

# PATENTS, DISCLOSURE, AND BIOPIRACY

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## ABSTRACT

One of the core requirements of patentability is that patent applicants provide background and contextual information about their invention to the patent office. This disclosure is expected to allow a patent examiner to ensure that the application meets patentability standards. However, because of the information asymmetry between expert patent applicants and generalist patent examiners, applicants can withhold useful information while still receiving the benefits of exclusive patent rights. While this is a problem in the patent system in general, the challenge is even worse in a subset of inventions. The information asymmetry is more pronounced in cases of inventions that rely on the genetic resource or traditional knowledge (TK) of indigenous peoples and local communities in their research. A good example is the practice of using traditional medicinal knowledge as research leads to develop modern drugs. Aspirin is one of the drugs developed out of traditional practices. A core question in these situations is whether patent applicants that rely on TK to develop their invention are required to disclose such information to the patent examiner. Reports of multiple instances show that patent applicants usually withhold information about their reliance on TK in their inventive process. As a result, they may claim exclusive property rights over what source communities have been practicing for generations. In reaction to the lack of recognition of their contribution, source communities are adopting a protectionist trend by creating restrictions on access to their resources.

This Article argues that the introduction of an explicit requirement in U.S. patent law, compelling patent applicants to disclose their use of TK, can create an efficient patent system and sustainable relationships in the relevant industries. It provides two justifications for the amendment of U.S. patent law. First, the Article makes a normative case for conceiving the disclosure of origin requirement as an information-forcing rule. Imposing an obligation to disclose the source of TK would elicit socially beneficial information about the validity and scope of a claimed application from the low-cost providers—patent applicants—thereby creating a more

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efficient patent system. Second, the Article argues that an explicit and enforceable disclosure requirement would reverse the inefficient and troubling protectionist trend by facilitating the tracking and enforcement of obligations that researchers may have in contracts with source communities or domestic laws of source countries. The requirement will create confidence in the patent system and encourage source communities to facilitate access to TK. The Article uses efficiency and social-welfare perspectives in contrast to the equity and distributive justice justifications dominating the literature. The focus of this Article on domestic U.S. law is another point of contrast to the focus of the literature on international law.

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## INTRODUCTION

In 1985, Robert Larson, a timber importer based in Sheboygan, Wisconsin, received U.S. Patent 4,556,562 for a storage stable neem tree extract and the process of making such extract to be used as a pesticide.<sup>1</sup> Mr. Larson imported samples of the tree and researched its pesticidal qualities for over a decade.<sup>2</sup> Three years after his patent was granted, he assigned the patent rights to the chemical conglomerate W.R. Grace,<sup>3</sup> which had received similar patents on a storage stable neem tree extract in the United States<sup>4</sup> and other jurisdictions.<sup>5</sup> Neemix, the pesticide that W.R. Grace developed using neem tree extract, grossed around \$60 million in annual global sales.<sup>6</sup> Mr. Larson had learned of the use of the neem trees as a pesticide while importing timber from India.<sup>7</sup> Although farmers in India have been using the neem tree as a pesticide for centuries,<sup>8</sup> Mr. Larson did not mention this fact or how he learned of the use of the neem tree as a pesticide in his patent application.<sup>9</sup> When the granting of patent rights was disclosed to the public, many scholars, activists, farmers, and government leaders protested what they argued was a new form of imperialism and an act of “piracy by patents.”<sup>10</sup> The public outcry resulted in the creation of an international coalition from thirty-five countries, and hundreds of scientific and agricultural groups supported by over 100,000 Indian farmers brought a legal challenge at the U.S. Patent and Trademark Office (PTO).<sup>11</sup>

The legal petition alleged that W.R. Grace is holding a patent right over what Indian farmers have been doing for centuries. While there are philosophical objections against the granting of rights over life forms, on

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1. Stable Anti-Pest Neem Seed Extract, U.S. Patent No. 4,556,562 (filed Mar. 19, 1984) (issued Dec. 3, 1985).

2. Vandana Shiva, *The Neem Tree—A Case History of Biopiracy*, THIRD WORLD NETWORK, <http://www.twn.my/title/pir-ch.htm> (last visited Mar. 22, 2019).

3. *Id.*

4. Storage Stable Azadirachtin Formulation, U.S. Patent No. 5,124,349 (filed Oct. 31, 1990) (issued Jun. 23, 1992).

5. *See, e.g.*, Storage Stable Azadirachtin Formulation, Eur. Patent No. EP0405291 B1 (filed Dec. 20, 1990) (issued Jan. 2, 1991) (the European counterpart of the same patent application).

6. Mara Bovsun, *FET Challenges U.S. Patent on India's Natural Pesticide*, BIOTECHNOLOGY NEWSWATCH, Sept. 18, 1995; Ralph T. King Jr., *Grace's Patent on a Pesticide Enrages Indians*, WALL ST. J., Sept. 13, 1995, at B1.

7. Shiva, *supra* note 2.

8. BD. ON SCI. & TECH. FOR INT'L DEV., NAT'L RESEARCH COUNCIL, NEEM: A TREE FOR SOLVING GLOBAL PROBLEMS 32 (1992).

9. It should be noted here that at the time the Larson patent was examined, U.S. patent law did not consider unpublished information from outside of the United States for patentability analysis. The 2011 America Invents Act has changed that, and under current law, unpublished information from anywhere in the world can be used in examining the validity of a patent application. Leahy-Smith America Invents Act, Pub. L. No. 112-29 § 3(b)(1), 125 Stat. 284, 285–87 (2011) (codified as amended at 35 U.S.C. § 102 (2018)).

10. Vandana Shiva & Radha Holla-Bhar, *Piracy by Patent: The Case of the Neem Tree*, in *THE CASE AGAINST THE GLOBAL ECONOMY: AND FOR A TURN TOWARD THE LOCAL* 146, 150–51 (Jerry Mander & Edward Goldsmith eds., 1996); Lori Wolfgang, *Patents on Native Technology Challenged*, 269 Sci. 1506, 1506 (1995).

11. *See* Request for Reexamination of Patent No. 5,124,349, 1182 OFF. GAZ. PAT. & TRADEMARK OFFICE 536, 536–37 (1996).

a technical level, the challenge argued that the invention lacked novelty and was obvious considering traditional practices in India.<sup>12</sup> W.R. Grace, on its part, claimed that the company's research resulted in increasing the shelf life for the extract from a couple of days to about two years.<sup>13</sup> The PTO agreed with W.R. Grace and found that the claimed invention had a significant level of advancement over the traditional practice and that it met the patentability requirement.<sup>14</sup> The European counterpart patent was invalidated based on evidence showing a scientific project that disclosed a storage stable neem tree extract decades before the patent application.<sup>15</sup>

An important point here is that, at the time the patent was granted, U.S. patent law did not consider unpublished information outside of the United States in patentability analysis.<sup>16</sup> That has since changed with the amendments to the patent law in the 2011 America Invents Act (AIA).<sup>17</sup> Under current U.S. law, unpublished information, such as the public use of the invention, anywhere in the world can be used as a prior art<sup>18</sup> reference against a claimed invention.<sup>19</sup> This may include traditional practices such as the use of neem tree extracts as pesticides in India. However, because the relevance of traditional practices for patentability has not been litigated in court, it is still not clear if the challenge would have come out differently if filed today. In practice, patent examiners hardly consult unpublished sources that may disclose the claimed invention before the patent application. So, even after the AIA, an invention that relies on the oral history and traditional practices of indigenous and local communities could still be granted without the source information being considered in patentability analysis. In fact, the proposals in this Article are timely con-

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12. *Id.*

13. John F. Burns, *Tradition in India vs. a Patent in the U.S.*, N.Y. TIMES (Sept. 15, 1995), <https://www.nytimes.com/1995/09/15/business/international-business-tradition-in-india-vs-a-patent-in-the-us.html>.

14. *See* Stable Anti-Pest Neem Seed Extract, *supra* note 1.

15. Although there are differences in the patent laws of the United States and the European Union (EU), years of international patent law harmonization has resulted in very similar patent systems on patentability requirements with only a few differences between the two jurisdictions. One of the main tools through which patent laws have been harmonized internationally is the World Trade Organization's (WTO) Trade-Related Intellectual Property Rights Agreement. *See* Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 3 (1994); *India Wins Landmark Patent Battle*, BBC, <http://news.bbc.co.uk/2/hi/science/nature/4333627.stm> (last updated Mar. 9, 2005, 4:04 PM); *Neem Tree Patent Revoked*, BBC (May 11, 2000, 1:34 PM), <http://news.bbc.co.uk/2/hi/science/nature/745028.stm>.

16. *See* 35 U.S.C. § 102 (2018); Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 680–83 (2002).

17. The AIA was passed by Congress and signed into law by President Barack Obama in September 2011. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

18. Simply stated, prior art is any acceptable evidence that the claimed invention was known or used by someone other than the patent applicant prior to the patent application. One of the key sections of the Patent Act that describes prior art states that an invention would not be patentable if it was "described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." *See* 35 U.S.C. § 102(a)(1).

19. *Id.*

sidering the AIA reforms. While the AIA has expanded the body of relevant prior art references to cover undocumented knowledge outside of the United States, patent examiners have no realistic way of accessing undocumented TK in other jurisdictions. In this sense, the disclosure requirement outlined in this Article is necessary to bring meaning to the AIA's expansion of prior art.

There are several cases where patent applicants relied on the genetic resource and TK of indigenous peoples and local communities and failed to disclose the source of the information.<sup>20</sup> The term genetic resources refers to “any material of plant, animal, microbial or other origin containing functional units of heredity,”<sup>21</sup> while the term “traditional knowledge” refers to the know-how, skills, innovations, and practices of indigenous peoples and local communities.<sup>22</sup> For the sake of brevity, both genetic resources and traditional knowledge will be referred to as “traditional knowledge” or “TK” for short.<sup>23</sup> The term “indigenous peoples” refers to native communities that reside with settler communities in physical or cultural enclaves, while “local communities” refers to traditional communities outside of the mainstream culture that reside in countries from which colonizing powers have left. The practice of using traditional medicinal knowledge as research leads to develop modern drugs is called bioprospecting, ethnopharmacology, or ethnomedicine, and most discussions around TK deal with these types of relationships.<sup>24</sup> Reliance on TK in the inventive process creates questions of patent validity, duty of disclosure, and entitlement to creative outcomes.

This Article proposes an amendment to U.S. patent law, which introduces an explicit obligation that patent applicants disclose the source of

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20. Other examples include: a patent right for the use of turmeric powder for wound healing, a practice widely used in Indian communities; a patent right over an appetite-suppressant compound extracted from the Hoodia tree, a practice used by the San People of South Africa for centuries; and a patent right over a process of producing teff flour, a famous ingredient used to make injera bread by millions of Ethiopians. For a non-exhaustive list of cases in which patent rights were accused of biopiracy, see JAY MCGOWAN, *OUT OF AFRICA: MYSTERIES OF ACCESS AND BENEFIT SHARING*, at i (Edmonds Inst., 2006); DANIEL F. ROBINSON, *CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES* 45–76 (2010); see generally ABENA DOVE AGYEPOMA OSSEO-ASSARE, *BITTER ROOTS: THE SEARCH FOR HEALING PLANTS IN AFRICA* (2014) (discussing five major cases of biopiracy arising from the African continent).

21. See Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 143, 146.

22. This definition is a narrow one and used to facilitate a pointed discussion about know-how of indigenous peoples and local communities. However, the definition of the term is highly contentious, and varied forms of definitions are used in the scholarship and in international deliberations. See Aman Gebru, *International Intellectual Property Law and the Protection of Traditional Knowledge: From Cultural Conservation to Knowledge Codification*, 15 *ASPER REV. INT'L BUS. & TRADE L.* 294, 330 (2015).

23. This Article is not the first one to use the term TK to refer to traditional knowledge and genetic resources. Some scholars have used the term TK to collectively refer to genetic resources, traditional knowledge, and traditional cultural expressions. See CHIDI OGUAMANAM, *INTERNATIONAL LAW AND INDIGENOUS KNOWLEDGE: INTELLECTUAL PROPERTY, PLANT BIODIVERSITY, AND TRADITIONAL MEDICINE* 172–76 (2d ed. 2006).

24. See Thomas Efferth & Henry Johannes Greten, *Traditional Medicine with Plants—Present and Past*, *MED. & AROMATIC PLANTS*, May 25, 2014, at 1, 1.

TK on which they rely. Such a requirement will facilitate sustainable relationships in industries that rely on TK and will create a more efficient patent system. The Article reaches this conclusion from a welfarist point of view, as opposed to the equity and distributive justice perspective that dominates the literature in this field of patents and TK. In doing so, I hope to engage a broader set of stakeholders beyond those interested in equity and distributive justice.

The Article relates the issues to a core mission of U.S. patent law: disclosure.<sup>25</sup> U.S. patent law grants exclusive rights to individuals that develop inventive products or processes. A key aspect of the system is a quid pro quo<sup>26</sup>—a social compact—in which inventors receive exclusive rights for twenty years in exchange for disclosing their inventions to the public.<sup>27</sup> This social compact faces a risk because patent applicants have both the motive and the opportunity to withhold essential information.<sup>28</sup> They have the motive because the validity and scope of a patent right depends on the level of information available to a patent examiner, and they have an interest to withhold potentially damaging information. Patent applicants have the opportunity because there is considerable information asymmetry in patent examination.<sup>29</sup> Most of the information used by patent examiners tends to be provided by patent applicants who have more information about the invention than the examiner could develop during the limited period of examination.<sup>30</sup>

To guard against this incentive to withhold information, the patent system includes obligations to disclose background and contextual information about the claimed invention.<sup>31</sup> Despite these measures, applicants use drafting techniques to receive rights over unpatentable inventions or to get vague patent rights that create a broader scope than the invention deserves.<sup>32</sup> Several scholars have reported this problem of withholding information to receive patent rights for undeserving claims.<sup>33</sup> This problem, however, is exacerbated in inventions that rely on TK. Because, unlike other prior art references, TK resources are undocumented or are documented in foreign languages, examiners rarely use such resources in

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25. See Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 560–62 (2009).

26. See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–87 (1933).

27. Jacob Adam Schroeder, *Written Description: Protecting the Quid Pro Quo Since 1793*, 21 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 63, 85 (2010).

28. See *infra* Section III.A.1 on information-forcing rules in patent law.

29. R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of Festo*, 151 U. PA. L. REV. 159, 218–19 (2002).

30. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1499–1500 (2001).

31. See Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 BERKELEY TECH. L.J. 1009, 1021 (2008).

32. John R. Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 J. MARSHALL J. COMPUTER & INFO L. 219, 226, 231 (1998).

33. Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH L.J. 147, 147 (2005); Wagner, *supra* note 29, at 214.

patent examinations, which in turn increases the information asymmetry and the incentive to withhold information.

Because U.S. patent law has a broad disclosure requirement,<sup>34</sup> arguably, patent applicants that rely on TK resources in the inventive process must disclose such information. However, there is legal uncertainty surrounding the issue, especially about the level of reliance required to trigger the obligation. An explicit requirement of disclosing reliance on TK would remove doubts and provide better guidance for both researchers and source communities. Reports of multiple instances of biopiracy<sup>35</sup> show that patent applicants usually fail to disclose their reliance on TK in their inventive process, and it is only ex post when the patent is challenged that such information is disclosed. Patentees in the United States have repeatedly been accused of engaging in biopiracy—the act of applying for and receiving patent rights over TK without the knowledge or consent of the source community.<sup>36</sup>

This Article argues that the heightened level of information asymmetry calls for the introduction of an explicit requirement that patent applicants disclose the source of TK they use in their research. Disclosure of source is expected to include disclosure of the level of reliance on TK. For the sake of brevity, this requirement to disclose reliance on TK will be referred to as “the requirement” throughout this Article. The Article makes two arguments that should convince legislators and policy makers to introduce such reform. First, the Article makes the normative case for conceiving the requirement as an information-forcing rule. Understood this way, the benefits of the requirement are that it would elicit socially beneficial information about the validity and scope of a claimed application from the low-cost providers of such information—patent applicants—thereby creating a more efficient patent prosecution process. Full disclosure of the prior art also helps ensure that only deserving inventions get a patent, and thus improves the quality of patents and reduces the social costs of meritless patents. Here, the Article builds on the literature examining the use of information-forcing rules to mitigate inefficiencies resulting from information asymmetry.

Conceiving the requirement as an information-forcing rule provides key insights about the governance of TK use. It points to the need to establish a requirement to compel information from the well-informed

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34. Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L. J. 369, 370 (2013).

