

## **PATIENTS v. PATENTS?: POLICY IMPLICATIONS OF RECENT PATENT LEGISLATION**

CHRIS J. KATOPIS\*

### INTRODUCTION

Ancient Greek philosophers, such as those depicted in Aristotle's *The Politics*, advocated recognition, awards, and honors for the achievements of discoverers.<sup>1</sup> At the same time, the Hippocratic Oath commands physicians to care for their patients ethically and selflessly.<sup>2</sup> These Hellenic ideas flourished and were widely embraced by civilizations around the globe and throughout the ages.<sup>3</sup> Yet recently, the western legal system has witnessed a collision between these ancient principles.

Patents for industrial and consumer innovation are common and are welcomed in our society.<sup>4</sup> Yet the widespread pursuit of patents for medical innovations has aroused strong opinions and has elicited powerful emotional reactions from the public, as if a reminder of one's own mortality.<sup>5</sup> Whether a society should rec-

---

\* J.D. 1994, Temple University; B.S. 1990, University of Pennsylvania. The author serves as a federal legislative attorney in Washington, D.C. Special thanks go to Temple University Law Professor Michael Libonati for his valuable insights on legislation, patents and Hellenism. All views and opinions expressed within this article should be exclusively attributed to the author.

<sup>1</sup> See ARISTOTLE, *THE POLITICS* 20-51 (Stephen Everson ed. & Benjamin Jowett trans., Cambridge Univ. Press 1988) (critiquing various property law philosophies, including those related to discovery); see also 1 PETER D. ROSENBERG, *PATENT LAW FUNDAMENTALS* § 1.09, at 1-45 (2d ed. 1996) (noting that Hippodamus and Miletus advocated honoring of discoveries).

<sup>2</sup> HIPPOCRATIC OATH, *reprinted in* CONTEMPORARY ISSUES IN BIOETHICS 138 (T. Beauchamp & L. Walters eds., 1978).

<sup>3</sup> See 1 ROSENBERG, *supra* note 1, § 1.09 (discussing extent of recognition of discoverers' achievements by Eastern and Western civilizations); see also F.D. Prager, *The Early Growth and Influence of Intellectual Property*, 34 J. PAT. OFF. SOC'Y 106, 111-17 (1952) (reciting historical underpinnings of intellectual property).

<sup>4</sup> 1 ROSENBERG, *supra* note 1, at vii ("From the very beginning, invention has been an integral part of the American scene.")

<sup>5</sup> Some public reaction is due to "speculative fears without considering the social

ognize, or, further, even protect a medical discovery implicates a host of questions from the fields of science, law, economics, and ethics.<sup>6</sup> This issue also implicates the proper roles of the federal government, the states, and the medical and legal professions in fostering the progress of science, medicine, and the public health.<sup>7</sup>

The United States Congress is vested with broad authority to enact statutes and to shape public policy. The historic 104th Congress tackled a long legislative agenda, including passing significant legislation to ensure patient access to health care, as part of the ongoing debate over a national health care policy.<sup>8</sup> Numerous intellectual property bills were also introduced to address the interests of patent, copyright, and trademark holders.

Legal worlds collided when a conflict arose between health care and patent law. Litigation over patents for medical procedures became a subject of political debate. In response, a restriction on medical procedure patent infringement remedies was introduced in the Congress and signed into law by the President. The outcome of this legislative activity reveals much about the perceptions of the medical and patent law professions, as well as the fundamental underpinnings of the United States patent system.

This Article explores whether the patent code can be changed in a way that enhances innovation and economic activity, especially in the biomedical arena. Consideration is given to aspects of the legal, economic, scientific, and ethical dimensions of the intersection of medicine and patent law. In light of recent

---

and medical benefits that innovation stimulated by the patent system could provide." Robertson, Letter, HASTINGS CENTER REP., Feb. 1985, at 48.

<sup>6</sup> See generally Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139 (1987) (discussing law and policy supporting patents and ethical objections raised in context of medical innovation).

<sup>7</sup> The Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8; see also *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) ("[T]he promotion of the progress of science and the useful arts is the 'main object' [of patents]; reward of inventors is secondary and merely a means to that end."). Congress must weigh numerous considerations in its creation of the rules governing the patent system, such as the social and economic cost of suppressing free market competition and permitting monopoly. See 1 ROSENBERG, *supra* note 1, § 1.03, at 1-7 to 1-20.2 (discussing concept of monopoly and its effects).

<sup>8</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (amending Internal Revenue code of 1986 to better portability and continuity of health insurance coverage).

litigation and legislation, this Article reviews the background and history of medical patents and discusses alternatives to the newly enacted change in the patent code. The next section of this Article advocates prior user rights as a narrowly tailored alternative course to solve some of the patent system's current flaws, both with biotechnology and generally. Finally, this Article examines these policies in the context of economic theory and legal principles.

### I. MEDICAL PATENT LEGISLATION

*"The reason for the patent system is to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits."*<sup>9</sup>

Recent medical patent litigation spurred a legislative chain reaction. In *Pallin v. Singer*,<sup>10</sup> eye surgeon Dr. Samuel Pallin sued several of his peers, including fellow eye surgeon, Dr. Jack Singer, for the infringement of a medical procedure patent covering a new cataract surgery technique.<sup>11</sup> Neither civil suits against doctors nor patent infringement litigation are uncommon on their own merits,<sup>12</sup> yet this suit is considered remarkable. It is a rare instance of one physician suing another over an invention such as a medical procedure patent.<sup>13</sup>

The invention at stake is patent number 5,080,111, a technique for making a chevron shaped incision into the white wall of the eye<sup>14</sup> in such a fashion to be "substantially self sealing" and sutureless.<sup>15</sup> The Pallin patent reportedly results in a "savings of

<sup>9</sup> Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (emphasis added).

<sup>10</sup> 36 U.S.P.Q.2d (BNA) 1050 (1995).

<sup>11</sup> *Id.* at 1051-52.

<sup>12</sup> The United States Patent and Trademark Office ("PTO") estimates that during Fiscal Year 1995, there were 1081 patent infringement suits in the federal district courts. U.S. PATENT AND TRADEMARK OFFICE, SETTING THE COURSE FOR OUR FUTURE, A PATENT AND TRADEMARK REVIEW 109 (1996).

<sup>13</sup> See *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. (1995) (statement of Michael K. Kirk, Executive Director, American Intellectual Property Law Association), 1995 WL 615737, at \*2 (discussing patents for medical treatment and procedure inventions) [hereinafter *Medical Hearings*].

<sup>14</sup> See *Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 3 (Oct. 19, 1995) (testimony of Dr. Jack A. Singer) (discussing patent No. 5,080,111) [hereinafter *Singer Hearings*].

<sup>15</sup> The abstract of the Pallin patent reads:

A substantially self sealing episcleral incision having an approximate cen-

\$17 per operation."<sup>16</sup> Despite these savings, the defendants objected to paying either the patent royalty fee of \$5 per operation<sup>17</sup> or a flat fee for a clinic of \$2,500 to \$10,000 per year.<sup>18</sup>

In the district court proceeding, Singer and the other defendants moved for summary judgment, alleging the invalidity of the patent.<sup>19</sup> The district court denied this motion on the grounds that the defendants failed to demonstrate the lack of a genuine issue of material fact regarding obviousness of the innovation, one of the key factors of patent validity.<sup>20</sup> Ultimately, the court entered a consent order declaring the four patent claims of

tral point 1.5 to 3.0 millimeters posterior to the limbus. Portion of the incision extending from the approximate central point extend laterally away from the curvature of the limbus. The configuration of the self-sealing incision allows the incision to seal as the eye is inflated following surgery and therefore requires no sutures for sealing. Accordingly, the probability of astigmatism is eliminated or greatly reduced and the reliance on sutures is eliminated.

U.S. Patent No. 5,080,111 (issued Jan. 14, 1992).

<sup>16</sup> See *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 4 (testimony of Dr. Samuel Lear Pallin) [hereinafter *Pallin Hearings*].

<sup>17</sup> See *Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 7 (Oct. 19, 1995) (testimony of Donald R. Dunner, Chair, Section of Intellectual Property Law, American Bar Association) [hereinafter *Dunner Hearings*].

<sup>18</sup> See *Hearings on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 4 (Oct. 19, 1995) (testimony of Dr. Charles D. Kelman, President, American Society of Cataract and Refractive Surgery) (discussing royalty fees under Pallin patent) [hereinafter *Kelman Hearings*].

<sup>19</sup> *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050, 1051 (1995). Defendants sought summary judgment based upon the assertion that plaintiff's claims of invention were barred under 35 U.S.C. §§ 102(g) & 103. *Id.* Defendants argued that since other doctors utilized the technique prior to the date plaintiff first used the procedure, plaintiff was precluded from receiving a valid patent. *Id.*

<sup>20</sup> *Id.* at 1053-54. "Nonobviousness" is a key statutory requirement for a patent. 35 U.S.C. § 103 (1994). Section 103 of the United States Code provides a subjective test that considers numerous factors for determining nonobviousness. See RONALD B. HILDRETH, *PATENT LAW: A PRACTITIONER'S GUIDE* 91 (2d ed. 1993) (discussing nonobviousness factors). "[S]ection 103 requires a Court to: (1) determine the scope and prior content of the prior art; (2) ascertain the differences between the prior art and the claims at issue; and (3) resolve the level of ordinary skill in the pertinent art." *Pallin*, 36 U.S.P.Q.2d at 1053 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1996) and *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991)). In addition, "secondary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham*, 383 U.S. at 17-18.

the Pallin patent in controversy to be invalid, and Dr. Pallin agreed not to enforce the remaining patent claims.<sup>21</sup>

During this litigation, the American Medical Association House of Delegates voted to condemn the patenting of medical and surgical procedures.<sup>22</sup> The Delegates further agreed to "work with Congress to outlaw this practice."<sup>23</sup> True to their pledge, this very subject was raised before the 104th Congress, which held seven physicians among its ranks.

In the House of Representatives, physician and Congressman Greg Ganske (R-IA) introduced "The Medical Procedures Innovation and Affordability Act of 1995," H.R. 1127,<sup>24</sup> which would create a moratorium on patents for medical procedures and therapies.<sup>25</sup> In the United States Senate, Senator Bill Frist (R-TN), a heart surgeon, introduced a similar bill, the "Medical Procedures Innovation and Affordability Act," S. 1334.<sup>26</sup> This measure would allow medical procedure patents to still be issued, but it would preclude an inventor from enforcing the patent or obtaining remedies against patent infringement by medical practitioners.<sup>27</sup>

<sup>21</sup> Pallin v. Singer, No. CIV.A.2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996).

<sup>22</sup> See William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 651 (1995) (stating that efforts to condemn patenting of medical and surgical treatments was response to *Pallin* case).

<sup>23</sup> *Id.* In addition, the American Academy of Ophthalmology is working with its lobbyists on Capitol Hill to urge the enactment of legislation exempting such procedures from patent protection. See *id.* at 652. However, in 1957 the Judicial Counsel of the American Medical Association issued an official opinion that medical patents were not necessarily unethical. See *id.* at 655.

<sup>24</sup> H.R. 1127, 104th Cong. (1995).

<sup>25</sup> The Amendment "would bar the U.S. Patent and Trademark Office from granting patents on surgical procedures and other medical techniques unrelated to patented drugs or devices." Noonan, *supra* note 22, at 652 n.7; see H.R. 1127, 104th Cong. (1995). It would exempt from this bar only those methods or processes which are performed by a machine which is itself separately patentable. *Id.*

<sup>26</sup> S. 1334, 104th Cong. (1995). The measure proposed amending 35 U.S.C. § 271 by adding the following subsection:

(j) (1) For any patent issued on or after the effective date of this subsection, it shall not be an act of infringement for a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis.

*Id.*

<sup>27</sup> See *id.* (denying enforcement of patent infringement claim). This is not the

Recent history clearly demonstrates that present congressional leaders are well versed in intellectual property law and have fought fiercely for its protection.<sup>28</sup> Yet a moratorium on any type of patentable subject matter or corresponding remedy is a radical departure in intellectual property law. After the introduction of H.R. 1127 and S. 1334, there was an active and successful effort by these young revolutionaries to gain congressional support for these bills. Consider as evidence of their success that 128 Members of the House of Representatives signed on as cosponsors of H.R. 1127.<sup>29</sup>

As part of the authorization process, the House Judiciary Subcommittee on Courts and Intellectual Property held hearings on the merits of the measure.<sup>30</sup> The United States Patent and Trademark Office (PTO) also scheduled hearings.<sup>31</sup> The United States Senate never held hearings, and there was no further action to advance either bill through the committee authorization process.

Nevertheless, the campaign by the medical community and legislators to advance the bills continued. The patenting of all procedures and processes was scorned as a new and unwise development. The attempt to patent medical procedures was likened to trying to patent "Ted William's baseball swing or Michael Jordan's jump shot."<sup>32</sup> Then, Representative Ganske

---

first time that Congress considered such an intellectual property policy initiative. In 1902, legislation to ban medical patents altogether was considered by the 57th Congress. See Noonan, *supra* note 22, at 654 & n.16 (discussing law concerning patenting methods of medical treatment at turn of century). Although the bill was reported by the House Committee on Patents, it did not receive additional consideration. See *id.* Similar legislation was introduced in the 58th Congress, but that effort was also unsuccessful. *Id.*

<sup>28</sup> See Orrin G. Hatch, *Better Late than Never: Implementation of the 1886 Berne Convention*, 22 CORNELL INT'L L.J. 171 (1989); Dana Rohrabacher and Paul Crilly, *The Case for a Strong Patent System*, 8 HARV. J.L. & TECH. 263, 270-72 (1995) (arguing that strong patent system is in Nation's best interest, but opposing implementing prior user rights).

<sup>29</sup> See 142 CONG. REC. H8276, H8289 (daily ed. July 24, 1996) (listing votes of members).

<sup>30</sup> See *supra* note 13.

<sup>31</sup> 142 CONG. REC. at H8277 (statement of Rep. Moorhead, Chairman, Judiciary Subcommittee on Courts and Intellectual Property) (noting that PTO held hearings on H.R. 1127).

<sup>32</sup> *Kelman Hearings*, *supra* note 18, at 3. Ironically, while Dr. Charles Kelman is a vocal opponent of medical procedure patents, a search of the U.S. patent database reveals that he has more than 70 U.S. medical device patents relating to ophthalmology, including U.S. Patent No. 4,728,182 "Bi-focal contact lens." See generally 1976-96 on-line patent database, <<http://patents.cndir.org>>.



undertook an alternate route. He offered a modified version of his bill as a floor amendment to the funding bill that prescribed the appropriations for the PTO.<sup>33</sup> This version of the bill intended to use the House's power of the purse to prevent the PTO from issuing medical patents.<sup>34</sup>

As part of the debate on the House floor for the measure, the sponsor argued the following five reasons in opposition to medical procedure patents:

No. 1, patient access to new surgical and medical procedures is being threatened by medical patents;

No. 2, medical patents permit patent owners to charge monopoly prices and contribute to our Nation's health care costs;

No. 3, physicians have an obligation to share their knowledge and skills for the benefit of humanity;

No. 4, medical patents are not necessary for the advancement of medicine. Did Oxner, the Mayo brothers, Lahey, or DeBakey need patents to advance medical knowledge?

And No. 5, 80 countries around the world, including most of Europe, expressly prohibit medical patents. The United States is virtually alone in the world in granting monopoly rights to these procedures.<sup>35</sup>

Other members joined in this passionate floor debate. Representative Norwood (R-GA), a dentist, stated, "[a]ll of my adult

<sup>33</sup> Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1997, H.R. 3814, 104th Cong. (1996); see also 142 CONG. REC. at H8276.

<sup>34</sup> The amendment reads as follows:

Sec. 615. (a) LIMITATION ON USE OF FUNDS TO ISSUE CERTAIN PATENTS. None of the funds made available in this Act may be used by the Patent and Trademark Office to issue a patent when it is made known to the Federal official having authority to obligate or expend such funds that the patent is for any invention or discovery of a technique, method, or process for performing a surgical procedure (defined as a treatment for curing or preventing disease, injury, illness, disorder, or deformity by operative methods, in which human tissue is cut, burned, or vaporized by the use of any mechanical means, laser, or ionizing radiation, or the penetration of the skin or body orifice by any means), performing a medical procedure (defined as a nonsurgical, nondiagnostic procedure for curing or preventing a disease, injury, illness, disorder, or deformity), or making a medical diagnosis (defined as the identification of a medical condition or a disease or disorder of a body).

*Id.* The amendment then specifically exempts medical devices and compositions of matter or biotechnological processes. *Id.*

<sup>35</sup> 142 CONG. REC. at H8277.

life I have been taught that as a health care provider, I should be very willing to share any knowledge I have on behalf of the patient."<sup>36</sup> Representative Tom Coburn (R-OK), an obstetrician, also argued against medical patents by stating:

I think this debate goes back down to one of the core issues in our country, whether a physician, no matter what particular oath they took, whether or not they are going to follow that oath, nowhere should a medical procedure get in the way of offering care to any other patient. I think most people will agree with that.<sup>37</sup>

Opponents<sup>38</sup> fired back by arguing that this issue is extremely complex and that the appropriations process was not the proper vehicle to advance this issue.<sup>39</sup>

Yet, during consideration of the appropriations bill, the amendment was overwhelmingly adopted by a vote of 295-128 in the House.<sup>40</sup> Despite this showing of support in the House, this funding limitation was never the subject of hearings or debate by the Senate and ultimately did not become law.

Instead, a modified version of S. 1334<sup>41</sup> was added as a "rider" to an omnibus appropriations bill and signed into law during the final days of the 104th Congress.<sup>42</sup> This occurred de-

<sup>36</sup> *Id.* at H8278 (statement of Rep. Norwood).

<sup>37</sup> *Id.* (statement of Rep. Coburn).

<sup>38</sup> Opponents included the Chairman of the Judiciary Subcommittee on Courts and Intellectual Property Carlos Moorhead (R-CA), Ranking Member Pat Schroeder (D-CO), and Appropriations Subcommittee Chairman Harold Rogers (R-KY). *Id.* at H8277-78.

<sup>39</sup> *See id.* at H8277 (remarks of Rep. Rogers) (arguing for authorization process rather than appropriations process).

<sup>40</sup> *See* 142 CONG. REC. at H8289-90 (listing votes of members). The measure was never enacted since the funding measure was defeated in an election year budget battle between Congress and the White House.

<sup>41</sup> The amendment would create the following new section to the Patent Code, amending 35 U.S.C. § 287:

(c)(1) With respect to a medical practitioner's performance, of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

142 CONG. REC. H11662, H11662 (daily ed. Sept. 28, 1996) (italics omitted). However, the compromise language would not apply to any medical process involving a compound subject to FDA or regulatory approval. *Id.* The law would also be prospective, applying only to patents issued after the provision's enactment. *Id.*

<sup>42</sup> The Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, 110 Stat. 30009 (1996). The new law reads, in pertinent part, as follows:

Section 287 of title 35, United States Code, is amended by adding at the



spite the fierce opposition of Senate leaders, including Senator Orrin Hatch (R-UT), Chairman of the Senate Judiciary Committee, and Senator Roth (R-DE), Chairman of the Senate Finance Committee.<sup>43</sup>

This new law presents extremely complex issues regarding the effects of medical process patents on the nation's public health care and intellectual property systems. Its analysis requires a quick review of the fundamentals of our constitutionally rooted system.

## II. INTELLECTUAL PROPERTY & CONGRESS

The Framers included a broad grant in the Constitution to ensure the "Progress of Science and the useful Arts."<sup>44</sup> While the Constitution is silent on any particular method of safeguarding intellectual property, Congress's authority in this arena flows from this provision, also known as the Copyright and Patent clause. In addition, there are other complementary forms of intellectual property involving commerce and trade, some of which are traditionally rooted in state law. Today, there are four forms of intellectual property protection in place to safeguard innovative endeavors: patents (e.g., inventions); copyrights (e.g., written and recorded works); trademarks (e.g., commercial logos); and trade secrets (e.g., proprietary information).

A number of policies have evolved to advance the Framers' goals and constitutional principles. There is a strong federal policy that discoveries and inventions in "general circulation" be

---

end the following new subsection:

(c) (1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

*Id.* § 616

<sup>43</sup> 142 CONG. REC. S11838, S11842-45 (daily ed. Sept. 30, 1996) (letter written by Senators Hatch and Roth). "I think there should be a very heavy burden on those advocating change of a law that appears to be working well and has worked well for a long time. In my view, this burden has not been met." *Id.* at 11844 (statement of Sen. Orrin G. Hatch, Chairman, Committee on the Judiciary). Senator Hatch warns that this measure, which is also opposed by the General Counsel of the Office of the United States Trade Representative, has serious consequences on the Patent Code and our international trade policy. *Id.* at 11843.

