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Compelling Trade Secret Sharing

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The unprecedented scale of the COVID-19 virus has brought to the forefront many questions associated with exclusive rights, information sharing, and innovation. How do we get effective vaccines, therapeutics, diagnostics, medical devices, and personal protective equipment (PPE) quickly, safely, and affordably to people around the world? More specifically, how do we ensure that effective products in sufficient quantities are researched and developed, approved by regulatory agencies, and produced for public distribution; that repairs of existing equipment can be performed as needed; that such health products are affordable; and that the needed products are equitably distributed globally and locally? Among many challenges on the road to these outcomes is the difficult question of how to handle information that is valuable, in part, because others do not know it. In other words, what do we do about trade secrets? Addressing this issue will continue to be critical to COVID-19 responses, as well as to responses to future pandemics and similar worldwide problems.

Because trade secrecy can apply to wide swaths of information, it can hide a shockingly broad range of critical and life-saving information from view. For this reason, assertions of trade secrets constitute much of the primary knowledge necessary for countries to combat and even potentially eradicate COVID-19. Indeed, trade secrets are everywhere in the battle to defeat COVID-19, including clinical trial data, pharmaceutical and medical equipment manufacturing processes, and regulatory compliance information.

Trade secrets raise three primary issues. First, if an entity is forced to share trade secrets to expedite development and to expand the supply of needed products, must or should the government compensate the rights holder? Although we address this

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question, we think it is largely unnecessary to answer it. This is because compensation is not *required* under international law (at least to address public health emergencies), because national law may sometimes already provide for compensation when compelling licensing (as well as when mandating sharing that eliminates secrecy), and because we think *reasonable* compensation *should* normally be provided for compelled trade secret sharing. Second, does international law prohibit governments from compelling the sharing of trade secrets, including by compulsory licensing? The short answer is no. Third, what authorities currently exist or could be adopted for governments to compel the sharing of trade secrets? We present below a general overview of a range of existing authorities, as well as a framework for addressing the latter two questions and for understanding the complexity of the first question.

Section 1 provides brief background on the nature of trade secrets, trade secret laws, and takings law. Within trade secrets, we distinguish between codified knowledge and recorded data on the one hand and uncodified "know-how," "show-how," and expertise on the other. All of these may qualify as trade secrets and may need to be shared to expedite or expand research and development (R&D) and manufacture of needed products such as pandemic vaccines, although it may be much more difficult both legally and practically to compel the sharing of uncodified knowledge.

Section 2 discusses COVID-19 and the experiences with trade secrets regarding vaccines. We use the COVID-19 vaccine example to explain why trade secret sharing is needed, why patent disclosures and compulsory licenses are inadequate to meet current needs, and what kinds of trade secrets may need to be shared from rights holders to other users, with or without rights holders' voluntary consent. We thus demonstrate the necessity of compelled trade secret sharing to address public health needs generally, as the voluntary sharing of trade secrets has proven inadequate to assure timely, affordable, and equitable global access to the medical products described above. The need for such trade secret sharing will only grow in the event of an even more serious, rapidly escalating future pandemic.

Section 3 explains why the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1] of the World Trade Organization (WTO)[2] does not prohibit governments from compelling trade secret rights holders to share trade secrets with others in the same or different jurisdictions, at least to address public health needs. Because such compelled sharing may take the form of compelled licensing where compensation is awarded, or because governments may themselves award compensation for the sharing, there should be no need for

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197.

[2] TRIPS is one of the international agreements adopted as part of the formation of the WTO. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144.

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additional compensation. Nevertheless, the TRIPS Agreement does not prohibit compelled sharing to address public health needs even when compensation is *not* provided.[3] And we do not believe any investor expropriation or unfair treatment claims for compensation against governments, under bilateral or regional investor–state dispute settlement (ISDS) treaties, would be successful (particularly if *some* compensation is already provided under national law for compelled trade secret sharing or licensing).

Section 4 surveys some of the existing authorities already possessed by federal and state governments in the United States and by the European Union to compel trade secret sharing, with or without compensation, or to compel trade secret licensing by trade secret rights holders. These authorities include the Defense Production Act (DPA),[4] antitrust authorities, federal health authorities, and state police powers (to the extent not preempted by federal law). The point of reciting these provisions is to demonstrate that compelling trade secret sharing is much less "exceptional" than opponents may claim, and that there is nothing, save for political opposition, standing in the way of assuring that trade secrets can be compulsorily shared or compulsorily licensed to ensure expanded R&D, clinical testing, and production to better protect global public health. We also discuss the possibility of legislative changes that would provide even more explicit authority, as well as the use of conditional funding approaches that would make the acceptance of government funds conditional on voluntary agreement to share trade secrets as needed.

We believe that global public health needs must be given greater importance in the debates on international policies concerning intellectual property (IP) rights and trade. These are ultimately political decisions, and legal authority already exists to make them. We explain the pathways for policymakers who choose to compel trade secret sharing, along with the theoretical foundations that underlie those pathways.

1 TRADE SECRET AND RELATED PROTECTION

In the COVID-19 context, trade secret law raises a critical policy question: Is information sharing needed to rapidly combat the spread of disease and to enable vaccine production? In the case of COVID-19 vaccines, potential trade secrets included manufacturing processes, test data, medical formulas, and other biological resources.[5] This is because vaccines and other biologic medicines, cell lines, genomic information, and other biological material can also be held as trade secrets. Similarly, data about the effectiveness of medicines and vaccines are trade secrets. Manufacturing processes – the "know-how" of producing vaccines – can be a

[3] TRIPS, *supra* note 1, art. 39.

[4] Defense Production Act of 1950, as amended, Pub. L. 81-774, 64 Stat. 798 (codified at 50 U.S.C. ch. 55).

[5] *See generally* David S. Levine, *COVID-19 Trade Secrets and Information Access: An Overview*, Info Justice (Jul. 10, 2020), https://infojustice.org/archives/42493 (last visited Dec. 14, 2023).

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paradigmatic trade secret,[6] or can fall into the amorphous quasi-trade secret categories of "know-how" or "show-how."[7] All of this information is essential to the rapid development of, and access to, safe and effective COVID-19 diagnostics, treatments, and vaccines worldwide.

Similarly, data for developing vaccines may be held as trade secrets.[8] Typically, clinical data are not required to be made public as a condition of regulatory marketing approvals, even if the government can use such data when evaluating requests for generic product approvals.[9] In many cases, such data and methods need not be disclosed to assure compliance with good manufacturing practices that permit product marketing.[10] Methods of assuring that the public can "make and use" patent disclosures and legal authorizations in the patent context, such as compulsory patent licenses, cannot assure private access when needed to scale up research, development, regulatory approvals, and manufacturing supplies.[11]

Methods for manufacturing may also be treated as trade secrets. Such methods often are colloquially known as "know-how," a subset of trade secrecy doctrine involving information that is valuable and difficult to transfer but that is not necessarily secret because it is generally known among industry players.[12] Such information may not always be protectable under trade secret law.[13] Nonetheless, because of its value in manufacturing processes and difficulty to acquire, know-how that does not achieve trade secret status operates similarly to trade secrecy as property that can be licensed.

In the case of COVID-19 research, product development, commercialization, and data and manufacturing processes are key trade secrets.[14] After all, if a company knows what works and what does not then it has a competitive advantage over others who lack that knowledge. When it possesses efficient means of production, the trade secret owner enjoys a significant competitive advantage. As has been evident regarding COVID-19 vaccine production from the beginning, such information

[6] *See* Allison Durkin et al., *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 Health Hum. Rts. 129, 133 (2021).

[7] *See generally* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023 (2016). *See also* W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 Science 912 (Aug. 21, 2020).

[8] *See* Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. Intell. Prop. L. & Pract., 1242, 1247 (2021).

[9] *See* Durkin et al., *supra* note 6, at 133.

[10] *See* Gurgula & Hull, *supra* note 8, at 1259.

[11] *See* Orit Fischman-Afori et al., A Global Pandemic Remedy to Vaccine Nationalism 21 (Apr. 20, 2021) (unpublished manuscript), https://ssrn.com/abstract=3829419 (last visited Dec. 14, 2023).

[12] *See* 3 Milgrim on Trade Secrets § 11.05 (2021).

[13] *See, e.g.*, Sharon Sandeen & David S. Levine, Information Law, Governance, and Cybersecurity 398 (2019).

[14] *See* Gurgula & Hull, *supra* note 8, at 1244.

