

## Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer

By Dr. Olga Gurgula\*

### Introduction\*\*

The COVID-19 pandemic has been ravaging the world since the beginning of 2020.<sup>1</sup> As we have passed the year and a half mark of living with this

global pandemic, it may be a good time to take stock of the world's response to it, acknowledging the successes and failures, as well as seeking to understand what needs to be done to finally repel

### Abstract

This policy brief explains that the currently discussed proposals at the WTO related to increasing the production of COVID-19 vaccines, including the EU proposal to clarify the use of compulsory licensing and the submission by South Africa and India on the intellectual property (IP) waiver, require complementary mechanisms to rapidly improve the production of COVID-19 vaccines that are urgently needed today. The key problem is that to accelerate the manufacture of COVID-19 vaccines, access to knowledge and know-how, that are protected by trade secrets owned by several pharmaceutical companies, is required. It is therefore important that governments implement an additional mechanism of compulsory licensing of trade secrets that would allow an involuntary transfer of COVID-19 vaccine technologies. Such a mechanism would be compliant with the TRIPS Agreement and relevant whether the TRIPS waiver is adopted or not agreed upon. While this mechanism must provide full access to the information necessary to manufacture the vaccines in question, it must also ensure the protection of the transferred trade secrets.

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*Este informe político explica que las propuestas que se están debatiendo actualmente en la OMC relacionadas con el aumento de la producción de vacunas contra la COVID-19, incluida la propuesta de la UE para aclarar el uso de las licencias obligatorias y la presentación de Sudáfrica e India sobre la exención de la propiedad intelectual (PI), requieren mecanismos complementarios para mejorar rápidamente la producción de las vacunas contra la COVID-19 que se necesitan urgentemente en la actualidad. El problema clave es que para acelerar la fabricación de las vacunas contra el COVID-19 se requiere el acceso a los conocimientos y a la experiencia, que están protegidos por secretos comerciales propiedad de varias empresas farmacéuticas. Por lo tanto, es importante que los gobiernos implementen un mecanismo adicional de licencia obligatoria de secretos comerciales que permita una transferencia involuntaria de las tecnologías de las vacunas COVID-19. Este mecanismo se ajustaría al Acuerdo sobre los ADPIC y sería pertinente tanto si se adopta la exención de los ADPIC como si no se acuerda. Si bien este mecanismo debe permitir el pleno acceso a la información necesaria para fabricar las vacunas en cuestión, también debe garantizar la protección de los secretos comerciales transferidos.*

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*Ce document explique que les projets en cours de discussion à l'OMC concernant l'augmentation de la production de vaccins COVID-19, y compris la proposition de l'UE visant à clarifier l'utilisation des licences obligatoires et la requête de l'Afrique du Sud et de l'Inde concernant la dérogation en matière de propriété intellectuelle (PI), nécessitent des mécanismes complémentaires pour améliorer rapidement la production des vaccins COVID-19, dont le besoin est urgent aujourd'hui. Le principal problème est que pour accélérer la fabrication des vaccins COVID-19, il faut avoir accès aux connaissances et au savoir-faire, qui sont protégés par des secrets commerciaux appartenant à plusieurs sociétés pharmaceutiques. Il est donc important que les gouvernements mettent en place un mécanisme supplémentaire de licence obligatoire des secrets commerciaux qui permettrait un transfert involontaire des technologies des vaccins COVID-19. Un tel mécanisme serait en conformité avec l'accord sur les ADPIC et pertinent, que la dérogation ADPIC soit adoptée ou non. Si ce mécanisme doit permettre un accès total aux informations nécessaires à la fabrication des vaccins en question, il doit également garantir la protection des secrets commerciaux transférés.*

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this virus. Some good progress has been made. In the first year of the pandemic, several vaccines against the COVID-19 virus were developed and more vaccines are in the pipeline, set at various stages of development.<sup>2</sup> However, these vaccines must now be produced in sufficient quantities and distributed across the world equitably and affordably. This has proven to be a serious challenge. It is estimated that around 11 billion doses are required to vaccinate 70 per cent of the world's population.<sup>3</sup> However, most of the vaccines manufactured to date have been acquired in excess by wealthy countries; at the same time, poor countries are lagging significantly behind. By the end of the summer 2020, the UK, EU countries, and Canada had procured enough doses to inoculate more than their entire populations, while the first purchases for low-income countries came only in January 2021.<sup>4</sup> According to the WHO, as of 5 May 2021, while more than 1.1 billion doses of vaccine had been administered globally, more than 80 per cent of them had been given in high- and upper-middle-income countries and only a tiny fraction of this amount—0.3 per cent—in low-income countries.<sup>5</sup> It is estimated that it may take several years for people in the lowest-income groups to be vaccinated.<sup>6</sup> This has raised a crucial question: how can the production of COVID-19 vaccines be accelerated and their equitable and affordable worldwide distribution ensured?

