The Physician’s Immunity Statute: 
A Botched Operation or a Model Procedure?

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I. INTRODUCTION ........................................................................................................... 944
II. BACKGROUND OF 35 U.S.C. § 287(c) ........................................................................ 945
   A. Origins of § 287(c): Concerns Prompting the Amendment ........................................ 945
   B. Statutory Construction of § 287(c) ............................................................................. 947
      1. The Development of § 287(c) .............................................................................. 947
      2. Immunity ............................................................................................................. 948
      3. Exceptions to Immunity ...................................................................................... 949
   C. Concerns Resulting from the Adoption of § 287(c) .................................................. 950
III. ANALYSIS .............................................................................................................. 951
   A. Research Hypothesis ............................................................................................. 951
   B. Survey Methodology ............................................................................................. 952
   C. Survey Results ...................................................................................................... 953
      1. Overall Awareness of the Physician’s Immunity Statute ....................................... 953
      2. Attitudes Towards the Patentability of Medical Procedures and the
         Physician’s Immunity Statute .............................................................................. 954
      3. Effects of the Statute on Daily Strategic Business Decisions ................................ 956
   D. Adequacy of the Current Legislative Solution ....................................................... 958
      1. Adequacy of § 287(c) ........................................................................................ 958
      2. Adequacy of the Immunity Exceptions .................................................................. 959
   E. Flaws of § 287(c) .................................................................................................... 960
   F. Section 287(c) as a Learning Experience: Addressing Access to
      Patented Biotechnology ......................................................................................... 961
IV. RECOMMENDATIONS .............................................................................................. 962
   A. Immunity for Health Care Providers That Use Patented Biotechnology for
      Diagnosis .............................................................................................................. 962

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I. INTRODUCTION

The American patent system stems from Article I, Section 8, of the United States Constitution, which authorizes Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”\(^1\) When Congress exercised this new grant of power in 1790, it charged Thomas Jefferson, the Secretary of State, with overseeing the development of the fledgling patent system.\(^2\) The fundamental idea driving the patent system was that Congress wanted to reward inventors with the right to exclude others from making, using, selling, or offering to sell their invention in exchange for the inventors’ voluntary disclosure of the detailed workings of their discovery to the public.\(^3\) To enforce these exclusive rights, Congress empowered patent holders to bring an infringement suit against persons using, practicing, selling, or offering to sell the invention without obtaining permission from the inventor.

It is unlikely that Jefferson or the Framers of the Constitution foresaw the day when the government would issue patents for medical procedures, such as a particular incision or suture.\(^4\) It is even less likely that the Framers foresaw the day when physicians would bring infringement suits against one another to prohibit the performance of patented medical procedures. That day came, however, in 1993, when Dr. Samuel Pallin brought an infringement suit against fellow physician, Dr. Jack Singer, for performing Pallin’s patented cataract surgery incision.\(^5\) Although the suit ultimately failed, it garnered significant national attention from both Congress and health care interest groups. The suit ultimately led to congressional adoption of the Physician’s Immunity Statute.\(^6\)

This Note argues that the Physician’s Immunity Statue is a flawed legislative solution to the problems associated with medical procedure patents, and that Congress has the opportunity to learn from these mistakes as it addresses health care provider use

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5. Pallin v. Singer, No. 5:93-202, 1995 WL 608365 (D. Vi. May 1, 1995). The suit failed because the court invalidated multiple claims in the Pallin patent and enjoined Pallin from enforcing the remaining claims against Singer or other potential infringers.
of patented biotechnology in subsequent legislation. Part II examines the legislative history and concerns that prompted Congress to adopt § 287(c), as well as the resulting criticisms from the legal and academic communities. Part III synthesizes interviews with professionals in the medical, insurance, and legal fields, and draws conclusions on how much impact the Physician’s Immunity Statute has on their daily business decisions, as well as their thoughts on the adequacy of the statutory solution. Part IV identifies the fundamental flaws of § 287(c) and uses these insights as a baseline for recommendations as to effective future legislation governing health care providers’ use of patented biotechnology.

II. BACKGROUND OF 35 U.S.C. § 287(c)

A. Origins of § 287(c): Concerns Prompting the Amendment

At its 1994 House of Delegates Meeting, the American Medical Association (AMA) issued one of the first major responses to *Pallin v. Singer* by adopting a resolution to “vigorously condemn the patenting of medical and surgical procedures and work with Congress to outlaw this practice.”7 The AMA joined forces with numerous medical specialty associations, such as the American Optometric Association, in lobbying efforts that ultimately resulted in Congress adopting 35 U.S.C. § 287(c), commonly referred to as the Physician’s Immunity Statute.8 An examination of the concerns these groups sought to address is critical to understanding the statutory provision.

The AMA articulated four primary concerns that fueled the legislative development of § 287(c).9 The first was that the ability to patent medical procedures would give patent owners the ability to exclude others from practicing the protected procedure and would lead to inadequate patient care.10 The medical community feared that exclusivity would limit a physician’s field of options from all known procedures to only those that were known and unpatented, potentially eliminating patented procedural advances that would help the patient.11 In addition, existing procedures, such as the basic suture, or minor variations thereof, may be subject to patent protection and widely used procedures may be withdrawn from the general field of available treatment procedures, thus reducing a physician’s repertoire.12

Commentators suggest that while this concern is technically correct as a statement of law and garners persuasive strength from the fears of all would-be patients, this dire hypothetical situation will likely never become a reality.13 Critics explain that a patent owner has a financial incentive to license the protected procedure, and even if the

7. Id. at 790.
10. Id.
11. Id.
12. Id. at 704.
owner chose not to license, a court is unlikely to enjoin a physician from performing a life-saving procedure.\textsuperscript{14} Indeed, there are no known cases in which the owner of a medical procedure patent has refused to license the right to perform the patented procedure.\textsuperscript{15} As an example of a court’s treatment of a physician that performs the procedure and is later accused of infringement, the \textit{Pallin} court focused its scrutiny on the validity of the patent as opposed to the liability of the physician that performed the patented procedure.\textsuperscript{16} While the physician in this case failed to obtain a license to perform the procedure in advance, the court did not find the physician guilty of infringement ex post facto.\textsuperscript{17}

The AMA’s second concern was that medical procedure patents would increase already expensive health care costs.\textsuperscript{18} Licensing and litigation expenses associated with obtaining and enforcing patent rights would drive up costs and leave health care providers or insurers to make a difficult decision between the patient’s well being and the bottom line.\textsuperscript{19} Commentators note that this concern is likely the most credible, and agree that health care providers would likely pass the added costs of royalties and attorney’s fees on to consumers through higher medical insurance premiums.\textsuperscript{20}

Private and government health insurers finance a majority of American health care, and both types of insurers limit the amount they will spend on medical procedures.\textsuperscript{21} Proponents of § 287(c) claim that additional licensing costs would inevitably prevent some patients from choosing insurance plans that cover patented procedures and could encourage physicians to use less aggressive methods of treatment to keep their services affordable.\textsuperscript{22} This possibility could deter patent owners from seeking exorbitant royalties because insurers place restrictions on a patient’s choice of physician and the insurance provider may exclude a licensing hospital’s physicians from a patient’s potential list of choices because of higher costs.\textsuperscript{23}

The third concern associated with medical procedure patents is that patient confidentiality might be compromised if a patent owner forced a physician and hospital to litigate.\textsuperscript{24} The AMA contended that patients’ records and personal medical history would be on display if physicians were required to give a procedure-by-procedure accounting in an infringement suit.\textsuperscript{25} Commentators view this as the weakest argument set forth by the AMA because it is already common practice to redact patient information in medical litigation or review sensitive documents in camera to reduce unwanted breaches of confidentiality.\textsuperscript{26} Numerous courts in situations outside the

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\textsuperscript{14} Id. at 630–31.
\textsuperscript{15} Id.
\textsuperscript{17} Id.
\textsuperscript{18} Lee, supra note 9, at 703.
\textsuperscript{19} Id.
\textsuperscript{20} Steve Dirksen, \textit{A Reconsideration of the Physician’s Immunity Statute}, 2001 DUKE L. & TECH. REV. 0027, ¶ 11.
\textsuperscript{21} Id. ¶¶ 10–11.
\textsuperscript{22} Id. ¶ 11.
\textsuperscript{23} Id. ¶ 13.
\textsuperscript{24} Lee, supra note 9, at 703.
\textsuperscript{25} Ho, supra note 13, at 633.
\textsuperscript{26} Id. at 634.
The Physician’s Immunity Statute

context of patent litigation have dealt with this problem successfully. Commentators suggest no reasons to believe that these same courts would not handle confidentiality issues successfully in patent infringement proceedings as well.