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sharing is critical to worldwide supply needs, but has occurred only to a limited extent through voluntary licensing among a mostly restricted set of global pharmaceutical companies and manufacturers.[15] Global pharmaceutical companies have rejected requests from various generic pharmaceutical producers to license the trade secrets and know-how to scale up production.[16]

A *What Are Trade Secrets?*

Often labeled as "confidential information,"[17] or "proprietary information,"[18] trade secrets can encompass vast quantities of information needed to discover, test, create, and manufacture diagnostics, treatments, medicines, and vaccines. Chemical formulas, when they are kept secret and cannot be reverse engineered, are classic trade secrets. So are processes for manufacturing. Even "negative information" – information about what does not work – can be a trade secret.[19]

Trade secrets are often, but are not always, a prerequisite to product, process, and commercial service development and innovation, as well as to the advancement of knowledge and science.[20] Federal laws, primarily the federal Defend Trade Secrets Act (DTSA)[21] and state laws modeled after the Uniform Trade Secret Act (UTSA),[22] enable trade secret owners (such as pharmaceutical companies) to bring trade secret misappropriation actions against former employees and others, particularly competitors that gain unauthorized access to their claimed trade secrets. The federal Economic Espionage Act (EEA)[23] allows federal prosecutors to bring criminal actions under certain circumstances, especially those involving what is colloquially called computer "hacking." Other federal and state laws can be used to prevent public disclosure of information that has been previously disclosed to public authorities.[24] At the international level, the European Union's Trade Secrets Directive and

[15] *See infra* Section 2.

[16] *See, e.g.*, Ashleigh Furlong, *Big Vaccine Makers Reject Offers to Help Produce More Jabs*, Politico (May 14, 2021), www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/ (last visited Dec. 14, 2023).

[17] *See* WIPO, *Trade Secrets* (Feb. 22, 2022), www.wipo.int/tradesecrets/en/ (last visited Dec. 14, 2023).

[18] *See Proprietary Information*, Inc. (Feb. 22, 2022), www.inc.com/encyclopedia/proprietary-information.html (last visited Dec. 14, 2023).

[19] Levine, *supra* note 5.

[20] *Id.*

[21] Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376.

[22] Unif. Trade Secrets Act (Unif. L. Comm'n 1985).

[23] Economic Espionage Act, 18 U.S.C. §§ 1831–1839 (1996).

[24] *See* Sandeen & Levine, *supra* note 13, at 638–640; Freedom of Information Act, 5 U.S.C. §552 (b)(4) (2006); *State Freedom of Information Laws*, National Freedom of Information Coalition (Feb. 23, 2022), www.nfoic.org/state-freedom-of-information-laws/ (last visited Dec. 14, 2023).

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the WTO's TRIPS Agreement article 39 provide or require similar trade secrets protections.[25]

Unlike patents, regulatory entities do not grant or confirm trade secrets; rather, one has a trade secret by keeping valuable information secret.[26] Thus, there is no specified term for trade secrets; instead, they exist for as long as they remain secret. This can be a long or short period of time depending upon several factors. Importantly, trade secrets can be lost due to no fault of the trade secret owner or any act of misappropriation. This can happen, for instance, if the alleged trade secrets are independently discovered by another or reverse engineered and thereafter made generally known.

The use of trade secrets is either by the entity that owns it or, as is relevant here, by another person or entity under a license. Trade secrets are not meant to be shared unless the owner authorizes the sharing, and then (usually) under a requirement of secrecy imposed on the authorized party.[27] As a result, trade secrets rely heavily on licensing.[28]

There are three amorphous categories of informational concepts that are also at play and relate to trade secrets. The first (and easiest to understand) is "confidential information." Such information has been "roughly" defined as "data, technology, or know-how that is known by a substantial number of persons in a particular industry (such that its status as a technical 'trade secret' is in doubt) but that, nonetheless, retains some economic and/or competitive value by virtue of the fact that it is unknown to certain industry participants."[29] While this information is not technically a trade secret, its limited availability renders it valuable. Thus, we consider it here due to its need for distribution to combat COVID-19 (albeit without having to overcome trade secret law challenges).

Arguably the most amorphous informational concept is the "know-how" associated with vaccine manufacturing. "Know-how" is a highly controversial term in trade secret law generally because "there are so many types of proprietary information that have value in an industrial environment."[30] As Eckstrom explains:

> Know-how encompasses trade secrets and unpatented manufacturing processes as well as other industrial or commercial techniques outside the public domain … Intangibles, such as laboratory practice, sampling techniques, marketing schemes, and the availability of consultations with skilled technicians or professional advisors,

[25] TRIPS, *supra* note 1, arts. 39(1)&(2)

[26] Elizabeth A. Rowe & Sharon K. Sandeen, Trade Secret Law: Cases and Materials (3d ed. 2021).

[27] *Id.*, at 322–323.

[28] Danielle M. Conway-Jones, *Technology Transfer Agreements: Licensing of Trade Secrets and Works in Development*, SM049 ALI-ABA 103, 105 (2006).

[29] Robert Unikel, *Bridging the "Trade Secret" Gap: Protecting "Confidential Information" Not Rising to the Level of Trade Secrets*, 29 Loy. U. Chi. L.J. 841, 844 (Summer 1998).

[30] Melvin F. Jager, 3 Eckstrom's Licensing in Foreign and Domestic Operations: The Forms and Substance of Licensing § 6:2 (2021).

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acting for the licensor, also fall within the definition of valuable, and therefore licensable, know-how.[31]

For present purposes, we define "know-how" (sometimes referred to by others as "tacit knowledge"[32]) as valuable information that may not rise to the level of a trade secret, and therefore is not protected by trade secret law if it is used in a way unauthorized by its owner. Nonetheless, because it is valuable and not easily accessible, it requires some "nudging" or "compulsion" (absent a voluntary license) to be transferred.

Lastly, some information that might be a trade secret can be designated as "show-how." This distinction has little meaning in the world of trade secrecy generally (because information is either a trade secret or it isn't) but is important to delineate for purposes of this chapter because of its need for sharing in order to address COVID-19's (and similar future) challenges. Put simply, whereas "know-how can be committed fairly easily to paper or to some other recorded form, ... show-how can only be transmitted effectively by demonstration, e.g., by in-house training."[33] In the same way as know-how, "show-how" requires a similar "nudge" or "compulsion" to be shared.

In sum, trade secrets, confidential information, know-how, and show-how are all at play in the COVID-19 arena. Because the lines between these concepts are blurry, and to avoid confusion, we will often collectively refer to all of them as "trade secrets." Where necessary, we may draw lines between trade secrets and the other informational concepts due to their differing methodologies for sharing and differing degrees of legal protection.

B *Trade Secret Policies and Considerations*

Trade secrets operate within a field of competing values, ranging (among other things) from property to contract concerns.[34] Conceived primarily as a body of law designed to protect trade secret owners from unfair competition,[35] trade secret law and doctrine leaves little ground for broader principles tied to sharing of information among competitors for reasons of public health.[36] Indeed, without permission or a license, there are only very limited scenarios when trade secrets might be accessed without at least some misappropriation concerns. Nevertheless, it is important to

[31] *Id.*

[32] Fischman-Afori et al., *supra* note 11, at 13–14. *See generally* Douglas O'Reagan, *Know-How in Postwar Business and Law*, 58 TECH. & CULTURE 121 (2017).

[33] JAGER, *supra* note 30.

[34] *See* Robert G. Bone, *A New Look at Trade Secret Law: A Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 281 (1998).

[35] *See* David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135, 173 (2007).

[36] Levine, *supra* note 5.

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distinguish both the kinds of information and the kinds of disclosures that might "result in the loss of associated information rights."[37]

The mere designation of information as a "trade secret" can result in wide swaths of information being withheld from public inspection, regardless of whether the information qualifies as a trade secret.[38] Government regulators can also run into challenges getting access to trade secrets, especially absent clear statutory mandates for such access.[39] Even when regulators are granted access to information deemed a trade secret, there are normally limitations on disclosure of the same information to the public.[40] Thus, the designation of information as a "trade secret" is among the most powerful legal weapons against public access, and even regulatory access, to information.

Primarily, trade secrecy is a form of information access control. Trade secrets are part of the control mechanisms that form what Frank Pasquale calls the "black box society," which includes a range of tools from the attorney–client privilege to exemptions from the application of the Freedom of Information Act (FOIA).[41] Additionally, trade secrets are at the center of national security concerns for many nations, including nations that produce COVID-19 vaccines.[42] As a general matter, if you want to stop information moving from one holder to another (whether trade secrets or not), raising "national security" concerns is the best way to halt the transfer.

Governments should and increasingly must decide what values and concerns are paramount. As explained by one of the authors, as "difficult, time-consuming, and expensive as it may be, because information may not qualify as a trade secret upon closer inspection and because public needs may need to trump private, profit-maximizing interests, we should always question, interrogate, and weigh any designations of untrammeled trade secret protection over valuable information."[43]

2 TRADE SECRECY AND COVID-19

Should actual trade secrets be shared? To answer this question, it is important to understand how and when trade secrets ensure that the protected information best

[37] Sharon K. Sandeen, *A Typology of Disclosure*, 54 Akron L. Rev. 657, 662 (2021).

[38] *See* FOIA, *supra* note 24 (this exemption provides protection over trade secrets, but also, "commercial or financial information obtained from a person [that is] privileged or confidential").

