

NELCO
NELCO Legal Scholarship Repository

New York University Law and Economics Working
Papers

New York University School of Law

12-2014

LEGAL BUT UNACCEPTABLE: PALLIN V. SINGER AND PHYSICIAN PATENTING NORMS

Katherine J. Strandburg
NYU School of Law, strandburg@exchange.law.nyu.edu

Follow this and additional works at: https://lsr.nellco.org/nyu_lewp

Part of the [Health Law and Policy Commons](#), [Intellectual Property Law Commons](#), and the [Law and Society Commons](#)

Recommended Citation

Strandburg, Katherine J., "LEGAL BUT UNACCEPTABLE: PALLIN V. SINGER AND PHYSICIAN PATENTING NORMS" (2014). *New York University Law and Economics Working Papers*. 402.
https://lsr.nellco.org/nyu_lewp/402

This Article is brought to you for free and open access by the New York University School of Law at NELCO Legal Scholarship Repository. It has been accepted for inclusion in New York University Law and Economics Working Papers by an authorized administrator of NELCO Legal Scholarship Repository. For more information, please contact tracy.thompson@nellco.org.

**LEGAL BUT UNACCEPTABLE:
PALLIN V. SINGER
AND PHYSICIAN PATENTING NORMS**

Katherine J. Strandburg*

In intellectual property discourse, the edge tends to be defined by disputes between producers and consumers or between upstream and downstream innovators. This Chapter tells a different kind of story, about the edge between the patent-based innovation system and a user innovator community governed by norms of reputation and sharing.¹ In this story, the user innovator community is the medical profession.

In the mid-1990s, at the height of a period of expansive patent rights, Dr. Samuel Pallin patented an improvement to cataract surgery procedure and sought to license it to other eye surgeons in return for royalty payments. One of those eye surgeons was Dr. Jack Singer. Singer responded to the royalty demand not only by refusing to pay it, but by spearheading what eventually became a political movement against medical procedure patents. Beginning in 1994, physicians lobbied Congress to redraw the line around patentable subject matter so as to exclude medical procedures. Though they did not achieve that objective, they succeeded in convincing Congress to pass 35 U.S.C. § 287(c) in 1997. § 287(c) eliminates remedies against physicians for infringement of many medical procedure patent claims.

Though physician inventors routinely patent medical devices, opposition to patents on medical procedures and medical diagnostic methods holds strong. This Chapter examines that opposition through the lens of user innovation.² User innovators invent and improve technologies for their own use, rather than to license or sell them to others. Examples of user innovations include

* Alfred B. Engelberg Professor of Law, New York University Law School. Note that the Author served as counsel for amici medical associations in briefing in the case of *Mayo Collaborative Servs. v. Prometheus Labs.*, 566 U.S. ___ (2012). The analysis described in this Article is this Author's alone and does not purport to represent the views of those clients. This Chapter reflects the truly excellent research assistance of Zachary King, Elizabeth Kimmel, and Chris Han. The generous support of the Filomen D. Agostino and Max E. Greenberg Research Fund is also gratefully acknowledged. The final edited version of this chapter appears in *INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP* (R. Dreyfuss and J. Ginsburg, eds.) (Cambridge University Press 2014), <http://www.cambridge.org/us/academic/subjects/law/intellectual-property/intellectual-property-edge-contested-contours-ip>.

¹ See, e.g. ERIC VON HIPPEL, *DEMOCRATIZING INNOVATION* (2005); E. von Hippel and G. von Krogh, Open source software and the "private-collective" innovation model: Issues for organization science, 14 *ORG. SCI.* 208 (2003); Katherine J. Strandburg, *User Innovator Community Norms at the Boundary Between Academic and Industrial Research*, 77 *FORDHAM L. REV.* 2237 (2009); Katherine J. Strandburg, *Norms and the Sharing of Research Materials and Tacit Knowledge* in *WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY*, Rochelle C. Dreyfuss, Harry First, and Diane L. Zimmerman, eds. (2010)

² Elsewhere, I undertake a more detailed exploration of these issues. Katherine J. Strandburg, *Physicians and Patents: A Tale of Two Innovation Systems* (work in progress).