The final argument advanced by the AMA was that the medical community does not need the personal financial incentives of patents because the respect and recognition that accompany publication in medical journals are sufficient to encourage innovation. The AMA argued that medical procedure development is the product of intellectual curiosity instead of the pursuit of financial gain. In addition, the Medical Ethics Code requires physicians to share information freely as a cornerstone of ethical medical practice.

Commentators note that patent rights do not necessarily go hand-in-hand with personal financial gain at the expense of the medical profession as a whole or with the diminished exchange of knowledge through journal publication. Patent ownership does not require the owner to charge royalties, and many inventors consider patent ownership alone to be a prestigious accolade. As noted earlier, one of the fundamental ideas of the patent system is that inventors fully disclose their invention in a way that enables others to practice their discovery in exchange for the right to exclude. Patent rights enhance the incentives of peer recognition and the dissemination of knowledge, and do not detract from the traditional incentives cited by the AMA.

These concerns laid the foundation for numerous congressional debates during the development of § 287(c). While scholars and commentators have since challenged the validity of each concern, the fears of the medical community were clearly dominant factors shaping the content and scope of § 287(c).

B. Statutory Construction of § 287(c)

1. The Development of § 287(c)

Congress considered many different approaches to addressing the concerns of the AMA and associated groups. The initial bill, authored by Representative Dr. Greg Ganske, focused on changing what inventions were patentable under 35 U.S.C.

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27. See id. (noting that patient files are disclosed in civil litigation, such as medical malpractice suits, and that the common practice is to redact personal information in this type of situation).
28. Id.
29. Lee, supra note 9, at 704.
30. Id.
31. Ho, supra note 13, at 624 (“The ‘Medical Ethics Code’ . . . prohibits withholding knowledge ‘for reasons of personal gain,’” but states that “[a] physician may patent a surgical or diagnostic instrument he or she has discovered or developed.”).
32. Id. at 633.
33. MERGES & DUFFY, supra note 2, at 633.
34. Ho, supra note 13, at 625.
35. Melvin, supra note 8, at 1095.
36. See Telephone Interview with Dr. Greg Ganske, former Republican Representative, Fourth District of Iowa (Oct. 12, 2007) [hereinafter Ganske Interview] (noting that pharmaceutical and biotechnology interest groups weighed in heavily during the development of the various legislative proposals).
37. Mossinghoff, supra note 6, at 795.
§ 101. \textsuperscript{38} Ganske’s proposal received heavy opposition from research-based pharmaceutical, biotechnology, and diagnostic industry interest groups because it excluded “surgical or medical procedures . . . or medical therapy” from patentable subject matter but failed to define these key terms. \textsuperscript{39} Opponents feared that such a change would stop them from obtaining patents or protecting advances in their respective fields. \textsuperscript{40} The interested parties reached a final compromise when drafters agreed to place the amendment within the section of the Patent Act dealing with remedies available to a patent owner. \textsuperscript{41} When asked about the compromise, Dr. Ganske stated that it resulted from the difficulty in finding statutory language that accomplished the goal of limiting liability for performing medical procedures without placing unwanted restrictions on biotechnology and pharmaceutical companies. \textsuperscript{42}

2. Immunity

Section 287(c)(1) grants immunity from patent infringement suits to both “medical practitioners” and “related health care entities” when they engage in protected “medical activity.” \textsuperscript{43} A “medical practitioner” is any licensed medical professional who can legally perform a “medical activity” or any person acting under the guidance of such a professional. \textsuperscript{44} “[R]elated health care entities” are all entities with which a medical practitioner may have a professional affiliation during the performance of a medical activity, such as hospitals, universities, medical schools, or health maintenance organizations. \textsuperscript{45} Finally, the term “medical activity” covers medical and surgical procedures performed on the body so long as they do not include or use: (1) a patented machine or manufacture, (2) composition of matter, or (3) a patented process in

\textsuperscript{38} Weldon E. Havins, \textit{Immunizing the Medical Practitioner “Process” Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?}, 77 U. DET. MERCY L. REV. 51, 63–64 (1999) (noting that Ganske’s original proposal attempted to prohibit patents on “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” and created exceptions that would continue to allow the patenting of “techniques, methods, or processes performed as a necessary component of a machine, manufacture, or composition of matter”).

\textsuperscript{39} \textit{Id.} at 64.

\textsuperscript{40} \textit{Id.}

\textsuperscript{41} \textit{See id} at 68 (noting that after lengthy debate and multiple failed drafts, Senate Bill 2105, which ultimately became § 287(c), passed out of the House without so much as a committee hearing and was passed by the Senate and signed by the President in the same day); Ganske Interview, \textit{supra} note 36 (explaining that excluding medical procedures from patent eligibility would eliminate the right of an inventor to exclude all others from practicing the invention, whereas creating an exemption for physicians that practice a patented procedure still leaves the inventor’s right to exclude intact, although unenforceable against parties named in § 287(c)).

\textsuperscript{42} Ganske Interview, \textit{supra} note 36 (additionally discussing that the fear that physicians would attempt to patent long-standing and widely accepted procedures and severely limit their peers’ abilities to treat patients motivated Dr. Ganske’s inclusion of his original amendment in 35 U.S.C. § 101).

\textsuperscript{43} 35 U.S.C. § 287(c)(1) (2006) (providing that “[w]ith 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 . . . shall not apply against the medical practitioner or against a related health care entity”).

\textsuperscript{44} \textit{Id.} § 287(c)(2).

\textsuperscript{45} \textit{Id.}
violation of a biotechnology patent.\textsuperscript{46}

3. Exceptions to Immunity

In defining “medical activity,” the Physician’s Immunity Statute sets forth three exceptions to the immunity from patent infringement and acts to narrow a physician’s liability exemption to purely medical procedure patents.\textsuperscript{47} The first immunity exception applies when a physician uses a patented device during the process of performing a patented medical procedure.\textsuperscript{48} The use of a patented device, such as a set of forceps, however, rarely results in patent infringement. A physician has an implied license to use the device as long as it is legally purchased from a vendor or manufacturer that has licensing rights to the device.\textsuperscript{49} Simply put, the patentee transfers the right to use a patented device to the purchaser at the time of sale.\textsuperscript{50}

The second immunity exception applies when a physician incorporates the patented use of a composition of matter into a patented medical procedure without obtaining the licensing rights for the use of the composition in advance.\textsuperscript{51} Courts construe “patented use of a composition of matter” to mean that the use is patented, but that the composition of matter itself is not patentable.\textsuperscript{52} For example, a physician could patent the use of a composition, such as an unpatented cream, as an anti-scarring agent.\textsuperscript{53} If a physician were to combine the patented use of a composition of matter, such as the cream used as an anti-scarring agent, with a patented procedure, such as applying the cream to the patient’s body, this may constitute infringement of the patented procedure and lead to liability for the physician.\textsuperscript{54}