[39] *See, e.g.*, Levine, *supra* note 5 ("legislatures have to pass laws mandating that source code about voting machines must be available to the state, and state boards of elections").

[40] DTSA, *supra* note 21.

[41] Frank Pasquale, The Black Box Society: The Secret Algorithms That Control Money and Information (2016).

[42] *See, e.g.*, Ellen Nakashima, *U.S. Officials Caution Companies about Risks of Working with Chinese Entities in AI and Biotech*, Wash. Post (Feb. 23, 2022), www.washingtonpost.com/national-security/us-officials-caution-companies-about-risks-of-working-with-chinese-entities-in-ai-and-biotech/2021/10/21/d8e8e300-32c1-11ec-9241-aad8e48f01ff_story.html (last visited Dec. 14, 2023).

[43] Levine, *supra* note 5.

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serves public uses, and how and when they do not. Here we focus on the vaccine manufacturing process.

In the COVID-19 context, certain possible trade secrets, like production processes, might serve society more thoroughly through wider public access to the information, allowing full technology transfer that would foster more rapid expansion of needed manufacturing capacity and also might reduce prices through greater competition and increased supplies. Other trade secrets, like those in the R&D phase, might be held as trade secrets to encourage market entrants to act quickly, although doing so may hinder follow-on competition.[44] Deciding when trade secrecy promotes or hinders such developments poses questions that historically have been answered by experts in vaccine manufacturing and industry structure, as the economics literature does not provide clear answers.[45] As they involve public choices about competing values, moreover, they invariably require political determinations.

Because trade secrecy spans the range of vaccine development, clinical practice, and regulatory approvals, production, and distribution, changes in how trade secrets are treated can have vast and rippling consequences. We do not address all these issues, much less the difficult issues involved in assuring better global public health systems and adequate supply and distribution chains.[46] Rather, we make the case that compelled knowledge sharing notwithstanding trade secret law is possible and desirable.

A *How Has the Lack of Sharing Impeded Production and Public Access to Vaccines?*

Trade secrets are causing bottlenecks throughout the effort to provide vaccines to the world.[47] Even with access to patents that cover vaccine IP, trade secrets still may block the best way for the patented inventions to be implemented. As explained by

[44] David S. Levine & Ted Sichelman, *Why Do Startups Use Trade Secrets*, 94 Notre Dame L. Rev. 751, 784 (2018), at 757.

[45] *See, e.g.*, Andrea Contigiani & David H. Hsu, *How Trade Secrets Hurt Innovation*, Harv. Bus. Rev. (Jan. 29, 2019); Bernhard Ganglmair & Imke Reimers, *Visibility of Technology and Cumulative Innovation: Evidence from Trade Secret Laws* (Aug. 17, 2019), ZEW Discussion Paper No. 19-035.

[46] *See, e.g.*, Michael Fleming et al., *Port to Patient: Improving Country Cold Chains for COVID-19 Vaccines*, McKinsey & Co. (Sep. 14, 2021), www.mckinsey.com/industries/public-and-social-sector/our-insights/port-to-patient-improving-country-cold-chains-for-covid-19-vaccines (last visited Dec. 14, 2023); US General Accounting Office, COVID-19 Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention, GAO-21-265 (Jan. 28, 2021), www.gao.gov/products/gao-21-265 (last visited Dec. 14, 2023).

[47] *See* Levine, *supra* note 5. *See also MSF Position on the Scope and Duration of the TRIPS Waiver for COVID-19*, MSF Access Campaign, https://msfaccess.org/msf-position-scope-and-duration-trips-waiver-covid-19 (last visited Apr. 27, 2022).

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several scholars who modeled an open trade secret pledge after the Open COVID Pledge for patents,[48]

> The [Open COVID] pledgers, however, have not committed to transfer those technologies [including materials, cell lines, prototypes, designs, plans, data, trial results, software, or anything else] to the implementers. They may not be willing to teach the implementers how the technology works, or how to make the product. . . . As a result, the implementers still need to develop or learn how to use these patented or patent pending technologies on their own.[49]

The authors go on to note that "unpatented know-hows, such as production methods or skills," face similar challenges.[50] These are all problems that derive from lack of access to trade secrets, and they prevent rapid manufacturing and distribution of COVID-19 vaccines.

Thus, trade secret sharing needs to be examined. To understand the parameters, we can look at product manufacturing as the primary area of concern. In a recent article, Olga Gurgula and John Hull explained the six-step "method required to make the mRNA vaccines currently supplied by Moderna and Pfizer-BioNTech."[51] The authors then explain that the various steps, methods, equipment, and experience of engineers in controlling the process "taken together constitute the kind of trade secret that, along with any patents protecting, say, the vaccine formula, create all-round protection for the product and the process by which it is produced."[52]

Based on Gurgula and Hull's description, there is a combination of traditional trade secrets ("equipment" and "method"), know-how ("steps required"), and show-how ("experience of the engineers controlling the process") that combine to make this method almost impossible to replicate without access to the foregoing information.[53] While others might make educated guesses at how these processes could work, or do the work to figure them out, neither approach is remotely optimal in the face of the dire demand for production outside of the few countries that have to date manufactured vaccines.[54] Thus, the need for sharing these collective trade secrets

[48] *About Us*, Open Covid Pledge, https://opencovidpledge.org/about/ (last visited Feb. 23, 2022). *See generally* Ginevra Assia Antonelli et al., *Exploring the Open COVID Pledge in the Fight against COVID-19: A Semantic Analysis of the Manifesto, the Pledgors and the Featured Patents*, 52 R&D Management 256 (2021).

[49] Richard Li-dar Wange et al., *A Concise Framework to Facilitate Open COVID Pledge of Non-Disclosed Technologies: In Terms of Non-Disclosed Patent Applications and Trade Secrets*, 121 J. Formosan Med. Ass'n 1, 3 (2021), https://doi.org/10.1016/j.jfma.2021.10.004 (last visited Dec. 14, 2023). *See Frequently Asked Questions*, Open Covid Pledge (last visited Feb. 23, 2022), https://opencovidpledge.org/faqs/ (last visited Dec. 14, 2023).

[50] *Id.*, at 4.

[51] Gurgula & Hull, *supra* note 8, at 1248.

[52] *Id.*, at 1249.

[53] *Id.*, at 1248. *See also, e.g.*, W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. Rev. 491, 533 (2014).

[54] World Health Organization, WHO Director-General's Opening Remarks at the Media Briefing on COVID (Feb. 23, 2022), www.who.int/director-general/speeches/detail/who-dir

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seems obvious, if the world is more effectively to address global shortages on a timely basis.

But manufacturing know-how is not the only concern. Bottlenecks also arise when production process trade secrets are combined with many other trade secrets at issue in COVID-19 vaccine creation, regulation, and distribution. These other trade secrets range from "test data, specific (unpatented) medical formulae, cell lines, genomic information and other biological materials," to "results collected from clinical trials."[55] It is no wonder that trade secrets "about the highly complex process of producing vaccines and other biologics can create natural exclusivities that are daunting to overcome."[56] Those "natural exclusivities" are arguably not natural but caused by specific policy choices.

Despite the foregoing, trade secrets have not received nearly as much attention as patents in the COVID-19 policy debates. Still, there has been some movement on the COVID-19 vaccine trade secret front. Perhaps the most noteworthy has been Afrigen Biologics' development of the mRNA COVID-19 vaccine using Moderna's publicly available sequence.[57] This occurred after the World Health Organization (WHO) called for the creation of COVID-19 vaccine "technology transfer hubs,"[58] and after the WHO's later support of a South African consortium to establish the first COVID-19 mRNA vaccine technology transfer hub.[59] The significance of this development, however, is the noted *lack* of trade secret sharing (including from Pfizer and Moderna), and the resulting delays that have yet to be fully overcome.[60]

The decision not to collaborate, of course, was based on preserving trade secrets. While Moderna did declare it would not enforce any of its COVID-19 vaccine

ector-general-s-opening-remarks-at-the-media-briefing-on-covid-19-23-february-2022 (last visited Dec. 14, 2023).

[55] Gurgula & Hull, *supra* note 8, at 1247.

[56] Fischman-Afori et al., *supra* note 11, at 13.

[57] Wendell Roelf, *In World First, South Africa's Afrigen Makes mRNA COVID Vaccine Using Moderna Data*, Reuters (Feb. 4, 2022, 12:58 AM), www.reuters.com/world/africa/world-first-safricas-afrigen-makes-mrna-covid-vaccine-using-moderna-data-2022-02-03/ (last visited Dec. 14, 2023).

[58] World Health Organization, *Call for Expression of Interest to: Contribute to the Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub* (Apr. 16, 2021), www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub (last visited Dec. 14, 2023). The WHO defined a technology transfer hub as "training facilities where the technology is established at industrial scale and clinical development performed." *Id.*

[59] World Health Organization, *WHO Supporting South African Consortium to Establish First COVID mRNA Vaccine Technology Transfer Hub* (Jun. 21, 2021), www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub (last visited Dec. 14, 2023).

