

# THE NEW PATENT INFRINGEMENT LIABILITY EXCEPTION FOR MEDICAL PROCEDURES

It would be really quite tragic if we were to find that a very large loophole were to be opened in the patent system that would cause investment in some of the most important technology-not from an economic point of view but from a life-saving point of view, to cause that investment to dry up.<sup>1</sup>

## I. INTRODUCTION

The current controversy over the patentability of medical procedures began in 1993 when Arizona ophthalmologist Samuel Pallin sued Dr. Jack Singer for infringing his patented cataract surgery procedure. Although Dr. Pallin lost his case,<sup>2</sup> many in the medical community became alarmed that medical procedure patents would inhibit the free flow of information among physicians and act to the detriment of the patients' best interests. The Medical Procedure Patents Coalition (MPPC)<sup>3</sup> subsequently commenced its effort to lobby Congress for legislation that would prohibit the patenting of medical procedures.

Congress responded in 1995 and 1996 by introducing legislation that would either ban medical procedure patents entirely or provide for a patent infringement liability exception for pure medical procedure patents.<sup>4</sup> These measures never passed, however, because they would have a crippling effect on the biotechnology industry. After reaching a compromise with the Biotechnology Industry Organization (BIO),<sup>5</sup> Congress tacked an amendment to the patent laws onto the 1997 Omnibus Consolidated Appropriations Act.<sup>6</sup>

This note examines the controversial medical procedure patent legislation in order to extract the fundamental policy issues and to provide a clear direction for future legislation. Part II surveys the legal and medical perspectives of medical procedure patents. Part III examines the unenacted 1995 medical procedure patent legislation, and Part IV examines the unenacted 1996 legislation. The new amendment to the patent

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1. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (quoting Bruce Lehman, Commissioner of Patents and Trademarks).

2. The district court of Vermont entered an unreported consent decree invalidating Dr. Pallin's patent claims at issue in the case. *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996). The decree did not specify reasons for the invalidation of Dr. Pallin's claims, but legislative history provides that the court found the technique was already in use. 142 CONG. REC. S11,847 (daily ed. Sept. 30, 1996) (dear colleague letter from Sen. Hatch).

3. The MPPC, led by the American Society of Cataract and Refractive Surgery, is composed of over fifteen medical specialty associations, including the American Medical Association.

4. H.R. 1127, 104th Cong. (1995), and the Ganske Amendment to H.R. 3814, 104th Cong. (1996), attempted to ban medical procedure patents. *See infra* notes 25, 38 and accompanying text. S. 1334, 104th Cong. (1995), provided for a patent infringement liability exception. *See infra* note 32 and accompanying text.

5. The BIO is a Washington-based group that represents almost 700 biotechnology companies and academic institutions. The biotechnology industry depends on patents to protect its large investments into the research and development of biomedical devices.

6. Pub. L. No. 104-208, 110 Stat. 3009 (1996), available in WESTLAW, 1996 HR 3610, at \*149-52. *See infra* note 52 and accompanying text.

laws is discussed in Part V.

## II. THE DEBATE OVER PATENTABILITY

### A. Constitutional and Statutory Basis for Medical Procedure Patents

The primary issue that confronts the legal community is whether medical procedure patents are legal. Medical procedure patents, as with patents in general, derive their legality from U.S. patent laws. Congress derives the power to pass these laws directly from the Constitution.<sup>7</sup> Under the patent laws, an inventor may obtain a patent if the invention is useful, novel, and non-obvious.<sup>8</sup> Medical procedures, as methods, are patentable subject matter under the patent laws.<sup>9</sup> As an indication of this, the Patent and Trademark Office (PTO) has permitted the issuance of medical procedure patents for over forty years.<sup>10</sup> And the U.S. Supreme Court has emphasized that contentions over patentable subject matter should be addressed by the Congress and the Executive, not by the courts.<sup>11</sup> Since current law allows the issuance of medical procedure patents, they are presumptively valid.<sup>12</sup>

### B. Concerns in the Medical Community

#### 1. Health Care Costs

One of the largest concerns in the medical community is that more frequently litigated medical procedure patents will increase health care costs, thus restricting patient access to medical care.<sup>13</sup> Opponents of medical procedure patents claim that

7. U.S. CONST. art. I, § 8, cl. 8. Congress shall have the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id.*

8. 35 U.S.C. §§ 101-103 (1996). 35 U.S.C. § 101, codifying the utility requirement, states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 102(a), codifying the novelty requirement, states that "[a] person shall be entitled to a patent unless . . . 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." 35 U.S.C. § 103(a), codifying the non-obvious requirement, states that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

9. 35 U.S.C. § 100 defines the term "process" as a "process, art or *method*." (Emphasis added). Therefore, medical procedures, as methods, fall within the statutory subject matter for patents.

10. In *Ex Parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954), the board expressly overruled an earlier decision that implied that all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body. For a listing of many medical and surgical procedure patents issued by the PTO, see William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 657-60 (1995).

11. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980). The Supreme Court nevertheless affirmed the wide scope of the patent laws by holding genetically engineered bacterium patentable. *Id.* at 318. For a contrasting view on the patentability of medical procedures, see Lara L. Douglass, *Medical Process Patents: Can We Live Without Them? Should We?*, 3 J. INTEL. PROP. L. 161, 174-77 (1995) (arguing that medical processes, like computer software programs, should be denied patent protection because they are created by building on incremental steps and by definition are obvious).