The third and final exception from immunity occurs when a physician performs a patented medical procedure in a manner that violates a biotechnology patent.\textsuperscript{55} For example, under the Physician’s Immunity Statute, a physician is immune from infringement when performing a patented surgical procedure to prevent a birth defect in a fetus.\textsuperscript{56} That same physician, however, may be subject to infringement liability for using genetic screening to identify a birth defect and then using gene therapy to treat the same condition without raising a scalpel so long as that gene is protected by a

\textsuperscript{46} Id.
\textsuperscript{47} Ho, supra note 13, at 640.
\textsuperscript{48} 35 U.S.C. § 287(c)(2).
\textsuperscript{49} Ho, supra note 13, at 638.
\textsuperscript{50} MERGES & DUFFY, supra note 2, at 914.
\textsuperscript{51} 35 U.S.C. § 287(c)(2); see also Ho, supra note 13, at 639 (noting that the scope of this exception is difficult to ascertain because it 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 matter does not ‘directly contribute’ to [the] achievement of the objective of the claimed method”).
\textsuperscript{52} Ho, supra note 13, at 639.
\textsuperscript{53} Id.
\textsuperscript{54} Id.
\textsuperscript{55} 35 U.S.C. § 287(c)(2); see also Lori B. Andrews, The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, 2 HOUS. J. HEALTH L. & POL’Y 65, 66 (2002) (stating that thousands of gene-related patents have been issued in America and that some patented genes, such as erythropoietin (used to make a treatment for kidney disease), generate more than $1.5 billion annually).
\textsuperscript{56} Ho, supra note 13, at 639.
patent.\textsuperscript{57} Courts face problems when determining the full scope of this exception, because legislators did not define the term “biotechnology patent” within the statute.\textsuperscript{58}

In addition to these three exceptions, the statute’s characteristics also narrow a physician’s protection. First, § 287(c) is not retroactive, so patent owners who filed a patent application before the amended statute took effect may still fully enforce their patent rights against physicians.\textsuperscript{59} Second, some commentators believe that only litigation will resolve the ambiguities of the statute’s vague language and that physicians will need to develop a full defense if they find themselves in an infringement suit, because immunity may not extend to their particular situation.\textsuperscript{60} These commentators claim that infringement immunity loses its desired appeal because the statutory ambiguities force cautious attorneys to prepare a full infringement defense just in case a court decides that an exception to § 287(c) applies.\textsuperscript{61}

\textbf{C. Concerns Resulting from the Adoption of § 287(c)}

The potential need for litigation to define the boundaries of § 287(c) leads to a necessary discussion of the two primary legal concerns that have developed since Congress enacted the statute.\textsuperscript{62} The Physician’s Immunity Statute has negative impacts on both the incentive to invent, hindering the invention process before or during development of the invention, and the incentive to invest, hindering the financial sponsorship during or after an invention is completed. The Physician’s Immunity Statute destroys the incentive to invent by denying inventors and patent owners the ability to exclude others from practicing the patented procedure.\textsuperscript{63} The fundamental bargain between the government and the inventor is based on a trade involving the full disclosure of the invention for the right to exclude others from practicing the invention.\textsuperscript{64} Commentators argue that by taking away the “teeth” of an infringement action, § 287(c) creates a system in which inventors of medical procedures cannot charge the public anything for the practice of their protected procedure.\textsuperscript{65} Thus, they are unable to recoup their investment of time and resources and may be forced to abandon future research and development. In response to this problem, the government has previously implemented a system known as a compulsory licensing scheme in limited circumstances.\textsuperscript{66} On these rare occasions, the patent owner always received a

\textsuperscript{57} Andrews, supra note 55, at 69. Andrews explains that genetic screening can lead to preventive medicine by enabling patients to avoid situations that would trigger the onset of genetic diseases. \textit{Id}. She also notes, however, that the patent holder on a disease gene can unilaterally control all uses, including diagnostic and therapeutic uses, of that gene and charge royalties and place restrictions on the use of the gene. \textit{Id}

\textsuperscript{58} Ho, supra note 13, at 641.

\textsuperscript{59} \textit{Id}. at 642. For example, a physician who obtained a patent on a medical procedure in 1999 could still sue another physician through 2019 for patent infringement.

\textsuperscript{60} \textit{Id}. at 644–45.

\textsuperscript{61} \textit{Id}

\textsuperscript{62} \textit{Id}. at 645–53.

\textsuperscript{63} Ho, supra note 13, at 646.

\textsuperscript{64} \textit{Id}. at 645–46.

\textsuperscript{65} \textit{Id}. at 646.

\textsuperscript{66} See \textit{id}. at 647–48 (noting that the Clean Air Act (CAA) provides for the compulsory licensing of a patent if voluntary negotiations fail between a patent holder who has developed an invention critical to CAA compliance and the government agency attempting to license the invention).
judicially determined reasonable royalty in exchange for the invention’s use.  

The second concern voiced by commentators after the adoption of § 287(c) was the detrimental impact on the incentive to invest in the development of medical procedures. Without the ability to exclude others from practicing patented procedures and securing royalties from licensing, the financial incentives for investors to fund private research on developing medical procedures largely disappear. 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 and a private venture capital group provided financial resources for the project in the prospect of financial gain after the National Institutes of Health denied funding. The private venture group would have been unwilling to invest such significant resources absent the reasonable guarantee of a return secured by a patent. While the SET procedure is an example of private funding enabling the development of a medical advance, critics of § 287(c) fear that many potential advances have already gone undeveloped because of the loss of incentives to potential investors after the adoption of the Physician’s Immunity Statute.

III. Analysis

A. Research Hypothesis

The previous sections discussed the concerns that prompted the development of § 287(c) and the concerns that resulted from its enactment. The following analysis examines the current relevance of those concerns to physicians, insurance companies, and attorneys. It also seeks to determine what effect the Physician’s Immunity Statute has on the business decisions each of these groups makes on a daily basis. In addition, this Part also examines the effectiveness of § 287(c) and its value as a future model for legislation addressing concerns associated with biotechnology patents.

The hypothesis advanced in this Note is that the Physician’s Immunity Statute is a flawed answer to the problems that arise from medical procedure and biotechnology patents. In the 12 years since Congress adopted the Physician’s Immunity Statute, the legal ramifications of § 287(c) have been less significant than originally anticipated. However, exceptions to the statute create a strong likelihood that further development, medical use, and patent protection of biotechnology will leave physicians, insurers, and the legal community no better off than they were prior to the statute’s enactment. In particular, they will face the same issues commentators raised in the wake of Pallin v. Singer.  

67. Id.  
68. Ho, supra note 13, at 648.  
69. Melvin, supra note 8, at 1104.  
70. Lee, supra note 9, at 716.  
71. Id.  
72. See id. (indicating that investors withheld funding for the development of the surrogate embryo transfer procedure due to the concern that the lack of patent protection would limit their profit from the investment).  
B. Survey Methodology

To support these contentions, I conducted a survey through interviews with a variety of professionals to obtain their thoughts on the patentability of medical procedures and the Physician’s Immunity Statute. The survey sought to gather information about: (1) the current level of awareness associated with the Physician’s Immunity Statute, (2) their attitudes toward the statute, (3) the effects of the statute on the daily strategic business decisions of the selected groups, and (4) whether the current legislative solution is adequate or whether Congress, in light of potential developments, should consider amending or repealing the statute. While I did not draw the survey questions from any particular source, the questions mirror many of the issues surrounding the adoption of § 287(c). 74

The groups selected for the survey were: (1) physicians and medical professionals, (2) medical malpractice and health care insurance providers, and (3) attorneys who counsel medical procedure patent holders or medical professionals. I was able to conduct interviews with multiple participants in each group. However, I did not include the entirety of their responses, but instead highlighted the most relevant portions of many interviews to provide representative coverage on each survey question. Each group plays a different role in the medical and legal marriage of patents and medical procedures, and together these groups provide diverse perspectives on § 287(c). Finally, each can expect a changed business landscape if Congress amends the statute.