<sup>44</sup> The Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

dedicated to the common good, unless narrowly restricted by some intellectual property law protection.<sup>45</sup> Again and again, our legal system stresses the policy of the "full and free" use of all ideas in the public domain.<sup>46</sup>

Judge Pauline Newman of the Court of Appeals for the Federal Circuit defined "technological innovation" as the process "of advancing the useful arts."<sup>47</sup> For her, patents are a vital tool and part of the constitutionally-based right that "carries the obligation to disclose the workings of the invention ... [that adds] to the store of knowledge without diminishing the patent-supported incentive to innovate."<sup>48</sup>

Under our federal system, states are preempted from establishing new monopolistic laws for protecting inventions outside the patent system.<sup>49</sup> Inventions in the public domain are unpatentable and may not be protected by a state regime.<sup>50</sup> The Supreme Court has noted that the Copyright and Patent Clause of the United States Constitution reflects a fundamental policy to ensure the national uniformity of intellectual property laws.<sup>51</sup>

The Copyright and Patent clause is not self-executing. Congress is responsible for creating federal protective devices, such as enacting intellectual property statutes. Consequently, patents are entirely a creature of federal statute;<sup>52</sup> there is no com-

---

<sup>45</sup> See *Lear, Inc. v. Adkins*, 395 U.S. 653, 668 (1969) (stating that federal law requires that ideas in general circulation be in public domain); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 237-38 (1964) (holding that intellectual property left within public domain by Patent and Copyright laws is not entitled to patent protection); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231-32 (1964) (holding that government cannot prevent copying information within public domain); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120 (1938) (citing *Singer Mfg. Co. v. June Mfg.*, 163 U.S. 169, 185 (1896)) (noting that when patent expires, right to make article passes to public).

<sup>46</sup> See *Lear*, 395 U.S. at 670 (noting that important public interest in allowing full and free utilization of ideas within that are part of public domain).

<sup>47</sup> *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985).

<sup>48</sup> *Id.* However, under trade secret law, an inventor who keeps his invention secret may enjoy de facto exclusivity and may rely on state enforcement of nondisclosure agreements. 1 ROSENBERG, *supra* note 1, § 3.01, at 3-2-3-5.

<sup>49</sup> See *Lear*, 395 U.S. at 677 (Black, J., concurring) (expressing belief that no state has right to allow monopoly on invention).

<sup>50</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 153 (1989) (noting that boat hull designs could not be patented where federal patent law preempts state laws).

<sup>51</sup> See *id.* at 162.

<sup>52</sup> Property in patents exists solely by virtue of federal statutory law, and incidents of that property are defined and determined by the patent statutes. See *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 40 (1923). The first

mon law of patents.<sup>53</sup> Likewise, Congress has the power to change the patent laws at its pleasure.<sup>54</sup> For this reason, all federal legislative activity pertaining to patents—including hearings, floor activity, and the enactment of statutes—is particularly worthy of careful consideration.

### III. PATENTS VERSUS TRADE SECRETS

The statutory requirements and conditions for receiving a patent for an invention are simple. The scope of patentability for inventions and discoveries under the statute includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement.”<sup>55</sup> “Invention” and “process” are defined under the statute.<sup>56</sup> The innovation, in addition, must be useful, novel, and non-obvious to those skilled in the pertinent technical discipline at the time of the inventive conception.<sup>57</sup>

Exceptions to the patentable subject matter requirements are extremely rare. The Supreme Court declared that “anything under the sun that is made by man”<sup>58</sup> is patentable. There is a public policy against the issuance of patents that are exclusively devoted to purposes harmful to the public welfare.<sup>59</sup> As a result, there currently exists a sole class of inventions, atomic weapons,

---

patent statute was enacted in 1790. Act of Apr. 10, 1790, 1 Stat. 109.

<sup>53</sup> See *In re McKellin*, 529 F.2d 1324, 1333 (C.C.P.A. 1976) (Markey, C.J., concurring) (noting that no common law patent exists).

<sup>54</sup> See *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843).

<sup>55</sup> 35 U.S.C. § 101 (1994). This is limited to “man-made” articles, and thus printed matter, naturally occurring articles, methods of doing business, and scientific principles may not be patented. See 35 U.S.C. § 102 (defining conditions for patentability); see also *MANUAL OF PATENT EXAMINING PROCEDURE* 706.03(b) (5th ed. 1993) (noting bar on atomic energy patents).

<sup>56</sup> “The term ‘invention’ means invention or discovery.” 35 U.S.C. § 100(a) (1994). “The term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” *Id.* at § 100(b).

<sup>57</sup> 35 U.S.C. §§ 101-103.

<sup>58</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citations omitted). The Court reasoned that a broad interpretation of the patent statute was necessary in light of its “core concept” to protect the unforeseeable fruits of the inventive process. *Id.* at 316. The Court stated that “[t]he Act embodied Jefferson’s philosophy that ‘ingenuity should receive a liberal encouragement.’” *Id.* at 308 (citation omitted).

<sup>59</sup> For example, an invention whose entire purpose is devoted to lock-picking, and lacks any other useful and socially redeeming characteristics, is said to be excluded.

that has earned a statutory prohibition.<sup>60</sup>

The bundle of patent rights that a successful inventor enjoys, the exclusive rights to make, use, and sell, only vest upon the issue of a federal patent. The rights of an inventor against infringement are provided by statute.<sup>61</sup> During the pendency, the time between the patent application and the PTO's final decision of its patentability, an inventor must take special precautions against infringers. During the pendency period, a patent application is held in secret and enjoys confidential, non-public status at the PTO.<sup>62</sup> Upon the grant of a patent, the technical information about an invention is published. In this way, the public's knowledge is enriched as interested parties can learn about the invention. Courts acknowledge that there is a quid pro quo. Namely, the disclosure of knowledge in return for a patent monopoly is the benefit of the bargain underlying the societal progress that the patent system promises.<sup>63</sup>

In its goal to promote scientific progress, the patent system advances several federal policy objectives that comport with scientific and economic theories. The "storehouse theory" is one such relevant legal property theory. It states that disclosure under the patent system "enlarges the public storehouse of knowledge."<sup>64</sup> The patent system grants a limited monopoly to the applicant who first contributes "a measure of worthwhile knowledge to the public storehouse."<sup>65</sup>

All medical patent moratorium legislation is criticized for frustrating important federal policy objectives, such as public

---

<sup>60</sup> See The Atomic Energy Act of 1954 § 151(1), 42 U.S.C. § 2181(a) (1994). Critics argue that the true rationale for this legislation was for the government to develop a monopoly in the atomic energy field. Burch, *supra* note 6, at 1164.

<sup>61</sup> 35 U.S.C. § 271 (1994) (defining liability for infringement of patents).

<sup>62</sup> *Id.* § 122.

<sup>63</sup> See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87 (1933) (distinguishing monopolies from patents and noting quid pro quo of patent system); *United States v. American Bell Tel. Co.*, 167 U.S. 224, 239 (1897) (supporting assertion that inventions ultimately add to sum of human knowledge, therefore, patent protection is justified); *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 247 (1832) (noting that patent system design allows public to benefit from invention while compensating inventor with temporary monopoly).

<sup>64</sup> Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024 (1989).

<sup>65</sup> *In re Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring). Thus, a patent is to be distinguished from a monopoly—which connotes the usurpation by one entity of the right to use something the public once freely enjoyed. See *Dubilier*, 289 U.S. at 186.

disclosure of invention technology. Opponents argue that denying full patent protection for medical innovation artificially blocks the efficient dissemination of knowledge, since information on new procedures revealed through patent publication falls outside the traditional forum of medical journals.<sup>66</sup> Similarly, the practice of prohibiting medical patents serves to deter physicians and researchers from making disclosures.<sup>67</sup> Clearly, rendering a class of patents virtually unenforceable due to the lack of adequate remedy leads to researchers securing fewer of these patents. In turn, the current statutory framework chills invention and frustrates the important federal objectives behind patents.

Two economic-oriented patent theories concerning the promotion of a favorable economic climate for inventive activity are the "prospect theory" and the "innovative theory." The "prospect theory" states that the opportunity to obtain a patent monopoly creates the incentive for investment in research for new inventions.<sup>68</sup> The "innovation theory" asserts that patents are necessary to induce firms to put existing inventions to practical use.<sup>69</sup> This theory rests upon the belief that even though the invention requires an investment, considerable subsequent investment must be made before its commercial exploitation is possible. Thus, regardless of the term of patent protection, the necessary costs of promoting, manufacturing, and refining may dwarf the required initial research investment that created the invention.<sup>70</sup>

<sup>66</sup> *Pallin Hearings*, *supra* note 16, at 2.

<sup>67</sup> *Id.* at 5.

<sup>68</sup> See Eisenberg, *supra* note 64, at 1024. Professor Eisenberg notes that many find the idea of granting exclusive rights in new knowledge to be counterintuitive to the goal of scientific progress. *Id.* at 1017. She also asserts that divergent views on how to promote scientific progress may conflict when subsequent researchers use patented inventions in their studies. *Id.*

<sup>69</sup> *Id.* at 1036-37. Professor Eisenberg suggests that while courts have primarily used the incentive theory to advance arguments in favor of the patent system, notable exceptions appear in *Picard v. United Aircraft Corp.*, 128 F.2d 632 (2d Cir. 1942), and *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 n.9 (2d Cir. 1981), where the courts strayed from the beaten path, advocating that stimulus to investment rather than innovation may be the central theme in the justification of the patent system. Eisenberg, *supra* note 64, at 1037 n.81. Like the "prospect theory," the "innovation theory" posits that the patent system best achieves its aims by offering monopoly profits "as a lure to promote desired behavior." *Id.* at 1037.

<sup>70</sup> *Id.* Patent protection, therefore, is needed to enhance the likelihood that a firm will be willing to undertake these substantial investments. *Id.*; see also FREDERIC M. SCHERER, INNOVATION AND GROWTH: SCHUMPETERIAN PERSPECTIVES 3-7 (1984) (describing phases of investment in development of inventions).

The term of a patent begins with the grant by the PTO and extends a maximum of twenty years after its initial filing.<sup>71</sup> This rule regarding term, however, is not absolute. Patents may be extended by a special act of Congress or under another promulgated statutory regime, such as the procedures designed to compensate patentees for time loss during FDA review of pharmaceutical or medical devices.<sup>72</sup>

In accord with federal objectives, there is also a strong policy mandating that patents which were improperly awarded should neither unduly fetter technology nor restrict competition. There are statutory bases to challenge the underlying validity of a patent, such as reexamination.<sup>73</sup> A separate statutory proceeding, called an interference, is used in challenges over the priority of the true inventorship.<sup>74</sup>

According to empirical studies, an overwhelming majority of patents are put to use before a patent's issuance.<sup>75</sup> Since the United States patent system awards no protection for an invention before the grant of a patent, the inventor often relies on some form of secrecy during the beginning stages of development.

The very name "patent" is derived from the Latin *patere*, which means "open."<sup>76</sup> In contrast, the cornerstone of trade se-

<sup>71</sup> 35 U.S.C. § 154(a)(2) (1994). This is a departure from the traditional 17 year term which was the rule for many years in the United States. However, a patent will have a term of at least 17 years if its processing by the PTO takes three or fewer years. The change was prompted by the United States' implementation of the General Agreement on Tariffs and Trade ("GATT"). See Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994).

<sup>72</sup> Drug Price Competition and Patent Term Restoration Act, 35 U.S.C. § 271(e) (1994).

<sup>73</sup> 35 U.S.C. § 302 (1994) ("Any person at any time may file a request for reexamination by the [Patent and Trademark] Office.").

<sup>74</sup> *Id.* § 135. The Board of Patent Appeals and Interferences determines questions of priority of inventions. *Id.*

<sup>75</sup> A study of a random sample of patents issued in 1938, 1948, and 1952, which were commercially exploited found that 40 percent are put to use before the filing of a patent application; approximately 50 percent are put to use during patent application pendency; and only 10 percent are first put to use after patent issuance. Barkev S. Sanders, *Some Difficulties in Measuring Inventive Activity*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS*, at 56, tbl. 1 (1962).

<sup>76</sup> In practice, a patent application made available to the public may not be very "open." As Judge Pauline Newman noted, "[i]t is a rare invention that cannot be deciphered more readily from its commercial embodiment than from the printed patent." *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985). Interestingly, the court explained that it did not believe "that the public interest is served by placing



crets is secrecy.<sup>77</sup> In practice, a common strategy for inventors is to use some combination of patents and trade secrets.

The Supreme Court has held that the federal intellectual property system, patents and copyrights, does not preempt, but in fact works in tandem with other forms of intellectual property protection (e.g., state trade secrecy law).<sup>78</sup> Accordingly, state laws are often complementary methods for protecting intellectual property.<sup>79</sup>

There is a positive public effect where dual systems of protection operate in concert.<sup>80</sup> State trade secret law harmoniously coexists with the federal patent system, providing the mechanism to achieve and maintain the necessary economic incentives to encourage invention.<sup>81</sup> Trade secrets are different devices

... [a] severe ... sanction on failure to file premature patent applications on immature inventions of unknown value." *See id.*

<sup>77</sup> *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 850 (1st Cir. 1985) (affirming trial court's finding that fraudulently asserting trade secret rights violated federal antitrust laws).

Trade secrets are creatures of state law and every state has some scheme to provide protection; there is no federal trade secret law. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which provides an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. *See* A.L.I. RESTATEMENT (FIRST) OF TORTS, § 757 cmt. b (1939).

<sup>78</sup> *Goldstein v. California*, 412 U.S. 546, 556-58 (1973). "[W]e cannot discern such an unyielding national interest as to require an inference that state power to grant copyrights has been relinquished to *exclusive* federal control." *Id.* at 558. Accordingly, the Court held that no conflict existed between state and federal copyright law. *Id.* at 570.

<sup>79</sup> *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-82 (1974). The Court noted that the patent statutes "do[] not explicitly endorse or forbid the operation of trade secret law." *Id.* at 480. The Court also stated that patents and trade secrets each have a "particular role to play, and the operation of one does not take away from the need for the other." *Id.* at 493.

<sup>80</sup> "Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention. Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention." *Id.* at 485. The court recognized that both systems are designed to encourage invention, and in that respect they will complement each other. *See id.* at 484.

<sup>81</sup> Gordon L. Doerfer, *The Limits on Trade Secret Law Imposed by Federal Patent and Antitrust Supremacy*, 80 HARV. L. REV. 1432, 1454 (1967) (stating that patent and trade secret systems have similar policy goals); *see also Kewanee Oil*, 416 U.S. at 484-85 (asserting that state and federal systems are unlikely to conflict with each other because both have similar policy goals).

which encourage innovation,<sup>82</sup> maintain business ethics, promote fair dealing,<sup>83</sup> foster sharing of knowledge, and promote efficient commercialization.<sup>84</sup> The most valuable aspect of trade secrets is neither the power to exclude competitors nor the certainty as to the duration of protection but rather, the head start to commercialization. This differs from the benefits flowing from patents, which include the power to exclude competitors, and the certainty of the duration of such protection.<sup>85</sup>

In deciding which form of protection to pursue, there are a number of strategic and personal questions the trade secret holder must consider. First, one must decide whether patent protection is warranted at all. This decision hinges on several questions, including: (1) whether the invention meets the requirements for a patent; (2) whether the patent system provides an adequate term of protection; (3) whether the inevitable public disclosure is counter to the concerns of the firm; and (4) the expense of enforcing a patent. Additionally, cynicism deters some from participating in the patent system altogether.<sup>86</sup>

In foregoing the patent route, an inventor must assess whether the trade secret can be kept adequately confidential.<sup>87</sup> A trade secret holder must also take steps to police the invention's secrecy. In order to be protected by law, it is necessary to take reasonable, but not heroic, precautions to protect the invention.<sup>88</sup>

There are no legal limits on the duration of a trade secret.

<sup>82</sup> *Id.* at 481; see also *CVD, Inc.*, 769 F.2d at 850 (stating that purpose of trade secret law is to encourage innovation).

<sup>83</sup> See *Kewanee Oil*, 416 U.S. at 481; see also *CVD, Inc.*, 769 F.2d at 850 (noting fair dealing promotion in trade secret protection).

<sup>84</sup> See *Kewanee Oil*, 416 U.S. at 493; see also Eisenberg, *supra* note 64, at 1037 (discussing commercialization of products).

<sup>85</sup> Doerfer, *supra* note 81, at 1448 (discussing distinctions between trade secret protection benefits and patent protection benefits).

<sup>86</sup> See EDWIN MANSFIELD, *THE ECONOMICS OF TECHNOLOGICAL CHANGE* 209 (1968); see also A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 Am. U. L. Rev. 1097, 1101 (1989) (positing that justification for patent protection in any country can be determined only after considering ratio of patent-induced inventions to non-patent-induced inventions).

<sup>87</sup> Critics of the patent system argue that firms patent only when they cannot keep an invention secret. See MANSFIELD, *supra* note 84; E. PENROSA, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* 12-17 (1973) (noting that because of costs inherent in patent system, patents are used only when secrecy is lost).

<sup>88</sup> *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851-52 (1st Cir. 1985) (stating that reasonable precautions are mandated); see also *USM Corp. v. Marson Fastener Corp.*, 393 N.E.2d 895, 896 (Mass. 1979) (analyzing whether plaintiff pursued course of conduct reasonably designed to preserve secrecy).

In fact, the medical profession is quick to point out that the Chamberlain family kept surgical forceps secret for four generations.<sup>89</sup> In theory, trade secret protection can last forever, or at least longer than the practical useful life of an invention. The public perception may be that trade secret protection is long-lived. Yet, despite the famously secret recipe for Coca-Cola,<sup>TM</sup> experts confess that the duration of such protection is really not very long-lived at all.<sup>90</sup>

Trade secret protection is considered far weaker than patent protection due to its indefinite term and limited ability to exclude others from the invention. An independent inventor using independent creation or reverse engineering who discovers a trade secret faces few obstacles in commercializing an invention on her own.<sup>91</sup>

Trade secret protection works best for inventions and proprietary data that are beyond public scrutiny (e.g., a manufacturing process or the ones and zeroes of a software program code). A patent, on the other hand, works best to protect a product that is easily analyzed, like a ceramic coffee mug. The process used at the factory behind the scenes to glaze the mug, by contrast, could sufficiently be guarded as a trade secret. There are other considerations, of course, including whether a technology is intended to be shown to other parties, assigned or licensed. The inventor, relying solely on trade secret protection, should be aware that in many cases she has no rights to exclude an independent rival inventor from making, selling, or using a similar invention and may face difficulty in securing licensing protection.

In light of the Framers' intent to foster broad policy objectives to advance the sciences, the Supreme Court has concluded that trade secrets are merely a complementary form of intellectual property protection.<sup>92</sup> This conclusion does not put society

---

<sup>89</sup> *Medical Hearings*, *supra* note 13, at 1995 WL 615761, at \*2 (testimony of Dr. Samuel Lear Pallin).

<sup>90</sup> See *Doerfer*, *supra* note 81, at 1448. The patent system is better designed to protect major product inventions, rather than minor product inventions or process inventions "which can often be kept secret for considerable lengths of time." MANSFIELD, *supra* note 86, at 209.

<sup>91</sup> See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 490 (1974) (noting that trade secret law does not forbid discovery of secret by independent creation or reverse engineering).

<sup>92</sup> See *id.* at 480 (recognizing settled federal preemption doctrine which states that when trade secret law clashes with objectives of federal patent law then "the

at risk since an inventor rarely chooses trade secrets over patent protection. Ultimately, despite their modest role in protecting some inventions, most trade secrets fade away because of independent discovery, difficulty in maintenance, abandonment due to obsolescence or unimportance, or an eventual yielding to the patent system.

True to the Framers' vision, the current legal system embraces both patent and trade secrets. Despite the overall complexity and vast history of this area, our intellectual property law system's traditional policy objectives have remained constant. These objectives include stimulating innovation, facilitating public disclosure, promoting free competition, and maintaining uniformity.<sup>93</sup> This Article asserts that certainty is another extremely important policy objective. In light of the long shared history and goals of medicine and patents, Congress must be mindful to promote certainty in addition to the aforementioned federal policy objectives as it refines intellectual property law.

#### IV. THE HISTORICAL UNION OF MEDICINE AND PATENTS

*"No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new [discovery] to mankind."<sup>94</sup>*

Patents were not always available as a means of protecting medical innovation. Some of the earliest trade secret cases on record involved the tort of misappropriation concerning formulas for varieties of "patent medicine."<sup>95</sup> In *Green v. Folgham*,<sup>96</sup> the trade secret was the formula for "Dr. Johnson's Ointment for the

---

state law must fall"); *Goldstein v. California*, 412 U.S. 546, 557-58 (1973) (holding that state trade secret protection law aligned with patent system goals are not preempted by federal patent law).

<sup>93</sup> *Patent Preemption of Trade Secret Protection of Inventions Meeting Judicial Standards of Patentability*, 87 HARV. L. REV. 807, 819 (1974) (noting history of intellectual property law and positing that policy objectives have remained constant).

<sup>94</sup> H.R. REP. No. 71-1129, at 2 (1930).

<sup>95</sup> There is some confusion in the terminology since the courts have permitted the term "patent medicine" to be used for those peccaries and concoctions which are proprietary in nature, but are not in fact deserving of patent protection. See *Jacobs v. Beecham*, 221 U.S. 263, 273 (1911) (recognizing widespread use of word "patent" to indicate medicines made by secret formulas).

<sup>96</sup> 1 Sim. & St. 398, 57 Eng. Rep. 159, 159 (Ch. 1823).