improved manufacturing processes, certain types of software, sports equipment, scientific research tools, and many business methods and service improvements.³ User innovation succeeds because it depends on users' superior, and "sticky," knowledge of unmet needs and the ways that technologies perform on the ground.⁴ Because of their shared interests, users of a particular type of technology often form communities in which the norm is to share information about problems with current technology, suggestions for improvements, innovations they have made, and critiques of those innovations.⁵ Patenting is generally eschewed by these communities and innovation is rewarded with reputation. Physicians who devise new medical procedures, diagnostic tests, medical devices, surgical instruments and the like are also user innovators.⁶ This Chapter views the story of *Pallin v. Singer* and the physician movement that led to the passage § 287(c) as a narrative of user innovator community norms.

I. Setting the Stage

During the nineteenth and early twentieth centuries, the medical profession and the patent office agreed that medical procedures should not be patented. The American Medical

³ See, e.g., VON HIPPEL, DEMOCRATIZING INNOVATION; K. R. Lakhani and B. Wolf, *Why Hackers Do What They Do: Understanding Motivation and Effort in Free/Open Source Software Projects*, in PERSPECTIVES ON FREE AND OPEN SOURCE SOFTWARE (J. Feller et al., eds. 2005) at 3; C. Lüthje et al., *User-Innovators and "Local" Information: The Case of Mountain Biking*, 34 RES. POL'Y 951 (2005); *Id.* at 8; see Sonali K. Shah, *From Innovation to Firm Formation in the Windsurfing, Skateboarding, and Snowboarding Industries* in *Proc. Sixth Ann. Mtg. Int'l Sports Engineering Ass'n* (2006), available at http://link.springer.com/chapter/10.1007%2F978-0-387-45951-6_6#page-1; Sonali Shah, *Open Beyond Software* in OPEN SOURCES 2.0, Chris Dibona et al., eds. (2005) at 339; Katherine J. Strandburg, *What If There Were a Business Method Use Exemption to Patent Infringement?*, 2008 MICH. ST. L. REV. 245.

⁴ See, e.g., VON HIPPEL, DEMOCRATIZING INNOVATION at 8; Susumu Ogawa, *Does Sticky Information Affect The Locus of Innovation? Evidence from the Japanese Convenience-Store Industry*, 26 RES. POL'Y 777 (1998).

⁵ See, e.g., N. Franke and S. Shah, *How Communities Support Innovative Activities: An Exploration of Assistance and Sharing among End-Users*, 32 RES. POL'Y 157 (2003); D. Harhoff et al., *Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing their Innovations*, 32 RES. POL'Y 1753 (2003); L. Janzik et al., *Motivation in Innovative Online Communities: Why Join, Why Innovate, Why Share?*, 15 INT'L J. INNOVATION MGMT. 797 (2011); C. Raasch et al., *The Dynamics of User Innovation: Drivers and Impediments of Innovation Activities*, 12 Int'l J. Innovation Mgmt. 377 (2008); W. Riggs and E. von Hippel, *Incentives to Innovate and the Sources of Innovation: The Case of Scientific Instruments*, 23 RES. POL'Y 459 (1994); Karim Lakhani and Eric von Hippel, *How Open Source Software Works: 'Free' User-to-User Assistance?*, 32 RES. POL'Y 923 (2003).

⁶ See, e.g., Aaron K. Chatterji et al., *Physician-Industry Cooperation in the Medical Device Industry*, 27 HEALTH AFF. 1532, 1533 (2008) ("Physicians may contribute directly to the innovation process by inventing medical devices themselves. This kind of 'user innovation' has been documented in diverse settings . . ."); Eric Von Hippel, *The Dominant Role of Users in the Scientific Instrument Innovation Process*, 5 RES POL'Y 212, 231 (1976) (suggesting that user innovation is responsible for "medical and dental innovations (e.g. new dental equipment is usually invented, first used and perhaps discussed in journals by dentists prior to commercial manufacture being undertaken by a dental equipment firm)"); Harold J. Demonaco et al., *The Major Role of Clinicians in the Discovery of Off-label Drug Therapies*, 26 PHARMACOTHERAPY 323 (2006); Sheryl Winston-Smith and Sonali Shah, *Do Innovative Users Generate More Useful Insights? An Analysis of Corporate Venture Capital Investments in the Medical Device Industry*, 7 Strategic Entrepreneurship J. 151 (2013); Sheryl Winston-Smith and Andrew Sfekas, *How Much do Physician Entrepreneurs Contribute to New Medical Devices?* (working paper), available at <http://www.ncbi.nlm.nih.gov/pubmed/23358387>.

