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Trade secrets protection and vaccines: The role of medicine regulatory agencies

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The recent announcement by the United States supporting a waiver of intellectual property rights for COVID-19 vaccines has increased the probability of adoption of a TRIPS waiver decision in the World Trade Organization (WTO).

Unsurprisingly, the announcement also triggered reactions arguing that in the case of vaccines the barrier is "less about intellectual property and more about knowledge transfer".[1] Moderna's CEO reportedly stated: "*Drug makers interested in manufacturing a similar mRNA vaccine would need to conduct the clinical trials, apply for authorization and then scale the manufacturing, which could take upward of 12 to 18 months.*"[2]

Camouflaged in these statements is the fact that information related to safety and efficacy as well as the manufacturing process critical to facilitating the rapid diversification and scaling up of production is protected as confidential information and trade secrets.

Trade secrets are a subset of confidential information that is protected against unfair competition and is treated as a form of intellectual property (IP). Although not all confidential information is IP-protected, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Article 39.2) defines a category of protected confidential information that is largely synonymous with how most countries define trade secrets. Confidential information becomes a trade secret that is protected when it satisfies the following three conditions: (i) the information should not be available or "accessible to persons within the circles that normally deal with the kind of information in question"; (ii) the information has commercial value because it is secret; and (iii) the firm or individual in control of the information has taken reasonable steps to keep the information secret.

The US Food and Drug Administration (FDA) specifically uses the term "trade secret" while the European Medicines Agency (EMA) deploys the term "commercially confidential information" to refer to almost the same set of information submitted for the marketing approval of health products including vaccines.

1 https://healthpolicy-watch.news/83451-2/

2 https://www.fiercepharma.com/pharma/moderna-ceo-says-he-s-not-losing-any-sleep-over-biden-s-endorsement-for-covid-19-ip-waiver

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In the TRIPS Agreement, secret information of commercial value is protected in Article 39 under the heading titled "Protection of Undisclosed Information". The proposal to waive TRIPS obligations includes a waiver of this clause of the Agreement.

Often developed countries repeat Big Pharma's narratives portraying developing-country manufacturers as lacking technological capability. On the contrary, evidence suggests otherwise. According to the Global Vaccine Market Report 2018, developing-country vaccine manufacturers supply at least 65% of the vaccine needs in all World Health Organization (WHO) regions except for the Euro region. In addition, 69 out of the 161 WHO prequalified vaccines are produced by manufacturers from developing countries, including India, China, Brazil, Cuba, Thailand, Senegal and Indonesia.[3]

Following interactions with the pharmaceutical industry, the Director-General of the WTO, Ngozi Okonjo-Iweala, has also recognized the need to "mobilize existing capacity", adding that "We heard from countries like Pakistan, Bangladesh, India, South Africa, and so on, Indonesia, Senegal, that there is some existing [manufacturing] capacity".[4]

However, the current approach of the multinational pharmaceutical industry to production and supply of vaccines is mainly premised on expanding internal capacity, establishing secretive contract manufacturing agreements with selected contractors and artificially constraining production and supply.[5] There are many examples of the industry turning down offers of help from other drugmakers, including those from developing countries, to boost global manufacturing and supply.[6]

While vaccine manufacturing is a complex process, undoubtedly there is significant vaccine manufacturing experience among developing-country manufacturers (as well as other manufacturers) beyond "Big Pharma". However, a major hurdle to the entry of non-originator vaccine manufacturers is the structure of the regulatory system and, linked to that, the role of regulatory agencies in de facto protecting trade secrets.

Regulatory pathways: Small molecules, biotherapeutics and vaccines

In the case of "small molecule drugs" (SMD) manufactured using chemical synthesis processes, such as HIV medicines, a national medicines regulatory authority (MRA) grants marketing approval to copy versions of the originator's medicines (commonly known as "generics") based largely on the safety and efficacy studies of the originator once the generic version is proven to be identical. For certain molecules, the MRAs may require that generic manufacturers provide small bioequivalence and bioavailability studies, but in any case the generic manufacturers do not need to have direct access to clinical studies and nor do they need to repeat safety and efficacy studies. As a result, generic entry takes less time and resources, leading to a sharp reduction in the price of generic medicines. The entry of generic versions can reduce the price by up to 90% compared with the originator's price.

In the case of biotherapeutics like monoclonal antibodies which involve more complex molecules and are produced through biological processes, there is an abbreviated regulatory pathway for the approval of the non-originator versions known as "biosimilars". Typically, the biosimilar approval pathway requires the biosimilar manufacturer to undertake a comparative Phase III clinical trial (against the originator biologic). This requirement has prevented significant price reductions (as seen in the case of SMD) as a major proportion of the biosimilar development cost is due to the need to purchase the originator product while the burden of proving similarity also increases the cost and duration of biosimilar development.