Understanding the limitations of the current vaccine development and manufacturing mechanisms, numerous calls for sharing vaccine technologies to boost their production have been made. This includes the WHO COVID-19 Technology Access Pool (C-TAP) that has called on the global community and, most importantly, pharmaceutical companies to voluntarily share the knowledge, intellectual property and data necessary to defeat the virus.<sup>7</sup> While this technology pool has the potential to accelerate the production of COVID-19 vaccines, it has attracted no contributions since it was established in May 2020 as pharmaceutical companies have refused to share their vaccine technologies through this and similar initiatives.<sup>8</sup> Striving to retain full control of their vaccine technologies, pharmaceutical companies are focused, instead, on scaling up their own manufacturing capacities and striking deals with other companies to produce their vaccines.<sup>9</sup> However, since this pandemic has a global dimension and, thus, billions of vaccines are required to be manufactured and distributed worldwide at an accelerated rate to contain the rapid spread and mutation of the

virus across the globe, the current setup of vaccine production is undoubtedly insufficient to protect the world's population against the pandemic.<sup>10</sup>

To overcome the problem of insufficient production of COVID-19 vaccines, two key proposals have been put forward at the WTO level. One of them is to clarify the currently available flexibilities in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement<sup>11</sup> in the form of compulsory licensing, which was championed by the EU in its submission of 4 June 2021 to the WTO Council for TRIPS.<sup>12</sup> This EU proposal was advanced to counter an earlier proposal by South Africa and India to temporarily waive IP rights in the TRIPS Agreement,<sup>13</sup> a move which is now partially supported by the US. This has raised heated debates as to the effectiveness of either of these proposals to ensure the rapid production and distribution of vaccines, and which of these paths should be taken by the global community to finally stop the pandemic.<sup>14</sup> While each of these mechanisms may help to improve the production of COVID-19 vaccines to various degrees, they both would need to be supplemented by other measures to ensure the effective and speedy increase in vaccine production that we need today.

The key problem is the need to rapidly access knowledge and know-how that are protected by trade secrets owned by several pharmaceutical companies. This has been a barrier for accelerating vaccine production as without accessing such know-how other manufacturers would require developing their own know-how, which may take a lot of time and effort. However, despite the need to swiftly increase the production of vaccines by utilizing all available manufacturing facilities worldwide to contain the spread and mutation of the COVID-19 virus pharmaceutical companies refuse to share their vaccine technologies with the C-TAP, as discussed earlier, as well as reject requests to license their vaccine technologies made by several pharmaceutical manufacturers.<sup>15</sup> For example, Biolyse, a Canadian manufacturer of cancer drugs, who can manufacture two million doses a month and, thus, has the potential to contribute to the global scaling-up of vaccine manufacturing capacities, sought to manufacture and export the Johnson & Johnson (J&J) adenovirus vaccine to developing countries. However, J&J refused to license its technology to Biolyse.<sup>16</sup>

It is currently acknowledged that there are no specific provisions in international and national IP laws, similar to the compulsory licensing mechanism developed for patents, that would allow access to trade

secrets held by pharmaceutical companies if they are not willing to share this information voluntarily.<sup>17</sup>

Therefore, this policy brief argues that to overcome the hurdle of accessing vaccine technologies rapidly an additional mechanism of compulsory licensing of trade secrets is necessary. If pharmaceutical companies continue to refuse to voluntarily share such information, then without such a mechanism the required know-how would have to be developed by potential manufacturers, which may take a lot of time significantly affecting our chances to end the pandemic in the near future. Several jurisdictions have been discussing the amendments to their IP laws, which would require patent owners to transfer corresponding know-how to the compulsory licensees.<sup>18</sup> The discussion in this policy brief, therefore, may be useful for such jurisdictions as it raises important issues that would need to be taken into account when adopting this mechanism, including the protection of public interests in increasing the production of COVID-19 vaccines while ensuring that legitimate private interests of technology owners are also secured. Finally, while the discussion in this policy brief is focused on the compulsory licensing of trade secrets to facilitate access to COVID-19 vaccines, the implementation of such a mechanism may also be useful for any involuntary technology transfer of complex biologic medicines that are typically protected by trade secrets, and which are becoming prevalent in healthcare today.

