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New and Heightened Public–Private Quid Pro Quos

Leveraging Public Support to Enhance Private Technical Disclosure

Peter Lee

Biopharmaceutical companies developed safe and effective COVID-19 vaccines in record time, thus providing hope in a devastating pandemic. While these vaccines have saved countless lives, global inequality in access to vaccines, particularly between developed and developing countries, has been highly controversial. While numerous factors contribute to such inequality, intellectual property (IP) rights have attracted significant attention. Biopharmaceutical companies hold patents on COVID-19 vaccines, and critics have argued that exclusive rights have constrained access to these lifesaving resources. Accordingly, developing countries, public health advocates, and even the US government argued for a recently enacted waiver of international IP rules with the aim of enhancing global manufacturing and distribution of patented COVID-19 vaccines.[1]

Not surprisingly, biopharmaceutical patentees opposed this IP waiver. Among their objections, they argued that weakening patents would do little to promote widespread production of COVID-19 vaccines. They asserted that even if third parties were not constrained by patents, they would still lack critical technical knowledge for manufacturing vaccines in industrial quantities. In particular, third

Thanks to Rochelle Dreyfuss, Daniel Hemel, Rachel Sachs, Sharon Sandeen, Katherine Strandburg, Madhavi Sunder, and participants at the *Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures* conference and the NYU School of Law Innovation Policy Colloquium for helpful comments. Parts of this chapter are adapted from Peter Lee, *An Organizational Theory of International Technology Transfer*, 108 Minn. L. Rev. 71 (2023).

[1] India & South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (IP/C/W/669), Council for Trade-Related Aspects of Intellectual Property Rights (2020). India and South Africa's original proposal would temporarily waive IP protections for all resources related to preventing, containing, or treating COVID-19. The Biden Administration endorsed a narrower version of a waiver focused on patented COVID-19 vaccines. Katherine Tai, Statement from Ambassador Tai on the Covid-19 Trips Waiver, May 5, 2021. In June 2022, the World Trade Organization adopted a similarly narrow waiver that temporarily lifts certain TRIPS obligations for most developing countries with respect to patented COVID-19 vaccines. World Trade Organization, *Draft Ministerial Decision on the TRIPS Agreement* (Jun. 17, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R1.pdf&Open=True (last visited Sep. 7, 2022).

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parties would lack two overlapping categories of technical knowledge held by vaccine developers: tacit knowledge, which constitutes personal, experiential knowledge that is not amenable to codification, and trade secrets, which constitute codified and uncodified technical knowledge that firms deliberately keep secret.

This state of affairs not only jeopardizes global access to COVID-19 vaccines, but also reveals a troubling paradox at the heart of the patent system. The patent system represents a quid pro quo in which inventors receive exclusive rights in exchange for disclosing a novel invention. Biopharmaceutical patentees, which enjoy exclusive rights over COVID-19 vaccines, have ostensibly disclosed their technologies. Yet these same patentees argue that third parties cannot manufacture these patented vaccines in the absence of privately held tacit knowledge and trade secrets. This chapter examines the causes and implications of that paradox and proposes several ways to resolve it.

The chapter explores several mechanisms to compel greater technical disclosure by patentees and other beneficiaries of public innovation support. It first focuses on modifying the patent quid pro quo to increase technical disclosure by patent applicants and patentees. It proposes rehabilitating the "best mode" requirement of patentability, and it considers the possibility of extending disclosure requirements for a finite period of time after patent filing. Beyond the requirements of patentability, this chapter argues that public funding provides a valuable lever for compelling greater technical disclosure by private innovators, including many patentees. Such measures would promote greater codification of tacit knowledge and public disclosure of trade secrets related to practicing publicly funded innovations. The chapter then focuses on the unique challenges of transferring purely tacit knowledge, which is not amenable to codification. Such knowledge is best transferred through direct interactions between technology generators and adopters. Imposing an obligation of direct tacit knowledge transfer through the patent system would be overly burdensome and fall outside the patent quid pro quo. However, the chapter suggests that additional policy levers can help motivate such tacit knowledge transfer and establish infrastructure to facilitate it.

Section 1 introduces the problem of unequal access to COVID-19 vaccines and the concern that patents contribute to such inequality. It also describes the movement to temporarily waive global IP rules to enhance access to patented vaccines. It further explores the argument that weakening patents would not appreciably increase generic production of COVID-19 vaccines because third parties lack the tacit knowledge and trade secrets to manufacture them. Section 2 discusses the paradox wherein biopharmaceutical patentees have ostensibly disclosed their COVID-19 vaccine technologies, yet third parties cannot practically manufacture vaccines without private knowledge from those patentees. It explores the importance of tacit knowledge and trade secrets to the effective manufacturing of patented vaccines, particularly in industrial quantities. Section 3 explores mechanisms to increase the disclosure of private technical knowledge. It suggests reforming patent

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law and utilizing the lever of public funding to compel greater technical disclosure by patentees and private innovators benefitting from government support. Section 4 explores the challenges of transferring purely tacit knowledge and proposes policy measures to promote such transfer.

1 PATENTS AND THE CHALLENGE OF GLOBAL ACCESS TO COVID-19 VACCINES

The introduction of safe and effective COVID-19 vaccines in late 2020 was a crucial turning point in the pandemic. Based in large part on massive government funding, biopharmaceutical firms introduced several vaccines, including the newest generation of so-called mRNA vaccines from Moderna and Pfizer–BioNTech. While these vaccines provided enormous relief, their unequal distribution quickly generated significant concern. Disparities in access have been especially stark on the global landscape, particularly between developed and developing nations. For instance, individuals in wealthy and middle-income countries received approximately 90 percent of the first 400 million doses of COVID-19 vaccines.[2] As of September 2022, 72.5 percent of individuals in high-income countries had received at least one dose of a COVID-19 vaccine, but only 22.8 percent of people in low-income countries had received at least one dose.[3]

While numerous factors contribute to such grossly unequal access, IP rights have attracted significant attention. Although biopharmaceutical companies introduced COVID-19 vaccines in record time, they had been developing and patenting the technologies underlying those vaccines for years. Empirical research shows that private companies have filed about 70 percent (80 out of 113) of the patent families covering the newest generation of mRNA vaccines.[4] A handful of companies – Moderna, CureVac, BioNTech, and GSK – own about half of the mRNA vaccine patent applications.[5] Proponents of strong IP rights argue that patents were necessary to induce biopharmaceutical companies to develop COVID-19 vaccines and that they will be necessary to encourage similar innovations to combat future pandemics.[6] However, critics contend that the exclusivity conferred by patents has constrained access to COVID-19 vaccines around the world, particularly for

[2] Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. Times (Mar. 21, 2021).

[3] United Nations Development Program, Global Dashboard for Vaccine Equity, https://data.undp.org/vaccine-equity/ (last visited Sep. 7, 2022).

[4] Cecilia Martin & Drew Lowery, *mRNA Vaccines: Intellectual Property Landscape*, 19 Nature Revs. Drug Discovery 578, 578 (2020).

[5] *Id.*

[6] *See, e.g.*, Christopher Rowland et al., *Drug Companies Defend Vaccine Monopolies in Face of Global Outcry*, Wash. Post (Mar. 20, 2021); Mario Biagioli, *Of Viruses and Licenses: Lessons from COVID-19 Vaccine Patent Debates*, L.A. Rev. of Books (Jul. 9, 2021) (discussing this view).

