Correspondence

Still Patently Unconstitutional: A Reply to Professor Nard

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In Defense of Geographic Disparity[1] is Professor Craig Nard's response to my article *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World (Patently Unconstitutional)*.[2] According to Professor Nard, my article advocates "the elimination of [the] geographic disparity" of 35 U.S.C § 102 in order to "protect developing nations and indigenous peoples from Western countries' patent law regimes."[3] Professor Nard is correct in his assertion that I seek the elimination of the geographical disparity in U.S. patent law; however, he misses the mark as to my reasons. My opposition to the geographical limitation does not derive from a desire to protect anyone from valid patent rights,[4] rather it is a result of my conclusion that § 102(b) is unconstitutional.[5]

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1. Craig Allen Nard, *In Defense of Geographic Disparity*, 88 MINN. L. REV. 222 (2003).

2. Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679 (2003).

3. Nard, *supra* note 1, at 223–24.

4. I do ascribe to the view, however, that the wholesale imposition of Western intellectual property rights schemes on developing countries via the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) is detrimental to many in the developing world. *See generally* Margo A. Bagley, *Legal Movements in IP: TRIPS, Unilateral Action, Bilateral Agreements and HIV/AIDS*, 18 EMORY INT'L L. REV. (forthcoming Fall 2003) (arguing that Western intellectual property rights schemes significantly impede treatment of HIV/AIDS in the developing world); Ruth L. Gana (Okediji), *Has Creativity Died in the Third World? Some Implications of the Internationalization of Intellectual Property*, 24 DENV. J. INT'L L. & POL'Y 109 (1995) (arguing that Western rights schemes negatively affect creativity in the developing world).

5. This conclusion is based on my analysis of evidence regarding (1) the

At least two key points from *Patently Unconstitutional* bear repeating to shed light on this subject. First, publicly accessible patents and printed publications[6] located *anywhere in the world*, in any language, have been considered prior art for patent-defeating purposes since the first patent statute.[7] Public accessibility has been judicially defined to include even a single copy of a doctoral thesis, in German, indexed and cataloged in a small German library, unlikely though it might be for an interested person to find that document.[8] The justification for such an expansive definition that prevents many patents from issuing is the Constitution: "Congress [in the exercise of the patent power] may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available."[9] With profound increases in world travel, technology, ethnobotanical research, and bioprospecting agreements, "libraries" today include traditional knowledge known and shared by indigenous groups in countries outside the United States.[10] The form and location of information can no longer credibly or constitutionally be maintained as a basis for determining patent-defeating ability when, to protect the public domain, public accessibility is the touchstone for determining prior art status.

Second, significant evidence supports my contention that the limitation in 35 U.S.C. § 102(b) that prevents prior knowledge and use of an invention outside the United States from being considered patent-defeating prior art violates the Intellec-

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Framers' intent in drafting the Intellectual Property Clause, (2) congressional and judicial interpretations of constitutional requirements, and (3) technology-driven changes in the public accessibility of foreign public knowledge and/or use. For a full analysis, see Bagley, *supra* note 2, at 704–24.

6. Courts have defined the term "printed publications" expansively. *See, e.g.*, *In re* Hall, 781 F.2d 897, 898 (Fed. Cir. 1986) ("The statutory phrase 'printed publication' has been interpreted to give effect to ongoing advances in the technologies of data storage, retrieval, and dissemination."). Thus, information on microfilm, videotape, or even the internet can be a printed publication within the meaning of § 102(b) so long as it meets one key requirement: public accessibility. *See id.*

7. See discussion and cited cases in Bagley, *supra* note 2, at 708–12; *see also* Hodosh v. Block Drug Co., 786 F.2d 1136, 1138–40 (Fed. Cir. 1986) (utilizing ancient Chinese texts as prior art).

8. *See Hall*, 781 F.2d at 899–900.

9. Graham v. John Deere Co., 383 U.S. 1, 6 (1966); *see also* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("[T]he stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.").

10. Bagley, *supra* note 2, at 712–17.

tual Property Clause of the Constitution.[11] Such evidence includes (1) understandings of the Framers' abhorrence of monopolies on non-novel, publicly available items; (2) comments by some of the Framers evidencing a belief that patents of importation were unconstitutional; and (3) actions of the First Congress in drafting the Patent Act of 1790 and explicitly deleting a provision that would have limited non-documentary prior art to the United States resulting in a non-geographically limited (in terms of prior art) first patent statute.[12]

In light of all this evidence, I find it puzzling that Professor Nard's response focuses on policy issues and fails to fully engage my constitutional arguments.[13] Professor Nard merely states that patent law is utilitarian and that the driving force behind the Constitution's Intellectual Property Clause is the enhancement of public welfare.[14] I agree that patent law is utilitarian and that the United States does not ascribe to a natural rights view of patents.[15] In fact, Congress is not required to grant patents at all; the Intellectual Property Clause simply authorizes it to do so if it chooses, in order to promote the progress of the useful arts.[16] To suggest, however, that we should grant patents solely based on their utility in "enhancing the public welfare," however that is defined, disregards constitutional constraints as well as a wealth of interpretive statutory and case law in this area. For example, patents of importation have never been statutorily adopted in the United States even though at the time of the Constitution and beyond, England granted such patents to encourage the introduction of products and ideas, known elsewhere but new to England, into

11. *See id.* at 712–17.

