

IP PROTECTION IN A POST-PANDEMIC WORLD.



INTRODUCTION

The World Health Organization declaration that “the global health emergency of COVID-19 is over” has removed the sense of urgency that for more than three years shaped global health discussions.¹ As a result of the pandemic, the topic of intellectual property (IP) and its influence on access to health technologies was widely and intensely discussed. The support gathered by a waiver proposal on certain parts of the Trade Related aspects of Intellectual Property (TRIPS) Agreement, the creation of the COVID-19 Technologies Access Pool (C-TAP) and a number of national and regional initiatives aimed at scaling up production of health goods are just some examples of where the needs of the many were framed above profits and monopolies.

Several policy processes that were set-aside, stalled or even stopped during the pandemic have resumed, while initiatives that originated in the response to the pandemic have either evolved or

run their course. This policy brief looks at some of the interventions designed during the COVID-19 pandemic to counter the impact of excessive use of IP protection tools. Secondly, it assesses recent post-pandemic policy discussions, at every level, regarding the role of IP in relation to access to innovation. Finally, it sets out several recommendations on the management of IP and related policy processes in order to improve access to health technologies.

THE TRIPS WAIVER

The TRIPS waiver proposal submitted by India and South Africa in October 2021, in the midst of deadly pandemic for which, at the time, there was no proven treatment, placed the relationship between IP and access to health technologies at the top of the global health agenda.² The wide support the proposal received both at the World Trade Organization (WTO) and elsewhere told of dissatisfaction, concern and mistrust. In certain quarters of the Global South, civil society and

academia, there was deep scepticism about the ability of the TRIPS agreement to deliver access to innovation in exchange for IP observance and enforcement.

The sense of frustration felt by many was exacerbated by the literal hoarding of vaccines and other life-saving health technologies by the European Union (EU) and other G7 member states, and in part fuelled the push for the waiver.

The outcome of the TRIPS waiver negotiations is not yet final, even if the process can be considered exhausted. A deadline of December 2022 came and went without consensus on how to extend the TRIPS Decision agreed at the 12TH WTO Ministerial Conference beyond vaccines to include diagnostics and therapeutics.³ The decision itself was never going to have a consequential effect on access to vaccines and few would call it a waiver. While the decision was lauded by some as one that would streamline and facilitate the use of compulsory licenses, in reality it added a bureaucratic layer to an already cumbersome process.

“The adoption of such a text constitutes a step backwards for the protection and promotion of public health, not only in pandemics and other health emergencies, but also in proceedings in other international forums like the World Health Organization. It also perpetuates a pattern of last-minute, unworkable and cumbersome deals on IP and access to health technologies with the implementation of the Paragraph 6 of the Doha declaration as an example.”^{iv}

PANDEMIC PREPAREDNESS

The shortcomings and failures of the global response to the pandemic, especially of mechanisms such as COVAX and the Access to COVID-19 Tools Accelerator (ACT-A), have been acknowledged by a number of constituencies.⁵ The need for a fresh approach to pandemic preparedness and response gained pace with the proposal by the President of the EU Council, Charles Michel, for an international treaty to codify the international commitment to an effectively coordinated global response.⁶ Some framed it as a response to the demands to put access to health technologies above profits, especially when public support was critical for their development in the first place. Other processes, such as amendments to the International Health Regulations (IHR) and the discussions around a sanitary counter measures platform, are also being pursued with the risk of overlapping in some areas and deserting others.

Just as with the lofty promises of public goods at the beginning of the pandemic, in the early stages of the discussion of a new international instrument or convention there was mention of the possible waiving of IP rights or more robust technology transfer mechanisms (not encumbered with data exclusivity, for instance).⁷ This, however, was removed in later versions of the document following insistence from US, EU and Switzerland.⁸

The process to reform the IHR through the Working on Group on Amendments to IHR 2005 (WGIHR) is also witnessing competing proposals from the African Group and others aiming at a closer research collaboration and better sharing of results against the need to grant access to outbreaks and guarantee the flow of health goods espoused by the European Commission and others.⁹

The Intergovernmental Negotiating Body (INB) and the WGHIR are working with WHO secretariat support and involvement and have varying degrees of transparency and civil society participation.¹⁰ The same cannot be said for the sanitary countermeasures platform, which, put

forward by the G20, has scarce accountability, focuses mostly on health security, and does not contemplate the need for enforceable measures to improve and secure access to health technologies, including putting health needs above trade rules.