35. ROBINSON, *supra* note 20.

36. The *Merriam-Webster* dictionary defines the term “biopiracy” as “the unethical or unlawful appropriation or commercial exploitation of biological materials (such as medicinal plant extracts) that are native to a particular country or territory without providing fair financial compensation to the people or government of that country or territory.” *Biopiracy*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/biopiracy> (last visited Mar. 22, 2019). This corresponds to the use of the term in the scholarships. Paul J. Heald, *The Rhetoric of Biopiracy*, 11 CARDOZO J. INT'L COMP. L. 519, 521 (2003) (critiquing the use of the term “biopiracy”).

party<sup>37</sup>: the patent applicant. The information-forcing rule's literature also suggests that the requirement should only require patent applicants to disclose the *source* from which they received TK and not the *origin* of the resource.<sup>38</sup> Requiring inventors to conduct more research to discover the origin of TK would create new transaction costs that may discourage them from engaging in TK-related research in the first place.<sup>39</sup> Furthermore, the literature also suggests that if the requirement is to provide its information-forcing effect, the penalty for nondisclosure should be robust<sup>40</sup> and include either a rejection of the patent application, patent invalidity, or unenforceability of granted patents.

The second reason to introduce the requirement is that it will reverse a rising protectionist trend which threatens the sustainability of research that relies on TK. This is a trend in which source communities are increasing restrictions on access to TK resources.<sup>41</sup> A requirement to disclose the source of TK used in an inventive process will play a key role in tracking use and enforcing obligations that inventors may have in the laws of source countries or in contracts with source countries. A requirement that enables source communities to have some power to enforce access and benefit-sharing conditions would undo this protectionist trend and create a more collaborative and efficient relationship between researchers and source communities. This, in turn, is expected to create and sustain a promising relationship in relevant industries and improve resource conservation. At a higher level of generalization, requiring disclosure is a way of establishing a more inclusive system of recognition and reward for innovation. Instead of rewarding the inventor at the end of the inventive process,<sup>42</sup> a different framework would seek to reward those that provide useful contribution earlier in that process.

Amending the U.S. Patent Act to explicitly introduce the requirement may be the most effective mechanism considering the twin goals of reversing a rising protectionist trend and compelling socially beneficial information from patent applicants. However, amending U.S. patent law may be infeasible given the lack of political interest to introduce such an amendment and the considerable opposition that may be expected from industry. Therefore, clarifying the duties of disclosure, candor, and good

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37. Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 94 (1989).

38. The source of a TK is the entity through which the patent applicant received access while the origin is the source community that was first to develop the resource. The source of a TK could be an intermediary such as a gene bank or an archive that is unrelated to the source community.

39. Ayres & Gertner, *supra* note 37, at 92.

40. *Id.* at 123–24.

41. Charles McManis, *Biodiversity, Biotechnology and Traditional Knowledge Protection: Law, Science and Practice*, in BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE 5, 5–7 (Charles McManis ed., 2007).

42. JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY 125–26 (1997) (criticizing the focus of IP laws for limiting recognition and reward for innovative activity to individuals making transformative contributions).



faith<sup>43</sup> that patent applications already have by explicitly introducing the requirement would be a feasible second-best measure. The Article also argues that the PTO, as the most suitable administrative agency for patent examination, should check for compliance with the requirement as well.

Part I introduces the U.S. patent system and the disclosure requirement under current law. It discusses existing disclosure problems created by the information asymmetry between patent applicants and examiners. The Part concludes by highlighting that the information asymmetry is even more pronounced in applications that rely on TK. Part II outlines the value of TK resources for modern industries and the dramatic rate at which they are disappearing. The Part also posits that there is a troubling and inefficient protectionist trend in which source communities are increasingly restricting access to their TK. Part III proposes to solve the disclosure problem in the context of TK use by amending U.S. patent law to include a requirement that patent applicants disclose the source of TK they use in their research. Part III makes the normative case for conceiving the requirement as an information-forcing rule. It explains how conceiving the requirement this way could provide important guidance on what features an effective requirement should include. The Part also points out that a carefully designed disclosure requirement has the potential to reverse the rising protectionist trend. Lastly, Part IV discusses the institutional mechanisms through which the requirement should be formulated in U.S. law.

#### I. PATENTS, INCENTIVES, AND DISCLOSURE

Think of a researcher who is about to decide whether to invest in research and development of a new product. If the idea behind the product can be copied, the researcher may face the risk that others may use it to produce the product and compete in the market against the researcher.<sup>44</sup> If the competition is high enough, the researcher may not recoup the cost of research and development, which may force the researcher to decide against investing in the project in the first place.<sup>45</sup> One option the researcher has is to keep the information secret and use the information to produce products.<sup>46</sup> The Coca-Cola Company has been able to produce and sell its products while keeping the formula secret for well over a century.<sup>47</sup>

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43. See 35 U.S.C. § 112 (2018); see also 37 C.F.R. § 1.56 (2018).

44. See generally Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348 (1968) (outlining an economic examination of the incentives involved in investing in innovation).

45. For a detailed discussion of the reasoning behind the monopolistic patent rights, see generally WILLIAM D. NORDHAUS, *INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE* 70–90 (1969).

46. See generally James Bessen, *Patents and the Diffusion of Technical Information*, 86 ECON. LETTERS 121 (2005) (developing an economic model comparing patent rights and trade secrecy as options for innovation and finding that patent rights do not necessarily do a better job).

47. Steven N. S. Cheung, *Property Rights in Trade Secrets*, 20 ECON. INQUIRY 40, 40–53 (1982).

However, the option of relying on secrecy has some limitations.<sup>48</sup> For one, the product must be of a kind that cannot be reverse engineered by others because, if it is, then others could just buy a product, reverse engineer it,<sup>49</sup> and discover the secret information. More importantly, for innovation policy purposes, researchers keeping the results of their research secret limits the potential for innovation. The sharing of information among researchers spurs innovation by enabling researchers to learn and be inspired by information they receive from one another.<sup>50</sup>

Patent law is designed to address the disincentive to invest in ideas that may be copied and the incentive to keep new information secret. Patent rights allow the patentee to practice an invention exclusively and enable her to recoup the costs of developing an idea that could have been copied by others. From the perspective of innovation policy, patents are desirable because they encourage researchers to invest in developing ideas that would otherwise not be developed, and they encourage those with useful information to disclose it to the public, thereby facilitating innovation.<sup>51</sup>

This utilitarian perspective is the standard justification for patent rights in the United States,<sup>52</sup> where rights are granted to “encourage the progress of . . . useful arts.”<sup>53</sup> The expectation is that inventors will invest resources to develop inventions in anticipation of the reward of an exclusive right to exclude others from using the invention. In economic parlance, the problem patent law seeks to solve is one of the nonexcludable nature of inventions. Patent law allows inventors to internalize the benefits of their research.<sup>54</sup>

Policy makers have implemented limitations to balance the incentive that patents grant to inventors with the interest of the public. One of the key limitations is the term limit on patent rights, which is a constitutionally

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48. See Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 311–13 (2008).

49. David D. Friedman, William M. Landes & Richard A. Posner, *Some Economics of Trade Secret Law*, J. ECON. PERSP., Winter 1991, at 61, 62.

50. Hsiu-Fen Lin, *Knowledge Sharing and Firm Innovation Capability: An Empirical Study*, 28 INT'L J. MANPOWER 315, 315–32 (2007).

51. The view of patents as an anti-secrecy tool has been studied by patent law scholars for decades. See, e.g., Anthony Arundel, *The Relative Effectiveness of Patents and Secrecy for Appropriation*, 30 RES. POL'Y 611, 611–24 (2001).

52. This standard justification has been challenged by scholars who suggest other competing justifications for the granting of patent rights. See, e.g., Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 31–32 (1989); Alfred E. Kahn, *Fundamental Deficiencies of the American Patent Law*, 30 AM. ECON. REV. 475, 475 (1940); Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 1–2 (1950).

53. U.S. CONST. art. I, § 8, cl. 8.

54. WILLIAM LANDES & RICHARD POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294 (2003).

mandated feature of patent laws.<sup>55</sup> The most common type of patent rights, utility patents, last twenty years after the date of application. This limitation allows the public to freely use the information disclosed in the patent application after the expiration of the exclusive patent right. Even while the patent has not expired, the public is free to “invent around” it—to use the information in the patent application to develop similar solutions without infringing the right. Furthermore, patent rights are granted to inventions that meet certain substantive and formal requirements.

There are three core requirements of patentability: novelty (newness), nonobviousness, and usefulness (utility).<sup>56</sup> Inventions must meet all three of these requirements to be eligible for patentability. To be considered novel, the claimed invention must be different from anything disclosed to the public through a publication, in another patent application, in products or services sold on the market, or in other ways.<sup>57</sup> An invention will be nonobvious if it involves such a high level of inventive step that a person with the average knowledge and skill in that field would be unable to recreate it easily.<sup>58</sup> To meet the usefulness requirement, an invention must be “minimally operable towards some practical purpose.”<sup>59</sup>

In addition to these statutory requirements, courts have excluded certain types of information from patentability—the three interrelated excluded subject matters are “laws of nature, physical phenomena, and abstract ideas.”<sup>60</sup> The excluded subject matters are meant to reserve the basic building blocks of research and natural processes from becoming the private property of a patent applicant.<sup>61</sup> Therefore, to get a patent right over a naturally occurring substance, applicants have to show that they have created something new using that substance. A common example is the development of synthetic versions of naturally occurring compounds. Innovative applications of abstract ideas, laws of nature, and physical phenomena may be patentable if they meet other patentability requirements.<sup>62</sup>

Furthermore, the application must disclose the invention and the manner of making and using it.<sup>63</sup> The requirement to disclose information about the claimed invention is a key part of patent law, and it is stated in

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55. U.S. CONST. art. I, § 8, cl. 8. The Constitution grants Congress the power “To promote the Progress of Science and useful Arts, by securing *for limited Times* to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” *Id.* (emphasis added).

56. 35 U.S.C. §§ 101–103 (2018).

57. 35 U.S.C. § 102.

58. 35 U.S.C. § 103(a).

59. FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 3 (2003).

60. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216–17 (2014) (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)). Courts have used these three phrases loosely and, at times, interchangeably.

61. *Alice Corp.*, 573 U.S. at 216; *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 70, 71 (2012).

62. *Alice Corp.*, 573 U.S. at 216–17 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

63. 35 U.S.C. § 112 (2018).

many forms. This principle is especially important for the discussions in this Article, and thus the following Section provides a detailed discussion of the content and scope of the duty to disclose under U.S. patent law.

#### A. *The Duty of Disclosure*

The core disclosure requirement in U.S. patent law is outlined under 35 U.S.C. § 112(a) of the Patent Act.<sup>64</sup> It states that patent applications “shall contain a written description of the invention, and of the manner and process of making and using it, in . . . full, clear, concise, and exact terms.”<sup>65</sup> In addition to describing the invention and the surrounding prior art in detail, the patent application is required to list references that situate the claimed invention. These references usually include other patents, printed publications, and other sources that hold information relevant for the examination of the patent application.

The requirement in 35 U.S.C. § 112(a) is supplemented by the duty of disclosure, candor, and good faith that is codified in 37 C.F.R. § 1.56, which is colloquially called “Rule 56.”<sup>66</sup> Under this duty, patent applicants must disclose any information that is deemed to be material for patentability. Information is deemed to be “material” if it “establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim” or if it “refutes, or is inconsistent with, a position the applicant takes.”<sup>67</sup> Although this definition seems to significantly limit the scope of the information required to be disclosed, the duty to disclose has a very broad interpretation. In clarifying the rule further, the relevant provision states that a *prima facie* case of unpatentability exists if an examiner would find a single claim in the application unpatentable giving the claim “its broadest reasonable construction . . . and before any consideration is given to evidence” which may rebut this finding.<sup>68</sup> The rule establishes a very broad understanding of what amounts to material information.

What makes Rule 56 even broader is its reference to the duty of candor and good faith. The PTO has explained, through its Manual of Patent Examining Procedure (MPEP), that the duties of candor and good faith are broader than the duty to disclose material information.<sup>69</sup> Furthermore, as the Federal Circuit explained in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*,<sup>70</sup> “Materiality is not limited to prior art but embraces any information that a reasonable examiner would be substan-

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64. *Id.* § 112(a).

65. *Id.*

66. 37 C.F.R. § 1.56 (2018).

67. *Id.* § 1.56(b)(1)–(2).

68. *Id.* § 1.56(b)(3).

69. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINATION PROCEDURE § 2001.04 (2018) [hereinafter MPEP], <https://www.uspto.gov/web/offices/pac/mpep/mpep-2000.pdf>.

70. 326 F.3d 1226 (Fed. Cir. 2003).

tially likely to consider important in deciding whether to allow an application to issue as a patent.”<sup>71</sup> Additionally, this expanded duty exists no matter how the patent applicant came across the information.<sup>72</sup> The applicant, for example, cannot engage in willful ignorance and avoid accessing explicit notice of material information.<sup>73</sup>

Parallel to statutory law, courts have used their power in equity to develop an independent and, at times, different duty than the one developed under the Patent Act and the PTO rules.<sup>74</sup> The Supreme Court in *Precision Instrument Mfg. Co. v. Automotive Co.*<sup>75</sup> held that a patent would be unenforceable if the patentee has “unclean hands.”<sup>76</sup> The Court held that there is a strong “public policy against the assertion and enforcement of patent claims infected with fraud and perjury.”<sup>77</sup> Although the unclean-hands doctrine was narrow when it was initially developed, courts have expanded the doctrine to apply to a wide range of cases in which the patent applicant was not upfront in her correspondence with the PTO.<sup>78</sup> In a key decision expanding the doctrine, the Court of Customs and Patent Appeals stated that the unclean hands doctrine “cannot be applied too narrowly if the relationship . . . between applicants and the Patent Office is to have any real meaning.”<sup>79</sup> Under this expanded duty, currently called inequitable conduct, a patent could be unenforceable if an applicant withholds information the courts deem relevant.<sup>80</sup> The Federal Circuit in *Hycor Corp. v. Schlueter Co.*<sup>81</sup> declared that “the highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.”<sup>82</sup> As the above discussions reveal, Rule 56, the case law, and the PTO manual repeatedly emphasize that patent applicants have the highest level of duty of disclosure, candor, and good faith.

The function of the disclosure requirement could be grouped into two: a teaching function and a limiting function.<sup>83</sup> The teaching function speaks to the value of disclosure in revealing useful information about the state of the art to the public. As the Supreme Court declared in *Kewanee*

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71. *Id.* at 1234.

72. MPEP, *supra* note 69, § 2001.06.

73. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383 (Fed. Cir. 2001) (discussing that if an applicant or the attorney knows that there is relevant information, they cannot ignore such notice to avoid the duty to disclose).

74. ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW & POLICY* 1104 (4th ed. 2007).

75. 324 U.S. 806 (1945).

76. *Id.* at 819.

77. *Id.*

78. MERGES & DUFFY, *supra* note 74.

79. *Norton v. Curtiss*, 433 F.2d 779, 795 (C.C.P.A. 1970).

80. MERGES & DUFFY, *supra* note 74. The inequitable conduct doctrine is not without criticism. *See generally* Nolan-Stevaux, *supra* note 33, at 161–62 (arguing that the inequitable conduct doctrine has been abused by defendants because it is used in almost all patent infringement lawsuits).

81. 740 F.2d 1529 (Fed. Cir. 1984).

82. *Id.* at 1538 (quoting *Norton*, 433 F.2d at 794).

83. Rantanen, *supra* note 34, at 375.

*Oil Co. v. Bicorn Corp.*,<sup>84</sup> the disclosure is meant to add to the public's "general store of knowledge."<sup>85</sup> In its limiting function, disclosure works to limit the scope of the claim in the patent application (the metes and bounds of the right granted to the inventor). Because patents are only granted to new inventions, the applicant cannot claim rights over information disclosed to the public before the patent application.

