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## NOTES

# Left To One's Devices: Congress Limits Patents on Medical Procedures

Brett G. Alten\*

### INTRODUCTION

Nearly three centuries ago in England, generations of doctors from the Chamberlen family saved women from death and injury with the predecessor of obstetric forceps.<sup>1</sup> To keep their forceps secret from other physicians, the Chamberlen doctors blindfolded the women during labor, sealed the delivery room from prying eyes, and rang bells and blew whistles during the procedure.<sup>2</sup> The Chamberlen doctors gained competitive advantage and profited from their remarkable invention because they kept it secret.<sup>3</sup>

Some believe, however, that the Chamberlen doctors would have patented their invention and the accompanying medical procedure had they been given the opportunity to do so.<sup>4</sup> Then, they could have publicized the forceps and the medical procedures

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1. See, e.g., M. Thiery, *De uitvinders van de verlostang en de obstetrische hefboom* [*The inventors of the obstetric forceps and the obstetric lever*], 54(1) VERH K ACAD GENEESKD BELG 45-53 (1992); R.M. Matthews, *Historical note (obstetrical forceps and Dr. Peter Chamberlen)*, 35(270) J.R. C. GEN. PRAC. 44 (1985); M. Dumont, *Histoire et petite histoire du forceps. [History and sidelights on the forceps]*, 13(7) J. GYNECOL. OBSTET. BIOL. REPROD. 743 (1984); Jeffrey I.D. Lewis, *Congressional Legislation Would Restrict Medical Patents*, N.Y. L.J., Apr. 8, 1996, at S1.

2. See Lewis, *supra* note 1, at S1 (noting that this may possibly be the origin of the term “bells and whistles”).

3. See *id.*

4. See *id.*

while still receiving financial gains.<sup>5</sup> Such disclosure of the procedures could have permitted further development and improvement.<sup>6</sup>

Until recently, patents on medical procedures were rarely granted and even more rarely enforced in the United States.<sup>7</sup> But by 1996 it was estimated that as many as fifteen medical procedures were patented every week.<sup>8</sup> As a result, leaders of the medical profession scrambled to stamp out that trend, based on the belief that medical procedure patents threaten innovation.<sup>9</sup>

On September 30, 1996, Congress included a limitation on medical procedure patent infringement in the Omnibus Consolidated Appropriations Act of 1997.<sup>10</sup> The provision, section 287(c),<sup>11</sup> created a safe haven from patent infringement liability under certain circumstances. Proponents of section 287(c) argue that it addresses problems with medical procedure patents and the infringement lawsuits that naturally flow from the ownership and enforcement of those patents.<sup>12</sup>

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5. *See id.*

6. *See, e.g.*, Thiery, *supra* note 1 (noting Rogier Roonhuysen's "more effective" instrument for dealing with the problem of an impacted head).

7. *See* Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties From Method Patents Stirs Debate*, AM. MED. NEWS, Sept. 5, 1994, at 3.

8. *See* Wendy W. Yang, *Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability*, 1 B.U. J. SCI. & TECH. L. 5 (1995); Carolyn Lederman, M.D., *Pallin patent is invalidated; Ophthalmic surgeon Samuel Pallin abandons patent for sutureless cataract procedure*, OPHTHALMOLOGY TIMES, June 1, 1996, at 34 (noting a paper prepared by the American Society of Cataract and Refractive Surgery, which estimated that medical procedure patents are issued by the United States Patent and Trademark Office at the rate of 750 per year); Rep. Greg Ganske, *Medical Procedure Patents Put Patients at Risk, Legal Restrictions on Life-Saving Techniques Increase Health Care Costs and Threaten Consumers*, ROLL CALL, Sept. 16, 1996 (reporting that as many as one hundred pure medical patents are issued each month).

9. *See* Sabra Chartrand, *Why is This Surgeon Suing?*, N.Y. TIMES, June 8, 1995, at D1.

10. Omnibus Consolidated Appropriations Act, Limitation On Patent Infringements Relating To A Medical Practitioner's Performance Of A Medical Activity, Pub. L. No. 104-208, 110 Stat. 3009, § 616 (codified as amended at 35 U.S.C. § 287(c) (Supp. 1996)).

11. 35 U.S.C. § 287(c).

12. *See President Signs Medical Patent Bill; Physicians Freed from Threat of New Medical Procedure Patent Lawsuits*, P.R. Newswire, Oct. 1, 1996, available in LEXIS, NEWS Library, CURNWS File [hereinafter *Medical Patent Bill*].

The recent enforcement of a medical procedure patent against a physician alerted the public to the possible ramifications of such a patent<sup>13</sup> and probably was the driving force behind the passage of section 287(c). The medical procedure patent at issue was granted to Dr. Samuel L. Pallin for a surgical procedure: stitchless cataract surgery.<sup>14</sup> Dr. Pallin's patented procedure reduces the probability of astigmatism, lowers the chance of infection, and shortens recovery time.<sup>15</sup> In exchange for disclosing the procedure in his patent to the medical profession, Dr. Pallin planned to charge ophthalmologists a royalty to use it.<sup>16</sup>

In 1994, Dr. Pallin initiated what may be the first United States patent infringement suit involving a medical procedure patent and physician defendant.<sup>17</sup> Opponents of medical procedure patents argued that because as many as half of all cataract procedures performed in the United States might employ Dr. Pallin's procedure, his patent represented a significant cost increase to patients and the health care system in general.<sup>18</sup> Dr. Pallin maintained, however, that the technique actually saves patients money, even with an estimated five-dollar royalty, because the procedure eliminates the need for a seventeen-dollar suture, resulting in a twelve-dollar saving.<sup>19</sup> In addition to saving patients money, Dr. Pallin contended that the procedure would not even be known or available to the medical profession had he not patented and disclosed it.<sup>20</sup> In

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13. See *Pallin v. Singer*, 36 U.S.P.Q.2d 1050 (D. Vt. 1995) (denying the motion for summary judgment by the alleged infringers of a patented surgical technique); see also Charles Craig, *Biotech Backers Fear Medical Patent Ban Will Hurt Industry*, BIOWORLD TODAY, July 26, 1996.

14. *Cataract Surgical Procedure*, United States Patent No. 5,080,111 (issued Jan. 14, 1992) [hereinafter *Cataract Surgical Patent*].

15. See *id.*

16. See McCormick, *supra* note 7, at 4.

17. See *Pallin*, 36 U.S.P.Q.2d at 1050.

18. See Chet Scerra, *Medical Patent Bill Gives Doctors New Protections*, OPTHALMOLOGY TIMES, Jan. 15, 1997, at 28.

19. See *Should Surgical Procedures be Patentable?*, WASH. POST, Aug. 22, 1995, at Z12 (reporting that the total cost of such a surgery is usually about \$1,000, making the \$5.00 fee equivalent to a 0.5% royalty).

20. 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. 134 (1995) [hereinafter *Hearings on H.R. 1127*] (testimony of Dr. Samuel Lear Pallin).

March 1996, however, the United States District Court for the District of Vermont terminated Dr. Pallin's suit by issuing a consent order that invalidated the claims at issue and enjoined Dr. Pallin from enforcing his patent.<sup>21</sup>

But the controversy surrounding the patentability of medical procedures did not end with the issuance of the *Pallin* consent order.<sup>22</sup> On the contrary, legislation pending in the United States Congress<sup>23</sup> was amended<sup>24</sup> and section 287 (c) became law.<sup>25</sup>

Section 287(c) precludes a plaintiff from filing a civil action for either monetary damages or injunctive relief against a medical practitioner or against a related health care entity for performing a "medical activity" that would otherwise constitute an infringement or inducement to infringe under United States patent law.<sup>26</sup> Therefore, when a medical procedure is found to be a "medical activity," that procedure, although patentable, is not enforceable.<sup>27</sup>

Section 287(c) did not become law quietly; vigorous debate surrounded its predecessor bills.<sup>28</sup> At the heart of the controversy was the question of whether a long tradition of sharing medical knowledge and techniques should give way to contemporary notions of intellectual property rights.<sup>29</sup> Some contended that doctors had an ethical obligation to disseminate innovations without charge.<sup>30</sup> Others believed that doctors had the same rights as engi-

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21. See *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407, at \*1 (D. Vt. Mar. 28, 1996) (issuing a consent order declaring all of Dr. Pallin's patent claims in the case invalid).

22. See *Eye Surgeon Loses Effort To Enforce His Patent*, N.Y. TIMES, Apr. 3, 1996, at D20; John D. Murnane & Lisa B. Kole, *Congress Debates M.D. Monopoly on Technique*, NAT'L L.J., Feb. 12, 1996, at C19; Chartrand, *supra* note 9, at D1.

23. See S. 1334, 104th Cong. (1995); H.R. 1127, 104th Cong. (1995).

24. See S. 2105, 104th Cong. (1996); H.R. 3814, 104th Cong. (1996).

25. Pub. L. No. 104-208, 110 Stat. 3009 (1996), available in WESTLAW, 1996 H.R. 3610, at \*149-52.

26. See H.R. CONF. REP. NO. 104-863 (1995).

27. The scope and meaning of the term "medical activity" is very difficult to determine. See discussion *infra* Part III.A.2.

28. See *supra* notes 23 and 24 (citing the predecessor bills).

29. See Steve Wilson, *Patents take Medicine Another Step in Wrong Direction*, ARIZ. REPUBLIC, June 9, 1995, at A2.

30. See Edward Felsenthal, *Medical patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1.

neers or chemists, who traditionally obtain patents and royalties for new techniques.<sup>31</sup>

This Note argues that Congress erred by passing section 287(c) because it prevents inventors of medical procedures from obtaining patent protection. Part I briefly discusses and reviews medical procedure patent law in the United States. Part II examines the legislative history of section 287(c) and explores various policy issues surrounding the patenting of medical procedures. Part III highlights problems associated with section 287(c), applies the legislation to two medical procedure patents, and demonstrates the ways in which the law is vague, substantively deficient, and an invitation to litigation. This Note concludes that section 287(c) should be repealed or at least significantly modified to avoid injustice.

## I. MEDICAL PROCEDURE PATENT LAW

A patent forms a social contract between an inventor and society.<sup>32</sup> The inventor provides a disclosure to society “that teaches one of ordinary skill in the art how best to make and use” a novel, useful, and non-obvious invention.<sup>33</sup> In exchange, society denies others, for a limited time, the right to make, use, sell, or import the invention.<sup>34</sup> This part discusses that mutual exchange, including the requirements for obtaining a patent in the United States and the rights of patent owners—especially medical patent owners.

### A. *Statutory Requirements to Obtain a United States Patent*

The United States Constitution empowers Congress to make laws which “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive

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31. See Wilson, *supra* note 29, at A2.

32. *Skewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974) (stating that a patent is a public bargain, granting exclusive use in return for disclosure). See generally Brian P. O’Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure Within the Unpredictable Arts*, 7 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 147, 149 (1996) (“The patent grant is a social contract.”).

33. *Id.*

34. See *id.*

Right to their respective Writings and Discoveries.”<sup>35</sup> This clause probably derives from fourteenth century English patent law<sup>36</sup> and reflects the Constitution’s underlying instrumentalist policy.<sup>37</sup> For example, Justice Story asserted in a very early case, that the main object of the constitutional grant is to promote science and the useful arts; reward to individual inventors is merely a means to an end.<sup>38</sup>

Although the Constitution empowers Congress to establish a patent system, the Constitution does not itself establish one.<sup>39</sup> Therefore, the Constitution does not provide inventors with any patent rights directly, and it sets no standards for the patentability of individual inventions.<sup>40</sup>

The first United States patent statute was passed in 1790 (“1790 Act”),<sup>41</sup> during the early days of the first Congress.<sup>42</sup> Originally, the 1790 Act granted patents under a procedure involving three high-level government officials, an arduous system, which Congress replaced in 1793 with pro forma registration.<sup>43</sup> In 1836, a formal system using professional examiners replaced the pro forma registration system.<sup>44</sup> Since that time, the patent system has developed substantially,<sup>45</sup> undergoing its first major revision in

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35. U.S. CONST. art. I., § 8, cls. 8, 18. According to the United States Constitution: [8] [The Congress shall have Power] To promote the Progress of Science and useful Art, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

.....  
[18] To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

*Id.*

36. See Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1144, n.28 (1987).

37. See *id.* at 1144.

38. See *Pennock v. Dialogue*, 27 U.S. (1 Pet.), 19 (1829).

39. See ROBERT PATRICK MERGES, PATENT LAW AND POLICY 36 (1992).

40. See *id.*

41. Patent Act of 1790, ch. 7, 1 Stat. 109-112 (1790).

42. See MERGES, *supra* note 39, at 7.

43. See *id.*

44. See *id.*

45. See *id.* at 7-8 (noting that the “more than novel” requirement was added in the

1952, which clearly defined the requirements an inventor must meet in order to obtain a patent.<sup>46</sup> Three of those requirements are set forth in section 101 of title 35 of the United States Code (“section 101”).<sup>47</sup>

Section 101 states that a patent may be granted to “who[m]ever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . .”<sup>48</sup> In other words, section 101 requires that an invention must be novel, useful, and fall within one of four statutory classes of subject matter—processes, machines, manufactures, and compositions of matter.<sup>49</sup> The usefulness and statutory subject matter requirements are explicit in section 101, but the novelty requirement, alluded to by the word “new” in section 101, is treated more fully under section 102 of title 35 of the United States Code (“section 102”).<sup>50</sup> In addition, section 103 of that title (“section 103”) further addresses novelty by precluding the grant of patents where the differences disclosed are obvious in light of the prior art.

Finally, to earn the grant of a patent, an inventor must provide, among other things, a disclosure of the invention that is sufficient to warrant the rights the inventor will receive. The specific requirements are set forth in section 112 (“section 112”).

### 1. Novelty

A requisite to obtain a patent for an invention is that a person must disclose and teach something new.<sup>51</sup> An invention is not new when all the elements of the invention are present in a single piece of relevant “prior art.”<sup>52</sup> Section 102 sets out in detail what is

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mid-nineteenth century to limit the number of patents issued at that time).

46. *See id.* at 9.

47. 35 U.S.C. § 101 (1952). According to section 101: “Who[m]ever 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.” *Id.*

48. *Id.*

49. *See* MERGES, *supra* note 39, at 9.

50. 35 U.S.C. § 102 (1975).

51. *See, e.g.*, HERBERT SCHWARTZ, PATENT LAW & PRACTICE 49-73 (2d ed. 1995) (providing a summary of the prerequisites to patentability).

52. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613 (Fed. Cir.

available as prior art.<sup>53</sup>

In order to show a claimed invention lacks novelty, a single prior art device or practice must anticipate the claimed invention—each and every element of the claimed invention must be disclosed in the single device or practice.<sup>54</sup> That is, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.<sup>55</sup> Thus, a party challenging novelty must demonstrate, among other things, identity of invention.<sup>56</sup> Essentially, section 102 ensures that only new products and processes are patentable.<sup>57</sup>

Under section 102(b), an invention may not be publicly used more than one year prior to the date of the application for a patent; otherwise, the invention will be barred.<sup>58</sup> That means that an invention may be publicly used and discussed up to one year before an application for a patent is filed in the Patent Office, without losing any United States patent rights.<sup>59</sup> Moreover, under the “experimental use” doctrine, an inventor may refine the invention or assess its value relative to the time and expense of prosecuting a patent application, even if that experimental use is more than one year before the filing date of the patent application.<sup>60</sup> Thus, it is well established that experimental use is not public use.<sup>61</sup>

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1985), *cert. dismissed*, 474 U.S. 976 (1985).

53. Thorough analysis of every subsection of section 102, however, is beyond the scope of this Note.

54. See ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 3.2, at 57 (3d ed. 1994).

55. See *id.* at 58.

56. See *Minnesota Mining & Mfg., Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992).

57. See SCHWARTZ, *supra* note 51, at 51.

58. 35 U.S.C. § 102(b) (1975).

59. Public disclosure of the invention, however, before the filing date of an application for patent would likely be sufficient to defeat patentability in most countries.

60. *In re Hamilton*, 882 F.2d 1576 (Fed. Cir. 1989).

61. See *Harrington Mfg. Co. v. Powell Mfg., Co.*, 815 F.2d 1478 (Fed. Cir. 1986); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529 (Fed. Cir. 1984); see also Melody L. Harness, *What is “Experimental” Medical Treatment?: A Legislative Definition is Needed*, 44 CLEV. ST. L. REV. 67 (1996). But see HARMON, *supra* note 54, at 82-86 (stating that a potential problem with the “experimental use” approach occurs with respect to “showing an experimental purpose”).

