



Finding a Remedy and Respect in Equity: Traditional Knowledge, Inventorship, and Perspective Biosystems v. Pharmacia Biotech

Trevor J. Clarke

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**FINDING A REMEDY AND RESPECT IN
EQUITY:
TRADITIONAL KNOWLEDGE, INVENTORSHIP,
AND *PERSEPTIVE BIOSYSTEMS V. PHARMACIA
BIOTECH***

I. INTRODUCTION

In the foreground, a blond, freckled, bespectacled “gringo,” suited from head to toe in adventure khaki, visibly sporting no less than five cargo pockets, leans over a bright green leaf. “So this plant cures stomachaches? And how is it prepared?” asks the *gringo*.

Juan, a dark skinned and colorfully dressed native, clearly at home amidst the lush foliage surrounding him, answers, “[s]imple. . . you dry it out well, and then. . .”

From beyond the picture comes a shout, “Hold on, Juan!!!”

Confused, Juan turns to his friend, “What’s up, Maria?”

“Be careful what you say. . .” Maria cautions.

So begins the “How to Protect Our Collective Knowledge” graphic pamphlet created by INDECOPI, the intellectual property

ministry of Peru.¹ Designed to be distributed to indigenous peoples in Peru, the pamphlet goes on to suggest that the indigenous community hold its traditions close until a community assembly agrees to let the “gringo”² sign a contract detailing his rights and responsibilities with regard to the community’s knowledge.³ Following contract approval by the ministry, the outsider is free to conduct studies on the plant, eventually developing his findings into a commercially viable product that funds a medical clinic in Juan and Maria’s community.⁴ This ideal arrangement described by INDECOPI ensures that the community receives adequate compensation for the knowledge that belongs to everyone in it, from the grandparents to the grandchildren.⁵

The problem INDECOPI hopes to stem through its pamphlet, the lack of adequate compensation for traditional knowledge, is neither new nor specific to Peru. Rather, it speaks to a struggle that has been ongoing for over a generation now, pitting the Global North—industrialized countries with strong intellectual property laws—against the Global South—developing nations rich in biodiversity and traditional cultural knowledge.⁶ Although the conflict exists in several fora, the most prominent venue for debate is in patent law.⁷ By and large, developing countries believe that

1. Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual [National Institute for the Defense of Competition and Intellectual Property Protection] [INDECOPI], *¿Cómo Proteger Nuestros Conocimientos Colectivos? [How to Protect our Collective Knowledge]*, at 1-2 (2006) [hereinafter INDECOPI Pamphlet] (on file with author).

2. The term “gringo” is used by the natives depicted in the pamphlet—and by persons in Peru and surrounding countries—as a moniker for non-Latin-Americans, particularly blond Caucasian non-Latin-Americans. *Id.* at 7; see also DICCIONARIO DE LA LENGUA ESPAÑOLA (Real Academia Española, 22nd ed. 2001), available at <http://buscon.rae.es/draeI/> (defining “gringo” as a fair skinned blond haired foreigner).

3. INDECOPI Pamphlet, *supra* note 1, at 3-7.

4. *Id.* at 13-14.

5. *Id.* at 3.

6. Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally* 11 CARDOZO J. INT’L & COMP. L. 547, 548-50 (2003).

7. See Paul Kuruk, *Goading a Reluctant Dinosaur: Mutual Recognition Agreements as a Policy Response to the Misappropriation of Foreign*

indigenous cultures deserve to be compensated for their contributions to patented innovations.⁸ In the developed world, however, rigid and technical inventorship standards make it nearly impossible for indigenous communities to directly obtain patent protection.⁹ Moreover, the costs inherent in either obtaining exclusive property rights over indigenous knowledge or preventing others from holding such rights often present a hurdle too high for indigenous communities to clear.¹⁰

Thus, an international discourse, broadly described in section II A of this Note, continues to unfold regarding the current and future status of traditional knowledge in patent law regimes. Section II B focuses on the patent law under which inventions are protected in the United States, with a particular focus on the statutory laws and equitable requirements relating to inventorship itself. The Note goes on in Section III to discuss the Federal Circuit's opinion in *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*¹¹ which declared several patents unenforceable for inequitable conduct

Traditional Knowledge in the United States, 34 PEPP. L. REV. 629, 630-31 (2007) (enumerating instances of misappropriated traditional knowledge, most of which include the granting of patents); Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Patent System and the Fight Against Biopiracy - The Peruvian Experience*, Eighth Session, Geneva, June 6-10, 2005, paras. 1-3, WIPO Doc. WIPO/GRTKF/IC/8/12 (May 30, 2005) [hereinafter *Peruvian Biopiracy Experience*] (detailing Peru's establishment of a National Anti-Biopiracy Commission to investigate patents on traditional knowledge).

8. STEPHEN HANSEN & JUSTIN VANFLEET, AM. ASS'N FOR THE ADVANCEMENT OF SCIENCE [AAAS], *TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY* 5 (2003), available at <http://shr.aaas.org/tek/handbook/>.

9. Rebecca M. Bratspies, *The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional Knowledge*, 31 AM. INDIAN L. REV. 315, 335 (2006/2007).

10. U.N. Conference on Trade and Development [UNCTAD], *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, para. 49, U.N. Doc. UNCTAD/DITC/TED/2004/14 (Feb. 15, 2006) (prepared by Joshua D. Sarnoff & Carlos M. Correa) [hereinafter *UNCTAD Disclosure Analysis*].

11. 225 F.3d 1315 (Fed. Cir. 2000) [hereinafter *PerSeptive IV*] (*reh'g denied, reh'g en banc denied*, 2000 U.S. App. LEXIS 31908 (Fed. Cir. Nov. 22, 2000)).

surrounding inventorship without giving effect to statutory inventorship laws. The case was driven heavily by a recitation of facts that, though not always apropos to the legal issues of inventorship before it, detailed a series of falsehoods and omissions on the part of the named inventors regarding the contributions of individuals unnamed (and potentially unnamable) as inventors.¹² *PerSeptive* may provide an arrow, albeit a rather flimsy one, to add to the quiver of biopiracy opponents. Section IV considers the court's reasoning and its ramifications regarding disputes over the role of traditional knowledge. Ultimately, this Note finds support for integrating more formal traditional knowledge disclosure requirements into United States patent law.

II. BACKGROUND

A. Indigenous Contributions and Compensation

According to many nations and academic observers, the current scope of intellectual property law does not adequately account for the wealth of biological and cultural resources flowing from biodiverse developing nations into the industrialized world.¹³ These critics point out that indigenous communities who often give researchers the leads necessary to identify and "invent" patentable subject matter relating to the communities indigenous genetic resources are seldom compensated for their intellectual contributions.¹⁴ Thousands of years of cultural development, not

12. Kuruk, *supra* note 7, at 632 ("Under these circumstances, it becomes critically important to determine the avenues for redress available in the American legal system to the foreign rights holders or custodians of such knowledge.").

13. See, e.g., Peruvian Biopiracy Experience, *supra* note 7, paras.1-3; VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 69-79 (1997). *But see* HANSEN & VANFLEET, *supra* note 8, at 5 (suggesting that an understanding of extant intellectual property law offers traditional knowledge holders some protection).

14. Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U.

necessarily recorded, may be necessary to identify and cultivate useful plants and treatments. Yet any resulting development has been defined as within the international public domain and, accordingly, is freely available to those in developed countries, countries with strong patent systems, to base their patents upon.¹⁵ Some argue that patents related to traditional uses of indigenous resources can *add* equity to indigenous communities by creating new markets for their resources in the developed world.¹⁶ Others believe that patents, and benefits resulting from the exclusive property right, are best characterized as “biopiracy” if the profits are not divided equitably with, or obtained under the authority of, indigenous communities.¹⁷ As one commentator suggested, “[i]f the infringement of patents . . . constitutes intellectual piracy, then so does the failure to recognize and compensate indigenous and traditional peoples for the creations arising from their knowledge.”¹⁸

The terminology itself is often subject to debate—what one calls biopiracy, invoking a range of negative connotations, another may characterize in a positive light as bioprospecting.¹⁹ One of this

J.L. & POL’Y 371, 375 (2000).

15. Bratspies, *supra* note 9, at 335; Javier Garcia, *Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*, 18 *BERKELEY LA RAZA L.J.* 5, 5-6 (2007); *see also* Jim Chen, *There’s No Such Thing as Biopiracy . . . and It’s a Good Thing Too*, 37 *MCGEORGE L. REV.* 1, 24 (2006) (stating that the free availability of ethnobiological knowledge is a positive from a utilitarian perspective).

16. *See* Hugh R. Morley, *Battle over a perk-me-up; Peru seeks to overturn N.J. company’s patent*, *THE RECORD*, (Hackensack, N.J.), March 4, 2004, at B1 (discussing and quoting the named inventor on a patent alleged to be based on traditional knowledge: “[W]e really enhanced the equity of maca itself,’ he said. ‘Maca has become a much bigger cash crop for the Peruvian people. . . . We shouldn’t be blamed; we should be thanked.’”).

17. *See UNCTAD Disclosure Analysis*, *supra* note 10, para. 35 (“Biopiracy may be defined as the effect of obtaining access to genetic resources without appropriate authority. It also may be defined more broadly to involve unauthorized commercialization resulting from access, derivation of unjustified benefits, or failure to provide for equitable benefit-sharing”).

18. IKECHI MGBEOJI, *GLOBAL BIOPIRACY: PATENTS, PLANTS AND INDIGENOUS KNOWLEDGE* 12 (2006).

19. Andres Barreda, *Biopiracy, Bioprospecting, and Resistance*, in *CONFRONTING GLOBALIZATION: ECONOMIC INTEGRATION AND POPULAR*

Note's key terms, however, is subject to less polarized dispute: "traditional knowledge" is generally accepted to refer to the information developed by a community over time through experience interacting with its environment, particularly with the biological resources in that environment.²⁰ Although traditional knowledge may descend from generations past, communities continually create innovative uses of the natural resources that surround them: their knowledge is "traditional" only in the manner in which it is accumulated and passed on; the term does not necessarily imply that the knowledge is old.²¹ Traditional knowledge is seldom written down, nor does it emerge from the "flash of creative genius" of a single individual.²² Rather, the information is inherently cumulative, building upon the collective efforts of an entire community.²³

The value of traditional knowledge to the industrial world is not disputed.²⁴ Perhaps the most salient example of its worth is "the ethnobotanical approach to drug discovery—the use of [indigenous] people's knowledge and experiences of the medicinal properties of plants and other genetic resources to guide drug discovery—[which] has yielded most of the plant based pharmaceuticals in use today."²⁵ In spite of a clear opportunity for

RESISTANCE IN MEXICO, 114-21 (Wise et al. eds. 2003) (describing popular resistance to government approved, undisclosed bioprospecting agreements).

20. HANSEN & VANFLEET, *supra* note 8, at 3; accord UNCTAD *Disclosure Analysis*, *supra* note 10, paras. 36-39; World Intellectual Property Organization, *Intellectual Property and Traditional Knowledge: Booklet No. 2*, at 4-6, WIPO Pub. No. 920(E) (2009).

21. *Id.*; MGBEOJI, *supra* note 18, at 9-11 (2006).

22. Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 240-43 (2001). The phrase "flash of creative genius" refers to a test once used by the Supreme Court to characterize a non-obvious innovation. *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 90-91 (1941). See also Jessica Silbey, *The Mythical Beginnings of Intellectual Property*, 15 GEO. MASON L. REV. 319, 327-30 (2008) (suggesting that our patent model is premised on a narrative myth that conflates inventive acts with American ideals like rugged individualism and, consequently, enjoys a false sense of legitimacy).

23. Dutfield, *supra* note 22, at 240-43.

24. See Chen, *supra* note 15, at 7; Garcia, *supra* note 15, at 5.

25. SARAH A. LAIRD & KERRY TEN KATE, *THE COMMERCIAL USE OF*

symbiotic exchange, agreements between drug developers and the ostensible sources of their knowledge, agreements that would allocate a portion of benefits from drug discoveries, patents, and commercialization to traditional knowledge providers, are few and far between.²⁶ Patents have been issued and profits have been reaped around the globe for both non-inventive step improvements on traditional knowledge and exact replications of traditional uses of indigenous resources; substantive involvement of, or benefit sharing with, the traditional knowledge developers has been lacking.²⁷ According to some, the likeliest cure for any apparent injustice lies in individual contractual agreements that would allow a party seeking to exploit traditional knowledge the chance to

BIODIVERSITY: ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING 61 (1999).

