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November 2015

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### Recommended Citation

Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries*, 7 DePaul J. Health Care L. 185 (2004)

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# WHO DESERVES THE PATENT POT OF GOLD?: AN INQUIRY INTO THE PROPER INVENTORSHIP OF PATIENT-BASED DISCOVERIES\*

Cynthia M. Ho\*\*

## INTRODUCTION

There is currently an information-age rush to find and patent all genetic nuggets of information. The players in this race, primarily corporations with research interests, see the area of gene patenting as a potential goldmine.<sup>1</sup> The first to isolate a new gene or gene sequence and identify its utility is rewarded a pot of gold with the typical exclusionary rights conferred by a patent.<sup>2</sup> In addition, the perceived

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\*\*Assistant Professor of Law, Loyola University of Chicago School of Law. I would like to thank Professor Mary Anne Bobinski for inviting me to participate in this symposium issue. In addition, thanks to Susan Kuo, Jacqueline Lipton, Angela Upchurch and Neil Williams for helpful comments on prior drafts of this article. Last, but not least, special thanks to Julie Fitzgibbons and Heather Nolan for their excellent research assistance. Comments and questions on this article are welcome at cho@luc.edu.

<sup>1</sup>See, e.g., Margaret Graham Tebo, *The Big Gene Profit Machine*, 87 A.B.A. J. 46, 47-48 (Apr. 2001) (describing how the evolution of patent rights in biological material has evolved into being worth potentially billions of dollars over time). Gene patents are highly valued for their relevance to commercial products; for example, the patent on the BRCA-1 gene that identifies breast cancer is seen as highly valuable because the patent allows its owner to essentially exclude all others from using the genetic marker to provide a commercial test without first paying a license fee. See, e.g., Sheldon Krinsky, *The Profit of Scientific Discovery and its Normative Implication*, 75 CHI.-KENT L. REV. 15, 37 (1999) (noting that the patent on BRCA-1 and BRCA-2 has resulted in screening test costs of about \$ 2400). Moreover, since there are nearly innumerable genes and gene markers, gold-diggers see a multitude of small gold nuggets that each can lead to riches. See, e.g., Kristen Philipkoski, *Incyte Incites Concern*, WIRED NEWS (Feb. 16, 2000), at <http://www.wired.com/news/technology/0,1282,34372,00.html> (noting plans to file patent applications on 15,000 gene sequences); Kristen Philipkoski, *Celera a Cinch in Patent Race*, WIRED NEWS (Jan. 11, 2000), at <http://www.wired.com/news/print/0,1294,33551,00.html>; Ronald Kotulak, *Taking License with Your Genes*, *Biotech Firms Say They Need Protection*, CHI. TRIB., Sept. 12, 1999, at C1 [hereinafter "*Taking License with Your Genes*"] (discussing Amgen's estimated \$ 100 million patent on an important blood forming hormone discovery).

<sup>2</sup>See *infra* notes 22-27 and accompanying text (explaining the patentability of genes and gene sequences).

value of these sequences is further enhanced because the stock market and popular press tend to exalt the discovery of each speck of gold as if it were a discovery of an actual cure.<sup>3</sup> However, as in a traditional case of gold-digging, there is a discrete amount of rare, valuable material that is embedded amidst much more useless information.<sup>4</sup> Luck typically plays a role; a select few who persevere to comb through material are rewarded with gold, although those rewarded are not necessarily those who worked the hardest.

The fortunes of some genetic gold-diggers are substantially enhanced by interactions with certain patients.<sup>5</sup> In particular, some patients may contribute unique genetic material that essentially provides a short-cut to where the gold lies.<sup>6</sup> Patients typically provide this valuable information without any knowledge that they are helping gold-diggers who will be unlikely to share the eventual pot of gold. In addition, even after patients realize that there is a pot of gold at stake, they are usually unsuccessful in getting a fair share of any nuggets of gold under the current patent law. Moreover, although patients who help pave the way to genetic gold usually do so for altruistic reasons, such as accelerating the discovery of a cure, they ironically become unwitting accessories to a situation where they, and other patients, will be *precluded* from the results of their help if a patent is obtained. This occurs because a patent owner has the right to prevent all others from encroaching on the patented invention; most patent owners today, including academic institutions and hospitals, utilize this right to charge higher prices for patented inventions, including new medicines or

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<sup>3</sup>See, e.g., Michael Waldholz, *Genes are Patentable; Less Clear is if Finder Must Know Their Role: AIDS Discovery Spurs Some to Challenge a Filing that Boosted HGS Stock*, WALL ST. J., Mar. 16, 2000 at A1 (noting that when investors believed that HGS was the sole discoverer of a breakthrough in AIDS research, its shares rose tremendously).

<sup>4</sup>In the case of gene patents, scientists must remove much "junk DNA" to reach isolated and purified material that can then be potentially patentable. See, e.g., Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale DNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557, 558 (1996) (explaining how complementary DNA sequences are created through the use of enzymes to redact "junk DNA"); Dorothy R. Auth, *Are Ests Patentable?*, 15 NATURE BIOTECHNOLOGY 911, 912 (1997) (describing the practice of patenting portions of DNA with no known function).

<sup>5</sup>For the purposes of this article, gold-diggers include both those who intentionally seek out genetic patents using patient contributors, as well as those who seek patents more generically, but have no qualms about patenting the results based upon patient contributors without any recognition or compensation to these contributors. In some cases, the gold-diggers are not necessarily maliciously denying rights to patients; rather, because of the complex dynamics of research and patent licensing, gold-diggers with patent rights often have no personal contact with the contributing patients. See *infra* notes 61-62 and accompanying text (contrasting patient perspectives with research realities, including the commercial overtones).

<sup>6</sup>See *infra* notes 42-43 (describing how researchers have sought out isolated populations because their limited genetic diversity accelerates the progress of research).

medical treatments.<sup>7</sup> In addition, while the patent owner's right of exclusion has been traditionally justified as an incentive or a reward to those who discover patentable information that is then shared with society, this reward seems perverse to patients who believe that they contributed just as much, if not more, towards the pot of gold.<sup>8</sup> Accordingly, patient contributors are left feeling like they are tour guides to the land of gold, but always excluded from the rewards reaped by those who follow them.

This article focuses on the current clash between patient perspectives and patent law, with respect to who should be entitled to the pot of gold that lies in patent rights. The focus on patient contributors advances the important issue regarding appropriate compensation, as well as whether current patent law definitions of inventorship and ownership are outdated. This article provides an important foundation of underlying issues, and explains the present failure of the patent system to accommodate and provide incentives to the patients who offer the unique ability to facilitate research. Although this article addresses potential short-term solutions under patent and contract law, it takes an important step beyond prior scholarship by drawing from multiple disciplines to promote an enduring and satisfying solution for patient contributors.<sup>9</sup>

Part I of this article begins with an introduction to patent laws and underlying policies to provide a basic foundation for the pertinent legal issues. Part II then highlights the present dichotomy between the

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<sup>7</sup>See 35 U.S.C. 271(a) (1994) (noting that patent owner has the right to exclude others from the patented invention); see also *infra* notes 53-63 and accompanying text (describing patient perceptions).

<sup>8</sup>See *infra* notes 56-68 and accompanying text (describing patient perceptions that they made substantial contributions to the patented invention). However, it should be noted that in the area of biotechnology, patents, as well as the high prices of patented medicines have often been justified because of enormous research and development costs in this area. Ceci Connolly, *Price Tag for a New Drug: \$ 802 Million*, WASH. POST, Dec. 1, 2001, at A10 (noting that Tufts University researchers recently calculated the cost of developing a new drug to reach \$ 802 million, whereas another consumer group alleges the numbers are less than \$ 300 million). Nonetheless, where patients provide a genetic short cut, they are at least arguably reducing the costs for companies, with no personal gain to themselves.

<sup>9</sup>For prior proposals suggesting immediate reform, see Marty Taylor Danforth, *Note, Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179, 193-95 (1988) (proposing a licensing scheme with a fixed fee set by Congress); Roy Hardiman, *Note, Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 263 (1986) (advocating creating property rights in the human body); Christopher S. Pennisi, *Note, More on Moore: A Novel Strategy for Compensating the Human Sources of Patentable Cell-Line Inventions Based on Existing Law*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 747, 778 (2001) (proposing a right to compensation based upon the "shop right doctrine" under patent law, or an alternative informed consent procedure). See also Radhika Rao, *Property, Privacy and the Human Body*, 80 B.U. L. REV. 358, 459-60 (2000) (concluding that the property and privacy interests in human body parts are applicable differently to living and deceased persons).

perspectives of patients with the present research reality, including the prominent role of patents. After fully describing the backdrop of the situation, Part III explains the legal implications of patient contributions under the present patent law. Section A begins by underscoring the importance of the inventorship concept in United States patent law. Then, Section B addresses the current law governing inventorship to explain why patient efforts in assisting with gold-digging have yet to provide them with the actual gold that inures to joint inventors.

This article then turns to potential methods of addressing patients' concerns in Part IV. Section A begins by considering whether an extension of joint inventorship law to include patients would adequately address patient concerns first articulated within Part II. This section suggests that underlying policies of patent law as well as joint inventorship could be interpreted to embrace patient contributors. However, this section concludes that including patients as joint inventors may nonetheless fail to provide patient contributors with a desired result because of a potential change in patent law. After concluding that joint inventorship may not address patient concerns completely, section B considers whether a contractual approach would be realistic. However, this section ultimately concludes that although patients can attempt to individually negotiate their preferences, this approach is unlikely to provide most patients with a workable solution. Section C then considers whether the sanction of an unenforceable patent could address patient concerns.

Section D moves beyond the short-term solutions to suggest a more comprehensive view of the problem. In particular, this section suggests specific areas that have analogous problems to the patient contributor issue, as a means towards reaching solutions that will be longer lasting and more efficacious. For example, this section raises the analogous issue of scientific authorship in an era where it is often difficult to provide proper credit to all contributors. In addition, the patient contributor problems are analogized to those of database creators, in considering whether the *sui generis* approach of the database creators would be helpful. Also, a comparison of patient contributor problems with the long-standing problem of industrial use of indigenous resources, often referred to as "bio-piracy," will be sketched briefly to highlight another area upon which patient advocates may consider in formulating a new-order solution. Finally, this section returns to patent law approaches, but suggests a broadened perspective of inventorship that considers not only patient contributors, but appropriate inventorship of all isolated genetic material, regardless of how it was derived.

## I. BACKGROUND

### A. Patent Law and Policy

United States patent laws and policy are founded upon the Constitution, which authorizes Congress to "promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."<sup>10</sup> Consistent with this mandate, Congress enacted the Patent Act, which gives inventors a right of exclusivity in the form of patent protection if certain requirements are met. In particular, a patent provides an inventor with the right to exclude all others from use of the invention during the term of the patent.<sup>11</sup> Exclusivity is considered essential in order to "stimulate ideas and the eventual development of further significant advances."<sup>12</sup> The requirements for patentability under the Patent Act are similarly intended to fulfill the constitutional mandate of promoting innovation.<sup>13</sup>

The Patent Act requires that for an invention to be patentable it must (1) constitute "patentable subject matter," (2) meet the technical requirements for patentability, which require that the invention be "new," "useful," and "nonobvious,"<sup>14</sup> and (3) disclose a written description of an invention, including the best mode of carrying it forth.<sup>15</sup> Although a patent must disclose an invention that fits within at least one statutory class of subject matter, the classes are very broad and expansively interpreted to effectuate the policy of promoting innovation.<sup>16</sup> The technical requirements are intended to ensure that the exclusive right is only provided in cases where an invention will be of

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<sup>10</sup>U.S. CONST. art. I, 8, cl. 8.

<sup>11</sup>See Patent Act of 1790, 1 Stat. 109 (1790) ("An Act to Promote the Progress of Useful Arts."); see also EDWARD C. WALTERSCHEID, *TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798-1836*, at 35-36 (1998) (noting that the framers elected for a system of providing exclusive rights, rather than other types of rewards known at the time such as medals, titles or bounties).

<sup>12</sup>See, e.g., *Kewanee Oil v. Bicron*, 416 U.S. 470, 481 (1974).

<sup>13</sup>See, e.g., *Bonito Boats v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989).

<sup>14</sup>See 35 U.S.C. 101-03 (1994) (detailing the statutory definitions).

<sup>15</sup>The application that becomes a patent must disclose the invention with sufficient definiteness such that someone of like ability - usually referred to as a person of "ordinary skill in the art" - could replicate the invention by following the patent. See 35 U.S.C. 112 (1994). In addition, the application must disclose the best way of practicing the invention known to the inventor at the time the application is filed. 35 U.S.C. 112.

<sup>16</sup>See 35 U.S.C. 101 (1994) (stating that patentable subject matter includes any process, machine, manufacture, or composition of matter); *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980). In particular, it has been noted that the "subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the progress of science and the useful arts' with all that means for the social and economic benefits envisioned by Jefferson." *Id.* at 315.

value to the public by requiring that a patented invention be not only new, but also not so obvious that it could be readily determined.<sup>17</sup>

The U.S. Supreme Court has explained that the federal patent system reflects a "carefully crafted bargain" - a social contract between the inventor and society - that encourages innovation and promotes increased knowledge in the public domain.<sup>18</sup> The grant of a patent is both an incentive to create and a reward for disclosure of the invention to the public.<sup>19</sup> The patentability requirements serve to ensure the validity of the social contract by requiring the inventor to disclose something of value to society in exchange for the right to exclude.<sup>20</sup> Disclosure benefits the public immediately because upon issuance of a patent, which is a public document,<sup>21</sup> the knowledge in the patent is immediately available to the public and can be instrumental to furthering innovation by others. Although use of the invention during the term of the patent is not available without authorization from the patent owner, the disclosed invention is immediately accessible upon expiration of the limited patent term.

## B. Patent Law, Policy and Genetic Material

### 1. Patentability

To most patients, as well as the public, the idea of patenting genes and gene sequences seems counter-intuitive. One frequently voiced opinion is that because genes are living material, they should not be patented.<sup>22</sup> However, the United States Patent Office (PTO) has long considered *isolated* and *purified* genetic material to be patentable, based on the premise that the isolated material does not exist naturally in that state and therefore is not a mere discovery; isolated material is typically created through recombinant DNA techniques to result in a more

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<sup>17</sup>See *Bonito Boats*, 489 U.S. at 156 (noting that "both the novelty and the nonobviousness requirements of federal patent law are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all"). Of course, there are those who contend that these technical requirements either are ineffective, or not strong enough to truly weed out irrelevant inventions. See, e.g., James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 44. But see *Patenting Business Methods: A White Paper of the AIPLA*, AIPLA, Nov. 27, 2000, at <http://www.aipla.org/html/whitepaper2.html> (advocating no change in the patent laws for business method patents).

<sup>18</sup>See *Bonito Boats*, 489 U.S. at 149.

<sup>19</sup>See, e.g., *Kewanee Oil*, 416 U.S. at 480 (noting that patents provide both an incentive to risk time, research and development, as well as a reward for disclosure of an invention).

<sup>20</sup>See *id.* at 480-81.

<sup>21</sup>See 35 U.S.C. 10-11, 13 (1994) (discussing the availability of patents to the public).

<sup>22</sup>See, e.g., David Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED & ETHICS 152 (2001) (discussing objections to genetic patenting on human dignity grounds).

"concentrated" product than that which could exist in nature.<sup>23</sup> Although this issue remains controversial in some international communities,<sup>24</sup> it is essentially settled in the United States that isolated genetic material is patentable *subject matter*.<sup>25</sup> However, it should be recalled that patentability requires both that there be patentable subject matter and that the subject matter also satisfy the technical patentability criteria.<sup>26</sup>

The application of technical patentability criteria to genetic inventions is still an evolving process. The Patent Act establishes that all the technical criteria of patentability - utility, novelty and nonobviousness - must be met for all inventions before a patent is issued. However, the application of these criteria to genetic inventions has not been static. For example, at one point isolated genes satisfied the utility requirement, even if their only known utility was as a genetic probe for further material.<sup>27</sup> However, the PTO recently stated that

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<sup>23</sup>See, e.g., *Genentech v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (affirming a patent for a DNA sequence); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) (upholding a patent on the purified and isolated gene sequence which encodes human erythropoietin); Lila Feisee & Brian Stanton, *Are Biotechnology Patents Important?*, PTO PULSE, Mar. 2000, at [www.uspto.gov/go/opa/pulse/200003.htm](http://www.uspto.gov/go/opa/pulse/200003.htm) (last visited Apr. 7, 2002); *Biotechnology Industry Organization, Backgrounder on Patenting Gene-Based Inventions, Genomics: Issues and Policies*, Mar. 2000, at [http://www.bio.org/genomics/gene based.html](http://www.bio.org/genomics/gene%20based.html) (noting that the PTO policy allowing the patentability of genes, expressed sequence tags, and single nucleotide polymorphisms is "well established" and has already resulted in many issued patents).

<sup>24</sup>See, e.g., Cynthia M. Ho, *International Intellectual Property Issues for Biotechnology*, in *ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY* 761, 766-69 (Thomas J. Murray & Maxwell J. Mehlman, eds., 2000) (summarizing types of biotechnology considered patentable subject matter in various countries); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1627-28 (2001) (noting the continuing controversy in Europe over the patenting of human DNA sequences based on perceived lack of utility, as well as morality concerns). In addition, even for countries that allow some genetic material to be patentable, the scope of patentability may vary greatly, depending on the definitions of the technical requirements of novelty, utility and nonobviousness. See, e.g., Carlos Correa, *Patent Rights*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 198 (Carlos M. Correa & Abdulqawi A. Yusuf, eds. 1998); J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 INT'L L. & POL. 11, 29-32, 36-39 (1996-97) (discussing the lack of universal standards of technical requirements of patentability, as well as specific issues for biotechnology).

<sup>25</sup>See, e.g., *supra* note 23 (citing authority that accepts isolated genetic material as patentable subject matter under United States laws); see also *infra* notes 27-30 and accompanying text (discussing modifications to the technical requirements of patentability, without questioning that subject matter is appropriate).

<sup>26</sup>See *supra* notes 14-15 and accompanying text (explaining technical requirements of patentability).

<sup>27</sup>See, e.g., Patent and Trademark Office Utility Examination Guidelines, 60 Fed. Reg. 36263, 36264 (July 15, 1995) (noting that utility is established so long as the applicant makes an assertion that would be credible to a person of ordinary skill in field); Arti Rai, *Regulating*



genetic applications must now establish "substantial and credible utility," - a standard intended to require that genetic patents must have more utility than merely being a gene.<sup>28</sup> In other words, a patentable gene or gene sequence must have at least identified functionality or an associated protein, in order to satisfy the utility requirement.

Regardless of the evolving application of technical patentability criteria to genetic inventions, gene patents have issued and will likely continue to issue in the foreseeable future.<sup>29</sup> In particular, the propriety of patenting genetic material is unlikely to be seriously challenged in the United States anytime in the near future.<sup>30</sup> Accordingly, the remainder of this article will assume that genetic inventions will continue to be patentable and will address other issues attendant to the issuance of these patents.

## 2. Inventorship versus Ownership

Inventorship and ownership are distinct, but often related, issues. The inventor creates the patented invention whereas the patent owner holds

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*Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 106-09 (1999) (describing liberalization of utility requirement).

<sup>28</sup>See Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001) (detailing the utility requirement for patent examiners).