Association's first Code of Ethics, adopted in 1847, deemed it "derogatory to professional character" for a physician to hold a patent.⁷ The absolute ban on patenting was softened only slightly in 1940, when it was revised to state that it was "unprofessional to receive remuneration from patents or copyrights on surgical instruments, appliances, medicines, foods, methods or procedures."⁸ Only in 1955 was the ethical principle revised to permit physicians to patent "surgical instruments, appliances, and medicines" as long as the receipt of remuneration did not "retard[] or inhibit[] research or restrict[] the benefits derivable therefrom."⁹ The ban on patenting medical procedures remained in place, though physicians were permitted to obtain copyrights associated with them.¹⁰ In 1957, the AMA overhauled and shortened its Principles of Ethics, removing explicit reference to patenting. The 1955 approach to patenting was, however, incorporated by reference as part of a compilation of sections said to be "included within the spirit and intent of the language of the 1957 edition."¹¹ A later ethical opinion adopted sometime before 1977 took an even more positive view of patents on medical instruments: "A physician may patent a surgical or diagnostic instrument he or she has discovered or developed. The laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery."¹² There was no such evolution in the AMA's opinions on medical procedures, however. Instead, a 1984 ethics opinion emphasized that, like medical knowledge, skills and techniques were not to be withheld from the community for reasons of personal gain.¹³

Until the middle of the twentieth century, the few judicial and patent office opinions involving medical procedure patents were in line with the medical profession's view. In 1862 the court in *Morton v. New York Eye Infirmary*,¹⁴ a case still cited for its discussion of the patentability of natural phenomena, invalidated a patent on the use of ether for anesthesia. In 1883, *Ex Parte Brinkerhoff* denied a patent on the grounds that "[t]he methods or modes of treatment of physicians of certain diseases are not patentable."¹⁵ As late as 1951, a district court opinion in

⁷ AM. MED. ASS'N, CODE OF MEDICAL ETHICS § 4 (1847).

⁸ *Organizational Section Proceedings of the New York Session*, 114 JAMA 2557, 2567 (1940), available at http://jama.jamanetwork.com/data/Journals/JAMA/7654/jama_114_26_014.pdf.

⁹ American Medical Association, *Report of Council on Constitution and Bylaws*, 1955 PROC. AM. MED. ASS'N CLINICAL MEETING 111, available at <http://www.ama-assn.org/ama/pub/about-ama/our-history/ama-historical-archives/the-digital-collection-historical-ama-documents.page>

¹⁰ *Id.*

¹¹ AM. MED. ASS'N, PRINCIPLES OF MEDICAL ETHICS 1957 (1958), available at http://www.ama-assn.org/resources/doc/ethics/1957_principles.pdf.

¹² COUNCIL ON ETHICS & JUDICIAL AFFAIRS, AM. MED. ASS'N, *Opinions on Professional Rights and Responsibilities*, in CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS 136, 150 (1996-1997 ed. 1996).

¹³ AMA CODE OF MEDICAL ETHICS, OPINION 9.08, *New Medical Procedures* (1984, 1994), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion908.page> (last visited Oct. 8, 2012).

¹⁴ *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862)

¹⁵ 24 Dec. Comm'r 349 (1883), reprinted in *New Decisions*, 27 J. PAT. & TRADEMARK OFF. SOC'Y 793, 798 (1945).