26. *Id.*; accord de Carvalho, *supra* note 14, at 375. The system established by INDECOPI, pursuant to Peruvian Law 27811, is not fully established and has yet to yield a contract. Ley No. 27811, *Ley Que Establece el Regimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas Vinculados a los Recursos Biológicos* [Regimen for Protecting Collective Knowledge and Associated Biological Resources], *El Peruano*, 10 Aug. 2002 (Peru); Sara Quinteros, Representative of INDECOPI, Remarks at the Peruvian Congressional Workshop on Genetic Resources and Traditional Knowledge: Protection of Traditional Knowledge (July 8, 2010). Another notable venture, the International Cooperative Biodiversity Groups (“ICBG”) Program, seeks to recognize and compensate the contributions of traditional knowledge holders and, though it named indigenous inventors on at least one provisional patent applications, no patents were ultimately issued naming indigenous contributors as co-inventors. McManis, *supra* note 6, at 565-70; see, e.g., USPTO database search for “Aguaruna,” <http://patft.uspto.gov/netahtml/PTO/search-bool.html> (last visited Sept. 27, 2010) (yielding no patents recognizing Aguaruna inventive contributions) add parenthetical explaining significance)

27. SHIVA, *supra* note 13, at 69-79; Laura Carlsen, *Biopiracy on the Border*, in *CONFRONTING GLOBALIZATION: ECONOMIC INTEGRATION AND POPULAR RESISTANCE IN MEXICO*, 83 (Wise et al. eds. 2003) (discussing the Enola bean patent's effect on the market for Mexican exporters); Submission by Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru and Venezuela to the TRIPs Council, *The Relationship Between the Trips Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, para. 4, WTO Doc. IP/C/W/403 (June 24, 2003) [hereinafter *Biodiverse Nations' TK WIPO Submission*] (referring to quinoa and ayahuasca patents).

negotiate terms of benefit sharing with knowledge providers.²⁸

These commonly proposed benefit sharing agreements might not be necessary if the contributions of indigenous cultures were recognized under established intellectual property law.²⁹ However, today's intellectual property regime, particularly within the United States, has little room to recognize whole traditional communities as bona fide inventors entitled to patent protection even if the communities do develop useful traditional cures, medicines, and foods.³⁰ In a just world order, critics assert, this cannot stand: these contributions to human knowledge, particularly in inventive endeavors, must be recognized and respected within states' intellectual property regimes.³¹

As detailed below, technical and statutory barriers can prevent many traditional knowledge holders from obtaining patent

28. Barreda, *supra* note 19, at 105-07; McManis, *supra* note 6, at 559.

29. Jacques de Werra, *Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?*, 42 VAND. J. TRANSNAT'L L. 143, 167-71 (2009) (discussing co-ownership and compulsory licensing); LAIRD & KATE, *supra* note 25, at 61. *But see* Chen, *supra* note 15, at 20-22 (suggesting that current trade secret and unfair competition law may protect traditional knowledge, but that such protection is counter to the greater good).

30. HANSEN & VANFLEET, *supra* note 8, at 10 (noting that traditional knowledge "may be considered *de facto* part of the prior art base" thus precluding traditional knowledge subject matter from patentability).

31. Convention on Biological Diversity arts. 8(j) and 16(5), June 5, 1992, 31 I.L.M. 818, 1760 U.N.T.S. 79. [hereinafter CBD] (Dec. 29, 1993); Erin Kathleen Bender, *North and South: The WTO, TRIPS, and the Scourge of Biopiracy*, 11 TULSA J. COMP. & INT'L L. 281, 290-96 (2003). Additionally, the Universal Declaration of Human Rights states:

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Universal Declaration of Human Rights, G.A. Res. 217A, art. 27, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948). *But see* SHIVA, *supra* note 13, at 7-17 (arguing against the imposition of any intellectual property rights on subject matter that includes living organisms or traditional knowledge because IP rights stifle creativity).

protection themselves.³² Accordingly, many have argued for the establishment of a *sui generis* system specifically to protect the rights of communities endowed with extensive traditional knowledge, communities who find no protection in the strict patent statutes.³³ Indeed, there are strong arguments for the necessity of such a system.³⁴ Alternatively—and sometimes concurrently—others seek to find a way to use extant or slightly modified intellectual property law to secure rights for indigenous communities and ensure that “misappropriation” of traditional knowledge ceases.³⁵

To that end, one proposed approach to including traditional knowledge holders in the current system of protection requires, *inter alia*, giving formal recognition of the contributions of traditional knowledge holders to patented inventions.³⁶ This approach may be affected through either of two strategies:³⁷ first,

32. HANSEN & VANFLEET, *supra* note 8, at 5.

33. See generally Conference on Trade and Development Commonwealth Secretariat Workshop on Elements of National *Sui Generis* Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework, Geneva, Switz., Feb. 4-6, 2004, *Draft Paper: Towards an International Framework for the Protection of Traditional Group Knowledge and Practice*, (prepared by Peter Drahos); HANSEN & VANFLEET, *supra* note 8, at 26-28; Bratspies, *supra* note 9, at 340 (“volumes have been written advocating some variation [of a *sui generis* system]”).

34. See Bratspies, *supra* note 9, at 333.

35. See Garcia, *supra* note 15, at 8 (citing the rejection of claims for the Enola bean—a plant long cultivated in Mexico—by the USPTO following a successful reexamination request by the International Center for Tropical Agriculture); see also *UNCTAD Disclosure Analysis*, *supra* note 10, para. 35 (defining misappropriation as the consequence of biopiracy, of violating authorized conditions of access, or of using the genetic resources to derive unjustified or inequitably shared benefits).

36. World Intellectual Property Organization [WIPO], Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge, at 50, WIPO Doc. UNEP/CBD/COP/7/INF/17 (Feb. 9, 2004) [hereinafter WIPO Technical Study] (stating that the failure to name the true inventor could invalidate a patent under many national patent regimes and suggesting that disclosure of the resource and knowledge is therefore required).

37. Sumathi Subbiah, Note, *Reaping What They Sow: The Basmati Rice Controversy and Strategies for Protecting Traditional Knowledge*, 27 B.C. INT'L

the traditional knowledge holders may be recognized as legitimate contributing inventors, entitled to appear named as such when a patent issues; this may require altering the definition of inventorship to accommodate communal inventions that develop over time.³⁸ Under a second strategy, patents may be rendered unenforceable if they are based on subject matter developed using traditional knowledge but fail to recognize the contributions of traditional knowledge holders through adequate disclosure.³⁹ Internationally, the latter approach has received more widespread support.⁴⁰ Indeed, some argue that such disclosure is already required of patent applicants,⁴¹ and the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) has recommended that states implement a disclosure requirement to comply with the CBD.⁴² However, a traditional knowledge disclosure requirement has never been explicitly articulated in

& COMP. L. REV. 529, 541-42 (2004).

38. See WIPO Technical Study, *supra* note 36, at 6; McManis, *supra* note 6, at 574.

39. WIPO Technical Study, *supra* note 36, para. 2 (stating that where the traditional knowledge constitutes an inventive contribution to the claimed invention the knowledge provider must be included as a joint or sole inventor, but where the traditional knowledge does not meet this standard, the traditional knowledge may have some use in assessing the patent's validity). According to biodiverse/traditional-knowledge-rich countries, "in the case of inventions based on biological resources and/or traditional knowledge related to the same, the source of origin of the resources and details of the traditional knowledge, are critical for ascertaining inventorship, that is, whether the applicant has "invented" what s/he claims in the patent, or whether s/he has just found it in nature or obtained it from traditional cultures." *Id.*

40. See de Carvalho, *supra* note 14, at 372 ("Instead of imposing [a disclosure requirement] as a condition of patentability, which conflicts with the TRIPS Agreement, WTO Members should make the enforceability of patent rights dependent on compliance with the [disclosure requirement]."); *UNCTAD Disclosure Analysis*, *supra* note 10, at v; WIPO Technical Study, *supra* note 36, at 1.

41. Biodiverse Nations' TK WIPO Submission, *supra* note 27, para. 6.

42. de Werra, *supra* note 29, at 152-55 (citing Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization, Decision VI/24/A, Conference of the Parties to the Convention on Biological Diversity, 6th mtg., The Hague, UN Doc. UNEP/CBD/COP/6/20 (Apr. 7-9, 2002)).

United States courts and, though President Clinton signed the CBD, the convention was never ratified by Congress.⁴³

Despite the absence of clear binding precedent or international law, one case decided by the Federal Circuit may provide modest support for a requirement to disclose the contributions of traditional knowledge, whether or not the contributions fall within the bounds of existing inventorship law.⁴⁴

B. Domestic or “Nationalistic”⁴⁵ Protection of Inventions

1. Where Exclusive Rights May Exist

Patents can be issued to claim “anything under the sun that is made by man.”⁴⁶ Patentable subject matter does not include abstract ideas, natural phenomena, or laws of nature.⁴⁷ Furthermore, patents are barred for lack of novelty when certain conditions are met.⁴⁸ A printed publication describing or patenting the invention, published either before the applicant’s date of invention or more than one year prior to the applicant’s filing, will destroy patentability.⁴⁹ If an invention was “known or used” in the United States before it was invented by the applicant, a patent will not issue.⁵⁰ Similarly, a patent will not issue if the invention was in public use or on sale in the United States more than one year prior to the filing of an application.⁵¹

43. List of Parties to the CBD, <http://www.cbd.int/information/parties.shtml> (last visited Sept. 4, 2010). Keeping the U.S. company as convention hold-outs are the Vatican [Holy See] and Andorra.

44. *PerSeptive IV*, 225 F.3d 1315. *PerSeptive IV* held that, even though actual inventorship was technically correct on an issued patent, the patent applicants could still be held accountable for inequitable conduct for failing to provide a full accounting of information *about* inventorship. *Id.* at 1317.

45. MGBEOJI, *supra* note 18, at 2 (stressing that aggressive nationalism underlies the globalization of patent law).

46. *Diamond v. Diehr*, 450 U.S. 175, 182, 185 (1981).

47. *Id.*

48. 35 U.S.C. § 102 (2006).

49. *Id.* § 102 (a)-(b).

50. *Id.* § 102(a).

51. *Id.* § 102(b).

Traditional knowledge, even if it describes each and every claim of a patent application, is highly unlikely to bar the issuance of a patent on these grounds. Traditional knowledge is generally passed down from generation to generation orally.⁵² Accordingly, no printed publications exist.⁵³ Moreover, the requirement that prior knowledge, use, or sale of an invention be *inside the United States* to defeat novelty on those grounds immediately disadvantages all traditional knowledge holders who only utilize their knowledge locally, save those traditional knowledge holders indigenous to the United States.⁵⁴

The obviousness inquiry, another means of rejecting a patent application, also ignores traditional knowledge held outside of the United States. Patents may only be issued for nonobvious inventions.⁵⁵ The invention is measured against prior art as defined above—printed publications from the world over could render an invention obvious in the eyes of an examiner, as could public use or sale in the United States.⁵⁶ Here, as with novelty, the use or oral description of an invention on foreign soil cannot constitute prior art and, thus, cannot be used to show obviousness.⁵⁷

Significantly, one statutory bar does not demand what one commentator called “nationalistic” requirements to defeat patentability.⁵⁸ 35 U.S.C. § 102(f) has no territoriality restriction. It simply prohibits patents issuing to an entity that “did not [it]self invent the subject matter sought to be patented.”⁵⁹ Thus, an invention consisting entirely of traditional knowledge acquired

52. Subbiah, *supra* note 37, at 545.

53. *Id.* However, there is a growing movement to change this fact by compiling databases of traditional knowledge and allowing a small set of people, namely patent examiners, to view the confidential databases in order to determine if novelty is defeated. India has established such a regime, and other nations are hoping to follow their lead.

54. 35 U.S.C. § 102.

55. *Id.* § 103.

56. *See, e.g., Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1563 (Fed. Cir. 1987).

57. 35 U.S.C. § 102.

58. MGBEOJI, *supra* note 18, at 2.

59. 35 U.S.C. § 102(f).

from an indigenous community, no matter where that knowledge originated or if it was recorded, cannot lawfully be the basis for a patent in the United States.⁶⁰ As simple as the rule sounds, however, the strict requirements of inventorship, the technical specificity of patent claims, and the nearly impossible task of proving derivation from another's invention in court, make reliance on this provision an unappealing option for traditional knowledge holders seeking to assert their status as true inventors.⁶¹

2. *The Statutory Inventorship Inquiries*

Many advocates for the rights of traditional knowledge holders criticize the very concept of invention common to industrial nations.⁶² In the United States, an invention is considered the result of discrete individual efforts; only those identifiable sources of distinct creative contributions are entitled to exclusive patent rights as compensation for their extraordinary efforts.⁶³ Advances achieved through traditional knowledge, in contrast, are the result of communal efforts, slowly aggregated over time, without any single protagonist or group of protagonists who could be named as inventors on a patent application.⁶⁴ This basic schism is considered by some commentators to severely handicap developing nations at the outset in attempts to protect their intellectual property rights.⁶⁵ Additionally, commentators note that technical hurdles to showing inventorship, establishing joint inventorship, or proving derivation make inventorship law

60. *Id.*

61. See Peruvian Biopiracy Experience, *supra* note 7, para. 1.

62. See, e.g., Bratspies, *supra* note 9, at 336-37 (suggesting that the dichotomy between natural and invented underlying the patent system is false); MGBEOJI, *supra* note 18, at 166 (faulting the industrialized nations' patent systems for reliance upon the idea that inventions are created by individuals, as opposed to communities).

63. MGBEOJI, *supra* note 18, at 166.

64. *Cuno Eng'g Corp.*, 314 U.S. at 91; SHIVA, *supra* note 13, at 67; Chen, *supra* note 15, at 21 (noting the traditional knowledge "rarely if ever satisfies" the inventive step requirement of patentability).

65. HANSEN & VANFLEET, *supra* note 8, at 10; Bender, *supra* note 31, at 312-13.

practically inaccessible to traditional knowledge holders.⁶⁶

Criticisms as to the concept underlying the inventorship standard aside, the legal standard in the United States has been clearly articulated. An invention comes into being, allowing an inventor to be determined, upon conception.⁶⁷ Conception, the “touchstone of invention,” is a wholly mental act, defined as the completion of the mental facet of inventing.⁶⁸ No physical embodiment of the invention is necessary.⁶⁹ Rather, an invention requires only a “definite and permanent idea” that could allow one skilled in the art to understand and create the invention.⁷⁰ Stated another way, provided that there is a “formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice,” there is a cognizable invention.⁷¹

Conception must envision the complete invention, including how it is to be applied, and must encompass all limitations of the claimed subject matter.⁷² Limitations are often very technical, beyond the technical acumen common to developers of traditional knowledge, even if the function and use of the invention is identical to traditional practices.⁷³ In effect, invention is thus a

66. Subbiah, *supra* note 37, at 546; David Conforto, *Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate*, 19 J. ENVTL. L. & LITIG. 357, 363-66 (2004).

