begin to wane.² So far, only one infectious disease comparable to COVID-19 in its broad geographic distribution has been eradicated, this disease is smallpox.

5. According to GAVI, even if eradication of COVID-19 is ultimately technically feasible, it will likely be extremely challenging.³ It cautions that given the uncertainty around the technical feasibility of

¹ Report of the United Nations Secretary-General's High-level Panel on Access to Medicines - *Promoting innovation and access to health technologies* (2016), at p. 22.

² Ling Ni, Fang Ye, Meng-Li Cheng et al *Detection of SARS-CoV-2-Specific Humoral and Cellular Immunity in COVID-19 Convalescent Individuals* 52, 971-977, June 16, 2020.

³ See the GAVI Vaccine Alliance <<https://www.gavi.org/vaccineswork/could-covid-19-ever-be-eradicated>>

eradicating COVID-19, the global community also needs to plan for the possibility that COVID-19 will be in global circulation indefinitely. In the absence of prophylaxis through a vaccine and more effective treatments, non-medical measures have been an important priority in dealing with the devastating impacts of COVID-19.

6. Other goods and services that are needed to tackle the epidemic include protective equipment such as masks, face shields, and hand sanitizers. Such equipment and material remain in critical shortage in many countries around the world. Many WTO Members lack domestic manufacturing capacity and would be dependent on imports to meet their medical needs.

7. When an exporting country is producing under a compulsory license mainly for export, the mechanism established by the 30 August 2003 decision, and later translated into an amendment of the TRIPS Agreement as Article 31*bis*, would be applicable. This mechanism waives the condition in Article 31(f) that a compulsory license should be predominantly for the supply of the domestic market. It should be noted that the implementation of the Article 31*bis* mechanism at a national level is very limited and may not achieve its intended objectives.⁴ In any event, many developing country Members may also face legal, technical and institutional challenges in using TRIPS flexibilities. This is especially true for countries that have never utilized flexibilities such as compulsory licenses.

8. The World Health Organization has launched the COVID-19 Technology Access Pool (C-TAP) *inter alia* calling on intellectual property holders to voluntarily license such rights on a "non-exclusive and global basis to the UNITAID-established and supported Medicines Patent Pool and/or through other public health research and development mechanisms, consortia or initiatives that facilitate global and transparent access; and/or voluntary non-enforcement of intellectual property rights, as appropriate, during the COVID-19 pandemic, to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world". However, to date no company has committed to doing so. Instead limited, exclusive and often non-transparent voluntary licensing is the preferred approach of pharmaceutical companies, which will be insufficient to address the needs of the current COVID-19 pandemic.

3 SOME EXAMPLES

3.1 Example 1: Big data outside of the health system

9. Smartphones, mobile data, artificial intelligence, databases and algorithms have been used in the COVID-19 pandemic to leverage the detection and control and control of the virus. Different types of IP rights are relevant to protect AI algorithms, some may be protected by copyright and trade secrets while other technology is protected by patents while database rights and trade secrets may also be relevant.

10. While these approaches help with efforts to contain the spread of the virus, they can raise issues about the right to privacy and personal freedoms. National security concerns may also arise in the context of Article 73 of the TRIPS Agreement.

3.2 Example 2: 3D printing technology

11. During this COVID-19 outbreak, an Italian hospital ran out of ventilator valves (which cost USD 11,000 each) and their regular supplier could not produce them on time. A duo after scanning an existing valve, 3D printed replacement valves which only cost about USD 1 each, saving ten lives as of the time of the article.

12. According to a news report, the original manufacturer was actually approached by the duo in hopes to ask for the valve's blueprints in an urgent attempt to save them time and produce the valves to instantly save the critical COVID-19 victims but they were declined.⁵ The pair then

⁴ WIPO CDIP/5/4 Annex II Categories of Different Provisions on Specific Flexibilities:

<https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex2.pdf#page=1>

⁵<<https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm>>

proceeded to manufacture the replicas by manually measuring the valves and 3D printing three different versions to see which one worked best.