Eyes.<sup>97</sup> As the nature of manufacturing and treatment administration evolved, patents became the superior means to protect new medical discoveries. This protection eventually became possible because medical inventions were allowed within the broadly construed scope of patentable subject matter.

Traditionally, the patent statute was silent on medical patents per se. This is one reason why the newly enacted change in section 287 is historic.<sup>98</sup> Opponents of medical process patents believe this type of patent is a troubling newcomer to the health care scene and that the PTO should not use its funding to issue this "new" type of patent. However, in fact, scores of United States patents on medical and surgical procedures have been issued over the past nearly one-hundred and fifty years.<sup>99</sup> Therefore, it is inaccurate to describe medical patents as a "new phenomenon."<sup>100</sup> The frequency of medical patents is already so high that they are even described as being in "common currency."<sup>101</sup> Medical process patents have ranged from the use of ether in surgery as an anesthesia<sup>102</sup> to new developments in genetic research.<sup>103</sup>

One of the principal arguments against medical procedure patents is that they are unnecessary to stimulate scientific medical discovery. Yet, history is filled with numerous examples of patented medical compounds whose prominence fueled research efforts.<sup>104</sup> These gained prominence due to their economic value and societal benefit. Even within the medical community there is general agreement that drugs and medical devices merit patent protection, due to the need to recoup the great investment in

---

<sup>97</sup> *Id.* The ointment ingredients were wrongfully disclosed by its holder in trust. *Id.* Although the plaintiff sought a sale of the secret, the court ordered an accounting for profits by its commercial user. *Id.* For further history tracing the development of the legal concept of trade secret protection in English common law, see 1 MELVIN F. JAGER, TRADE SECRETS LAW § 2.01, 2-3 (1996).

<sup>98</sup> See *supra* note 42 (listing changes to section 287).

<sup>99</sup> Noonan, *supra* note 22, at 658-60 (noting long history of medical process patents).

<sup>100</sup> *Id.* at 652 (citing *AMA Opposes Patents for Medical, Surgical Procedures*, AMA NEWS, July 4, 1994, at 6).

<sup>101</sup> Noonan, *supra* note 22, at 652.

<sup>102</sup> U.S. Patent No. 4848 (issue date 1846).

<sup>103</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980) (determining that patent protection could extend to artificial organisms produced by genetic engineering).

<sup>104</sup> Noonan, *supra* note 22, at 659 (listing prominent patented medical compounds).

research, development, and governmental regulatory approval.<sup>105</sup>

At the turn of the century, one of the most important common cures arose from the industrial chemical industry. The United States Patent Code, unlike the laws of other nations at the time, provided industrial chemical firms protection for both their products and processes.<sup>106</sup> Author Jan McTavish concludes that it is unlikely that medical uses for acetylsalicylic acid (aspirin) would ever have been discovered were it not for the research laboratory established to exploit the relationship between industrial chemicals and pharmaceuticals.<sup>107</sup> The German Bayer company was hence able to enjoy a complete 17-year monopoly in the United States through patent protection (1900-1917).<sup>108</sup> The Bayer company thereafter enjoyed limited success maintaining its aspirin product protection through another form of intellectual property, vigorous trademark enforcement.<sup>109</sup> Today, "aspirin" is a household word on every continent.<sup>110</sup>

There is dramatic historical evidence correlating the patenting of a medical breakthrough and the cure's prominence.<sup>111</sup> The discovery of anesthesia, for example, resulted in one of history's greatest and earliest medical patent controversies. Until the middle of the Nineteenth Century, people suffering dental problems avoided visiting a dentist because of the fear of pain. Then in 1844, Connecticut dentist Horace Wells discovered anesthesia, which (somewhat) changed the way many felt about seeking out care from dentists.<sup>112</sup>

<sup>105</sup> *Id.* at 656.

<sup>106</sup> Jan R. McTavish, *What's in a Name? Aspirin and the American Medical Association*, 61 BULL. HIST. MED. 343, 347 (1987).

<sup>107</sup> *Id.* at 363.

<sup>108</sup> *Id.* at 346.

<sup>109</sup> *Id.* at 363. While United States' courts severely limited the scope of the trademark protection for the term "aspirin," Canadian courts provided far greater rights to Sterling, the company which succeeded Bayer as the holder of rights in the period after World War II. *Id.* at 362 n.56.

<sup>110</sup> McTavish, *supra* note 106, at 346.

<sup>111</sup> In contrast, experts assert that the lack of patent litigation in areas where the medical profession has never sought to enforce its medical procedure patents, a multi-million dollar technology, like Surrogate Embryo Transfer (SET), is the real indicator of a patent's value or lack thereof. See *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 14 (1995) (testimony of Dr. William D. Noonan) (noting that patents are "unimportant to medical progress") [hereinafter *Noonan Hearings*].

<sup>112</sup> Malvin E. Ring, *The Rubber Denture Murder Case: The True Story of the Vulcanite Litigations*, 32 BULL. OF THE HIST. OF DENTISTRY 1, 3-4 (1984).



There was another related medical breakthrough in dentistry in 1844. Charles Goodyear received a patent for his discovery of vulcanized rubber. One way this technology was put to use was as a denture material. The Goodyear Company recognized the possible commercial applications of this promising technology and devised a system to extract patent royalties from the dental profession.<sup>113</sup> This led to considerable opposition by the dental profession and a series of infringement lawsuits. One highly frustrated dentist, Dr. Samuel P. Chalfant, went so far as to repeatedly move his practice across the country to avoid paying a licensing fee for the rubber denture patent.<sup>114</sup> Ultimately, Dr. Chalfant pursued Goodyear's chief licensing agent to a hotel in San Francisco and shot him dead.<sup>115</sup> This ordeal tempered the dental professional's resolve never to be the subject of "profiteering" patent licensing again.<sup>116</sup>

The rise of medical drug, device, and process patents was possible, in part, because of the construction of the patent laws. The judiciary possesses the power to review the validity of medical process patents and to construe the patent code.<sup>117</sup> The development of the case law was initially fraught with inconsistency. Modern courts, however, looked to the legislative intent underlying the enactment of patent laws as a guide to ascertaining whether patent protection was merited, ethically just, and in furtherance of the public good.<sup>118</sup> These courts properly interpreted the patent laws by balancing the interests between inventors and society and invalidating patents on those medical procedures which failed to satisfy the requirements for patent

---

<sup>113</sup> *Id.* at 5.

<sup>114</sup> *Id.* at 15.

<sup>115</sup> *Id.* at 16.

<sup>116</sup> *Id.* at 17; see also Noonan, *supra* note 22, at 652-53 (discussing Goodyear's patent on vulcanizing rubber, subsequent infringement lawsuits against dentists, and frustrated dentist's murder of Goodyear's licensing agent).

<sup>117</sup> 35 U.S.C. § 145 (1994) ("An applicant dissatisfied with the decision of the Board of Patent Appeals and Interferences ... may ... have remedy by civil action against the Commissioner in the United States District Court for the District of Columbia."); see also *Lee Pharms. v. Kreps*, 577 F.2d 610, 612 (9th Cir. 1978) (stating that rejection of patent application by Board of Patent Appeals may be brought for judicial review).

<sup>118</sup> See Burch, *supra* note 6, at 1149-51 (recognizing that Congress ultimately determines whether patent serves public good and until Congress passes legislation prohibiting patents for medical technology, courts are likely to apply "mechanical analysis" and grant patentability).

protection.<sup>119</sup>

Over the years, the issue concerning patentability of medical devices and processes has been confused by both federal courts and the PTO administrative boards. A basic doctrine of patent law is that "qualities of nature" may not be patented.<sup>120</sup> This issue was considered in *Morton v. New York Eye Infirmary*,<sup>121</sup> where the court denied the patentability of ether as a general anesthetic due to a finding that such use lacked novelty.<sup>122</sup> Subsequent cases, such as *Ex parte Brinkerhoff*,<sup>123</sup> construed *Morton* to stand for the proposition that medical processes could not be patented whatsoever.<sup>124</sup> This decision was subsequently overruled by the PTO Board of Patent Appeals in *Ex parte Scherer* which upheld the patentability of medical or surgical methods.<sup>125</sup>

*Martin v. Wyeth*<sup>126</sup> represents the modern judicial tendency to uphold the validity of medical patents. In *Martin*, while noting that the statute does not expressly mention medical process patents, the court held that medical process patents fall within the law's patentable subject matter.<sup>127</sup> The court, however, ob-

<sup>119</sup> See, e.g., *Martin v. Wyeth*, 96 F. Supp. 689, 695-96 (D. Md.) (holding veterinary process patent invalid), *aff'd*, 193 F.2d 58 (4th Cir. 1951); *Morton v. New York Eye Infirmary*, 17 F. Cas. 879, 883 (S.D.N.Y. 1862) (No. 9865) (holding that use of ether as general anesthetic failed to meet statutory requirements for patent validity).

<sup>120</sup> *Morton*, 17 F. Cas. at 883-84; see also *LeRoy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852); *Wall v. Leck*, 66 F. 552, 557 (9th Cir. 1895) ("[A] natural physical force, is not the product of inventive skill.").

<sup>121</sup> 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9865).

<sup>122</sup> *Id.* at 883-84. A patent will be granted if the applicant can establish that the invention is the first of its kind (novelty), it is useful (utility), and it is not an obvious extension of what was already known (non-obviousness). See 35 U.S.C. §§ 101-103 (1994).

<sup>123</sup> 24 OFF. GAZ. PAT. 349 (Comm'r Pat. Off. 1883) (rejecting medical process patent for treating hemorrhoids due to nonuniform results in treatment), *reprinted in* *New Decisions*, 27 J. PAT. OFF. SOC'Y 793, 797-98 (1945).

<sup>124</sup> See Burch, *supra* note 6, at 1146.

<sup>125</sup> 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) ("We do not believe that [*Morton*] ... is sufficient to establish ... that all methods involving treatment of the body are ... not patentable."). Despite the *Brinkerhoff* court's narrow interpretation of *Morton* and two failed attempts by Congress to prohibit medical patents, courts now generally uphold the grant of medical patents. Noonan, *supra* note 22, at 654; see also Burch, *supra* note 6, at 1149-51 (examining how courts have broadened definitions of "process" in upholding medical process patents).

<sup>126</sup> 96 F. Supp. 689 (D. Md.), *aff'd*, 193 F.2d 58 (4th Cir. 1951).

<sup>127</sup> *Id.* at 694. "[I]t is at least assumed by counsel for both sides in this case that a medical or surgical method may, if otherwise patentable, be placed in the category of an art and therefore within reach of the statute." *Id.* at 695. Beginning with the 1790 Patent Act, the subject matter for a patent included an "art." See *Diamond v.*

served that while patent protection has been extended to numerous chemical compounds as part of a therapeutic regimen, valid medical process patents are rare.<sup>128</sup>

The judiciary offered its most strenuous defense of the vast scope of biomedical patents in *Diamond v. Chakrabarty*.<sup>129</sup> In *Diamond*, the Supreme Court upheld the broad scope of patentable subject matter by holding that genetically engineered microorganisms were patentable subject material.<sup>130</sup> The Court boldly declared that the broad bounds of patentable subject matter included "anything under the sun that is made by man."<sup>131</sup>

This broad pronouncement, consistent with the ideals underlying patent protection, paved the way for greater scientific breakthroughs and triumphs. Shortly after *Chakrabarty*, Harvard University applied for and received a patent on a genetically altered mouse.<sup>132</sup> Genetically altered animals are now becoming a popular method to produce pharmaceutical compounds for use in therapeutic methods to treat humans.<sup>133</sup>

Diehr, 450 U.S. 175, 182-84 (1981) (discussing historical treatment of processes as art). The 1952 Patent Act replaced this term with "process." 35 U.S.C. § 101 (1994). The Supreme Court noted, however, that this change did not alter the judicial interpretation of the statute. *Diamond*, 450 U.S. at 184.

<sup>128</sup> *Martin*, 96 F. Supp. at 695.

<sup>129</sup> 447 U.S. 303 (1980).

<sup>130</sup> *Id.* at 309.

<sup>131</sup> *Id.* (quoting S. REP. NO. 82-1979, at 5; H.R. REP. NO. 82-1923, at 6 (1952)).

The Court reasoned that a broad interpretation of the patent statute was necessary in light of its "core concept" to protect the unforeseeable fruits of the inventive process. *Id.* at 316.

<sup>132</sup> U.S. Patent No. 4,736,866, U.S. Patent and Trademark Off., U.S. Dep't of Com., Index of Patents, pt. I, 1380 (1988). As a result of the genetic manipulation, the transgenic mouse is abnormally prone to developing breast cancer. Eisenberg, *supra* note 64, at 1084. The mice are marketed for approximately \$50 each. Laurie Hays, *DuPont Co. to Sell Gene-Spliced Mice to Scientists in Labs Studying Cancer*, WALL ST. J., Nov. 16, 1988, at B5. This is the first patent issued for a "higher form of life." Keith Schneider, *Harvard Gets Mouse Patent, A World First*, N.Y. TIMES, Apr. 13, 1988, at A1. For a detailed discussion of the patentability of genetically-altered organisms, see Dan L. Burk, *Patenting Transgenic Human Embryos: A Non-use Cost Perspective*, 30 HOUS. L. REV. 1597 (1993).

<sup>133</sup> See Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 407 (1988) (stating that "transgenic animals are ... expected to have commercial value in three primary areas: agriculture, biomedical research, and the pharmaceutical industry"). For a description of this process, known as "molecular farming," see *id.* at 408-09. For a detailed discussion of the impact of genetically altered animals on the pharmaceutical industry, see David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417 (1991).

While some experts conclude that congressional action is unnecessary because the judicial system can prevent potential abuse in the medical patents arena,<sup>134</sup> the political dimensions of medical patents clearly make it a question best suited for the legislative process. The courts appear to agree with the latter proposition.<sup>135</sup> Evolving from a mere vague doctrine of misappropriation, a vast array of patents currently sustain the legal protection for biomedical breakthroughs. This development has fueled the debate over the conflict between bioethics and technology.

## V. ETHICAL DIMENSIONS OF BIOMEDICAL PATENTS

Medical procedure patents are only one example of an issue that punctuates the tension between what is ethical and what is permitted by law.<sup>136</sup> The ethical concerns are certainly legitimate since many people believe that "alleviating human suffering does not belong to the area of economic endeavour or trade and commerce."<sup>137</sup> The fundamental theory underlying our society, however, asserts that allowing intellectual property rights in medical innovation benefits society.<sup>138</sup> The ethical dilemma presented by these conflicting viewpoints is whether biomedical innovation is of a special character which should not be patentable. The more immediate inquiry in recent public debate was the narrower question of whether society should limit medical technology patent protection.

---

<sup>134</sup> Burch, *supra* note 6, at 1170; *see, e.g.*, *Vitamin Technologists v. Wisconsin Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1945); *Martin v. Wyeth*, 96 F. Supp. 689 (D. Md.), *aff'd*, 193 F.2d 58 (4th Cir. 1951).

<sup>135</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) ("Congress, not the courts, must define the limits of patentability ...."); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933) ("[Courts] should not read into the patent laws limitations and conditions which the legislature has not expressed.").

<sup>136</sup> "The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage." *Martin*, 96 F. Supp. at 695.

<sup>137</sup> *Wellcome Found., Ltd. v. Commissioner of Patents*, 1983 N.Z.L.R. 385, 388 (1983) (citation omitted); *see Burch, supra* note 6, at 1152-61 (discussing ethical considerations in context of physician-patient relationship and methodology of medical science).

<sup>138</sup> *See generally* Timothy J. McCoy, *Biomedical Process Patents - Should They be Restricted by Ethical Limitations?*, 13 J. LEGAL MED. 501-02 (1992) (suggesting that granting of intellectual property rights in medical innovations is necessary to continued development of products and techniques which benefit society as whole).

The tools and skills of the healing arts have long been considered a "gift from nature to humanity"<sup>139</sup> which is "held in trust by physicians and apothecaries for the good of mankind."<sup>140</sup> At one time it was considered unethical, if not immoral, to keep such information secret, exploit it for personal gain, or distribute products to the sick without the advice or consent of a doctor.<sup>141</sup>

Scientific and economic forces, however, drive changes in health care and its mores. During the health care reform movement, the acceptability of newly patented drug products hinged on their "degree of commercialism."<sup>142</sup> This attitude represents a departure from the long-standing position of the AMA which considered the rise of ready made drug preparations detrimental to society.<sup>143</sup>

The medical profession was originally concerned with the rising number of prominent synthetic drugs and other patented substances. Echoing the same fears sounded today, physicians voiced concerns about the anticipated role of a pharmacist and "the erosion of the doctor's traditional role as final arbiter of his patient's welfare."<sup>144</sup> These physicians viewed the availability of prefabricated elixirs and nostrums as evidence of the decline of medical education, the profession's public image, and professional ethics.<sup>145</sup>

The pharmaceutical industry similarly opposed the proprietary protection of drugs and medicines.<sup>146</sup> In 1897, the president

<sup>139</sup> McTavish, *supra* note 106, at 343.

<sup>140</sup> *Id.*; see also Joseph M. Reisman, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355, 370 (1995).

The honored ideals of the medical profession imply that the responsibilities of the physician extend not only to the individual [patient], but also to society where these responsibilities deserve [the physician's] interest and participation in activities which have the purpose of improving both the health and the well-being of the individual and the community.

*Id.* (alteration in original) (citing AMA PRINCIPLES OF MEDICAL ETHICS § 10 (1971)).

<sup>141</sup> McTavish, *supra* note 106, at 343.

<sup>142</sup> *Id.* at 344.

<sup>143</sup> *Id.* The AMA continues to oppose the issuance of medical process patents. Sally Squires, *AMA Condemns Patents for Medical Procedures*, WASH. POST, June 20, 1995, at A1.

<sup>144</sup> McTavish, *supra* note 106, at 349.

<sup>145</sup> A representative of the AMA questioned whether those doctors who prescribed drugs which carried patent or trademark protection could be "distinguished from the peanut vendor of the street." *Id.* at 343

<sup>146</sup> *Id.* at 344 (noting that the American Pharmaceutical Industry worked closely with the AMA on reform).

of the American Pharmaceutical Association proclaimed that all physicians must avoid any involvement with substances protected by patent, trademark, or secrecy so that "the nostrum trade would soon be forced back to the lowest depths of the infernal regions from whence it came."<sup>147</sup> This reaction was based upon the understanding that a majority of these protected substances could otherwise be easily and inexpensively duplicated by pharmacists.<sup>148</sup>

As patented drugs became a medical mainstay, the debate shifted to other aspects of health care delivery. The 1953 edition of the AMA's *Principles of Medical Ethics* stated that it was unethical for physicians to patent medical devices such as instruments and appliances.<sup>149</sup> Today, this prohibition is no longer in place and, it is ethical, according to the AMA, for physicians to patent medical devices.<sup>150</sup>

Public debate also focused upon another aspect of health care delivery, namely, medical techniques and process patents. The congressional testimony of Dr. H. Dunbar Hoskins, Jr. of the American Academy of Ophthalmology clarified the position of the profession: "[Physicians] are not against patenting the scalpel. We are against patenting the incision made with the scalpel. We are not against patenting the thermometer. We are against patenting the method by which it is used to take our temperature."<sup>151</sup>

Despite the long history supporting medical procedure patents, experts conclude that these patents have had little legal

<sup>147</sup> McTavish, *supra* note 106, at 344 (citing Frank E. Stewart, 29 JAMA 356 (1897)).

<sup>148</sup> McTavish, *supra* note 106, at 344. The battle ensnared even the most important medical discoveries. The American diphtheria antitoxin patent by Emil von Behring was condemned as "an attempt to blackmail suffering humanity in the interest of a foreign manufacturer." *Id.* at 348.

<sup>149</sup> *Pallin Hearings*, *supra* note 16, at 6.

<sup>150</sup> See Squires, *supra* note 143, at A1 (discussing AMA's vehement condemnation of medical procedure patents).

<sup>151</sup> *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcom. on Courts and Intellectual Property of the House Comm. on the Judiciary*, at 2 (testimony of Dr. H. Dunbar Hoskins, Jr.) [hereinafter *Hoskins Hearings*]. Medical professionals are not immune to the pressures imposed by their fellow practitioners to condemn the practice of patenting medical procedures. Patent applicant Dr. Pallin admitted that he was cautioned to avoid patenting his procedure as a pure medical process. Rather, he was advised to develop an instrument to utilize during the process and receive royalties through the use of the device as opposed to the procedure. *Pallin Hearings*, *supra* note 16, at 6.



importance or economic value.<sup>152</sup> These experts rely primarily upon the paucity of lawsuits seeking to enforce procedure patents. Procedure patents, however, are rarely enforced for several reasons: (1) it is extremely difficult to monitor and detect infringement of process patents; (2) it is even harder to stop such infringement considering the thousands of clinics and practitioners in practice; and (3) the ethical dimensions of medical process patents reside in their true implications on patient care and its cost, not upon the amount of litigation surrounding their enforcement.

