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# Patents and Biopiracy:

# Disclosure of Origin Requirement as Information-Forcing

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Abstract

*Inventors sometimes rely on the genetic resource or traditional knowledge (GRTK) 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. Issues about the contribution of GRTK resource arises when the inventor applies and receives a patent right. 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 requirement is expected to allow a patent examiner to ensure that the application meets patentability standards. A question that arises then is whether patent applicants that rely on GRTK 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 GRTK in their inventive process. They, as a result, may claim exclusive property rights over what indigenous peoples and local communities have been practicing for generations.*

*This paper argues that the inclusion of an explicit requirement in US patent law compelling patent applicants disclose the source of GRTK resources they relied on can create sustain relationships in the relevant industries and create an efficient patent system. It provides two justifications for the amendment of US patent law. First, it highlights a rising and inefficient protectionist trend in which source communities increasingly introduce restrictions on access to GRTK. The paper argues that an explicit and enforceable disclosure requirement would reverse this trend by creating confidence in the patent system and encouraging source communities to facilitate access to GRTK. Second, the paper makes a descriptive and normative case for conceiving the disclosure of origin requirement as an information-forcing rule. Imposing an obligation to disclose the source of GRTK 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 efficient patent system. The paper uses efficiency and social welfare perspectives in contrast to the equity and distributive justice justifications dominating the literature. The focus of this paper on domestic US law is another point of contrast to the focus of the literature on international law.*

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## INTRODUCTION

Robert Larson, a timber importer from Wisconsin, received a US patent over a neem tree extract for use as a pesticide.[1] Mr. Larson had learned of the use of the neem trees as a pesticide while importing timber from India.[2] Although farmers in India have been using the neem tree as a pesticide for centuries,[3] Mr. Larson did not mention this fact or how he learned of the use of neem tree as a pesticide.[4] There are several of these types of cases where inventors rely on the genetic resource and traditional knowledge (GRTK) of indigenous peoples and local communities.[5] The term genetic resources (GR) refers to "any material of plant,

[1] Robert O. Larson, STABLE ANTI-PEST NEEM SEED EXTRACT (1985), https://patents.google.com/patent/US4556562A/en?q=storage&q=stable&q=neem&q=tree&q=extract&oq=storage+stable+neem+tree+extract (last visited Jun 21, 2018)

[2] Vandana Shiva, THE NEEM TREE - A CASE HISTORY OF BIOPIRACY THIRD WORLD NETWORK (2013), http://www.twn.my/title/pir-ch.htm (last visited Jun 21, 2018)

[3] NEEM: A TREE FOR SOLVING GLOBAL PROBLEMS, 32 (1992), https://www.nap.edu/catalog/1924/neem-a-tree-for-solving-global-problems

[4] It should be noted here that at the time the Larson patent was examined US patent law did not consider unpublished information from outside of the US 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. This point is further elaborated in text accompanying notes 21 and 22. [NB]

[5] Other examples include, a patent right for the use of turmeric powder for would healing, a practice widely used in Indian communities; appetite suppressant compound extracted from the Hoodia tree, a practice used by the San People of South Africa for centuries; a patent right over a process of producing teff flour, a famous ingredient used to make Injera bread among millions of Ethiopians. [NB: Cite to ___ p. 45 – 76; Bitter Roots; Out of Africa]

animal, microbial or other origin containing functional units of heredity"[6]; while the term "traditional knowledge" (TK) refers to the know-how, skills, innovations, and practices of indigenous peoples and local communities.[7] The most famous examples involve what is called bioprospecting, ethnopharmacology or ethnomedicine - the practice of using traditional medicinal knowledge as research leads to develop modern drugs. Reliance on GRTK in the inventive process creates questions of patent validity, duty of disclosure, and entitlements to creative outcomes.

This paper argues that an amendment to US patent law which introduces an explicit obligation that patent applicants disclose the source of GRTK on which they rely could create a more efficient patent system, and one that could sustain innovations in fields that rely on GRTK. The paper focuses on efficiency and social welfare as the primary perspectives in contrast to the equity and distributive justice approaches predominantly adopted in the literature. It adopts such approach in hopes of engaging stakeholders uninterested in equity and distributive perspectives.

US patent law grants exclusive rights to individuals that develop inventive products or processes. A key aspect of the system is a quid pro quo – a social compact – in which inventors receive exclusive rights for 20 years in exchange for disclosing their inventions to the public.[8] This social compact faces a risk because patent applicants have both the motive and the opportunity to withhold essential information.[9] They have the motive because the validity and scope of a patent right depend on the level of information available to a patent examiner and it is in their best interest to withhold potentially damaging information. They have the opportunity because there is considerable information asymmetry in patent examination. 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 through the limited period of examination.

To guard against this incentive to withhold information, the patent system includes obligations to disclose background and contextual information about claimed invention. Despite these measures, applicants use drafting technics to receive rights over unpatentable inventions or to get vague patent rights that create broader scope than the invention deserves. Several scholars have reported this problem of withholding information to receive patent rights for undeserving claims. This problem, however, is exacerbated in the case of inventions that rely

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[6] See Article 2, THE CONVENTION ON BIOLOGICAL DIVERSITY, (1993), https://www.cbd.int/doc/legal/cbd-en.pdf.

[7] 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. Aman Gebru, *International Intellectual Property Law and the Protection of Traditional Knowledge: From Cultural Conservation to Knowledge Codification*, 15 ASPER REV. INT, 293 (2015).

[8] [NB Cite]

[9] [NB: Cite.] Cite to Section XX on Information-Forcing Rules in Patent Law.

on the GRTK. Because GRTK resources involve unique features that make them inaccessible, examiners rarely use such resources in patent examinations, which in turn, increases the information asymmetry and the incentive to withhold information.

Since US patent law has a broad disclosure requirement, arguably, patent applicants that rely on GRTK 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. Reports of multiple instances show that patent applicants usually fail to disclose their reliance on GRTK in their inventive process and it is only *ex-post* when the patent is challenged that such information is disclosed. On multiple occasions, a patent application is held valid despite withholding information about reliance on GRTK.

In the face of this practice, scholars, politicians, community leaders, and activists have been calling for reform of patent laws around the world. Labeling these practices as biopiracy, they are pushing for the invalidation of non-inventive patent applications and the recognition of the contributions of source communities. Most of these discussions are taking place at the international level with some domestic experiences form selected jurisdictions. One of the key tools advocates have called for is the disclosure of origin (DOO) requirement – which creates an obligation on patent applicants to disclose the origin or source of GRTK they use in their inventive process. Advocates have used negotiations at the international level to introduce the DOO requirements in a few treaties and protocols. However, these proposals have created heated debates among commentators, scholars, and government representatives. While the requirement could improve the quality of granted patents and help establish a more equitable benefit sharing scheme, it may also create costs related to legal uncertainty and innovation-deterring burdens.

In contrast to the focus of the scholarship at the international level, this paper discusses the costs and benefits of amending US patent law to include a DOO requirement. The paper argues that two key effects of the DOO requirement should convince legislators and policymakers to introduce the requirement in US patent law. First, the paper argues that the DOO requirement will reverse a rising protectionist trend in which source communities are increasing restrictions on access to GRTK resources. A DOO 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 a sustain a promising relationship in relevant industries and help with 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, a different framework would seek to reward those that provide useful contribution earlier in that process.

Second, the paper makes the descriptive and normative case for conceiving the DOO 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. Conceiving the DOO requirement as an information-forcing penalty rule provides key insights about the governance of GRTK use. First it points to the need to establish a DOO requirement to compel information from the well-informed party – the patent applicant. Second, the information-forcing rules literature suggests that the DOO requirement should only require patent applicants to disclose the *source* from which they received GRTK and not the *origin* of the resource.[10] Requiring inventors to conduct more research to discover the origin of GRTK would create new transaction costs that may discourage them from engaging in GRTK-related research in the first place. Third, the literature also suggests that, if the requirement is to provide its information-forcing effect the penalty for non-disclosure should be robust and include a rejection of the patent application or invalidity/unenforceability of granted patents.

Amending the US patent act to introduce an explicit DOO 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 US 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, the paper suggests that clarifying the duties of disclosure, candor and good faith that patent applications already have by introducing an explicit DOO requirement would be a feasible second-best measure. It also argues that the PTO as the most suitable administrative agency for patent examination should check for compliance with the DOO requirement as well.

Part I introduces the US patent system, the disclosure requirement and the challenges that arise when inventors rely on the genetic resources or traditional knowledge of indigenous peoples and local communities. Part II outlines the value of GRTK resources for modern industries, the cost and benefit of introducing a DOO requirement and the alternative forms it could take. Part III makes a normative case for the potential of a DOO requirement to reverse a rising protectionist trend and establish an effective and collaborative relationship between researchers and source communities. Part IV makes a descriptive and normative case for conceiving the DOO requirement as an information-forcing rule. It explains how conceiving the requirement this way could provide important guidance on what features an effective DOO requirement should include. Lastly, Part V discusses the institutional mechanisms through which the DOO requirement should be formulated in US law.

[10] The source of a GRTK is the entity through which the patent applicant received access while the origin is the source community that claims to be the first to develop the resource. [NB: Section xx] below provides a more detailed discussion on this topic.

## I. PATENTS, "BIOPIRACY"[11] & DISCLOSURE

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.[12] Before applying for the patent, Mr. Larson, who had learned of the use of neem tree extracts as pesticides during his time in India, imported samples of the tree and conducted research for over a decade.[13] Three years after his patent was granted he assigned the patent rights to the chemical conglomerate W.R. Grace[14] (Grace patent) and the company has received similar patents on a storage stable neem tree extract in the US[15] and other jurisdictions.[16] Revenue from Neemix, the pesticide that Grace developed using neem tree extract, was sold in the US and abroad, and its annual sales grossed around $60 million.[17]

When the granting of patent rights was disclosed to the public many scholars, activists, farmers and government leaders protested what they argue was a new form of imperialism and an act of "piracy by patents."[18] The protest arose because, for centuries, Indians have used the neem tree and its extracts for several purposes, including as a pesticide. Indian farmers would break the neem tree seeds, soak them in water or alcohol and use the compound that remains as a pesticide.[19]In addition to traditional uses, Indian scientists had demonstrated the value of neem tree extract as a pesticide since the 1920s.[20] So the granting of a

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[11] 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". This corresponds to the use of the term in the scholarships.

[12] Robert O. Larson, STABLE ANTI-PEST NEEM SEED EXTRACT (1985), https://patents.google.com/patent/US4556562A/en?q=storage&q=stable&q=neem&q=tree&q=extract&oq=storage+stable+neem+tree+extract (last visited Jun 21, 2018).

[13] Vandana Shiva, THE NEEM TREE - A CASE HISTORY OF BIOPIRACY THIRD WORLD NETWORK (2013), http://www.twn.my/title/pir-ch.htm (last visited Jun 21, 2018).