12. *See id.* at 704–08.

13. My arguments in *Patently Unconstitutional* focused on an analysis of the unconstitutionality of the § 102(b) geographical limitation on prior art. *See id.* at 704–24. I also pointed out that the limitation was bad policy, but such arguments were, of course, secondary to my central thesis. *See id.* at 727–29.

14. Nard, *supra* note 1, at 224–25.

15. In rejecting a natural rights view of intellectual property protection, Thomas Jefferson stated:

> Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.

Graham, 383 U.S. at 9 n.2 (quoting 6 WRITINGS OF THOMAS JEFFERSON 180–81 (Henry A. Washington ed., 1853–54)).

16. U.S. CONST. art. 1, § 8, cl. 8.

the realm.[17] Such patents would have been very useful to the fledgling American republic, greatly in need of industry and ideas, yet apparently, because they were believed to be unconstitutional, they were not allowed.[18] Thus, the patenting of even very useful information in the global public domain violates the Constitution, regardless of its potential to "create wealth" or "enhance public welfare."

Certainly patents on subject matter that is non-novel and/or obvious in view of prior knowledge and the use of information available outside the United States may result in some pharmaceuticals reaching the market that otherwise might not.[19] That, however, does not justify retaining the geographical limitation on prior art any more than it justifies eliminating patents and printed publications as patent-defeating prior art. *Any* novel or nonobviousness limitation on patentability, including the traditional limitations for prior art patents and printed publications, prevents an entity from patenting public domain information even if such a patent, if allowed, would enhance the public welfare. With these existing limitations in mind, the real question should be whether a patent enhances the public welfare, and the answer to this question depends on how "public welfare" is defined.

Professor Nard's arguments reflect a somewhat narrow view that public welfare is enhanced if products that otherwise might not have been developed are commercialized and made available to the public as a result of patents,[20] but that is only part of the equation. What about the costs to the public, such as lack of competitive entrants, of a patent on publicly accessible information? What about the costs to traditional knowledge holders within *and* outside of a contracting group or the cost to traditional knowledge holders who desire to share knowledge freely, but not have it under any exclusive control? What about

17. Bagley, *supra* note 2, at 704–08.

18. James Madison opined, "Your idea of appropriating a district of territory *to the encouragement of imported inventions* is new and worthy of consideration. *I cannot but apprehend however that the clause in the constitution which forbids patents for that purpose will lie equally in the way of your expedient.*" Letter from James Madison to Tech Coxe (Mar. 28, 1790), *in* THE PAPERS OF JAMES MADISON 128 (Charles F. Hobson & Robert A. Rutland eds., 1981) (first emphasis added); *see also* Bagley, *supra* note 2, at 696–98 (describing the origins and early history of patent law in the United States).

19. *See* Nard, *supra* note 1, at 226, 229–31.

20. *See id.* at 231–37 (arguing that commercialization benefits consumers, pharmaceutical companies, and indigenous populations alike).

the environmental costs and the cost to future biodiversity efforts if the continued development of such traditional knowledge disappears? Surely such concerns and reductions in competition and free access would have to be subtracted from any potential benefit in order to ascertain a true net effect on public welfare.

I also find Professor Nard's arguments supporting retention of the geographical limitation in U.S. patent law troubling for a different reason. As Professor Nard notes, "there is a tendency to adopt a paternalistic attitude when discussing patent rights and the developing world."[21] Unfortunately, Professor Nard's arguments regarding retention of the geographic limitation are perfect examples of such paternalism. Professor Nard seeks to retain the patent-defeating status of information known or used (but not patented or published) in the United States while denying such status to comparable information known outside of the United States.[22] By seeking to retain geographic limits on prior art only for information known or used outside the United States, Professor Nard effectively devalues the information created and maintained by traditional knowledge holders, since such information does not have the same ability to defeat patents as other publicly accessible information. Using a different patentability standard to evaluate prior art based on *who* developed the information and *how* it has been preserved implicitly suggests that knowledge held by traditional knowledge-holding groups (TKHGs) has less value than other types of information.[23] Maintaining this double standard in order to ostensibly and haphazardly "create wealth" for certain indigenous groups and provide incentives for pharmaceutical companies to obtain patent-based monopolies over obvious and/or non-novel information is demeaning and unwise.

