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## NOTE

INDUCING IMMUNE INFRINGEMENT: THE  
INTERPLAY OF SECTION 287(c) AND SECTION  
271(b)<sup>†</sup>

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*When the Physician's Immunity Statute was enacted in 1997, its statutory language and legislative history left open an important question—under what circumstances should the medical practitioner's immunity be extended to the inducer of an infringement?*

*This Article explores the relationship between the two patent statutes central to answering this question: the Physician's Immunity Statute, 35 U.S.C. § 287(c), which grants immunity to medical practitioners who infringe a medical method patent, and the inducement statute, 35 U.S.C. § 271(b), which states that a patent holder may recover from a party who actively induces patent infringement. It concludes that there is indeed a conflict between the Physician's Immunity Statute's language and intent, especially when considered in conjunction with inducement statute's policy of providing a useable remedy to infringement.*

*To resolve this conflict, the Article lays out a proposed framework for courts to determine when an inducer should be held liable for the infringement of a medical method patent. Courts should carefully interpret the language of section 287(c), and limit section 271(b) in some settings, in order to give proper effect to the policy that section 287(c) expresses.*

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*“[I]t is important not to kill the goose that lays the golden egg, that is, the incentive for medical research.”*<sup>2</sup>

This Article explores the relationship between two patent statutes: first, the Physician’s Immunity Statute, section 287(c), which grants immunity to medical practitioners who infringe a medical method patent;<sup>3</sup> and second, the inducement statute, section 271(b), which states that a patent holder may recover from a

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2. 142 Cong. Rec. 26,642 (1996) (letter from Sen. Orrin G. Hatch to U.S. Patent and Trademark Office Comm’r Bruce Lehman) (internal quotation marks omitted).

3. 35 U.S.C. § 287(c) (2006).

party who “actively induces” patent infringement.<sup>4</sup> In what circumstances, if any, should the medical practitioner’s immunity be extended to the inducer?

Medical method patents are now regularly issued by the U.S. Patent and Trademark Office.<sup>5</sup> While the issuance of these patents in the United States is now a foregone conclusion,<sup>6</sup> many countries do not issue medical method patents for public policy reasons.<sup>7</sup> Even within the United States, considerable controversy remains regarding the extent to which medical method patents can be enforced.<sup>8</sup> In response to the controversial case of *Pallin v. Singer*,<sup>9</sup> section 287(c) was enacted in 1997 to limit infringement actions against doctors.<sup>10</sup> The statutory language and legislative history of section 287(c) left open several questions, including the scope of inducement liability.

Determining if immunity extends to inducers begins with the express terms of section 287(c) and the legislative choices it represents. This Article concludes that there is indeed a conflict between section 287(c)’s language and intent, especially when considered in

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4. 35 U.S.C. § 271(b) (2006).

5. See, e.g., U.S. Patent No. 7,912,554 (filed Apr. 29, 2005) (“Method for treatment of aneurysms”); U.S. Patent No. 7,285,124 (filed Dec. 31, 2003) (“Single-tailed suturing method”); U.S. Patent No. 6,231,496 (filed Jul. 7, 1999) (“Medical treatment method”) (claiming a method of human sterilization); U.S. Patent No. 6,383,172 (filed Apr. 2, 1999) (“Retrograde venous perfusion with isolation of cerebral circulation”); U.S. Patent No. 6,209,545 (filed Mar. 22, 1999) (“Method of recovering peripheral nerves functionality”).

6. See *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) (ruling that medical methods cannot be held to be unpatentable subject matter, or be subject to a higher patentability standard, merely because they involve treating the human body).

7. See Julie A. Burger and Justin Brunner, *A Court’s Dilemma: When Patents Conflict with Public Health*, 12 Va. J. L. & Tech. 7, 32 (2007); see also Jasmine Chambers, *Patent Eligibility of Biotechnological Invention in the United States, Europe, and Japan: How much patent policy is public policy?*, 34 Geo. Wash. Int’l L. Rev. 223, 226–40 (2002) (surveying the U.S., European, and Japanese policy approaches to the patent eligibility of medical methods).

8. See, e.g., *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, 702 F. Supp. 2d 181, 232–37 (S.D.N.Y. 2010) (ruling gene analysis method and cancer therapeutic screening method claims unpatentable subject matter), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011) (overruling invalidation of screening method claim), *petition for cert. filed*, (U.S. Dec. 7, 2011) (No. 11–725); *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*, 79 U.S.L.W. 3710 (U.S. June 20, 2010); *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. dismissed*, 548 U.S. 124 (2006).

9. *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (first infringement case brought against a physician for infringing a medical method patent).

10. See Leisa T. Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 Tex. Intell. Prop. L.J. 299, 307 (2008).

conjunction with section 271(b)'s policy of providing a useable remedy to infringement. To resolve this conflict, courts should carefully interpret the language of section 287(c), and limit section 271(b) in some settings, in order to give effect to the policy section 287(c) expresses.

Part I of this Article briefly lays out the legislative history and policy of section 287(c). Part II explains the statutory framework of section 287(c) and flags several questions for determining the scope of inducement liability. Part III introduces inducement liability and its importance for medical methods, including the breadth of potential liability. Finally, Part IV lays out a proposed framework for courts to determine when an inducer should be held liable for infringement of a medical method patent.

## I. THE PHYSICIAN'S IMMUNITY STATUTE<sup>11</sup>

Section 287(c) lays out a complicated framework for immunizing medical practitioners from patent infringement suits. To date, section 287(c) has not been successfully invoked as a defense.<sup>12</sup>

### A. Legislative History

In 1996, Congress added section 287(c) to the patent statute through an appropriations rider.<sup>13</sup> The so-called "Physician's Immunity Statute" immunizes a medical practitioner or related health care entity from damages, injunctive relief, and attorney's fees in a patent infringement suit for performance of a medical activity on a body.<sup>14</sup>

The Physician's Immunity Statute was enacted at the behest of the American Medical Association (AMA) and various other advocacy groups in response to several concerns, including the perceived threat that medical method patents would have on open discourse in the medical field.<sup>15</sup> Although the United States Patent and

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11. 35 U.S.C. § 287(c). For the full text of section 287(c), see *infra* Appendix A.

12. As of this writing, only one case, *Emtel, Inc. v. Lipid Labs, Inc.*, 583 F. Supp. 2d 811 (S.D. Tex. 2008), has invoked section 287(c) as a possible defense. The patent was held not infringed, so no inquiry was made into the requirements for a section 287(c) defense.

13. Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, section 616, 110 Stat. 3009, 3009-67 (1996) (codified as 35 U.S.C. § 287(c) (2006)).

14. 35 U.S.C. § 287(c)(1).

15. See Jeff S. Rundle, *The Physician's Immunity Statute: A Botched Operation or a Model Procedure?*, 34 J. Corp. L. 943, 945 (2009); Brett Alten, *Left to One's Devices: Congress Limits Patents on Medical Procedures*, 8 Fordham Intell. Prop. Media & Ent. L.J. 837, 862 (1998). See generally Eric M. Lee, *35 U.S.C. § 287(c)—The Physician*

Trademark Office (USPTO) had been granting medical method patents for several years, the first lawsuit against a doctor for infringing a medical method patent in 1994 spurred the AMA's legislative efforts to amend the Patent Act.<sup>16</sup>

The case, *Pallin v. Singer*, involved both direct and induced infringement claims by one ophthalmologist, Dr. Pallin, against another competing ophthalmologist, Dr. Singer. Dr. Pallin held a patent on a method of performing a sutureless cataract surgery.<sup>17</sup> Dr. Singer both performed the surgery, constituting direct infringement, and taught other ocular surgeons the surgery technique, constituting induced infringement.<sup>18</sup> Even though the case was later dismissed by a consent order invalidating the claims and enjoining Dr. Pallin from enforcing his patent,<sup>19</sup> the potential liability of doctors and other medical professionals led Congress to begin investigating ways to stop medical method suits.

The AMA, joined by several other medical associations, first attempted to pass legislation that would have prevented the USPTO from issuing medical method patents by placing medical methods outside the reach of 35 U.S.C. § 101.<sup>20</sup> These groups argued that medical method patents harm the health care system in several ways. First, the AMA argued that patents would restrict peer review of medical procedures and the sharing of information for fear of infringement lawsuits. Second, the costs of licensing, litigation, and searching patents would restrict patient access to the best care. Third, the AMA worried that allowing litigation over medical methods would breach patient confidentiality. Finally, the

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*Immunity Statute*, 79 J. Pat. & Trademark Off. Soc. 701, 710 (1997) (noting the arguments from the medical community in favor of section 287(c)); Fariba Sirjani & Dariush Keyhani, 35 *U.S.C. § 287(c): Language Slightly Beyond Intent*, 3 *Buff. Intell. Prop. L.J.* 13, 25–26 (2005) (listing the lobbying groups supporting and opposing the language of section 287(c)).

16. *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050, 1050 (D. Vt. 1995).

17. *See id.*; U.S. Patent No. 5,080,111 (filed June 28, 1990).

18. *Pallin v. Singer*, 36 U.S.P.Q.2d at 1051.

19. *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407, at \*1 (D.Vt. Mar. 28, 1996).

20. Am. Med. Ass'n, *Patenting of Medical Procedures, Reports of Council on Ethical and Judicial Affairs*, House of Delegates Proceedings, 144th Annual Meeting 200–06 (June 18–22, 1995) [hereinafter *AMA Proceedings*]. *See also* H.R. 1127, 104th Cong. (1995) (“LIMITATION ON ISSUANCE OF PATENTS. On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture or composition of matter may claim such technique, method, or process.”).

AMA contended that medical method patents were not a necessary incentive for doctors and other health care researchers to create new methods of treatment.<sup>21</sup> This approach was strongly opposed by the biotechnology and pharmaceutical industry. These groups worried that the AMA's proposal to amend section 101 would prevent them from obtaining patent protection and securing funding for their research.<sup>22</sup>

In response to these competing concerns, Senator Frist (R-Tenn.) proposed an amendment to section 271 which would have stated that it was not an act of infringement to use or induce certain people to perform patented medical methods.<sup>23</sup> This bill was criticized for severely limiting the exclusionary powers of a patent.<sup>24</sup> Furthermore, the Frist amendment was accused of discriminating both on the basis of the technology of the patent and the identity of the infringer.<sup>25</sup>

These two early approaches of excluding medical methods from issuance or infringement were quickly abandoned. In their place, H.R. 3610 proposed to immunize some infringements of medical methods patents. H.R. 3610 was sent to the Senate as a conference agreement, meaning that it could not be amended and was only subject to an up or down vote.<sup>26</sup> The bill did not pass through the judiciary committee nor was any hearing held on its exact terms, despite including language that was not present in any previous bill. Nevertheless, the bill was passed by the Senate by a vote of 84–15 and was signed by the President later that evening.<sup>27</sup>

According to a letter written by Senator Orrin Hatch, R-Utah, there were too many unresolved issues to “sweep” the legislation into an end-of-the-session omnibus appropriations bill.<sup>28</sup> In particular, 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. Senator Hatch also objected to the legislation because of its potential to set undesirable

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21. See AMA Proceedings, *supra* note 20.

22. See, e.g., *The Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the H. Judiciary Subcomm. on Courts and Intellectual Property*, 104th Cong. 92 (1995) (statement of Frank Baldino, Jr., President and CEO, Cephalon, Inc.).

23. See Lee, *supra* note 15, at 706.

24. See Alten, *supra* note 15, at 873.

25. See Alten, *supra* note 15, at 871.

26. See Alten, *supra* note 15, at 875. See also Appropriations Bill (H.R. 3610) Containing Patent Limitations on Medical Procedures, 52 Pat., Trademark & Copyright J. (BNA) 612 (October 3, 1996).

27. See Alten, *supra* note 15, at 875.

28. See 142 Cong. Rec. 26,642 (1996).

precedent for United States trade policy.<sup>29</sup> Inducement liability is just one of many questions left open by the text of the bill and its legislative history. None of the legislative history of section 287(c) or its prior bills addresses the question of whether immunity should extend to an inducer.

### *B. The Policy Behind the Statute*

The AMA's original opposition to the issuance of medical method patents, and later its support for the Physician's Immunity Statute, is based on its concerns regarding the effects that medical methods patents might have on the medical profession. Several of these concerns about a medical practitioner's direct liability also apply to the liability of an inducer.

#### 1. Free and Open Disclosure in the Medical Profession

The Hippocratic Oath requires doctors to share information.<sup>30</sup> The AMA Code of Medical Ethics also requires sharing of medical knowledge and public disclosure of a physician's knowledge and research.<sup>31</sup> By immunizing both direct and induced infringement on the part of the medical practitioner and the related health care entity, the Physician's Immunity Statute allows medical practitioners to share information freely without fear of liability.<sup>32</sup> However, non-licensed researchers do not fall within the protection of section 287(c).<sup>33</sup>

#### 2. Access to New Advances in Health Care for Patients

An important driving force behind section 287(c) is the fear that patients will not be able to have adequate access to new developments in medical technology without immunizing those who

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29. See, e.g., Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. Davis L. Rev. 601, 669 (2000) (suggesting that section 287(c) violates the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)).