[14] *Id.*

[15] Charles G. Carter et al., STORAGE STABLE AZADIRACHTIN FORMULATION (1992), https://patents.google.com/patent/US5124349A/en?oq=US+5124349 (last visited Jun 28, 2018).

[16] See for instance, the European counterpart of the same patent application. Charles G. Carter et al., STORAGE STABLE AZADIRACHTIN FORMULATION, PATENT NO. EP0405291 B1 (1991), http://www.google.ca/patents/EP0405291A1 (last visited Apr 22, 2016).

[17] 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 Street Journal, September 13, 1995

[18] 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 (Jerry Mander & Edward Goldsmith eds., 1996); L. Wolfgang, *Patents on native technology challenged*, 269 SCIENCE 1506–1506 (1995).

[19] Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B. C. INT'L & COMP. L. REV. 279–296, 283 (1999).

[20] NEEM: A TREE FOR SOLVING GLOBAL PROBLEMS, 32 (1992), https://www.nap.edu/catalog/1924/neem-a-tree-for-solving-global-problems.

private right over what millions of Indian farmers have been doing for centuries and studied scientifically for decades seemed absurd and unfair to many.[21] The public outcry resulted in the creation of an international coalition from 35 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 (USPTO).[22]

The legal petition alleged that the 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 a technical level, the challenge argued that the invention lacks novelty and is obvious considering traditional practices in India.[23] W.R. Grace on its part claimed that the company's research has resulted in increasing the shelf life for the extract from a couple of days to about two years.[24] The PTO agreed and found that the claimed invention had a significant level of advancement over the traditional practice that it met the patentability requirement.[25] An important point here is that at the time the patent was granted, US patent law did not consider unpublished information outside of the US in patentability analysis.[26] That has since changed with the amendments to the patent law in the 2011 America Invents Act.[27] Under current US law, unpublished information, such as the public use of the invention, anywhere in the world can be used as a prior art[28] reference against a claimed invention.[29] This may include traditional practices such as the use of neem tree extracts as pesticides in India. However, since this relevance of traditional practices for patentability has not been litigated in court, it is still not clear if it the challenge would have come out differently if filed today.[30]

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[21] [NB: Herma Shukla – in Zotero file] The objections to the patent over the neem tree extract are not limited to the non-inventive nature of the claim but are also tied to broader objections to the patenting of life forms and age-old practices. For many Indians the Neem tree has spiritual components as well. [NB: NEEM – report]. The Sanskrit name for the neem tree "sarva-roga nivarini" meaning "curer of all ailments" describes the regard that many Indians have for the neem tree. See Wolfgang, *supra* note 13

[22] *See* Request for Reexamination of patent no. 5,124,349. (Off. Gaz. Pat. Office Jan. 16, 1996) available in Lexis, Patent Library

[23] See Request for Reexamination of patent no. 5,124,349. (Off. Gaz. Pat. Office Jan. 16, 1996) available in Lexis, Patent Library

[24] Burns, *supra* note 21.

[25] [NB: citation needed]

[26] See, 35 U.S.C. § 102. See also, Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679–742 (2002).

[27] [NB: citation needed] The Leah-Smith America Invents Act (AIA) was passed by Congress and signed into law by President Barack Obama in September 2011.

[28] [Define prior art]

[29] [NB: citation needed] –Merges & Duffy

[30] The validity of the W.R. Grace patent considering traditional Indian practice is further discussed in Section [X]

Although advocates failed in challenging the US patent, they did succeed in their challenge against the European counterpart patent[31] over the storage stable neem tree extract.[32] The coalition to invalidate the European patent included the EU parliament's Green Party leaders, various Indian government agencies, and international organizations and it took over ten years.[33] The European Patent Office declared that the claimed invention fails patentability requirements based on evidence showing the use of storage-stable neem tree extract in India years before the patent application.[34]

While the literature on the topic focuses on international law, this paper focuses on US law. It examines questions around patentability standards, especially when it comes to claims for inventions that are based on GRTK. Before proceeding to analyze questions at the intersection of patent law and the use of genetic resources and traditional knowledge (GRTK), it is necessary to first outline the basic patent application process under US law.

## A. The Patent Prosecution Process

There are three core requirements of patentability – novelty (newness), non-obviousness and usefulness (utility).[35] 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.[36] An invention will be non-obvious 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 create it easily.[37] To meet the usefulness requirement, an invention must be "minimally operable towards some practical purpose."[38]

In addition to these substantive requirements, courts have excluded certain subject matters from patentability. The three interrelated excluded subject matters

[31] Although there are differences in the patent laws of the US and the 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, AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS OF THE GENERAL AGREEMENT ON TARIFFS AND TRADE, (1994).
[32] India wins landmark patent battle, BBC, March 9, 2005, http://news.bbc.co.uk/2/hi/science/nature/4333627.stm (last visited Jun 25, 2018); Neem tree patent revoked, BBC, May 11, 2000, http://news.bbc.co.uk/2/hi/science/nature/745028.stm (last visited Apr 22, 2016).
[33] India wins landmark patent battle, *supra* note 32.
[34] *Id.*
[35] 35 U.S.C. § 101, 102, 103
[36] 35 U.S. Code § 102. [NB: define prior art + cite to case law]
[37] 35 U.S. Code § 103 (a)
[38] ROGER SCHECHTER & JOHN THOMAS, PRINCIPLES OF PATENT LAW 2 (1 edition ed. 2004).

are "laws of nature, physical phenomena, and abstract ideas."[39] 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.[40] Therefore, to get a patent right over a naturally occurring substance, applicants have to show that they have created something new using such substance. Innovative applications of abstract ideas, laws of nature, physical phenomena may be patentable if they meet other patentability requirements.[41]

Lastly, a patent application must disclose the invention and the manner of making and using it.[42] The requirement to disclose information about the claimed invention is a key part of patent law, and it is stated in many forms.[43] This principle is especially important for the discussions in this paper, and so the following section provides a discussion of the content and scope of the duty to disclose under US patent law.

### B. The Duty of Disclosure

The core disclosure requirement in US patent law is outlined under 35 U.S. Code § 112 (a) of the patent act.[44] It states that the 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."[45] 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. This references usually include other patents, printed publications and other sources that hold information relevant for the examination of the patent application.

The disclosure requirement in § 112 supplemented by the duty of disclosure, candor and good faith that is codified at 37 CFR 1.56 and is colloquially called 'Rule 56'.[46] 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

[39] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. _, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014) (citing Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. _, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972, 1979 (2013). Courts have used these three phrases loosely and at times interchangeably.
[40] Alice Corp., 134 S. Ct. at 2354, 110 USPQ2d at 1980; Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71, 101 USPQ2d 1961, 1965 (2012)
[41] Alice Corp., 134 S. Ct. at 2354, 110 USPQ2d at 1980 (citing Gottschalk v. Benson, 409 U.S. 63, 67, 175 USPQ 673, 675 (1972)
[42] 35 U.S. Code § 112
[43] [NB: Cite to section on disclosure] The requirements of enablement, written description, definiteness and best mode are designed to make patent applicants disclose all of the relevant information about their claimed invention to the examiner.
[44] 35 U.S. Code § 112 (a)
[45] 35 U.S. Code § 112 (a)
[46] 37 CFR 1.56

position the applicant takes…"[47] Although this definition seems to significantly limit the scope of the information required to be disclosed, the rest of the rule makes clear that within the limits of materiality, the duty to disclose includes a very broad interpretation of the duty. 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.[48] The rule is establishing 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 USTPO 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.[49] Furthermore, as the Federal Circuit explained in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.,* "[m]ateriality is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent."[50] Additionally, this expanded duty exists no matter how the patent applicant came across the information.[51] The applicant, for example, cannot engage in willful ignorance and avoid accessing explicit notice of material information.[52]

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.[53] The Supreme Court in *Precision Instrument Mfg. Co. v. Automotive Co.* held that a patent would be unenforceable if the patentee has "unclean hands."[54] The court held that there is a strong "public policy against the assertion and enforcement of patent claims infected with fraud and perjury."[55] 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 their correspondence with the PTO.[56] In a key decision expanding the doctrine, the Court of Customs and Patent Appeals in stated that the unclean hands doctrine "cannot be applied too narrowly

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[47] 37 CFR 1.56 (b) (1) & (2)
[48] 37 CFR 1.56 (b) (3)
[49] Manual of Patent Examining Procedure (MPEP) § 2001.04 (January 2018) available at: < https://www.uspto.gov/web/offices/pac/mpep/mpep-2000.pdf>
[50] Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234, 66 USPQ2d 1481, 1486 (Fed. Cir. 2003)
[51] Manual of Patent Examining Procedure (MPEP) § 2001.06 (January 2018) available at: < https://www.uspto.gov/web/offices/pac/mpep/mpep-2000.pdf>
[52] Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1383, 60 USPQ2d 1482, 1490 (Fed. Cir. 2001) (If an applicant or the attorney know that there is relevant information, they can not ignore such notice to avoid the duty to disclose)
[53] Merges and Duffy, Patent Law and Policy, 7th ed., at 979
[54] Precision Instrument Mfg. Co. v. Automotive Co., 324 U.S. 806, 819 (1945)
[55] Precision Instrument Mfg. Co. v. Automotive Co., 324 U.S. 806, 819 (1945)
[56] Merges and Duffy, Patent Law and Policy, 7th ed., at 979

if the relationship between applicants and the Patent Office is to have any real meaning."[57] Under this expanded duty currently called inequitable conduct, a patent could be unenforceable if an applicant withholds information the courts deem relevant.[58] The Federal Circuit in *Hycor Corp. V. Schlueter Co.* 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."[59] 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.[60] The teaching function speaks to the value of disclosure to reveal useful information about the state of the art to the public. As the Supreme Court declared in *Kewanee Oil Co. V. Bicron Corp.*,[61] the disclosure is meant to add to the public's "general store of knowledge."[62] In its limiting function, disclosure works to limit the scope of the claim in the patent application, i.e. the metes and bounds of the right granted to the inventor. Since patents are only granted to new inventions, the applicant cannot claim rights over information disclosed to the public before the patent application.

