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A RECONSIDERATION OF THE PHYSICIANS' IMMUNITY STATUTE

The author assesses the "physicians' immunity statute" from legal policy, ethical, and financial perspectives, and concludes that alternatives such as licensure and monetary incentives would better serve the goal of encouraging invention more effectively by rewarding it.

INTRODUCTION

¶ 1 In a controversial case, a physician, Samuel Pallin, sued another physician, Jack Singer for infringing a patent that Pallin received for a single stitch cataract surgery technique.¹ Believing that such patents were inappropriate, Singer fought the lawsuit and moved for summary judgment declaring the patent invalid.² While the court denied Singer's summary judgment motion, the court did invalidate some of Pallin's patent claims at trial.³ Because Singer demonstrated to the court that Singer had performed the procedure one month before Pallin filed his patent application, the court partially invalidated Pallin's patent, and Pallin agreed not to enforce his remaining valid claims against Singer.⁴

¶ 2 In response to the Pallin case, Representative Greg Ganske and other physicians in Congress sought to limit the ability of a patentee to enforce his rights against a practicing physician. They supported their position by citing a patient's restricted access to care, the higher costs of health care caused by patent royalties, and the duty of physicians to share knowledge with others. They took the position that patents are unnecessary to advance medicine, and cited other countries' prohibitions on medical procedure patents.⁵ Although the initial attempt to protect practicing physicians was unsuccessful, Congress eventually chose to protect physicians and health care facilities from patent infringement liability if they performed a medical procedure on the human body that does not involve patented machines, patented matter, or valid biotechnology patents.⁶ This statute, more commonly known as the "physicians' immunity statute," states 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 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.⁷

¶ 3 The following paper examines the statute's implications from a legal, ethical, and health insurance perspective and suggests a possible alternative to the current regime.

LEGAL POLICY ANALYSIS

¶ 4 While the physicians' immunity statute laudably seeks to increase access to patient care at reduced cost, it conflicts with the policies underlying the patent system. The patent policy of creating incentives to invent supports eliminating physicians' immunity for three reasons. First, the elimination of all remedies for infringement destroys the incentive to invent. A physician-inventor invests human capital and financial capital to perform routine health care services. A physician often will notice problems or complications in the physician's field and may discover a new way to eliminate these complications through routine practice. Routine payments to physicians do not include a concurrent reward to improve the state of the art, and inventors who labor trying to solve a modest complication receive no compensation for their investments. Furthermore, many patented procedures require extensive clinical research that is left uncompensated by the physicians' immunity statute.⁸ For example, Surrogate Embryo Transfer (SET) technology required extensive clinical research to develop the technique for a patent. Procedures like SET require private investment that only will be obtained by offering the monopoly incentives protected by infringement remedies under the patent statute. While many medical procedures with low capital investment still may find their way to the market, high capital procedures require that protections afforded by infringement remedies for these procedural innovations be offered to patients.⁹

¶ 5 In addition to the need to recover invested capital, the physicians' immunity statute also differentiates the roles played by academic and commercial medicine by eliminating the incentives for innovation in the private sector. In academic medical research, scientists obtain funding through NIH grant applications, private donations, and technology transfers initiated under the Bayh-Dole Act.¹⁰ Successful academic medical researchers have a strong incentive to invent created by their dependence on outside funding while unsuccessful academic researchers will face difficulties funding their projects. The inherent funding structure in academic research partially alleviates the elimination of patent incentives caused by the physician immunity statute. On the other hand, private physicians, who constitute the vast majority of practicing physicians today, have no such incentives. They must rely on the commercial market to recover their investments, which is a questionable assumption under the current structure of the

American health care system. This distinction created between academic and commercial medicine prevents optimal use of the intellectual resources present in the medical community.

¶ 6 Although the physicians' immunity statute has limited the ability of doctors to enforce a medical procedure patent, they have continued to file for these patents for the reputational benefits associated with patent ownership. However, the enhanced reputational value created by patent ownership will not allow a patentee to recover his or her investment, lowering the incentive to invest in researching the new techniques in the first place. As such, unless the physicians' immunity statute is changed, society can expect fewer medical procedure innovations in the future as fewer physicians invest the time and money in research.

ETHICAL ANALYSIS

¶ 7 While the economic benefits of invention present the strongest arguments for patenting medical procedures, the strongest arguments against patenting medical procedures derive from the professional ethics of medicine. The American Medical Association ("AMA") requires a physician not to withhold information for financial gain.¹¹ The paradigm for a physician under the medical ethics code is one of a "teacher who imparts knowledge of skills and techniques to colleagues, and a student who constantly seeks to keep abreast of new medical knowledge."¹² However, the AMA's teacher-student paradigm is inconsistent with the realities of education because it ignores that financial incentives envelop the teacher-student relationship at all educational levels. Students pay teachers precisely because the teacher has invested high amounts of capital to obtain their knowledge, and as such, are compensated financially for their investment. Similarly, a physician-inventor could expect reasonable compensation for teaching others as long as he does not withhold his knowledge for personal gain. Similarly, student-physicians could expect to pay teacher-physicians for their expertise.