30. "I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow." Louis Lasagna, *The Hippocratic Oath - Modern Version* (1964), available at [http://ethics.ucsd.edu/journal/2006/readings/Hippocratic\\_Oath\\_Modern\\_Version.pdf](http://ethics.ucsd.edu/journal/2006/readings/Hippocratic_Oath_Modern_Version.pdf).

31. American Medical Association, *Code of Medical Ethics of the American Medical Association*, § 9.08 (2008–2009 ed.).

32. 35 U.S.C. § 287(c)(1) (2006).

33. *Id.* § 287(c)(2)(B).

develop or disseminate information regarding new treatments.<sup>34</sup> Because simply providing instructions or advertising a method of use is considered conduct constituting “active inducement,”<sup>35</sup> the potential liability for insurers, instructors, textbook authors, and authors of scholarly papers would sharply limit the spread of information.

Additionally, it can be very difficult to determine whether something is patented, or if claimed in a patent, whether the patent is valid and enforceable. The difficulty of determining what is patented can lead to over-deterrence, and therefore discussion of procedures that are in fact in the public domain would also be chilled through inducement liability.<sup>36</sup>

### 3. Costs to Health Care

Today, health care costs are a source of frequent public ire.<sup>37</sup> If inducers were held liable for patent infringement, health care costs could go up in a number of ways. Insurance against inducement liability, acquiring licenses for patented technologies, and even reliance on older, more expensive technology would all increase the costs of patient care.<sup>38</sup> Presumably these costs would be passed onto patients.

### 4. Peer Review of Medical Procedures

Under the prospect theory of patents we assume that the inventor should have control of the invention and its future development.<sup>39</sup> In medical practice, however, a group-development model of medical care dominates, which emphasizes peer-reviewed proce-

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34. See Lee, *supra* note 15, at 710; Rundle, *supra* note 15, at 945–46.

35. See *infra* Part IV.A.1.

36. See generally Stewart E. Sterk, *Property Rules, Liability Rules, and Uncertainty about Property Rights*, 106 Mich. L. Rev. 1285, 1331–1334 (2008) (noting that there is great uncertainty regarding the scope and existence of patent rights and that the cost of determining these rights can be prohibitively expensive).

37. See, e.g., Uwe E. Reinhardt, *Fees, Volume, and Spending at Medicare*, New York Times Economix (December 24, 2010, 6:00 AM), <http://economix.blogs.nytimes.com/2010/12/24/fees-volume-and-spending-at-medicare/>.

38. See generally Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 Nw. J. Tech. & Intell. Prop. 280 (2010) (arguing that preventing the patenting of medical diagnostic and therapeutic methods may be a way of effectively reducing health care costs); Amy Lynn Sorrell, *Tinkering with Patents: Decisions Muddy the Waters on Legal Rights*, Am. Med. News (May 26, 2008), <http://www.ama-assn.org/amednews/2008/05/26/prsa0526.htm> (arguing that enforcing sweeping medical process patents can increase health care costs and reduce health care quality).



dures. The importance of peer-review and discussion to the group-development model has led to concerns over the possibility of patent law having a chilling effect on discourse. This was one of the primary motivators behind enacting the Physician's Immunity Statute.<sup>40</sup>

## 5. Patient Confidentiality

The AMA was also concerned that infringement suits would force doctors to breach patient confidentiality.<sup>41</sup> In order to be held liable for either induced or direct infringement, the patentee must prove that actual infringement took place. This would require a patentee to prove that the method was performed by the medical practitioner or that a patient infringed the method.<sup>42</sup> Thus, the AMA worried that the patentee could force the doctor to disclose confidential information during the discovery phase of an infringement suit. The concern really only supports a non-infringement statute, rather than an immunized infringement statute, since to invoke section 287(c) in the first place the medical practitioner's activity must "constitute an infringement."<sup>43</sup>

## II. THE STATUTORY FRAMEWORK OF SECTION 287(c)

Section 287(c) lays out a multipart framework for determining if a medical practitioner is immune from liability. In order to qualify for immunity,<sup>44</sup> the infringement must be: (1) a "medical practitioner's"<sup>45</sup> performance of a (2) "medical activity"<sup>46</sup> (3) on a "body."<sup>47</sup> Then, the various liability provisions<sup>48</sup> of the Patent Act will not apply against the medical practitioner or a "related health care entity."<sup>49</sup>

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39. See generally Mark A. Lemley, *Ex ante versus Ex Post Justifications for Intellectual Property*, 71 U. Chi. L. Rev. 129, 132–33 (2004) (describing the prospect theory of patents).

40. See Lee, *supra* note 15 at 710.

41. *Id.*

42. *Id.* at 715.

43. *Id.*

44. See 35 U.S.C. § 287(c)(1) (2006).

45. *Id.* § 287(c)(2)(B).

46. *Id.* § 287(c)(2)(A).

47. *Id.* § 287(c)(2)(E).

48. 35 U.S.C. § 283 (2006) (injunction); 35 U.S.C. § 284 (2006) (damages); 35 U.S.C. § 285 (2006) (attorney fees).

49. *Id.* § 287(c)(2)(C) ("[A]n entity . . . under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.").

*A. Immunity from infringing . . .*

As a preliminary matter, section 287(c) must be interpreted as creating an exception to liability, rather than an exception to infringing behavior. If practicing a medical patent is not an infringement, then no one can be liable for inducement, since inducement requires an actual, direct infringement. If the statute is only creating an immunity, then inducement could still occur despite a lack of liability attaching to the direct infringer. This question can be answered by looking at both the express terms of the statute and the legislative history of section 287(c). Both support the view that the statute creates an immunity to infringement liability.

First, the language of the statute states that the performance of a medical activity “constitutes an infringement,” either a direct infringement or an inducing infringement, and then states that the remedies provisions of the patent act will not apply against the medical practitioner.<sup>50</sup> Additionally, section 287 is titled “Limitation on damages and other remedies.” On a plain meaning basis, this supports the view that the statute recognizes a statutory infringement, but then immunizes it from legal remedies.