Moreover, Professor Nard's arguments for retaining the geographical limitation on prior art are inconsistent with the

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21. *Id.* at 237.

22. *Id.* at 231–37. This limitation even applies to information from our neighbors Canada and Mexico. *See, e.g.*, Bagley, *supra* note 1, at 701–04.

23. Others have aptly illustrated this value bias. For example, in her discussion of the Western, value-laden focus on writing, Professor Ruth Gana (Okediji) quoted the following: "[T]he use of letters is the principal circumstance that distinguishes a civilized people from a herd of savages incapable of knowledge or reflection." Gana (Okediji), *supra* note 4, at 114 (quoting EDWARD GIBBONS, 1 THE HISTORY OF THE RISE AND FALL OF THE ROMAN EMPIRE 234–35 (Womersley ed., 1994).

reality that traditional knowledge is dynamic, not static, as are the locations of members of TKHGs.[24] Traditional knowledge about plants and animals is often shared among multiple cultures that may not be located in the same geographic area.[25] Professor Ruth Okediji notes that in addition to different cultures sharing traditional knowledge, individual members of TKHGs often leave the local group and move to other parts of the world, taking their knowledge with them.[26] Professor Okediji also articulates two implications of these realities: (1) the geographical limitation allows individuals who have left the group to obtain patents on obvious inventions derived from the traditional knowledge, and (2) any agreement between a research entity and a TKHG is likely to exclude many holders of traditional knowledge covered by the agreement.[27]

Professor Nard and I agree that traditional knowledge holders should be compensated for the knowledge they share with entities that later obtain patents based on the shared information;[28] however, we disagree on the role patent law generally and the geographical limitation in particular should play in achieving that compensation. I am intrigued by Professor Nard's proposal for a statutory scheme requiring compensation agreements between patent applicants and traditional knowledge holders for patentable (novel and nonobvious) subject matter derived from traditional knowledge.[29] Fraudulent activity and violation of sovereign rights in relation to genetic resources such as plants should be bases for rendering a patent unenforceable when such actions are proven.[30]

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24. Ruth L. Okediji, Making Room at the Table: The Protection of Traditional Knowledge at the Interstices of Intellectual Property, International Law, and Human Rights 23 (2003) (unpublished manuscript, on file with author).

25. *Id.*

26. *Id.*

27. *Id.* at 25–26.

28. *See* Nard, *supra* note 1, at 231. I also believe traditional knowledge holders should be able to obtain patents on novel and nonobvious inventions to the same extent as anyone else, whether or not the inventions are based on traditional knowledge. I also advocate the exploration, as WIPO is doing, of the feasibility of a sui generis system to protect traditional knowledge that does not fit within Western patent parameters. *See Intellectual Property Needs and Expectations of Traditional Knowledge Holders* 7, World Intellectual Property Organization (WIPO) (Apr. 2001), http://www.wipo.org/globalissues/tk/ffm/report/final/pdf/part1.pdf.

29. *See* Nard, *supra* note 1, at 232–33.

30. *See id.* at 232 n.56.

But how would one craft and implement such a requirement? What about TKHGs that do not want exploitation of their knowledge and/or genetic resources even with compensation? In a compensation agreement, who has to be compensated? At what level must they be compensated? Some agreements to share traditional knowledge may result in multiple valuable patents, not just one. Yet even the Merck-INBio agreement applauded by Professor Nard does not appear to tie royalties to patented subject matter,[31] and the uncertainty associated with the ultimate grant of any patents and the relatively unequal bargaining power would likely depress any negotiated rates.[32] More importantly, however, ensuring compensation for traditional knowledge holders does not require retention of the geographical limitation on prior art. We can and should have one without the other. The underlying subject matter of any given patent still must not remove publicly accessible information from the public domain.[33]

Professor Nard views the geographical limitation as a tool to increase wealth for TKHGs while bringing desirable new drugs to the marketplace.[34] These are lofty and generally unexceptional goals; Professor Nard has simply selected an inappropriate and largely ineffective tool to achieve them. Even if the geographical limit on prior art were constitutional, retaining it in order to obtain new pharmaceuticals, as Professor Nard suggests,[35] would still be a bad idea, somewhat akin to using a meat cleaver to perform a delicate surgical procedure. A patent is a very powerful weapon with an effective seventeen-year term[36] that allows for the creation of a monopoly in the claimed subject matter.[37] The geographic limitation is too overbroad for

31. *See id.* at 233–34.

32. Such bargaining power would likely be even more unequal in deals between large multinationals and local indigenous groups.