[60] *See id.*; Wendell Roelf, *WHO-Backed Vaccine Hub for Africa to Copy Moderna COVID-19 Shot*, Reuters (Sep. 15, 2021), www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14/ (last visited Dec. 14, 2023).

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patents during the pandemic,[61] that didn't address the problem of information sharing needed for production. As explained by Reuters in October 2021, "it is hard to replicate a vaccine without the information on how it is made, and the World Health Organization-backed tech transfer hub in South Africa – set up in June [2021] to give poorer nations the know-how to produce COVID-19 vaccines – has so far not reached a deal with the company."[62]

Nonetheless, in November 2021, Afrigen began developing the first complete lab sample from Moderna's publicly available genetic sequence for the vaccine.[63] The patent, unsurprisingly, failed to disclose the trade secrets necessary for production. Petro Terblanche, managing director of Afrigen, noted that the patent is "written very carefully and cleverly to not disclose absolutely everything."[64] While most of the equipment and specialized ingredients have been disclosed, they "don't know some of the mixing times – some of the conditions of mixing and formulating," including how to replicate Moderna's essential "lipid nano-particle" technology, the carrier for the mRNA strand at the heart of the vaccine[65] (regarding which Moderna itself is accused of infringing Arbutus' and Genevant's patents).[66]

On February 3, 2022, Afrigen announced that it had made its own version of the mRNA COVID-19 vaccine using Moderna's publicly available sequence.[67] Again noting the roadblocks from failure to share trade secrets, Terblanche explained, "We haven't copied Moderna, we've developed our own processes because Moderna didn't give us any technology. We started with the Moderna sequence because that gives, in our view, the best starting material. But this is not Moderna's vaccine, it is the Afrigen mRNA hub vaccine."[68] Interestingly, Afrigen had help from unknown "outside advisers" in developing the vaccine.[69] And because it is an Afrigen vaccine, it needs to undergo separate clinical trials and regulatory approvals.

The Afrigen consortium hoped to be able to test the shot on humans before the end of 2022.[70] Meanwhile, Moderna announced it would work to build its own

[61] *Moderna Will Not Enforce COVID-19 Vaccine Patents during Pandemic*, Reuters (Oct. 8, 2021), www.reuters.com/article/health-coronavirus-moderna/moderna-will-not-enforce-covid-19-vaccine-patents-during-pandemic-idUSL4N2GZ2D6 (last visited Dec. 14, 2023).

[62] *Id.*

[63] *Id.*

[64] Nurith Aizenman, *Moderna Won't Share Its Vaccine Recipe. WHO Has Hired an African Startup to Crack It*, NPR (Oct. 19, 2021), www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun (last visited Dec. 14, 2023).

[65] *Id.*

[66] *See, e.g.*, Amruta Khandekar, *Arbutus Files Patent Infringement Lawsuit against Moderna Related to COVID Shot*, Reuters (Feb. 28, 2022).

[67] Roelf, *supra* note 57.

[68] *Id.*

[69] Lesley Wroughton, *Frustrated by Vaccine Inequity, a South African Lab Rushes to Replicate Moderna's Shot*, Wash. Post (Nov. 28, 2021), www.washingtonpost.com/world/2021/11/28/afrigen-south-africa-vaccine-moderna/ (last visited Dec. 14, 2023).

[70] Roelf, *supra* note 57.

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manufacturing and distribution facilities in Africa for its vaccines.[71] One can only speculate how much faster vaccines might have been distributed in Africa, which in early 2022 had an 11 percent vaccination rate,[72] and at what cost, had the critical manufacturing trade secrets been shared in 2020 or 2021. Duplication of effort is inefficient for global health, generates a massive waste of resources, and in the case of a pandemic results in otherwise avoidable losses of life.

B *Inadequacy of Patent Disclosures to Assure R&D, Testing, and Production at Scale*

The basic quid pro quo of granting patent rights is to place the public in possession of the patented invention by disclosure and publication of the specification of the invention in the patent application.[73] The US patent statute itself requires a specification that describes the invention and the "manner and process of making it . . . to enable any person skilled in the art . . . to make and use" it.[74] Under the current case law interpreting this statutory language, the patent specification does not need to actually describe *all aspects* of how to make or use the invention.

Nor does the specification have to describe all (or even any, as there may have been none identified at the time of filing[75]) preferred claim embodiments or methods ("best modes"[76]) for making or using any embodiments. Rather, the disclosure is adequate so long as a skilled practitioner in the relevant technological field can make and use *some* unspecified range of embodiments within any given claim without "[un]reasonable" or "undue" experimentation.[77] Accordingly, patent disclosures typically are not required to disclose any trade secrets beyond the basic nature of the invention sufficient to meet the patent law "enablement" requirement.

In other words, notwithstanding that the public is supposed to receive the benefit of the bargain of being placed in "possession" of the invention, and that inventors are normally described as having to choose between patent rights and trade secrecy, inventors now may routinely seek to protect their innovations through simultaneous use of both patents and trade secrets. For this reason, compulsory licensing of only patent rights may not be sufficient to assure competitive R&D, testing, regulatory approval, and manufacturing at scale. Sharing trade secret knowledge may also be

[71] Wroughton, *supra* note 69.

[72] United Nations, *Africa Needs to Ramp Up COVID-19 Vaccination Rate Six-Fold* (Feb. 3, 2022), https://news.un.org/en/story/2022/02/1111202 (last visited Dec. 14, 2023).

[73] *See, e.g.*, Eldred v. Ashcroft, 536 U.S. 186, 216 (2003) (invention disclosure is "the price paid for the exclusivity secured"). *See generally* Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred*, 19 Berkeley Tech. L.J. 1315 (2004).

[74] 35 U.S.C. § 112(a).

[75] *See, e.g.*, N. Telecom Ltd. V. Samsung Elec. Co., 215 F.3d 1281, 1286 (Fed. Cir. 2000).

[76] 35 U.S.C. § 112(a).

[77] *See* Amgen, Inc. v. Sanofi, 598 U.S. 594 (2023); In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

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necessary, and where patent holders also possess relevant trade secret rights, the compelled sharing of those trade secrets may be needed as well.

3 COMPELLING TRADE SECRET SHARING COMPLIES WITH INTERNATIONAL TREATY LAW

Any government-compelled actions may make a trade secret public (and thus destroy its secrecy) or may only assure competitors' abilities to use the trade secret (as by compelled licensing that also requires secrecy relative to the public).[78] Either the loss of the trade secret through publicity or the government-authorized third-party use of the secret may be compensated. This should (in most cases) avoid concerns about uncompensated regulatory expropriation of the value of the trade secret. And even if international law does not prohibit – or even if it explicitly authorizes – compelled trade secret sharing, national laws may need to be amended or existing national legal authorities may need to be exercised, such as by issuing orders compelling the sharing.

The WTO's TRIPS Agreement is the principal international treaty governing IP. The TRIPS Agreement incorporates relevant provisions of the Paris Convention for the Protection of Industrial Property.[79] But the TRIPS Agreement does not expressly or impliedly prohibit governments from compelling trade secret sharing, unlike its provision expressly prohibiting compulsory licensing of trademarks.[80] Further, as a matter of interpretation, the obligations for trade secrets ("undisclosed information") apply only to protection against "unfair competition," defined as "disclos[ur]e . . . or use" "contrary to honest commercial practices";[81] for "undisclosed test or other data," the provision applies only to protection against "unfair commercial use."[82] Although the nature of the prohibited acts has not been officially interpreted in any dispute resolution proceeding in the WTO,[83] it is unlikely that the TRIPS Agreement prohibits *governmental* decisions to compel sharing of such information for public need or public benefit, as the recited prohibitions are focused on *commercial* morality.

Even if the TRIPS Agreement did impliedly prohibit compelled licensing or other compelled sharing of trade secrets, the TRIPS Agreement's national security exception[84] may authorize national governments to compel trade secret sharing in a

[78] *See, e.g.*, Sandeen, *supra* note 37, at 662.
[79] TRIPS, *supra* note 1, art. 2(1).
[80] *Id.*, art. 21.
[81] *Id.*, arts. 39(1)&(2). *See* Paris Convention, art. 10bis(1)); *id.* art. 10bis(2); art. 10ter(1).
[82] TRIPS, *supra* note 1, art. 39(3).
[83] *See, e.g.*, Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 549 & n.768 (5th ed. 2021).
[84] TRIPS, *supra* note 1, art. 73(b)(iii).

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pandemic.[85] Specifically, article 73 provides that "nothing in this Agreement shall be construed: . . . (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests . . . (iii) taken in time of war or other emergency in international relations."[86] In short, the TRIPS agreement cannot and does not prohibit member countries from compelling trade secret sharing to address public health needs.[87] Nor would any ISDS treaties authorize any injunctive relief to prevent trade secret sharing from being compelled.

