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| **From:** | Dr Olga Gurgula, Senior Lecturer in Intellectual Property Law, Brunel University London; Olga.Gurgula@brunel.ac.uk  |
| **To:** | The Registry of the Office of the High Commissioner for Human Rights (OHCHR) |
| **Re:** | **Input to HRC resolution 50/13 – challenges** |
| **Date:**  | 30 November 2023 |

Dear Sir/Madam,

I would like to submit my input to assist the OHCHR in preparing its analytical study on key challenges in ensuring access to medicines, vaccines and other health products to be presented to the Human Rights Council at the fifty-sixth session in June 2024. This contribution is focused on the following question:

***(f) What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?***

1. ***Regarding the impact of the existing intellectual property rights regime on access to medicines, vaccines and other health products***

When the COVID-19 outbreak began in late 2019 – and with the WHO declaring the COVID-19 outbreak a global pandemic on 11 March 2020 - the world faced a number of serious challenges. The first enormous task was to swiftly develop vaccines against this coronavirus. While the development of a vaccine typically requires significant time,[[1]](#footnote-1) this challenge was successfully overcome within a relatively short period.[[2]](#footnote-2) This was possible because of international collaboration on an unprecedented scale. The open publication of the genetic sequence of COVID-19 virus in early January 2020 by a team of Chinese and Australian researchers made this information freely available for access by researchers worldwide.[[3]](#footnote-3) The subsequent development of life-saving vaccines would not have been possible without this collaborative research.[[4]](#footnote-4) However, there was a stark contrast between the open approach to the sharing of the genetic sequence of the virus, and the subsequent strategies taken by pharmaceutical companies to the vaccine technologies.

Once viable vaccine candidates emerged, the next significant hurdle in combating the pandemic concerned the manufacture and distribution of the COVID-19 vaccines across the globe in a speedy, equitable and affordable manner. Once vaccines became viable, the global scientific community expressed the view that the most effective way to end the COVID-19 pandemic would be through the mass vaccination of populations around the world.[[5]](#footnote-5) Given the global dimension of the pandemic, billions of vaccine doses needed to be produced and distributed worldwide to contain the rapid spread and mutation of the virus across the globe. At the height of the pandemic, particularly during 2021, companies were simply unable to produce enough vaccines to inoculate the majority of the world population within an optimal period to contain the pandemic.[[6]](#footnote-6) The failure to achieve vaccine equity has contributed to the prolonging of the COVID-19 pandemic leading to millions of deaths (as of 22 November 2023, there have been 6,981,263 deaths reported to the WHO).[[7]](#footnote-7)

Global vaccine inequity was predictable. Anticipating the inadequacy of the vaccine development and manufacturing mechanisms, numerous calls for sharing vaccine technologies to boost the production of vaccines were made early on, starting in May 2020 with the WHO COVID-19 Technology Access Pool (C-TAP).[[8]](#footnote-8) C-TAP calls for action within the global community, and most importantly by pharmaceutical companies, to voluntarily share knowledge, intellectual property and data necessary to combat COVID-19. However, C-TAP attracted no contributions from major vaccine producers, as pharmaceutical companies refused to share their vaccine technologies with this or other similar initiatives such as the WHO mRNA Hub in South Africa.[[9]](#footnote-9) Moreover despite production levels falling short, relying on strong IP protection pharmaceutical companies rejected vaccine technology licensing requests from several pharmaceutical manufacturers,[[10]](#footnote-10) including quality assured manufacturers in Canada, Bangladesh, and Denmark.[[11]](#footnote-11) Instead, pharmaceutical companies – in particular mRNA vaccine technology holders Moderna and Pfizer-BioNTech – prioritised keeping a tight control of IP, concentrating on their own manufacturing capacities and only striking limited bilateral deals.[[12]](#footnote-12)

Fundamentally, this pandemic has shown that the current system of medical innovation and access to medicines is not designed to tackle such extraordinary situations as the COVID-19 pandemic.[[13]](#footnote-13) In normal times, the IP system is supposed to balance the private interests of companies and the public interest in access to health technologies (although the adequacy of this balance has been increasingly questioned).[[14]](#footnote-14) A lesson of the COVID-19 pandemic is that during emergencies, this system should be rebalanced with the public interest in protecting (global) public health taking precedence over private financial interests of pharmaceutical corporations.