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low-income countries.[7] Access constraints were particularly pronounced in the first year after the introduction of vaccines, before biopharmaceutical firms ramped up supply.[8] Even today, developing countries have limited access to the newest and most effective COVID-19 vaccines, mRNA vaccines, which are produced by Moderna and Pfizer–BioNTech.[9] As of July 2022, 93 percent of all mRNA vaccine doses had gone to wealthy countries.[10]

The concern that IP rights can constrain access to vaccines (and other technologies needed to fight the pandemic) motivated calls to weaken those rights. Attempts to do so, however, faced obstacles from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[11] The TRIPS Agreement, which is part of the framework that created the World Trade Organization (WTO), establishes minimum standards for IP protection for all WTO member states. It represents the result of "upward harmonization" that requires relatively stringent protection for IP rights – including patents – for almost all countries in the world.[12] Among other provisions, TRIPS establishes an expansive conception of patentable subject matter – which includes health technologies, such as vaccines – and imposes regulations on the granting of compulsory licenses.[13] As such, any member state that weakens patents in derogation of TRIPS minimum requirements would violate its WTO obligations.

To mitigate this barrier, in October 2020 India and South Africa proposed a temporary waiver of various TRIPS provisions in light of the exigencies of the coronavirus pandemic.[14] This so-called TRIPS waiver would temporarily suspend TRIPS requirements for IP protection for innovations related to the "prevention, containment or treatment of COVID-19."[15] To the surprise of many, in May 2021 the Biden Administration announced its support for a limited version of a waiver that would temporarily lift TRIPS obligations for most developing countries with respect to patents on COVID-19 vaccines.[16] In June 2022, the WTO adopted such a limited waiver for patented COVID-19 vaccines.[17]

[7] *See, e.g.*, Achal Prabhala et al., *Want Vaccines Fast? Suspend Intellectual Property Rights*, N.Y. Times (Dec. 7, 2020); Matthew Kavanagh & Madhavi Sunder, *Opinion: Poor Countries May Not Be Vaccinated until 2024. Here's How to Prevent That*, Wash. Post (Mar. 10, 2021).

[8] *See* Chris Kay et al., *World Moves from Shortages to Possible Glut of Covid-19 Vaccines*, Bloomberg (Mar. 29, 2022).

[9] Achal Prabhala, *Monopolies Are Getting in the Way of mRNA Vaccines*, Scientific American (Jul. 11, 2022).

[10] *Id.*

[11] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (TRIPS Agreement).

[12] *See* Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Calif. L. Rev. 1571, 1572 (2009).

[13] TRIPS Agreement, arts. 27, 31.

[14] India & South Africa, *supra* note 1.

[15] *Id.*

[16] Tai, *supra* note 1; Thomas Kaplan et al., *Taking "Extraordinary Measures," Biden Backs Suspending Patents on Vaccines*, N.Y. Times (May 5, 2021).

[17] WTO, *supra* note 1. The decision indicates that within six months, WTO members will decide whether to extend the waiver to patented COVID-19 diagnostics and therapeutics. *Id.*

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Not surprisingly, biopharmaceutical patentees opposed the TRIPS waiver. Their principal argument was that a TRIPS waiver, and a concomitant weakening of patent rights, would undermine incentives to invent, both in the present and going forward. Additionally, opponents of a TRIPS waiver argued that weakening patents would do little to achieve the waiver's goal of increasing global manufacturing and distribution of COVID-19 vaccines. Biopharmaceutical patentees asserted that even if governments did not enforce patents, unauthorized third parties would not be able to manufacture COVID-19 vaccines without tacit knowledge and trade secrets from vaccine developers themselves.[18] This argument had, for a while, particular traction coming from Moderna, which publicly pledged in October 2020 that it would not assert its vaccine patents against entities manufacturing COVID-19 vaccines during the pandemic.[19] Moderna has subsequently reneged on its pledge in several ways, thus calling into question whether generic manufacturers can reasonably rely on it.[20] Moderna, however, continues to maintain that it will not assert its patents against manufacturers in developing countries and that its patents are not preventing generic manufacturing of its COVID-19 vaccine. However, the company opposed the TRIPS waiver, and it has refused to publicly disclose its tacit knowledge and trade secrets for manufacturing its vaccine.[21]

2 THE PATENT QUID PRO QUO, TACIT KNOWLEDGE, AND TRADE SECRETS

Biopharmaceutical patentees cite the inability of third parties to manufacture patented vaccines without proprietary tacit knowledge and trade secrets as a reason to oppose the TRIPS waiver. This chapter, however, argues that this phenomenon reveals a more fundamental divergence between existing patent practice and the overarching principles of the patent system. Specifically, biopharmaceutical

Notwithstanding this TRIPS waiver, member states may be bound by bilateral or regional agreements outside of the WTO that require minimum standards of IP protection. Additionally, nations may choose to maintain TRIPS standards voluntarily.

[18] Ian Lopez, *Vaccine IP Enforcement Takes Stage in Global Immunization Fight*, Bloomberg L. News (Apr. 27, 2021).

[19] Moderna, Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (Oct. 8. 2020), https://investors.modernatx.com/Statements–Perspectives/Statements–Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx (last visited Sep. 7, 2022).

[20] In March 2022, Moderna issued an "updated" patent pledge stating that it would not enforce its COVID-19 vaccine patents against companies manufacturing vaccines in or for low- and middle-income countries, as long as those vaccines were only used in such areas. However, Moderna "expects" entities manufacturing vaccines for wealthy countries to "respect the Company's intellectual property." Moderna, Moderna's Updated Patent Pledge (Mar. 7, 2022), https://s29.q4cdn.com/435878511/files/doc_news/2022/03/07/Moderna-Patent-Pledge_7-March_Final.pdf (last visited Mar. 25, 2024). In August 2022, Moderna sued Pfizer and BioNTech for allegedly infringing its patents on mRNA technology. Rebecca Robbins & Jenny Gross, *Moderna Sues Pfizer and BioNTech over Covid Vaccine Technology*, N.Y. Times (Aug. 26, 2022).

[21] *See* Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. Times (Sep. 22, 2021).

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patentees' nondisclosure of private knowledge necessary for manufacturing patented vaccines offends the essential bargain at the heart of the patent system.

The patent system represents a "quid pro quo" in which inventors receive twenty years of exclusive rights in exchange for disclosing a novel invention.[22] In the United States, various disclosure obligations are codified in statute and elaborated in case law. In particular, a patent must: teach a person of ordinary skill in the art how to make and use an invention, provide an adequate written description of the invention, and (at least technically) disclose any best mode the inventor knows as the most effective way of practicing it.[23] Robust disclosure plays a central role in the patent system. Patent disclosures comprise an "invisible college of technology" that enriches the public storehouse of knowledge and represents one of the primary benefits of the patent system.[24]

Among other functions, robust patent disclosure ensures that competitors are on an equal footing with patentees upon patent expiration. As the Supreme Court observed:

> [U]pon the expiration of that [patent] period, the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use. To this end the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it to use.[25]

While patent expiration means that the public can practice an invention without restraint, the public gains the information to practice that invention immediately – at the time of patent grant – rather than at the end of the patent term.[26] Robust technical disclosure represents the consideration that inventors provide in exchange for exclusive rights. However, the controversy over access to patented COVID-19 vaccines gives rise to an unsettling paradox: if biopharmaceutical patentees have disclosed their COVID-19 vaccines in patents, why do third parties need so much private (undisclosed) knowledge to practice them?[27]

[22] Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944) ("[T]he *quid pro quo* [for the patent grant] is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted").

[23] 35 U.S.C. § 112.

[24] *See* Carolyn C. Cooper, *Nineteenth-Century American Patent Management as an Invisible College of Technology*, *in* Learning and Technological Change 40, 40 (Russ Thompson ed., 1993); Robert Patrick Merges & John Fitzgerald Duffy, Patent Law and Policy 247 (7th ed. 2017).

[25] United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933) (citations omitted).

[26] In practice, public disclosure often occurs even earlier, as most pending US patent applications are published eighteen months after filing. 35 U.S.C. § 122(b).

[27] *Cf.* Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 Yale J.L. & Tech. 1, 3 (2012) ("Traditionally, trade secrecy and patent rights have been considered mutually exclusive").