A *The TRIPS Agreement Does Not Prohibit Compelled Trade Secret Sharing*

As shown below, the plain text of the TRIPS Agreement, traditional interpretive principles, legislative history, and the national security exception all support an interpretation of the TRIPS Agreement to retain within national discretion the authority to compel trade secret sharing. The contrary view is likely the result of misplaced (and particularly American) concerns that governments should not compel the actions of individuals or of corporations and should not intrude on markets to establish industrial policy. As the COVID-19 example has shown (particularly regarding the Defense Production Act),[88] however, governments (including the US government) engage in industrial policy all the time, particularly in the context of pandemic responses.

Textual Interpretation of TRIPS Supports the View That It Does Not Prohibit Governments from Compelling Trade Secret Sharing

The TRIPS Agreement imposes on countries obligations to adopt minimum requirements for protection of various forms of intellectual creations or intangible products or associations with them. These include the obligations to protect trade secrets against "unfair competition"[89] and for undisclosed test or other data noted above against "unfair commercial use."[90] Unlike with trademarks,[91] however, the TRIPS Agreement does not prohibit compulsory licensing (much less compelled sharing) of trade secrets or undisclosed data. And unlike for patents,[92] the TRIPS Agreement does not regulate compulsory licensing of trade secrets.

[85] *See, e.g.*, Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. Int'l Econ. L. 1, 13, 26 (2020).
[86] TRIPS, *supra* note 1, art. 73(b)(iii).
[87] WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments–Results of the Uruguay Round, 33 I.L.M. 1125 (1994).
[88] *See infra* Section 4.A.
[89] TRIPS, *supra* note 1, arts. 39(1)&(2). *See* Paris Convention, art. 10bis(1); *id.*, art. 10bis(2); art. 10ter(1).
[90] TRIPS, *supra* note 1, art. 39(3).
[91] *Id.*, art. 21.
[92] *Id.*, art. 31.

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Generally, interpretation under the TRIPS Agreement applies the interpretive principles of the Vienna Convention on the Law of Treaties (VCLT), particularly articles 31 and 32.[93] The Vienna Convention requires understanding the text of the TRIPS Agreement in good faith and in light of its language, structure, and context. If interpretation remains ambiguous, negotiating history may also be consulted.

Significantly, for trade secrets in general ("undisclosed information"), the TRIPS Agreement requires *only* that they be protected against disclosure, acquisition, or use by third parties "in a manner contrary to honest commercial practices."[94] The latter phrase is explained in a footnote to "mean 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."[95] Therefore, the focus is not only on commercial actions (and thus commercial actors), but also third parties who know or should know that their actions are *improper*.

Importantly, nothing suggests *any* application to governmental action, much less any limitation on governmental ability to provide such disclosures for use by third parties. Nor does it imply that action by a government, when authorized by law to *provide or compel sharing of* such information would be either a "commercial" activity or one "contrary to honest commercial practices." This "plain" textual meaning of article 39's prohibition requirements is supported by inferences derived by the structure of the text and the context of usage within the TRIPS Agreement.

Canons of Construction and General Principles against Legislating Unexpressed Treaty Provisions by Interpretation Support the View That the TRIPS Agreement Does Not Preclude Compelled Trade Secret Sharing

Starting with the text of the TRIPS Agreement, two standard structural interpretive principles apply here. The first is the *expressio unius est exclusio alterius* canon of construction,[96] where a text having expressed something implies the exclusion of

[93] Vienna Convention on the Law of Treaties, arts. 31 & 32, May 23, 1969, 1155 U.N.T.S. 331; Dispute Settlement Understanding, *supra* note 87, art. 3.2. *See, e.g.*, WTO, Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline* (WT/DS2/AB/R) (Apr. 29, 1996), at 17. *See generally* Bryan Mercurio & Mitali Tyagi, Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements, 19 Minn. J. Int'l L. 262, 299 (2010); Susy Frankel, *WTO Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 Va. J. Int'l L. 365, 384-90 (2005); Daya Shanker, *The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the DOHA Declaration on the TRIPS Agreement*, 36 J. World Trade 721 (2002).

[94] TRIPS, *supra* note 1, arts. 39(1)&(2).

[95] *Id.*, art. 39.2 n. 10 (emphasis added).

[96] *See generally, e.g.*, Richard Gardiner, *Book Reviews*, 30 Eur. J. Int'l L. 1077 (2019); Sean D. Murphy, *The Utility and Limits of Canons of Construction in Public International Law*, in Between. The Lines 4 (online version) (Joseph Klingler, Yuri Parkhomenko & Constantinos Salonidis eds., 2018) https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=2591&context=faculty_publications (last visited Dec. 14, 2023).

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something not mentioned – and conversely where the failure to express something implies its exclusion where something similar is mentioned elsewhere. By expressly adopting a prohibition on compulsory licensing of trademarks,[97] the drafters of the TRIPS Agreement should be understood to have intentionally imposed *no* similar *prohibition* on compulsory licensing or compulsory sharing of trade secrets. The second relevant structural canon of construction is the rule of interpreting language to avoid redundancy or surplusage. If silence on compulsory licensing or sharing alone were interpreted to preclude such actions (for trade secrets), then the corresponding express prohibition against compulsory trademark licensing would be unnecessary surplusage. Further, courts and arbitral bodies applying the Vienna Convention are reluctant to impose terms or conditions that treaty language does not itself supply. This is because treaties by their very nature are limitations on the otherwise unfettered sovereignty of nations. Thus, such "derogations" from the natural state of international relations are to be construed narrowly. And the drafting history, to the extent the textual interpretation were unclear, similarly does not support a prohibition on compulsory trade secret sharing. The failure to reach agreement on, or to even discuss, compulsory trade secret sharing or licensing invokes the principle of the Vienna Convention and the WTO's interpretive framework that matters not resolved by treaty text are left to country discretion.[98]

The National Security Exception and Implied Authority to Adopt Regulatory Exceptions

Even assuming that the TRIPS Agreement were to prohibit compelled trade secret sharing or licensing under article 39, article 73's national security exception may provide adequate authority to adopt domestic measures as "exceptions or limitations" to article 39's requirement. Specifically, article 73 provides that "nothing in this Agreement shall be construed: … (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests … (iii) taken in time of war or other emergency in international relations."[99] Significantly, the article by its own terms focuses on a member's self-determined perception of "necessity," which may largely preclude contrary judgments by the WTO's Dispute Settlement Understanding.[100]

Particularly in light of the express "protect the public" language of article 39.3,[101] it is highly unlikely that the WHO would find members that compelled trade secret

[97] *See* TRIPS, *supra* note 1, arts. 21 and 31.

[98] *See generally*, *e.g.*, Sean D. Murphy, *The Utility and Limits of Canons of Construction in Public International Law*, in Between. The Lines 4 (online version) (Joseph Klingler, Yuri Parkhomenko & Constantinos Salonidis eds., 2018), at 4. Levine & Sarnoff, supra note *, 74 Hastings L.J. at 1022–1024 (citing sources).

[99] TRIPS, *supra* note 1, art. 73(b)(iii).

[100] *See* Abbott & Reichman, *supra* note 85, at 13 n. 58 (citing WTO, Report of the Panel, Russia – Measures Concerning Traffic in Transit, WT/DS512/R, Apr. 5, 2019, at, ¶¶ 7.51–7.52, 7.102–107.103 & 7.131–7.139).

[101] TRIPS, *supra* note 1, art. 39.3.

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sharing to address public health needs to be in violation of their TRIPS obligations, particularly in light of the TRIPS Agreement's objectives and principles,[102] and with regard to the regulatory authority of states to protect public health.[103] And, again invoking the *expressio unius* canon, the TRIPS Agreement provides no provision restricting trade secret exceptions and limitations to article 39 obligations. Similarly, article 8.2 provides that "[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of IP rights by right holders or the resort to practices which unreasonably restrain trade *or adversely affect the international transfer of technology*."[104] Article 66.2, moreover, *obligates* developed-country members to provide incentives to private entities to foster technology transfer to least-developed country members.[105]

Finally, it is important to remember human rights obligations when interpreting treaty requirements, which may form *jus cogens* or create other obligations in addition to topical treaty rights and obligations.[106] Article 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) "recognize[s] the right of everyone … [t]o enjoy the benefits of scientific progress and its applications."[107] Access to needed medical products to protect against or to treat pandemic disease and potential death should clearly fall within the scope of that right (as may corresponding research and manufacturing),[108] as well as the article 12(1) "right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[109]

B *The Proposal for a TRIPS "Waiver" and the Adopted Ministerial Decision*

The TRIPS Waiver Proposal

Within about six months after the COVID-19 pandemic became widespread, the governments of India and South Africa introduced at the WTO a proposal to waive the regulatory requirements and enforcement obligations of the TRIPS

[102] *Id.*, arts. 7 & 8. *See, e.g.*, Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979, 997 (2009).