1. ***How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?***

While voluntary agreements remain the most efficient tool to enable rapid transfer of IP-protected technologies, including in crises, there may be cases where such voluntary agreements are not available or appropriate. The failure of voluntary engagement by pharmaceutical companies – vaccine technology owners – during the COVID-19 pandemic highlights the crucial importance of reviewing the currently available mechanisms of involuntary technology transfer to make them more effective.

Patent law contains a specific tool for involuntary technology transfer in the form of compulsory licensing. A compulsory licence is the permission granted by a state authority that authorises a third party to use a patented invention without the patent holder’s consent.[[15]](#footnote-15) At the international level, the use of this mechanism in relation to the domestic market is regulated by Article 31 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (‘TRIPS’),[[16]](#footnote-16) while Article 31*bis* TRIPS regulates the process of issuing a compulsory licence of patents for the manufacturing and export of pharmaceutical products to third countries with public health concerns. At the beginning of the pandemic several countries issued COVID-19-related compulsory licences on the existing small molecule medicines, which were thought to be efficient against COVID-19 virus. In particular, Hungary and Russia granted compulsory licences for Remdesivir, and Israel for Lopinavir/Ritonavir.[[17]](#footnote-17) Moreover, in anticipation of possible challenging access to yet to be developed COVID-19 medicines and vaccines, some countries began to take certain measures to prevent situations in which patents and other exclusivities would create barriers to access. This includes amendments to national compulsory licensing laws by e.g. Australia, Canada and Germany.[[18]](#footnote-18) These legislative changes are particularly interesting because pre-pandemic this mechanism was mainly used by developing countries, while developed countries avoided using it following the rationale put forward by pharmaceutical companies that granting a compulsory licence would affect their incentives to innovate. Once COVID-19 medicines and vaccines were developed, such changes to national patent legislations proved to be justified in light of the actions of some vaccine manufacturers who, as was discussed above, refused to voluntarily license their vaccine technologies to the technology pools (such as the WHO C-TAP),[[19]](#footnote-19) and other manufacturers with production capacities, thwarting governments’ plans to rapidly vaccinate their populations to fight the pandemic.

Despite the catastrophic failure to promptly inoculate people worldwide due to the limited supply, on the one hand, and the resistance of pharmaceutical companies to share their vaccine technologies with other manufacturers who had the capacity to produce vaccines and thus accelerate their production, on the other hand, none of the countries issued any compulsory licences on COVID-19 vaccines. The only exception was the US that issued 59 compulsory licences to these very pharmaceutical companies – the COVID-19 vaccine technology owners – as part of the vaccine development scheme Operation Warp Speed.[[20]](#footnote-20) The main reason for restraining issuance of compulsory licences of COVID-19 vaccines was political. Nevertheless, even if a government would be willing to issue a compulsory licence on patents protecting a vaccine, this would not be sufficient for the compulsory licensee to be able to produce a COVID-19 vaccine because the current mechanism of compulsory licensing is inadequate in the case of vaccines.

Vaccines are complex biologics, and their manufacture is challenging because of, *inter alia*, the special facilities and equipment needed, the complex processes involved, and the specialist knowledge and experience required.[[21]](#footnote-21) Such knowledge is typically protected by patents and, more importantly, by trade secrets. Unlike small-molecule drugs that are easier to reverse engineer and reproduce by others without them needing to know a specific manufacturing process, with such a complex biological therapy as a vaccine, the knowledge on how to produce it may be critical.[[22]](#footnote-22) Some argue that in the area of vaccines, ‘a manufacturing process is a product’.[[23]](#footnote-23) Therefore, without such knowledge, a compulsory licence of patents would be insufficient,[[24]](#footnote-24) and there is no obligation for patent owners to pro­vide any additional information under a compulsory licence beyond what is included in a patent specification.[[25]](#footnote-25)

Therefore, even if some countries would have attempted to initiate an involuntary technology transfer of a COVID-19 vaccine, they would not be able to do this because currently there is no equivalent mechanism in IP laws for compulsory licensing of trade secrets similar to the mechanism of compulsory licensing developed for patents (there are, however, some limited tools in other laws,[[26]](#footnote-26) as those, for instance, available under competition law[[27]](#footnote-27)).[[28]](#footnote-28) This results in a dependence of countries, both developed and developing, upon pharmaceutical companies, resulting in countries’ inability to promptly protect public health.[[29]](#footnote-29) This is even though, the research for most of the vaccines was heavily subsidised by public funding.[[30]](#footnote-30) Therefore, the development of a mechanism that would supplement compulsory licensing of patents and allow compulsory access to and transfer of the trade secrets that protect vaccine technologies and other biologic medicines is urgently needed.[[31]](#footnote-31)