67. *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

68. *Id.*

69. *See, e.g., Pfaff v. Wells Elecs.*, 124 F.3d 1429, 1434 (Fed. Cir. 1997) (finding an offer for sale sufficient to constitute an on-sale bar when the invention had yet to be reduced to practice), *aff'd*, 525 U.S. 55 (1998), .

70. *Burroughs Wellcome*, 40 F.3d at 1228.

71. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson *On Patents* 532 (1890)).

72. *Brown v. Barbacid*, 276 F.3d 1327, 1336 (Fed. Cir. 2002) (quoting *Singh v. Brake*, 222 F.3d 1362, 1367 (Fed. Cir. 2000)).

73. *See* Delegation of Peru, *Patents Referring to Lepidium meyenii (Maca): Responses of Peru*, para. 46, WIPO Doc. GRTKF/IC/5/13 (2003) (stating that maca had been used for treatment of fertility issues since its earliest cultivation). Compare, for example, the alcoholic extract claimed in U.S. Patent No. 6,267,995 (filed Mar. 3, 1999), specifying a *maca* composition containing four elements with quantities determined through chemical analysis with the

mental activity that relies on specific scientific knowledge, terminology, and quantification methods (especially in the biotechnology fields) that may not be available in communities that develop traditional knowledge.⁷⁴ Moreover, conception may not be baldly asserted by a putative inventor in order to have effect in court—it must be corroborated by additional evidence.⁷⁵

While inventorship law does not recognize designations of an entire community as an inventor, it does provide for designating multiple individuals as joint inventors.⁷⁶ The essential requirement here is that each joint inventor contributes to the conception of the invention.⁷⁷ The contributions need not be equal, nor do the designated joint inventors need to contribute to every claim of the patent, nor must they work together on the invention at the same place and time.⁷⁸ With such flexibility, it comes as little surprise that one court described deciding just who contributed to the conception of an invention as an inquiry into “one of the muddiest concepts in the muddy metaphysics of the patent law.”⁷⁹ However,

traditional preparation of *maca*, which is made using a similar process but has not been analyzed to accurately determine its component parts.

74. Subbiah, *supra* note 37, at 546. Although the courts have not held that “the final size and shape of every part and the location of every nut, screw, and bolt must be exactly foreseen before the conception of an apparatus can be said to be complete,” the person who conceived the invention must still be able to make a disclosure to one of skill in the art that would enable him or her to recreate the invention without extensive research or experimentation. In re Tansel, 253 F.2d 241, 243 (C.C.P.A. 1958). Given that the courts have never recognized traditional knowledge holders as a group of skilled artisans, it is unlikely that a disclosure by one who conceived of an invention in traditional knowledge terms would be capable of an enabling disclosure to a skilled artisan. See Conforto, *supra* note 66, at 365.

75. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997).

76. 35 U.S.C. § 116 (2006).

77. U.S. PAT. & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2137.01 (8th ed., 7th rev., 2008) [hereinafter MPEP]; see also Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc., 333 F.3d 1330, 1340 (Fed. Cir. 2003) (“Invention requires conception.”).

78. 35 U.S.C. § 116 (2006).

79. Sean B. Seymore, *My Patent, Your Patent, or Our Patent? Inventorship Disputes Within Academic Research Groups*, 16 ALB. L.J. SCI. & TECH. 125,

even in this muddy realm, conception is analyzed claim by claim.⁸⁰

The inquiry into joint inventorship involves questions of law and fact: while inventorship itself is a question of law, the underlying basis for determining inventorship relies on questions of fact.⁸¹ Clear and convincing proof is necessary to modify inventorship.⁸² Thus, a finding of a contribution sufficient to support a claim of joint inventorship will depend, largely, on the facts of a given case. There are no bright lines, and the clearest positive guidance available from the Federal Circuit suggests that co-inventors are those who make contributions to conception that are “not insignificant.”⁸³ To define the standard negatively: neither suggesting an end result without indicating how to achieve that end nor following the instructions of another who conceived an invention is sufficient to establish joint inventorship.⁸⁴ Moreover, if an inventor maintains intellectual domination, ideas, suggestions, and materials may be adopted from others.⁸⁵

The law provides a mechanism to correct a patent that does not name the proper inventive entity when initially issued.⁸⁶ If a person is named or excluded in error, the patent may be corrected to name the proper inventor(s), provided the error arose without deceptive intent on the part of the inventor.⁸⁷ The court’s focus when evaluating a petition to correct inventorship belongs on the intent of the true inventor *not* named on the patent, as opposed to the intent of the named inventors.⁸⁸

Finally, if the inventorship specified on a patent is completely in error, that is to say, if the inventive entity named on the issued

135 (2006) (citing *Mueller Brass v. Reading Indus.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972), *aff’d*, 487 F.2d 1395 (2d Cir. 1973)).

80. *See Bd. of Trs. of Fla. State Univ.*, 333 F.3d at 1340.

81. *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed. Cir. 2004).

82. *Id.*

83. *Fina Oil & Chem. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997).

84. DONALD S. CHISUM, 1-2 CHISUM ON PATENTS § 2.02 [2][b]-[c](2010).

85. MPEP, *supra* note 77, § 2137.01.

86. 35 U.S.C. § 256 (2006).

87. *Id.*

88. *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1552 (Fed. Cir. 1997). The lack of clarity on this point resulted in the improper application of the law in *PerSeptive II*.

patent did not in fact invent the claimed subject matter, but rather *derived* it from the true inventor, the patent may be invalidated.⁸⁹ Derivation requires two distinct showings: conception and communication.⁹⁰ Both must be proven with clear and convincing evidence.⁹¹ Conception must, as detailed above, include each claimed limitation of the invention.⁹² If the evidence of conception comes from the alleged true inventor, it must be corroborated by additional evidence.⁹³ Similarly, self-serving evidence of communication given by the alleged true inventor will not often stand on its own.⁹⁴ The court must be convinced that communication of a disclosure of the invention sufficient to enable one of skill in the art to practice the invention without undue experimentation has occurred before finding derivation.⁹⁵

3. *The Equity-Grounded “Inequitable Conduct” Doctrine*

Inventorship issues extend beyond the statutory requirements: as applied in *PerSeptive III* and *IV* and progeny—discussed in detail below—inequitable conduct surrounding inventorship can also play a key role in determining the viability of a patent.⁹⁶ However, here, as with much of the judicially-created inequitable conduct law, the tests and analysis applied by courts are inconsistent.⁹⁷ A full discussion of inequitable conduct is beyond the scope of this Note: scholarship and case law on the doctrine is vast; a review article doing justice to the nuance, evolution, and inconsistencies

89. See *Gambro Lundia*, 110 F.3d at 1576.

90. *Id.*

91. *Id.*

92. *Brown*, 276 F.3d at 1336.

93. *Gambro Lundia*, 110 F.3d at 1576.

94. See, e.g., *Brand v. Miller*, 487 F.3d 862, 867 (Fed. Cir. 2007).

95. *Id.* at 869-70.

96. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 F. Supp. 2d 69 (D. Mass. 1998) [hereinafter *PerSeptive III*], *aff'd*, 225 F.3d 1315 (Fed. Cir. 2000); *PerSeptive IV*, 225 F.3d 1315.

97. See *Therasense, Inc. v. Becton, Dickinson and Co.*, 374 Fed. Appx. 35 (Fed. Cir. 2010) (deciding to hear an appeal *en banc* to clarify inequitable conduct standards).

of judicial application is a Sisyphean endeavor.⁹⁸ Nonetheless, an acceptance of the historical mutability of the doctrine⁹⁹ coupled with an understanding of considerations relevant to inequitable conduct will suffice to evaluate both the options available to biopiracy opponents and the application of the doctrine in *PerSeptive*.

Inequitable conduct arises when a patent applicant breaches the duty of candor she owes to the United States Patent and Trademark Office [USPTO].¹⁰⁰ Conduct must be proven by clear and convincing evidence.¹⁰¹ The duty of candor applies throughout patent prosecution and, consequently, courts look to the entire history of patent prosecution for instances of inequitable conduct.¹⁰² The inventor(s), along with each individual associated with the filing of the patent, are saddled with the duty to disclose information to the USPTO because the “[p]ublic interest is best served . . . when . . . the Office is aware of and evaluates the teachings of all information *material* to patentability.”¹⁰³ A violation of the duty could include the misrepresentation of a material fact, the failure to disclose material information, or the submission of false material information.¹⁰⁴ Questions arise as to the extent of disclosure required by the USPTO, which in turn relies on a determination of the materiality of the piece of

98. 3 CHISUM, *supra* note 84, § 19.03 [introduction]. Chisum's treatment of the subject alone fills over 350 PDF pages. Moreover, the doctrine is presently under review *en banc* in *Therasense*. *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 828, 835 (Fed. Cir. 2010) (Rader, J., concurring) (suggesting that decisions on any less “egregious” allegations of inequitable conduct be postponed until the *en banc Therasense* decision is handed down).

99. 3 CHISUM, *supra* note 84, § 19.03.

100. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

101. *McKesson Info. Solutions v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007).

102. *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803 (Fed. Cir. 1990) (“The duty of candor extends throughout the patent's entire prosecution history. In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents.”).

103. 37 C.F.R. § 1.56 (1996).

104. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178-79 (Fed. Cir. 1995).

information in question.¹⁰⁵ This begs the question: what makes a piece of information material?

i. Materiality

Courts use two basic tests as standards for determining materiality.¹⁰⁶ The first standard, found in rules promulgated by the USPTO prior to March 16, 1992, requires applicants to disclose information if there is a “substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”¹⁰⁷ In March of 1992, the USPTO promulgated new rules, narrowing the scope of materiality by defining a material reference as one that is not cumulative and (1) establishes a *prima facie* case of unpatentability or (2) refutes or is inconsistent with a position the applicant takes in opposing an argument of unpatentability relied on by the Office or asserting patentability of a claim.¹⁰⁸ Although the broader reasonable examiner standard is usually used to evaluate allegations of inequitable conduct in patents prosecuted before March of 1992, patents challenged since then have been subjected to both tests, with no clear preference by the courts for either one.¹⁰⁹

Applicants are required to file an oath declaring, *inter alia*, that they believe themselves to be the “original and first inventor” of the subject matter for which the application is filed.¹¹⁰ As a patent cannot issue without this oath, the information contained therein

105. See 37 C.F.R. § 1.56.

106. Compare 37 C.F.R. § 1.56(a) (1990) with 37 C.F.R. § 1.56(b) (1996). In the past, the Federal Circuit has used additional tests, including the much stricter “but for” standard. CHISUM, *supra* note 84, § 19.03[3].

107. 37 C.F.R. § 1.56(a) (1990).

108. 37 C.F.R. § 1.56(b) (1996). For an extensive discussion of the materiality standards, the courts' inconsistent use of the two tests, and differing standards in inequitable conduct litigation generally, see Tom Brody, *Duty to Disclose: Dayco Products v. Total Containment*, 7 J. MARSHALL REV. INTELL. PROP. L. 325, 372-75 (2008).

109. Brody, *supra* note 108, at 372-75; see also *Advanced Magnetic Closures*, 607 F.3d at 829.

110. 35 U.S.C. § 115 (2006).

has been defined as material.¹¹¹

The Manual of Patent Examining Procedure [MPEP] gives additional advice on what to disclose, providing another barometer of materiality, albeit a nonbinding one.¹¹² Included in the MPEP is an admonition to applicant attorneys and agents to ask questions to inventors about inventorship and, if any doubts surface, to raise them to the patent office.¹¹³ This reflects a well-accepted axiom of disclosure requirements: if any information is on the border of materiality, the applicant should always err on the side of safety by disclosing it to the USPTO.¹¹⁴

ii. Intent

A court reviewing inequitable conduct allegations must also consider the state of mind of the party that withheld information from the USPTO.¹¹⁵ Inequitable conduct requires a culpable state of mind—in other words, an intent to deceive the patent office—related to the disclosure of a material piece of information.¹¹⁶ Direct evidence of an intent to deceive is rarely available, so courts allow the inference of intent from the sum total of all circumstances.¹¹⁷ This sum total analysis grants a court considerable leeway, although mere negligence or errors in judgment do not constitute culpable intent.¹¹⁸ Moreover, evidence of good faith must be considered to counteract evidence of bad

111. *Stark*, 119 F.3d at 1555-56.

112. MPEP, *supra* note 77, § 2004.

113. *Id.*

114. *See, e.g.*, *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001) (quoting *LaBounty Mfg. Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992)); *Critikon*, 120 F.3d at 1257 (Fed. Cir. 1997) (quoting the same).

115. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1394-95 (Fed. Cir. 1988).

116. *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991).

117. *See, e.g.*, *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1330 (Fed. Cir. 1998); *Critikon*, 120 F.3d at 1256.

