

4-2023

## Compelling Trade Secret Sharing

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### Recommended Citation

David S. Levine and Joshua D. Sarnoff, *Compelling Trade Secret Sharing*, 74 HASTINGS L.J. 987 (2023).  
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# Compelling Trade Secret Sharing

DAVID S. LEVINE<sup>†</sup> & JOSHUA D. SARNOFF<sup>†</sup>

*The unprecedented COVID-19 virus has brought to the forefront many challenges associated with exclusive rights in information, data, and know-how, all of which may constitute protected trade secrets. While patents have received more attention, trade secret information has limited the ability to perform research, develop, test, gain regulatory approval for, manufacture, and distribute globally and at sufficient scale and affordable prices the needed vaccines, therapeutics, diagnostics, medical devices, and personal protective equipment. Voluntary licensing efforts have proven inadequate to supply pandemic needs. Thus, compelling the sharing or licensing of trade secrets is needed not only to properly address COVID-19, but more importantly to address future pandemics and other serious global problems such as climate change.*

*This Article explains the nature of trade secrets and their protection. It then describes the failures in COVID-19 responses resulting from trade secrets that were not voluntarily licensed. It explains why patent law disclosures have been inadequate to assure competitive global research, development, and production.*

*Given the need for compelled trade secret sharing, this Article surveys the relevant international intellectual property law treaties addressing trade secrets. It demonstrates that, consistent with international law obligations, governments are free to compel trade secret sharing. Further, governments may not be obliged to award compensation for such sharing when regulating to address public health. Given this national freedom to act, this Article then provides numerous examples of existing United States, European, and other authorities that have been or could be used to compel the sharing or licensing of trade secrets. It also notes the potential to adopt more explicit legislation authorizing compelled or induced behaviors. This survey of authorities illustrates that compelling trade secret sharing or licensing should be unobjectionable whenever there is a need to protect lives, health, or the economy. Accordingly, this Article provides a first critical step toward rethinking the nature of international trade secret protections and seeks to develop the political will for governments to protect the global public from the harms that trade secret rights can generate.*

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*It's . . . about pragmatic solidarity with those in need of assistance.*

— Dr. Paul Farmer<sup>1</sup>

*Lamentably, it is a historical fact that privileged groups seldom give up their privileges voluntarily. Individuals may see the moral light and voluntarily give up their unjust posture; but, as Reinhold Niebuhr has reminded us, groups tend to be more immoral than individuals.*

— Martin Luther King, Jr.<sup>2</sup>

#### INTRODUCTION

The unprecedented 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 (“R&D”), 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 the 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 shield a shockingly broad range of critical and lifesaving 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 supply of needed products, must or should the government compensate the rights holder? Although we address this 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

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1. Ellen Barry & Alex Traub, *Paul Farmer, Pioneer of Global Health, Dies at 62*, N.Y. TIMES, <https://www.nytimes.com/2022/02/21/obituaries/paul-farmer-dead.html> (Feb. 22, 2022) (commenting on lowering intellectual property law barriers for COVID-19 vaccine development). Dr. Paul Farmer was a public health giant.

2. MARTIN LUTHER KING, WHY WE CAN'T WAIT 82 (1st ed. 1964).

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 a general overview of a range of existing authorities, as well as a framework for addressing the latter two questions and understanding the complexity of the first question.

Part I of this Article provides 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 uncoded “know-how,” “show-how,” and expertise on the other. All these forms of trade secrets may need to be shared to expedite or expand 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 uncoded knowledge.

Part II discusses COVID-19 and the experiences with trade secrets regarding vaccines in particular. We use the COVID-19 vaccine example to explain why trade secret sharing is needed, why patent disclosures and patent 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.

Part III explains why the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS” or “TRIPS Agreement”)<sup>3</sup> of the World Trade Organization (WTO)<sup>4</sup> 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 additional compensation. Furthermore, the TRIPS Agreement does not prohibit compelled sharing to address public health needs even when compensation is *not* provided.<sup>5</sup> And we do not believe any investor expropriation or unfair treatment claims for

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3. 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. 318, 33 I.L.M. 1213 [hereinafter TRIPS].

4. TRIPS is a 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.

5. TRIPS, *supra* note 3, art. 39; *see infra* notes 185–238 and accompanying text.

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.<sup>6</sup>

The original proposal to waive various TRIPS obligations (“Waiver Proposal”),<sup>7</sup> which would have waived trade secret and pharmaceutical and agricultural regulatory data requirements for COVID-19-related products, would have made even clearer the lack of any need for compensation for compelled trade secret sharing. The actual Ministerial Decision (“Decision”) adopted by the TRIPS Council on June 17, 2022,<sup>8</sup> however, was much more limited; it only expanded conditions for compulsory licensing of patent rights (which include compensation obligations) and COVID-19-related vaccines. Given the limitations of a waiver in the COVID-19 context to patent rights, the Waiver Proposal was neither necessary nor sufficient for governments to compel trade secret sharing for public health needs. But the Decision may provide some additional support for governments seeking to protect against claims brought by investors in the unlikely event that an ISDS claim for uncompensated expropriation might otherwise be successfully pursued by a trade secret rights holder. Additionally, as the trade secrets would likely be held within technologically advanced jurisdictions, any compensation obligations resulting from compelling such sharing would likely be sought from and paid by wealthier countries.

Part IV surveys some of the existing authorities already established by federal and state governments in the United States, by the European Union, and by Canada 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”),<sup>9</sup> antitrust authorities, federal health authorities, and state police powers (to the extent they are 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 assure expanded R&D, clinical testing, and production to better protect global public health. We also discuss the possibility of legislative

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6. See *infra* notes 266–82 and accompanying text.

7. Council for Trade-Related Aspects of Intellectual Property Rights, *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); Council for Trade-Related Aspects of Intellectual Property Rights, *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) [hereinafter *Waiver Proposal*].

8. World Trade Organization, Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30, WT/L/1141 (June 22, 2022) [hereinafter Ministerial Decision].

9. Defense Production Act of 1950, ch. 932, 64 Stat. 798 (codified as amended in scattered sections of 50 U.S.C.).

changes that would provide even more explicit authority to compel sharing, as well as the use of conditional funding approaches that would make the acceptance of government funds dependent on voluntary agreement to share trade secrets as needed.

The end of Part IV then focuses on measures beyond voluntary and compulsory licensing of trade secrets, although compulsory licensing certainly is possible and is needed when voluntary licensing either has not occurred or has not been sufficient to address R&D, clinical testing, or manufacturing needs. Compulsory licensing, sometimes pejoratively referred to as “forced technology transfer,”<sup>10</sup> is a highly controversial topic, and invokes national trade policies and international competitive advantage concerns. Compulsory licensing, as well as other methods of compelling sharing of trade secrets and know-how to improve national technological proficiency, have been the subject of extensive concern in the context of U.S.-China trade relations<sup>11</sup> and related bilateral trade arrangements.<sup>12</sup> Because there are other policy and market levers to use, including conditioning government funding on assuring trade secret sharing, and because we recommend providing *reasonable* compensation for compelled sharing or licensing, we believe our recommendations are unlikely to generate the overblown rhetorical opposition that normally accompanies discussion of these issues.

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

## I. TRADE SECRET AND RELATED PROTECTION

Trade secrets are comprised by a complicated and diverse body of law with significant variations in international and national law, including those that address limitations on and exceptions to trade secret rights.<sup>13</sup> Trade secret applications are extremely fact- and sector-specific, and the existence of a trade secret must be assessed individually against its value in the industry sector in

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10. See generally, e.g., Dan Prud'homme, Max von Zedtwitz, Joachim Jan Thraen & Martin Bader, “Forced Technology Transfer” Policies: Workings in China and Strategic Implications, 134 *TECH. FORECASTING & SOC. CHANGE* 150 (2018).

11. See generally KAREN M. SUTTER, CONG. RSCH. SERV., “MADE IN CHINA 2025” INDUSTRIAL POLICIES: ISSUES FOR CONGRESS (2022).

12. Jyh-An Lee, *Forced Technology Sharing in the Case of China*, 26 *B.U. J. SCI. & TECH. L.* 324, 326 (2020). But see David S. Levine, *Covid-19 Should Spark a Reexamination of Trade Secrets’ Stranglehold on Information*, *STAT* (July 10, 2020), <https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/> (“[T]rade secrets . . . are everywhere in the battle to defeat Covid-19, from clinical data to pharmaceutical manufacturing processes.”).

13. See generally ELIZABETH A. ROWE & SHARON K. SANDEEN, *TRADE SECRET LAW: CASES AND MATERIALS* (3d ed. 2021).

which it operates.<sup>14</sup> Therefore, few blanket prohibitions or rules of conduct apply when discussing the role of trade secrets in innovation and production.

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.<sup>15</sup> Vaccines, other biologic medicines, cell lines, genomic information, and other biological material can also be held as trade secrets.<sup>16</sup> Similarly, data about the effectiveness of medicines and vaccines are trade secrets.<sup>17</sup> Manufacturing processes can be a paradigmatic trade secret,<sup>18</sup> or can fall into the amorphous quasi-trade secret categories of “know-how”<sup>19</sup> or “show-how.”<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup> In many cases, such data and methods need not be disclosed to assure compliance with good manufacturing practices that permit product marketing.<sup>23</sup> 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

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14. David S. Levine, *COVID-19 Trade Secrets and Information Access: An Overview*, INFOJUST. (July 10, 2020), <https://infojustice.org/archives/42493>.

15. *Id.*

16. *Id.*

17. *Id.*

18. See Allison Durkin, Patricia Anne Sta Maria, Brandon Willmore & Amy Kapczynski, *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 HEALTH & HUM. RTS. 129, 133 (2021) (“[T]rade secret protections permit pharmaceutical companies to keep . . . the manufacturing process for medications confidential.”).

19. See *infra* notes 68–70.

20. See *infra* note 71; see also W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Sharing for Large-Scale Vaccine Manufacturing*, 369 SCI. MAG. 912, 912 (Aug. 13, 2020). See generally W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016).

21. 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. & PRAC. 1242, 1247 (2021) (“[M]ethods of manufacture, . . . test data, specific (unpatented) medical formulae, cell lines, genomic information and other biological materials may also be protected as trade secrets.”).

22. See Durkin et al., *supra* note 18 (“Even after patent and data exclusivity periods for drugs expire, trade secret protections permit pharmaceutical companies to keep the precise composition or manufacturing process for medications confidential. This effectively slows the release of generic competitor drugs by preventing their reliance on existing engineering and manufacturing data.”).

23. See Gurgula & Hull, *supra* note 21, at 1259 (“One of the barriers that also needs to be overcome when issuing a compulsory license on a medicine or vaccine relates to data and marketing exclusivity that protects clinical test data submitted by the originator to the relevant regulator. Such exclusivity aims to prevent other pharmaceutical companies from relying on such data during the term of protection to obtain a marketing authorization for their generic or biosimilar version of the originator’s medicine.”).



access when needed to scale up research, development, regulatory approvals, and manufacturing supplies.<sup>24</sup>

Methods for manufacturing may also be treated as trade secrets. Such methods often are colloquially labeled “know-how,” a subset of trade secrecy doctrine involving information that is valuable and difficult to transfer, but that is not necessarily secret.<sup>25</sup> Such information may not always be protectable under trade secret law.<sup>26</sup> Nonetheless, because of its value 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.<sup>27</sup> 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 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.<sup>28</sup> Global pharmaceutical companies have rejected requests from various generic pharmaceutical producers to license the trade secrets and know-how in order to scale up production.<sup>29</sup>

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24. See Orit Fischman-Afori, Miriam Marcowitz-Bitton & Emily Michiko Morris, *A Global Pandemic Remedy to Vaccine Nationalism* 21 (Apr. 20, 2021) (unpublished manuscript), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3829419](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3829419) (“While compulsory licensing seems, at first blush, like a promising mechanism for achieving greater access and fair pricing of vaccines, it has notable disadvantages. For example, the issuance of compulsory licenses requires an administrative procedure and sometimes legislative action. Compulsory licensing also has little value when licensees are inefficient and unable to manufacture products at a meaningfully lower price than their licensors.”).

25. See 3 MILGRIM ON TRADE SECRETS § 11.05 (2022) (“The salient distinction between trade secrets and know-how relates to the extent to which the matter is known within an industry. For example, a formula, process or similar information known only by a few competitors in a large industry will be regarded as a trade secret, whereas information that is known by all or almost all of the competitors in an industry will not be deemed a trade secret. The latter information, although widely known within the industry, may nonetheless be valuable to one who desires to enter the industry.”).

26. See, e.g., SHARON K. SANDEEN & DAVID S. LEVINE, *INFORMATION LAW, GOVERNANCE, AND CYBERSECURITY* 398 (1st ed. 2019) (“Note how trade secret law forces courts to confront fundamental questions about what constitutes protectable information.”).

27. See Gurgula & Hull, *supra* note 21, at 1244 (“Vaccines are complex biologics, and their manufacture is challenging because of the . . . complex processes involved and the specialist knowledge and experience required. Such knowledge is typically protected by patents and, more importantly, by trade secrets.”).

28. See *infra* Part II.

29. See, e.g., Ashleigh Furlong, *Big Vaccine Makers Reject Offers To Help Produce More Jabs*, POLITICO (May 14, 2021, 12:21 PM), <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/> (reporting on Johnson & Johnson’s and AstraZeneca’s rejections of offers to partner with generic drug manufacturers to increase production).

### A. WHAT ARE TRADE SECRETS?

Often labeled as “confidential information”<sup>30</sup> or “proprietary information,”<sup>31</sup> trade secrets encompass vast quantities of information needed to discover, test, create, and manufacture diagnostics, treatments, medicines, and vaccines.<sup>32</sup> Chemical formulas are classic trade secrets.<sup>33</sup> So are processes for manufacturing.<sup>34</sup> Even “negative information”—information about what does not work—can be a trade secret.<sup>35</sup>

Trade secret legal protections stem back to at least the early 1800s in England.<sup>36</sup> In the United States, the Supreme Court of Massachusetts appears to be the first court to describe a view on trade secret protections.<sup>37</sup> The famous example of the “best-kept trade secret in the world” involves the recipe for Coca-Cola.<sup>38</sup> The exclusivity of the formula makes the soft drink an “extremely valuable asset” that competing innovators may want to uncover in order to enter competition and make the item less exclusive.<sup>39</sup>

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.<sup>40</sup> Federal laws, primarily the Federal Defend Trade Secrets Act (“DTSA”),<sup>41</sup> and state laws modeled after the Uniform Trade Secret Act (“UTSA”)<sup>42</sup> enable trade secret owners like pharmaceutical companies to bring trade secret misappropriation actions against former employees and others, particularly competitors who gain unauthorized access to their claimed trade secrets. The Federal Economic Espionage Act (“EEA”)<sup>43</sup> 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.<sup>44</sup> As a result, trade secrets are a powerful exemption from state and federal access-to-information

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30. See *Trade Secrets*, WIPO, <https://www.wipo.int/tradesecrets/en/> (last visited Apr. 1, 2023) (“Trade secrets are intellectual property (IP) rights on confidential information which may be sold or licensed.”).

31. See *Proprietary Information*, INC., <https://www.inc.com/encyclopedia/proprietary-information.html> (Jan. 5, 2021) (“Proprietary information, also known as a trade secret, is information a company wishes to keep confidential.”).

32. Levine, *supra* note 14.

33. *Id.*

34. *Id.*

35. *Id.*

36. Michael Risch, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1, 13 (2007).

37. *Id.*

38. *Coca-Cola Bottling Co. of Shreveport, Inc. v. Coca-Cola Co.*, 107 F.R.D. 288, 289 (D. Del. 1985).

39. Jonathan R. Chally, *The Law of Trade Secrets: Toward a More Efficient Approach*, 57 VAND. L. REV. 1269, 1277 (2004).

40. Levine, *supra* note 14.

41. See Defend Trade Secrets Act of 2016, 34 U.S.C. § 41310.

42. See *generally* UNIF. TRADE SECRETS ACT (amended 1985), 14 U.L.A. 529 (1985).

43. See Economic Espionage Act of 1996, 18 U.S.C. §§ 1831–1839.

44. See SANDEEN & LEVINE, *supra* note 26, at 638–40 (discussing the Federal Privacy Act and the Trade Secret Act, among other statutes).

laws, like the Freedom of Information Act (“FOIA”).<sup>45</sup> At the international level, the European Union’s Trade Secrets Directive and the WTO’s TRIPS Agreement article 39 provide or require similar trade secrets protections.<sup>46</sup>

Under the UTSA, a trade secret is defined as

a formula, process, device, or other business information that is kept confidential to maintain an advantage over competitors; information – including a formula, pattern, compilation, program, device, method, technique, or process – that (1) derives independent economic value, actual or potential, from not being generally known or readily ascertainable by others who can obtain economic value from its disclosure or use, and (2) is the subject of reasonable efforts, under the circumstances, to maintain its secrecy.<sup>47</sup>

The UTSA was enacted in 1979 and has been adopted by forty-nine states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.<sup>48</sup> Prior to the UTSA, “the improper use or disclosure of trade secrets was traditionally a common law tort.”<sup>49</sup>

On the federal level, trade secret theft is prohibited by the EEA<sup>50</sup> and, more recently, the DTSA. Congress passed the EEA as the “first major federal statute to address trade secret misappropriation”; it “criminalized trade secret misappropriation and authorized broad domestic and international enforcement measures against trade secret misappropriation.”<sup>51</sup> The EEA criminalized trade secret theft as a response to an “environment of digitalization and intense worldwide competition.”<sup>52</sup> Under the EEA, the federal government alone can prosecute such theft.

Ongoing concern about the EEA’s (and state laws’) ability to confront misappropriation led to the introduction of the DTSA in Congress on July 29, 2015, supported by “a number of high-technology and manufacturing firms, the U.S. Chamber of Commerce, and the Section of the Intellectual Property Law of the American Bar Association.”<sup>53</sup> The DTSA was then signed into law in May 2016, and allows trade secret owners to bring a civil action in federal court for

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45. See Freedom of Information Act, 5 U.S.C. §552(b)(4). See generally *State Freedom of Information Laws*, NAT’L FREEDOM OF INFO. COAL., <https://www.nfoic.org/state-freedom-of-information-laws/> (last visited Apr. 1, 2023).

46. See *infra* Part IV.

47. UNIF. TRADE SECRETS ACT § 1(4) (UNIF. L. COMM’N 1985).

48. *Trade Secret*, CORNELL L. SCH.: LEGAL INFO. INST., [https://www.law.cornell.edu/wex/trade\\_secret](https://www.law.cornell.edu/wex/trade_secret) (last visited Apr. 1, 2023).

49. *Id.*

50. See 18 U.S.C. §§ 1831–1839.

51. Robin J. Efron, *Trade Secrets, Extraterritoriality, and Jurisdiction*, 51 WAKE FOREST L. REV. 765, 765 (2016).

52. *Id.*

53. Christopher B. Seaman, *Introduction: The Defend Trade Secrets Act of 2015*, 72 WASH. & LEE L. REV. ONLINE 278, 281–82 (2015), <https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1030&context=wlulr-online>.

trade secret misappropriation.<sup>54</sup> The DTSA is functionally similar to the UTSA and “is not intended to alter the balance of current trade secret law or . . . specific court decisions.”<sup>55</sup> The DTSA has been described as a “wake-up call” to companies that value and protect their intellectual property as trade secrets.<sup>56</sup>

Unlike patents, regulatory entities do not grant or confirm trade secrets; rather, one has a trade secret by keeping valuable information secret.<sup>57</sup> Thus, there is no specified term for trade secrets; instead, they exist for as long as they remain secret.<sup>58</sup> 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 trade secrets are reverse engineered<sup>59</sup> or independently discovered by another<sup>60</sup> and thereafter made generally known.

The best way to keep a trade secret is simply not to disclose it.<sup>61</sup> However, while that works as a theoretical matter (and most jurisdictions also require affirmative measures to protect secrecy), in most instances, it renders the trade secret nearly useless. Thus, the paradigm trade secret suit is one alleging the trade secret’s misappropriation by a former employee or competitor that hires the employee through alleged theft—typically in violation of contractual obligations of the employee, or enabled by sloppy trade secret management.<sup>62</sup>

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.<sup>63</sup> As a result, trade secrets rely heavily on licensing.<sup>64</sup> As the American Law Institute has explained:

Exploiting the value of trade secrets through licensing has long been a common practice. Arguably, no other form of intellectual property is more dependent on licensing mechanisms than trade secrets. The license instrument provides the mechanism for conveying the benefits embodied by the trade

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54. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (codified at 34 U.S.C. § 41310).