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While disclosure plays a central role in the patent system, patent disclosure is limited in several ways.[28] At a foundational level, patent law requires disclosure through codification, but not all technical knowledge is capable of codification. As further explored later in this section, purely tacit technical knowledge may be highly valuable for practicing a patented invention, yet it is not amenable to codification. Additionally, the patent disclosure requirements focus on enabling a basic version of an invention, which may be a far cry from a fully developed commercial product.[29] This emphasis on enabling a basic version of an invention serves to limit patent disclosure, particularly given that inventors tend to file patent applications as soon as possible on early-stage, embryonic inventions.[30]

Relatedly, priority rules discourage patent applicants from adding "new matter" to their disclosures after filing.[31] As a result, the disclosure obligation is largely "fixed" at the time of filing a patent application, which further limits patent disclosure. While inventors continue to gain important knowledge about their creations throughout patent prosecution and commercialization,[32] the patent system actually disincentivizes patent applicants from disclosing such information. More broadly, patentees have strong commercial incentives to superficially comply with the requirements of patent disclosure while disclosing as little information as possible.[33] It is very difficult, moreover, for the Patent and Trademark Office (PTO) or courts to know if a patentee is retaining private knowledge about an invention that the patentee should disclose. All of these factors combine to significantly limit patent disclosure.

Of particular note is that patents do not disclose significant amounts of tacit knowledge about inventions. Because tacit knowledge plays a central role in the controversy over access to patented COVID-19 vaccines, some further elaboration is warranted. Tacit knowledge encompasses personal, experiential knowledge that is not amenable to codification.[34] For example, a professional tennis player could write

[28] For representative critiques of the disclosure requirement, *see* Sean B. Seymore, *The Teaching Function of Patents*, 85 Notre Dame L. Rev. 621 (2010); Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539 (2009); Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 Vand. L. Rev. 1715 (2016).

[29] In re Gay, 309 F.2d 769, 774 (C.C.P.A. 1962); CFMT, Inc. v. YieldUp Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003) ("Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect").

[30] Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. 65, 69 (2009).

[31] *See* 35 U.S.C. § 132(a) ("No amendment shall introduce new matter into the disclosure of the invention"). Addition of "new matter" may lead a patent applicant to lose an original priority date and establish a less desirable later one.

[32] *See* Fromer, *Dynamic*, *supra* note 28, at 1720–1721.

[33] *See* Brenner v. Manson, 383 U.S. 519, 534 (1966) (acknowledging "the highly developed art of drafting patent claims so that they disclose as little useful information as possible – while broadening the scope of the claim as widely as possible").

[34] *See* Michael Polanyi, The Tacit Dimension 4 (1967) ("*[W]e can know more than we can tell*").

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instructions on how to serve a tennis ball, but such instructions would necessarily fail to convey tacit knowledge derived from years of training, inherent athletic skill, and even muscle memory.[35] In the realm of novel technologies, tacit knowledge entails "non-codified, disembodied know-how" possessed by an inventor.[36] It consists of "intangible knowledge, such as rules of thumb, heuristics, and other 'tricks of the trade.'"[37] In the context of COVID-19 vaccines, biopharmaceutical patentees have developed tacit knowledge in the course of developing and commercializing their vaccines, and they argue that third parties cannot manufacture these vaccines in industrial quantities without it.

In describing tacit knowledge, it is useful to draw several distinctions. First, tacitness is not a binary on–off designation but a question of degree. At one end of the spectrum lies purely tacit knowledge, which is incapable of codification. At the other end of the tacitness spectrum is latent knowledge, which is technically codifiable yet not presently codified.[38] Second, tacit knowledge has an intrinsically dynamic character. Novel technologies often arise with a significant tacit dimension, as perhaps only the inventors themselves can truly understand them. However, as novel principles become part of the generally accepted knowledge in a field, tacitness decreases.[39] Third, tacit knowledge may be useful for understanding a basic invention, but it can be particularly useful for extending, modifying, and commercializing that invention.[40] The process of translating a new invention into a commercial product presents a host of technical challenges, and the tacit knowledge of the original inventor can be very helpful in overcoming them. Almost by definition, however, tacit knowledge related to a patented invention is not disclosed in the patent.

In addition to tacit knowledge, patents may fail to disclose proprietary trade secrets relevant to practicing a patented invention. A trade secret consists of technical or business information that derives economic value from secrecy and is the subject of reasonable efforts to maintain that secrecy.[41] There is some overlap between tacit

[35] *Cf.* Richard R. Nelson & Sidney G. Winter, An Evolutionary Theory of Economic Change 73 (1982) (noting that the knowledge underlying "skills" such as serving a tennis ball is largely tacit).

[36] Jeremy Howells, *Tacit Knowledge, Innovation and Technology Transfer*, 8 Tech. Analysis & Strategic Mgmt. 91, 92 (1996); *see also* Paul A. David & Dominique Foray, *Economic Fundamentals of the Knowledge Society*, 1 Pol'y Futures Educ. 20, 25 (2003).

[37] Ashish Arora, *Contracting for Tacit Knowledge, The Provision of Technical Services in Technology Licensing Contracts*, 50 J. Dev. Econ. 233, 234 (1996).

[38] Ajay Agrawal, *Engaging the Inventor: Exploring Licensing Strategies for University Inventions and the Role of Latent Knowledge*, 27 Strategic Mgmt. J. 63 (2006).

[39] *See* Lynne G. Zucker et al., *Intellectual Human Capital and the Birth of U.S. Biotechnology Enterprises*, 88 Am. Econ. Rev. 290, 291 (1998).

[40] Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 Calif. L. Rev. 1503, 1529 (2012).

[41] *See* Unif. Trade Secrets Act § 1(4) (Unif. L. Comm'n 1985); Defend Trade Secrets Act, 18 U.S.C. § 1839(3).

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knowledge and trade secrets, though the two categories of information are far from coextensive. Because of its difficult-to-convey nature, tacit knowledge may satisfy the secrecy requirement to qualify for trade secret protection; indeed, firms often protect tacit knowledge as trade secrets. However, trade secrets encompass a much wider range of undisclosed information, including codified knowledge, such as instructional manuals, research and testing data, and manufacturing specifications. For example, a written vaccine "recipe" with detailed instructions to make a COVID-19 vaccine does not represent tacit knowledge, and firms are likely to protect such information as a trade secret.

Patentees routinely do not disclose tacit knowledge and trade secrets related to practicing their inventions. Of course, one of the functions of the patent system is to incentivize the codification and public disclosure of otherwise tacit knowledge.[42] Technically speaking, however, the patent system can only stimulate the codification of latent knowledge; purely tacit knowledge is not capable of codification. Furthermore, as mentioned, patentees have significant incentives not to disclose invention-related trade secrets as long as they can appear to satisfy the disclosure requirements of patentability.

Undisclosed tacit knowledge and trade secrets, moreover, can be critical to practicing and commercializing a patented invention. In the life sciences, for example, when biotech scientists disclose a novel biologic compound in a patent, they often retain substantial tacit knowledge regarding their creation.[43] Patent disclosures simply cannot convey all the nuances and details of how inventors create and use complex biological macromolecules. Furthermore, while the tacit knowledge of inventors is helpful to producing a biologic compound in a laboratory setting, it is especially helpful to manufacturing such compounds in industrial quantities. According to legal scholars Nicholson Price and Arti Rai, "slight variations in the manufacturing process can change the quality, safety, or efficacy of the final product."[44] In some cases, such knowledge ultimately becomes codified for internal purposes, in which case a biotech firm may protect it as a trade secret. Such private information may be highly valuable to practicing a patented invention, yet patents often do not disclose it.

Tacit knowledge and trade secrets play an important role in enabling the manufacture of patented COVID-19 vaccines. As noted, Moderna and Pfizer contend that even in the absence of patents, unauthorized manufacturers would be unable to

[42] Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 Berkeley Tech. L.J. 1009, 1012 (2008).