[103] WTO, Appellate Body Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/AB/R & WT/DS441/AB/R, ¶ 6.642 (Jun. 9, 2020). *See generally* Thamara Romero, *Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective*, South Centre Research Paper 108 (Apr. 2020).

[104] TRIPS, *supra* note 1, art. 8.2 (emphasis added).

[105] *id.*, art. 66.2 (emphasis added).

[106] Destaw A. Yigzaw, *Hierarchy of Norms: The Case for the Primacy of Human Rights over WTO Law*, 38 Suffolk Transnat'l L. Rev. 33, 64 (2015).

[107] International Covenant on Economic, Social & Cultural Right, G.A. Res. 2200A (XXI), U.N. Doc. A/RES/21/2200, art. 15(1)(b) (Dec. 16, 1966).

[108] *See also id.*, art. 15(1)© General Comment 17.

[109] *Id.*, art.12(1). *See* ECOSOC, General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights (art. 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights) ¶ 8 (Apr. 30, 2020).

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Agreement.[110] The subsequently introduced version of the waiver proposal clarified the application of the waiver, limited it to "health products and technologies," and provided for a minimum three-year duration, followed by annual evaluations and termination at a date determined by the General Council after deciding that the "exceptional circumstances" justifying the waiver have ceased to exist.[111] The waiver proposal, which has not been adopted, would have applied to *all* of the regulatory requirements in Part II of TRIPS, including copyrights, industrial designs, patents, and undisclosed information (which includes article 39's trade secret and regulatory approval data provisions) but not to trademarks, as well as applying to any enforcement obligations relating thereto in Part III.[112]

The TRIPS Ministerial Decision

On June 17, 2022, the TRIPS Council adopted a Ministerial Decision on the TRIPS Agreement.[113] In contrast to the waiver proposal, the Decision did not generally waive substantive provisions of the TRIPS Agreement during the COVID-19 pandemic. Rather, it expanded for five years various flexibilities regarding the existing article 31 and article 31*bis patent* compulsory licensing provisions, and only in regard to COVID-19 vaccine production. In particular, the Decision authorized such compulsory licensing of COVID-19 vaccine-related patents by administrative or judicial orders (which could include "emergency orders") even without compulsory licensing legislation in place.[114]

The Decision permits restricting the requirement to predominantly supply domestic markets and makes clear that required remuneration for compulsory patent licenses can be based on emergency conditions to assure access and not on "'ordinary' market principles."[115] But the Decision also adds a requirement to undertake "all reasonable efforts to prevent the re-exportation of products manufactured under the authorization," that is, to prevent diversion and price arbitrage.[116] Although the Ministerial Decision is limited to patent rights, it does reflect an international consensus that such patent rights should not pose restrictions to compulsory licensing for manufacturing for export of vaccines needed to address the COVID-19 pandemic.

[110] Communication from India & South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/669 (submitted Oct. 2, 2020) (requesting waiver of certain TRIPS sections to encourage the sharing of pandemic-related trade secrets), as amended by Communication from the Africa Group et al., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/669 Rev.1 (submitted May 25, 2021).

[111] *Id.*, ¶¶ 4, 5, Annex ¶ 2.

[112] *Id.*, Annex, ¶ 1.

[113] *See* WTO, Doha Ministerial 2001 Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

[114] *Id.*, ¶ 2.

[115] *Id.*, ¶ 3(d).

[116] *Id.*

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Compensation Considerations

The waiver proposal would have waived any need for compensation by eliminating any obligation to protect trade secrets. Nevertheless, we think it is advisable to provide *reasonable* compensation (but not lost profits based on monopoly prices, or unreasonably high royalties) to trade secret rights holders for the use of their IP when expanding capacity and assuring affordable access.

C *ISDS and Compensation Obligations*

Compelling trade secret sharing may not necessarily result in any loss of trade secret status and may sometimes require compensation under domestic law (particularly if it occurs in the form of compulsory licensing with secrecy obligations). Where compensation is already provided under domestic legal systems, there should generally be no grounds for a trade secret owner to complain about an uncompensated or unfair "taking" of their property. Nevertheless, many ISDS treaties permit filing of claims without "exhausting" domestic law remedies.[117] But even without such compensation, such as when exercising public interest exceptions to trade secrecy rights, so long as the exceptions *predated* the investments no "taking" would occur and no compensation would be required.[118]

New legislation to provide more explicit authority to compel trade secret sharing that is adopted after such investments *may* be more likely to result in successful ISDS claims. This assumes that similar authority did not previously exist, that adequate compensation was not awarded, and the investment was made prior to enactment of the relevant legislation. But even then, ISDS treaties implicitly recognize the right to regulate to protect public health, even if adopted by new legislation.[119] It is important to note that nothing in ISDS treaties would provide grounds to *prevent* the adoption or exercise of domestic authorities to compel trade secret sharing.[120]

4 NATIONAL ROUTES FOR EXPANDING ACCESS TO TRADE SECRETS

Compelling trade secret sharing or requiring compulsory licensing of trade secrets *is not in any way unusual or exceptional*. Even if it is not a "commonplace" occurrence, the authority exists to be employed whenever it is appropriate to do so. Such authority has been used routinely in the past without any concern for destroying the

[117] *See, e.g.*, Prabhash Ranjan, *Compulsory Licenses and ISDS in Covid-19 Times: Relevance of the New Indian Investment Treaty Practice*, 16 J. INTELL. L. & PRAC. 748, 750 (2021).

[118] Henning Grosse Ruse-Khan & Federica Paddeu, *A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights under International IP and Investment* Agreements (S. Centre, Research Paper No. 144, 2022), at 21.

[119] *See* Grosse Ruse-Khan & Paddeu, *supra* note 118, at 25, 28 (citations omitted).

[120] *Primer on International Investment Treaties and Investor–State Dispute Settlement*, Columbia Center on Sustainable Investment (updated Jan. 2022), https://ccsi.columbia.edu/content/primer-international-investment-treaties-and-investor-state-dispute-settlement (last visited Dec. 14, 2023).

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trade secret status or for the adequacy of compensation to the rights holder. It is only where legislation specifically and expressly prohibits agencies from exercising authority to publicize trade secrets that the authority to share (much less to publicize, and thus render no longer secret) a trade secret may be lacking.[121]

A *Existing Mechanisms under US and EU law*

Numerous mechanisms exist under US and European laws to compel trade secret sharing, and which have been used during the COVID-19 pandemic or could be used to address COVID-19 and other health emergencies. These include: (1) the US Defense Production Act (DPA),[122] which was invoked "to equip two Merck facilities to the standards necessary to safely manufacture the J&J vaccine" and "to expedite critical materials in vaccine production, such as equipment, machinery, and supplies";[123] (2) antitrust (competition law) authorities; (3) public health powers; and (4) state law authorities. This list is not exclusive, as other powers (including more general emergency powers[124]) may also provide such authority.

Defense Production Act

From the beginning of the COVID-19 pandemic, discussions focused on the question of whether there were specific policy levers that could be used to ramp up production of COVID-19-related medical products to address health needs ranging from masks to medical devices to vaccines.[125] Given the analogy of the fight against COVID-19 to "war,"[126] it should be no surprise that people looked to "war powers" to see if there were ways to spur or force rapid production.[127]

Attention quickly turned to the Defense Production Act.[128] Under the DPA, the President can prepare for and respond to "natural or man-caused disasters" by

[121] *See generally* Christopher Morten, *Publicizing Corporate Secrets*, 171 U. Pa. L. Rev. 1319 (2023), at [29–71], https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4041556 (last visited Dec. 14, 2023).

[122] *See supra* note 4.

[123] Sydney Lupkin, *Defense Production Act Speeds Up Vaccine Production*, NPR (Mar. 13, 2021), www.npr.org/sections/health-shots/2021/03/13/976531488/defense-production-act-speeds-up-vaccine-production (quoting President Joe Biden) (last visited Dec. 14, 2023).

[124] *See generally* Brennan Center for Justice, New York University, *A Guide to Emergency Powers and Their Use* (rev. Sep. 4, 2019).

[125] *See, e.g.*, Dalindyebo Shabalala, *US Support for Waiving COVID-19 Vaccine Patent Rights Puts Pressure on Drugmakers – but What Would a Waiver Actually Look Like?*, The Conversation (May 10, 2021), https://theconversation.com/us-support-for-waiving-covid-19-vaccine-patent-rights-puts-pressure-on-drugmakers-but-what-would-a-waiver-actually-look-like-160582 (last visited Dec. 14, 2023).

[126] *Is Fighting a Pandemic Like Fighting a War?*, BBC News (Mar. 14, 2021), www.bbc.com/news/world-us-canada-56324047 (last visited Dec. 14, 2023).

[127] *See, e.g.*, E&C Republicans, *President Trump Invokes Defense Production Act to Support Covid-19 Response* (Aug. 24, 2020), https://republicans-energycommerce.house.gov/news/blog/president-trump-invokes-defense-production-act-to-support-covid-19-response/ (last visited Dec. 14, 2023).