<sup>29</sup>See, e.g., Tebo, *supra* note 1, at 48 (noting recent statistics from the PTO indicating that 1000 patent applications involving human or animal DNA have been filed, in addition to 200 already issued patents); John Carey, *The Genome Gold Rush*, BUS. WK., June 12, 2000, at 147, 152 (illustrating that even junk DNA may be patentable); Pamela Sherrid, *It's All About Cures and Cash*, 130 U.S. NEWS & WORLD REP., Jan. 8, 2001, at 35 (noting that genomics companies have been flooding the patent office with thousands of applications); *Taking License With Your Genes*, *supra* note 1, at C1 (noting that there are over 7,000 pending patent applications on genetic patents).

<sup>30</sup>This is especially true since the United States Supreme Court recently gave strong affirmance to the principle of broad subject matter patentability in upholding the patentability of plants despite overlapping protection provided under both the Plant Patent Act as well as the Plant Variety Protection Act. See *J.E.M. AG Supply, Inc. v. Pioneer Hi-bred Int'l, Inc.*, 122 S.Ct. 593, 596 (2001); see also Martin Bobrow & Sandy Thomas, *Patents in a Genetic Age*, 409 NATURE 763 (Feb. 15, 2001) (noting that thousands of patent claims to human DNA sequences have been filed and granted and few have been subject to legal challenge thus far). However, even United States patents on genetic material are not without controversy. See, e.g., Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, 107th Cong. (2001) (proposing an amendment to the Patent Act to allow for compulsory licensing of certain inventions relating to health); Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L. J. 783 (2000) (discussing whether patentability is appropriate for DNA sequences); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 J. L. & POL'Y 247 (2000) (discussing resurgent argument against patenting of biological inventions that invoke overtones of morality, as well as providing comparative perspective of European Patent System, which expressly includes morality as a consideration in the evaluation of patentability). In addition, the tension in this area is also evident from recently proposed, but un-enacted Congressional bills to limit the enforceability of some such patents. See Genomic Science and Technology Act of 2002, H.R. 3966, 107th Cong. (2002); Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

the rights inherent in a patent.<sup>31</sup> It is possible that the inventor is also the patent owner; in fact, the default rule in the United States is that a patent is granted to the inventor.<sup>32</sup> However, because patents can be conveyed like other types of property, the inventor may assign his interest in the patent; in such a case, someone other than the inventor would own the patent.<sup>33</sup>

From the perspective of patentability, inventorship is of primary importance, while ownership is a mere housekeeping issue. As discussed earlier, a patent can only be granted to inventions that are shown to be new, useful, and nonobvious.<sup>34</sup> To establish these technical requirements, inventors must certify that they believe themselves to be the first to have discovered the invention.<sup>35</sup> The PTO independently assesses whether the technical requirements of patentability are met by comparing the patent application to the inventions of others, commonly referred to as "prior art" comparison.<sup>36</sup>

Ownership issues are irrelevant to patentability, except to the extent that joint ownership of inventions may help to avoid an obviousness rejection.<sup>37</sup> In addition, ownership of patent rights is contingent upon the initial patentability inquiry succeeding in the first

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<sup>31</sup>See *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993) ("It is elementary that inventorship and ownership are separate issues ... [I]nventorship is a question of who actually invented the subject matter claimed in a patent ... who ultimately possesses ownership rights ... has no bearing whatsoever on the question of who actually invented that subject matter.").

<sup>32</sup>See, e.g., *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996) (noting that an invention presumptively belongs to its creator).

<sup>33</sup>The Patent Act actually explicitly clarifies that patents "shall have the attributes of personal property." 35 U.S.C. 261 (1994).

<sup>34</sup>See *supra* note 14 and accompanying text. In addition, the patent application must sufficiently describe the invention such that a person of similar experience could replicate the invention. See 35 U.S.C. 112 (1994). The application must also disclose the best method of using the invention, as of the time of the application. 35 U.S.C. 112.

<sup>35</sup>See 35 U.S.C. 102, 103, 111 (1994) (listing the patentability requirements and oath requirement); see also 37 C.F.R. 1.63; U.S. DEP'T OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE 602, 600-26-29 (7th ed. 1998; rev. 2000) [hereinafter "MPEP"], available at <http://www.uspto.gov/web/office/pac/mpep/mpep.html>. Because the patent laws are intended to further the progress of science and also promote the disclosure of inventions, the patent laws do have provisions that bar patentability to inventors who unduly delay in requesting patents. See *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756 (Fed. Cir. 1995) (noting the dual purposes of rewarding the first patent inventor and also prompt disclosure).

<sup>36</sup>See MPEP, *supra* note 35, at 2100-8-15. This process includes not only what other inventors have done, but may also include acts of the inventor himself in certain situations where an inventor is considered to have not timely requested a patent after having discovered it. See 35 U.S.C. 102(b), 102(g) (1994).

<sup>37</sup>See 35 U.S.C. 103 (1994); MPEP, *supra* note 35, at 700-1 to 700-177 (describing the PTO prior art examination and providing no consideration of ownership, except with regard to avoiding an obviousness rejection).

instance. Although rights may be transferred with regard to a pending patent application, the assignment of title is merely a procedural issue.<sup>38</sup>

## II. THE PATIENT-PATENT INTERPLAY

### A. The Patient Input

The specific factual scenarios that give rise to patentable subject matter are important because they help to provide a context for patient perspectives, as well as implications for patent law and policy. Accordingly, before addressing the specific patent issues raised by patient contributions, some typical situations in which patients provide biological material that eventually leads to a patent will be outlined.

#### 1. *Sample Scenarios*

##### a. *"Normal" Course of Treatment*

Occasionally, a patient will have biological material removed from her body during the normal course of medical treatment. This biological material may subsequently be used for experimentation, although *Moore v. Regents of the University of California* is the only published case where the material eventually resulted in a patent.<sup>39</sup> Thus far, courts consider patients to have no property interest in materials removed from their body attendant to the normal course of treatment.<sup>40</sup> Of even greater consequence in the context of patent issues, however, is that other than in a case of extreme breach of fiduciary duty, patients who have biological material removed during the routine course of medical treatment are unlikely to be aware of the taking or subsequent

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<sup>38</sup> See *supra* note 33 and accompanying text (noting that patents may be assigned). There are rules that permit a patent to issue to an inventor's assignee immediately upon patent grant. See 35 U.S.C. 152 (1994) (noting that patents may be granted to the assignee of the inventor). Pre-assignment of patent rights is often the norm. For example, employment agreements typically pre-ordain that any patents created on the premises shall be assigned to the corporation; inventions that resulted from research done in the course of work for a corporate entity are usually assigned to the corporation. See, e.g., Lucy Gamon, Note, *Patent Law in the Context of Corporate Research*, 8 J. CORP. L. 497, 498 (1983). In addition, assignment of inventions created in an academic context are also common. See, e.g., *Chou v. Univ. of Chi.*, 254 F.3d 1347, 1356-57 (Fed. Cir. 2001) (affirming a district court holding that a university scientist could assign all her patent rights to her university employer even without an actual contract because her acceptance of her academic post was subject to the faculty handbook which included a provision for assignment of inventions). See generally Steven Cherenksy, *A Penny For Their Thoughts: Employee-Inventors, Preinvention Assignment Agreements, Property, and Personhood*, 81 CAL. L. REV. 595, 602-04 (1993).

<sup>39</sup> See e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 480 (Cal. 1990).

<sup>40</sup> See e.g., *id.*

profits arising from their contribution.<sup>41</sup> Accordingly, such patients are unlikely to be even aware of any resulting patent profits.

*b. Doctors Who Seek out "Special" Populations*

As early as the 1970s, scientists have been seeking out isolated populations with unique gene pools because of the increased chance of scientific success. In particular, studies of isolated populations with common genes can ease the scientific path to discovery of genetic disorders by limiting the number of variables with which scientists must contend.<sup>42</sup> Scientists can more easily find genetic markers by comparing genetic profiles of all individuals in an isolated population who suffer from a genetic disorder, compared with those who do not. In addition, isolated populations often more easily yield extensive genealogies and other health information that may further assist scientific research. For example, the discovery of the breast cancer gene, BRCA-1, was achieved after a decade of sampling and testing Mormon families in Utah who had genetic commonality, as well as extensive genealogy information available to researchers.<sup>43</sup>

*c. Special Patients Who Seek Researchers*

In addition to scientists who seek out special populations, patients may present themselves for research. This is particularly true for patients suffering from presently incurable diseases; in such cases, there is a high incentive for patients to volunteer blood and other biological material with the hope that scientists will more readily identify a genetic marker that can result in specific treatment.

In addition, some people have presented themselves or others to doctors for research purposes when there is no clear disease, but there are anomalous symptoms. For example, one man presented himself for research when he realized that he had been repeatedly exposed to the

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<sup>41</sup>However, in one particularly egregious case of breach of fiduciary duty, patient John Moore's doctor not only took out a diseased organ, but required the patient to make repeated return trips to provide additional biological material including blood and semen samples that were not actually medically necessary. *Id.* at 481-82.

<sup>42</sup>*See, e.g.,* LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE 43-44 (2001).

<sup>43</sup>*See, e.g., id.* Another isolated group that has been utilized for genetic testing is the Amish in Pennsylvania. *Id.* at 42-43; *see also* Robin Marantz Henig, *Tricky Truths About Ethnicity and Genetics*, WASH. POST, Oct 5, 1997, at C1 (noting the efficiencies of screening a selected population with similar genes, such as Ashkenazi Jews). Similarly, some companies have sought and obtained even larger populations of relatively pure samples in Iceland and Canada. *See, e.g.,* Henry T. Greely, *Iceland's Plan for Genomics Research: Facts and Implications*, JURIMETRICS 153 (2000); *see also* Michael J. Smith, Comment, *Population-Based Genetic Studies: Informed Consent and Confidentiality*, 18 SANTA CLARA COMPUTER & HIGH TECH. L.J. 57, 68-72 (2001) (discussing similar projects in Estonia, as well as proposed studies in the United Kingdom, Italy, Tonga, and even the U.S. in limited instances).

AIDS virus, but never contracted the virus himself.<sup>44</sup> Similarly, one woman presented her cat for study when it showed signs typical of immunodeficiency, but failed to test for feline leukemia, which was the only known immunodeficiency disorder in cats at the time.<sup>45</sup>

In addition, patients sometimes present not only themselves, but may also locate similarly afflicted people and present the combined biological material for researchers to study. For example, Nancy Wexler, a psychologist who had a substantial genetic risk of Huntington's disease, spearheaded the discovery and collection of blood samples from a concentrated population of family members in Venezuela.<sup>46</sup> Similar situations have resulted in the location of genes that cause cystic fibrosis and predispose patients to breast cancer.<sup>47</sup> More recently, the parents of a child born with Canavan disease, a genetic disorder that leads to brain degeneration, recruited a researcher, organized a nationwide collection of biomaterial, and also financed the research itself.<sup>48</sup> Similarly, the patient-based group PXE International established a bank of biological material relating to the genetic disorder PXE, to assist research regarding this disorder.<sup>49</sup>

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<sup>44</sup>Morley Safer, 60 Minutes: *Whose Body Is It Anyway? Companies Patenting Genetic Makeups* (CBS television broadcast, Feb. 25, 2001) (noting that Steve Crohn offered himself up to the Aaron Diamond AIDS Research Center in New York for study when he was puzzled as to why he consistently tested negative for HIV despite regular exposure and became convinced that he was carrying some kind of immunity).

<sup>45</sup>See *infra* notes 134-57 and accompanying text (describing the case of Marlo Brown and the negative legal reception she received for her claims before two different courts).

<sup>46</sup>This enabled researchers to compare the genetic material of those afflicted with Huntington's versus their unaffected relatives to accelerate the research process. See ALICE WEXLER, *MAPPING FATE: A MEMOIR OF FAMILY, RISK AND GENETIC RESEARCH* (1996); see also ANDREWS & NELKIN, *supra* note 42 at 50; Thomas H. Maugh II, *Unraveling the Secrets of Genes: Genetic Experiments Have Exploded and Could Hold the Key to Making Such Diseases as Cystic Fibrosis, Huntington's and Lou Gehrig's Obsolete, but Ethical Questions Remain*, L.A. TIMES, Oct. 31, 1993, at A1 (describing the analysis performed on the genetic material of cystic fibrosis, Huntington's and Lou Gehrig's disease patients); Gerardo Jimenez-Sanchez, *Human Disease Genes*, 409 NATURE 853, 853-55 (Feb. 15, 2001) (focusing on the protein produced by specific genes and choosing functional designations that were largely informed by the features of pathology).

<sup>47</sup>See *supra* note 43 and accompanying text (concerning the discovery of BRCA-1, the breast cancer gene).

<sup>48</sup>See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918, 921 (N.D. Ill. 2002). Over the course of seven years, the Greenbergs provided tissue and blood samples of their family, including a tissue sample of their son's organs, after his death from Canavan disease. *Id.* at 921.

<sup>49</sup>See, e.g., Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 407 NATURE 821 (Oct. 19, 2000); Matt Fleischer, *Seeking Rights to Crucial Gene*, NATIONAL L. J., June 25, 2001, at C1; Andy Coghlan, *People With Inherited Diseases are Ready to Challenge Pro-Lifers Over the Future of Medical Research*, *New Scientist*, Feb. 2, 2001, at 4 (quoting the chairman of PXE International as noting that patent ownership was desirable to "accelerate the research process, control royalty and license fees, and eliminate turf wars between researchers"). PXE is a relatively rare genetic disorder that causes connective

## 2. *Informed Consent*

Each of the situations that give rise to patient contributions has important implications for informed consent. In particular, the doctrine of informed consent requires that doctors, as well as researchers, explain their care or research prior to operating on patients, removing material from them, or subjecting them to testing.<sup>50</sup> In the case of patient contributions, although a procedure for obtaining informed consent is typically used, patients have a perception that their consent was not truly informed, as will be discussed in the next section.

To provide a foundation for evaluating patient perceptions, it is important to first understand the basic requirements of informed consent, as well as how it is usually obtained. On a practical level, the doctrine of informed consent has evolved into a disclosure form that states the procedure to be done and its associated risks. Patients are asked to sign the form to indicate their assent to the procedure after being apprised of the risks.<sup>51</sup> Some of these forms also request the patient's consent to allow information obtained through the procedure to be used for research purposes, without identification of the individual patient. However, these forms typically do not indicate that this research may culminate in a patent application, let alone the fact that a patent would legally allow limited access to a patented medical treatment.<sup>52</sup>

Moreover, even if a researcher did attempt to include potential patents in the official consent form *and* a patient understood the implications, it is still unclear whether this would impact the net

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tissue to harden. *Id.* There was no known treatment for this disease when the patient group PXE International was formed. *Id.*

<sup>50</sup>See *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479 (1990); RESTATEMENT (SECOND) OF TORTS, 829B cmt. I (1979).

<sup>51</sup>The form may include other information that the patient is asked to consent to, including, for example, agreement to release confidential information to insurers to secure reimbursement.

<sup>52</sup>The failure of the informed consent form to specifically indicate that patent rights may be sought has been raised in at least one lawsuit. *Greenberg*, 208 F. Supp.2d at 921-22 (asserting that the patients were not informed of any intent to seek a patent on the research for which patients were assisting and alleging several causes of action, including lack of informed consent, breach of fiduciary duty, unjust enrichment, and conversion). In addition, most patients contend that the scientists they worked with never even mentioned that their research might result in a patent application. *Id.* at 921 (noting the contrary expectation of patients that their contributions would be used to develop medical procedures that would remain within the public domain); *Moore*, 793 P.2d at 485 (describing the fiduciary duty a doctor owes a patient); see also ANDREWS & NELKIN, *supra* note 40, at 56 (listing the conflicts researchers have as a factor for this problem); Fleischer, *supra* note 49, at A14 (describing how parents of blood donors did not know how their children's blood would be used); Justin Gillis, *Gene Research Success Spurs Profit Debate*, WASH. POST, Dec. 30, 2000, at A1 (describing the donors as feeling exploited).

outcome.<sup>53</sup> In particular, because many patients who donate biological material are at a loss for other options because of the lack of existing treatments, it is unclear whether they could properly evaluate the pros and cons of consenting to patents derived from their donations.<sup>54</sup> Any remote monetary consequences that may arise from their participation may be irrelevant to patients who have no treatment alternatives. In addition, patients without other avenues for treatment may fail to appreciate that they could decline to waive intellectual property rights based upon their contributions, let alone attempt to bargain for different outcomes.<sup>55</sup>

### 3. Patient Perceptions

The patient perspective is a key component to addressing the problems raised by patents based upon their contributions. As already noted, the largest gap exists between patient perception and current reality with respect to the fact that a patent may result from their contributions. A corollary gap in understanding is the fact that patents provide their owners with the right to exclude others, including the potential to charge higher prices.<sup>56</sup> Many patients improperly assume that all research and results based upon their contributions will be made freely available to help other similarly situated patients.<sup>57</sup> Accordingly, patients are typically shocked when they discover that their aid has actually resulted in limited access to tests and treatments because their

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<sup>53</sup>For example, an informed consent form could more explicitly require patients to waive rights to future claims or interests in resulting intellectual property. However, because most patients have, at best, a rudimentary understanding of patents, a consent form that adequately explains the results of a patent may be difficult for patients to comprehend. *See infra* notes 63-66 and accompanying text (explaining patient misperceptions concerning patents).

<sup>54</sup>*See, e.g.,* Danforth, *supra* note 9, at 198.

<sup>55</sup>*See infra* notes 194-96 and accompanying text (discussing the "option" that patients have in contracting for different outcomes).

<sup>56</sup>*See* 35 U.S.C. 271(a) (1994) (providing that the patent owner has the right to exclude all others from making, using, selling, offering to sell, or importing the patented invention); *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (noting that "[a] patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."); *W. L. Gore & Associates, Inc. v. Carlisle Corp.*, 381 F.Supp. 680, 701 (D. Del. 1974) (noting that the patent right is about charging "what the market will bear").

<sup>57</sup>*See, e.g., Greenberg*, 208 F. Supp.2d at 921 (noting patients' expectations that any resulting tests would benefit the "population at large" and that patients were surprised to find that organizations with free testing programs were threatened with litigation); Fleischer, *Patent Thyself*, AM. LAWYER, at 84, 87 (June 2001) (noting that a number of families who donated blood in the hopes of discovering a test for Canavan's disease had done so under the assumption that the test would be available to all); Gillis, *supra* note 52, at A1 (quoting one contributing patient who was reacting in shock to the discovery of a patent based on his contribution, "all of us felt that was a real slap in the face ... It was a common understanding that we were all doing this to benefit the common good.").

assistance resulted in a patent.<sup>58</sup> There are two central components to the patients' experience of shock and dismay: (1) an often false presumption about the neutrality of doctors and researchers with whom they deal; and (2) a lack of comprehension about patents.