#### A. Patient Care

One of the most important ethical questions raised in the debate concerning medical procedure patents is whether these patents interfere with patient care.<sup>153</sup> During congressional testimony, objections were raised asserting that medicine's special character counseled against patenting medical procedures.<sup>154</sup> These opponents argued that patents change the physician-patient relationship since inherent in the patent is the patentee's right to exclude others from an innovation. A patent would therefore limit a physician's choice of care and infringe upon the ability of patients to choose their physician. Additional questions arise concerning the efficacy of these procedures. Unlike certified drugs, the lack of a procedure certification process leads to uncertainty for physicians since the doctor must determine whether a given procedure accomplishes the claimed result.<sup>155</sup>

It is critically important to remember the context in which this debate arises. Notwithstanding patents, the discretion and autonomy of doctors are never absolute. The ethical debate over medical process patents must address whether they are merely

<sup>152</sup> See Noonan Hearings, *supra* note 111, at 4-7.

<sup>153</sup> There are numerous additional patient care issues facing the medical profession; including confidentiality, insurance limits that may prevent coverage, and problematic restrictions arising from a covenant against competition. See, e.g., *Vascular & Gen. Surgical Assocs., Ltd. v. Loiterman*, 599 N.E.2d 1246, 1251 (Ill. App. Ct. 1992) (enforcing two year restriction on vascular surgeon's right to practice); *Medical Specialists, Inc. v. Sleweon*, 652 N.E.2d 517, 522 (Ind. Ct. App. 1995) (enforcing restrictive covenant in contract of infectious-disease specialist). See generally Ferdinand S. Tinio, Annotation, *Validity and Construction of Contractual Restrictions on Right of Medical Practitioner to Practice, Incident to Employment Agreement*, 62 A.L.R.3d 1014 (1975).

<sup>154</sup> *Kelman Hearings*, *supra* note 18, at 6.

<sup>155</sup> *Burch*, *supra* note 6, at 1160.

another tool alongside drug and medical device patents. The ethical debate must also consider whether such protection advances the overall public health and is consistent with other limits imposed upon the responsibilities of a physician.<sup>156</sup>

The medical debate must also confront the underlying economic reality. The opponents of process patents couch their attacks in the economic terms of consumer cost and access. In reality, process patents are far less costly than the costs of drugs and medical devices.<sup>157</sup> Dr. Pallin explained to Congress that drug and medical device royalties will “always contribute to the cost of care far more dramatically than a few medical” patents.<sup>158</sup> Another patent expert testified that “patenting medical devices raises virtually all the same social costs as does patenting medical methods.”<sup>159</sup>

### B. *Litigation Over Patent Infringement*

The AMA's recent Report of the Council of Ethical and Judicial Affairs makes several revealing points about the crisis in the profession. The Report indicates that the primary issue confronting the profession is not that physicians are obtaining patents on medical procedures. Rather, the current controversy exists because doctors are suing one another to enforce economic rights relating to patents. The *Pallin* case, noted as one of the first of its kind on record, reveals that this trend has serious implications on the perception of physicians' professionalism.

Physicians fear that they will be held liable as process patent infringers without notice of their infringement. These physicians believe that medical devices and pharmaceuticals are items whose royalties have been paid by a manufacturer and, therefore, may be used without any concern of infringement liability. These physicians reason that a medical device or pharmaceutical compound comes virtually ready to use out of the box and does not pose uncertainty concerning authenticity or satisfaction of royalty and licensing payments obligations. While a physician who lacks notice may inadvertently perform a pat-

---

<sup>156</sup> *Id.* at 1154 n.85. “[T]wo wrongs do not make a right” and permitting additional limits on physician autonomy is not justified merely because some limitations already exist. *Id.*

<sup>157</sup> *Pallin Hearings*, *supra* note 16, at 5 (testimony of Dr. Samuel Pallin).

<sup>158</sup> *Id.*

<sup>159</sup> *Dunner Hearings*, *supra* note 17, at 4.

ented technique, it is highly unlikely that a physician would construct and use an article, and hence infringe a patent. Physicians therefore believe that they are immune from patent infringement since the articles in hospitals and doctors' offices are presumed legitimate and bona fide. The popular belief is that any risk of patent infringement lies exclusively with the manufacturers and distributors, not the practitioners.

Dr. Jack Singer, a practitioner and defendant in the most recent ophthalmological litigation, also testified before Congress. He explained that his suit with Dr. Pallin arose from his independent development of the identical cataract procedure. Dr. Singer warned of the dangers involved in issuing medical process patents: "Medical method patents will produce a spiraling inflation of health care costs by *inhibiting* the free exchange of information and by *adding* the cost of license fees, royalty payments, and patent applications."<sup>160</sup> He further warned of the financial costs imposed upon presumably innocent doctors' unknowing infringement upon medical patents.<sup>161</sup>

This perception is based on an unfortunate and incomplete understanding of the law. Under the doctrine of contributory infringement, physicians are liable for patent infringement if they use counterfeit patented drugs or devices.<sup>162</sup> This is a risk that physicians already face. The new medical process patent law, applied prospectively, does not insulate doctors from the infringement of those innovations that have already been awarded a patent.<sup>163</sup>

In sum, the ethical concern is not patient care. It is not patient cost. It is the ethics of infringement liability. Quite legitimately, the medical profession is concerned about an erosion of control and the risk of litigation.

### C. *Alternatives to the Sub-Section 287(c) Moratorium*

The ultimate response to objections voiced by the experts condemning protection of medical device and process patents is

<sup>160</sup> *Singer Hearings, supra* note 14 (summary of testimony of Dr. Jack A. Singer).

<sup>161</sup> *Id.*

<sup>162</sup> *See* 1 ROSENBERG, *supra* note 1, § 17.02(2)(b) (discussing basic principles of doctrine of contributory negligence).

<sup>163</sup> Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3011 (1996) (to be codified at 35 U.S.C. § 287(c)(4)).

found in the fundamental objectives of the patent system. Patents foster the development of inherent societal benefits by advancing the progress of medical knowledge, improving public health, quality of life, and efficient care delivery. Patents attract much needed private research funding.<sup>164</sup> Any ethical debate concerning the patentability of medical devices and processes must consider the risks in prohibiting patents; cures, therapies, and new surgical techniques may never be discovered, and consequently never reach the public.

The ethical implications of issuing biomedical patents also raise many philosophical questions. One such question is whether the boundaries of science have been pushed too far. Once a new procedure is developed or a fundamental science is discovered, such as genetically treating cancer or Alzheimer's disease, it is difficult to restrict that technology. Some of these technologies are troubling because they are not purely therapeutic in nature. Futurists predict that the alternate uses of therapies may be cosmetic in nature, like changing one's eye color, or even reminiscent of eugenics, such as choosing the features of unborn children.<sup>165</sup>

Of course, ethics imply the existence of a choice. E. R. Squibb declined to patent his improved method for manufacturing anesthetic ether because he believed that this discovery was too important not to share freely with the world.<sup>166</sup> Similarly, the medical profession does not have to adopt the most drastic forms of retaliation which hurt the public. Congress has several avenues available to modify the patent system to meet the ethically troubling concerns raised without a radical departure from prior law.

The first option that Congress explored was the imposition of a strict moratorium on the issuance of medical device and process patents. In 1995, Congress considered HR 1127, a proposal to restrict completely the availability of patent protection

---

<sup>164</sup> Burch, *supra* note 6, at 1158; Fern Schumer Chapman, *Going for Gold in the Baby Business*, FORTUNE, Sept. 17, 1984, at 42 (asserting that "private capital could find its way into ... medical research if investors can look to high returns from patentable procedures").

<sup>165</sup> This type of human gene therapy, known as "enhancement therapy," involves the "modification of cells to produce different character traits ... [such as] height, hair color, eye color, [and] intelligence." See Diane E. Hoffmann, *The Biotechnology Revolution and its Regulatory Evolution*, 38 DRAKE L. REV. 471, 482 (1989).

<sup>166</sup> McTavish, *supra* note 106, at 348 n.14.

for medical devices and processes. Patent expert Dr. Noonan testified that the moratorium on medical and surgical procedures patents which H.R. 1127 sought was an overbroad response to an alleged problem which would effectively change the scope of patentable subject matter.<sup>167</sup> Instead, he suggested that tension in this area may be alleviated through the enactment of a "compulsory licensing provision that would require an owner of a therapeutic or diagnostic procedure patent to license the technology at a reasonable royalty."<sup>168</sup> While the radical policy of a strict moratorium sought by H.R. 1127 was not enacted, the change in § 287 represents a significant departure.

As a second option, lawmakers could also retain the present scope of patentable subject matter, while merely modifying the base term of medical process patents or prohibiting future term extensions. This would temper frustration by altering the pricing horizon and balancing the ability to recoup investment capital with restricting competition. Unfortunately, this is unlikely to be a politically favored solution. This alternative merely mitigates, but does not solve, the underlying problem since the risks of infringement and associated problems remain, albeit through a smaller window of time.

Another alternative to a complete moratorium is merely to limit the scope of the restriction. Congress could allow medical procedure patents only for those techniques that require FDA approval.<sup>169</sup> This compromise preserves the benefit of uniformity throughout the subject matter of the patent system and provides physicians with some notice of proprietary methods.<sup>170</sup>

The present ethical dilemma facing lawmakers may ultimately be rendered moot as a result of the continued efforts of the United States to harmonize its patent system with the systems adopted by the rest of the world.<sup>171</sup> More than 80 nations

---

<sup>167</sup> See Noonan, *supra* note 22, at 663 (contending that outright ban on patenting medical and surgical procedures may be overbroad).

<sup>168</sup> *Id.* at 664.

<sup>169</sup> Noonan Hearings, *supra* note 111, at 12.

<sup>170</sup> Congress ultimately adopted this approach. See Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3011 (1996).

<sup>171</sup> According to Senate Judiciary Committee Chairman Orrin G. Hatch, the global trade implications are of serious consequence. See 142 CONG. REC. S11845 (daily ed. Sept. 30, 1996) (asserting that proposed Ganske-Fiske amendment undercuts GATT by inviting other nations to amend their patent laws to prevent worldwide enforcement of U.S. patents); see also 138 CONG. REC. S5288, 5289 (daily ed. Apr. 9, 1992) (statement of Sen. DeConcini) (noting significant international efforts

around the world refuse to recognize medical and surgical patents.<sup>172</sup> The European Patent Convention, for example, expressly prohibits patents for “[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.”<sup>173</sup> It may be inappropriate, however, to cite the foreign experience within the context of a medical patent moratorium since the foreign approach illustrates the free rider problem. The entire world may be benefiting from the inventive and research efforts of companies in the United States that are made possible by the traditional and historic scope and effects of our patent laws.<sup>174</sup>

In addition to the free rider dilemma, the inconsistency between the different approaches adopted by the United States and other foreign nations creates trade issues. One such issue arises under the GATT agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).<sup>175</sup> Under TRIPS, signatory nations may prohibit patents for reasons relating to public order, morality, and protection of the environment.<sup>176</sup> Hence, a signatory nation could deny patent protection for any diagnostic, therapeutic, and surgical methods of humans or animals.<sup>177</sup>

Medical procedure patents are not the only variation be-

to harmonize patent laws); Robert W. Pritchard, *The Future is Now — The Case for Patent Harmonization*, 20 N.C. J. INT'L L. & COM. REG. 291, 291 n.1 & 299-311 (1995) (discussing progress in patent harmonization movements).

<sup>172</sup> See 142 CONG. REC. H8276, H8277 (daily ed. July 24, 1996) (statement of Rep. Ganske) (noting that “80 countries around the world, including most of Europe, expressly prohibit medical patents”); 141 CONG. REC. S15291, S15292 (daily ed. Oct. 18, 1995) (statement of Sen. Frist); *Hoskins Hearings*, *supra* note 151, at 8.

<sup>173</sup> Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, art. 52, 33 I.L.M. 270, 285.

<sup>174</sup> No fewer than 71 Americans have received the Nobel Prize for the category “Physiology or Medicine” since its establishment in 1905. 20 ENCYCLOPEDIA AMERICANA 393-94 (1994).

<sup>175</sup> See 142 CONG. REC. S11845 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch) (asserting that Gaske-Fiske amendment undercuts TRIPS).

<sup>176</sup> See General Agreement on Trade in Services, Dec. 15, 1993, Annex 1B, art. XIV, 33 I.L.M. 1167, 1177 (establishing exceptions to GATT provisions for purposes of public order, morality, and health); Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, art. 27, cl. 2, Dec. 15, 1993, 33 I.L.M. 1197, 1208 (providing that members of treaty may exclude from patentability inventions to protect public order, morality, and environment); see also *Hoskins Hearings*, *supra* note 151, at 7.

<sup>177</sup> Agreement on Trade Related Aspects of Intellectual Property Rights, Annex 1c, art. 27, Dec. 15, 1993, 33 I.L.M. 1197, 1208 (allowing members to refuse grant of patent for diagnostic, therapeutic, and surgical methods for treatment of humans or animals); *Hoskins Hearings*, *supra* note 151, at 7 (citing Article 27 of TRIPS).



tween the United States patent system and patent systems of other countries. One feature absent from the United States patent system, but common throughout the world, is prior user rights.<sup>178</sup> The enactment of prior user rights in the United States would be a narrowly tailored alternative. It would alleviate tensions in the medical patent arena while leaving the traditional scope of patentable subject matter intact. The enactment of prior user rights also has the benefit of generally improving the overall functioning of the United States patent system.

## VI. PRIOR USER RIGHTS

Another patent reform introduced in the 104th Congress was the "Prior Domestic Commercial Use Act of 1995."<sup>179</sup> Proponents of this measure argued that enacting prior user rights will improve the patent system and spur increased progress in the sciences and arts while conferring benefits to the public.<sup>180</sup> Critics, however, reiterated their arguments used in the past to defeat similar congressional proposals and portrayed the proposal as a radical change that would "turn the entire patent system 'on its ear.'"<sup>181</sup>

In light of the historical dovetail between patents and trade secrets, this Part asserts that: (1) the active commercial users of trade secrets confer a benefit to the public; (2) current United States law under-acknowledges the protective rights that trade secret users deserve; (3) prior user rights enhance trade secret protection; (4) trade secret users deserve limited protective

<sup>178</sup> See Daniel C. Munson, *The Patent-Trade Secret Decision: An Industrial Perspective*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 689, 703-04 (1996) (stating that although United States does not offer prior user rights, the concept is common in Europe).

<sup>179</sup> H.R. 2235, 104th Cong. (1995).

<sup>180</sup> Proponents contend that enacting prior user rights would further the purpose underlying the grant of patent protection embodied in the Constitution. See U.S. CONST. art. I, § 8, cl. 8 (providing that Congress shall have power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"); see also Paul R. Morico, *Are Prior User Rights Consistent with Federal Patent Policy?: The U.S. Considers Legislation to Adopt Prior User Rights*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 572, 580 (1996) (concluding that legislation to adopt prior user rights promote "the progress of science").

<sup>181</sup> Robert Rines & Skip Kaltenheuser, *Proposed Patent Laws Would Harm Inventors*, NAT'L L.J., Nov. 28, 1994, at A23; see also Chris P. Konkol, *Prior-Invention Rights: The Excluded Middle*, 77 J. PAT & TRADEMARK OFF. SOC'Y 666, 672 (1995) (demonstrating how prior user rights may undermine U.S. patent system).

rights against subsequent patent holders; and, (5) limited prior user rights are the equitable protection for these trade secret users and enhance the current balance between patents and trade secrets.

#### A. *Current United States Practices*

Although politically controversial, prior user rights are simply a limited legal defense against patent infringement.<sup>182</sup> Under the current system, an inventor who is awarded a patent has exclusive rights to make, sell, and use an invention, even against those persons who independently and unknowingly produce the same innovation.<sup>183</sup> In our "winner-takes-all" system, an inventor who relied on trade secrecy to protect her invention may find herself infringing on another person's patent that was awarded on that same discovery.<sup>184</sup>

It is an established rule of United States law that a patentee is the "winner" and takes credit for the invention, even if the discovery was first made by another.<sup>185</sup> The Supreme Court enunciated this rule in *Bates v. Coe*:

Inventors may, if they can, keep their invention secret; and if they do for any length of time, they do not forfeit their right to apply for a patent, unless another in the mean time has made the invention, and secured by patent the exclusive right to make, use, and vend the patented improvement. Within that rule and subject to that condition, inventors may delay to apply

---

<sup>182</sup> See Vito J. DeBari, *International Harmonization of Patent Law: A Proposed Solution to the United States' First-to-File Debate*, 16 *FORDHAM INT'L L.J.* 687, 694 (1993) (noting that prior user rights "provide[] a limited defense against patent infringement claims" to a person who used or prepared to use invention before filing a patent); Kyla Harriel, *Prior User Rights in a First-To-Invent Patent System: Why Not?*, 36 *IDEA* 543, 546 (1996) (stating that person who is sued for patent infringement may raise limited defense of prior user rights).

<sup>183</sup> 35 U.S.C. § 154 (1994) (providing that patentee, or his heirs or assigns, has right to prevent others from making, using, or selling his invention within United States); F. Andrew Ubel, *Who's on First - The Trade Secret Prior User or a Subsequent Patentee*, 76 *J. PAT. & TRADEMARK OFF. SOC'Y* 401, 407 (1994) (recognizing that U.S. system prevents good faith inventor from using his invention).

<sup>184</sup> Ubel, *supra* note 183, at 407 (stating that winner takes all system may result in enjoining of bona fide inventor from use of his own invention).

<sup>185</sup> See *Bates v. Coe*, 98 U.S. 31, 46 (1878); *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 496 (1850) ("[T]he party who invents is not strictly speaking the first and original inventor.... Yet his patent is valid if he discovered it by the efforts of his own genius.").

for a patent.<sup>186</sup>

Prior user rights are deemed to establish an equitable balance by splitting the patentee's bundle of rights between the inventor who first uses the invention but foregoes filing for a patent, and the subsequent inventor who filed for and received a patent.

The United States is one of the few nations whose patent system relies on a "first-to-invent" regime, awarding priority to the first true inventor in time.<sup>187</sup> By contrast, most other nations use a "first-to-file" system, awarding priority in rights to whomever first files a patent application.<sup>188</sup> A "first-to-invent" system is laudable because it is rooted in the American tradition of individualism and prevents the inequitable results that may occur if inventors are forced to race to file patent applications at the PTO.<sup>189</sup>

Patents and trade secrets, as noted earlier, dovetail and hence serve complementary roles in fostering innovation and guarding against the risks of inventive investment. The decision whether to patent an invention or pursue protection through prior user rights can be a matter of business or personal judgment.<sup>190</sup> In determining whether to apply for a patent, the inventor weighs several factors, including whether the statutory requirements are satisfied, the expense and burden of an application, and the means available to best protect inventive investment. Inventors whose products can be inspected or reverse engineered by the public risk easy copying; therefore, these arti-

---

<sup>186</sup> *Bates*, 98 U.S. at 46.

<sup>187</sup> See 35 U.S.C. § 102(f) (1994) (providing that patent shall not be issued to person who "did not himself invent the subject matter sought to be patented").

<sup>188</sup> See Doris Estelle Long, *The Protection of Information Technology in a Culturally Diverse Marketplace*, 15 J. MARSHALL J. COMPUTER & INFO. L. 129, 142 n.47 (1996) (stating that only United States and Philippines use first-to-invent regime).

<sup>189</sup> See *Paulik v. Rizkalla*, 760 F.2d 1270, 1272 n.2 (Fed. Cir. 1985) (stating that first-to-invent system "respects the value of the individual in American tradition" and avoids unfairness that may result from race to PTO) (quoting Final Report of the Advisory Committee on Industrial Innovation, U.S. Dep't of Commerce, Sept. 1979, p. 174).

<sup>190</sup> *Prior User Rights (Relative to Patents): Hearings Before the Subcomm. on Intellectual Property and Judicial Admin. of the House Comm. on the Judiciary*, 103rd Cong. 6 (1994) (testimony of Bruce A. Lehman, Commissioner of PTO) (noting that under certain circumstances, it may be commercially sound for manufacturer to forego patent protection and to rely solely upon trade secrecy to protect invention) [hereinafter *Prior User*].

cles are prime candidates for patent protection.<sup>191</sup> In contrast, processes or products which are beyond public inspection or internally utilized within a firm are likely choices for some type of trade secrecy, in lieu of a patent.

Under current United States law, the prior disclosed use of an invention is a method of defeating a patent application.<sup>192</sup> Disclosed activity includes the public sale of a product or the public use of a product for more than one year.<sup>193</sup> Such disclosure may cause the technology to be regarded as "prior art."<sup>194</sup>

A conflict exists between trade secrets and patents under United States law where prior disclosure defeats a patent while undisclosed innovation may not lead to such a result. The undisclosed activity counts against the first inventor but does not necessarily bar the second subsequent inventor from receiving a patent. Further, the law does not recognize the prior non-disclosed use as a defense to a patent infringement action brought by the subsequent inventor. Hence, the prior user cannot obtain a patent and, worse yet, is precluded from continuing to use the technology since the first inventor is subject to the exclusive rights of the second inventor.