55. Seaman, *supra* note 53, at 279–80.

56. Manny Schechter, *The Changing Trade Secret and Patent Equilibrium*, TECHCRUNCH (June 20, 2016, 5:00 PM), <https://techcrunch.com/2016/06/20/the-changing-trade-secret-and-patent-equilibrium>.

57. ROWE & SANDEEN, *supra* note 13, at 51.

58. *Id.* at 2.

59. UNIF. TRADE SECRETS ACT § 1 cmt. (UNIF. L. COMM’N 1985) (citing RESTATEMENT (SECOND) OF TORTS § 757 cmt. f (AM. L. INST. 1975)) (defining “reverse engineering” as a proper means of acquisition).

60. *Id.* (citing RESTATEMENT (SECOND) OF TORTS § 757 cmt. f (AM. L. INST. 1975)) (defining “independent invention” as a proper means of acquisition).

61. Eric Goldman is credited for this line from his intellectual property teaching notes (on file with authors).

62. See David S. Almeling, Darin W. Snyder, Michael Sapoznikow, Whitney E. McCollum & Jill Weader, *A Statistical Analysis of Trade Secret Litigation in Federal Courts*, 45 GONZ. L. REV. 291, 303 (2010) (“Most alleged misappropriators are someone the trade secret owner knows. In over 85% of cases, the alleged misappropriator was either an employee or business partner.”).

63. *Id.* at 322–23 (“The data show that if the trade secret owner takes the following steps, a court is more likely to find that the owner engaged in reasonable efforts: (1) agreements with employees; (2) agreements with business partners; and (3) restricting access to certain persons, such as by adopting need-to-know rules.”).

64. Danielle M. Conway-Jones, *Technology Transfer Agreements: Licensing of Trade Secrets and Works in Development* 103–05 (Am. L. Inst.-Am. Bar Ass’n, Working Paper No. SM049, 2006).

secret to the awaiting public while still protecting and creating incentives for the labor and effort expended on marshalling of the trade secret.<sup>65</sup>

As discussed in Part II, licensing is at the center of the COVID-19 trade secrecy challenges. Vaccine manufacturers generally have been unwilling to share their trade secrets in ways that would sufficiently advance widespread worldwide access to affordable vaccines. Even as overall production of COVID-19 vaccines has increased over time, the inequitable distribution of and access to vaccines has persisted, and may have increased.<sup>66</sup> We can, and must, do better.

Additionally, there are three amorphous categories of informational concepts related to trade secrets that are also at play. 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.<sup>67</sup>

While this information is not technically a trade secret, its limited availability renders it valuable. Thus, we consider it here in light of 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.”<sup>68</sup> 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, acting for the licensor, also fall within the definition of valuable, and therefore licensable, know-how.<sup>69</sup>

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65. *Id.*

66. *See, e.g.*, Moosa Tatar, Jalal Montazeri Shoorekchali, Mohammad Reza Faraji, Mohammad Abdi Seyyedkolae, José A. Pagán & Fernando A. Wilson, *COVID-19 Vaccine Inequity: A Global Perspective*, 12 J. GLOB. HEALTH 1, 2 (2022) (“World Gini coefficients for COVID-19 vaccines were 0.91 and 0.88 on June 7 and December 7, 2021, respectively, denoting severe COVID-19 vaccine inequality. . . . Our results are consistent with prior research that reported extreme disparities and inequalities during the COVID-19 pandemic (e.g., in testing, infections, hospitalizations, and mortality). . . . Our results show that not only has the distribution of COVID-19 vaccinations not improved, but the inequality of COVID-19 vaccinations was also more severe by December 7, 2021. Moreover, while the distribution of vaccines was slightly less severe between continents (0.61), the inequality within continents was very severe.”).

67. 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 (1998).

68. 3 MELVIN F. JAGER, *ECKSTROM’S LICENSING IN FOREIGN AND DOMESTIC OPERATIONS: THE FORMS AND SUBSTANCE OF LICENSING* § 6:2, Westlaw (database updated May 2023).

69. *Id.*

For present purposes, we define “know-how” (sometimes referred to by others as “tacit knowledge”)<sup>70</sup> 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, absent a voluntary license, its sharing requires some “nudging” or “compulsion.”

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 is not), but is important to delineate for purposes of this Article 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.”<sup>71</sup> Like know-how, sharing “show-how” requires a similar “nudge” or “compulsion.”

Importantly, “know-how” and “show-how” should not be confused with the “general skill and knowledge” held by individuals that is never treated as proprietary relative to others.<sup>72</sup> Such information, like what an employee learns about how to do their job, while valuable, is not the property of the entity that helped the employee acquire it. Instead, it is treated as information that may be used freely by the individual and competitors or others who may seek to employ the individual’s knowledge.<sup>73</sup>

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 degrees of legal protection.

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70. Orit Fischman-Afori et al., *supra* note 24, at 13–14 (explaining that tacit knowledge includes “the kinds of skills and knowledge that are difficult to communicate without extensive personal practice, experience, and interaction,” and noting that such knowledge “is common in less predictable fields like biotechnology”). See generally Douglas O’Reagan, *Know-How in Postwar Business and Law*, 58 *TECH. & CULTURE* 121 (2017) (discussing adoption of the terminology of know-how and trade secrets regarding employee technical skills and other relevant information relating to technological processes, increasing protection of know-how, and the relationship of know-how protection to patent and antitrust laws).

71. 5 DAVID EPSTEIN, *ECKSTROM’S LICENSING IN FOREIGN & DOMESTIC OPERATIONS* § 23:102, Westlaw (database updated 2023).

72. See generally Camilla A. Hrdy, *The General Knowledge, Skill, and Experience Paradox*, 60 *B.C. L. REV.* 2409 (2019) (discussing the legal treatment of general knowledge).

73. ROWE & SANDEEN, *supra* note 13, at 135.

## B. TRADE SECRET POLICIES AND CONSIDERATIONS

Trade secrets operate within a field of competing values, ranging (among other things) from property to contract concerns.<sup>74</sup> Conceived primarily as a body of law designed to protect trade secret owners from unfair competition,<sup>75</sup> trade secret law and doctrine leaves little ground for broader principles tied to information sharing among competitors for public health reasons.<sup>76</sup> Indeed, without permission or a license, there are only very limited scenarios when trade secrets can be accessed without at least some misappropriation concerns. Nevertheless, it is important to distinguish both the kinds of information and the kinds of disclosures that might “result in the loss of associated information rights.”<sup>77</sup>

Moreover, the primary scenarios for sharing trade secrets without a rights holder’s consent that are recognized by current trade secret law do not apply to the COVID-19 concerns that this Article contemplates. For example, the DTSA includes a limited exception for “whistleblowing,”<sup>78</sup> and the European Union’s Trade Secret Directive offers limited support for journalists revealing trade secrets in the “public interest.”<sup>79</sup> There are also specific situations, like defendants interrogating breathalyzer machine accuracy in assessing driving impairment for criminal prosecutions, where limited trade secret access has been granted to individuals or parties to a court proceeding.<sup>80</sup>

The power of trade secrecy as a tool of information control is so extensive that there was even a debate about whether the names of businesses that received federal COVID-19 relief loans were themselves trade secrets.<sup>81</sup> The mere

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74. See Robert G. Bone, *A New Look at Trade Secret Law: A Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 304 (1998) (“I have argued that the way out of the muddle is to recognize trade secret law for what it is: a collection of contract and tort theories grouped together by nature of the subject matter they regulate.”).

75. See David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135, 173 (2007) (“[U]nfair competition (like stealing a trade secret) violates general norms of ethical business conduct and keeping certain information secret from competitors is often believed (rightly or wrongly) to be a prudent business decision.”).

76. Levine, *supra* note 14 (“As of now, there is no general principle in trade secret law that establishes a public interest in its access, or that mandates its sharing with competitors.”). *But see* TRIPS, *supra* note 3, arts. 7–8 (outlining “objectives” and “principles” for “social and economic welfare” and “public health” in intellectual property law generally).

77. Sharon K. Sandeen, *A Typology of Disclosure*, 54 AKRON L. REV. 657, 662 (2021).

78. Daniel Sakaguchi & Monica Mucchetti Eno, *Evolving Whistleblower Immunity Under the Defend Trade Secrets Act of 2016*, LAW.COM (July 18, 2019, 6:51 PM), <https://www.law.com/therecorder/2019/07/18/evolving-whistleblower-immunity-under-the-defend-trade-secrets-act-of-2016>.

79. Mark Ridgway & Taly Dvorkis, *A Comparison of the EU Trade Secrets Directive and the US Defend Trade Secrets Act*, PATENTLYO (May 16, 2016), <https://patentlyo.com/patent/2016/05/comparison-secrets-directive.html>.

80. See generally David S. Levine, *The Impact of Trade Secrecy on Public Transparency*, in THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 423 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2009) (discussing two state appellate court cases in which courts considered limited trade secret access in the context of breathalyzer machines).

81. See, e.g., Alex Daugherty, *Rubio Vowed To Make PPP Loans Public. Now He Asks If They Are Trade Secrets*, MIAMI HERALD (June 14, 2020, 9:58 AM), <https://www.miamiherald.com/news/politics-government/article243493196.html>.

designation by government or a business of particular information as a “trade secret” can result in wide swaths of information being withheld from public inspection, regardless of whether the information actually qualifies.<sup>82</sup> Government regulators can also run into challenges accessing trade secrets, especially absent clear statutory mandates for such access.<sup>83</sup> 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.<sup>84</sup> Thus, the designation of information as a “trade secret” is among the most powerful legal weapons against public, and even regulatory, access to information.

There are several policy considerations to keep in mind when considering the various approaches to information-access challenges relating to COVID-19 or other public health and public interest concerns.<sup>85</sup> First, 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 FOIA.<sup>86</sup> Trade secret law has governed (and thereby denied) public access to information about many issues of worldwide importance, like the safety of fracking,<sup>87</sup> the operation of voting machines,<sup>88</sup> and the composition of our food supply (such as the “pink slime” in beef products).<sup>89</sup>

Because trade secret law is one of the most powerful levers for information-access control, changing the scope and power of trade secrecy rights can have an impact beyond the mere commercial-secret holder and trade secret law itself. IBM’s chief patent counsel, Manny Schecter, who supported the passage of the DTSA, cautioned “against making trade secrets too strong so as to ‘upset the balance’ between trade secrets and patents,” especially where “patents go the extra step of sharing information and promoting collaboration,” and trade secrets “do essentially the opposite.”<sup>90</sup> Conversely, the U.S. Trade Representative has

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82. See 5 U.S.C. § 552(b)(4) (providing a protective exemption for trade secrets, in addition to “commercial or financial information obtained from a person [that is] privileged or confidential”).

83. See, e.g., Levine, *supra* note 80, at 422 (“Legislatures have to pass laws mandating that source code about voting machines must be available to the state, and state boards of elections . . .”).

84. See 34 U.S.C. § 41310.

85. The following policy discussion is adapted from a previous David Levine blog post. See Levine, *supra* note 14.

86. See generally FRANK PASQUALE, *THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION* (2015) (discussing the tools corporations use to shroud their data collection processes in secrecy).

87. Letter from Mary L. Lyndon, Professor, St. John’s Univ., & David S. Levine, Professor, Elon Univ. Sch. of L., to the Bureau of Land Mgmt. (Aug. 23, 2013), <http://infojustice.org/wp-content/uploads/2013/08/Lyndon-Levine-August-2013.pdf>.

88. Levine, *supra* note 14.

89. *Iowa State University Research on “Pink Slime” Barred from Public To Protect Trade Secrets, Judge Ruled*, REPS. COMM. FOR FREEDOM OF THE PRESS (Apr. 16, 2013), <https://www.rcfp.org/iowa-state-university-research-pink-slime-barred-public-protect-trad>.

90. See generally Michael Loney, *Schecter Warns Against Upsetting Balance Between Trade Secrets and Patents*, BUS. SOURCE COMPLETE: MANAGING INTELL. PROP. (Nov. 21, 2016), <https://www.managingip.com/article/2a5c0ug7x98j3sn3wslc/schecter-warns-against-upsetting-balance-between-trade-secrets-and-patents>.



reported that robust trade secret protection supports “critical advances with respect to key environmental challenges, including the mitigation of, and adaption to, climate change.”<sup>91</sup> While the world has adopted and altered trade secret laws despite a dearth of empirical data on their use,<sup>92</sup> recognition that such changes can amount to uncontrolled experiments with real-life consequences must be weighed in the balance.

Additionally, trade secrets are at the center of national security concerns for many nations, including nations that produce COVID-19 vaccines.<sup>93</sup> As noted above, in the United States, the EEA raises the national security specter in the trade secret context.<sup>94</sup> Under FOIA, “national security” is usually the most powerful basis for preventing access to information held by governments.<sup>95</sup> As a general matter, if you want to stop information (trade secrets or other) moving from one holder to another, raising “national security” concerns is the best way to halt the sharing.

The foregoing is not to suggest that national security concerns are not valid. When the United States grapples with China, Russia, and other state actors that steal valuable information from U.S. companies, trade secret law is front and center.<sup>96</sup> Because trade secret theft is directed at vital information regarding weapons systems and technologies, artificial intelligence, and a host of other critical information and technologies, the national security overlay and comparative trade advantage cannot be ignored.<sup>97</sup> Thus, COVID-19 information sharing is tethered to national security concerns, at least in part.

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91. Krista Cox, *More Notes on the USTR 2012 Special 301 List*, KNOWLEDGE ECOLOGY INT’L (May 2, 2012), <https://www.keionline.org/21836>.

92. David S. Levine & Ted Sichelman, *Why Do Startups Use Trade Secrets*, 94 NOTRE DAME L. REV. 751, 785 (2018) (“Unfortunately, other than the limited data released to date from the Berkeley Study, there is very little empirical data on the use of trade secrecy in the biotechnology sector.”).

93. See, e.g., Ellen Nakashima, *U.S. Officials Caution Companies About Risks of Working with Chinese Entities in AI and Biotech*, THE WASH. POST (Oct. 22, 2021, 4:22 PM), [https://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](https://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) (“U.S. counterintelligence officials have begun a concerted push to warn companies and universities about the risks of working with Chinese entities in key emerging technologies such as artificial intelligence, biotechnology and quantum computing.”).

94. See 18 U.S.C. §§ 1831–1839.

95. See 5 U.S.C. § 552(b)(1) (“This section does not apply to matters that are (A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order.”). See generally John A. Bourdeau, Annotation, *What Matters Are Exempt from Disclosure Under Freedom of Information Act ( 5 U.S.C.A. § 552(b)(1)) as “Specifically Authorized Under Criteria Established by an Executive Order To Be Kept Secret in the Interest of National Defense or Foreign Policy,”* 169 A.L.R. Fed. 495 (2001).

96. Deb Ricchmann, *China, Russia, and Iran Are Working Harder To Steal US Trade Secrets and Pose a ‘Significant Threat to America’s Prosperity,’ According to Government Report*, ASSOC. PRESS (July 26, 2018, 2:59 PM), <https://www.businessinsider.com/china-russia-and-iran-working-harder-to-steal-us-trade-secrets-2018-7>.

97. See generally EXEC. OFF. OF THE PRESIDENT, ADMINISTRATION STRATEGY ON MITIGATING THE THEFT OF U.S. TRADE SECRETS (2013) (“Trade secret theft threatens American businesses, undermines national security, and places the security of the U.S. economy in jeopardy.”).

Moreover, trade secrets are used in a variety of ways depending on the particular industry at issue.<sup>98</sup> The traditional trade secret is one that has commercial value to others, and it is already defined quite broadly wherever the label is used.<sup>99</sup> Overly powerful trade secret law can have the effect of hampering the development, creation, and use of new forms of information and innovation, whereas weak law can encourage theft and dampen innovation.

Still, it is impossible to predict such outcomes with a one-size-fits-all perspective about trade secrecy's importance because some industries may heavily rely on trade secrecy while others do not rely on it at all. Similarly, even within an industry, a company may use trade secrecy in one context but forego trade secrecy in another for the same information.<sup>100</sup> Thus, any consideration of COVID-19 trade secret sharing must be considered first through the narrow lens of its usefulness and impact within vaccine, therapeutics, diagnostics, and other industries, without the broad-brush labeling that is common in intellectual property law debates.<sup>101</sup>

No doubt, changes in how people share information can have both positive and negative implications. The Obama Administration discussed the "rise in the US workforce of different expectations regarding work, privacy, and collaboration" as a "cultural shift" that will "likely disrupt security procedures and provide new openings for collection of sensitive US economic and technology innovation."<sup>102</sup> Industrialized countries have reacted to this shift with increased penalties for the violation of current commercial norms and by making trade secret law increasingly uniform.<sup>103</sup> However, the COVID-19 pandemic has created new and unprecedented challenges to trade secrecy's dominance, calling into question this cultural shift toward increasing information and knowledge protection.

If entities are compelled to share trade secrets, governments need to decide how and when that compulsion should occur. To date, courts have generally been unwilling to force trade secret access unless an extremely persuasive reason arises, like a defendant's ability to present exculpatory evidence in a criminal

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98. See, e.g., Levine & Sichelman, *supra* note 92, at 784 ("To the extent that there are any consistent findings, the chemical industry tends to value trade secrecy more than others. On the other end, industries that produce innovations that can be easily copied or duplicated naturally tend to find trade secrecy less desirable.").

99. See Levine, *supra* note 14.

100. See, e.g., Levine & Sichelman, *supra* note 92, at 798 ("These results are important because they provide support for the theory that patents and trade secrets may act as complements, at least for companies that hold many patents.").

101. See generally Mark Lemley, David S. Levine & David G. Post, *Don't Break the Internet*, 64 STAN. L. REV. 34 (2011); Christopher Garrison, *What Is the 'Know-How Gap' Problem and How Might It Impact Scaling Up Production of Covid-19 Related Diagnostics, Therapies and Vaccines?*, MEDS. L. & POL'Y (Dec. 16, 2020), <https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/>.

102. OFF. OF THE NAT'L COUNTERINTEL. EXEC., FOREIGN SPIES STEALING U.S. ECONOMIC SECRETS IN CYBERSPACE: REPORT TO CONGRESS ON FOREIGN ECONOMIC COLLECTION 6 (2011).

103. Levine, *supra* note 14.

trial.<sup>104</sup> Government agencies, on the other hand, have been more willing to pierce trade secret protection during wartime, such as threatening to compel takeovers and induce other forms of industrial pooling.<sup>105</sup> Thus, what was a trade secret at one time may be rendered accessible at another.

As has become clear since the COVID-19 pandemic began, trade secret owners' interests are not the only concerns that governments, regulatory bodies, and international organizations should consider. This is a largely new framing for trade secret protection, and one that must be taken up now.

From state regulators to the public at large, and even potentially other competitors, the case can be made that there is a wider pool than might traditionally have been thought of relevant stakeholders and interests to balance against trade secret owners and their interests in proprietary rights.<sup>106</sup> Governments should and increasingly must decide what values and concerns are paramount.

When governments make such determinations, trade secrets should not be afforded a sacrosanct pedestal of protection. As has been discussed, trade secrecy is often crucial and necessary to innovation. However, not all secrets deserve unwavering protection, and not all alleged "trade secrets" are actual trade secrets. 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 untrammelled trade secret protection over valuable information."<sup>107</sup> The remainder of this Article lays out the brief history of trade secrecy and COVID-19 thus far, describes the options at our disposal to compel trade secret sharing in the effort to provide COVID-19 vaccines and other needed medical products to the world's population, and addresses the primary challenges to compelling such sharing.

## II. TRADE SECRECY AND COVID-19

If it turns out that an alleged "trade secret" is, in fact and in law, a bona fide trade secret, then a difficult question must be addressed: Should the trade secret be shared anyway? To answer this question, it is important to first explain how and when trade secrets assure that the protected information best serves public uses. Take, for example, the vaccine manufacturing process. In the COVID-19 context, certain trade secrets, like production processes, might serve society more thoroughly through wider public access to the information, by allowing full technology sharing that would foster more rapid expansion of needed manufacturing capacity, and also might reduce prices through greater

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104. *Id.*

105. *See id.* and accompanying text.

106. *Id.*

107. *Id.*

competition and increased supplies.<sup>108</sup> 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 might hinder follow-on competition.<sup>109</sup> 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 to these questions.<sup>110</sup> And as they involve public choices about competing values, they invariably require political determinations.

COVID-19 has created a unique opportunity to make compelling public policy arguments in the interests of developing new health technologies for the world's population and ensuring that the supply and prices of those technologies are not exclusively in the control of trade secret owners. As one of the Authors wrote in 2020: "For example, clinical data access might be justified by virtue of the clinicians' need for access to all relevant information when making treatment decisions, the requirement of patient informed consent, and the researchers' obligation to verify, validate, challenge, or aggregate earlier evidence, among other reasons."<sup>111</sup>

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. This Article does not aim to address all these issues, much less the difficult issues involved in assuring better global public health systems and adequate supply and distribution chains.<sup>112</sup> Rather, it makes the case that compelled knowledge sharing, notwithstanding trade secret law, is possible and desirable. It is up to governments and policymakers in the public health and biopharmaceutical industries to decide whether and how to use the various options that are suggested here, determining what information should be shared and when.