*a. Assumed Neutrality of Doctors and Researchers*

Patient contributors typically assume that the scientists and doctors with whom they interact are involved solely in the pursuit of knowledge and are therefore immune to commercial interests.<sup>59</sup> This assumption may stem, at least in part, from the patients' own voluntary and philanthropic acts.<sup>60</sup> In addition, patients may be unaware that doctors and researchers may have commercial interests that ordinarily would not be disclosed during the course of medical care or research.<sup>61</sup> Moreover, even if a researcher does not personally have a commercial interest, the fact that many researchers work for commercial entities will result in commercialization of their research. For example, in the *Canavan* case, the researcher was required to seek a patent by his employer, and in fact had assigned his interests in any potential patents to his employer prior to the patient contributions.<sup>62</sup>

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<sup>58</sup>In one recent case, patients who provided biomaterial had no idea that the research they sponsored would result in a patent; they only discovered the patent when the patent owner, Miami Children's Hospital, began to limit testing by academic laboratories. *See, e.g., Greenberg*, 208 F. Supp.2d at 921; Gillis, *supra* note 52, at A1.

<sup>59</sup>Vicki Brower, *Canavan Families Slam Scientists over Test Patent Profits*, BIOTECH. NEWSWATCH, Dec. 4, 2000, at 1 (noting that they did not realize that the tissue they donated would be used for profit, or to restrict use of any resulting tests to other families); *see also* Gina Kolata, *Sharing of Profits is Debated as the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A17 (quoting Michigan law professor Rebecca Eisenberg as noting that "people may contribute their tissue in the expectation that nobody is going to make a profit on it, but that's a little naive. There's no free lunch here.") *Id.*

<sup>60</sup>*See, e.g.,* Brower, *supra* note 59, at 1 (noting that the family of children who died of Canavan's disease donated the brain tissue of their children to a researcher for testing).

<sup>61</sup>*See, e.g.,* Alice Dembner, *Research Integrity Declines*, BOSTON GLOBE, Aug. 22, 2000, at E2 (describing commercialization of scientific research in the area of medical care); Penni Crabtree, *From Prof to Profit; Money and Scientists Mingle, Creating Companies and Concerns*, S. D. UNION-TRIBUNE, Oct. 29, 2000, at H-1 (describing conflicts of interest.); *see also* Pilar N. Ossorio, *Pills, Bills & Shills: Physician-Researcher's Conflicts of Interest*, 8 WID. L. SYMP. J. 75, 77 (2001) (describing conflicts of interest for doctors who are also researchers); Janet Fleetwood, *Conflicts of Interest in Clinical Research*, 8 WID. L. SYMP. J. 105, 106-09 (2001) (listing factors that hamper full disclosure of patient understanding of consent forms); Jennifer Washburn, *Informed Consent*, WASH. POST MAG., Dec. 30, 2001, at W16 (describing the conflict of interest of doctor-researchers with a focus on conflict of interests involved in soliciting patients to join clinical studies).

<sup>62</sup>*See, e.g.,* Kolata, *supra* note 59, at A17 (noting that researcher Dr. Reubon Matalon's employment contract required that every invention he made would be owned by his employer); Gillis, *supra* note 52, at A1 (noting that researcher and doctor Reuben Matalon was obliged to tell the hospital that he worked for about the patentable discovery, which then was applied for and granted to Miami University Children's Hospital).



### *b. Patent System Misperception*

Most patients do not comprehend the basis upon which patents are granted. In particular, while patients may be correct that it was their "idea" that a genetic problem existed, patents are not granted for ideas or observations alone.<sup>63</sup> In most cases where patients have contributed biological material to scientists, the scope of the actual patent is quite different from the mere concept that the patient's genes were an anomaly.<sup>64</sup> In particular, scientists usually must perform additional testing to determine the genetic marker that controls for the anomaly and it is the discovery of the marker, rather than the patient's identification of an aberration, that is granted a patent.<sup>65</sup>

In addition, patients perceive the exclusivity inherent in patent rights to be fundamentally inequitable. Patient contributors are often affronted by the current scheme that enables patent owners to charge heightened prices to everyone including those who contributed to the discovery of the invention.<sup>66</sup> Accordingly, some patient contributors are interested in patent ownership as a way of controlling access to patented inventions, or at least control of licensing of the invention.<sup>67</sup> In particular, when patients realize that someone else is reaping profits based upon their contributions, the patients may feel that the obvious equitable solution would be that they must be entitled to a part of the thing, which creates profits, i.e. the patent. This is particularly true for patients who claim that scientists could not have created the patentable invention without their assistance.<sup>68</sup>

## **B. Research Reality**

### *1. Commercial Interests*

This section will clarify that the general perception among patients that doctors and scientists are principally devoid of commercialism does not accurately reflect the current situation. There is a growing body of literature regarding the increasing commercialization of science, particularly bio-medical sciences.<sup>69</sup> For example, academic scientists in

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<sup>63</sup>Funk Bros. Seed Co. v. Kaola Inoculant Co., 333 U.S. 127, 130-32 (1948). See generally 35 U.S.C. 101 (1994).

<sup>64</sup>See *infra* note 100-76 and accompanying text (explaining why patient contributions, including John Moore's, fail to rise to the level of inventorship).

<sup>65</sup>See *id.*

<sup>66</sup>See, e.g., *Greenberg*, 208 F. Supp.2d at 921 (alleging that defendants earned significant royalties from the resulting patent, as well as the fact that the researcher they worked with has personally profited).

<sup>67</sup>See *supra* notes 48-49 and accompanying text (discussing PXE situation).

<sup>68</sup>See, e.g., *Safer*, *supra* note 44 (quoting patient contributor Fuchs as stating that "without my blood ... they would not have had this discovery" and that it was his idea that his immune system was unique, such that he should share in the patent profits).

<sup>69</sup>Kathleen Cranley Glass & Trudo Lemmens, *Conflict of Interest and Commercialization*

these areas often also have financial ties to pharmaceutical and genomic industries.<sup>70</sup> Moreover, regardless of any industrial ties, many universities currently view patents, particularly their potential licensing revenue, as one way to supplement an ever-decreasing pool of federal funding for research.<sup>71</sup>

Some of this commercialization, and particularly an increased focus on patents in the bio-medical area, is often attributed to the U.S. Supreme Court's 1980 holding in *Diamond v. Chakrabarty*, that genetically engineered bacteria could constitute patentable subject matter; this decision has been seen as opening the flood-gates to patents on living matter and fostering the then nascent biotechnology field.<sup>72</sup> Subsequent to this important case, major federal legislation also encouraged commercialization of research. For example, changed federal rules enabled industry to patent and accordingly reap commercial rewards from research that was initially based upon publicly funded projects.<sup>73</sup> In addition, federal legislation specifically

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*of Biomedical Research Office*, in THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL AND POLICY ISSUES (Caufield & Williams-Jones, eds. 1999; OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 45-69 (1991)) (describing the financing of biotechnology); OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY 411-30 (U.S. Gov't Printing Office 1991) (discussing relationships between university and industry); Moore v. Regents of the Univ. of Cal., 793 P.2d at 506-23 (Mosk, dissenting).

<sup>70</sup> See, e.g., Krimsky, *supra* note 1, at 15-20 (giving the historical development of how scientists interact with industry, focusing on molecular genetics); Zach W. Hall & Christopher Scott, *University-Industry Partnership*, 291 SCIENCE 553 (2001) (editorializing about the relationship between universities and private industry in the biomedical research community); Kolata, *supra* note 59, at A17 (quoting Professor Hank Greely of Stanford Law school as stating that "these days, there is very little academic research that doesn't have some commercial interest, and almost always now the researcher has a potential commercial interest"); Ronald Kotulak, *Playing Doctor ... or Playing God? Patents are University's Gold Mine*, CHI. TRIB., Dec. 9, 2001, at C1 (discussing the University of Wisconsin's use of patents to earn \$ 1.65 billion in licensing and investment revenues since 1927).

<sup>71</sup> See e.g., Karen W. Aronson, *Columbia Sets Pace in Profiting Off Research*, N.Y. TIMES, Aug. 2, 2000, at B1 (noting Columbia as a particularly aggressive academic institution in deriving profits from patents); Hall & Scott, *supra* note 70, at 553. See also Jeff Gottlieb, *UCI Case Raises Issue of Schools' Ties to Business*, L.A. TIMES, Dec. 27, 1998, at A1 (noting that UC-Irvine is more dependent than some other institutions on private funds because it only obtains about half of its research funding from the federal government).

<sup>72</sup> See *Diamond v. Chakrabarty*, 447 U.S. 308, 318 (1980) (holding that the Patent Act fairly embraces organisms produced by genetic engineering. See also Krimsky, *supra* note 1, at 23-25 (describing how *Chakrabarty* allows some biological material to be patented); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Inventions in the American Patent System*, 50 EMORY L. J. 101, 105 (2001) (noting that *Chakrabarty*, in combination with the newly created Federal Circuit, helped to foster the development of pro-biotechnology jurisprudence); Kenneth Sutherlin Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD DRUG L.J. 453, 494 (1997) (discussing *Chakrabarty* decision and the subsequent growth of biotechnology after Genentech's initial public offering).

<sup>73</sup> Bayh-Dole Act, 35 U.S.C. 200-11 (1994); Steven-Wydler Act, 15 U.S.C. 3701-14 (1994); see also GARY W. MATKIN, TECHNOLOGY TRANSFER AND THE UNIVERSITY 81-94 (1990)

promoting collaboration among government and industry was also enacted.<sup>74</sup>

## *2. Patent Impact: Restricted Access*

One side effect of the commercialization of biotechnology has been the increased active enforcement of patents. In particular, both corporations as well as universities have been more aggressive in pursuing licensing agreements or suing those who refuse to agree to license terms.<sup>75</sup> Patient advocates assert that licensing fees for the use of patented diagnostic tests have been priced exorbitantly high, such that clinics either refuse to offer the test or only offer the test at prices that far exceed what most consumers can pay.<sup>76</sup> This is particularly true because the demand of licensing fees is often a precursor or a concomitant threat of litigation for unauthorized use of a patent.<sup>77</sup>

Although restricted access and increased costs are a direct result of the patents, this result is actually contemplated and encouraged by some underlying patent policy principles. Fundamentally, a patent provides its owner with the legal right to exclude all others who make, use, or sell the patented invention.<sup>78</sup> This fact is supported by theories of patent law that permit the exclusivity of patents as an incentive to create, as well as a means to recoup development costs.<sup>79</sup> In addition,

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(describing how four specific academic institutions have utilized patents). However, whether firms will be able to continue to patent the results of research that is partially funded by the government is uncertain in light of recent public opposition. *See, e.g.,* Peter Arno & Michael Davis, *Paying Twice for the Same Drug*, WASH. POST, at A21 (Mar. 27, 2002) (editorial criticizing the government for failing to properly supervise the federal financing of patented drugs).

<sup>74</sup>the Technology Transfer Act allows government researchers to patent their inventions and also obtain patent-based royalties (up to \$ 150,000). 15 U.S.C. 3710(c)(a)(3) (1994). In addition, the act allows and encourages government researchers to enter into commercial arrangements with for-profit companies. *Id.* at 3701-14 (1994) (providing for CRADA).

<sup>75</sup>*See, e.g.,* MATKIN, *supra* note 73, passim (describing the creation of technology transfer offices at universities after patents became more common); Dueker, *supra* note 72, at 464-67 (noting the increased patent licensing activity among universities after the enactment of the Bayh-Dole Act); Kotulak, *supra* note 70, at C1 (noting the University of Wisconsin's effective patent licensing program).

<sup>76</sup>*See, e.g.,* Tebo, *supra* note 1, at 50-51 (citing Jeremy Rifkin, who noted that genetic tests based on non-patented genes cost around \$ 50 while tests based on patented genes can cost \$ 2500 after licensing fees are considered).

<sup>77</sup>*See Greenberg*, 208 F.Supp. 2d at 921 (noting that patent owner sent "enforcement letters" to centers offering the patented test for free and also sought to limit the total number of labs using the patented disease through exclusive licensing agreements; Tebo, *supra* note 1, at 50-51 (comparing current gene patent enforcement to historical surgical procedure patent enforcement)).

<sup>78</sup>*See* 35 U.S.C. 271 (1994) (providing that patent owners have the right to exclude all others from making, using, selling, offering to sell, or importing the patented invention).

<sup>79</sup>*See supra* notes 10-21 and accompanying text (describing patent law theory that supports the patent owner right to exclusivity).

because the time invested in creating a patentable invention, as well as the time and money spent procuring a patent is substantial, those that undergo this process have a financial incentive to ensure that others are not usurping their exclusive right to use the patented invention.

However, although patent laws may contemplate the fact that patents result in restricted access, there are also health policy arguments for tempering the usual patent laws when they negatively impact public health.<sup>80</sup> In addition, in the case of patents that are based upon patient contributions, such restricted access ironically excludes those who helped secure the patent.<sup>81</sup> Moreover, patents based upon patient contributions have a potential negative feedback cycle that threatens further research and collaboration.<sup>82</sup> In particular, patients who believe

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<sup>80</sup>See, e.g., 35 U.S.C. 271(e)(1) (1994) (providing limited exception to infringement to enable acceleration of FDA approval of generic medications); *Canada - Patent Protection of Pharmaceutical Products (Generic Medicines)*, Report of the Panel, WT/DS114/R (March 17, 2000), available at <http://www.wto.org/english> (considering public health impacts in evaluating patent rights in an international dispute before an arbitration panel of the World Trade Organization). The increasing number of patents and patent players has been criticized as impeding the progress of science in many areas. See also Rebecca Eisenberg, *Technology Transfer and The Genome Project: Problems with Patenting Research Tools*, 5 RISK HEALTH SAFETY & ENV'T. 163 (1994) (describing limitations to licensing of all patent rights essential to continue research); Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 EMORY L. J. 823, 827-36 (2000) (describing problems inherent in patent licensing of basic research, especially transaction costs); see also HUGO Statement on Patenting of DNA Sequences (April 2000), at <http://www.gene.ucl.ac.uk/hugo/patent2000.html> (clarifying opposition to patenting of genetic components where there is a negative impact on the further progress of research); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Incentives, Costs, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192-94 (2001) (describing the potential problem of patents on early-stage genomics research for later commercialization); *Taking License With Your Genes*, *supra* note 1, at C1 (discussing the impact of the increasing gene patents on medical research and health care costs).

<sup>81</sup>For example, the hospital that owned the patent rights related to the gene for Canavan's disease threatened to sue clinics who provided the test for free and demanded a royalty payment that would essentially prevent the clinics from continuing to provide a service to patients. See, e.g., *Greenberg*, 208 F. Supp.2d at 921; *Brower*, *supra* note 59, at 1 (noting that the Canavan Foundation was blocked from offering free genetic screening after refusing to pay royalties and follow licensing restrictions by patent owner Miami Children's Hospital which requested that the tests be limited in number, as well as in location); Gillis, *supra* note 52, at A14 (describing different licensing approaches taken by patent owner Miami Children's Hospital including a failed attempt to exclusively license the patent); *Taking License With Your Genes*, *supra* note 1, at C1 (noting some doctors have stopped offering a test for Down Syndrome because the patent licensing fees, together with low Medicare payments, do not make it a viable commercial option); James Meek, *Doctors Hindered by Company's Gene Patent*, THE GUARDIAN, Feb. 7, 2002, at 8 (noting that doctors' ability to study haemochromatosis, a disease affecting up to 20,000 Britons, is hindered because the patent owner on the underlying gene has enforced the patent against laboratories resulting in a reduction of testing by about one third).

<sup>82</sup>Many patients provide contributions on the assumption that resulting research will be freely available to all; if patients realize the commercial realities, they may refuse to participate. See *supra* notes 57-59 and accompanying text (noting that patients were shocked to discover the results of their contributions patented because they had assumed all treatments would be freely available).

that they will merely be used as means to get a patent may refuse to contribute their biological materials, or may require licensing of their biological materials, which would further increase the overall costs of obtaining a patent.<sup>83</sup>

In addition, although patients and patent owners could theoretically "strike a bargain," that has been unlikely because of how research is currently conducted.<sup>84</sup> In particular, researchers often are obligated to assign any inventions that they discover during the course of their work to their employer.<sup>85</sup> Accordingly, many of the scientists who work with patient contributors have little control over whether a patent is sought and often have already ceded any ownership interest in patents to their employers. Moreover, the organization that owns a patent typically views a patent as an income-generating device, rather than something that would create deep-seated resentments or have negative impact on further research. In fact, in the typical situation where a researcher works with patient contributors but is required to give the corporate employer patent ownership, the patent owner would have no direct interaction with the impacted patient population.

Although patient perceptions are not reflected in the current medico-research reality, a reasoned inquiry into whether patients are overlooked as potential inventors under patent laws is an important question. If patients could be considered patent inventors, or otherwise gain some control over the patent, some of their negative perceptions would be allayed, if not alleviated.

### III. ADDRESSING THE INVENTORSHIP ISSUE

#### A. The Importance of Inventorship

##### 1. *Inventorship Policy*

The significance of inventorship in patent law is underscored repeatedly in the United States Patent Act. From the first application for a patent, correct identification of the inventor is underscored. Not only must the original inventor(s) request a patent application,<sup>86</sup> but

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<sup>83</sup> See Fleischer, *Seeking Rights to Crucial Gene*, *supra* note 49, at C16 (citing Professor Eisenberg for criticizing the PXE approach as potentially hindering research efforts because of the increasing number of individuals seeking rights).

<sup>84</sup> However, this possibility is nonetheless discussed as a possible option. See *infra* notes 194-96 and accompanying text (discussing the contractual approach taken by patient group PXE).

<sup>85</sup> See *supra* note 38 (noting that inventions may be assigned prior to patent grant); see also *supra* note 62 and accompanying text (noting that the researcher who worked with patient contributors in the *Canavan* case had in fact been required to assign his rights as part of his employment contract).

<sup>86</sup> 35 U.S.C. 111 (1994) (noting that application shall be made, or authorized to be made by an inventor and include an oath by the inventor).

also the inventor(s) must submit oaths declaring their belief that they are the first and true inventors.<sup>87</sup> These procedural rules help ascertain whether the patentability requirement that the invention is indeed new, rather than derived from another, is satisfied.<sup>88</sup> In addition, the importance of these rules is underscored by the fact that improper naming of inventors can result in invalidation of the patent, i.e., total loss of all patent rights.<sup>89</sup>

Inventorship is also emphasized by certain unique aspects of United States patent law that have repeatedly withstood pressure to comply with a different international norm. The United States is the only industrialized country to continue to insist that patents be granted only to those who are first inventors ("first to invent" rule), as opposed to a rule that rewards those who are first to request a patent ("first to file" rule).<sup>90</sup> The United States' distinct position has been fairly consistent throughout the history of the Patent Act.<sup>91</sup> Congress has rejected proposals to adopt a first to file system thus far and interested organizations, including independent inventors, have strongly denounced such proposals as inimical to U.S. patent policy.<sup>92</sup> The

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<sup>87</sup>35 U.S.C. 115 (oath requirement for inventor).

<sup>88</sup>See 35 U.S.C. 102(f).

<sup>89</sup>See, e.g., *id.* see also *Jamesbury Corp. v. United States*, 518 F.2d 1384, 1395 (1975) (noting that inclusion of less than all the inventors can make a patent void, if established by clear and convincing evidence); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech*, 12 F. Supp.2d 69 (D.Mass. 1998) (holding patent unenforceable on grounds of inequitable conduct because of failure to name inventors). However, there are procedures that would typically be applicable to correction of inventorship, including either the issuance of a certificate of correction or the re-issuance of a patent, depending on a number of other factors. These factors include whether the inventors agreed to the change as well as whether there were other errors in the patent. See 35 U.S.C. 251 (1994); 35 U.S.C. 255 (listing the requirement for certificate of correction); 35 U.S.C. 256 (listing the requirement for correction of the named inventor); see also *Merry Mfg. Co. v. Burns Tool Co.*, 335 F.2d 239, 242 (5th Cir. 1964).