The following example clarifies the fundamental fairness dilemma that prior user rights seek to solve. The primary goal underlying the United States patent system is the fostering of innovation that benefits the public. These laws also seek to reward the first inventor who benefits the public. When several inventors make the same discovery, our patent laws dictate several possible consequences. One inventor's actions may negate the patentability of the invention for all parties. The actual first inventor who kept his invention a secret may have to forfeit all of his rights and yield to the second inventor. Prior user rights may resolve this dilemma. Apropos of King Solomon's wisdom, prior user rights allow for an equitable decision. A prior party

---

<sup>191</sup> See *id.* at 92 (statement of R. Carl Moy) (proposing statutory clarification that would render information available through reverse-engineering in public use and suggesting that 35 U.S.C. § 102(a)-(b) may already categorize such information as public use).

<sup>192</sup> See 35 U.S.C. § 102(a) (1994) (providing that person is not entitled to patent if invention was known or used by others or described in publication before applicant's invention).

<sup>193</sup> 35 U.S.C. § 102(b) (1994).

<sup>194</sup> See Ubel, *supra* note 183, at 405-06 (stating that prior use may or may not be prior art, depending on whether prior use is "secret use" or "noninforming public use").

who is using an invention before the filing date of another party wins the limited rights to continue the use, despite the issuance of the patent to another inventor. Although this is a departure from current United States practice, it is deemed equitable.<sup>195</sup>

Medical procedure patents are within that class in nature that may be best protected through some combination of inventions and trade secrecy. An instrument, like a new type of stethoscope, may be viewed, analyzed, dissected, or reverse engineered. Since such public access facilitates copying, the inventor's rights would be best protected by a patent. An operation, in contrast, occurs within a sequestered environment shielded from public inspection. An innovative procedure, therefore, could be protected by several different means, including secrecy.

In the *Pallin* medical patent procedure infringement case, for example, several of the defendants claimed that they used the medical process before Pallin's patent application.<sup>196</sup> If United States patent law acknowledged prior user rights, the results of that conflict would have been entirely different. The defendants would have been shielded from liability and the claims of the patent-holder would not have been challenged and instead would have been subsequently invalidated.<sup>197</sup>

### B. Potential Benefits

Since the United States does not acknowledge prior user rights, there is no domestic experience or judicial precedent available to guide policy-makers.<sup>198</sup> Predicting the impact on our

---

<sup>195</sup> In evaluating the possible inequitable results from an inventor forgoing patent protection in lieu of available alternatives, the Seventh Circuit noted that "it would be unjust to hold that such an election should impair his right to continue diligent efforts to market the product of his own invention." *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 37 (7th Cir. 1975) (holding that public use of golf balls made with special coating forecloses finding of hidden use even though use did not disclose inventive concept).

<sup>196</sup> See *supra* notes 10-21 and accompanying text.

<sup>197</sup> Some may question whether prior user rights would even apply to those medical processes originating from universities and hospitals. This question, however, has not been squarely addressed due to the lack of experience with this proposal. These facilities are likely to be considered sufficiently commercial to qualify for prior user rights since medicine is considered an applied field, rather than a basic science. See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609, 623 (1962) (suggesting that profit-incentive of research in universities and hospitals should be replaced by government control and funding).

<sup>198</sup> In a statement to the House Judiciary Subcommittee on Intellectual Property

society from the adoption of a prior user protection requires focusing on foreign experiences with these rights, economic theory, and the views presented before Congress.

Unfortunately, the foreign experience with prior user rights proves a difficult yardstick in measuring this impact. First, foreign patents are unlike their American counterparts due to the fundamental differences in many features, such as the individual nations' claiming systems, which may affect the economic value of protected patents.<sup>199</sup> The economic value of overseas patents, therefore, may not justify pursuing infringement litigation for many inventions in situations where prior user rights protected the innovation.<sup>200</sup> Second, while many nations have patent systems that grant prior user rights, all of the foreign prior user regimes vary with regard to important characteristics, such as the scope of the rights and the ability to transfer or license the right to another party or firm.<sup>201</sup>

In the United States, proponents of prior user rights posit several reasons why domestic law should encompass prior user rights. First, prior user rights are a fair, efficient, and equitable defense. Second, adoption of these rights furthers the effort to

---

and Judicial Administration, Professor Robert P. Merges noted the paucity of European cases involving prior user rights. *Prior User*, *supra* note 190, at 40 (statement of Robert P. Merges). For example, prior user rights were never raised as a defense in England during the first 14 years since their creation; in Italy the defense was not asserted for over 13 years; and merely 4 cases were reported in France over the past 20 years. *Id.* at 41.

<sup>199</sup> See Toshiko Takenaka, *Doctrine of Equivalents After Hilton Davis: A Comparative Law Analysis*, 22 RUTGERS COMPUTER & TECH. L.J. 479, 502 & nn.143-44 (1996) (noting that United States utilizes peripheral claiming system rather than central claiming system utilized by majority of other countries, most notably Japan and Germany) [hereinafter *Doctrine of Equivalents*]. A central claiming system requires a patentee to define the underlying inventive principle or solution in the language of the patent claims. *Id.* at 503. Under a peripheral claiming system, the scope of a patent is more narrowly determined by the language of the claim itself. Toshiko Takenaka, INTERPRETING PATENT CLAIMS: THE UNITED STATES, GERMANY, AND JAPAN 113-34 (17 IIC Studies—Studies in Industrial Property and Copyright Law 1995); *Doctrine of Equivalents, supra*, at 503.

<sup>200</sup> Telephone interview with Prof. R. Carl Moy, Professor of Law, William Mitchell College of Law (Dec. 12, 1996).

<sup>201</sup> See Robert L. Rohrback, *Prior User Rights: Roses or Thorns?*, 2 U. BALT. INTEL. PROP. L.J. 1, 35-36 (1993) (listing various prior user rights regimes adopted by countries). Canada and Italy are among the countries which limit the prior user rights according to the scope and extent of commercialization. *Id.* at 35. Japan and Mexico grant prior user rights without any apparent transfer limitation. *Id.* The Philippines, one of the world's only other first-to-invent nations, also grants prior user rights. *Id.*



harmonize the United States patent system with the rest of the world.<sup>202</sup> Third, these rights would eliminate the disparate treatment between corporations in the United States and foreign firms.<sup>203</sup> Finally, adoption of such rights also resolves certain conflicts between trade secrecy and patentability that have merged to frustrate firms, especially within the software industry.<sup>204</sup>

Several powerful trade arguments further support the enactment of prior user rights. Currently, American markets are more open to foreign imports, and forty-five percent of United States patents issued each year are from overseas inventors.<sup>205</sup> A nation that grants prior user rights exclusively for its domestic firms will likely experience a shift in the balance of international trade in its favor.<sup>206</sup> Prior user rights would also help transfer wealth from foreign patentees to domestic firms since the largest number of consumers of United States intellectual property are arguably Americans. In any event, domestic job creation would be spurred. Prior user rights would help temper the frustration that Americans feel for foreign inventors. For example, public sentiment strongly opposed German and other foreign drug manufacturers who were recouping royalty profits on aspirin and other compounds.<sup>207</sup>

In terms of some strategic aspects of commercialization, prior user rights help resolve some of the balkanization among

<sup>202</sup> *Prior User*, *supra* note 190, at 75 (testimony of William D. Budinger, Chairman, Rodel, Inc.) (noting differences between American and foreign patent systems by stating, “[i]f you patent only in the United States, you give everybody else a free cookbook on how to practice your invention [while unfortunately] the cost of patenting overseas is so huge”).

<sup>203</sup> *See id.* at 62-63 (noting that “American manufacturers are not operating on a level playing field with their foreign competitors,” but prior user rights “will correct the problem”).

<sup>204</sup> *See id.* at 7 (testimony of Bruce Lehman) (“[P]rior user defense could help resolve concerns that have been expressed in the software industry ... regarding prior use of poorly documented techniques that are later patented by another.”).

<sup>205</sup> *See Changes in U.S. Patent Law and Their Implications for Energy and Environment Research and Development: Hearings Before the Subcomm. on Energy and Env’t of the House Comm. on Science*, 104th Cong. (1996), at 1996 WL 241728, at \*7 (statement of Michael K. Kirk, Executive Dir., Amer. Intell. Prop. L. Assoc.) (stating that forty-five percent of all U.S. patent applications are foreign and perhaps half of remainder are also filed abroad); *Prior User*, *supra* note 190, at 80 (testimony of R. Carl Moy) (stating that “40 to 45 percent of our patents are being taken out by foreigners”).

<sup>206</sup> *Prior User*, *supra* note 190, at 86 (statement of R. Carl Moy).

<sup>207</sup> *See supra* notes 106-10 and accompanying text.

the varying trade secret laws of the fifty states. Any change in the patent statute, such as the adoption of prior user rights, benefits national uniformity within the United States legal system. Unification, arguably one of the principal federal objectives of our intellectual property system, offers an important advantage in terms of domestic legal policy. From a legal, economic, and a practical perspective, certainty is another important domestic policy that will be advanced with prior user rights which, in turn, guards the return on inventive investment.

The populist argument asserts that an additional benefit of prior user rights is the insulation of inventors from the expense and complexity of the present legal system and its painful litigation scenarios.<sup>208</sup> Unfortunately, this prediction proves doubtful. Practitioners note that proponents of prior user rights criticize the current system as insufficiently protecting their innovations when the fault in fact lies with inventors who failed to seek proper patent counsel, or obtained incorrect legal advice, willfully or negligently avoided the patent, or harbored a disdain of the patent system.<sup>209</sup> These proponents fail to recognize that prior user rights are a defense, not a complete immunization from litigation.

Unfortunately, many of the problems cited in this critique of the patent system are more directly related to problems of current litigation practices, such as expense, limited discovery, or over-crowded dockets, rather than the substance of patent law.<sup>210</sup> The essence of the substantive issues allegedly plaguing the patent system relates to risks of invention, including technological, financial, and legal uncertainty.<sup>211</sup>

### C. *The Scope of the Right*

The 1994 prior user rights legislative proposal grants rights to those who have commercially used the subject matter before

---

<sup>208</sup> Keith M. Kupferschmid, *Prior User Rights: The Inventor's Lottery Ticket*, 21 AM. INTEL. PROP. L. ASSOC. Q.J. 213, 224 (1993) (noting that both patent holders and prior users will benefit from foregone litigation costs as result of adoption of prior user rights); Testimony Before the House of Representatives Comm. on Judiciary Intellectual Property & Judicial Admin., 1994 WL 499999, at \*9-10, Sept. 13, 1994 (testimony of Bruce A. Lehman, Chairman, PTO).

<sup>209</sup> See Rohrbach, *supra* note 201, at 6.

<sup>210</sup> *Id.* at 19-20. The author cites 20 reasons against implementing prior user rights in the United States, 16 of which relate to litigation. *Id.* at 13-19.

<sup>211</sup> *Id.* at 16.

the effective filing date of another's patent.<sup>212</sup> This is a change in the way the current system views novel inventions. Novelty is currently one of the principal statutory requirements for a patent.<sup>213</sup> Prior user rights would resolve certain inequitable ambiguities concerning the novelty requirement which have arisen under the existing patent law.

When an inventor does not diligently take steps to protect her work, the invention may develop into "prior art" and, therefore, fail to meet the novelty requirement. Under the current law's novelty requirements, applicants lose the right to a patent if the invention was already patented, known, described, or in public use before the application.<sup>214</sup> Judging novelty requires an assessment of what is within the scope and content of the public domain and, hence is "prior art." The law reflects the underlying federal policy to keep those inventions and discoveries benefiting the public in continued use. Among the public benefits derived from the novelty requirement is increased commercial activity. The public is also protected from potentially disruptive economic dislocation where a patent unexpectedly issues and knocks-out the user of a technology by changing their market power or preventing their use. In addition to innovation and commercialization, another potential benefit is the promoting of the principal federal policy of competition by narrowing the patent monopoly and allowing another competitor to enter the market.

<sup>212</sup> H.R. 2235, 104th Cong. § 273(b)(1) (1995).

<sup>213</sup> 35 U.S.C. § 102 et. seq. (1994).

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

....

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

*Id.*

<sup>214</sup> See *supra* note 213.

Prior user rights also comport with all the major property and economic law theories previously discussed. In particular, a firm whose inventive efforts are protected from economic dislocations has its inventive investment guarded consistent with the legal "prospect theory."<sup>215</sup> Prior commercial users enjoy an efficient mode of safeguarding their inventive efforts under the "innovation theory" of intellectual property.<sup>216</sup> Facilitating the development of an environment where inventions are put to use will ultimately lead to an increased storehouse of public knowledge where the know-how of employees is disseminated.<sup>217</sup> The storehouse of knowledge is enriched as the trade secret inevitably, as history demonstrates, leaks into the public domain.

The threshold issue judging an invention's novelty is the character of its use. The initial inquiry is whether a prior use is a public use, which bars a patent after one year.<sup>218</sup> In addition, courts must inquire whether the inventor engaged in activities designed to bring about public or commercial use of the invention, which is also sufficient to create a bar to a patent after one year.<sup>219</sup>

Any determination regarding the character of an invention's use—public versus experimental—rests on a host of factors involving all relevant circumstances.<sup>220</sup> The point at which an invention leaves the inventor's research sphere and truly enters the public is not easily judged. The use of the invention of a new corset, for instance, worn by only one woman and beyond all public view, was once deemed a public use.<sup>221</sup> Yet the construc-

<sup>215</sup> See *supra* note 68 and accompanying text.

<sup>216</sup> See *supra* note 69 and accompanying text.

<sup>217</sup> See *supra* notes 64 & 65 and accompanying text.

<sup>218</sup> *Gillman v. Stern*, 114 F.2d 28, 31 (2d Cir. 1940).

<sup>219</sup> *Del Mar Eng'g Lab. v. United States*, 524 F.2d 1178, 1185 (Ct. Cl. 1975).

<sup>220</sup> *TP Lab., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984). Among the factors to be considered are whether payment is made for the device, whether a user agreed to use secretly, whether records were kept of progress, whether persons other than the inventor conducted the asserted experiments, how many tests were conducted, [and] how long the testing period was in relationship to tests of other similar devices.

*Id.*

<sup>221</sup> *Egbert v. Lippmann*, 104 U.S. 333, 337 (1881). *But see id.* at 339 (Miller, J., dissenting) ("If the little steel spring inserted in a single pair of corsets, and used by only one woman, covered by her outer-clothing, and in a position always withheld from public observation, is a public use of that piece of steel, I am at a loss to know the line between a private and a public use.") (emphasis omitted).

tion and use of a new public road was considered to be experimental.<sup>222</sup>

Notice that while a use may be public, it may also be secret or hidden. It is said of this legal threshold, “[m]aking the invention publicly known requires only that the public enjoy the *benefits* or the use of the prior invention.”<sup>223</sup> In addition to public use, there are a range of other activities that result in the forfeiture of novelty under § 102(g)—abandonment, concealment, and suppression. As with the determination of public use, there are a variety of factors to consider in judging whether novelty is defeated on the aforementioned grounds. Unfortunately, no definite meaning of “suppressed, or concealed” as prescribed in § 102(g) has developed under the case law.<sup>224</sup> Any determination as to whether an inventor has “suppressed or concealed” an invention has been deemed a matter of law, not a finding of fact, leading to some difficulty in the statute’s application.<sup>225</sup> While a use may be a public use, it is also possible that such use is hidden in character, and thus does not inform the public or cause disclosure.<sup>226</sup> Such a public use that does not disclose the inventive concept may lead to a patent bar due to a loss of novelty under § 102(g).<sup>227</sup>

Secrecy surrounding an invention leads to an array of interesting consequences. The secret inventor who has neither taught the art to the public nor enriched the public storehouse of knowledge, is not considered the “first inventor.”<sup>228</sup> The abandonment of an invention does not create “prior art,” but is said to establish “lost art,” as if only waiting to be discovered again by another.

<sup>222</sup> *Elizabeth v. Pavement Co.*, 97 U.S. 126, 134-36 (1877).

<sup>223</sup> *Friction Div. Prods., Inc. v. E.I. DuPont de Nemours & Co.*, 658 F. Supp. 998, 1013-14 (D. Del. 1987) (citing *Del Mar Eng'g*, 524 F.2d at 1185).

<sup>224</sup> *Paulik v. Rizkalla*, 760 F.2d 1270, 1279 (Fed Cir. 1985) (Rich, J., concurring). The statute reflects the intent to codify prior case law pertaining to priority determinations in interference or infringement cases. *Id.* Thus, one must look to the facts of prior cases to ascertain the true meaning of the words. *Id.*

<sup>225</sup> *Id.* at 1280.

<sup>226</sup> *See Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 37 (7th Cir. 1975) (holding that “a public use of an invention forecloses a finding of suppression or concealment even though the use does not disclose the discovery”).

<sup>227</sup> *See Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973) (holding that finding of concealment under § 102(g) is warranted despite commercial use of invention where such use conveys no knowledge of invention to public).

<sup>228</sup> *Gillman v. Stern*, 114 F.2d 28, 31 (2d Cir. 1940) (concluding that keeping manufacturing invention secret, except to secure agents to sell end product, precluded finding that inventor was “first inventor”).

Observers conclude that "[b]y definition a trade secret has not been placed in the public domain."<sup>229</sup>

Strictly speaking, a truly secret use, one quarantined from the outside world, is not a public use.<sup>230</sup> In an industrial context, the determination of a commercial use considers the relationship between employees and members of the public. The rule as stated in *Metallizing Engineering Co.*, is that a commercial use is a public use even if its use is kept secret.<sup>231</sup> Congressional witnesses warned that while this broad rule has caused difficulty, Congress should avoid enacting broad legislation overruling the case.<sup>232</sup> Thus far Congress has heeded that warning and adhered to the principals set forth in that case. As a result, the commercial character of a use may be sufficient to deem it a public use.<sup>233</sup>

---

<sup>229</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). A trade secret cannot be protected by a patent and retain its character as a secret because such information is revealed to the public when patented. See 69 C.J.S. *Patents* § 1 (1951).

<sup>230</sup> *Gillman*, 114 F.2d at 31; see also *A. Schrader's Sons, Inc. v. Wein Sales Corp.*, 9 F.2d 306, 308 (2d Cir. 1925) (positing that use may still be secret even if two individuals have access to and knowledge of such use). The number of people who have access to the invention and whether they have sworn to secrecy are relevant factors in determining whether an invention has been sufficiently quarantined from the outside world to constitute a "secret use." *Peerless Roll Leaf Co. v. H. Griffin & Sons Co.*, 29 F.2d 646, 648 (2d Cir. 1928), overruled on other grounds by *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946).

<sup>231</sup> *Metallizing Eng'g*, 153 F.2d at 520; see also *Painton & Co. v. Bourns, Inc.*, 442 F.2d 216, 224 n.6 (2d Cir. 1971). " 'Public use or sale' may be found even though the inventor has contracted for secrecy by a user or, for that matter, has practiced the invention solely for his own purposes." *Id.* The reasoning underlying this principle was initially explained in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829).

If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any farther use than what should be derived under it during his fourteen years; it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

*Id.* at 19.

<sup>232</sup> *Prior Domestic Commercial Use Act of 1995: Hearings on H.R. 2235 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. 47 (1995) (statement of Prof. Richard Schwaab). "Overruling Learned Hand's doctrine will not do the trick, and indeed may be too radical a solution at this time." *Id.*

<sup>233</sup> *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 390 (Fed. Cir. 1984) (stating that resolving issue of whether use of machine was public or secret is unnecessary be-



The public use of an invention is not dispositive with regard to § 102(g). Perhaps this is why certain industries, including the software industry, seek prior user rights to avoid the conflicting consequences of commercialization. For example, public use of the invention, even without disclosing its details to the public, is deemed sufficient to negate abandonment, suppression, or concealment.<sup>234</sup> In addition, the pursuit of a patent application may provide evidence that the inventor was not abandoning an invention under § 102(g).<sup>235</sup>

There are several instances where, after the conception of an innovative concept, an inventor will not reveal her activity to the public in a timely fashion. Certainly, there are numerous examples where an inventor conceals an invention in order to gain a distinct advantage. Yet, other circumstances exist where an inventor may cease development of one invention in order to pursue other projects, only to later renew the prior effort. The realities of inventive activity pose a self-defeating threat under the current patent laws.

There is a vast difference between deliberate concealment and negligence. Over one-hundred years ago, the Supreme Court, in *Kendall v. Winsor*,<sup>236</sup> held that the "progress of science and the useful arts" is frustrated by those inventors who "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public."<sup>237</sup> However, there is a stark contrast between withholding knowledge of an invention from the public and profiting from the use of its inventive fruits through commercialization. Never-

---

cause even if use was secret, its commercial character rendered it public use).

<sup>234</sup> *Del Mar Eng'g Labs v. United States*, 524 F.2d 1178, 1185 (Ct. Cl. 1975); *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 37 (7th Cir. 1975). Three justifications are given for finding that public use negates abandonment, suppression, or concealment. First, the public receives the benefit of the invention, therefore, no suppression has occurred in any economic sense. Second, since the invention is accessible to the public, it is likely that a competitor will uncover the secret before the time a patent would have expired if the inventor had applied in a timely fashion. Third, an inventor has no duty to apply for a patent and may choose to risk his entitlement to monopoly protection. This election should not hinder his right to continue to market the product of his invention. *Dunlop*, 524 F.2d at 37.