## 2. Utility

In order to obtain a patent, a person must teach something useful.<sup>62</sup> Interestingly, although utility is a relatively rare issue of contention during the prosecution and enforcement of patents,<sup>63</sup> courts have used issues of functional utility to deny medical patents. Today, the utility requirement is met provided that the invention works in a way to solve the problem it was designed to solve<sup>64</sup> and the invention provides some minimum social benefit or utility.<sup>65</sup> The social benefit or utility aspect is most relevant to medical procedure patents.

The issue of whether a particular invention had social utility was at issue in several early court decisions. For example, in one case, Justice Story noted that a socially useful invention is one that is beneficial and not injurious to the morals, health, or good order of society.<sup>66</sup> In another case, Justice Story explained that utility would be lacking if an invention were "frivolous or injurious to the well-being, good policy, or sound morals of society."<sup>67</sup> In other words, the invention "must achieve a human purpose that is not illegal, immoral or contrary to public policy."<sup>68</sup>

Historically, the courts have disallowed patents on inventions on such public policy grounds in a number of cases.<sup>69</sup> For example, during the nineteenth century, the doctrine of social utility was often invoked to deny patents on gambling devices and products or processes useful only for perpetrating fraud.<sup>70</sup> That is, a patent was withheld only if the invention could not have been used for

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62. See SCHWARTZ, *supra* note 51, at 51.

63. See MERGES, *supra* note 39, at 147.

64. See *id.*

65. See, e.g., *id.* (cautioning that the invention may not be completely harmful or deleterious).

66. See *Bedford v. Hunt*, 3 F. Cas. 37 (C.C.D. Mass. 1817) ("By useful invention, in the statute, is meant such a one as may be applied to seem beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society.").

67. *Lowell v. Lewis*, 15 F. Cas. 1018 (No. 8568) (C.C.D. Mass. 1817).

68. 1 DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 4.01 (1996).

69. See *id.* § 4.03.

70. See MERGES, *supra* note 39, at 156.

any honest and moral purpose. But, as some commentators have argued, the courts should not apply subjective ideas of honesty and morality because those ideas change with time.<sup>71</sup> Therefore, when properly viewed, the public policy doctrine should be a narrow one.<sup>72</sup> Nonetheless, throughout this early period, courts invoked the doctrine of social utility to deny certain types of patents.<sup>73</sup>

In 1941, the courts began turning away from the doctrine of social utility to deny patents, especially when based on indeterminate moral standards.<sup>74</sup> In 1966, the Supreme Court, under the direction of Chief Justice Warren, lowered the utility threshold further and required the government to refuse the grant of a patent unless an inventor proved any existing, practical use.<sup>75</sup> Later, the Supreme Court refined this rule and held that an invention must have a specific social benefit, i.e., “practical utility,” in a currently available form to justify patentability.<sup>76</sup> More recently, the Eighth Circuit

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71. See *id.* at 157. Another commentator has noted that:

Courts have in some instances talked of “morals, health, and good order of society” in determining utility. Anyone whose life has spanned a decade or two in the 20th Century has witnessed how moral standards can change in a period of a few years. Gambling devices, frowned upon early in the century, are legalized in several states; race tracks and lotteries are now used to generate substantial amounts of income in many states. Birth control devices, in a period of thirty to forty years, have come from a position of illegality to a position where they are welcomed by some as a means of curbing a population explosion. Thus, in determining “utility” based on public morals, the courts should apply a test which will not penalize an inventor who may be prescient enough to be anticipating basic needs of a society changed by forces yet unrecognized by the general public.

R. CHOATE, PATENT LAW—CASES AND MATERIALS 380 (1973), quoted in CHISUM, *supra* note 68, § 4.03.

72. See CHISUM, *supra* note 68, § 4.03.

73. See, e.g., MERGES, *supra* note 39, at 156 (recounting the denial of patents on inventions related to gambling); see also, e.g., *Schultz v. Holtz*, 82 F. 448 (N.D. Cal. 1897) (denying a patent on coin return device for coin-operated machines because the invention had potential applications to slot machines); *National Automatic Device Corp. v. Lloyd*, 40 F. 89, 90 (N.D. Ill. 1889) (denying a patent on a toy horse race course because the course was used in bars for betting purposes).

74. See *Chicago Patent v. Genco*, 124 F.2d 725, 728 (7th Cir. 1941) (distinguishing pinball from gambling to uphold a patent on a pinball machine); see also MERGES, *supra* note 39, at 156.

75. See JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES § 3.02[3], at 3-6 (1996).

76. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 529-36 (1966) (holding that

Court of Appeals lowered the utility threshold even further by holding that even a slight degree of utility is sufficient; in short, “the defense of non-utility cannot be sustained without proof of total incapacity.”<sup>77</sup>

### 3. Patentable Process Subject Matter

In addition to being useful, the subject matter of the invention must fall within a statutory class of subject matter.<sup>78</sup> In order to be patentable, the invention must be either a process, machine,<sup>79</sup> manufacture,<sup>80</sup> or composition of matter.<sup>81</sup> Under section 100(b), the term “process” means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.<sup>82</sup>

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“[u]nless and until a process is refined and developed to this point—where specific benefit exists in currently available form, there is insufficient justification for permitting and applicant to engross what may prove to be a broad field”); *see also, e.g.*, SCHLICHER, *supra* note 75, at 4 (summarizing three factors set forth in *Brenner* for determining practical utility: (1) the concern about cartels, (2) the quid pro quo ideas about the dissemination of invention, and (3) the quid pro quo ideas about use after expiration).

77. *E.I. du Pont de Nemours Co. v. Berkeley*, 620 F.2d 1247, 1260 n.17 (8th Cir. 1980).

78. *See* SCHWARTZ, *supra* note 51, at 49.

79. *See, e.g.*, *Honolulu Oil Corp. v. Halliburton*, 306 U.S. 550 (1939) (equating the term “machine” with the term “apparatus”); *Expanded Metal Co. v. Bradford*, 214 U.S. 366 (1909) (detailing that historically the Supreme Court required a machine to be “a thing visible to the eye” and “an object of perpetual observation”); *Corning v. Burden*, 56 U.S. 252 (1854) (explaining that the term “machine” includes “every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result”).

80. *See, e.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (finding that the term “manufacture” means “articles prepared for use from raw materials by giving to these materials new forms, qualities, properties, or combination, whether by hand labor or by machinery”); *Riter-Conley Mfg. Co. v. Aiken*, 203 F. 699 (3d Cir.) (holding that the term “manufacture” is “anything manmade that is not a machine or a composition of matter”), *cert. denied*, 229 U.S. 617 (1913).

81. *See, e.g.*, *Diamond*, 447 U.S. 303 (explaining that the term “composition of matter” means all compositions of two or more substances and all composite articles, whether the result of chemical union, or of mechanical mixture, or whether gases, fluids, powders, or solids).

82. *See id.*

#### 4. Non-obviousness

In addition to the requirements set forth in sections 101 and 102, an invention under section 103 (“section 103”) must be non-obvious to be patentable.<sup>83</sup> That is, if the differences between the claimed invention and the prior art are obvious, no patent will be granted for that invention.<sup>84</sup> Again, the focus is to earn a patent for teaching and disclosing to the public something significant.

The Supreme Court applied section 103 in four steps: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, (3) resolving the level of skill of one of ordinary skill in the art, and (4) determining the obviousness of the subject matter against the background of the first three steps.<sup>85</sup>

When determining the scope and content of the prior art, it is generally accepted that printed publications, prior use or knowledge, United States patent applications, and another’s invention in the United States, are relevant.<sup>86</sup> Therefore, in contrast to novelty,

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83. 35 U.S.C. § 103 (1952). Section 103 provides, in pertinent part:

A patent may not be obtained . . . 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 person having ordinary skill in the art to which said subject matter pertains.

*Id.*

84. *See id.*

85. *See* *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). According to the *Graham* court:

Under 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations 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.

*Id.*

86. *See* SCHWARTZ, *supra* note 51, at 60. Schwartz detailed the content of prior art as including (1) printed publications or patents from anywhere in the world that were published or issued before the applicant’s date of invention, (2) prior use or prior knowledge that occurred in the United States before the applicant’s date of invention, (3) a United States patent application that subsequently issued and was filed before the applicant’s date of invention, and (4) another’s invention that was made in the United States and was not abandoned, suppressed, or concealed before the invention date of the invention in question. *Id.*

a patent may be denied to an inventor if the invention is obvious in view of one or more pieces of prior art, even though any single reference does not describe the invention identically.<sup>87</sup>

Moreover, whether an invention is patentable over the prior art depends upon whether the subject matter of the claim, taken “as a whole,” would have been obvious to one of ordinary skill in the art at the time the claimed invention was made.<sup>88</sup>

### 5. Disclosure, Enablement, and Best Mode

Not only must an inventor teach—the inventor must teach correctly. When a patent is granted to an inventor, society’s right to make, use, or sell an invention is deferred for a limited time in exchange for a disclosure that teaches the public how best to make and use that invention.<sup>89</sup> The disclosure of the invention in the patent is the *quid pro quo* for the grant of rights.<sup>90</sup> The theory is based on the assumption that the amount of goods and services will increase because some secrets will be disclosed immediately and used freely after the patent expires.<sup>91</sup>

The standard for disclosure set forth in section 112 requires that the specification, i.e., the descriptive portion of the patent, must contain a written description that enables any person skilled in the art to make and use the invention, and set forth the best mode contemplated by the inventor.<sup>92</sup> Section 112 also mandates that the inventor must claim the invention with definiteness.<sup>93</sup> A

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87. *See id.*

88. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983) (stating that a court must evaluate a “claim as a whole” and not unduly focus on one facet of the claimed invention), *cert. denied*, 469 U.S. 851 (1984); *In re Yettito*, 274 F.2d 953 (1960).

89. *See O’Shaughnessy*, *supra* note 32, at 149.

90. *See SCHLICHER*, *supra* note 75, § 2.18[3].

91. *See id.*

92. 35 U.S.C. § 112 (1975). According to section 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*Id.*

93. *Id.* Section 112 states that “[t]he specification shall be concluded with one or

claim is a brief, one-sentence definition of the invention for which rights are granted.<sup>94</sup> In summary, an adequate disclosure must contain an enabling written description, the best mode contemplated by the inventor, and at least one definite claim.<sup>95</sup>

An enabling written description is considered the most important element of adequate disclosure.<sup>96</sup> The inventor must describe the invention clearly enough so one skilled in the field of the invention can make and use it without a great deal of experimentation.<sup>97</sup> The inventor also must describe clearly what is actually claimed in the patent.<sup>98</sup>

The “best mode” requirement forces the inventor to tell the public the best embodiment that the inventor knows for practicing the claimed invention.<sup>99</sup> The applicant must disclose the invention fully, including the relevant “tricks of the trade,” such as specific techniques, instrumentalities, or characteristics for best putting the invention into practice.<sup>100</sup> Since 1965, courts have used this requirement to compel inventors to describe the most commercially valuable embodiment of the invention, the most efficient way of making it, and the most valuable way of using it known to the inventor at the time the application was filed.<sup>101</sup>

Finally, the requirement of claim definiteness ensures the public can discern the boundaries of the inventor’s legal right.<sup>102</sup> Where the claims fail to apprise a skilled reader of the scope of the invention, or whether they are broader than the invention justifies, the Patent and Trademark Office is required to refuse to grant a patent and the courts are required to hold it invalid if the Patent

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more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards has his invention.” *Id.*

94. See SCHLICHER, *supra* note 75, § 7.02.

95. The requirement for an “enabled written description” is really two separate requirements, including “enablement” and “written description.” For the purpose of this Note, however, they have been combined and treated as a single requirement.

96. See MERGES, *supra* note 39, at 516.

97. See *id.*

98. See *id.*

99. See *id.* at 517.

100. See O’Shaughnessy, *supra* note 32, at 160.

101. See SCHLICHER, *supra* note 75, § 7.02.

102. See MERGES, *supra* note 39, at 516.

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and Trademark Office inadvertently grants it.<sup>103</sup>

The preamble is an introductory phrase of a claim that may summarize the invention, its relation to prior art, or its intended use or properties.<sup>104</sup> According to one court, however, the preamble may be more than mere introductory language, concluding that the preamble is as significant as the claim filer desires.<sup>105</sup> In fact, the preamble itself has been found to act as a claim limitation to define what is covered by the patent in precisely the same way as words in the claim's body.<sup>106</sup>

### B. *Medical Patent Infringement and Relief*

Generally, a patentee enjoys the rights to stop infringers and exact damages from them. Occasionally, the courts impose compulsory licenses when the act of stopping the infringers is inequitable or may cause the public harm. Courts are willing to deny injunctive relief when there is a substantial risk of harm to the public interest, but seem less likely to deny injunctive relief when the patent is not a medical necessity or lifesaving device.<sup>107</sup> This section discusses infringement, the patent right to injunctive relief, and the duty to provide compulsory licenses to infringers where the public interest so mandates.

#### 1. General Background

The Patent Act defines the rights granted to a patentee.<sup>108</sup> The

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103. See SCHLICHER, *supra* note 75, § 7.02[1][a].

104. See CHISUM, *supra* note 68, § 806[1](b).

105. See *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) (citations omitted). According to the *Bell Communications* court:

[The] preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.

*Id.*

106. See *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

107. See CHISUM, *supra* note 68, § 20.04.

108. See 35 U.S.C. § 154(a)(1) (1980). According to section 154(a)(1):

Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United

intellectual property rights of patent holders are often compared to the real property rights of real estate owners.<sup>109</sup> If a patent is analogized to real property, its claims correspond to the metes and bounds recited in a deed, and an infringer of those claims corresponds to a trespasser.<sup>110</sup> The infringement of claims and the trespassing on real estate are both civil wrongs, but patent infringement is a statutory wrong, governed by federal law and defined under section 271.<sup>111</sup>

Patent infringement analysis involves two steps. First, the construction of the meaning and scope of the asserted claim and second, the comparison of the accused device to the properly construed claim.<sup>112</sup> Even though the construction of the meaning and scope is purely a matter of law,<sup>113</sup> the court may consider the language of the claim, the specification of the patent, and the prosecution history of the application for the patent in the Patent and Trademark Office.<sup>114</sup> Expert testimony and other extrinsic evidence may be used as an aid to understand the patent.<sup>115</sup> Technical treatises and dictionaries are preferred sources of extrinsic evidence.<sup>116</sup>

There are two types of infringement—literal infringement and infringement under the doctrine of equivalents. Literal infringement occurs when each and every limitation of the patent claim exists, precisely as claimed, in the accused activity or device.<sup>117</sup> In-

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States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, . . . referring to the specification for the particulars thereof.

*Id.*

109. See O'Shaughnessy, *supra* note 32, at 151.

110. See D. ROSENBERG, PATENT LAW BASICS § 16.02, at 16-4 (1996).

111. *Id.* Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States during the term of the patent, infringes the patent." 35 U.S.C. § 271(a).

112. See, e.g., *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (creating two-part patent infringement test), *aff'd*, 517 U.S. 370 (1996).

113. See *id.*

114. See *id.* at 979.

115. See *id.* at 980-81.

116. See *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996); *C.C.P.I. Inc. v. American Premier, Inc.*, 996 F. Supp. 813, 818 n.10 (D. Del. 1997).

117. See *Johnston v. I.V.A.C. Corp.*, 885 F.2d 1574, 1580 (Fed. Cir. 1989).

fringement under the doctrine of equivalents “prevents a copyist from evading patent claims with insubstantial changes.”<sup>118</sup> Although application of this doctrine by the courts is rarely simple, it is well-settled that there can be infringement under the doctrine only if there is objective proof that any differences between the claimed invention and accused device are merely “insubstantial.”<sup>119</sup>

Summary judgment may be appropriate in a patent case where infringement is the issue to be decided, because “construction of a patent, including terms of art within its claim, is exclusively within the province of the court.”<sup>120</sup> The standard for summary judgment in a patent case is the same as in any other type of action.<sup>121</sup> Summary judgment is appropriate only where the materials submitted for and against the motion show that “there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.”<sup>122</sup> The standard is high<sup>123</sup> to avoid depriving a party of its right to trial.<sup>124</sup> Summary judgment is not proper if evidence supporting a factual dispute is shown requiring a trier of fact to resolve the parties’ differences at trial.<sup>125</sup>

Although patents are presumed valid, their validity may be challenged in proceedings such as motions for summary judgment.<sup>126</sup> Invalidity must be shown by clear and convincing evidence as to all material facts.<sup>127</sup> To meet this high burden on summary judgment, a challenger must show that no fact material to the issue of invalidity is in dispute, and that even if all material factual inferences are drawn in favor of the patentee, the challenger is still

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118. *Valmont Indus. v. Reinke Mfg.*, 983 F.2d 1039, 1043 (Fed. Cir. 1993).

119. *Hilton Davis Chem., Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17 (1997).

120. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (creating two-part patent infringement test), *aff'd*, 517 U.S. 370 (1996).

121. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1571 (Fed. Cir. 1984).