[43] *Cf.* Office of Technology Assessment, Commercial Biotechnology – An International Analysis 388 (1984) ("Because of their complex and unknown nature, many biological inventions, especially organisms, cannot be sufficiently described in writing to allow their predictable reproducibility on the basis of that description alone").

[44] W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023, 1028 (2016).

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produce their vaccines because the process is too complex and requires specialized facilities.[45] Academic commentators confirm this view, arguing that for "some complex COVID-19 vaccines and biological therapeutics, fast manufacturing, particularly of products originally developed by other firms, will require not only physical capacity but also access to knowledge not contained in patents or in other public disclosures."[46] In similar fashion, vaccine expert Alain Alsalhani from Doctors Without Borders noted: "You need someone to share all the process, because it's a new technology . . . One of the problems we have is that the scientific literature about industrial-scale manufacturing of mRNA vaccines is so slim. This is why it's not just about a recipe, it's about an active and full tech transfer."[47] Transfer of private information – including tacit knowledge and trade secrets – is critical for the manufacture of patented COVID-19 vaccines.

3 LEVERAGING THE PATENT SYSTEM AND GOVERNMENT FUNDING TO INCREASE DISCLOSURE OF PRIVATE TECHNICAL KNOWLEDGE

A *Modifying the Patent Quid Pro Quo*

The current state of affairs reveals an unsettling paradox: biopharmaceutical patentees have ostensibly disclosed their vaccines, yet third parties cannot practically manufacture them without private information held by patentees. This paradox, moreover, reveals a conflict between the overarching aims of patent disclosure and the current state of the doctrine. Patent disclosure seeks to put other technical artisans on cognitive footing comparable to the patentee. However, this objective is not met by biopharmaceutical patentees who have ostensibly disclosed their technologies. This in turn suggests the need to modify the existing patent quid pro quo. This chapter provides several suggestions for increasing the disclosure requirements of patentability, which would compel greater disclosure of invention-related tacit knowledge and trade secrets.

The chapter first suggests strengthening the "best mode" requirement of patentability. Under US patent law, the enablement requirement mandates that a patent must teach a technical artisan in the field how to make and use an invention.[48] As noted, this requirement is aimed at enabling a basic version of a patented invention. Technically, US patent law also requires patent applicants to disclose the best mode for practicing their inventions, which encompasses any "specific instrumentalities or techniques which are recognized by the applicant at the time

[45] Stephanie Nolen, *Here's Why Developing Countries Can Make mRNA Covid Vaccines*, N.Y. Times (Oct. 22, 2021).
[46] W. Nicholson Price II et al., *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 Science 912 (2020).
[47] Nolen & Stolberg, *supra* note 21 (quoting Alain Alsalhani, Doctors Without Borders).
[48] *See* 35 U.S.C. § 112.

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of filing as the best way of carrying out the invention."[49] The best mode requirement aims "to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of the inventions they have in fact conceived."[50] The requirement has both subjective and objective elements. If a patent applicant has subjective knowledge of a best mode at the time of filing a patent application, the applicant must disclose it in an objectively adequate manner.[51] Historically, the best mode requirement has provided an incentive for patent applicants to disclose invention-related trade secrets.[52] In theory, it can also promote disclosure of certain kinds of tacit knowledge (which may or may not be formally recognized as trade secrets).

While the best mode requirement plays a valuable role in compelling disclosure of private information, it has attracted criticism for unduly increasing the expense and complexity of litigation.[53] Accordingly, in 2011, Congress reformed the best mode requirement in a manner that renders it essentially toothless. Disclosing any known best mode is still technically a requirement of patentability, but failure to do so is no longer a permissible ground for canceling, invalidating, or rendering unenforceable a patent claim.[54] This chapter argues for restoring the best mode requirement as a fully enforceable patentability requirement. Doing so would compel patentees to disclose private knowledge (including tacit knowledge and trade secrets) concerning the best way to practice their inventions. More broadly, this change would help achieve the overarching objective of placing competitors on equal cognitive footing with patentees. Rehabilitating the best mode requirement would help mitigate the anomaly where, for instance, vaccine developers obtained patents but retained private information critical to practicing their inventions.[55]

A more aggressive, and more controversial, variant of this proposal would increase the time period over which patent applicants and patentees must comply with the disclosure obligations of patentability – including a rehabilitated best mode requirement. Current patent doctrine assesses compliance with the disclosure requirements of patentability as of the date of filing a patent application.[56] However, inventors continue to gain valuable information about their inventions throughout the

[49] Spectra-Physics, Inc. v. Coherent Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987).
[50] Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1330 (Fed. Cir. 2002)
[51] *Id.* (describing the subjective and objective prongs).
[52] *See, e.g.*, Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 930 (Fed. Cir. 1990) (invalidating a patent on a grommet for failure to disclose a best mode where the composition of the grommet was a trade secret and not disclosed in the patent).
[53] *See* Love & Seaman, *supra* note 27, at 8–9.
[54] Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (codified in scattered sections of 35 U.S.C.); *see generally* Love & Seaman, *supra* note 27.
[55] Short of rehabilitating the best mode requirement, legal scholars Brian Love and Chris Seaman suggest several ways in which existing equitable doctrines, such as inequitable conduct, patent misuse, and unclean hands, could approximate such a rehabilitation. Love & Seaman, *supra* note 27, at 20–23.
[56] *See* Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004).

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processes of prosecuting and ultimately commercializing their patents.[57] Indeed, it is possible that vaccine developers satisfied the enablement and best mode requirements for their vaccines as of the date of filing and developed knowledge about the best way of manufacturing COVID-19 vaccines at a later date, which would fall outside the statutory disclosure requirements. To address that condition, this chapter suggests extending the disclosure requirements for some reasonable period of time (for example, five years) after patent filing. In essence, patentees would have an ongoing requirement to update disclosure of a best mode for a period of five years after filing a patent application. Failure to do so could lead to denial of patent claims (if the patent is still in prosecution) or invalidation of patent claims (if the patent has already issued). Such an ongoing obligation of technical disclosure would provide significant incentive for patentees to disclose and update private information relevant to practicing an invention.

A more specific variant of this latter proposal would target technical disclosure for a class of regulated technologies that includes COVID-19 vaccines. Any proposal to compel a patentee's disclosure of tacit knowledge and trade secrets will encounter difficulties of monitoring and enforcement. The PTO and courts cannot easily know what is in a patentee's mind, and they may be unaware that the patentee has knowledge (or updated knowledge) of a best mode within five years after filing a patent application. In some cases, however, it is evident that the patentee possesses such private information because the patentee discloses it to another government entity. Vaccines, along with diagnostics and therapeutics, are somewhat unique among patented technologies because they are heavily regulated by government agencies such as the US Food and Drug Administration (FDA), the European Medicines Agency, and comparable agencies in other jurisdictions. As a condition of obtaining regulatory approval, developers of these technologies must often submit detailed manufacturing information to regulators. Such submissions can compel the codification of tacit knowledge and the disclosure of codified trade secrets.[58] Regulators may also engage in hands-on investigation of manufacturing processes; as part of granting authorization for Moderna's COVID-19 vaccine, the FDA sent inspectors to Moderna's production facilities and clinical trial sites.[59] The FDA ordinarily treats such submissions as confidential, thus allowing them to remain the private knowledge of submitters. However, the patent quid pro quo provides a lever for compelling patentees to disclose such information publicly. If such manufacturing knowledge exists at the time of filing a patent application (or, under the more aggressive proposal, within five years of filing), then it would fall within the mandate of the best mode requirement to disclose it.

[57] *See* Fromer, *Dynamic*, *supra* note 28, at 1720–1721.

[58] Price et al., *supra* note 46, at 913 ("[R]egulatory approval typically requires the extensive codification of tacit manufacturing knowledge").