Second, section 271(e)(1), also known as the clinical trial exemption, creates a statutory exception from infringement, stating that “it shall not be an act of infringement” to conduct research related to the development and submission of information to the FDA. This shows that Congress knew what to say if it wanted to create an exception to infringement, rather than just an immunized infringement. By choosing not to use that same language in section 287(c), section 271(e)(1) should be understood as giving a different meaning.

Finally, the legislative history of section 287(c) indicates that Congress intended an immunized infringement rather than no infringement. A prior version of section 287(c) would have created an express exception to infringement under section 271. In Senate Bill 1334, Senator Frist proposed adding a new subsection (j) to section 271 which would have stated:

[I]t shall not be an act of infringement for a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a

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50. *Id.* § 287(c)(1).

surgical or medical therapy, or making a medical diagnosis. . . .<sup>51</sup>

A number of concerns emerged about S. 1334. Seizing upon the lack of litigation among medical practitioners of patented procedures, opponents took issue with exempting a specific class of inventions and a specific profession from the patent statutes.<sup>52</sup> They argued that this would set a dangerous precedent under the patent laws and that it was inconsistent with the purposes of the patent system.<sup>53</sup>

This change in position from earlier versions of the bill indicates that section 287(c) must be interpreted as recognizing a statutory infringement, but then providing an immunity defense to the medical practitioner, or related health care entity, who infringes or induces others to infringe.

#### *B. For a medical practitioner . . .*

The first requirement for immunity under section 287(c) is that a medical practitioner carry out the infringement.<sup>54</sup> A medical practitioner is defined as “any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.”<sup>55</sup> This means that non-licensed researchers will not be immunized under section 287(c)(1). It does, however, immunize someone working under the control of a state-licensed medical practitioner.

#### *C. Performing a medical activity . . .*

The second requirement under section 287(c) is for the infringing activity to be a “medical activity.”<sup>56</sup> A medical activity is defined as “the performance of a medical or surgical procedure on a body”<sup>57</sup> but with three exemptions in the definition. First, it exempts patents that utilize a patented machine, manufacture, or composition of matter in performing the method. Second, it exempts patented methods of using compositions of matter (e.g. pharmaceuticals), whether the drug is patented or not. Finally, it

51. Medical Procedures Innovation and Affordability Act, S. 1334, 104th Cong. § 2 (1st Sess. 1995).

52. Richard P. Burgoon, Jr., *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c)*, 4 U. Balt. Intell. Prop. L.J. 69, 77 (1996).

53. *See id.*

54. 35 U.S.C. § 287(c)(1).

55. *Id.* § 287(c)(2)(B).

56. *Id.* § 287(c)(1).

57. *Id.* § 287(c)(2)(A).

categorically exempts all processes that violate biotechnology patents from immunity.<sup>58</sup>

These exemptions indicate that Congress limited the scope of the statute in response to pressures from the biotechnology, pharmaceutical, and medical device industries. By including the three specific exemptions in section 287 (c)(2)(A), Congress has attempted to limit the scope of the immunity to only “pure” method claims. However, the exemptions still leave open several loopholes that could affect the patent rights of many commercialized technologies. In deciding if the immunity of the infringer should extend to the inducer, a court will have to ask if Congress intended for these exemptions to occupy the field or instead if the general purposes of the statute should prevail.

Sections 287(c)(2)(A)(i) and (ii) limit the applicability of section 287(c) to “pure” method patents—those that do not involve a *patented* machine, manufacture, or composition of matter, or patented use of *any* composition of matter.<sup>59</sup> This is supposed to prevent a physician from claiming immunity for using a patented medical device (e.g., implanting a patented stent using a patented method). However, it is unclear if the statute applies where the device is patented but the device claims are later held invalid or unenforceable.<sup>60</sup>

Finally, section 287(c)(2)(A)(iii) broadly exempts all biotechnology patents from the immunity protection of the statute: clearly an intended result of biotechnology and genetics industry lobbying. Although the term “biotechnology patent” is not defined in the statute, the corresponding Conference Report states that it “includes a patent on a ‘biotechnological process’ as defined in 35 U.S.C. § 103(b), as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level.”<sup>61</sup>

#### D. On a body . . .

Third, in order to be immune under section 287(c), the medical activity must take place “on a body.”<sup>62</sup> “Body” is defined as “a

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58. *Id.* § 287(c)(2)(A)(i)–(iii).

59. This requires the court to engage in an initial inquiry into the subject matter of the method patent—such as another Markman hearing—to see if it is appropriate to allow a section 287(c) defense to go forward at trial.

60. There is also no requirement that the device be patented in the United States or patented by the same or a related entity to the method patent.

61. H.R. Rep. No. 104-863, at 854 (1996) (Conf. Rep.) (quoting 35 U.S.C. § 103(b)); Lee, *supra* note 15, at 720.

62. 35 U.S.C. § 287(c)(2)(A).

human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.”<sup>63</sup> This is potentially a huge loophole depending on how broadly this term is construed by the courts. Nonhuman animals used in research include patented animals such as transgenic mice.<sup>64</sup> Research is also performed on excised human tissues, animal tissues, human cells lines, and animal cell lines, etc. If section 287(c) is seen as immunizing research on tissue and cell lines, the statute will have a much broader scope than Congress originally contemplated.

*E. And related health care entities . . .*

Section 287(c)(1) immunizes both medical practitioners and related health care entities from infringement liability. Congress’s rationale for immunizing related health care entities is illustrated by the facts of the *Pallin v. Singer* litigation.

Dr. Pallin sued both Dr. Singer and the clinic he was affiliated with for performing the patented sutureless cataract surgery.<sup>65</sup> Immunizing only Dr. Singer, and not the associated clinic, would not have stopped the *Pallin* suit. In fact, the clinic may have been a more desirable target because of its deeper pockets. The AMA feared that clinics would stop their employees from performing infringing methods in order to avoid infringement liability.<sup>66</sup> Immunizing the “related health care entity” was seen as necessary to effectuate the policy of the statute.

Congress’s choice to expressly immunize a party aside from the medical practitioner strongly suggests that they did not intend to immunize any more parties.<sup>67</sup> Congress provided broad definitions of both “medical practitioners”<sup>68</sup> and “related health care enti-

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63. *Id.* § 287(c)(2)(E).

64. U.S. Patent No. 4,736,866 (filed June 22, 1984).

65. *See Pallin v. Singer*, 36 U.S.P.Q.2d 1050, 1051 (D.Vt. 1995).

66. *See Lee*, *supra* note 15, at 703.

67. *Expressio unius est exclusio alterius*.