<sup>90</sup>Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws, 66 Fed. Reg. 15409, 15410 (Mar. 19, 2001) (noting current U.S. adherence to the first-to-invent rule in contrast to the remainder of the world); 21st Century Patent System Improvement Act, Congressional Record - House of Representatives, 105th Cong., 1st Sess., April 23, 1997, 143 Cong. Rec. H1719-03, at H1727 (clarifying that the United States is a first to invent, rather than first to file nation); *Steal American Technologies Act*, 142 CONG. REC. H6718-02 (daily ed. June 25, 1996) (statement of Rep. Rohrabacher) (noting that the U.S. is the only country in the world operating under the first-to-invent system).

<sup>91</sup>Beginning with the 1790 Patent Act, the first incarnation of the current Patent Act, there was consideration and rejection of a first-to-file system in favor of the current system of rewarding the first true inventor. See, e.g., Edward C. Walterscheid, *Priority of Invention: How the United States Came to Have a "First-to-Invent" Patent System*, 23 AIPLA Q.J. 263, 286-88 (1995).

<sup>92</sup>See, e.g., Edwin A. Suominen, Re-Discovering Article 1, Section 8 - The Formula for First-to-Invent, J. PAT. OFF. SOC'Y 641 (2001); Edward G. Fiorito, *The "Basic Proposal" for Harmonization of U.S and Worldwide Patent Laws Submitted by WIPO*, 73 J. PAT. OFF. SOC'Y 83 (1991). However, the United States may eventually succumb to international pressures in the interest of securing an efficient global system of patent filing. See, e.g., Tod Preston, *The World Intellectual Property Organization's Conference on the International Patent System*, 3

United States' resistance to abandoning the first to invent policy is further underscored by the fact that the current system actually results in a far more complex process of determining who is entitled to a patent.<sup>93</sup>

Although United States patent policy favors the first to invent, the nomenclature "first to invent" is somewhat of a misnomer since the system is not one of absolute priority. Rather, priority is tempered by another important social policy underlying the patent system; namely, the idea that patents are to be rewarded to those who first share their inventions with the public such that the greater public knowledge is benefited. For example, if an individual is the absolute first to conceive the invention, but keeps it secret from the public for one hundred years, a later inventor who quickly divulges the invention will nonetheless be awarded a patent because that second inventor was the first to bring an invention to society's knowledge.<sup>94</sup> Similarly, even if a first inventor does not keep an invention secret, but unduly delays between conceiving the invention and reducing it to practice while a second inventor is the first to reduce the invention to practice, the first inventor can lose the right to the patent because of the strong policy favoring prompt disclosure of inventions to society.<sup>95</sup> Accordingly, the patent rules mediate between the policy of providing the patent to the first inventor while also encouraging prompt disclosure of inventions.<sup>96</sup>

## *2. The Implications of Inventorship on Patent Ownership*

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USPTO TODAY, at 3, 5 (Mar./Apr. 2002), at <http://www.uspto.gov/go/opa/ptoday/mar-apr2002.pdf> (noting recent consideration of first to file issue); Waltersheid, *supra* note 91, at 264.

<sup>93</sup>See 35 U.S.C. 102(g) (1994). The complex adjudicatory system for determining the first inventor is officially called a patent interference in which the PTO determines which of two entities was the true first inventor. See 35 U.S.C. 135 (providing for interference procedure); MPEP, *supra* note 35, at 2300-1 to 2300-36 (providing information on interferences for patent examiners).

<sup>94</sup>35 U.S.C. 102 (g) (1994); see also *Correge v. Murphy*, 705 F.2d 1326, 1330 (Fed. Cir. 1983) (quoting *International Glass v. United States*, 408 F.2d 395, 403 (Ct. Cl. 1968) (noting that "the courts have consistently held that an invention though completed, is deemed abandoned, suppressed, or concealed if, within a reasonable time after completion, no steps are taken to make the invention publicly known. Thus, failure to file a patent application; to describe the invention in a publicly disseminated document; or to use the invention publicly, have been held to constitute abandonment, suppression, or concealment.")); see also 35 U.S.C. 102(b) (1994) (barring patentability of invention if inventor unduly delays between publicizing the invention and filing for a patent); *LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577 (Fed. Cir. 1986) (noting that one of the purposes of 102(b) is to encourage early filing).

<sup>95</sup>See, e.g., *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983); see also 35 U.S.C. 102(g) (1994).

<sup>96</sup>See *Checkpoint Sys.*, 54 F.3d at 761 (noting that one of the purposes of 102(g) is to ensure that the patent goes to the first inventor while another purpose is to encourage prompt disclosure of the invention).

The importance of inventorship also extends into patent ownership. In particular, patent laws reward inventors with presumptive ownership of patents on their inventions. The ownership presumption is crucial because patent ownership conveys the right to exclude all others from any use of the patented invention without the owner's consent; accordingly, ownership of a widely utilized invention can be of huge financial importance.<sup>97</sup>

Patent ownership rules also favor inventors who jointly create an invention by providing *each* joint inventor with the same presumptive right to patent ownership. The Patent Act explicitly provides that patents have attributes of personal property and that each joint inventor can license the patented invention without consent or even accounting to other co-owners.<sup>98</sup> Accordingly, being the inventor or even a joint inventor of a patent conveys extensive privileges.

Inventorship is a key issue for patient contributors who seek to control the results of their contributions. For example, if patient contributors were considered inventors or even joint inventors of patents under current rules, they could license any entities they wished, even over the objections of other joint inventors. In addition, courts have held that in the case of joint inventors, a complete defense to one joint inventor's infringement claim is a license by the other joint inventor.<sup>99</sup> Accordingly, if patients were joint inventors, they could potentially trump the desires of the other joint inventor to sue for patent infringement or to charge exorbitant license fees. For example, in the *Canavan* case, if the contributing patients were considered joint inventors, they could have provided royalty-free licenses to the labs that wished to provide the patented test and thereby insulate these labs from the prospect of infringement suits from the other joint inventors. Thus, the power inherent in present joint inventorship rules could theoretically provide patients with the very control that they seek in promoting broader access to patented technology. However, there

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<sup>97</sup> See, e.g., Kotulak, *supra* note 1, at C1 (noting Amgen's estimated \$ 100 million patent); see also *supra* note 3 and accompanying text (noting public perception that gene patents are very valuable)

<sup>98</sup> See 35 U.S.C. 261 (1994) (noting that patents "shall have the attributes of personal property."); 35 U.S.C. 262 (providing that "in the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, *without the consent of and without accounting to the other owners.*") (emphasis added). However, there does appear to be some issue as to the whether each co-owner can assign the patent to others since enforcement of a patent requires joinder of all patent owners. See Rochelle C. Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership and Accountability*, 53 VAND. L. REV. 1161, 1211-12 (2000).

<sup>99</sup> See, e.g., *Ethicon, Inc. v. Yoon*, 64 F.3d 671 (1995); *Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997).



remains the legal problem that the present law makes it difficult for patients to be considered joint inventors. An additional and potentially more critical problem is a possible change to the legal implications of joint inventorship that would eliminate the type of control presently available to joint inventors.

## B. Applying Current Law to Patients

### 1. *What is the (Patentable) Invention?*

To determine whether patient contributors have a viable claim to inventorship, it is important first to re-visit what constitutes a patentable invention. As previously mentioned, the mere idea of a problem is not sufficient for a patent; a patentable invention is more complex than merely realizing a problem or observing natural phenomena.<sup>100</sup> However, a simplistic definition of what *is* patentable is more elusive without further description of the patent examination process.

Essentially, a patentable invention is determined based upon the patent "claims" that conclude the patent application. By definition, "claims" consist of one or more sentences which define the scope of the patentable invention for purposes of both patentability as well as for enforcement of patent rights once a patent issues.<sup>101</sup> The claims are central to the patentability determination because they define the invention;<sup>102</sup> in particular, the PTO compares the claimed invention with what exists previously (referred to as "prior art") to determine if the patent application really claims an invention that satisfies the technical requirements of being new and non-obvious.<sup>103</sup>

### 2. *Who Invented the Claimed Invention?*

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<sup>100</sup> See *supra* notes 14-17 and accompanying text (explaining basic patentability standards); see also *supra* note 63 and accompanying text (explaining why patient contributions constitute unpatentable material).

<sup>101</sup> See, e.g., *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950) (a claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257-58 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention."); *In re Van Geuns*, 26 U.S.P.Q.2d 1057, 1185 (Fed. Cir. 1993) (noting that claims define scope of invention); see also 35 U.S.C. 112 (1994) (noting that a patent application "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention").

<sup>102</sup> However, the claims must also be read in conjunction with the rest of the application referred to as the "specification." See 35 U.S.C. 112 (1994); *Warner-Jenkinson Co. v. Hilton Chem. Co.*, 520 U.S. 17, 29 (1999).

<sup>103</sup> See 35 U.S.C. 102-03 (1994); see also *supra* note 36 (describing PTO prior art search).

In addition to the preliminary issue of patentability, claims are also critical to determining inventorship, which is typically a preliminary basis of patent ownership rights. Accordingly, the claims of the patent are central to determining the validity of patients' claims to inventorship. Moreover, there may be multiple inventors of patent claims, with each joint inventor being entitled to equal rights.

Before discussing joint inventorship, fundamental components of invention, as well as individual inventorship will first be discussed. In particular, invention is divided into the steps of first conceiving the invention ("conception"), followed by reducing the invention to practice ("reduction to practice").<sup>104</sup> The delineation of these steps reflects that part of an invention may be primarily mental, or conceptual, whereas to ensure that an invention functions as intended, there may need to be a working model created, or some other way to "reduce" the mental conceptions to practice.

#### *a. Conception*

Conception is a critical starting point with respect to determining inventorship issues. In fact, some courts have referred to conception as the "touchstone of invention."<sup>105</sup> Conception is defined as the completion of the mental activity involved in formulating the invention.<sup>106</sup> It requires a mental picture of the invention, which is sufficiently definite that another person with adequate skill in the area could understand the invention.<sup>107</sup> Accordingly, conception requires specificity and a particular solution to a problem, rather than a general goal or research plan.<sup>108</sup> As noted by one court, the conception requirement is intended to "ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention."<sup>109</sup> In the area of biotechnology, conception of a

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<sup>104</sup>Typically the conception of an invention will be followed by a "reduction to practice" which involves making the inventive concept work. Although the two steps are considered separate, in certain areas, such as biotechnology, courts have found that there must be *simultaneous* conception and reduction to practice because the realities of finding chemical compounds are such that the idea of finding a specific compound may be far removed from the prospect of actually finding such a compound. *See, e.g., Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

<sup>105</sup>*See, e.g., Burroughs Wellcome v. Barr*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

<sup>106</sup>*Id.*

<sup>107</sup>*See id.* at 1228; *see also Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (defining conception as requiring the "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").

<sup>108</sup>*Burroughs Wellcome*, 40 F.3d at 1228; *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994).

<sup>109</sup>*See, e.g., Burroughs Wellcome*, 40 F.3d at 1228

genetic component requires knowledge of a specific chemical structure.<sup>110</sup>

*b. Can Patients Conceive the Claimed Invention?*

Although patients typically do not claim sole inventorship of patents, looking at whether patients could satisfy this standard is nonetheless helpful in illustrating a gap between patient perceptions and patent law with respect to inventorship as a whole. As noted earlier in this section, the first step to determining proper inventorship is to examine the patent claims. When the steps to determining inventorship are outlined and applied to patients, it becomes clear that the patients' perceptions do not match the present patent laws. In most cases, the actual patent claims do not include any activities that patients directly performed. For example, patent claims to isolated gene sequences, or methods of detecting diseases based upon the isolation of gene sequences, typically require knowledge of biological sciences beyond the realm of most patients. In addition, although patients may perceive their efforts to have substantially advanced ultimate accomplishments, the definition of conception does not extend to those who assist; rather, conception of the invention requires an actual mental picture of the claimed invention. A patient who presents the raw material that a researcher can examine and use to isolate a patented gene is not presenting anything that can be claimed because her own genetic material, in its natural state, fails to satisfy the patent law requirement of novelty.<sup>111</sup> Moreover, such a patient would fail to satisfy the requirement for conception of the chemical components of the isolated genetic material, unless the patient happened to be a genetic research scientist herself. In most cases, however, the patient's contribution is more analogous to a general research plan or goal that courts have dismissed as unpatentable for failing to have the requisite specificity to constitute a solution to a problem.<sup>112</sup>

One illustration of the distinction between patient contribution and patentable invention lies in the legendary case of *Moore v. Regents of the University of California*, in which the surreptitious scientists who removed Moore's spleen and other bodily fluids<sup>113</sup> applied for and received a patent that claimed a cell line derived from Moore's spleen

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<sup>110</sup> See, e.g., *id.* at 1229; *Amgen*, 927 F.2d at 1206.

<sup>111</sup> See, e.g., *supra* notes 23-26 and accompanying text (noting that natural discoveries are not patentable, although modified genetic material, such as isolated gene sequences, are patentable).

<sup>112</sup> See *Sewall*, 21 F.3d at 415.

<sup>113</sup> Over a period of months, Moore contributed blood, skin, bone marrow aspirate, as well as sperm. See *Moore*, 51 Cal. 3d at 126.

cells. The patent itself claimed a cell line of T-lymphocytes that are not naturally occurring, as well as methods of using the cell line to produce lymphokines.<sup>114</sup> Although scientists created the cell-line based upon patient Moore's actual cell, the claim to the artificially created cell line was not a function of Moore's own mental conception. In addition, the claimed invention did not claim Moore's cell, nor could it, because discoveries of naturally existing compounds are not patentable; among other things, naturally occurring compounds would fail to meet patent law's novelty requirement.<sup>115</sup> Accordingly, a claim by Moore to have either invented the *claimed* invention, or to have a patentable invention in his own cells, would fail.

A more recent case, *Greenberg v. Miami Children's Hospital*, also provides a good illustration of patient contributions that assist, but do not invent a patentable compound.<sup>116</sup> In this case, parents of children afflicted with Canavan's disease provided biological material and financial support to a doctor.<sup>117</sup> Although the doctor ultimately was successful in isolating the gene responsible for the disease, the patent that was applied for and granted to the doctor's employer, the Miami Children's Hospital Research Institute, prevented the free testing that the patients had envisioned.<sup>118</sup> Although the patients sued on a number of legal grounds, including breach of contract and lack of informed consent, they notably did not include a claim regarding inventorship of the patent.<sup>119</sup> Although they engaged in more activities than patient Moore, they would still fail to meet the inventorship requirement. For example, many of the patent claims refer to "an isolated nucleic acid molecule" having certain specific sequences, which the patients would not have participated in creating since only the doctor isolated the specific material.<sup>120</sup> None of the patent claims refer to the raw material from which the doctor determined the isolated material.<sup>121</sup> Moreover, as in *Moore*, claims to natural compounds would not be patentable because natural discoveries cannot satisfy the novelty requirement.<sup>122</sup>

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<sup>114</sup> See *id.* at 127.

<sup>115</sup> See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128-30 (holding that patents cannot issue for the discovery of phenomena of nature); *In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977).

<sup>116</sup> See *Greenberg*, 208 F. Supp.2d at 918.

<sup>117</sup> *Id.* at 921.

<sup>118</sup> *Id.* (noting that the plaintiffs were never informed that the hospital intended to seek a patent).

<sup>119</sup> See *id.* at 921-22 (listing the plaintiffs' allegations).

<sup>120</sup> See Matalon et al., *Aspartoacylase Gene, Protein and Methods of Screening for Mutations Associated with Canavan Disease*, U.S. Patent No. 5,679,635 (Oct. 21, 1997).

<sup>121</sup> See generally *id.* (containing no claims to raw material).

<sup>122</sup> See *supra* note 115 and accompanying text (explaining that phenomena of nature, even if unusual, are not patentable).

### 3. Are There Joint Inventors?

Although patients alone are unlikely to be considered sole inventors, the patent law also provides for joint inventorship. In general, joint inventors must have jointly created the patentable invention. In particular, the statutory definition of joint inventors states that inventors may be joint "even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."<sup>123</sup> However, case law has imposed additional requirements, such as the requirement that co-inventors collaborate in the conception of the invention, as the following section will explain.<sup>124</sup>

#### a. Conception Requirements for Co-Inventors

A pertinent case to illustrate the requirement of joint collaboration in conception for co-inventors is the *Burroughs Wellcome* case, in which scientists from the National Institutes of Health (NIH) unsuccessfully tried to claim co-inventorship of the AZT compound, as well as a method of using it to treat AIDS.<sup>125</sup> Burroughs Wellcome and NIH scientists, were simultaneously pursuing an HIV cure using different approaches.<sup>126</sup> Burroughs Wellcome's original research goal of finding a method to treat AIDS would have failed to meet the required specificity for conception.<sup>127</sup>

However, by the time that the Burroughs Wellcome scientists applied for a patent on the compound AZT, claiming utility against HIV, they had more than a general hope. Their patent application could confer the knowledge about AZT to anyone with sufficient expertise in the area - accordingly, they had conceived and formulated the idea that AZT had activity that appeared to be useful in treating HIV.<sup>128</sup>

NIH scientists claimed that they should be entitled to joint inventorship status because they had confirmed that AZT was active

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<sup>123</sup>35 U.S.C. 116 (2001).

<sup>124</sup>See, e.g., *Burroughs Wellcome*, 40 F.3d at 1229-30.

<sup>125</sup>*Id.* at 1228.

<sup>126</sup>*Id.* at 1225 (stating Burroughs Wellcome utilized mouse retroviruses, while NIH used a live human cell line).

<sup>127</sup>*Id.* at 1229.

<sup>128</sup>*Id.* (noting that Burroughs Wellcome had "thought of the particular antiviral agent with which they intended to address the HIV treatment problem" and formulated the idea of the invention to the point that they could express it clearly in the form of a draft patent application").

against HIV in humans, using their live human cell line.<sup>129</sup> However, the court found that the invention of using AZT to treat AIDS was already *conceived* by Burroughs Wellcome before the NIH confirmation.<sup>130</sup> In particular, the court noted that the patent application draft "shows that the idea was clearly defined in the inventors' minds; all that remained was to reduce it to practice - to confirm its operability and bring it to market."<sup>131</sup>

In addition, assistance towards a patentable invention in the form of general ideas and information does not give rise to joint inventorship because of the lack of participation in the conception of the invention. For example, one who merely provided ideas and information on what was currently available on the market was held not to be a joint inventor of a device which did not use any such information.<sup>132</sup> Similarly, one who made suggestions for potential material to be used in the creation of a balloon angioplasty catheter was deemed to be "no more than a skilled salesman," and accordingly, not a joint inventor of a patent on the catheter.<sup>133</sup>

#### *b. Can Patients Count as Joint Inventors?*

The critical question for many patient contributors is whether they can be joint inventors, such that they can obtain control over the patent. However, as this section will show, the suggestion that patients have contributed significantly enough to be rewarded with joint inventorship lacks substantial basis within the actual law. This section will first consider the argument that present law can embrace patients within the definition of joint inventorship. However, this argument ultimately fails because it overlooks the previously described requirements of conception. In addition, this section will discuss specific cases in which courts have addressed the issue of whether patient contributors constitute joint inventors; however, this section reveals that none of the case law thus far supports patients' claims. Accordingly, the final section looks to analogous claims of joint inventorship based on causation to see if a similar legal theory can assist the patients' claim.