[128] 50 U.S.C. Ch. 55.

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expanding domestic production as needed (by prioritizing private contracts and by requiring the performance of government contracts by private industry).[129] As Congress found, "the security of the United States is dependent on the ability of the domestic industrial base to supply materials and services for the national defense and to prepare for . . . natural or man-caused disasters."[130]

The DPA defines "services," "industrial resource," "critical technology," and "critical technology item" in ways that seem to encompass vaccine production.[131] President Trump and later President Biden used the DPA to prioritize production and input supply needs for a range of diagnostic, therapeutic, preventive, and other products, from ventilators to vaccines.[132] Because the President "is authorized under the DPA to create, maintain, protect, and expand the domestic industrial base essential for the national defense,"[133] managing information like trade secrets in the national interest is contemplated.

Under the DPA, the President may "allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense."[134] Accordingly, allocating the knowledge and processes required for vaccine production falls within the President's remit under the DPA. Moreover, confidential information can be "published or disclosed" if "the President determines that the withholding thereof is contrary to the interest of the national defense."[135] Again, the DPA seems explicitly to authorize emergency disclosure of trade secrets.

The DPA also generally allows the President to prioritize contracts and requires private persons (including corporations) to accept those contracts "to ensure timely availability of critical materials, equipment, and services."[136] This prioritization power means that the President can alter the private ordering of production by requiring private producers to share trade secret information rapidly so as to act on prioritized orders first. Those who have studied the DPA agree that such levers exist.[137] Additionally, President Biden used the DPA in March 2021 to give Merck priority in securing equipment for two facilities that Merck agreed (under threat of

[129] 50 U.S.C. § 4511.
[130] 50 U.S.C. § 4502.
[131] 50 U.S.C. § 4552.
[132] *See, e.g.*, Shayan Karbassi, *Understanding Biden's Invocation of the Defense Production Act*, Lawfare (Mar. 4, 2021), www.lawfareblog.com/understanding-bidens-invocation-defense-production-act (last visited Dec. 14, 2023); E&C Republicans, *supra* note 127.
[133] 50 U.S.C. § 4533(a)(1)(A).
[134] 50 U.S.C. § 4511(a)(2).
[135] 50 U.S.C. § 4555(d).
[136] Congressional Research Service, The Defense Production Act of 1950: History, Authorities, and Considerations for Congress 6 (updated Mar. 2, 2020).
[137] *See, e.g.*, Zain Rizvi et al., *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, Health Affairs (Aug. 6, 2021), www.healthaffairs.org/do/10.1377/forefront.20210804.101816/full/ (last visited Dec. 14, 2023).

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further invoking the DPA[138]) to be used for production of Johnson & Johnson's COVID-19 vaccine.[139]

Antitrust Authorities

Compelled trade secret sharing and licensing are commonplace in the context of antitrust matters, whether as judicial or regulatory responses to violations of antitrust laws or to obtain regulatory approvals for mergers and acquisitions, Accordingly, such sharing is required frequently in consent decrees. For example, in the important prewar and wartime case of United States v. National Lead Co.,[140] the defendants were held to have violated Section 1 of the Sherman Act[141] by forming an "international cartel" for titanium compounds in the form of a patent pool. At an early stage of the cartel, there was also associated know-how sharing.[142] The judicially ordered remedial decree required that third parties can license manufacturing know-how ("methods and processes").[143] The decree also imposed a reasonable pricing term on such licensing, and retained jurisdiction for the judge to assure that the actual royalty rate charged for any such license was reasonable.[144]

More recently, the US Federal Trade Commission (FTC) has ordered or approved through consent orders mandatory know-how licensing or sharing as a remedial measure in the context of patent and copyright antitrust violations. For example, the FTC required sharing formulas, blueprints, manuals, tests, and other information when Xerox violated unfair competition requirements[145] following a series of mergers in the paper copier market.[146] Similarly, the FTC has ordered mandatory know-how licensing or sharing in the context of prior approval of mergers or acquisitions, including under the Hart–Scott–Rodino Antitrust Improvements Act.[147] In the same vein, European antitrust decrees have ordered mandatory data sharing in the information technology sector.[148]

[138] *See, e.g.*, Amy Kapczynski & Jishian Ravinthiran, *How to Vaccinate the World, Part 2*, LPE Project, https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/ (last visited Dec. 14, 2023).

[139] Christopher Rowland & Laurie McGinley, *Merck Will Help Make Johnson & Johnson Coronavirus Vaccine as Rivals Team Up to Help Biden Accelerate Shots*, Wash. Post (Mar. 3, 2021), www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/ (last visited Dec. 14, 2023).

[140] United States v. National Lead Co., 63 F. Supp. 513 (S.D.N.Y. 1945), *aff'd*, 332 U.S. 319 (1947).

[141] 15 U.S.C. § 1.

[142] National Lead Co., 63 F. Supp. at 523. *See id.*, at 518, 527, 532.

[143] 63 F. Supp. at 534

[144] *See id.*

[145] *See* 15 U.S.C.§ 45.

[146] *See* Xerox Corp., 86 F.T.C. 364 (1975).

[147] 15 U.S.C. § 18a; *see* Baxter Int'l Inc., 123 F.T.C. 904 (1997); Ciba-Geigy Ltd., 123 F.T.C. 842 (1997).

[148] Thibault Schrepel, *Alternatives to Data Sharing*, The Regulatory Review (Feb. 21, 2022), www.theregreview.org/2022/02/21/schrepel-alternatives-data-sharing/ (last visited Feb. 22, 2022) (citing Radio Telefis Eireann v. Commission, Cases C-241/91 P & C-242/91 P, Judgment of the

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Federal Public Health Regulatory Authorities

Section 3(c)(1)(F) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which was discussed in the Ruckelshaus v. Monsanto case,[149] currently requires ten-year data exclusivity for new chemical entities (and applications relating solely to new uses) before the EPA can rely on it to approve competing products.[150] In other cases, EPA can rely on that data for competitive approvals so long as compensation for the originator's data generation costs is either agreed upon or subject to binding arbitration.[151] Under current federal drug and biologics laws, new active moiety pharmaceutical products may be provided with "market exclusivity rights" for differing time periods.[152] Given these provisions, any requirement to share such trade secret data, or for the government to share that data with competitors, may violate the Trade Secrets Act, which criminalizes the release of trade secret data in the government's possession without legal authorization.[153] These market-exclusivity protections are additional to any patent rights, and there are complex provisions regarding regulatory approval linkage to such patent rights.[154]

Congress could amend the relevant federal laws to explicitly authorize the sharing of trade secrets or to require licensing of trade secrets in exchange for regulatory approvals, without triggering any unconstitutional conditions.[155] Further, Congress might rebalance the market-exclusivity provisions themselves by conditioning them on the government's potential need to share trade secrets or compel trade secret licensing to address significant public health needs. The exercise of such rights could also be compensated. Such additional protection for the public, whether in the United States or elsewhere, may be a bargain relative to the massive amounts of economic damage that pandemics can cause, or even relative to the amounts of donations of the more limited supplies of products that are being purchased and exported at taxpayer expense.[156]

Court (Apr. 6, 1995); IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG, Case C-418/01, Judgment of the Court (Fifth Chamber) (Apr. 29, 2004); and Microsoft v. Commission, Case T-201/04, Judgment of the Court of First Instance (Grand Chamber) (Sep. 17, 2007)).

[149] 467 U.S. 986 (1984).

[150] 7 U.S.C. § 136a.

[151] *See id.*

[152] Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Hatch–Waxman Act, 21 U.S.C § 355(j)(5)(F)(ii); Public Health Service Act (PHSA), as amended by the Biologics Price Competition and Innovation Act (BPCIA), 42 U.S.C. § 262(k)(7).

[153] 18 U.S.C. § 1905.

[154] *See* 23 U.S.C. § 355; 35 U.S.C. § 271(e)(2)-(4); 42 U.S.C. § 267.

[155] *See* Ruckelshaus, 467 U.S. at 1007. *See generally* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413 (1989).

[156] *See, e.g.*, David M. Cutler & Lawrence H. Summers, *The COVID-19 Pandemic and the $16 Trillion Virus*, 324 J. AM. MED. ASS'N 1495 (2020) (estimating the cost of the pandemic in America at $16 trillion by year-end 2021).

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In contrast, European health regulatory authorities may more readily compel the sharing of regulatory data with third parties, which then permits third parties to prepare and provide their own regulatory approval requests. As Gurgula and Hull have explained, third parties have a right to access marketing authorization information, including clinical trial data, submitted to the European Medicines Agency, and public interest concerns may override an exception to the right of access when disclosure would undermine commercial interests.[157]

State Police Powers

States have inherent powers to regulate to protect the health and welfare of their citizens.[158] These powers are not readily preempted by federal law, including federal constitutional law.[159] To the extent that trade secret rights may interfere with the ability of states to protect their citizens from pandemic diseases, states may be able to exercise their powers to compel trade secret sharing through legislation or executive order. This is true regardless of whether the trade secret is protected by federal law, by state law, or by both.