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108. *See supra* Part I.

109. Levine & Sichelman, *supra* note 92, at 757 ("Although startups can maintain a lead-time advantage simply because of the inherent failure of competitors to innovate, a primary reason for choosing trade secrecy is to extend a lead-time advantage by preventing the disclosure of specific information that provides the advantage.").

110. *See, e.g.*, Andrea Contigiani & David H. Hsu, *How Trade Secrets Hurt Innovation*, HARV. BUS. REV. (Jan. 29, 2019), <https://hbr.org/2019/01/how-trade-secrets-hurt-innovation> ("At least in the academic literature, the effect of stronger protections for trade secrecy is ambiguous."); Bernhard Ganglmair & Imke Reimers, *Visibility of Technology and Cumulative Innovation: Evidence from Trade Secret Laws I* (ZEW Centre for Eur. Econ. Rsch., Discussion Paper No. 19-035, 2019) ("We find that while stronger trade secrets encourage investment in R&D, they may have negative effects on overall welfare—the result of a significant decline in follow-on innovation.").

111. Levine, *supra* note 14.

112. *See, e.g.*, Michael Fleming, Peter Okebukola & Kathryn Skiba, *Port to Patient: Improving Country Cold Chains for COVID-19 Vaccines*, MCKINSEY & CO. (Sept. 14, 2021), <https://www.mckinsey.com/industries/public-and-social-sector/our-insights/port-to-patient-improving-country-cold-chains-for-covid-19-vaccines>; U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-265, COVID-19 CRITICAL VACCINE DISTRIBUTION, SUPPLY CHAIN, PROGRAM INTEGRITY, AND OTHER CHALLENGES REQUIRE FOCUSED FEDERAL ATTENTION (2021), <https://www.gao.gov/assets/gao-21-265.pdf>.

A. HOW HAS THE LACK OF SHARING IMPEDED PRODUCTION AND PUBLIC ACCESS TO VACCINES?

There is no question that IP rights, and particularly patents, have played a significant role in the COVID-19 vaccine story.<sup>113</sup> As Allison Durkin and her colleagues have noted, “[p]atents . . . are legally granted temporary monopolies that create both incentives for the development of medicines and barriers to affordable medicines.”<sup>114</sup> Indeed, the recognition of their importance impelled a number of scholars to produce the Open COVID Pledge, which “calls on organizations around the world to make their patents and copyrights freely available in the fight against the COVID-19 pandemic.”<sup>115</sup> Significantly, Moderna pledged in 2020 not to assert its patents for COVID-19 vaccine technology during the pendency of the pandemic—although it subsequently revised its pledge somewhat in 2022 and then sued Pfizer, claiming that it could unilaterally determine when the pandemic is over.<sup>116</sup> Beyond vaccines, a 2021 study of the Open COVID Pledge and related patent-sharing pledges noted that “there has been an increased adoption of patent pledges [among medical companies] to make IP relevant to COVID-19 freely available to potential users.”<sup>117</sup>

No such pledges have been made by owners regarding their COVID-19-related trade secrets. Even the Open COVID Pledge eschewed addressing trade secrecy, focusing only on patents and copyrights.<sup>118</sup> As of October 2021, there was “no proposal to extend the Open COVID Pledge for confidential pending patents and trade secrets.”<sup>119</sup> Put simply, whereas COVID-19 patents in many

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113. Nevertheless, recent lawsuits suggest that patents may have played much less of a role than they otherwise might have because of infringement by key players in developing their COVID-19 vaccines. *See, e.g.*, Ian Lopez, *Covid Vaccine ‘Windfall Profits’ Under Attack by Patent Holders*, BLOOMBERG L. (Aug. 17, 2022, 9:44 AM), <https://news.bloomberglaw.com/health-law-and-business/covid-vaccine-windfall-profits-under-attack-by-patent-holders> (“At least seven lawsuits have been launched against makers of mRNA COVID-19 vaccine.”).

114. *See* Allison Durkin, Patricia Anne Sta Maria, Brandon Willmore & Amy Kapczynski, *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 HEALTH HUM. RTS. J. 129, 130 (2021).

115. *About Us*, OPEN COVID PLEDGE, <https://opencovidpledge.org/about/> (last visited Apr. 1, 2023).

116. *See, e.g.*, Scott Berinato, *Moderna v. Pfizer: What the Patent Infringement Suit Means for Biotech*, HARV. BUS. REV. (Sept. 16, 2022), <https://hbr.org/2022/09/moderna-v-pfizer-what-the-patent-infringement-suit-means-for-biotech>; Warren Woessner, *Moderna to Pfizer: “The Pandemic Is Over,”* NAT’L L. REV. (Sept. 6, 2022), <https://www.natlawreview.com/article/moderna-to-pfizer-pandemic-over>.

117. Ginevra Assia Antonelli, Maria Isabella Leone & Riccardo Ricci, *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 MGMT. 255, 256 (2021).

118. *Frequently Asked Questions*, OPEN COVID PLEDGE, <https://opencovidpledge.org/faqs/> (last visited Apr. 1, 2023). Indeed, the website’s answer to the FAQ, “Is the pledgor required to supply licensees with any materials?” is that the Pledge “does not require the pledgor to provide materials, cell lines, prototypes, designs, plans, data, trial results, software or anything else to a licensee.” *Id.*

119. Richard Li-dar Wang, Chung-Lun Shen, Tung-Che Wu & Wesley Wei-Wen Hsiao, *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 1425, 1425 (2021). “Confidential pending patents” are generally considered trade secrets. *See* Catherine Lui, *The Interplay of Patents and Trade*

instances have been restricted by patent-holder pledges from posing a risk of enforcement, COVID-19 trade secrets almost completely remain under lockdown, treated the same as the famous Coca-Cola formula—intellectual property whose sharing is decided solely by the owner, based upon the owner’s assessments and interests (unless governments induce the owner to act otherwise).

Trade secrets are causing bottlenecks throughout the effort to provide vaccines to the world.<sup>120</sup> Even with access to patents that cover vaccine IP, trade secrets may block the best way for the patented inventions to be implemented. As explained by several scholars who modeled an open trade secret pledge after the Open COVID Pledge:

The [Open COVID] pledgers, however, have not committed to transfer those technologies to the implementers. They may not be willing to teach the implementers how the technology works, or how to make the product. . . . [A]s a result, the implementers still need to develop or learn how to use these patented or patent pending technologies on their own.<sup>121</sup>

The authors go on to note that “unpatented know-hows, such as production methods or skills,” face similar challenges.<sup>122</sup> These are all problems that derive from lack of access to trade secrets, and 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 explain the six-step “method required to make the mRNA vaccines currently supplied by Moderna and Pfizer-BioNTech”<sup>123</sup>:

- *Step 1*: using an appropriate bacterial culture, produce the precise DNA sequence that needs to be transcribed into mRNA.
- *Step 2*: in a bioreactor, using appropriate enzymes, produce the mRNA using the DNA from step 1.
- *Step 3*: produce lipids with positively charged groups on them. Producing these at scale is a complex step.

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*Secrets in Protecting IP*, JDSUPRA (Aug. 25, 2020), <https://www.jdsupra.com/legalnews/the-interplay-of-patents-and-trade-59895/> (“Because the USPTO keeps provisional patent applications confidential and does not publish them, if companies take other reasonable measures to keep the information confidential, the trade secrets contained within the provisional patent application should remain a trade secret . . . .”)

120. See Levine, *supra* note 14 (“Trade secrets . . . are everywhere in the battle to defeat Covid-19, from clinical data to pharmaceutical manufacturing processes.”); see also *MSF Position on the Scope and Duration of the TRIPS Waiver for COVID-19*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, <https://msfaccess.org/msf-position-scope-and-duration-trips-waiver-covid-19> (last visited Apr. 1, 2023) (“[R]egulatory information related to the manufacturing of the medical product . . . is not revealed and is treated as a trade secret, impeding the early entry of follow-on manufacturers for biotherapeutics, vaccines and other health technologies.”).

121. Wang et al., *supra* note 119.

122. *Id.*

123. Gurgula & Hull, *supra* note 21, at 1246.

- *Step 4* is the most complex step in the chain. It consists of combining the Step 2 mRNA and Step 3 lipids into lipid nanoparticles. This requires the production of a ‘. . . well-defined mix of solid nanoparticles with consistent mRNA encapsulation . . .’. This, in turn, requires a bespoke microfilter device that enables the manufacture of very precisely created nanoparticles. Such a device enables very precise mixing, flow rates, concentrations and temperature controls necessary to produce the end product.
- *Steps 5 and 6* consist in the fill and finish steps and distribution (in the case of the Pfizer-BioNTech vaccine, at very low temperatures) to the desired destinations.<sup>124</sup>

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.”<sup>125</sup>

Based on Gurgula and Hull’s description, there is a combination of traditional trade secrets (i.e., “equipment” and “method”), know-how (i.e., “steps required”), and show-how (i.e., “experience of the engineers controlling the process”) that combine to make this method almost impossible to replicate without access to the foregoing information. 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.<sup>126</sup> Thus, the need for sharing these collective trade secrets seems obvious, if the world is to more effectively address global shortages on a timely basis.

But manufacturing know-how is not the only concern, even if pharmaceutical manufacturing processes are known to be frequently treated as protected trade secrets.<sup>127</sup> Bottlenecks also arise when those production-process

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124. *Id.*

125. *Id.*

126. Tedros Adhanom Ghebreyesus, WHO Director-General, WHO, WHO Director-General’s Opening Remarks at the Media Briefing on COVID (Feb. 23, 2022), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-23-february-2022> (“Much of this inequity has been driven by the fact that globally, vaccine production is concentrated in a few mostly high-income countries. One of the most obvious lessons of the pandemic, therefore, is the urgent need to increase local production of vaccines, especially in low- and middle-income countries.”).

127. See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 533 (2014) (“[T]rade secrets have long been important to protecting manufacturing processes.”); see also Tara Nealey, Ronald M. Daignault & Yu Cai, *Trade Secrets in Life Science and Pharmaceutical Companies*, COLD SPRING HARBOR PERSPS. MED. 1, 3 (2015) (“Non-exclusive examples of trade secrets are . . . (perhaps most significantly for pharmaceutical and other biotech companies) manufacturing processes, formulas, and development research, including preclinical data.”). See generally *Invado Pharms., Inc. v. Forward Sci. Distrib. LLC*, No. 18 C 2515, 2018 WL 5013556 (N.D. Ill. Oct. 16, 2018) (granting plaintiffs’ injunction based on claimed trade secrets in manufacturing, distribution, and sales strategies).

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.”<sup>128</sup> 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.”<sup>129</sup>

Those “natural exclusivities” are arguably not natural but caused by specific policy choices. Over the past several years, there has been extensive lobbying in support of strengthening trade secret law, and thereby increasing power to control information flow. As previously mentioned, the DTSA created the first federal private cause of action for trade secret misappropriation, allowing trade secret plaintiffs direct access to federal courts.<sup>130</sup> This was no accident, as “[n]umerous large industrial, high-technology, and pharmaceutical and medical device firms,” including pharmaceutical companies Eli Lilly, Johnson & Johnson, and Pfizer, “promoted enactment of the DTSA” and “engaged in extensive lobbying efforts.”<sup>131</sup>

Despite the foregoing, trade secrets have received far less attention than patents in the COVID-19 policy debates. The issues raised and debated between WTO member states under the Waiver Proposal have largely focused on patents.<sup>132</sup> To date, public discussions around trade secrets in the COVID-19 context have mostly focused on “compulsory” trade secret sharing rather than on compensated, compulsory licensing.<sup>133</sup> As discussed in Part I, such compulsory sharing of trade secrets is rare in trade secret law, even though it should be considered among a range of options that are generally available for governments.<sup>134</sup>

In contrast, arguments about compelled sharing of trade secrets have given critics an easy target for rhetorical opposition. For example, the Geneva Network

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128. Gurgula & Hull, *supra* note 21, at 1247; *see also supra* Part I.

129. Orit Fischman-Afori, et al., *supra* note 24, at 13.

130. *See supra* Part I.

131. Sharon K. Sandeen & Christopher B. Seaman, *Toward a Federal Jurisprudence of Trade Secret Law*, 32 BERKELEY TECH. L.J. 829, 855 (2017).

132. *See infra* Part IV; *see also* Council for Trade-Related Aspects of Intellectual Property Rights, *Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities*, WTO Doc. IP/C/W/666 (July 17, 2020) (raising questions about how to increase trade secret sharing in light of the pandemic and a lack of voluntary sharing by manufacturers); *Waiver Proposal*, *supra* note 7; Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19 – Responses to Questions*, WTO Doc. IP/C/W/672 (Jan. 15, 2021) (addressing claims that the current TRIPS Agreement and voluntary waivers were sufficient to address the pandemic).

133. *See* Parsa Erfani, Lawrence O. Gostin, & Vanessa KerryMay, *Beyond a Symbolic Gesture: What’s Needed To Turn the IP Waiver into COVID-19 Vaccines*, STAT (May 19, 2021), <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/> (arguing that WTO must implement an IP waiver and the sharing of intellectual property).

134. *See supra* Part I.



issued a report, funded in part by the “biopharma industry,”<sup>135</sup> arguing that the “TRIPS Waiver proposal would undermine innovation and collaboration, now and in the future. Its unprecedented proposal to allow countries to destroy trade secrets and require involuntary sharing of know-how would distract innovators from addressing this pandemic and chill future collaboration, investment, and innovation.”<sup>136</sup>

Similarly, George Mason University’s Center for Intellectual Property x Innovation Policy published a white paper by two law firm attorneys who asserted that the Waiver Proposal would

have important negative consequences for the protection of trade secrets, would significantly undermine the TRIPS disciplines on the matter, and would inject considerable uncertainty (as well as economic harm) for innovative industries which rely on such protection and to those who rely on those innovations, including for reasons of public health.<sup>137</sup>

At the same time, civil society groups like Public Citizen and Doctors Without Borders that might oppose such strong trade secrets protections simply lack the lobbying firepower and resources to take on the efforts of the biopharmaceutical industry to maintain or strengthen trade secret protections.<sup>138</sup> Doctors Without Borders urged support for the Waiver Proposal, calling it a “lifefaving move by India and South Africa to make sure human lives are prioritized and countries can tackle this pandemic by scaling up every COVID-19 medical tool that exists.”<sup>139</sup> But to the extent that resources are scarce and the analysis is complicated, there may be reticence to take on trade secrecy concerns when patents have built-in modes for disclosure.<sup>140</sup> Moreover, as Public Citizen has noted in arguing for a generic waiver of IP rights, there are significant

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135. MARK F. SCHULTZ, TRADE SECRECY AND COVID-19: HOW TRADE SECRETS AND OTHER IPRs UNDERPIN INNOVATION AND MANUFACTURING OF COVID-19 VACCINES 24 & n.1 (2021), <https://geneva-network.com/wp-content/uploads/2021/09/Trade-secrets-and-Covid-19-1.pdf>.

136. *Id.* at 23.

137. ERIC M. SOLOVY & DEEPAK RAJU, RECENT THREATS TO GLOBAL TRADE SECRET PROTECTION: WHY COMPULSORY LICENSING IS NOT (AND SHOULD NOT BE) A VIABLE LEGAL OPTION 2 (2021), <https://cip2.gmu.edu/wp-content/uploads/sites/31/2021/10/GMU-CIP2-Solovy-Raju-1021-WEB.pdf>.

138. Eduardo J. Gómez, *Civil Society in Global Health Policymaking: A Critical Review*, 14 *GLOBALIZATION & HEALTH* 73, 78 (2018) (“[D]ue to civil society’s comparatively weaker position within international health organizations, lack of financial resources and in some instances lack of access to policymakers, [non-governmental organizations] and activists very rarely influenced legislative design.”).

139. *India & South Africa Propose No Patents on COVID-19 Medicines & Tools During the Pandemic*, DRS. WITHOUT BORDERS (Oct. 7, 2020), <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/india-and-south-africa-propose-no-patents-covid-19-medicines-and-tools>.

140. *See infra* Part II.B; *see also* Felix Stein, Katerina Tagmatarchi Storeng & Antoine de Begny Puyvallée, *Global Health Nonsense*, *BMJ*, Dec. 2022, at 2 (“A final form of global health nonsense is to leave out relevant information, such as frank discussions of political and economic choices, challenges, and shortcomings. Leaders of high-income countries and public-private partnerships repeatedly insisted on the importance of multilateralism, the urgency of global vaccine equity, and the truism that ‘nobody is safe until everyone is safe.’ They often made such generic points instead of discussing concrete matters like vaccine hoarding; soaring prices for covid-19 diagnostics, treatments, and vaccines; the limits of intellectual property in pandemic times; how publicly funded public-private partnerships spend their budgets; or what exactly the public should expect in return for subsidizing the pharmaceutical industry in times of crisis.”).

challenges inherent in compulsory licensing of multiple forms of intellectual property rights: “Pharmaceutical firms have made it harder to effectively use compulsory licensing in any context by creating broader intellectual property ‘thickets’ of numerous patents, copyrights, trade secrets and industrial designs. Each type of these protections on COVID-19 technologies would require a license.”<sup>141</sup>

Still, while it is fair to say that the focus of international concern has been mostly on patent protection, 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.<sup>142</sup> This occurred after the World Health Organization (WHO) called for the creation of COVID-19 vaccine “technology transfer hubs,”<sup>143</sup> and after its later support of a South African consortium to establish the first COVID-19 mRNA vaccine technology transfer hub.<sup>144</sup>

The significance of this development, however, is the noted *lack* of trade secret sharing, and the resulting delays that have yet to be fully overcome. The South African hub was to include several pharmaceutical companies, including Afrigen, as well as universities and governments.<sup>145</sup> But in September 2021, Pfizer and Moderna declined to collaborate in development of the hub, forcing the consortium to develop the vaccine on its own.<sup>146</sup>

The decision not to collaborate was, of course, based on preserving trade secrets. While Moderna did declare it would not enforce any of its COVID-19 vaccine patents during the pandemic,<sup>147</sup> that didn’t address the problem of information sharing needed for production. As explained by Reuters in October 2021:

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141. *Waiver of the WTO’s Intellectual Property Rules: Existing TRIPS “Flexibilities” Unworkable for Necessary Scale Up of COVID-19 Medicines Production*, PUB. CITIZEN (Apr. 5, 2021), <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-existing-trips-flexibilities-unworkable-for-scale-up-of-covid-19-medicines-production>.

142. Wendell Roelf, *In World First, South Africa’s Afrigen Makes mRNA COVID Vaccine Using Moderna Data*, REUTERS (Feb. 3, 2022, 9:58 AM), <https://www.reuters.com/world/africa/world-first-safricas-afrigen-makes-mrna-covid-vaccine-using-moderna-data-2022-02-03/>.

143. *Call for Expression of Interest To: Contribute to the Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub*, WORLD HEALTH ORG. (Apr. 16, 2021), <https://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>. The WHO defined a technology transfer hub as “training facilities where the technology is established at industrial scale and clinical development performed.” *Id.*

144. *WHO Supporting South African Consortium To Establish First COVID mRNA Vaccine Technology Transfer Hub*, WORLD HEALTH ORG. (June 21, 2021), <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>.

145. *Id.*

146. Wendell Roelf, *WHO-Backed Vaccine Hub for Africa To Copy Moderna COVID-19 Shot*, REUTERS (Sept. 15, 2021, 11:13 PM), <https://www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14>.

147. *Moderna Will Not Enforce COVID-19 Vaccine Patents During Pandemic*, REUTERS (Oct. 8, 2021, 4:46 AM), <https://www.reuters.com/article/health-coronavirus-moderna/moderna-will-not-enforce-covid-19-vaccine-patents-during-pandemic-idUSL4N2GZ2D6>.

[I]t 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.<sup>148</sup>

Nonetheless, in November 2021, Afrigen began developing the first complete lab sample from Moderna's publicly available genetic sequence for the vaccine.<sup>149</sup> Unsurprisingly, the patent 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."<sup>150</sup> While most of the equipment and specialized ingredients have been disclosed, they "don't know some of the mixing times [and] 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<sup>151</sup> (regarding which Moderna itself has been accused of infringing Arbutus's and Genevant's patents).<sup>152</sup>

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.<sup>153</sup> 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."<sup>154</sup> Interestingly, Afrigen had help from unknown "outside advisers" in developing the vaccine.<sup>155</sup> And because it is an Afrigen vaccine rather than replicated production of Moderna's 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.<sup>156</sup> Meanwhile, Moderna announced it would work to build its own manufacturing and distribution facilities in Africa for its vaccines.<sup>157</sup> One can only speculate how much faster vaccines might have been distributed in

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148. *Id.*

149. *Id.*

150. Nurith Aizenman, *Moderna Won't Share Its Vaccine Recipe. WHO Has Hired an African Startup To Crack It*, NPR (Oct. 19, 2021, 6:27 PM), <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun>.