### **1. Why is the additional mechanism in the form of compulsory licensing of trade secrets necessary to address the problem of the COVID-19 vaccine shortage?**

As was mentioned above, both proposals, i.e., the clarification of some aspects of compulsory licensing and the IP waiver, have the potential to facilitate an increased production of COVID-19 vaccines. They, however, can achieve this to different degrees as the EU's proposal would not overcome the territorial limitations nor substantially change the burdensome mechanism provided for in Article 31*bis*. Importantly, to make these proposals work effectively they need to be supplemented by additional measures that would facilitate technology transfer. 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.<sup>19</sup> 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.<sup>20</sup> Some argue that in the area of vaccines, "a manufacturing process is a product".<sup>21</sup> Therefore, as was mentioned above, without the expeditious transfer of such knowledge by pharmaceutical companies that own it, the rapid increase in the production of vaccines would not be possible. This is because it may take a lot of time and effort for new manufacturers to develop such knowledge themselves.<sup>22</sup>

Moreover, concerned about being subjected to the compulsory licensing of patents, pharmaceutical companies may be inclined to rely even more on trade secrets.<sup>23</sup> This has led some authors to argue that trade secrets can be considered "among the most powerful legal weapons against [the] public".<sup>24</sup> Currently, however, IP laws provide no mechanisms to force pharmaceutical companies to disclose their lifesaving COVID-19 vaccine technologies protected by trade secrets without their consent to voluntary sharing<sup>25</sup> (there are, however, some limited tools in other laws,<sup>26</sup> as those, for instance, available under competition law<sup>27</sup>). This results in a dependence of countries, both developed and developing, upon pharmaceutical companies, resulting in countries' inability to promptly protect public health.<sup>28</sup> This is even though, the research for most of the vaccines was heavily subsidized by public funding.<sup>29</sup> Therefore, the development of a mechanism that would supplement compulsory licensing of patents or the IP waiver, and allow compulsory access to and transfer of the trade secrets that protect COVID-19 vaccine technologies is urgently needed.

### **2. Is compulsory licensing of trade secrets consistent with international IP law?**

While Article 39 of the TRIPS Agreement may be considered to be the guiding world standard for the protection of trade secrets, it is useful to consider whether there are other elements of the TRIPS Agreement which may act to counterbalance the protection given to them.

Article 39 is drafted in terms of protection against unfair competition.<sup>30</sup> It requires members to protect undisclosed information "[i]n the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967)". The regime of unfair competition essentially protects against unfair commercial practices. The

law of trade secrets, as set out in TRIPS, protects against **misappropriation** of trade secrets, which is actionable if the trade secrets were acquired **improperly** and are either used or disclosed or in violation of a duty to maintain confidentiality.<sup>31</sup> Specifically, an acquisition of a trade secret by improper means occurs “ if it was obtained through theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or through espionage, including electronic espionage.”<sup>32</sup>

At the same time, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health<sup>33</sup> lay down important principles and objectives in relation to the protection of public health. In particular, Article 7 TRIPS, provides that “[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the **transfer and dissemination of technology, ... in a manner conducive to social and economic welfare, ...**” (emphasis added). In addition, Article 8 states that “Members may, in formulating or amending their laws and regulations, **adopt measures necessary to protect public health**” and that “[a]ppropriate measures may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which .... **adversely affect the international transfer of technology**” (emphasis added). Finally, paragraph 4 of the Doha Declaration states that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health” and that it “can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all”.<sup>34</sup> Therefore, the interpretation of these provisions may lay down the grounds for a compulsory licensing of trade secrets under TRIPS to ensure the protection of public health, especially during the COVID-19 pandemic, by facilitating the production of vaccines through an international technology transfer.<sup>35</sup>

Moreover, the TRIPS Agreement contains no specific exclusions that would prevent compulsory licensing of trade secrets. In particular, while TRIPS has a provision on compulsory licensing of patents, it expressly prohibits compulsory licensing of trademarks. Article 21 states that it is “understood that the compulsory licensing of trademarks shall not be permitted” It could be argued that had the drafters intended to exclude

this mechanism from being applied to trade secrets, they would have explicitly stated so. Instead, the TRIPS Agreement remains silent on this issue, thus, arguably, leaving this matter for national legislation. Therefore, this could be construed as allowing governments to issue compulsory licensing of trade secrets when required, including for the protection of public health.