### B. Disclosure Problems in Current Law

Despite the heightened level of the disclosure requirement in U.S. patent law, research<sup>86</sup> has shown that patent applicants withhold information from the PTO and, as a result, receive a right where one is not deserved or receive a broader right than the invention they developed. This dynamic is created because of the inherent information asymmetry between the patent applicant and the examiner.<sup>87</sup> The inventor who applies for an invention would usually have dedicated a considerable amount of time researching in the field to develop a new, nonobvious, and useful invention. Furthermore, patent applicants use vague wording and other claim-drafting techniques to introduce confusion about the scope of the claimed invention that they could later exploit to their advantage.<sup>88</sup> This information asymmetry and the *ex parte* nature of patent prosecution provides both the motive and the opportunity for patent applicants to withhold important information from the examiner. This issue has been highlighted by many patent law scholars<sup>89</sup> and is examined in further detail in a later Section.<sup>90</sup>

## II. PROBLEMS IN THE CONTEXT OF TRADITIONAL KNOWLEDGE

The problems of withholding important information from patent examiners is exacerbated in inventions that rely on TK resources. This is because the inherent information asymmetry in the patent system is even more stark in the case of TK use. One of the common features of TK resources is that they are inaccessible. In contrast to the emphasis on documenting knowledge in Western societies, indigenous peoples and local

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84. 416 U.S. 470 (1974).

85. *Id.* at 481.

86. See Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. REV. 1421, 1465 (2009); Fromer, *supra* note 25, at 560–62; Lemley, *supra* note 30, at 1499–1500; John M. Olin, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2024 (2005); Dan Callaway, Note, *Patent Incentives in the Semiconductor Industry*, 4 HASTINGS BUS. L.J. 135, 143–44 (2008).

87. See generally Lisa Larrimore Ouellette, *Pierson, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1828 (2016).

88. See Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1163–64 (2002); Ben Klemens, *The Rise of the Information Processing Patent*, 14 B.U. J. SCI. & TECH. L. 1, 35 (2008) (finding that software and IT related patents are "virtually useless for disclosure purposes"); Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, 157 U. PA. L. REV. 2083, 2127–28 (2009).

89. Cotropia & Lemley, *supra* note 86, at 1499–1500; Wagner, *supra* note 29.

90. See *infra* Section III.A.1 on information-forcing rules in patent law.

communities predominantly use oral traditions to conserve and transfer knowledge.<sup>91</sup> In the rare cases where TK resources are codified, they tend to be codified in local languages that may not be understood by patent examiners. Therefore, the unique features of TK that make it inaccessible increase the information asymmetry between an inventor who managed to gain access to TK and a patent examiner working to decide the patentability of the claimed invention. The following Sections outline the issues that arise and problems that must be addressed when modern industries rely on TK resources in their inventive process.

*A. The Value & Loss of TK Resources*<sup>92</sup>

The relationship between the requirement and the use of TK resources can be explained through the example of modern drug discovery and development. Although the example of TK use in the biopharmaceutical field is used as an example throughout this Article, one can imagine the multiple areas of modern research and development that could benefit from the use of TK.<sup>93</sup>

It is no secret that research and development takes considerable time and resources in the biotechnology and pharmaceutical (hereafter biopharmaceutical) industries. For instance, by one estimate, the out-of-pocket preapproval cost of the development of a drug to the point of marketing is around \$802 million.<sup>94</sup> And the average time from human testing to post-regulatory approval is estimated to be over nine years.<sup>95</sup> One approach that biopharmaceutical firms have adopted to reduce this cost is “ethnopharmacology” or “ethnomedicine,” which is the use of TK in the

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91. Gebru, *supra* note 22, at 300.

92. TK resources may be useful in two ways. The resources are used by indigenous peoples and local communities as they have been used for centuries, for example for traditional healthcare, agricultural management, and environmental conservation. Another way TK resources are useful is as an input in modern industries. This Section focuses on this second type of use because of its relevance for the requirement. This, however, is not meant to discount the independent use of that TK resources have for the source community. The independent use of TK resources has been essential for the survival of indigenous peoples and local communities. For instance, the World Health Organization has stated that 70–80% of the population in developing countries relies on the independent use of traditional medicine and substantial portions of the population in developed countries rely on some form of alternative medicine. See Xiaorui Zhang, *Traditional Medicine: Its Importance and Protection*, in U.N. CONF. ON TRADE & DEV., PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS, at 3, 3 U.N. Doc. UNCTAD/DITC/TED/10 (2004).

93. For instance, research into agriculture and environmental protection have considerably benefited from the knowledge and resources of indigenous peoples and local communities. See generally INT’L PROGRAM ON TRADITIONAL ECOLOGICAL KNOWLEDGE & INT’L DEV. RESEARCH CTR., TRADITIONAL ECOLOGICAL KNOWLEDGE: CONCEPTS AND CASES 1, 15 (Julian T. Inglis ed., 1993).

94. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (This data is from the year 2000 and with annual inflation at 2.4% since 2000, the current cost of an average drug would therefore be over \$1.1 billion).

95. KI Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 356, 358 (2010).

search of resources with medicinal value.<sup>96</sup> Empirical research has proved that ethnopharmacology has reduced the time and cost of developing biopharmaceutical products.<sup>97</sup> One of the key benefits of using TK resources is in increasing the efficiency of initial screening of biodiversity candidates for further examination. For instance, in one study, the chances of getting a preliminary hit<sup>98</sup> in plant screening increased from 6% without the use of TK to 25% with the use of TK.<sup>99</sup> Additional research indicated that the use of TK increased the efficiency of screening plants in the development of a cure for HIV/AIDS.<sup>100</sup> While some claims of traditional medicines have had questionable efficacy,<sup>101</sup> the empirical evidence points to the significant potential that TK resources have as an input for modern industries. The trial and error from the centuries-old use of biodiversity resources by communities has been serving as a diverse pool upon which biopharmaceutical firms build to develop modern drugs.

Despite the value of biodiversity and TK resources, they increasingly face an alarming rate of loss.<sup>102</sup> Conservationists have been warning of the high rate of biodiversity loss since the later decades of the twentieth century.<sup>103</sup> Caused by human activity such as changes in land use, pollution,

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96. See generally Gordon C. Rausser & Arthur A. Small, *Valuing Research Leads: Bioprospecting and the Conservation of Genetic Resources*, 108 J. POL. ECON. 173, 178 (2000) (“Indeed, some firms base their entire product discovery programs on leveraging the experience of traditional healers concerning the therapeutic properties of plants used in herbal medicine.”).

97. Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENVTL. HEALTH PERSP. 69, 69 (Supp. 2001); Axel Helmstadter & Christiane Staiger, *Traditional Use of Medicinal Agents: A Valid Source of Evidence*, 19 DRUG DISCOVERY TODAY 4, 4 (2014); P.J. Houghton, *The Role of Plants in Traditional Medicine and Current Therapy*, 1 J. ALTERNATIVE COMPLEMENTARY MED. 131, 136 (1995); M.L. Wilcox et al., *A “Reverse Pharmacology” Approach for Developing an Anti-Malarial Phytomedicine*, MALARIA J., Mar. 2011, at 1.

98. Rebecca Deprez-Poulain & Benoit Deprez, *Facts, Figures and Trends in Lead Generation*, 4 CURRENT TOPICS IN MED. CHEMISTRY 569, 580 (2004); Benoit Deprez & Rebecca Deprez-Poulain, *Hit-to-Lead: Driving Forces for the Medicinal Chemist*, 4 CURRENT TOPICS IN MED. CHEMISTRY I, at i (2004).

99. Cf. C. Haris Saslis-Lagoudakis et al., *Phylogenies Reveal Predictive Power of Traditional Medicine in Bioprospecting*, 109 PNAS 15835, 15835 (2012).

100. Daniel Goleman, *Shamans and Their Lore May Vanish with Forests*, N.Y. TIMES (June 11, 1991), <http://www.nytimes.com/1991/06/11/science/shamans-and-their-lore-may-vanish-with-forests.html> (“In a field study in the rain forest in Belize, Dr. [Michael] Balick [director of the Institute of Economic Botany at the New York Botanical Garden] compared using a random collection of plant species with an ethnobotanical approach, in which only the plants that local people say have medical uses are collected. . . . Of the 20 plants collected on the shaman’s advice, five killed the AIDS virus but spared the T cells. But of 18 plant species gathered randomly, just one did so.”).

101. The term “traditional medicine” is at times conflated with questionable medical practices such as voodoo medicine, the efficacy of which has not been proved scientifically. The World Health Organization, for instance, has noted the problem and is working to ensure that traditional medicine continues to be practiced safely. WORLD HEALTH ORG., WHO TRADITIONAL MEDICINE STRATEGY 2014–2023, at 12 (2013).

102. Paul R. Ehrlich, *The Loss of Diversity: Causes and Consequences*, in BIODIVERSITY 21, 21–22 (E.O. Wilson & Frances M. Peter eds., 1988).

103. Timothy R. Tomlinson, *Preface* to MEDICINAL PLANTS: THEIR ROLE IN HEALTH AND BIODIVERSITY, at ix, ix–xi (Timothy R. Tomlinson & Olayiwola Akerele eds., 1998); Luis Maffi, *Linguistic and Biological Diversity: The Inextricable Link*, 29 ANN. REV. ANTHROPOLOGY 599, 601 (2005) (discussing the high rate of cultural and linguistic loss that impacts the knowledge of the uses of biodiversity).



climate change, and invasion of invasive species, the loss of biodiversity has been estimated to be 100–1000 times the rate it would be without human interference.<sup>104</sup> For example, the normal rate of biodiversity loss used to be in the range of “1–10 species per million per year,” but in recent years that number has risen to “hundreds or low thousands per million per year.”<sup>105</sup> Researchers have calculated the annual loss from ecosystem services to be around \$250 billion.<sup>106</sup> To save this valuable resource from disappearing, world leaders worked towards the signing of the Convention on Biological Diversity in 1992.<sup>107</sup> Two of the key contributions of the Convention to our current purposes were: (1) the recognition that source countries have sovereign rights in their biodiversity resources,<sup>108</sup> and (2) the recognition that indigenous peoples and local communities should equitably benefit from the innovations arising out of TK resources.<sup>109</sup>

In addition to the inherent harm caused by the loss of biodiversity, this alarming rate of loss impacts the sustainability of innovation in the bioprospecting industry. Because only a small portion of the world’s biodiversity has been scientifically studied,<sup>110</sup> the high rate of loss means inventors (and by implication, the public) miss out on the development of products with potential to enhance welfare.

### B. A Rising Protectionist Trend

One of the key contributions of this Article is to highlight a rising protectionist trend that should worry anyone interested in encouraging innovation in industries that rely on TK resources. The protectionist trend is one in which source communities and countries rich in TK resources are increasingly introducing barriers to access to these resources. While the tendency to keep TK secret because of fears of biopiracy have been mentioned in other publications,<sup>111</sup> these references tend to be made only in

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104. See V. H. HEYWOOD, UNITED NATIONS ENV’T PROGRAMME, GLOBAL BIODIVERSITY ASSESSMENT 5 (1995); see also MILLENNIUM ECOSYSTEM ASSESSMENT, LIVING BEYOND OUR MEANS: NATURAL ASSETS AND HUMAN WELL-BEING 1, 3 (2005). For research on the human contribution to biodiversity loss, see Deborah J. Forester & Gary E. Machlis, *Modeling Human Factors that Affect the Loss of Biodiversity*, 10 CONSERVATION BIOLOGY 1253, 1253 (1996).

105. PETRA EBERMANN, PATENTS AS PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE? A LAW AND ECONOMICS APPROACH 26 (2012).

106. MILLENNIUM ECOSYSTEM ASSESSMENT, ECOSYSTEMS AND HUMAN WELL-BEING (2005).

107. Convention on Biological Diversity, *supra* note 21, at 1–2.

108. *Id.* at 1.

109. *Id.*

110. See Mark J. Costello, *Biodiversity: The Known, Unknown, and Rates of Extinction*, 25 CURRENT BIOLOGY R368, R368 (2015). *National Geographic* has discussed the possibility of an overwhelming majority of species still being unknown. See Traci Watson, *86 Percent of Earth’s Species Still Unknown?*, NAT’L GEOGRAPHIC NEWS (Aug. 25, 2011), <https://news.nationalgeographic.com/news/2011/08/110824-earths-species-8-7-million-biology-planet-animals-science>.

111. See, e.g., Nuno Pires De Carvalho, *From the Shaman’s Hut to the Patent Office: A Road Under Construction*, in BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE 241, 245–46 (Charles R. McManis ed., 2007).

passing. This Article makes the case that there is a strong and rising protectionist trend among source communities that policy makers should seriously consider.

Biodiversity resources are unevenly distributed throughout the world. Countries in the Global South<sup>112</sup> are home to a high percentage of biodiversity resources. For instance, megadiverse countries<sup>113</sup>—the top seventeen biodiversity-rich countries in the world—hold between 60–80% of the world’s flora and fauna.<sup>114</sup> Only two of the seventeen megadiverse countries—the United States and Australia—are economically developed countries. On the other hand, the capacity to exploit these resources on a commercial scale is concentrated in the Global North. This uneven distribution of resources, coupled with the lack of legal protection for TK resources and the absence of research and business practices that recognize the contribution of source communities, create what many consider to be an unfair relationship. This is one of the major concerns that led to the convening, and later signature, of the Convention on Biological Diversity.<sup>115</sup>

While the signing of the Convention was a major milestone to conserve biodiversity and ensure benefit sharing, the implementation of the Convention was far from what source communities and countries hoped for. This legal lacuna and many high-profile cases of biopiracy<sup>116</sup> have forced many source communities and jurisdictions to create barriers to access to TK resources. While the Convention’s mission was to facilitate access to TK resources in exchange for benefit sharing, its failure seems to have encouraged quite the opposite. As one scholar noted:

[T]he [Convention on Biodiversity] has . . . stimulated a wave of national legislation having the effect (whether intended or unintended) of restricting, rather than facilitating, access to genetic resources in the developing world, pending the industrialized world’s adoption of a meaningful benefit-sharing measures.<sup>117</sup>

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112. The term “Global South” is a rough reference to developing countries which are concentrated south of the equator. Nour Dados & Raewyn Connell, *The Global South*, CONTEXTS, Winter 2012, at 12, 12 (“The phrase ‘Global South’ refers broadly to the regions of Latin America, Asia, Africa, and Oceania. It is one of a family of terms, including ‘Third World’ and ‘Periphery,’ that denote regions outside Europe and North America, mostly (though not all) low-income and often politically or culturally marginalized.”).

113. The term “megadiverse countries” refers to the top biodiversity rich countries in the world, which hold a minimum of five thousand endemic plant species and a marine ecosystem within their borders. See, e.g., *Areas of Biodiversity Importance: Megadiverse Countries*, BIODIVERSITY A–Z, <http://www.biodiversitya-z.org/content/megadiverse-countries> (last visited Mar. 14, 2019).

114. RUSSELL A. MITTERMEIER & CRISTINA GOETTSCHE MITTERMEIER, MEGADIVERSITY: EARTH’S BIOLOGICALLY WEALTHIEST NATIONS 18 (2005).

115. THE CONVENTION ON BIOLOGICAL DIVERSITY: FROM CONCEPTION TO IMPLEMENTATION 1, 4–5 (2004), <https://www.cbd.int/doc/publications/CBD-10th-anniversary.pdf>.

116. ROBINSON, *supra* note 20.

117. McManis, *supra* note 41, at 5.

The Convention was signed because member countries understood that access to biodiversity resources was necessary for innovation in certain fields. Thus, evidence of a rising protectionist trend should worry policy makers tasked with encouraging the “[p]rogress of . . . useful arts.”<sup>118</sup>

The rise in protectionist trend can be observed in at least two features of domestic legal activity. The first is the increasing number of new legislation creating barriers to access to TK, or the amendment of existing legislation (including intellectual property (IP)<sup>119</sup> laws) to include TK protection.<sup>120</sup> Several of the major biodiversity hotspots of the world have enacted domestic legislation with the effect of restricting access to TK.<sup>121</sup> For instance, in June 2018, the second biggest megadiverse country, Indonesia, strengthened its laws to protect its biodiversity from biopirates.<sup>122</sup> While legislation governing TK resources may be crafted to facilitate access, because most are reacting to allegations of biopiracy, they do not seem to meet the right balance between access and restriction.

The second feature that signals a rising protectionist trend is the creation of restricted TK databases or registers. While the practice of documenting TK in databases is still new, many of the jurisdictions that have decided to invest in these databases seem to have adopted highly restrictive measures. For instance, the pioneering TK database is the Indian government’s Traditional Knowledge Digital Library (TKDL), which boasts the codification of over 250,000 medical formulations from Indian traditional medicinal knowledge.<sup>123</sup> While those who manage the TKDL claim the database is accessible due to the translation of its contents into five of the leading international languages, access to the database is granted only to patent examiners for the sole purpose of patent examination.<sup>124</sup> Patent

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118. U.S. CONST. art. I, § 8, cl. 8.