122. FED. R. CIV. P. 56(c).

123. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

124. *See Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986).

125. *See Scripps Clinic & Research Found. v. Genentech*, 927 F.2d 1565, 1571 (Fed. Cir. 1991).

126. *See* 35 U.S.C. § 282.

127. *See Key Pharm., Inc., v. Hercon Labs*, 981 F. Supp. 299, 310 (D. Del. 1997).

still entitled to judgment as a matter of law.<sup>128</sup> Thus, the burden of showing invalidity by summary judgment is higher than that of infringement, but involves much of the same analysis.<sup>129</sup>

If patent infringement is shown, equitable relief is normally available to the patent owner under the law.<sup>130</sup> For example, since 1819,<sup>131</sup> courts have granted patent owners injunctive relief to prevent infringement of a patent.<sup>132</sup> Over the years, two exceptions developed to this principle, thereby denying injunctive relief in certain circumstances. The first applies where an injunction would cause substantial injury to the public interest.<sup>133</sup> In that case, courts require a patent owner to grant a compulsory license to the infringer.<sup>134</sup> The second applies where the detriment to the infringer severely outweighs the benefit to the patent owner.<sup>135</sup> The courts however, rarely use this exception.<sup>136</sup> For the purposes of this Note, the first exception is the most relevant.

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128. See *Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1265 (Fed. Cir. 1991).

129. See, e.g., *SmithKline Diagnostics v. Helena Lab. Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988) (holding that “claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses”).

130. See 35 U.S.C. §§ 281, 283-285.

131. See Act of February 15, 1819, ch. 19, 3 Stat. 481, 481-82 (codified at 35 U.S.C. § 283); see also SCHWARTZ, *supra* note 51, at 97 n.503 (explaining that the Patent Act of 1819 granted the federal courts “[u]pon any bill in equity [the] . . . authority to grant injunctions, according to the course and principles of courts of equity . . . on such terms and conditions as the said courts may deem fit and reasonable”).

132. See *King Instruments Corp. v. Perego*, 65 F.3d 941 (Fed. Cir. 1995). The *King Instruments* court noted that:

The market may well dictate that the best use of a patent is to exclude infringing products, rather than market the invention . . . . Under this situation, the Patent Act is working well. The patentee is deriving proper economic return on its investment in acquiring a patent right. The public benefits from the disclosure of the invention and the ability to exploit it when the patent term expires.

*Id.* at 950. This strong public policy is often enforced by providing injunctive relief. *Id.* at 960 (Nies, J., dissenting); see also *B.F. Goodrich Flight Sys. Inc. v. Insight Instruments Corp.*, 22 U.S.P.Q.2d 1832, 1844 (S.D. Ohio 1992) (opining that “all of society benefits from the protection of patent rights, since it is the seed of inventive genius the Constitution and the statutes construing it seek ultimately to protect”).

133. See SCHWARTZ, *supra* note 51, at 98 n.505; *Bliss v. Brooklyn*, 3 F. Cas. 706 (C.C.E.D.N.Y. 1871) (No. 1,544).

134. See *Bliss*, 3 F. Cas. 706.

135. See SCHWARTZ, *supra* note 51, at 98 nn.506, 507.

136. See *id.*

When the public interest is at issue, courts use an equitable balancing approach in deciding whether to award injunctive relief or to require a compulsory license. For example, a court denied injunctive relief to an owner of a patent covering medical test kits because of an overriding public interest.<sup>137</sup> In fact, a number of courts held that injunctive relief will not be awarded to a patent owner when contrary to the notions of equity.<sup>138</sup> One court went so far as to conclude that, under section 1498 of title 28 of the United States Code, the government may even be able to “take” an invention if warranted by public interest concerns and provide “adequate compensation” to the patent holder.<sup>139</sup>

Nonetheless, even when courts find that an injunction is contrary to the public interest, they have proposed creative solutions that attempt to minimize public harm while respecting owners' patent rights. One court granted a permanent injunction but provided a one-year grace period to the owner of a patent involving rapid-exchange catheters.<sup>140</sup> The grace period was apparently in-

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137. See *Continental Paper Bag Co. v. E. Paper Co.*, 210 U.S. 405, 424-30 (1908) (finding that a patent owner may enforce its rights under a patent irrespective of that owner's use of the invention); *Hybritech, Inc. v. Abbott Lab.*, 4 U.S.P.Q.2d 1001 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988).

138. See, e.g., *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (denying an injunction to the owner of a patent covering surgical cutters because to “suddenly withdraw these [cutting] devices from the market could have a serious disruptive effect on surgical practice”); *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 64 U.S.P.Q. 285 (9th Cir. 1945) (finding that public interest was sufficient to deny an injunction on the process of irradiation of margarine); *Ca. Med. Prod. Inc. v. Emergency Med. Prod. Inc.*, 796 F. Supp. 640, 648 (D.R.I. 1992) (denying injunctive relief because “[w]hile there is a public interest in product availability, it is unlikely that the public would suffer from a shortage of extrication collars if the injunction were granted”).

139. *King Instruments Corp. v. Perego*, 65 F.3d 941, 960 (Fed. Cir. 1995). It was pointed out by Justice Nies, however, that this conclusion may only be possible if one elevates rewards to patentees over other public interests. *Id.*; see also 28 U.S.C. § 1498. According to section 1498:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. § 1498.

140. See *Schneider (Europe) A.G. v. SciMed Life Sys., Inc.*, 852 F. Supp. 813 (D.

tended to minimize the impact to the medical community that would otherwise occur if the infringing devices were removed from the marketplace at once.<sup>141</sup> By providing notice to the medical community that the infringer's devices would not be available after one year, that community apparently could anticipate and prepare for the removal of the infringing devices.<sup>142</sup> In *Schneider*, the court concluded that even though a physician prefers an infringer's device, which alone does not justify the denial of an injunction.<sup>143</sup> It is noteworthy, however, that the court considered important that alternative devices were available to physicians and found that the infringer's device was not significantly or objectively superior to other catheters in performance.<sup>144</sup>

In another patent case involving a catheter, the court agreed that, although it was in the public interest to minimize the disruption in hospitals in terms of their selection of safety catheters by denying injunctive relief, the disruption would best be minimized by granting the preliminary injunction.<sup>145</sup> The court held that if the preliminary injunction was denied, the defendant might have persuaded additional hospitals to buy and use its safety catheter.<sup>146</sup> Then, if the patentee succeeded in obtaining a permanent injunction at the trial, those additional hospitals would also be disrupted.<sup>147</sup>

Other courts have enforced injunctions against the manufacture

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Minn. 1994). The *Schneider* court maintained that:

The permanent injunction . . . shall contain a one-year transition period to allow an efficient and non-disruptive changeover for those institutions and physicians who now employ the [infringer's product] exclusively. Defendant shall pay Plaintiffs a 15% royalty rate on Defendant's sales . . . during that time. After the transition period ends, the permanent injunction . . . shall take effect.

*Id.* at 861-62 (internal citations omitted).

141. *See id.*

142. *See id.*

143. *Id.* (holding that the "physician preference of the infringer's device does not justify the denial of an injunction").

144. *Id.* (noting that injunctive relief was granted because "all the non-infringing catheters were not defective, unsafe, or incapable of performing as intended and required during the medical procedure").

145. *See Critikon Inc. v. Becton Dickinson Vascular Access Inc.*, 28 U.S.P.Q.2d 1362, 1371 (D. Del. 1993).

146. *Id.* at 1373.

147. *See id.*

of patented medical devices. One court granted a permanent injunction against an infringer's sale of a cardiac defibrillation device.<sup>148</sup> Another court granted injunctive relief to the patent holder because the accused infringing device was not a "medical necessity."<sup>149</sup> Congress and the courts, however, have not substantially elaborated on what is meant by the terms "medical necessity" and "lifesaving devices."<sup>150</sup>

## 2. With Respect to Medical Procedures

Ever since the constitutional grant of power of 1787, United States patent law has attempted to define what constitutes patentable subject matter with respect to medical procedure patents.<sup>151</sup>

In *Morton v. New York Eye Infirmary*,<sup>152</sup> the court upheld the unpatentability of a surgeon's use of ether on patients to minimize suffering during surgery.<sup>153</sup> The court concluded that even though a discovery is brilliant and useful, it may not be patentable unless it is "set to work," and is in connection or combination with the means by which, or the medium through which, it operates."<sup>154</sup>

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148. See *Eli Lilly & Co. v. Medtronic Inc.*, 7 U.S.P.Q.2d 1439, 1445 (E.D. Pa. 1988), *rev'd & remanded*, 872 F.2d 402 (Fed. Cir.), *reh'g denied*, 879 F.2d 849 (Fed. Cir. 1989). According to the *Eli Lilly* court:

While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices [by denying injunctive relief] . . . , Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free competition in the goods.

*Id.*

149. *Syntex (U.S.A.) Inc. v. Paragon Optical Inc.*, 7 U.S.P.Q.2d 1001, 1033 (D. Ariz. 1987).

150. *Eli Lilly*, 7 U.S.P.Q.2d at 1441.

151. See CHISUM, *supra* note 68, § 1.03[3], at 1-70.

152. 17 F. Cas. 879 (S.D.N.Y. 1862).

153. *Id.*

154. *Id.* at 884. According to the *Morton* court:

A discovery may be brilliant and useful, and not patentable. No matter through what long, solitary vigils, or by what importunate efforts, the secret may have been wrung from the bosom of Nature, or to what useful purpose it may be applied. Something more is necessary. The new force or principle brought to light must be embodied and set to work, and can be patented only in connection or combination with the means by which, or the medium through which, it operates.

*Id.*

Unfortunately, the rationale of *Morton* is less than clear, especially when read as an application of the traditional rule that new analogous uses of old products are not patentable because the new use of ether “seemed strikingly new and non-analogous.”<sup>155</sup>

Some twenty years after *Morton*, in *Brinkerhoff v. Aloe*,<sup>156</sup> the Supreme Court upheld the invalidity on a method of treating piles and stated that “the methods or modes of treatment of physicians of certain diseases are not patentable.”<sup>157</sup> For authority, the Court relied on *Morton*, but clearly stated the rationale for the *per se* rule excluding medical methods—namely, the uncertainty that any medical method will achieve the desired result.<sup>158</sup>

About fifty years later, a court recognized the significance of medical procedure patents and signaled a retreat from the rule set forth in *Brinkerhoff*.<sup>159</sup> Although relying in part on *Morton*, *Dick v. Lederle Antitoxin Laboratory*,<sup>160</sup> held that a method for performing a skin test was the proper subject of a patent because the test was an “operable method.”<sup>161</sup> Following *Dick*, a number of decisions retreated from the position that medical methods are unpatentable.<sup>162</sup> In *Ex parte Scherer*,<sup>163</sup> the *per se* rule of *Brinkerhoff*, in which medical methods were found to be unpatentable, was overruled by the Board of Appeals for the Patent and Trademark Office.<sup>164</sup> In *Scherer*, the Board of Appeals upheld the validity of a patent on a method of injecting medicine by a pressure jet.<sup>165</sup> The Board of Appeals held that the *utility*, not the certainty of the results, should determine whether a medical procedure is patentable.<sup>166</sup> One commentator, however, notes that *Scherer* is a Patent and Trademark Office decision that serves as precedent only

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155. CHISUM, *supra* note 68, § 1.03[3], at 1-71.

156. 146 U.S. 515 (1892).

157. *Id.* at 519.

158. *Id.*

159. See *Dick v. Lederle Antitoxin Lab.*, 43 F.2d 628 (S.D.N.Y. 1930).

160. 43 F.2d 628 (S.D.N.Y. 1930).

161. *Id.* at 630.

162. See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 187 n.49 (1987).

163. 103 U.S.P.Q. (BNA) 107 (1954).

164. See CHISUM, *supra* note 25, at 1-73.

165. *Scherer*, 103 U.S.P.Q. at 107.

166. See CHISUM, *supra* note 25, at 1-73.

within that office and is limited to its context; it cannot be considered persuasive authority for the patentability of medical and surgical procedures generally.<sup>167</sup>

In *Martin v. Wyeth*,<sup>168</sup> the Fourth Circuit affirmed the invalidation of two method claims on the basis of obviousness. The claims merely applied an old device to a new use, but the new use was analogous to former uses of the device.<sup>169</sup> The court did remark, however, that patents for medical or surgical methods have been found valid,<sup>170</sup> and it was assumed 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.”<sup>171</sup>

Thus, until section 287(c) became law, neither Congress, the courts, nor the United States Patent and Trademark Office introduced any special provisions for medical procedure patents, even though Congress revised the patent statute four times since the Patent Act of 1790.<sup>172</sup> There were no special hurdles to overcome in order to obtain a medical procedure patent. The “utility” standard set forth in *Scherer*, and the “operability” standard set forth in *Dick*, remained the tests for determining the patentability of medical procedures inside and outside the Patent and Trademark Office, respectively.

## II. LEGISLATIVE HISTORY OF SECTION 287(C)

Although the enforcement of Pallin’s patent against a physician in 1994 brought the controversy concerning medical procedure patents to an apex, the controversy is not new.<sup>173</sup> For example, in the 1870s, the controversy became so heated that a dentist, who was sued for patent infringement by the Goodyear Company on a method of making rubber dentures, murdered a Goodyear Offi-

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167. *See id.*

168. 96 F. Supp. 689, *aff’d*, 193 F.2d 58 (4th Cir. 1951).

169. *See id.* at 695.

170. *See Ruskin v. Coe*, 58 F. Supp. 424 (D.D.C. 1945); *Dick v. Lederle Antitoxin Lab.*, 43 F.2d 628 (S.D.N.Y. 1930); *Bayer Co., Inc. v. United Drug Co.*, 272 F. 505, 507 (S.D.N.Y. 1921).

171. *Martin*, 96 F. Supp. at 695.

172. *See Burch*, *supra* note 36, at 1145.

173. *See Medical Patent Bill*, *supra* note 12.

cer.<sup>174</sup> Also, at about the same time, the press portrayed German pharmaceutical companies as “blackmailing humanity” because they obtained certain medical procedure patents.<sup>175</sup>

In response to these events, a House Committee on Patents in 1902 submitted to the House of Representatives a Report recommending the passage of House Bill 12451.<sup>176</sup> House Bill 12451 sought to relieve medical and dental practitioners from “unjust burdens imposed by patentees holding patents covering methods and devices for treating human diseases . . . .”<sup>177</sup> Before failing in Congress, the bill was approved by thirty-eight state dental associations and would have allowed qualified dentists to perform operations “free of royalties for the benefit of society.”<sup>178</sup> Many of the objections cited by the Committee in support of the 1902 bill are similar to the ones cited by modern proponents in support of recent legislation,<sup>179</sup> including objections on ethical, moral, and lack of utility grounds.<sup>180</sup> Nonetheless, the early legislation failed and the controversy was put to rest for some time.

In response to the more recent Pallin controversy, Representative John Bryant of Texas again raised the issue of the patentability of medical procedures in the House of Representatives in 1994.<sup>181</sup> By March of 1995, the Medical Procedures Innovation and Affordability Act (“House Bill 1127”) was introduced claiming to address the issue of medical procedure patents by limiting their is-

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174. See Ring, *The Rubber Denture Murder Case: The True Story of the Vulcanite Litigations*, 32 BULL. HIST. DENT. 3 (1984).

175. *Medical Patent Bill*, *supra* note 12.

176. H.R. REP. NO. 57-2702 (1902).

177. *Id.* at 17.

178. *Id.* at 1 (explaining that the bill would have permitted “all legally qualified dentists to freely perform various operations upon the mouth and teeth in the interests of the public and of special benefit to the public health”).

179. See H.R. 3814, 104th Cong. (1996); H.R. 1127, 104th Cong. (1995); S. 1334, 104th Cong. (1995).

180. See H.R. REP. NO. 57-2702, at 2. According to House Report 57-2702:

That patents of this sort are obnoxious and are useless in promoting the industrial arts is evident . . . . [T]hey interfere with the clear, moral [r]ight—in fact, duty—of the physician and surgeon to do for his patients with his own hands whatsoever may be required to effect a cure or relieve suffering.

*Id.*

181. See 140 CONG. REC. E1754 (daily ed. Aug. 17, 1994) (statement of Rep. Bryant).

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suance.<sup>182</sup> In October of 1995, an alternative act (“Senate Bill 1334”), which had the same name as the previous House version, was introduced and claimed to address the purported problems associated with medical procedure patents by limiting their enforcement.<sup>183</sup>

Those bills were subject to judicial hearings, involving congressional testimony.<sup>184</sup> The legislation that eventually became law, however, was not subject to judicial hearings and contained language not previously considered by the United States Congress.<sup>185</sup>

This part provides an accurate legislative history of the new section 287(c). Accordingly, it discusses each of the precursor bills considered by Congress that proposed limiting medical procedure patents, relevant congressional testimony, and various public commentary. Finally, it describes the new section 287(c) and a House Conference Report interpreting it.