Finally, TRIPS itself encourages technology transfer to developing countries that lack manufacturing capacity. In particular, in the context of Article 31bis of TRIPS, it states that:

Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

Therefore, it could be argued that compulsory licensing of trade secrets that enables technology transfer is not only consistent with the TRIPS Agreement but is also directly promoted by its various provisions.

It is, therefore, important to implement this mechanism in national IP laws supplementing compulsory licensing of patents with a similar mechanism for trade secrets. This would ensure that governments can effectively facilitate access to medicines by granting compulsory licensing on patents and trade secrets. More fundamentally, this mechanism is necessary because, as was mentioned above, increasingly more and more medicines, including COVID-19 vaccines, are characterized as complex biologics, protected not only by patents but also by a significant number of trade secrets. Therefore, without such an additional mechanism, compulsory licensing of patents may become a “shallow” and ineffective tool, and, hence, this flexibility envisaged in Article 31 TRIPS that was implemented to balance strong proprietary patent rights would have limited or no effect. Therefore, as TRIPS is silent about compulsory licensing of trade secrets, while at the

same time encouraging technology transfer, countries are free to implement such provisions in their national IP laws. It would be also desirable to harmonize this instrument at the international level by including relevant provisions in the TRIPS Agreement.

### **3. The complex nature of a compulsory license of trade secrets and its key elements**

Compulsory licensing of trade secrets may be possible by governmental orders (similar to “government use” of patents), which would oblige vaccine producers to disclose and provide access to all the information, including trade secrets, required to manufacture a vaccine. However, in contrast to compulsory licensing of patents, where the patent owner may continue to enjoy their patent rights after the license is terminated, compulsory licensing of trade secret is more complex. This is because the value of this right is precisely in it being secret; once such information ceases to be secret, its value may be lost. In this sense, compulsory licensing of trade secret differs from a similar mechanism developed for patents. Despite its compulsory nature, it would also need to balance the interests of all the parties involved. Specifically, to preserve the fairness of this mechanism, a compulsory license must, on the one hand, ensure full access to a vaccine technology necessary for its production, while, on the other hand, it must guarantee the protection of the transferred trade secrets to avoid their inadvertent disclosure and, thus, deprive them of their value and damage the owner’s business.

Any government intent on putting a compulsory license into the hands of a licensee must, as a first step, identify a potentially suitable licensee. In particular, a national law may establish a mechanism for identifying such a licensee, which may include both requests from a potential licensee and identification of a licensee by the government upon its own initiative. That licensee must have, at least, plant, equipment and some degree of expertise in this kind of manufacturing. The licensee would need to “set up, calibrate and test equipment, and train scientists and engineers to run it”.<sup>36</sup>

There are a number of elements that a compulsory license of trade secrets must contain that are akin to those which would be typically included in a voluntary licensing agreement and those that would need to reflect the compulsory nature of the license.<sup>37</sup> The two key elements of such a

license are the scope of the transfer and confidentiality. In particular, the license must identify the scope of technology transfer, including the scope of information necessary for production, and how much technical assistance will be needed to enable the licensee to make effective use of the technology. The license must also contain confidentiality clause imposing strict obligations on the parties to maintain confidentiality, including an obligation to introduce and observe security for the information transferred under the license.