12. 35 U.S.C. § 282 (1996) explicitly states that "[a] patent shall be presumed valid."

13. The rate at which medical procedure patents are being issued has increased (currently the PTO issues about 15 of these patents a week), and the vigor with which these patents are being enforced

health care costs will rise because rural physicians, who may be unable to spread the license fee across enough cases to make it economically feasible, will therefore be forced to charge a higher fee for the patented procedure.<sup>14</sup> Proponents of medical procedure patents, citing one of the basic justifications for all patents, counterclaim that royalties are justified where most of the costs for development and marketing are funded by private interest groups, who would not have invested had it not been for the possibility of profiting from the licensing of the patented technology.<sup>15</sup> Although most medical funding is directed toward the development of drugs and medical devices and not pure medical procedures,<sup>16</sup> any increase in health care costs due to patent protection for medical procedures will most likely be minimal when compared to the increase due to the amount of litigation that often surrounds the medical community.

## 2. Best Interests of Patients

In addition to spiraling health care costs, the medical community is concerned about the fiduciary duty of physicians to act in the best interests of their patients. Opponents contend that physicians will resist using a better-suited procedure if they can avoid paying a licensing fee on the better alternative.<sup>17</sup> Proponents respond by asserting that physicians have the duty to inform their patients of all options, including superior patented methods. This leaves the decision to the patients whether they want to proceed with the alternative method, and better protects the physicians from malpractice suits if the patients forego this alternative since the physicians have not violated any duties owed to the patients.<sup>18</sup> So the patentability of medical procedures will hinder the fiduciary duty of physicians to act in the best interests of their patients only if the physicians place their personal financial interests above their responsibilities to the

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appears to have escalated dramatically in recent years. *Hearing on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. (1995), available in 1995 WL 615751, at \*9, \*12-13 (testimony of Dr. Charles D. Kelman, President, American Society of Cataract and Refractive Surgery). However, no evidence shows that the number of enforcement actions is beyond the normal range expected of protective litigation.

14. Silvy A. Miller, *Should Patenting of Surgical Procedures and Other Medical Techniques by Physicians Be Banned?*, 36 IDEA 255, 267 (1996).

15. *Id.* In some instances, the efficiency of a patented medical procedure may actually reduce the overall cost of an operation, even after the licensing fee is imposed. For instance, any doctor utilizing Dr. Pallin's patented cataract surgery procedure would pay a license fee of \$3 to \$4 per operation, but would save \$17 due to the efficiency of the procedure. *Id.* at 268.

16. Some medical procedures, however, may require patent protection in order to recoup investment costs. For example, the Surrogate Embryo Transfer (SET) technology of the 1980s is a medical procedure that synchronizes ovulation between an embryo donor and recipient, inseminates the donor woman with sperm, lavages the donor uterus to recover the embryo, and transfers the embryo to the recipient's uterus. The research that developed this procedure was financed with \$500,000 of venture capital because the National Institute of Health would not fund the research; it seems unlikely that the inventor of the SET procedure would have gotten this private funding if the process was not patentable subject matter. See Noonan, *supra* note 10, at 656-57.

17. Joseph M. Reisman, *Physicians and Surgeons As Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355, 371 (1995). The California Supreme Court faced a similar situation when university physicians violated their fiduciary duty to their patient on account of a medical patent. Because the physicians used bodily samples from their patient, without consent, for research that led to a medical patent, the court held that the physicians, in order to satisfy their fiduciary duty and to obtain the patient's informed consent, must disclose their research interest because it may affect their medical judgment. *Moore v. Regents of the University of California*, 793 P.2d 479, 485 (Cal. 1990). Courts have not decided whether the fiduciary duty of full disclosure would require physicians to inform patients of other physicians' patented procedures or those held personally.

18. Miller, *supra* note 14, at 263.

medical profession.

### 3. Accessibility of Medical Research

The medical community also fears that medical procedure patents will restrict the traditionally free flow of information to other physicians. This ideal is embodied in the American Medical Association's (AMA) ethical code, which encourages physicians to share the benefits of their work with their colleagues and condemns the intentional withholding of new medical knowledge for reason of "personal gain."<sup>19</sup>

In accordance with this ideal, physicians and some medical associations believe that patenting, rather than publishing, medical discoveries slows the release of this information to the community.<sup>20</sup> They fail to consider, however, that publication of a newly-discovered medical process can occur immediately, with no effect upon the patentability of the process, so long as the application is filed within a year of initial disclosure.<sup>21</sup> Furthermore, the entire purpose of the patent system is to disclose new inventions to the community in return for exclusive rights of use for twenty years.<sup>22</sup>

Others argue that "opportunistic inventors, by utilizing freely available medical information, may claim ownership over procedures that others developed and willingly contributed to the medical profession."<sup>23</sup> The proponents of this argument also misunderstand the inherent nature of the patent system. The patentability requirements of novelty and non-obviousness, coupled with the fact that anyone may challenge the validity of an issued patent at any time, would prevent the stealing of inventions.<sup>24</sup> Thus, the patent system has built-in safeguards to protect the medical community's tenet to share medical research.