## C. Disclosure Problems in Current Law

Despite the heightened level of disclosure requirement in US patent law research[63] has shown that patent applicants withhold information from the patent office 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. The inventor who applies for an invention would usually having dedicated a considerable amount of time researching in the field to develop a new, non-obvious and useful invention. The patent examiner on the other hand, has a very limited amount of time to examine the patentability of the claimed invention and as a result would have less knowledge about the scope of knowledge surrounding the claimed invention. Furthermore, patent applicants use vague wordings and other claim drafting techniques to introduce confusion about the

[57] Norton v. Curtiss, 433 F.2d 779 (C.C.P.A. 1970)
[58] Merges and Duffy, Patent Law and Policy, 7th ed., at 979; The inequitable conduct doctrine is not without criticism. See for instance, Nolan-Stevaux, Inequitable Conduct Claims in the 21st Century (arguing that the inequitable conduct doctrine has been abused by defendants because it is used in almost all patent infringement lawsuits.)
[59] Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1538 (Fed. Cir. 1984) (quoting Norton v. Curtiss, 433 F.2d 779, 794 (C.C.P.A. 1970))
[60] [NB] Rantanen, *Infra* note 126 at 375.
[61] 416 U.S. 470
[62] Kewanee Oil Co. V. Bicron Corp. 416 U.S. 470, 481
[63] [NB: citation needed] Mark Lemley, Rationale Ignorance at the Patent Office; R. Polk Wagner, Reconsidering Estoppel]

scope of the claimed invention that they could later on exploit to their advantage.[64] 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[65] and is examined in further detail in a later section.[66]

## II. PROBLEMS IN THE CONTEXT OF GRTK

The problems of withholding important information from patent examiners is exacerbated in the case of inventions that rely on GRTK resources. This is because the inherent information asymmetry in the patent system is even more stark in the case of GRTK use. One of the common features of GRTK resources is that they are inaccessible. Indigenous peoples and local communities predominantly use oral traditions to conserve and transfer knowledge in contrast to the emphasis on documenting knowledge in Western Societies.[67] In the rare cases where GRTK resources are codified, they tend to be codified in local languages that may not be understood by patent examiners. Therefore, the unique features of GRTK that make it inaccessible increase the information asymmetry between an inventor who managed to gain access to GRTK 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 GRTK resources in their inventive process.

### A. The Value & Loss of GRTK Resources[68]

The relationship between the DOO requirement and the use of GRTK resources can be explained through the example of modern drug discovery and development. Although the example of GRTK use in the biopharmaceutical field

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[64] [NB: Citation needed]
[65] Mark Lemley, Rationale Ignorance at the Patent Office; R. Polk Wagner, Reconsidering Estoppel]
[66] [NB: See Section XX on Information-Forcing Rules in Patent Law.]
[67] Aman Gebru, Intellectual Property Law and Traditional Knowledge: From Cultural Conservation to Knowledge Codification [NB]
[68] GRTK 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 GRTK resources are useful is as an input in modern industries. This section focuses on this second types of use because of its relevance for the DOO requirement. This however is not meant to discount the independent use of that GRTK resources have for the source community. The independent use of GRTK 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 relies on some form of alternative medicine. See Xiaorui Zhang, *Protecting Traditional Knowledge, Innovations and Practices* (United Nations Conference on Trade and Development, 2000) at 2-3

is used as an example throughout this paper, one can imagine the multiple areas of modern research and development that could benefit from the use of GRTK.[69]

It is no secret that research and development take considerable time and resources in the biotechnology and pharmaceutical (hereafter biopharmaceutical) industries. For instance, by one estimate the out-of-pocket pre-approval cost of the development of a drug to the point of marketing is around $802 million (in 2000 dollars)[70] and the average time from human testing to post regulatory approval is estimated to be over nine years.[71] One approach that biopharmaceutical firms have adopted to reduce this cost is "ethnopharmacology" or "ethnomedicine" – which is the use of GRTK to develop drugs more efficiently.[72] Empirical research has proved that ethnopharmacology has reduced the time and cost of developing biopharmaceutical products.[73] One of the key benefits of using GRTK resources is in increasing the efficiency of initial screening biodiversity candidates for further examination. For instance, in one research the chances of getting a preliminary hit[74] in plant screening increased from 6% without the use of GRTK to 25% with the use of such resource.[75] In another research, the use of GRTK increased the efficiency of screening plants in the development of a cure for HIV/AIDS.[76] While some claims of traditional

[69] For instance, research into agriculture, and environmental protection have considerably benefited from the knowledge and resources of indigenous peoples and local communities. [NB: Citation needed]

[70] Joseph A DiMasi, Ronald W Hansen & Henry G Grabowski, *The price of innovation: new estimates of drug development costs*, 22 JOURNAL OF HEALTH ECONOMICS 151–185 (2003). With annual inflation at 2.4% since 2000, the current cost of an average drug would therefore be over $1.1 billion dollars.

[71] K. I. Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 356–361.

[72] See generally, Gordon C. Rausser & Arthur A. Small, *Valuing Research Leads: Bioprospecting and the Conservation of Genetic Resources*, 108 JOURNAL OF POLITICAL ECONOMY 173–206, 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.").

[73] M.L. Willcox et al., *A "Reverse Pharmacology" Approach for Developing an Anti-malarial Phytomedicine*, 10 MALARIA JOURNAL S8 (2011); Axel Helmstadter & Christiane Staiger, *Traditional Use of Medicinal Agents: A Valid Source of Evidence*, Volume 19 DRUG DISCOVERY TODAY 4–7 (2014); P. J. Houghton, *The role of plants in traditional medicine and current therapy*, 1 J ALTERN COMPLEMENT MED 131–143 (1995); D S Fabricant & N R Farnsworth, *The value of plants used in traditional medicine for drug discovery.*, 109 ENVIRON HEALTH PERSPECT 69–75 (2001).

[74] Benoit Deprez & Rebecca Deprez-Poulain, *Hit-to-Lead: Driving Forces for the Medicinal Chemist (Guest Editor: Benoit Deprez and Rebecca Deprez-Poulain*, 4 CURRENT TOPICS IN MEDICINAL CHEMISTRY i–i (2004); Rebecca Deprez-Poulain & Benoit Deprez, *Facts, figures and trends in lead generation*, 4 CURR TOP MED CHEM 569–580 (2004).

[75] C. Haris Saslis-Lagoudakis et al., *Phylogenies Reveal Predictive Power of Traditional Medicine in Bioprospecting*, 109 PNAS 15835–15840 (2012).

[76] Daniel Goleman, *Shamans and Their Lore May Vanish With Forests*, THE NEW YORK TIMES, June 11, 1991, http://www.nytimes.com/1991/06/11/science/shamans-and-their-lore-may-vanish-with-forests.html (last visited Mar 3, 2015)"In a field study in the rain forest in Belize, Dr.

medicines have had questionable efficacy,[77] the empirical evidence points to the significant potential that GRTK resources have as an input for modern industries. The trials and errors from the centuries-old use of biodiversity resources by communities have been serving as a diverse pool on which biopharmaceutical firms build to develop modern drugs.

Despite the value biodiversity and GRTK resources, they increasingly face an alarming rate of loss.[78] Conservationists have been warning of the high rate of biodiversity loss since the later decades of the 20th century.[79] Caused by human activity such as changes in land use, pollution, 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 humans interfere.[80] 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."[81] Researchers have calculated the annual loss from ecosystem services to be around US$250 billion.[82] To save this valuable resource from disappearing, world leaders worked towards the signing of the Convention on Biological Diversity (CBD) in 1992.[83] Two of the key contributions of the CBD to our current purposes were: 1) the recognition that source countries have sovereign rights in their biodiversity resources[84] and 2) the recognition that

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[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."

[77] 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 practices safely. "WHO Traditional Medicine Strategy 2014- 2023," (2013) at 12 <http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1.>

[78] Paul r. Ehrlich, The Loss of Biodiversity, in BIODIVERSITY, eds. E.O.Wilson and Frances M. Peter

[79] MEDICINAL PLANTS: THEIR ROLE IN HEALTH AND BIODIVERSITY, (Timothy R. Tomlinson & Olayiwola Akerele eds., 1998); Luis Maffi, *Linguistic and biological diversity: The inextricable link*, 29 ANN.U. REV. ANTHROPOL. 599–617 (2005) (discussing the high rate of cultural and linguistic loss which impact the knowledge of the uses of biodiversity.)].

[80] See, Heywood, V.H. (ed.) (1995) Global Biodiversity Assessment, UNEP, Cambridge, UK: Cambridge University Press.; See also, Millennium Ecosystem Assessment Living beyond Our Means: Natural Assets and Human Well-being, Washington, DC: Island Press. (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 1253–1263 (1996).

[81] PETRA EBERMANN, 10 PATENTS AS PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE? A LAW AND ECONOMICS APPROACH 26 (2012), http://intersentia.be/nl/patents-as-protection-of-traditional-medical-knowledge-13991.html (last visited Jun 15, 2015).

[82] Millennium Ecosystem Assessment, Ecosystems and Human Well-Being. Biodiversity Synthesis, Washington, DC: Island Press. (2005)

[83] the Convention on Biological Diversity (CBD)

[84] the Convention on Biological Diversity (CBD), preamble, para 4.

indigenous peoples and local communities should equitably benefit from the innovations arising out of GRTK resources.[85]

It should be highlighted here that 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. Since only a small portion of the world's biodiversity has been scientifically studied,[86] the high rate of loss means inventors (and by implication the public) miss out on potentially welfare enhancing products from being developed.

## B. A Rising Protectionist Trend

One of the key contributions of this paper is to highight a rising protectionist trend that should worry anyone interested in encouraging innovation in industries that rely on GRTK resources. The protectionist trend is one in which source communities/countries rich in GRTK resources are increasingly introducing barriers to access to these resources. While the tendency to keep GRTK secret because of fears of biopiracy have been mentioned in other publications,[87] these references tend to be made only in passing. This paper makes the case that there is a strong and rising protectionist trend among source communities that policymakers should take seriously consider. A careful consideration of this trend should influence the debate around the costs and benefits of the DOO requirement.

As highlighted earlier,[88] the biodiversity resources are unevenly distributed throughout the world. Countries in the Global South[89] are home to a high percentage of biodiversity resources. For instance, megadiverse countries[90] –the top 17 biodiversity-rich countries in the world – hold between 60 - 80% of the

[85] the Convention on Biological Diversity (CBD), preamble, para 12.
[86] [NB: citation needed]
[87] [NB: See for instance, Margo; Carvalho] 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, 245 (2007)
[88] See section II (A) [NB]
[89] The term "Global South" is a rough reference to developing countries which are concentrated south of the equator. "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" (internal quotation marks omitted). See, Nour Dados & Raewyn Connell, *The Global South*, 11 CONTEXTS 12–13, 12 (2012).
[90] The term "megadiverse countries" refers to the top biodiversity rich countries in the world which hold a minimum of 5000 endemic plant species and a marine ecosystem within their borders. See text accompanying *infra* note **Error! Bookmark not defined.**.

world's flora and fauna.[91] Only two of the 17 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 GRTK resources and the absence of research/business practice of recognizing 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 (CBD).[92]

While the signing of the CBD was a major milestone to conserve biodiversity and ensure benefit sharing, the implementation of the convention was far from what source communities/countries hoped for. This legal lacuna and many high-profile cases of biopiracy[93] have forced many source communities and jurisdictions to create barriers to access to GRTK resources. While the CBD's mission was to facilitate access to GRTK resources in exchange for benefit sharing, its failure seems to have encouraged quite the opposite. As one scholar noted:

> [T]he CBD 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."[94]

Since the CBD was signed because member countries understood that access to biodiversity resources was necessary for innovation in certain fields, evidence of a rising protectionist trend should worry policy makers tasked with encouraging the "progress of … useful arts."[95]

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 GRTK or the amendment of existing legislation (including IP laws) to include GRTK protection.[96] Several of the major

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[91] RUSSELL A. MITTERMEIER, CRISTINA GOETTSCH MITTERMEIER & EDWARD O. WILSON, MEGADIVERSITY: EARTH'S BIOLOGICALLY WEALTHIEST NATIONS (Patricio Robles Gil ed., 1st edition ed. 2005).