It is important to note that in April 2023 the European Commission proposed to implement a new EU-wide compulsory licensing regime.[[32]](#footnote-32) In its proposal the Commission seems to appreciate the challenge discussed above and implicitly addresses this problem by proposing that it may also require additional information from the patent owner to fulfill the purpose of the compulsory licence.[[33]](#footnote-33) The power of the Commission to request additional information is strengthened by its right to impose financial sanctions on the rights-holder in case of failure to provide such information.[[34]](#footnote-34) Moreover, in its draft report on the Commission’s proposal the European Parliament’s Committee on Legal Affairs has proposed two amendments to Recital 32. It proposes to require not only the disclosure of necessary information, but specifically refers to the disclosure of trade secrets and establishes of what essentially results in the obligation of the right holder to support the licensee in obtaining a marketing authorisation of its generic medicine under the compulsory licence.[[35]](#footnote-35) This is an important clarification that will undoubtedly help to significantly improve this compulsory licensing regime. Other countries should implement similar provisions to make their compulsory licensing mechanisms more effective.

**PS. If you need more information regarding the above, please do not hesitate to contact me at** **Olga.Gurgula@brunel.ac.uk**

**For a more detailed discussion on these issues, please see:**

* Olga Gurgula and John Hull, ‘Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer’ (2021) 16 Journal of Intellectual Property Law & Practice 1242. <<https://academic.oup.com/jiplp/article/16/11/1242/6446977>>
* Olga Gurgula, ‘Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer’ (2021) The South Centre policy brief 102 <<https://www.southcentre.int/wp-content/uploads/2021/09/PB102_Accelerating-COVID-19-Vaccine-Production-via-Involuntary-Technology-Transfer_EN.pdf>>
* Olga Gurgula, ‘Compulsory Licensing vs. the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic?’ (2021) The South Centre Policy brief 104 <<https://www.southcentre.int/wp-content/uploads/2021/10/PB104_Compulsory-licensing-vs.-the-IP-waiver_EN-2.pdf>>
* Olga Gurgula and Luke McDonagh, ‘Access Denied: the Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools’ (2023) STOPAIDS & JUST TREATMENT <<https://stopaids.org.uk/wp-content/uploads/2023/03/Trade-Secrets-Report-FINAL-1.pdf>>

Olga Gurgula, ‘On the European Commission’s Proposal to Create a New EU-wide Compulsory Licensing Regime’ (2023) Forthcoming in the European Intellectual Property Review (EIPR) <<https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4552851>>

1. Hilde Stevens *et al.*, ‘Vaccines: Accelerating Innovation and Access. Global Challenges Report’ WIPO (2017) 14 <<https://www.wipo.int/publications/en/details.jsp?id=4224>>. [↑](#footnote-ref-1)
2. #  [William Petri](https://theconversation.com/profiles/william-petri-947533), ‘COVID-19 vaccines were developed in record time – but are these game-changers safe?’ The Conversation (2020) <<https://theconversation.com/covid-19-vaccines-were-developed-in-record-time-but-are-these-game-changers-safe-150249>> .

 [↑](#footnote-ref-2)
3. [Mukhisa Kituyi](https://www.weforum.org/agenda/authors/mukhisa-kituyi), Secretary-General, UNCTAD, ‘Covid-19: Collaboration is the engine of global science – especially for developing countries’ World Economic Forum (2020) <https://www.weforum.org/agenda/2020/05/global-science-collaboration-open-source-covid-19/>. [↑](#footnote-ref-3)
4. ibid. [↑](#footnote-ref-4)
5. OECD, ‘[OECD Policy Responses to Coronavirus (COVID-19)](https://www.oecd.org/coronavirus/en/policy-responses). Enhancing public trust in COVID-19 vaccination: The role of governments’ (2021) <https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/>. [↑](#footnote-ref-5)
6. Sarah Newey, ‘Pharmaceutical leaders admit 'we dismally failed' at global Covid vaccine rollout’ (*The Telegraph,* 16 December 2021) <https://www.telegraph.co.uk/global-health/science-and-disease/pharmaceutical-leaders-admit-dismally-failed-global-covid-vaccine/>. [↑](#footnote-ref-6)
7. WHO, ‘[WHO Coronavirus (COVID-19) Dashboard](https://covid19.who.int/)’ <https://covid19.who.int/?mapFilter=deaths>. [↑](#footnote-ref-7)
8. WHO, ‘WHO COVID-19 Technology Access Pool’ <https://www.who.int/initiatives//covid-19-technology-access-pool>. [↑](#footnote-ref-8)
9. #  [Michael Safi](https://www.theguardian.com/profile/michael-safi), ‘WHO platform for pharmaceutical firms unused since pandemic began’ (*The Guardian,* 22 January 2021) <<https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>>; WEMOS ‘Covid-19 Technology Access Pool (C-TAP)’ <<https://covid19response.org/c-tap/>>.