## III. UNENACTED 1995 LEGISLATION

### A. House Bill 1127

On March 3, 1995, Representatives Greg Ganske (R-Iowa) and Ron Wyden (D-Or.) introduced the first significant legislation pertaining to medical procedure patents. Their legislation, the Medical Procedures Innovation and Affordability Act,<sup>25</sup> would

19. See Reisman, *supra* note 17, at 369.

20. Jeffrey A. Taylor, *Medical Process Patents and Patient Privacy Rights*, 14 J. MARSHALL J. COMPUTER & INFO. L. 131, 138 (1995).

21. 35 U.S.C. § 102(b) (1996). This is known as the *public use or on-sale bar*, which states that a patent may not issue if "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." *Id.*

22. Patents are contracts "made by the acceptance by the government of the offer which the patentee by his application makes to *disclose* his invention, in consideration that the United States will secure to him the exclusive use and sale of it for [20] years." *Century Elec. Co. v. Westinghouse Elec. & Mfg.*, 191 F. 350, 359 (8th Cir. 1911) (emphasis added). 35 U.S.C. § 154(a)(2) (1996) sets the patent term "beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed."

23. Joel J. Garris, *The Case for Patenting Medical Procedures*, 22 AM. J.L. & MED. 85, 97 (1996).

24. 35 U.S.C. §§ 102-103 (1996). See *supra* note 8.

25. H.R. 1127, 104th Cong. (1995). The following bill, introduced by Reps. Ganske and Wyden, was referred to the House Judiciary Committee:

#### SECTION 1. SHORT TITLE.

This Act may be cited as the 'Medical Procedures Innovation and Affordability Act'.

#### SEC. 2. LIMITATION ON ISSUANCE OF PATENTS.

have prohibited the issuance of patents for new medical procedures except as a necessary component of a patentable medical device or machine. The standard of patentability proposed by this Act resembled the standard in the European Patent Convention.<sup>26</sup> The AMA worked with the MPPC to influence the passage of this legislation.

Rep. Ganske asserted that patent protection is not necessary to encourage the development of innovative medical procedures because medicine develops through a process of "'evolution' not 'revolution.'"<sup>27</sup> However, he failed to realize that the 1952 Patent Act explicitly refuted this argument with its formulation of the non-obvious requirement of patentability.<sup>28</sup> Rep. Ganske further claimed that medical procedure patents prevent innovative surgical techniques from becoming widespread, and consequently, that these patents "only serve to limit physicians' options and to deny patients access to the best possible medical care."<sup>29</sup> The PTO opposed this legislation, arguing that "it would threaten the patent system's incentives to develop and share useful medical advances."<sup>30</sup> Both intellectual property law practitioners and biotechnology industry representatives "shared the PTO's concern about the breadth of the Act's patent prohibitions."<sup>31</sup> The bill died in committee.

#### B. Senate Bill 1334

In response to concerns that the House proposal might deny patent protection for biotechnology companies, Senator Bill Frist (R-Tenn.) introduced similar legislation under the same title on October 18, 1995.<sup>32</sup> The language in this bill "would have

On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process.

*Id.*

26. Reisman, *supra* note 17, at 360. The European Patent Convention allows the issuance of patents for distinct products having medical uses, but not for surgical or therapeutic processes. *Id.*

27. *Id.* at 361.

28. Prior to the 1952 Patent Act, the common law held that "[a] new device, however useful it may be, must reveal the flash of creative genius not merely the skill of the calling." *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941). This precedent embodies the ideal that a patent should reward *revolution*, not *evolution*, as Rep. Ganske asserts. However, the 1952 Patent Act created the non-obvious requirement of patentability in 35 U.S.C. § 103, which states, in part, that "[p]atentability shall not be negated by the manner in which the invention was made." 35 U.S.C. § 103(c) (1996). In applying this statute, the Supreme Court subsequently held that "[i]t also seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase 'flash of creative genius.'" *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966) (citation omitted). As a result, all patents since the 1952 Patent Act have rewarded *evolution* along with *revolution*.

29. Reisman, *supra* note 17, at 361.

30. *Bill with PTO Funding and Patent Reform on Medical Procedures Is Signed into Law*, Pat. Trademark & Copyright L. Daily (BNA), at D-5 (Oct. 7, 1996), available in WESTLAW, 10/7/96 PTD d5, at \*2.

31. *Id.*

32. S. 1334, 104th Cong. (1995). The following bill, introduced by Sen. Frist, was referred to the Senate Judiciary Committee:

##### SECTION 1. SHORT TITLE.

This Act may be cited as the 'Medical Procedures Innovation and Affordability Act'.

##### SEC. 2. NONINFRINGEMENT USE.

Section 271 of title 35, United States Code, is amended by adding at the end

created an infringement liability exemption at § 271(j)(1) of Title 35 for patients, physicians, other licensed health professionals and health care entities using patented medical techniques.”<sup>33</sup> Under this legislation, inventors would have the right to enforce their medical procedure patents against a company that profited by selling software describing their techniques, for instance, but would not be permitted to sue individual physicians who used the procedures.<sup>34</sup> Moreover, this bill would “not exempt those engaged in the commercial manufacture of drugs or medical devices regulated by the Food and Drug Administration (FDA).”<sup>35</sup>

Although the Senate proposal originated as a compromise with the biotechnology industry, the BIO wanted language included in the bill that “compromised the MPPC’s goals even further.”<sup>36</sup> However, the MPPC would not make further concessions.<sup>37</sup>

thereof the following new 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. This section does not apply to the use of, or inducement to use, such a patented technique, method, or process by any person engaged in the commercial manufacture, sale, or offer for sale of a drug, medical device, process, or other product that is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(2) For the purposes of this subsection—