118. *N.V. Akzo v. E.I. du Pont de Nemours & Co.*, 810 F.2d 1148, 1152 (Fed. Cir. 1987).

faith intent.¹¹⁹

iii. Striking a Balance

Finding threshold levels of materiality and intent met, the court must then balance the substance of those two inquiries.¹²⁰ An inequitable conduct finding renders all claims of a patent unenforceable, a very severe penalty for a patent holder.¹²¹ Accordingly, the ideal application of the courts' balancing test will only penalize those deserving of punishment: a relatively unimportant piece of information withheld from the USPTO with no real malice will not result in a finding of inequitable conduct.¹²² On the other hand, withholding a highly material reference without a clear intent to deceive can be considered inequitable conduct, just as a blatant attempt to mislead the USPTO by withholding a piece of information of relatively low materiality can be considered inequitable conduct.¹²³ Thus, with two vague threshold requirements, one for determining materiality, one for determining intent, and a balancing test to weigh the two, the court enjoys a considerable amount of freedom in deciding inequitable conduct.¹²⁴ Additionally, in "exceptional cases" the court is empowered to award reasonable attorney fees to parties prevailing on an inequitable conduct defense.¹²⁵

119. *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1398 (Fed. Cir. 1986) (superseded by federal regulation 37 C.F.R. § 1.97, on other grounds, *as recognized in In re OxyContin Antitrust Litig.*, 530 F. Supp. 2d 554, 573 n.8 (S.D.N.Y. 2008)).

120. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

121. *Id.*

122. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 875 (Fed. Cir. 1988).

123. *Cf. Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1336 (Fed. Cir. 1998) (finding the failure to disclose a novelty-negating § 102(b) sale insufficient for inequitable conduct where the applicants acted in good faith).

124. *See Lisa A. Dolak, Beware the Inequitable Conduct Charge!*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 558, 558 (2009) (discussing the court's recent expansion of the inequitable conduct doctrine).

125. 35 U.S.C. § 285 (2006); *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001).

III. SUBJECT OPINION

A. Introduction to the Named Inventors and the Controversy

Synosys, later known as PerSeptive Biosystems, Inc., was formed in the summer of 1987 by three scientists intent on supplying an existing market.¹²⁶ But Drs. Frank Regnier, Robert Dean, and Noubar Afeyan quickly shifted the focus of their enterprise¹²⁷ and, soon thereafter, patented a new method to separate solutes that they coined “perfusive chromatography.”¹²⁸ The patented process earned Dr. Regnier a publication in the prestigious journal *Nature*.¹²⁹ Synosys launched the career of a highly successful entrepreneur in Dr. Afeyan.¹³⁰ Dr. Dean proudly points to his involvement with PerSeptive and HPLC among his substantial list of accomplishments.¹³¹ However, roughly 200 pages of judicial opinion capped by a panel majority at the Federal

126. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, No. 93-12237-PBS, 1997 U.S. Dist. LEXIS 8600, at *18 (D. Mass. Mar. 31, 1997) [hereinafter *PerSeptive II*] (suggesting their goal was to capitalize on the large molecule separation market by supplying hardware and software), *vacated in part, motion denied*, 12 F. Supp. 2d 69 (D. Mass. 1998), *aff’d*, 225 F.3d 1315 (Fed. Cir. 2000).

127. *Id.* at *16 (noting a shift to high performance liquid chromatography (HPLC) media).

128. *Id.* at *18 (discussing the company's “refocus”). The three patents were derived from a single application and directed to a method for practicing perfusive chromatography, a particle used for perfusive chromatography, and a matrix of particles used for perfusive chromatography, respectively. *PerSeptive IV*, 225 F.3d at 1317 (discussing U.S. Patent No. 5,019,270 (filed Oct. 9, 1990); U.S. Patent No. 5,228,989 (filed Dec. 9, 1992); U.S. Patent No. 5,384,042 (filed May 10, 1993)).

129. Fred E. Regnier, *Perfusion Chromatography*, 350 *NATURE* 634 (1991). This article is just one of Dr. Regnier's 281 publications to date. See Fred Regnier Publication List, http://www.chem.purdue.edu/people/faculty/PubList.asp?faculty_id=56 (last visited Sept. 19, 2010).

130. Noubar Afeyan Biography, <http://www.flagshipventures.com/team/nafeyan.html> (last visited Sept. 19, 2010).

131. Robert C. Dean Biography, <http://engineering.dartmouth.edu/faculty/emeriti/robertdean.html> (last visited Sept. 19, 2010).

Circuit ultimately rendered the perfusive chromatography patents unenforceable for inequitable conduct because of these distinguished scientists' behavior.¹³² Judge Newman, in dissent, took an entirely different view of the facts by applying the rigorous law of inventorship.¹³³

B. The Birth of Perfusive Chromatography

Since 1977, Polymer Laboratories (PL) and its president, Fred Warner, had been making material used to separate different sized molecules through column chromatography.¹³⁴ In 1985, Mary Ann Rounds, a research assistant in the Purdue University lab of prominent chromatography expert Regnier,¹³⁵ asked PL about providing column packing material.¹³⁶ PL would supply the material if Rounds and Regnier supplied information regarding the material's performance.¹³⁷ Loose terms agreed upon, the parties commenced a collaborative relationship.¹³⁸ The collaboration

132. See *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, No. 93-12337-PBS, 1996 U.S. Dist. LEXIS 21908 (D. Mass. January 9, 1996) [hereinafter *PerSeptive I*], *motion denied*, 1997 U.S. Dist. LEXIS 8600 (D. Mass. Mar. 31, 1997), *vacated in part, motion denied*, 12 F. Supp. 2d 69 (D. Mass. 1998), *aff'd*, 225 F.3d 1315 (Fed. Cir. 2000); *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600; *PerSeptive III*, 12 F. Supp. 2d 69; *PerSeptive IV*, 225 F.3d 1315.

133. *PerSeptive IV*, 225 F.3d at 1323-31 (Newman, J., dissenting).

134. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *9. Column chromatography requires packing a column with a specially created material, tiny beads in the case of PL. The beads display different properties depending on their inherent structure or any coating applied on the beads (in a process known as derivitization). When a solute rich solvent is passed through the particle packed column, different solutes exhibit different affinities to the beads and pass through the column at different rates. Collecting the liquid that comes out of the column in a series of fractions-- small quantities of liquid-- enables scientists to separate unique solutes. See, e.g., U.S. Patent No. 5,019,270 (filed Oct. 9, 1990).

135. Regnier Publication List, *supra* note 129 (citing many papers on chromatography published by Dr. Regnier prior to the mid 1980's).

136. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *10.

137. *Id.* at *10-12.

138. *Id.* Numerous documents used the word "collaborate," or some form thereof, a fact that the district court makes abundantly clear through added

began well: Rounds coated 300Å and 1000Å pore PL particles in a process (known as “SAX”) patented by Regnier and supplied her results to PL, which commercialized the SAX particles and subsequently visited Rounds to learn her coating technique.¹³⁹ Strengthening their relationship, PL funded six months of SAX coating research by Rounds and Regnier.¹⁴⁰

A senior scientist at PL, Linda Lloyd, used SAX coating on a class of particles with larger pores (4000 Å) and compared them to the Rounds-coated 1000Å pore particles.¹⁴¹ Lloyd publicly presented her comparisons twice in the fall of 1987 and, following the second presentation, PL asked Regnier and Rounds to analyze the larger SAX coated particles,¹⁴² which PL supplied.¹⁴³ Rounds’ analysis included the generation of two chromatograms in early 1988 that showed “spectacular” results, according to Regnier.¹⁴⁴

Regnier immediately discussed these results with Afeyan and Dean, prompting Dean to draft documents postulating perfusion through the particles.¹⁴⁵ As Regnier was conferring with his now incorporated business partners and acquiring SEM images of the PL particles,¹⁴⁶ Rounds continued openly communicating with PL,

emphasis. *Id.* at *13-16, *20.

139. *Id.* at *13; *PerSeptive IV*, 225 F.3d at 1328-29. PL got a non exclusive license to practice the patented process from Regnier. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *30.

140. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *30-31. This also became a sore point between the two entities when PL had to cease funding because of its small size. *Id.* at *32.

141. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *14; *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *33-34.

142. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *14-16. Following this request, Rounds drafted a research plan. *Id.* at *16.

143. *Id.*

144. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *41. Rounds described the initial results, obtained in December of 1987, as “really good,” “surprisingly high capacity” of 4000Å pore particles. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *16. She communicated these results to Lloyd at PL. *Id.* at *17.

145. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *46-47. The notes openly asked about the presence of channels through the particles while the subsequent memo declared that, assuming such channels exist, perfusion was possible. *Id.* at *48.

146. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *21-22.

informing PL that Regnier believed the great results could be the result of “flow through” and sending them copies of the “spectacular” chromatograms.¹⁴⁷

In March of 1988, Synosys commenced “product development” on 4000Å pore particles and proposed an exclusive contract with PL.¹⁴⁸ Concurrently, Lloyd and Warner presented a paper comparing the large and small pore SAX particles, citing differences and explaining that the larger particles performed better.¹⁴⁹ A few months later, Regnier presented on the same particles (using the same chromatograms), but “crossed out” the PL label.¹⁵⁰ Regnier called the particles “Poros” and suggested that “Poros” was in the process of being patented.¹⁵¹ Following the presentation, an alarmed Warner asked Afeyan if the particles were, in fact, being patented—Afeyan replied in the negative.¹⁵²

However, Synosys did intend to patent the particles.¹⁵³ That fall, Dean suggested to Synosys’ patent council that Synosys, along with PL, might be entitled to a patent on the structure of the particles.¹⁵⁴ To Warner and PL, however, Afeyan disclosed that the group was only taking steps to patent a particle coating.¹⁵⁵ By the close of 1988 Regnier had written the disclosure that would become the issued patents, therein stating that the necessary flow and conditions for perfusive chromatography had never been disclosed before.¹⁵⁶

Unaware of the application in the works, PL continued its dealings with Synosys and Rounds, supplying the particles used

147. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *44-45.

148. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *19-20.

149. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *45-46. Though Warner did not know why: he thought it was due to surface area, and was dubious of Regnier’s perfusive explanation. *Id.* at *50.

150. *Id.* at *62-63.

151. *Id.* He also passed out abstracts. *Id.* at *111. Warner also followed up the presentation with a letter, expressing his anger that PL wasn’t given credit. *Id.* at *67.

152. *Id.* at *64.

153. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *150-51.

154. *Id.* at *85-86.

155. *Id.* at *88-89. As opposed to the perfusive chromatography itself.

156. *Id.* at *92. The court found the June 1988 presentation to disclose just such figures.

for research; in March of 1989, PL agreed to a distribution deal with Synosys and received a draft of a paper containing data from both labs.¹⁵⁷ By that July, an application had been filed that named Afeyan, Dean, and Regnier as the sole inventors of “perfusive chromatography,” and designated PL as but one source of useful perfusive material fabricated in an effort “initiated” by Regnier and pursuant to Regnier’s suggestion that PL make particles with a larger pore size.¹⁵⁸

The patent examiner initially rejected the Synosys application on prior art by PL, Rounds, and Regnier.¹⁵⁹ In traversing the rejection, the applicants argued disingenuously that two Lloyd references were cumulative, and that a Rounds reference displayed a flow rate slower than that claimed in the patent.¹⁶⁰ The alleged inventors argued that their invention was created sometime between June 22, 1988,¹⁶¹ and January 1st, 1989,¹⁶² and that prior to that time, none of the inventors were aware of pores bisecting the particles.¹⁶³ In a declaration of inventorship that used Rounds chromatograms from early 1988, dates redacted, as proof of

157. *Id.* at *79-80.

158. *Id.* at *93, *100-01.

159. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600 at *107. The original application even attempted to ensnare particles produced exclusively by PL. *Id.* at *102.

160. *Id.* at *106-07. In fact, the Lloyd references disclosed different flow rates, including one very high, and the Rounds reference disclosed a rate within the claimed range. The applicants also failed to disclose a third Lloyd reference, from March of 1988, that they were aware of and that disclosed figures used in the actual application. *Id.* at *103-04.

161. *Id.* at *108. The date of Regnier's presentation on the “Poros” particle that the examiner could have used as prior art. *Id.* at *63. Although Regnier distributed abstracts and presented slides at the presentation, during prosecution he explicitly stated that no such materials were distributed in what appeared to be an effort to stem argument that the display served as prior art. The alleged inventors also represented to the PTO that the presentation was not enabling, but Regnier later admitted that the results could be reproduced by anyone within a matter of hours. *Id.* at *116.

162. *Id.* at *113. This date corresponds to when an article describing Regnier's June 1988 presentation was published. *Id.* at *142-43.

163. *Id.* at *108-09. Afeyan went so far as to say he didn't know about the through pores until October. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *23.

reduction to practice, the alleged inventors further argued that not one of them knew about particle flow through before June of 1988.¹⁶⁴ In an attempt to diminish the contribution of PL, the applicants argued that “some batches” of large pore SAX coated PL particles displayed extraordinary separation results, but even these inconsistent materials were not used in, or available to the public prior to June, 1988—both arguments were false.¹⁶⁵ The misrepresentations did not stop at the USPTO: Regnier assured Purdue that he had never collaborated with PL and that the perfusion patents were in a different field than his lab work at the University.¹⁶⁶ Nonetheless, three patents pertaining to perfusion chromatography were issued from the original invention disclosure and patent application.¹⁶⁷

*C. The District Court’s Initial Treatment of the Invention:
PerSeptive I and II*

In *PerSeptive I*, PerSeptive Biosystems, Inc. [“PerSeptive”], brought an infringement suit against alleged infringers Pharmacia Biotech, Inc., et al. [“Pharmacia”].¹⁶⁸ PerSeptive was met with an affirmative defense asserting that its patents were invalid for failure to designate their true inventors.¹⁶⁹ The district judge sided with the defense, finding clear and convincing evidence showing that, at the very least, scientists from PL contributed to the invention as co-inventors by practicing the invention and

164. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *114.

165. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *24.

166. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *120. Of course, the patents contained images created in his laboratory, on materials created by PL. Regnier went on to suggest that reduction to practice occurred outside of Purdue, and that performance of particles in the Purdue labs was inadequately slow. *Id.* at *121-23.