[92] The Convention on Biological Diversity: From Conception to Implementation, 5 (2004), https://www.cbd.int/doc/publications/CBD-10th-anniversary.pdf.

[93] ROBINSON, *supra* note 85 at 45–76.

[94] Charles McManis, *Biodiversity, Biotechnology and Traditional Knowledge Protection: Law, Science and Practice*, *in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY, & TRADITIONAL KNOWLEDGE, 5 (2007).

[95] U.S. Constitution, Article I, Section 8, Clause 8

[96] A search for GRTK related legislation on the WIPO legal text database results in 167 records. Almost all of these legislations were enacted after the CBD, and the overwhelming majority are among countries of the Global South. Some of these legislations cover several issues including

biodiversity hotspots of the world have enacted domestic legislation with the effect of restricting access to GRTK.[97] For instance, in June 2018, the second biggest megadiverse country – Indonesia – strengthened its laws to protect its biodiversity from bio-pirates.[98] While legislation to govern GRTK resources may be crafted to facilitate access, since most of these legislations 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 GRTK databases or registers. While the practice of documenting GRTK in databases is still new practice, many of the jurisdictions that have decided to invest in these databases seem to have adopted highly restrictive measures. For instance, the pioneering GRTK 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.[99] While those who manage the TKDL claim that the translation of the contents of the database into five of the leading international languages, access to the database is granted only to patent examiners for the sole purpose of patent examination.[100] Patent offices interested in gaining access to the database will have to sign a non-disclosure agreement after negotiating the specific terms with the Indian government.[101] Other countries are adopting this practice of making GRTK databases restrictive.[102]

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traditional knowledge, traditional cultural expression, and genetic resources. See, http://www.wipo.int/tk/en/databases/tklaws/search_result.jsp?searchPage=2.

[97] 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 565–594, 757–76 (Keith E. Maskus & Jerome Reichman eds., 2005) (outlining national legislations enacted to protect TK in India, Brazil, Peru, the Philippines, and the Africa model legislation.); Carvalho, *supra* note 144.

[98] Harish Mehta, *Indonesia Strengthens Laws Against Biopirates*, THE BUSINESS TIMES, June 8, 2018, https://www.businesstimes.com.sg/opinion/indonesia-strengthens-laws-against-biopirates (last visited Jun 13, 2018).

[99] See the "Abouts TKDL" section, TKDL, *supra* note 86.

[100] 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 1200 patent applications. *Id.*

[101] For instance, see TKDL Access Agreement, *supra* note 87; TKDL Access Agreement, *supra* note 87; TKDL Access Agreement, *supra* note 87.

[102] Council for Scientific and Industrial Research (CSIR), SAFEGUARDING THE FUTURE OF INDIGENOUS KNOWLEDGE THROUGH ICT: NATIONAL RECORDAL SYSTEM, http://www.csir.co.za/meraka/National_Recordal_System.html; Tom Suchanandan & Carol van Wyk, 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; Brief Introduction of China Traditional Chinese Medicine

Policy makers should be concerned that, instead of increased access that spurs improvements, researchers now face restrictions. Since the ultimate result of a research project is usually unpredictable, researchers need access to a wide range of input including GRTK. If states with huge biodiversity resources continue adopting a restrictions stance, it is easy to imagine how such trend could affect research in industries that benefit from GRTK, including the biopharmaceutical sector. Even if researchers find a way around restrictions legislation and GRTK 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 GRTK 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.[103] However, the overwhelming majority of source communities and many megadiverse countries lack the financial and human resource capacity to develop GRTK resources into commercial products. Furthermore, the are multiple reports sounding the alarm on the very high rate of biodiversity loss[104] and GRTK resources rely heaving on biodiversity. Protectionism in the face of such a high rate of resource loss will result in numerous GRTK 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 community to independently commercialize GRTK results in the under-utilization of this valuable resource. This is undesirable from the perspective of global social welfare because increased access to research input is expected to encourage innovation, not increased restrictions.

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(TCM) Patent Database, , http://221.122.40.157/tcm_patent/englishversion/help/help.html; Traditional Chinese Medicine, , http://www.sipo.gov.cn/; Jeongyoon Choi, INTRODUCTION OF KOREAN TRADITIONAL KNOWLEDGE PORTAL (KTKP) (2011), http://www.wipo.int/edocs/mdocs/tk/en/wipo_tkdl_del_11/wipo_tkdl_del_11_ref_t9_4.pdf; The Korean Traditional Knowledge Portal, , http://www.koreantk.com/en/m_about/about_01.jsp?about=1.

[103] 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 (2011) (suggesting the extension trade secrecy protection for traditional knowledge.).

[104] CHARLES PERRINGS ET AL., BIODIVERSITY LOSS: ECONOMIC AND ECOLOGICAL ISSUES (1997); LOSS OF BIODIVERSITY, (Sharon L. Spray & Karen L. McGlothlin eds., 2003); ALEXANDER WOOD, PAMELA STEDMAN-EDWARDS & JOHANNA MANG, THE ROOT CAUSES OF BIODIVERSITY LOSS (1 edition ed. 2000); John G. Robinson, *The Limits to Caring: Sustainable Living and the Loss of Biodiversity*, 7 CONSERVATION BIOLOGY 20–28 (1993); Stuart L. Pimm et al., *The Future of Biodiversity*, 269 SCIENCE 347–350 (1995).

Ultimately, a rising protectionist trend means that the status quo in which firms use GRTK resources to develop products is unsustainable in the long run. Because of this protectionist trend, researchers and firms that have the means to commercialize GRTK 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 misses 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 GRTK resources been used to develop products. The increasing number of restrictions created by several jurisdictions show that this worrying protectionist trend is on the rise.

## III. ADDRESSING DISCLOSURE IN GRTK CONTEXT

A major contribution of the paper is justifying the need to create a DOO requirement based on efficiency and welfare perspectives. The requirement would lead to welfare enhancing outcomes instead of the inefficient status quo where researchers face a rising protectionist trend or where the PTO grants patent rights to undeserving applicants. So 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 the DOO requirement has been discussed internationally, a robust discussion of the cost and benefit of introducing the requirement in domestic US law is lacking. The next two sections turn to the normative case for the introduction of an explicit DOO requirement in US patent law. The stated goal of the US patent system is to encourage "the progress of … useful arts."[105] The rest of the article argues that the introduction of a carefully calibrated and explicit DOO requirement would be consistent with this goal.

### A. DOO Requirement as Information-Forcing

This section makes the normative case for the introduction of an explicit requirement that would compel patent applicants to disclose the source of GRTK they used in their patent application. It also makes a descriptive case for 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. The article posits that the cost and benefit analysis of introducing the requirement should be re-considered in light of its conception as an information-forcing rule.

[105] U.S. Constitution, Article I, Section 8 Clause 8

Information-forcing default rules have been examined in many contexts. Perhaps, the first strong case for the adoption of such rules was made in the contracts context.[106] In their seminal paper discussing information-forcing rules,[107] 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". The parties avoid adding a contractual term because the *ex-ante* cost of adding that term 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 a private information creates a contractual gap by withholding a privately held information that, if revealed, would result in a socially optimal outcome. 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 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 maybe observed in the employment contracts sense. While the default employment contract in the US is "at will" most employees erroneously believe that they cannot be fired from their jobs without "just cause".[108] 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 it's employee have, while being able to terminate any individual without cause. Courts or 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,

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[106] Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE LAW JOURNAL 87 (1989).
[107] Ayres and Gertner [Filling Gaps in Incomplete Contracts]
[108] [J. H. Verkerke, Legal Ignorance and Information-Forcing rules, at 923] [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, 697 (2005)

therefore, serve 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;[109] 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 penalty default rule.[110] 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.[111]

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

Intellectual property law scholars have embraced the information-forcing rules literature as a helpful lens to examine various doctrines.[112] This is even more so the case in the patent law field.[113] The predominance of a utilitarian justification for patent law lends itself to an incentives-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

[109] David M. Driesen & Shubha Gosh, The Functions of Transaction Costs: Rethinking Transaction Cost Minimization in a World of Friction, 47 Ariz. L. Rev. 61, 71-71 (2005)
[110] Shawn Pompian, Note, *Is the Statute of Frauds Ready for Electronic Contracting?* 85 VA. L. REV. 1447, 1453 (1999)
[111] 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 - 611 (2006); See for example, Alex Reinert, *Pleading as Information-Forcing*, 75 Law & Contemp. Probs. 1–36 (2012); Bradley C. Karkkainen, *Information-Forcing Environmental Regulation*, 33 Fla. St. U. L. Rev. 861 (2005), http://heinonline.org/HOL/Page?handle=hein.journals/flsulr33&id=875&div=&collection=
[112] Christopher Sprigman, *Reform(aliz)ing Copyright*, 57 STAN. L. REV. 485, 556 (2004) (Comparing default licenses in copyright to "penalty defaults"); 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* 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 CAL. 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".)
[113] Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 157, 159-60 (2005) (Describing the "inequitable conduct" as an information-forcing rule designed to discourage patent applicants from engaging in strategic behavior); R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PA. L. REV. 159, 159, 218-19 (2002) (Positing that prosecution history estoppel should be conceived of as an information-forcing default rule); 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.)

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 and 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 give patent applicants "the motive and the opportunity" to withhold information from the patent examiner.[114]

More importantly, for our current context, the various rules compelling patent applicants to disclose information about the claimed invention have information-forcing qualities. The relationship in patent law is generally described as a "social contract" between the inventor and the public. The inventor shares useful information about a new and non-obvious invention – information that could otherwise be kept a secret[115] – 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 keep 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/services embodying the claimed invention.

However, as outlined in Part I,[116] patent law has devised several tools to guard against these types of strategic behavior by patent applicants. The many forms of the disclosure requirement - enablement, written description, definiteness and "best mode"[117] - 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/unenforceability of granted patents. These rules have the quality of information-forcing rules in that

[114] R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. PA. L. REV. 159, 159, 215 (2002)
[115] See for example, James J. Anton & Dennis A. Yao, *Expropriation and Inventions: Appropriable Rents in the Absence of Property Rights*, 84 THE AMERICAN ECONOMIC REVIEW 190–209, 204 (1994).
[116] [NB: Part I (B)]
[117] 35 U.S. Code § 112 (a) (b)

they elicit information from the well-informed party for the benefit of a less informed party (patent examiner) or third parties (competitors; the public). In this way patent prosecution could be described as a negotiation between the patent applicant and the patent examiner.[118]

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.[119] Patent applicants have a choice to make before applying for a patent and during patent prosecution. They can either claim broadly and take a risk that the patent examiner would 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. 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. In 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.[120]

As discussed earlier,[121] 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. 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. 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".[122] (Internal citations omitted) 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.[123]

The inequitable conduct defense is also another instance where patent law adopts a penalty default rule that seeks to compel patent applicants to disclose useful information.[124] As highlighted in the preceding paragraphs, patent

[118] R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, FACULTY SCHOLARSHIP, 216 (2002), https://scholarship.law.upenn.edu/faculty_scholarship/743 See text accompanying note 194.
[119] *Id.* at 211–221.
[120] *Id.* at 217.
[121] See Section IV [NB]
[122] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (2011)
[123] MERGES AND DUFFY, *supra* note 123 at 977.
[124] Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECHNOLOGY LAW JOURNAL 147, 159–60 (2005).