119. The term “intellectual property” is generally used to refer to the rights granted over scientific, literary, and artistic creations that meet a set of requirements under the law. The three core types of intellectual property rights are patents, copyrights, and trademarks. See *What Is Intellectual Property?*, WORLD INTELL. PROP. ORG., <https://www.wipo.int/about-ip/en> (last visited Mar. 22, 2019).

120. A search for TK-related legislation on the WIPO legal text database results in 173 records. Almost all of these legislations were enacted after the Convention on Biological Diversity (CBD), and the overwhelming majority are among countries of the Global South. Some of these legislations cover several issues including TK, traditional cultural expression, and genetic resources. WIPO LEX SEARCH, <https://wipolex.wipo.int/en/legislation/results?subjectMatters=18> (last visited Mar. 22, 2019).

121. Carvalho, *supra* note 111, at 245–46; Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 565, 565–94 (Keith E. Maskus & Jerome H. Reichman eds., 2005) (outlining national legislations enacted to protect TK in India, Brazil, Peru, the Philippines, and the Africa model legislation).

122. Harish Mehta, *Indonesia Strengthens Laws Against Biopirates*, BUS. TIMES (June 8, 2018, 5:50 AM), <https://www.businesstimes.com.sg/opinion/indonesia-strengthens-laws-against-biopirates>.

123. See *About TKDL*, TRADITIONAL KNOWLEDGE DIGITAL LIBR., <http://www.tkdlib.res.in/tkdlib/langdefault/common/Abouttkdl.asp?GL=Eng> (last visited Mar. 22, 2019).

124. By granting access to several patent offices around the world, including the PTO, the TKDL has already been credited for the revocation, suspension, or amendment of 206 patents in multiple jurisdictions. Additionally, the Indian government has submitted challenges against over 1,200 patent applications. See *id.*

offices interested in gaining access to the database have to sign a nondisclosure agreement after negotiating the specific terms with the Indian government.<sup>125</sup> Other countries are adopting this practice of making TK databases restrictive.<sup>126</sup>

Policy makers should be concerned that, instead of increased access that spurs improvements, researchers now face restrictions. Because the ultimate result of a research project is usually unpredictable, researchers need access to a wide range of input, including TK. If states with huge biodiversity resources continue adopting a restrictive stance, it is easy to imagine how such a trend could affect research in industries that benefit from TK, including the biopharmaceutical sector. Even if researchers find a way around restrictions, legislation, and TK registries, the increase in transaction costs of accessing these resources creates inefficiencies.

The move towards protectionism is even more troubling because most source communities do not have the capacity to independently develop TK into modern products. For instance, if source communities could develop their traditional medicinal knowledge into a drug that could be marketed globally, then the restrictions would function in the same way trade secrets help firms develop products while keeping commercially valuable information hidden.<sup>127</sup> However, the overwhelming majority of source communities and many megadiverse countries lack the financial and human resource capacity to develop TK resources into commercial products. Furthermore, there are multiple reports sounding the alarm on the very high rate of biodiversity loss,<sup>128</sup> and TK resources rely heavily on biodiversity. Protectionism, in the face of such a high rate of resource loss,

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125. See *Traditional Knowledge Digital Library (TKDL) Access Agreement*, TRADITIONAL KNOWLEDGE DIGITAL LIBR., <http://www.tkdlib.org/TKDL/TKDL-Access-Agreement.pdf> (last visited Mar. 22, 2019).

126. REPUBLIC OF S. AFR. DEP'T OF SCIENCE & TECH., THE NATIONAL RECORDAL SYSTEM: PRESENTED TO THE NATIONAL BIODIVERSITY INITIATIVE 8, 17 (2013), [http://www.abs-initiative.info/uploads/media/Carol\\_van\\_Wyk\\_\\_Tom\\_Suchanandan\\_-\\_DST\\_-\\_National\\_Recordal\\_System.pdf](http://www.abs-initiative.info/uploads/media/Carol_van_Wyk__Tom_Suchanandan_-_DST_-_National_Recordal_System.pdf); Bandile Sikwane, *National Recordal System: Safeguarding the Future of Indigenous Knowledge Through ICT*, CSIR SCI. SCOPE 60, 60–61 (2015); Korean Intellectual Property Office, *Introduction of Korean Traditional Knowledge Portal (KTKP)*, WORLD INTELL. PROP. ORG. (2011), [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_tkdl\\_del\\_11/wipo\\_tkdl\\_del\\_11\\_ref\\_t9\\_4.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_tkdl_del_11/wipo_tkdl_del_11_ref_t9_4.pdf); *KTKP Introduction*, KTKP, [http://www.koreantk.com/en/m\\_about/about\\_01.jsp?about=1](http://www.koreantk.com/en/m_about/about_01.jsp?about=1) (last visited Mar. 22, 2019); Song Jiangxiu, State Intellectual Prop. Office of the People's Republic of China, *Introduction of China Traditional Chinese Medicine Patent Database*, WORLD INTELL. PROP. ORG. (Dec. 16–17, 2009), [https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_ipmk\\_bkk\\_09/wipo\\_ipmk\\_bkk\\_09\\_topic5\\_2.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipmk_bkk_09/wipo_ipmk_bkk_09_topic5_2.pdf).

127. Doris Estelle Long, *Trade Secrets and Traditional Knowledge: Strengthening International Protection of Indigenous Innovation*, in *THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH* 495, 536 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011) (suggesting the extension of trade secrecy protection for TK).

128. See generally BIODIVERSITY LOSS: ECONOMIC AND ECOLOGICAL ISSUES (Charles Perrings et al. eds., 1997); Ben A. Minteer, *Valuing Nature*, in *LOSS OF BIODIVERSITY* 75, 86 (Sharon L. Spray & Karen L. McGlothlin eds., 2003); *THE ROOT CAUSES OF BIODIVERSITY LOSS* 9 (Alexander Wood et al. eds., 2000); Stuart L. Pimm et al., *The Future of Biodiversity*, 269 SCIENCE 347, 347–50 (1995); John G. Robinson, *The Limits to Caring: Sustainable Living and the Loss of Biodiversity*, 7 CONSERVATION BIOLOGY 20, 25 (1993).

will result in numerous TK resources disappearing for eternity before being examined for their bioprospecting potential. In other words, a protectionist stance, coupled with the lack of capacity in source communities to independently commercialize TK, results in the underutilization of this valuable resource.<sup>129</sup> This is undesirable from the perspective of global social welfare because increased access to research input is expected to encourage innovation, not increased restrictions.<sup>130</sup>

Ultimately, a rising protectionist trend means that the status quo in which firms use TK resources to develop products is unsustainable in the long run. Because of this protectionist trend, researchers and firms that have the means to commercialize TK resources will be unable to access the resources (or may face high transaction costs), and their bioprospecting effort will be curtailed. The unfortunate results will be that the public will miss out on innovative products, firms in the field will see the costs of doing research rise because of high transaction costs, and source communities will miss out on a share of the profits that they would have received had their TK resources been used to develop products. The increasing number of restrictions created by several jurisdictions show that this worrisome protectionist trend is on the rise.

### III. ADDRESSING DISCLOSURE IN THE TK CONTEXT

A major contribution of the Article is using a welfareist perspective to justify introducing the requirement in U.S. patent law. The requirement would lead to welfare-enhancing outcomes instead of the inefficient and unsustainable status quo where researchers face a rising protectionist trend or where the PTO grants patent rights to undeserving applicants. Amending U.S. law to introduce the requirement is justified based on the twin goals of improving patent quality and reversing a rising protectionist trend.

While some version of the requirement has been discussed internationally,<sup>131</sup> a robust discussion of the costs and benefits of introducing the requirement in domestic U.S. law is lacking. The next two Sections turn to the normative case for explicitly introducing the requirement into U.S.

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129. DARRELL A. POSEY & GRAHAM DUTFIELD, *BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES* 1–2 (1996).

130. The core purpose of the CBD is to create increased access to TK resources so that researchers can use the resources for further innovation. *See* Convention on Biological Diversity, *supra* note 21, at 1–2.

131. CARLOS M. CORREA, *TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: ISSUES AND OPTIONS SURROUNDING THE PROTECTION OF TRADITIONAL KNOWLEDGE* 19 (2001); IKECHI MGBEOJI, *GLOBAL BIOPIRACY: PATENTS, PLANTS, AND INDIGENOUS KNOWLEDGE* 174 (2005); Peter Drahos & Susy Frankel, *Indigenous Peoples' Innovation and Intellectual Property: Time Issues, in INDIGENOUS PEOPLE'S INNOVATION: INTELLECTUAL PROPERTY PATHWAYS TO DEVELOPMENT* 1, 26 (Peter Drahos & Susy Frankel eds., 2012); OGUAMANAM, *supra* note 23; Joshua D. Sarnoff & Carlos M. Correa, U.N. Conf. on Trade & Dev., *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, at iii, U.N. Doc. UNCTAD/DITC/TED/2004/14 (2006); Nuno Pires De Carvalho, *From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent*, 17 WASH. U. J.L. & POL'Y 111, 184 (2005).

patent law. The stated goal of the U.S. patent system is to encourage “the progress of . . . useful arts.”<sup>132</sup> The rest of the Article argues that the introduction of a carefully calibrated and explicit requirement to disclose the source of TK used in inventive processes would be consistent with this goal.

#### *A. Information-Forcing Rules*

This Section makes the normative case for the introduction of an explicit requirement that would compel patent applicants to disclose the source of TK they used in their application. It also outlines the value of conceiving the requirement as an information-forcing rule. The requirement should be designed as an information-forcing rule that can elicit socially beneficial information from the least-cost providers (i.e., patent applicants). Conceiving the requirement in this way reveals that it will improve patent quality and reduce costs in the patent system without unduly burdening researchers. This Article posits that the cost-benefit analysis of introducing the requirement should be reconsidered through the lens of an information-forcing rule.

While information-forcing rules have been examined in many contexts, the first strong case for the adoption of such rules was made in the contracts context.<sup>133</sup> In their seminal article discussing information-forcing rules,<sup>134</sup> Ian Ayres and Robert Gertner identify two types of scenarios in the context of contracts that would benefit from the adoption of default-penalty rules. One scenario is in which parties facing significant transaction cost *ex ante* create contractual gaps with the intention of having the gaps filled with an *ex post* court interpretation based on the standard of “what the parties would have wanted.”<sup>135</sup> The parties avoid adding a contractual term because the *ex ante* cost is higher than the *ex post* cost of having a court interpret the contract. The cost of interpreting the contractual term is, therefore, an externality born by publicly supported courts.

The second type of scenario that Ayres and Gertner identify is one in which a party with private information creates a contractual gap by withholding privately held information that, if revealed, would result in a socially optimal outcome.<sup>136</sup> The well-informed party withholds the information because, even if the disclosure of information would increase the pie, the party’s portion of the pie will be smaller than if the party kept the information private. In this second scenario, default rules can be designed to force the well-informed party to reveal the privately held information and thereby enable a socially beneficial deal to take place. In a sense, the

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132. U.S. CONST. art. I, § 8, cl. 8.

133. Alex Reinert, *Pleading as Information-Forcing*, 75 LAW & CONTEMP. PROBS., no. 3, 2012, at 1, 3.

134. Ayres & Gertner, *supra* note 37, at 91.

135. *Id.* at 92–93.

136. *Id.* at 94.

default rules function against a strategic, rent-seeking behavior that a well-informed party may take in a contract negotiation.

This second type of relationship may be observed in the employment contract sense. While the default employment contract in the United States is “at will,” most employees erroneously believe that they cannot be fired from their jobs without “just cause.”<sup>137</sup> Sophisticated employers who usually draft a boilerplate employment contract can be expected to know the “at will” nature of their employment relationship with their employees. By concealing the “at will” nature of an employment contract, an employer may benefit from the false sense of job security that its employee may have, while being able to terminate any individual without cause. Courts and legislators can (and do in some circumstances) adopt a default rule that the employment contract will be presumed to be a “just cause” employment unless the employer explicitly communicates the “at will” nature of employment to their potential employees. Adopting such a default rule will ensure that the well-informed party (the employer) discloses the privately held information (the “at will” nature of employment) to the employee, thereby ensuring a real meeting of the minds when the parties enter into an employment contract. The adoption of information-forcing default rules in these contexts, therefore, serves the core purpose of contract law: ensuring that there is a meeting of the minds between parties to the contract.

Several other doctrines of contract law could be described as information-forcing (or information-eliciting) default rules. The rule that vague terms in contracts will be construed against the drafting party,<sup>138</sup> and the presumption, in the Statute of Frauds, that parties do not intend to have a legally enforceable agreement unless it is made in writing, can be understood as a default-penalty rule.<sup>139</sup> Information-forcing rules have been identified in other areas of law including constitutional law, employment law, legal ethics, the law of corporations, environmental law, arbitration, and criminal law.<sup>140</sup>

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137. J. H. Verkerke, *Legal Ignorance and Information-Forcing Rules*, 56 WM. & MARY L. REV. 899, 923 (2015); Rachel Leiser Levy, Comment, *Judicial Interpretation of Employee Handbooks: The Creation of a Common Law Information-Eliciting Penalty Default Rule*, 72 U. CHI. L. REV. 695, 695 (2005).

138. David M. Driesen & Shubha Gosh, *The Functions of Transaction Costs: Rethinking Transaction Cost Minimization in a World of Friction*, 47 ARIZ. L. REV. 61, 72 (2005).

139. Shawn Pompian, Note, *Is the Statute of Frauds Ready for Electronic Contracting?*, 85 VA. L. REV. 1447, 1453 (1999).

140. For an extensive list of different areas in which information-forcing rules have been identified and analyzed, see Ian Ayres, *Ya-Huh: There Are and Should Be Penalty Defaults*, 33 FLA. ST. U. L. REV. 589, 601–11 (2006); see, e.g., Bradley C. Karkkainen, *Information-Forcing Environmental Regulation*, 33 FLA. ST. U. L. REV. 861, 861 (2005); Reinert, *supra* note 133.

### 1. Information-Forcing Rules in Patent Law

IP law scholars have embraced the information-forcing rule's literature as a helpful lens to examine various doctrines.<sup>141</sup> This is even more so the case in the patent law field.<sup>142</sup> The predominance of a utilitarian justification for patent law lends itself to an incentive-based analysis. More importantly, the various doctrines in patent law seem to have been designed to force patent applicants to disclose as much information as possible. The information-forcing default rules literature is especially well placed as a useful analytic tool in patent law because of the unique dynamics involved between the different "parties"—patent applicants, patent examiners, courts, competitors, and the public. Patent applicants (inventors) are usually the leading experts in the particular field of scientific inquiry to which their invention belongs and, as a result, they tend to have the most relevant information about their invention. Although patent examiners have a scientific background, they cannot be expected to have expert knowledge of every invention they examine. Furthermore, patent applicants have the incentive to withhold information from patent examiners, their competitors, and the public. Disclosing relevant information about prior art may limit the scope of their patent claims, and the more information inventors reveal about their invention, the more they may be giving up their competitive advantage. The fact that patent claims are drafted by patent applicants and that the scope of the exclusive patent right is based on the amount of information disclosed gives patent applicants "the motive and the opportunity" to withhold information from the patent examiner.<sup>143</sup>

More importantly, for our current context, the various rules compelling patent applicants to disclose information about the claimed invention have information-forcing qualities.<sup>144</sup> The relationship in patent law is generally described as a "social contract" between the inventor and the

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141. Mary De Ming Fan, *Governing Copyright in Cyberspace: The Penalty Default Problem with State-Centric Sovereignty*, 43 JURIMETRICS J. 315, 317 (2003) (highlighting an international copyright treaty's creation of a nonenforcement default for digitally transmitted material in signatory states that would benefit from such protection); Catherine L. Fisk, *Authors at Work: The Origins of the Work-for-Hire Doctrine*, 15 YALE J.L. & HUMAN. 1, 54–55 (2003) (describing the holding in *Boucicault v. Fox*, 3 F. Cas. 977 (S.D.N.Y. 1862), as a penalty default encouraging employers who want to own the copyright resulting from the work of their employees to contract expressly); Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CALIF. L. REV. 1889, 1962 n.305 (2002) (noting the 1991 European Union Software Directive as setting a penalty default of interoperability encouraging copyright owners to make interface information "readily available"); Christopher Sprigman, *Reform(aliz)ing Copyright*, 57 STAN. L. REV. 485, 556 (2004) (comparing default licenses in copyright to "penalty defaults").