167. *PerSeptive IV*, 225 F.3d at 1317.

168. The suit was brought against defendants Pharmacia Biotech, Inc., Sepracor Inc., Pharmacia LBK Biotechnology AB, Pharmacia Biotech. and Biosepra, Inc. by PerSeptive Biosystems, Inc., formerly Synosys, Inc., and the Purdue Research Foundation. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *1-3.

169. *Id.* at *3-4.

collaboratively refining materials, even if they did not understand exactly why the invention functioned.¹⁷⁰ However, the court recognized that the failure to name all proper inventors could be corrected through 35 U.S.C. § 256, provided that the named inventors did not act with deceptive intent in excluding the other true inventors.¹⁷¹ Declaring the record insufficient to determine whether the named inventors acted deceptively in excluding the others, the judge ordered a new trial to flesh out Afeyan, Dean, and Regnier's intentions.¹⁷² A finding of good faith, the judge ruled, would allow the correction of a valid patent.¹⁷³

In *PerSeptive II*, the court laid out the facts regarding the named inventor's behavior in an extended discussion, not once referring to the claims of the three patents.¹⁷⁴ Picking apart the behavior of the applicants, the judge enumerated four fundamental failures in honesty. First, the named inventors misrepresented the role of PL to the USPTO by dismissing PL as a mere raw materials supplier¹⁷⁵ that had produced 4000Å pore SAX particles in an effort initiated by Regnier.¹⁷⁶ Even if PL scientists were not inventors, the court reasoned, the duty of candor incumbent upon applicants required them to disclose the exact relationship of the important collaborators, allowing the examiner to make the ultimate legal determination.¹⁷⁷ Second, the named inventors misrepresented the timing of the invention: they were aware of particle flow-through far earlier than they represented.¹⁷⁸ Moreover, the court stated that

170. *Id.* at *39-41. The court articulated the standard of conception as a mental idea, but pointed out that the unnamed inventors obtained consistent results and understood the functioning of the particles and further asserted that merely stating a theory (as Regnier, Dean, and Afeyan apparently had) did not qualify as an invention. *Id.* at *30-31.

171. *Id.* at *42. This articulation of the law was incorrect, as the *Stark* decision, considered by the court in *PerSeptive III*, made clear. *PerSeptive III*, 12 F. Supp. 2d at 71.

172. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *45.

173. *Id.* The court placed the burden of showing no deceptive intent on *PerSeptive*. *Id.* at *45-46.

174. *See PerSeptive II*, 1997 U.S. Dist. LEXIS 8600.

175. *Id.* at *139.

176. *Id.* at *142.

177. *Id.* at *141-42.

178. *Id.* at *142. The judge adds Regnier's assertion that the June, 1988,

in furtherance of candor with the USPTO the dates of the chromatograms submitted as evidence of reduction to practice should not have been redacted.¹⁷⁹ Third, Regnier's assertions to Purdue that the inventions were outside the scope of his laboratory studies were either grossly negligent or outright lies.¹⁸⁰ And finally, the statements made by Synosys members to PL about their intent to pursue patent rights were deceptive.¹⁸¹ This "pattern of misrepresentations" by the applicants in pursuing their patents prevented the court from finding that PerSeptive acted without deceptive intent.¹⁸² Accordingly, PerSeptive's motion to correct inventorship was denied.¹⁸³

*D. Making Use of an Erroneously Pursued Intent Inquiry:
PerSeptive III*

Following issue of *PerSeptive II*, the Federal Circuit decided *Stark*, therein ruling that the proper inquiry for correcting inventorship under 35 U.S.C. § 256 was into the intent of the *unnamed* true inventor.¹⁸⁴ The district court reconvened the parties in *PerSeptive III* in light of the new understanding of the law.¹⁸⁵ The "unnamed true co-inventors," Warner and Lloyd, did not act with deceptive intent, according to the court, so the patents were correctable under § 256.¹⁸⁶ Relying again on *Stark*, the court turned its focus to the duty of candor the former applicants owed to the USPTO, purportedly limiting that focus to representations made regarding the collaborative nature of the inventions.¹⁸⁷

presentation was not accompanied by paper abstracts or slides, to a list of dishonest acts in this category. *Id.* at *149.

179. *Id.* at *147.

180. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600 at *150.

181. *Id.*

182. *Id.* at *156.

183. *Id.*

184. *PerSeptive III*, 12 F. Supp. 2d at 70-71 (citing *Stark*, 119 F.3d at 1552).

185. *PerSeptive III*, 12 F. Supp. 2d at 70-71.

186. *Id.* at 71. The court also noted that these inventors may be estopped from asserting ownership interests in light of their failure to intervene in the proceedings. *Id.*

187. *Id.* Although the court also pointed out the four material

The court laid out the elements of inequitable conduct—materiality and intent to deceive¹⁸⁸—noting that “close cases should be resolved by disclosure [to the USPTO], not unilaterally by the applicant.”¹⁸⁹ Failing to name an inventor with deceptive intent would constitute filing a false oath, and thus be material.¹⁹⁰ Given the consistent course of misrepresentations concerning the relationship between the named inventors and Warner and Lloyd, the court found “clear and convincing evidence of deceptive intent on inventorship.”¹⁹¹ The district court concluded that PerSeptive had committed inequitable conduct because it failed to either disclose these relationships or articulate a theory of joint inventorship under § 116 that accounted for the exclusion of Lloyd and Warner as named inventors.¹⁹²

However, the court’s logical clarity dissipated when it refused to entertain PerSeptive’s request for a jury verdict on the proper inventive entity¹⁹³ and asserted that the record bore enough evidence to support the court’s earlier determination of joint inventorship by Warner and Lloyd under a summary judgment standard.¹⁹⁴ Denying PerSeptive’s request to introduce additional evidence relating to any misrepresentations,¹⁹⁵ the court stated that the “basis of [its] conclusion that there was inequitable conduct [was the court’s] finding of a deliberate omission of a true

misrepresentations were made concerning the timing of the invention, it focused its inequitable conduct inquiry on the omission of inventors because that issue was substantially the same as that litigated in the § 256 hearing and, thus, would not create any unfair surprise prejudicing the parties. *Id.* at 72.

188. *Id.* at 72 (“Inequitable conduct resides in the failure to disclose material information with an intent to deceive or mislead the PTO” (quoting *Critikon*, 120 F.3d at 1257)).

189. *PerSeptive III*, 12 F. Supp. 2d at 72.

190. *Id.*

191. *Id.* at 73.

192. *Id.*

193. *Id.*

194. *Id.*

195. The court assumed that the additional evidence PerSeptive intended to introduce was related to misrepresentations because PerSeptive suggested, in *PerSeptive II*, that it had evidence to show that the misrepresentations were not material. *PerSeptive III*, 12 F. Supp. 2d at 74.

inventor,” *not* misrepresentations.¹⁹⁶ Accordingly, the court found in favor of Pharmacia on its inequitable conduct defense.¹⁹⁷

E. The Federal Circuit Weighs In: PerSeptive IV

A divided Federal Circuit affirmed the district court, albeit under slightly different reasoning.¹⁹⁸ Writing for the majority, Judge Clevenger downplayed the importance of the district court’s holding that inventorship on the patents was incorrect, noting instead that the “persistent course of material misrepresentations, omissions and half truths to the PTO” concerning inventorship was highly material.¹⁹⁹ “The district court specifically stated that the *PerSeptive I* conclusion—that inventorship of the patents was incorrect—was unnecessary to the inequitable conduct decision,” Clevenger explained.²⁰⁰ “[F]alsehoods and omissions” were designed to cloud the issue of inventorship, an essential condition of patentability and examination.²⁰¹

Although *PerSeptive* argued that by narrowing the claims during prosecution to avoid reading on any contribution by Warner or Lloyd it had cured any possible inventorship issues, the majority found its arguments irrelevant.²⁰² Correct inventorship upon issuance does not make statements made during prosecution any less material, the court reasoned, as the test for materiality does not depend on what is correct, but rather what a “reasonable examiner” would consider important.²⁰³ The majority would have the patent

196. *Id.* at 74.

197. *Id.*

198. *PerSeptive IV*, 225 F.3d at 1317.

199. *Id.* at 1321 (citing *PerSeptive III*, 12 F. Supp. 2d at 73).

200. *PerSeptive IV*, 225 F.3d at 1321. However, as discussed in the preceding paragraph, the *PerSeptive III* court also held that the deliberate omission of a true inventor, and not misrepresentations, was the basis for its inequitable conduct ruling. 12 F. Supp. 2d at 73.

201. *PerSeptive IV*, 225 F.3d at 1321 (citing 35 U.S.C. § 102(f); 35 U.S.C. § 116; MPEP, *supra* note 77, §§ 2004, 2137.01; and 37 C.F.R. § 1.56). This assertion is disputed by the dissent, which noted that examiners must accept inventorship as asserted by the applicants. *PerSeptive IV*, 225 F.3d at 1330.

202. *PerSeptive IV*, 225 F.3d at 1322.

203. *Id.* The Federal Circuit agreed with the district court that inventorship is still material under the new PTO rule that states “information is material to

examiner provided with an excess of information, allowing her to make the critical inventorship determination.²⁰⁴ Additionally, the court reasoned that intentional false statements may be material even if independent of the claims, as the inquiry is focused not on “inventorship per se, but misinformation about inventorship.”²⁰⁵

Concluding that the district court made no clear error in finding intentional falsehoods presented to the USPTO all directed towards the issue of inventorship and, thus, did not abuse its discretion in finding the patents unenforceable for inequitable conduct, the Federal Circuit affirmed.²⁰⁶

*F. A Different Take—Judge Newman’s Dissenting Focus on
Inventorship Law*

In her vehement dissent, Judge Newman took issue with the majority’s failure to give due effect to the patented claims or acknowledge the very definition of inventorship.²⁰⁷ Focusing her analysis on inventorship as opposed to inequitable conduct, Newman found no legally sanctionable behavior on the part of the named inventors.²⁰⁸ She explained that inventorship depends on who conceived of an invention—who had a “definite and permanent” *idea*, such that one skilled in the art could understand the invention—not on who developed it or reduced it to practice.²⁰⁹

Likewise, she reasoned, legally cognizable contributions to invention come from contributors who co-conceived of the subject

patentability when . . . it refutes, or is inconsistent with, a position the applicant takes in asserting an argument of patentability.” *Id.* (quoting 37 C.F.R. § 1.56(b)(2)(i)-(ii) (1999)). Yet the reasonable examiner standard still holds as law today. *See Advanced Magnetic Closures*, 607 F.3d at 829.

204. *Id.* *But see id.* at 1330 (Newman, J., dissenting) (explaining that an examiner would not be permitted to make a rejection of the application on § 102(f) grounds on the facts of this case).

205. *Id.* at 1322. Judge Newman, in dissent, responded that inventorship is determined based upon the claims, thus for any statement regarding inventorship to be material, it must be related to the claims. *Id.* at 1324.

206. *Id.* at 1322-23.

207. *Id.* at 1324.

208. *Id.* at 1331.

209. *PerSeptive IV*, 225 F.3d at 1324 (emphasis added).

matter—mere collaboration on a project with a common end would not constitute joint invention.²¹⁰ Whereas Warner was on record as rejecting the perfusion concept claimed in the patents, named inventors Regnier, Afeyan, and Dean studied and determined *why* the columns performed as they did.²¹¹ Newman reasoned that this understanding, arrived at through scientific study and reflected in the issued claims limitation that particles contain pore sizes sufficient for perfusion chromatography, was the heart of the invention because its disclosure would allow others to practice the invention and obtain consistent results.²¹² The named inventors alone were responsible for this conception and, thus, were the only true inventors of the patented subject matter.²¹³ Moreover, even if inventorship was incorrect, on Newman's view of the facts²¹⁴ there was no inequitable conduct because "an error in determining inventorship is not by itself inequitable conduct."²¹⁵

IV. ANALYSIS

Though decided 10 years ago, a key rule of law from

210. *Id.* at 1324-25.

211. *Id.* at 1325.

212. *Id.* at 1327. However, the district court found evidence to suggest that the inconsistency in results was not the fault of the particles, but rather problems elsewhere in the column. Thus, PL could produce consistent results prior to the patents' disclosure. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *72-73.

213. *PerSeptive IV*, 225 F.3d at 1327.

214. Judge Newman found fault with each of the majority's specific instances of misrepresentation. *Id.* at 1328. She reasoned that the patents' statement that Regnier "initiated" particle production was correct, as his lab made the initial contact with PL, but even if false, the statement was immaterial as PL, the collaborators, played no part in the conception of the claimed invention. *Id.* at 1329. Similarly, none of the undisclosed prior art the majority and the district court found indicative of inventive discovery related to the substance of the claimed invention—perfusives chromatography. *Id.* In addition, Newman reasoned that reporting on collaborative relationships and exchange of scientific data to the USPTO is unnecessary when the collaboration and data exchange don't reflect the claimed invention. *Id.* at 1329-30. Finally, Judge Newman found the statement that PL was a source of raw materials to be true, not misleading. *Id.* at 1330.

215. *Id.* at 1327 (quoting *Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1576 (Fed. Cir. 1996)).