Martin v. Wyeth Inc. noted that “[i]nstances of valid patents for a method of medical or surgical treatment have been rare indeed, although a few cases may be found in which therapeutic agents, such as aspirin, have been held patentable.”¹⁶ In 1954, however, the patent office in *Ex Parte Scherer* expressly overruled *Brinkerhoff*, allowing a claim to a method of “injecting fluids into the human body” by a pressure jet.¹⁷ From that point on, medical procedure patents were available in principle, though they seem to have been rare (or at least not salient to physicians) during the next few decades.¹⁸

The seeds of controversy over medical procedure patents began to be sown in the 1980s. At that time, optimism about the potential for patents to facilitate medical advances, particularly through the newly emerging field of biotechnology, was high. The Bayh-Dole Act¹⁹ reflected an assumption that patents would facilitate the commercialization of the neglected fruits of academic research, particularly in the biomedical sciences. The Supreme Court’s approval of the patenting of living organisms in *Diamond v. Chakrabarty*²⁰ gave the green light to biotechnology patenting. The Federal Circuit Court of Appeals was established in 1982, centralizing patent appeals in a single forum, largely because of Congress’s sense that courts were unfriendly to patenting.²¹ The pro-patent mood continued throughout the 1990s when, for example, the 1994 WTO-based TRIPS Agreement established robust minimum requirements for intellectual property protection internationally²² and the Federal Circuit expanded patentable subject matter to the point that any method producing a “useful, concrete, and tangible” result was deemed patentable.²³

II. The Story of *Pallin v. Singer*

Given the generally pro-patent mood of the time and the fact that medical device patenting by physicians had become commonplace, it is perhaps unsurprising that in 1990, when our story begins, Dr. Samuel Pallin was tempted to catch the wave by patenting an improvement in cataract surgery technique. His attempt to enforce that patent against Dr. Jack Singer unleashed the storm of physician opposition to medical procedure patents that led Congress to enact § 287(c).²⁴

¹⁶ 96 F. Supp. 689, 694-95 (D. Md. 1951), *aff’d*, 193 F.2d 58 (4th Cir. 1951).

¹⁷ *Ex Parte Scherer*, 103 U.S.P.Q. (BNA) 107 (B.P.A.I July 23, 1954).

¹⁸ See, e.g., *AMA Speaks out on Managed Care*, UPI, June 14, 1994 (AMA general counsel states that “methods patents” are a new phenomenon in medicine).

¹⁹ P.L. 96-517, Patent and Trademark Act Amendments of 1980, codified at 35 U.S.C. § 200-212.

²⁰ 447 U.S. 303 (1980).

²¹ See, e.g., S. REP. NO. 97-275, at 2, 5-6 (1981).

²² AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (1994), available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

²³ *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373-75 (Fed. Cir. 1998)

²⁴ There had been some controversy about method patents brewing by the time Pallin filed his patent application, but it was concentrated in the reproductive technology arena. See e.g., U.S. Patent No. 4,009,260 (1977) (method for sex selection); U.S. Patent No. 4,339,434 (1982) (same); U.S. Patent No. 4,874,693 (1989) (method for prenatal

A. Sutureless Cataract Surgery

Human beings have suffered from, and treated, cataracts (opacity of the optic lens) for millennia.²⁵ Treatment methods have involved breaking up the clouded lens, pushing it away from the line of vision (“couching”) and removing the lens entirely. During the early twentieth century, lens removal methods improved greatly, yet removal left patients with better, but still poor vision. In the 1940s, physician Harold Ridley revolutionized treatment by developing the intraocular lens – an artificial replacement lens permanently implanted in the eye. When improved removal methods permitted smaller incisions, flexible lenses, which could be folded for insertion, were developed.

Surgeons also sought to minimize trauma to their patients’ eyes by improving their incision techniques. By 1989, cutting-edge surgeons used a “scleral tunnel” technique. The lens of the eye sits behind an outer layer consisting of three parts: the sclera, or “white” of the eye; the cornea, or outer lens; and the limbus, a ring of tissue connecting the cornea and sclera. An “anterior chamber” lies between the cornea and inner lens. In the scleral tunnel technique, the surgeon would make an incision partway through the sclera at some distance from the cornea, “tunnel” through the sclera to reach the anterior chamber, remove the defective natural lens and insert the artificial replacement through the tunnel, and suture the wound. Sutures were problematic, however, because they could induce astigmatism as the wound healed. In the late 1980s, Dr. John Shepherd introduced a technique for closing the wound with a single, loose stitch, thus avoiding some of the problems previously caused by suturing. Some, including the well-known Florida ophthalmologist James Gills, began to suggest the possibility of sutureless surgery.²⁶