3 https://extranet.who.int/pqweb/vaccines/prequalified-vaccines

4 https://www.wto.org/english/news_e/spno_e/spno9_e.htm

5 http://infojustice.org/archives/43142

6 Big vaccine makers reject offers to help produce more jabs, https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/

However, this more complex procedure for biosimilars is in the process of changing with the UK Biosimilar Guideline and WHO's Draft Guidelines on Evaluation of Similar Biological Products. They propose making the requirement of a comparative Phase III trial an exception, required only when there is insufficient evidence of biosimilarity.[7]

Unlike with SMD and biosimilars, however, there is no abbreviated pathway for the approval of follow-on non-originator vaccines, although the need for such a pathway has been suggested in the scientific community.[8] Currently, to obtain marketing approval for vaccines, manufacturers would generally have to repeat most of the clinical studies of the originator, including Phase III efficacy trials, an exercise that involves significant resources and time.[9]

[Phase I and II trials are safety trials in a small number of people. Phase III trials are efficacy trials where the vaccines are given to thousands of people, to measure the efficacy. These trials are also large enough to reveal evidence of any side-effects.]

According to WHO, efficacy trials are not required in the following situation: "*Vaccine efficacy trials are not necessary if it is established that clinical immunological data can be used to predict protection against disease. For example, if there is an established ICP* [immune correlate of protection] *against a specific disease (for example, antitoxin levels against diphtheria and tetanus toxins, or antibody against hepatitis B surface antigen) the candidate vaccine should be shown to elicit satisfactory responses based on the relevant correlate(s).*"[10] Further, in certain circumstances, it may not be feasible to conduct efficacy trials due to various reasons, including the short outbreak of an epidemic.[11]

[An ICP is a type and amount of immunological response that correlates with vaccine-induced protection against an infectious disease and that is considered predictive of clinical efficacy. It is a measurable biomarker that can be used to interpret the immune responses to a specific antigenic component.]

However, efficacy data is required in the following circumstances, according to WHO:[12]

- "*There is no established ICP that could be used to predict the efficacy of the new candidate vaccine.*
- *There is no existing licensed vaccine with documented efficacy against a specific infectious disease to allow for bridging to a new candidate vaccine.*
- *Use of immune responses to bridge the documented efficacy of a licensed vaccine to a new candidate vaccine is not considered to be possible. For example, because there is no known relationship between specific immune response parameters and efficacy or because the new candidate vaccine does not elicit immune responses to the same antigen(s) as the licensed vaccine.*
- *There are sound scientific reasons to expect that the efficacy of a vaccine cannot be assumed to be similar between the population(s) included in the prior efficacy trial(s) and one or more other populations.*
- *It cannot be assumed that the vaccine efficacy demonstrated against disease due to specific strains of a pathogen (for example, serotypes or subtypes) would apply to other strains.*"

Often ICP development takes time. Further, MRAs may not permit the waiver of efficacy trials even after the satisfaction of the abovementioned conditions.

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7 https://cdn.who.int/media/docs/default-source/biologicals/ecbs/who-sbps_22-april-2021.pdf?sfvrsn=f283c924_5

8 https://pubmed.ncbi.nlm.nih.gov/19803764/ and https://www.centerforbiosimilars.com/view/biosimilarity-a-novel-approach-to-develop-therapies-and-vaccines-for-covid19

9 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3551877/

10 https://cdn.who.int/media/docs/default-source/prequal/vaccines/who-trs-1004-web-annex-9.pdf?sfvrsn=9c8f4704_2&download=true

11 Ibid.

12 Ibid.

Were a non-originator to follow the same manufacturing process of the originator and be able to demonstrate that its vaccine is able to meet the same safety and efficacy end points as the originator, the non-originator may be exempted from producing safety and efficacy trials, or may only be required to conduct abridged Phase III trials. However, critical information pertaining to the manufacturing process (including protein sequence identity, cell lines used for production, media conditions for those cell lines, isolation protocols, storage and delivery conditions, type and location of post-translational protein modifications, structure-function studies, lot-to-lot variation studies etc.[13]) is often protected as trade secrets. And generally, there is no mechanism like compulsory licensing existing in national laws to provide the trade secrets to competing manufacturers to meet public health needs including in the current pandemic.[14]

MRAs' role in protecting vaccine trade secrets

Generally speaking, there is no legal prohibition of discerning trade secrets through technological means. However, even with the legal freedom to operate and technological capabilities to emulate the originator's vaccines, the requirements of the regulatory authority disincentivize non-originator production.