TRIPS FLEXIBILITIES NAVIGATOR

Initiated as a result of a collective deliberation process during a “Diplohack” on how to better harness IP rights to improve and secure access to health technologies, the TRIPS flexibilities navigator has been a reality for the last 18 months.¹¹

Apart from being a one-stop shop of research, legal and administrative information for academics, policymakers, advocates and lawmakers on the use of TRIPS flexibilities, the Navigator is becoming a community to share ideas and best practice on how to use policy tools to improve access to medicines.¹²

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REGIONAL

The revision of the European Pharmaceutical Strategy is one of the most ambitious health endeavours ever attempted by the EU. In its inception it placed the need for affordable medicines and reliable supply mechanisms at the centre of thorough revision of the pharmaceutical legislation, including incentives such as data exclusivity.¹³

After several consultations and delays, the package¹⁴ presented by the European Commission for consideration of the European Parliament and EU council in April 2023 included:

- Review of pharmaceutical legislation (Directive+Regulation) would offer a combination of incentives linked to public health objectives of equitable access and reliable supply of medicines. Such incentives would include additional data exclusivity for companies launching products in all EU member states or developing products for unmet medical needs. An additional period of protection would also be granted for the repurposing of off-patent medicines.¹⁵
- Patent package with special emphasis on the use of compulsory licenses (CL) and the optimisation of the Supplementary Protection Certificates (SPC) regime. While the use of CL would be limited to a “last resort mechanism”, it would be exercised, after negotiations for a voluntary license, through a new EU-wide instrument and catering to EU demand. Regarding SPC, the Commission proposal introduces a new figure: the unitary SPC that would complement the unitary patent and be valid in participating member states.¹⁶ A centralised procedure for granting national SPCS would also be instituted.¹⁷
- Council recommendation on antimicrobial resistance (AMR) would introduce new pull incentives in the form of lump-sum market entry rewards or milestone payments.¹⁸

CONCLUSIONS

The TRIPS waiver proposal, and ensuing discussions leading up to 12th WTO Ministerial Conference TRIPS decision, revealed a profound divide within the international community regarding the role and use of IP protection mechanisms in relation to health technologies. The need for novel approaches is widely acknowledged by most concerned parties and stakeholders.

It is deeply concerning that the issue of health-oriented IP management is not a substantive part of the discussions around pandemic preparedness and response. The use of TRIPS flexibilities in non-emergency settings should also be endorsed in international and regional settings.

Some of the proposals emanating from the European Commission regarding the reform of the European Pharmaceutical Strategy, such as setting out rules for an EU-wide compulsory license, greater transparency in the granting of supplementary protection certificates and decreasing data exclusivity periods are, if followed through, positive steps.

RECOMMENDATIONS

- Higher visibility should be given to the IHR and INB processes and greater access be granted to public-interest civil society so public interest organisations can contribute their expertise, including relaying demands from Global South entities. Also, national governments should be held accountable for the positions held in the negotiations and their coherence with current policies, previous commitments and future plans in non-health domains.
- To ensure more equitable access to health technologies during pandemics and other health emergencies, negotiating parties at INB should agree binding clauses on overriding IP rules in case of a declaration of International Public Health emergency.
- The review of the EU pharmaceutical policy and associated initiatives is an historic opportunity to place affordability of medicines, transparency of R&D costs and health-oriented use of IP high in the public agenda. It is critical that lawmakers, both at the EU and national levels, actively engage in the scrutiny and debate. Civil society has a role to play in educating the public on the importance of the legislation.
- In the post-pandemic global health landscape, IP issues will remain contentious and in need of an evidence-based discussion amongst stakeholders across constituencies. Civil society contribution to this conversation is critical to ensure public interest. Tools like the TRIPS flexibilities navigator should be scaled up to achieve their potential and contribute to a better understanding, at national level, of the cost of too stringent IP protection for access to health technologies.
- Governments should direct international organisations including WHO, WTO and WIPO to take specific steps to explore the feasibility of an international instrument or convention acknowledging the condition of therapeutics, vaccines and diagnostics as global public goods in case of a pandemic or health emergency.
- The inclusion of additional IP-based incentives in the European Pharmaceutical Strategy, such as TEVs, should be opposed. Safeguards to avoid misuse and abuse of the patent system, especially on those products developed with public support and funding, should be made explicit and enforceable.

ENDNOTES

¹World Health Organization (WHO) statement on the fifteenth meeting of the IHR (2005) Emergency Committee on the COVID-19 pandemic. 5 May 2023. Available at [https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic). Consulted 8 May 2023.