<sup>235</sup> *Cosden Oil & Chem. Co. v. American Hoechst Corp.*, 543 F. Supp. 522, 537 (D. Del. 1982) (finding that abandonment of patent application does not necessarily indicate intent to abandon invention); *Jacquard Knitting Mach. Co. v. Ordinance Gauge Co.*, 213 F.2d 503, 508 (3d Cir. 1954) (holding pursuance of application showed intent not to abandon).

<sup>236</sup> 62 U.S. (21 How.) 322 (1858).

<sup>237</sup> *Id.* at 328.

theless, an inventor today may jeopardize her patent rights in an invention by simply withholding it from the public for "too long."

A majority of inventions are put to use before patents are issued because the PTO processing time is considered "too long." Industries are concerned with the pre-application use of inventions because such use could negate patentability.<sup>238</sup> Practical tensions also arise since pre-application industrial use can show an inventions' limitations or weaknesses.<sup>239</sup> Therefore, creating greater flexibility in the pre-application stage of inventive activity will foster benefits to the public through increased innovation.

Another area where pre-application activities cause frustration for inventors relates to priority—who is the first inventor in the eyes of the law. Judge Howard T. Markey, former Court of Appeals for the Federal Circuit, noted that flexibility in construing inventive activity in light of § 102(g) is equitable.<sup>240</sup> Prior user rights are most equitable and useful in national legal systems that are "first-to-file" and thus do not present the United States conflicts regarding priority. Yet, prior user rights benefit American inventors and small firms who would inevitably face extreme difficulties with the bureaucracy of the patent application process.

This is true for those small entities who find it difficult, if not impossible, to "participate" in a patent system where they must otherwise compete with large firms possessing the resources to flood the PTO.<sup>241</sup> Prior user rights, therefore, present another potential benefit in limiting PTO activity. Such a limitation will serve the public interest by conserving limited PTO resources. In addition, it is in the public's interest to preempt all non-novel, or otherwise meritless patent applications. Further, it is in the public's interest to preempt "small-time" patents.

Critics of patent monopolies, particularly members of the medical community who oppose medical procedure patents, should take some comfort in this well-founded policy and begin

---

<sup>238</sup> Sanders, *supra* note 75, at 70. Sanders notes that the United States patent laws preclude patenting any invention that has been used commercially for a period exceeding twelve months. *Id.* Thus, the inventions that are used prior to receipt of a patent may "inadvertently be used too long and thereby be disqualified." *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> Paulik v. Rizkalla, 760 F.2d 1270, 1283 (Fed. Cir. 1985) (Markey, C.J., *add'l* views).

<sup>241</sup> *Id.*

to reap the benefits of prior user rights. Foremost among these benefits is the minimization of the risk of a lawsuit. Moreover, the health care establishment benefits if it is unfettered by the current proprietary restraints. This enables enhanced use of an invention, and, in turn, therapeutic treatment will follow. The public benefits from more discoveries, more inventions, and more applications put to use. The workload and bureaucracy of the PTO is certain to decrease since patent applications are discouraged as the need for defensive patents decreases. The enhanced inventive activity advances the rate of innovation, stimulating new inventions of higher quality. As older inventions become outmoded, the technology is freed and more readily available to the public.

R. Carl Moy, associate professor of law at William Mitchell College, is highly critical of those advocates who seek broad prior user rights in order to secure enhanced trade secret protection.<sup>242</sup> Trade secret holders are acknowledged for conferring a benefit to society through the production of new products—the fruits of their innovation. Their motivation, however, is not considered “philanthropic.”<sup>243</sup> Since pursuing the patent or trade secret route is a strategic choice for the inventor, the benefits of prior user rights would definitely enhance the role of trade secrecy in industry. Moy contends that any secrecy strategy is a pricing decision<sup>244</sup> related to an inventor’s expectation of increased profit according to the “single-source” monopolistic control over patented inventions.<sup>245</sup>

Objections to enacting broad prior user rights appear grounded in the potential frustration with major federal policy objectives. First, the measure appears to hinder the policy of free competition. Second, the measure also appears to frustrate the traditional bargain bestowing a limited monopoly in exchange for benefits to the public. The current system is defended as maximizing the policies of free competition and public disclosure.

---

<sup>242</sup> *Prior User*, *supra* note 190, at 91 (statement of R. Carl Moy).

<sup>243</sup> *Id.* Moy asserts that trade secret holders effectuate the following: (a) set a price on their products that reflects the fact that they hold a monopoly on the technical innovation; (b) try to take advantage of this benefit for an indefinite period whereas a patent holder can only do so for a limited time and; (c) at the same time, refuse to disclose the technology. *Id.*

<sup>244</sup> *Id.*

<sup>245</sup> *Id.* at 85.

On these grounds, the objections may be squarely addressed. Prior user rights preserve the traditional objectives of United States intellectual property law. Moreover, they advance another important value, certainty, as it pertains to legal, inventive, and economic activity. Prior user rights add certainty of return on investment during the inventive process for the user. As will be discussed in the next section, uncertainty—the enemy of inventive activity—is minimized through prior user rights.

The benefits of prior user rights, beyond the advantage of certainty, are highlighted when other policy objections are defused. Any objection as to whether this policy hampers free competition hinges on whether the enhanced trade secret protection arising under prior user rights frustrates federal policy objectives. There is an apparent tension between the traditional term for patent and trade secret protection.

While the patentee becomes a “single-source” monopolist for a limited period, the trade secret holder or prior user can only accomplish this for an uncertain period. It is worth emphasizing that it is an *uncertain* or *indefinite* period. Unfortunately, some wrongly equate these terms with “infinite.” Recall that trade secret protection, contrary to popular opinion, is not long-lived.<sup>246</sup> In addition, since both inventors have economic rights in an invention, the price of the technology will approach the societal optimum. Prior user rights advance uniform free competition policies as technologies become more competitive.<sup>247</sup>

Prior user rights bolster current trade secret policies. They do more than promote trade secret rights; they change the fundamental nature of the bargain underlying the commercialization strategy. Consider the following: under current United States patent practices, an inventor receives a limited monopoly for her benefit to the public, which includes commercialization and public disclosure via an issued patent. This limited monopoly encompasses certain traditional exclusive rights, including the ability to transfer or license the technology. The current patent application process also poses certain risks, such as delaying the head start to commercialization, as well as the costs (e.g.,

---

<sup>246</sup> See *supra* note 90 and accompanying text.

<sup>247</sup> Gary L. Griswold & F. Andrew Ubel, *Prior User Rights - A Necessary Part of a First-To-File System*, 26 J. MARSHALL L. REV. 567, 577 (1993) (stating that prior user rights enhance global competitiveness and equalize patent rights world-wide through creation of more uniform patent system).

government and attorney's fees) and burdens related to the patent process.

Trade secret protection, by contrast, bears many risks despite its superficial appeal. It does not yield prompt disclosure and insecurely guards against inventive risk since a later patentee can trump all of the trade secret holder's rights. Current patent law is a "winner takes all" scenario that can lead to severe economic dislocations.<sup>248</sup>

Prior user rights provide another, similar secondary bargain between an inventor and the public balancing the rights in a technology and its commercialization. A worthwhile contribution should be rewarded consistent with the aforementioned theories of property law. In exchange for the commercialization of a new innovation which promptly benefits the public, the first inventor who is a prior user obtains a more narrowly tailored monopoly in return for that commercial activity. Additionally, the inventor obtains a head start to the market and enjoys economic efficiency by saving the costs involved in the patent system. As a corresponding downside, the inventor does not win the traditional patent rights afforded by forfeiting the patent route. (In truth, these rights may never have been a relevant concern for the inventor). This is a not a sacrifice for the inventor, but a consequence of making the strategic decision of not abiding by the traditional patent system *quid pro quo*.

There are several key differences among the rights belonging to the traditional patentee and the prior user of a technology. A patentee has the ability to license or transfer the technology; a prior user does not.<sup>249</sup> The patentee gains this valuable privilege and the right to dispose and transfer an invention in return for the public disclosure; a prior user does not.<sup>250</sup> Further, she has the right to exclude others from making, using, and selling the invention, important traditional rights belonging solely to the patentee.<sup>251</sup> Thus, the prior user may have whatever limited economic rights and market power she possesses trumped by a second comer who becomes a patentee, who can exercise numerous rights in the invention.

---

<sup>248</sup> See Ubel, *supra* note 183, at 407 (discussing some negative effects of winner-takes-all system including invalidation of otherwise valid patents).

<sup>249</sup> 35 U.S.C. § 271 (1994).

<sup>250</sup> 35 U.S.C. §§ 111-113 (1994).

<sup>251</sup> 35 U.S.C. § 154(a)(1) (1994).

All factors combined, the prior user defense enhances the traditional societal-inventor bargain under the current patent system. Society benefits from the speedier access to the technology, even though there may be a delayed or less forthcoming disclosure in a short term time-frame. It is equitable and consistent with our principles since a first inventor, through innovation and the commercial use of the process, merits special legal protection in return for bestowing upon the public the benefit of new products and industrial efficiencies through commercialization.<sup>252</sup>

Just as patents and trade secrets dovetail, prior user rights help reach the aforementioned important federal policy objectives and property theories. While there is an apparent tension between patents and trade secrets, in *Kewanee Oil*, the Supreme Court concluded that abolishing trade secret protection would not increase the disclosure of discoveries of nonpatentable subject matter.<sup>253</sup> Hence, it is necessary to consider the concerns of critics such as Moy regarding the impact of prior user rights on our current system that disfavors trade secrets.

Since critics argue that any prior user rights legislation should be modified to protect trade secrets in a narrowly tailored way, it is worth noting the changes in the congressional proposals subsequent to Moy's 1994 testimony. The prior user rights bill in the 104th Congress heeded these warnings and contained several significant limitations over the bill introduced in the 103rd Congress. Under the revised legislation, the prior user defense cannot be asserted unless the commercial activity is commenced more than one year prior to the patentee's application

---

<sup>252</sup> *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 37 (7th Cir. 1975) ("If the new idea is permitted to have its impact in the marketplace, and thus to 'promote the Progress of Science and useful Arts,' it surely has not been suppressed in the economic sense."). To be entitled to a patent, the applicant must be the original and first inventor of the invention claimed. See *Radio Corp. of America v. Radio Eng'g Lab. Inc.*, 293 U.S. 1, 3 (1934) ("The prize of an exclusive patent falls to one who had the fortune to be [the] first [inventor]."); *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 587 (7th Cir. 1934) (noting plaintiff's correct assertion of law that only actual inventor is entitled to patent).

<sup>253</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974). The Court based its conclusions on the fact that a patent cannot be granted for an invention unless it falls within one of the statutory categories of 35 U.S.C. § 101. *Id.* Whether or not trade secret protection exists, the inventor whose invention falls outside a § 101 category has no reason to apply for a patent. *Id.*



date.<sup>254</sup> Of course, the most important safeguard of any prior user rights measure is strictly freezing the scope and volume of user's rights in accord with the actual commercial use before the patent's filing date.<sup>255</sup>

Without these limitations, prior user rights may prove to be as troublesome as the proverbial "submarine patent," by protecting an invention that lies in wait only to arise unexpectedly and cause severe economic dislocations and create uncertainty for the subsequent innovator. Unlike pure trade secret law, this tempering of the prior user defense balances the equities. Experts note that prior user rights are a practical convenience, only used for minor or unimportant process inventions. Tempered prior user rights provide an enhanced incentive to patent. This would certainly continue to drive important innovations into the public sphere, and benefit the public by disclosure through the traditional patent system of publication.

Finally, there is one last certain conclusion. The prior user defense serves as both a shield and a sword. Since it works both ways, it proves a mixed blessing depending on the perspective of a firm.<sup>256</sup> Consider the possible perspective of a small inventor who specializes in licensing new industrial developments. It would be worrisome to have a very large corporation assert the rights against a small-time inventor. A small American firm, by contrast, would benefit from the privilege. Such a firm would be shielded from licensing or being enjoined against an innovation it had previously developed and put to use. This is a right widely enjoyed by its overseas counterparts. Thus, one clear benefit for firms of all sizes is that prior user rights are a useful hedge against inventive risk, especially for those inventions of uncertain or costly patentability.<sup>257</sup> The challenge of developing a judicious prior user rights policy to best balance the equities be-

---

<sup>254</sup> H.R. 2235, 104th cong., 35 U.S.C. § 273(c)(6) (1995). In addition, the bill limits the right to transfer the invention, *id.* § 273(b)(2), contains a high threshold for its application, *id.* at § 273(c), places the burden of proof on the person asserting the defense, *id.* § 273(c)(3), and provides for attorney's fees in certain cases where the defense is unsuccessfully asserted. *Id.* § 273(d).

<sup>255</sup> By contrast, proposed § 273(c)(1) of H.R. 2235 extends prior user rights to "variations in the quantity or volume of use of the claimed subject matter." *Id.*

<sup>256</sup> *Prior User*, *supra* note 190, at 121 (testimony of Arnold L. Newman, President, Synexus Corp.).

<sup>257</sup> *Id.* at 45 (statement of Prof. Robert P. Merges). For example, prior use could serve as a defense to patent infringement liability in a case where a company had made commercial use of an "old" technique which had been patented. *Id.* at 37-38.

tween patents and trade secrets requires understanding the fundamental theories regarding risk, secrecy, and monopoly power as they apply to intellectual property.

#### VII. INTELLECTUAL PROPERTY: HEDGING RISK AND GUARDING INCENTIVE

*"All enlightened governments reward the inventor [sic] ... Such results not only enrich a nation, but render it illustrious."*<sup>258</sup>

A full appreciation of the government's promotion of progress in the sciences and arts, including the biomedical disciplines, requires examining the economic underpinnings of patents and trade secrets. Ideally, it would be enough to acknowledge an inventor's contribution to the public storehouse of knowledge with an acknowledgment or title. In practice, compensating physicians and corporate investors to undertake research may be accomplished in many ways. It is believed that physicians are guided by an ethical duty, coupled with standard professional benefits. Traditionally, mere recognition and career opportunities available to innovators were satisfactory motivation.<sup>259</sup> Generally, this is the case with famous medical procedures (e.g., the Heimlich maneuver).

Two policies drive patent law—individual reward and public benefit. The former drives the latter, thus rewarding inventors is simply a means to an end. For one model economic system, scholars posit, "the reward for invention would be completely separated from any charge to the users of the information."<sup>260</sup> Another theory advances the notion that the most efficient allocation of resources in a society occurs by awarding the patentee a lump sum in exchange for the unfettered dissemination of the information.<sup>261</sup> However, critics are quick to acknowledge the

<sup>258</sup> *Wilson v. Rousseau*, 45 U.S. (4 How.) 646, 692 (1846).

<sup>259</sup> See *Kelman Hearings*, *supra* note 18, at 11. "Most people who are not familiar with the patent system are astonished to learn that someone can 'own' a particular way of moving a scalpel for a surgical incision [or] a specific method of reading and interpreting an ultrasound image ...." *Id.* at 2. Many assert that in some cases, the same physicians who could profit from such patents are denouncing them. See *Noonan Hearings*, *supra* note 111 at 5.

<sup>260</sup> Arrow, *supra* note 197, at 617. Arrow notes that this separation existed in the former U.S.S.R. *Id.* at 617 n.5. Arrow contrasts his model with a free enterprise system by asserting that in such an economy, the need to make an invention profitable causes a non-optimal allocation of resources. *Id.* at 617.

<sup>261</sup> MANSFIELD, *supra* note 86, at 208 n.7. For example, Alexander Hamilton suggested that the United States government should award lump sum amounts for

practical difficulties of such a bargain.<sup>262</sup> To ensure scientific and artistic results are in accord with constitutional goals, there should be a certain level of creative investment within our society, and economic theory helps guide society as to the appropriate investment levels. This premise of creative investment holds true for both the toy business and biomedical technology.

All types of research and development require certain safeguards to protect investments. Among the necessary safeguards, economists recognize special "protecting devices" including patents, trade secrets, and previously secured long-period contracts to minimize the risk and uncertainty of investments.<sup>263</sup>

The cost of transmitting information concerning a particular invention is very low.<sup>264</sup> This will surely remain true as communication facilities increase due to the inception of new media such as the Internet, and its associated cost decreases. Therefore, since the information regarding an invention can be distributed at virtually no cost, any other source of the information, such as reproduction, can easily negate the first inventor's monopoly.<sup>265</sup>

Economist Joseph Schumpeter is one of the principal scholars who argues that economic investment in technological change can be measured by waves of innovation followed by subsequent waves of imitation.<sup>266</sup> His economic model suggests that, repeatedly, one industry may inspire an invention, another one manufacture it, and yet a third one use it.<sup>267</sup> Economics plainly

important inventions. *Id.* at 210 n.13.

<sup>262</sup> *Id.* at 208 n.7. The practical difficulties of such a system include selecting which inventions should be awarded patents and the appropriate amount of the lump sum. *Id.* at 210 n.13, 211.

<sup>263</sup> JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 88 (3d ed. 1950). These protecting devices are recognized as "normal elements of rational management" by most economists. *Id.* Such devices are necessary to ensure entrepreneurial actions against "hedging." *Id.*

<sup>264</sup> Arrow, *supra* note 197, at 614. In addition, migration of employees from one firm to another is an additional means by which information regarding an invention is transmitted. *Id.* at 615.

<sup>265</sup> *Id.* This necessitates the need for legal protection of inventions. *Id.* Otherwise the true monopoly would be the use of the discovery by the inventor alone. *Id.* This would be of little benefit to either the inventor or society. *Id.*

<sup>266</sup> See SCHUMPETER, *supra* note 263, at 83 (discussing different views of economic and technological change); see also Eisenberg, *supra* note 64, at 1038-40 (discussing Schumpeterian theory in general).

<sup>267</sup> SCHUMPETER, *supra* note 263, at 81-86. Schumpeter's model contends that monopolies foster innovation which, in turn, causes revolutionary changes in the economic system through a process he terms "creative destruction." Eisenberg, *su-*

depicts that "copycats" make invention and authorship a risky business.

The inherent high risk in initiating an investment increases the likelihood of underinvestment in inventions.<sup>268</sup> Underinvestment in medical inventions, however, poses serious risks for the public health. Generally, the decision of how much to invest is a function of the firm's risk preference and its ability to estimate the probability of the invention's success.<sup>269</sup> Economists list several factors which prospective inventors may use to gauge uncertainty:

- (1) the nature of the payoff function;
- (2) the degree to which the information is available or outside their control or knowledge; and
- (3) the ability to reduce relevant uncertainties.<sup>270</sup>

The final inquiry into the uncertainty problem is the extent to which a decision-maker can keep the set of possible alternatives open, and thus not commit in any way, until more information regarding the consequences of any choice it makes is received.<sup>271</sup>

*pra* note 64, at 1038-39. Schumpeter states that this process "incessantly revolutionizes the economic structure *from within*, incessantly destroying the old one, incessantly creating a new one." SCHUMPETER, *supra* note 263, at 83. In this process, old firms providing obsolete goods and services are driven out by new firms creating new innovations. Eisenberg, *supra* note 64, at 1039.

<sup>268</sup> *Id.* at 1025. "Since it is a risky process, there is bound to be some discrimination against investment in inventive and research activities." Arrow, *supra* note 197, at 616. Inventions with potentially large social benefits might, therefore, never come about unless private returns for invention were increased above their free market values. Eisenberg, *supra* note 64, at 1025. Arrow also suggests that because there does not exist an adequate market to shift risk, the fear of risks will lead to underinvestment. Arrow, *supra* note 197, at 611-14. *But see* John S. McGee, *Patent Exploitation: Some Economic and Legal Problems*, 9 J.L. & ECON. 135, 136 (1966) (asserting that risk in some cases may produce over-investment in invention).

<sup>269</sup> Eisenberg, *supra* note 64, at 1025 n.33. Some scholars suggest that people who enjoy risk will tend to "overinvest in inventive activity." *Id.* It has been noted, however, that there are many different models of decision theory. Richard R. Nelson, *The Link Between Science and Invention: the Case of the Transistor*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 551 n.7 (1962).

<sup>270</sup> *Id.* at 550-51. Included in the ability to reduce the uncertainties factor is the ability to learn. *Id.* at 551.

<sup>271</sup> *Id.* In the case of Bell Telephone Laboratories' semiconductor research, due to uncertainty regarding the feasibility of the project, rather than commit to a specific goal, researchers focused instead on learning in general. *Id.* at 566. The company conducted extensive research to learn about the best types of conductors in order to limit the chance of error in the future and increase the chance of certainty regarding the product. *Id.*

The ability to promote the public health is embodied in these choices.