An originator, when submitting a dossier to obtain regulatory approval for a vaccine, will usually include robust information regarding the vaccine such as its manufacturing process, its formulation and dosage, its method of delivery, its storage conditions, and its indicated uses along with safety and efficacy information.[15] The information submitted also generally includes a description of characterization of the drug substance, method of manufacture, specifications of drug substance etc. The description of the method of manufacture includes a detailed description of the animal sources (including fertilized avian eggs), virus sources, cellular sources, purification and downstream and synthetic drug substance. It also describes the quality control systems used throughout the manufacturing process to ensure consistent safety, efficacy, stability etc. Although the dossier contains crucial information that could allow non-originator manufacturers to replicate the product without the cooperation of the originator, the regulatory information is protected as a trade secret by the MRA. The regulatory institution has thus become the de facto enforcement agency for the originator's trade secret.

For instance, WHO's Emergency Use Listing (EUL) states: "*As WHO is responsible for the EUL assessment process, the ownership of the reports arising from or relating to the EUL assessment process lies with WHO. Thus, WHO shall be entitled to use and publish such reports, subject always, however, to the protection of any commercially sensitive confidential information of the manufacturer. Confidential information in this context means:*

- *confidential intellectual property, know-how, and trade secrets (including, e.g. formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks, patents, etc.); and*
- *commercial confidences (e.g. structures and development plans of a company).*"[16]

Stringent regulatory agencies like the US FDA and EMA also follow the same practice. Interestingly, however, the broader trade secret regimes in the US and the EU do recognize the need for trade secret disclosure in the public interest.

The EMA Guidance Document[17] on the identification of commercially confidential information (CCI) treats many aspects of quality and manufacturing of medicines including biologics contained in the marketing approval dossier as a trade secret.

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13 https://www.fda.gov/media/73614/download

14 https://solv.nl/en/blog/a-compulsory-licence-on-trade-secrets-in-times-of-corona-much-is-possible/ or https://academic.oup.com/jiplp/article/15/11/849/5998264?login=true

15 https://www.fda.gov/media/73614/download

16 https://cdn.who.int/media/docs/default-source/medicines/eulprocedure_a63b659c-1cdc-4cee-aa2d-ef5dd9d94f0b.pdf?sfvrsn=55fe3ab8_7&download=true

17 https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies/european-medicines-agency-guidance-document-identification-commercially-confidential-information_en.pdf

EMA's vaccine assessment reports including for COVID-19 vaccines include the following statement: "*Assessment report as adopted by the CHMP* [Committee for Medicinal Products for Human Use] *with all information of a commercially confidential nature deleted.*"[18]

EMA's policy on access to documents states that "*EMA will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information*".[19] At the same time, the same policy states that it has to balance between public and private interests: "*in case of a document containing information of commercial interest EMA has to strike the balance between the right of the requester to gain access to documents and the interest of industry to have commercial confidential information duly protected*".[20] The policy does not provide any concrete instances of when commercial confidential information should be disclosed in the public interest.

The broader EU Directive on Trade Secrets provides exceptions to trade secrets protection in Article 5, which states: "*Member States shall ensure that an application for the measures, procedures and remedies provided for in this Directive is dismissed where the alleged acquisition, use or disclosure of the trade secret was carried out in any of the following cases*:

(a) for exercising the right to freedom of expression and information as set out in the Charter [Charter of Fundamental Rights of the European Union]*, including respect for the freedom and pluralism of the media;*
(b) for revealing misconduct, wrongdoing or illegal activity provided that the respondent acted for the purpose of protecting the general public interest;
(c) disclosure by workers to their representatives as part of the legitimate exercise by those representatives of their functions in accordance with Union or national law, provided that such disclosure was necessary for that exercise;
(d) for the purpose of protecting a legitimate interest recognised by Union or national law."