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 means that they have a huge incentive to provide full disclosure.[125] Applicants can avoid this penalty by honestly providing all material information to the PTO.[126] 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. DOO Requirement as Information-Forcing

The requirement that patent applicants disclose GRTK resources used in their inventive process should be conceived of as an information-forcing rule compelling a patent applicant to divulge socially beneficial information. To make the case, both descriptively and normatively, for the conception of the DOO requirement as an information-forcing default 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,[127] 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 DOO requirement as an information-forcing default 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(s) and patent attorney, involved in preparing the patent application. Considering a scenario in which a new and non-obvious 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.[128] 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 as part of the patent

[125] Clarisa Long, *Patent Signals*, 69 UNIVERSITY OF CHICAGO LAW REVIEW 625–679, 668–670 (2002).
[126] Nolan-Stevaux, *supra* note 173 at 160.
[127] Ayres and Gertner, *supra* note 156.
[128] Wagner, *supra* note 167 at 206, 212–14.

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 has developed over time.[129] Because the PTO is famously under-funded and patent examiners work under tight schedules,[130] 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 number of granted patents are either amended or invalidated.[131] 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.[132] 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.[133] 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.[134] 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 lease-cost-provider of the most relevant information about the claimed invention.

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[129] MERGES AND DUFFY, *supra* note 123 at 978.

[130] John Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, GEORGETOWN LAW FACULTY PUBLICATIONS AND OTHER WORKS (2001), https://scholarship.law.georgetown.edu/facpub/306 (discussing the PTO budget and patent examiner dockets).

[131] Are more than 90 percent of patents challenged at the PTAB defective?| Patents & Patent Law, IPWATCHDOG.COM | PATENTS & PATENT LAW (2017), http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/ (last visited Jun 19, 2018); Jennifer Turchyn, *Improving Patent Quality Through Post-Grant Claim Amendments: A Comparison of European Opposition Proceedings and U.S. Post-Grant Proceedings*, 114 MICHIGAN LAW REVIEW 1497–1530 (2016) (highlighting, among other points, the increasing rate of patent invalidity created by the America Invents Act).

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

[133] Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 41 USPQ2d 1865, 1875 (1997), .

[134] Long, *supra* note 174 at 669.

### *b) Information Asymmetry*

It is commonly accepted that there is significant information asymmetry in patent prosecution.[135] 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.[136] Although it is not conclusive, the large number of challenged patents being either amended or invalidated implies that information asymmetry may have enabled the granting of a patent right for undeserving patent applications.[137] While some scholars have posited alternative measures of addressing this information asymmetry,[138] 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 GRTK resources. That is because inaccessibility of GRTK resources is one of the main concern regarding claims of biopiracy. Source communities that provide GRTK resources tend to reside in remote regions of the world; their traditional knowledge is predominantly transmitted through oral traditions;[139] and many of the codified knowledge is documented in inaccessible databases.[140] It is revealing that many of the alleged acts of biopiracy are based on GRTK resources that are well known

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[135] Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System Symposium - Patent System Reform*, 17 BERKELEY TECH. L.J. 763–798 (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.).

[136] Long, *supra* note 174 at 667.

[137] Are more than 90 percent of patents challenged at the PTAB defective?, *supra* note 180 (showing a high number of patents challenged at the Patent Trials and Appeals Board being amended or invalidated.); See generally, Turchyn, *supra* note 180.

[138] 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, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495–1532 (2000) 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. Since, in the current contexts, the information required of patent applicants is that which is already in their possession, elliciting such information from the patent applicant seems more efficient than encouraging competitors to conduct searches *ex-post*.

[139] Gebru, *supra* note 36 (discussing the prevalence of oral transmission of traditional knowledge and suggesting legal intervention to encourage more codification.).

[140] The managers of the Indian Traditional Knowledge Digital Library 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 comendable, these level of accessbiliity is not matched by the other major traditional knowledge databases from other jurisdcitions. TKDL, *supra* note 86.

among members of the source community.[141] 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.[142]

### *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 GRTK resources in their inventive process.[143] Although patent applicants must disclose information deemed to be material for the patentability examination,[144] 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.[145] 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,[146] this risk is minimal. In addition to being able to withhold information about the use of GRTK, 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,[147] and it can be expected that patent applicants engaged in biopiracy could make use of this practice as well.

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[141] ROBINSON, *supra* note 85 at 45–76 (listing the major cases of biopiracy involving patent applications.).

[142] Soman K. Das & Hari Har P. Cohly, USE OF TURMERC IN WOUND HEALNG (1995); K. S. Jayaraman, US PATENT OFFICE WITHDRAWS PATENT ON INDIAN HERB NATURE (1997), https://www.nature.com/articles/37838 (last visited Jun 20, 2018); Larson, *supra* note 7; Kadidal, *supra* note 20.

[143] Under the duty of candor and good faith, patent applicantsh forbidden from withholding information material for patentability, 37 CFR § 1.56, So the worry is not that so much that patent applicants will outright provide false information to the PTO. Since the duty of candor and good faith does not include a duty to conduct prior art searches, patent applicants could just claim that they were unaware of the existence of GRTK resources.

[144] *Id.*

[145] Wagner, *supra* note 167 see text accompanying note 189.

[146] Only about 1 - 2 percent of granted patents are litigated. See for instance, Jason Rantanen, PATENTS, LITIGATION AND REEXAMINATIONS PATENTLY-O, https://patentlyo.com/patent/2011/12/patents-litigation-and-reexaminations.html (last visited Jun 21, 2018).

[147] 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 Note*, 5 J. INTELL. PROP. L. 365–396 (1997) (discussing the "gray languaged" used by patent applicants).

What is even more enabling of strategic behavior is that for centuries GRTK resources have been considered to be raw materials for the inventive process and part of the public domain free for anyone to use.[148] Thus, the omission of information about GRTK 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.[149] However, the list of cited references only lists two other patent applications unrelated to the neem tree, and six scientific papers that discuss various aspects of the benefits of the neem tree.[150] 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. The fact that farmers in India have been using the neem tree extracts as pesticides – information that he would reasonably be expected to be exposed to as an importer of timber from India is not cited anywhere in the granted patent or the document added during prosecution.[151] Despite the omission of what seems to be material information the patent was granted and remained valid for the life of the patent, even though the European patent office invalidated an identical patent application at after evidence of the use of neem tree extract by one Indian firm was submitted to the office.[152] 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.[153]

What may further complicate the information asymmetry in the case of GRTK use is the confusion about the level of reliance required before patent applicants would have to disclose their use of GRTK resources. The level of reliance on GRTK 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 traditional knowledge or practice. It is not clear where in this spectrum the reliance develops attains a level which triggers an obligation to disclose GRTK use.[154] Patent applicants can (and some do)[155] use

[148] 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 GRTK resources.
[149] Shiva, *supra* note 8.
[150] Larson, *supra* note 7.
[151] See patent and certificate of correction, *Id.*
[152] Shiva, *supra* note 8.
[153] For a non-exhaustive list of cases of biopiracy and detailed discussion, see ROBINSON, *supra* note 88 at 45–76; See also, ABENA DOVE AGYEPOMA. OSSEO-ASARE, BITTER ROOTS: THE SEARCH FOR HEALING PLANTS IN AFRICA (2014), (last visited Nov 28, 2014) (discussing five major cases of biopiracy arising from the African continent.).
[154] Section VI (x)[NB] discusses what level of reliance should trigger a disclosure requirement.
[155] The question of what level of reliance on GRTK resources should trigger the DOO 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 GRTK resources was only minimal or that they did not rely on such resource at all. Lack of

this confusion to their benefit by not disclosing GRTK use and claiming when challenged, that the traditional knowledge 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 GRTK resources without disclosing such 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 may patent scholars.[156] The monopolistic nature of patent rights is tolerated only because it is expected to provide incentives for inventions.[157] If a patent right is granted for a claimed element that is not new; or 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 20 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[158] 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[159] the financial

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novelty or non-obviousness has affected many of the patent applications invalidated after GRTK evidence is produced which implies that the confusion regarding the level of reliance required to trigger GRTK resources is a big problem. ROBINSON, *supra* note 85 at 45–76 (discussing several alleged cases of biopiracy.).

[156] See for instance, JAMES BESSEN & MICHAEL JAMES MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK (2008); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (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 (2004), http://yulib002.mc.yu.edu:2201/stable/j.ctt7t655 (last visited Jun 24, 2018).

[157] The US 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.,.

[158] The cost of patenting starting from initial filling and including multiple responses to office acitons etc. varies heavily based on the type of invention. See for instance, Quinn, THE COST OF OBTAINING A PATENT IN THE US IPWATCHDOG.COM (2015), http://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/ (last visited Jun 24, 2018); Lemley, *supra* note 187 at 1498.

[159] The PTO was allocated a budget of over $3.5 billion which is income from fees collected for its services. US FEDERAL BUDGET FOR FISCAL YEAR 2018 - DEPARTMENT OF COMMERCE APPENDIX, 199, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/com.pdf.

resources spent on patent prosecution is still a waste for the portion of patents that should not have been granted. Furthermore, there are opportunity costs of the human resource expended on the prosecution of undeserving patents. Then there are costs of litigation[160] at the different levels of appeal that many stakeholders want to reduce.[161] 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[162] 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.[163] The existence of an overly-broad patent that should have either been invalidated or narrowed will have the effect of discouraging investment. Firms conducting research would fear that a patent right maybe asserted against them at any point in the R & D process. Additionally, vaguely worded claims create uncertainty about the "metes and bounds" of the patent right thereby creating unnecessary risk for innovators.[164]

There are other undesired outcomes particularly relevant to the context of GRTK use in inventive processes. Biopiracy and the granting of undeserving patent rights over GRTK use have forced many source communities to mistrust researchers in general and the patent system in particular.[165] This mistrust underpins the protectionist trend discussed earlier.[166] Furthermore, the granting of undeservingly broad patent rights without recognizing the contributions of the

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[160] 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 187 at 1502.

[161] 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 for instance, Lawrence Hurley, *U.S. high court sets record for intellectual property caseload*, REUTERS, February 27, 2014, https://www.reuters.com/article/us-usa-court-ip-analysis/u-s-high-court-sets-record-for-intellectual-property-caseload-idUSBREA1Q09B20140227 (last visited Jun 24, 2018).