#### A. *House Bill 1127*

Representatives Greg Ganske and Ron Wyden introduced House Bill 1127 to the House of Representatives on March 3, 1995.<sup>186</sup> If passed into law, House Bill 1127 would have prohibited the United States Patent and Trademark Office from issuing patents on medical procedures, unless the claimed procedures were used in combination with patentable medical products.<sup>187</sup>

##### 1. Summary of House Bill 1127

House Bill 1127 stated that “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

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182. H.R. 1127, 104th Cong. (1995).

183. S. 1334, 104th Cong. (1995).

184. *See Hearings on H.R. 1127, supra* note 20, at 134.

185. H.R. REP. NO. 57-2702.

186. H.R. 1127. House Bill 1127, introduced by Representatives Ganske and Wyden, proposed to preclude the issuance of a patent for any invention of a method or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. *See* H.R. REP. NO. 104-879 (1995).

187. *See id.*

or medical therapy, or making a medical diagnosis . . . .” It provided an exception stating that patents may be issued “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.”

## 2. Comments on House Bill 1127

House Bill 1127 was introduced to Congress primarily because of lobbying efforts by the American Society of Cataract and Refractive Surgery in the form of a coalition called the Medical Procedure Patents Coalition.<sup>188</sup> Other medical organizations supported House Bill 1127, such as the American Medical Association and the American Academy of Ophthalmology, by objecting to medical procedure patents primarily on ethical, monetary, and moral grounds.<sup>189</sup>

On October 19, 1995, the Congressional Subcommittee on Courts and Intellectual Property held a hearing on House Bill 1127.<sup>190</sup> Testimony was received from Congressmen, physicians, patent attorneys, and other interested parties.<sup>191</sup>

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188. See Silvy A. Miller, *Should Patenting of Surgical Procedures and Other Medical Techniques by Physicians be Banned?*, 36 IDEA 255, 255 (1996) (noting that the American Society of Cataract and Refractive Surgery included over fifteen medical associations, including the powerful American Medical Association).

189. See Miller, *supra* note 188, at 255; see also Todd R. Miller, *The International Suture: A comparative Approach to Patenting Methods of Medical Treatment*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 443, 445 (1996).

190. See H.R. REP. NO. 104-879 (1995).

191. See *id.* The following individuals testified at the hearing: the Honorable Greg Ganske, U.S. House of Representatives, 4th District, Iowa; the Honorable Ron Wyden, U.S. House of Representatives, 3rd District, Oregon; G. Lee Skillington, Counsel, Office of Legislative and International Affairs, Patent and Trademark Office United States Department of Commerce; Dr. Samuel L. Pallin, The Lear Eye Clinic, Sun City, Arizona; Dr. Jack Singer, Hitchcock Clinic, Randolph, Vermont; Dr. Charles D. Kelman, President, American Society of Cataract & Refractive Surgery; Dr. William D. Noonan, Klarquist Sparkman Campbell Leigh & Whinston, Patent, Trademark and Copyright Law Litigation and Licensing; Dr. H. Dunbar Hoskins, Jr., Executive Vice President, American Academy of Ophthalmology; and Mr. Donald R. Dunner, Chair, Section of Intellectual Property Law, American Bar Association. *Id.*

Opponents of House Bill 1127 criticized the legislation as being over broad and vague.<sup>192</sup> Although the bill categorically prohibited the patenting of certain types of medical processes, including performance of surgical or medical procedures, administration of surgical or medical therapies, and making medical diagnoses,<sup>193</sup> the legislation was criticized as not defining them.<sup>194</sup> For example, what constitutes a “surgical procedure” is subject to widely different interpretations.<sup>195</sup> Also, the biotechnology industry, which relies heavily on patents to protect investments in research and development, expressed concern regarding the meaning of a “medical therapy,” which they believed might reach their industry.<sup>196</sup>

The purportedly over broad language contained in House Bill 1127 may have created more problems than solutions.<sup>197</sup> One commentator asked what would happen “if a patented process is granted under H.R. 1127 and later found to apply to humans?”<sup>198</sup> In that case, the commentator asked whether it would be necessary to rescind the patent.<sup>199</sup>

Furthermore, House Bill 1127 may have compelled doctors to deceive the United States Patent and Trademark Office.<sup>200</sup> For example, if House Bill 1127 became law, a doctor who might have discovered an innovative medical procedure may have chosen to hide the inventive aspect of the discovery by obtaining a patent for an instrument capable of performing the procedure.<sup>201</sup>

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192. See *Hearings on H.R. 1127*, *supra* note 20 (statement of Mr. Baldino) (arguing that many exciting new inventions in biotechnology involving new uses for old compounds would no longer be patentable); see also *id.* (statement of Dr. William Noonan) (arguing that although it is desirable to limit patents on medical procedures in accordance with foreign patent laws, House Bill 1127 would make United States patent law “much more restrictive than even present European patent practices because it would ban U.S. patents on new uses of known drugs or products of biotechnology”).

193. H.R. 1127, 104th Cong. (1995).

194. See *id.*

195. Joel J. Garris, *The Case for Patenting Medical Procedures*, 22 AM. J.L. & MED. 85, 104 n.186 (1996).

196. *Hearings on H.R. 1127*, *supra* note 20 (statement of Mr. Baldino).

197. See *Hearings on H.R. 1127*, *supra* note 20.

198. *Id.*

199. See *id.*

200. *Id.*

201. See *id.*

Testifying before Congress, one physician argued that although House Bill 1127 attempted to mitigate the purportedly over broad terms by providing an exemption for procedures performed as a necessary component of a patentable machine, the exemption was rendered “meaningless”<sup>202</sup> because an infringer of a patented process would already be an infringer of the patented machine, thereby providing no additional patent protection and no motivation to disclose the procedure.<sup>203</sup>

Various legal associations opposed House Bill 1127 because of the legislation’s generally flawed approach. For example, counsel for the Office of Legislative and International Affairs, on behalf of the Clinton administration, said that “excluding surgical and medical procedures from patentability” was not the proper way to address the issues concerning medical patents.<sup>204</sup> Also, the Executive Director of the American Intellectual Property Law Association, Dr. Kirk, opposed the legislation because there was no demonstrated need for such legislation.<sup>205</sup> In fact, Dr. Kirk argued that the “underlying concepts of [House Bill 1127] is so failing in merit that all of the technical problems are not worth addressing.”<sup>206</sup>

Also, House Bill 1127 may have allowed commercial predators to unfairly benefit from research and development efforts of others,<sup>207</sup> by making vendors immune to contributory infringement or inducement of infringement.<sup>208</sup> This benefit would have been to the detriment to the biotechnology and pharmaceutical companies because there would have been arguably little incentive to develop new uses for available products.<sup>209</sup>

Moreover, because the legislative approach of House Bill 1127 would have limited certain subject matter from patentability, vari-

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202. *Hearings on H.R. 1127, supra* note 20 (statement of Dr. Kirk).

203. *See id.*

204. *Hearings on H.R. 1127, supra* note 20 (statement of G. Lee Skillington).

205. *Hearings on H.R. 1127, supra* note 20 (statement of Dr. Kirk) (arguing that the legislation would undesirably remove patent incentives and create an undesirable international precedent).

206. *Id.*

207. *See Hearings on H.R. 1127, supra* note 20 (statement of Mr. Baldino).

208. *See HARMON, supra* note 54, at 238-243 (noting that both contributory infringement and inducement of infringement require direct infringement).

209. *See Hearings on H.R. 1127, supra* note 20 (statement of Mr. Baldino).

ous commentators have expressed concern that the bill may have been in conflict with, and opposed to, our international position encouraging the expansion of patentable subject matter. Although this approach may have been technically in accord with Article 27 of the TRIPs Agreement,<sup>210</sup> at least one commentator testifying before Congress argued that such exclusionary provisions were included in the TRIPs agreement only at the urging of developing nations over the objections of the United States.<sup>211</sup> Therefore, if the United States wishes to narrow or eliminate such exclusionary provisions, the United States should not simultaneously take advantage of them.<sup>212</sup>

No Judiciary Committee markups were held on House Bill 1127. Nonetheless, by March of 1996, the House Bill 1127 had 129 cosponsors, including 25 Democrats and 103 Republicans.<sup>213</sup> The biotechnology industry, however, wanted to add language to the bill to which the Medical Procedure Patents Coalition would not agree.<sup>214</sup> Thus, the bill never passed into law.

#### B. *House Bill 3814*

In response to the criticisms of House Bill 1127, Representative Ganske introduced a modified version as an amendment to 1997 appropriations legislation House Bill 3814.<sup>215</sup> Unlike House Bill 1127, the Ganske amendment would have cut the United States Patent and Trademark Office's funding in 1997 for issuing patents for new medical procedures, except as a necessary component of a patentable medical device or machine.<sup>216</sup>

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210. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement].

211. See *Hearings on H.R. 1127*, *supra* note 20 (statement of Dr. Kirk) (maintaining that Article 27 allows member nations to exclude diagnostic, therapeutic, and surgical methods for the treatment of humans or animals as well as plants and animals other than micro-organisms).

212. See *id.*

213. See Garris, *supra* note 195, at 101 n.172.

214. See Keven Murphy, *Procedure Patent Bills Face Hefty Opposition*, OCULAR SURGERY NEWS, Dec. 15, 1995, at 13.

215. See 142 CONG. REC. H8030 (1996) (noting that Rep. Ganske "offered" House Bill 3814).

216. See H.R. 3814, 104th Cong. (1996).

## 1. Summary of House Bill 3814

The Ganske amendment<sup>217</sup> states that no funds made available by the appropriations bill could be used by the United States Patent and Trademark Office to issue medical procedure patents, including methods for performing a surgical procedure,<sup>218</sup> performing a medical procedure,<sup>219</sup> or making a medical diagnosis.<sup>220</sup> The amendment made two exceptions to this rule.<sup>221</sup> The first exception was for a procedure performed by or as a necessary component of a patentable machine, manufacture, or composition of matter.<sup>222</sup> The second exception occurred when the patent was for “a new use of a composition of matter or biotechnological process.”<sup>223</sup>

## 2. Comments on House Bill 3814

Representative Ganske explained to the House of Representatives that House Bill 3814 “borrows from and improves” the original language of House Bill 1127.<sup>224</sup> In particular, Representative

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217. *Id.* House Bill 3814 is also referred to as the Ganske amendment because Representative Ganske introduced it. *See* 142 CONG. REC. H8030 (noting that Rep. Ganske “offered” House Bill 3814).

218. H.R. 3814. House Bill 3814 defines a surgical procedure 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.” *Id.*

219. *Id.* House Bill 3814 defines a medical procedure as a “nonsurgical, nondiagnostic procedure for curing or preventing a disease, injury, illness, disorder, or deformity.” *Id.*

220. *Id.* House Bill 3814 defines a medical diagnosis as the “identification of a medical condition or a disease or disorder of a body.” *Id.*

221. *Id.* According to House Bill 3814, “[t]he 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 . . .” *Id.*

222. *Id.* Under House Bill 3814, the exception occurs when:  
[T]he 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 . . .

*Id.*

223. *Id.*

224. 142 CONG. REC. H8254, at H8277 (daily ed. July 24, 1996) (statement of Rep. Ganske).

Ganske set out five policy reasons that the legislation should be supported.<sup>225</sup> First, patient access to new surgical and medical procedures is being threatened by medical patents;<sup>226</sup> second, medical patents permit patent owners to charge monopoly prices and contribute to our Nation's health care costs;<sup>227</sup> third, physicians have an obligation to share their knowledge and skills for the benefit of humanity;<sup>228</sup> fourth, medical patents are not necessary for the advancement of medicine;<sup>229</sup> and fifth, 80 countries around the world already prohibit medical patents.<sup>230</sup>

Representative Ganske maintained that House Bill 3814 was different from House Bill 1127 because it would ensure that all "presently patentable new drugs . . . machinery and devices for treating and diagnosing disease . . . biologic products . . . new uses for nonpatentable drugs and biological products" would have remained patentable.<sup>231</sup> Representative Ganske also emphasized during its introduction that the law, if the bill were passed, would not prohibit patents on gene therapy or other similar procedures.<sup>232</sup> Nonetheless, the biotechnology industry rejected the proposed legislation because of a belief that it would "undermine the patenting of gene therapy treatments."<sup>233</sup>

Moreover, the legislation was opposed on procedural grounds because it was attached as a rider to the House appropriations bill, a non-substantive bill that funds the Departments of Commerce, Justice and State—a procedure that the Senate generally "eschews."<sup>234</sup> Accordingly, during the introduction of House Bill

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225. *Id.*

226. *See id.*

227. *See id.*

228. *See id.*

229. *See id.*

230. *See id.*

231. 142 CONG. REC. H8254, at H8277 (daily ed. July 24, 1996) (statement of Rep. Ganske).

232. *Id.* Representative Ganske stated that House Bill 3814 contained "an additional exception for biotechnological process to make absolutely clear that this amendment does not, let me repeat, does not prohibit patents on gene therapy or other similar procedures." *Id.*

233. *Bill with PTO Finding and Patent Reform on Medical Procedures Is Signed into Law*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), Oct. 7, 1996, at D5.

234. *BIO gets House backing on SBIR, but loses on procedure patents*,

3814, various Representatives argued against inclusion of the Ganske amendment on procedural grounds.<sup>235</sup> Representative Rogers also argued that the Patent and Trademark Office had been conducting public hearings on issues related to medical procedure patents and proposed that they should “address the issues raised by the legislation by modifying their internal, administrative procedures.”<sup>236</sup> However, this was not the case when Representative Ganske introduced his amendment.<sup>237</sup>

House Bill 3814 was also opposed on substantive grounds, primarily on charges of being over broad and vague.<sup>238</sup> Representative Dooley argued that the law was so broad that it would affect up to a third of all biotechnology patents in the United States.<sup>239</sup> One patent attorney considered the amendment so vague that he dubbed it the “patent lawyers full employment act.”<sup>240</sup>

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BIOTECHNOLOGY NEWSWATCH, Aug. 19, 1996, at 3.

235. See 142 CONG. REC. H8254, at H8277 (daily ed. July 24, 1996) (statements of Rep. Rogers, Rep. Moorhead, and Rep. Mollohan). Representative Rogers agreed that it is “a very important subject that needs to be addressed by the authorization committee,” but he was “in reluctant opposition to the amendment . . . on a procedural basis . . .” *Id.* Representative Moorhead maintained that the amendment should be rejected because the “subject matter” of the bill was “within the jurisdiction of the Judiciary Committee” and the problems addressed by the amendment might be better remedied by modifying the “internal, administrative procedures” at the United States Patent and Trademark Office. *Id.* Representative Mollohan, in opposition to the amendment, argued that the amendment was “not the appropriate [subject of this] bill” and “should best be decided by the authorizing committee.” *Id.*

236. 142 CONG. REC. H8254, at H8277 (daily ed. July 24, 1996) (statement of Rep. Rogers).

237. See Bradley J. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. LEGIS. 265, 272 (1997).

238. See 142 CONG. REC. H8278. According to Representative Dooley, the “language is far too broad.” *Id.* (statement of Rep. Dooley). Representative Kennedy attacked the language as well; while agreeing “with the underlying fundamental goal of this amendment,” he maintained that the bill was flawed because it bans all medical procedure patents and “creates two somewhat vague exceptions.” *Id.* (statement of Rep. Kennedy). Representative Kennedy also noted that the amendment “has been likened to cutting one’s fingernails with a chain saw.” *Id.* In addition, Representative Schroeder argued “that the problems identified by the medical profession relating to patents on medical and surgical procedures can be solved by the U.S. Patent and Trademark Office through steps that are less drastic . . .” *Id.* (statement of Rep. Schroeder).

239. *Id.* (statement of Rep. Dooley) (“The broad implications of the language threaten to invalidate up to one-third of all the biotech patents in the United States.”).

240. Julie Rovner, *Congress moves to restrict medical-procedure patents*, LANCET,

An important difference between House Bill 1127 and the amendment contained in House Bill 3814 is that the amendment prevented the United States Patent and Trademark Office from using funds appropriated by the appropriations bill to issue patents on certain medical procedures, rather than prohibiting their issuance outright.<sup>241</sup> Accordingly, the bill was criticized as not addressing the purported “underlying problem.”<sup>242</sup> Also, the bill was an appropriation bill for a single fiscal year, i.e., 1997, making it at best a temporary solution.