To accomplish the survey goals, I utilized a two-step interview process with all participants. The first step consisted of providing the interviewee with some basic information on the Physician’s Immunity Statute in an introductory email. The “Statutory Background and Definitions” document attached to that email contained three types of information. 75 First, the document included information on the origins of the statute and the date on which Congress adopted it. Second, it included the statutory language of § 287(c), in addition to definitions of key terms included in the statute. Third, the document included basic information on the rights and remedies of the patent system. I asked each interviewee to read the “Statutory Background and Definitions” document before proceeding to the second step. 76

In addition to this educational component, the first step of the process also consisted of providing interviewees with a set of questions and asking the interviewee to review those questions in preparation for an interview. 77 The questions sought to elicit information on the respondents’ attitudes toward the patenting of medical procedures and toward the Physician’s Immunity Statute. 78 The questions also called

74. See, e.g., Ho, supra note 13, at 613–34 (discussing the concerns of the legal and medical communities upon the adoption of the Physician’s Immunity Statute); Lee, supra note 9, at 703–04 (outlining the arguments of the medical community for immunity from patent infringement).
75. Jeff Rundle, Statutory Background and Definitions (Oct. 19, 2007) (on file with author).
76. See, e.g., E-mail from Jeff Rundle, author, to Dr. Eric Steenlage, M.D., owner of a Medical Procedure Patent (Oct. 26, 2007, 10:14:55 CST) (on file with author).
77. Id.
78. Jeff Rundle, Survey Interview Questions (Oct. 2, 2007) (on file with author). The questions attempted to gain insight into the interviewee’s level of awareness of the statute, attitudes toward the statute and the patentability of medical procedures, opinions on the effect of the statute on daily and strategic business decisions, and opinions on future approaches to the enforcement or patentability of medical
for respondents to comment on the use of biotechnology in the medical field and the associated ramifications of patent infringement liability for the use of patented biotechnology products or processes.

The second and final step of the interview process consisted of the actual interview that I conducted in person or via telephone. A majority of the interviews occurred via telephone because of the nature of the scheduling constraints of the interviewees in each of the respective fields. In addition, some interviewees desired to remain anonymous because they felt more comfortable providing honest feedback and opinions when they knew that their names and employers would not be identified.

C. Survey Results

The next section of this Note summarizes the survey findings and places them in the context of the concerns prompting § 287(c) and of the subsequent academic criticism.

1. Overall Awareness of the Physician’s Immunity Statute

Throughout the course of the interview process, I noted a low level of awareness of the Physician’s Immunity Statute in each selected group of interviewees. Former congressman Dr. Greg Ganske, surgeon and the author of the first proposed draft of the § 287(c) amendment, related that even he was not aware that medical procedure patents could be granted prior to the Pallin litigation.79 Dr. Ganske instead remarked that while he had been a practicing physician for many years before his service as a Congressman, medical patents were not then, and are not currently, a daily concern of medical practitioners.80 Dr. Ganske indicated that he is not the owner of a patent, nor has he made a habit of searching for medical patents in advance of performing a procedure or to stay updated on newly patented procedural innovations.81

Interviews with professionals in other selected fields also support the conclusion that awareness of the Physician’s Immunity Statute is low.82 This low level of awareness is not surprising even when viewed against claims that the overall number of medical procedure patents is rising.83 Because § 287(c) directly limits enforcement of medical procedure patents against physicians and affiliated medical entities, only those physicians or companies developing and patenting new procedures are likely to be

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79. Ganske Interview, supra note 36.
80. Id.
81. Id.
82. See Telephone Interview with Susan Stoddard, Ph.D., Tech. Licensing Manager, Office of Intellectual Property, Mayo Clinic (Nov. 15, 2007) [hereinafter Stoddard Interview] (noting that the Physician’s Immunity Statute was a brief topic of discussion in the past but that she was not familiar with the statute beyond a basic recognition level). Dr. Stoddard also indicated that she was not aware of any Mayo physicians that owned medical procedure patents or any attempts by Mayo’s legal department to gain or enforce such patents. Id.
83. See Tresa Baldas, As Medical Patents Surge, So Do Lawsuits, NAT. L.J., July 16, 2007, at 4, available at http://law.com/jsp/law/LawArticleFriendly.jsp?id=1184576791631 (indicating that the number of medical patents has doubled since the 1980s and that as many as 100 medical procedure patents are issued on a monthly basis).
aware that certain procedures are receiving patent protection. Unlike an infringement suit against a hospital or physician, the development of a patented procedure rarely makes headlines. Proponents of the statute could cite the low level of awareness of § 287(c) as proof that the immunity it offers is serving the desired purpose: immunity from infringement suits takes the concerns associated with exclusive patent rights to medical procedures off physicians’ minds. Opponents of the statute, on the other hand, may claim that infringement concerns were never on health care providers’ minds in the first place and that the statute simply undermines the fundamental principles of the patent system while providing little value in return.

2. Attitudes Towards the Patentability of Medical Procedures and the Physician’s Immunity Statute

While the respondents’ awareness of the Physician’s Immunity Statute was low, their attitudes toward the statute and toward the patentability of medical procedures were largely consistent with the concerns originally expressed by the AMA after Pallin. When asked about his thoughts on the issue of the government granting exclusive rights on medical procedures to one physician or company, Jeff Bone, an insurance adjustor for a medical malpractice and health insurance provider, expressed concern. Bone noted that patents on medical procedures could certainly add “artificial costs” to medical procedures that would drive up health or malpractice insurance premiums. This was arguably the most valid concern expressed by the AMA when lobbying for an amendment to the Patent Act. Bone’s company insures a number of smaller physician groups in Western Kansas, and he expressed concern about the effects of additional licensing fees on the price of health care and insurance in remote areas.

When asked about his attitude toward the Physician’s Immunity Statute, Bone stated that providing immunity to physicians and medical entities was a step in the right direction. He also indicated, however, that excluding medical procedures from patent eligible subject matter might be a better long-term solution. Bone specifically expressed concern about the exceptions to the statute that allow physicians to be sued for infringement when performing a patented procedure that includes the use of patented biotechnology. Bone predicts that the use of such treatments will only

84. See Lee, supra note 9, at 703–04 (articulating the four primary concerns raised by the AMA that prompted the Physician’s Immunity Statute: (1) lack of physicians’ access to patented procedures, (2) increased cost associated with procedures, (3) fear of compromising patient confidentiality, and (4) the claim that patents provide an unneeded incentive to a community that already shares ideas willingly and for nonfinancial motives).
85. Telephone Interview with Jeff Bone, J.D., Insurance Adjustor (Oct. 29, 2007) [hereinafter Bone Interview]. Bone obtained his J.D. from Washburn University and practices as a registered emergency room nurse in addition to advising his employer on medical malpractice settlement issues. Id.
86. Id.
87. See Lee, supra note 9, at 703 (listing increased medical costs as a concern expressed by the AMA in opposition to the Patent Act).
88. Bone Interview, supra note 85.
89. Id.
90. Id.
91. Id.
increase in the future, and his instincts are supported by the fact that more than three million gene-related biotechnology patent applications have been filed with the Patent and Trademark Office to date.