(A) the term ‘device’ has the same meaning as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h));

(B) the term ‘drug’ has the same meaning as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g));

(C) the term ‘health care entity’ means a for-profit or nonprofit entity that provides health care services, including a hospital, medical school, health maintenance organization, group medical practice, or a medical clinic;

(D) the term ‘licensed health care practitioner’ means an individual other than a physician who is licensed by a State to provide health care services;

(E) the term ‘patient’ means an individual who uses a patented technique, method, or process to self-administer a medical procedure, therapy, or method of diagnosis prescribed or recommended by a physician or other licensed health care practitioner;

(F) the term ‘physician’ means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State;

(G) the term ‘product’ means a machine, manufacture, or composition of matter or improvement thereof;

(H) the term ‘professionally affiliated with’ includes privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which the physician or licensed health care practitioner provides health care services (including teaching or instructional services) on behalf of or in association with a health care entity; and

(I) the term ‘State’ means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

*Id.*

33. Pat. Trademark & Copyright L. Daily, *supra* note 30. The infringement liability exception means that the PTO can issue patents on medical procedures, but the inventors may not recover damages against the patients, physicians, etc. who infringe the patents.

34. Kevin Murphy, *Procedure Patent Bills Face Hefty Opposition*, OCULAR SURGERY NEWS, Dec. 15, 1995, at para. 3 <<http://www.slackinc.com/eye/osn/199512b/washup.htm>>.

35. Pat. Trademark & Copyright L. Daily, *supra* note 30.

36. Murphy, *supra* note 34, at para. 4.

37. *Id.*

Thus, this bill similarly died in committee.

#### IV. UNENACTED 1996 LEGISLATION

##### A. Ganske Amendment to House Bill 3814

On July 24, 1996, Rep. Ganske incorporated into fiscal year 1997 appropriations legislation an amended version of his original proposal that would have cut the PTO's funding for issuing patents for new medical procedures except as a necessary component of a patentable medical device or machine.<sup>38</sup> He reasserted that "[p]hysicians do not need incentives provided by patent law as a stimulus to innovation," and further maintained that "the Patent Office is ill-equipped to evaluate the novelty of medical procedures."<sup>39</sup> In opposition, Representative Charlie Norwood (R-Ga.) voiced his concern that such patents may "forc[e] providers into using less advanced procedures because they want to avoid the additional costs of using the patented procedure."<sup>40</sup>

Rep. Ganske nevertheless set out five explicit reasons for the Members' support:

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. . . .

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

38. 142 CONG. REC. H8276 (daily ed. July 24, 1996). Rep. Ganske offered the following amendment on the House floor:

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).

(b) EXCEPTIONS.—The limitation established in subsection (a) shall not apply to the issuance of a patent when it is made known to the Federal official having authority to obligate or expend such funds that—

(1) the patent is for a machine, manufacture, or composition of matter, or improvement thereof, that is itself patentable subject matter, and the technique, method, or process referred to in subsection (a) is performed by or is a necessary component of the machine, manufacture, or composition of matter; or

(2) the patent is for a new use of a composition of matter or biotechnological process.

*Id.*

39. 142 CONG. REC. H8277 (daily ed. July 24, 1996) (statement of Rep. Ganske). Rep. Ganske based his assertion concerning the capability of the Patent Office solely on his experience "as a physician for 20 years." *Id.*

40. 142 CONG. REC. E1389 (daily ed. July 26, 1996) (statement of Rep. Norwood).

in granting monopoly rights to these procedures.<sup>41</sup>

Opponents did not object to the basic thrust of the legislation. They voiced substantive concerns in two peripheral areas: that this amendment bypasses the proper legislative channels and that the PTO may have an alternative administrative solution.<sup>42</sup> First, Representative Hal Rogers (R-Ky.) criticized Rep. Ganske for "bypass[ing] the authorization process by tacking this legislation onto this appropriations bill."<sup>43</sup> Representative Anna Eshoo (D-Cal.) agreed, explaining that a bill should be brought to the House for consideration only after hearings are held, testimony is taken, and subcommittee and full committee "have the opportunity to mark up [the] legislation."<sup>44</sup> Rep. Rogers further emphasized that this amendment "strip[s] the Judiciary Committee of its jurisdiction over this issue."<sup>45</sup> Second, Rep. Rogers noted that the PTO had been conducting public hearings on issues related to patenting of medical procedures, and that there was a very good chance that the PTO could "address the issues raised by the legislation by modifying their internal, administrative procedures."<sup>46</sup> However, by the time Rep. Ganske introduced his amendment, the PTO had not resolved this issue administratively.

The biotechnology industry continued to oppose the reform, believing that it would "undermine the patenting of gene therapy treatments."<sup>47</sup> This bill overwhelmingly passed in the House, but died in the Senate.

### B. Senate Bill 2105

On September 24, 1996, Sen. Frist introduced a bill that struck a balance between the proposed Ganske amendment and representatives of the biotechnology and pharmacology industries.<sup>48</sup> Sen. Frist recognized that pharmaceuticals and medical

41. Ganske, *supra* note 39. Britain, France, and Israel, as well as countries like South Africa, Colombia, and Saudi Arabia, are among those that expressly prohibit medical patents. 142 CONG. REC. E1389 (daily ed. July 26, 1996) (statement of Rep. Norwood).