On March 1, 1990, the trade journal *Ocular Surgery News* (OSN) reported sutureless cataract surgery by Dr. Michael McFarland, an Arizona ophthalmologist.²⁷ OSN was the typical forum for early reporting of new surgical techniques. As Dr. Howard Fine later explained in deposition testimony, OSN is “part of the medical press rather than a peer-review journal, but it has become the single most important source of new technology for ophthalmologists in the world today because it is accurate, it is timely, and it allows information out years before it would become available in peer-review journals.”²⁸ McFarland had performed his first sutureless surgery in

testing for Down syndrome); U.S. Patent No. 4,127,118 (1978) (method for enhancing an erection); U.S. Patent No. 4,816,257 (1989) (surrogate embryo transfer); U.S. Patent No. 4,986,274 (1991) (method for determining fetal gender).

²⁵ See Thomas V. DiBacco, *The Long View of Cataract Surgery*, WASH. POST, July 11, 1995, at F9.

²⁶ Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff’s Opposition to Defendants’ Motion for Summary Judgment at ¶ 14. Note that all court documents cited in this Chapter are found in the record of *Pallin v. Singer*, No. 2:93-cv-202 (D. Vt. Mar. 28, 1996).

²⁷ *Surgeon Undertakes Phaco, Foldable IOL Series Sans Sutures*, OCULAR SURGERY NEWS, Mar. 1, 1990, at 1.

²⁸ Deposition of I. Howard Fine, M.D. at 40.

January 1990. By the time the OSN report went to press, he had performed 25 more sutureless procedures. Shortly after his initial success, McFarland phoned Dr. Paul Ernest, a clinical professor of medicine at Wayne State University, to discuss his procedure. Ernest replicated McFarland's technique in February 1990, then adapted it by extending the scleral tunnel a small distance through the limbus into the cornea before it emerged into the anterior chamber. Ernest believed that such a "corneal lip" was critical to safe sutureless surgery.

At around the same time, Dr. Steven Siepser, a Pennsylvania ophthalmologist, developed his own sutureless technique, which he reported at the March 1990 meeting of the American Society of Cataract and Refractive Surgery (ASCRS). At its meetings, the ASCRS holds "film festivals," at which videos of eye surgeries are screened. Siepser's film of his sutureless surgery received an award.

Siepser's film and OSN's report of McFarland's technique generated both excitement and skepticism among cataract surgeons, inspiring many efforts to replicate and improve upon their techniques. At least three of those so inspired, James Gills, Samuel Pallin, and Jack Singer, believed that the shape of the initial incision might be important for safe sealing of the wound. All three developed similarly-shaped incisions. As a result, all three played important roles in the *Pallin v. Singer* lawsuit – Pallin as patentee, Singer as accused infringer, and Gills as creator of the most significant prior art.

Gills, who had specialized almost exclusively in cataract surgery for nearly twenty years, described his proposed incision shape, which he first tested on March 19, 1990, as an "inverted V."²⁹ He published a photo of the healed wound from that surgery in his August 1990 monograph, *SMALL-INCISION CATARACT SURGERY*.³⁰

Singer first tried what he called a "frown incision" on March 20, 1990.³¹ Singer, who was particularly noted for his films, published a videotape of that surgery in the *Audiovisual Journal of Cataract and Implant Surgery*.³² Singer's surgery was not sutureless; he used Shepherd's single suture technique. Singer began performing sutureless surgeries in February 1991, adopting Ernest's corneal lip seal in conjunction with his frown incision.³³

B. Dr. Samuel Pallin's Chevron Incision Patent

²⁹ Declaration of James P. Gills, M.D. at ¶ 7; Deposition of Dr. James P. Gills at 9.