An interview with Dr. John Uphold, a practicing emergency room physician and owner of Beverly Emergency Medical Group in Monticello, California, further supported the AMA’s claims that the patent system does not motivate the medical community to invent or improve. Rather, Dr. Uphold noted that both patents and publications in medical journals seek to fully disclose the details of a medical procedure in a manner that would allow a competent medical practitioner to perform the procedure. According to Dr. Uphold, the critical distinction between medical publication and patent protection is that the former encourages sharing of medical advances and invites other physicians to perform and validate the effectiveness of the disclosed procedure in a variety of circumstances. Conversely, while the patent process disseminates information, patent rights do not invite others to perform and validate the procedure, but rather exclude others from practicing a procedure and may leave questions about the overall effectiveness of the procedure under varied circumstances.

Dr. Uphold believes that as long as medical procedures remain eligible for patent protection, infringement immunity is necessary to continue to promote the spread of knowledge within the medical community.

While Dr. Susan Stoddard, a technology licensing manager at the Mayo Clinic, declined to comment on whether patenting a medical procedure is proper, her primary concerns with medical procedure patents are associated with patented diagnostic tests. Such diagnostic tests are increasingly covered by biotechnology patents, excepting them from infringement immunity and opening physicians up to infringement suits, and could certainly fit under the definition of “medical activity” set forth in the Physician’s Immunity Statute. Stoddard cited the difficulties associated with licensing from certain prominent biotechnology patent holders such as

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92. Id.
94. Telephone Interview with Dr. John Uphold, Emergency Room Physician and Owner, Beverly Emergency Med. Group (Nov. 1, 2007) [hereinafter Uphold Interview]. Dr. Uphold owns and operates Beverly Emergency Medical Group, a management group that coordinates the staffing and decisions of multiple emergency rooms in California. Id.
95. Id.
96. Id.
97. Id.
98. Uphold Interview, supra note 94.
99. Stoddard Interview, supra note 82 (noting that patented diagnostic tests are still a legally contentious area, but that it is Mayo’s policy to make diagnostic tests available in a broad fashion to enable better patient care).
100. See Gregory P. Lekovic, Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend “The Physician Immunity Statute,” 4 Yale J. Health Pol’y L. & Ethics 275, 275–77 (2004) (noting that pediatric genetic disorders such as Alpert’s disease, Crouzon’s disease, hemophilia A, and Canavan disease can all be identified through prenatal genetic screening and noting that many of these diagnostic techniques have patent protection).
Myriad Genetics as an example of the potential issues associated with the exceptions to the Physician’s Immunity Statute. Overall though, Stoddard agreed with the fundamental AMA logic that physicians should be more concerned with the health of their patients than with the patents they might be infringing and suggested that § 287(c) is a step toward that goal.

Patent attorney, John Dragseth, offered a different perspective on the value of the Physician’s Immunity Statute, stating that the act achieves very little. Dragseth claimed that a majority of medical procedure patents are assigned to medical device makers because medical device makers are able to commercialize aspects of the procedure by designing complementary devices to be used with the procedure. If these device companies filed infringement suits against doctors and hospitals, they would be suing their primary customers, a fundamentally bad business practice.

Overall, when interviewees first considered the concept of exclusive patent rights on medical procedures, they seemed alarmed and concerned. While a majority of interviewees agreed that action was appropriate in light of the Pallin litigation, opinions diverged as to the effectiveness of the statute, the value of medical patents, and their relevance in today’s legal and medical arenas.

3. Effects of the Statute on Daily Strategic Business Decisions

The effects of the Physician’s Immunity Statute on daily and strategic business decisions appear to be minor in the fields studied in the survey. The statute impacted physicians and insurers the least, and understandably so. Dr. Ganske noted that even after the adoption of the Physician’s Immunity Statute, he does not attempt to stay current on medical procedure patents in an attempt to avoid performing procedures that could fall under one of the statute’s exceptions. Dr. Uphold opined that medical journals and other publications have traditionally played a more effective role in keeping physicians up to speed on new procedures than medical procedure patent applications. Patent searches are a less efficient and more costly way of staying abreast of current medical technology in an environment where an infringement suit against a physician is unlikely at best.

From an insurance standpoint, Bone indicated that medical procedure patent infringement is not a subject that even makes the agenda at the malpractice defense seminars he attends. When asked whether patent infringement liability would affect

102. Stoddard Interview, supra note 82 (citing an example of Myriad Genetics’ refusal to license patented genetic diagnostic rights to hospitals such as the Mayo clinic when those rights would enable physicians to screen for breast cancer at the local level); see also Mowzoon, supra note 93, at 1093 (explaining that Myriad Genetics owns the patent on a breast cancer gene, BRCA1 and BRCA2, and that Myriad requires that all tests for these genes be done at Myriad laboratories at a cost of $2500 per test).
103. Telephone Interview with John Dragseth, Attorney, Fish & Richardson (Dec. 7, 2007) [hereinafter Dragseth Interview].
104. Id.
105. Id. (noting also that the associated cost to bring an infringement action would rarely be justified in a suit against a single practitioner or even a single hospital).
106. Ganske Interview, supra note 36.
107. Uphold Interview, supra note 94.
108. Bone Interview, supra note 85.
malpractice or health insurance premiums if § 287(c) was amended or repealed, Bone believes that infringement litigation would not likely be a major concern in the malpractice insurance field unless it became popular. At that point, he suggested that insurance lobbyists would likely call for change.\textsuperscript{109}

As someone who deals with the licensing and intellectual property for a major research hospital, Stoddard indicated that she spends significant time educating physicians on the fundamentals of patent law but that § 287(c) is not a topic of conversation.\textsuperscript{110} Stoddard also noted that a common point of confusion for most physicians is the erroneous association between the notoriety of medical journal publication and the issuance of a patent.\textsuperscript{111} Stoddard did not indicate that the Physician’s Immunity Statute affected her daily business decisions per se, but did indicate that when a physician comes to her with an invention, one of the first conversation topics is patent protection and subsequent enforcement.\textsuperscript{112} Often times, when a physician understands that a patent only bestows the right to exclude others from practicing the invention, the physician has second thoughts about patent protection and may decide that it defeats the purpose of the work.\textsuperscript{113}

Because of the immunity provided to physicians by § 287(c), Dragseth indicated that he only sees infringement actions brought against medical device manufacturers for inducing infringement.\textsuperscript{114} While he is certainly aware of the statute when counseling clients seeking medical procedure patents, the impact of the statute on his daily practice is minimal.\textsuperscript{115} Even though patent owners can no longer sue physicians for performing patented medical procedures, these suits rarely occurred before congressional adoption of § 287(c). These suits consumed a nominal amount of billable hours for even the most specialized of patent litigators.\textsuperscript{116}

In summary, § 287(c) affects the daily and strategic business decisions of the medical, legal, and insurance professions only on a limited level. Those in the legal community have a higher level of exposure and awareness if they are writing patents for, or litigating over, medical procedures. Section 287(c) still appears to have a minimal effect on the decisions of medical and legal professionals. Again, some would claim this limited effect is evidence of the statute functioning in an efficient manner and accomplishing the desired outcomes, while others would contend that the statute adds very little value to the health care field, while diminishing the integrity of the patent system.