PerSeptive—that full inventorship inquiry is not necessary for a finding of inequitable conduct related to inventorship—is still used today²¹⁶ and may be of use to litigants opposing alleged biopirates. Where the statutory requirements of inventorship law offered no salient punitive options, the more-amenable-to-interpretation inequitable conduct doctrine allowed the court to reach a “just” result.²¹⁷ Discussed below, Judge Newman’s dissent, especially in light of the extensive record at the district court, suggested that the holding may not have stood for long and, consequently, would offer no footing for biopiracy opponents. Alternatively, a reading of the case marrying Judge Newman’s inventorship-focused dissent with the majority’s inequitable conduct holding would likewise provide little aid to those seeking to render patents unenforceable if obtained with the unrecognized aid of traditional knowledge. However, subsequent case law suggests that under some sets of circumstances, including those posited below, *PerSeptive IV* may provide some support for patent challengers. This little bit of leeway, this thin area of gray, could provide opponents of the inequitable practice of biopiracy the legal hook they need when technical claim requirements and statutory inventorship considerations are stacked so clearly against them. Admittedly, the supports for a patent challenge that relies on an inequitable conduct affirmative defense are shaky and present large evidentiary and financial hurdles, but the very ambiguity in the law lends credence to calls for a more formalized system of disclosure requirements regarding traditional knowledge.

216. See, e.g., *Advanced Magnetic Closures*, 607 F.3d at 828, 832 (stating that a determination of inventorship is not necessary for a finding of inequitable conduct surrounding inventorship and citing *PerSeptive IV* as an instance of the court finding patents unenforceable for the named inventors misrepresentation of a relationship with others who might have been true inventors).

217. Antigone Kriss, *Misrepresentation of Inventorship and the Inequitable Conduct Defense: PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 FED. CIR. B.J. 285, 318 (2002).

A. Interpreting the Decision

1. As Establishing a Broadened Inventorship Inquiry

While inventorship depends on who actually conceived the invention, disclosures surrounding inventorship should encompass anything a reasonable patent examiner might find important in determining who conceived of an invention.²¹⁸ This formulation casts a wider net and, in *PerSeptive IV*, did so without considering the claimed invention of the issued patent.²¹⁹ It is therefore unclear how the *PerSeptive IV* majority determined just what was related to invention. This blurry vision regarding the law of inventorship allowed the court to make the correct equitable decision.²²⁰

Perhaps the key to this decision, derided by at least one commentator for its logical failings regarding inventorship, is the notion of equity.²²¹ The applicants behaved dishonestly in general.²²² Perhaps the judiciary could not condone such behavior with regard to the patent office²²³ or support an applicant lying to collaborators,²²⁴ whether those collaborators contributed to the invention or not. As Judge Newman noted in her dissent, behavior unrelated to inventorship was not far beneath the surface in the majority opinion.²²⁵ An extended recitation of facts detailing

218. *PerSeptive IV*, 225 F.3d at 1321. This requirement could presumably include product suppliers, collaborative partners, sources of knowledge, etc.

219. *Id.* at 1331 (Newman, J., dissenting).

220. Kriss, *supra* note 217, at 318. See also “Equity,” “Equitable,” THE LAW DICTIONARY, (Anderson Publishing Co. 2002) (defining equity itself as referring to “fairness,” while equitable outcomes are described as “fair, reasonable, or proper.”). Indeed, historically, it was the courts of equity that had the power to apply novel remedies to the cases brought before them. Equity is also described as “the recourse to principles of justice to correct or supplement the law as applied to particular circumstances.” BLACK’S LAW DICTIONARY 619 (9th ed. 2009).

221. Kriss, *supra* note 217, at 317-18.

222. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *139-50.

223. *Id.* at *133-42 (detailing dishonest behavior towards the USPTO).

224. *Id.* at *64 (Afeyan assuring PL that no patent application was under preparation).

225. *PerSeptive IV*, 225 F.3d at 1331 (Newman, J., dissenting) (noting that

dishonest acts unrelated to the issue of inventorship may have given both the district and appellate courts overwhelming motivation to find against the patentees.²²⁶ Thus, it is unsurprising that the court found a way to punish the dishonest applicants.²²⁷ Aid to opponents of biopiracy lies in this reading of the case: though statutory inventorship requirements are stacked against traditional knowledge holders, a court disinclined to reward the dishonest behavior inherent in biopiracy may resort to *PerSeptive IV*'s broadened inventorship inequitable conduct inquiry to achieve an equitable result.

2. *As Decided Incorrectly*

However, it is difficult to dismiss assertions that the case was incorrectly decided. On their face, Judge Newman's arguments against the majority are thoughtful, well reasoned, logically sound, and of no help to potential biopiracy opponents seeking an inequitable conduct finding regarding inventorship.²²⁸ At least one other commentator seems to agree that the case was incorrectly decided, noting that the majority's holding runs counter to settled inventorship inquiries and related disclosure requirements.²²⁹ As Judge Newman articulated, inventorship depends on claims,

the majority's reference to an asserted commercial threat by *PerSeptive* against PL is "unrelated to inventorship or inequitable conduct in the PTO").

226. See *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *133-51.

227. *PerSeptive IV*, 225 F.3d at 1317.

228. *Id.* at 1323-31. It appears, however, that not all inequitable conduct arguments would be foreclosed under Judge Newman's dissent. In *PerSeptive II*, a key factor for the district court was the evidence of reduction to practice obtained in January and February of 1988 by Rounds, which the named inventors used to support a declaration that the invention was conceived five months later. Although the district court pointed out that reduction to practice does not precede conception, Judge Newman looked past this finding in considering the propriety of inventorship as designated. A court, on remand, may also have pointed to the named inventors' failure to disclose prior art unrelated to inventorship, such as failing to mention the full invention disclosure that occurred at the June 1988 meeting, or failing to inform examiner that slides were present and abstracts handed out then, in finding the patent unenforceable for inequitable conduct.

229. Kriss, *supra* note 217, at 317-18.

specifically on who first conceived of a claimed invention.²³⁰ Inequitable conduct based on failure to invent would thus, per Judge Newman's view, require an inquiry into who actually conceived of claimed subject matter.²³¹ Without recourse to a clear inventorship disclosure standard, the decision *could*, as Newman suggested, open up the door for a "plague" of essentially baseless inequitable conduct allegations.²³² As both the act of conception and the technical nature of the claims are likely outside the capacity of traditional knowledge holders, Judge Newman's suggested inquiry would effectively eliminate the need to disclose traditional knowledge contributions by restricting the scope of an inventorship inquiry to the claims as issued. Moreover, the seemingly contradictory statements from *PerSeptive III* (stating that the inequitable conduct was based on the intentional omission of a true inventor²³³) and the majority in *PerSeptive IV* (characterizing the *PerSeptive III* court as relying on a series of misrepresentations to find inequitable conduct²³⁴) lend further support to the notion that the case was decided in error.

3. *As Focusing on the Timing of the Statements*

Alternatively, the majority's inequitable conduct finding could be reconciled with Judge Newman's inventorship inquiry by considering the timing of the "misrepresentations" at issue. When the maligned statements were made to the examiner, Lloyd and Warner—creators and testers of the perfusive material—may have

230. *PerSeptive IV*, 225 F.3d at 1324.

231. *Id.* at 1324-25. Judge Newman restricted her inequitable conduct inquiry to inventorship issues in a manner congruent with the prejudice arguments of *PerSeptive*. In order to avoid any prejudice arguments *PerSeptive* might bring for its inability to introduce evidence not relevant to the § 256 issue, the district court excluded some of the most culpable behavior by the named inventors from playing an active role in the logic of its holding.

232. *Id.* at 1329 (Newman, J., dissenting) ("The panel majority's requirement that collaborative relationships must be reported to the PTO, whether or not any collaborator is an inventor of what is claimed, is as incorrect as it is unworkable. This ruling will outdistance any earlier 'plague' of attacks on patents.").

233. *PerSeptive III*, 12 F. Supp. 2d at 74.

234. *PerSeptive IV*, 225 F.3d at 1319-20.

had some inventive right to the claims as they then existed.²³⁵ Indeed, just making the argument that narrowing claims in prosecution “cur[ed]” the problem with regard to inventorship suggests that before the claims were narrowed there was a problem with inventorship designation.²³⁶ Inequitable conduct may occur at any point in the prosecution of the patent; an analysis of the applicant’s conduct with regard to the claimed invention, as it exists at each point in time during the prosecution, seems warranted.²³⁷ Accordingly, a rigorous inventorship inquiry into the claims *as filed*, considering conception in light of each claim limitation, may have revealed the culpable statements and misrepresentations to be material even under Judge Newman’s standards.²³⁸ Had the majority articulated such an inquiry, the decision may have received unanimous support from the Federal Circuit panel, yet the potential value to biopiracy opponents would have been eliminated.

4. Courts Applying the Broadened Inquiry

Subsequent case law reveals that the decision has been interpreted as suggesting that the inquiry for inequitable conduct regarding inventorship is broader than the inquiry for inventorship itself.²³⁹ Indeed, the majority’s failure to focus on claims was never

235. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *101 (claim 20, as filed, read on the PL particles). The duty of candor applies throughout the patent process. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995).

236. *PerSeptive IV*, 225 F.3d at 1322.

237. *Molins PLC*, 48 F.3d at 1182; 37 C.F.R. § 1.56(a).

238. *PerSeptive IV*, 225 F.3d at 1323-24. Without the limitation “suitable for perfusion,” there would be no need for co-inventors to understand the scientific basis that Newman argues is so important to conception.

239. *Id.* at 1322 (“the issue is not inventorship per se, but misinformation about inventorship”). *See Powell v. Home Depot U.S.A., Inc.*, 2010 U.S. Dist. LEXIS 52592, *19-20 (S.D. Fla. May 28, 2010) (recognizing that the disclosure of a saw was warranted to inform the examiner on inventorship even though the disclosure would not have proven improper inventorship); *Leviton Mfg. Co. v. Universal Sec. Instruments, Inc.*, 606 F.3d 1353, 1360-62 (Fed. Cir. 2010) (finding a duty to disclose a patentee’s earlier patent application which claimed the same subject matter as a patent under prosecution, yet named a different set

specifically repudiated and, contrary to Judge Newman's dire warning, subsequent decisions citing the *PerSeptive IV* holding show that the court's seemingly novel equitable power has not been abused.²⁴⁰ *PerSeptive IV* has been applied very infrequently and only, as in *Advanced Magnetic Closures*, when circumstances clearly demonstrate inequitable behavior.²⁴¹ The *PerSeptive IV* rule allows the court to find patents granted to dishonest applicants unenforceable without going through the formal steps of inventive inquiry.

In *Advanced Magnetic Closures*, *PerSeptive IV* was cited for the

of inventors and recognizing that, regardless of whether inventorship was technically correct, the examiner had a right to inspect both applications to assess inventorship because an issue of inventorship may still exist); *Hypoxico, Inc. v. Colo. Altitude Training, LLC*, 2008 U.S. Dist. LEXIS 67222, *44-46 (S.D.N.Y. Sept. 3, 2008) (explicitly recognizing that inquiries into inventorship under § 102(f) are not to be confused with inventorship disclosure requirements in the context of an inequitable conduct inquiry). However, in some decisions where inventorship was determined prior to analysis of inequitable conduct claims, the finding of proper inventorship was relied on by the court in rejecting claims for inequitable conduct for failure to disclose information material to inventorship. See *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 2010 U.S. Dist. LEXIS 36127, *88-89 (S.D. Cal. Apr. 13, 2010) (finding disclosure of an inventorship dispute "very unlikely" to be material when a jury had rejected an improper inventorship claim on the same grounds); *Sunbeam Products, Inc. v. Wing Shing Products (BVI) Ltd.*, 311 B.R. 378, 398 (S.D.N.Y. 2004) (stating that the failure to disclose information related to an alleged co-inventor could not be the basis for an inequitable conduct finding where another court had already determined the individual not to be a co-inventor: "[s]ince the Bankruptcy Court determined (and this Court affirmed) that Mr. Coffee was not a joint inventor of the Patent, Sunbeam's first point could not be the basis for finding inequitable conduct sufficient to deem the Patent unenforceable." (citing *PerSeptive IV* at 1321.)), *aff'd* 153 Fed. Appx. 703 (Fed. Cir. 2005); *Bd. of Trs. of Fla. State Univ.*, 333 F.3d at 1344 (finding that information regarding the contributions of an individual determined by the court not to be an inventor could not be material to any issue of patentability).

240. See *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1126, 1137-38 (E.D. Cal. 2002) (finding that one of many conversations with fellow scientists regarding a patent's subject matter did not need to be disclosed to the examiner to properly disclose information regarding inventorship).

241. *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, No. 98 Civ. 7766 (PAC), 2008 U.S. Dist. LEXIS 54615, *6, *27-30 (S.D.N.Y. July 17, 2008), *aff'd* 607 F.3d 817 (Fed. Cir. 2010).

proposition that a determination of inventorship isn't necessary for inventorship based inequitable conduct.²⁴² Although the facts and procedural history here differ from the *PerSeptive* decisions in some key aspects,²⁴³ general misconduct by the applicant towards the USPTO regarding inventorship once again obviated the need for a specific finding of inventorship.²⁴⁴ Again, as in *PerSeptive*, the court saw no threat of prejudice in making an inequitable conduct ruling involving inventorship without giving the parties a chance to brief the inventorship issue as a standalone question.²⁴⁵ Thus, where the facts found by the district court generally detailed dishonest behavior on the part of a patentee, the court again asserted some freedom to make equitable determinations surrounding inventorship without delving into a rigid claim interpretation and conception discussion.²⁴⁶

B. *PerSeptive* Applied to Biopiracy

With the scene set by the INDECOPI pamphlet described in this Note's introduction as a jumping off point, it is not hard to imagine

242. *Advanced Magnetic Closures*, 607 F.3d at 827-28.