Several methods are available to firms to overcome the risks and uncertainties present in inventive investments. In theory, a firm can self-insure against losses attributable to the inventive process.<sup>272</sup> Theory also dictates that, when a device is available that can insure against loss, it has the positive effect of increasing investment to a level closer to the societal optimum.<sup>273</sup> In addition, investment in new inventions may also be secured by entering a market with a "head start" advantage, as may often be secured by secrecy.<sup>274</sup> Accordingly, Arrow posits that, if individuals can avoid risk and there is no available "insurance" mechanism, then there is less spent than is socially desirable on risky activities such as inventing.<sup>275</sup>

Patents are desirable protective devices because they possess relative certainty in the duration of their protective terms. Today, the term of patent protection is approximately 17 years, depending on PTO pendency.<sup>276</sup> Yet, even a relatively short duration period for a "protecting device" is more desirable than none at all. Overall, many new goods and services are introduced to markets in experimental or unsatisfactory forms; such products have a limited chance of success among consumers.<sup>277</sup>

---

<sup>272</sup> See Arrow, *supra* note 197, at 616 (discussing fact that invention is risky and needs protection). A company can self-insure against inventive losses by keeping research projects relatively small. Arrow asserts, however, that this would weaken the incentive to succeed. *Id.* Arrow also states that moral factors will affect what type of risk insurance or risk-bearing companies will decide to use. *Id.*

<sup>273</sup> *Id.* at 612. To attain the societal optimum, insurance would have to cover every perceivable event. Unfortunately, the shifting of risks is incomplete. *Id.* Insurance covers only a small range of events. *Id.* Securities are more important in shifting risks and are, therefore, used more frequently. *Id.*

<sup>274</sup> Eisenberg, *supra* note 64, at 1026 (citing FREDERIC M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 384-87 (1970)). This "headstart" advantage "may provide a sufficient incentive to promote investment in research." *Id.*

<sup>275</sup> 35 U.S.C. § 154 (1994) (stating that patents are granted for term beginning on date of issuance and ending 20 years from date on which patent application was filed). This law grants assignees the right to exclude others from "using, offering for sale or selling [the product] throughout the United States." *Id.*

<sup>276</sup> This is based on the current operation of law under GATT which provides for twenty-years of protection less PTO processing time. See *supra* note 71.

<sup>277</sup> SCHUMPETER, *supra* note 263, at 92. The introduction of unsatisfactory and experimental forms of innovation into the market facilitates the improvement of the quality of products. *Id.*

The level of successful investment should be rationally<sup>278</sup> related to the level of profitability.<sup>279</sup> According to the world's various patent systems, patents must be periodically renewed through some action or payment by the patentee, otherwise the patent expires.<sup>280</sup> This helps to decrease the amount of "bad patents" that exist,<sup>281</sup> a benefit acknowledged around the world.<sup>282</sup> These weeding practices create little financial incentive for inventors to pay money to renew unprofitable patents and, therefore, technology is freed.<sup>283</sup> In the United States system, the patent process is considered overly litigious.<sup>284</sup> Preserving patents may, however, have a defensive value, as they may protect against claims of infringement of related or overlapping technology. If patent protection is unavailable as a legal means to recoup investment, other protective means must be secured to justify investment.<sup>285</sup>

Patents also play an important role in setting an affordable level of prices for new inventions.<sup>286</sup> This is a prime concern for proponents of a moratorium on medical procedure patents. Schumpeter is among those economists who note that, in a capitalist system which lacks the "protecting devices" of intellectual property protection, one alternative method for guarding an in-

<sup>278</sup> As used here and in economic terms, "rational" is defined as cost reduction oriented.

<sup>279</sup> See MANSFIELD, *supra* note 86, at 207-08 n.5 (discussing profitability of various patents). Sanders' study of inventions found that two-thirds of inventions in past use were profitable and, one-third reported a loss. *Id.* For inventions in current use, nine-tenths were profitable and one tenth were a loss. *Id.* (citing Barkev S. Sanders, *Patterns of Commercial Exploitation of Patented Inventions by Large and Small Companies*, 8 PAT., TRADEMARK & COPYRIGHT J. OF RES. & EDUC. 52 (1964).

<sup>280</sup> See, e.g., 35 U.S.C. §§ 111, 155, 156 (1994) (discussing procedures necessary to obtain patents and patent term extension procedures).

<sup>281</sup> See MANSFIELD, *supra* note 86, at 210 (discussing need to "weed out worthless patents").

<sup>282</sup> *Id.* Some countries have implemented annual fee requirements by patentees to assist in weeding out these "bad" patents. *Id.*

<sup>283</sup> *Id.* Another means of "weeding out" is a system of general compulsory licensing in which anyone can obtain licenses under any patent, therefore, decreasing the hope of obtaining attractive monopoly royalties. *Id.*

<sup>284</sup> See generally 17 U.S.C. §§ 131-146 (discussing examination of patent application and appeals process at all levels).

<sup>285</sup> SCHUMPETER, *supra* note 263, at 88. These other protective means may include additional investment or a price policy that encourages the ability to write-off expenses. *Id.*

<sup>286</sup> See, e.g., Laura Johannes, *Serono Wins Approval for AIDS Drug*, WALL. ST. J., Aug. 27, 1996, at B4 (explaining how pressure from public interest groups forced company to cap price of new growth hormone drug).



vestment is a price policy that recoups costs more quickly than other policies. Economic theory does not support the political rhetoric which alleges that patents create a burdensome or costly impact on patients or consumers.

Economic theory dictates that, without patents, new medical and surgical innovations would be able to enter the marketplace only at very high prices. These prices would then remain at such levels until information regarding the invention is disseminated and competition among various providers eventually drives them down. Disclosure of the innovation<sup>287</sup> would quickly disseminate throughout the market without any financial or psychological return to the original developers. Consequently, this lack of benefit for these investors would lead to limited patient access to new discoveries as people would be reluctant to invent. Since intellectual property is a protective device establishing a mechanism to distribute costs over a period of time, the public benefits when patents maintain relatively low and steady medical prices while allowing for the possibility of new discoveries.

The Framers envisioned a system where the government provided incentives and means for the private sector to pay for scientific and technological progress, rather than direct subsidization.<sup>288</sup> In fulfilling this goal, patents allow for the creation and preservation of various firms. The entire intellectual property system's purpose is economic; it is simply an investment tool used to facilitate commerce by permitting patentees to obtain financing and stock equity.<sup>289</sup>

Today, biotechnology and medical firms fund their research from equity capital, not product sales.<sup>290</sup> Patents are funding

---

<sup>287</sup> See SCHUMPETER, *supra* note 263, at 83. Innovation refers to the development of new consumer goods, new methods of production, new markets and new forms of industrial organization. *Id.* Schumpeter asserts that these are "[t]he fundamental impulses that set and keep the capitalist engine in motion." *Id.*

<sup>288</sup> Burch, *supra* note 6, at 1166. It has been asserted that denying medical process patents would dilute the constitutional policy favoring private sector financing for innovations. *Id.* at 1166 n.135. Burch states that this cost should be considered within an ethical analysis when determining whether to finance innovations and to create medical process patents. *Id.*

<sup>289</sup> See *Prior User*, *supra* note 190, at 8 (testimony of Bruce Lehman, PTO Comm'r); see also *Medical Hearings*, *supra* note 13, at 1995 WL 618644, at \*2 (testimony of Dr. Frank Baldino, Jr., President & CEO, Cephalon, Inc.).

<sup>290</sup> *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 4 (Oct. 19, 1995) (testimony of Dr. Frank Baldino, Jr., President & CEO Cephalon, Inc.). Since 1991, Dr. Baldino's company, Cephalon, Inc., has raised over

mechanisms that put assets on a firm's balance sheet. If patents are not enforceable, however, they become both meaningless and economically worthless. Firms would be unable to attract the capital needed to offset inventive risk without them. Today, this inventive risk is distributed throughout the market by investors willing to risk their capital and buy stock in these biomedical firms.<sup>291</sup> Observers note that the cost of medical research is increasing at a "time when noncommercial sources of [medical] funding are decreasing."<sup>292</sup> Increased risk would cause the rate of invention to plummet.

Economists also suggest that an efficiency exists in the interplay between a patentee and society, where the patentee can merely extract a price consistent with the utility consumers derive from the invention. The economics of this exchange guarantee that a patentee cannot charge more for the patent's use than its societal utility, since consumers will not pay more than the invention is worth.<sup>293</sup> It is argued, however, that since individuals will always place a very high premium on their health and will be willing to pay for it, medicinal costs will remain high. Beyond pricing concerns, the importance of a healthy society requires the promotion of better technology.

Medical and surgical innovation pose different challenges to setting a commodity's price. First, government involvement in the public health system is already present.<sup>294</sup> State govern-

---

\$250 million in equity capital. This reflects the fact that most biotechnology companies are not in a position to borrow capital. *Id.* The principal capital source for research support is, in fact, equity financing. *Id.*

<sup>291</sup> *Id.* "There is substantial risk and expense associated with biotechnology research and investors need to know that the inventions of our companies cannot be pirated by our competitors." *Id.* Baldino further states that investors will be reluctant to provide capital to fund research if there is inadequate protection of inventions, and such capital is imperative to inventing. *Id.*

<sup>292</sup> Burch, *supra* note 6, at 1143. "If the relationship between the availability of patents and research funds can be inferred from these facts, then a flat rejection of medical process patents creates at least some element of paradox." *Id.*

<sup>293</sup> Eisenberg, *supra* note 64, at 1026 n.34. As such, patents permit inventors to use their monopoly positions to obtain "a price that more closely approaches the value that users receive from inventions." *Id.* at 1026. Society benefits from the social value of the inventions. *Id.* But see William F. Baxter, *Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis*, 76 YALE L.J. 267, 270 (1966). "The argument is unsound because it fails to take into account indirect costs not borne by the inventor that the monopoly device imposes on society. These costs diminish the net social value of the invention and upset the private value-social value equation." *Id.*

<sup>294</sup> See Johannes, *supra* note 286, at B4 (stating that government approval proc-

ments are highly involved with physician licensing and the federal government safeguards the general public from very experimental and innovative medical inventions through a stringent quality and safety assurance process (e.g., the FDA).<sup>295</sup> Second, patents are already tempered by the existence of many exceptions for parties, including competitors, to use patented technology or inventions in their research and experimentation.<sup>296</sup> These factors tend to drive up the price of medicine as a result of the unavoidable delay and inevitable loss of market share. Eliminating the government's inability to enforce certain medical patents undoubtedly decreases their value and has severe negative implications for firms and consumers in the health care marketplace.

### VIII. SECRECY

A moratorium on any patent or corresponding right will decrease communication of technical information, foreclosing an important alternative means of publication. Inevitably, there will be a rise in hidden uses and trade secret protection of processes among doctors. The enactment of prior user rights that this paper advocates, however, also leads to increased secrecy.

A critical inquiry is whether the inevitable consequence of a rise in secrecy in either case frustrates the country's goal of progress in the arts and sciences is beneficial. Specifically, the consequences of the rise of secrecy in medicine must be mindfully considered. Any analysis must weigh some of the popular myths concerning secrecy against the facts existing regarding science.

There is a popular belief that secrecy is something negative. Scholars have cautioned that the intense secrecy of the medieval guild system "retarded technological progress and economic growth."<sup>297</sup> During the House's hearings on H.R. 1127, one Con-

---

ess delays availability of drug to AIDS patients).

<sup>295</sup> See *id.* (discussing FDA's safety procedures for gaining approval); see also *Eli Lilly & Co. v. Medtronic, Inc.*, 5 U.S.P.Q. (BNA) 1760, 1760 (E.D. Pa. 1987) (discussing fact that new drug must receive FDA approval); *People v. Mari*, 183 N.E. 858, 859 (N.Y. 1933) (discussing criteria for licensed physicians in New York).

<sup>296</sup> See, e.g., 35 U.S.C. § 271(e)(1) (1994 & Supp. 1996). "It shall not be an act of infringement ... for uses reasonably related to the [federally regulated compound] development." *Id.*; see also *Eli Lilly & Co.*, 496 U.S. at 669-74 (1990) (holding that 35 U.S.C. § 271(e)(1) provides for medical devices, as well as compounds).

<sup>297</sup> MANSFIELD, *supra* note 86, at 208. "Secrecy makes it difficult for inventors to sell or license their inventions to others because it is difficult to persuade someone to pay for an idea without disclosing it, yet once the invention is disclosed, the in-

gressman even questioned whether there would be a rise in secretive medical clinics as a result of patents.<sup>296</sup> History also denigrates the secrecy of Robert Koch, who discovered the tubercle bacillus and attempted to cure the disease by tuberculin inoculation; he is called "conceited, intolerant, [and] quackish."<sup>299</sup>

Today, the medical profession is portrayed as cooperative and teamwork oriented.<sup>300</sup> Further, it is viewed as a collegial system, featuring open communication, the sharing of ideas, and intellectual honesty; doctors are thought to be teachers and sharers.<sup>301</sup> The good of the patient is the primary focus.<sup>302</sup> Hence, any changes in our system promising new modes of medical treatment at affordable prices, should first promote the best for patient care.

Despite the negative views of secrecy, there exists a beneficial role for trade secrecy in protecting inventive investment and warding off risk. Beyond the industrial sphere, proponents of prior user rights and the enhanced secrecy protection argue that secrecy impacts minimally upon research and development.<sup>303</sup> Some scholars agree that secrecy has a positive value for the advancement of science; it serves as a protective device against the theft of ideas, avoiding disputes over priority, and acknowledging the worthiness of research.<sup>304</sup>

---

ventor has nothing left to sell." Eisenberg, *supra* note 64, at 1029.

<sup>296</sup> See *Medical Hearings*, *supra* note 13, at 1995 WL 11096027, at \*1 (testimony of Greg Ganske) (noting that patent protections for surgical methods work against medical progress).

<sup>299</sup> McTavish, *supra* note 106, at 348.

<sup>300</sup> *Medical Hearings*, *supra* note 13, at 1995 WL 11095852, at \*3 (testimony of G. Lee Skillington) ("Because of the tradition in the medical community to freely share knowledge and skills, the inducements offered by the patent system are perhaps not as urgent in [the medical] field as in others.").

<sup>301</sup> See *Hoskins Hearings*, *supra* note 151, at 6 (noting that "in the practice of medicine and surgery, publication and teaching of innovations is the norm, a much encouraged pattern of behavior"). Dr. Hoskins asserts that the medical community does not have the incentive of monopolies which benefits the public. *Id.* The medical community has never needed monopoly profits to encourage invention. *Id.*

<sup>302</sup> See generally 61 AM. JUR. 2d *Physicians, Surgeons, and Other Healers* §§ 166-167 (1981).

<sup>303</sup> *Prior User*, *supra* note 190, at 41 (testimony of Robert P. Merges) (citing Lise Osterborg, *Towards a Harmonized Prior User Right Within a Common Market Patent System*, 12 INT'L REV. INDUS. PROP. & COPYRIGHT 447, 461 (1981)). Mr. Merges states that any objection to prior user rights as having a negative impact on research and development, has been minimal in other countries. *Id.* Furthermore, there has been no evidence of such negative impact. *Id.*

<sup>304</sup> Eisenberg, *supra* note 64, at 1062-63 (citing Ian I. Mitroff, *The Subjective Side of Science*, 39 AM. SOC. REV. 579, 592-93 (1974)). Additionally, even when se-

Secrecy in the early stages of scientific research promotes individualism and independence among researchers.<sup>305</sup> While such values are important, they are at odds with the monitoring and control of coordinated research.<sup>306</sup> Thus, proponents of individualism and independence are critical of coordinated teamwork in industrial research because it is likely to be scientifically "arid."<sup>307</sup>

In the basic research sphere, secrecy translates into researchers ensuring their professional recognition by safeguarding their ideas and theories from misappropriation and protecting the incentive to discover and invent. In the industrial sphere, secrecy likewise ensures researchers freedom from use by competitors of their proprietary data.

Secrecy is faulted for leading to organizational and disciplinary inefficiencies, imposing a net cost on the allocation of society's resources, and increasing duplicative research.<sup>308</sup> If secrecy does lead to duplicative research, however, the result is not necessarily harmful.<sup>309</sup> With duplicative research, problems may be solved more quickly and different inventions are more likely to

crecy leads to duplicative research, such research may still be valuable because multiple, simultaneous research efforts tend to increase the likelihood that a problem will be resolved quickly and promotes the increase of knowledge. Eisenberg, *supra* note 64, at 1063. Furthermore, the extra research increases the chances that such research will eventually be made known to the scientific community. *Id.* at 1064. Independent discoveries help create greater validity for new research claims. *Id.* Typically, duplicate researchers will use somewhat different approaches, make different mistakes, and perhaps obtain different results. *Id.* at 1064. Therefore, duplicate research is really not redundant, but helpful. *Id.*

<sup>305</sup> Eisenberg, *supra* note 64, at 1063. Allowing secrecy may encourage researchers to develop new plans, conduct new studies, and keep their studies secret until publishing them in exchange for recognition. *Id.* The author further acknowledges, however, that these secrecy benefits are not widely touted. *Id.* This independence argument is more sensible in cases where the course of the research cannot be charted in advance and the effort's success therefore depends upon the investigation's creativity. *Id.* at 1067.

<sup>306</sup> *Id.* at 1065.

<sup>307</sup> Eisenberg, *supra* note 64, at 1066. Individualism and independence promote progress and individual initiative and creativity, which are impeded by coordination of research. *Id.* The coordination theory is mainly concerned with efficiency while the individualism and independence approach focuses on scientific progress as a goal. *Id.* These differences are greatly disputed as reasons for adopting one over the other. Critics of the independence scheme suggest it is wasteful in that it leads to duplicative research, but others suggest that this so-called "waste" is actually productive. *Id.* at 1063-64; see *supra* note 304 (countering argument that redundancy leads to waste).

<sup>308</sup> Eisenberg, *supra* note 64, at 1062-63.

<sup>309</sup> *Id.* at 1063.

arise.<sup>310</sup> The more researchers working on a problem or reaching the same conclusions, the more likely it is that these efforts will be incorporated into scientific knowledge.<sup>311</sup> Multiple research teams investigating the same problem can also help to validate particular research results.<sup>312</sup> Moreover, research duplication among competing research teams is rarely entirely redundant.<sup>313</sup> The use of different approaches, backgrounds, and techniques promises beneficial results.<sup>314</sup> It is also probable that multiple investigators will draw different conclusions and recognize new implications from the same discovery.<sup>315</sup>

Another highly beneficial research strategy is for inventors to work in parallel.<sup>316</sup> This may be described as a hybrid strategy coordinating independent groups. Parallel research leads to increased innovation and greater alternative designs, raising the odds of an increased storehouse of knowledge and allowing alternate designs to be ranked by likelihood of success.<sup>317</sup> The benefits of the parallel research strategy include,

- (1) increased returns corresponding to the number of alternatives;
- (2) a higher rate of "learning;"
- (3) lower costs at the initial stages of the enterprise; and,
- (4) greater "differences" among the resulting solutions.<sup>318</sup>

Unfortunately, too much of any good thing, including se-

<sup>310</sup> *Id.* Coordination of such efforts would compromise researchers' independence, thereby reducing the efficiency of the effort. *Id.* at 1065; see *supra* note 287 (discussing positive effects of duplicate research).

<sup>311</sup> Eisenberg, *supra* note 64, at 1065; see also *supra* note 287.

<sup>312</sup> Eisenberg, *supra* note 64, at 1064. "Multiple independent discoveries help establish the validity of new research claims, serving as a substitute for after-the-fact replication." *Id.*

<sup>313</sup> *Id.* The prolific publication of scientific research results, even after publication by others, illustrates the value of overlapping research. *Id.* at 1064 n.204.

<sup>314</sup> *Id.* at 1065 (stating that duplicate research serves valuable function).

<sup>315</sup> *Id.*

<sup>316</sup> See Richard R. Nelson, Introduction, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 3, 9-10 (1962) (noting that uncertainty in research and development necessitates running several investigative efforts in parallel).

<sup>317</sup> *Id.* at 10 (stating that success of parallel research is intuitively reasonable but difficult to prove).

<sup>318</sup> *Id.* (noting positive implications of parallel efforts). The primary effect would be an increase in the number of independent efforts to devise similar products or reduce the costs of publication. *Id.*



crecy, leads to diminishing economies of scale and bears negative consequences. Therefore, a balancing of the equities must be struck. Extreme and long-lived secrecy frustrates federal policy objectives. Research and development must exist in concert with fora for publication and public scrutiny.

In practice, a healthy dose of secrecy in basic research and medicine, as well as commerce, is useful and has positive effects. At the initial stages of research, secrecy serves as a protective device by averting risk and ensuring an increase in the public's storehouse of knowledge in the sciences and arts. Today, in the field of biomedical research, the traditional dividing line between the basic research of academic study, and applied research of industrial technology, is blurred.<sup>319</sup> While important research discoveries are increasingly likely to be patented, they also require some type of enhanced secrecy protection from the onset. This synergistic dovetail between patents and trade secrets enhances the research environment and advances the federal policies for innovation, free competition, and speedier public disclosure.

#### IX. MONOPOLIES AND MEDICINE

Any protective device, whether patents, secrecy, or contracts, conveys market power and restricts competition.<sup>320</sup> Conditions breed the monopolistic result, and even in some limited form, any protective device has some monopolistic<sup>321</sup> effect.<sup>322</sup>

---

<sup>319</sup> Eisenberg, *supra* note 64, at 1018; see also Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 196 (1987) ("Academic and industrial researchers ... often work[] on the same or closely related problems, whether competitively or collaboratively.")