[59] Denise Grady et al., *F.D.A. Authorizes Moderna Vaccine, Adding Millions of Doses to U.S. Supply*, N.Y. Times (Mar. 16, 2021).

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Of course, these proposals to enhance the disclosure requirements of patentability raise several complications. Rehabilitating the best mode requirement would give rise to several objections that led Congress to weaken it in the first place. Critics contend that the best mode requirement increased the expense and complexity of litigation, especially the need to inquire into an inventor's subjective knowledge at the time of filing a patent application.[60] Furthermore, the best mode requirement was unique to US patent law, and rehabilitating it would undermine international patent harmonization.[61]

There is reason to believe, however, that these criticisms are overblown. As Professors Brian Love and Chris Seaman argue, the requirement to disclose a best mode (rather than maintain it as a trade secret) could actually *decrease* litigation expense and complexity by reducing instances when a patentee asserted both patent infringement and misappropriation of trade secrets against a defendant.[62] Against objections that a rehabilitated best mode requirement would undermine international harmonization and burden foreign inventors, it is important to note that US law *already* has a best mode requirement. Rehabilitating the best mode requirement would simply give more teeth to an existing obligation of US patent law with which all inventors (domestic and foreign) should comply.[63] While it would be ideal for other countries to adopt the best mode requirement, such widespread adoption would not be necessary to meaningfully increase patent disclosure. Given the lucrative nature of the US market, inventors from around the world routinely seek to patent their technologies in the United States, where they are legally obligated to disclose a best mode if they know of one.

Extending the time period for disclosure requirements would also raise several technical complications. Such extension would require changing prevailing rules and practice whereby a disclosure is largely "fixed" at the time of filing a patent application.[64] Furthermore, safeguards would have to establish that a patentee could amend a specification for the purposes of updating a best mode, but such amendments could not be the basis for expanding claims. Additionally, given that patents (and patent applications) often change hands, policymakers would have to consider how assigning a patent would affect ongoing disclosure obligations. A logical option would be for disclosure obligations to follow assignment of the patent; that is, the assignee (who is likely to take the lead in commercializing a patent) would bear the obligation of updating the best mode for a prescribed period of time.

Finally, a requirement for patentees to publicly disclose information submitted to other regulatory agencies also raises certain challenges. Existing doctrine holds that forced public disclosure of legally protected trade secrets by government agencies

[60] Love & Seaman, *supra* note 27, at 8–9.
[61] *Id.*, at 9.
[62] *Id.*, at 16.
[63] *Id.*, at 19–20.
[64] *See* 35 U.S.C. §§ 132, 251.

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may constitute a taking that falls within the protections of the Fifth Amendment.[65] This suggests that public agencies can only take such information for public use, and they must provide just compensation to the trade secret holder. However, unlike an ex post taking, the proposal here envisions an ex ante agreement by a patent applicant to publicly disclose invention-related knowledge in exchange for exclusive rights. As such, these obligations would not fall within the ambit of the Fifth Amendment any more than the general disclosure requirements of patent law, which compel the disclosure of private information in exchange for a government benefit. Additionally, there is some concern that forcing public disclosure of regulatory information would discourage patentees from seeking regulatory approval for their vaccines, diagnostics, and therapeutics. However, given that regulatory approval is a necessary gateway to marketing and thus profiting from these innovations, it is unlikely that heightened disclosure requirements would significantly chill such submissions.

B *Leveraging Government Funding*

While modifying the patent quid pro quo can lead to greater disclosure of tacit knowledge and trade secrets related to practicing inventions, the patent system is not the only policy lever for increasing access to private technical knowledge. The federal government provides massive funding to private technology firms (many of which are also patentees), and this public funding provides leverage to insist upon greater dissemination of private information by funding recipients. In the context of patented COVID-19 vaccines, the federal government could condition massive funding for vaccine developers on commitments to disclose or share tacit knowledge and trade secrets for manufacturing them.[66]

The federal government has been investing for decades in the technologies underlying COVID-19 vaccines. It has long supported research on coronaviruses,[67] and publicly funded research on vaccines for other conditions, such as HIV and MERS, contributed to developing today's COVID-19 vaccines.[68] The federal government's support for COVID-19 vaccines is most evident for the newest generation

[65] *See* Ruckelshaus v. Monsanto, 467 U.S. 986, 1003–1004 (1984).

[66] This chapter generally uses the term "disclose" to refer to public disclosure of information. However, in some circumstances, government support can induce private innovators to "share" (rather than publicly disclose) technical information with designated parties (including the government itself) in a manner that maintains the confidentiality of that information. *Cf.* Sharon K. Sandeen, *A Typology of Disclosure*, 54 Akron L. Rev. 657, 659 (2020) ("[I]t is possible for information to be disclosed to another, including government officials, without the information becoming public").

[67] Jocelyn Solis-Moreira, *How Did We Develop a COVID-19 Vaccine So Quickly?*, Medical News Today (Dec. 15, 2020); *see also* Richard G. Frank et al., *It Was the Government That Produced COVID-19 Vaccine Success*, Health Affairs Blog (May 14, 2021).

[68] *See* Jeffrey E. Harris, *The Repeated Setbacks of HIV Vaccine Development Laid the Groundwork for SARS-CoV-2 Vaccines* (NBER, Working Paper 28587, Mar. 2021); Gina

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of mRNA vaccines.[69] Federally funded research was critical to developing several innovations at the heart of these vaccines, such as genetically engineered spike proteins[70] and techniques for modifying mRNA to allow it to evade the body's immune system.[71] Quite simply, federal funds were crucial to developing COVID-19 vaccines.

While the federal government has supported research leading to COVID-19 vaccines for decades, its most visible contributions have occurred since the outbreak of the pandemic. In late April 2020, the Trump Administration launched Operation Warp Speed, an ambitious initiative aimed at producing 300 million doses of safe and effective COVID-19 vaccine.[72] This initiative provided about $18 billion to six vaccine developers, including Moderna, Pfizer, and Johnson & Johnson. Operation Warp Speed provided vaccine developers with several kinds of financial support, including grants to cover vaccine development, advance-purchase commitments for final doses, and, in some cases, both. In addition to financial support, Operation Warp Speed also provided logistical and operational support to expand manufacturing capacity for some grantees.[73] Federal support helped rapidly accelerate vaccine development. While it ordinarily takes three to nine years to move from sequencing a virus to Phase 1 clinical trials,[74] in the case of COVID-19 vaccines that time period was significantly condensed to about ten weeks.[75]

These enormous public contributions to private vaccine development provide the federal government with certain claims on resulting vaccines. The prospect of leveraging public funding to enhance access to vaccines – particularly in developing countries – has attracted significant attention.[76] This chapter, however, argues that

Kolata & Benjamin Mueller, *Halting Progress and Happy Accidents: How mRNA Vaccines Were Made*, N.Y. Times (Jan. 15, 2022).

[69] Frank et al., *supra* note 67 (noting that BARDA provided hundreds of millions of dollars to support mRNA vaccine research); Elie Dolgin, *The Tangled History of mRNA Vaccines*, 597 Nature 318, 323 (2021).

[70] Arthur Allen, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, Scientific American (Nov. 18, 2020); Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed's $18 Billion Sprint for a Vaccine*, Bloomberg Businessweek (Oct. 29, 2020).

[71] Luis Gil Abinader, *Foundational mRNA Patents Are Subject to the Bayh–Dole Act Provisions*, Knowledge Ecology Int'l (Nov. 30, 2020), www.keionline.org/34733 (last visited Sep. 12, 2022).

[72] Centers for Disease Control & Prevention, CDC Museum COVID-19 Timeline, www.cdc.gov/museum/timeline/covid19.html (last visited Sep. 12, 2022).