42. See 142 CONG. REC. H8277, H8279 (daily ed. July 26, 1996).

43. 142 CONG. REC. H8277 (daily ed. July 24, 1996) (statement of Rep. Rogers).

44. 142 CONG. REC. H8279 (daily ed. July 24, 1996) (statement of Rep. Eshoo).

45. Rogers, *supra* note 43.

46. *Id.*

47. Pat. Trademark & Copyright L. Daily, *supra* note 30, at \*3. The biotechnology industry opposed the reform despite Rep. Ganske's explicit assertion that this amendment does not prohibit patents on gene therapy or other similar procedures. Ganske, *supra* note 39. However, Rep. Dooley stated that the broad implications of this amendment's language threaten to invalidate up to one-third of all the biotechnology patents in the United States. This would halt development of gene therapies which could find cures for such diseases as cystic fibrosis, AIDS, and Alzheimer's. 142 CONG. REC. H8278 (daily ed. July 24, 1996) (statement of Rep. Dooley).

48. 142 CONG. REC. S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist). The following bill, introduced by Sen. Frisk, was referred to the Senate Judiciary Committee:

**SECTION 1. LIMITATION ON PATENT INFRINGEMENTS RELATING TO A MEDICAL PRACTITIONER'S PERFORMANCE OF A MEDICAL ACTIVITY.**

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

(2) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code of 1986), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a



devices require patent protection in order to attract capital for critical research and development.<sup>49</sup> However, he worried that allowing health professionals to be sued for using innovations in pure medical or surgical procedures would have four disastrous consequences:

First, health care costs would explode if doctors charged licensing fees for every new surgical or medical techniques they developed. . . .

Second, it would greatly jeopardize patients' right to privacy. In order to know if a patent was infringed upon, patent holders could demand access to surgical notes and other detailed medical records to know precisely what kinds of procedures were used. . . .

machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than laboratory services provided in a physician's office), if such activities are—

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office); and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(3) For purposes of this subsection:

(A) The term 'body' means—

(i) a human body, organ, or cadaver; or

(ii) a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(B) The term 'medical activity' means the performance of a medical or surgical procedure on a body, but shall not include—

(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent;

(ii) the practice of a patented use of a composition of matter in violation of such patent; or

(iii) the practice of a process in violation of a biotechnology patent.

(C) The term 'medical practitioner' means any natural person who is—

(i) licensed by a State to provide the medical activity described under paragraph (1); or

(ii) acting under the direction of such natural person in the performance of the medical activity.

(D) The term 'patented use of a composition of matter' does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter if the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

(E) The term 'professional affiliation' means staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides a medical activity on behalf of, or in association with, a health care entity.

(F) The term 'related health care entity'—

(i) means an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs a medical activity; and

(ii) includes without limitation such an affiliation with a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(G) The term 'State' means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(4) This subsection shall not apply to any patent issued before the date of enactment of this subsection.

S. 2105, 104th Cong. (1996).

49. Frist, *supra* note 48.

Third, allowing pure procedure patents would undermine the medical community's tradition-and ethical duty-of freely exchanging information for the benefit of patients.

Fourth, it will open the door to FDA regulation of all aspects of medical practice [instead of the current regulation of only medical devices and pharmaceuticals].<sup>50</sup>

This bill likewise never made it out of the Senate.

## V. THE NEW LAW

### A. The 1997 Omnibus Consolidated Appropriations Act

On September 30, 1996, the President signed into law an almost identical version of Rep. Frist's most recent bill,<sup>51</sup> which appeared as § 616 in the 1997 Omnibus Consolidated Appropriations Act.<sup>52</sup> The medical procedure reform creates a new subsec-

50. 142 CONG. REC. S12,023-24 (daily ed. Sept. 30, 1996) (statement of Sen. Frist). The response to those who have advocated comprehensive FDA regulation of medical practice has been that checks and balances, such as the peer review process, already exist to assure that patients receive appropriate care. Sen. Frisk argued that if Congress undermines the peer review process by injecting patent-seeking into the practice of medicine, then it will have opened the door for proponents of more expansive FDA regulation. *Id.* at S12,024.

51. S. 2105, 104th Cong. (1996).

52. Pub. L. No. 104-208, 110 Stat. 3009 (1996), available in WESTLAW, 1996 HR 3610, at \*149-52. The law provides the following:

SEC. 616. LIMITATION ON PATENT INFRINGEMENTS RELATING TO A MEDICAL PRACTITIONER'S PERFORMANCE OF A MEDICAL ACTIVITY.

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

(2) For the purposes of this subsection:

(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

(B) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term "professional affiliation" shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.

(E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of

tion (c) at 35 U.S.C. § 287, which is the patent laws' provision of damages limitations. The new law deprives patentees of remedies for infringement by a medical practitioner's performance of a medical activity, absent exceptions.<sup>53</sup> The biotechnology industry, which had insisted upon patent protection for gene therapy treatments, accepted this legislation because it allows remedies where the claim in a patented use of a composition of matter contributes to the novelty of the claimed method.<sup>54</sup>

## B. Opposition to the New Law

This new law produced an enormous amount of opposition with two primary concerns. The first concern is that no emergency need exists for this legislation. In the case that spawned this controversy, the patent system worked.<sup>55</sup> And the inherent nature of the patent system resolves most, if not all, of the concerns raised by those in the medical community.<sup>56</sup> The second concern addresses the underhanded manner in which this new law passed. By tacking this legislation onto an appropriations bill, the appropriate committees never received the opportunity to hold hearings and vote on issues like whether this patent infringement liability exception is necessary or violates certain international treaties. The following subsections examine the viewpoints of the primary authorities in opposition to this new law.