The US FDA Emergency Use Authorization for COVID-19 vaccines states: "*The purpose of any closed session would be limited to the review and discussion of manufacturing information that is considered confidential commercial or trade secret information exempt from public disclosure.*"[21]

The US FDA also treats part of the information submitted by companies, including information related to the manufacturing process, as a trade secret. According to 21 CFR 20.61: "*A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.*"[22] Further, 21 CFR 601.51 explicitly excludes certain information on biologics from being disclosed: "*manufacturing methods or processes, including quality control procedures*" and "*quantitative or semiquantitative formulas*".[23]

However, 21 CFR 20.89 allows disclosure of trade secret information concerning manufacturing methods and processes to foreign MRAs albeit subject to confidentiality commitments,[24] including that: "*The foreign government agency has provided both a written statement establishing its authority to protect confidential*

18 https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf
19 https://www.ema.europa.eu/en/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf
20 Ibid.
21 https://www.fda.gov/media/142749/download
22 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.61
23 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=601.51
24 https://www.fda.gov/drugs/cder-international-program/international-agreements-information-sharing

commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status".[25] When deciding on such disclosure of information, the FDA Commissioner or the Commissioner's designee has to consider whether the: "*Disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation*".[26]

In the US, at the federal level, although the initial law dealing with trade secrets, i.e., the Uniform Trade Secrets Act (UTSA), is silent on the exceptions to trade secrets protection, the courts have recognized the public policy limitations.[27] However, subsequent legislations, i.e., the Economic Espionage Act (EEA) and the Defend Trade Secrets Act, permit disclosure of trade secrets in certain circumstances such as to report a suspected violation of law. Apart from reporting unlawful activity, the EEA also provides an exception for "any otherwise lawful activity conducted by a governmental entity of the United States, a State, or a political subdivision of a State".[28]

In many countries, especially common law countries, including the US, the scope of public policy exception is determined by the court taking into account facts and circumstances. In the US, courts have ordered the compulsory licensing of a trade secret even after a finding of misappropriation of the trade secret.[29] Similarly, the US Federal Trade Commission (FTC) ordered the compulsory disclosure of trade secrets in many cases including those relating to medical products.[30] Further, the Defence Production Act (DPA) provides enough powers to the US government to obtain the trade secrets on vaccines from the originator companies and then facilitate the scaling up of vaccine production in a foreign territory.[31] In the past, the US Biomedical Advanced Research and Development Authority (BARDA) has carried out trainings to facilitate influenza vaccine production in foreign countries.[32]

Despite occasional public interest exceptions, regulatory requirements for marketing approval provide asymmetric power to originators. This power asymmetry is further bolstered by MRAs' protection of information contained in the originator's marketing dossier as a trade secret. Reproducing the relevant trade-secret-protected know-how is a time-consuming process and can delay the utilization of additional production capacity in pandemic times. In the present circumstances, the proposed TRIPS waiver at the WTO will bring legal clarity about countries' right to develop broad and robust public health exceptions to trade secrets to facilitate biopharmaceutical manufacturing to satisfy unmet needs.

Trade secrets under Article 39 of the TRIPS Agreement

As mentioned above, trade secrets are protected under Article 39 of the WTO TRIPS Agreement, in Section 7 on "Protection of Undisclosed Information". Article 39.1 obligates WTO Members to protect undisclosed information in accordance with Article 39.2 and data submitted to the government in accordance with Article 39.3.

25 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.89
26 Ibid.
27 Peter S Menell et al., *Intellectual Property in the New Technological Age: 2016*, p. 128, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2780190
28 https://www.congress.gov/104/plaws/publ294/PLAW-104publ294.pdf
29 https://patentlyo.com/patent/2014/07/compulsory-license-misappropriation.html
30 https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals
31 https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/
32 Ibid.

Article 39.2 mandates WTO Members to provide a mechanism to natural or legal persons "to prevent information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices". "A manner contrary to honest commercial practices" is explained in a footnote as meaning "at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition." Further, as stated above, Article 39.2 sets out the three criteria for information to qualify as protected information (trade secret). Generally speaking, trade secrets laws in many countries lack clearly defined exceptions and limitations to protection and enforcement of trade secrets as in the case of copyright or patent laws.

Data protection under Article 39.3 of the TRIPS Agreement

Article 39.3 of the TRIPS Agreement states: "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products 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.*"

The protection to be granted under Article 39.3 is two-fold, against "unfair commercial use" and against "disclosure" of the relevant protected regulatory information.

This sub-paragraph of Article 39 has long been a subject of dispute between developed and developing countries. Developed countries interpret it as requiring data exclusivity whereby data submitted by originator companies for purposes of obtaining marketing approval for new pharmaceutical products cannot be relied upon for a specific duration of time for the approval of non-originator generic alternatives.

On the other hand, developing countries interpret Article 39.3 as not preventing MRAs from granting marketing approval to non-originator/generic versions of pharmaceutical products on the basis of the data submitted by the originator company. The divergence in interpretation was set to be tested in a WTO dispute between the US and Argentina but eventually in 2002 the dispute was mutually settled.