68. 35 U.S.C. § 287(c)(2)(B) (defining a medical practitioner as “any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.”).

ties.”<sup>69</sup> It would be incongruous with the terms of the statute to extend liability to inducers outside of those two groups.

*F. But not for commercial developers?*

Section 287(c)(3) includes a broad exception from immunity where the infringing activities are 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).”<sup>70</sup> Because there is no legislative history accompanying this provision, in section 287(c) as adopted or in any prior version, it is unclear what Congress intended with this provision.

One interpretation is that section 287(c)(3) is meant to direct the reader to look to section 271(e). Section 271(e), the clinical trials exemption, states that it is “not . . . an act of infringement” to conduct infringing research for the purpose of submitting information to the FDA.<sup>71</sup> This is a likely interpretation of section 287(c)(3) since it specifically calls out FDA-regulated activities and the “commercial development” of new technologies.

However, under a broader interpretation, section 287(c)(3) could potentially strongly limit the applicability of the immunity provision. For example, if a surgeon practices an infringing method for the purpose of improving the method and developing a device for performing the improved method, would he be liable? His performance of the patented method is “directly related” to the commercial development of a new device, but he is also involved in an effort to improve existing medical techniques and patient care. This interpretation of the statute could conflict with the goals of the statute—to protect the peer-review system of medical treatment.<sup>72</sup>

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69. *Id.* § 287(c)(2)(C)–(D) (defining a related health care entity as “an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic,” and defining a professional affiliation as “staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.”).

70. *Id.* § 287(c)(3).

71. 35 U.S.C. § 271(e)(1) (2006).

72. *See supra* Part II.B.

## III. THE SCOPE OF THE INDUCEMENT PROBLEM

A. *Introduction to Inducement Liability*

Section 271(b) was codified in the 1952 Patent Act in order to provide an effective remedy against infringement where it is impractical or infeasible to sue the direct infringer.<sup>73</sup> Section 271(b) entitles the patent holder to the same relief against the inducer as against the direct infringer—the possibility of damages (including willful damages), an injunction, and attorney’s fees.<sup>74</sup> The objective of inducement liability is to give patent holders effective protection in circumstances where the direct infringer either is not the truly culpable party or is impractical to sue. Inducement liability requires findings about the accused inducer’s knowledge and intent, and some conduct which “actively induces” the infringement of a third party.<sup>75</sup>

The knowledge and intent requirements for inducement were recently clarified by the Supreme Court in *Global-Tech Appliances, Inc. v. SEB S.A.*<sup>76</sup> *Global-Tech* holds that induced infringement under section 271(b) “requires knowledge that the induced acts constitute patent infringement.”<sup>77</sup> Knowledge may be established through the willful blindness doctrine, but “deliberate indifference to a known risk” is insufficient.<sup>78</sup> Because of the knowledge and intent requirements, inducement liability is a poor vehicle to rely on for effective patent protection. However, in many cases, inducement liability is the only available avenue for effectively protecting a patent.

## 1. What Counts as Inducing Conduct

Section 271(b) requires “active inducement” of direct infringement. The conduct which can be relied upon to find active inducement has the potential to be very broad.<sup>79</sup> While the action which is inducing must be intentional, it may be “as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent.”<sup>80</sup>

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73. See 35 U.S.C. § 271(b) (“Whoever actively induces infringement of a patent shall be liable as an infringer.”).

74. 35 U.S.C. § 283 (2006) (injunction); 35 U.S.C. § 284 (2006) (damages); 35 U.S.C. § 285 (2006) (attorney’s fees).

75. Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 228 (2005).

76. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

77. See *id.* at 2068.

78. *Id.*

79. Lemley, *supra* note 75, at 229.

80. *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963).

Because the lower courts have found that extremely low levels of conduct may constitute active inducement (when coupled with the requisite intent and knowledge), medical device suppliers, insurers, medical instructors, and even authors of medical papers could be liable for induced infringement.

*a. Providing Instructions*

Provision of instructions for how to perform a medical method is extremely common. This could be found in product inserts, product demonstrations, advertisements, or even in non-commercial forms like health care training, demonstrations at conventions, medical journals, or textbooks.

In other contexts involving non-medical technologies, defendants were liable for inducing infringement based on their providing instructions to others on how to undertake a patented process or implement a patented design. Instructions included with a product have also been found sufficient to induce infringement. In *Corning Inc. v. SRU Biosystems*, the manufacturer of an infringing product was also found to have induced infringement of method claims by customers who used the product in accordance with the manufacturer's instructions.<sup>81</sup> In *Tristrata Technology, Inc. v. Mary Kay, Inc.*, advertisements and product inserts were found to have induced customers to practice the patented method using an unpatented product.<sup>82</sup>

In *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, the Federal Circuit upheld a finding of inducement liability against a party that advertised and sold a rotary saw for cutting concrete.<sup>83</sup> The saw, capable of multiple uses, was advertised for use in a manner that infringed the plaintiff's patent claims for a method of cutting concrete. Because at least one possible mode of use recommended and instructed by defendant's advertisements infringed on plaintiff's method claims, the defendant was found to have intentionally induced its customers' infringement.

In the medical device case of *C.R. Bard, Inc. v. U.S. Surgical Corp.*, the defendant-manufacturer was found to have induced infringement of the plaintiff's method claim although the accused product did not infringe the plaintiff's device claims.<sup>84</sup> The case involved a

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81. *Corning Inc. v. SRU Biosystems*, 400 F. Supp. 2d 653, 665–66 (D.Del. 2005).

82. *Tristrata Technology, Inc. v. Mary Kay, Inc.*, 423 F.Supp.2d 456, 465–66 (D.Del. 2006).

83. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303, 1311–12 (Fed. Cir. 1998).

84. *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 258 F.Supp.2d 355, 361 (D. Del. 2003).



surgical hernia plug manufactured by the defendant that could be trimmed to fit the patient. Pursuant to manufacturer's instructions for reducing the plug's bulk, surgeons trimmed the "petals" of the plug during surgery. This practice supported the finding that surgeons were directly infringing the plaintiff's method claim, which called for "detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis." The court held that the manufacturer was actively induced such infringement based on the manufacturer's instructions provided with the product.<sup>85</sup>

The Federal Circuit has also upheld inducement where the defendant published medical articles that encouraged the performance of an infringing method. In *Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings*, the defendant published medical articles targeting doctors, specifically suggesting in the articles the infringing use of a patented assay to identify a vitamin deficiency.<sup>86</sup> The court found that

LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.<sup>87</sup>

These cases demonstrate that the potential inducement liability for medical method patents is extremely broad, and potentially affects a number of different actors.