¶ 8 The AMA also argues that the physicians' immunity statute is necessary to avoid undesirable secrecy among the medical professionals.¹³ According to the AMA, if physicians can enforce their patents, they will be forced to keep their innovations secret. While secrecy is inherently associated with the patent system, this argument overlooks the intrinsic procedures of the patent system to encourage public disclosure. For example, to obtain a patent, the applicant must disclose a written description detailing to one of skill in the art how to make and use the invention. In addition, the patent system has a one-year grace period to file an application that allows the applicant to disclose publicly the invention and still obtain a patent.¹⁴ As such, information in the American patent system reaches the public as soon as the technique has been

perfected.

¶ 9 The AMA has another valid ethical concern supporting the physicians' immunity statute: restricted access to patient care. If physicians must pay heavy licensing fees, they will face an ethical conflict between their financial interests and the best interest of the patient.¹⁵ Physicians may be deterred by the threat of liability every time they seek to modify or use patented procedures.¹⁶ The patentee also may unreasonably limit the number of licensees or charge unreasonable royalties that may make access to a lifesaving medical procedure unavailable from a practical standpoint.¹⁷

HEALTH CARE FINANCING ANALYSIS

¶ 10 In the United States, health care is financed through three mechanisms: private insurance, government insurance, and self-insurance. Private insurance companies, such as Blue Cross/Blue Shield, offer a variety of insurance policies such as managed care or fee-for service.¹⁸ Private insurance is most commonly provided by a person's employer although individual plans are also available.¹⁹ These plans may provide a limited network of approved providers to consumers.²⁰ Government insurance comes from two publicly funded programs for select populations, Medicare and Medicaid, which generally cover the elderly and the poor respectively.²¹ Over 42 million Americans do not qualify for government insurance or receive private insurance from their employers, and they collectively form the self-insured population.²²

¶ 11 The financial burden of paying patent royalties presents perhaps the strongest objection to allowing recovery of patent royalties for infringing medical procedure patents. Since both private insurance and government insurance have capped the amount that they will spend for medical procedures, any extra royalty payment is likely to be passed onto consumers through higher premiums. Such an increase in rates will likely adversely affect enrollment or benefits because people will be unable to afford the higher costs. Moreover, insurance companies may deny coverage of patented procedures until the patent's term expires, forcing doctors to use less innovative techniques or absorb the royalty costs themselves. Finally, insurers may choose to force the provider to bear the cost by maintaining payments under the contract. The provider again will have a financial incentive to use less innovative techniques.

¶ 12 In addition to the financial burden presented by patent royalties, the distribution of patent royalties also presents an objection to eliminating physicians' immunity. Allowing patent royalties and infringement liability would harm those Americans who are self-insured because

they are unprotected from high medical costs by insurance price ceilings. Any patent royalty would fall directly on the self-insured, an outcome that is inconsistent with medical public policy requiring medical access to all.

¶ 13 On the other hand, the restricted consumer choice currently presented by health insurance companies supports the elimination of the physicians' immunity statute. The limited network of physicians that a patient under private insurance can choose inherently denies the medical procedure patentee the benefit of his patent. If an inventor makes a better widget, he will be able to market his improvements to the public, and once the public recognizes this improvement, the patentee will be able to receive monopoly profits under his invention. However, in the current system, a medical invention patentee is not guaranteed to receive higher profits because consumers are not able to select the better procedure or physician. Consumers are limited to the providers covered by their insurance contract, and a doctor must rely on his reputation to receive referrals. While some consumers will request referral to the patentee, insurance plans will force other consumers to seek treatment from physicians who are either not licensed to practice the patent or unskilled in the new procedure. The restriction by insurance companies of patients' ability to choose the patentee as their physician decreases the incentive for the physician to invent under the patent system.

POTENTIAL REFORM TO PHYSICIAN IMMUNITY

¶ 14 As demonstrated above, the legal, ethical, and insurance arguments supporting the physicians' immunity statute are mixed at best because the system fails to recognize the necessity of allowing physicians to recover the investment they made in researching the innovation. A better solution would be to allow a medical procedure patentee to recover his or her investment by licensing the technology. Just as Congress created a zero dollar price tag for infringement of a medical procedure patent under section 287(c)(1), Congress should have a similar power to provide a limited remedy that does not preclude preserving patent incentives to invent. If the physician refused to license a technology, Congress could create a nominal damages provision allowing other physicians to use the procedure by paying small, nominal damages.