<sup>320</sup> See *United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377, 400-01 (1956) (holding that exclusion, rather than restriction, creates monopoly power over prices under Sherman Act); *Digidyne Corp. v. Data Gen. Corp.*, 734 F.2d 1336, 1341-42 (9th Cir. 1984) (noting that requisite economic power is presumed from copyright). Cf. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 11 (1984) (recognizing that, in context of exclusive contract, not every refusal to sell more than one product restrains competition). "A common misconception has been that a patent or copyright ... suffices to demonstrate market power.... [I]t is also possible that [such] a seller ... will have no market power: for example, a patent holder has no market power ... if there are close substitutes for the patented product." *Id.* at 37 n.7 (O'Connor, J., concurring) (citing Landes & Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937 (1981)); *Abbott Lab. v. Brennan*, 952 F.2d 1346, 1354-55 (Fed. Cir. 1991) (stating that no presumption of market power is established from intellectual property right); *Northlake Mktg. & Supply, Inc. v. Glaverbel, S.A.*, 861 F. Supp. 653, 662-63 (N.D. Ill. 1994) (noting that mere possession of patent does not create presumption of market power for antitrust inquiry).

<sup>321</sup> The word "monopoly" is derived from the Greek, meaning "alone to sell." 1

Denouncing the monopolies arising from medical patents is a staple in the political debate to influence public policy.

One of the main arguments against biomedical patents is that they monopolize health care. The demagoguery of decrying monopolies has a long tradition among conservatives, even during times when monopolies were not problematic and markets were perfectly competitive.<sup>323</sup> Proponents of the moratorium claim that patents are powerful monopolies, hurting the nation's health care system. Economic theory reveals the opposite. Many inventors attest from experience that a patent is an extremely weak monopoly.<sup>324</sup>

Today, patents are referred to as "intellectual property" rather than as a monopoly privilege. Economists trace this nomenclature back to the nineteenth century where proponents of the patent system engaged in a deliberate "political ruse." In order to advance their cause, patent advocates used the label "property" rather than "monopoly privilege" due to its positive connotation.<sup>325</sup>

The negative connotation of monopolies is pervasive and still serves as a powerful propaganda tool. This perception may exist due to, or in spite of, the truth that monopolies are quite common in day-to-day life. It is written that a monopolist is one "who sells anything that is not in every respect, wrapping and location

ROSENBERG, *supra* note 1, § 1.03, at 1-9.

<sup>322</sup> U.S. DEP'T OF JUSTICE ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.2, n.9 (1995).

Market power can be exercised in other economic dimensions, such as quality, service, and the development of new or improved goods and processes. It is assumed in this definition that all competitive dimensions are held constant except the ones in which market power is being exercised; that a seller is able to charge higher prices for a higher-quality product does not alone indicate market power. The definition in the [DoJ-FTC] text is stated in terms of a seller with market power. A buyer could also exercise market power (e.g., by maintaining the price below the competitive level, thereby depressing output).

*Id.*

<sup>323</sup> SCHUMPETER, *supra* note 263, at 100.

<sup>324</sup> MANSFIELD, *supra* note 86, at 208. "The patent [however] gives the inventor the right to charge ... for the use of the information" or invention, reducing the availability of knowledge below a level which is "socially optimal." *Id.*

<sup>325</sup> Fritz Machlup and Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 16-17 (1950) ("It happens that those who started using the word property in connection with inventions had a very definite purpose in mind: they wanted to substitute a word with a respectable connotation, 'property,' for a word that had an unpleasant ring, 'privilege.'").

and service included, exactly like what other people sell."<sup>326</sup> Hence, even the corner grocer in a small town, for example, may be a monopolist for a certain product, at that location, even if merely for a few hours a day.<sup>327</sup>

Aside from medical and surgical patents, the medical profession is not in perfect competition. Their numbers, for instance, are limited by state licensing boards. Their ability and talents range widely. A lone country doctor could be a monopolist.

Recently, the debate over the changing nature of the medical marketplace has begun to broaden its focus from medical patents, specifically, to the larger array of monopolies, in general. There is growing concern about the medical field being dominated by mega-mergers resulting in merely a few large HMOs or other entities controlling a region's health care. Dr. Noonan suggests that the controversy regarding medical and surgical patents is merely part of a larger debate concerning the transfer of control of medicine to large corporate entities.<sup>328</sup>

Some economists argue that there is an inherent conflict between large corporations and innovation. This reasoning lies in the theory that the priority of business, to conserve capital, conflicts with new investment. Similarly, economist Joseph Schumpeter argues that whenever a field is controlled by a few large entities, they *can* and *will* fight the progress of innovation to preserve their capital structure.<sup>329</sup>

Business studies provide mixed results as to the role of patents in encouraging research, development, and innovation.<sup>330</sup> Studies reveal that large corporations patent fewer inventions than smaller firms.<sup>331</sup> The results apparently vary by industry,

<sup>326</sup> SCHUMPETER, *supra* note 263, at 99.

<sup>327</sup> *Id.* at 102.

<sup>328</sup> Noonan, *supra* note 22, at 662. "[T]he existence of these mammoth for-profit medical corporations calls into question the argument that medicine is an altruistic calling that should somehow be treated differently by the patent law than any other industrial endeavor." *Id.*

<sup>329</sup> SCHUMPETER, *supra* note 263, at 96.

<sup>330</sup> MANSFIELD, *supra* note 86, at 209 (noting that "[p]atents are much more important for independent inventors and small firms").

<sup>331</sup> Jacob Schmookler, Comment, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 78, 79-80 (1962). Data confirms that during the middle of the Twentieth Century, corporate research and development rose several-fold, but the number of patents over the same period only rose by twenty percent. *Id.*

with the electronic, chemical, and drug industries valuing patent protection, while the auto, paper and rubber industries do not.<sup>332</sup>

Patents are arguably more valuable to small entities and independent inventors, rather than large firms. Studies indicate that, as a percentage, the number of patents awarded to individuals has steadily declined since the turn of the century while the number of patents going to corporations during the same period has increased.<sup>333</sup> Another study reports that small firms use a greater percentage of patents than do large firms.<sup>334</sup>

Empirical studies, however, are not entirely helpful in measuring the effect of a large entity dominating a field and precluding innovation. Experts explain that large firms are more fit than smaller firms to carry out their inventions without the protection of the patent system.<sup>335</sup> There are many other important reasons why some large entities patent less, including, (1) the sharp rise in the compulsory licensing of thousands of corporate patents spurred by the United States' strong antitrust policies; (2) conflicts among many judicial decisions concerning corporate Research and Development ("R&D"); (3) changes in the economics of the inventive process due to the government's increased involvement in corporate R&D; (4) extensive administrative delays and costs in processing a patent application; and (5) corporate strategies viewing a superior head start time to the market as a sufficient protective device.<sup>336</sup>

On the other hand, monopolies clearly pose benefits that

---

<sup>332</sup> See MANSFIELD, *supra* note 86, at 209 (noting that some firms find "patents make little difference in their search for ... new products and processes").

<sup>333</sup> The following chart shows the percentage of issued patents between individuals and companies.

| Year of Issue | Percent to Individuals | Percent to Companies |
|---------------|------------------------|----------------------|
| 1901          | 81.8                   | 18.2                 |
| 1938          | 42.9                   | 57.0                 |
| 1952          | 42.5                   | 55.5                 |
| 1957          | 35.5                   | 62.3                 |

Sanders, *supra* note 75, at 62.

<sup>334</sup> The Sanders study of a random sample of patents granted found that for patents assigned as of the issue date, 51 percent were used by large companies; 71 percent were used by small companies and; 49 percent of patents unassigned as of the issue date were used commercially. MANSFIELD, *supra* note 86, at 207 n.5.

<sup>335</sup> *Id.* at 209 ("[P]atents are not really important as incentives to the large corporation, since it cannot afford to fall behind in the technological race, regardless of whether or not it receives a patent.").

<sup>336</sup> Schmoekler, *supra* note 331, at 79-80 (noting that where corporate research expenditures rose several fold between 1940 and mid-50s, patents increased by only one-fifth).

must also be recognized. There are scenarios where a monopoly brings greater economies of scale, organizational efficiency, or a superior combination of resources and talent. Thus, monopoly prices are not necessarily higher, nor is output necessarily smaller than in competitive markets.<sup>337</sup>

In evaluating firms with monopolies, an informed public policy choice needs to measure both the societal benefits and costs. While a large entity may dominate a given field, even a sole independent inventor can exert significant market power with a protective device such as a patent. A patentee can exert quality control through a patent. The control that a patent ensures may also help to police prices in the market. Other protective devices may also ensure these results.

Despite allegations to the contrary, a moratorium or a restriction on infringement remedies risks economic hardships. The popular belief is that a patentee of a new technique keeps prices high.<sup>338</sup> However, once a clinic or medical group establishes the price for a procedure, there is no guarantee that other physicians who oppose these medical patents will philanthropically help bring down the cost of health care. While a patentee may be able to affect a pricing level, recall that the Pallin patent brought down the price of cataract surgery.

Physicians without competition within a geographic area may infringe valid medical patents, disregard licensing terms, and charge whatever price the market will bear, even up to and beyond the patent holders instructed price. For the patent holder, the price represents recouping the original investment. For the "free rider," it represents pure profit. Hence, patents are a legal device which allows for cost control and access to quality health care in spite of their monopolistic attributes.

Most importantly, there are several reasons why the market power of any physician's patent is limited. Foremost, a patent is itself a limited monopoly. It is limited in many ways, most notably the duration of its term. While a particular invention may be excluded by the patentee, inevitably there are alternatives waiting to be discovered and utilized.

The patent system fosters invention in spite of exclusive

<sup>337</sup> SCHUMPETER, *supra* note 263, at 101.

<sup>338</sup> See Silvy A. Miller, *Should Patenting of Surgical Procedures and Other Medical Techniques by Physicians Be Banned?*, 36 IDEA J.L. & TECH. 255, 267 (1996).

rights.<sup>339</sup> The incentive to "invent around" a valid patent and develop functional substitutes is a policy embraced by the courts.<sup>340</sup> It must also be emphasized that within the Nation's health care system, the qualifications on medical patents are compounded by state and other regulatory requirements for the medical profession.

A patent's exclusive rights are also tempered in several other important ways, including, (1) the federal government's exercise of eminent domain rights; (2) the vast antitrust laws; and, (3) the ability of local governments to continue using equipment and facilities purchased with public funds even when patent infringement is found.<sup>341</sup>

From a political perspective, the "monopoly problem" in medicine, whether it be patents, the rise of HMOs, or the supply of care givers regulated by the states, is an issue yet to be fully explored by the government. It is important to emphasize that the protective devices of patents, trade secrecy, and contracts are limited by the Constitution, antitrust laws, and other regulations. Ultimately, one may safely conclude that our health care system encourages increased knowledge and a heightened quality of life, by sanctioning certain monopolistic protective devices as well as their strict regulation.<sup>342</sup>

---

<sup>339</sup> "[I]nstances of any situations where somebody obtains a patent ... [giving] them a real monopoly [are rare]... [A] patent ... stimulate[s] others to invent around it, to improve upon it, to find a different way to do the same thing, and it spurs competition rather than restricts competition." *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House of Representatives Comm. on the Judiciary*, 100th Cong. (1988) [hereinafter *Transgenic Hearings*].

<sup>340</sup> See *State Indus., Inc. v. A. O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."); see also *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 278 (Fed. Cir. 1985) (holding that patent holder's attempt to invent around its licensed patent did not justify enhancement of damages to licensee in licensee's patent infringement suit).

<sup>341</sup> Rohrbach, *supra* note 201, at 7-8. "Congress and the courts have heretofore regarded patentee's exclusive rights as essentially sacrosanct and have permitted their erosion, even to a very limited extent, only upon a clear showing of public interest of the highest order, but not to protect a private, commercial investment." *Id.* at 7.

<sup>342</sup> *Griffith Rubber Mills v. Hoffar*, 313 F.2d 1, 3 (9th Cir. 1963). "Patents are issued not for private benefit but for the public good; they grant a monopoly for a limited period as an incentive to the disclosure of innovations which in the end will add to the fund of freely available knowledge." *Id.* (citing *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330-31 (1945)); see also *Evr-Klean Seat Pad Co. v.*



## X. HEALTH ECONOMICS AND PATENT REFORMS

Changes in the United States patent code must take into account the Nation's traditional major federal policy objectives: innovation, disclosure, competition, and uniformity. Any changes must also seek to maximize certainty in the inventive and creative investment processes. Proponents of the moratorium on medical patents or infringement remedies contend that patents contribute to the Nation's health care costs.<sup>343</sup>

The medical profession has abandoned its prior advocacy of a moratorium on protection for medical devices and compounds. Yet it now takes the more radical and contradictory position concerning medical innovation. A patent moratorium on medical processes will result in trade secrecy becoming the only available method of protection. All of these practices imply monopolistic pricing, limiting patient care, and other ethically troubling outcomes.

Proponents of recent medical patent legislation search to maintain their eroding autonomy and insulate themselves from risk of lawsuits. While these motivations may be characterized as either politically prudent or intellectually impure, intellectual property policies and the Nation's health system may have been indiscriminately and unwittingly thrown back over 150 years. Unfortunately, the debate is filled with false claims that patents silence the dissemination of knowledge. Yet invention is the antecedent for disclosure. Severing the remedy from its corresponding right inevitably ties the hands of an inventor and frustrates the innovation process. The public health consequently suffers.

The health care system will be legally impacted by denying credible patent protection to medical processes. Medical innovation is hindered by insecure capital and heightened risk in the inventive process. Additionally, competition in the medical marketplace is obstructed through a loss of firms and innovation. Medical process patents could reduce costs as new simple procedures replace expensive devices and compounds.

---

Firestone Tire & Rubber Co., 118 F.2d 600, 602 (8th Cir. 1941) ("The patent law was not invented as a dam to divert natural changes and evolutionary progress in the arts into the laterals of monopoly.").

<sup>343</sup> See Lara L. Douglass, *Medical Process Patents: Can We Live Without Them? Should We?*, 3 J. INTELL. PROP. L. 161, 178 (1995) ("[T]he increase in price resulting from a monopoly is simply not as offensive in other industries as it is in the medical field.").

As an alternative to medical process patents, there will be a rise in outright trade secret protection for procedures. Protection of new techniques through state trade secret law will only lead to medical technology being secured under the dizzying crazy quilt of state trade secret law, which will hinder health care access through the legal and financial uncertainty of introducing medical breakthroughs from state to state.

Prior user rights, by contrast, serve the Nation's important policy objectives as a narrowly tailored solution addressing the aforementioned health care system concerns. Prior user rights promote certainty and hedge risk in legal and financial activity. Just as we have traditionally sought to protect the fruits of invention, in the future we must be certain to guard the root of the inventive process just as strenuously. Maintaining a strong, comprehensive intellectual property system, including medical patents, enhances the likelihood that future resources and inspiration will be invested in the innovation process.

While the patent system is criticized for distorting economic activity and undermining efficiency, this system can be improved.<sup>344</sup> Critics contend that the economic value of patents is lessened and the pursuit of applications is decreased as the lag time between filing and granting increases.<sup>345</sup> In a race to the patent office, firms may misallocate resources by trying to develop inventions too quickly, where the same result could be achieved by a more efficient resource allocation, greater independence, lower costs, and less intensive research efforts.<sup>346</sup> Ultimately, consumers bear this surcharge as firms restructure their output pricing due to the processing lag. Since intellectual property requires protective devices to guarantee a certain rate of advancement, not just merely progress, the cost and pricing advantages of prior user rights are worth considering.

When inventors invest less in research and development, the rate of invention in a society decreases. Slowed innovation puts individuals requiring medical care and expecting breakthroughs

---

<sup>344</sup> Eisenberg, *supra* note 64, at 1027 ("The patent system may divert too many resources away from productive activities in which returns are limited by the forces of competition ....").

<sup>345</sup> Sanders, *supra* note 75, at 70. This, added to the growing costs and uncertainty of patent litigation, rendering patent application less favorable. *Id.*

<sup>346</sup> Eisenberg, *supra* note 64, at 1027 (citing FREDERIC M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 379, 386-87 (Rand McNally, ed. 1970)).

at risk. Prior user rights help guarantee inventive development and maintain a societally optimal innovation rate; eviscerating medical patents does not.

Prior user rights alter the cost-benefit balance of the current patent system.<sup>347</sup> The use and price of patented inventions, and the related inventive risk, should be nearer the social optimum. Moreover, prices should be lower in a system with prior user rights because prior user rights interrupt patent exclusivity and hence, the patentee must share the market with the prior user right holders.

Finally, prior user rights offer an important economic advantage for the Nation's health care system: enhanced stability. Prior user rights are a stabilizing force hedging against the disruptive economic activity that occurs when a patent unexpectedly issues on technology already in use. Prior user rights also create more competitive markets in those areas involving patented medical inventions.

New medical technologies promise increased health, longevity, and an improved quality of life. The unforeseeable horizons and genius of modern medical research promise new treatments for cancer, Alzheimer's disease, and other congenital developmental disorders. The genius of these bright horizons must not be darkened by foreclosing the historical promise of our patent system.

#### CONCLUSION

The patent system is a broad legal instrument with policy objectives rooted in the Constitution. Some consider it merely a means to promote science and the arts.<sup>348</sup> Others view it as an economic device, affecting the nature of investment, risk, and commerce, simultaneously enriching both inventors and the public. Recently, Congress considered how the patent system should interact with the Nation's health care regime. While the patent system is flawed, critics and scholars cannot find its substitute.<sup>349</sup> The political process, while also imperfect, is clearly

<sup>347</sup> *Prior User*, *supra* note 190, at 85 (statement of R. Carl Moy).

<sup>348</sup> MANSFIELD, *supra* note 86, at 244. Patents further the constitutional goal, "[t]o promote the Progress of Science and useful Arts ...." U.S. CONST. art. I, § 8, cl. 8.

<sup>349</sup> MANSFIELD, *supra* note 86, at 244 (stressing social costs arising from monopolies and questioning importance of patents as incentives in modern economy).

the best forum to address the multiplicity of ethical, economic and societal issues at stake in this important debate.

Supporters concede that over the past 150 years, medical process patents have had a nominal effect on the delivery of health care in this country.<sup>350</sup> For example, the inventor of Surrogate Embryo Transfer (SET)<sup>351</sup> admits he has never attempted to enforce the patent. The individuals behind the rapid progress of science which improves the promise and value of health care delivery undoubtedly deserve broad protective devices, including effective rights and remedies.

In the larger debate on biomedical patents, groups have raised legitimate warnings that the "rapid pace of this technology is outstripping society's capacity for considered moral judgment."<sup>352</sup> The debate on medical patents has invoked fears of "wild-eyed scientists and Frankenstein monsters."<sup>353</sup> The gothic classic *Frankenstein* illustrates the dangers of secretive machinations involving the medical arts. The result is clearly disastrous. The moral, unfortunately, is not as obvious. The role of secrecy and rewards within the medical profession raises fundamental questions about the nature of our intellectual property policies.

In the modern film adaptation of *Frankenstein*,<sup>354</sup> Captain Walton eulogizes the Doctor by reading the following *Bible* passage:

And, yea, I gave my heart to wisdom, and to know madness and folly, and I perceived that all is vanity ... and vexation of spirit. For in much wisdom is much grief. And he who increaseth knowledge, increaseth sorrow. For god shall bring every work and every secret thing into judgment whether it be good or it be evil.<sup>355</sup>

Proponents of biomedical patents assert that the motivation is not to play God, but rather to play doctor and uphold the rev-

<sup>350</sup> Noonan, *supra* note 22, at 663. "In a few instances ... the availability of patent protection may have helped raise money to privately develop medical techniques." *Id.*

<sup>351</sup> The research to develop SET was financed with \$500,000 from private funding, which would not have been possible if the process was not patentable. Noonan, *supra* note 22, at 657.

<sup>352</sup> *Transgenic Hearings*, *supra* note 339, at 398.

<sup>353</sup> Gwen Roberts, *Opposition to Life Patents*, L.A. TIMES, May 29, 1995, at B12.

<sup>354</sup> MARY SHELLEY'S FRANKENSTEIN (Columbia TriStar 1994).

<sup>355</sup> *Id.*; see also *Ecclesiastes* 1:16-18.

erence for human life.<sup>356</sup> In the earthly realm, however, Congress remains the forum where the merits of medical patents will be judged. In doing so, all sides of this issue must be heard, not merely the fears and interests of any particular group.

In the future, Congress should restore all medical process patents rights and enact prior user rights. While this debate inevitably requires a review of the underpinnings of our intellectual property system and the Nation's major policy objectives, it is also an opportunity to improve the patent system for all users, including physicians and patients. Prior user rights are a narrowly tailored solution that temper frustration and pose economic and research benefits of their own, ensuring a smoother running patent system, lower prices, and new discoveries. The legislative process must be true to the Framers' vision. For certainly, what Congress prevents medical science from knowing will hurt the public.

---

<sup>356</sup> Edmund L. Andrews, *Religious Leaders Prepare to Fight Patents on Genes*, N.Y. TIMES, May 13, 1995, at 35 (comments of Lisa Raines). Religious leaders respond that an inherent tension underlies biomedical patents since the "[r]everence for all life created by God may be eroded by subtle economic pressures." *Transgenic Hearings*, *supra* note 339, at 398.