142. Robert P. Merges, *The Law and Economics of Employee Inventions*, 13 HARV. J.L. & TECH. 1, 36–37 (1999) (describing rules granting patent ownership to consultants as a way of forcing employers to disclose information about the complementarity of the consultant's invention to the employer's assets); Nolan-Stevaux, *supra* note 33, at 159–60 (describing the "inequitable conduct" as an information-forcing rule designed to discourage patent applicants from engaging in strategic behavior); Wagner, *supra* note 29, at 221 (positing that prosecution history estoppel should be conceived of as an information-forcing default rule).

143. Wagner, *supra* note 29, at 215.

144. Fromer, *supra* 25, at 560–62.



public. The inventor shares useful information about a new and nonobvious invention—information that could otherwise be kept a secret<sup>145</sup>—in exchange for a limited monopoly right to exclude anyone from making, using, or selling the claimed invention. The validity and scope of a patent claim are directly related to the information disclosed in the patent application. A patent applicant can act strategically by withholding relevant information and applying for the broadest patent scope feasible. If the patent examiner misses the relevant prior art reference and grants a patent right with broad claims, the patent applicant could have her cake and eat it too—she can keep the most useful information secret while being able to use the broad patent right to exclude competitors from making, using, or selling products and services embodying the claimed invention.

However, as outlined in Part I,<sup>146</sup> patent law has devised several tools to guard against these types of strategic behaviors by patent applicants. The many forms of the disclosure requirement—enablement, written description, definiteness, and “best mode”<sup>147</sup>—compel patent applicants to disclose information relevant for patent scope or validity. Failure to comply with these requirements would result in the rejection of a patent application or the invalidation and unenforceability of granted patents. These rules have the quality of information-forcing rules in that they elicit information from the well-informed party for the benefit of a less informed party (patent examiner) or third party (a competitor, or the public). In this way, patent prosecution could be described as a negotiation between the patent applicant and the patent examiner.<sup>148</sup>

Scholars have described other patent law doctrines as information-forcing default rules. For instance, the doctrine of prosecution history estoppel, which restricts patent applicants from extending the scope of their claim during enforcement to areas that were abandoned during patent prosecution (negotiation), has been described as an information-forcing rule.<sup>149</sup> Patent applicants have a choice to make before applying for a patent and during patent prosecution. They can claim broadly and take a risk that the patent examiner may ask them to amend their claim, which means the amendment becomes part of the prosecution history, and thus the patent applicant is blocked from claiming the abandoned scope through the doctrine of equivalents.<sup>150</sup> Alternatively, in anticipation of prosecution history estoppel, the applicant can submit a narrow claim that truly reflects the scope of the invention in the original application to avoid creating amendments that could be used against the applicant at a later stage.<sup>151</sup> In

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145. See, e.g., James J. Anton & Dennis A. Yao, *Expropriation and Inventions: Appropriable Rents in the Absence of Property Rights*, 84 AM. ECON. REV. 190, 204 (1994).

146. See *infra* Section I.A.

147. 35 U.S.C. § 11(a)–(b) (2018).

148. Wagner, *supra* note 29, at 216 n.194; see *infra* Section III.A.2.b.

149. Wagner, *supra* note 29, at 211–21.

150. *Id.* at 215–16.

151. *Id.* at 217.

this sense, prosecution history estoppel functions as an information-forcing rule that patent applicants can avoid by providing a more honest disclosure than they would have provided in the absence of such a requirement.<sup>152</sup>

As discussed earlier,<sup>153</sup> patent applicants have a duty of candor and good faith in dealing with the PTO. One of the main channels through which this duty is enforced is the inequitable conduct defense.<sup>154</sup> Defendants accused of patent infringement can point to inequitable conduct that the patentee engaged in during the patent application process, and if the defense is successful, all the claims in the patent application will be unenforceable.<sup>155</sup> As the Federal Circuit put it, “the remedy for inequitable conduct is the ‘atomic bomb’ of patent law. Unlike validity defenses, which are claim specific . . . inequitable conduct regarding any single claim renders the entire patent unenforceable.”<sup>156</sup> The inequitable conduct defense is designed to protect the integrity of the patent system by tapping into the power of private actors to investigate inequitable conduct.<sup>157</sup>

The inequitable conduct defense is also another instance where patent law adopts a default-penalty rule that seeks to compel patent applicants to disclose useful information.<sup>158</sup> As highlighted in the preceding paragraphs, patent applicants have both the incentive to withhold information damaging to the scope of their patent and the expectation that patent examiners might not notice the lack of full disclosure, thereby granting them a broader patent right than is justified. While minimal disclosure is tempting for patent applicants, the potential risk of their whole patent becoming unenforceable because of inequitable conduct creates a huge incentive to provide full disclosure.<sup>159</sup> Applicants can avoid this penalty by honestly providing all material information to the PTO.<sup>160</sup> In this sense, the inequitable conduct doctrine functions as an information-eliciting default rule. In a general sense, both prosecution history estoppel and inequitable conduct rules are designed to ensure that patentees fulfill the part of the deal in the “social contract” they enter into with the public, which is the disclosure of all material information about the claimed invention.

## 2. The Requirement as Information Forcing

The requirement that patent applicants disclose TK resources used in their inventive process should be conceived of as an information-forcing

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152. *Id.*

153. *See supra* Section I.A.

154. 37 C.F.R. § 1.56 (2018).

155. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (internal citations omitted).

156. *Id.*

157. MERGES & DUFFY, *supra* note 74, at 977.

158. Nolan-Stevaux, *supra* note 33, at 159–60.

159. Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 668 (2002).

160. Nolan-Stevaux, *supra* note 33, at 160.

rule compelling a patent applicant to divulge socially beneficial information. Although the concept of requiring patent applicants to disclose the source of TK has been discussed in scholarship and in international negotiations, this Article is the first to provide a detailed examination of the requirement as an information-forcing rule.

To make the case for the conception of the requirement as an information-forcing rule, it seems necessary to look at the dynamics between the parties involved and the effect the rule would have on these parties. As outlined by Ayres and Gertner,<sup>161</sup> and other scholars who have examined the concept subsequently, information-forcing rules are best applied to scenarios involving: (1) a well-informed party; (2) who, based on information asymmetry; (3) behaves strategically; (4) to block a socially beneficial outcome from being realized. This Section will follow the same structure to make the case for the conception of the requirement as an information-forcing rule.

#### a. The Well-Informed Party

A useful grouping of the different parties within the universe of patent applications involves the patent applicant, the examiner, competitors, courts, and the public. Of these groups of participants, patent applicants are the most well-informed. Here, the term “patent applicant” refers to the group of people, including the inventor and patent attorney, involved in preparing the patent application. Considering a scenario in which a new and nonobvious invention is being claimed, the person who came up with the invention—the inventor—by definition, has the most relevant expertise regarding the claimed invention.<sup>162</sup> One can imagine the considerable time, energy, and expertise needed to develop a patentable invention. If other participants had the same level of information, they would have rushed to the PTO to apply for a patent right. Patent attorneys who work with the inventor and are hired to conduct prior art searches as part of the patent application will also have the most relevant information about the claimed invention.

The other participants in the patent universe tend to have less information than patent applicants. Patent examiners have scientific training and are expected to independently conduct prior art searches to decide whether the patent application is in fact valid. However, patent examiners cannot be expected to develop the same level of expertise in their prior art searches as an inventor who has developed an invention over time.<sup>163</sup> Because the PTO is famously underfunded and patent examiners work under

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161. Ayres & Gertner, *supra* note 37, at 91.

162. Wagner, *supra* note 29, at 212–13.

163. MERGES & DUFFY, *supra* note 74, at 729.

tight schedules,<sup>164</sup> one cannot expect examiners to spend the time and resources required to develop the same level of expertise as the inventor or her attorney. In fact, the numbers show that the overwhelming amount of granted patents are either amended or invalidated.<sup>165</sup> The other participants in the patent application process have even less chance of being exposed to the most relevant information. Competitors of the patent applicant may have some information about the claimed invention if they work in the same field of research as the inventor. However, another fact that complicates the information provided in a patent application is that patent rights protect more than what is stated in the claim.<sup>166</sup> The doctrine of equivalents expands the scope of patent rights to include activities considered to be “equivalent” to an element claimed in a patent application.<sup>167</sup> This expansive reading of claim language enables patent applicants to utilize vague wording and other claim drafting strategies to distort the real scope of a patent claim and increase the cost for observers of conducting a thorough investigation.<sup>168</sup> Even if competitors may at some point be able to gather information comparable to the patent applicant, they would have to spend significant resources to do so. Ultimately, the patent applicant is the least-cost provider of the most relevant information about the claimed invention.

#### b. Information Asymmetry

It is commonly accepted that there is significant information asymmetry in patent prosecution.<sup>169</sup> The ex parte nature of patent prosecution means that the patent applicant and examiner are the two key players at the heart of the process, and because of the dynamics outlined above, patent applicants tend to have more information about their invention than patent examiners. The role of patent examiners is therefore to investigate the credibility of the claims made by patent applicants based on the information submitted to the examiners and after searching for relevant prior art.<sup>170</sup> Although it is not conclusive, the large number of challenged patents

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164. John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314, 316 (2001) (discussing the PTO budget and patent examiner dockets).

165. Jennifer Turchyn, Note, *Improving Patent Quality Through Post-Grant Claim Amendment: A Comparison of European Opposition Proceedings and U.S. Post-Grant Proceedings*, 114 MICH. L. REV. 1497, 1497 (2016) (highlighting, among other points, the increasing rate of patent invalidity created by the AIA); Steve Brachmann & Gene Quinn, *Are More Than 90 Percent of Patents Challenged at the PTAB Defective?*, IP WATCHDOG (June 14, 2017), <http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343>.

166. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 606 (1950) (explaining the doctrine of equivalents through which the scope of a patent covers infringing activity that is equivalent to what is stated in the claims, even if it may not be literally identical to what is claimed).

167. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997).

168. Long, *supra* note 159, at 669.

169. Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 763 (2002) (noting that the common knowledge that the PTO has knowledge deficiency about the relevant prior art for claimed inventions, and suggesting multiple alternatives to address the problem).

170. Long, *supra* note 159, at 667.

being either amended or invalidated implies that information asymmetry may have enabled the granting of a patent right for undeserving patent applications.<sup>171</sup> While some scholars have posited alternative measures of addressing this information asymmetry,<sup>172</sup> the majority of patent law scholarship admits to the pervasiveness of unequal access to information.

The information asymmetry that is observed in the patent system is even more pronounced in patent applications for inventions that rely on TK resources. That is because inaccessibility of TK resources is one of the main concerns regarding claims of biopiracy. Source communities that provide TK resources tend to reside in remote regions of the world, their TK is predominantly transmitted through oral traditions,<sup>173</sup> and much of the codified knowledge is documented in inaccessible databases.<sup>174</sup> It is revealing that many of the alleged acts of biopiracy are based on TK resources that are well-known among members of the source community.<sup>175</sup> In the examples cited earlier, information asymmetry between the researchers (patent applicants) and the patent examiners is to blame for the granting of patent rights for the process of using turmeric powder to heal surgical wounds or over neem tree extracts used as pesticides when generations of Indians have used the same plant extracts for the same purpose.<sup>176</sup>

### c. Strategic Behavior

The information asymmetry between the well-informed party (the patent applicant) and the patent examiner gives applicants considerable incentive and opportunity to act strategically by withholding the use of TK resources in their inventive process.<sup>177</sup> Although patent applicants must

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171. *Id.* at 663.

172. For instance, Mark Lemley has argued that patent applicants face high costs of conducting prior art searches. He therefore suggests that competitors should be encouraged to conduct these searches since they will only choose to challenge valuable patents and decide to selectively conduct prior art searches. *See* Lemley, *supra* note 30, at 1510. While Professor Lemley's analysis does make sense if the policy question is who should conduct prior art searches, patent applicants are still the best low-cost providers of information in their possession—information that was used to develop the claimed invention. Because, in the current contexts, the information required of patent applicants is that which is already in their possession, eliciting such information from the patent applicant seems more efficient than encouraging competitors to conduct searches *ex post*.

173. Gebru, *supra* note 22, at 327 (discussing the prevalence of oral transmission of TK and suggesting legal intervention to encourage more codification).

174. The managers of the TKDL have worked to make the database accessible by, for instance, translating the contents of the database into multiple major international languages and by developing accessible classification methods. While this attempt is commendable, this level of accessibility is not matched by the other major TK databases from other jurisdictions. *About TKDL*, *supra* note 123.

175. ROBINSON, *supra* note 20 (listing the major cases of biopiracy involving patent applications).

176. Sahdeo Prasad & Bharat B. Aggarwal, *Turmeric, the Golden Spice: From Traditional Medicine to Modern Medicine*, in *HERBAL MEDICINE: BIOMOLECULAR AND CLINICAL ASPECTS* 263, 263 (Iris F. F. Benzie & Sissi Wachtel-Galor eds., 2d ed. 2011).

177. Under the duty of candor and good faith, patent applicants are forbidden from withholding information material for patentability, so the worry is not so much that patent applicants will outright provide false information to the PTO. 37 C.F.R. § 1.56 (2018). Because the duty of candor and good

disclose information deemed to be material for the patentability examination,<sup>178</sup> they are not required to conduct extensive prior art search outside of what the inventor is exposed to during the inventive process; nor are they required to provide context to their claimed invention.<sup>179</sup> Therefore, to get the broadest possible scope for their claims, patentees will only provide information the concealment of which would be a clear violation of their duty of disclosure. It is true that patentees may be worried about their patent being challenged by their competitors post-grant, but given that only a fraction of granted patents are challenged,<sup>180</sup> this risk is minimal. In addition to being able to withhold information about the use of TK, patent applicants can use overly vague terms so that they can claim to have met their duty of disclosure if challenged at a later point. This practice of patent applicants using vague terms to benefit from the resulting confusion is not rare in patent practice,<sup>181</sup> and it can be expected that patent applicants engaged in biopiracy could make use of this practice as well.

What is even more enabling of strategic behavior is that for centuries TK resources have been considered to be raw materials for the inventive process and part of the public domain—free for anyone to use.<sup>182</sup> Thus, the omission of information about TK use in a patent application may not be seen as omission of material information. For example, Robert Larson, who was granted a patent right over a “process for preparing a storage stable neem seed extract,” knew of the benefits of the neem tree from the time he spent in India.<sup>183</sup> However, the list of cited references only includes two other patent applications unrelated to the neem tree and six scientific articles that discuss various aspects of the benefits of the neem tree.<sup>184</sup> He only mentions India twice, and even then in a very general sense to indicate that the tree grows in the country, among other places.<sup>185</sup> The fact that farmers in India have been using the neem tree extracts as pesticides—information that it is reasonable to expect he would have been exposed to as an importer of timber from India—is not cited anywhere in the granted patent or the document added during prosecution.<sup>186</sup> Despite the omission of what seems to be material information, the patent was

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faith does not include a duty to conduct prior art searches, patent applicants could just claim that they were unaware of the existence of TK resources.

178. *Id.*

179. Wagner, *supra* note 29, at 215.

180. Only about 1-2% of granted patents are litigated. *See, e.g.*, Jason Rantanen, *Patents, Litigation and Reexaminations*, PATENTLY-O (Dec. 29, 2011), <https://patentlyo.com/patent/2011/12/patents-litigation-and-reexaminations.html>.

181. *See generally* Stephen J. Stark, *Key Words and Tricky Phrases: An Analysis of Patent Drafter's Attempts to Circumvent the Language of 35 U.S.C. § 112*, 5 J. INTELL. PROP. L. 365, 366 (1997) (discussing the “gray language” used by patent applicants).

182. The protectionist trend outlined in earlier sections seems to have followed the recognition, by the Convention on Biological Diversity, of some form of ownership over TK resources. *See* Convention on Biological Diversity, *supra* note 21, at 1–2.

183. Stable Anti-Pest Neem Seed Extract, *supra* note 1; Shiva, *supra* note 2.

184. Stable Anti-Pest Neem Seed Extract, *supra* note 1.

185. *Id.* at Background of the Invention and Example I.