33. *See* Baxter Int'l, Inc. v. Cobe Labs., Inc., 88 F.3d 1054, 1058 (Fed. Cir. 1996). Whether oral or written prior art is publicly accessible is a question of fact, determined on a case by case basis. *Id.* Unfortunately, the geographical limitation prevents the fact question from even being asked.

34. *See* Nard, *supra* note 1, at 229–37.

35. *See id.* at 229–31.

36. See 35 U.S.C. § 154 (2000). United States utility patents have a term of twenty years from the date of filing the first nonprovisional application. *Id.* If the applicant does nothing to delay prosecution of the application by the USPTO, the patent should have a term of at least seventeen years. *Id.*

37. *See id.*; *see also* Gary L. Reback, *Patently Absurd: Too Many Patents Are Just as Bad for Society as Too Few*, Forbes.com, *at* http://www.forbes.com/asap/2002/0624/044_print.html (June 24, 2002) ("[P]atents are enormously

Professor Nard's stated purposes because it not only excludes knowledge and use information related to pharmaceuticals, but also such information for *any* kind of invention.[38] Furthermore, the geographic limitation excludes knowledge and use generated in *developed* countries outside the U.S. as well as such information derived by indigenous groups in developing countries.[39] Pharmaceutical patents allow drug pricing far beyond what many consumers can afford yet they last for quite a long time.[40] A solution tailored to the specific problem of pharmaceutical development from traditional knowledge sources would better balance the need for incentives with the maintenance of a robust public domain.

An example of such a tailored solution for achieving pharmaceutical development of publicly accessible information is the Orphan Drug Act.[41] This Act provides seven years of marketing exclusivity to FDA-approved companies that develop drugs ineligible for patent protection or which otherwise would not be developed because they are only useful to small patient populations.[42] Such a statute provides important limited-term incentives for pharmaceutical development outside of the patent system. For patent law academics such as Professor Nard and myself, it is natural and understandably tempting to seek patent law–based solutions to many problems. Nevertheless,

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powerful competitive weapons that are proliferating dangerously, and the [USPTO] has all the trappings of a revenue-driven, institutionalized arms merchant."). A patent is not a true monopoly because it only gives its owner the right to exclude others from an invention, not necessarily the right to practice the claimed invention. That right to exclude, however, can be the basis for the creation of a true monopoly and at a minimum, can allow for monopoly-type pricing. *See* 35 U.S.C. § 271(a) (2000).

38. For example, the neem tree controversy discussed by Professor Nard and myself dealt with patents on pesticides, not drugs. *See* Bagley, *supra* note 2, at 680–82; Nard, *supra* note 1, at 222–23.

39. *See* 35 U.S.C. § 102(b) (2000).

40. *See id.* The lengthy term of copyrights at life of the author plus seventy years makes the twenty-year term of patents seem insignificant by contrast. *Compare* 17 U.S.C. § 302 (2000) *with* 35 U.S.C. § 154(a)(2) (2000).

41. *See* Orphan Drug Act, 21 U.S.C. §§ 360aa–360ee (2000). Interestingly, the constitutionality of the Orphan Drug Act itself is a source of debate. *See, e.g.*, Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 4 U. ILL. L. REV. 1187–89 (2000) (asserting that the provision is constitutional); John J. Flynn, *The Orphan Drug Act: An Unconstitutional Exercise of the Patent Power*, 1992 UTAH L. REV. 389, 414 (arguing that the provision violates the Constitution).

42. *See* 21 U.S.C. §§ 360aa–360ee.

patents are neither the only nor often the best solution to many problems, even in the realm of pharmaceuticals.

U.S. patents on inventions that are truly novel and non-obvious in view of publicly accessible information should be available to any inventor, regardless of race, national origin, or other suspect criteria. Congress's power to set patent policy is circumscribed by constitutional limitations designed to provide necessary incentives for innovation while protecting the public domain from monopolies over publicly available information.[43] While retaining the geographical limitation on prior art might result in some desirable benefits, such an argument could be made for any of the patentability requirements, and does not provide a compelling basis for the limitation's continued presence in U.S. law. While I appreciate Professor Nard's willingness to engage in discussion on a topic of such significance, his defense of the geographic limitation alleviates neither its constitutional infirmity nor its negative policy implications for, among other things, patent harmonization.[44] We still live in a small, small world, and the geographic limitation on prior art is still patently unconstitutional.

43. Graham v. John Deere Co., 383 U.S. 1, 5 (1966) ("[T]he federal patent power stems from a specific constitutional provision which authorizes the Congress 'To promote the Progress of . . . useful Arts by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.' . . . The clause is both a grant of power and a limitation.") (citation omitted).

44. Space constraints prevent me from addressing all of Professor Nard's policy points. I refer the interested reader to *Patently Unconstitutional* for a fuller explication of my general arguments on this topic. *See* Bagley, *supra* note 2.

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