\textsuperscript{109} Id.
\textsuperscript{110} Stoddard Interview, supra note 82.
\textsuperscript{111} Id. Stoddard related an anecdote about an academic medical research institution that surveyed all employee-physicians to generate a list of publications and patents held by those physicians. Id. That type of survey furthered the misunderstanding that a patent is the equivalent endorsement of the validity of a medical procedure as is a peer-reviewed journal publication, when in fact they both measure very different qualities of the given procedure. Id.
\textsuperscript{112} Id.
\textsuperscript{113} Stoddard Interview, supra note 82.
\textsuperscript{114} Dragseth Interview, supra note 103 (explaining that a medical device company induces infringement by encouraging customers to use the medical device to perform a patented medical procedure and violate the exclusive rights of the patent owner).
\textsuperscript{115} Id.
\textsuperscript{116} Id.
D. Adequacy of the Current Legislative Solution

1. Adequacy of § 287(c)

When asked to comment on the adequacy of § 287(c) as a remedy to the concerns articulated by the AMA, responses naturally varied across the respective fields. Dr. Ganske’s original amendment was aimed at addressing the patentability of medical procedures, and additional interviews with physicians supported the idea that medical procedures should not qualify as patent-eligible subject matter. The general consensus of the physicians interviewed was that the medical community is harmed by the ability to patent procedures only because others are deprived of the right to use and review the advances. Consistent with the original approach of the AMA, physicians still advocate for repealing the patentability of medical procedures. In the absence of a change in patent-eligible subject matter, though, immunity from infringement is preferred. Uphold did note, however, that he was uncomfortable with the fact that the statute was not retroactive and that there are still some medical patents that are enforceable for the next eight years.

Insurers agreed with physicians’ preference of the repeal of patent eligibility for medical procedures to all other options, but their analysis was more economic in nature. Bone predicted that in the absence of the Physician’s Immunity Statute, medical malpractice insurance premiums might rise minimally because of increased infringement litigation. On the other hand, he recognized that unregulated licensing fees present a greater, and more tangible, economic danger to drive up health care insurance premiums for patients. A mandatory licensing option does provide price stability and assurance of minimal litigation, but insurance premiums would still be higher than in the current system.

In contrast, attorneys have greater economic incentives to see patent rights enforced to the full extent. According to an anonymous source who serves as general counsel to a large research hospital, physicians within that hospital are encouraged to patent medical devices, and the hospital licenses patented diagnostic procedures on a regular basis. Many research institutions, including universities, receive substantial

117. Ganske Interview, supra note 36 (indicating that in negotiations with representatives of pharmaceutical and biotechnology companies, the representatives were very concerned about the potential elimination of patent protection for those products if medical procedures were excluded from the list of patent eligible subject matter).
118. See, e.g., Uphold Interview, supra note 94 (affirming the central role of cooperation and knowledge sharing within the medical community as the primary method for validating the benefits of a procedure as opposed to a pronouncement from the Patent Trademark Office that the procedure is valid and useful).
119. See, e.g., id. (stating that the peer review process is a cornerstone of the development of any medical procedure because it provides the medical community the opportunity to evaluate the validity of the procedure when performed by physicians of varying skill).
120. Id.
121. Id.
122. Bone Interview, supra note 85.
123. Id.
124. Id.
125. Interview with Anonymous Source, General Counsel, large research hospital (Nov. 9, 2007) [hereinafter General Counsel Interview] (noting that he was not aware of any physicians in the hospital that
financial benefits from patent licensing and depend on enforcement through litigation to protect the value of their intellectual property.\textsuperscript{126} When asked to comment on the effectiveness of the Physician’s Immunity Statute, the general counsel noted that it protected physicians from the “relatively unlikely danger” of an infringement suit, but the exceptions left large holes in immunity.\textsuperscript{127} He noted that, from a purely “selfish perspective,” the statute took one additional concern off of his plate. Still, he indicated his preference for a judicially regulated licensing system because it preserved the rights of patent holders and incentivized invention while granting access to the public.\textsuperscript{128}

In summary, most interviewees agreed that the Physician’s Immunity Statute is a better option than infringement liability, but none were completely satisfied with the statute. The exclusion of medical procedures from the list of patent eligible subject matter and a regulated licensing system requiring patent owners to provide access in exchange for payment were both preferred options to the current statute. The medical community still has valid concerns about the lack of retroactivity that leaves physicians vulnerable to infringement of medical procedure patents issued before 1996. Interviewees also expressed concerns about the exceptions created for biotechnology patents and the effect that the immunity exception has on the rights of patent holders.\textsuperscript{129}

### 2. Adequacy of the Immunity Exceptions

During the portion of the interviews dealing with the adequacy of the immunity exceptions, the primary topic was the exception associated with biotechnology patents. Many of the interviewees, including Stoddard, Bone, and the anonymous general counsel, noted that biotechnology patents, particularly those covering genetic screening processes, will continue to become more prevalent as physicians increasingly use them in medical diagnoses.\textsuperscript{130} While Stoddard believes that biotechnology will progress slowly enough that many valuable biotechnology patents will expire before the use of such diagnostic tools and therapies becomes widespread, she realizes that patent infringement actions may increase if they do not.\textsuperscript{131}

Physicians such as Ganske and Uphold are hopeful that advances in biotechnology will be subject to the sharing norms of the medical field,\textsuperscript{132} but the greater involvement of private industry in the development of these technologies would indicate otherwise.\textsuperscript{133} The anonymous general counsel cited multiple examples of difficult

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\textsuperscript{126} Id.
\textsuperscript{127} Id.
\textsuperscript{128} Id.
\textsuperscript{129} Id.
\textsuperscript{130} Stoddard Interview, supra note 82; Bone Interview, supra note 85; General Counsel Interview, supra note 125.
\textsuperscript{131} Stoddard Interview, supra note 82.
\textsuperscript{132} Ganske Interview, supra note 36; Uphold Interview, supra note 94.
\textsuperscript{133} See Mowzoon, supra note 93, at 1092 (noting that problems such as patent thickets, royalty stacking, and reach-through rights have all developed because of the high level of corporate involvement in gene-related patents and that these developments restrict access for both research and diagnostic purposes).
licensing issues that have developed as his hospital attempts to provide patients with the best diagnostic services. He believes that the health care industry is quickly approaching the time in which the need for access to patented biotechnology will necessitate a more efficient delivery system that provides greater flexibility for physicians and hospitals. As drugs and therapies are developed and further incorporated into patient treatment, the hindrances of elusive licenses and the threat of infringement litigation are likely to take a toll on both health care providers and, potentially, patients. While the current status quo has thus far sufficed, fully enforceable patent rights in the biotechnology field are not a sustainable solution.

E. Flaws of § 287(c)

The legal and medical community’s response to the Physician’s Immunity Statute has been lukewarm to date. The conflicting opinions and interests of interviewees demonstrate the tension between a patient’s access to the best medical treatment available and the economic realities that go hand-in-hand with the development of these procedures. Legislators sought to balance these interests through the Physician’s Immunity Statute, but the solution that emerged is flawed and near-sighted for a number of reasons.

The Physician’s Immunity Statute is a flawed solution for three primary reasons. First, it does not apply retroactively to medical procedure patents issued before 1996 and therefore partially fails at the primary goal of protecting physicians and associated medical entities from infringement suits for the next eight years. Second, it undercuts the fundamental rights of patent holders by denying them the ability to enforce their patents through infringement suits. This results in depriving patent owners of the bargaining chip necessary to secure a reasonable royalty on their invention, thereby threatening the development of procedures that require large amounts of initial financial investment for their development. Without the teeth provided by a potential infringement suit, no incentives exist for a hospital to enter into a licensing agreement with an inventor. The ability of inventors or investors to recover their investments of time and resources becomes severely limited. Finally, the Physician’s Immunity Statute fails to provide the health care community valuable access to patented biotechnology by excluding this category of patents from the infringement immunity coverage. Health care providers are still liable for infringement if they use patented biotechnology, such as gene therapies or drugs developed from patented genes, to treat patients.