### 1. Clinton Administration

The Commerce Department opposes the new law, stating that "it is premature to adopt such drastic steps when" the PTO may utilize "administrative measures to mitigate the problem."<sup>57</sup> The PTO similarly opposes the new law. Bruce Lehman, commissioner of the PTO, warns that "[t]his could be a case of overreaction to a specific circumstance," and that "it is important not to kill the goose that lays the golden egg, that is, the incentive for medical research." Commissioner Lehman explains that

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matter does not directly contribute to achievement of the objective of the claimed method.

(G) the term "State" shall mean any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(4) This subsection shall not apply to any patent issued before the date of enactment of this subsection.

*Id.* See appendix for legislative history.

53. *Id.*

54. *Id.* at \*1922.

55. *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996). See *supra* note

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56. See *supra* Part II(b).

57. 142 CONG. REC. S11845 (daily ed. Sept. 30, 1996) (dear colleague letter from Sen. Hatch).

"[t]here is no requirement that patent applications be filed," and that "[h]istorically, surgical procedures are not patented. When they are patented, it is usually . . . required as part of a business plan to attract the necessary capital for research and development." Commissioner Lehman also declares that the United States would not have "the medical and pharmaceutical industry that leads the world if it weren't for the patent system."<sup>58</sup>

## 2. American Intellectual Property Law Association (AIPLA)

In addition, the AIPLA contends that the proponents have failed to demonstrate a need for the new law. A specific area of concern is that the new law "will proclaim an open season for exceptions to patent protection to address other alleged problems."<sup>59</sup> The AIPLA also mirrors the United States Trade Representative's concern that the U.S. would take the lead in weakening the patent protection required under the Agreement on Trade-Related Aspects of Intellectual Property Rights, which is administered by the World Trade Organization under the General Agreement on Tariffs and Trade Uruguay Round Agreement (GATT-TRIPs). This in turn would harm the interests of American industry.<sup>60</sup>

## 3. American Bar Association (ABA) Section of Intellectual Property Law

On a further note, the ABA Intellectual Property Law Section opposes the new law because it violates the fundamental principle of law under which patent protection is available without discrimination as to field of invention of technology. The infringement liability exemption approach is "doubly discriminatory in that it would achieve this result by discriminatory treatment based on the identity or profession of the infringer."<sup>61</sup> The ABA also raises several concerns which have not been examined by any committee of Congress. These concerns include the negative impact on America's world leadership in scientific and technological development, the international impact of making this change to accommodate narrow domestic interests, and the unworkability and ineffectiveness of the new law.<sup>62</sup>

## 4. United States Trade Representative (USTR)

The USTR also has serious concerns about the consistency of the new law with GATT-TRIPs.<sup>63</sup> Since the new law allows an infringement liability exception, other

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58. *Id.*

59. *Id.* at S11846.

60. *Id.*

61. *Id.* (letter from John R. Kirk, Jr., chair of the American Bar Association).

62. *Id.*

63. 142 CONG. REC. S11,843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, general counsel to the office of the U.S. Trade Representative). Ms. Hillman wrote the following:

Although TRIPs Article 27:3 permits Members to exclude diagnostic, therapeutic and surgical techniques from patentability, we believe that if a member makes patents available for this field of technology, a Member must accord the full rights required under the TRIPs Agreement. Article 27:1 requires that patent rights be enjoyable without discrimination as to the field of technology. Those rights are specified in Article 28 and include the right to prevent third parties from the act of using a patented process. Moreover, TRIPs Articles 44 and 45 specify remedies, including injunctions and damages; [sic] that must be made available to address patent infringement.

While TRIPs Article 30 permits Members to provide limited exceptions to the exclusive rights conferred by a patent, such exceptions must not unreasonably conflict with the normal exploitation of the patent and must not unreasonably prejudice the legitimate

GATT-TRIPs members might follow this example and apply this type of exception to other technologies.<sup>64</sup>

### 5. Intellectual Property Owners (IPO)

On the industry side, the IPO represents companies and inventors who own patents, copyrights and trademarks in all fields. The IPO claims that the new law will harm members of its association who presently invest in medical research. Moreover, the IPO asserts that attorneys and the PTO will spend enormous amounts of money "litigating the scope of the amendment, adding to the already too high cost of obtaining and enforcing patents."<sup>65</sup>

### 6. Chairmen of Senate Committees on the Judiciary and Finance

In Congress, Senator Orrin Hatch (R-Utah), chairman of the Senate Committee on the Judiciary, opposes the new law. He currently deals with all of the statutes under the Committee's primary jurisdiction, which includes the patent laws. For this reason he is extremely disappointed that the new law "circumvents the normal Committee process by misusing the appropriations mechanism to amend a highly technical and very complex area of substantive patent law."<sup>66</sup> He also asserts that the case for changing the patent law has not been made.<sup>67</sup> Ironically, in the case that precipitated

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interests of the patent holder. Precluding the grant of damages and injunctive relief for patent infringement under the circumstances set forth in the proposed legislation, goes far beyond other exceptions provided in title 35 and raises questions about whether the exception is covered by Article 30.