186. Certificate of Correction of U.S. Patent No. 4,556,562 (issued Dec. 3, 1985).

granted and remained valid for the life of the patent, even though the European patent office invalidated an identical patent application after evidence of the use of neem tree extract by one Indian firm was submitted to the office.<sup>187</sup> Instead of being an example of an outlier case, the dynamics between the various participants in the neem tree patent issue is representative of the relationship between patent applicants and examiners in other cases in which biopiracy was alleged.<sup>188</sup>

What may further complicate the information asymmetry in the use of TK is the confusion about the level of reliance required before patent applicants would have to disclose their use of TK resources. The level of reliance on TK resources could be put on a spectrum from minimal reliance as an inspiration to a maximum reliance in which the patent applicant simply claims an element directly copied from TK or practice. It is not clear where in this spectrum the reliance attains a level that triggers an obligation to disclose TK use.<sup>189</sup> Patent applicants can (and some do)<sup>190</sup> use this confusion to their benefit by not disclosing TK use and claiming, when challenged, that the TK or practice was only an inspiration. All these opportunities to withhold information enable patent applicants to benefit from the information asymmetry with minimal risk of patent invalidation.

#### d. Undesirable Outcome

The granting of patent rights for non-innovative or overly broad patent claims is an undesirable outcome, and this includes patent rights that relied on TK resources without disclosing that fact. The PTO has been criticized for granting patent rights to undeservingly broad claims, and the problems associated with such practice have been stated by many patent scholars.<sup>191</sup> The monopolistic nature of patent rights is tolerated only because it is expected to provide incentives for inventors.<sup>192</sup> If a patent right

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187. See *id.*; Ulrike Hellerer & K.S. Jarayaman, *Greens Persuade Europe to Revoke Patent on Neem Tree*, 405 NATURE INT'L J. SCI. 266, 266 (2000).

188. For a non-exhaustive list of cases of biopiracy and detailed discussion, see ROBINSON, *supra* note 20; see generally ABENA DOVE OSSEO-ASARE, BITTER ROOTS: THE SEARCH FOR HEALING PLANTS IN AFRICA 19 (2014).

189. See *infra* Section III.A.4 discusses what level of reliance should trigger a disclosure requirement.

190. The question of what level of reliance on TK resources should trigger the requirement is one of the key areas of contention on international deliberations. Additionally, a common theme in the defense that patent applicants in alleged acts of biopiracy raise is that their reliance on TK resources was only minimal or that they did not rely on such resource at all. Lack of novelty or non-obviousness has affected many of the patent applications invalidated after TK evidence is produced, which implies that the confusion regarding the level of reliance required to trigger TK resources is a big problem. ROBINSON, *supra* note 20 (discussing several alleged cases of biopiracy).

191. See, e.g., JAMES BESSEN & MICHAEL JAMES MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 23 (2008); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 52 (2009); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 20 (2004).

192. The U.S. Constitution granted power to Congress “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” U.S. CONST. art. I, § 8, cl. 8.

is granted for a claimed element that is not new, is obvious, or has not been fully described, a monopoly is granted without the redeeming qualities of innovation. An idea that should be shared freely at no or low-cost ends up being locked up in an exclusive patent right for twenty years. Under the social contract theory of patents, the public gets less than what it bargained for while granting the exclusive right. There are multiple negative effects of granting patent rights to undeserving claims.

Regarding financial costs, patent prosecution drains financial resources of the patent applicant, the PTO, and the court system (if the patent is litigated post-grant). The cost of applying for a single patent could be anywhere between \$10,000–\$30,000,<sup>193</sup> and that cost would be higher for the many applications that involve extensive negotiation with the examiner over validity and scope. Although the PTO is funded through fees it collects for its services,<sup>194</sup> the financial resources spent on patent prosecution are still a waste for the portion of patents that should not have been granted. Furthermore, there are opportunity costs of the human resources expended on the prosecution of undeserving patents.<sup>195</sup> Then, there are costs of litigation<sup>196</sup> at the different levels of appeal that many stakeholders want to reduce.<sup>197</sup> Given that many stakeholders prioritize the reduction of litigation costs in the patent system, the adoption of an information-forcing rule that could create ex ante incentives<sup>198</sup> that may reduce ex post costs of litigation seems highly beneficial.

There are also costs associated with the granting of patent rights that may not readily be described as financial costs. Non-innovative or overly broad patents deter innovation in the relevant industry without providing anything in return.<sup>199</sup> The existence of an overly broad patent that should

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193. The cost of patenting, starting from initial filing and including multiple responses to office actions, etc., varies heavily based on the type of invention. *See, e.g.*, Lemley, *supra* note 30, at 1498; Gene Quinn, *The Cost of Obtaining a Patent in the US*, IP WATCHDOG (Apr. 4, 2015), <http://www.ip-watchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485>.

194. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, FY 2018 PERFORMANCE AND ACCOUNTABILITY REPORT 120–21 (2018), <https://www.uspto.gov/sites/default/files/documents/USPTOFY18PAR.pdf>.

195. *See generally* Jay P. Kesan & Andres A. Gallo, *Why “Bad” Patents Survive in the Market and How Should We change?—The Private and Social Costs of Patents*, 55 EMORY L.J. 61, 87 (2006) (explaining the pressure under which patent examiners work that results in the granting of undeserving patent rights).

196. Professor Lemley had estimated the annual cost of patent litigation to be around \$2.4 billion in 2001. Given the increasing complexity and number of patent cases, that number should be significantly higher in recent years. *See* Lemley, *supra* note 30, at 1502.

197. The cost of litigation in patent law has been one of the issues of concern that the PTO, the courts, and the White House have been attempting to address. *See, e.g.*, Lawrence Hurley, *U.S. High Court Sets Record for Intellectual Property Caseload*, REUTERS, Feb. 26, 2014, <https://www.reuters.com/article/us-usa-court-ip-analysis/u-s-high-court-sets-record-for-intellectual-property-caseload-idUSBREA1Q09B20140227>.

198. Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 77, 79 (2005) (arguing for the benefit of creating ex ante incentives in the patent system).

199. There are many examples of patents being used to block innovation from developing in a certain field. *See, e.g.*, Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003) (providing empirical



have either been invalidated or narrowed will have the effect of discouraging investment. Firms conducting research will fear that a patent right may be asserted against them at any point in the research and development (R&D) process.<sup>200</sup> Additionally, vaguely worded claims create uncertainty about the “metes and bounds” of the patent right, thereby creating unnecessary risk for innovators.<sup>201</sup>

There are other undesired outcomes particularly relevant to the context of TK use in inventive processes. Biopiracy and the granting of undeserving patent rights over TK use have forced many source communities to mistrust researchers in general—and the patent system in particular.<sup>202</sup> This mistrust underpins the protectionist trend discussed earlier.<sup>203</sup> Furthermore, the granting of undeservingly broad patent rights, without recognizing the contributions of the source community, denies the community any benefits from the resulting innovation. More broadly, the absence of recognition for the source community is a missed opportunity to create a more inclusive patent system in which source communities that provide TK resources and collaborate in research could feel a sense of belongingness.

### 3. Benefits of Disclosure

The above discussion shows that the context in which patent applicants use TK resources in their inventive process but withhold such information from the PTO meets the requirements for the scenarios that Ayres and Gertner described in their article.<sup>204</sup> The well-informed party (patent applicant) behaves strategically by using privately held information (withholding information about the reliance on TK resources) to get private benefits that are socially undesirable (undeservingly broad patent rights). Thus, the requirement should be designed as an information-forcing rule that would elicit socially desirable information from patent applicants.

There are multiple benefits to the patent system when the requirement is complied with. The production of complete information benefits the

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evidence of clinicians shying away from clinical testing because of the threat of patent infringement or licensing costs); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) (describing the proliferation of patent right as being one of the problems barring the production of useful products and services in the biomedical field).

200. The term research and development (R&D) is used to refer to the variety of steps that firms take from the inception of an idea up to the point of marketing products.

201. Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents*, 6 INNOVATION POL'Y & ECON. 27, 32 (2006).

202. Alison L. Hoare & Richard G. Tarasofsky, *Asking and Telling: Can “Disclosure of Origin” Requirements in Patent Applications Make a Difference?*, 10 J. WORLD INTELL. PROP. 149, 150 (2007).

203. See *supra* Section II.B.

204. Ayres & Gertner, *supra* note 37.

PTO, source communities, competitors, and the public. First, it will increase the quality of issued patents<sup>205</sup> by rejecting non-innovative claims and by making issued patents provide more socially beneficial information. The requirement will mean that the patent applicant discloses one of the key sources of input for her invention. This may lead patent examiners, who usually have considerable resource constraints,<sup>206</sup> to use these limited resources efficiently and target prior art from source communities in their examination. This is especially useful in the TK context because patent examiners usually focus on accessible sources such as patents or scientific publications in their examination, while the overwhelming majority of TK is unpublished.<sup>207</sup>

Second, it will raise the cost of prosecuting low-value patents, thereby enabling the use of PTO resources for more inventive claims<sup>208</sup>: claims that improve on TK resources. Requiring applicants to disclose TK use will increase the risk of invalidity of low-quality patents. Therefore, the value of applying for these types of patents will significantly decrease, while the added burden of complying with the requirement will increase costs, albeit only slightly. If the quality of patent is very low, the requirement would change the cost-benefit analysis of such applications and disincentivize those types of applicants from going to the PTO. Third, the patent office receives information essential for patent examination from the least-cost provider (the patent applicant), which should reduce the cost of prosecuting inventions that rely on TK resources. The PTO already has over seventy TK databases that it can use to search for prior art.<sup>209</sup> However, the databases are not comprehensive compared to the wealth of knowledge held by indigenous and local communities.<sup>210</sup> Therefore, patent examiners would face transaction costs of accessing TK resources that are not documented or are documented in a foreign language. Requiring the applicant to disclose TK use will transfer the cost of prior art search to the least cost provider: the patent applicant.

Compliance with the requirement will also have benefits for the source communities. Source jurisdictions that have passed legislation on TK access and benefit sharing can track the use of TK by researchers and

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205. Parchomovsky & Wagner, *supra* note 198, at 70–71.

206. See generally Kesan & Gallo, *supra* note 195, at 66 (explaining the pressure under which patent examiners work, which results in the granting of undeserving patent rights).

207. See Gebru, *supra* note 22, at 303.

208. See Parchomovsky & Wagner, *supra* note 198, at 71.

209. *Alphabetical Listing of All TK Resources*, U.S. PAT. & TRADEMARK OFF. (Mar. 24, 2016, 4:18 PM), <https://www.uspto.gov/learning-and-resources/support-centers/scientific-and-technical-information-center-stic/alphabetical>.

210. It is generally understood that the majority of the knowledge of indigenous peoples is undocumented and thus the databases that the PTO uses will include the undocumented knowledge of the different indigenous communities around the world. See, e.g., Ghate Utakarsh, *Documentation of Traditional Knowledge: People's Biodiversity Registers*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE, AND SUSTAINABILITY* 190, 191 (Christophe Bellman et al. eds., 2003).

enforce obligations arising out of these rules more efficiently by searching for TK use through accessible patent databases. Source communities and countries that engage in protectionism out of fear of biopiracy can be more confident that they can enforce domestic legislation abroad on researchers who gain access to TK resources. This confidence can, in turn, be expected to result in a more collaborative and trusting relationship<sup>211</sup> between the various stakeholders involved in bioprospecting.

Compliance with the requirement would also enable competitors of the applicant or source communities to challenge the validity or scope of the claimed invention using the ex ante TK disclosure. Given the self-interest of competitors or source communities, the full force of the private actor could be used as a tool to check the validity or scope of a patent application. Following the AIA, third parties now have four different types of challenges to a patent right: pre-issuance review, inter partes review, post-grant review, and Covered Business Method Patent Review.<sup>212</sup> A bioprospecting relationship in which researchers have increased access to TK resources can be expected to result in the production of biopharmaceutical products cheaply and quickly. To achieve this socially desirable outcome, the requirement should create the right incentives without imposing too much burden on patent applicants or the patent system.

#### 4. Guidance for Policy

The information-forcing rule literature offers guidance on how to craft an effective and efficient requirement. A well-drafted requirement would be able to address concerns around legal uncertainty and innovation-detering burdens while still being able to encourage the disclosure of reliance on TK. If a default rule is to succeed in compelling information from a well-informed party, it should be designed against the interest of that party.<sup>213</sup> It is because of this rule that the well-informed party reveals the socially beneficial information. In the current context, the requirement should create a penalty against the interest of an applicant, which points to the need to adopt penalties of patent invalidity for applications that violate the requirement. If the requirement is to be effective, the default-penalty rule should put the patent applicant in a worse position than she would have been in had she taken a risk and the risk materialized.

Three levels of reliance on TK could be used to further extrapolate the trigger of an obligation under the requirement. First, the minimal level of reliance could be described as “mere inspiration”—the inventor was inspired by what she understood from TK, but the traditional practice was

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211. Source communities increasingly mistrust the patent system because it has been used as a tool for biopiracy. See Hoare & Tarasofsky, *supra* note 202. The requirement has the potential of developing trusting relationships.

212. 35 U.S.C. §§ 122(e), 311, 321 (2018); 37 C.F.R. § 42.302 (2018).

213. Ayres & Gertner, *supra* note 37, at 98.

not relevant for the development of the claimed invention. A relevant example here may be the rosy periwinkle plant, which is native to Madagascar and was traditionally used to treat diabetes.<sup>214</sup> Scientists at Eli Lilly and the University of Western Ontario, after years of research, learned that the plant has cancer-fighting qualities.<sup>215</sup> Eli Lilly used extracts from the plant to develop vinblastine and vincristine—medicines used to treat Hodgkin’s disease and childhood leukemia.<sup>216</sup> If the TK of using the plant for diabetes or processes of extracting ingredients did not contribute to the development of vinblastine and vincristine,<sup>217</sup> then the duty to disclose the source of TK would be unreasonably burdensome. The inventors in this case were inspired to test it for its cancer-treating potential after being exposed to the traditional use of the plant to treat diabetes. Therefore, the traditional use is not “material for patentability.” The claimed invention is not substantively based on the TK. Thus, the scope of the patent right that will ultimately issue is not affected by disclosure of the minimal input from TK. Under this scenario, the patent applicant has an incentive to abide by the requirement because the applicant has nothing to lose—disclosure will not affect the patent scope. However, as explained in Part I,<sup>218</sup> the duty of candor and good faith is broader than the duty to disclose material information. Any information that an examiner might have wanted to know should be included in this broader requirement of candor and good faith. Still, the patent applicants have an incentive to disclose the traditional use of the rosy periwinkle to treat diabetes for the same reason stated earlier.<sup>219</sup>

Second, a higher level of reliance on TK could be described as “substantial reliance” and could fairly give rise to a duty to disclose under 35 U.S.C. § 112 and Rule 56. Substantial reliance is a situation where, without access to the TK, the invention may not have been produced, or the process would have taken significantly more time or resources. The neem tree case discussed in the introduction to this Article is a good example of this. Presuming that Mr. Larson knew that Indian farmers have been using the neem tree extract as a pesticide and presuming a storage stable neem tree extract was not in prior use, his patent application for a storage stable neem tree extract to be used as a pesticide should be thought of as having substantially relied on TK. This is especially the case if, as claimed by

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214. MICHAEL F. BROWN, WHO OWNS NATIVE CULTURE? 136 (2003).

215. Srividhya Ragavan, *Protection of Traditional Knowledge*, MINN. INTELL. PROP. REV., 2001, at 8; Roger A. Sedjo, *Property Rights, Genetic Resources, and Biotechnological Change*, 35 J.L. & ECON. 199, 199 (1992).

216. Shayana Kadidal, *Plants, Poverty, and Pharmaceutical Patents*, 103 YALE L.J. 223, 223 (1993).

217. BROWN, *supra* note 214, at 137 (discussing the challenges of assigning ownership in the Rosy Periwinkle case).

218. *See supra* Section I.A.

219. *See supra* Section I.A. As discussed earlier, this is because failure to disclose a material information may result in the invalidation of the patent right post-grant. *See* 35 U.S.C. § 112(a) (2018); *see also* 37 C.F.R. § 1.56(a) (2018).

representatives of W.R. Grace, the claimed compound and process resulted in increasing the stability of the extract from a couple of days to two years.<sup>220</sup> In this case, Mr. Larson and the scientists involved in the second W.R. Grace patent should disclose that extracts of the neem tree have been used in India as a pesticide because such information is “material for patentability.” The improvement in stability of the compound depends on the extent of the traditional use in a stable neem tree extract.