One of the main difficulties that may affect the effectiveness of this mechanism in practice is the enforcement of such a compulsory license. This may occur if a licensor does not wish to comply with a compulsory license. In such a case the license would need to be enforced through an administrative order or by the court. If the licensor is a local company, such an enforcement would pose little difficulty. However, the situation becomes more complicated if a compulsory license imposed by a government in one country against a licensor-technology owner domiciled in another country (which is currently the case for most developing countries). If the prospective licensor refuses to comply with the order issued in another country, some form of reciprocal enforcement of a foreign government or foreign court order would be necessary in the country where it is domiciled to oblige the licensor to comply. The reciprocal recognition and enforcement of foreign judgments depends on whether countries have concluded treaties to recognize and enforce another country’s court orders. For many countries no such reciprocal system exists. Therefore, to make compulsory licensing of trade secrets work effectively some jurisdictions, along with implementing this mechanism, may also need to reform their enforcement regime. This problem, however, would need to be analyzed separately.

### **Conclusion**

To defeat the COVID-19 pandemic, the accelerated production of COVID-19 vaccines and their equitable distribution worldwide are urgently needed. For this, access to vaccine technologies is required. However, such technologies are protected by an array of IP rights that are owned by pharmaceutical companies, that have been refusing to share them with technology pools or other potential manufacturers capable of producing COVID-19 vaccines and thus increasing their availability. It is, therefore, important that governments implement a mechanism that would enable a compulsory transfer of COVID-19 vaccine technologies. Such a mechanism would

be compliant with the TRIPS Agreement, which, on the one hand, does not explicitly prohibit compulsory licensing of trade secrets while, on the other hand, mandates that its principles should be construed in a manner supportive of the WTO members' right to protect public health. Importantly, this mechanism would be relevant both in the case of the adoption of the TRIPS IP waiver, as well as if such a mechanism could not be agreed upon and, thus, WTO members would need to rely on the existing compulsory licensing mechanism. More fundamentally, as more and more drugs on the market are complex biologics and, thus, are protected by trade secrets, the suggested mechanism would remain relevant beyond the pandemic, ensuring access to such medicines.

#### Endnotes:

- <sup>1</sup> This policy brief is based on the article by Olga Gurgula and John Hull, "Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer" (Journal of Intellectual Property Law & Practice, forthcoming) Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3872796](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3872796).
- <sup>2</sup> "COVID-19 vaccine tracker". Available from <https://covid19.trackvaccines.org/vaccines/> ("As of 29 August 2021, 22 different vaccines approved worldwide and 139 vaccine candidates").
- <sup>3</sup> Mary B Marcus, "Ensuring Everyone in the World Gets a COVID Vaccine", *Duke Global Institute*, 20 January 2021. Available from <https://globalhealth.duke.edu/news/ensuring-everyone-world-gets-covid-vaccine>; Aisling Irwin, "What it will take to vaccinate the world against COVID-19? A special report outlines the challenges - from unleashing the power of mRNA vaccines, to the battle for temporary intellectual property relief", *Nature*, vol. 592, 25 March 2021, p. 176.
- <sup>4</sup> Launch & Scale Speedometer, "Tracking Covid-19 Vaccine Purchases Across the Globe". Available from <https://launchandscalefaster.org/covid-19/vaccinepurchases>.
- <sup>5</sup> "Director-general's opening remarks at One Shared World event", *WHO*, 5 May 2021. Available from <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-one-shared-world-event>.
- <sup>6</sup> Oxfam press release, "Companies warn that 9 out of 10 people in poor countries are set to miss out on COVID-19 vaccine next year", 9 December 2020. Available from <https://www.oxfam.org/en/press-releases/campaigners-warn-9-out-10-people-poor-countries-are-set-miss-out-covid-19-vaccine>. Owen Dyer, "Covid-19: Many poor countries will see almost no vaccine next year, aid groups warn" *BMJ* 2020;371:m4809, December 2020.
- <sup>7</sup> "WHO COVID-19 Technology Access Pool". Available from <https://www.who.int/initiatives/covid-19-technology-access-pool>.
- <sup>8</sup> Michael Safi, "WHO platform for pharmaceutical firms unused since pandemic began", *the Guardian*, 22 January 2021. Available from <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>.
- <sup>9</sup> Irwin (No. 3).
- <sup>10</sup> Olga Gurgula and Wen Hwa Lee, "How can governments end the COVID-19 pandemic?", *Oxford Martin School blog*, 28 May 2021. Available from <https://www.oxfordmartin.ox.ac.uk/blog/how-can-governments-end-the-covid-19-pandemic/>.
- <sup>11</sup> 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.
- <sup>12</sup> Communication From the European Union to the Council for TRIPS, "Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property", Brussels, 4 June 2021. Available from [https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc\\_159606.pdf](https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf).
- <sup>13</sup> Communication from India and South Africa, "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19" (2 October 2020) IP/C/W/669 <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?fileame=q:/IP/C/W669.pdf&Open=True>. The revised proposal was submitted on 21 May 2021. See "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Revised Decision Text". Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?fileame=q:/IP/C/W669R1.pdf&Open=True>.
- <sup>14</sup> See e.g., Bryan Mercurio "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review", *Virginia Journal of International Law Online* (Forthcoming 2021), Available at <https://ssrn.com/abstract=3789820>; Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries", the South Centre, Policy Brief 91, April 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>; Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Duffield, "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic", LSE Legal Studies Working Paper, 2021, Forthcoming. Available from [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3851737](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737).
- <sup>15</sup> Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries" (n 14) (Some companies – Incepta from Bangladesh, Biolyse from Canada, Getz Pharma from Pakistan, Teva from Israel – have reported that current vaccine producers have dismissed or not even responded to requests to obtain licenses for production).