[162] Gideon Parchomovsky & R Polk Wagner, *Patent Portfolios*, 154 UNIVERSITY OF PENNSYLVANIA LAW REVIEW` 77, 69 (2005) (arguing for the benefit of creating *ex-ante* incentives in the patent system.).

[163] There are many examples of patents being used to block innovation from developing in a certain field. See for instance, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698–701 (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.); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 THE JOURNAL OF MOLECULAR DIAGNOSTICS 3–8 (2003) (providing empirical evidence of clinicians shying away from clinical testing because of the threat of patent infringement or licnesing costs.).

[164] Adam B. Jaffe & Josh Lerner, *Innovation and its Discontents*, 6 *in* INNOVATION POLICY AND THE ECONOMY 27–66, 32 (2006).

[165] Hoare and Tarasofsky, *supra* note 155 at 150.

[166] See Section V (A) [NB]

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 GRTK resources and collaborate in research could feel a sense of belongingness.

### 3. Efficiency Outcomes

The above discussion shows that the context in which patent applicants use GRTK resources in their inventive process but withhold such information from the patent office meets the requirements for the scenarios that Ayres and Gertner described in their paper.[167] The well-informed party (patent applicant) behaves strategically using privately held information (withholding information about the reliance on GRTK resources) to get private benefits which are socially undesirable (undeservingly broad patent rights). Thus, the penalty for the violation of a DOO requirement should be conceived of and be designed as an information-forcing rule.

There are multiple benefits to the patent system when the DOO requirement is complied with. The production of complete information benefits the PTO, source communities, competitors and the public. First, it will increase the quality of issued patents[168] by rejecting non-innovative claims and by making issued patents provide more socially beneficial information. The DOO 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, to use these limited resources efficiently and target prior art from source communities in their examination. This is especially useful in the GRTK context because patent examiners usually focus on accessible sources such as patents or scientific publications in their examination, while the overwhelming majority of GRTK is unpublished.[169]

Second, it will raise the cost of prosecuting low-value patents thereby enabling the use of PTO resources for more inventive claims[170] - claims that improve on GRTK resources. Requiring applicants to disclosed GRTK 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 DOO requirement will increase costs, albeit only slightly. If the quality of patent is very low, the DOO 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

[167] Ayres and Gertner, *supra* note 156.
[168] Parchomovsky and Wagner, *supra* note 211 at 70–71.
[169] [NB: Citation needed]
[170] *Id.* at 71.

essential for patent examination from the least-cost-provider (the patent applicant) which should reduce the cost of prosecuting inventions that rely on GRTK resources. The PTO already has over 70 TK databases that it can use to search for prior art. However, the databases are not comprehensive compared to the wealth of knowledge held by indigenous and local communities. Therefore, patent examiners would face transaction costs of accessing GRTK resources that are not documented or are documented in a foreign language. Requiring the applicant to disclose GRTK use will transfer the cost of prior art search to the least cost provider – the patent applicant.

Compliance with the DOO requirement will also have benefits for the source communities. Source jurisdictions which have passed legislation on the access and benefit sharing mechanisms can enforce these rules more efficiently by searching for GRTK use through accessible patent databases. Source communities and countries engaged in protectionism for fear of biopiracy can be more confident that they can enforce domestic legislation abroad on researchers after they gain access to GRTK resources. This confidence can, in turn, be expected to result in a more collaborative and trusting relationship[171] between the various stakeholders involved in bioprospecting.

Compliance with the DOO requirement would also enable competitors of the applicant to challenge the validity or scope of the claimed invention using the *ex ante* GRTK disclosure. Given the self-interested competitor, the full force of the private actor could easily bear the burden of ensuring the validity or scope of a patent application or one that has already been granted. Following the AIA, third parties now have three different types of challenging a patent right: pre-issuance review, inter partes review,[172] post-grant review, and Covered Business Method Patent Review.[173] A bioprospecting relationship in which researchers have increased access to GRTK resources can be expected to result in the production of biopharmaceutical products more cheaply and quickly. To achieve this socially desirable outcome, the DOO 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 DOO requirement that addresses the key debates examined earlier.[174] A well-drafted DOO requirement would be able to address concerns around uncertainty and undue burdens while still being able to encourage the

[171] Source communities increasingly mistrust the patent system because it has been used as a tool for biopiracy. See, Hoare and Tarasofsky, *supra* note 155 at 150 The DOO requirement has the potential of developing trusting relationships. .
[172] 35 USC Ch. 31 §311 - §319
[173] [NB: citation needed]
[174] See section [x] [NB]

disclosure of reliance on GRTK. If a default rule is to succeed in compelling information from a well-informed party, it should be designed against the interest of such party.[175] It is by avoiding this penalty default rule that the well-informed party reveals the socially beneficial information. In the current context, the DOO requirement should create a penalty default rule that that goes against the interest of a patent applicant – which points to the need to adopt a default penalty rule of rejecting patent applications that violate the DOO requirement. If the requirement is to be effective, the default penalty rule should put the patent applicant at a state worse than they would be if they complied with the requirement.

Three levels of reliance on GRTK could be used to further extrapolate trigger of an obligation under a DOO requirement. First, the minimal level of reliance could be described as 'mere inspiration' – the inventor was inspired by what she understood from GRTK, but the traditional practice was 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.[176] Scientists at Eli Lilly and the University of Western Ontario, after years of research, learned that the plant has cancer-fighting qualities.[177] Eli Lilly used extracts from the plant to develop vinblastine and vincristine - medicines used to treat Hodgkin's disease and childhood leukemia.[178] If the traditional knowledge of using the plant for diabetes or processes of extracting ingredients did not contribute to the development of vinblastine and vincristine,[179] then the duty to disclose the source of GRTK 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 GRTK. Thus, the scope of the patent right that will ultimately issue is not affected by disclosure of the minimal input from GRTK. Under this scenario, the patent applicant has an incentive to abide by the DOO requirement, because the applicant has nothing to lose - disclosure will not affect the patent scope. However, as explained in Part (B),[180] the duty of candor and good faith are broader than the duty to disclose material information. Any information that an examiner might have wanted to know should be included in this broader terminology of candor and good faith. Still, the patent applicants have

[175] Ayres and Gertner, *supra* note 156 at 98.
[176] Michael F. Brown, Who Owns Native Culture? 136–38 (2003)
[177] Srividhya Ragavan, Protection of Traditional Knowledge, 2 MINN. INTELL. PROP. REV. 1, 8 (2001); Roger A. Sedjo, Property Rights, Genetic Resources, and Biotechnological Change, 35 J.L. & ECON. 199, 199 (1992).
[178] Shayana Kadidal, Plants, Poverty, and Pharmaceutical Patents, 103 YALE L.J. 223, 223 (1993)
[179] Michael F. Brown, Who Owns Native Culture? 136–38 (2003) (discussing the challenges of assigning ownership in the Rosy Periwinkle case)
[180] [NB: Part I (B)]

an incentive to disclose the traditional use of the rosy periwinkle to treat diabetes for the same reason stated earlier.

Second, a higher level of reliance on GRTK could be described as "substantial reliance" and could fairly give rise to a duty to disclose under 35 U.S. Code § 112 and Rule 56. Substantial reliance is a situation where "but for" the GRTK the inventor may not have developed the claimed invention. The neem tree case examined at the beginning of this paper is a good example of this.[181] Presuming that Mr. Larson knew of that Indian farmers have been using the neem tree extract as a pesticide and presuming a storage stable neem tree extract was in 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 GRTK. This is especially the case if, as claimed by representatives of W.R. Grace, the claimed compound and process resulted in increasing the stability of the extract form a couple of days to 2 years.[182] In this case, Mr. Larson and the scientists involved in the second 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 extent of the traditional use in a stable neem tree extract.

In this second scenario, the level of reliance on GRTK is so substantial that 'but for' the use of GRTK the claimed invention would not have been developed. If the improvement does not develop something totally different, disclosure of substantial reliance on GRTK under this scenario may narrow the scope of the patent right. If the default penalty 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 DOO 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 of rejection an application or invalidity of a granted patent

The highest level of reliance could be a claim to an "invention" that provides only minimal improvement on GRTK. Patent law standards of novelty and non-obviousness 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 GRTK. A good example here is the patenting of a process for treating wounds by applying turmeric powder. In1995, two researchers at the University of Mississippi Medical Center, Soman K. Das and Hari Har P. Cohly, received a US patent.[183]

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[181] See section I (B) [NB]
[182] [NB] Cite to Interview of W. R. Grace CEO
[183] US Patent 5,401,504. Soman K. Das & Hari Har P. Cohly, USE OF TURMERC IN WOUND HEALNG (1995).

The patent covered a method of administering turmeric powder orally and topically to heal surgical wounds and ulcers. People in India had used turmeric powder to treat wounds for centuries. The Council of Scientific and Industrial Research (CSIR) – an agency of the Indian government - challenged the validity of the patent in the United States Patent and Trademark Office (USPTO). CSIR submitted 32 printed publications from India providing evidence of the use of turmeric powder to heal wounds for centuries.[184] The USPTO revoked all six claims in the patent for failing to meet substantive patentability requirements.[185] Information about the reliance of GRTK in these scenarios is obviously material for patentability analysis. The patent application in this and other similar cases[186] is claiming rights over the traditional uses of a resource or only provides a minimal improvement, or in the worst of cases, no improvement is made to GRTK at all. In these cases, Rule 56 would require the disclosure of GRTK. 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 DOO requirement because compliance with the rule will result in the same outcome as the penalty. In this scenario, the DOO requirement will have little incentive to disclose reliance on GRTK because the penalty for violation is the same as the outcome from compliance. Thus, policymakers should adopt a harsher penalty than patent invalidity. This includes disgorgement of profits, or even going outside of the patent system to establish criminal sanctions such as fine or imprisonment. One additional benefit of the DOO requirement to note is that the default penalty will discourage researchers from going to the patent office before making a considerable improvement on GRTK resources, which is a socially desirable outcome. Thus, in addition to the compelling information from applicants, the DOO 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 DOO requirement as an information-forcing default rule solves two of the three issues of concern. First, it solves the questions of what

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[184] Re-examination Certificate B15,401,504. Das and Cohly, *supra* note 1.

[185] Re-examination Certificate B15,401,504. *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 GRTK may be used but remains unreported.*; See for instance, Confronting Biopiracy, at 45 - 76

[186] There are multiple examples of cases in which the patent applicant simply requests patent right 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 meal in both countries. The gluten free nature of the flour is a natural result of the teff flour. While the US patent has been invalidated, a very similar European patent (EP 1646287b1) is still in force. See Regine Andersen and Tone Winge, The Access and Benefit-Sharing Agreement on Teff Genetic Resources: Facts and Lessons

type of penalty to impose for violations of the requirement. While some suggest the penalty should be weak[187] (including the suspension of the patent right until the requirement is fulfilled) others argue that anything short of patent invalidity or the rejection of patent applications would be ineffective.[188] If the DOO 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, since the applicant knows she does not have a patentable invention in the first place, patent invalidity will not be sufficient. In that case a harsher penalty such as fines or other criminal penalties is needed to compel information.