151. *Id.*

152. See, e.g., Amruta Khandekar, *Arbutus Files Patent Infringement Lawsuit Against Moderna Related to COVID Shot*, REUTERS (Feb. 28, 2022, 1:54 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/arbutus-files-patent-infringement-lawsuit-against-moderna-2022-02-28>.

153. Roelf, *supra* note 142.

154. *Id.*

155. Lesley Wroughton, *Frustrated by Vaccine Inequity, a South African Lab Rushes To Replicate Moderna's Shot*, THE WASH. POST (Nov. 28, 2021, 5:00 AM), <https://www.washingtonpost.com/world/2021/11/28/afrigen-south-africa-vaccine-moderna>.

156. Roelf, *supra* note 142.

157. Wroughton, *supra* note 155.

Africa, which in early 2022 had an 11% vaccination rate,<sup>158</sup> and at what cost, were the critical manufacturing trade secrets 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.

Thus, it is apparent that trade secrets remain a major bottleneck to rapid COVID-19 vaccine development, regulatory approval, production, and distribution. Refusing to share trade secrets and thereby requiring the replication of existing knowledge is not only a waste of resources, but also costs lives. As the next Subpart explains in more detail, there is only so much work that not enforcing patents can do to address this and, perhaps more importantly, future crises (including more lethal COVID-19 variants).

#### 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.<sup>159</sup> The U.S. patent statute itself requires that:

The specification shall contain a written description of the invention, and of the manner and process of making it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.<sup>160</sup>

Significantly, 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<sup>161</sup>) preferred claim embodiments or methods (“best modes”) 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*

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158. *Africa Needs To Ramp Up COVID-19 Vaccination Rate Six-Fold*, UNITED NATIONS (Feb. 3, 2022), <https://news.un.org/en/story/2022/02/1111202>. More recently, COVID-19 vaccine manufacturer BioNTech announced that it was sending six “mobile vaccine production units” to Rwanda. *BioNTech Mobile mRNA Vaccine Labs Reach Rwanda*, AFRICANEWS (Mar. 14, 2023), <https://www.africanews.com/2023/03/14/biontech-mobile-mrna-vaccine-labs-reach-rwanda/>.

159. *See, e.g.*, *Eldred v. Ashcroft*, 536 U.S. 186, 216 (2003) (defining invention disclosure as “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).

160. 35 U.S.C. § 112(a).

161. *See, e.g.*, *N. Telecom Ltd. v. Samsung Elec. Co.*, 215 F.3d 1281, 1286 (Fed. Cir. 2000).

unspecified range of embodiments within any given claim without “undue experimentation.”<sup>162</sup>

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. Patents are not required to disclose any trade secret know-how identified to develop commercial-scale manufacturing activities, which is normally developed long after the patent is filed. Similarly, most biopharmaceutical patents are filed well before clinical trial development, based on *in vitro* testing that shows the promise of potential therapeutic efficacy.<sup>163</sup> Thus, except when seeking particular dosage or method-of-use claims discovered before such clinical trials, biopharmaceutical patents will not normally disclose any trade secret clinical trial data.

Finally, the “best mode” requirement in patents is particularly important regarding development and production of biopharmaceuticals. This is because the ability to reproduce the claimed invention using a particular mode may be essential to achieving a similar effect or commercial regulatory approval of the pharmaceutical. Thus, biological deposits and access to them may be particularly important for such products, but may not be required if the “best mode” is only determined after the patent is filed (or otherwise is not required to be identified).<sup>164</sup>

Perhaps more importantly, inventors may discover a generic property, class of object, or method, and patent it so long as they meet both the enablement and written description requirements.<sup>165</sup> Thus, another barrier to trade secret sharing and access is created. The current articulation of the written description requirement requires objectively demonstrating in the specification that the applicant had a subjective mental “possession” of the claimed invention—in the sense of sufficient mental recognition of the full scope of species encompassed

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162. See *In re Wands*, 858 F.2d 731, 737–40 (Fed. Cir. 1988) (listing eight factors to consider in determining whether required experimentation is “undue”); cf. *Min. Separation, Ltd. v. Hyde*, 242 U.S. 261, 262 (1916) (“A patent for a process of ore concentration which, because of the varied character of the subject matter, necessarily requires preliminary tests by the user to apply it most successfully to the ores treated is not on that account invalid if the process is described in the claims with sufficient definiteness to guide those skilled in the art to a successful use of it.”); *Amgen, Inc. v. Sanofi*, 987 F.3d 1080, 1084 (Fed. Cir. 2021), *reh’g denied*, 850 F. Appx. 794 (Fed. Cir. 2021), *cert. granted*, No. 21-757 (Nov. 4, 2022).

163. See, e.g., *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

164. See, e.g., *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1211–12 (Fed. Cir. 1991) (setting forth that substance need not be reproduced exactly based on description); *Scripps Clinic & Rsch. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed. Cir. 1991) (same).

165. See, e.g., Peter Lee, *New and Heightened Public-Private Quid Pro Quos: Leveraging Public Support To Enhance Private Technical Disclosure*, in *INTELLECTUAL PROPERTY, COVID-19, AND THE NEXT PANDEMIC: DIAGNOSING PROBLEMS, DEVELOPING CURES* (Madhavi Sunder & Haochen Sun eds., Cambridge Univ. Press forthcoming 2023) (manuscript at 1), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4058717](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4058717) (“[T]his paradox – in which biopharmaceutical patentees have disclosed their inventions yet those disclosures do not enable technical artisans to effectively practice them – is highly problematic.”).

by any particular genus claim—at the time of filing the application.<sup>166</sup> Although generic (i.e., broad) claiming, particularly using functional claiming language (i.e., describing an invention based upon what it does), has become more difficult in regard to both the written description and enablement requirements,<sup>167</sup> generic claiming remains inherent in any claim given the potential for multiple forms of embodiment.

Thus, patent law doctrine generates further trade secret challenges in the context of fighting a rapidly evolving pandemic. First, generic claiming may make determination of the commercially most valuable (and thus protectable as a trade secret) embodiment or method of production *follow* rather than *precede* the patent’s disclosure of the invention, slowing down innovation. With generic claiming, even the most valuable (commercial) form of the invention need not be separately patented to exclude others from independently using that species for commercial activity. Additionally, generic claiming may hinder R&D activity intended to identify the most commercially valuable species within the scope of the generic claims, including prohibiting reverse engineering of any legally acquired commercial species. Moreover, the patent may also prevent any post-regulatory approval of manufacturing activity intended to scale up commercial production of such species, given the limited interpretation of the “experimental use” exception for research done with any commercial purpose and the limited interpretation of the regulatory approval (“Bolar”) exception to patent infringement liability and its restriction from research-tool uses.<sup>168</sup>

Furthermore, best mode has become nearly an afterthought in patent law practice and doctrine. Although the best mode is still required to be disclosed by patent applicants, in practice it may no longer be routinely included by

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166. *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349–51 (Fed. Cir. 2010) (en banc) (“[A]n adequate written description of a claimed genus requires more than a generic statement of an invention’s boundaries . . . . [A] sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus . . . the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” (citations omitted)).

167. *See, e.g., id.; Sanofi*, 987 F.3d at 1085–87 (“Amgen argues that the court erred by focusing on the effort required to discover and make every embodiment of the claims . . . while failing to recognize that Sanofi could not identify any antibody that cannot be made by following the specification’s teachings. . . . We agree with the district court’s finding that the specification here did not enable preparation of the full scope of these double-function claims without undue experimentation. . . . The binding limitation is itself enough here to require undue experimentation.” (citations omitted)); *Biogen Int’l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333, 1343 (Fed. Cir. 2021) (“The . . . [p]atent as issued, features multiple claims that are drawn exclusively to the specific DMF480 dose, but the specification’s focus on basic research and broad DMF-dosage ranges show that the inventors did not possess a therapeutically effective DMF480 dose at the time of filing in 2007.”), *reh’g denied*, 28 F.4th 1194 (Fed. Cir. 2022), *cert. denied*, No. 21-1567 (Oct. 3, 2022).

168. *See* 35 U.S.C. § 271(e)(1); *Merck KGaA v. Integra Lifescis. I, Ltd.*, 545 U.S. 193, 202–08 (2005); *Proveris Sci. Corp. v. Innovasys., Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008); *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–63 (Fed. Cir. 2002). *See generally* *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

applicants in their specifications. Under new legislation adopted in 2011,<sup>169</sup> the failure to disclose the best mode is not grounds for invalidating any granted claim once a patent issues.<sup>170</sup> Further, the U.S. Patent and Trademark Office does not typically inquire into whether an applicant has in fact disclosed the best mode for practicing each claim of a patent application.<sup>171</sup> Thus, patent applicants and their attorneys may be less careful about determining whether a best mode exists such as, for example, a best chemical input for a process. As a result, patent applicants can preserve that best mode as a commercially valuable trade secret, creating an enormous barrier to rapid scaling of production in a pandemic.

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

### III. COMPELLING TRADE SECRET SHARING COMPLIES WITH INTERNATIONAL TREATY LAW

To assess whether international treaty law prohibits or supports compelling trade secret sharing requires an understanding of a few basic principles. First, it is important to understand exactly what international treaty law prohibits or authorizes generally, before analyzing the legality of government measures compelling trade secrets sharing from one private entity to another under specific international treaties.<sup>172</sup> It is also important to distinguish the sharing of codified knowledge (including, for example, clinical trial data already in the government’s possession) from compelling companies to share uncoded know-how and show-how (such as by providing employees to train others). Furthermore, any government-compelled actions may either make the trade

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169. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 28 U.S.C. and 35 U.S.C.).

170. See 35 U.S.C. § 282(b)(3)(A) (“[T]he failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable . . .”).

171. See, e.g., USPTO, MPEP § 2165.04 (9th ed. Rev. 31, July 2022), <https://www.uspto.gov/web/offices/pac/mpep/s2165.html> (“In determining the adequacy of a best mode disclosure, only evidence of concealment (accidental or intentional) is to be considered. That evidence must tend to show that the quality of an applicant’s best mode disclosure is so poor as to effectively result in concealment.”).

172. Although trade secrets are protected in the United States by both the Federal Defend Trade Secrets Act and by state laws (often adopting the Uniform Trade Secrets Act), see *supra* notes 41–42 and accompanying text, they may similarly be protected by national or subnational jurisdictions of other countries. The international law analysis applies without regard to the source of the trade secret protections at the regional, national, or subnational level.

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 general public).<sup>173</sup> 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. Finally, 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, as discussed below in Part IV.A, existing national legal authorities may need to act by, for example, issuing orders compelling the sharing.<sup>174</sup>

Determining the relevant treaty principles is a complex but not insurmountable endeavor. As discussed in Subpart A, the WTO's TRIPS Agreement is the principal international treaty governing intellectual property. The TRIPS Agreement incorporates relevant provisions of the Paris Convention for the Protection of Industrial Property.<sup>175</sup> 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.<sup>176</sup> This is true even if trade secrets, unlike trademarks, are not viewed as property rights but only things warranting regulatory protection. Further, as a matter of interpretation, the obligations for trade secrets ("undisclosed information") apply only to protection against "unfair competition," defined as "disclos[ure] . . . or use[]" "contrary to honest commercial practices";<sup>177</sup> for "undisclosed test or other data," the provision applies only to protection against "unfair commercial use."<sup>178</sup> Although the nature of the prohibited acts has not been officially interpreted in any dispute resolution proceeding in the WTO,<sup>179</sup> it is unlikely that the TRIPS Agreement prohibits *government* decisions to compel sharing of such information for public

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173. See, e.g., Sandeen, *supra* note 77, at 662 ("[T]he acts of disclosures that are at issue in information law cases often involve the sharing of information between the information owner/holder and another that does not result in the public dissemination of the information, or, in trade secret parlance, that does not make the information 'generally known' among the public or within an industry.").

174. To the extent that contracts require such sharing of trade secrets, national legal authorities may not be needed. Governments may impose such technology sharing obligations through R&D, manufacturing, or purchasing contracts. In such cases, the failure of trade secret rights holders to share knowledge as contractually required may then be actionable by government or third-party litigation (where third parties have intended beneficiary rights under the contracts) and by consequent judicial orders.

175. TRIPS, *supra* note 3, art. 2.1 (incorporating articles 1 through 12 of the Paris Convention for purposes of obligations and enforcement).

176. *Id.* art. 21.

177. *Id.* art. 39.1–2. Paris Convention for the Protection of Industrial Property arts. 10bis(1)–(2), 10ter(1) Mar. 20, 1883, 828 U.N.T.S. 305 (effective July 7, 1884, amended June 2, 1934, and July 14, 1967) [hereinafter Paris Convention].

178. TRIPS, *supra* note 3, art. 39.3.

179. See, e.g., DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 549 & n.768 (5th ed. 2021).



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<sup>180</sup> may authorize national governments to compel trade secret sharing in a pandemic.<sup>181</sup> Specifically, article 73 provides that "nothing in this Agreement shall be construed: . . . to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations."<sup>182</sup> Similarly, potential residual authority to regulate—and thus to adopt limitations and exceptions to TRIPS obligations—also might authorize such actions. The WTO's international obligations and enforcement provisions, moreover, do not actually prevent countries from adopting measures that diverge from TRIPS treaty requirements. Rather, the WTO treaty structure only requires countries to come into prospective conformity with obligations, and, absent such conformity, authorizes compensation or trade retaliation ("suspension of concessions") to countries that bring successful claims of another country's failure to implement WTO treaty requirements.<sup>183</sup> In short, the TRIPS Agreement cannot and does not prohibit member countries from compelling trade secret sharing to address public health needs.

As discussed in Subpart B, the TRIPS Waiver Proposal would have suspended national obligations regarding trade secret TRIPS requirements, which would then have precluded any claims in the WTO *even if* the TRIPS Agreement were somehow thought to preclude compelled trade secret sharing. The Ministerial Decision that was adopted, however, does not address trade secrets directly, so Subpart A's discussion remains highly relevant (as it would for any non-COVID-19 pandemic or other health emergency).

Finally, as discussed in Subpart C, countries that compel trade secret sharing might be subject to investor-state treaty claims for compensation if adequate compensation for the loss of trade secrecy or for the compelled third-party uses were not already provided.<sup>184</sup> But adoption of the Ministerial Decision might nevertheless inform any interpretation of investor-state obligations to preclude compensation. Regardless of compensation, however, any such investor-state claims would not preclude countries from adopting the discussed measures, nor authorize any injunctive relief to prevent the trade secret sharing from being compelled.

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180. TRIPS, *supra* note 3, art. 73(b)(iii).

181. *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. 535, 546–47 (2020).

182. TRIPS, *supra* note 3, art. 73(b)(iii).

183. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 415 [hereinafter *Dispute Settlement Understanding*].

184. *See infra* notes 273–80 and accompanying text.

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.”<sup>185</sup> As the COVID-19 example has shown (and as discussed in regard to the Defense Production Act below),<sup>186</sup> however, governments (including the U.S. government) engage in industrial policy all the time, and have done so particularly in the context of pandemic responses.

1. *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,”<sup>187</sup> and undisclosed test or other data noted above against “unfair commercial use.”<sup>188</sup> Unlike with trademarks,<sup>189</sup> however, the TRIPS Agreement does not prohibit compulsory licensing (much less compelled sharing) of trade secrets or undisclosed data. And unlike for patents,<sup>190</sup> the TRIPS Agreement does not regulate compulsory licensing of trade secrets.

As a general rule, any interpretation of the TRIPS Agreement applies the interpretive principles of the Vienna Convention on the Law of Treaties, particularly articles 31 and 32.<sup>191</sup> Article 31 provides the “[g]eneral rule of interpretation”:

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185. *But see generally, e.g.,* ASIAN DEV. BANK, DEVELOPMENT AND MODERN INDUSTRIAL PRACTICE: ISSUES AND COUNTRY EXPERIENCES (Jesus Felipe ed., 2015).

186. *See infra* Part IV.A.

187. TRIPS, *supra* note 3, art. 39.1–2; *see* Paris Convention, *supra* note 177.

188. TRIPS, *supra* note 3, art. 39.3.

189. *Id.* art. 21.

190. *Id.* art. 31.

191. Vienna Convention on the Law of Treaties arts. 31–32, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT]; Dispute Settlement Understanding, *supra* note 183, art. 3.2 (“[P]rovisions of the covered agreements [are to be clarified] . . . in accordance with customary rules of interpretation of public international law.”); *see also, e.g.,* Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline*, 17, WTO Doc. WT/DS2/AB/R (adopted May 20, 1996) (“That general rule of interpretation [VCLT art. 31(1)] has attained the status of a rule of customary or general international law. As such, it forms part of the ‘customary rules of interpretation of public international law’ which the Appellate Body has been directed, by Article 3(2) of the DSU, to apply in seeking to clarify the provisions of the General Agreement and the other ‘covered agreements’ of the Marrakesh Agreement Establishing the World Trade Organization . . . .”); Susy Frankel,

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
  - (a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;
  - (b) any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
  - (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
  - (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
  - (c) any relevant rules of international law applicable in the relations between the parties.
4. A special meaning shall be given to a term if it is established that the parties so intended.<sup>192</sup>

Article 32 of the Vienna Convention provides for resort to “[s]upplementary means of interpretation” in limited circumstances:

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

- (a) leaves the meaning ambiguous or obscure; or
- (b) leads to a result which is manifestly absurd or unreasonable.<sup>193</sup>

Thus, 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.

That brings us to what the TRIPS Agreement actually prohibits as a textual matter, and in particular whether article 39 limits or prohibits *governments* from compelling the sharing or licensing of trade secrets without authorization by the trade secret owner. Significantly, for trade secrets in general (“undisclosed information”), the TRIPS Agreement requires *only* that they be protected against

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*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). 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. 275 (2010); 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).

192. VCLT, *supra* note 191, art. 31.

193. *Id.* art. 32.

disclosure, acquisition, or use by third parties “in a manner contrary to honest commercial practices.”<sup>194</sup> 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.”<sup>195</sup> 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 government action, much less any limitation on governments’ 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.” In contrast, and particularly where significant investments were made to develop the trade secrets, some may view the receipt and use by third parties of government-compelled, shared information (particularly if uncompensated) as “unfair” and “contrary to honest commercial practices.” We do not share that view, based on the text and structure of TRIPS.<sup>196</sup>

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. Because they overlap with traditional “canons of construction” and background understandings of international law regarding the nature of sovereignty and treaty-based limits on such sovereignty, they are addressed collectively in the next Subpart.

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194. TRIPS, *supra* note 3, art. 39.1–2.

195. *Id.* art. 39.2 n.10 (emphasis added).

196. We thank Professor Rochelle Dreyfuss for making this counterargument, even if we respectfully find it unconvincing. This is because governments inherently set the market conditions for what is considered “fair” commercial conduct. Additionally, we do not think that TRIPS (or the Paris Convention) sufficiently harmonized the minimal conditions for such regulation but instead left them to national discretion. Similarly, we find unconvincing the argument that there “must” be a limit that prevents the government from being able to compel the uncompensated sharing of *any* trade secret, and not just in a pandemic context. This is because the text of TRIPS and the interpretive canons discussed below suggest the absence (not the presence) of any limit on governmental authority in this regard, and because treaty interpreters are not supposed to impose limits on governments that were not agreed to and are not reflected in the treaty text. Nor do we think that treaty interpreters would or should impose their normative views to impose limits on government when the treaty text itself does not. Lastly, one might consider the analogue to nineteenth-century takings principles, which limited relief to physical possessory invasions and not economic value. See Steven A. Siegel, *Understanding the Nineteenth Century Contracts Clause: The Role of the Property-Privilege Distinction and “Takings” Clause Jurisprudence*, 60 S. CAL. L. REV. 1, 76–103 (1986). Indeed, states could sometimes modify state franchise contracts (even retrospectively) based upon the public’s needs. Thus, there is plenty of room to question whether there is anything inherently “unfair” about compelled trade secret sharing in the COVID-19 context.

2. *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 or Licensing.*

Starting with the text of the TRIPS Agreement, two standard structural interpretive principles apply. The first is the *expressio unius est exclusio alterius* canon of construction,<sup>197</sup> where a text having expressed something implies the exclusion of 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,<sup>198</sup> the TRIPS Agreement should be understood to impose *no* similar prohibition on compulsory licensing or compulsory sharing of trade secrets. Similarly, had the drafters intended to impose conditions on compulsory licensing of trade secrets, they would have imposed conditions such as those for patent compulsory licensing.<sup>199</sup> By expressing prohibitions and conditions elsewhere, the Agreement should be understood to impose no similar prohibitions or conditions where they are not mentioned.

