TRIPS-Compliant Alternatives for Overcoming Intellectual Property Barriers to COVID-19 Countermeasures

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Introduction

In the aftermath of the recent WTO Ministerial Decision on the TRIPS Agreement (adopted June 17, 2022), there may be some confusion about the many options that countries have for overcoming intellectual property barriers to allow alternative production, distribution, and use of COVID-19 countermeasures. Of course, visibility into the patent landscape for particular products is essential to understanding freedom to operate in terms of products, ingredient, and manufacturing processes, and that work is complicated, though aided by the Medicines Patent Pool MedsPaL and VaxPaL databases and work done by other researchers on COVID-19 vaccine and therapeutics patents . Overcoming patent barriers on ingredients will not be a significant barrier if existing, patent-owning/licensed suppliers have adequate supplies and will sell at an affordable price. If compulsory licenses need to be issued that cover export/import sources of ingredients, the process for gaining freedom to operate becomes that more difficult.

Jamie Love has previously written a cogent analysis of many of these alternatives, saying that the then proposed TRIPS Decision was only the fifth best alternative. This brief analysis summarizes some of the alternatives he discussed but lays out a fuller and broader description of alternatives. The new Decision's plus-and-minuses for the most part compare negatively to the described alternatives which include: (1) Article 73 national security declarations, (2) Article 31(k) competition-based licenses, (3) Article. 44.2 judicial licenses on patents and trade secrets, (4) an Article 30 production-for-export exception to Article 31(f), (5) Article 6 parallel importation of countermeasures produced under a compulsory license, (6) regular non-predominate export under Article 31, (7) Article 31 bis licenses, (8) an Article 39.3 exception to allow disclosure of manufacturing-related data, and (9) an Article 39.2 public interest/public health exception to trade secrets/confidential information.

TRIPS compliant alternatives for overcoming IP barriers to COVID-19 countermeasures

1. Using Article 73, Members can declare a national security exception to all relevant intellectual property protections (patents, trade-secrets/confidential information, data protection, copyright, and industrial design) in light of the COVID-19 pandemic (see, analyses by Carlos Correa, Alexander Beyleveld, and Fred Abbott). Freedom to operate domestically would be fully enabled, though there might still be difficulties sourcing ingredients manufactured in other countries.
2. Using Article 31(k),[1] Members can issue unlimited quantities to remedy anti-competitive practices, which could include excessive pricing, refusal to license, and essential facilities

[1] "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The

doctrine,[2] and can also reduce adequate remuneration accordingly. Although a process to determine anticompetitive behaviour must be followed, it need not be judicial or require judicial appeal.[3]

3. Using Article 44.2,[4] Members can, under domestic law, limit judicial remedies for infringement of patents to payment of adequately remuneration. Granting judicial licenses is widely used in the U.S. under the *E-Bay* decision and has been done without reference the requirements of Article 31(f). As Jamie Love has pointed out, some US E-Bay decisions have allowed for unlimited export[5] whereas others have involved trade secrets as well as patents.
4. Using Article 30,[6] Members can explore creating an additional exception to Article 31(f) as had been previously advocated during the negotiation of the August 30 Waiver Decision[7] and as has been incorporated domestically in some cases, e.g., Uganda.[8]
5. Using Article 6,[9] Members can adopt international exhaustion rules and import products produced under a compulsory license without deference to any narrow "consent" rule.[10]

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need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;"

[2] Brook K. Baker, A FULL DESCRIPTION OF WTO TRIPS FLEXIBILITIES AVAILABLE TO ARIPO MEMBER STATES AND CRITIQUE OF ARIPO'S COMPARATIVE STUDY ANALYZING AND MAKING RECOMMENDATIONS CONCERNING THOSE FLEXIBILITIES, 28 (March 5, 2019) https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf.

[3] See generally, Ong, B. (2015). Compulsory Licences of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines?. In: Hilty, R., Liu, KC. (eds) Compulsory Licensing. MPI Studies on Intellectual Property and Competition Law, vol 22. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-54704-1_13.

[4] "Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available."

[5] *Edwards Lifesciences Ag v. Corevalve, Inc.*, 699 F.3d 1305 (Fed. Cir. 2013).

[6] "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."

[7] Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008) https://www.researchgate.net/publication/23165526_Ending_Drug_Registration_Apartheid_Taming_Data_Exclusivity_and_PatentRegistration_Linkage.