<sup>16</sup> 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. Available from <https://www.keionline.org/35587>.

<sup>17</sup> David S. Levine, “Covid-19 Trade Secrets and Information Access: An Overview”, *Infojustice*, 10 July 2020. Available from <http://infojustice.org/archives/42493>; Muhammad Zaheer Abbas, “Treatment of the novel COVID-19: why Costa Rica’s proposal for the creation of a global pooling mechanism deserves serious consideration?”, vol. 7, No 1, *Journal of Law and the Biosciences*, 26 June 2020.

<sup>18</sup> On 11 August 2021, the Brazilian Senate approved a Compulsory Licensing Bill (#12/2021), which amends the Brazilian Patent Statute (Law #9,279/96). The amendments require the patent or patent application holder to provide the necessary and sufficient information (e.g., know-how, technical aspects, biological material, test results and other data) for the effective reproduction of the object protected by the patent or patent application. On 02 September 2021, the bill was sanctioned with vetoes by Brazilian President who signed the law 14.200/2021. The president vetoed the provisions regarding sharing such information by the owner of technology as part of a compulsory licence (see [Casimir Jones SC](#), “Compulsory Licensing in Brazil: Updates and Perspectives”, *Lexology*, 17 August 2021. Available from <https://www.lexology.com/library/detail.aspx?g=4adf38aa-3a49-4230-b129-82b3f750993e>; Louis Lozouet, “Brazil: New Compulsory Licensing Rules For Patents In Brazil”, September 2021. Available from <https://www.mondaq.com/Article/1111706>). Also, certain changes to the compulsory licensing mechanism are being discussed in France, where it is suggested to oblige the patent owner, whose patent is under a compulsory license, to share the corresponding know-how so that the license can be implemented in practice, as well as to **provide the information necessary to obtain the marketing authorisation**. (see Matthieu Dhenne, “French bill proposal authorizing the granting of an ex officio license in the interest of public health in the event of an extreme health emergency”, *Kluwer Patent Blog*, 28 April 2021. Available from <http://patentblog.kluweriplaw.com/2021/04/28/french-bill-proposal-authorizing-the-granting-of-an-ex-officio-license-in-the-interest-of-public-health-in-the-event-of-an-extreme-health-emergency/>).

<sup>19</sup> John Smeaton and Lydia Harriss, “Manufacturing COVID-19 vaccines”, UK Parliament, 14 January 2021. Available from <https://post.parliament.uk/manufacturing-covid-19-vaccines/>; Derek Lowe, “COVID\_19: Myths of Vaccine Manufacturing”, *Science Translational Medicine blog*, 2 February 2021. Available from <https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing>.

<sup>20</sup> Aisling McMahon, “Patients, access to health and COVID 19 – the role of compulsory and government-use licensing in Ireland” *NI Legal Quarterly*, vol. 7, No. 3, 5 November 2020, p. 338; Sara Eve Crager, “Improving Global Access to New Vaccines: Intellectual Property,

Technology Transfer and Regulatory Pathways”, *Am Jo Pub Health*, vol. 104, No. 11, November 2014, p. e87 (arguing that for a successful vaccine access strategy “[a]ccess to manufacturing process information protected by trade-secret law, as well as access to technology and know-how held by the innovator company, will likely be necessary”).