On July 24, 1996, Ganske’s legislation was passed by the House<sup>243</sup> as an amendment to the Commerce, Justice, State and Judiciary Appropriations bill.<sup>244</sup> The legislation, however, later died in the Senate.<sup>245</sup>

#### B. *Senate Bill 1334*

Due to the strong opposition to the approaches taken in House Bill 1127 and House Bill 3814, Senator Frist, in favor of limits on medical procedure patents, introduced Senate Bill 1334 as an alternative.<sup>246</sup> Unlike the former approaches, which either limited the issuance of certain medical procedures or restricted funding for the granting of such patents, Senate Bill 1334 would have created an infringement liability exception for medical professionals using patented medical procedures.<sup>247</sup>

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Oct. 12, 1996, at 1025 (quoting David Schmickel, patent counsel for the Biotechnology Industry Organization), *available in* LEXIS, NEWS Library, CURNWS File.

241. H.R. 3814, 104th Cong. (1996).

242. *Ganske Wins Ban on Licensing Medical Methods*, HEALTH LEGISLATION & REGULATION, July 31, 1996 (noting that Senator Frist said that he “want[s] to treat the underlying problem, not stop funding one of the symptoms”), *available in* LEXIS, NEWS Library, ARCNWS File.

243. *See* 142 CONG. REC. S12,023, at S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist) (noting that the legislation passed in a 295-128 vote).

244. *See id.*

245. *See* Meier, *supra* note 237, at 271.

246. *See* 141 CONG. REC. S15291, at S15291 (daily ed. Oct. 18, 1995) (statement of Sen. Frist) (noting that Senator Frist introduced Senate Bill 1334, also entitled the “Medical Procedures Innovation and Affordability Act”).

247. S. 1334, 104th Cong. (1995).

### 1. Summary of Senate Bill 1334

Senate Bill 1334 would have amended section 271 of title 35 of United States Code by adding new subsection (j).<sup>248</sup> The legislation stated that it would not be infringement for certain persons to use certain patented methods,<sup>249</sup> or to use or induce others to use certain patented medical processes.<sup>250</sup> The legislation also stated that it would not apply to patented procedures used by persons having a commercial interest in a regulated drug, medical device, process, or other product.<sup>251</sup>

The terms “device” and “drug” would have the same meanings as the same terms defined in sections 201(h) and (g) of the Federal Food, Drug, and Cosmetic Act.<sup>252</sup> The terms “health care entity” and “licensed health care entity” would mean any entity that provides health care services.<sup>253</sup> The terms “patient,” “physician,” “product,” “professionally affiliated with” and “state” were defined in various subsections of the legislation.<sup>254</sup>

### 2. Comments on Senate Bill 1334

Senate Bill 1334 was the subject of congressional testimony on October 19, 1995. Senate Bill 1334 was criticized by a physician as an attempt to fix “a fundamentally unsound and conceptually flawed” proposal by narrowing its exclusionary provisions where there were “policy or political impediments to enactment of the legislation.”<sup>255</sup>

It was also attacked because it provides physicians “unprecedented special rights to a professional group, giving them the ap-

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248. See 141 CONG. REC. S15291, at S15291 (daily ed. Oct. 18, 1995) (statement of Sen. Frist).

249. S. 1334.

250. *Id.*

251. *Id.*

252. 21 U.S.C. §§ 321(g), 321(h) (1994).

253. S. 1334. Under section 271(j)(2)(C) and (D), the terms “health care entity” and “licensed 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.” *Id.*

254. *Id.*

255. 142 CONG. REC. S11,845, at S11,846 (daily ed. Sept. 30, 1996) (letter from Dr. Kirk).

pearance of being 'above the law.'"<sup>256</sup> One commentator also pointed out that for this reason, Senate Bill 1334 might conflict with the Due Process Clause of the Fifth Amendment.<sup>257</sup> In fact, Senate Bill 1334 was dubbed "doubly discriminatory" because it discriminated based on the field of invention of technology and the identity or profession of the infringer.<sup>258</sup>

According to some commentators, although Senate Bill 1334 was not intended to immunize commercial suppliers, such suppliers may exploit the immunity through health care entities under a literal interpretation of the bill.<sup>259</sup> Senate Bill 1334 states that it is not infringement for "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.<sup>260</sup> The term "health care entity," means a "for-profit or non-profit entity that provides health care services."<sup>261</sup> Therefore, if a commercial interest would have provided materials used in a patented method performed by such a health care entity, that commercial interest may have been immune from infringement as well.<sup>262</sup>

Even if a commercial interest was found liable for infringement under Senate Bill 1334, the result may be inequitable.<sup>263</sup> In particular, the term "health care entity" may include a person "engaged in a commercial sale."<sup>264</sup> In that case, it may have been inequitable for a willfully infringing health care entity, such as a health management organization buyer of drugs, not to share liabil-

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256. *Hearings on H.R. 1127, supra* note 20 (statement of Dr. Noonan).

257. *See* Garris, *supra* note 195, at 104.

258. 142 CONG. REC. S11,845, at S11,845 (daily ed. Sept. 30, 1996) (letter from Mr. Hatch letter); *see also* *Hearings on H.R. 1127, supra* note 20 (statement of Dr. Noonan) (arguing that the approach of 1334 is "unpalatable because it grants unprecedented special rights to a professional group, giving them the appearance of being 'above the law,' and inviting other groups to claim similar immunity").

259. *See* Murnane & Kole, *supra* note 22, at C19.

260. S. 1334, 104th Cong. (1995).

261. *Id.*

262. *See* Murnane & Kole, *supra* note 22, at C19 ("It is not difficult to imagine scenarios in which the health care entity, which may be for-profit or non-profit, enters into a lucrative relationship with a commercial supplier that provides materials used in the patented method.").

263. *Id.*

264. S. 1334.

ity with the commercial interest, the manufacturer of those drugs.<sup>265</sup>

Furthermore, some commentators argue that Senate Bill 1334 may have been ambiguous as to whether a physician participating in the sale of a medical product would have been exempted from the immunity granted to physicians by the bill.<sup>266</sup> Although a person participating in the sale of certain regulated products or processes is exempt from immunity, the bill does not require these regulated products or processes to be related to any patented method.<sup>267</sup> Therefore, a physician may be immune to patent infringement, even when that doctor participates in the sale of unrelated patented medical products.<sup>268</sup>

A possible advantage to Senate Bill 1334 over the other versions of legislation is that it would only have limited the enforceability, not prohibited the issuance, of such patents, thereby having the benefit of not affecting the procedures of the United States Patent and Trademark Office.<sup>269</sup>

Senate Bill 1334 may have also been superior to House Bill 1127 because the approach taken in Senate Bill 1334 was arguably more consistent with the approach taken in section 271(c) of title 35 of the United States Code—the related patent statute.<sup>270</sup> Section 271(c), also known as the “clinical trial exemption,” states that it is not an act of infringement to use or sell a patented invention solely for uses reasonably related to the development and submission of information under federal laws that regulate drugs or veterinary biological products.<sup>271</sup> Like section 271(c), Senate Bill 1334 states that it is not an act of infringement for certain individuals to use or induce others to use certain medical methods.<sup>272</sup> Therefore, like

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265. See Murnane & Kole, *supra* note 22, at C19.

266. See *id.*

267. See *id.* (“The Frist bill exempts from immunity any person engaged in the commercial manufacture, sale or offer for sale of regulated drugs, medical devices or processes, without linking such items with the patented method to which immunity is attached.”).

268. See *id.*

269. S. 1334

270. See *Hearings on H.R. 1127, supra* note 20 (statement of Mr. Kelman).

271. 35 U.S.C. § 271(c)(1) (1994).

272. S. 1334.

section 271(c), Senate Bill 1334 exempts certain acts from being acts of infringement.<sup>273</sup>

The remedy restrictive approach, however, taken by Senate Bill 1334 may not achieve an important intended result of the legislation—the prevention of lawsuits against medical practitioners for the practice of patented medical procedures.<sup>274</sup> Because expensive discovery proceedings would probably have been required before the merits of the case could be judged, the legislation likely would not have provided the relief sought by practitioners.<sup>275</sup> One commentator argued that Senate Bill 1334 would actually increase litigation through a combination of a failure to reduce existing litigation and additional litigation over the meaning and effort of the legislation itself.<sup>276</sup>

Furthermore, House Bill 1334 may not have precluded enforcement against those involved in the commercial manufacture of drugs or medical devices “subject to the regulation under the Federal Food, Drug, and Domestic Act or the Public Health Service Act.”<sup>277</sup> In effect, this approach would have provided patent protection only to medical methods that require approval by the Food and Drug Administration (“FDA”). Because this approach would have made patentable only those medical procedures subject to regulatory review—thus making the scope of patentable protection flexible—the approach was arguably superior to House Bill 1127 and House Bill 3814.<sup>278</sup> The approach, however, may be flawed because some believed it to undesirably expand the scope of FDA review to reach the medical practice.<sup>279</sup>

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273. *Id.* Unlike Section 271(c), however, the acts defined by Senate Bill 1334 are not related to government regulation. *Id.*

274. See 142 CONG. REC. S11,845, at S11,846 (daily ed. Sept. 30, 1996) (letter from Dr. Kirk).

275. See *id.*

276. See *id.*

277. H.R. 1334.

278. See *Hearings on H.R. 1127, supra* note 20 (statement of Dr. Noonan) (“The scope of patent protection would also be flexible, and could expand if the jurisdiction of the FDA was enlarged.”).

279. See *id.*; see also 142 CONG. REC. S12,023, at S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist). According to Senator Frist, such legislation would “inject patent-seeking in the heart of medicine” and “undermine the peer review process,” thereby opening the door for more expansive FDA regulation. 142 CONG. REC. S12,023,

#### D. Senate Bill 2105

On September 24, 1996, Senator Frist introduced a bill that he believed struck a balance between various competing interests.<sup>280</sup> On one hand, Senator Frist believed that medical patents, other than for procedures, required patent protection to attract capital for research and development.<sup>281</sup> On the other hand, he worried that patent infringement suits involving doctors and other health care professionals would have several undesirable consequences.<sup>282</sup> In any case, Senate Bill 2105 died before making it to the House.

#### E. Section 616 of House Bill 3610

Although Senate Bill 2105 never passed into law itself, it initiated a legislation chain reaction that led to section 287(c).<sup>283</sup> Its passage into law took less than one week and included language not in any previous bill.<sup>284</sup>

On September 28, 1996, with a vote of 370 to 37, House Bill 3610 was passed by the House after an all-night session.<sup>285</sup> During that session, the House chose not to amend the bill, opting to pass it without amendment to the Senate for consideration.<sup>286</sup> Because House Bill 3610 was sent to the Senate as a conference agreement,

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at S12023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist). Senator Frist also noted that, “[w]hile the FDA regulates medical devices and pharmaceuticals, it has no authority to regulate the general practice of medicine . . . .” *Id.*

280. *See id.*

281. *Id.*

282. *Id.* According to Senator Frist, patent infringement suits involving health care practitioners may lead to undesirable results. *Id.* First, health care costs could explode if doctors charged licensing fees for every new surgical or medical techniques they developed. *See id.* Second, it could greatly jeopardize patients’ rights to privacy. *See id.* 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 which procedures were used. *See id.* Third, allowing pure procedure patents could undermine the medical community’s tradition of freely exchanging information for the benefit of patients. *See id.* And fourth, it could open the door to FDA regulation of all aspects of medical practice, instead of the current regulation of only medical devices and pharmaceuticals. *See id.*

283. Pub. L. No. 104-208, 110 Stat. 3009 (1996).

284. *See* 142 CONG. REC. S12,049, at S12,049 (daily ed. Oct. 1, 1996) (statement of Mr. Lott).

285. *See* 142 CONG. REC. S11,815, at S11,816 (daily ed. Sept. 30, 1996) (statement of Mr. Lott).

286. *See id.*

it could not be amended; it was only subject to an up or down vote.<sup>287</sup> The Senate passed House Bill 4278 on September 30, by a vote of 84-15,<sup>288</sup> and also passed House Bill 3610, which was signed by the President that evening.<sup>289</sup> House Bill 3610 contained section 287(c), which deprives owners of medical procedure patents the right to seek damages or injunctive relief when such patents are infringed by certain health care providers.<sup>290</sup>

### 1. Summary of Section 287(c)

Section 287(c)(1) provides “medical practitioners” engaged in “medical activity” with immunity from the provisions contained in sections 271, 281, 283, 284, and 285.<sup>291</sup> Under section 287(c)(2)(A), the term “medical activity” is defined as the “performance of a medical or surgical procedure on a body,” but does not include the use of patented machines, practices, or processes.<sup>292</sup> Section 287(c)(2)(B) defines the term “medical practitioner” to mean “any natural person who is licensed by a State to provide the medical activity described in Subsection 287(c)(1) or who is acting under the direction of such a person in the performance of the medical activity.”<sup>293</sup> Section 287(c)(2)(C) defines the term “re-

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287. *See id.*

288. *See* 142 CONG. REC. S12,049, at S12,049 (daily ed. Oct. 1, 1996) (statement of Mr. Lott).

289. *See id.*

290. H.R. 3610, 104th Cong. (1996).

291. 35 U.S.C. § 287(c)(1). Section 287(c)(1) states that:

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.*

292. *Id.* § 287(c)(2)(A). Section 287(c)(2)(A) defines the term “medical activity” to mean “performance of a medical or surgical procedure on a body,” but does 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.

*Id.*

293. *Id.* § 287(c)(2)(B).

lated health care entity” as “an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity.”<sup>294</sup> Under section 287(c)(2)(D), the term “professional affiliation” is defined as “staff privileges, medical staff membership, employment of contractual relation, partnership or ownership interest, academic appointment, or their affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.”<sup>295</sup> Section 287(c)(2)(E) defines the term “body” as a “human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.”<sup>296</sup> According to section 287(c)(2)(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 matter does not directly contribute to achievement of the objective of the claimed method.”<sup>297</sup> Section 287(c)(2)(G) defines the term “state” as “any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.”<sup>298</sup>

Section 287(c)(3) exempts certain activities performed by commercial interests from section 287(c).<sup>299</sup> Specifically, “persons 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 . . . .”<sup>300</sup> Section 287(c)(3)(A) and (B) defines the type of exempted activities.<sup>301</sup> According to section 287(c)(3)(A), the exempted activity must be “directly related” to certain commercial

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294. *Id.* § 287(c)(2)(C). Section 287(c)(2)(C) further defines a related health care entity as “including, but not limited to, nursing home, hospital university, medical school, health maintenance organization, group medical practice, or a medical clinic.” *Id.*

295. *Id.* § 287(c)(2)(D).

296. *Id.* § 287(c)(2)(E).

297. *Id.* § 287(c)(2)(F).

298. *Id.* § 287(c)(2)(G).

299. *Id.* § 287(c)(3).

300. *Id.*

301. *Id.* §§ 287(c)(3)(A), 287(c)(3)(B).

activities.<sup>302</sup> Under section 287(c)(3)(B), the exempted activity must also be “regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.”<sup>303</sup>

## 2. House Report 2702

According to House Report 2702, section 287(c) is intended to “preclude the filing of civil action” for damages or injunctive relief “against a medical practitioner” or a “related health care entity” who performs a medical activity that would otherwise constitute an infringement or inducement to infringe under section 271.<sup>304</sup> Under section 287(c)(2)(A), there are three exceptions to the definition of “medical activity.”<sup>305</sup>

The House Report explained that the term “patented use of a composition of matter,” under section 287(c)(2)(A)(ii), is limited by section 287(c)(2)(F)<sup>306</sup> and, under section 287(c)(2)(F), 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.<sup>307</sup>

Also, the House Report explained that a use of a composition of matter as a step in a claim “will direct[ly] contribute” to the achievement of the objective of the claimed method if it is “novel or if it contributes to or is necessary to establish the non-obviousness of the claim as a whole.”<sup>308</sup> In addition, when each of the method steps in a method claim recites a “use of a composition

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302. *Id.* § 287(c)(3)(A). According to section 287(c)(3)(A), the activity must be “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) . . .” *Id.*

303. *Id.* § 287(c)(3)(B). According to section 287(c)(3)(B), the activity exempted by section 287(c)(3) must also be “regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.” *Id.*

304. H.R. CONF. REP. NO. 104-2702 (1996).

305. 35 U.S.C. § 287 (c)(2)(A).