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<sup>129</sup>The two organizations collaborated on one level: the NIH sought compounds from pharmaceutical companies, including Burroughs Wellcome, to screen, using a unique live HIV virus. *Burroughs Wellcome*, 40 F.3d at 1225. Before the patent applications decision, Burroughs Wellcome had sent a sample of AZT to NIH laboratories for testing with the live human cell line, although the sample was not identified. *Id.* at 1226.

<sup>130</sup>*Id.* at 1230.

<sup>131</sup>*Id.* (citing *Haskett v. Colebourne*, 671 F.2d 1362, 1365-66 (C.C.P.A. 1982) for the proposition that enabling patent applications can corroborate conception).

<sup>132</sup>*Pro-Mold and Tool Co., Inc., v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1575-76 (Fed. Cir. 1996).

<sup>133</sup>*Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 981 (Fed. Cir. 1997).

However, this section ultimately concludes that there is no present case law that supports an inclusion of patient contributors within the current definition of joint inventorship.

#### i. Actual Patient Contributor Cases

There are only three published opinions involving the issue of whether patient contributors can be co-inventors, all arising from the same set of facts.<sup>134</sup> In the first two cases, the defendant Synbiotics Corporation raised the inventorship issue as a defense to patent infringement.<sup>135</sup> In the third case, *Brown v. Regents of the University of California*, the patient initiated an action to correct inventorship of the patent to include herself.<sup>136</sup> Although the courts in each of these cases found against the patient contributor, the specific rationales help explain the current problem of with including patient contributors as joint inventors.

In *Synbiotics I*, the opinion addressed a host of procedural issues, with the court opining on the inventorship issue as merely one of several invalidity defenses alleged against the plaintiff's motion for a preliminary injunction.<sup>137</sup> The inventorship issue was not central to the court's ultimate denial of the plaintiff's preliminary injunction motion and appeared to have been ill-framed as a defense.<sup>138</sup> In addition, the court's opinion on the inventorship issue may have been colored by its negative perception of the defendant's other claims.<sup>139</sup> However, the court's approach to the inventorship issue in *Synbiotics I* is nonetheless important because of its impact on subsequent cases.

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<sup>134</sup>Although there is an additional opinion involving one of the same patents, the issue of inventorship based on patient contribution was not considered. *See Regents of University of California v. Hansen*, 54 U.S.P.Q.2d 1473, 1484 n.9 (S.D. Cal. 1994) (noting the additional argument that the patent should be suspect for failure to give inventorship credit to Marlo Brown "has been litigated in other cases and the court does not address this irrelevant issue here").

<sup>135</sup>*See Univ. of Cal. v. Synbiotics Corp.*, 29 U.S.P.Q.2d 1463, 1466-67 (S.D. Calif. 1993) [*Synbiotics I*]; *Regents of Univ. of California v. Synbiotics Corp.*, 849 F. Supp. 740, 741 (S.D. Calif. 1994) [*Synbiotics II*].

<sup>136</sup>*Brown v. Regents of Univ. of California*, 866 F. Supp. 439 (N.D. Cal. 1994).

<sup>137</sup>Synbiotics claimed, among several other defenses to patent infringement, that the patent was invalid for failure to include patient Marlo Brown as a joint inventor. *Synbiotics I*, 29 U.S.P.Q.2d at 1466-67. Synbiotics also made the more traditional argument that the patented invention was invalid on grounds of obviousness or in the alternative, unenforceable. *Id.* The procedural context of this case is actually fairly complex - the failure to join an inventor defense, was merely one of four defenses against the patents' validity or enforcement to oppose a preliminary injunction motion; in addition, the opinion considered an appeal from the magistrate judge's order over discovery disputes. *Id.* at 1463-44.

<sup>138</sup>*Id.*

<sup>139</sup>*See, e.g., id.* at 1465 (characterizing the defendant's claims as constituting "delay tactics").

The inventorship argument presented in *Synbiotics I* was whether patient contributor Marlo Brown was a co-discoverer of the FIV virus that was used to develop patented diagnostic methods for FIV.<sup>140</sup> However, the patent in question did not claim the FIV virus, but rather, a *method* for diagnosing the virus.<sup>141</sup> Accordingly, it is not surprising that the court summarily dismissed the argument that Brown's contribution of observing that her cats had human AIDS-like symptoms and bringing them to researchers for study failed to qualify her as a joint inventor of the claimed invention.<sup>142</sup> Rather, the court analogized Brown's contribution to suggesting an idea for a desired result, rather than a specific method, which has been previously held to be inadequate for joint inventorship.<sup>143</sup> The court noted that conception required the idea of the invention's structure, as well as an operable method of making it.<sup>144</sup> Moreover, the court suggested that in this case, conception might not have been able to be established until the invention was actually reduced to practice long after Brown's contribution.<sup>145</sup> The court clarified that:

[a]t most Brown suggested that her cats showed symptoms of an immunosuppressive disease and provided ... the infected cats. On the other hand, [the named inventors'] discovery included the identification of a complete and operative method for isolating the new virus, actually isolating the new virus, and a complete and operative method for diagnosing cats that

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<sup>140</sup>*Id.* at 1466. The court noted that "Synbiotics attacks the validity and enforceability of the ... patent on four grounds: 1) the patentability ... is based solely on the non-obviousness of the discovery of the FIV virus. Consequently, ... the role of Marlo Brown in the discovery of the FIV virus is crucial to the determination of the validity and enforceability of the ... patent; 2) Marlo Brown was a co-discoverer of the FIV virus. ..." *Id.*

<sup>141</sup>Neils Peders and Janet Yamamoto, *Feline T-Lymphotropic Lentivirus Assay*, U.S. Patent No. 5,118,602 (June 2, 1992) (claiming a "method for diagnosing viral infection in a susceptible host, said method comprising: obtaining a physiological specimen from said host; and determining the presence of feline T-lymphotropic virus (FTLV) or antibodies to FTLV in a physiological specimen from said host").

<sup>142</sup>*See Synbiotics I*, 29 U.S.P.Q.2d at 1466 (characterizing the allegation of joint inventorship as "meritless").

<sup>143</sup>*Id.* at 1467 (citing *Garrett Corp v. United States*, 422 F.2d 874, 881 (Ct. Cl. 1970) and *Amgen v. Chugai Pharmaceutical Co.*, 9237 F.2d 1200, 1206 (Fed. Cir. 1991)).

<sup>144</sup>*Id.*

<sup>145</sup>*Id.* (relying heavily on *Amgen v. Chugai* for the idea that this invention required simultaneous conception and reduction to practice). However, even if only conception were required, Brown would likely still have difficulty meeting this test because her idea of a problem did not include knowledge of the chemical structure of the compound, let alone a method for detecting the virus as was required by the claims.



are infected with FIV virus. Brown can hardly be deemed a co-inventor or discoverer.<sup>146</sup>

In the second case, *Synbiotics II*, the inventorship issue was central to the opinion.<sup>147</sup> In particular, the plaintiffs moved for partial summary judgment that Marlo Brown was not a co-inventor of the patent-in-suit, as well as on some propositions of law that flowed from that presumption.<sup>148</sup> The court considered the inventorship issue more thoroughly than it did in *Synbiotics I*, but ultimately came to the same conclusion, based upon essentially the same principles.<sup>149</sup> In particular, *Synbiotics II* found that in the case of patents on genes or chemicals, the law required simultaneous conception and reduction to practice.<sup>150</sup> Patient contributor Brown's status as a non-scientist effectively excluded her from inventorship under this definition because the reduction to practice of the relevant genes required skills beyond her expertise. The court noted that:

Brown *admits* in her deposition that she made no contribution to the isolation of the virus or to the determination of its structure, name, or chemical or physical properties. In essence, Brown's sole contribution to the discovery of FIV is that she brought her sick cats, along with her written observations of the cats' symptoms to UC Davis with a suspicion that the cats may have a virus similar to the human AIDS virus. These facts do not support a claim that Brown is a co-inventor ... .<sup>151</sup>

In the subsequent case, *Brown v. Regents of the University of California*, the patient contributor Marlo Brown directly asserted a claim of co-inventorship in an action to correct the patent

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<sup>146</sup>*Id.*

<sup>147</sup>The opinion addressed the issue of whether the defendant *Synbiotics* could amend its answer to add the affirmative defense of license, in addition to the partial summary judgment issues. *See Synbiotics II*, 849 F. Supp. at 741.

<sup>148</sup>In particular, the court considered whether one who is not a co-inventor, such as Brown could validly confer a patent license. *See Id.*

<sup>149</sup>In particular, the court considered whether one who is not a co-inventor, such as Brown could validly confer a patent license. *See Id.*

<sup>150</sup>In particular, the court accepted the proposition suggested by plaintiffs that "discovery of the FIV virus ... is similar to the discovery of a gene or chemical compound. ... Accordingly, the Court holds that conception, in this case, did not occur until the virus was isolated, or the concept was reduced to practice." *Id.*

<sup>151</sup>*Id.* (emphasis added).

inventorship.<sup>152</sup> Although the *Brown* case was before a different court than the *Synbiotics* cases and purported to address the issue "anew,"<sup>153</sup> its ultimate conclusion was strikingly similar.<sup>154</sup> In particular, after affirming the fact that the principle of simultaneous conception and reduction to practice should apply in this case, the court concluded that Brown "at most played a substantial role in the discovery of FIV," but discounted Brown's role for patent purposes.<sup>155</sup> In particular, the court noted that because the patents do not only claim discovery of the FIV virus, but claim "isolation and substantial purification of the virus, as well as methods for diagnosing the virus by detecting the presence of the virus itself ..."<sup>156</sup> In addition, although the court acknowledged Brown's "substantial role" in discovering the FIV virus, the court characterized Brown's role in the patented product as minimal; in the court's own words: "Ms. Brown is a non-scientist who played no role in the laboratory work involved in isolating the virus; therefore, *regardless of the value of her research leads, she cannot be deemed to have contributed to the conception of the inventions* covered by the patents."<sup>157</sup>

#### ii. Analogous Cases Based Upon Causation Theories

Although cases are limited on the issue of patient contributors' status as inventors, there are nonetheless analogous cases pertinent to the issue. In particular, patient contributors have claimed that they were the factor that led to the patented invention, or that the invention could not have been made but for their contribution.<sup>158</sup> In other words, the patient contributor cases can be analogized to inventorship cases premised on a causation theory.

The most analogous causation case is *Boehringer v. Schering-Plough*, in which the court rejected a defense of patent invalidation based on failure to join all inventors.<sup>159</sup> The patent in this case claimed a method of growing and isolating a specific pig virus, which the

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<sup>152</sup> *Brown*, 866 F. Supp. at 439.

<sup>153</sup> *Id.* at 441 n.3 (clarifying that the court could not merely follow the prior rulings in the *Synbiotics* cases because Ms. Brown was not a party to the prior actions and accordingly could not be bound to the holdings in those cases as a matter of law).

<sup>154</sup> *Synbiotics I* and *II* were opinions of the Southern District of California, while *Brown* was an opinion of the Northern District of California. Although the *Synbiotics* cases were not legally binding, because both courts were district courts within the same circuit, the *Synbiotics* cases would at least have been persuasive authority to the Brown court as a sister district court.

<sup>155</sup> *Brown*, 866 F. Supp. at 445.

<sup>156</sup> *See id.*

<sup>157</sup> *Id.* (emphasis added).

<sup>158</sup> *See supra* note 68 and accompanying text (noting patient's claim that he was essential to the patentable invention because of his own idea that his immune system was unique).

<sup>159</sup> *Boehringer v. Schering-Plough Corp.*, 984 F. Supp. 239 (D.N.J. 1997).

plaintiff claimed was instrumental in developing a vaccine for the pig virus.<sup>160</sup> As in *Synbiotics I*, the joint inventorship claim arose in the context of a defense against infringement.<sup>161</sup> In particular, the defense argued that the claimed isolation was a collaborative effort, and that *but for* the fact that the alleged co-inventors had provided the inoculum containing the virus, the named patent inventor would never have been able to inoculate the virus.<sup>162</sup> The court rejected the inventorship claim, although it agreed with what had been provided:

[t]he court agrees that had Collins and Benfield not provided Harris with the inoculum containing the virus, they would not have been able to isolate the virus, but that does not mean that they should be entitled to joint inventorship rights. Harris might have obtained necessary material from Collins and Benfield, but the patent does not claim a compound. It claims a method developed exclusively by Harris.<sup>163</sup>

The damning fact in this court's analysis of the situation is not that the patent claimed a method, but that what was claimed was distinct from what was *contributed*.<sup>164</sup> In this sense, the case is very analogous to that of patients who contribute material that leads to the discovery of a patentable compound, but do not contribute to the claimed isolated compound itself. In both instances, the conception of the claimed

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<sup>160</sup>*Id.* at 244; see also U.S. Patent No. 5,476,778 (issued Dec. 19, 1995) (claiming "[a] method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises inoculating the virus on a full or partial sheet of simian cells in the presence of serum in a suitable growth medium and incubating the inoculated cell sheet at about 34 degrees C. to 37 degrees C. until CPE is observed.").

<sup>161</sup>See *Boehringer*, 984 F. Supp. at 259. In particular, the opinion disposed of a motion for a preliminary injunction and a substantial part of the opinion dealt with other issues, including claim construction and invalidity based on nonobviousness. In fact, obviousness was deemed the "most compelling challenge" to the patent's validity by the court. *Id.* at 253. Moreover, the co-inventorship claim is discussed subsequent to the obviousness discussion under the catchall heading of "Other Validity Arguments." *Id.* at 259.

<sup>162</sup>*Id.* at 260. Although it is possible to argue that the *Boehringer* did not precisely foreclose the theory of a causation theory of co-inventorship, the court's handy dismissal of the claim is nonetheless pertinent to the discussion of whether patient contributors have any claim that would likely survive. For example, although the court notes that its decision on the issue of inventorship will not impact the ultimate decision relating to a motion for preliminary judgment, the court nonetheless described the co-inventorship claim to "lack substantial merit" and to be "unavailing" as a defense. *Boehringer*, 984 F. Supp. at 259.

<sup>163</sup>*Id.*

<sup>164</sup>It is noted that the opinion focused on the fact that the patent claimed a method, not a compound, but the more important point is that the contributors could not have contributed to a patentable compound. See *id.*

invention relates to matter that is performed exclusively by the named inventor after the contribution.

Another analogous case is *Buildex, Inc. v. Kason Industries, Inc.*, in which inventorship once again arose as a defense to patent infringement.<sup>165</sup> In *Buildex*, the disputed issue was whether an individual who recognized a problem could be considered a joint inventor. The patent in the case related to a hinge-activated switch assembly and the alleged co-inventor was the first to recognize a problem with prior switches.<sup>166</sup> However, although both parties acknowledged that they "would not have solved the ... problem if [the allegedly omitted inventor] had not raised the problem first, this scenario is still consistent with the notion that [the named inventor] was the real inventor. It is one thing to suggest a better mousetrap ought to be built, it is another thing to build it."<sup>167</sup> Nonetheless, the fact that the court so easily dismissed this issue without even considering joint inventorship status suggests that individuals who suggest ideas of a desirable invention, rather than a complete conception of the actual patented invention, will find a cold reception before the courts.

#### IV. ADDRESSING THE PATIENT-PATENT INTERPLAY

##### A. Should Joint Inventorship Be Extended?

###### 1. *Re-Considering Joint Inventorship Cases*

Although the actual and analogous cases of joint inventorship regarding patient contributors have not established any legal rights for such contributors, it is possible that these cases should be viewed through the more narrow procedural context in which they were raised, rather than as whole-sale dismissals of the possibility of including patients within the definition of joint inventors. Admittedly, the ability of patients to establish joint conception of genetic sequences is difficult. However, it should nonetheless be noted that in each of the litigated cases where joint inventorship has been an issue, it was raised under procedural burdens that substantially reduced its likelihood of success. In particular, there is always a presumption that the named inventor of a patent is the only true inventor - a presumption that can only be overcome by clear and convincing proof.<sup>168</sup> Moreover, in *Synbiotics I*, the first published opinion concerning patient contributors, the court may have been negatively pre-disposed on the issue of inventorship

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<sup>165</sup> *Buildex, Inc. v. Kason Indus., Inc.*, 665 F. Supp. 1021, 1024-25 (E.D.N.Y. 1987).

<sup>166</sup> *See, e.g.*, *Hess v. Advanced Cardiovascular*, 106 F.3d 976, 980 (Fed. Cir. 1997) (noting that the allegation of inventorship must be established by clear and convincing proof).

<sup>167</sup> *Buildex*, 665 F. Supp. at 1025

<sup>168</sup> *See, e.g., id.*

because the court perceived the party to be engaging in delay tactics, rather than legitimate defenses.<sup>169</sup> This case, in turn, may have been interpreted over broadly to exclude patient contributors from the definition of inventors, without accounting for the unique procedural context of *Synbiotics I*.

Although there is no clear legal precedent for considering patients to be joint inventors, one case, albeit in a dissent, has in fact suggested that joint inventorship should be interpreted to embrace this scenario. In addressing the removal of cells from patient Moore, Judge Mosk argued that the *spirit* of the joint inventorship law should embrace patients such as Moore, regardless of whether they were within the literal bounds of the inventorship statute.<sup>170</sup> Mosk argued that "the joint invention provision guarantees that all who contribute in a substantial way to a product's development benefit from the reward that the product brings."<sup>171</sup> However, even he probably realized that this was an overstatement of the actual inventorship laws, as he conceded that the patented cell line was primarily the product of the named inventors' efforts.<sup>172</sup> Nonetheless, he argued that "no one can question Moire's crucial contribution to the invention; *but for* the cells of Moire's body ... there would have been no [patented] cell line."<sup>173</sup> Moreover, Mosk noted that although patient contributors do not further the development of the product in any intellectual or conceptual sense, "what the patients did do, knowingly or unknowingly, is *collaborate* with the researchers by donating their body tissue. By providing the researchers with unique raw materials, without which the resulting product could not exist, the donors become necessary contributors to the product."<sup>174</sup>

Judge Mosk's language is powerful and persuasive, but is not anchored within the present joint inventorship law. In particular, his comments overlook the fact that inventorship is a function of the *claimed* invention, which is often quite distinct from what patients contribute. Judge Mosk's description of patients contributing to the end product is more analogous to assistance that courts have found to lack a

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<sup>169</sup> See *supra* notes 138-39 and accompanying text (noting that inventorship issue was weakly framed). Similarly, the analogous cases based upon causation should also be considered within their procedural context. For example, the *Boehringer* case decided the issue of inventorship on a motion for preliminary injunction; in addition, the issue was couched in the context of whether the patent should be invalidated for misdesignation of the inventor with purposely deceptive intent. *Boehringer*, 984 F. Supp. at 259-60.

<sup>170</sup> *Moore v. Regents of Univ. of Cal.*, 51 Cal.3d 120, 168-69 (Cal. 1990) (Mosk, J., dissenting) (acknowledging that "strictly speaking" patients would not fall within the bounds of the law, but that the "spirit" of the law should suffice).

<sup>171</sup> *Id.* at 169 (Mosk, J., dissenting).