[8] Uganda, Industrial Property Act (2014), section 44(e).

[9] "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[10] Carlos Maria Correa, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, 71 (Oxford University Press, 2d ed., 2020).

6. Issuing a regular compulsory license under Art. 31, Members automatically allow licensees to export non-predominate quantities to other countries,[11] which might be a credible alternative for producers in larger countries or that are producing smaller quantities; if relying on "emergencies or matters of extreme urgency grounds" – clearly justified with respect to COVID-19 – there would be no obligation of prior negotiations.
7. Issuing an Art. 31 bis, Members can allow production for export compulsory license with all required notifications and limitations. Key limitations include that non-LDC importing countries would have to notify the WTO of their insufficient domestic manufacturing capacity (LDCs automatically eligible), differentiate the appearance of their product (not an issue for vaccines), take some measures against the risk of diversion (though not nearly as stringent as adopted in the June 22 WTO TRIPS Decision), strictly limit export to notified quantities, and file additional notifications. On the plus side compared to the new Decision, there are no limitations on countries eligible to produce and export or to import and use (though some countries have unwisely opted out of importation rights or limited them to national emergency situations), there is only a single remuneration in the case of CLs being issued in both the exporting and importing country, and there is some right of regional export/import in regional groups with LDC members.
8. Relying on Art. 39.3,[12] countries do not have to allow a form of protection for regulatory data that would prevent regulatory authorities from allowing alternative producers to reference or rely on such data (or the fact of regulatory approval itself) to allow abbreviated regulatory approval on the follow-on equivalent medicine (most relevant for small-molecule medicines where bioequivalence or other evidence is sufficient to establish comparable safety and efficacy). Countries can also use the language of Art. 39.3 to allow disclosure of "test and other data" when "necessary to protect the public, or unless steps are taken to ensure that such data is protected against unfair commercial use." According to Third World Network authors, this language could allow disclosure of manufacturing and quality assurance data and other information submitted to regulatory authorities. This disclosure, even if regulated with respect to further confidentiality and its limited use, could be used to enable compulsory licensees or others authorized to address public health needs to more quickly and effectively manufacture alternative sources of supply. This possibility goes beyond a compulsory licensing exception to TRIPS-plus data exclusivity and patent-registration linkage rule adopted in some countries.
9. Relying on Art. 39.2, countries can establish (and frequently have established) public interest and public health exceptions to trade-secret/confidential information protections – that's why in the U.S. there are SEC disclosure requirements, food labeling

[11] Art 31(f): "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use … ."

[12] "Members, when requiring, as a condition of approving the marketing of pharmaceutical … which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

requirements, and countless examples of companies being required to disclose information they might otherwise hope to keep confidential. There is nothing in Art. 39.2 prohibiting such exceptions for access to COVID-19 countermeasures, and the goal of ensuring the right to effectuate compulsory licenses might often require access to trade-secrets/confidential information given the incompleteness of patent disclosures to actually effectuate the working of a patent. There have been numerous calls for creating exceptions to trade-secret/confidential information protections, including a compulsory licensing alternative that would provide some measure of compensation.

10. Issuing a patent authorization under the new COVID-19 vaccine Decision has only a single true advantage – the right to export unlimited quantities to eligible developing countries only; however, in addition to eligibility to produce or import exclusions (developed countries and China and any other developing countries that opt out). There are numerous notification requirements, stringent anti-diversion requirements, the risk of double remuneration, a relatively short duration of the authorization period (five years admittedly with the possibility of extension(s)), and a stringent requirement that the authorization be "necessary" to address the COVID-19 pandemic (a necessity some countries or companies might challenge because of adequacy of supply, the offer of tiered prices, or subsidized supply through COVAX or other mechanisms).

It is important to note that some of these options may be curtailed by subsequent binding interpretation at the WTO and/or, as South Centre emphasizes, by bilateral and plurilateral free trade agreements, and investment treaties. Investment treaties may give rise to investor-state-dispute-settlement even when countries decline to exercise state-state-dispute settlement if they convince arbitrators that their IP rights have been indirectly expropriated or that they have been subject to unfair or inequitable treatment.[13]

[13] Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOYOLA CHICAGO L.J. 479-513 (2017) https://www.luc.edu/media/lucedu/law/students/publications/llj/pdfs/vol-49/issue-2/13_Baker.pdf; Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement* 23 J. INTEL. PROP. L. 1-59 (2015) https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1249&context=jipl.