In this second scenario, the level of reliance on TK is so substantial that “but for” the use of TK, the claimed invention would not have been developed. If the improvement does not develop something totally different, disclosure of “substantial reliance” on TK under this scenario may narrow the scope of the patent right. If the penalty default is the reduction of patent scope (or other similarly weak penalties such as the temporary suspension of prosecution), the applicant would have an incentive to withhold information in hopes that the PTO or third parties will not discover the information on their own. In other words, if the ex post discovery of a violation of the requirement results in the same outcomes as an ex ante disclosure, then the applicant has hardly any incentive to disclose. Therefore, legislators would need to address this incentive to withhold information by setting up a penalty resulting in the rejection of an application or the invalidity of a granted patent.

The highest level of reliance could be a claim to an “invention” that provides only minimal improvement on TK. Patent law standards of novelty<sup>221</sup> and nonobviousness<sup>222</sup> may be helpful here. The improvement would be minimal if the traditional use of the resource anticipates it or if it would be obvious to the average person in that field with knowledge of the relevant TK. A good example here is the patenting of a process for treating wounds by applying turmeric powder. In 1995, two researchers at the University of Mississippi Medical Center, Soman K. Das and Hari Har P. Cohly, received a U.S. patent.<sup>223</sup> The patent covered a method of administering turmeric powder orally and topically to heal surgical wounds and ulcers.<sup>224</sup> People in India had used turmeric powder to treat wounds for centuries.<sup>225</sup> The Council of Scientific and Industrial Research (CSIR), an agency of the Indian government, challenged the validity of the patent in the PTO.<sup>226</sup> The Council submitted thirty-two printed publications from India providing evidence of the use of turmeric powder to heal wounds for centuries.<sup>227</sup> The PTO revoked all six claims in the patent for failing to

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220. Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art, and the Neem Patent Controversy*, 37 IDEA 371, 374–75 (1997).

221. 35 U.S.C. § 102.

222. *Id.* § 103.

223. Use of Turmeric in Wound Healing, U.S. Patent No. 5,401,504 (issued Mar. 28, 1995).

224. *Id.*

225. Prasad & Aggarwal, *supra* note 176, at 264.

226. Re-examination Certificate of U.S. Patent No. 5,401,504 (issued Apr. 21, 1998).

227. *Id.*

meet substantive patentability requirements.<sup>228</sup> Information about the reliance of TK in these scenarios is obviously material for patentability analysis. The patent application in this and other similar cases<sup>229</sup> is claiming rights over the traditional uses of a resource, provides only a minimal improvement or, in the worst of cases, no improvement is made to TK at all. In these cases, Rule 56 would require the disclosure of TK.<sup>230</sup> Furthermore, the patent application in most of these cases will fail to meet the patentability requirements.

In this third scenario, the patent applicant has an incentive to violate the requirement because compliance with the rule will result in the same outcome as the penalty. In this scenario, the requirement will have little incentive to disclose reliance on TK because the penalty for violation is the same as the outcome from compliance. Thus, policy makers should adopt a harsher penalty than patent invalidity. This includes disgorgement of profits or levying fines. One additional benefit of the requirement to note is that the penalty default will discourage researchers from going to the PTO before making a considerable improvement on TK resources, which is a socially desirable outcome. Thus, in addition to compelling information from applicants, the requirement may impact patenting behavior. The three scenarios outlined above are a simplified version of what might happen in bioprospecting projects, and they are used here to illustrate the various incentive structure of the patent applicant.

Conceiving the requirement as an information-forcing default rule solves two of the three issues of concern. First, it solves the questions of what type of penalty to impose for violations of the requirement. If the requirement is conceived of as an information-forcing rule, then the penalty for infringement in the first two cases would have to be a rejection of a patent application and invalidity of a granted patent. For the third scenario, because the applicant knows she does not have a patentable invention in the first place, patent invalidity will not be sufficient. In these types of cases, a harsher penalty such as disgorgement of profits or fines is needed to compel information.

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228. *Id.* Although the turmeric case shows a patent system working as it is supposed to, many similar cases take many years of litigation and considerable expenses. One can imagine the numerous cases in which TK may be used but remains unreported. *See, e.g.,* ROBINSON, *supra* note 20.

229. There are multiple examples of cases in which the patent applicant simply requests patent rights without making significant improvements. For instance, a Dutch company has received patents in numerous countries over a gluten-free flour made from teff. Teff is a flour native to Ethiopia and Eritrea and an input in injera, which is a spongy flat bread and a ubiquitous part of everyday meals in both countries. The gluten-free nature of the flour is a natural result of the teff flour. While the U.S. patent has been invalidated, a very similar European patent (Eur. Patent No. 1646287b1) is still in force. *See* REGINE ANDERSEN & TONE WINGE, FRIDTJOF NANSENS INSTITUTE, THE ACCESS AND BENEFIT-SHARING AGREEMENT ON TEFF GENETIC RESOURCES: FACTS AND LESSONS (2012), [http://www.abs-initiative.info/fileadmin/media/Knowledge\\_Center/Publications/FNI/FNI-R0612.pdf](http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Publications/FNI/FNI-R0612.pdf).

230. 37 C.F.R. § 1.56 (2018).

For the first two scenarios, anything short of patent invalidity or non-enforcement would fail to encourage patent applicants to disclose their reliance on TK resources. A voluntary system in which patent applicants will face no repercussions for noncompliance would mean a reasonable applicant would not risk patent invalidity or the reduction of the scope of her patent by providing potentially damaging information. There are no benefits to doing so unless the applicant wants to fulfill some form of moral obligation. The cost-benefit analysis is similar under a regime in which the penalty is suspension of patent prosecution. If, for example, Mr. Larson's patent over storage stable neem tree extract would be narrowed down upon his disclosure of traditional practices in India, he would initially take a risk of noncompliance. If on the off chance that the patent examiner discovers the traditional practice in India (which in most cases is very unlikely), then Mr. Larson can comply with the requirement. This would result in most applicants being noncompliant.

Most cases of bioprospecting or biopiracy can be expected to fall under either the first or second scenario. This is because TK tends to involve basic information<sup>231</sup> about the benefits of biodiversity resources on which researchers could relatively easily make considerable improvements. For example, Indian farmers had used the neem tree as a pesticide for centuries,<sup>232</sup> but the PTO found Mr. Larson's "improvement"<sup>233</sup> of creating a storage stable neem tree extract innovative enough to grant it a patent.<sup>234</sup> Furthermore, because of the uncertainty regarding the validity of a patent application, patent applicants can reasonably expect that the scope of their patent application will only be narrowed rather than completely rejected.

While a penalty is needed to encourage patent applicants to divulge information, legislators should also consider the impact that such rules may have on the incentive to obtain the information in the first place.<sup>235</sup> One of the costs of the requirement is that the duty to disclose may discourage researchers from using TK resources in the first place.<sup>236</sup> Thus, legislators should ensure the requirement is an efficient one—that there are sufficient incentives for researchers to use TK resources while ensuring that such use is disclosed to the PTO.

Second, the information-forcing rule's literature provides answers to the question of whether to request that patent applicants disclose the

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231. Carvalho, *supra* note 111, at 244–45 (discussing the ease with which users can copy TK); Mark C. Suchman, *Invention and Ritual: Notes on the Interrelation of Magic and Intellectual Property in Pre-literate Societies*, 89 COLUM. L. REV. 1264, 1272 (1989) (describing the basic nature of TK).

232. BD. ON SCI. & TECH. FOR INT'L DEV., *supra* note 8, at 1.

233. Stable Anti-Pest Neem Seed Extract, *supra* note 1.

234. *Id.*

235. While penalizing nondisclosure has the effect of encouraging disclosure, if the penalty is so significant, researchers may hesitate to acquire the information in the first place for fear of the potential of being penalized. See Ayres & Gertner, *supra* note 37, at 128.

236. Hoare & Tarasofsky, *supra* note 202, at 164.

original source (or *origin*) of TK or just the *source* from which they received the resource. This is an important issue because many researchers access TK through intermediaries such as research databases, databanks, or gene banks.<sup>237</sup> Many TK resources are conserved and used by multiple communities, and these resources have predominantly been transmitted to other cultures near and far.<sup>238</sup> As per the information-forcing rules literature, forcing well-informed parties to incur further costs may block a transaction from taking place.<sup>239</sup> The requirement of disclosing origin (as opposed to source) may discourage researchers from using TK in the first place. Therefore, the requirement should not compel patent applications to conduct prior art searches more than they already did during the research that led to a claimed invention. If the penalty of patent invalidity, disgorgement of profits, and fines are adopted, then a requirement to conduct an additional search for relevant TK resources would be too tasking. This is especially the case given the inaccessibility of TK resources and the challenges of tracking original sources. Therefore, the requirement should only require that patent applicants disclose TK-related information the researcher used and discovered in the normal course of research rather than imposing a positive obligation to disclose the original source of TK or other relevant information.<sup>240</sup>

In addition to the *ex ante* benefits of compelling patent applicants to disclose potentially damaging information, the requirement has important *ex post* benefits. As explained earlier, patent examiners are at a disadvantage because of the information asymmetry inherent in patent prosecution.<sup>241</sup> The disclosure of reliance on TK would enable competitors of the applicant, source communities, and the public to assess the validity or scope of claimed inventions. This *ex post* benefit harnesses the private interest of competitors and source communities in ensuring the applicant does not get a broader patent right than she deserves. This *ex post* benefit is essential given the significant resource restraints that the PTO faces. The *ex post* benefits of disclosure also include the facilitation of the enforcement of rules around access to TK and benefit sharing that source communities and countries may have established. Furthermore, just like the general disclosure requirement is useful in creating spillover effects from the disclosure of useful information to the public, the disclosure of reliance on TK in the development of a claimed invention may encourage competitors of the applicant to research the TK for similar purposes. The value of such

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237. See GRAHAM DUTFIELD, QUAKER UNITED NATIONS OFFICE, OCCASIONAL PAPER 18, THINKING ALOUD ON DISCLOSURE OF ORIGIN 3 (2005).

238. See OGUAMANAM, *supra* note 23, at 18; see also MANUEL RUIZ MULLER, INT'L CTR. FOR TRADE & SUSTAINABLE DEV., ISSUE PAPER 3, PROTECTING SHARED AND WIDELY DISTRIBUTED TRADITIONAL KNOWLEDGE: ISSUES, CHALLENGES AND OPTIONS 8–9 (2013).

239. Ayres & Gertner, *supra* note 37, at 128.

240. Patent applicants do not have an obligation to conduct prior art searches. Their obligation is to disclose material information in their possession. See 37 C.F.R. § 1.56 (2018).

241. See *supra* Section III.A.2.b.



information may be significant given reports of bioprospectors focusing on selected TK resources for further investigation.<sup>242</sup>

Lastly, one of the recurring challenges in the literature on bioprospecting is understanding the actual value of TK resources in bioprospecting projects. While source communities and some scholars argue that the resources have considerable value,<sup>243</sup> some firms argue that they either do not use TK at all,<sup>244</sup> or that the value of such resources is very minimal.<sup>245</sup> The lack of information about the extent of the reliance of the industry on TK contributes to the confusion on the correct policy measure that should govern bioprospecting projects. The requirement could address this concern by providing clear information on the value of TK as an input in inventive ideas. This does not mean that the full value of TK could be evaluated based on the disclosure in patent applications. But disclosure could shed some light on the value that should be put on TK as an input in producing innovative products.

#### *B. Reversing the Protectionist Trend*

A requirement designed as an information-forcing rule will have innovation-encouraging effects instead of being a burden on the patent system as argued by some. The requirement has the potential to reverse the rising and inefficient protectionist trend outlined earlier. To achieve this goal, the requirement would have to strike a balance between interests of source communities and TK users<sup>246</sup> such as researchers and modern firms. If the requirement addresses the interests of source communities without meeting the needs of users, then the intervention might discourage the engagement that users would have with TK. If the requirement addresses the interests of users without satisfying the needs of source communities, it will fail to change the current trends of protectionism.

The past experiences of researchers accessing TK, developing products, and failing to recognize the contributions of the source community have created significant trust issues.<sup>247</sup> Decades of alleged biopiracy have made source communities hesitant to share their resource. To overcome this mistrust, a robust and clear signal of change from the status quo is needed. Because existing patent law is considered to be part of the problem

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242. See Rausser & Small, *supra* note 96, at 173.

243. See *supra* Section II.A for a discussion of the value of TK.

244. See Dominic Keating, *The WIPO IGC: A U.S. Perspective*, in THE WIPO INTERGOVERNMENTAL COMM. ON INTELLECTUAL PROP. & GENETIC RES., TRADITIONAL KNOWLEDGE & FOLKLORE, PROTECTING TRADITIONAL KNOWLEDGE 265, 271 (Daniel F. Robinson, Ahmed Abdel-Latif & Pedro Roffe eds. 2017).

245. See Jim Chen, *There's No Such Thing as Biopiracy . . . And It's a Good Thing Too*, 37 MCGEORGE L. REV. 1, 25–28 (2006).

246. The term “users” refers to multiple entities that rely on TK in their inventive process. This includes for-profit firms, public research institutions, and independent researchers.

247. See Shiva & Holla-Bhar, *supra* note 10, at 151.

by source communities,<sup>248</sup> minor tinkering may fail to send the strong signal needed to reverse the protectionist trend.

The introduction of the requirement should take into consideration its effects on users. Users can be expected to be interested in legal certainty about the contents of the requirement and penalties for violations.<sup>249</sup> Researchers interested in using TK resources may be discouraged if they have doubts about their obligations and potential penalties. Additionally, users with a for-profit orientation can also be expected to emphasize costs associated with access to TK and requests for benefit sharing if an innovative product is produced. Policy makers should seriously consider these interests to craft an efficient and workable requirement.

The requirement can undo the lose-lose relationship in the status quo by giving source communities (the party with weaker bargaining power) some leverage to enforce rules that the community may place around access and benefit sharing. This leverage can encourage source communities and biodiversity-rich countries to be more open and willing to engage in R&D collaborations with researchers.

The use of databases provides a good example of how a collaborative relationship between source communities and users would work. Instead of screening resources for potential value, researchers could use the knowledge of indigenous peoples and local communities as research leads. Take the example of the TKDL. The more than 250,000 medicinal formulations documented in the database could be a great source to develop modern drugs. A collaborative (as opposed to restrictive) use of the contents could create significant welfare gains for patients everywhere. Biopharmaceutical firms could use their impressive resources to screen the database for promising research leads. However, in the absence of an effective mechanism that can convince source communities that they will share from the benefits arising out of follow-on innovation, they may not be willing to engage in this collaborative and welfare-enhancing endeavor.

#### IV. INSTITUTIONAL MECHANISMS

If one accepts that the requirement should be introduced, then several institutional questions arise. This Section outlines the institutional mechanism for introducing the requirement in U.S. patent law. It argues that amending the Patent Act to introduce an explicit requirement compelling applicants to disclose the source of TK may be the most effective mechanism to signal a change in U.S. patent policy and establish confidence among source communities and countries. However, amending U.S. patent law to introduce the requirement seems infeasible given the lack of political interest to introduce such an amendment and the considerable opposition that may be expected from industry. Therefore, this Section suggests

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248. *Id.* at 152.

249. See Tim Roberts, *The Protection of Traditional Knowledge: An Industry View*, in U.N. CONF. ON TRADE & DEV., *supra* note 92, at 93, 93.

that clarifying the duties of disclosure, candor, and good faith that patent applications already have, by explicitly introducing the requirement, would be a feasible second-best measure. It also argues that the PTO, as the most suitable administrative agency for patent examination, should be tasked with checking for compliance with the requirement.

The key institutional questions that may arise include: (1) How should the requirement be formalized?; (2) Which entity is best suited to check for compliance?; (3) What should be the content of the required disclosure?; (4) What should trigger the obligation?; (5) What should be the penalty for noncompliance?; and (6) Who should have standing? These questions are dealt with in further detail below.

#### *A. How Should the Requirement Be Formalized?*

Considering the twin goals of compelling socially beneficial information from patent applicants and reversing a rising protectionist trend, amending the Patent Act to introduce an explicit requirement may be the most effective mechanism. The many cases of biopiracy happened in the face of existing disclosure obligations under U.S. patent law. Therefore, an explicit amendment of the Patent Act would send a strong signal of policy change in U.S. patent policy and would establish confidence among source communities and countries. This strong signal is needed to reverse the rising protectionist trend in which source communities and countries create barriers to access TK. Dozens of countries around the world, including some industrialized nations, have amended their patent act to introduce the requirement.<sup>250</sup> Although it is too early to observe the impact of the reform, early evidence suggests that there have not been significant negative effects in the domestic patent systems of these countries.<sup>251</sup>

Reforming U.S. patent law to reflect policy changes is not a new endeavor. The Patent Act has been amended multiple times since its first iteration in 1790<sup>252</sup> with the most recent amendment—the AIA<sup>253</sup>—enacted in 2011 to modernize the U.S. patent system. Therefore, amending the Patent Act to include the requirement is not an implausible idea. In fact, the 1980 Bayh-Dole amendment<sup>254</sup> to the Patent Act has similar features to the requirement. The AIA brought about major changes in U.S.