[73] Sharon LaFraniere et al., *Politics, Science and the Remarkable Race for a Coronavirus Vaccine*, N.Y. Times (Nov. 30, 2020); U.S. Government Accountability Office (USGAO), Operation Warp Speed, at *2 (Feb. 2021).

[74] Penny M. Heaton, *The Covid-19 Vaccine-Development Multiverse*, 383 N. Eng. J. Med. 1986, 1987 (2020).

[75] Nicole Lurie et al., *Developing Covid-19 Vaccines at Pandemic Speed*, 382 N. Eng. J. Med. 1969, 1971 (2020).

[76] Udo Bullman, a German member of the European Parliament observed, "We funded the research, on both sides of the Atlantic . . . You could have agreed on a paragraph that says 'You

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governments can leverage public funding to enhance access not only to finished vaccine doses but also to the tacit knowledge and trade secrets necessary to manufacture them. In this manner, government agencies can exploit a different kind of public quid pro quo other than the patent system to increase technical disclosure by private innovators.

Government agencies can leverage public innovation funding to essentially bargain for greater codification and disclosure of private technical knowledge. At root, this would simply be an application of traditional contract principles: the federal government provides enormous funds to contractors, and it can condition such funds on those contractors codifying tacit knowledge and conveying trade secrets for practicing subject technologies. For instance, in Operation Warp Speed, the federal government could have included a provision in multibillion-dollar contracts that required grantees to codify and publicly disclose (or privately share) best manufacturing techniques for any successful COVID-19 vaccines. These agreements would have comprised ex ante bargains in which the federal government negotiated with contractors to deliver not just some good but also the knowledge for making it, and they would be less intrinsically coercive than ex post takings. If the contractor did not want to commit to codifying and disseminating private knowledge, including tacit knowledge and trade secrets, it could decline to take federal funds.

Notably, existing federal procurement law already contemplates this kind of quid pro quo of public funds for access to private information. In general, civilian federal procurement contracts are governed by the Federal Acquisition Regulations (FAR).[77] Subject to some exceptions, the FAR provides the federal government with "unlimited rights" in data first produced under subject contracts and data delivered under subject contracts.[78] While these provisions do not compel the codification of tacit knowledge, they provide valuable access to codified trade secrets related to government contracts. The FAR defines "data" expansively to include all "recorded information."[79] This includes "technical data," which comprises "recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including *computer* databases and *computer software documentation*)."[80] Furthermore, the FAR defines "unlimited rights" as enabling the government "to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display [data], in any manner and for

are obliged to give it to poor countries in a way that they can afford it.' Of course you could have." Gebrekidan & Apuzzo, *supra* note 2; *see also* Maria Cheng & Lori Hinnant, *Countries Urge Drug Companies to Share Vaccine Know-How*, Assoc. Press (Mar. 1, 2021).

77 While the FAR applies to civilian agencies, the Department of Defense utilizes the Defense FAR Supplement (DFARS).

78 FAR 52.227-14 (b)(1).

79 FAR 52.227-14 (a).

80 FAR 52.227-14 (a) (italics in original).

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any purpose, and to have or permit others to do so."[81] Government data rights represent a bargain in which contractors must provide access to data in exchange for federal funding.

These government data rights may provide an avenue for the federal government to widely disseminate the COVID-19 vaccine recipes arising from billions of dollars of public funds.[82] Consistent with the FAR, the authorizing statute for the Biomedical Advanced Research and Development Authority (BARDA) requires it to condition grants to contactors on obtaining access to "all data related to or resulting from countermeasure and product advanced research and development."[83] BARDA's Operation Warp Speed contract with Moderna specifically requires Moderna to share all of its submissions to the FDA with BARDA.[84] It also allows BARDA not only to obtain all raw data produced under the contract but also to share it with outside parties, consistent with the FAR.[85] Public Citizen's analysis of BARDA's 2020 contract with Moderna for $483 million yielded two important insights concerning data:

> First, BARDA gained access to the entire "vaccine recipe." This includes Moderna's dossiers containing chemistry, manufacturing, and controls information, which provide manufacturing instructions in step-by-step detail. Second, BARDA obtained "unlimited rights" to data first produced by Moderna using contract funding ("Unlimited Rights Data").[86]

Under prevailing regulations, a federal agency only obtains "limited rights in data generated prior to entering or outside the scope of the contract, and data developed at private expense."[87] While this provision provides a slim avenue for Moderna (and other contractors) to claim that certain information can remain proprietary, the redacted nature of publicly disclosed contracts prevents knowledge of the exact scope of data over which the government only has "limited rights." Analysis based on available sources, however, suggests that the scope of "limited rights" data is quite narrow and that the government enjoys "unlimited rights" in data concerning scaling up of the manufacture of Moderna's vaccine and transferring production to other manufacturing sites.[88] Government officials, including Senator Elizabeth Warren, have pressed the Biden Administration to clarify what kinds of data are subject to unlimited rights by the government under the BARDA–Moderna

[81] FAR 52.227-14 (a).
[82] *See* Bridie Telford et al., *The Global COVID-19 Contract Conundrum*, Think Global Health (Dec. 8, 2021).
[83] Pandemic and All-Hazards Preparedness Act. 42 U.S.C. § 247d–7e.
[84] BARDA-Moderna Contract 27 (Apr. 16, 2020), www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf (last visited Sep. 12, 2022).
[85] *Id.*, at 24.
[86] Zain Rizvi, Sharing the NIH–Moderna Vaccine Recipe 6 (2021).
[87] *Id.*, at 12.
[88] *Id.*, at 15.

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contract.[89] From all available evidence, however, it appears that public funding and government procurement regulations provide federal agencies with broad rights to private data from vaccine developers, including information on how to manufacture COVID-19 vaccines.

4 RELATIONAL AND ORGANIZATIONAL MECHANISMS TO PROMOTE TACIT KNOWLEDGE TRANSFER

While leveraging patent rights and public funding can compel innovators to disclose private information – including tacit knowledge and trade secrets – such measures are in some ways limited. As noted, some tacit knowledge is not amenable to codification at all. While enhanced disclosure requirements can help capture the "low hanging fruit" of latent knowledge, they cannot compel the codification of purely tacit knowledge. Furthermore, while leveraging public quid pro quos can encourage the disclosure of codified trade secrets, technology transfer through codified texts can be rather inefficient. Relatedly, heightened disclosure requirements may lead to unhelpful "data dumps" of technical information that is expensive to codify yet may not be particularly valuable to technology adopters. Accordingly, this chapter now turns to relational and organizational mechanisms for transferring technical knowledge and policy levers that can promote such transfer.

Given the difficulty of transferring purely tacit knowledge, oftentimes the only (or most efficient) way to effectuate such transfer is through direct interpersonal interaction with the inventor. As economist Joanne Oxley observes, tacit knowledge "is extremely difficult to transfer without intimate personal contact, involving teaching, demonstration, and participation."[90] Similarly, economist David Teece has likened the transfer of tacit knowledge to an apprenticeship model in which an apprentice works directly alongside a master craftsperson.[91] The value of interpersonal interaction with an inventor persists even when that inventor has ostensibly "disclosed" an invention in a patent. While reading a text is valuable, sometimes there is no substitute for directly talking with an inventor about a novel technology.

The active participation of inventive entities in technology transfer serves several valuable functions. First, direct transmission of tacit knowledge can aid a technology adopter in assimilating a new invention. Second, as noted, an inventor's tacit

[89] Elizabeth Warren et al., Letter to White House and BARDA on Moderna Contract (Oct. 12, 2021).

[90] Joanne E. Oxley, *Appropriability Hazards and Governance in Strategic Alliances: A Transaction Cost Approach*, 13 J. L. Econ. & Org. 387, 393 (1997); *see also* Scott Shane, *Selling University Technology: Patterns from MIT*, 48 Mgmt. Sci. 122, 124 (2002) ("[W]hen information is tacit, it must be transferred through interpersonal contact, and economic actors must develop relationship-specific assets to facilitate that transfer").