The second relevant structural canon of construction is the rule of interpreting language to avoid redundancy or surplusage.<sup>200</sup> This canon establishes that the TRIPS drafters' failure to impose any prohibition on compulsory sharing or licensing of trade secrets cannot evidence an intent to make the obligation to protect trade secrets non-derogable in this regard. Otherwise, the prohibition against compulsory trademark licensing<sup>201</sup> would be unnecessary surplusage.<sup>202</sup>

Although there are alternative structural canons of construction that could be supplied to contradict the application of any particular canon,<sup>203</sup> there is no *compelling* reason to adopt alternative interpretations to those above. In contrast,

197. See generally, e.g., Richard Gardiner, *Between the Lines of the Vienna Convention? Canons and Other Principles of Interpretation in Public International Law*, 30 EUR. J. INT'L L. 1077 (2019) (book review) (discussing *expressio unius est exclusio alterius* canon); Sean D. Murphy, *The Utility and Limits of Canons of Construction in Public International Law*, in BETWEEN THE LINES OF THE VIENNA CONVENTION 4 (Joseph Klingler et al. eds., 2018) (“*Expressio unius est exclusio alterius* (the express statement of one is the exclusion of the other): when something is stated expressly in the treaty, any similar matter omitted from the treaty is presumed to have been omitted intentionally.”).

198. See TRIPS, *supra* note 3, art. 21.

199. See *id.* art. 31.

200. See generally, e.g., Murphy, *supra* note 197 (“*Ut res magis valeat quam pereat* (so that the matter may flourish rather than perish) (also known as ‘*effet utile*’): an interpreter should avoid reading the treaty in a manner that would render language in the treaty redundant, void or ineffective.”).

201. TRIPS, *supra* note 3, art. 21.

202. This is true even if the nature of the underlying TRIPS requirements to provide protection reflects different conceptual understandings of trademarks as property rights and trade secrets as requirements for government regulation. In either case, if expressing a requirement for the government to regulate in a particular fashion alone prevented any and all derogation, then there would be no need for a prohibition on any particular forms of derogation.

203. See, e.g., Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons About How Statutes Are To Be Construed*, 3 VAND. L. REV. 395, 401 (1950); Murphy, *supra* note 197, at 3.

Eric Solovy and Deepak Raju argue that the definition of such *commercial* practices is not exhaustive, without addressing the interpretive canons above or the additional interpretive canon *eiusdem generis* (that a general term is to be construed in light of the specific examples recited for its application). They further argue that the *absence* of any codified exceptions in article 39.3 (other than the public health exception) means that the TRIPS Agreement can *only* be interpreted under Vienna Convention principles as *prohibiting* compulsory licensing of trade secrets.<sup>204</sup> Courts and arbitral bodies applying the Vienna Convention, however, are reluctant to impose terms or conditions that treaty language does not itself supply.<sup>205</sup> 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.<sup>206</sup>

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204. See Eric M. Solovy & Deepak Raju, *Compulsory Licensing of Trade Secrets: Illegality Under International and Domestic Laws*, 55 INT’L L. 221, 228–35 (2022); *id.* at 230 (“Where a WTO obligation is unaccompanied by an exception, it would simply be impermissible for an adjudicator to create one. This is precisely what those advocating for compulsory licensing of trade secrets are attempting to do.”); *id.* at 232 (“[Article 39’s] examples, preceded by the phrase ‘shall mean at least[.]’ do not constitute a definition, and they are not exhaustive. They do provide relevant context for understanding that, if a WTO member’s government were to force disclosure of a trade secret—particularly if such disclosure was in breach of a contract . . . —a violation of Article 39.2 would result.”). This argument is simply unconvincing. So is their response to the argument by Gurgula and Hull that article 39’s “silence” on the issue implies national discretion rather than a prohibition on national conduct. *Id.* at 234 (“Finally, Gurgula and Hull claim that because ‘the TRIPS Agreement remains silent’ on compulsory licensing of undisclosed information, they can therefore deduce from that ‘silence’ that the ‘matter’ may be left for ‘national legislation. According to Gurgula and Hull, this silence implies that governments are permitted ‘to issue compulsory licensing of trade secrets when required, including for the protection of public health.’ If silences in the TRIPS Agreement were interpreted as providing exceptions, one could invent any number of exceptions and bring down the entire TRIPS Agreement with those exceptions.” (citing Gurgula & Hull, *supra* note 21, at 1251)). This response fails to recognize that *all* treaties are interpreted by reference to sovereign freedom except where the treaty expressly prohibits domestic action. Silence thus *does not* imply a prohibition, and in any event the public health exception explicitly repudiates one.

205. See, e.g., RICHARD K. GARDINER, TREATY INTERPRETATION 161 (2d ed. 2015); *cf.* Rights of Nationals of the United States of America in Morocco (France v. U.S.), Judgment, 1952 I.C.J. 199, 199 ¶ 3 (Aug. 27, 1952) (“The Court can not, by way of interpretation, derive from the Act a general rule as to full consular jurisdiction which it does not contain.”); *In re B (FC)* [2005] UKHL 19, [3 ¶ 9] (appeal taken from Eng.) (opinion of Lord Hope) (“There is no warrant in [Article 31] for reading into a treaty words that are not there. It is not open to a court, when it is performing its function, to expand the limits which the language of the treaty itself has set for it.”).

206. See, e.g., Anthony J. Bellia Jr. & Bradford R. Clark, *The International Law Origins of American Federalism*, 120 COLUM. L. REV. 835, 852, 854–55 (2020) (“Surrender or modification of sovereign rights was a momentous act and was not to be inferred from vague or ambiguous provisions. . . . To avoid such dangerous misunderstandings, the law of nations furnished a set of rules to govern the interpretation of documents alleged to alienate or divest sovereign rights. . . . [I]f one sovereign expressly surrendered its rights under the law of nations in clear and precise terms, the parties were expected to give effect to the natural meaning of those terms. On the other hand, if a provision was ambiguous or vague with respect to the alteration of a state’s sovereign rights, then the provision did not constitute a surrender of such rights.”); Thomas Cottier, *Industrial Property, International Protection*, in MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW ¶ 27 (2010) (“[The TRIPS Agreement] is best characterized by a model of multilayered governance where some, but not all, legal requirements are defined on the global level, while others are left to regional and national law. International law defines the policy spaces allocated to domestic law.”); *cf.*, e.g., 3 SHAMBIE SINGER, STATUTES AND STATUTORY

3. *The Drafting History Regarding Trade Secrets and Undisclosed Information Supports the View That the TRIPS Agreement Does Not Preclude Compelled Trade Secret Sharing.*

The lack of a textual prohibition on compelled trade secret sharing or compulsory trade secret licensing (as supported by structural inferences in the text) is also evident from the drafting history. Still, it is important to remember that Vienna Convention article 32 provides for resort to such materials *only* when interpretation under article 31 “leaves the meaning ambiguous or obscure[] or . . . leads to a result which is manifestly absurd or unreasonable”; neither of which applies here.<sup>207</sup> Thus, this Subpart is only offered to rebut possible counterarguments based on drafting intent, as the text, structure, and context of interpretation already provide a clear and unambiguous understanding.

During the drafting of TRIPS, the parties approached trade secret protection tentatively, incorporating the principles of the Paris Agreement, which were understood to retain significant flexibility for national approaches to protecting against what the parties viewed as improper “commercial” behaviors, and debating strenuously over the new and additional protections for pharmaceutical and agricultural data submitted to governments to obtain regulatory marketing approval.<sup>208</sup> Thus, 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.<sup>209</sup> This issue also recurs below in Subpart B, when discussing retained regulatory powers and implied power to adopt exemptions to explicit TRIPS requirements.

The context of the Paris Agreement and its interpretation was clearly relevant to what was negotiated in the relevant provisions of TRIPS. As Bodenhausen has noted:

What is to be understood by “competition” will be determined in each country according to its own concepts: countries may extend the notion of acts of unfair competition to acts which are not competitive in a narrow sense, that is,

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CONSTRUCTION § 62:1 (8th ed. 2020) (“[C]ourts strictly, or narrowly, construe statutes in derogation of sovereignty.”); Jefferson B. Fordham & J. Russell Leach, *Interpretation of Statutes in Derogation of the Common Law*, 3 VAND. L. REV. 438, 438 (1950) (“[A] statute in derogation of the common law is to be strictly construed.”). See generally Frederick Cowell, *Sovereignty and the Question of Derogation: An Analysis of Article 15 of the ECHR and the Absence of a Derogation Clause in the ACHPR*, 1 BIRBECK L. REV. 135 (2013).

207. VCLT, *supra* note 191, art. 32.

208. See G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967, at 144 (1968) (discussing Paris Convention article 10bis); see also GERVAIS, *supra* note 179, at 546–53. See generally Sharon K. Sandeen, *The Limits of Trade Secret Law: The Story of Article 39 of TRIPS and the Limited Scope of Trade Secret Protection in the United States*, in THE LAW AND THEORY OF TRADE SECRECY, A HANDBOOK OF CONTEMPORARY RESEARCH (Rochelle Dreyfuss & Katherine Strandburg eds., 2011).

209. See, e.g., Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶45, WTO Doc. WT/DS50/AB/R (Dec. 19, 1997) (stating that the principles of interpretation set out in article 31 of the Vienna Convention “neither require nor condone the imputation into a treaty of concepts that were not intended”).

within the same branch of industry or trade, but which unduly profit from a reputation established in another branch of industry or trade and thereby weaken such reputation. Any act of competition will have to be considered unfair if it is contrary to honest practices in industrial or commercial matters.<sup>210</sup>

Again, nothing here addresses actions by the government to regulate industrial and commercial matters, including mandated sharing of undisclosed information.

Rather, regulation of commercial activity by *government* action in protection of undisclosed information was specifically addressed *only* in TRIPS article 39.3, and then only for “pharmaceutical or . . . agricultural chemical products which utilize new chemical entities,” and only in regard to “the submission of undisclosed test or other data.”<sup>211</sup> Again, what is required by the governments to which such data has been supplied is protection against “unfair commercial use” of that information.<sup>212</sup> The subsequent sentence, moreover, expressly requires, “[i]n addition,” the protection of 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.”<sup>213</sup> The use of “[i]n addition” strongly suggests that the drafting parties understood that disclosure by a *government* was *not* included within the prohibition against “unfair commercial use” in the prior sentence. Thus, government *regulation* of information within a private company’s possession that compels private trade secret *sharing* from one company to another is not addressed at all, and article 39.3 restricts *disclosure by the government* of only certain kinds of data already in its possession. Even then, the government *may* disclose that information to commercial parties where needed to protect the public or where doing so will not result in “unfair” commercial use. Again, what is “unfair” in this context is unlikely to include anything that the government requires for public health.

Further, as Gervais has noted, it is wholly unclear from the negotiating history and subsequent interpretation of TRIPS that it requires *data exclusivity* under article 39.3 as a necessary form of protection against “unfair commercial use” of pharmaceutical or agricultural chemical data submitted to government authorities as part of regulatory approvals. To the extent that article 39.3 only requires data compensation, again it would impose no barrier to compelled trade secret sharing or compulsory licensing.<sup>214</sup>

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210. BODENHAUSEN, *supra* note 206.

211. TRIPS, *supra* note 3, art. 39.3. *Expressio unius* again suggests that the general provisions of article 39.2 do not reach any forms of government action.

212. *Id.*

213. *Id.*

214. *See, e.g.*, SHAMNAD BASHEER, PROTECTION OF REGULATORY DATA UNDER ARTICLE 39.3 OF TRIPS: THE INDIAN CONTEXT 20, 23 (Intell. Prop. Inst. 2007) (arguing that TRIPS article 39.3 does not require data exclusivity, but rather only requires “compensatory liability” for competitive use of previously submitted data for regulatory approvals of third-party products).



Moreover, the Doha Declaration on the TRIPS Agreement and Public Health<sup>215</sup> is a “subsequent agreement” for interpretation, which affirmed “that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” A group of countries thus took the view that data exclusivity is not required by TRIPS. This view was explicitly recognized by commentators such as Gervais:

In sum, one can safely conclude that the protection required goes beyond nondisclosure. Beyond that, whether it requires full “data exclusivity” is much less clear, especially in light of variegated state practice, positions articulated at the TRIPS Council, and the negotiating history. It seems safe to conclude that data exclusivity is one safe form of implementation of art. 39.3. There may, however, be other forms of protection meant to target unfair commercial use that would be considered to meet the obligations contained in art. 39.3. This assessment should be done on a case-by-case basis.<sup>216</sup>

In sum, the TRIPS Agreement does not expressly or impliedly prohibit the government from compelling trade secret sharing among private companies or from compelling third-party trade secret licensing. Nor does it impose any requirements that would be inconsistent with a government undertaking such actions. In fact, subsequent negotiation of “TRIPS-plus” provisions that require data exclusivity suggests that the TRIPS Agreement by itself does *not* require data exclusivity, even without regard to the provision authorizing the disclosure of submitted regulatory data for marketing approval “where necessary to protect the public.”<sup>217</sup>

Although bilateral or multilateral “TRIPS-plus” treaties may potentially add to TRIPS article 39.3 requirements by imposing data-exclusivity requirements for pharmaceutical and agricultural data,<sup>218</sup> such treaties typically do not prevent countries from taking regulatory actions to protect public

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215. World Trade Organization, Doha Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

216. GERVAIS, *supra* note 179, at 552; *see* WHO, DATA EXCLUSIVITY AND OTHER “TRIPS-PLUS” MEASURES 3 (2017), <https://apps.who.int/iris/bitstream/handle/10665/272979/Data-exclusivity.pdf?sequence=1&isAllowed=y> (“[L]egal and public health experts believe that TRIPS requires data protection, but not data exclusivity . . .”); *see also* BASHEER, *supra* note 214, at 8.

217. TRIPS, *supra* note 3, art. 39.3.

218. *See, e.g.*, Dominican Republic-Central America-United States Free Trade Agreement ch. 15, art. 15.10, Aug. 2, 2004, 119 Stat. 462, 43 I.L.M. 514 [hereinafter DR-CAFTA] (“Measures Related to Certain Regulated Products”); UNITED NATIONS SEC’Y-GEN.’S HIGH-LEVEL PANEL ON ACCESSIBILITY OF MEDS., REPORT OF THE UNITED NATIONS SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 19 (2016), <http://www.unsgaccessmeds.org/final-report> (“A number of provisions found in bilateral and regional FTAs exceed the minimum standards for intellectual property protection and enforcement required by the TRIPS Agreement. These provisions may impede access to health technologies, including those requiring governments to ease standards of patentability, drug regulatory authorities to link marketing approval to the absence of any claimed patent and *the requiring of test data exclusivity* instead of test data protection, to list a few.” (emphasis added)).

health.<sup>219</sup> And in any event, such TRIPS-plus agreements may lack any enforcement mechanisms other than the inherent risk of trade retaliation or war. Accordingly, the TRIPS Agreement simply does not prohibit countries from compelling trade secret sharing or trade secret licensing *to or among* private entities as a *regulatory* matter to protect public health, and it is unlikely that any TRIPS-plus data-exclusivity requirements do so as well.

#### 4. *The National Security Exception and Implied Authority To Adopt Regulatory Exceptions*

Even assuming that the TRIPS Agreement prohibits compelled trade secret sharing or licensing under article 39, article 73's national security exception provides 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: . . . to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations."<sup>220</sup> 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.<sup>221</sup> In contrast, one panel decision (that the complainant, Qatar, agreed not to seek adoption of by the Dispute Settlement Body) held such determinations justiciable, imposing an objective reasonableness test for invoking the security exception and requiring a plausible relationship to that emergency for the measures being challenged.<sup>222</sup>

Even if such a holding (which contradicts the position of the United States and other powerful nations that the national declaration of an emergency in international relations is not justiciable) were to extend in the future to the context of pandemic diseases, it is unlikely that a national declaration would be held objectively unreasonable, or that actions taken to address public health threats such as compulsory licensing of trade secrets would be found to be improper exercises of the exception.<sup>223</sup> Particularly because of the express

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219. See, e.g., DR-CAFTA, *supra* note 218, art. 15.10(d) ("For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public . . .").

220. TRIPS, *supra* note 3, art. 73(b)(iii).

221. Although the United States argued that the determination of necessity was nonjusticiable, a panel of the WTO's Dispute Settlement Understanding rejected that position but still "signal[led] substantial deference to the determination made by the invoking Member." Abbott & Reichman, *supra* note 181, at 547 n.58 (citing Panel Report, *Russia—Measures Concerning Traffic in Transit*, ¶¶ 7.51–52, 7.102–103, 7.131–139, WTO Doc. WT/DS512/R (Apr. 5, 2019)).

222. See Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights, Report of the Panel, WT/DS567/R, ¶¶ 7.242, 7.267, 7.285 (June 16, 2020); Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights, Communication from Qatar, WT/DS567/11 (Apr. 25, 2022).

223. See Susy Frankel, *COVID-19, Vaccines, and International Knowledge Governance on Trial*, 12 Q. MARY J. INTELL. PROP. 441, 457–61 (2022); Fred Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* 7–8 (S. Centre, Research Paper No. 116, 2020), <https://ssrn.com/abstract=3682260>. *But cf.* Rochelle Cooper Dreyfuss, *ISDS and Intellectual Property in 2020 - Protecting the Public*

“protect the public” language of article 39.3,<sup>224</sup> it is highly unlikely that the WHO would find members that compelled trade secret sharing to address public health needs to be in violation of their TRIPS obligations. But again, even if it did, this would not prohibit the members from legally imposing such measures; it would only authorize trade sanctions against the member or compensation for rights holders in response to the measures.

Further, the TRIPS Agreement is to be interpreted in light of its objectives and principles,<sup>225</sup> and with regard to the regulatory authority of states to protect public health.<sup>226</sup> As noted in an important WTO Appellate Body decision regarding a regulation that required tobacco trademark owners to use plain packaging, the exclusionary trademark rights in the TRIPS Agreement do not convey “positive” rights to use the trademark that are subject to regulatory control to protect public health. Rather, the TRIPS Agreement only conveys negative rights against third parties that make unfair commercial use of the same trademark.<sup>227</sup>

Similarly, nothing in the TRIPS Agreement treats as a “positive right” the required trade secret protection against unfair competition by third parties in article 39.2. Nor does TRIPS treat as a positive right the government’s obligation to protect from disclosure regulatory submission data for new chemical entities for pharmaceutical and agricultural products in article 39.3. Rather, governments retain the power and duty to regulate commercial activity to protect the public.

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*Health in the Age of Pandemics* 9–11 (NYU Sch. of L., Public Law Research Paper No. 22-05, 2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3966419](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3966419) (discussing international investment agreements that lack a security exception or limit it to military threats, and noting problems in asserting security exceptions in a pandemic context).

224. TRIPS, *supra* note 3, art. 39.3.

225. *Id.* arts. 7–8; *see, e.g.*, Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUSTON L. REV. 979, 997 (2009).

226. *See, e.g.*, Dr. Jan Yves Remy, *Lessons from the Appellate Body’s Parting Shot in the WTO Tobacco Plain Packaging Dispute*, SHRIDATH RAMPHAL CENTRE (June 12, 2020), <https://shridathramphalcentre.com/lessons-from-the-appellate-bodys-parting-shot-in-the-wto-tobacco-plain-packaging-dispute> (“[B]y upholding Australia’s right to regulate public health through its tobacco control measures, the Appellate Body elevated ‘health’ over ‘trade’ at a time when an unprecedented global pandemic is crippling the world economy.”). *See generally* Tamara Romero, *Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective* (S. Centre, Research Paper No. 18, 2020).

227. Appellate Body Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, ¶ 6.642, WTO Doc. WT/DS435/AB/R & WT/DS441/AB/R (June 9, 2020) (“In section 6.3.1 above, we have explained that Article 16.1 of the TRIPS Agreement, which addresses the rights conferred on an owner of a trademark, does not confer upon the owner a positive right to use its trademark, or a right to protect the distinctiveness of that trademark through use. Rather, Article 16.1 ‘provides for a *negative* right to prevent all third parties from using signs in certain circumstances.’ Likewise, nothing in the text of Article 20 indicates that ‘the use of a trademark in the course of trade’ is a positive right conferred on a trademark owner. Rather, the opening clause of Article 20 (‘[t]he use of a trademark in the course of trade . . .’) suggests that this provision regulated the imposition of special requirements in the factual scenario when there is a use of a trademark in the course of trade. The fact that Article 20 presupposes that the use of a trademark may be encumbered ‘justifiably’ further indicates that there is no positive right of use of a trademark by its owner, nor is there an obligation on Members to protect such a positive right.”).