³⁰ James P. Gills, *Sutureless Cataract Surgery: From 3 to 3.5mm Incision with Foldable Lens to 6mm Incision with Phacoemulsification and Standard PMMA Lens*, in *Small-Incision Cataract Surgery* (James P. Gills and Donald R. Sanders, eds.) (Slack, Inc. 1990 USA) at p. 129.

³¹ Declaration of Jack A. Singer, M.D. in Support of Motion for Summary Judgment of Invalidity at ¶ 8.

³² This appeared in the third issue of the journal's sixth volume in 1990. *Id.* at ¶ 9.

³³ *Id.* at ¶ 18.

Pallin developed his method, later patented as “Method of Making Self-Sealing Episcleral Incision”³⁴ after he saw the McFarland and Siepser reports, in an attempt to devise an incision that would permit the sutureless insertion of a hard, rather than folding, intraocular lens. Because Pallin found McFarland’s and Siepser’s techniques unworkable for hard lenses, he conceived the idea of a “chevron” incision on April 16, 1990. He performed his first sutureless chevron incision surgery the next day. The obese diabetic patient suffered congestive heart failure during the surgery and had to be hospitalized, giving Pallin “no opportunity to place sutures.” When the patient returned a week later “the wound had self-sealed.”³⁵

Having successfully performed sutureless cataract surgery, Pallin immediately sought to publish his results. His April 1990 submission to the peer-reviewed Journal of Cataract and Refractive Surgery (JCRS) was rejected in July 1990.³⁶ Pallin’s work was, however, reported by OSN on August 15, 1990³⁷ and described in detail in a Letter to the Editor published in JCRS in November 1990.³⁸ In April 1991 Pallin presented a paper and film entitled “Chevron Sutureless Closure for Rigid Lenses: A Preliminary Report” at an ASCRS symposium.³⁹ He eventually published a report of much extensive work (700 surgeries)⁴⁰ in JCRS as part of an October 1991 special volume devoted to sutureless cataract surgery, which included articles by Pallin, Siepser, Gills, Ernest, Singer, and at least thirteen others.⁴¹

While pursuing publication, Pallin also took the unusual step of applying for a patent. By April 29, 1990, he had obtained patent counsel.⁴² His attorney filed an application on June 28, 1990, and Pallin’s patent was issued on January 14, 1992.⁴³ Claims 1 and 7 are representative:

1. A method of making a substantially self-sealing episcleral incision comprising; providing incision making means; making an incision in the sclera with said means; and said incision having an appropriate central point 1.5 to 3.0 millimeters posterior to the limbus

³⁴ U.S. Patent No. 5,080,111 (1992).

³⁵ Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment at ¶¶ 18-21.

³⁶ Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment at ¶ 27.

³⁷ See Deposition of Samuel L. Pallin, M.D. Volume II at 210-212.

³⁸ S. L. Pallin, *Chevron Incision For Cataract Surgery*, 16 J. CATARACT REFRACT. SURG. 779 (Nov. 1990).

³⁹ Curriculum Vitae Samuel Lear Pallin, M.D., F.A.C.S. at 5, Entry No. 42, App. D, Exhibit 1.

⁴⁰ Samuel L. Pallin, *Chevron Sutureless Closure: A Preliminary Report*, 17S J. CATARACT & REFRACTIVE SURGERY 706, 707 (1991).

⁴¹ *Small Incision Surgery: Wound Construction and Closure*, 17S J. CATARACT & REFRACTIVE SURGERY 659 (1991).

⁴² Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment at ¶ 26.

⁴³ U.S. Patent No. 5,080,111 (filed June 28, 1990).

wherein portions of said incision extend away from said approximate central point and extend laterally away from the curvature of said limbus.