*Id.*

64. *Id.* at S11,844. Additionally, Sen. Hatch warns that U.S. obligations under GATT-TRIPs are highly significant. "Virtually every trade expert believes that worldwide adherence to [GATT-TRIPs] means jobs for American workers and lowered costs for American consumers as piracy of products is reduced and others pay their fair share of research and development costs." 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch).

65. 142 CONG. REC. S11,846 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch). The ABA similarly believes that the new law might increase litigation and litigation costs, through a combination of failure to reduce existing litigation and additional litigation over the meaning and effort of the legislation itself. *Id.* (letter from John R. Kirk, Jr.). The chair of the ABA wrote the following:

One key exception in the proposal, relating to patented use of a composition of matter, provides that the exception does not apply to such use unless the use "directly contribute(s) to achievement of the objective of the claimed method." This is clearly an issue which is fact bound to a high degree, and not one that is likely to be resolved at the pleadings or motion stages of litigation. Proponents of the Coalition proposal suggest that legislative history can be treated to establish legislative intent that these fact intensive questions can be decided by motion to dismiss or summary judgment. However, legislative history accompanying amendments to title 35 are unlikely to be found to be controlling legislative intent regarding application of Rules of Civil Procedure which are unchanged by the legislation, particularly when the intent expressed is in conflict with the express language of the Rules themselves. (The Coalition suggests that a movant for summary judgment under Rule 56 may prevail by showing by a "preponderance of evidence" that certain essential facts exist. However, Rule 56 states that such a motion may be rendered only if "there is no genuine issue as to any material fact").

*Id.* at S11,846-47.

66. 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (dear colleague letter from Sen. Hatch). Sen. Hatch contends that "[t]his is precisely the type of non-germane amendment that Senators Hatfield and Byrd and others have admonished the Senate not to incorporate within this type of omnibus appropriations vehicle." *Id.*

67. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch). Sen. Hatch insists that "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." 142 CONG. REC. S11,844 (daily ed. Sept. 30,

the current controversy, the Pallin cataract surgery procedure case, the patent system worked and the courts have not enforced the patent.<sup>68</sup> Sen. Hatch maintains that “[t]he patent laws should not be changed on the basis of anecdotal evidence” such as the Pallin case.<sup>69</sup> He urges Congress’s careful consideration before it takes away the rights of individual inventors by not allowing enforcement against patent infringement by multi-million dollar corporations such as health maintenance organizations.<sup>70</sup>

Because the new law implicates U.S. obligations under GATT-TRIPs, it falls under the Finance Committee’s jurisdiction on international trade agreements. Senator William Roth (R-Del.), chairman of the Senate Committee on Finance, strongly opposes the new law because it may not comply with GATT-TRIPs.<sup>71</sup> The Finance Committee has not even had “an opportunity to hold a hearing on this matter to consider these broader ramifications for U.S. trade policy.”<sup>72</sup> And if the new law has “unwittingly misinterpreted” the TRIPs accord, Sen. Hatch has no doubt that then Congress will look to the Finance Committee for an explanation.<sup>73</sup>

## VI. CONCLUSION

Congress recently amended the patent laws to insulate medical practitioners and health care entities from patent infringement liability for pure medical procedures. This legislation addressed the concerns of many in the medical community who have a deep interest in preserving manageable health care costs, the best interests of patients, and the free flow of information among physicians. Although the inherent nature of the patent system resolves most, if not all, of these issues, this new law nevertheless degrades the system that has established the United States as the leader in medical and pharmaceutical technology.

An even greater injustice is that Congress tacked this highly controversial legislation onto an end-of-the-term appropriations bill, after previous attempts to pass similar legislation through the appropriate committees had failed. By not sending this legislation through the appropriate channels, Congress displayed a serious lack of legislative integrity. No emergency need justified its hasty passage, and no hearings were held to examine the domestic and international ramifications of this new law.

Congress should reconsider this new law by reintroducing the medical procedure legislation to the appropriate committees.

*Bradley J. Meier\**

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1996) (statement of Sen. Hatch).

68. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch).

69. *Id.*

70. *Id.* Sen. Hatch also warns that due to the “overall federal budgetary pressures” constraining the growth of the National Institute of Health’s funding, this may not be the proper time “to decrease private sector incentives to invest in certain types of biomedical research.” 142 CONG. REC. S11,847 (daily ed. Sept. 30, 1996) (dear colleague letter from Sen. Hatch).

71. 142 CONG. REC. S11,843 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch and Sen. Roth).

72. *Id.*

73. 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch).

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## APPENDIX

The House Conference Report, H.R. CONF. REP. NO. 104-863, at 852-55 (1996), provides the following legislative intent for the new law:

Sec. 616.-The conference agreement includes section 616, which includes language not in either the House or Senate-reported bill, that addresses the subject included in the House bill as section 619 and deleted by the Senate-reported bill. The provision included in this conference agreement precludes the filing of civil action for damages or injunctive relief against a medical practitioner licensed by the State to provide the medical activity or related health care entity who performs a medical activity that would otherwise constitute an infringement or inducement to infringe under 35 U.S.C. 271(a) or (b) for patents issued after its enactment.