This interpretation of article 39's obligations on member states as preserving states' right to regulate is consistent with the principles and objectives of the TRIPS Agreement. As article 8.1's "principles" explain: "Members may, in formulating or amending their laws and regulations, adopt measures *necessary to protect public health* and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."<sup>228</sup> As noted, regulatory measures to compel trade secret sharing are consistent with article 39, and may be "necessary to protect public health."<sup>229</sup>

Importantly, the TRIPS Agreement provides no express provision restricting trade secret exceptions and limitations to article 39 obligations. This stands in stark contrast to the article 13 and article 30 "three-step" tests for assessing exceptions or limitations to copyrights and patent rights.<sup>230</sup> Thus, even if article 39's interpretation were ambiguous about governments' regulatory authority to compel trade secret sharing, article 8.1, the *expressio unius* canon, and the presumption that states retain authority except where expressly prohibited would suggest reading TRIPS to permit unrestricted (reasonable) limitations or exceptions 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 intellectual property rights by right holders or the resort to practices which unreasonably restrain trade *or adversely affect the international transfer of technology*."<sup>231</sup> Government authority to compel the *international* sharing of trade secrets—including but not limited to trade secrets necessary for manufacturing, or submitted clinical trial and other data needed for foreign regulatory approvals—would similarly prevent such rights from adversely affecting international transfer of technology and would simultaneously address worldwide public health needs.

Article 66.2, moreover, *obligates* developed country members to provide incentives to private entities to foster technology transfer to least-developed country members: "Developed country Members *shall provide* incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."<sup>232</sup> Although private actions are voluntary under article 66.2, government creation of incentives for such private actions are not. Accordingly, failure to implement

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228. TRIPS, *supra* note 3, art. 8.1 (emphasis added).

229. *Id.* art. 39.3.

230. *Id.* arts. 13, 30. See generally Christophe Geiger, Daniel J. Gervais & Martin Senftleben, *The Three-Step-Test Revisited: How To Use the Test's Flexibility in National Copyright Law*, 29 AM. U. INT'L L. REV. 581 (2014).

231. TRIPS, *supra* note 3, art. 8.2 (emphasis added).

232. *Id.* art. 66.2 (emphasis added).

this domestic-law incentives requirement may be taken into account when considering what measures have become “necessary to protect public health” in developing countries. Where the failure to provide such incentives results in a lack of technology transfer for local R&D and manufacture of needed medical products, developed country members may be understood to have violated their TRIPS obligations. Conversely, compelled trade secret sharing by developed country members may be viewed as one such “incentive” in the strong form of a legal requirement.

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.<sup>233</sup> Article 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights “recognize[s] the right of everyone . . . [t]o enjoy the benefits of scientific progress and its applications.”<sup>234</sup> 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,<sup>235</sup> as well as the article 12(1) “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>236</sup> As noted in the UN Economic and Social Council Committee on Economic, Social and Cultural Rights, General Comment 25:

The term “benefits” refers first to the material results of the applications of scientific research, such as vaccinations, fertilizers, technological instruments and the like. Secondly, benefits refer to the scientific knowledge and information directly deriving from scientific activity, as science provides benefits through the development and dissemination of the knowledge itself. Lastly, benefits refer also to the role of science in forming critical and responsible citizens who are able to participate fully in a democratic society.<sup>237</sup>

Obviously, intellectual property withholding—such as the failure to share trade secret know-how and clinical data—may be in substantial tension with access to these “material results.” This is particularly likely if such withholding results in disease or death that prevents citizens from “participat[ing] fully” in

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233. 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) (“[R]egardless of whether human rights form part of *jus cogens*, they have primacy over all other treaties by virtue of their unique nature—their being the very standards of political legitimacy.”).

234. G.A. Res. 2200A (XXI), International Covenant on Economic, Social & Cultural Rights, art. 15(1)(b) (Dec. 16, 1966) [hereinafter ICESCR].

235. The ability to perform research or to manufacture needed products may also be invoked by this right, as well as by the correlative article 15(1)(c) “right to benefit from the protection of moral and material interests resulting from any scientific . . . production of which he or she is the author.” Economic and Social Council Res. 17, U.N. Doc. E/C.12/GC/17, art. 15 ¶ 1(c) (Jan. 12, 2006) (explaining the Committee on Economic Social and Cultural Rights’ (CESCR) thirty-fifth session in November 2005).

236. ICESCR, *supra* note 234, art. 12(1).

237. Economic & Social Council, Gen. Cmt. No. 25, U.N. Doc. E/C.12/GC/25, ¶ 8 (Apr. 30, 2020) (regarding the science and economic, social and cultural rights (citing ICESCR, *supra* note 234, art. 15(1)(b), (2)-(4))).

society. Thus, General Comment 25 states that “States should take appropriate measures to foster the positive effects of intellectual property on the right to participate in and to enjoy the benefits of scientific progress and its applications, while at the same time avoiding its possible negative effects.”<sup>238</sup>

In summary, the TRIPS Agreement (and other agreements) do not prohibit compelled trade secret sharing or compulsory trade secret licensing. Arguments to the contrary are simply misguided. Such arguments, moreover, are harmful in that they discourage countries from exercising their authority to compel such sharing to address worldwide pandemic technology-development, manufacturing, and regulatory-approval needs. The relevant questions are thus what domestic authorities exist to take such action (as addressed in Part IV), and whether governments have the political will to exercise those authorities. But before turning to those authorities, it is worth discussing both the pending TRIPS Waiver proposals and the potential for governments to face monetary liability under ISDS (also referred to as “bilateral investment treaties” or “international investment agreements” (“IIAs”)) regarding claims for compensation, in addition to any compensation that may be provided or required when governments compel such trade secret sharing or trade secret licenses.

## B. THE PROPOSAL FOR A TRIPS “WAIVER” AND THE ADOPTED MINISTERIAL DECISION

### 1. *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 Agreement.<sup>239</sup> 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 upon a determination that the “exceptional circumstances” justifying the waiver have ceased to exist.<sup>240</sup> The Waiver Proposal 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; it also would have applied to any enforcement obligations relating thereto in part III.<sup>241</sup>

Three important things are worth noting about the Waiver Proposal and its relationship to compelling trade secret sharing. First, although the Waiver

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238. *Id.* ¶ 62.

239. *Waiver Proposal*, *supra* note 7, ¶ 1.

240. *Id.* ¶¶ 4–5, annex ¶ 2.

241. *Id.* annex ¶ 1.

Proposal would have been self-executing at the WTO if it had been adopted, it would not by itself have overridden any national requirements that had transposed TRIPS obligations into domestic law (except in jurisdictions where international treaty obligations such as TRIPS are constitutionally treated as self-executing).<sup>242</sup> Similarly, the Waiver Proposal would not by itself have waived any “TRIPS-equivalent” or “TRIPS-plus” obligations imposed by regional or bilateral free-trade agreements, to the extent they do not contain sufficient flexibility to authorize national-law departures from such TRIPS obligations to address public health needs.<sup>243</sup> Nevertheless, adopting the Waiver Proposal at the international level would have further justified national-law determinations that exercising existing TRIPS-compliant authorities (such as the article 73 national security exception) are non-pretextual and warranted.<sup>244</sup> Similarly, the waiver proposal would have informed decisions of judicial authorities not to impose injunctive relief under domestic law in suits brought by rights holders against private parties or governments who used intellectual property without authorization to address COVID-19 public health needs.<sup>245</sup>

Second, unlike existing compulsory licensing authorities under TRIPS for patent rights, waiver of obligations would have relieved (as a matter of international treaty law, but not necessarily of domestic law) any potential obligation to pay compensation to rights holders whose rights have been waived during the Waiver’s operation.<sup>246</sup> Again, unless also modified, domestic law or TRIPS-plus agreements might still have required such compensation.

Third, and most importantly, once adopted at national levels, the provisions of the Waiver Proposal would have avoided the need for governments processing potentially multiple compulsory licenses in multiple jurisdictions to authorize third-party R&D, manufacturing, clinical trial data generation for regulatory submissions, and (possibly) regulatory approvals, thus avoiding substantial delays in vaccine production.<sup>247</sup> Any compensation that might have been awarded thus might have been provided *ex post* to uses, rather than requiring the grant of the compulsory licenses, and *ex ante* determination of the terms thereof, which would further expedite such activities.<sup>248</sup> As has been

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242. See, e.g., Srividhya Ragavan, *Waive IP Rights and Save Lives 2–3* (S. Centre, Working Paper No. 21-59, 2021) (discussing views of Professor Peter Yu).

243. See *supra* notes 217–19 and accompanying text.

244. See *supra* notes 217–19 and accompanying text.

245. See generally, e.g., Joshua D. Sarnoff, *TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection* (S. Centre, Research Paper No. 119, 2020).

246. *Waiver Proposal*, *supra* note 7, annex ¶ 1.

247. *Id.*

248. Of course, third parties or government actors might simply seek to use the relevant intellectual property without authorization on the assumption that courts would not issue injunctive relief in this emergency context given public interest concerns, and could similarly determine *ex post* any required compensation amounts. See, e.g., Sarnoff, *supra* note 245, at ii–iv. However, third parties might be less willing to risk making significant investments without greater assurances that they would not be subject to injunctive relief. Further, such discretion to refuse injunctive relief might not as clearly apply to customs and border control authorities, and

alleged in recent patent lawsuits seeking prospective, ex post compensation, both Moderna and Pfizer infringed third-party patent rights in order to expedite their development of COVID-19 vaccines, thereby avoiding voluntary or compulsory licensing.<sup>249</sup> Assuming the allegations are proven, the health benefits of such infringement to the world have been obvious.

Accordingly, the Authors supported the Waiver Proposal in principle, as a means to expedite the sharing of technology by expanding and authorizing worldwide R&D and manufacturing of needed medical products for the COVID-19 pandemic, and (even without its adoption) inducing rights holders to more widely license their technologies voluntarily and at lower costs to achieve similar results.<sup>250</sup> The Waiver Proposal would have been most relevant to assuring that *patent rights* would not deter or delay development of R&D and manufacturing for small molecule therapeutics and other products, such as diagnostics, medical devices, and PPE, for which the sharing of trade secret know-how may be less important. And as the United States recently noted regarding expanding the Ministerial Decision to cover diagnostics and therapeutics, countries should make use of the “full range of existing flexibilities in the TRIPS Agreement.”<sup>251</sup> As discussed extensively above in Part III.A, compelling trade secret sharing is one of those flexibilities.

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adopting a waiver would avoid litigation costs, which are not insignificant. *See, e.g.,* Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics To End the COVID-19 Pandemic* 23 (L. Soc’y Econ. Working Papers, Working Paper No. 06/2021, 2021) (“Given the problems of disclosure, transparency and overlapping patents outlined above, the benefit of a universal waiver of patents on COVID-19 vaccines and health technologies is that it would allow manufacturers freedom to operate without the risk of litigation or the fear that exported vaccines could be seized in transit and impounded for alleged patent infringement.”). Of course, third parties might prefer greater assurances ex ante about the amount of compensation they would owe to rights holders than obtained ex post from government administrative entities or judges. Even waiving rights while providing ex post compensation might prove inadequate to induce such third-party investments.

249. *See, e.g.,* Ian Lopez, *Covid Vaccine ‘Windfall Profits’ Under Attack by Patent Holders*, BLOOMBERG L. (Aug. 17, 2022, 9:44 AM), <https://news.bloomberglaw.com/health-law-and-business/covid-vaccine-windfall-profits-under-attack-by-patent-holders>; *supra* note 152 and accompanying text.

250. *Cf., e.g.,* Thambisetty et al., *supra* note 248, at 25 & n.153 (noting that even critics of the Waiver have acknowledged that the existence of the proposal has been effective in inducing voluntary licensing that would not otherwise have occurred, and that the Waiver Proposal also has promoted greater transparency in regard to vaccine manufacturing (citing Sven J.R. Bostyn, *Why a COVID IP Waiver Is Not a Good Strategy* (May 10, 2021) (unpublished manuscript), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3843327](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3843327); Erfani et al., *supra* note 133)).

251. *See* Press Release, Off. of U.S. Trade Rep., U.S. To Support Extension of Deadline on WTO TRIPS Ministerial Decision; Requests USITC Investigation To Provide More Data on COVID-19 Therapeutics and Diagnostics (Dec. 6, 2022), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/december/us-support-extension-deadline-wto-trips-ministerial-decision-requests-usitc-investigation-provide-0> (“The United States respects the right of its trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement, such as in Articles 30, 31, and 31*bis*, and the Doha Declaration on the TRIPS Agreement and Public Health, as well as the flexibilities in the Ministerial Decision. These existing flexibilities are available as part of the effort to scale up the production and distribution necessary to overcome the challenges of the ongoing COVID-19 pandemic.”).



## 2. *The TRIPS Ministerial Decision*

On June 17, 2022, the TRIPS Council adopted a Ministerial Decision on the TRIPS Agreement.<sup>252</sup> 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 regarding COVID-19 vaccine production. In particular, the Decision authorized such compulsory licensing of COVID-19 vaccine-related patents by administrative or judicial order (which could include “emergency orders”), even without compulsory licensing legislation in place.<sup>253</sup> Specifically, paragraphs 1 and 2 of the Decision provide:

1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter “the Agreement”) by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.
2. For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder’s consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the “law of a Member” referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.<sup>254</sup>

Significantly, a footnote clarifies that the “subject matter of a patent required for production and supply ‘includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.’”<sup>255</sup> Although the purpose of this footnote is not clear, it would seem to extend the scope of permitted compulsory licensing to address patents on upstream inputs and on manufacturing processes, as well as patents on vaccine products themselves. It would not, of course, authorize compulsory licensing of trade secrets that may be necessary to efficiently or effectively employ those upstream inputs or manufacturing processes. Nevertheless, the Decision makes clear—without changing any meaning of the TRIPS requirements—that governments may provide regulatory approval for vaccines produced under the Decision’s

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252. See Ministerial Decision, *supra* note 8.

253. *Id.* ¶ 2.

254. *Id.* ¶¶ 1–2.

255. *Id.* at n.2.

compulsory licenses—and thus such regulatory approval is not an “unfair commercial use.”<sup>256</sup>

The rest of the Decision largely tracks existing authority under article 31 and article 31*bis*. It makes clear that:

- prior negotiation of the compulsory licensee with the rights holder is not required<sup>257</sup> (which is already recognized in article 31(b) in a country-determined “case of a national emergency or other circumstance of extreme urgency”<sup>258</sup>);
- the Decision permits waiving the requirement of article 31(f) to limit compulsory licensing “predominantly to supply its domestic market” by permitting unlimited export to eligible members under the Decision,<sup>259</sup> thereby expanding and avoiding some of the requirements of prior notification and specification of amounts for compulsory licenses under article 31*bis* and its annex regarding supply of a “pharmaceutical product” for export;<sup>260</sup>
- such authorization comes with an “undertak[ing of] all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization,” so as to prevent parallel importation and retain price discrimination in developed country markets;<sup>261</sup> and
- the required “adequate remuneration” for any compulsory authorization can be based on medical emergency needs rather than “ordinary” market principles, to assure affordable access. Because the language is relevant to the next Subparts, it is repeated in full:

Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.<sup>262</sup>

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256. *Id.* ¶ 4; see TRIPS, *supra* note 3, art. 39.3 (“Members . . . shall protect [undisclosed test or other] data against unfair commercial use.”).

257. Ministerial Decision, *supra* note 8, ¶ 3(a).

258. TRIPS, *supra* note 3, art. 31(b). It is less clear that this supersedes TRIPS article 31(a)’s requirement for considering a compulsory authorization “on its individual merits,” and thus whether the reference to “emergency decrees” and “government use authorizations,” etc., can provide for general (nonspecific) authorization of any needed patent rights (particularly *ex ante*, with compensation to be worked out later). *Id.* art. 31(a).

259. Ministerial Decision, *supra* note 8, ¶ 3(b) (providing that “eligible members” are limited to “developing country Members” of the WTO, while “encourag[ing]” such members (as China) with manufacturing capacity not to use the Decision).

260. See TRIPS, *supra* note 3, art. 31*bis* ¶ 1, annex ¶ 2.

261. Ministerial Decision, *supra* note 8, ¶ 3(c).

262. *Id.* ¶ 3(d).

Although the Ministerial Decision is limited to patent rights, it reflects 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. There is little doubt that this provision, like the Doha Declaration of 2001,<sup>263</sup> should be considered “subsequent practice” under the Vienna Convention for interpreting the TRIPS Agreement’s obligations. How far beyond patents those principles extend has yet to be seen.

Nothing in the language of the Ministerial Declaration suggests that the flexibilities already provided under the TRIPS Agreement are to be constricted by its adoption, or by the fact that a broader Waiver Proposal was not adopted. Again, the background rule of interpretation is that absent agreement by treaty language, countries remain free to regulate as they see fit.<sup>264</sup> In fact, the Decision itself expressly provides that it should not be interpreted to constrict any existing TRIPS flexibilities that may exist.<sup>265</sup>

### 3. *Compensation Considerations*

As explained above, TRIPS *does not* require compensating trade secret holders for compulsory sharing of their trade secrets to enable broader R&D, clinical trials, regulatory approvals, manufacturing, and distribution for affordable access to address public health needs. Further, the Waiver Proposal and Ministerial Decision did not and do not specifically address the issue of trade secret compensation. The Waiver Proposal would have waived any need for compensation by eliminating any obligation to protect trade secrets; the Ministerial Decision retains requirements for compensating *patent holders* for compulsory licenses issued under its provisions and expressly preserves preexisting flexibilities. Further, many restricted and unrestricted government disclosures of trade secret information simply cannot be considered a taking of the trade secrecy justifying compensation when there are public interests to be served by such disclosure,<sup>266</sup> and particularly when information is submitted to the government pursuant to an understanding that public uses or disclosures of the information by the government may occur.<sup>267</sup>

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263. World Trade Organization, Ministerial Declaration of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 ILM 746 (adopted on Nov. 14, 2001).

264. Unlike interpretation of treaty language under *expressio unius*, the most that can be said from the comparison to the adoption of the Decision is that there was not a consensus to adopt the broader *additional* flexibilities for national law that the Waiver Proposal would have granted.

265. Ministerial Decision, *supra* note 8, ¶ 9 (“This Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b).”).

266. *See infra* note 269. *See generally* Christopher Morten, *Publicizing Corporate Secrets*, 171 U. PA. L. REV. (forthcoming 2023).

267. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005–06 (1984) (“Governmental action short of acquisition of title or occupancy has been held, if its effects are so complete as to deprive the owner of all or

Nevertheless, we think it is advisable to provide *reasonable* compensation—but not lost profits based on monopoly prices, nor unreasonably high royalties—to trade secret rights holders for the use of their intellectual property when expanding capacity and assuring affordable access.<sup>268</sup> Adoption of the Ministerial Decision, moreover, may also affect assessments of the need for and propriety of awarding compensation under ISDS in regard to addressing COVID-19 public health needs. After all, at least regarding patent rights, the Ministerial Decision expressly recognized that any required compensation for such compulsory licensing was to be based on pandemic pricing considerations, not on “normal” market returns. We turn next to the issue of compensation in the context of private rights against states should a country refuse to supply compensation directly or by requiring that compensation (*ex ante* or *ex post*) to be paid to the rights holder by a compulsory licensee.

### C. ISDS AND COMPENSATION OBLIGATIONS

As discussed in Parts I.B and II.C above, 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).<sup>269</sup> 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 claims without “exhausting” domestic law remedies.<sup>270</sup>

But even without such compensation, such as when exercising public interest exceptions to trade secrecy rights, so long as the exceptions predate the investments, no “taking” would occur and no compensation would be required. Even in jurisdictions where trade secrecy rights are based on property rather than tort concepts, “limits inherent in the IP regime of the host State . . . cannot, without more, amount to for example expropriation or unfair treatment.”<sup>271</sup>

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most of his interest in the subject matter, to amount to a taking. . . . A ‘reasonable investment-backed expectation’ must be more than a ‘unilateral expectation or an abstract need.’ . . . We find that with respect to any health, safety, and environmental data that Monsanto submitted to EPA after the effective date of the 1978 FIFRA amendments . . . Monsanto could not have had a reasonable, investment-backed expectation that EPA would keep the data confidential beyond the limits prescribed in the amended statute itself. Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.” (citations omitted).

268. This means *not* requiring compensating rights holders for uncertain profits at monopoly prices in future markets for as-yet undeveloped products, based on the rights holders’ desires to maximize future profits by hoarding trade secret knowledge and limiting competitive development with patent rights, for competitive and national trade advantages.

269. See *supra* notes 59–65, 76–89 and accompanying text.

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

271. 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.