<sup>172</sup> *Id.* at 168.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 169 (quoting Danforth, *supra* note 9, at 197).

sufficient link to the conception of the invention itself.<sup>175</sup> To give patients inventorship status based solely upon their contribution of starting materials would require a phenomenal change in the law to overcome the requirement that joint inventors jointly *conceive* of the actual invention itself. Accordingly, while Judge Mosk provides good rhetoric, there remains a large gap between his reasoning and the reality of the present laws.

## 2. Commercial Research Realities

Although Judge Mosk's arguments do not reflect present law, they are nonetheless useful for considering whether patent policy should consider patients as joint inventors. In particular, the patent system is intended to foster innovation.<sup>176</sup> Patient contributors currently foster innovation in areas that are low priorities for research companies who typically devote more resources to projects with large commercial impact.<sup>177</sup> Patient contributors typically suffer from diseases that impact limited populations and accordingly are less likely to be studied.<sup>178</sup> In fact, some patients must solicit and finance researchers to analyze their biological material.<sup>179</sup>

There is some recent precedent for amending the joint inventorship requirements to adjust patent incentives. However, the patient contributor concerns are substantially different than those that animated the recent amendment. In particular, the joint inventorship

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<sup>175</sup> See *supra* note 140-57 and accompanying text (describing the Marlo Brown case).

<sup>176</sup> See *supra* notes 10-13 and accompanying text (describing goals of the patent system).

<sup>177</sup> Rather, most companies direct research towards diseases that affect large populations, and hence large potential profits. See, e.g., Robert A. Bohrer & John T. Prince, *A Tale of Two Proteins*, 12 HARV. J. L. & TECH. 365, 366-67 (1999); Steven R. Salbu, *AIDS and Drug Pricing: In Search of a Policy*, 71 WASH. U. L. Q. 691, 703 (1993). Although there is a mechanism outside the patent laws that theoretically could encourage companies to research areas that impact limited populations, the fact that no research was occurring in areas that patient contributors desired underscores the failure of present laws to provide adequate incentives to encourage such research. See generally David Duffield Rohde, *The Orphan Drug Act: An Engine of Innovation? At What Cost*, 55 FOOD & DRUG L. J. 125, 126-31 (2000) (describing the impetus behind Congressional enactment of the Orphan Drug Act to provide economic incentive for the pharmaceutical industry to invest in research and development of drugs for rare diseases that otherwise would not allow for recovery of research costs, let alone profits); see also Pub. L. No. 97-414, 96 Stat. 2049 (1983), codified as amended at 21 U.S.C. 360 (1988) (providing patent-like benefits for research that will impact small populations). Moreover, the Orphan Drug Act itself has been criticized, including the fact that it over-compensates some companies. See *supra* Rohde, at 133-39; Bohrer & Prince, *supra* at 382-83; Janice Hogan, *Revamping the Orphan Drug Act: Potential Impact on the World Pharmaceutical Market*, 26 L. & POL'Y INT'L BUS. 523, 530-34. (1995).

<sup>178</sup> For example, Canavan disease is a rare genetic disorder that almost exclusively strikes Ashkenazi Jews. See, e.g., Kolata, *supra* note 59, at A17. Similarly, PXE is a rare genetic disease. See Fleisher, *Patent Thyself*, *supra* note 57, at 84.

<sup>179</sup> See *supra* notes 44-49 and accompanying text (discussing patients who spear headed research efforts or solicited and financially funded research).

and obviousness sections of the Patent Act were previously amended to prevent unnecessary invalidation of patents, as well as to ensure that patents would provide an incentive to collaborate.<sup>180</sup> However, an amendment to include patients as inventors would likely be highly controversial. In particular, any amendment to provide rights for patients would be creating rights for *more parties*, rather than cementing the rights of the existing status quo. Major companies had nothing to lose from the former amendment and plenty to gain; in particular, the change reduced the danger of losing patent protection because of diffuse working arrangements within large companies. Moreover, because most companies require employees to assign their rights to inventions, the amended patent laws yielded a bigger patent pot of gold for many large companies. In addition, whereas many companies helped to usher the last amendment of joint inventorship into law, those companies would likely oppose any additional amendment to include patient contributors, because this would require sharing the pot of gold.

### 3. A Potential Shift in the Law

In addition, amending joint inventorship to include patients may be a dubious proposition because of a potential change in the implications of joint inventorship. In particular, the recent case of *Ethicon v. Yoon* addressed the issue of whether equivalent rights for all joint inventors is proper in cases where inventors provided differing degrees of contribution.<sup>181</sup> Although the *Ethicon* majority held that a joint inventor of only a minority of patent claims may nonetheless license the entire patent, a strong dissent by Judge Newman questions whether this proposition will continue to hold.<sup>182</sup> This case is particularly relevant to

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<sup>180</sup> See, e.g., Dreyfuss, *supra* note 98, at 1180 (describing amendment to joint inventorship law). Among other things, the Patent Act changed the definition of inventorship to clarify and further define "joint inventors" who can now qualify to jointly own a patent even if they did not work together physically, or even make the same type of contribution to the patent. See 35 U.S.C. 116 (2001). At the same time, Congress also altered the standard of obviousness to allow for serial collaboration within the same organization, such that different working groups would not thwart patentability of a later group when there was common ownership of a patent. See Patent Law Amendments Act of 1984, 35 U.S.C. 103 (1994); see also W. Fritz Fasse, *The Muddy Metaphysics of Joint Inventorship: Cleaning up After the 1984 Amendments to 35 U.S.C. 116*, 5 HARV. J. L. & TECH. 153, 167-72 (1992).

<sup>181</sup> *Ethicon v. Yoon*, 135 F.3d 1456 (Fed. Cir. 1998).

<sup>182</sup> Panel decisions, such as *Ethicon* remain binding precedent on future cases, although they may be overturned by the court en banc. See *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652 n.6 (Fed. Cir. 1987). Usually, the Federal Circuit only hears cases *en banc* when there are divergent panel decisions. In the case of joint inventorship and its impact on patent ownership, there is no present sign of an en banc ruling. However, the lack of uniformity among *Ethicon* nonetheless is noteworthy in considering whether joint inventorship is the appropriate concept to strive for, if there is a possibility that current rules will be reversed.

patient contributors, who are unlikely to have contributed equally to all parts of the claimed invention. In particular, the differing opinions in *Ethicon* suggest that the full ownership rights traditionally accompanying joint inventorship may no longer continue to exist. To better understand the potential implications of such a shift in the law for patient contributors, the dichotomy of views in the *Ethicon* case will be further elaborated.

*a. The Traditional View: Ethicon Majority Opinion*

The majority opinion in *Ethicon* assumed that Congress's amendment to the joint inventorship requirements, without a concomitant change to the rules of joint ownership, must dictate that Congress did not intend to alter the ownership rules. In particular, the majority suggested that property rights, including ownership, should continue to be based on entire patents rather than claims, even if the amended inventorship rules allow joint inventors to invent only one claim of a patent.<sup>183</sup> In addition, the majority noted that because the un-amended ownership provision refers to joint owners of a *patent*, rather than joint owners of a claim, a joint inventor to only one claim should enjoy a "presumption of ownership in the entire patent."<sup>184</sup> The court explicitly spelled out the logical extension of this assumption - namely, that the "co-inventor of only one claim might gain entitlement to ownership of a patent with dozens of claims" without an express agreement to the contrary.<sup>185</sup> The majority's literal interpretation left no room to consider whether the traditional rule that joint inventors own equal shares of the patent as tenants-in-common was still applicable because it was developed during an era where joint inventors by definition jointly contributed in equal parts to the invention.<sup>186</sup>

*b. Challenging Tradition: Judge Newman's Dissent*

Contrary to the majority opinion, Judge Newman declared that "[n]either the law of joint invention nor the law of property so *requires*" that joint inventorship be identical to joint ownership.<sup>187</sup> Rather, she

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<sup>183</sup> *Id.* at 1465.

<sup>184</sup> *Id.* at 1466.

<sup>185</sup> This single statement that implies potential inequity is the extent of the majority's discussion of equitable issues; the majority did not appear to feel that equity warranted further discussion, or even a more in-depth look at legislative intent behind the inventorship amendment. *Id.*

<sup>186</sup> Previously, the statute had required that "when an invention is made by two or more persons jointly, they shall apply for patent jointly." *Kimberly-Clark v. Proctor & Gamble*, 973 F.2d 915 (Fed. Cir. 1992). In addition, this had been interpreted by courts to require joint collaboration of the invention by two or more people. *Id.* (citing *Shields v. Halliburton*, 667 F.2d 1232, 1236-37; *Monsanto v. Kamp*, 269 F. Supp. 818, 824 (D.D.C. 1967)).

<sup>187</sup> *Ethicon*, 135 F.3d at 1468 (Newman, J., dissenting).



noted that the result of the majority's reliance on the present statutory language produced such inequitable results that looking beyond the literal language was justified. In Judge Newman's view, the 1984 amendments "simply permitted persons to be named on the patent document" as co-inventors to prevent invalidation of the patent (for failure to name all inventors), but had no bearing on the previous law of ownership that only made those who conceived of the entire invention owners.<sup>188</sup> She explained that the amendment was a technical amendment to account for a changing commercial reality in which team research efforts resulted in multiple contributors of an invention who did not necessarily satisfy the joint conception requirement.<sup>189</sup> In addition, she noted that the amendment was intended to avoid complex filing of many separate applications to account for separately conceived inventions; moreover, she explained that the amendment avoided the ultimate problem of patent invalidation for failure to name all inventors who contributed to all of the claims.<sup>190</sup>

Judge Newman's rationale focused primarily on equity principles, rather than specific statutory or judicial authority. In contrast to her explanation of the amended joint inventorship provision in which she cited more than ample authority to illustrate that prior law needlessly invalidated patents, she cited almost no authority for her proposition that joint owners today must be more than joint inventors under the statute. For example, she stated that "the law of shared ownership was founded on shared invention; a situation that admittedly does not here prevail ... . No theory of the law of property supports such a distortion of ownership rights."<sup>191</sup> Similarly, she noted, without citing authority, that "it is not an implementation of the common law of property, or its statutory embodiments to treat all persons, however minor their contribution, as full owners of the entire property as a matter of law. The law had never given a contributor to a minor portion of an invention a full share of the originator's patent."<sup>192</sup> Moreover, she

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<sup>188</sup>She noted that allowing the naming of additional persons as co-inventors under the amended statute does not "automatically endow" such persons with "full and common ownership of the entire invention ... . That is not a reasonable consequence of the change in the law of naming inventors ... ." *Id.* at 1469 (Newman, J., dissenting).

<sup>189</sup>*Id.* at 1469-70 (Newman, J., dissenting) (emphasis added).

<sup>190</sup>*Id.* (Newman, J., dissenting) (citing numerous cases where patents were invalidated for failure to include all inventors).

<sup>191</sup>*Id.* at 1472 (Newman, J., dissenting). In particular, she noted that prior to the 1984 amendments the joint inventor in this case, Mr. Choi, could not have been named a joint inventor because he had not conceived and contributed to the *entire invention*, as was required under the previous statute. *Id.* at 1468 (Newman, J., dissenting) (quoting *Stearns v. Barrett*, 22 F.Cas. 1175, 1181 (C.C.D. Mass. 1816) (Story, J.) (noting that joint invention must be the simultaneous production of the genius and labor of both parties)).

<sup>192</sup>*Id.* at 1471.

seemed to suggest that no specific authority was necessary to support her point. In particular, she noted that: "By amending [Patent Act section] 116 in order to remove an antiquated pitfall whereby patents were being unjustly invalidated, the legislators surely did not intend to create another inequity. Apparently no one foresaw that judges might routinely transfer pre-1984 ownership concepts into the changed inventorship law."<sup>193</sup>

### B. Contracting Around Current Inventorship Laws

Regardless of whether the traditional link between joint inventorship and joint ownership continues, patients can nonetheless obtain patent rights through current mechanisms that exist outside the patent system. In particular, patients can contract for outcomes other than the default patent rules discussed in the previous section. Although patients may not qualify as joint inventors, because patent *ownership* is subject to assignment, patients can negotiate for at least partial assignment of ownership rights even if they are not joint inventors.

Although still relatively rare, some patients have had the foresight and ability to contract for part-ownership of prospective patent rights before granting access to any biological material. In particular, patient-based group PXE International set up its own bank of biological material and requires that interested researchers must agree to share any resulting patent rights before accessing the material.<sup>194</sup> Although a lawyer for PXE International has cast some doubt on the language of previous contracts used by the group, the principle of contracting for different results should be a sound one that is specifically contemplated by the current patent laws.<sup>195</sup>

While this may provide a ray of hope to some patients who have the incredible legal foresight to demand a contract for rights in any potential patent before providing a biological sample, the logistics would obviously fail to embrace most, if not all, patients who could attempt to do this. For example, although PXE has established a convenient mechanism for collecting biological material from patients,

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<sup>193</sup> *Id.*

<sup>194</sup> Fleischer, *Seeking Rights to Crucial Gene*, *supra* note 49, at C1.

<sup>195</sup> The attorney for PXE who didn't see the contract until afterwards noted that although the document stated that "any patent shall be applied for jointly," the implication that this suggested that the parties were joint inventors should not hold. See Fleischer, *Patent Thyself*, *supra* note 57, at 87 (noting that he would have to look more closely at the terms). See also Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, NATURE, Oct. 19, 2000 (noting that a "joint patent application" had been filed by PXE International, which had provided scientists at the University of Hawaii with biological material from the PXE's private blood and tissue bank); 35 U.S.C. 116 (2001) (patents have attributes of personal property and can accordingly be conveyed).

the contract model is atypical. In addition, if there is no pre-existing patient group for a patient contributor to contact, a single patient would be at a significant disadvantage in demanding any terms of agreement from researchers. In fact, the prospect of having to take additional steps may be a disincentive for those initially inclined to contribute.

Although it is possible to envision a situation where the contractual approach is more accessible to patients, this possibility may still be remote in the typical situation where the patient is at a loss for any alternatives. Accordingly, even if procedures were implemented to require that patients receive more informed consent regarding the potential consequences of their donations, it is questionable whether this would impact their decisions significantly. Detailed disclosure of potential commercialization, or even the ability to seek counsel, may have little impact on a contributing patient who has no other present treatment options. Accordingly, although contracting is a legal option, it may not be a viable one to patients in this position.

In addition, it is questionable whether the PXE approach is the optimal approach for either protecting patient rights or for promoting research. Although the PXE approach does allow patients to share their contributions and have a "voice" in the dissemination of resulting technology, it requires a patient-based group, as well as sufficient numbers of afflicted individuals, to agree to work together. In addition, allowing patients leverage in terms of licensing patents may further exacerbate an existing problem in biotechnology, with respect to a seeming plethora of patents that must be negotiated around before any work may be done.<sup>196</sup> The additional requirements imposed by a patient group may actually deter researchers from a certain field because of the administrative burdens.

### C. *Moore* Thoughts: Patent Sanctions

Another possibility for patient contributors who seek to control access of patented technology is to penalize patent owners with unenforceability. For example, Judge Mosk's dissent in *Moore* suggested that where a patent was obtained without proper informed consent, the patent should be unenforceable as a matter of equity.<sup>197</sup> Of course, Mosk was remarking on the unique factual situation of the

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<sup>196</sup> See, e.g., Eisenberg, *supra* note 80, at 163; Long, *supra* note 80, at 827-36; Rai, *supra* note 80, at 192-94. See also Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 5-6 (2001) (noting that there has been increasing difficulty in accessing patented research tools and that transaction costs are likely to continue to escalate as companies continue to acquire proprietary tools).

<sup>197</sup> *Moore*, 51 Cal. 3d at 168 (Mosk, J., dissenting). In addition, he noted that "a patent is not a license to defraud." *Id.*

*Moore* case in which the patient contributions were obtained almost entirely under fraudulent pretenses. The *Moore* case is markedly different than those where patients donate biological materials to researchers.<sup>198</sup> In most cases, patients are arguably misled because of their failure to comprehend the implications of their contributions.<sup>199</sup> However, Mosk's argument for complete unenforceability of a patent is less compelling without explicit fraudulent overtones. This is particularly true because unenforceability is considered a very severe penalty that typically applies only to egregious conduct during patent procurement.<sup>200</sup>

In addition, while general equity principles may provide justification for a change in the law, the typical circumstances where courts find patents unenforceable do not readily embrace Mosk's suggestion. Currently, the conduct that gives rise to unenforceability is fraudulent procurement of the patent, sometimes referred to as "fraud on the PTO;"<sup>201</sup> moreover, only if fraud rises to the level of inequitable conduct will the high penalty of total unenforceability of a patent be exacted.<sup>202</sup> In particular, the fraud must be considered material to the patentability analysis, meaning that the information would have been at least relevant to a reasonable patent examiner's determination of patentability, if not precluding patentability altogether.<sup>203</sup> In addition to

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<sup>198</sup> See *supra* notes 39-49 and accompanying text (describing sample scenarios for patient contributions).

<sup>199</sup> See *supra* notes 56-68 and accompanying text (describing patient perceptions).

<sup>200</sup> See *infra* note 201.

<sup>201</sup> The other situation where fraud may arise in a patent context involves antitrust claims, although such a case typically requires more than fraudulent procurement of a patent. Accordingly, because of the remoteness of this, it is not discussed within this section. See *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 203 F. Supp.2d 306, 317 (D.N.J. 2002).

<sup>202</sup> See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995) (noting that loss of a patent is a justified penalty for inequitable conduct because the statutory period of exclusivity was sought through improper means). This is a particularly severe penalty because unlike defenses against the patent's invalidity, an accusation of inequitable conduct of even some claims will make the entire patent unenforceable. See *Kingsdown v. Hollister*, 863 F.3d 867 (Fed. Cir. 1988); 35 U.S.C. 116 (2001) (noting that invalidity of one claim does not impact the validity of the other claims); see also *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983) (noting that while underlying conduct that renders a patent unenforceable may later be purged, the patent is permanently unenforceable). Moreover, inequitable conduct during the procurement of one patent may taint related patents, making them also unenforceable. See *Consolidated Alum. Corp. v. Foseco Intern, Ltd.*, 910 F.2d 804 (Fed. Cir. 1990). The severity of the penalty is also reflected by the stringent level of proof required; there must be clear and convincing evidence of intentional misrepresentation or withholding of material facts to form the basis of an inequitable conduct charge. See, e.g., *In re Harita*, 847 F.2d 801, 808 (Fed. Cir. 1988) (noting that violation of duty of disclosure must be established by clear and convincing evidence).

<sup>203</sup> See, e.g., *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989); see also 37 C.F.R. 56 (providing specific criteria on what constitutes information that is material to patentability). Typically, acts that could form the basis of such a claim include

being material to patentability, the law of inequitable conduct requires an actual *intent* to deceive the PTO because complete unenforceability of a patent is such a severe penalty.<sup>204</sup> However, in the case of failing to disclose patient contributions, unless the law changes with respect to whether patients can jointly conceive of an invention, failure to disclose the identity of patients, or even their contributions, would not rise to the level of material information for patentability purposes. Although patients believe that but for their actions, no patentable invention would have been conceived in the first instance, this information is not material to whether the ultimate invention is patentable. In addition, allowing information that is not material to the patentability analysis to be the basis for inequitable conduct runs counter to the traditional basis for such unenforceability.<sup>205</sup> Moreover, it should be noted that allegations of fraud are considered to be a "much-abused and too often last-resort allegation" already, without pushing the boundaries of what is considered fraud.<sup>206</sup>

In addition, even if the patent laws were amended to make patents unenforceable if patient contributions were not properly disclosed to the patent office, it is unclear whether this would be an optimal approach. In particular, for patients who want a share of patent profits, creating a new rule for unenforceability would negate any such hope of profits. Nonetheless, if patients cannot be considered joint inventors, an unenforceability rule might provide a helpful bargaining platform for some patients. Accordingly, perhaps patients should advocate a new patent rule requiring all patent applicants to disclose the extent of patient contributions to the invention, as well as what compensation, if any, has been provided for such contributions.<sup>207</sup> Such a rule would represent a major shift in the law of unenforceability. However, it is mentioned as one potential pathway that could be further developed into a useful tool for patients.