243. Here, there was deposition evidence that the named inventor did not in fact invent the subject matter claimed. *Id.* at 824. The district court here did construe the patent claims, and questioned the alleged inventor about their conception, only to find that he had no apparent familiarity with the conceived subject matter. *Advanced Magnetic Closures*, 2008 U.S. Dist. LEXIS 54615, at *6, *27-30. "We believe that the district court's findings showing that Mr. Bauer was not the true inventor support its finding of intent to deceive." *Advanced Magnetic Closures*, 607 F.3d at 830.

244. *Advanced Magnetic Closures*, 607 F.3d at 830. The court enumerated several specific findings concerning the named inventor's veracity in attempting to assert his inventive act, noting specifically that he did not appear to understand the science behind his alleged conception, that sketches submitted to support his conception were later admitted to be reconstructions, and that he gave "evasive, argumentative, and at times contradictory testimony on his status as inventor." *Id.* at 830.

245. The parties had a chance to address inventorship in the context of an inequitable conduct hearing for attorney's fees, and as indicated by their briefs, they knew that inventorship was an issue. *Id.* at 827.

246. See *PerSeptive IV*, 225 F.3d at 1331 (Newman, J., dissenting). The burdens of proof for inequitable conduct still apply.

a situation analogous to *PerSeptive* or its progeny that would allow a court, armed with *PerSeptive* and a strong sense of fairness, to exercise its equitable powers to “respect”²⁴⁷ the contributions of traditional knowledge holders.

1. *A New Cure for the North*

Juan, Maria, and the “gringo,” Mike are in Juan and Maria’s Amazonian village, a community steeped in traditional knowledge and endowed with a rich reserve of biodiversity. Juan guides Mike to a small vine and explains that generations of his ancestors have used the vine as a cure for stomachaches.²⁴⁸ Mike, an American ethnobotanist who specializes in herbal remedies for stomach problems, listens intently, paying close attention to the vine’s suggested use.²⁴⁹ Intrigued, he takes a sample back to the U.S.A. to run some tests. Mike returns to the village a few months later, having determined the major alkaloids of the vine, but seeing no indication of significant pain relief in vine-ingestion animal studies. After revealing his negative results to Juan, Mike learns that the vine must be dried thoroughly in the sun, rinsed in water, then macerated for a week in aguardiente—a strong alcohol used by the native Amazonians—to unlock its healing properties.²⁵⁰ This knowledge, along with more samples of the vine, accompany Mike back to his home country, where he converts the knowledge

247. CBD, *supra* note 31, art. 8(j), 1760 U.N.T.S. at 149. It is important to note that a successful inequitable conduct suit can provide direct *dignitary* respect, but only attenuated *financial* respect. A finding of inequitable conduct will render a patent unenforceable. This may deter prospective biopirates from exploiting additional traditional knowledge, but it will not provide an indigenous community with compensation for knowledge already exploited.

248. The community’s history of preparation and use of the vine is analogous to PL’s history of developing particles suitable for column chromatography. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *9.

249. Like Dr. Regnier in *PerSeptive*, Mike is a noted expert in the field relating to the patentable subject matter. Regnier Publication List, *supra* note 129.

250. PL, the resource provider, engaged in a similar open exchange of information with Regnier, never suspecting that the result might ultimately preclude it from doing whatever it pleased with the products it developed. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600 at *79-80.

shared with him by Juan into a scientific procedure that comprises dehydrating the vine, immersing it in water, then macerating the plant material in 96 percent ethanol.²⁵¹ The resultant concentrated extract *does* exhibit an effect in animal studies. Mike publishes the results of his studies and announces his finding: a stomachache cure previously unknown to herbal medicine. He neglects to mention that the cure had been in use by Juan's community for generations.²⁵² Citing his personal publication along with a few old articles from a journal of ethnobiology as prior art, Mike applies for, and is granted, a patent on the vine extract containing certain percentage ranges of the alkaloids he identified which is useful to treat stomachaches.²⁵³

Back in the Amazon, Juan and Maria see a surge in demand for their native vine. The vines, once valued primarily for their medicinal properties, are harvested indiscriminately as locals rush to capitalize on the plant's new cash value.²⁵⁴ Confused at first, Juan and Maria soon learn the cause of their environmental flux: with a patent securing his investment, Mike has poured resources into both an operation to harvest mass amounts of the vine for extraction and a marketing campaign extolling the virtues of the Amazonian wonder vine.²⁵⁵ Mike and his new vertically integrated enterprise monopolize the vine market—no other company can legally produce the vine extract without infringing Mike's patent, and Mike threatens suit on any company attempting to enter the

251. Similarly, Regnier, Dean, and Afeyan conducted tests on materials supplied in good faith by PL, eventually elucidating properties unknown to PL. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *20-21.

252. Regnier's relabeling of PL particles as his own "Poros" technology is analogous to this deceptive behavior. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600 at *62-63.

253. Mike's failure to mention information gleaned from Juan parallels Regnier's failure to cite PL publications that read on specific claims of the perfusion chromatography patent applications. *Id.* at *106-07.

254. The right to control resources in the interest of preserving biodiversity is essential to an equitable system of intellectual property rights and, as described here, is lacking under the current system. Bratspies, *supra* note 9, at 329.

255. Regnier similarly trumpeted his discovery of perfusion chromatography in the hopes of creating a large market for the technology he would claim as his own. *PerSeptive II*, 1997 U.S. Dist. LEXIS 8600, at *62-63.

vine extract market.²⁵⁶

Juan and Maria are distressed—not only is their local resource being depleted at an alarming rate,²⁵⁷ but they are also receiving less than they might for the loss because of Mike’s market domination.²⁵⁸ Determined not to let Mike exploit their resources and knowledge without a fight, the two, with the support of their community, start harvesting the vine themselves and selling its extract to companies formed by Amazonians living in the United States.²⁵⁹ Mike brings an infringement suit against the U.S. companies offering the extract for sale and litigation ensues.²⁶⁰

2. *A Dearth of Remedies for the South*

Assuming the companies buying vine extract from Juan and Maria can find and afford adequate legal representation for a patent dispute, they face generally bleak legal prospects. These

256. PerSeptive sought similar monopoly control, even with regard to material produced by its own supplier, PL. *PerSeptive I*, 1996 U.S. Dist. LEXIS 21908, at *1-3.

257. SHIVA, *supra* note 13, at 72-77 (characterizing patents on biological resources as consumptive of biodiversity).

258. *See, e.g.*, Carlsen, *supra* note 27, at 85-86 (describing the effect of a patent claiming the Enola bean, and a resultant royalty cost, on Mexican producers of similar beans).

259. To even raise an inequitable conduct argument Juan and Maria face an uphill battle. They cannot challenge the patent directly through the USPTO because the USPTO only allows for reexamination based on prior art patents or printed publications. 37 C.F.R. § 1.510(a) (2009). Even a single argument not directed to claim validity in light of prior art patents or publications will disqualify an otherwise valid reexamination request. MPEP, *supra* note 77, § 2205. Alternatively, Juan and Maria could not assert an inequitable conduct charge based only on Mike’s alleged improper dealings with the USPTO. Inequitable conduct is an affirmative defense and, as such, can only be brought after a party has been accused of infringement or in a declaratory judgment suit where the threat of an infringement action is palpable enough to establish an actual case or controversy. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007).

260. 35 U.S.C. § 271 (2006) (“whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent”).

alleged infringers cannot argue that Mike's patent is invalid for lack of novelty or obviousness: no printed publications describing the vine, its preparation, and use existed—the Amazonian community's knowledge was passed from generation to generation orally.²⁶¹ Arguing that Mike derived the invention from their community is similarly futile: the patented extract consisted of specific percentages of component nutrient parts that the community had never even heard of, let alone quantified. Moreover, even if a court found that the community had inherently conceived of the patented invention, Juan would still have to prove communication—his uncorroborated testimony, recounting the communication to Mike in the middle of the forest, would not likely serve as adequate proof.²⁶²

An unenforceability argument, however, is more likely to succeed. Relying on *PerSeptive IV*, Juan and Maria's patrons can argue that, just as Polymer Labs provided particles to Regnier, the Amazonian community provided the vine to Mike. Mike and Juan both sought to use the vine with a common end in mind, and they engaged in a free exchange of information in achieving their intended outcome, just as PL and Regnier both sought to use the PL particles for efficient solute separation and shared information regarding the same. Although the idea conceived of by Regnier, Afeyan, and Dean was beyond the ken of PL, just as the conception attributed to Mike in his patent was beyond the grasp of Juan and Maria, an inquiry into the conception of a claimed invention is unnecessary in an inequitable conduct action.²⁶³ Mike disclosed the geographical source of the vine in order to satisfy the patent statute's enablement requirement, but his failure to mention the knowledge shared with him by Juan may give a court grounds to find his otherwise unscrupulous behavior sanctionable under the inequitable conduct doctrine. Mike's omission was "about inventorship;" arguably, a reasonable examiner would want to know the exact relationship between Mike and his indigenous vine

261. Subbiah, *supra* note 37, at 545.

262. See *Brand*, 487 F.3d at 869-70.

263. *PerSeptive IV*, 225 F.3d at 1327 (Newman, J., dissenting) (criticizing the majority's lack of attention to the claims).

supplier.²⁶⁴

Admittedly, such an argument is thin gruel to sustain an inequitable conduct charge.²⁶⁵ Mike's good faith belief that he had no duty to disclose the contributions from Juan to his invention may shelter him from an inequitable conduct finding.²⁶⁶ And yet, Juan, Maria, and their buyers would seem to have no other options under the patent law. They would be forced to rely on the court's sympathies to their plight, in association with its broad equitable power under *PerSeptive*, in achieving a legally supportable inequitable conduct defense and, consequently, a "just" outcome to their case.²⁶⁷

C. An Opportunity for Progress

1. Steadying the Inequitable Conduct Doctrine

As beneficent as a ruling protecting the rights of the Amazonian community might be, in the above hypothetical the disclosure requirements and final disposition are far from certain. Yet, such

264. *Id.* at 1322 ("the issue is not inventorship per se, but misinformation about inventorship").

265. Without positing an unlikely set of egregious and unnecessary misrepresentations to the USPTO on behalf of Mike—for example, stipulating an invention disclosure that details how the patented subject matter reached Mike's consciousness through a series of dreams—a consistent pattern of misrepresentation, like that found in *PerSeptive*, is lacking. Indeed, without printed prior art asserted by an examiner, and arguments to overcome the same by the applicant, there would not likely be an opportunity to establish any pattern of behavior, good or bad. This would make the requisite showing of intent, inferred from all circumstances, very hard to achieve. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-29 (Fed. Cir. 2009) (establishing heightened pleading standards in inequitable conduct, including the requirement that intent to deceive the patent office is the "single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard of proof" (citing *Star Scientific*, 537 F.3d at 1365)).

266. *See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006) (stating that the absence of a good faith belief that a reference was immaterial was not sufficient to infer an intent to deceive).

267. Kriss, *supra* note 217, at 317-18.

uncertainty in the applicability of a legal requirement is contrary to the basic rule of law—laws are to be clear and predictable.²⁶⁸ Implementing specific disclosure requirements would provide clarity in traditional knowledge patents, stem possible charges of inequitable conduct when patents are not obtained from traditional knowledge,²⁶⁹ and still allow courts to maintain their powers of equity when statutory inventorship law would reward unscrupulous applicants. Judge Newman vigorously protested the potential application of the *PerSeptive IV* majority holding on the grounds of certainty, lamenting that requiring a broad disclosure of collaborators or inventive issues not necessarily related to claims would outstrip any prior inequitable conduct ruling in expanding the scope of who could claim the doctrine.²⁷⁰ One commentator shared Newman’s pessimism about inventorship designation in basic research settings: considering an interconnected research environment, *PerSeptive IV* offered little guidance as to where one could safely draw a line separating material collaborators, whose efforts should be disclosed as having a bearing on inventorship, from those who need not be discussed in a disclosure.²⁷¹ Other commentators bemoaned unclear disclosure requirements as well: just what is required to be disclosed, and don’t limitless disclosure requirements create a heavy burden on the patent examiner, forced to wade through all the disclosed material in a limited time frame?²⁷²

Rather than leave this area of law gray, however, specific guidance could be provided to aid all parties involved: clearer standards could allow patent applicants to disclose the proper

268. See Thomas Bingham, *The Rule of Law*, 66 CAMBRIDGE L.J. 67, 69-71 (2007).

269. *UNCTAD Disclosure Analysis*, *supra* note 10, para. 58.

270. *PerSeptive IV*, 225 F.3d at 1329 (Newman, J., dissenting) (“The panel majority’s requirement that collaborative relationships must be reported to the PTO, whether or not any collaborator is an inventor of what is claimed, is as incorrect as it is unworkable. This ruling will outdistance any earlier “plague” of attacks on patents.”).

271. Kriss, *supra* note 217, at 329.

272. *E.g.* Dolak, *supra* note 124, at 567; Kriss, *supra* note 217, at 329 (stating that disclosures could prove to be an unreasonable burden on applicants and examiners).

information, with less fear of possible inequitable conduct unenforceability, while simultaneously giving patent challengers a better gauge of their chances in challenging an issued patent.²⁷³ Because inequitable conduct law is currently under review,²⁷⁴ providing clarification of inequitable conduct inventorship disclosure requirements would not disrupt a well-settled doctrine. In clarifying, the courts or the USPTO could bring the U.S. up to speed with international law without imposing a substantial burden on the patent prosecution process in the United States.²⁷⁵ Simultaneously, formal clarification has the potential to prevent the issuance of bad patents.²⁷⁶ Requiring a patent applicant seeking to claim subject matter related to genetic resources or traditional knowledge known or used in another country to fully disclose the origin of the material and extant traditional knowledge would begin to bring the United States into line with the suggestions of the Bonn guidelines interpreting the requirements of the CBD.²⁷⁷ This change could ultimately result in fewer legal instances of intellectual property misappropriation from developing nations.