#### *b. Unassembled Kits*

The provider of an unassembled kit, where the kit creates an infringing device when assembled, may be liable for inducing the purchaser to create the infringing device. In a case involving a fireplace kit claimed as a device, the Federal Circuit found a manufacturer liable for induced infringement through selling a kit which included instructions for assembling the fireplace burner in an infringing combination.<sup>88</sup>

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85. *Id.*

86. *Metabolite Labs, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d. 1354, 1365 (Fed. Cir. 2004).

87. *Id.* Metabolite's patent was filed prior to the enactment of 35 U.S.C. § 287(c) (2006), so the immunity could not apply. *See* U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

Even infringement of method claims may be induced through the kit or assembly theory.<sup>89</sup> In *nCube Corp. v. Seachange Int'l, Inc.*, the Federal Circuit found that the defendant induced infringement of a patent for a method of providing multimedia data in networked system. The defendant sold systems without a relevant component to customers whose networks already contained their own version of relevant component. By combining the defendant's systems with pre-existing customer systems, the new combined system infringed the patent.

Sometimes method claims are a "method of providing" a device that includes the limitations of the device and requires providing those components according to the claim limitations "for use" in a medical procedure.<sup>90</sup> For example, claim 11 of an external insulin pump technology patent claims:

A method of making a delivery device for delivering an infusion medium to a user, the method comprising: providing a first housing portion . . . providing a second housing portion . . . arranging a plunger within the interior of the reservoir and moveable along an axial direction of the reservoir; supporting a slide member on the second housing portion . . . .<sup>91</sup>

Such claims could provide the basis for direct infringement by a medical provider who assembles the device and then uses it in the medical context. If the assembled device is not patented, then the surgeon will be immune from suit.<sup>92</sup> However, the manufacturer of the kit could be liable for inducement.

Overall, the potential for inducement liability on the part of manufacturers or even instructors of medical practitioners is enormous. If merely describing a patented method in a manner that encourages others to perform it constitutes conduct of "active inducement" then liability for medical methods patents could be widespread.

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88. *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1364–65 (Fed. Cir. 2006).

89. *nCube Corp. v. Seachange Int'l, Inc.*, 436 F.3d 1317, 1325 (Fed. Cir. 2006).

90. *See, e.g.*, U.S. Patent No. 7,736,344 (filed Nov. 22, 2006) (claim 11); U.S. Patent No. 7,678,078 (filed Oct. 21, 2008) (claim 20).

91. U.S. Patent No. 7,736,344 (filed Nov. 22, 2006) ("Infusion Medium Delivery Device and Method with Drive Device for Driver Plunger in Reservoir").

92. *See* 35 U.S.C. § 287(c)(2)(A) (although a medical practitioner is immune from suit for the "medical activity," that immunity does not apply to the use of a patented "machine, manufacture, or composition of matter.").

*B. Medical Methods Require Protection Against Induced  
Infringement*

The traditional justification for the patent system is that it encourages inventors to disclose their inventions to the public in exchange for a limited monopoly.

From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.<sup>93</sup>

This justification is no less true in the case of medical procedure patents. Even though “historically, surgical procedures [were] not patented,” there are incentives for patenting procedures to attract investment and capital in research and development.<sup>94</sup> The earliest medical method patent is believed to be a patent on the method of using ether as a surgical anesthetic, granted by the PTO in 1846.<sup>95</sup> By the 1960s, the PTO routinely issued medical method patents.<sup>96</sup> Today there are venture-funded companies that are protected solely by medical method patents.<sup>97</sup> Even the AMA agrees that there is some medical technology that would not be available today without the patent incentive.<sup>98</sup>

Many medical method patents can only be effectively protected through inducement liability. For example, a patient may be the

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93. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

94. Ho, *supra* note 29, at 617.

95. See U.S. Pat. No. 4,848 (filed Oct. 27, 1846).

96. See *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) (ruling that medical methods cannot be held to be unpatentable subject matter, or be subject to a higher patentability standard, merely because they involve treating the human body).

97. See, e.g., *Patents: Commitment to Innovation*, Acclarent, <http://www.acclarent.com/company/patents/> (last visited Dec. 8, 2011) (listing patents granted on a method of opening sinus passageways with an unpatented balloon catheter assembly).

98. See American Medical Association, Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, 53 Food & Drug L. J. 341, 348 (1998). The most commonly cited example of a procedure that may have gone undeveloped had patent protection not existed is the Surrogate Embryo Transfer (SET) procedure. The SET procedure cost over \$500,000 to develop. After the NIH denied funding, a private venture capital group provided research funding for the project. The private venture group would have been unwilling to invest without the assurances against free-riding secured by a patent. See George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, 14 Hastings Cent. Rep. 25, 25–26 (1984).

direct infringer of a method patent when he takes a drug to treat a specific condition.<sup>99</sup>

An example of this is the patent on using Rogaine to treat hair loss.<sup>100</sup> Rogaine the compound (Minoxidil) was already well known at the time of the patent so the compound could not be patented. Thus, the only effective protection over the discovery that Rogaine can be used to treat hair loss is a method patent. However, the patient would be the direct infringer of such a patent. To sue the patient would be both impractical (the patient may be judgment proof, difficult to find, and effective protection of the method patent would require numerous individual suits), and the patient is not the truly culpable party.

In other situations, the direct infringer of a medical method is a doctor. For example, the Acclarent patents would be infringed by a doctor performing the steps of the method using a non-patented balloon catheter and introducer assembly.<sup>101</sup> Suing the doctor generally presents the same difficulties as the patient.

In both of these situations, section 271(b) gives the patentee the only effective protection of their technology.

### C. Possible Medical Methods Inducers

Given the broad scope of activity that has been considered inducing conduct, many activities related to medical method patents could give rise to inducement liability. Not only are many activities potentially inducing, but also many different actors.

#### 1. Patients

A patient could be an inducer of a medical method patent. For example, a patent claiming a method of treating back pain by performing various chiropractic maneuvers on a patient's body<sup>102</sup> would be a "medical activity" within the terms of section 287(c).

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99. This example would not invoke section 287(c) because patented uses of compositions of matter are exempted from the definition of medical activities in section 287(c)(2)(A)(ii).