306. H.R. CONF. REP. NO. 104-2702 (1996).

307. *Id.*

308. *Id.*

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.<sup>309</sup> Moreover, “[u]ses of compositions of matter” include, without limitation, a wide variety of novel uses and methods.<sup>310</sup> The House Report offered the treatment for diabetes as an example of a claim that does not fall within the scope of a “medical activity.”<sup>311</sup>

The House Report also introduces the concept of a “hybrid” claim.<sup>312</sup> In order to determine whether a “hybrid” claim is exempted from the definition of a “medical activity,” the test established by section 287(c)(2)(F) must be applied.<sup>313</sup> The hybrid claim is not a “medical activity” when it includes the patented use of a composition of matter that directly contributes to the objective of the claim.<sup>314</sup>

The test set forth in the House Report has two parts.<sup>315</sup> Before applying the two-part test, however, the hybrid claim must be divided into (1) steps that recite the use of composition of matter, namely, composition steps, and (2) steps that do not recite the use of a composition of matter, namely, procedure steps.<sup>316</sup> The first part of the test determines the objective of the claimed method taking into account all of the process steps set forth in the claim.<sup>317</sup> The second part of the test determines “whether the steps involving

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309. *Id.*

310. *Id.* The House Report expressly included the following novel uses and methods: “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).” *Id.*

311. *Id.* The example claim recites that “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.” *Id.*

312. *Id.* The House Report defines a hybrid claim to be “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) . . . .” *Id.*

313. *Id.*

314. *Id.*

315. *Id.*

316. *Id.*

317. *Id.*

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.”<sup>318</sup>

According to the House Report, when 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,” the hybrid claim is not a medical activity.<sup>319</sup> Therefore, when one or more steps that use compositions of matter are combined with one or more steps that involve collectively obvious medical or surgical techniques to produce a novel and non-obvious method, the ones that use compositions of matter “may still directly contribute,” as defined by section 287(c)(2)(F), thereby making the hybrid claim exempt from section 287(c).<sup>320</sup>

Section 287(c)(2)(A) provides for procedures that do not constitute a “medical activity.”<sup>321</sup> The House Report provided an example of a surgical procedure that qualifies as a medical activity.<sup>322</sup> The example involves the transplantation of a healthy heart into a patient with a diseased heart, including “administering a conventional anesthetic” and performing “a novel and non-obvious surgical transplantation procedure.”<sup>323</sup> Under the test set forth in the House Report, that procedure is not a patented use of a composition of matter within the meaning of section 287(c)(2)(A)(ii).<sup>324</sup> Therefore, assuming none of the other exceptions apply,<sup>325</sup> the surgical procedure qualifies as a “medical activity.” In contrast, the House Report explains that “where the administration of the anes-

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318. *Id.*

319. *Id.*

320. *Id.* According to House Report 104-2702:

[E]ven 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.

*Id.*

321. 35 U.S.C. § 287(c)(2)(A).

322. H.R. CONF. REP. NO. 104-2702 (1996).

323. *Id.*

324. *Id.*

325. See 35 U.S.C. §§ 287(c)(2)(A)(i), 287(c)(2)(A)(ii), 287(c)(2)(A)(iii).

thesia was accomplished . . . using a novel anesthetic or a novel dosing schedule,” the procedure would fall within the meaning of section 287(c)(2)(A)(ii) and the procedure would not qualify as a medical activity.<sup>326</sup>

The House Report also purports that the determination of whether section 287(c)(2)(A)(ii) applies, can be decided by a motion to dismiss or summary judgment,<sup>327</sup> and proposes a two-pronged test for making such a determination.<sup>328</sup> An accused infringer would “ordinarily prevail” under the two prong test if the accused infringer can show “by clear and convincing evidence” that the recited uses of the compositions of matter, both individually and collectively, lack novelty, and “by a preponderance of the evidence” that the medical or surgical procedure steps are, by themselves, novel and non-obvious, thereby allowing the accused infringer to concede non-obviousness instead of making the required evidentiary showing.<sup>329</sup>

Section 287(c)(2)(A)(iii) excludes from the definition of “medical activity” the practice of a patented process in violation of a biotechnology patent.<sup>330</sup> The House Report explains that for purposes of this provision, the definition of the term “biotechnology patent” includes patents on a (1) “biotechnological process” as defined in section 103(b), and (2) the “process of making or using

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326. H.R. CONF. REP. NO. 104-2702 (1996). According to House Report 104-2702, “the objective of the claimed method would include the provision of a novel use of an anesthetic in transplantation surgery and the use of the composition of matter (i.e., the anesthetic) would directly contribute to the achievement of the objective.” *Id.*

327. *Id.* (“It is intended that the applicability of the exception in 287(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.”).

328. *Id.*

329. *Id.* The House Report notes that the movant must show:

- (1) . . . by clear and convincing evidence that the recited uses of the compositions of matter, both individually and collectively, lack novelty, and
- (2) . . . 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.

*Id.*

330. 35 U.S.C. § 287(c)(2)(A)(iii).

biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level.”<sup>331</sup> Moreover, “biological materials” include “a variety of cellular, intracellular, extracellular, and acellular substances.”<sup>332</sup> Additionally, “*ex vivo* manipulation” includes “propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biological characteristics of these substances outside of a human body.”<sup>333</sup> Therefore, medical procedures that do not involve *ex vivo* cellular or molecular manipulation of a biological material are excluded from section 287(c)(2)(iii).<sup>334</sup> The House Report explains that a heart transplantation surgery that includes the use of a heart-lung machine is excluded from section 287(c)(2)(iii) because the manipulation is not *ex vivo*, and not at the cellular or molecular level.<sup>335</sup>

### 3. Comments on Section 287(c)

The Medical Procedure Patents Coalition, again led by the Society of Cataract and Refractive Surgery, supported the legislation.<sup>336</sup> Specifically, the Medical Procedure Patents Coalition supported the language exempting certain activities relating to

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331. H.R. CONF. REP. NO. 104-2702 (1996).

332. *Id.* According to House Report 104-2702:

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.

*Id.*

333. *Id.*

334. 35 U.S.C. § 287(c)(2)(iii).

335. H.R. CONF. REP. NO. 104-2702 (1996).

336. *See Medical Patent Bill, supra* note 12. The other members of the Medical Procedure Patents Coalition are the American Academy of Dermatology, American Academy of Ophthalmology, American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology—Head and Neck Surgery, American Association of Neurological Surgery, American College of Radiology, American College of Surgeons, American Institute of Ultrasound in Medicine, American Medical Association, American Society of Dermatologic Surgery, American Society of Plastic and Reconstructive Surgery, American Urological Association, Association of American Medical Colleges, Society of Cardiovascular and Interventional Surgery, and the Society of Vascular Technology. *Id.*

commercial development and distribution and provision of pharmacy or clinical laboratory services, which effectively broadened the exemption already objected to by Dr. Kirk.<sup>337</sup>

One aspect of the legislation related to claims involving the patented use of a composition of matter. This aspect narrows the scope of the exemption by requiring that that use “directly contribute to [the] achievement of the objective of the claimed method.”<sup>338</sup> According to Dr. Kirk, this aspect of the legislation was a matter of fact, and thus unlikely to be resolved at the pleadings or motion stages of litigation.<sup>339</sup> Therefore, for the same reasons that Senate Bill 1334 would not have avoided costly and time-consuming litigation between physicians, this legislation would not have as well.<sup>340</sup>

Legislative proponents, however, argued that the history of the legislation would establish the clear legislative intent required to resolve such fact intensive matters by motion to dismiss or summary judgment.<sup>341</sup> Nevertheless, as Dr. Kirk testified, legislative history is not controlling when in conflict with the rules of civil procedure.<sup>342</sup> For example, a proponent suggests that a movant for summary judgment under Rule 56<sup>343</sup> should ordinarily prevail if certain essential facts are shown by a “preponderance of the evidence.”<sup>344</sup> According to Dr. Kirk, however, such a suggestion expressly conflicts with Rule 56, which states that a party should prevail only if “there is no genuine issue as to any material fact.”<sup>345</sup>

According to a letter written by Senator Orrin Hatch, there were too many unresolved issues to “sweep” the legislation into an end-of-the-session omnibus appropriations bill.<sup>346</sup> In particular,

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337. 142 CONG. REC. S11,845, at S11,846 (daily ed. Sept. 30, 1996) (letter from Dr. Kirk).

338. *Id.*

339. *Id.*

340. *See id.*

341. *See id.*

342. *Id.*

343. FED. R. CIV. P. 56.

344. 142 CONG. REC. S11,845, at S11,846 (daily ed. Sept. 30, 1996) (letter from Dr. Kirk).

345. *Id.*

346. 142 CONG. REC. S11,845, at S11,845 (daily ed. Sept. 30, 1996) (letter from Mr.

Senator Hatch objected to the amendment on procedural grounds because the proposal was never the subject of hearings or amendments in either the House or Senate.<sup>347</sup> Senator Hatch also objected to the legislation because of its undesirable precedent setting nature for United States trade policy.<sup>348</sup>

### III. SECTION 287(C) IS VAGUE, DISCRIMINATORY, AND INEFFECTIVE

This Note proposes a three-part analytic framework for determining whether a defendant should be granted relief under section 287(c)(1). It analyzes two exemplary medical procedure patents under this proposed framework and identifies problems inherent in the current statute. The proposed framework is necessary because section 287(c) is vague, discriminatory, and ineffective at solving the purported problems that motivated its enactment.

#### A. Analytical Framework

This Note proposes the following three-part analytical framework for determining whether a party is entitled to relief under section 287(c)(1).

##### 1. "With Respect to a Medical Practitioner"

The first part of the three-part analysis involves determining whether the performance of an accused infringer is "with respect to a medical practitioner."<sup>349</sup> This determination depends upon whether the defendant is a medical practitioner.<sup>350</sup> Section 287(c)(2)(B) provides that the term "medical practitioner" encompass any person licensed by a state to provide the medical activity described in section 287(c)(1), or any person acting under the direction of such a person in the performance of the medical activity.<sup>351</sup> If the performance by an accused infringer is not "with re-

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Hatch letter).

347. *Id.* (noting that there was no "purported emergency").

348. *Id.* According to Senator Hatch, the Senate Finance and House Ways and Means Committees should have consulted with the United States Trade Representative before this legislation was brought up for a vote. *Id.*

349. 35 U.S.C. § 287(c)(1) (1996).

350. *See id.*

351. § 287(c)(2).

spect to a medical practitioner's performance," a defendant cannot seek relief under section 287(c)(1).<sup>352</sup>

## 2. "A Medical Activity"

The second part of the three-part analysis determines whether the claimed procedure is directed to "a medical activity." A medical activity is a medical or surgical procedure on a body. Under section 287(c)(2)(E), a body must be human or nonhuman.<sup>353</sup> If nonhuman, the body must be used in research or instruction "directly relating to the treatment of humans."<sup>354</sup> Therefore, a performance on a "human" body would be a medical activity, but the same performance on a "nonhuman" body would likely generate substantial litigation depending on how "directly related" that performance is to the treatment of humans.<sup>355</sup>

The term "medical activities" does not cover three circumstances.<sup>356</sup> The three exceptions are the use of a patented machine, manufacture, or composition of matter in violation of such a patent, the practice of a patented use of a composition of matter in violation of such a patent, and the practice of a process in violation of a biotechnology patent.<sup>357</sup>

According to the exception in section 287(c)(2)(A)(i), a "medical activity" does not include the use of patented technology such as a "patented machine, manufacture, or composition of matter in violation of such patent."<sup>358</sup> Although not yet addressed in the case law, patented technology apparently could be covered by another claim in the same patent as the one also claiming the medical procedure or in a claim of an entirely different patent.

The question of whether a medical procedure uses a patented

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352. § 287(c)(1).

353. *Id.* § 287(c)(2)(E).

354. *Id.*

355. *See* discussion *supra* notes 61-62 and accompanying text (describing the term experimental use). A better approach to protecting experimental and research use would be analogous to the experimental use exception under section 102(b), 35 U.S.C. § 102(b), which is already established and substantially tested.

356. § 287(c)(2)(A) (1996).

357. *Id.*

358. § 287(c)(2)(A)(i).

technology would likely be answered in a two-step inquiry analogous to the conventional two-step infringement inquiry set forth in *Markman*.<sup>359</sup> This two-step procedure would first require establishing the meaning and scope of the claimed “patented technology,” and then a comparison of the properly construed meaning and scope of the claimed “patented technology” with the activity and equipment use of the medical practitioner. The first step would be used to determine if any patented technology exists<sup>360</sup> and then to establish the meaning and scope of any claims to any such patented technology. The second step would determine whether the performance of the medical practitioner is in violation of that patented technology. Thus, a medical practitioner seeking relief under section 287(c)(1) might be required to prove non-infringement of other patented technologies conceivably embodied in any of several unrelated patents.<sup>361</sup> Alternatively, the patentee may be required to prove that the exception applies after the medical practitioner proves a prima facie case. In either case, there appears to be an additional litigation burden on the medical practitioner.

Any *Markman*-like inquiry would likely be time-consuming and expensive. Taking guidance from *Markman*, the first question to be addressed under section 287(c) regarding the meaning and scope of the patent claim would be a matter of law,<sup>362</sup> and the second question regarding the comparison of the properly construed claims with the physician’s performance of the medical practitioner would be a question of fact, to be submitted to a jury.<sup>363</sup> Although the first question is a question of law, a court can use intrinsic and extrinsic evidence in deciding that question.<sup>364</sup> Such

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359. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (creating two-part patent infringement test), *aff’d*, 517 U.S. 370 (1996).

360. The term “patented” in this context is vague. It is unclear whether the term refers to technology covered by any patent or just by United States patents. Also, it is uncertain whether the term includes enforceable patents only. If so, it appears that this exception would illogically and inequitably depend on the enforceable status of one or more completely independent patents.

361. 35 U.S.C. § 287(c)(1).

362. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (creating two-part patent infringement test), *aff’d*, 517 U.S. 370 (1996).

363. *See id.*

364. *See id.* at 979.

evidence includes patents, their prosecution histories,<sup>365</sup> and any evidence external to the patents and prosecution histories, including expert and inventor testimony, dictionaries, and learned treatises.<sup>366</sup>

Thus, determining the answer to the threshold question of the meaning and scope of a patented technology may pose a substantial burden on the physician. Moreover, determining the answer to the second question by comparing the meaning and scope with the practitioner's performance, which is purely a matter of fact, may impose an even higher litigation burden on the medical practitioner. The analysis required to determine the answers to those questions would likely require substantial resources on behalf of the medical practitioner defendant. This is in contrast to section 287(c)'s proponents' purported objective of preventing the rise in cost of health care.<sup>367</sup>

In fact, coupling a defendant's immunity in a medical procedure patent infringement suit to another patent infringement unfairly and unreasonably increases the burden on the practitioner. In order to avoid infringement of a medical procedure patent, a medical practitioner may be required to argue non-infringement of a second unrelated patent. This is without precedent. In addition to increasing the burden on the medical practitioner, the pairing is undesirable because it provides a motive for medical patent owners to instigate additional unrelated patent infringement suits. The incentive to file additional suits surely could not have been an intended result of section 287(c)(1).<sup>368</sup>

According to the exception in section 287(c)(2)(A)(ii), a medical activity does not include "the practice of a patented use of a composition of matter in violation of such patent."<sup>369</sup> In contrast to the first exception, which concerns the use of patented technology,

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365. *See id.*

366. *See id.* at 980 ("This evidence may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history. Extrinsic evidence may demonstrate the state of the prior art at the time of the invention.").

367. *See Scerra, supra* note 18, at 28.

368. 35 U.S.C. § 287(c)(1).

369. § 287(c)(2)(A)(ii).

the second exception concerns the patented use of a composition of matter.<sup>370</sup>

The term “patented use of a composition of matter” is limited by subsection 287(c)(2)(F),<sup>371</sup> which states that a patented use does not include a patented method that uses a composition of matter not “directly contribut[ing]” to the achievement of the claimed method’s objective.<sup>372</sup> The House Report states that a patented use will directly contribute if that use is “itself novel or if it contributes to or is necessary to establish the non-obviousness of the claim as a whole.”<sup>373</sup> Thus, to show that a use “directly contributes,” the defendant may have to prove that the use of the composition of matter is not itself novel or does not contribute to or is not necessary to establish the non-obviousness of the claim as a whole.<sup>374</sup>

If a medical practitioner fails to prove that the use of the composition of matter in a step of the claim does not contribute to or is not necessary to establish the non-obviousness of the claim as a whole, the defendant’s case may be harmed while the patentee’s case is advanced. This result may arise because the defendant may undesirably establish that the remaining portion of the claim is non-obvious. In other words, medical practitioners would have little incentive to prove that the use of the composition of matter does not contribute to or is not necessary to establish the non-obviousness of the claim as a whole, and patentees would correspondingly not endeavor to prove the opposite.<sup>375</sup> This strange result suggests that the proposed method for resolving whether a use

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370. *Id.*

371. § 287(c)(2)(F). According to section 287(c)(2)(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 matter does not directly contribute to achievement of the objective of the claimed method.

*Id.*

372. *Id.*

373. *Id.* (“A use of a composition of matter as a step in a claim will directly 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.”).

374. *Id.*

375. Moreover, a party would be averse to challenging novelty because of the heavy burden of showing identity between prior art and the claimed invention.

“directly contributes” is untenable.