[91] David J. Teece, *The Market for Know-How and the Efficient International Transfer of Technology*, 458 Annals AAPSS 81, 83 (1981).

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knowledge may be particularly useful for extending, modifying, and commercializing an invention.[92] In the life sciences, for example, direct interactions with inventors can greatly accelerate industrial-scale manufacturing of biologic products. As economist Gary Pisano observes, "In the absence of well-defined and well-understood scale-up recipes, ensuring product integrity requires extensive interactions between the scientists who designed a cell in the laboratory and bioprocessing engineers charged with developing the production process."[93] An inventor's participation in active technology transfer can allow a technology adopter to benefit from the inventor's tacit knowledge to navigate unpredictable challenges on the path toward commercialization.

Given the highly personal nature of tacit knowledge transfer, relational and organizational mechanisms are critical to effectuating such transfer. Inventive entities and technology adopters use a variety of interpersonal and organizational linkages to transfer technical knowledge.[94] In some cases, firms licensing a patent will hire the inventor as a consultant, thus obtaining direct access to the inventor's tacit knowledge. For example, firms licensing university patents routinely hire the faculty inventors of those inventions to aid in technology transfer and commercialization.[95] Organizational linkages between inventive entities and technology adopters can also promote tacit knowledge transfer. This can be accomplished through joint ventures between technology firms or research consortia, such as SEMATECH, a consortium of US semiconductor firms that facilitates "cooperative research, development, and testing projects."[96] At the far end of the spectrum, the goal of transferring tacit knowledge between two entities can even motivate them to integrate, becoming a single organization. This is evident, for example, in the vertical integration of small biotech firms that produce novel biologic compounds and large pharmaceutical companies that develop those biologics into marketable drugs.[97] Such vertical integration accelerates tacit knowledge transfer by bringing technology generators and adopters under the same organizational roof.

Tellingly, relational and organizational mechanisms play an important role in transferring tacit knowledge and trade secrets for manufacturing COVID-19 vaccines. Moderna and Pfizer emphasize the difficulty of transferring their technology

[92] Lee, *Transcending*, *supra* note 40, at 1529.

[93] Gary P. Pisano, *The Governance of Innovation: Vertical Integration and Collaborative Arrangements in the Biotechnology Industry*, 20 RES. POL'Y 237, 244 (1991); *Cf.* Price & Rai, *supra* note 44 (explaining the challenges of replicating large-molecule biologic drugs).

[94] Arora, *supra* note 37, at 235; Lynn G. Zucker et al., *Commercializing Knowledge: University Science, Knowledge Capture, and Firm Performance in Biotechnology*, 48 MGMT. SCI. 138, 141 (2002).

[95] Lee, *Transcending*, *supra* note 40, at 1531–1533 (presenting case studies where licensees of university patents hired faculty inventors as consultants).

[96] Larry D. Browning et al., *Building Cooperation in a Competitive Industry: Sematech and the Semiconductor Industry*, 38 ACAD. MGMT. J. 113, 115 (1995).

[97] *See* Peter Lee, *Innovation and the Firm: A New Synthesis*, 70 STAN. L. REV. 1431, 1455–1466 (2018).

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to cast doubt on the efficacy of the TRIPS waiver. However, Moderna and Pfizer have actively transferred their technology to foreign entities, thus demonstrating the feasibility of such transfer. They have employed relational and organizational mechanisms that facilitate a high degree of interaction between technology generators and adopters. Put differently, they have transferred technology within what I have called "bounded entities" – organizational constructs such as fully integrated firms, joint ventures, and even "thick" contractual relationships between long-term partners.[98] Such bounded entities facilitate the intensive communications and interpersonal interactions that are necessary to transfer purely tacit knowledge and that accelerate the transmission of virtually all technical knowledge.

At one end of the spectrum, Moderna is "transferring" its vaccine technology internationally within its own corporate boundaries by establishing manufacturing sites in Kenya, Australia, and Canada.[99] Such "in-house" transfer illustrates the principle that it is easier to transfer tacit knowledge within an organization rather than between two separate ones. Additionally, both Moderna and Pfizer have transferred vaccine technology internationally by utilizing a different kind of "bounded entity": "thick" contractual engagements with long-term partners that facilitate repeated interactions. For instance, Moderna entered into a ten-year "strategic collaboration agreement" with Swiss chemicals and biotechnology company Lonza to manufacture Moderna's COVID-19 vaccine.[100] Far from a one-off engagement, this long-term agreement provides for active technology transfer from Moderna to Lonza.[101]

Pfizer has agreements with over twenty contract manufacturing organizations around the world that provide for intensive technology transfer.[102] Again, these are not one-off interactions in spot markets. While Pfizer's technology transfer engagements usually last up to three years, in the case of its COVID-19 vaccines, it

[98] *See* Peter Lee, *An Organizational Theory of International Technology Transfer*, 108 MINN. L. REV. 71, 109–118 (2023).

[99] *See* Moderna, Moderna to Build State-of-the-Art mRNA Facility in Africa to Manufacture up to 500 Million Doses Per Year (Oct. 7, 2021); Moderna, Moderna and Australia Announce Collaboration to Bring mRNA Manufacturing to Australia (Dec. 13. 2021); Moderna, Moderna and Canada Announce Collaboration to Bring mRNA Manufacturing to Canada (Aug. 10, 2021).

[100] *See* Moderna, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) against Novel Coronavirus (May 1, 2020); *see also* Moderna, Resilience to Manufacture mRNA for Moderna's COVID-19 Vaccine (Sep. 8, 2021) (describing a multi-year agreement between Moderna and Canadian firm National Resilience to provide mRNA for Moderna's vaccine).

[101] *See* Moderna, Lonza, *supra* note 100.

[102] Kate Silver, Shot of a Lifetime: How Pfizer Is Partnering with CMOs to Increase COVID-19 Vaccine Production and Reach More People (Oct. 7, 2021), www.pfizer.com/news/articles/shot_of_a_lifetime_how_pfizer_is_partnering_with_cmos_to_increase_covid_19_vaccine_production_and_reach_more_people (last visited Sep. 12, 2022).

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accelerated that time frame to between five and eighteen months. As Pfizer describes it:

> For the COVID-19 vaccine, the team at the external facility would need to be trained on many aspects of this complex manufacturing process – from learning the intricacies of formulating lipid nanoparticles that encapsulate the mRNA and sterilizing the product to make it safe for injection to filling it into vials, labeling the vials, packaging them, and distributing them around the world.[103]

Such "thick," intensive interactions over long periods of time accelerate technical knowledge transfer, especially the transfer of tacit knowledge.[104]

What are the implications of this relational model of tacit knowledge transfer for the patent quid pro quo? One possibility would be to mandate that patentees directly work with technology adopters to transfer tacit knowledge and other technical information to satisfy the enablement and best mode requirements. For a variety of reasons, however, this chapter argues against such a proposal. Patent law currently contemplates disclosure of technical information through *codification*, and requiring other forms of information sharing, such as interpersonal interactions, would constitute a major paradigm shift. It would, of course, be impossible for a patentee to individually transmit tacit knowledge to the same universe of entities that can read a patent; while codified text is nonrival and nonexcludable, interpersonal interactions are rivalrous and excludable. The personnel demands of transferring tacit knowledge to all technology adopters would be onerous and would require redirection of technical staff from other responsibilities. Furthermore, the PTO and courts are ill-equipped to assess the sufficiency of interpersonal tacit knowledge transfer by patentees. Ultimately, this chapter does not argue for requiring patentees to engage in interpersonal tacit knowledge transfer. The patent system, however, is only one of several policy levers available to encourage such transfer.