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250. For a latest list of countries with some form of a requirement to disclose the source of TK used in the inventive process, see WORLD INTELLECTUAL PROP. ORG., DISCLOSURE REQUIREMENT TABLE (2017),

[www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic\\_resources\\_disclosure.pdf](http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf).

251. See Bagley, *supra* note 16, at 736–40.

252. Patents Act of 1790, ch. 7, 1 Stat. 109 (1970).

253. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

254. The Bayh-Dole amendment is codified in 35 U.S.C. Chapter 18. While there are many similarities between the requirement and the disclosure required under the Bayh-Dole Act, there are significant limitations. While the subject matter of both requirements deals with upstream innovation, and thus share some features, the Bayh-Dole Act deals with improvements that can easily meet the patentability requirement, while most TK resources do not meet core patentability requirements.

patent law, one of which relates to a disclosure requirement. The Act mandates that any invention that uses federal funds in the inventive process include, on the face of issued patents, a disclosure of the government's interest in the patent.<sup>255</sup> The Bayh-Dole disclosure has enabled the U.S. government to track federally funded inventions, thereby facilitating the enforcement of obligations that the inventor and contractors have under the Act.<sup>256</sup> A carefully crafted requirement can have a similar tracking effect in facilitating the enforcement of access and benefit-sharing agreements between source communities or countries and researchers.<sup>257</sup>

However, amending U.S. patent law to introduce the requirement seems infeasible considering the lack of political interest in the amendment and the considerable opposition that may be expected from the industry. Therefore, clarifying the duties of disclosure, candor, and good faith that patent applicants already have by introducing an explicit requirement would be a feasible second-best measure. As stated earlier, patent applicants already have a very broad duty of disclosure as stated in the Patent Act, under federal rules, and in the case law.<sup>258</sup> Thus, updating the federal rules and the PTO manual to include an explicit requirement would be an efficient and feasible reform that can satisfy the twin benefits identified in this Article.

#### *B. Which Institution Is Best Suited?*

The general duty of disclosure is owed to the PTO. The requirement imposed on patent applicants to describe the invention in "full, clear, concise, and exact terms" relates to the specification section of a patent application.<sup>259</sup> The first entity that examines the patent application, including the specification section, is the PTO. Although courts have the power to review the validity of granted patents, there is a presumption of patent validity<sup>260</sup> and a level of deference courts grant the PTO prosecution.<sup>261</sup> Furthermore, the rules under 37 C.F.R. § 1.56(a) clearly state that the duty of

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255. 35 U.S.C. § 202(c)(6) (2018). The provision highlights the disclosure requirement that should be inserted in funding agreements. It states that contractor has an obligation "to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support." *Id.*

256. WENDY H. SCHACHT, CONG. RESEARCH SERV., RL 32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 7 (2013).

257. See Carvalho, *supra* note 111, at 163; see also Bagley, *supra* note 16, at 741-42.

258. See *supra* Section I.A.

259. 35 U.S.C. § 112(a) (2018).

260. 35 U.S.C. § 282(a). "A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

261. Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199, 221-22 (2000).

disclosure exists “in dealing with the Office.”<sup>262</sup> These rules extend beyond the examiner to include anyone at the PTO.<sup>263</sup> It seems that the rules direct the general duty to disclose towards the PTO, at least initially, because it is the most suitable entity to check for compliance with the rules. Since the duty of disclosure is directed at the PTO, it seems reasonable to also direct a duty to disclose to the same organ. This should especially be the case if the requirement is introduced through an updated MPEP that includes an explicit requirement.

The literature from administrative law supports this conclusion. The general theory in administrative law is that administrative agencies are best suited to interpret rules governing activities in their area of expertise.<sup>264</sup> This theory also applies in deciding the level of information that should be submitted for proceedings in that agency.<sup>265</sup> Given the unique position of the Federal Circuit as a specialized appeals court for patent cases, patent law was considered to be different from regulatory areas where administrative law theories applied.<sup>266</sup> However, the AIA granted the PTO considerable administrative power to decide key issues regarding patent validity.<sup>267</sup> Considering its newly expanded powers, the PTO should be the first entity that decides whether an applicant has complied with the requirement. This conclusion is further supported by the fact that the PTO has considerable expertise—both regarding technical knowledge and patent prosecution. This, however, does not mean that the Patent Trials and Appeals Board (PTAB) or the courts should not review these decisions. The requirement, like other requirements in U.S. patent law, should be reviewable by the courts.

### C. What Should Be the Content of the Required Disclosure?

As highlighted in earlier Sections,<sup>268</sup> the requirement should entail an obligation to disclose the *source* from which the patent applicant received TK instead of the *origin* of the resource. Requiring patent applicants to conduct further research to identify the original source of the TK would create a considerable disincentive against relying on TK resources. The origin of the majority of TK resources is controversial and, therefore, requiring researchers to investigate and disclose the origin creates a duty that

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262. 37 C.F.R. § 1.56(a) (2018).

263. MPEP, *supra* note 69, § 2001.03. The duty extends to proceedings at the Patent Trial and Appeal Board and the Office of the Commissioner for Patents. *Id.*

264. See *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council*, 435 U.S. 519, 521–24 (1978); see also Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 511 (1989).

265. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001).

266. Christopher J. Walker, *Chevron Deference and Patent Exceptionalism*, 65 DUKE L.J. ONLINE 149, 158 (2016).

267. Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1976 (2013).

268. See *supra* Section III.A.

is far from the scientific research in which firms have expertise.<sup>269</sup> As the information-forcing rules literature reveals, rules should not be applied if the net effect could result in a disincentive to participate in the “deal” in the first place.<sup>270</sup> Limiting the content of required disclosure only to the source from which the applicant received TK ensures that the requirement does not impose an undue burden that may deter innovation.<sup>271</sup> This may create an opportunity for strategic behavior where patent applicants would select a jurisdiction that does not have domestic access and benefit-sharing rules to avoid having to comply with rules in the actual source jurisdiction. But, because this risk seems highly limited considering the heavy penalty for fraud and inequitable conduct, legislators should not drive away researchers for fear of such a limited risk of strategic behavior.

#### *D. What Should Trigger the Obligation?*

Based on the three levels of reliance outlined earlier, the trigger for the requirement should be a *substantial reliance* standard. Patent applicants should have a duty to disclose if they would not have developed the claimed invention or if the invention would take considerable time and resources without the reliance on TK. This includes examples such as the neem tree patent where the development of storage stable neem tree extract for use as a pesticide would face additional risks had it not been for the traditional use of the resource as a pesticide.<sup>272</sup>

A broad interpretation of “substantial reliance” is suggested in this Article. The balance between requiring a specific type of reliance (substantial) but accepting a broad range of inputs as triggering the requirement strikes an efficient balance that would meet a key purpose of the requirement—disclosure of relevant information without significantly affecting the incentive to innovate. Such a standard is expected to encourage source communities to provide increased access to TK resources while ensuring that they are not cheated out of their equitable share by strategic patent claim drafting.

#### *E. What Should Be the Penalty for Noncompliance?*

Countries around the world have adopted a wide range of penalties for noncompliance with their domestic requirement to disclose the source of TK used in inventive processes.<sup>273</sup> These penalties include the suspension of a patent application until the applicant fulfills her obligation under the requirement, the rejection of the patent application, and the invalidity

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269. The preference for source instead of origin has also been suggested by some scholars. See DUTFIELD, *supra* note 237, at 2.

270. See Ayres & Gertner, *supra* note 37, at 91.

271. See, e.g., Keating, *supra* note 244, at 270–71.

272. Shiva, *supra* note 2.

273. For a latest list of countries with some form of a requirement to disclose the source of TK used in the inventive process, see WORLD INTELLECTUAL PROP. ORG., *supra* note 250.

or unenforceability of a granted patent. Some jurisdictions have also adopted criminal sanctions in the form of fines or imprisonment. In contrast to these penalties, some jurisdictions have adopted a voluntary system in which patent applicants are encouraged to disclose TK, but noncompliance will have no repercussion.<sup>274</sup>

The penalty for noncompliance advocated for in this Article ranges from the rejection of the patent application or (if a patent application has been granted) the invalidity or unenforceability of the patent right, to fines, and disgorgement of profits in extreme cases. The twin functions of the requirement outlined below—its information-forcing function<sup>275</sup> and the reversal of a rising protectionist trend<sup>276</sup>—would not be satisfied if the requirement is voluntary. If patent applicants are left to their own will in disclosing potentially damaging information about their reliance on TK resources, it can be presumed that a reasonable applicant would choose to withhold such information. The information-forcing nature of the requirement emanates from a penalty rule that is set against the interest of the well-informed party.<sup>277</sup> In the absence of such a penalty, a reasonable patent applicant will act strategically by withholding information about their reliance on TK and the source that provided such a resource. While the penalty for minimal and substantial reliance should be rejection of the application, patent invalidity, or patent unenforceability, the penalty for those who only make minimal improvements should include fines or disgorgement of profits. In the absence of harsher penalties than patent invalidity, an applicant who knows their application would fail patentability examination would have little interest to disclose the damaging information. The penalty in an ex post finding of noncompliance would be the same as the ex ante risk of withholding the information, and thus the requirement would fail to produce the desired information-eliciting function. These suggestions about the forms of penalty are supported by the two goals of the requirement outlined in this Article—the ability of the requirement to compel socially beneficial information and its effect in reversing the rising protectionist trend.

#### *F. Who Should Have Standing?*

Patent rights, as “rights to exclude” others from making and using a claimed invention, have considerable public interest implications. As a result, the U.S. patent system allows third parties to challenge the validity or scope of patent rights based on a wide range of doctrines.<sup>278</sup> Although the patent examiner is the first person who works to ensure the application

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274. See *Communication from the Commission to the Council and the European Parliament on a European Community Biodiversity Directive*, at 6, COM (1998) 42 final (Feb. 4, 1998), <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51998DC0042&from=EU>.

275. See *supra* Section III.A.

276. See *supra* Section III.B.

277. Ayres & Gertner, *supra* note 37, at 123–24.

278. See 35 U.S.C. § 311 (2018) (inter partes review); 35 U.S.C. § 321 (post-grant review).

meets the patentability requirements, interested third parties are allowed, through many channels, to challenge the validity or scope of a claimed invention.<sup>279</sup> The AIA has expanded the opportunity that third parties have to challenge patents before<sup>280</sup> and after<sup>281</sup> the patent has been granted.<sup>282</sup> Any party with a “legally cognizable injury” has standing to challenge a claim in a patent application or against a granted patent.<sup>283</sup> This includes competitors of the applicant and third parties that may be affected by the potential enforcement of the patent right.

Failure to comply with the requirement may impact competitors, source communities, and the public by granting exclusive patent rights to undeserving claims. Therefore, these stakeholders should have standing to bring a challenge against a patent that violates the requirement. Competitors may be affected because the patentee may bring an infringement lawsuit against them after the patent issues. Source communities may be affected because the patentee may use the exclusive right in ways that affect the traditional use of their TK or the importation of products based on the TK into the United States<sup>284</sup> In case source communities are unable to bring a challenge, for example, because they are not well organized, the countries in which such communities reside should be able to bring a challenge. Furthermore, given the considerable public interest in the granting of an undeserving patent right, nongovernmental organizations and other entities working in the relevant industry (e.g., environmental conservation, agricultural management, biopharmaceutical research) should have standing to challenge a claimed invention for noncompliance with the requirement.

Consultation should be undertaken with all relevant stakeholders including industry associations and leaders, indigenous peoples and local communities, and government agencies within and outside of the United States. The PTO could engage with other patent offices that have been implementing some version of a requirement that compels the disclosure of the source of TK used in research. The PTO can develop best practices and learn from challenges faced in other patent offices. Through the policy

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279. For discussions on the changes brought about by the AIA and its implication for U.S. patent law, see Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 10 (2012).

280. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 8, 125 Stat. 284, 315–16 (2011) (amending 35 U.S.C. § 122 to add a new subsection (e)).

281. *Id.* § 6, 125 Stat. 284, 299 (amending 35 U.S.C. § 321).

282. The AIA introduced Post-Grant Review (PGR), and Inter Partes Review (IPR); while Ex Parte Re-examination (EPR) was introduced in 1981. *Id.*

283. See John F. Duffy, *Standing to Challenge Patents, Enforcement Risk, and Separation of Powers*, 83 GEO. WASH. L. REV. 628, 629 (2015).

284. See Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 106 (2001).



guidance and institutional mechanisms outlined above, the PTO could introduce an effective requirement that addresses concerns around legal uncertainty and innovation-detering burdens.

*G. How Would the Requirement Benefit Source Communities?*

An important question that may arise from the description of the requirement provided in this Article is how the requirement may benefit source communities. An increasing number of source countries either have or are in the process of introducing domestic legislation<sup>285</sup> that provide obligations around benefit sharing from the use of TK. Source countries can use the disclosure of reliance on TK provided in U.S. patent applications to track and enforce obligations of benefit sharing that are included in their domestic legislation. The requirement gives the laws of source countries some teeth by facilitating its enforcement. This, of course, requires that the source country have domestic legislation that includes obligations of benefit sharing. Because U.S. courts enforce foreign judgments in many areas of law,<sup>286</sup> judgments based on violations of the source country's benefit-sharing laws should be similarly enforced in the United States.

#### CONCLUSION

This Article has argued for the introduction of an explicit requirement in U.S. patent law that compels patent applicants to disclose the source of TK they used in their inventive process. While most of the literature has focused on the international aspect, this Article analyzed the costs and benefits of introducing the requirement in the United States. The Article makes two arguments that should convince legislators to explicitly introduce the requirement in U.S. patent law. First, the Article makes the normative case for conceiving the requirement as an information-forcing rule. Understood this way, the benefits of the requirement are that it would create an efficient patent examination by eliciting socially beneficial information about the validity and scope of a claimed application from the low-cost providers of such information—patent applicants.

Second, the Article argues that explicitly introducing the requirement has potential to reverse a rising protectionist trend in which source communities and countries are increasing restrictions on access to TK. This trend threatens to disrupt promising practices in which researchers build on TK resources to develop welfare-enhancing products and services. By granting source communities and countries the ability to track use of their TK and enforce domestic laws or contracts in which researchers have obligations, the requirement creates confidence in the patent system and encourages increased access and collaboration.

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285. For a latest list of countries with some form of a requirement to disclose the source of TK used in the inventive process, see WORLD INTELLECTUAL PROP. ORG., *supra* note 250.

286. William C. Strum, *Enforcement of Foreign Judgments*, 95 COM. L.J. 200, 201 (1990).

Conceiving the requirement as an information-forcing penalty rule provides key insights into what form the requirement should take to meet its goal of encouraging innovation while ensuring equitable sharing of benefits with source communities. The literature on information-forcing rules suggests that the requirement should only require patent applicants to disclose the source from which they received TK so as not to discourage them from engaging in TK-related research in the first place. The literature also suggests that if the requirement is to provide its information-forcing effect the penalty for nondisclosure should be a rejection of the patent application and the invalidity or unenforceability of granted patents.

To further address concerns about the requirement, the Article outlined three levels of reliance on TK that may have different implications for the duty to disclose. Minimal reliance on the resource in which the inventor is inspired by TK but develops the claimed invention independently of TK should not trigger a duty under the requirement. However, “substantial reliance” in which the applicant would not have invented the claimed invention “but for” the reliance on TK should trigger an obligation to disclose. Substantial reliance should include cases in which the use of TK resulted in the reduction of time or resources necessary to develop a claimed invention.

A carefully calibrated requirement that follows the guidelines outlined above can address concerns around legal uncertainty and the creation of innovation-detering burdens. Introduction of the requirement in U.S. patent law could create a world in which researchers have increased access to TK resources, such as the 250,000 medical formulations in the Indian TK database, to develop products and services in return for an equitable sharing of benefits with source communities or countries. This is important for the U.S. economy considering the dominance of U.S. firms in sectors that rely on TK for part of their innovative output, including the pharmaceutical and agricultural industries. The Article advocates for amendment of the federal rules and PTO manual as the most feasible channel to explicitly introduce the requirement, which, if carefully calibrated, would create more efficient patent examination and reverse the rising protectionist trend.