For the first two scenarios, anything sort of patent invalidity or non-enforcement would fail to encourage patent applicants to disclose their reliance on GRTK resources. A voluntary system in which patent applicants will face no repercussions for non-compliance 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 non-compliance, but if in 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 non-compliant.

Most cases bioprospecting/biopiracy can be expected to fall under either the first or second scenarios. This is because traditional knowledge tends to involve basic information[189] 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,[190] but the PTO found Robert Larson's "improvement"[191] of creating a storage-stable neem tree extract innovative enough to grant it a patent.[192] Furthermore, because

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[187] See for instance, Bagley, *supra* note 120 (arguing for the adoption of a the DOO requirement as a formality rather than a substantive requirement the violation of which would affect patent validity.).

[188] GRAHAM DUTFIELD, THINKING ALOUD ON DISCLOSURE OF ORIGIN 10 (2005), http://www.quno.org/sites/default/files/resources/Thinking%2BAloud%2Bon%2BDisclosure%2Bof%2BOrigin.pdf.

[189] Mark C. Suchman, *Invention and Ritual: Notes on the Interrelation of Magic and Intellectual Property in Preliterate Societies*, 89 COLUM. L. REV. 1264, 1272 (1989) (describing the basic nature of traditional knowledge.); Carvalho, *supra* note 144 at 244–245 (discussing the ease with which users can copy traditional knowledge).

[190] Vandana Shiva, THE NEEM TREE - A CASE HISTORY OF BIOPIRACY (2013).

[191] Wolfgang, *supra* note 13; India wins landmark patent battle, *supra* note 32.

[192] Larson, *supra* note 7.

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 rule 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.[193] As highlighted earlier,[194] one of the points that opponents of the DOO requirement raise is that a strong DOO requirement may discourage researchers from using GRTK resources in the first place.[195] This argument should be taken seriously, and legislators should ensure that the net effect of the DOO requirement is an efficient one – that there are sufficient incentives for researchers to use GRTK resources while ensuring that such use is disclosed to the PTO.

Second, the information-forcing rules literature provides answers to the question of whether to request that patent applicants to disclose the original source (or *origin*) of GRTK or just the *source* from which they received the resource. Many GRTK resources are conserved and used by multiple communities, and these resources have predominantly been transmitted to other cultures near and far. Forcing well-informed parties to incur further costs may block a transaction from taking place.[196] Therefore, a DOO 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 default penalty of rejection or invalidity is adopted, then a requirement to conduct an additional search for relevant GRTK resources would be too tasking. This is especially the case given the inaccessibility of GRTK resources and the challenges of tracking original sources. Therefore, the DOO requirement should only require that patent applicants disclose GRTK 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 GRTK or other relevant information.[197]

In addition to the *ex-ante* benefits of compelling patent applicants to disclose potentially damaging information, the DOO requirement has important *ex-post* benefits. As explained earlier, patent examiners are at a disadvantage because of the information asymmetry inherent in patent prosecution. The disclosure of reliance on GRTK would enable competitors of the applicant, source communities

[193] Ayres and Gertner, *supra* note 156 at 107 (warning legislators that penalty default rules may sometimes create a disincentive in obtaining the private information in the first place.).
[194] See Section II (C)[NB]
[195] Hoare and Tarasofsky, *supra* note 155 at 164.
[196] Ayres and Gertner, *supra* note 156 at 107.
[197] Patent applicants do not have an obligation to conduct prior art searches. Their obligation is to disclose material information in their possession. See 37 CFR § 1.56, *supra* note 192.

and the public to assess the validity or scope of claimed inventions. These *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 GRTK and benefit sharing that source communities/countries may have established.[198] 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 GRTK in the development of a claimed invention may encourage competitors of the applicant to research the GRTK for similar purposes. The value of such information may be significant given reports of bio-prospectors focusing on selected GRTK resources for further investigation.[199]

Lastly, one of the recurring challenges in the literature on bioprospecting is one of understanding the actual value of GRTK resources in bioprospecting projects. While source communities and some scholars argue that the resources have considerable value,[200] some firms argue that they either do not use GRTK at all[201] or that the value of such resources is very minimal. The lack of information about the extent of the reliance of the industry on GRTK contributes to the confusion on the correct policy measure that should govern bioprospecting projects. The DOO requirement could address this concern by providing clear information on the value of GRTK as an input in inventive ideas. This does not mean that the full value of GRTK could be evaluated based on the disclosure in patent applications. But disclosure could shed some light on the value that should be put on GRTK as an input in producing innovative products.

## B. Reversing the Protectionist Trend

A DOO 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.[202] 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 GRTK users[203] such as researchers and modern firms. If the requirement addresses the interests source communities without meeting the

[198] For more on the rules for access to GRTK and benefit sharing, see Section [x] on The Development of the DOO Requirement.
[199] [Valuing Research Leads, at 71?]
[200] [See Section [X] on the value of GRTK]
[201] [BIO intervention at WIPO – IGC]
[202] See section [X] on the debate around the DOO requirement.
[203] The term "users" refers to multiple entities that rely on GRTK in their inventive process. This includes for-profit firms, public research institutions, and independent researchers.

needs of users, then the intervention might discourage the engagement that users would have with GRTK. If the requirement addresses the interests of users without satisfying the needs of source communities, it will fail change the current trends of protectionism.

The past experiences of researchers accessing GRTK, developing products, and failing to recognize the contributions of the source community have created significant trust issues.[204] 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. Since existing patent law is considered to be part of the problem by source communities,[205] minor tinkering may fail to send the strong signal needed to reverse the protectionist trend.

The introduction of the DOO 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.[206] Researchers interested in using GRTK resources maybe 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 GRTK and requests for benefit sharing if an innovative product is produced. Policy makers should seriously consider these interests to craft an efficient and workable DOO requirement.

The DOO 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 Indian Traditional Knowledge Digital Library. 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

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[204] Alison L. Hoare & Richard G. Tarasofsky, *Asking and Telling: Can "Disclosure of Origin" Requirements in Patent Applications Make a Difference?* 10 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 149–169, 150 (2007).
[205] Vandana Shiva, Piracy by Patents [NB]
[206] Roberts, Tim. "The Protection of Traditional Knowledge: An Industry View." In Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions, 93–94. New York and Geneva: United Nations Conference on Trade and Development, 2004. http://unctad.org/en/docs/ditcted10_en.pdf

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 FOR DOO REQUIREMENT

If one accepts that the DOO requirement should be introduced, then several institutional questions arise. This section outlines the institutional mechanism for introducing a DOO requirement in US patent law. It argues that amending the patent act to introduce an explicit DOO requirement may be the most effective mechanism to signal a change in US patent policy and establish confidence among source communities/countries. However, amending US patent law to introduce a DOO 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 that clarifying the duties of disclosure, candor and good faith that patent applications already have by introducing an explicit DOO 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 DOO requirement.

The key institutional questions that may arise include: 1) how the requirement should 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 DOO obligation? 5) what should be the penalty for non-compliance? 6) Who should have standing? These questions are dealt with in further detail below.

*How should the DOO requirement be formalized?*

Considering the twin goals of reversing a rising protectionist trend and compelling socially beneficial information from patent applicants - amending the patent act to introduce an explicit DOO requirement may be the most effective mechanism. The many cases of biopiracy happened in the face of existing disclosure obligations under US patent law. Therefore, an explicit amendment of the Patent Act would send a strong signal of policy change in US patent policy and establishes confidence among source communities/countries. Therefore, amending the patent act would have the strongest effect in reversing the worrying protectionist trend in which source communities/countries create barriers to access GRTK. Dozens of countries around the world, including some industrialized nations have amended their patent act to introduce DOO

requirements.[207] Although it is 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.[208]

Reforming US patent law to reflect policy changes is not a new thing. The patent act has been amended multiple times since its first iteration in 1790[209] with the most recent amendment – the Leahy-Smith America Invents Act (AIA)[210] – enacted in 2011 modernize the US patent system. Therefore, amending the patent act to include a DOO requirement is not an implausible idea. In fact, the 1980 Bayh-Dole amendment[211] to the patent act has similar features to the DOO requirement. The act brought about major changes in US 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.[212] The Bayh-Dole disclosure has enabled the US government to track federally funded inventions thereby facilitating the enforcement of obligations that the inventor and contractors have under the act.[213] A carefully crafted DOO requirement can have a similar tracking effect in facilitating the enforcement of access and benefit sharing agreements between source communities/countries and researchers.[214]

However, amending US patent law to introduce a DOO requirement seems infeasible considering the lack of political interest to introduce such an amendment and considerable opposition that may be expected from industry. Therefore, clarifying the duties of disclosure, candor and good faith that patent applicants already have by introducing an explicit DOO 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.[215] Thus, updating the federal rules and the PTO manual to include an

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[207] See Section (II) (b) [NB]
[208] See Section (II) (b) [NB]
[209] The Patent Act of 1790 (1 Stat. 109) Available at: < http://legisworks.org/sal/1/stats/STATUTE-1-Pg109.pdf>
[210] Leahy-Smith America Invents Act (AIA) [NB]
[211] The Bayh-Dole amendment is codified in 35 U.S.C. Chapter 18. While there are many similarities between the DOO 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 GRTK resources do not meet core patentability requirements.
[212] 35 U.S.C. 202(c)(6). 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."
[213] [NB] [CSR Report for Congress]
[214] [NB: [Carvalho,] [Margo, at 93]
[215] See Section [III] [NB]

explicit DOO requirement would be an efficient and feasible reform that can satisfy the twin benefits identified in this paper.

*Which institution is best suited?*

The general duty of disclosure is owed to the PTO. The requirement imposed on patent applicants under 35 U.S. Code § 112 to describe the invention in "full, clear, concise, and exact terms" relates to the specification section of a patent application. 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[216] and a level of deference courts granted the PTO prosecution.[217] Furthermore, the rules under 37 C.F.R. 1.56 (a) clearly states that the duty of disclosure exists "in dealing with the Office."[218] This rule extends beyond the examiner to include anyone at the PTO.[219] 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 origin to the same organ. This should especially be the case if the requirement is introduced through an updated MPEP that includes an explicit DOO 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.[220] This theory also applies in deciding the level of information that should be submitted in proceedings in that agency.[221] Given the unique position of the Federal Circuit as a specialized appeals court for patent cases, patent law was thought to be different from other regulatory areas that administrative law theories did not apply.[222] However, the 2011 America Invents Act (AIA) brought forth considerable administrative power to the PTO giving it the power to decide key issues

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[216] 35 U.S. Code § 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."
[217] [NB] [Merges & Duffy]
[218] 37 C.F.R. 1.56 (a)
[219] [MPEP Section 2001.03] [NB] The duty extends to proceedings at the Patent Trial and Appeal Board and the Office of the Commissioner for Patents
[220] Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519 (1978); See also Scalia, Antonin. "Judicial Deference to Administrative Interpretations of Law." Duke Law Journal 1989 (1989): 511–21.
[221] Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)
[222] Christopher J. Walker, Chevron Deference and Patent Exceptionalism, Duke Law Journal Online, 65; 149 (2016)

regarding patent validity.[223] Considering its newly expanded powers, the PTO should be the first entity that decides whether an applicant has complied with the DOO requirement. This conclusion is further supported by the fact that the PTO has considerable expertise - both regarding technical knowledge and in patent prosecution. This, however, does not mean that the Patent Trials and Appeals Board (PTAB) or the courts should not review these decisions. The DOO requirement, like other requirements in US patent law, should be reviewable by the courts.