#### D. Considering Analogous Areas

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affirmative misrepresentations of material fact, failure to disclose material information, or submissions of intentionally misleading information. Moreover, information that is not prior art is typically considered to not be material, even if the information might have made a patent examiner consider the invention unpatentable. *See, e.g.*, Northern Telecom v. Datapoint Corp., 908 F.2d 931, 934-35 (Fed. Cir. 1990); Environmental Designs v. Union Oil, 713 F.2d 693, 996-97 (Fed Cir. 1993); Specialty Composites v. Cabot Corp, 845 F.2d 981 (Fed Cir 1988).

<sup>204</sup> *See Tol-O-Matic v. Proma Produkt-Und Mktg.*, 945 F.2d 1546, 1553 (Fed. Cir. 1991); *Halliburton v. Schlumberger*, 925 F.2d 1435, 1439 (Fed. Cir. 1991).

<sup>205</sup> *See supra* note 203.

<sup>206</sup> *See FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed. Cir. 1987); *see also Burlington v. Dayco*, 849 F.2d 1418, 1421 (Fed. Cir. 1988) (noting that "charging inequitable conduct in almost every major patent case has become an absolute plague").

<sup>207</sup> *See generally* 35 C.F.R. 1.56 (providing current rules of information disclosure).

This section considers alternative approaches to address the concerns of patient contributors. In particular, this section broadens the inquiry to consider analogous problems in other disciplines, as well as patent law itself. For example, problems in the definition of scientific authorship offer a parallel situation to the problem of including patient contributors within the definition of joint inventors. Similarly, some of the assertions of patient contributors mirror claims of database owners who seek protection for their compilations of factual information that are currently unprotected by patent or copyright laws, but which may soon be entitled to *sui generis* protection. Also, the situation of patient contributors bears striking resemblance to that of indigenous communities who have had their biological material taken from them without compensation, but for whom there are now growing legal strategies to counter this phenomenon. Finally, this section returns to patent law to consider the analogous issue of *all* situations where genetic gold-diggers are able to obtain patent rights, rather than focusing on the smaller subset of gold-diggers involved with patient contributors. This final section's suggestion complements the discussions of appropriate credit and proper incentive in other areas, and returns full circle to the realm of patent law, in proposing a reevaluation of inventorship of isolated genetic material.

### 1. *Scientific Authorship*

The issue of whether the authorship credit of scientific articles should be adjusted to better reflect changing times offers an important parallel area of consideration. Although the standards for patent inventorship and scientific authorship are distinct, both require some type of novelty.<sup>208</sup> In addition, both provide a reward to individuals for their innovation, albeit with different types of rewards. For example, scientific authorship does not convey the same types of monetary rewards typically associated with patents. Rather, in the scientific

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<sup>208</sup>See *supra* notes 14-17 and accompanying text (explaining the patentability requirements of novelty and nonobviousness); Authors, CELL, at <http://www.cell.com/misc/authors.shtml> (noting that only "novel results" in the area of experimental biology are considered for publication); *How to get published in Nature*, NATURE, at [http://www.nature.com/nature/submit/get published/index.html](http://www.nature.com/nature/submit/get%20published/index.html) (requiring "original scientific research" of "outstanding importance" that has not been previously reported); *Information and Help for Science Authors*, at <http://www.sciencemag.org/feature/contribinfo/home.shtml> (noting publication requirement of "best original scientific research," with priority given to "papers that reveal novel concepts of broad interest"). In addition, it is possible to receive a patent and publish an article concerning the same invention. However, a patent application must be filed no later than one year from the date of the publication, or first public disclosure. See 35 U.S.C. 102(b) (1994). In addition, the rule for most countries outside the United States prohibit patents that are applied at any time after the date of publication. See, e.g., Convention on the Grant of European Patents, Oct. 4, 1973, 13 I.L.M. 270 arts. 54-55.

arena, the reward is not monetary, but more a matter of attribution that translates into positive professional recognition.<sup>209</sup> However, a recent challenge in both areas has been the changing nature and types of contributions.<sup>210</sup> In particular, the increasing collaboration among scientists that impacted the inventorship definition in patent law also impacted the definition of scientific authorship.

The increasing collaborations among scientists produced problems in determining authorship because the traditional model assumed a single author was solely responsible for all of the work involved.<sup>211</sup> If the definition of authorship were narrowly construed to approximate the prior model of a single author, some contributors were denied any authorship credit. The unfairness of a narrow definition of scientific authorship is analogous to claims of patient contributors who, "while not engaged in the conceptualization and writing of a certain publication, *still made such work possible*."<sup>212</sup> Alternatively, a broader scope of authorship would inequitably inflate the term by recognizing minor and major contributions identically.<sup>213</sup> The broader authorship concept is also somewhat analogous to the patent context because a wider scope of patent inventors would convey greater rights to a larger group of people and possibly be inconsistent with established principles of inventorship.

The similar problems in the scientific and patent context, combined with actual modifications of scientific authorship suggest that the patent concepts may be usefully modified, based upon the analogous area of scientific authorship. In particular, specific organizations responsible for publishing scientific journals have adjusted their definition of authorship to better reflect current research realities. For example, some leading scientific journals such as the JOURNAL OF AMERICAN MEDICINE (JAMA) have substituted the word *contributor* for the word and concepts typically associated with the word "author" to provide adequate attribution to each person "who has added usefully to the work."<sup>214</sup> The number of contributors is not

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<sup>209</sup> See, e.g., Mario Biagioli, *Rights or Rewards? Changing Context and Definitions of Scientific Authorship*, 27 J.C. & U.L. 83, 84-85.

<sup>210</sup> See, e.g., *id.* at 83 (noting the impact that the increasing collaborative environment within academia has for the definition of scientific authorship, as well as for patent law).

<sup>211</sup> *Id.* at 92 (noting that changing research methods created problems in the definition of scientific authorship because it became difficult to conceive of a single author who "had the idea, did the work, wrote the paper, and took credit and responsibility ...").

<sup>212</sup> *Id.* at 93.

<sup>213</sup> For example, where there was a substantial collaboration, a long list of authors failed to distinguish those who provided the initial impetus for the project from those who oversaw the project, from those who carried out the instructions of others. Accordingly, to some authors, creating too many authors actually diluted the authorship credit.

<sup>214</sup> Biagioli, *supra* note 209, at 96 (quoting Rennie et al., *When Authorship Fails: A*

limited, but each contributor's actual contribution, expressed as a numerical figure, is denoted on the article's first page.<sup>215</sup>

The evolving definition of scientific authorship may convey some important lessons to the patient contributor scenario. In particular, the principles supporting the new definition of contributors could be utilized to redefine joint inventorship in a manner that encompasses patient contributors. Just as the prior definition of scientific authorship was too narrow to some contributors, so to the present definition of joint inventorship is too narrow to include patient contributors. The parallel is particularly compelling for patient contributors in cases where *but for* their assistance - even if it does not rise to the level of inventorship - the patentable invention would not have been discovered, or discovered as quickly.<sup>216</sup> Even the cases that deny inventorship status to patients acknowledge that they did provide some contribution towards the invention.<sup>217</sup> Accordingly, the contribution scenario for scientific authorship would seem to more readily embrace and acknowledge patients' efforts. Although the precise definition of contribution would likely be difficult to agree upon, a broad definition that included all whose contributions were essential to development of the patented invention would be a starting point for including patient contributors.<sup>218</sup>

However, the JAMA approach would likely not be incorporated wholesale into patent laws because of important distinctions between scientific authorship and patent inventorship. As a practical matter, because scientific authorship is not a legal concept, it was easier to modify.<sup>219</sup> Moreover, patent inventorship typically conveys actual

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*Proposal to Make Contributors Accountable*, 278 JAMA 579, 582 (1997).

<sup>215</sup>*Id.*

<sup>216</sup>*See supra* notes 42-49 and accompanying text (discussing the research value of using isolated populations to isolate genetic links); *supra* notes 170-73 (discussing Judge Mosk's arguments concerning patient Moore's pivotal role in the patented compound).

<sup>217</sup>*See, e.g., supra* notes 155-57 and accompanying text (noting court's recognition of patient contribution, although ultimately denying inventorship rights to her); *see also supra* notes 158-67 (discussing cases where inventorship was denied to those who arguably were essential to the development of the patented invention).

<sup>218</sup>For example, conception could be re-conceived to include all persons who were necessary contributors to a patented invention. *See generally Moore*, 51 Cal.3d at 169 (Mosk, dissenting). However, it is acknowledged that this would likely be difficult because even in cases where patients supply an important contribution, it is possible that they only accelerate a result, but that the result could have been created without them. *See generally supra* notes 42-43 (noting that scientists sought certain groups to assist in the *acceleration* of research).

<sup>219</sup>There is more flexibility to provide differing approaches to scientific authorship since there have historically been differing laws for different disciplines and institutions, in contrast to the uniform federal definition of joint inventors. *See Biagioli, supra* note 209, at 83 (noting that "definitions of scientific authorship, far from being codified in a corpus of doctrine like intellectual property law, do change across disciplines and institutions"). In addition, while patent rights may be transferred contractually, scientific credit and authorship are not



rights that impact others, whereas scientific authorship primarily provides recognition to individuals.<sup>220</sup> The patent rights that are inherently tied to joint inventorship accordingly do not dovetail with the concept of proportional contribution. In particular, the contribution approach does not resolve the apportionment of ownership rights, which are currently directly tied to inventorship.<sup>221</sup>

A possible modification of the scientific contribution approach to the patent context would be to provide differing ownership interests, based upon the amount of contribution. However, this is only suggested as a starting point for discussion since it may be difficult to build consensus on definitions of contribution and ownership. In addition, if all contributors were provided partial ownership interests, rather than the current control provided to joint inventors, patients may have less control over the total outcome than under the traditional joint inventorship and ownership model. Nonetheless, a modified contribution standard may be a much more realistic option. In particular, whereas joint inventorship is a difficult threshold for patients to meet, a contribution standard might be more easily satisfied. Additionally, although partial ownership rights would not completely satisfy their desire for control, some rights would at least begin to address some of the current problems with patient perceptions. Perhaps of even greater value, though, is that so long as *some* rights are provided to patient contributors, they may enable patient contributors to negotiate more effectively for rights that better fulfill their ideals and goals. At a minimum, any rights provided to patients at this point would be better than the default scenario that the PXE group is contracting against, in which patients are presumed to have *no* rights at all. Of course, the precise balance of rights is the linchpin of an eventual solution, but the scientific authorship scenario should encourage efforts to consider solutions outside the current framework of joint inventorship.

## 2. Database Rights

Another analogous issue to the patient contributors' lack of compensation exists in the fringes of the copyright arena.<sup>222</sup> In

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considered property rights, but rather, are considered inseparable from the actual author. *Id.* at 91 (noting that while intellectual property rights may be transferred contractually, scientific authorship is seen as inalienable from the original author).

<sup>220</sup> *See id.* at 97 (noting that one of the reasons the new definition of "contributor" works for scientific authorship is that the system is one based on rewards, not rights).

<sup>221</sup> *See supra* notes 97-99 and accompanying text (explaining the correlation between inventorship and ownership).

<sup>222</sup> In addition, although beyond the scope of this article, the consideration of joint inventorship rights for patient contributors could potentially be compared with those of joint

particular, the patient contributor claims mildly echo those of database compilers who allege that they should be entitled to copyright ownership, or at least copyright-like protection that would provide recognition of their work.<sup>223</sup> In both cases, the claims are essentially that effort or natural ability should be rewarded under intellectual property laws, or under new laws that provide similar scope of protection. Current copyright law does not protect mere effort itself; rather, copyright protection only applies when there is a sufficient modicum of creative expression.<sup>224</sup> The underlying data, as opposed to the *expression* or presentation of data, is not protected.<sup>225</sup> In addition, while contract law could be utilized in both instances, a contract

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authors, who are provided analogous protection under copyright laws, albeit with important distinctions. For example, joint copyright owners must account to all joint authors, whereas joint inventors currently have no such requirement. *Compare* 17 U.S.C. 203 (2000) with 35 U.S.C. 262 (1999). In addition, the respective standards for protection, as well as scope of protection are different. See *infra* note 256 and accompanying text (noting that the patentability threshold of novelty is higher than the copyright standard of originality and that the scope of a patent is broader than the scope of copyright protection). Nonetheless, the issue of joint authorship in the copyright arena is a similarly contentious issue. See, e.g., *Dreyfuss, supra* note 98, at 1161; see also F. Jay Dougherty, *Not a Spike Lee Joint? Issues in the Authorship of Motion Pictures Under U.S. Copyright Law*, 49 UCLA L. REV. 225 (2001) (examining contributors to motion pictures who currently fail to qualify as co-authors under the copyright laws and proposing alternative rules of copyright ownership); Mary LaFrance, *Authorship, Dominance, and the Captive Collaborator: Preserving the Rights of Joint Authors*, 50 EMORY L.J. 193 (2001) (proposing a narrowing of the definition of joint authorship that is arguably more consistent with the language and purpose of copyright law); Russ VerSteeg, *Defining 'Author' For Purposes of Copyright*, 45 AM. U. L. REV. 1275 (1996).

<sup>223</sup> See, e.g., Status of Intellectual Property Law and the Internet, 146 CONG. REC. S10986-06, 106th Cong., 2d Sess. (Oct. 25, 2000) (arguing that creators of databases invest substantial resources in creating the databases and need legal protection akin to copyright protection to ensure that investment in databases will not diminish, to the detriment of society); Legal Protection for Data Bases, 143 CONG. REC. S10263, 105th Cong., 1st Sess. (Oct. 1, 1997) (arguing that legal protection of databases is an important national and international issue, based, in part on a report by the U.S. Copyright Office); Statement of Hon. Carlos Moorhead, The Database Investment and Intellectual Property Anti-Piracy Act of 1996, 142 Cong. Rec. E 890, 104th Cong., 2d Sess. (May 23, 1996) (commenting that compilations of factual material are "absolutely indispensable to the American economy on the verge of the new century" and that because of changes in copyright law, new legislation is necessary to continue to provide incentives for a strong U.S. market). In addition, there is some international pressure to provide protection for database creators because the EU has already provided similar protection and the EU Directive stipulates that database protection in Europe will only be provided to foreign database owners if their home countries have adopted similar legislation. See Directive 96/9/EC of the European Parliament and of the Council of the EU of 11 March 1996 on the Legal Protection of Databases, 1996 O.J. L (77) 20, *reprinted in* THE NAT'L RESEARCH COUNCIL, A QUESTION OF BALANCE: PRIVATE RIGHTS IN SCIENTIFIC AND TECHNICAL DATABASES (1999), Appendix A, recital 56.

<sup>224</sup> *Feist Publ'n, Inc. v. Rural Tel. Serv.*, 499 U.S. 340, 344-45 (1991).

<sup>225</sup> See *id.* See also 17 U.S.C. 102 (1994) (limiting copyright protection to "original works of authorship that are fixed in any tangible medium of expression").

approach is necessarily less comprehensive because it requires negotiation of every individual situation.<sup>226</sup>

Database owners have argued for a change in the law to protect the data itself. In particular, it has been argued that without specific protection of database rights, there will actually be a disincentive to create stores of factual material that are, in fact, in society's best interest.<sup>227</sup> In addition, while a database owner may endeavor to keep the database proprietary, the risk that others could copy substantial parts without legal ramification has been cited as an additional reason for the need of another legal right.<sup>228</sup> Accordingly, several proposals have been introduced before Congress that provide a so-called "database right" to these owners.<sup>229</sup> However, the propriety of such a right remains controversial.<sup>230</sup>

Although the underlying calls to recognize efforts that currently fall short of intellectual property protection is similar to that expressed in the patient contributor situation, the situations diverge on the underlying issues. For the typical database owner, the increased protection is desirable from a purely financial standpoint; the owner desires to recoup investment and maximize profit. However, patients who would contribute to a database are not solely interested in monetary concerns. Rather, patients are also interested in ensuring that

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<sup>226</sup>See *supra* notes 194-96 and accompanying text (describing the ability of patients to contract for rights relating to their contributions, but also recognizing that most patients would be unable to effectively do so). Moreover, database owners have asserted that contract rights alone are inadequate protection.

<sup>227</sup>See *supra* note 223 and accompanying text (noting arguments in support of a database right).

<sup>228</sup>*Id.*

<sup>229</sup>See, e.g., Consumer and Investor Access to Information Act, H.R. 1858, 106th Cong., 1st Sess. (1999); Collections of Information Antipiracy Act II, H.R. 354, 106th Cong., 2d Session (1999) (proposing to amend the copyright act to provide protection for database information); H.R. 1858 106th Cong., 1st Sess., (1999); Database Investment and Intellectual Property Antipiracy Act, H.R. 3531, 104th Cong. (1996); Collections of Information Antipiracy Act, H.R. 2652 (1997); see also A QUESTION OF BALANCE, *supra* 223, at 73-110 (1999) (providing an overview of federal bills, as well as specific recommendations from the National Research Council); Michael Freno, Note, *Database Protection: Resolving the U.S. Database Dilemma with an Eye Toward International Protection*, 34 CORNELL INT'L L. J. 165 (2001) (providing an overview of the various legislative proposals, as well as the international framework for database protection and a suggested compromise proposal for a database right).

<sup>230</sup>For example, some believe that it is inappropriate to create a right for those who the Supreme Court has clearly held to be outside the Copyright Act. See A QUESTION OF BALANCE, *supra* note 223, at 57 (noting that some argue that Congress lacks the ability to extend copyright beyond the minimum necessary to provide sufficient incentive to authors to make their works available); J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 51 (1997) (endorsing some type of legal relief to assist in the creation and distribution of electronic data, but opposing the creation of any strong legal barriers to entry in the field).

their contributions will result in treatments that are publicly available.<sup>231</sup> In addition, unlike the pure database situation, the information available from a patient database may not be commercially valuable in the first instance. Rather, further research may be required before any commercial value is attained. Accordingly, the database model is not a direct corollary for the issues of patient contributors. In addition, none of the proposed database rights would satisfy the goals of patients. In particular, all of the proposals for enhanced legal protection thus far merely protect another from copying the contents of the database; none would demand that rights be provided to the initial database owner for any derivative products.<sup>232</sup>

Nonetheless, the fact that patient contributor concerns are not presently addressed in legislative proposals does not foreclose that option. Indeed, consideration of alternative viewpoints as to why a database right should be adopted may be productive for the present database proponents as well. In addition, collaboration with database proponents may be fruitful for patients because there is already strong political impetus behind the proposals. Alternatively, patient contributors can consider the legislative proposals of database proponents as merely an example of a new *sui generis* system of protection; patients can propose their own legislation that is more tailored to their concerns.<sup>233</sup>

### 3. Bio-Piracy of Indigenous Populations

The patient-patent problem is also strikingly similar to the global problem regarding bio-piracy of indigenous populations. In both situations, those who provide or facilitate the provision of raw materials that result in a patentable composition are typically denied

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<sup>231</sup> See *supra* notes 57-58 and accompanying text (noting that patient contributors want and expect the results of their contributions to be freely available to others).