 [↑](#footnote-ref-9)
10. #    Carlos M. Correa, ‘Expanding the production of COVID-19 vaccines to reach developing countries’ (2021) 91 South Centre Policy Brief <<https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>>; Arianna Schouten, ‘Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low Income Countries, may test Canada’s compulsory licensing for export law’ (*KEI,* 12 March 2021) *<*<https://www.keionline.org/35587>> .

 [↑](#footnote-ref-10)
11. Brook K. Baker, ‘Third-Way Proposals from Big Pharma and the WTO are the Same-Old Way – Commercial Control of Supply, Price, and Distribution’ (2021) The People’s Vaccine Policy Brief <<https://healthgap.org/wp-content/uploads/2021/05/Baker.The-Third-Way-is-the-Same-Old-Way-Final1.pdf>> [↑](#footnote-ref-11)
12. #  [Aisling Irwin](https://www.nature.com/articles/d41586-021-00727-3#author-0), ‘What it will take to vaccinate the world against COVID-19’ (2021) Nature <<https://www.nature.com/articles/d41586-021-00727-3>>; K M Gopakumar, Chetali Rao and Sangeeta Shashikant*, ‘*Trade secrets protection and vaccines: The role of medicine regulatory agencies’ (2021) Third World Network Briefing Paper.

 [↑](#footnote-ref-12)
13. E. Richard Gold, ‘What the COVID-19 pandemic revealed about intellectual property’ (2022) 40 Nat Biotechnol 1428 <<https://doi.org/10.1038/s41587-022-01485-x>>. [↑](#footnote-ref-13)
14. Olga Gurgula, ‘Drug Prices, Patents and Access to Life-Saving Medicines: Changes Are Urgently Needed in the COVID-19 Era’ (2021) 43 European Intellectual Property Review 381. [↑](#footnote-ref-14)
15. Olga Gurgula, ‘Compulsory Licensing vs. the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic?’ (2021) 104 South Centre Policy Brief <https://www.southcentre.int/policy-brief-104-october-2021/>. [↑](#footnote-ref-15)
16. WTO Agreement on Trade-Related Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, as amended on 23 January 2017. [↑](#footnote-ref-16)
17. The South Centre, ‘Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic’ (2021) the South Centre <<https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/>>; Katrina Perehudoff , Ellen 't Hoen and Pascale Boulet, ‘Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too’ (2021) BMJ Global Health 2021;6:e005518. doi:10.1136/ bmjgh-2021-005518. [↑](#footnote-ref-17)
18. MSF Briefing Document,‘Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies’ (May 2021) <<https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>>; [Louis Lozouet](https://www.mondaq.com/Home/Redirect/1956174?mode=author&article_id=1111706), ‘Brazil: New Compulsory Licensing Rules For Patents In Brazil’ (*Montag*, 17 September 2021) <<https://www.mondaq.com/Article/1111706>>. [↑](#footnote-ref-18)
19. ‘WHO COVID-19 Technology Access Pool’ <<https://www.who.int/initiatives/covid-19-technology-access-pool>>. [↑](#footnote-ref-19)
20. #  [James Love](https://www.keionline.org/author/james-love), ‘KEI review of 62 COVID 19 contracts reveals 59 authorizations for non-voluntary use of third party patents under 28 USC 1498’ (*KEI*, 20 July 2022) <<https://www.keionline.org/37987>>.