Moreover, no provision except section 287(c) makes the remedy available to a patent owner in any way contingent on less than all of the steps of a claim.<sup>376</sup> In fact, nowhere else does the patentability or enforceability of a claim depend solely on the novelty or non-obviousness of a step; they always depend on the claim when taken “as a whole.”<sup>377</sup> Indeed, proving the novelty or non-obviousness, or lack thereof, of one or more individual steps places a burden on the patentee, or the medical practitioner, respectively, that is even greater than the burden already met by the patentee in order to obtain the patent. At least for this reason, the novel and non-obviousness step test places an unprecedented burden on litigants that both contravenes logic and departs completely from traditional American patent law.

The House Report also suggests an undesirable strategy for determining whether a “performance of a medical or surgical procedure” falls within the exception defined by section 287(c)(2)(A)(ii) for two categories of claims.<sup>378</sup> The first category includes medical procedure claims in which every step of the claim recites a “use of a composition of matter.”<sup>379</sup> The second category includes medical procedure claims having at least one step that recites such a use and at least one step that does not.<sup>380</sup> The House Report refers to those claims as “hybrid” claims.<sup>381</sup> The strategy is undesirable because the applicability of the exception under section 287(c)(2)(A)(ii) hinges on the vagaries of claim drafting, rather than on the substantive issue of whether the claim is directed to an intended type of medical performance.<sup>382</sup>

Furthermore, the House Report submits that a claim in the first category “cannot represent a ‘medical activity’ because the use of a composition of matter [in each of the method steps] must necessarily contribute to the novelty and, therefore, to the objective of the

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376. 35 U.S.C. § 287(c).

377. O’Shaughnessy, *supra* note 32, at 149.

378. H.R. CONF. REP. NO. 104-2702 (1996).

379. *Id.*

380. *See id.*

381. *Id.*

382. 35 U.S.C. § 287(c)(2)(A)(ii).

claimed method.”<sup>383</sup> The House Report lists a series of qualifying examples of “uses of compositions of matter,” but states that the list is not exhaustive, and specifically qualifies the list with the phrase “includes, without limitation.”<sup>384</sup> The House Report provides an example of a claim that uses a composition of matter that is not a medical activity, that is, one that recites only the novel use of a drug for the treatment of diabetes involving the administration of a drug at a particular time or at a certain dose or with a specified concomitant medicinal therapy.<sup>385</sup> The House Report gives no examples, and thus gives no guidance, as to when a use would *not* qualify.<sup>386</sup>

The House Report incorrectly asserts that the use of a composition of matter in “each” claimed step must mean that it directly contributes to the achievement of the objective.<sup>387</sup> This is because the claim draftsman may have included the use of the composition of matter in each step unnecessarily, or even inadvertently.<sup>388</sup> The claim’s novelty may reside in an aspect of the steps other than the use of the composition of matter, especially because the claim was considered by the United States Patent and Trademark Office with respect to the claim as a whole,<sup>389</sup> not with respect to a particular use of a composition of matter.

For example, every step of a surgical claim might use a composition of matter because it is preferable, not because it contributes to the novelty of the claim or the achievement of its objective. To illustrate, each step of a surgical technique might include “flushing” a region with water or saline solution. Flushing water would be a use of a composition of matter. In this case, however, the flushing may merely improve the results of the otherwise novel claim.

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383. H.R. CONF. REP. NO. 104-2702.

384. *Id.*

385. *Id.*

386. *Id.*

387. *Id.*

388. This rule provides a clever patent prosecutor a means to evade section 287(c)(A)(1) by merely adding conventional uses of such compositions to each step in claim. This would be particularly simple in single step procedure claims where the use of a flushing agent would be standard practice.

389. See O’Shaughnessy, *supra* note 32, at 149.

The House Report submits that a claim in the second category, a hybrid claim, has “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.”<sup>390</sup> A two-step test for analyzing a hybrid claim is included in the House Report.<sup>391</sup> The first step is to determine “the objective of the claimed method taking into account all of the process steps set forth in the claim.”<sup>392</sup> The second step is to “determine whether the [claimed] 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.”<sup>393</sup>

In practice, neither determination would be easy. The first step involves determining only one objective of the claimed method.<sup>394</sup> This task may be difficult—or even impossible—because a single invention may have many objectives.<sup>395</sup> The second step involves determining whether the claimed steps involving the use of the compositions of matter alone or in combination directly contribute to the achievement of the objective found in the first step.<sup>396</sup> Such a determination would be unprecedented, requiring detailed analysis on the level of one or more steps. The question whether any claimed steps “directly contribute to the achievement of the objective” is entirely new. Therefore, the process of answering such a question would likely require litigation.

Yet another significant problem with the House Report’s categorical approach is its undesirable dependence on the structure of the claim at issue.<sup>397</sup> Claim drafting is an art, and the structure of a claim is flexible. What constitutes a claimed “step” is in many

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390. H.R. CONF. REP. NO. 104-2702 (1996); *see also supra* note 320 (quoting House Report 104-2702).

391. H.R. CONF. REP. NO. 104-2702 (1996).

392. *Id.*

393. *Id.*

394. *Id.*

395. Often, multiple objectives of an invention are listed in the summary of the invention. *See, e.g.*, Method of Preventing Repetitive Stress Injuries During Computer Keyboard Usage, United States Patent No. 5,638,831 (issued June 17, 1997) [hereinafter Repetitive Stress Patent] (including fifteen objects of the invention).

396. *See* H.R. CONF. REP. NO. 104-2702 (1996).

397. *Id.*

cases merely a matter of how the claim was drafted.<sup>398</sup> Thus, the question as to whether “each of the method steps” includes the use of a composition of matter could be compounded by the additional question of what constitutes a step.<sup>399</sup>

For example, a method claim includes one or more steps, but each of the steps may itself be a combination of sub-steps. The difference between a step and a sub-step is often a matter of formality, with no substantive basis. Thus, a two-step claim, including one step that recites the use of a composition of matter and one step that does not, could be combined into a one-step claim having two sub-steps.<sup>400</sup> Determining whether such a two-step claim is a “medical activity” requires the two-step analysis suggested by the House Report.<sup>401</sup> If the form of the claim were changed, however, by combining the steps to include a single step, it must include the use of a composition of matter, and the claim could not be a medical activity under the exception defined by section 287(c)(2)(A)(ii).<sup>402</sup> Thus, the determination of what constitutes a medical activity under this exception undesirably depends on the form of the claim.<sup>403</sup>

The House Report also proposes a two-part test for determining whether a motion to dismiss or summary judgment can be used to determine whether an accused infringer falls within the second exception.<sup>404</sup> Motions to dismiss under Rule 12(b)(6)<sup>405</sup> or for summary judgment under Rule 56<sup>406</sup> are not practical tools for resolving the issue of whether a medical procedure falls under the

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398. *Id.*

399. *Id.*

400. This is especially true if both steps are to be performed simultaneously.

401. *Id.*

402. 35 U.S.C. § 287(c)(2)(A)(ii).

403. Moreover, the House Report's proposed analysis does not address the role of a claim's preamble. H.R. CONF. REP. NO. 104-2702 (1996). The preamble of a claim might include the use of composition of matter. It is not clear how such a use in the preamble would affect the two-part test.

404. *Id.* (“It is intended that the applicability of the exception in 287(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 [Fed. R. Civ. P.] Rule 12(b) or Rule 56, respectively, of the Federal Rules of Civil Procedure.”).

405. FED. R. CIV. P. 12(b)(6).

406. FED. R. CIV. P. 56.

exception defined under section 287(c)(2)(A)(ii).<sup>407</sup>

A motion to dismiss for failure to state a claim under Rule 12(b)(6) would likely not reduce the likelihood of medical procedure patent litigation.<sup>408</sup> As a rule, dismissal of a suit for failure to state a claim is considered a drastic measure, and rarely occurs.<sup>409</sup> The Supreme Court has held that a complaint should not be dismissed under Rule 12(b)(6) “unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief.”<sup>410</sup> Therefore, a court must assume, for purposes of deciding a motion, that the medical procedure patent owner will prove any necessary factual allegations.<sup>411</sup> Because such motions are rarely successful, the availability of such a motion would likely not prevent, or even reduce, litigation.

Also, a motion to dismiss under Rule 56 would not lower the likelihood of medical procedure patent litigation.<sup>412</sup> Under Rule 56(c), a summary judgement may be rendered only if “there is no genuine issue as to any material fact.”<sup>413</sup> A court may therefore only consider the undisputed material facts of the case.<sup>414</sup> Then, only using the undisputed facts, “the moving party is entitled to a judgement as a matter of law.”<sup>415</sup> A patent owner, however, need only dispute material facts to make such a judgement unlikely or impossible. Therefore, a motion for summary judgement under Rule 56 would likely not prevent litigation because the existence of even one material fact in dispute, renders summary judgement impossible.<sup>416</sup>

A medical practitioner has different burdens of proof for each of the two conditions suggested by the House Report.<sup>417</sup> The ra-

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407. 35 U.S.C. § 287(c)(2)(A)(ii).

408. FED. R. CIV. P. 12(b)(6).

409. See JOSEPH W. GLANNON, CIVIL PROCEDURE, EXAMPLES AND EXPLANATIONS 290 (2d ed. 1992).

410. Conley v. Gibson, 355 U.S. 41, 45-46 (1957).

411. FED. R. CIV. P. 12(b)(6).

412. FED. R. CIV. P. 56.

413. *Id.* 56(c).

414. *Id.*

415. *Id.*

416. *Id.*

417. H.R. CONF. REP. NO. 104-2702 (1996).

tionale for requiring “clear and convincing evidence” of the lack of novelty in the recited uses of the compositions of matter, while requiring “a preponderance of the evidence” demonstrating that the medical or surgical procedure steps are novel and non-obvious is uncertain.<sup>418</sup> Under this framework, a medical practitioner would have a disincentive to try to prove that certain steps of the claim at issue are, by themselves,<sup>419</sup> novel and non-obvious.<sup>420</sup> Thus, not only does the burden of proof for the two conditions appear arbitrary, but satisfying them could also be hazardous for an accused infringer.

Even if a defendant met the burdens of proof, thereby preventing a trial, the defendant would still have been subject to substantial pre-trial litigation. The minimum burden on a defendant would be to show that the recited uses of the compositions of matter lack novelty.<sup>421</sup> A determination of novelty under section 102, however, may not be trivial.<sup>422</sup> Moreover, nothing under the law prevents a patent owner from bringing a patent infringement suit. Such a suit may be desirable to obtain a declaration of infringement for proving contributory infringement under section 271(c),<sup>423</sup> for which no relief is provided in section 287(c).<sup>424</sup> Thus, even if a motion to dismiss under Rule 12(b) or a motion for summary judgement under Rule 56 were granted, the substantial burden of pre-trial litigation would not be avoided.

According to the exception in section 287(c)(2)(A)(iii), a medical activity does not include “the practice of a process in violation of a biotechnology patent.”<sup>425</sup> The House Report explains that a biotechnology patent includes a patent on a biotechnological

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418. *Id.*

419. The phrase “by themselves” is ambiguous. The phrase could refer to steps of the claimed method that do not involve uses of compositions of matter in combination or individually. This question would likely be another source of litigation.

420. The House Report indicates that a medical practitioner may concede non-obviousness instead of making the required evidentiary showing. *See* H.R. CONF. REP. NO. 104-2702.

421. This is true in the unlikely event that the practitioner concedes that the medical or surgical procedure steps are novel and non-obvious.

422. *See* SCHWARTZ, *supra* note 51, at 51.

423. 35 U.S.C. § 271(c).

424. § 287(c).

425. § 287(c)(2)(A)(ii).

process, as defined in section 103(b),<sup>426</sup> 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.<sup>427</sup> Nevertheless, the House Report's proffered definition of a biotechnology patent does not help medical practitioners avoid litigation.

The question of whether a medical procedure falls under the third exception would likely be answered in the two-step *Markman*-like inquiry described with respect to the first and second exceptions.<sup>428</sup> In this case, it would include establishing the meaning and scope of claimed "biotechnology patent," and comparing the properly construed meaning and scope of the claimed subject matter with the performance of the medical practitioner.

As is the case with the first and second exceptions,<sup>429</sup> an inquiry in the case of the third exception is also undesirable. Chief among these reasons is the substantial burden of pre-trial litigation. In addition, the third exception has further weaknesses. The precise definition of what constitutes a biotechnology patent is so vague and potentially broad that the third exception arguably swallows the rule set forth in section 287(c)(1).<sup>430</sup>

The first type of biotechnological patent is a "biotechnological process," as defined by a relatively new and complicated statute, namely, section 103(b)(3).<sup>431</sup> There is no case law construing the scope and meaning of that definition. Thus, any use of section 287(c) could lead to substantial litigation over the intended meaning and scope of the term biotechnological process.

The second type of biotechnological patent is a patented process of making or using biological materials manipulated *ex vivo* at the cellular or molecular level. The House Report defines a biological material very broadly, including cellular, intracellular, ex-

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426. § 103(b).

427. H.R. CONF. REP. NO. 104-2702 (1996).

428. See discussion *supra* note 358 and accompanying text (describing the exception under section 287(c)(2)(A)(i)); discussion *supra* notes 306-329 and accompanying text (describing the exception under section 287(c)(2)(A)(ii)).

429. See 35 U.S.C. §§ 287(c)(2)(A)(i), 287(c)(2)(A)(ii).

430. § 287(c)(1).

431. § 103(b)(3).

tracellular, and even acellular substances.<sup>432</sup> The House Report does not provide a single example of a material that would not meet the definition of “a biological material.”<sup>433</sup> Furthermore, the definition of “ex vivo manipulation” is so broad that the exception defined by section 287(c)(2)(A)(iii) practically engulfs the rule.<sup>434</sup> “Ex vivo manipulation” of a biological material includes “propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biological characteristics of these substances outside of a human body.”<sup>435</sup> This inclusive definition is so broad that nearly any patented process performed on any biological substance outside a human body appears to be included.

Thus, the third exception is over broad and ineffective at reducing patent litigation. Accordingly, any application of the third exception, as defined by section 287(c)(2)(A)(iii), would not advance the policy goal voiced by many of its proponents, that is, protecting doctors from such litigation.<sup>436</sup>

### 3. “Constitutes an Infringement”

The third part of the proposed three-part analysis will only be reached if the questions raised in the first and second parts of the analysis are affirmatively answered. Otherwise, the liability exception available under section 287(c) would be unavailable.<sup>437</sup>

This third part involves determining whether the medical activity constitutes an infringement under Sections 271(a) or 271(b).<sup>438</sup> Section 271(a) states that “who[m]ever without authority makes, uses, offers to sell or sells any patented invention . . . infringes the patent.”<sup>439</sup> Section 271(b) states that whomever “actively induces infringement of a patent shall be liable as an infringer.”<sup>440</sup> Thus, but for new section 287(c)(1), a medical activity would otherwise

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432. H.R. CONF. REP. NO. 104-2702 (1996).

433. *Id.*

434. 35 U.S.C. § 287(c)(2)(A)(iii).

435. *Id.*

436. H.R. CONF. REP. NO. 104-2702 (1996).

437. 35 U.S.C. § 287(c).

438. §§ 271(a), 271(b).

439. § 271(a).

440. § 271(b).

constitute infringement if a medical practitioner either makes, uses, offers to sell, or sells the claimed invention, or induces the same.<sup>441</sup>

According to section 287(c)(1), if the medical activity constitutes an infringement in accordance with step three, no remedy for infringement would be available to the patent owner, including injunctions, damages, and attorney fees, against the medical practitioner or a “related health care entity” with respect to the medical activity.<sup>442</sup> Under section 287(c)(2)(C), a “related health care entity” is an entity with which a medical practitioner has a “professional affiliation” under which the medical practitioner performs the medical activity.<sup>443</sup> Under that section, a health care entity may be, but is not limited to, a nursing home, hospital, medical school, or health maintenance organization.<sup>444</sup> Under section 287(c)(2)(D), a “professional affiliation” is broadly construed to be, among other things, employment contracts and ownership interests.<sup>445</sup>

Any application of this third part would not likely cause substantial litigation because infringement under sections 271(a) and 271(b) would most likely be conceded by a defendant wishing to obtain immunity in a patent infringement suit. The statute is nevertheless discriminatory because it provides a liability exception only for medical practitioners and related health care entities. As a result of the discriminatory nature of section 287(c),<sup>446</sup> it fails to protect medical patients, who are not medical practitioners nor related health care entities, from patent infringement suits arising from the performance of unauthorized medical procedures, including lifesaving procedures.<sup>447</sup> For this reason, section 287(c) does not solve the purported problem with medical procedure patents of restricting life-saving medical procedures.

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441. §§ 271(a), 271(b).

442. § 287(c)(1).

443. § 287(c)(2)(C).

444. *Id.*

445. § 287(c)(2)(D).

446. § 287(c).