This chapter argues that governments can play an important role in facilitating this relational model of technology transfer. First, governments can condition public funding on commitments by grantees to pursue relational modes of tacit knowledge transfer. This represents another example of a public–private quid pro quo. Government agencies can leverage public funds to encourage grantees not only to codify tacit knowledge (and disclose codified trade secrets) but also to actively transfer tacit knowledge to technology adopters. To maintain feasibility, this would not entail a broad obligation to work with all parties that wished to adopt some government-funded technology – such an obligation would place enormous

[103] *Id.*

[104] It is important to note that this relational and organizational model promotes international technology transfer in at least two ways. First, transferring technical knowledge within a shared organizational context greatly facilitates tacit knowledge transfer. Second, transferring technical knowledge within a "bounded entity" mitigates external knowledge leakage to unauthorized parties. *See* Lee, *supra* note 98.

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burdens on government grantees. Rather, this approach would entail individually negotiated agreements by which government grantees would commit to transferring tacit knowledge to select downstream manufacturers (which they could approve) as a condition of receiving public funds.[105]

Such agreements could have significantly enhanced tacit knowledge transfer from Operation Warp Speed. For instance, federal agencies could have conditioned funds on grantees agreeing to actively transfer resulting technical knowledge to a predetermined and mutually agreeable list of vaccine manufacturers. Such commitments to actively transfer technology could have been a condition of receiving research and development funds and/or advance purchase commitments, which were worth billions of dollars to vaccine developers. Had federal agencies adopted this approach, technology transfer agreements with less than a dozen sites around the world would have greatly accelerated global production of vaccines (particularly mRNA vaccines) at a critical time.[106]

Public funds may be necessary not only to incentivize relational tacit knowledge transfer, but also to enable it. Building relational and organizational links to transfer tacit knowledge is costly. As such, if a federal agency negotiates for grantees to transfer technology through consulting engagements, demonstrations, and on-site problem solving, that agency may have to fund such activities.[107] Additionally, government entities can support relational technology transfer in other ways as well. For instance, State Department officials can assist with visas allowing for the travel of key technical personnel, as they did in Operation Warp Speed.[108] Furthermore, public funds may be valuable not only to encourage innovators to "push" tacit knowledge to technology adopters, but also to increase the "absorptive capacity" of those technology adopters.[109] Investments in equipment, training, and even hiring personnel can greatly assist foreign entities seeking to absorb technology from the United States and other countries. For instance, Operation Warp Speed could have devoted funds to enhance the absorptive capacity of vaccine manufacturing facilities around the world to help ramp up vaccine production.

Second, beyond providing funding, governments and international organizations can actively build knowledge-sharing infrastructure to accelerate tacit knowledge

[105] One option for structuring these agreements would allow innovators to bind transferees to nondisclosure agreements. Such agreements would promote greater information sharing while avoiding full public disclosure of technical knowledge.

[106] *See* Nolen, *supra* note 45 (profiling ten facilities around the world that are well positioned to manufacture COVID-19 mRNA vaccines).

[107] Bernard M. Hoekman et al., *Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options*, 33 World Dev. 1587, 1590–1591, 1594 (2005).

[108] USGAO, *supra* note 73, at *2.

[109] Wesley M. Cohen & Daniel A. Levinthal, *Absorptive Capacity: A New Perspective on Learning and Innovation*, 35 Admin. Sci. Q. 128 (1990); *see* Hoekman et al., *supra* note 107, at 1588 ("[S]trong absorptive capacity and the ability to adapt foreign technology are important for [international technology transfer] to effect local technical change").

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transfer. For example, in May 2020 the World Health Organization (WHO) and its partners established the COVID-19 Technology Access Pool (C-TAP). This initiative created a resource for sharing "intellectual property, knowledge and data" concerning innovations for fighting the pandemic.[110] Importantly, C-TAP is more than just a passive repository of information. One of the implementing institutions within C-TAP, the Tech Access Partnership, "facilitates connections between experienced manufacturers and local manufacturers in developing countries to share key data, knowledge and other relevant support though a coordinated network."[111] While illustrating the power of public institutions to facilitate tacit knowledge transfer, unfortunately no major biopharmaceutical firms have yet to participate in C-TAP.[112]

Public institutions, however, have had more success with establishing a technology transfer hub for mRNA vaccines in South Africa.[113] The WHO, a South African consortium, and partners from COVAX have established a hub in which "[f]oreign manufacturers will share techniques with local institutions and WHO and partners will bring in production know-how, quality control and will assist with the necessary licenses."[114] South African researchers at this technology transfer hub recently recreated a prototype of Moderna's mRNA vaccine (without any assistance from Moderna).[115] The tech transfer hub is now transferring mRNA vaccine technology to six African nations.[116] While technology transfer and development would have proceeded much faster with the participation of Moderna or Pfizer, this success illustrates the potential for public infrastructure to catalyze tacit knowledge sharing.

5 CONCLUSION

Controversy over access to patented COVID-19 vaccines has revealed a significant technical challenge to ramping up global production of these essential resources. While patient populations lack access to vaccine doses themselves, third-party manufactures lack access to the information and knowledge to manufacture them, particularly for the newest generation of mRNA vaccines. This state of affairs is

[110] World Health Organization, WHO COVID-19 Technology Access Pool, www.who.int/initiatives/covid-19-technology-access-pool (last visited Sep. 12, 2022).

[111] United Nations, Tech Access Partnership, www.un.org/technologybank/tech-access-partnership (last visited Sep. 12, 2022).

[112] Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on Covid-19 Products*, STAT (May 28, 2020).

[113] World Health Organization, *Towards Africa's First mRNA Vaccine Technology Transfer Hub* (Sep. 17, 2021), www.afro.who.int/news/towards-africas-first-mrna-vaccine-technology-transfer-hub (last visited Sep. 12, 2022).

[114] *Id.*

[115] Amy Maxmen, *South African Scientists Copy Moderna COVID Vaccine*, 602 NATURE 372, 372 (2022).

[116] Wendell Roelf & Alexander Winning, *African Countries to Get mRNA Vaccine Technology in WHO Project*, REUTERS.COM (Feb. 18, 2022).

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paradoxical given that biopharmaceutical patentees have ostensibly disclosed their vaccines as part of the patent quid pro quo. This chapter has explored various causes and implications of this paradox. In a variety of ways, patent disclosure is often limited. In particular, patentees routinely do not disclose tacit knowledge – personal, experiential knowledge that is not amenable to codification – and trade secrets related to their inventions. As a result, patentees often retain valuable private information about their inventions, such as COVID-19 vaccines, while also enjoying patent exclusivity.

To ameliorate this situation, the chapter suggests new and heightened public–private quid pro quos to increase technical disclosure by private innovators. It first argues that patentees' retention of private knowledge necessary to practice patented inventions offends the social bargain at the heart of the patent system. Accordingly, it suggests increasing patent law's disclosure obligations by rehabilitating the best mode requirement. This requirement – which already exists but is rarely enforced – compels patentees to disclose private knowledge about the best way to practice a patented invention. This chapter has also raised the possibility of extending the time period for disclosure obligations beyond the date of filing to capture additional technical information gained by patentees. In the case of patented vaccines and other health products, this approach may also compel patentees to disclose manufacturing information submitted to regulatory agencies. More broadly, federal funding represents a powerful lever for enhancing access to private technical information. In the context of Operation Warp Speed, government agencies could have conditioned billions of dollars on commitments by grantees to disclose latent knowledge and codified trade secrets.

Such obligations, however, are limited to the extent that purely tacit knowledge is not amenable to codification. Rather, such knowledge is best transferred through relational and organizational linkages between technology inventors and adopters. This chapter argues against requiring patentees to engage in interpersonal tacit knowledge transfer as part of the patent quid pro quo. However, it argues that public institutions can encourage such activity through leveraging public funds and establishing infrastructure to catalyze technical knowledge transfer.

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