²Health Action International (HAI) TRIPS laid bare: Learning the lessons of COVID-19 to improve access to health technologies. October 2022 pp. 5-6. Available at <https://haiweb.org/wp-content/uploads/2022/10/TRIPS-Agreement-Laid-Bare.pdf>. Consulted 5 May 2023.

³World Trade Organization (WTO) Ministerial Decision on the TRIPS Agreement. Adopted 17 June 2022 WT/MIN(22)/30. 22 June 2022. Available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>. Consulted 5 May 2023.

⁴See HAI statement on the outcome of TRIPS negotiations at WTO MC12. 20 June 2022. Available at <https://haiweb.org/publication/hai-statement-on-the-outcome-of-trips-negotiations-at-wto-mc12/>. Consulted 5 May 2023.

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⁶Statement by the members of the European Council on COVID-19 and health. 25 February 2021. Available at <https://www.consilium.europa.eu/en/press/press-releases/2021/02/25/statement-of-the-members-of-the-european-council-on-covid-19-and-health-25-february-2021/>. Consulted 5 May 2023.

⁷See European Commission President Von der Leyen on Coronavirus Global Response: World stands united against coronavirus and will win. 5 May 2020. Available at https://ec.europa.eu/commission/presscorner/detail/en/ac_20_811. Consulted 5 May 2023.

⁸Especially relevant is Numeral 43 of the preamble: *Recognizing the concerns that intellectual property on life-saving medical technologies continues to pose threats and barriers to the full realization of the right to health and to scientific progress for all, particularly the effect on prices, which limits access options and impedes independent local production and supplies, as well as noting structural flaws in the institutional and operational arrangements in the global response to the COVID-19 pandemic, and the need to establish a future pandemic prevention, preparedness and response mechanism that is not based on a charity model, and Article 7.4.a: In the event of a pandemic, the Parties: will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products; See WHO Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting .WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (“WHO CA+”) A/INB/4/3 1. February 2023. Available at https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf. Consulted 5 May 2023; On the overlapping of PPR processes and the role of IP (and equity) see Cullinan, K., WHO’s Two Pandemic Negotiation Processes Prepare for Joint Meetings as Equity and IP Dominate Talks Health Policy Watch (HPW). 4 May 2023. <https://healthpolicy-watch.news/whos-two-pandemic-negotiation-processes-prepare-for-joint-meetings/>. Consulted 5 May 2023; also Anderson, S., Pharmaceutical CEOs to G7: Protect Intellectual Property Rights and Pathogen Access in WHO Pandemic Accord Health Policy Watch (HPW) 14 April 2023 <https://healthpolicy-watch.news/pharmaceutical-ceos-to-g7-protect-intellectual-property-rights-and-pathogen-access-in-who-pandemic-accord/>. Consulted 5 May 2023; On US stance see US Department Of State Joint Update by the Department of State and the Department of Health and Human Services on Negotiations Toward a Pandemic Accord. 8 March 2023. <https://www.state.gov/joint-update-by-the-department-of-state-and-the-department-of-health-and-human-services-on-negotiations-toward-a-pandemic-accord/>. Consulted 5 May 2023.*

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¹¹HAI's Great Health Hack Delivers Great Ideas for Access to Medicines 24 November 2020. Available at <https://haiweb.org/great-health-hack/>. Consulted 5 May 2023.

¹²Critical to the success of the TRIPS flexibilities navigator is the TRIPS Flexibilities Database maintained and updated by Medicines Law and Policy. Available at <http://tripsflexibilities.medicineslawandpolicy.org/>. Consulted 5 May 2023; Other resources include the European Patent Office (EPO) and the Medicines Patent Pool (MPP) patents and licences database MedsPaL available at <https://medicinespatentpool.org/what-we-do/medspal>; See also Vidal, J., Introducing the TRIPS Flexibilities Navigator. 9 May 2022. Available at <https://haiweb.org/introducing-the-trips-flexibilities-navigator>. Consulted 5 May 2023.

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¹⁵European Commission proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency. 26 April 2023. Available at https://health.ec.europa.eu/publications/proposal-regulation-laying-down-union-procedures-authorisation-and-supervision-medicinal-products_en. Consulted 5 May 2023; European Commission proposal for a Directive on the Union code relating to medicinal products for human use. 26 April 2023. Available at https://health.ec.europa.eu/publications/proposal-directive-union-code-relating-medicinal-products-human-use_en. Consulted 5 May 2023.

¹⁶The 25 states participating in enhanced cooperation to bring about the Unitary Patent system are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden. See European Patent Office (EPO) Unitary Patent. Available at <https://www.epo.org/applying/european/unitary/unitary-patent.html>. Consulted 5 May 2023.

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