 [↑](#footnote-ref-20)
21. #  [John Smeaton](https://post.parliament.uk/authors/john-smeaton/) and [Lydia Harriss](https://post.parliament.uk/authors/lydia-harriss/), ‘Manufacturing COVID-19 vaccines’ (*UK Parliament,* 14 January 2021) <<https://post.parliament.uk/manufacturing-covid-19-vaccines/>>; Derek Lowe, ‘COVID\_19: Myths of Vaccine Manufacturing’ (*Science Translational Medicine blog,* 2 February 2021) <<https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing>>.

 [↑](#footnote-ref-21)
22. Aisling McMahon, ‘Patients, access to health and COVID 19 – the role of compulsory and government-use licensing in Ireland’ (2020) 7(3) *NI Legal Quarterly* 338; Sara Eve Crager, ‘Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer and Regulatory Pathways’ (2014) 104(11) *Am Jo Pub Health* e87. [↑](#footnote-ref-22)
23. For a discussion see [Nicola Searle](https://www.gold.ac.uk/icce/staff/searle-nicola/), ‘The process may (or may not) be the product: trade secrets and COVID research’ (*the IPKat*, 3 August 2020) <<https://ipkitten.blogspot.com/2020/08/the-process-may-or-may-not-be-product.htm>./>. [↑](#footnote-ref-23)
24. Olga Gurgula and John Hull, ‘Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer’ (2021) 16 Journal of Intellectual Property Law & Practice 1242. [↑](#footnote-ref-24)
25. Olga Gurgula and Luke McDonagh, ‘Access Denied: the Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools’ (2023) STOPAIDS & JUST TREATMENT <<https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4484507>>. [↑](#footnote-ref-25)
26. *E.g*., based on the US Defense Production Act of 1950 (‘DPA’) the President has the power to require pharmaceutical companies that produce COVID-19 vaccines to share information and data needed to facilitate increased production. *See* Amy Kapczynski and Jishian Ravinthiran, ‘How to vaccinate the world. Part 2’ (*LPE Project*, 4 April 2021) <<https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>>. [↑](#footnote-ref-26)
27. #  *See*, e.g., *FTC v Mallinckrodt Ard Inc*, ‘Stipulated Order for Permanent Injunction and Equitable Monetary Relief’, Case Number: 1:17-Cv-120 EGS (20 January 2017, US District Court for the District of Columbia) <<https://www.ftc.gov/system/files/documents/cases/stipulated_order_for_permanent_injunction_mallinckrodt.pdf>> (In this decision the US Federal Trade Commission imposed a compulsory licence on a pharmaceutical company, according to which the company had to share its technology related to a biologic drug, adrenocorticotropic hormone (ACTH), including patents and trade secrets, with a designated third-party licensee).

 [↑](#footnote-ref-27)
28. Gurgula and Hull (n 24). [↑](#footnote-ref-28)
29. Safi (n 9); [Grace Ren](https://healthpolicy-watch.news/author/grace-ren/), ‘Progress on COVID-19 Technology Pool Inches Along as Sister Initiative to Pool Vaccine Procurement Accelerates’, *Health Policy Watch*, 25 September 2020) <<https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/>>. [↑](#footnote-ref-29)
30. [Kayvan Bozorgmehr](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2821%2900467-0/fulltext) *et* *al*, ‘Free licensing of vaccines to end the COVID-19 crisis’ (2021) 397 the Lancet 1261 (‘These pharmaceutical companies have benefited greatly from huge sums of public funding for research and development and advance purchase commitments, amounting to between US$2.2 billion and $4.1 billion (by Feb 1, 2021) from Germany, the UK, and North America combined’). [↑](#footnote-ref-30)
31. Gurgula and Hull (n 25). [↑](#footnote-ref-31)
32. European Commission, ‘Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006’ (Brussels, 27.4.2023 COM(2023) 224 final). [↑](#footnote-ref-32)
33. ibid, text of the Proposed Regulation, Recital 32. [↑](#footnote-ref-33)
34. ibid, text of the Proposed Regulation, Recital 34, Articles 15 and 16. [↑](#footnote-ref-34)
35. See e.g. European Parliament Committee on Legal Affairs, ‘Draft Report on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))’ (16 September 2023) <https://www.europarl.europa.eu/doceo/document/JURI-PR-753706\_EN.pdf>. For a more detailed discussion of the Commission’s proposal see Olga Gurgula, ‘On the European Commission’s Proposal to Create a New EU-wide Compulsory Licensing Regime’ (2023) Forthcoming in the European Intellectual Property Review (EIPR) <<https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4552851>>. [↑](#footnote-ref-35)