In addition, the statute was largely unnecessary because very few medical procedure infringement suits were filed before the adoption of the statute. While a

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134. See General Counsel Interview, supra note 125 (noting that many patent owners require that genetic testing be completed at their own specified labs at considerably greater cost and in a less timely fashion than a hospital could complete it if it were able to perform the test locally).
135. Id.
136. Compare Baldas, supra note 83 (quoting patent attorney Glen Belvis as stating that medical procedure patents “allow for innovation to advance and force people to play by the rules”), with Uphold Interview, supra note 94 (noting that patents run counter to the sharing norms of the medical community and attempt to validate procedures while skirts the valuable process of peer review).
137. See Havins, supra note 38, at 69 (stating that § 287(c) was “much ado about nothing” because it formalized the informal agreement that physicians would not sue one another, an attitude that was prevalent
handful of cases have involved medical procedure infringement, none have resulted in injunctions that compromised the health of a patient. A legitimate debate exists over whether medical procedures should be eligible for patent protection in the first place. They remain patentable, however, and turning a blind eye to their enforcement seriously weakens the patent system and only provides minimal benefits to the health care community.

In short, § 287(c) is flawed because it fails to fully protect health care providers from patent infringement suits by lacking a retroactive feature. In addition, it also undercuts fundamental principles of the patent system and jeopardizes funding for future research. Finally, it does not provide physicians with necessary access to patented biotechnology. Unfortunately, these are legislative errors not easily reversible, and a simple remedy does not exist. Addressing the flaws of § 287(c) would likely involve legislative action to exclude medical procedures from patent eligibility, eliminate infringement immunity altogether, or extend infringement immunity to past and present medical procedure patents while implementing a required licensing system. The following portion of this Note proposes possible solutions to the third flaw, a lack of physician access to patented biotechnology.

F. Section 287(c) as a Learning Experience: Addressing Access to Patented Biotechnology

While the damage wrought by § 287(c) is likely done in the field of medical procedure patents, Congress does have a chance to address the final flaw: infringement liability for the health care community based on the use of patented biotechnology. In doing so, Congress must learn from its mistakes and take a new approach to solving this problem. In fact, Congress has already considered some potential approaches. Representative Lynn Rivers sponsored the Genomic Research and Diagnosis Accessibility Act of 2002 (GRDAA) as a potential solution. The GRDAA sought to allow physicians and researchers to use patented gene sequences for research and diagnostic purposes without obtaining a license and required patent applicants to disclose DNA sequences at the time of application. The Act, however, died when Rivers lost her seat to Representative John Dingell, and legislators have not proposed a similar bill since. However, Congress debated a proposal that would authorize the Office of Science and Technology Policy (OSTP) to study the relationships between

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138. See Pallin v. Singer, No. 5:93-202, 1995 WL 608365 (D. Vt. May 1, 1995); Young v. Lumenis, 492 F.3d 1336 (Fed. Cir. 2007) (reversing the district court’s finding of patent invalidity and remanding on the issue of infringement after the patent owner of a surgical method for declawing a cat brought an infringement action against a veterinarian for performing the patented procedure).

139. See Stoddard Interview, supra note 82; see also Bone Interview, supra note 85 (predicting an increase in biotechnology patent litigation as gene-based therapies and drugs become more commonplace in health care).


141. Lekovic, supra note 100, at 296–97.

142. Id.

143. Id.
genetic research, development, and policy to promote maximum innovation, but the OSTP has not offered a statutory recommendation to date.\textsuperscript{144}

Because of the fundamental differences in medical procedure patents and genetic patents,\textsuperscript{145} the legislative approach calls for a comprehensive and well-researched strategy. Biotechnology patent owners are traditionally companies (as opposed to individuals) that have the resources and incentives to seek full enforcement of their patent rights. In addition, these owners are not subject to the same Code of Ethics governing physicians and have invested more capital in the research and development of their patented biotechnology, making them more likely to file an infringement action than a physician. Congress must carefully balance the competing interests of the access of patented biotechnology to patients and physicians with the necessary incentives required to promote innovation and financial investment in new genetic-based treatments.

IV. RECOMMENDATIONS

Based on the findings of the interviews viewed in light of academic criticisms, I propose a two-prong approach to amending § 287(c)(2)(A)(iii), the portion of the Physician’s Immunity Statute that addresses biotechnology patents.\textsuperscript{146} The recommendation considers the flaws of § 287(c), such as the lack of retroactive immunity and unenforceable patent rights, while addressing the issue of physician’s access to patented biotechnology. The first prong extends retroactive and prospective infringement immunity to physicians and associated health care entities for diagnostic uses of biotechnology patents. The second prong creates federally regulated patent pools for all biotechnology patents that would serve as a licensing clearinghouse with predetermined fees.

A. Immunity for Health Care Providers That Use Patented Biotechnology for Diagnosis

The first prong of this proposal addresses patient and physician access in the same way the current Physician’s Immunity Statute does—by proposing the elimination of infringement liability for approved uses. Physicians and affiliated health care entities require the ability to address the diagnostic needs of patients without the threat of patent infringement litigation.\textsuperscript{147} By limiting immunity to diagnostic uses, the inventors and investors of genetic research still have financial incentives that lead to

\textsuperscript{144} See Mowzoon, supra note 93, at 1099–1100 (noting that the drawback to the proposed Genomic Science and Technology Innovation Act of 2002 is that it is a time-consuming study and may not keep pace with the developments of the biotechnology industry).

\textsuperscript{145} See Andrews, supra note 55, at 79 (noting that genetic patent holders can prevent diagnosis, research, and development of gene therapies associated with a particular gene because biotechnology patents are often granted for all scientific and medical uses related to that gene). Compare this to the much narrower scope of a medical procedure patent that simply limits a physician from performing a specific medical procedure.


\textsuperscript{147} See Stoddard Interview, supra note 82 (noting that the Mayo Clinic allows diagnostic use of all patented biotechnology as a common practice but indicating that this is certainly not the case for all biotechnology patent owners).
the recovery of their investment in the form of: (1) royalties paid for genetic therapies, (2) drugs subsequently developed from the initial genetic research, and (3) future research on the patented gene. Like the GRDAA, this proposal chooses diagnostic testing as the line for noninfringing use because it accomplishes the balance of allowing patent owners to retain property interests in drugs and therapies developed from the biotechnology patent, while still enabling the patient to benefit from the diagnostic value of the gene. Unfettered gene-based diagnostic testing will allow physicians to make the best recommendations on a course of treatment, one likely involving gene-based drugs or therapies. This moderate approach strikes an appropriate balance between completely undercutting the enforcement rights of a patent holder and providing necessary access to health care.

The retroactive aspect of the proposal helps overcome one of the missteps of § 287(c). Congress chose to establish a prospective immunity provision when it adopted § 287(c) but still left physicians open to infringement suits for any procedure patent filed between 1976 and 1996. Dr. Ganske noted that physicians do not regularly check patent records and any gap in infringement immunity could create a potential for infringement litigation. The retroactive quality of the proposal eliminates the need for health care providers to endure a 20-year period of uncertainty as they wait for current biotechnology patents to expire.

Predictably, established biotechnology patent owners who are currently gouging the health care industry with extreme licensing fees will likely oppose the retroactive nature of this approach, but the proposal does not eliminate financial incentives for these patent holders altogether. Coupled with an appropriate licensing fee, this recommendation allows biotechnology patent owners to continue to derive income from their valuable investments. In addition, a retroactive amendment treats biotechnology patent owners equally, even though current owners would likely dispute the fairness of the approach.