¶ 15 Such a threat of nominal damages will not encourage significant litigation, should encourage reasonable licensing agreements, and should offer a modest return on investment for a procedure to the patentee. For an invention derived from everyday medical experience, a nominal damages provision would preserve a small incentive to invent that should be the reward

for proper invention.

¶ 16 However, imposing nominal damages does not solve the larger question of whether society should allow expensive procedures, such as SET, to obtain full patent protection to raise capital or encourage private investment in research. A nominal damages provision will not accomplish this goal even in the aggregate with large numbers of infringement actions or low priced licenses. Several commentators have proposed a full patent damages provision for high capital inventions that require investment for research, development, and regulatory costs.²³ While this type of provision encourages investment, the financing mechanisms and cost control techniques of insurance companies will decrease access to these techniques for most patients and further increase the burden on the self-insured population. A remedy for the problems presented by these capital-intensive medical procedures comes down to a pure policy choice between access and increasing innovation.

¶ 17 As a practical concern, removal of the physicians' immunity statute opens a potential floodgate for litigation. Physicians may choose to enforce their patent rights vigorously and try to use the patent to seek expensive licenses if full royalty remedies are restored. However, the Pallin case teaches would-be claimants to act at their own peril because a medical procedure patent may be invalidated through proper evidence.²⁴ Proving infringement liability for procedural patents is extremely difficult.²⁵ Increased opportunities for litigation also may encourage physicians to license their patent rights to large insurance companies who are better equipped to engage in expensive litigation. This could drastically alter the current insurance financing schemes and significantly decrease access to care. Any changes made to the physician immunity statute must be carefully designed, and the need to encourage investment in medical procedures may better be met by increased funding.²⁶

CONCLUSION

¶ 18 The physicians' immunity statute responded to a public concern over the Pallin case but may have been a hasty reaction to the problem. It became effective over the protest of several prominent senators who objected to hasty passage of the legislation.²⁷ It protects the ethical concerns highlighted by health care professionals by protecting access to care and physician autonomy. However, the statute places severe constraints on the ability to invent by undervaluing human capital and private investment in medical research. The statute also protects all insured parties from royalty costs and helps to alleviate the burden of the self-insured. While these considerations are important, reconsideration of the elimination of

monetary incentives for research should be considered to protect the Constitutional foundation of the patent system to promote science and the useful arts.^{[28](#)}

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Footnotes

[1.](#) Pallin v. Singer, 1995 U.S. Dist. LEXIS 20824, at **8, 36 U.S.P.Q.2d 1050 (D.Vt. 1995).

[2.](#) Id. at **8.

[3.](#) Id.

[4.](#) Pallin v. Singer, 1996 WL 274407 (D.Vt. 1996); Seth Shulman, Cashing In on Medical Knowledge, Technology Review 38, 43 (March, April 1998).

[5.](#) 142 Cong. Rec. at H8277.

[6.](#) 35 U.S.C. §287(c)(1) (West 2001).

[7.](#) Id. §287(c)(1).

[8.](#) Beata Gocyk-Farber, Note, Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics, 18 Cardozo L. Rev. 1527, 1551 (1997).

[9.](#) Id. at 1554.

[10.](#) Tamsen Valoir, Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-In Rights Controversy, 8 Tex. Intell. Prop. L.J. 211, 232 (2000) (discussing the Bayh-Dole Act's success).

[11.](#) AMA Council on Judicial and Ethical Affairs, Ethical Issues in the Patenting of Medical Procedures, 53 Food & Drug L.J. 341, 343 (1998).

[12.](#) Id.

[13.](#) Eric M. Lee, 35 U.S.C. §287(c)--The Physician Immunity Statute, 79 J. Pat. & Trademark Off. Soc'y 701, 711 (1997).

[14.](#) Id.

[15.](#) AMA Council, supra note 12, at 345.

[16.](#) Id.

[17.](#) Gocyk-Farber, supra note 9, at 1545.

[18.](#) Douglas A. Hastings et al, Fundamentals of Health Law, 245-249 (1995).

[19.](#) Id. at 254.

[20.](#) Id. at 245-249.

[21.](#) Id. at 193, 234.

[22.](#) Health Care Statistics (visited 4/6/01) . (Based on most recent figures from 1999 for Americans under 65 who self-insure.

[23.](#) Linda Rabin Judge, Issues Surrounding the Patenting of Medical Procedures, 13 Santa Clara Computer & High Tech. L.J. 181, 212 (1997).

[24.](#) Shulman, supra note 4, 43.

[25.](#) Chris J. Katopis, Patients v. Patents: Policy Implications of Recent Patent Legislation, 71 St. John's L. Rev. 329, 355 (1997).

[26.](#) Gocyk-Farber, supra note 9, at 1557.

[27.](#) Katopis, supra note 26, at 337.

[28.](#) U.S. Const. art. I §8, cl. 8.