Unlike federal government regulatory powers,[160] state powers to protect their citizens are plenary. Thus, there should be no concern that states are interfering with core functions of the federal government when they do so, particularly regarding pandemic diseases. Nor would such compelled trade secret sharing (so long as it does not involve sharing inherently dangerous products or pose national security risks[161]) interfere with federal authority in international relations, even if the transfers were to companies in foreign countries. Instead, such state government-compelled sharing of trade secrets should be effective, assuming that they are properly adopted as legislative or administrative measures under state constitutions and legislation and are not expressly preempted by or in conflict with specific federal laws.

It is unlikely that either federal patent law or federal trade secret law would preempt such state-compelled sharing of trade secrets. In Kewanee Oil Co. v. Bicron Corp.,[162] the US Supreme Court held that a state trade secrecy law that protected unpatentable or doubtfully patentable inventions would not unduly

[157] Gurgula & Hull, *supra* note 8, at 8.

[158] *See, e.g.*, Jacobson v. Commonwealth of Mass., 197 U.S. 11, 25 ("According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety") (citations omitted).

[159] *See, e.g.*, Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 518 (1992); 42 U.S.C. § 264(e).

[160] *See, e.g.*, Nat'l Fed. of Indep. Bus. v. Dept. of Labor, Occupational Health and Safety Admin., 142 S.Ct. 661, 665 (2022).

[161] *See, e.g.*, Export Control Reform Act of 2018, Section 1758 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. 115-232; International Emergency Economic Powers Act, 50 U.S.C. §§ 1701–1708.

[162] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974).

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interfere with federal patent applications and consequent public disclosure incentives, nor would providing such protection deter potentially successful patent applicants from applying, given the differences in strength of protection afforded by the different rights.[163] Perhaps more importantly, Kewanee Oil implied that gaps in federal patent standards were not necessarily preclusive of the simultaneous exercise of state authority to regulate such gaps as trade secrets.[164] Similarly, the failure of federal trade secret regulation to address state government-compelled sharing suggests preserving such authority to the states, particularly when addressing traditional police powers and when federal trade secrecy law contains an express nonpreemption provision.[165]

B *New Legislation to Compel or Induce Trade Secret Sharing*

More explicit new legislation also could be adopted to provide compulsory trade secret sharing authority, at least for important matters like pandemic R&D, testing, regulatory approvals, and manufacturing. Although new legislation might impose compensation obligations regarding retrospective investments if any subsequent sharing or licensing resulted in a regulatory taking, the legislation should *prospectively* avoid the need for any such compensation requirements where the conditions have been met. Such legislation nevertheless could provide for compensation in such circumstances, which then should be determined to be adequate precisely because no constitutional compensation obligations should exist.

For example, Nicholson Price and Arti Rai have suggested providing incentives or mandates to disclose trade secrets: (1) by amending US patent law's initial disclosure requirements (and adding supplemental disclosure requirements) to better permit competitive manufacturing; (2) by requiring public access to already codified information submitted to the FDA for biologics approvals or by offering additional exclusivity periods or accelerated regulatory approval reviews; and (3) by encouraging collaborative research, including through financial incentives.[166] To the extent that the suggested incentives proved insufficient, presumably trade secret owners simply would not apply.

Thus, we recommend creating a general "emergency power" exception to federal trade secret rights that would explicitly authorize compelled trade secret sharing and licensing. Adopting explicit limits on the scope of trade secret rights directly granted (even if the limits are imposed by other statutory provisions) would make clear that there is nothing sacrosanct regarding trade secret protection. It also would not trigger conflicts between statutory regimes requiring interest-balancing or rights-balancing

[163] *See id.*, at 479, 483, 485–486, 491.
[164] *See id.*, at 493.
[165] *See* DTSA, 18 U.S.C. § 1833 Note.
[166] *See* Price & Rai, *supra* note 7, at 1050–60.

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measures. Perhaps more importantly, making clear that trade secrets are always a matter of a limited grant of rights should help quell political opposition and rhetorical efforts to prevent the exercise of such authorities when needed. After all, like patents,[167] trade secret rights do not exist in "natural law." Like all other forms of IP law, trade secrecy should serve society broadly, in addition to the private interests of trade secret holders.

Between overt government compulsion and purely voluntary actions, moreover, there are several legislative actions that can induce private willingness to share or license trade secrets. Such "nudges"[168] are endemic to our legislative policies, including things such as tax incentives, rebates, and regulatory discounts that induce people to take actions.[169] The US National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority provided extensive up-front funds and advance-purchase commitments to induce private companies to engage in costly and risky R&D, clinical trials, regulatory approvals, and manufacturing scale-up.[170] Similarly, the threat to exercise the DPA or other government powers may have induced voluntary licensing even without it actually having to be formally invoked, as well as having provided incentives to assure supplies that in turn may have influenced willingness to license technology to others.

New legislation could also be adopted to provide greater incentives to nudge private trade secret rights holders toward fulfilling sharing or licensing needs. Such legislative measures again would not run afoul of any constitutional concern. Politically, such nudges may be easier to enact. However, precisely because they may be insufficient to induce the desired actions in particular cases of urgent need, they may be inadequate substitutes for government compulsion or voluntary, private, moral conduct.

5 CONCLUSION

Because the sharing of, or failure to share trade secrets creates life-or-death consequences for hundreds of millions of people around the world, COVID-19 has forced the question of public access to trade secrets to the front of the long list of global health challenges that we face. If we are to defeat pandemics in a safe, effective, and expeditious manner, then we will need to find a new balance between the interests

[167] *See, e.g.*, Millar v. Taylor, (1769) 98 Eng. Rep. 201, 230–231 (K.B.) (Yates, J.).

[168] *See, e.g.*, Richard Thaler & Cass Sunstein, Nudge (2008); Cass Sunstein, Why Nudge? The Politics of Liberal Paternalism (2014).

[169] *See, e.g.*, Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 Emory L.J. 1087, 1117–1128 (discussing various forms of subsidies, including taxation, administrative subsidies, and foreign aid).

[170] *See, e.g.*, Congressional Research Service, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials* (updated Mar. 1, 2021), https://crsreports.congress.gov/product/pdf/IN/IN11560. *See generally* Knowledge Ecology International, BARDA Archives, www.keionline.org/tag/barda (last visited Feb. 22, 2022).

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of trade secret owners and the public. As a recent review has noted, when arguing for changing worldwide IP and health rules through the yet-to-be negotiated Pandemic Treaty, the COVID-19 funding agreements did not adequately transfer know-how for vaccine production, leaving many parts of the world without needed protection.[171]

The ability to compel trade secret sharing is critically important, and not just for COVID-19 pandemic protection. Adding these measures to the routine arsenal of government actions can help address future pandemics and other global problems, such as climate change mitigation and adaptation.[172] This chapter makes the case that it is also unexceptional to do so, as worldwide sentiment has already produced significant agreement (albeit with some gaps) on sharing requirements for different kinds of information that might be kept as trade secrets or as confidential business information – that is, access to the pathogens themselves and to genetic sequence information that can accelerate global response to pandemic diseases.[173]

The potential for litigation and compensation, and the desire to preserve competitive trade and technology advantages, should not deter governments (particularly wealthy governments) from taking needed actions to compel trade secret sharing to protect global health. Even without treating this as a moral obligation (the "Golden Rule"),[174] it will likely protect the citizens of the sharing jurisdiction from death, disease, and hardship far more than any short-term competitive advantages and benefits that might otherwise be obtained.

[171] Katrina Perehudoff et al., *A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-How and Technology*, 7 BMJ Global Health e009709, at 1, 2 (2022).

[172] *See, e.g.*, Coalition for Epidemic Preparedness Innovations (CEPI), *CEPI and SK Bioscience Partner to Advance mRNA Vaccine Technology to Build Vaccine Library Enable Rapid Response against Disease X* (Oct. 25, 2022), https://cepi.net/news_cepi/cepi-and-sk-bioscience-partner-to-advance-mrna-vaccine-technology-to-build-vaccine-library-enable-rapid-response-against-disease-x/ (last visited Dec. 23, 2022).

[173] *See generally, e.g.*, Dario Piselli, *International Sharing of Pathogens and Genetic Sequence Data: What Linkages With the Nagoya Protocol and the PIP Framework*, Global Health Centre Policy Brief (2002), https://graduateinstitute.ch/globalhealth (last visited Dec. 23, 2022).

[174] *See, e.g.*, Leviticus 19:18 (Jewish Publication Soc. of A.); Matthew 7:12 (World English Version); Russell Freedman, Confucius: The Golden Rule (2002), https://philpapers.org/rec/FRECTG (last visited Dec. 23, 2022).

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