The main prevailing understanding of Article 39.3 is as interpreted by developing countries, whereby a regulatory agency would not be prevented from relying on the data presented by one company to assess submissions by other companies related to similar products, or from relying on the fact of regulatory approval of the first product to allow regulatory approval of a therapeutical equivalent. This avoids duplicative and ethically questionable clinical studies, while facilitating generic competition and thereby increasing affordability of medicines.

Nonetheless, developed countries have persistently and consistently advocated restrictive interpretations of Article 39.3 and hampered use of flexibilities, pressuring developing countries to restrict the approval of generic medicines on the basis of data submitted by the originator company.

For instance, the 2020 EU report on the protection and enforcement of intellectual property rights in third countries finds that "*[a]nother area of continued concern reported by right holders is the absence of an effective system for protecting undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products. [...] This problem affects the European industry mainly in Argentina, Brazil, China, India, Indonesia, Malaysia, the Russian Federation, the Kingdom of Saudi Arabia, Ukraine and the United Arab Emirates.*"[33]

[33] https://trade.ec.europa.eu/doclib/docs/2021/april/tradoc_159553.pdf

Similarly, the US Special 301 reports often cite reliance on originator data for generic approval as one of the reasons for keeping countries on the priority watch list. For instance, the 2020 Special 301 report states: "*USTR* [the Office of the US Trade Representative] *identifies India on the Priority Watch List for lack of sufficient measurable improvements to its IP framework on long-standing and new challenges that have negatively affected U.S. right holders.*" Among other "challenges", the report says that India "*still has not established an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceuticals and certain agricultural chemical products*".[34]

[The obligation under Article 39.3 is in the context of pharmaceutical products which "utilize new chemical entities" (typically intended to apply to small molecule drugs) and arguably may not be applicable to biologics including vaccines that do not "utilize new chemical entities". In practice though, regulatory authorities protect regulatory dossiers for biologics and vaccines as trade secrets.]

Under Article 39.3, there are two exceptions where disclosure by governmental authority is allowed: (i) when disclosure is necessary to protect the public; and (b) when steps are taken to ensure that the data will not be used in a commercially unfair manner.

There is little clarity on the parameters of these exceptions. For instance, would disclosure of confidential regulatory information of an originator vaccine company by a regulatory authority to another manufacturer to facilitate manufacturing of similar vaccines fall within the scope of either of the exceptions? The only real final authority on this legal question is the Appellate Body of the WTO. Meanwhile the legal uncertainty and decades of pressure from developed countries and Big Pharma can create a chilling effect on regulatory agencies and their effective use of the policy space to allow disclosure – hence the need for a waiver from TRIPS requirements of trade secrets protection in order to address the COVID-19 pandemic.

Conclusion

The current pandemic situation demands rapid diversification of manufacturing and scale-up of supply of vaccines. Under the current regulatory framework, the demand for safety and efficacy data, especially Phase III trial data, delays the entry of follow-on vaccines. In this context, lifting trade secrets protection and allowing the sharing of regulatory dossiers containing safety and efficacy data as well as information about the manufacturing process, especially with other regulatory agencies and potential manufacturers, can accelerate the production and approval of follow-on non-originator vaccines. Further, funding agencies which possess some of this information also can disclose it to potential manufacturers if a waiver is in place.

The sharing of regulatory information can also prevent regulatory delays. Experts have argued that "*Given the gravity of the current situation and limitations on travel, the need for such 'regulation through reliance' on the work products of trusted agencies to assure efficient, yet scientifically robust, assessments requires full reports be made available immediately either on demand or, better, on an agency website for ease of access by other regulators. The default position should be that companies concur with this process and will not raise 'confidentiality' or 'trade secret' arguments that result in time-consuming redactions and documents with inadequate information for the receiving agency*."[35]

The IP regime attempts to strike a balance between IP protection and public interest. Unfortunately, there is little articulation of flexibilities surrounding trade secrets protection in the context of protecting public health. This urgently necessitates the waiver of such protection in the context of COVID-19 medical products.

34 https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

35 https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.1932

Last but not least, the current situation is also a wake-up call to design and incorporate various public interest flexibilities, including public health safeguards, in the context of trade secrets protection. All forms of IP protection are subject to exceptions and limitations, and trade secrets protection and enforcement should not be an exception to this rule. Countries can and should explore avenues for creating exceptions to trade secret/confidential information protections that would require disclosure of such information and even sharing of cell lines sufficient to allow alternative producers to manufacture essentially identical products via essentially identical processes.

Feedback on this paper is welcome and can be sent to twn@twnetwork.org