B. Development of Federal Biotechnology Patent Pools

The second prong calls for the development of federally regulated patent pools for all genetic patents that would centralize the licensing process and establish predetermined royalties for all participants. A patent pool serves as a common clearinghouse for patents relating to a specific subject matter and allows potential licensees to communicate with one entity when it attempts to license many related patent rights. The initial establishment of genetic patent pools would require significant time and resources to develop the appropriate scope of the respective pools, establish a system of royalties that fairly values the existing patents, and then

148. See Lekovic, supra note 100, at 296 (noting that Representative Rivers’s broader proposal also required disclosure of DNA sequence at the time of the patent and provided immunity for research-based uses of patented biotechnology).
149. Ganske Interview, supra note 36.
150. See Andrews, supra note 55, at 101–02 (citing the patent pool developed by the American Society of Composers, Authors and Publishers (ASCAP) as an example of a clearinghouse that allows potential licensees to purchase a blanket license and play any song from the ASCAP pool, and speculating on the effectiveness a potential breast cancer genetic patent pool).
predetermine the licensing fees assigned to future participants.\footnote{151} Failing to establish such licensing fees before a patent owner has exploited a market leads to the same problems as the current system and would likely lead to increased resistance from a patent owner that has carved out a lucrative niche before joining a pool. This proposal is admittedly more bold and difficult than the first prong, but provides numerous advantages for many constituents once the initially painful development process is complete.\footnote{152}

**C. Advantages and Criticisms of Patent Pools**

The first advantage of patent pools is a dramatically increased efficiency in the licensing process because a licensee need only negotiate with one entity for all licensing needs. The current system requires a licensee to negotiate with each patent holder for an individual license, a process that could lead to hundreds of transactions based on all of the genetic combinations potentially required to develop a specific therapy or drug.\footnote{153} Patent owners may also benefit from the increased efficiency because of the lower transaction costs and the additional royalties that may arise from unrealized future developments.\footnote{154}

The second advantage to the patent pool is the removal of research blockades in the form of unwilling licensors.\footnote{155} It is not unusual for a researcher to find herself at the mercy of a biotechnology patent holder because of the unexpected need to license additional patented genes to complete a research project.\footnote{156} While she may have already invested significant time into the project and significant resources into patent licenses, the dependency on the newly identified genetic patent can result in a blocking effect on her research and leave her in a very poor bargaining position.\footnote{157}

The third advantage to a patent pool is that licensees pay a reasonable predetermined fee based upon the patents that are included in the pool. This approach


\footnotesize{152}. See id. at 530–31 (indicating that establishment of the pool requires cooperation from all patent holders and the balancing of complex public and private interests, but citing multiple examples of successful patent pools, such as the MPEG-2 pool established in 1997 by major electronic manufacturers to provide access to the technology required for “efficient transmission, storage and display of digitized images”).

\footnotesize{153}. Andrews, supra note 55, at 101; see also Stoddard Interview, supra note 82 (recalling the difficulties associated with coordinating multiple licenses and of dealing with unwilling licensors—problems addressed by a patent pool).

\footnotesize{154}. See Neilsen & Samardzija, supra note 151, at 531 (indicating that expensive litigation or hold-ups (when a patent owner intentionally drives up the licensing fee because the patent is necessary to continue research already in progress) of a patent may stop companies from realizing certain royalty-generating developments).

\footnotesize{155}. General Counsel Interview, supra note 125; Stoddard Interview, supra note 82 (both indicating that licensing can become a troublesome legal undertaking and that unwilling licensors can make the process expensive and difficult).

\footnotesize{156}. See Mowzoon, supra note 93, at 1092 (noting that up to 40 patent licenses were required to develop a malaria vaccine and that broad genetic patents can burden future research by providing “unfairly high levels of compensation” to the patent holder simply because the research becomes dependent on a potentially nominal gene).

\footnotesize{157}. Id.
levels the negotiation playing field and limits the ability of a patent holder to extort large amounts of money in a hold-up situation, thus impeding the progress of research. While some patent owners that commanded large royalties in an open licensing system would receive reduced royalties, many necessary but financially undervalued patents would receive a higher royalty than otherwise available. In addition, some patent holders that did not previously have a market in which to license their invention may now become valuable players in a larger pool.

Commentators have criticized patent pools as a method for dealing with complex licensing issues or providing greater access to patented materials. The first criticism is that patent pools may serve as a shield for invalid patents. A biotechnology licensee could potentially end up paying royalties for the use of a genetic technology that does not deserve patent protection to begin with. When patent owners include a questionably valid patent in a pool it will likely be licensed in a multilicense agreement and it becomes less likely that someone will challenge the individual validity of that patent. Patent pool advocates claim that private and governmental entities could exercise oversight to eliminate this problem, including careful examination by independent experts of each patent entering the pool.

The second primary criticism is that patent pools can encourage anticompetitive behavior and violate antitrust laws. Critics argue that patent pools encourage “collusion and price fixing,” evils more readily avoidable with an open market valuation of individual patents. To address this concern, commentators suggest that courts apply a rule of reason to weigh the anticompetitive effects against the procompetitive benefits of a challenged patent pool. While the appropriate balance between the pros and cons is only likely to be decided through litigation, proponents argue that the treble damages associated with antitrust violations, combined with appropriate oversight, will dissuade the misuse of patent pools.

D. Recommendation Summary

While the first prong of this approach, standing alone, would be an improvement to the current Physician’s Immunity Statute, the second prong establishes a system that


159. Id.; see also Stoddard Interview, supra note 82 (explaining that the limited resources of many health care providers would make paying unnecessary licensing fees associated with a patent pool a financial burden for both hospitals and patients).

160. Mireles, supra note 158, at 221–22.

161. Id.

162. Id.

163. See id. at 223 (listing “price-fixing” and “anticompetitive exclusionary practices” as potential concerns and “advantages flowing from integrating complementary technologies” and lower litigation costs as benefits).

164. See Dragseth Interview, supra note 103 (noting that patent pools can involve costly attorneys’ fees during the initial development and the subsequent litigation over licensing agreements or patent validity).

165. See Mireles, supra note 158, at 222 (quoting Professor Carl Shapiro as he cautiously notes that “antitrust law can potentially play such a counterproductive role [in cooperative business arrangements], especially since antitrust jurisprudence starts with a hostility towards cooperation among horizontal rivals”).
provides a needed framework to a growing and unwieldy field. Certain biotechnology patent holders will undergo a painful process as they release their stranglehold on specific markets through retroactive legislation, but everyone benefits from a system that furthers research through increased access to information and appropriately compensates those that invest in that research. Health care providers and patients benefit from the diagnostic use of patented biotechnology, while patent owners maintain valuable exclusionary rights in genetic therapies and drugs. In addition, the retroactive nature of the recommendation treats all patent holders equally and frees the health care community from the cloud of potential infringement actions.

The patent pool proposal is responsive to interviewee suggestions relating to a regulated licensing system and also addresses the § 287(c) issue of rendering patents unenforceable. In a patent pool, every patent retains financial worth and an inventor receives compensation for disclosing his invention to the public. A patent owner may still seek enforcement of his patent rights through infringement actions, but the necessity of this action is greatly reduced because physicians, health care providers, and researchers have streamlined access to necessary biotechnology at a reasonable price.

V. Conclusion

The medical community voiced some valid concerns prior to the congressional adoption of § 287(c), but the statutory solution was riddled with flaws. In an attempt to deal with the relatively rare occurrence of physicians suing physicians over patented procedures, Congress adopted an approach that compromised the basic principles of the patent system while providing a solution both shortsighted and incomplete. Feedback from professionals in the medical, legal, insurance, and research fields supports this conclusion.

As biotechnology patents expand to cover more genes and gene-based treatment becomes the medical norm, Congress will have another opportunity to craft an appropriate solution that balances the needs of the patient with the rights of the patent owner. Congress can strike that balance by providing retroactive and prospective immunity to health care providers that use patented biotechnology for diagnostic purposes and by simultaneously creating a system of federally regulated patent pools that provide reasonable returns and incentives for investors and patent holders alike. While this approach requires a greater level of cooperation and a focus on the collective good, the fundamental principles of the patent system, nurtured by Jefferson in 1790, can coexist with the cutting-edge advances that so rapidly expand the health care frontier in the twenty-first century.