*What should be the content of the required disclosure?*

As highlighted in earlier sections,[224] the DOO requirement should entail an obligation to disclose the *source* from which the patent applicant received GRTK instead of the *origin* of the resource. Requiring patent applicants to conduct further research to identify the original source of the GRTK would create a considerable disincentive against relying on GRTK resources. The origins of the majority of GRTK resources is controversial and, therefore, requiring researchers to investigate and disclose the origin creates a duty that is far from the scientific research in which firms have expertise.[225] As the information-forcing rules literature reveals, default penalty rules should not be applied if the net effect of the rule could result in a disincentive to participate in the 'deal' in the first place.[226] Limiting the content of required disclosure only to the source from which the applicant received GRTK ensures that the DOO requirement does not impose an undue burden that may deter innovation.[227] 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. 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.

In addition to the requirement to disclose the source, applicants should be asked to produce evidence of prior informed consent and/or equitable benefit sharing agreement from jurisdictions that already have such a system in their domestic law. As the actor with the most relevant information, the patent applicant is the low-cost provider of information about whether she has received consent or have entered into an agreement. It is possible that source communities

[223] [NB] Melissa F. Wasserman, The Changing Guard of Patent Law: Chevron Deference for the PTO
[224] Section II (B) & Section V (C) [NB]
[225] The preference for source instead of origin has also been adopted by Graham Dutfield, see Graham Dutfield, Thinking Aloud on Disclosure of Origin Requirement, at 2
[226] Ayres & Gertner [NB]
[227] [NB: See section [X] on the arguments against the adoption of the DOO requirement] see also Dominique Keating, WIPO-IGC: The US Perspective

can use disclosure of source as a tool to ensure that researchers that have accessed their GRTK comply with conditions of access. Source countries such as India and Brazil do have the resources to conduct these types of monitoring and enforcement. However, the vast majority of source communities and countries may not be able to monitor compliance with conditions of access. Thus, having such a requirement will connect the requirement to the domestic laws of source countries. In addition to the international comity benefit, such a condition will give domestic legislation some teeth thereby creating an incentive to provide access to GRTK resources and curb the rising protectionist trend. However, applicants should not be required to produce evidence of consent or benefit sharing agreements if the jurisdiction has not set up such a system. Given the high level of red tape and bureaucracy, especially in developing countries of the Global South, that researchers and firms are concerned about, there should also be a system where applicants can show unfair delay or unfair terms and conditions in source countries to suspend the DOO obligation.

*What should trigger the DOO obligation?*

Based on the three level of reliance outlined earlier, the trigger for the DOO 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 GRTK. 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.

A broad interpretation of substantial reliance is suggested in this paper. 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 DOO 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 GRTK resources while ensuring that they are not cheated out of their equitable share by strategic patent claim drafting.

*What should be the penalty for non-compliance?*

Countries around the world have adopted a wide range of penalty for non-compliance with their domestic DOO requirement.[228] These penalties include the suspension of a patent application until the applicant fulfills her obligation under the requirement, the rejection of the patent application, the invalidity or

[228] [NB: See section [X]]

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 GRTK, but non-compliance will have no repercussion.[229]

The penalty for non-compliance advocated for in this paper 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 criminal sanctions such as fines. The twin functions of a DOO requirement outlined below – the reversal of a rising protectionist trend,[230] and its information-forcing function[231] - 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 GRTK resources, it can be presumed that a reasonable applicant would choose to withhold such information. The information-forcing nature of a DOO requirement emanates from a default penalty rule that is set against the interest of the well-informed party.[232] In the absence of such penalty, a reasonable patent applicant will act strategically by withholding information about their reliance on GRTK and the source that provided such resource. While the penalty for minimal and substantial reliance should be rejection of the application, patent invalidity or unenforceability, the penalty for those who only make minimal improvements should include criminal sanctions such as fines. These suggestions for the nature and content of the DOO requirement are supported by the two goals of the requirement outlined in the subsequent sections – the ability of the requirement to undo a rising protectionist trend,[233] and its information-forcing effects.[234]

*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 US patent system allows third parties to challenge the validity or scope of patent rights based on a wide range of doctrines. Although the patent examiner is the first person who works to ensure the application meets the patentability requirements, interested third parties are allowed, through many channels, to challenge the validity or scope of a claimed invention.[235] The 2011 America Invents Act has expanded the opportunity that third parties have to challenge

[229] See EU Biodiversity Directive (1998) [NB]
[230] [NB: See section [X]]
[231] [NB: See section [X]
[232] [NB: See section [X]
[233] [NB: See section [X]
[234] [NB: See section [X]
[235] For discussions on the changes brought about by the AIA and its implication for US patent law, see Armitage, Robert A. "Understanding the America Invents Act and Its Implications for Patenting." AIPLA Quarterly Journal 40 (2012): 1–134, at 10-14.

patents before[236] and after[237] the patent has been granted.[238] Any party with "legally cognizable injury" has the standing to bring a challenge to a claim in a patent application or against a granted patent.[239] This includes competitors of the applicant and third parties that may be affected by the potential enforcement of the patent right.

In the case of DOO requirement, 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 DOO 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 GRTK or the importation of products based on the GRTK into the US.[240] 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, NGO and other entities working the relevant industry (e.g., environmental conservation, agricultural management, biopharmaceutical research) should have standing to challenge a claimed invention for non-compliance with a DOO requirement.

Having provided some answers to questions of institutional formulation of the DOO requirement, it may be beneficial to provide a model wording that, on the one hand, responds to the concerns raised in this paper about uncertainty or innovation-deterring burdens, and on the other, provides the benefits expected from a DOO requirement. As discussed earlier, the DOO requirement could be included as an amendment to the Patent Act, the federal rules or PTO manual. The wording of this model legislation could be changed to fit the right form of an amendment. Given the preceding discussion, a DOO requirement could be drafted with the following formulation:

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[236] Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 8, § 122, 125 Stat. 315-16 (2011) (amending § 122 to add a new subsection (e)).
[237] Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6, § 321.
[238] The American Invents Act introduce Post-Grant Review (PGR), and *Inter Partes* Review (IPR); while *Ex Parte* Re-examination (EPR) was introduced in 1981. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6
[239] John F. Duffy, Standing to Challenge Patents, Enforcement Risk, and Separation of Powers, The George Washington Law Review, Vol. 83 No. 2, 629 – 646, at 629 (2015)
[240] Neil D. Hamilton, Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms by, Drake Journal of Agricultural Law Vol6 81 – 117, 106 (2001)

(i) The duty of disclosure, candor and good faith under 37 C.F.R. 1.56, includes a duty to disclose the source of a genetic resource or traditional knowledge used in their inventive process if their reliance was substantial enough that the claimed invention would not have been developed, or it would have taken substantially more time or resource. If the source jurisdiction requires prior informed consent or agreement as conditions for access, applicants must submit evidence of compliance with such requirements. Patent applicants may request an exception from an obligation to submit evidence of prior informed consent or mutual access agreement by showing undue burden imposed by the source jurisdiction.

(ii) The term "genetic resources" refers to any material of plant, animal, microbial or other origin containing functional units of heredity.

(iii) The term "traditional knowledge" refers to the know-how, skills, innovations, and practices of indigenous peoples or local communities. Indigenous peoples and local communities may be identified in domestic laws of the country or state in which they reside. Reference should be made to such rules when engaging with communities identified as native, indigenous, or aboriginal.

(iv) Failure to comply with this requirement may result in the rejection of a patent application or the invalidation or unenforceability of a granted patent.

Depending on the level of reform required, consultation should be undertaken with all relevant stakeholders including industry associations and leader, indigenous peoples and local communities, and government agencies from other jurisdictions. The PTO could engage with other patent offices that have been implementing DOO requirements to develop best practices and learn from challenges faced in those agencies. Through these steps, the PTO could introduce an effective DOO requirement that addresses concerns around uncertainty and innovation-deterring burdens raised by opponents of the requirement.

## CONCLUSION

This paper has argued for the introduction of an explicit DOO requirement in US patent law. While most of the literature has focused on the international aspect, this paper analyzed the cost and benefit of the introduction of the requirement in the US. It outlined two key effects of the DOO requirement that should convince legislators to reform US patent law. The first is the potential for

an explicit DOO requirement to reverse a rising protectionist trend in which source communities and countries are increasing restrictions on access to GRTK. This trend threatens to disrupt promising practices in which researchers build on GRTK resources to develop welfare enhancing products and services. By granting source communities and countries some power to impose access and benefit sharing conditions, the DOO requirement creates confidence in the patent system and encourages increased access and collaboration.

Secondly, the paper makes the descriptive and normative case for conceiving the DOO 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 self-interested low-cost-providers if such information - patent applicants - thereby creating a more efficient patent prosecution process. Conceiving the DOO requirement as an information-forcing default 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 information-forcing rules literature suggests that the DOO requirement should only require patent applicants to disclose the source from which they received GRTK so as not to discourage them from engaging in GRTK-related research in the first place. The literature also suggests that, if the requirement is to provide its information-forcing effect the penalty for non-disclosure should be a rejection of the patent application and the invalidity or unenforceability of granted patents.

To further address concerns with the DOO requirement, the paper outlined three levels of reliance on GRTK that may have different implications for the duty to disclose. Minimal reliance on the resource in which the inventor is inspired by GRTK but develops the claimed invention independently of GRTK 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 GRTK should trigger an obligation to disclose. Substantial reliance should include cases in which the use of GRTK resulted in the reduction of time or resource it would take to develop a claimed invention.

A carefully calibrated DOO requirement that follows the guidelines outlined above can address concerns around legal uncertainty and the creation of innovation-deterring burdens. Introduction of the requirement in US patent law could create a world in which researchers have increased access to GRTK resources, such as the 250,000 medical formulations in the Indian traditional knowledge database, to develop products and services in return for an equitable sharing of benefits with source communities or countries. This is important for the US economy considering the dominance of US firms in sectors that rely on GRTK for part of their innovative output, including the biopharmaceutical and agricultural industries. The paper advocates for amendment of the federal rules

and PTO manual as the most feasible channel to introduce an explicit DOO requirement.