2. *PerSeptive as a Launching Point for International Accord*

There is broad support for this disclosure requirement to be found in international treaties, international organizations, and

273. *UNCTAD Disclosure Analysis*, *supra* note 10, para. 58.

274. *See Advanced Magnetic Closures*, 607 F.3d at 835 (Rader, J., concurring) (suggesting that additional inequitable conduct cases be decided after the court clarifies the doctrine in the *en banc Therasense* appeal).

275. The patent examiner would still be required to assume the inventorship is correct as declared in the inventorship oath, thus adding little more burden than a filing burden to the patent prosecution. MPEP, *supra* note 77, §§ 2137.01, 706.02(g). *But see* de Carvalho, *supra* note 14, at 391 (noting the United States argument that disclosure requirements would increase the cost of record keeping resulting in an increased cost of production).

276. Kuruk, *supra* note 7, at 680. Given the tremendous financial burden of litigating the enforceability of an issued patent and biopiracy opponents' very limited financial means, firm guidance from the federal courts resulting from a biopiracy related judgment is highly unlikely. Rules promulgated by the USPTO provide a better arena for establishing specific disclosure requirements.

277. *See* de Werra, *supra* note 29, at 152-55.

scholarly literature.²⁷⁸ The CBD, finalized in 1992, attempts to address some of the concerns of developing biodiverse nations about exploitation by the industrialized powers.²⁷⁹ Specifically, the CBD seeks to precipitate an international legal regime that acknowledges the inventive contributions of indigenous communities and allows all global citizens to benefit from genetic resources and traditional knowledge in a fair and equitable manner.²⁸⁰ Towards that end, in the Bonn Guidelines, the Parties to the Convention recommended implementing national legislation that encourages disclosure of traditional knowledge when “the subject matter of the application concerns or makes use of [traditional] knowledge in its development.”²⁸¹

In light of the CBD, the World Intellectual Property Organization [WIPO] issued a detailed technical study on disclosure requirements and traditional knowledge that found inventorship disclosures detailing traditional knowledge contributions warranted in instances where the knowledge: (1) provided part of the descriptive background of an invention, (2) constituted material prior art, (3) directly contributed to the

278. See *id.* (suggesting that a duty to disclose is advocated widely and arguing that it is insufficient to adequately protect traditional knowledge holders' rights); Fritz Dolder, *Improving the Legal Position of Stakeholders of Bioresources in the Statutory Law of developed industrial Countries*, translated from "Patente auf der Grundlage biologischer Ressourcen aus Entwicklungsländern," 8/9 MITTEILUNGEN DER DEUTSCHEN PATENTANWÄLTE 349-72 (2003); Biodiverse Nations TK WIPO Submission, *supra* note 27, PARA. 1.

279. Conforto, *supra* note 66, at 379-84.

280. CBD, *supra* note 31. Article 8(j) encourages the use and sharing of traditional knowledge, while at the same time recognizing the need to protect that knowledge and to ensure that any benefits derived from its utilization are shared with the traditional knowledge holders. Article 15(1) recognizes a sovereign right of nations to determine who accesses their genetic resources, defined as resources with functional units of heredity. Article 15 further calls for parties to obtain informed consent from genetic resource providers (15(5)) and to take measures to ensure that any benefits realized through the commercialization of genetic resources are shared equitably with the resource provider (15(7)). Additionally, Article 16(5) obliges contracting states to ensure that their intellectual property laws and procedures support the CBD.

281. WIPO Technical Study, *supra* note 36, at 35.

inventive concept, and (4) constituted a component of the inventive concept itself.²⁸² Additionally, WIPO recognized that a duty to disclose such traditional knowledge contributions may be inherent in extant patent law regimes.²⁸³ However, the CBD alone is virtually unenforceable, relying instead on member states implementing national legislation to give effect to the convention's provisions.²⁸⁴ Furthermore, despite a presence throughout the

282. *Id.* at 37. The report described these possibilities in four examples: TK [traditional knowledge] may be relevant to the inventive concept in several ways:

- the TK may have pointed the way in a very general sense to the line of research that in turn led to the invention (e.g. traditional knowledge that a certain plant could be used to make a pleasant tasting beverage, which led researchers to investigate medicinal properties of the plant);
- the TK may have provided a more direct pointer to the invention (e.g. traditional knowledge that a plant has certain medicinal properties may lead researchers to explore other possible medicinal properties of active compounds in the plant);
- the TK may have directly contributed to the inventive concept (e.g. traditional knowledge that a certain plant extract was effective in treating skin infections may have led researchers to conclude that active compounds in the plant were effective antibiotics);
- the TK may be a component of the inventive concept itself (e.g. a traditional knowledge holder may have communicated to a researcher a new or undisclosed medicinal property of a plant extract, when this property is central to the invention as claimed).

283. *Id.* (“Further elaboration may be necessary to determine their range of operation and their relationship with patent law and the international patent system”).

284. *See* United Nations Environment Program [UNEP], *Manual on Compliance with and Enforcement of Multilateral Environmental Agreements*, at 289 U.N. Doc. No. DC/0817/NA (2006) (encouraging strong national enforcement of laws implementing the CBD); Conforto, *supra* note 66, at 381 (suggesting the difficulty in enforcing the CBD). Some countries have given effect to the CBD's provisions. For example, Peru, enacted law No. 27811 to establish a “Protection Regime of Indigenous Peoples' Collective Knowledge Relating to Biological Resources.” Ley No. 27811, *supra* note 26. Similarly, the Commission of the Andean Community adopted Decision 391, *Regimen Común sobre Acceso a los Recursos Genéticos* [Common Regime on Access to

treaty's negotiations, the U.S. has not ratified the CBD and, thus, is under not under a legal obligation to implement its provisions.²⁸⁵

It is also important to note that mere disclosures of traditional knowledge contributions to patented subject matter are not sufficient to meet the goals of the Convention.²⁸⁶ Although a traditional knowledge disclosure requirement may serve to "respect" the contributions of traditional knowledge holders, additional requirements, including prior informed consent by communities and equitable benefit sharing agreements between patentees and indigenous resource providers, are the mechanisms most likely to generate economic benefits.²⁸⁷

3. Instituting a Formal Traditional Knowledge Disclosure Requirement

Full and fair disclosures will still allow examiners to assume inventorship as sworn in an oath, but at the same time will facilitate prior art searches, including searches of traditional knowledge databases currently under construction.²⁸⁸ The disclosure requirements could also include an automatic notification sent to the country of origin of genetic resources or traditional knowledge, though without a pre or post grant opposition procedure to challenge a suspicious patent,²⁸⁹

Genetic Resources] on July 2, 1996 to implement provisions of the CBD, available at <http://www.comunidadandina.org/ingles/normativa/d391e.htm>. China recently passed provisions to implement portions of the CBD as well. Margo A. Bagley, *The New Invention Creation Activity Boundary in Patent Law*, 51 WM. & MARY L. REV. 577, 586 (2009).

285. List of Parties to the CBD, *supra* note 43. However, as a signatory to the treaty, the U.S. is under an obligation not to act inconsistent with the treaty's purpose. Vienna Convention on the Law of Treaties art. 18, May 23, 1969, 8 I.L.M. 679, 1155 U.N.T.S. 331.

286. CBD, *supra* note 31, art. 8(j).

287. *Id.*

288. India, for example, has undertaken to catalog its traditional knowledge in a single database, accessible to patent examiners throughout the world. HANSEN AND VANFLEET, *supra* note 8, at 15-18.

289. Challengers in opposition proceedings, unlike Federal Court patent litigants, do not need to show an actual case or controversy to voice their arguments. See, e.g., Convention on the Grant of European Patents (European

notification would be of less value in the United States than in other patent regimes.²⁹⁰ The requirements could reduce uncertainties, make national laws more coherent, prevent misappropriation, assist in identifying suspicious situations and facilitating corrective actions, and aid in substantive patent review.²⁹¹ Obviously, if Mike's patent application had included a full description of the knowledge provided to Mike by Juan and the Amazonian community, there would be no concealment to point to in an inequitable conduct allegation.

Exactly how inequitable conduct litigation (based on a failure to disclose all potentially relevant inventorship information) meshes with other current disclosure enforcement proposals is the subject of debate.²⁹² The lack of disclosure could serve to prevent a patent from issuing, or it could be asserted as an additional element of an applicant's overall duty of disclosure, with enforcement coming only through subsequent litigation.²⁹³ Several international intellectual property commentators have suggested that enforcement of a formal disclosure requirement is best conducted in arguments similar to Pharmacia's unenforceability affirmative defense.²⁹⁴ Thus, *PerSeptive IV*-based arguments seem to align with general international opinion.

Nonetheless, the United States still vigorously opposes such a formal requirement, suggesting that it adds to the burden of patent applicants and examiners and adds uncertainty to the patent process.²⁹⁵ Predictably, biodiverse countries disagree.²⁹⁶ They

Patent Convention) art. 99, Oct. 5, 1973, 13 I.L.M. 268, Art. 99, 1065 U.N.T.S. 254 (amended in 2000).

290. *Id.* (providing for a nine month post grant opposition period).

291. *UNCTAD Disclosure Analysis*, *supra* note 10, at iv-v.

292. *Id.* paras. 4-5. Interestingly, many proposals include a required showing of an intent to deceive.

293. de Carvalho, *supra* note 14, at 372.

294. *Id.* at 372, 399 ("courts should be able to sanction the lack of candor of patent applicants who knowingly failed to disclose the source in a manner that would facilitate benefit sharing, as established by article 15 of the CBD").

295. Submission by United States to the WTO, *Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/434, paras. 14-15 (Nov. 24, 2004).

296. Submission by Brazil and India to the WTO, *Article 27.3(B)*,

argue that a clear requirement to disclose, *inter alia*, traditional knowledge used in creating patentable subject matter would add certainty to the disclosure requirements.²⁹⁷ As *PerSeptive IV* suggests, the disclosure requirements are already unclear; formal clarification could only serve to enhance patent certainty. Moreover, the biodiverse nations' assertion that imposing requirements does not add any significant administrative burden²⁹⁸ is entirely reasonable when the patent applicant is already in possession of information regarding the source of traditional knowledge.²⁹⁹

Though it will not allow traditional knowledge holders to exert full control over their resources and knowledge at the outset, creating a formal duty to disclose traditional knowledge contributions may deter potential biopirates from misappropriating or failing to respect indigenous knowledge and could give biopiracy litigators an incentive to pursue cases. Currently there is a paucity of litigation brought by developing countries for one key reason: cost.³⁰⁰ Patent suits are prohibitively expensive for developing nations to litigate.³⁰¹ Inequitable conduct allows for the awarding of attorney's fees to the victor in exceptional cases, if culpability is severe enough.³⁰² With a clear disclosure requirement, parties willfully choosing not to disclose contributions of traditional knowledge are more likely to fall into that "exceptional" category, thereby warranting an award of attorney's fees against them. Thus, monetarily motivated inequitable conduct litigation, or fear thereof, could provide a potential enforcement mechanism or create an incentive for the knowledge appropriator to comply with the disclosure requirements.

Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore: Observations on issues raised in a communication by the United States, WTO Doc. IP/C/W/443, para. 18 (Mar. 18, 2005).

297. *Id.* para. 8.

298. Biodiverse Nations' TK WIPO Submission, *supra* note 27, para. 12.

299. See *UNCTAD Disclosure Analysis*, *supra* note 10, para. 28.

300. See de Werra, *supra* note 29, at 157.

301. *Id.*

302. 35 U.S.C. § 285; *Brasseler*, 267 F.3d at 1380.

Admittedly, even this step forward will not go directly towards the ultimate goal of adequately reimbursing the inventive communities.³⁰³ *PerSeptive IV* calls merely for recognition of the inventive contributions of indigenous communities, without any requirement for showing the communities' informed consent of the use of its resources or any benefit sharing arrangement.³⁰⁴ Moreover, as discussed in detail by other commentators, a shift in approach from punitive measures to a "proactive approach aimed at ensuring that communities will truly benefit" is undoubtedly preferable to uncertain unenforceability litigation.³⁰⁵ Yet, given extant domestic opposition even to formal changes in disclosure requirements, such grand proactive aspirations remain on the distant horizon.

V. CONCLUSION

As long as the odds may be, the broad duty to disclose information about inventorship established by the *PerSeptive IV* majority—a duty imposed without regard to the issued patent claims and irrespective of their actual inventorship—still offers a potential litigation strategy for biopiracy opponents. A formal duty to disclose traditional knowledge, supported by much of the world, or a *sui generis* system designed to respect and reward the inventive contributions of traditional knowledge would undoubtedly serve the interests of traditional knowledge holders more effectively. However, in the United States, in the face of high statutory hurdles and continued resistance to binding international reform, traditional knowledge holders demanding respect under the patent law for their inventive contributions have the little else to go on.

As we have been told, "you go to war with the army you have ... not the army you might want, or wish to have at a later time."³⁰⁶ For biopiracy opponents seeking inventorship respect for

303. de Werra, *supra* note 29, at 156.

304. See Biodiverse Nations' TK WTO Submission, *supra* note 27, para. 1.

305. de Werra, *supra* note 29, at 159.

306. Thomas E. Ricks, *Rumsfeld Gets Earful From Troops*, THE WASHINGTON POST, Dec. 9, 2004, at A01 (quoting Donald Rumsfeld).

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traditional knowledge, the armor provided by *PerSeptive IV* is the best protection around.

Trevor J. Clarke