447. See H.R. CONF. REP. NO. 104-2207 (1996). The Heimlich maneuver is an example of a medical procedure that, if patented, would arguably not be protected by section 287(c).

### B. Two Medical Procedure Patents Examples

The proposed three-part analytical framework would determine whether section 287(c) would be applied to a defendant. To illustrate the mechanisms of this structured inquiry, it will now be applied to two distinct patent claims in the United States, that is, Patent Numbers 5,638,831 and 4,886,831.

#### 1. Brown: United States Patent Number 5,638,831

In 1997, New York concert pianist Stephanie Brown was issued a United States patent for her method of preventing repetitive stress injuries while using a computer keyboard.<sup>448</sup> Brown developed the technique for musicians and later adapted it to computer keyboard operations.<sup>449</sup> The method prevents repetitive stress injuries by providing “a natural line” between the hand, wrist, and forearm.<sup>450</sup>

The Brown method includes five steps.<sup>451</sup> In the first step, the hand and wrist move in a straight line so that the forearm forms a natural line position.<sup>452</sup> In the second step, the hand reaches for an object while allowing the elbow to follow the hand naturally.<sup>453</sup> In the third step, the hand and wrist are angled sideways relative to the forearm.<sup>454</sup> In the fourth step, the hand, wrist, and forearm are returned to the natural line position.<sup>455</sup> And in the fifth and last step, the hand is placed on a keyboard while maintaining the natu-

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448. See Repetitive Stress Patent, *supra* note 395.

449. See *id.*

450. *Id.*

451. *Id.* The Brown method reads as follows:

A method for providing a natural line between the hand, wrist and forearm, comprising the steps of: moving the hand and wrist in a straight line with the forearm thereby forming a natural line position reaching for an object with the hand and allowing the elbow to follow the hand naturally; angling the hand and wrist sideways relative to the forearm, thereby forming an angled wrist position; returning the hand, wrist and forearm to said natural line position; and placing the hand on a keyboard while maintaining said natural line position.

*Id.*

452. *Id.*

453. *Id.*

454. *Id.*

455. *Id.*

ral line position.<sup>456</sup>

The proposed three-part framework is now applied to the Brown method. Summarizing, the three-part framework involves determining whether (1) the performance of an accused infringer is “with respect to a medical practitioner,” (2) the claimed procedure is directed to “a medical activity,” and (3) the medical activity constitutes an infringement under section 271(a) or 271(b).

The first step involves determining whether the claimed method is with respect to a medical practitioner’s performance.<sup>457</sup> According to section 287(c)(1), claim 1 is with respect to a medical practitioner’s performance if it is performed under the direction of a medical practitioner.<sup>458</sup> Conversely, if a medical practitioner is not performed under such direction, the claim would not be with respect to a medical practitioner’s performance.<sup>459</sup>

The second step involves determining whether the claim is directed to a medical activity. A medical activity, as defined by section 287(c)(2)(A), means a “medical or surgical procedure on a body,” but does not include the three exceptions expressly defined in the section.<sup>460</sup> The Brown method is probably a medical activity because it does not appear to fall under any of the three exceptions. Claim 1 of the Brown patent probably does not fall under the first exception because it does not involve the use of a patented machine, manufacture, or composition of matter.<sup>461</sup> Nor does claim 1 of the Brown patent fall under the second exception because there is no use of a composition of matter, let alone a patented use of one.<sup>462</sup> Finally, claim 1 does not fall under the third exception because it does not involve the use of a biotechnology patent, as defined by section 103(b).<sup>463</sup>

The third step of the proposed analysis involves determining whether the medical practitioner’s performance constitutes direct

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456. *Id.*

457. 35 U.S.C. § 287(c)(1)

458. *Id.*

459. *Id.*

460. § 287(c)(2)(A)

461. *See* § 287(c)(2)(A)(i).

462. *See* § 287(c)(2)(A)(ii).

463. *See* § 287(c)(2)(A)(iii).

infringement under section 271(a) or inducement to infringe under section 271(b).<sup>464</sup> A court would likely find direct infringement, if the medical practitioner practices the method himself, or inducement to infringe, if the practitioner encourages someone else to practice the claimed method.<sup>465</sup> The nature of the claimed method, however, probably precludes the making, offering to sell, or selling of the invention.

Thus, the availability of relief under section 287(c)(1) depends on the identity or profession of the patient. If the patient is a medical practitioner (or under the direction of a medical practitioner), the activity falls within the meaning of section 287(c)(1).<sup>466</sup> In that case, relief under section 287(c) would be available to an accused infringer.<sup>467</sup> If the patient is not a medical practitioner (nor under the direction of a medical practitioner), however, the activity would not fall within the meaning of section 287(c)(1) and relief would not be available.<sup>468</sup> This leads to the inequitable result that medical practitioners can practice the patented invention with immunity while the general public can not. Clearly, this is neither desirable nor intended.

Moreover, section 287(c)(1) fails to advance the policy goals voiced by many of its proponents.<sup>469</sup> One such goal was to prevent restriction of useful medical procedures by the public, including relatively simple ones like the Heimlich maneuver.<sup>470</sup> A direct comparison of the Brown method to a hypothetical claim covering the Heimlich maneuver illustrates this point. Like the Heimlich maneuver, the Brown method can be used without a medical practitioner and practiced without the aid of any patented device or drug. And, for the same reasons that the Brown method is a medical activity, a hypothetical claim covering the Heimlich maneuver would also be a medical activity. Being such, both the Brown

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464. See §§ 271(a), 271(b).

465. See §§ 271(a), 271(b). Infringement would be determined under a two-step *Markman*-like analysis. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (creating two-part patent infringement test), *aff'd*, 517 U.S. 370 (1996).

466. 35 U.S.C. § 287(c)(1).

467. § 287(c).

468. § 287(c)(1).

469. See H.R. CONF. REP. NO. 104-2702 (1996).

470. See *id.*

method and the Heimlich maneuver would not be protected under section 287(c)(1), and performance by the public would therefore be punishable under the law.<sup>471</sup> Thus, even though section 287(c)(1) is available, the public still would not be entitled to freely practice either of the claimed procedures. This result is clearly not consistent with the policy goals voiced by the proponents of section 287(c)(1).<sup>472</sup>

Thus, while the public would not be permitted to use the Brown method, or the Heimlich maneuver, if patented, medical practitioners would be allowed without restriction. Accordingly, section 287(c)(1), like its statutory predecessor Senate Bill 1334,<sup>473</sup> creates a discriminatory infringement liability exception for medical practitioners.<sup>474</sup> Moreover, section 287(c)(1) further discriminates based on the field of invention, i.e., medical procedures as opposed to other type of procedures.<sup>475</sup> If the intended result of section 287(c) is to make patented medical procedures available with less restriction, the exemption should apply to all patients, regardless of their identity or profession.<sup>476</sup>

## 2. Marcos: United States Patent Number 4,886,831

In 1989, a patent for the medical uses of phycocyanin was issued to N. Charlie Marcos.<sup>477</sup> The Marcos method describes a photochemical method for treating atherosclerosis or cancer.<sup>478</sup> The Marcos method includes three steps.<sup>479</sup> In a first step, a

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471. 35 U.S.C. § 287(c)(1).

472. See H.R. CONF. REP. NO. 104-2702 (1996).

473. S. 1334, 104th Cong. (1995).

474. 35 U.S.C. § 287(c)(1).

475. *Id.*

476. *Id.*

477. See Medical Uses For Phycocyanin, United States Patent No. 4,886,831 (issued Dec. 12, 1989) [hereinafter Phycocyanin Patent].

478. Atherosclerosis is characterized by irregularly distributed lipid deposits that may lead to a variety of more serious conditions. See ILLUSTRATED STEDMAN'S MEDICAL DICTIONARY 136 (24th ed. 1982). Cancer is usually characterized by malignant growths or tissue. See *id.* An advantage of the Marcos treatment is that the atherosclerotic plaques and cancer growths are selectively destroyed with little or no damage to the surrounding healthy cells or tissue. See Phycocyanin Patent, *supra* note 477.

479. *Id.* The Marcos patent reads as follows:

A method for treating atherosclerosis by destroying atherosclerotic plaques

physiologically compatible solution containing an effective amount of phycocyanin is intravascularly injected.<sup>480</sup> In a second step, means for irradiating the plaques in contact with the phycocyanin is intravascularly inserted.<sup>481</sup> And, in a third step, the plaques are irradiated for a period of time effective to destroy the plaques with the means for irradiating.<sup>482</sup>

The proposed three-part analytical framework is now applied to the Marcos method. First, a performance is “with respect to a medical practitioner,” when the defendant is a medical practitioner or under the supervision of a medical practitioner.<sup>483</sup> Invasive techniques, especially ones that involve intravascular insertion of medical devices, are almost certainly procedures within the domain of a medical doctor. Such a doctor would either be licensed by a state or under the direction of one (as in the case of a clinical internship).<sup>484</sup> Thus, it is more likely than not that any performance of the Marcos method would be with respect to a medical practitioner.

A medical activity under section 287(c)(2)(A) must be a “medical or surgical procedure on a body,” but may not fall under any of the three statutory exceptions.<sup>485</sup> Clearly the Marcos method is a medical procedure; the question is whether it satisfies an exception. Unfortunately, the determination of whether any of these exceptions applies requires answering many vague and fact-based questions.

Under the first exception, a “medical activity” does not include

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comprising:

- a. Intravascular injection of a physiologically compatible solution containing an effective amount of phycocyanin to effect contact of said phycocyanin with said atherosclerotic plaques;
- b. Intravascular insertion of a means for irradiating said plaques in contact with said phycocyanin with light of certain wavelengths; and
- c. Exposure of said plaques to said means of irradiating light for period of time effective to destroy said plaques.

*Id.*

480. *Id.*

481. *Id.*

482. *Id.*

483. 35 U.S.C. § 287(c)(2)(B)

484. *See* § 287(c)(2).

485. *Id.* § 287(c)(2)(A).

the use of a “patented technology.”<sup>486</sup> The question of whether a given performance of the Marcos method is in violation of a patented technology requires (1) establishing the meaning and scope of claimed patented technology, and (2) comparing the properly construed meaning and scope of the claims with the performance of the medical practitioner. The first step of the Marcos patent calls for the use of a “physiologically compatible solution containing an effective amount of phycocyanin.”<sup>487</sup> Thus, if the solution was separately patented, the medical practitioner’s performance could be in violation of the patent covering the solution. Moreover, the second and third steps of the Marcos method call for the use of a “means for irradiating.”<sup>488</sup> Thus, if that means were separately patented, the medical practitioner’s performance could also be in violation of the separate patent covering the means.

In either case, a doctor who practiced the Marcos method might have to show non-infringement of both of those viable patented technologies in order to obtain relief under section 287(c)(1) with respect to the original medical procedure patents.<sup>489</sup> The more patent infringement suits brought against a medical practitioner, the more thinly limited resources must be spread to defend against the suits. Due to the increased risk inherent in multiple litigation, a medical practitioner would be even less likely to prevail unscathed, especially if juries are involved. If the medical practitioner is found to infringe just one patented technology, relief under section 287(c)(1) would be unavailable.<sup>490</sup> The additional litigation burden created by section 287(c)(1) could not have been one of the results intended by its proponents.<sup>491</sup>

Under the second exception, a practice of the Marcos method would not be a medical activity if it included “the practice of a patented use of a composition of matter in violation of such patent,” unless that use does not directly contribute to the achievement of

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486. See *supra* note 360 (discussing the uncertainty surrounding the term patented).

487. Phycocyanin Patent, *supra* note 477; see also *supra* note 479 (quoting the Phycocyanin Patent).

488. Phycocyanin Patent, *supra* note 477.

489. 35 U.S.C. § 287(c)(1).

490. *Id.*

491. See H.R. CONF. REP. NO. 104-2702 (1996).

the objective of the claimed method. The first step of the Marcos method uses a “physiologically compatible solution containing an effective amount of phycocyanin.”<sup>492</sup> The Marcos patent itself explains that there are at least two other patented procedures for delivery and irradiation of phycocyanin in atherosclerotic arteries.<sup>493</sup> Thus, any analysis of the Marcos method would probably include analysis of those two patents.

This analysis must determine if the use of the physiologically compatible solution “directly contributes” to the achievement of the objective of the Marcos patent. The use of the physiologically compatible solution will directly contribute if it is “itself novel or if it contributes to or is necessary to establish the non-obviousness of the claim as a whole.”<sup>494</sup> Any determination of novelty would probably be contested, at least in light of the prior art disclosed in the Marcos patent and any other art that may be discovered along the way. Therefore, any determination regarding the non-obviousness of the Marcos method in view of its use of the solution would require the establishment of a new fact-based standard. Moreover, litigants would be averse to contesting novelty and non-obviousness because doing so may compromise other related litigation positions. Thus, the “directly contributes” standard is an unworkable tool for resolving whether the use of the physiologically compatible solution directly contributes to the achievement of the objective of the Marcos method.

If the first two parts of the proposed analysis are answered in the affirmative, thereby permitting us to reach the third and final part, the accused infringer would likely concede infringement under section 271(a) or 271(b) and obtain immunity under section 287(c).<sup>495</sup> Relief, however, would only be available under section 287(c) if the accused infringer successfully defended herself against any and all infringement suits that may arise under the three exceptions.<sup>496</sup>

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492. Phycocyanin Patent, *supra* note 477.

493. *Id.*

494. *See* 35 U.S.C. § 287(c)(2)(A).

495. § 287(c).

496. *Id.*

## CONCLUSION

Section 287(c) fails to address many of the problems that prompted its enactment. Chief among them are that medical procedure patents force doctors to engage in unnecessary litigation, allow patent owners to abuse life-saving medical procedures, and chill the open informational exchange that exists among physicians. Furthermore, section 287(c) is both discriminatory and unacceptably vague.

Medical procedure patents are problematic because they invite doctors to litigate in courtrooms rather than perform surgery in operating rooms. Section 287(c) does nothing to solve that purported problem. On the contrary, section 287(c) will probably provide fertile ground for new litigation because the statute defines many new definitions and tests, the scope of which have yet to be accurately defined.

Most of the definitions and tests are for the purpose of determining whether a particular medical performance is a “medical activity,” as defined by section 287(c)(2)(A). The first issue that may arise is how “directly related” a performance on a nonhuman body must be to a treatment of a human body to qualify as a medical activity.

After establishing that the performance is a medical activity, it is necessary to see if the performance falls under any of the three expressly stated exceptions. A patent owner seeking relief against a medical practitioner should argue that one or more of the exceptions apply to attempt to prevent the accused infringer from escaping liability via section 287(c). Thus, in the first exception, “a patented machine, manufacture, or composition of matter,” in the second exception, “a patented use of a composition of matter,” and in the third exception, “a biotechnology patent” are terms that will be certain subjects of litigation, especially in light of the precedents proposed in the House Report.

For each exception, determining whether a practitioner may avail himself of that exception depends on whether his performance is “in violation” of a claim in the same patent or other patents. Because this question is just another way of inquiring whether the defendant infringes other patented subject matter referred to by the

exceptions, a completely separate infringement analysis would be required for each of the relevant exceptions. The proponents of section 287(c) could not possibly have intended this litigation chain reaction.

Another problem purportedly addressed by section 287(c) is that medical procedure patents allow patent owners to abuse life-saving procedures by preventing or restricting their use. Section 287(c), however, is unnecessary to protect against such abuse because a court would likely deny an owner of a patented life-saving medical procedure relief in the form of damages, injunctive relief, or attorney's fees.

Yet another purported problem of medical procedure patents allegedly addressed by section 287(c) is that these patents hinder the free informational exchange among health-care providers, thereby causing a chilling effect between them. Under section 287(c), medical procedures are still patentable, just not enforceable. Therefore, any resulting chilling effect is not reduced because that process is left unchanged. Moreover, there is little support for the argument that patents have a chilling effect on communication within any technological field. Under United States patent law, an inventor may freely discuss with peers the invention immediately upon its discovery, and still obtain patent protection, as long as a patent application is filed within one year of its disclosure. Section 287(c) does not change this. Thus, the statute does not address, let alone solve, the purported problem of hindering the free informational exchange that many proponents of the statute believe exists between physicians.

In addition to failing to address the problems that called for its enactment, section 287(c) is discriminatory in at least two ways. First, it provides a liability exception for "medical practitioners" and "related health care entities," but not for the general public. Therefore, the general public would still be subject to relief granted under sections 281, 283, 284, and 285. Second, the statute discriminates with respect to a single field of invention, namely, the field of medical procedures. That discrimination removes the financial incentive to invent and to fully disclose inventions to the medical community.

As a consequence of these failures, section 287(c) is destined

to cause even more litigation and inequitable results. At minimum, the section needs significant modification. The best solution, however, may be to repeal the section in its entirety.