Furthermore, even if no compensation is awarded under national law, and the trade secret's value is entirely destroyed, ISDS treaties "generally allow expropriation of foreign-held assets[] on the condition that the expropriation is for a public purpose, conducted in a non-discriminatory manner, in accordance with due process, and against compensation."<sup>272</sup> This should remain true even if the exceptions in domestic law were not previously been exercised, as the occasion for such exercise, such as differences of political judgment, should not engender "reasonable investment-backed expectations"<sup>273</sup> that the government would never exercise such exceptions.

In contrast to expropriation obligations, other obligations such as "fair and equitable treatment" ("FET") in such treaties are less well defined. They typically involve considerations such as

- (1) stability, predictability and the protection of legitimate expectations; (2) transparency; (3) due process and denial of justice; (4) legality and compliance with contractual obligations; (5) freedom from coercion and harassment; and (6) good faith, as well as protection against discrimination and arbitrariness.<sup>274</sup>

Thus, exercising existing authorities to compel trade secret sharing may trigger the filing by private entities of ISDS FET claims, even if they are unlikely to be successful.<sup>275</sup>

New legislation to provide more explicit authority to compel trade secret sharing that is adopted after such investments *may* be more likely to ground successful ISDS claims. This assumes that similar authority did not previously exist, that adequate compensation was not awarded, and that the investment was made prior to enactment of the relevant legislation.<sup>276</sup> But even then, ISDS treaties implicitly recognize the right to regulate to protect public health, even if adopted by new legislation:

IIAs and ISDS awards have explicitly recognized the State's right to regulate in the public interest, also referred to as the doctrine of "police powers." This right results from the customary international law limits which are commonly accepted to apply to investment protection (including when applied to IP rights), and is based on the notion of State sovereignty.

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Centre, Research Paper No. 144, 2022); *cf. Ruckelshaus*, 467 U.S. at 1011 n.15 ("If, however, a public disclosure of data . . . causes . . . a decline in the potential profits from sales of the product, that decline in profits stems from a decrease in the value of the [product] to consumers, rather than from the destruction of an edge the submitter had over its competitors, and cannot constitute the taking of a trade secret."). *See generally* Rochelle Cooper Dreyfuss & Susy Frankel, *Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?*, 21 VAND. J. ENT. & TECH. L. 377 (2020).

272. Grosse Ruse-Khan & Paddeu, *supra* note 271, at 21.

273. *Cf. Ruckelshaus*, 467 U.S. at 1006–07.

274. Grosse Ruse-Khan & Paddeu, *supra* note 271, at 23.

275. Exercising contractual conditions that have the same effect as exercising preexisting legal authorities similarly should not result in successful ISDS claims, as the investor had agreed to those terms.

276. *Cf. Grosse Ruse-Khan & Paddeu*, *supra* note 271, at 28–29.

. . . [T]here seems to be some convergence on the basic proposition that “[i]t is an accepted principle of customary international law that where economic injury results from a bona fide non-discriminatory regulation within the police power of the State, compensation is not required.”<sup>277</sup>

Further, any such ISDS claims may need to await the exercise of such compelled trade secret sharing authority to be asserted.

It is important to note that nothing in ISDS treaties provides grounds to prevent the adoption or exercise of domestic authorities to compel trade secret sharing. Rather, the sole remedies for a violation of ISDS treaty obligations involve compensation to investors.<sup>278</sup> ISDS arbitral panels are not authorized under such treaties to provide injunctive relief to prevent physical or indirect expropriations, given that such treaties do not waive governmental sovereign immunities. Accordingly, like any domestic “takings” compensation obligations for compelled trade secret sharing, ISDS obligations merely impose “take and pay” compensation obligations, and do not prohibit the “regulatory taking” in the first instance, particularly when done for such obvious public purposes as pandemic disease control.

Finally, as “any form of domestic suspension or additional limitation of intellectual property rights beyond existing TRIPS flexibilities could be perceived by investors as a significant change in the domestic IP system, such changes could trigger ISDS claims.”<sup>279</sup> The TRIPS Waiver provision as originally proposed thus might have triggered domestic law changes that, once authority to compel trade secret sharing under those domestic authorities had been exercised, would ground a successful ISDS claim.<sup>280</sup> This may have been particularly likely in light of apparent increasing willingness of arbitral panels to scrutinize domestic laws departing from international standards.<sup>281</sup> However, the international nature of the Waiver and its suspension of compensation obligations would have tended to undermine the force of such claims, particularly as waivers from TRIPS and other WTO obligations are part of the structure of the WTO<sup>282</sup> and thus form the international context for such investments in the first place. Similarly, although not specifically addressed to trade secrets and undisclosed information, adoption of the Ministerial Decision

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277. *Id.* at 25, 28 (citations omitted).

278. *Primer on International Investment Treaties and Investor-State Dispute Settlement*, COLUM. CTR. ON SUSTAINABLE INV., <https://ccsi.columbia.edu/content/primer-international-investment-treaties-and-investor-state-dispute-settlement> (last visited Apr. 1, 2023) (“ISDS tribunals . . . typically award monetary damages to investors . . .”).

279. Grosse Ruse-Khan & Paddeu, *supra* note 271, at 24.

280. *See, e.g.*, Cynthia Ho, *Potential Claims Related to IP and Public Health in Investment Agreements: COVID-19, the TRIPS Waiver, and Beyond* 3 (S. Centre, Policy Brief No. 24, 2021).

281. *See, e.g.*, Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOY. U. CHI. L.J. 479, 501–05 (2017).

282. *See, e.g.*, *Waiver Proposal*, *supra* note 7 (requesting the Council for Trade-Related Aspects of Intellectual Property Rights to recommend the waiver to the WTO General Council).

may similarly color the background of any ISDS challenge to the exercise of domestic authority to compel trade secret sharing when addressing pandemic diseases.

#### IV. NATIONAL ROUTES FOR EXPANDING ACCESS TO TRADE SECRETS

The purpose of the following examples of U.S. and other governments' authorities for mandating compelled trade secret sharing is not to provide an exhaustive list of current authorities. Instead, the point is to make clear that 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 to assure needed R&D, regulatory approvals, and manufacturing. Such authority has been used routinely in the past in those circumstances, without any concern for destroying 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.<sup>283</sup>

##### A. EXISTING MECHANISMS UNDER U.S. AND EU LAW

Numerous mechanisms exist under U.S. and European laws to compel trade secret sharing, which have been used during the COVID-19 pandemic and could be used to address other health emergencies as well. These include: (1) the U.S. Defense Production Act,<sup>284</sup> 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"<sup>285</sup>; (2) antitrust authorities; (3) public health powers; and (4) state law authorities. This list is not exclusive, as other powers (including more general emergency powers<sup>286</sup>) may also provide such authority. We discuss these four categories of power to demonstrate that broad authority to compel trade secret sharing already exists, and to reiterate that its use only requires political will.

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283. See Morten, *supra* note 266, at 35–71 (discussing how agencies can create "bounded gardens" of information access or can publicly disclose trade secrets in public agency possession based on public interests, and why agency enabling acts; the Federal Trade Secrets Act, 18 U.S.C. § 1905; and the Fifth Amendment Takings Clause, U.S. CONST. amend. V, normally will not pose any restriction to doing so).

284. See *supra* note 9.

285. Sydney Lupkin, *Defense Production Act Speeds Up Vaccine Production*, NPR (Mar. 13, 2021, 7:00 AM), <https://www.npr.org/sections/health-shots/2021/03/13/976531488/defense-production-act-speeds-up-vaccine-production> (quoting President Joe Biden).

286. See generally *A Guide to Emergency Powers and Their Use*, BRENNAN CTR. FOR JUST., <https://www.brennancenter.org/our-work/research-reports/guide-emergency-powers-and-their-use> (Sept. 4, 2019).

### 1. *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.<sup>287</sup> Given the “war” analogy of the fight against COVID-19,<sup>288</sup> it should be no surprise that people looked to “war powers” to see if there were ways to spur or force rapid production.<sup>289</sup>

Attention quickly turned to the Defense Production Act.<sup>290</sup> Under the DPA, the President can prepare for and respond to “natural or man-caused disasters” by expanding domestic production as needed such as by prioritizing private contracts and requiring the performance of government contracts by private industry.<sup>291</sup> 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.”<sup>292</sup>

The DPA defines “services,” “industrial resource,” “critical technology,” and “critical technology item” in ways that seem to encompass vaccine production.<sup>293</sup> 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.<sup>294</sup> Because the President “is authorized under the DPA to create, maintain, protect,

287. See, e.g., Dalindybo 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, 8:34 AM), <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>.

288. *Is Fighting a Pandemic Like Fighting a War?*, BBC NEWS (Mar. 14, 2021), <https://www.bbc.com/news/world-us-canada-56324047>. But see Alissa Wilkinson, *Pandemics Are Not Wars*, VOX (Apr. 15, 2020, 8:10 AM), <https://www.vox.com/culture/2020/4/15/21193679/coronavirus-pandemic-war-metaphor-ecology-microbiome>.

289. See, e.g., *President Trump Invokes Defense Production Act To Support COVID-19 Response*, H. COMM. ON ENERGY & COM. (Aug. 24, 2020), <https://republicans-energycommerce.house.gov/news/blog/president-trump-invokes-defense-production-act-to-support-covid-19-response/> [hereinafter *President Trump Invokes DPA*] (“The Trump administration implemented DPA agreements more than a dozen times to increase ventilator supplies through repurposing manufacturing plants and mobilizing General Motors, Philips, and several other companies to rapidly produce ventilators to meet patient needs.”); *supra* note 282 and accompanying text.

290. Defense Production Act of 1950, ch. 932, 64 Stat. 798 (codified as amended in scattered sections of 50 U.S.C.).

291. 50 U.S.C. §§ 4502(a), 4511(a).

292. *Id.* § 4502(a).

293. *Id.* § 4552(3)–(4), (12), (16)(A)–(D).

294. See, e.g., Shayan Karbassi, *Understanding Biden’s Invocation of the Defense Production Act*, LAWFARE (Mar. 4, 2021, 8:01 AM), <https://www.lawfareblog.com/understanding-bidens-invocation-defense-production-act/>; *President Trump Invokes DPA*, *supra* note 289; Gavin Bade, *Despite Expanded DPA, Confusion Reigns over Coronavirus Industrial Response*, POLITICO (Apr. 3, 2020, 6:12 PM), <https://www.politico.com/news/2020/04/03/trump-dpa-medical-goods-164036>; Yelena Dzhanova, *Trump Compelled These Companies To Make Critical Supplies, but Most of Them Were Already Doing It*, CNBC (Apr. 3, 2020, 1:21 PM), <https://www.cnbc.com/2020/04/03/coronavirus-trump-used-defense-production-act-on-these-companies-so-far.html>.



and expand the domestic industrial base essential for the national defense,”<sup>295</sup> the Act appears to contemplate managing information like trade secrets in the national interest. 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.”<sup>296</sup> Accordingly, allocating the knowledge and processes required for vaccine production falls within the President’s ambit under the DPA. Importantly, the DPA authorizes the President to

obtain such information from, . . . make such inspection of the books, records, and other writings, premises or property of, and take the sworn testimony of, and administer oaths and affirmations to, any person as may be necessary or appropriate, in his discretion, to the enforcement or the administration of this chapter and the regulations or orders issued thereunder.<sup>297</sup>

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.”<sup>298</sup> Again, the DPA seems to explicitly authorize emergency disclosure of trade secrets.

The DPA also generally allows the President to prioritize contracts. As explained by the Congressional Research Service:

The *priority* performance authority allows the federal government to ensure the timely availability of critical materials, equipment, and services produced in the private market in the interest of national defense, and to receive those materials, equipment, and services through contracts before any other competing interest. Under the language of the DPA, a *person* (including corporations, as defined in statute) is required to accept prioritized contracts/orders . . . .<sup>299</sup>

Thus, 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. For example, one group of scholars has asserted that under “the plain text of the DPA, the president can mandate the sharing of know-how from US-based pharmaceutical companies to support the national defense need of global vaccination.”<sup>300</sup> Because “know-how” is at the center of the trade secrets at issue, this authority

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295. 50 U.S.C. § 4533(a)(1).

296. *Id.* § 4511(a)(2).

297. *Id.* § 4555(a).

298. *Id.* § 4555(d).

299. CONG. RSCH. SERV., R43767, THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS 6 (2020).

300. Zain Rizvi, Jishian Ravinthiran & Amy Kapeczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act To End the Pandemic Worldwide*, HEALTH AFFS. FOREFRONT (Aug. 6, 2021, 11:11 PM), <https://www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/full/>.

grants power that can challenge the dominance of trade secrecy as an information-control mechanism.

The DPA loomed large in a deal between Johnson & Johnson and Merck. The arrangement, announced in March 2021, requires that Merck “dedicate two facilities to Johnson & Johnson’s” COVID-19 vaccine.<sup>301</sup> The Washington Post explained at the time that President Biden was “wielding the powers of the [DPA], a Korean War-era law, to give Merck priority in securing equipment it will need to upgrade its facilities for vaccine production, including the purchase of machinery, bags, tubing and filtration systems.”<sup>302</sup> Johnson & Johnson said in a statement that “the collaboration with Merck will enhance our production capacity so that we can supply beyond our current commitments.”<sup>303</sup>

While the White House gave credit to the companies for working together, noting that they “stepped up as good, corporate citizens with the spirit of cooperation that the President has called for during this crisis,”<sup>304</sup> other analyses heavily credited the DPA for getting the parties to that point. As one commentator explained:

The deal requires precisely the kind of knowledge sharing that activists and advocacy groups have been calling for with respect to manufacturers at home and abroad in order to scale up global vaccine production. Though the US government said that the deal was voluntary, it is unconventional for rivals to cooperate like this. A senior administration official told the press that the shadow of the Defense Production Act played a role, since the US knew that they could mandate the cooperation if the companies did not agree.<sup>305</sup>

In sum, because the COVID-19 vaccine addressed an emergency that the DPA contemplated, the President could use the DPA to compel disclosure of the trade secrets required to manufacture the COVID-19 vaccine. The same will be true for any future pandemic, or for any other similar type of emergency affecting national security, such as climate change.

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301. Christopher Rowland & Laurie McGinley, *Merck Will Help Make Johnson & Johnson Coronavirus Vaccine as Rivals Team Up To Help Biden Accelerate Shots*, THE WASH. POST (Mar. 3, 2021, 1:49 PM), <https://www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/>.

302. *Id.*

303. Berkeley Lovelace Jr., *Biden Says Merck Will Help Make Johnson & Johnson’s Covid Vaccine*, CNBC (Mar. 2, 2021, 8:46 AM), <https://www.cnbc.com/2021/03/02/covid-vaccine-biden-to-announce-merck-will-help-make-johnson-johnsons-shot.html>.

304. Press Release, White House, Press Briefing by White House COVID-19 Response Team and Public Health Officials (Mar. 3, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/03/03/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-10/>.

305. Amy Kapczynski & Jishian Ravinthiran, *How To Vaccinate the World, Part 2*, LPE PROJECT (May 5, 2021), <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/>. Of course, use of the DPA may not be an unalloyed worldwide good, given that the United States may have prioritized vaccine input supplies to the detriment of producers in other countries. See, e.g., Thomas J. Bollyky & Chad P. Bown, *The Real Vaccine Procurement Problem: Why America Should Make Its Supply Chain More Transparent*, FOREIGN AFFS. (June 24, 2021), <https://www.foreignaffairs.com/united-states/real-vaccine-procurement-problem> (“[O]ne unintended consequence of ordering suppliers of specialized inputs to prioritize contracts with companies manufacturing vaccines in the United States has been to fuel popular belief, especially abroad, that the DPA is being used to halt exports of these inputs to other countries that desperately need them.”).

## 2. 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 in order 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.*,<sup>306</sup> the defendants were held to have violated section 1 of the Sherman Act<sup>307</sup> 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.<sup>308</sup> The judicially ordered remedial decree required that third parties have the ability to license manufacturing know-how (“methods and processes”).<sup>309</sup> 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.<sup>310</sup>

More recently, the U.S. 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<sup>311</sup> following a series of mergers in the paper-copier market.<sup>312</sup>

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.<sup>313</sup> For example, the FTC ordered Baxter International, Inc. to divest an inhibitor treatment line when seeking approval to acquire Immuno International AG.<sup>314</sup> As part of that order, Baxter was also required to license Immuno’s fibrin sealant to a government-approved licensee, to provide all information related to an FDA application, to continue the application with the FDA, and even to produce fibrin sealant for the

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306. 63 F. Supp. 513 (S.D.N.Y. 1945), *aff’d*, 332 U.S. 319 (1947).

307. 15 U.S.C. § 1.

308. *Nat’l Lead Co.*, 63 F. Supp. at 523; *see id.* at 518, 527, 532 (“[I]t was their intention that the advance in the art, accelerated by the exchange of patents, patent applications and ‘know-how,’ should as far as possible remain the private prize of the parties, and constitute their shield and weapon against outsiders. . . . Agreements creating a world-wide patent pool of all present and future patents of the parties, covering an entire industry, and embracing a division of the world into exclusive territories within which each of the parties is to confine its business activities, with respect to patent protected commodities, as well as unpatented, for the purpose and with the effect of suppressing imports into and exports from the United States, are unlawful under the Sherman Act; they constitute an unreasonable restraint of trade. . . . The exchange of know-how between NL and DP was abandoned in 1940 when, as DP says, the industry matured. The exchange of patents and patent applications continues.”).

309. *Id.* at 534.

310. *See id.*

311. *See* 15 U.S.C. § 45.

312. *See generally* Xerox Corp., 86 F.T.C. 364 (1975).

313. 15 U.S.C. § 18a.

314. *See generally* Baxter Int’l Inc., 123 F.T.C. 904 (1997).

licensee for a period after approval.<sup>315</sup> The FTC also ordered Ciba-Geigy and Sandoz, when merging to form Novartis, to divest Sandoz's herbicide business to BASF and to grant a nonexclusive license to Rhone Poulenc Rorer to use and sell gene therapies under Sandoz's patent rights.<sup>316</sup> That license included a right for RPR to obtain technical information, know-how, or material owned or controlled by Novartis, as well as technical assistance and training.<sup>317</sup>

In the same vein, European antitrust decrees have ordered mandatory data sharing in the information technology sector. Several legal decisions established precedent for data-sharing remedies, including *Magill* in 1995, *IMS* in 2004, and *Microsoft* in 2007.<sup>318</sup> Moreover, the European Union is poised to mandate such data sharing more generally in the Data Governance Act.<sup>319</sup>

It is only in the biopharmaceutical sector that such mandatory data and know-how sharing has somehow been considered exceptional or unacceptable. But that is changing. Even the U.S. National Institutes of Health ("NIH") now requires funded researchers and institutions to provide plans to implement data sharing that is as publicly available as possible within a reasonable timeframe.<sup>320</sup>

### 3. Federal Public Health Regulatory Authorities

Section 3(c)(1)(F) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which was discussed in *Ruckelshaus v. Monsanto Co.*,<sup>321</sup> currently requires ten-year data exclusivity for new chemical entities (and applications relating solely to new uses) before the EPA can rely on them to approve competing products.<sup>322</sup> In other cases, the 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.<sup>323</sup> Under current federal drug and biologics laws, new, active moiety pharmaceutical products may be provided with "market exclusivity rights" for differing time

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315. *See id.* at 921.

316. *See generally* Ciba-Geigy Ltd., 123 F.T.C. 842 (1997).

317. *See id.* at 864.

318. Thibault Schrepel, *Alternatives to Data Sharing*, THE REGUL. REV. (Feb. 21, 2022), <https://www.theregreview.org/2022/02/21/schrepel-alternatives-data-sharing/>. *See generally* Landgericht [LG] [General Court] Apr. 29, 2004, 4 CMLR 28 (2008) (Ger.); Case T-201/04, *Microsoft Corp. v. Comm'n of the Eur. Cmty.*, 2007 E.C.R. II-3619; *Proposal for a Regulation of the European Parliament and of the Council on European Data Governance (Data Governance Act)*, COM (2020) 767 final (Nov. 25, 2020); *Moving Towards a European Data Space: New EU Law for Data-Sharing*, EUR. COMM'N (Jan. 7, 2022), <https://data.europa.eu/en/news/moving-towards-european-data-space-new-eu-law-data-sharing>.

319. *European Data Governance Act*, EUR. COMM'N, <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act> (last visited Apr. 1, 2023).

320. *See* Final NIH Policy for Data Management and Sharing and Supplemental Information, 85 Fed. Reg. 68890, 68891 (Oct. 30, 2020).

321. 467 U.S. 986 (1984).

322. 7 U.S.C. § 136a(c)(1)(F)(i).