<sup>232</sup> See *supra* note 229 (noting proposals for a database right).

<sup>233</sup> Of course, *sui generis* intellectual property protection that provides analogues to both patent and copyright law exists beyond the database issue. The most analogous area would be the Orphan Drug Act, which provides patent-like exclusivity for drugs that might not otherwise be developed by large pharmaceutical companies because of limited the scope of diseases. Although the Orphan Drug Act is premised on providing a reward to the company who creates a new discovery, perhaps an amendment of the Act itself, or a similar approach, could be helpful in providing an incentive to companies, as well as a reward to patients. Although further consideration of this may be fruitful, it is presently beyond the scope of this article. However, for some useful information on the current Orphan Drug Act, see Rohde, *supra* note 177, at 125; Bohrer & Prince, *supra* note 177 at 365. However, it should be also noted that the underlying premises of this Act have been questioned. See, e.g., John Flynn, *The Orphan Drug Act: An Unconstitutional Exercise of the Patent Power*, 1992 UTAH L. REV. 389 (1992). Moreover, whether a *sui generis* approach is even proper, is an additional issue with respect to database protection. See Jacqueline Lipton, *Matters of Fact: Refocusing the Database Debate* (manuscript on file with author).

any rights in a resulting patent. The parallel situation is particularly interesting since the patent-owner in both cases is typically a relatively large life-science company that does not interact directly with the contributors.<sup>234</sup> In addition, just as this Article has explored whether providing property rights would advance the cause of patient contributors, so too have advocates of indigenous populations considered granting property interests for indigenous populations under either traditional schemes of intellectual property protection, or via *sui generis* legislation.<sup>235</sup>

The criticisms of patient contributors are very similar to the complaints waged against companies criticized for taking knowledge and biological material from indigenous populations of other countries. The bad press that is beginning to circulate concerning patents derived from patient contributors also echoes the negative press that companies face regarding the use of indigenous knowledge and biological materials.<sup>236</sup> In addition, just as well-publicized incidents of bio-piracy based upon indigenous agricultural resources have created distrust, the patient contributors who are used without reward are also beginning to show signs of distrust and reluctance as well.<sup>237</sup> As already seen in the context of indigenous contributions, when trust deteriorates, cooperation is stymied and ultimately, greater knowledge to society may be frustrated.<sup>238</sup>

The problems that patients face in attempting to contract for desired results are also similar to those of indigenous groups who attempt to contract with the multi-national groups. In both of these situations, any contract entered into is unlikely to be a contract between equal parties.<sup>239</sup> In addition, both situations share a fundamental

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<sup>234</sup> See *supra* notes 59-62 and accompanying text (noting the fact that many patient contributions ultimately are owned by corporations because researchers are often required to assign all interests as part of their employment agreement).

<sup>235</sup> See, e.g., Michael J. Huft, Comment, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678 (1995) (considering whether contribution of indigenous knowledge would constitute joint inventorship under the patent laws); Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919 (1996) (critiquing the present patent and plant breeder rights' regimes as inappropriate answers to appropriation of knowledge of indigenous communities).

<sup>236</sup> These companies were often charged with accusations of biopiracy and at a minimum, had public relations problems. See Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?* 6 EUR. INTELL. PROP. REP. 245 (2001).

<sup>237</sup> See *supra* notes 56-68 and accompanying text (describing negative patient perceptions to the discovery that patents exclude them from medical treatment).

<sup>238</sup> Drahos, *supra* note 236, at 246-47.

<sup>239</sup> See *id.* at 267 (noting that "clearly, a contract between an indigenous group and a multinational corporation is not a contract between equally well-resourced parties"); see also

problem in contract negotiations because the information disclosed is valuable, but of *unknown* value at the time of negotiation. Admittedly, the knowledge disclosed reduces uncertainty for companies searching for patentable genes. However, there remains some degree of uncertainty in whether the company that obtains the contributions can actually harness the knowledge because of a number of additional factors ranging from scientific expertise, to the competitive market, patent concerns, and the nature of science itself.<sup>240</sup>

One approach to the unequal bargaining power has been utilized in both situations as well. In particular, the idea of a collecting society or agency has been utilized or proposed in both areas, although it is not the norm yet for either. For example, as previously mentioned, potential patient contributors with PXE created their own collecting society that wielded sufficient influence to demand that researchers agree to share patent rights before providing access to any biological materials.<sup>241</sup> In addition, even in the case of the *Canavan* contributors, there was a smaller-scale organization of similarly situated patients, although the group did not attempt to leverage their numbers.<sup>242</sup> Nonetheless, both situations reflect proposals that have been suggested for addressing the parallel issues encountered with indigenous populations. Namely, there have been suggestions for the creation of a global bio-collecting society to better integrate efforts as well as provide enhanced bargaining abilities during contractual negotiations.<sup>243</sup>

Because of the parallels, the more extensive lessons from contributions of indigenous populations could be considered, rather than approaching the patient contributor problem anew. In addition, although bio-piracy problems often focus on preserving biodiversity, which is not typically an issue for patient contributors, there is prior experience and even an international context that provides a basis for the sharing of research benefits with contributors. For example, the

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Sarah Laird, *Contracts for Biodiversity Prospecting*, in *Biodiversity Prospecting* 99 (describing the contractual approach, as well as potential problems for indigenous companies).

<sup>240</sup> See Drahos, *supra* note 236, at 247.

<sup>241</sup> See *supra* note 49 (describing the PXE contractual approach). In addition, PXE actually attempted to take their approach to the global level. See, e.g., Andy Coghlan, *People With Inherited Diseases are Ready to Challenge Pro-Lifers Over the Future of Medical Research*, NEW SCIENTIST, Feb. 2, 2001, at 4 (noting attempts to create a global alliance to represent patients with rare hereditary conditions that was presented by PXE International founders at a BioVision meeting on Biotechnology in Lyons, France).

<sup>242</sup> See *supra* note 48 and accompanying text (describing the fact that Canavan patients organized the collection of biological materials from a pool of patients to accelerate research progress).

<sup>243</sup> See Drahos, *supra* note 236, at 247-249. In addition, even if there is no official collecting society, another approach that can be borrowed from the bio-piracy area is to create and widely distribute model contract agreements. See, e.g., Downes et al., *Biodiversity Prospecting Contract*, in BIODIVERSITY PROSPECTING 255-87 (1993).

Convention on Biological Diversity (CBD) promotes sharing research results - it provides that member states should take "legislative, administrative or policy measures ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources."<sup>244</sup> Similarly, the Human Genome Organization has emphasized that researchers should share the benefits of their research with subjects who have assisted in the enterprise.<sup>245</sup> In addition, individual corporations have taken steps to compensate indigenous communities in some circumstances.<sup>246</sup>

#### 4. *Re-Defining Inventorship of Isolated Genetic Material*

A final analogous area to consider is a reevaluation of inventorship of *all* isolated genetic material, regardless of patient assistance. In particular, this section suggests that the current law, which recognizes the one who isolates a genetic compound as the creator of a patentable composition, should be questioned. While this may seem to be a radically different approach, as well as one that would be resisted strongly by established pharmaceutical and genomic companies, it nonetheless should be considered as an alternative in the reconceptualization of a framework that provides proper incentives.

This proposal stems from the under-current to patient contributor claims that named inventors of patents based on patient contributions are over-compensated. Interestingly, with the exception of groups such as PXE, patients typically do not seek inventorship rights in the first instance. Rather, they assume and expect that research will just result in greater good for all. Accordingly, patients' claims to joint inventorship are more typically an attempt to realign perceived

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<sup>244</sup>CBD art. 15(7); *see also* Council Directive 98/44 on Legal Protection of Biotechnological Inventions 1998 O.J. (L 213) 13 (providing that materials taken from patients for patenting should at least be acknowledged); Francesca Grifo & David Downes, *Agreements to Collect Biodiversity for Pharmaceutical Research: Major Issues and Proposed Principles*, in BRUSH & STABINSKY, VALUING LOCAL KNOWLEDGE 281-304 (1996). Interestingly, the CBD also offers a suggestion on another topic that relates to patient contributions - informed consent. In particular, the CBD provides that "access to genetic resources shall be subject to prior informed consent." *Id.* at Art. 15(5). As discussed earlier, however, whether consent is meaningful is a complex and thorny issue.

<sup>245</sup>*See* Human Genome Organisation, HUGO Ethics Committee, Statement on Benefit-Sharing (April 9, 2000), at <http://www.hugo-international.org/hugo/benefit.html>; *see also* Paul Smaglik, *Genetic Diversity Project Fights for Its Life... As Companies are Urged to Share Benefits*, 404 NATURE 912 (April 27 2000).

<sup>246</sup>*See, e.g.*, Stephen King et al., *Biological Diversity, Indigenous Knowledge, Drug Discovery & Intellectual Property Rights*, in BRUSH & STABINSKY, VALUING LOCAL KNOWLEDGE (describing different compensation strategies that have been used by Shaman Pharmaceuticals that extend beyond traditional post-commercialization profit sharing).

inequities. The patients perceive that their provision of unique raw material is at least as important, if not more important than the activities of scientists who isolate the patentable sequence.<sup>247</sup> While the patient claims admittedly are based on intuitive logic, this section suggests that they can be grounded within patent law principles or at least presented as a proposal to reform patent law principles regarding inventorship of biotechnology.

To put the objections of patient contributors in the appropriate intellectual property jargon, they suggest that isolation of genetic material is not inventive, or at least no more inventive than their own contributions of raw material that scientists use for the isolation process. This assertion extends beyond pure inventorship into the area of patentability, including whether such compounds are truly novel. While most practicing attorneys likely would dismiss this suggestion as untenable because of extensive precedent holding otherwise, that is a circular argument.<sup>248</sup> However, the patentability of isolated compounds and genetic sequences has historically been highly controversial, even if the legal challenge has shifted from appropriate subject matter to technical patentability requirements.<sup>249</sup>

The perception that isolated genetic sequences lack sufficient inventive quality to merit patent protection reflect not only the views of a few patients, but also an unsettled international issue. In contrast to the broad patentability of genetic material under United States law, other countries have declared such material to be unpatentable for lack of sufficient novelty or utility.<sup>250</sup> In countries with more restrictive patenting of genetic material, the inventorship issue is possibly less of an issue. However, the patient contributor situation in combination

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<sup>247</sup> See *Brown*, 866 F. Supp. at 445 (noting that patient believed that her contribution was crucial to the conception of the patented invention); see also *supra* note 68 and accompanying text (describing patients who consider their contribution to be critical to the patented invention).

<sup>248</sup> See generally *supra* notes 23, 27-30 and accompanying text (noting that patentability of genetic material is firmly established under United States law, although the technical patentability requirements have been evolving).

<sup>249</sup> See, e.g., Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 735 (2000) (noting the intense controversy over the patentability of gene fragments, including divergent opinions among academics on the issue); Eisenberg, *supra* note 4, at 558-61 (providing a historical perspective of the controversy over corporate attempts to patent gene sequences).

<sup>250</sup> See, e.g., *supra* notes 22-30 and accompanying text (noting that although such material is patentable under United States law, the approaches of other countries are not uniform). Although some might suggest that the United States laws regarding patentability of isolated genetic material should be subject to renewed scrutiny, such proposals are beyond the scope of this paper. However, for an interesting discussion of utilizing a registration scheme, rather than patentability, to reward innovation with respect to gene sequences, see Holman & Munzer, *supra* note 249, at 813-20.



with the broad patentability suggests that perhaps inventorship is another important issue with respect to the patentability of a compound that is isolated after performing routine steps and procedures.<sup>251</sup> In particular, although present law considers a wide variety of genetic material patentable, equity arguments concerning genetic material could potentially be accommodated through a revised definition of inventorship.

In addition, reconceiving the inventorship of genetic material might better reflect scientific norms. After all, scientists who are capable of isolating and purifying patentable material often react negatively to gene patents.<sup>252</sup> In other words, scientists with the capacity for creating patentable material question are often the very individuals who question whether patents are appropriate. Accordingly, perhaps it is time to reconsider whether the current requirements of conception and reduction to practice within biotechnology are consistent with inventorship policies, which tend to favor those with creative vision, rather than those who labor extensively.<sup>253</sup>

Returning once again to the intuitive objections of patients, the claim against allowing scientists to be inventors of isolated genetic material could be considered as a claim that the current definition of conception of such inventions is improper. Although patients may not explicitly articulate a rationale for why scientist efforts are unworthy, their objection could be conceived as a claim that the process of isolating a natural gene and discovering the function of the gene still lacks sufficient inventiveness to qualify for a patent and instead may only reflect hard work. Although "hard work" is not a traditional ground for denying patentability, it has been a basis for exclusion from copyright protection. In particular, the United States Supreme Court has held that work that is produced under the "sweat of the brow," without sufficient creative expression, fails to meet basic requirements for copyright law.<sup>254</sup> Copyright law requirements are very different than patentability requirements, although most people think of

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<sup>251</sup>In addition, while the isolation of a gene may be unpredictable in terms of when or even whether it will occur, the actual process that leads to the result is not a novel concept; indeed, the process is more analogous to a game of trial and error.

<sup>252</sup>See, e.g., Auth, *supra* note 4, at 911 (questioning whether ESTs should be patentable). Granted, scientists may have mixed feelings about patenting any compound because of the potential negative ramifications for their own research. In addition, it is often difficult to separate whether the objections are regarding patentability of the subject matter or the idea that someone should be considered an inventor over the subject matter.

<sup>253</sup>See *supra* notes 31-38 and accompanying text (explaining concepts of inventorship, as well the underlying policy justifications).

<sup>254</sup>*Feist*, 499 U.S. at 353.

patentability as a higher threshold.<sup>255</sup> In particular, any expression with a modicum of creativity - not necessarily one that is new and nonobvious - is copyrightable if it is fixed in a tangible medium from which it can be perceived.<sup>256</sup> Although copyright law rewards creativity, rather than innovation, the two standards are analogous and stem from the same constitutional clause.<sup>257</sup>

In addition, the Supreme Court's statements in the copyright context are particularly important here because they suggest that providing protection to material beyond the scope of the underlying constitutional clause is impermissible.<sup>258</sup> Accordingly, if the activities of scientists who isolate and purify genetic material were to be re-conceptualized as hard work, but nonetheless fail to be of sufficient inventive quality to merit patent protection, this could require a fundamental shift in patent laws.

Of course, it is acknowledged that this suggestion for a reconsideration of patentability of isolated genetic material is a radical proposition.<sup>259</sup> Indeed, there is long-standing precedent within the United States for considering isolated and purified genetic material to be patentable, with inventorship going to the individual responsible for conceiving of the actual chemical sequence of the isolated compound.<sup>260</sup> In addition, biotechnology companies who presently are rewarded with

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<sup>255</sup> See, e.g. *Robert R. Jones Assocs., Inc. v. Nino Homes*, 858 F.2d 274, 278 (6th Cir. 1988) (noting that originality is easier to establish than novelty); *Alfred Bell & Co. v. Catalda Fine Arts*, 191 F. 2d 99, 102 (2d Cir. 1951) (noting that satisfying the originality requirement of copyright law is easier than the novelty requirement of patent law in light of the broader scope of patent protection); 1 NIMMER ON COPYRIGHT, at 2.01[A] (2002) (clarifying that it is "now clearly established" that the originality required for copyright only requires independent creation, but not novelty).

<sup>256</sup> See 17 U.S.C. 102(a) (2000); *Feist*, 499 U.S. at 345 (stating that "the requisite level of creativity is extremely low; even a slight amount will suffice").

<sup>257</sup> See generally U.S. CONST. art. I, 8., cl. 1.

<sup>258</sup> See *Feist*, 499 U.S. at 346-48.

<sup>259</sup> However, the suggestion for a re-conceptualization of the presumption that, when isolated, a purified material may be "invented," may not be as radical considering the PTO's changing position on the patentability of gene sequences themselves. For example, although the PTO previously issued patents on gene fragments and genes of unknown function, the PTO did respond to criticism that such patents failed to meet the requirement of utility under patent laws by specifically amending its guidelines on utility to prevent isolated sequences of unknown function from patentability. See *supra* notes 27-28 and accompanying text (regarding changing definition of utility with respect to genes and gene fragments). Similarly, the PTO material for its own patent examiners has suggested a narrow scope for gene fragments with respect to full genes to reduce the likelihood of blocking power. See U.S. PATENT & TRADEMARK OFFICE, Written Description Guidelines, at <http://www.uspto.gov>.

<sup>260</sup> See *supra* notes 104-10 and accompanying text (explaining inventorship rules for conception of chemical and genetic inventions).

many patents under the current system would strongly resist such a change.<sup>261</sup>

However, bowing to the economic argument of biotechnology companies is not only doctrinally improper, but also unnecessary. In particular, it should be remembered that the frequent claim of biotechnology companies that patents are critical to their survival is in fact the same argument of database proponents who are currently deprived of copyright protection, but seeking an alternative system of compensation.<sup>262</sup> Accordingly, the suggestion is not to strip biotechnology companies of all rights based upon their important work in isolating genetic material, but rather to reconsider whether their efforts are over-compensated and potentially even unconstitutional.<sup>263</sup>

## CONCLUSION

It remains to be seen whether patients will be entitled to share in the patent pot of gold that presently exists for isolated genetic material, or whether there will even be a pot of gold to share. This article takes an important step in defining the present concerns and misperceptions of patient contributors. In addition, specific avenues have been outlined to provide patients and their advocates with more options to achieve an equitable result. In particular, the broad-based consideration of patient contributor issues alongside analogous areas should foster a reasoned discussion of incentives and a reconsideration of current norms to reach a situation that better reflects and rewards patient contributors.

In addition, the multi-disciplinary approach of this article should have continued value beyond the patient contributor situation. Particularly in the area of biotechnology, there seem to be inherent conflicts that arise from the patenting of material that has important implications for both research and medical treatment. Although there is a tendency to consider every conflict in isolation, this article suggests a new framework for considering such conflicts that should hopefully provide for more sustaining solutions. In addition to forestalling overly narrow approaches, geared principally towards short-term solutions, this approach is more likely to succeed on a global level because it

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<sup>261</sup> See generally *supra* note 1 and accompanying text (describing the race to patent genes because of lucrative profits).

<sup>262</sup> See *supra* notes 223, 227-28 and accompanying text (describing argument of database proponents that legal protection analogous to copyright protection is necessary).

<sup>263</sup> See Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119 (2000).

inherently requires considerations of impacted parties other than those currently in conflict.

The search for more broad-based solutions is critical for the future development of patent law, including how it accommodates new technology. After all, although the United States law concerning the patentability of isolated genetic material may appear immutable, at one point, this too was an area that was controversial and the ultimate resolution could have been a very different one. The continuing evolution of patent law and technologies it must accommodate will require further consideration of novel issues. Accordingly, the multidisciplinary approach outlined here may have continued validity in future disputes regarding the patent pot of gold beyond resolving the issues of patient contributors.