100. U.S. Patent No. 4,596,812 (filed Aug. 28, 1980).

101. Compare Acclarent, *supra* note 97, with, e.g., U.S. Patent No. 7,654,997 (filed Apr. 21, 2004) ("A method for enlarging an ostium of a paranasal sinus of a subject, said method comprising the steps of: placing in the subject's head a port device having a lumen through which a balloon catheter may be inserted; positioning a light emitting portion of a light emitting instrument within the paranasal sinus; emitting light from the light emitting portion of the light emitting instrument; observing the emitted light; advancing a balloon dilation catheter through the port device to a location within the ostium of paranasal sinus; and inflating a balloon of the balloon catheter to expand the ostium and modify bone that directly underlies mucosa of the ostium.").

The patient, by requesting the treatment, would induce the doctor, who is the direct infringer. This could lead to an anomalous situation where a patient who is a state-licensed medical practitioner would be immune from suit, but a “lay” patient would not be! Of course, the owner of the method patent would still have to overcome the difficulties of finding and suing individual patients to enforce the patent.

## 2. Insurers

Insurance companies could also be inducers of a medical method patent. An insurance company may choose to only reimburse doctors for using a new, patented method of treatment because it is cheaper or more reliable than prior art methods. The doctor would be immune under section 287(c), but the immunity of the inducer would depend on whether or not they can qualify as a “related health care entity” under section 287(c)(2)(C). Health maintenance organizations (HMO’s) are considered related health care entities, as are entities with which a doctor has a “professional affiliation.”

It would be wholly counter to Congress’s intentions if the immunity of an insurance company depended on the terms of its contractual relationships with its doctors. A group like Kaiser Permanente, which operates its own hospitals and labs, may be totally immune because it could readily qualify as a “related health care entity.” Small insurance groups on the other hand may not, and thus could be sued for inducing infringement.

## 3. Device Manufacturers

Device manufacturers who provide the tools or instructions for infringement could be liable for inducing the infringing activities of doctors. As described above, merely providing instructions is considered inducing conduct.

## 4. Medical Articles—Authors and Publishers

Another category of potential inducers is authors and publishers of medical articles or medical training and teaching materials.<sup>103</sup> There is no doubt that an author who publishes a description of an improved medical technique would be shocked to find himself a

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102. U.S. Patent No. 6,209,545 (filed Mar. 22, 1999) (claiming a method of manually massaging the nerves in the human body to restore function of the nerves. No device, other than the hands, is associated with the method).

103. See, e.g., *Metabolite Labs, Inc. v. Laboratory Corp. of American Holdings*, 370 F.3d. 1354 (Fed. Cir. 2004).

defendant in a patent infringement suit for inducing the infringement of doctors. This situation also leads to discriminatory results based on the licensing status of the author—a medically licensed author would be a “medical practitioner” under section 287(c)(2)(B) and therefore immune, while a non-licensed person could not avail himself of the immunity of section 287(c)(1).

#### IV. RESOLVING THE CONFLICT BETWEEN THE STATUTORY LANGUAGE OF SECTION 287(c) WITH THE POLICY CONSIDERATIONS OF SECTION 287(c) AND SECTION 271(b)

The careful balance drawn by Congress in section 287(c) between the competing interests of the medical community and the device, biotech, and pharmaceutical industries is threatened by inducement liability. The question of inducement liability sets up a conflict between the major policies behind section 287(c) and with both the plain meaning of section 287(c) and traditional justifications of the patent system.

If section 287(c) is interpreted to take away inducement liability, a much broader range of conduct will be immunized than was originally contemplated in the bargain. On the other hand, to hold inducers immune would leave some technologies totally unprotected by the patent system, despite reliance on intellectual property protection for their development and financing.

This approach is consistent with earlier Supreme Court treatment of medical patent statutes. In *Eli Lilly & Co. v. Medtronic, Inc.* the Supreme Court extended section 271(e), the clinical trials exemption, to cover medical devices, not just pharmaceuticals.<sup>104</sup> Eli Lilly sued to enjoin Medtronic from testing and marketing of a pacemaker. Medtronic’s defense rested on a broad interpretation of section 271(e)(1), which authorizes the manufacture, use, or sale of a patented article “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” The District Court of the Eastern District of Pennsylvania concluded that section 271(e)(1) does not apply to medical devices and, after a jury trial, entered judgment on verdicts for Eli Lilly. The decision was reversed by the Federal Circuit.<sup>105</sup>

In an opinion authored by Justice Scalia, the Supreme Court affirmed the reversal, holding that the phrase “a Federal law which regulates the manufacture, use, or sale of drugs,” is ambiguous and

104. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

105. *Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033 (E.D. Pa. 1988) *rev’d*, 872 F.2d 402 (Fed. Cir. 1989).

should be read as applying to medical devices as well as drugs.<sup>106</sup> The court explained that the purpose of the act was to rectify two problems with limited patent terms for technology that requires extensive pre-market approval: first, the patentee loses time at the beginning of his patent while waiting for market approval; second, the public loses time at the end of the patent while waiting for a competitor to obtain market approval. Because this problem applies equally to drugs and devices, the clinical trials exception was read as applying to both drugs and devices.<sup>107</sup>

The Court's willingness to effectuate Congressional policy and rectify common-sense problems with the regulation of medical technology suggests that the policy of section 287(c) could be realized through a functional analysis of inducement liability rooted in the text of section 287(c).

A court will of course begin with the express terms of the statute. Section 287(c) addresses some inducement liability situations. However, other significant situations are not addressed by the statute. Because a categorical rule of immunity or no immunity in those cases would undermine the balance created by section 287(c), courts will have to determine on a case-by-case basis if the inducer is entitled to immunity. To determine if infringement extends to an inducer, courts should consider two things: the intention of the inducer and the primary activities of the inducing party.

*A. Parties who are Immune under the Express Terms of Section 287(c)*

Section 287(c)(1) states that the activities of medical practitioners and related health care entities are immune from suits based on either direct infringement *or* induced infringement.<sup>108</sup> This addresses the easy cases, such as *Pallin v. Singer*, where the patentee sues both the directly infringing doctor and the inducing clinic that offers the patented procedures. Additionally, this immunizes doctors and hospitals in suits where the patient is the direct infringer and the medical practitioner and/or related health care entity is the inducer.<sup>109</sup>

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106. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. at 665–69.

107. *Id.* at 675–78.

108. 35 U.S.C. § 287(c)(1) (2006).

109. However, subject to logistical constraints, the patients could be sued as direct infringers. *See* Part II.B *supra*.