13. According to another news report, "potential legal and medical issues have stopped Fracassi from distributing the digital design file more widely, despite receiving hundreds of requests for the 3D-printed valves".⁶

14. Following this case, a law firm warned "...manufacturers should be aware of the complex intellectual property issues concerned with this 3D printing technology. Parts such as valves or other medical devices and equipment are capable of protection by patent and/or registered design. Unregistered design rights and copyright will also apply to the part itself and/or the digital model or CAD file. Some or all of these rights might apply in respect of a single component".⁷

15. The firm cautioned "In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts)".⁸ Furthermore the firm advises that any person or company intending to manufacture parts using 3D printing should carry out some due diligence to identify:

- who ultimately holds the intellectual property rights in the component;
- whether the part is protected by patent or registered design; and
- whether the rights holder is willing to permit the parts to be manufactured in return for a small or nominal royalty for the wider public benefit; and
- whether any regulatory approval is needed for supply of the parts.

16. This case clearly demonstrates the interface between IP and new technologies such as 3D printing and may require a better understand of how a balance may be achieved between rights holders and third parties. More collaborative approaches have been achieved through various pooling mechanisms for access to medicines, this is also true for more generic IP pledges that covers a broad range of equipment, software, network and device applications useful in healthcare, containment, tracking, diagnostics, emergency response and social distancing. Such approaches nonetheless are limited and may require action on the side of national authorities to ensure access to such technologies where pledges or voluntary licenses cannot be secured on commercially reasonable terms.

3.3 Example 3: Trade Secrets

17. Trade secrets encompass vast quantities of information needed to discover, test, create, and manufacture diagnostics, treatments, and vaccines.

18. Potential trade secrets include manufacturing processes, test data, medical formulas, and more. For vaccines and other biologic medicines, cell lines, genomic information, and other biological material can also be held as trade secrets. Data about the effectiveness of medicines and vaccines are trade secrets. Even so-called negative information — information about what does not work — can be a trade secret.

19. Article 39.2 of TRIPS Agreement requires Members to protect undisclosed information which is secret, has commercial value and has been subject to reasonable steps to be kept secret. Both voluntary and compulsory licenses, though common in other forms of IP are unusual in trade secrets.

20. Professor David. S Levine⁹ posits that: "Clearly, there should be times when trade secrecy's ability to lock down information gives way to broader national and international information sharing concerns. If there were ever a case for re-examining trade secrecy's unquestioned dominance, a public health crisis on the scale of Covid-19 would be the time." He concludes by saying: "What

⁶ <<https://www.forbes.com/sites/amyfeldman/2020/03/19/talking-with-the-italian-engineers-who-3d-printed-respirator-parts-for-hospitals-with-coronavirus-patients-for-free/#1529841378f1>>

⁷ <<https://www.shoosmiths.co.uk/insights/articles/3d-printing-social-responsibility-vs-legal-risks>>

⁸ Ibid.

⁹ 'Covid-19 should spark a re-examination of trade secrets' stranglehold on information.'

< <https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/>>

seems initially like a narrow issue involving intellectual property law and innovation may actually be a critical barrier to our ability to rapidly, effectively, affordably, and safely solve the Covid-19 pandemic. The time is now to examine, and re-examine, trade secrecy's hold on information and our collective health."¹⁰

4 QUESTIONS

1. To what extent are TRIPS flexibilities embedded in areas outside patent protection well understood? If so, how are Members implementing such understandings in their national and regional laws?
 2. What are the likely difficulties that Members may face in dealing with a changing technology landscape where embedded IP rights may affect the dichotomy between IP rights as private rights and the public interest dimensions recognised in the TRIPS Agreement?
 3. What are the benefits and limitations of initiatives such as voluntary licenses and pledges to access much needed technology to deal with the COVID-19 pandemic?
 4. Are there circumstances where trade secrets can be shared more broadly? If so, what are those circumstances? Would national or international health pandemics fall within this category?
-

¹⁰ Ibid.