The term "medical activity" as defined in subsection 287(c)(2)(A) does not include "the practice of a patented use of a composition of matter." The term "patented use of a composition of matter" as used in subsection (c)(2)(A)(ii) is limited by subsection (c)(2)(F). Subsection (c)(2)(F) provides that the term "patented use of a composition of matter" does not include any claim for performing a medical or surgical procedure on a body that recites the use of the composition of matter where the use of the composition of matter does not directly contribute to the achievement of the objective of the claimed method. A use of a composition of matter as a step in a claim will direct contribute to the achievement of the objective of the claimed method if it is itself novel or if it contributes to or is necessary to establish the non-obviousness of the claim as a whole.

For a method claim in which each of the method steps recites a "use of a composition of matter" the claim cannot represent a "medical activity" because the use of a composition of matter must necessarily contribute to the novelty-and, therefore, to the objective-of the claimed method. "Uses of compositions of matter" include, without limitation, novel uses of drugs, novel uses of chemical or biological reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs, novel methods for combining drug therapies, and novel methods for providing genetic or other biological materials to a patient (including gene therapies.) A particular example would be a claim that recites only the novel use of a drug for the treatment of diabetes that involves the administration of a drug at a particular time of day and/or at a specified dose and/or with a specified concomitant medicinal therapy could not be construed as a "medical activity."

For a "hybrid" claim, ie., a claim with at least one step that recites the use of a composition of matter and at least one step that is not directed to the use of a composition of matter (e.g., a surgical step), the test established by subsection (c)(2)(F) must be applied to determine whether the claim as a whole is exempted from the definition of a "medical activity" because it is a patented use of a composition of matter. The first step in this test is to determine the objective of the claimed method taking into account all of the process steps set forth in the claim. The second part of this test is to determine whether the steps involving the use of one or more compositions of matter either alone or in combination contribute directly to the achievement of the objective of the claimed method. It is interested that this part of the test will have been met if the uses of the compositions of matter, either individually or collectively, represents novel subject matter, or if one or more of these steps contributes to or are necessary to establish the non-obviousness of the claim as a whole. Thus, even where the steps involving uses of one or more compositions of matter are not novel individually or in combination with each other, these uses may still directly contribute to the achievement of the objective of

the claimed method if, in combination with the steps that involve collectively obvious medical or surgical techniques, they produce a novel and non-obvious method.

As an example, in the case of a surgical method for transplanting a healthy heart into a patient with a diseased heart, the inclusion of the step administering a conventional anaesthetic in a claim reciting a novel and non-obvious surgical transplantation procedure would not cause the surgical procedure to be treated as a patented use of a composition of matter within the meaning of subsection (c)(2)(A)(ii). Therefore, assuming none of the other exceptions in subsection (c)(2)(A) apply, the claimed surgical method would necessarily qualify as a medical activity. In contrast, where the administration of the anaesthesia was accomplished, for example, using a novel anaesthetic or a novel dosing schedule, the objective of the claimed method would include the provision of a novel use of an anaesthetic in transplantation surgery and the use of the composition of matter (i.e., the anaesthetic) would directly contribute to the achievement of the objective.

It is intended that the applicability of the exception in (c)(2)(A)(ii) for a patented use of a composition of matter can usually be decided by a motion to dismiss or summary judgment under Rule 12(b) or Rule 56, respectively, of the Federal Rules of Civil Procedure. For example, an accused infringer seeking to invoke the relief from remedies afforded under 287(c)(1) would ordinarily prevail under such a motion if the following conditions are met: (1) the movant shows by clear and convincing evidence that the recited uses of the compositions of matter, both individually and collectively, lack novelty, and (2) the movant also shows by a preponderance of the evidence that the steps of the claimed method that do not involve uses of compositions of matter (i.e., the medical or surgical procedure steps) are, by themselves, novel and non-obvious, provided, however, that the movant may concede the non-obviousness in lieu of making the required evidentiary showing.

Paragraph (c)(2)(A)(iii) excludes from the definition of "medical activity" the practice of a patented process in violation of a biotechnology patent. For the purposes of this provision, the definition of the term "biotechnology patent" includes a patent on a "biotechnological process" as defined in 35 U.S.C. S 103(b), as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level.

Biological materials which may be manipulated *ex vivo* at the cellular or molecular level include a variety of cellular, intracellular, extracellular, and acellular substances. Cellular substances include (but are not limited to) cultured microbial and mammalian cells. Intracellular substances include (but are not limited to) genetic materials, such as DNA and RNA that is obtained from within the cell. Extracellular substances include (but are not limited to) proteins and other molecules that are secreted or excreted by cells. Acellular substances include (but are not limited to) viruses and other vectors for transmitting genetic material. *Ex vivo* manipulation includes propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biological characteristics of these substances outside of a human body.

This definition excluded medical procedures which do not involve *ex vivo* cellular or molecular manipulation of a biological material. For example, a patent on a method of performing heart transplantation surgery, including the use of a heart-lung machine, is excluded from this definition on two grounds: first, the method involves manipulation *in vivo*, not *ex vivo*, and second, the method does not manipulate the cellular or molecular characteristics of the heart.

The House bill included a provision which prohibited funds from being used



by the Patent and Trademark Office to issue patents for surgical and medical procedures and diagnoses, with certain exceptions for medical and biomedical devices and processes.