<sup>21</sup> For a discussion see Nicola Searle, “The process may (or may not) be the product: trade secrets and COVID research”, *the IPKat*, 3 August 2020. Available from <https://ipkitten.blogspot.com/2020/08/the-process-may-or-may-not-be-product.htm/>.

<sup>22</sup> McMahon (n 20) 338; Crager (n 20) e87 (arguing that “although patent protection remains the major barrier to the production of affordable small-molecule generics, access to trade-secret – protected information and know-how present major additional obstacles to generic production of vaccines”).

<sup>23</sup> Sebastian Alvarado, “Chile: Trade Secrets as a Response to Compulsory Licensing”, *Mondaq*, 23 July 2020. Available from <https://www.mondaq.com/trade-secrets/968600/trade-secrets-as-a-response-to-compulsory-licensing>.

<sup>24</sup> Levine, “Covid-19 Trade Secrets and Information Access: an Overview” (No. 17).

<sup>25</sup> Ibid (“Government regulators can also run into challenges getting access to trade secrets, especially absent clear statutory mandates for access.”).

<sup>26</sup> 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. Available at <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>.

<sup>27</sup> 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). Available from [https://www.ftc.gov/system/files/documents/cases/stipulated\\_order\\_for\\_permanent\\_injunction\\_mallinckrodt.pdf](https://www.ftc.gov/system/files/documents/cases/stipulated_order_for_permanent_injunction_mallinckrodt.pdf). (In this decision the US Federal Trade Commission recently imposed a compulsory licence on a pharmaceutical company, according to which the company had to share its technology related to a biologic drug, adrenocorticotrophic hormone (ACTH), including patents and trade secrets, with a designated third-party licensee). For more information on this decision and compulsory licensing of trade secrets – see Gurgula and Hull (No. 1).

<sup>28</sup> Safi (No. 8) (explaining that the C-TAP has attracted zero contributions since it was established in May 2020); Grace Ren, “Progress on COVID-19 Technology Pool Inches Along as Sister Initiative to Pool Vaccine Procurement Accelerates”, *Health Policy Watch*, 25 September 2020. Available from <https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/> (“unlike the COVAX Facility, which has received broad industry support, the COVID-19 Technology Access Pool has been dismissed by the pharmaceutical industry, which holds much of the rights to the

technology, data, and research that the Pool would aim to more freely distribute”).

<sup>29</sup> Kayvan Bozorgmehr 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”).

<sup>30</sup> International Chamber of Commerce, “Protecting Trade Secrets – Recent EU and US Reforms”, 2019, p. 8. Available from

<https://iccwbo.org/content/uploads/sites/3/2019/04/final-icc-report-protecting-trade-secrets.pdf>; Tanya Aplin, “Right to Property and Trade Secrets” in *Research Handbook on Human Rights and Intellectual Property*, Christopher Geiger, ed., (Edward Elgar, 2015) p. 422.

<sup>31</sup> Karl F. Jorda, “Trade Secrets and Trade-Secret Licensing” in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Anantole Krattiger et al., ed. (Concept Foundation 2007) 1047.

<sup>32</sup> Ibid.

<sup>33</sup> Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/MIN(O1)/DEC/2 (20 November 2001) (hereinafter “the Doha Declaration”).

<sup>34</sup> Levine, “Covid-19 Trade Secrets and Information Access: an Overview” (No. 17).



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<sup>35</sup> Kung-Chung Liu, “The need and justification for a general competition-oriented compulsory licensing regime”, IIC - International Review of Intellectual Property and Competition Law, vol. 43, No. 6, 2012, p. 683; H. Xue, “Enforcement for development: why not an agenda for the developing world?”, in *Intellectual Property Enforcement – International Perspectives*, X. Li and C. Correa, eds. (Edward Elgar, 2009) p. 148.

<sup>36</sup> Liz Szabo et al, “Why Even Presidential Pressure Might Not Get More Vaccine to Market Faster”, *KHN*, 26 January 2021. Available from <https://khn.org/news/article/ramping-up-covid-vaccine-production-could-take-months-even-with-bidens-best-tool-to-pressure-companies/>.

<sup>37</sup> For a detailed analysis of the substance and elements of a compulsory license of trade secrets see Gurgula and Hull (No. 1).

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