323. *See id.* § 136a(c)(1)(F)(iii).

periods.<sup>324</sup> 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 without legal authorization for trade secret information in the government's possession.<sup>325</sup> These market exclusivity protections are additional to any patent rights, and there are complex provisions regarding regulatory approval linkage to such patent rights.<sup>326</sup>

To the extent that the market exclusivity provisions have expired, however, the *Ruckelshaus* case may suggest that the government is authorized to share or disclose to the public any trade secrets contained in the data. Nevertheless, 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.<sup>327</sup> 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.<sup>328</sup>

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324. See Federal Food, Drug and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.); Public Health Service Act, ch. 373, 58 Stat. 682 (1944) (codified as amended in scattered sections of 42 U.S.C.).

325. 18 U.S.C. § 1905 (“Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Federal Housing Finance Agency, or agent of the Department of Justice . . . or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.”).

326. See 21 U.S.C. § 355(a); 35 U.S.C. § 271(e)(2)–(4); 42 U.S.C. § 267.

327. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (“Monsanto has not challenged the ability of the Federal Government to regulate the marketing and use of pesticides. Nor could Monsanto successfully make such a challenge, for such restrictions are the burdens we all must bear in exchange for ‘the advantage of living and doing business in a civilized community.’ . . . That Monsanto is willing to bear this burden in exchange for the ability to market pesticides in this country is evidenced by the fact that it has continued to expand its research and development and to submit data to EPA despite the enactment of the 1978 amendments to FIFRA.” (citation omitted)). See generally Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413 (1989).

328. 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, 1495 (2020) (estimating the cost of the pandemic in America at \$16 trillion by year end 2021).

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:

In the pharmaceutical field, a third party has the right to access certain information submitted as part of a marketing authorization dossier, including clinical trial data. For example, in the EU, the European Medicines Agency (“EMA”) provides third parties with access to clinical trial data under Regulation 1049/2001/EC on access to documents and the EMA’s Policy 0070. These two policy instruments contain the right to access documents held by public authorities, including the EMA. Such access, however, is subject to exception in the event that the disclosure would undermine the commercial interests of a natural or legal person, including IP rights (the so-called commercially confidential information (“CCI”)), unless there is an overriding public interest. In 2020, the Court of Justice of the European Union (“CJEU”) issued several decisions in disputes, where originators sought to annul the EMA’s decisions to grant a third-party access to a document containing data submitted in the context of a marketing authorization application. The CJEU confirmed that there was no general presumption of confidentiality for clinical and toxicological study reports and upheld the General Court’s refusal to dismiss EMA’s decisions granting access.<sup>329</sup>

Similarly, as recognized by Health Canada, the Canadian Food and Drugs Act authorizes Health Canada to share confidential business information in its possession (as a result of companies seeking market authorization) with individuals and nonprofit organizations that “carr[y] out functions relating to the protection or promotion of human health or the safety of the public,”<sup>330</sup> provided that the recipient plans to use the information “to protect or promote human health or the safety of the public.”<sup>331</sup> Further, such information can be shared without imposing terms of confidentiality upon the recipient, as confirmed by a federal court,<sup>332</sup> “as long as the recipient provides a written undertaking ‘that no subsequent disclosure of the information will be made in a form that could reasonably be expected to identify the individual to whom it relates.’”<sup>333</sup> No provision is made for compensation for the public health use of such submitted data.

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329. Gurgula & Hull, *supra* note 21, at 1249.

330. Food and Drugs Act, R.S.C. 1985, c F-27, § 21.1(3)(c) (Can.).

331. MATTHEW HERDER, ‘THE PERFECT SHOULDN’T BE THE ENEMY OF THE GOOD’—WHAT CANADA CAN DO TODAY, TOMORROW & NEXT WEEK TO ENHANCE EQUITABLE ACCESS TO COVID-19 BIOPHARMACEUTICAL INTERVENTIONS: A BRIEF SUBMITTED TO THE HOUSE OF COMMONS STANDING COMMITTEE ON FOREIGN AFFAIRS AND INTERNATIONAL DEVELOPMENT (FAAE) 5 (2022).

332. *See id.*

333. *Id.* (quoting the Privacy Act, R.S.C. 1985, c. P-21, § 8(1)(j) (Can.), which is intended to protect the interests of clinical trial participants).

#### 4. State Police Powers

States have inherent police powers to regulate to protect the health and welfare of their citizens.<sup>334</sup> These powers are not readily preempted by federal law, including federal constitutional law.<sup>335</sup> 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 police 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, state law, or both.

Unlike federal government regulatory powers, state police powers to protect their citizens are plenary.<sup>336</sup> 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 interfere with federal authority in international relations, even if the sharing were to companies in foreign countries.<sup>337</sup>

Instead, such state government–compelled trade secret sharing 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. In the context of federal trade secret rights under the DTSA, there is neither express preemption nor implied field preemption of state authority.<sup>338</sup> That leaves only

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334. *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1904) (“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.”).

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

336. *Cf. Nat’l Fed. of Indep. Bus. v. Dep’t of Lab.*, 142 S. Ct. 661, 665 (2022) (“Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.”); *id.* at 667 (Gorsuch, Thomas, & Alito JJ., concurring) (“The only question is whether an administrative agency in Washington, one charged with overseeing workplace safety, may mandate the vaccination or regular testing of 84 million people. Or whether, as 27 States before us submit, that work belongs to state and local governments across the country and the people’s elected representatives in Congress.”). In other jurisdictions, comparative national and subnational competence to regulate to protect health may reflect different constitutional arrangements. Without addressing any specifics, it is enough to note here that as international law does not prohibit nations from compelling trade secret sharing (as discussed above in Part III.A), subnational compulsion of trade secret sharing is solely a question of the constitutional arrangements and of the jurisprudence of each nation or supranational arrangement.

337. The one exception is for technologies considered inherently dangerous and thus posing potential risks to national security. However, such sharing would likely be analyzed solely for prohibition under federal export control legislation or presidential orders pursuant to similar legislation. *See, e.g.*, John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, § 1758, 132 Stat. 1636, 2218–23 (2018); International Emergency Economic Powers Act, 50 U.S.C. §§ 1701–06. To the extent that such state actions would interfere with federal functions or accomplishment of the purposes of federal export-control legislation, they should be analyzed under preemption principles discussed immediately below.

338. *See, e.g.*, 18 U.S.C. § 1833 note (“Nothing in the amendments made by this section . . . shall be construed . . . to preempt any other provision of law.”); *Yeiser Rsch. & Dev. LLC v. Teknor Apex Co.*, 281 F. Supp. 3d 1021, 1057 (S.D. Cal. 2017) (“Importantly, the DTSA generally does not ‘preempt or displace any other remedies, whether civil or criminal, provided by . . . State . . . law for the misappropriation of a trade secret . . . .’” (citing 18 U.S.C. § 1838)); *McCandless Grp., LLC v. Coy Collective, Inc.*, No. 21-cv-02069, 2022 WL 2167686, \*5 (C.D. Cal. Feb. 14, 2022) (“DTSA shall not preempt any state law remedy . . . .”); *cf. Beneficial*

the possibility of “purposes and objectives” conflict preemption with federal legislation.<sup>339</sup>

It is unlikely that either federal patent law or federal trade secret law would preempt such state-compelled trade secret sharing. In *Kewanee Oil Co. v. Bicron Corp.*,<sup>340</sup> the Supreme Court held that a state trade secrecy law that protected unpatentable or doubtfully patentable inventions would not unduly 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.<sup>341</sup> 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.<sup>342</sup> Similarly, the failure of federal trade secret regulation to address compelled state government sharing suggests preserving such authority to the states, particularly when addressing traditional police powers and when federal trade secrecy law contains an express non-preemption provision.<sup>343</sup>

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Nat'l Bank v. Anderson, 539 U.S. 1, 8 (2003) (finding that complete preemption only occurs where a federal statute provides the “exclusive” cause of action). Similarly, because the EEA applies only to private conduct defined as a federal crime, it should not be understood to preempt state regulatory action. See Economic Espionage Act of 1996, 18 U.S.C. §§ 1831–1839.

339. See, e.g., *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

340. 416 U.S. 470 (1974).

341. See *id.* at 479, 483, 485–86, 491–92 (“Just as the States may exercise regulatory power over writings so may the States regulate with respect to discoveries. . . . Abolition of trade secret protection would, therefore, not result in increased disclosure to the public of discoveries in the area of nonpatentable subject matter. Also, it is hard to see how the public would be benefited by disclosure of customer lists or advertising campaigns; in fact, keeping such items secret encourages businesses to initiate new and individualized plans of operation, and constructive competition results. . . . Even as the extension of trade secret protection to patentable subject matter that the owner knows will not meet the standards of patentability will not conflict with the patent policy of disclosure, it will have a decidedly beneficial effect on society. Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention. Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention. . . . [Without trade secret protection,] [t]he innovative entrepreneur with limited resources would tend to confine his research efforts to himself and those few he felt he could trust without the ultimate assurance of legal protection against breaches of confidence. As a result, organized scientific and technological research could become fragmented, and society, as a whole, would suffer . . . [S]ince there is no real possibility that trade secret law will conflict with the federal policy favoring disclosure of clearly patentable inventions[,] partial pre-emption is inappropriate.”). Although *Kewanee’s* holding may be questionable, particularly considering some of the changes to patent law noted above, see *supra* notes 159–71 and accompanying text, the savings provision of the DTSA would seem to make such a conflict preemption argument much more difficult to maintain.

342. See *Kewanee*, 416 U.S. at 493 (“Trade secret law and patent law have co-existed in this country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other. . . . Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.”). But cf. Benjamin Kaplan, *An Unhurried View of Copyright: Proposals and Prospects*, 66 COLUM. L. REV. 831, 835–41 (1966) (explaining why legislative gaps are often important and reflect conscious decisions not to regulate rather than holes to be filled).

343. See 18 U.S.C. § 1833 note.



Finally, it bears mentioning one patent case decided by the U.S. Court of Appeals for the Federal Circuit, *Biotechnology Industry Organization v. District of Columbia* (“*BIO*”),<sup>344</sup> which held preempted state price control legislation prohibiting excessive pricing of patented pharmaceuticals, notwithstanding its recognition of state police powers to regulate to protect public health.<sup>345</sup> In that case, the Federal Circuit held that Congress in the Hatch-Waxman Act<sup>346</sup> had adopted a legislative balance that precluded states from restricting the compensation that patent holders could obtain through market mechanisms.<sup>347</sup> In theory, this holding could also be extended to the balance of protection and market incentives under the DTSA. But *BIO* is clearly distinguishable from compelled trade secret sharing to assure pandemic protection, and the reasoning of *BIO* would become facially ludicrous if extended. State laws protecting citizens from harmful products where state regulation is not otherwise preempted by federal regulatory authorities inherently interfere with patent-holder compensation incentives. Thus, the reasoning of *BIO* would prevent all state health and safety regulation regarding products protected by intellectual property rights.

#### B. NEW LEGISLATION TO COMPEL OR INDUCE TRADE SECRET SHARING

To the extent that existing authorities might prove inadequate to compel needed trade secret sharing or licensing in particular circumstances, explicit new legislation could be adopted to provide such 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.<sup>348</sup> 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.

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344. 496 F.3d 1362 (Fed. Cir. 2007).

345. *See id.* at 1373 (“It is unquestioned that the District has general police power within its borders and that ‘[w]hatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits.’” (quoting *Webber v. Virginia*, 103 U.S. 344, 348 (1880))).

346. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 35 U.S.C. § 156).

347. *See Biotech. Indus. Org.*, 496 F.3d at 1374 (“By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs. In the District’s judgment, patents enable pharmaceutical companies to wield too much exclusionary power, charging prices that are ‘excessive’ for patented drugs. The Act is a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers. This may be a worthy undertaking on the part of the District government, but it is contrary to the goals established by Congress in the patent laws.”).

348. *See supra* notes 329–40 and accompanying text.

For one example, Nicholson Price and Arti Rai have suggested providing incentives or mandates to disclose trade secrets (1) by amending U.S. 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.<sup>349</sup> To the extent that the suggested incentives prove insufficient, presumably trade secret owners simply would not apply. More importantly, Price and Rai recognize that “as a matter of political economy, it is unclear whether any powerful interest group would support mandatory disclosure” in the FDA (or PTO).<sup>350</sup> Thus, obtaining legislation to authorize such changes may be difficult. In contrast, obtaining more express emergency power authority to address trade secrets in pandemics may be less difficult a legislative lift.

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 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,<sup>351</sup> trade secret rights do not exist at “natural law.” Like all other forms of intellectual property law, trade secrecy should serve society broadly, in addition to the private interests of trade secret holders.

Adopting such measures within national trade secret legislation would also correspond to similar limitations in the TRIPS Agreement on government obligations to provide data protection for chemical and agricultural products, easing the political argument for adopting exclusions “necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”<sup>352</sup> Similar provisions could be adopted within other

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349. See Price & Rai, *supra* note 20, at 1050–60; see also *id.* at 913–14 (discussing sharing of codified manufacturing knowledge as “club good[s],” patent pooling, and efforts to share tacit knowledge, and identifying international organizations, national governments, regional organizations, and nongovernmental organizations as potential facilitators of such know-how sharing).

350. *Id.* at 1054.

351. See, e.g., *Millar v. Taylor* (1769) 98 Eng. Rep. 201, 230–31 (KB) (arguing that property rights in functional ideas (inventions), unlike in literary authorial ideas (published words), did not arise under natural law; such invention rights could exist only by the positive act of a government—the grant of patents—and were not otherwise recognized at common law); cf. *Donaldson v. Becket* (1774) 98 Eng. Rep. 257, 258 (HL) (finding that the Statute of Anne displaced any common law copyrights, reversing *Millar*).

352. TRIPS, *supra* note 3, art. 39.3.

statutes, including the FFDCA or the PHSA, conditioning market regulatory approvals on acceptance of such limitations. Alternatively, legislation could be adopted to provide the executive branch freestanding authority to adopt such trade secret–compelling measures, as additional “emergency” authority for Presidents or for agencies to employ, with or without compensation obligations.

It is also important to note that nothing in the grant of trade secret rights prevents rights holders from voluntarily authorizing uses of their trade secrets, know-how, show-how, and data, generally or particularly. For example, numerous rights holders, excluding biopharmaceutical companies, have thus adopted the previously discussed Open COVID Pledge<sup>353</sup> and similar voluntary measures:

Immediate action is required to halt the COVID-19 Pandemic and treat those it has affected. It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment.

We therefore pledge to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.

We will implement this pledge through a license that details the terms and conditions under which our intellectual property is made available.<sup>354</sup>

Even if companies must, as a matter of corporate law, seek to maximize shareholder value,<sup>355</sup> such voluntary measures in emergencies would likely generate enormous goodwill for rights holders. Accordingly, it is possible that decisions to forego short-term profits for public health would readily withstand any challenges based on breach of fiduciary duties or other shareholder causes of action. All it takes is the willingness for leaders of those companies to take actions already within their powers, just like government officials.

Between overt government compulsion and purely voluntary actions, there are several legislative actions that can induce private willingness to share or license trade secrets. Such “nudges”<sup>356</sup> are endemic to our legislative policies, including things like tax incentives, rebates, and regulatory discounts that induce people to take action.<sup>357</sup> The U.S. NIH and the Biomedical Advanced Research and Development Authority provided extensive upfront funds and advance purchase commitments to induce private companies to engage in costly and risky

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353. *See supra* Part II.

354. *The Pledge*, OPEN COVID PLEDGE, <https://opencovidpledge.org/the-pledge/> (last visited Apr. 1, 2023).

355. *See supra* notes 73–76 and accompanying text.

356. *See generally, e.g.*, RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* (2008); CASS R. SUNSTEIN, *WHY NUDGE? THE POLITICS OF LIBERTARIAN PATERNALISM* (2014).

357. *See, e.g.*, Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 *EMORY L.J.* 1087, 1117–28 (discussing various forms of subsidies, including taxation, administrative subsidies, and foreign aid).

R&D, clinical trials, regulatory approvals, and manufacturing scale-up.<sup>358</sup> 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 provided incentives to assure supplies that in turn may have influenced willingness to license technology to others.<sup>359</sup> 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.<sup>360</sup> Politically, such nudges may be easier to enact, although none of the foregoing is easy. 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 authority or voluntary, private, moral conduct.

#### 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 of trade secret owners and the public. As a recent review has noted, when arguing for changing worldwide intellectual property and health rules through the yet-to-be negotiated Pandemic Treaty, the COVID-19

    funding agreements have not enabled the sharing of manufacturing know-how to scale up vaccine production and make access more equal. As a result, large parts of the world were left unprotected from the virus, allowing the rise of new variants and prolonging the pandemic for everyone.

    . . . .

    A pandemic treaty should require governments to prepare their national laws for sharing the rights to inventions, data and access to know-how and biological resources before a pandemic strikes.<sup>361</sup>

Unfortunately, addressing trade secrets to confront pandemic diseases is not an easy task, as trade secret law operates best at a granular level, and political pressures make compelling trade secret sharing difficult. Currently, there is no general principle within most national trade secret laws that automatically limits

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358. See, e.g., CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS (2021); *KEI Letter to Speaker Pelosi Regarding Use of "Other Transaction Authority" (OTA) in Coronavirus Bill To Escape Bayh-Dole Public Interest Safeguards*, KNOWLEDGE ECOLOGY INT'L (Mar. 23, 2020), <https://www.keionline.org/32530>.

359. See *supra* notes 290–92 and accompanying text.

360. See *supra* notes 273, 338 and accompanying text.

361. Katrina Pehudoff et al., *A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-How and Technology*, BMJ GLOB. HEALTH, July 15, 2022, at 1–2.

or eliminates trade secrecy rights when they interfere with public health objectives to research, develop, test, obtain approval for, manufacture, and distribute needed vaccines, therapeutics, diagnostics, medical devices, PPE, and other medical products.

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. It is critically important to get our global infrastructure in place rapidly, to research, develop, test, obtain approval for, manufacture, and distribute the needed products before even worse problems occur in a future pandemic.<sup>362</sup> This Article 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—in other words, access to the pathogens themselves and to genetic sequence information derived from them that can accelerate global response to pandemic diseases.<sup>363</sup>

Perhaps equally important, it is critical to ensure that intellectual property rights are not treated as sacrosanct, but rather serve public needs. Where compensation is both necessary and appropriate, it should be provided, given that profit-seeking of private industry, competitive advantage, and national technological advantage is both understandable and celebrated in capitalist economies and in our global trading system. But the potential for litigation and compensation, and the desire to preserve competitive trade and technology advantages, should not deter governments (particularly wealthy ones) from taking needed actions to compel trade secret sharing to protect global health. Even without treating this as a moral obligation (the “Golden Rule”),<sup>364</sup> it will likely protect the citizens of the compelling jurisdiction from death, disease, and hardships far more than any short-term competitive advantages and benefits that might otherwise be obtained. It will likely be a win for all involved.

We must have the conversation about compelled trade secret sharing now. To do so, we must ask whether there is an actual trade secret that might be

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362. See, e.g., *CEPI and SK Bioscience Partner To Advance mRNA Vaccine Technology To Build Vaccine Library, Enable Rapid Response Against Disease X*, CEPI (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/](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/).

363. Cf. *Global Immunology and Immune Sequencing for Epidemic Response (GIISER) Sites in Africa*, GLOB. GRAND CHALLENGES (Apr. 20, 2021), <https://gch.grandchallenges.org/challenge/global-immunology-and-immune-sequencing-epidemic-response-giiser-sites-africa>. See generally, e.g., Dario Piselli, *International Sharing of Pathogens and Genetic Sequence Data Under a Pandemic Treaty: What Linkages with the Nagoya Protocol and the PIP Framework?* (Glob. Health Centre, Policy Brief No. 6, 2022).

364. See, e.g., *Leviticus* 19:18 (Jewish Publ'n Soc. of Am.) (“[L]ove thy neighbour as thyself”); *Matthew* 7:12 (World Eng.) (“Therefore, whatever you desire for men to do to you, you shall also do to them; for this is the law and the prophets.”); RUSSELL FREEDMAN, *CONFUCIUS: THE GOLDEN RULE* 30 (2002) (“Do not impose on others what you do not wish for yourself.”).

shared, and if so, whether, when, and how it should be shared. If we can get answers to those questions, we will have a much better chance of seeing COVID-19 and other global threats addressed and eradicated more quickly and with less loss of life, health, social welfare, and economic disruption. We can get ahead of these problems and prevent human suffering, rather than react to the problems while people die or suffer needlessly.

These are not unanswerable questions or insurmountable problems. It is in our capacity as humans to answer and solve them. But addressing them will require industry, governments, international bodies, and civil society groups to listen and understand each other's individual interests, and to collaborate to find solutions to the costly barriers that trade secrecy laws and practices have created.

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