*B. Parties who are Not Immune under the Express Terms of Section 287(c)*

There are three situations where a party would not be immune from inducement liability because section 287(c)(1) itself does not apply to the medical practitioner or related health care entity. If the medical practitioner or related health care entity is not immune, then there is no basis for holding the inducer immune. These exceptions will allow for inducement liability in a substantial number of situations.

First, Section 287(c)(3) states that the protections of section 287(c)(1) do not apply to the activities of individuals which are “directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician’s office)” and are “regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.”<sup>110</sup>

While the scope of subsection (3) is unclear, it at least allows for liability against companies who are developing new medical products that will require FDA approval. In those cases, section 271(e) will determine whether they are infringing and if another party may be liable inducing their activities.<sup>111</sup>

Second, section 287(c) does not apply to “any patent issued based on an application the earliest effective filing date of which is prior to September 30, 1996.”<sup>112</sup> Because of this exception, some older cases may have turned out differently if section 287(c) had applied. For example, in *C.R. Bard v. US Surgical*, US Surgical was held liable for inducing infringement of a method claim, although they did not infringe the patent’s device claim. The patent was filed in 1993, so section 287(c) did not apply.<sup>113</sup>

Third, section 287(c)(1) does not apply if one of the three exceptions to the definition of “medical activity” is invoked. That is, if the medical method involves the use of a patented machine, manufacture, or composition of matter; or a patented method of using any composition of matter, whether patented or not; or a biotechnology patent. This makes section 287(c) inapplicable to vir-

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110. 35 U.S.C. § 287(c)(3)(A)–(B).

111. See Carrie S. Martin, *Proving Inducement of Infringement of Method-of-use Patents in Hatch-Waxman Act Litigation: Are the Standards Realistic of the Pharmaceutical Industry?*, 32 AIPLA Q.J. 163 (2004).

112. 35 U.S.C. § 287(c)(4).

113. U.S. Patent No. 5,356,432 (filed Feb. 5, 1993). The patent in *Metabolite Labs* was also filed prior to the effective date of section 287(c).



tually all methods of using a drug (whether the drug is patented or not).

*C. Parties who are Not Addressed by the Express Terms of the Statute*

In some cases, the express terms of the statute do not dictate whether immunity will extend to an inducer or not. In those situations the court should look to two considerations to determine if immunity will extend to the inducer. These considerations are an attempt to effectuate the core policies of the statute—to protect the free exchange of ideas amongst medical practitioners and allow for peer review and improvement of medical techniques. The inquiries also attempt to curb immunity to avoid an end-run around medical method patents by enterprising copycats. Finally, this inquiry will not be a great additional burden on the court because the intent and conduct of the inducer must be examined to determine if the requirements for inducement liability under section 271(b) itself are met.

1. Intent of the Inducer

The court should first consider the intent of the inducer. The main goal of this inquiry is to determine if the inducement occurred for educational or research reasons, or if the inducement was intended to produce commercial gains. While this flavor of intent inquiry is not traditionally an element of inducement liability, a court could look to the inducer's intent—based on an interpretation of the language in section 287(c)(3)—to decline to immunize conduct that is directly related to commercial development.

In some cases this intent test will be determinative. For example, where the inducer is selling a non-patented or non-infringing device with instructions to perform a patented method, the inducer will not be immune. Thus cases like *C.R. Bard v. U.S. Surgical Corp* will come out the same way.

Where the inducer is merely an academic author without a financial stake in the inducement, the inducer should be immune. This would protect non-physician researchers, who are not medical practitioners under the statute, from liability for researching and improving medical techniques. It would also protect non-state-licensed instructors who teach infringing methods from inducement liability. This inquiry helps preserve the free flow of information and peer review that is necessary in the medical profession for self-regulation and improved patient care.

However, this may still be a difficult analysis for the court. For example, in *Metabolite Labs*, the trial court found induced infringement on the basis of published articles in medical journals. The Metabolite patent was filed prior to the effective date of section 287(c) so immunity was not at issue in the case. In a case like that, where the inducer is publishing educational articles, but with the intention of driving business to itself, the court would have to continue on to the second inquiry and look at the other activities of the inducer to determine if immunity should be extended.

## 2. Primary Activities of the Inducer

If the court cannot resolve the intent question either way, the court may next look to the other activities of the inducer. If the inducer is not primarily involved in commercialization of medical technologies, but is instead primarily involved in treatment, education or research activities the inducer should not be held liable. On the other hand, if the inducer is primarily engaged in the commercialization of medical technologies they should be held liable for inducing infringement. This inquiry is again based on the legislative intent of the statute embodied in section 287(c)(3) and in Congressional debates over precursor bills to section 287(c).

The major themes of the debate over section 287(c) were the protection of medical sharing norms versus the necessity of effective patent protection for funding development of medical products. By inquiring into the primary activities of the inducer and the inducer's intent, the courts should be able to weed out cases where the activities of the inducer are meant to circumvent the patent bargain of public disclosure in exchange for the right to exclude.

Courts would implement this test by looking at the inducers activities as a whole. For example, in *Metabolite Labs* inducement liability would still attach because LabCorp is a company that profits off the commercialization of medical technologies.

This two-step analysis best reflects the goal of Congress as embodied in section 287(c)—to protect the development of medical knowledge amongst practitioners without destroying the patent bargain of the inventor. Although the express terms of the statute only represent interest groups who secured exemptions to “medical activities,” courts should not allow either inducers or patentees to circumvent the intended scope of section 287(c) by creating a rigid *yea* or *nay* rule in all cases of inducement.

## V. CONCLUSION

The interaction of the Physician's Immunity Statute and inducement liability presents many complex questions that the courts will have to answer soon enough. Given the breadth of conduct that can give rise to inducement liability it is only a matter of time before courts confront this issue. There is no clear answer to the question of extending the direct infringer's immunity to the inducer from either the text of the statute or the conflicting policies of section 287(c) and section 271(b). Instead, the court would have to rely on the legislative decisions behind section 287(c) and section 271(b) and try to balance two competing interests—the medical community's desire for open discourse over medical methods, and the patent owners ability to effectively enforce their monopoly rights.

## APPENDIX A: 35 U.S.C. § 287(c)

35 U.S.C. § 287: Limitation on damages and other remedies; marking and notice

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

(2) For the purposes of this subsection:

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

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

(C) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital,

university, medical school, health maintenance organization, group medical practice, or a medical clinic.

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

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

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

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

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

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

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

(4) This subsection shall not apply to any patent issued based on an application the earliest effective filing date of which is prior to September 30, 1996.