7. The method of claim 1 further including making an incision having a curvilinear configuration.

Though there was, as we have seen, no lack of relevant professional literature about cataract surgery, the patent examiner considered only seven prior art references, each of which was a patent directed to a *device* for ophthalmic surgery

C. Pallin Seeks Royalties and Singer Resists

On June 4, 1993, Pallin's attorneys sent a cease and desist letter to Singer and the Hitchcock Associates clinic where he practiced, alleging that Singer's frown incision technique infringed Pallin's patent. (The clinic is associated with Dartmouth Medical College, where Singer was a clinical professor.) The letter offered Singer a license in return for what it termed a "reasonable royalty" and Singer's agreement to reference the patent when promoting the frown incision technique.⁴⁴ A month later, after Pallin and Singer failed to come to terms, Pallin sued Singer and the Hitchcock Clinic for patent infringement. Settlement negotiations ensued, during which, according to Singer, a "graduated royalty of \$2,500 - \$10,000 per year, which can be increased annually at Dr. Pallin's discretion" was proposed.⁴⁵ No settlement was reached during the fall of 1993.

Following the failure of the initial settlement negotiations, Singer made an unanticipated move. He decided to use the lawsuit as a vehicle for fighting what he believed was a dangerous trend toward medical procedure patenting. In February 1994, he sent a mass mailing to fellow ophthalmologists soliciting contributions to a litigation defense fund:

The Clinic and Dr. Singer are vigorously defending this action. We see no merit in the specific allegations, nor do we agree with the underlying premises of Dr. Pallin's suit, i.e., that surgeons can or should patent the shape of incisions, or that giving reports on your own surgical experiences at professional meetings can constitute inducement of infringement. We believe that such patenting and such interpretation of what constitutes infringement is inconsistent with the applicable code of professional conduct and the advancement of medical science through the free and open exchange of ideas.⁴⁶

⁴⁴ Complaint at ¶ 15, Letter from John M. White to Jack L. Singer, Entry No. 1, Exhibit B.

⁴⁵ Singer 2/17/94 Letter to Fellow Ophthalmologists, at 1, Entry No. 24, Ex. B.

⁴⁶ Letter from Jack A. Singer and John C. Collins at 1, Entry No. 24, Exhibit B.

A similar letter to the editor was published in OSN on April 1, 1994.⁴⁷

Recall that, by this time, the AMA no longer had a specific ethical prohibition against medical procedure patenting on the books, though the longstanding prohibition incorporated by reference into the Principles of Medical Ethics in 1957 had never been challenged. The historical trend was toward greater acceptance of physician patenting, as reflected in the rosy view that “laws governing patents are based on the sound doctrine that one is entitled to protect one’s discovery” expressed in the AMA ethics opinion on device patenting. In light of the generally pro-patent mood of the times, physician acquiescence in medical procedure patenting might have seemed an inevitable next step. Instead, Singer’s call for support galvanized the medical community and catalyzed the political movement against medical procedure patenting that resulted in 35 U.S.C. § 287(c).

In April 1994 Singer received a standing ovation after giving an impassioned speech entitled “Free Exchange of Surgical Knowledge” at a meeting of the American Society of Ocular Surgeons (ASOS).⁴⁸ One of Pallin’s attorneys, who had attended the speech, immediately sent Singer a settlement offer that was considerably more conciliatory than earlier offers.⁴⁹ “[R]ecognizing Dr. Singer’s contributions in promoting the incision and its benefits,” it proposed a “single one time payment of \$5,000” and had “no objections to Dr. Singer continuing to promote the frown incision in whatever way he likes.” Noting that Singer’s speech made clear that his “fundamental objection is not to the Pallin patent alone, but to the present availability of method patents on surgical techniques,” the letter argued that, while Singer had a right to work for legal reform, he had “unearthed no proof of invalidity [of Pallin’s claims] sufficient to overcome the presumption of validity.”

Unappeased, Singer pressed Pallin to disclaim his patent and to agree not to enforce it against other ophthalmologists. The response of Pallin’s attorney nicely illustrates the culture clash between the patent system’s emphasis on individual entitlements and the medical profession’s community-based approach to disseminating and rewarding procedure innovation:

What we do with the patent in the future with respect to others who are not defendants in this law suit is our business and has no proper part in any settlement. However, there is no reason to disclaim the patent and we will not do so. The patent is valid and infringed and you have provided no evidence to the contrary.⁵⁰

⁴⁷ Jack A. Singer & John C. Collins, Letter to the Editor, *Defense Fund*, OCULAR SURGERY NEWS, Apr. 1, 1994, at 4.

⁴⁸ Physicians [sic] Program at 52, Entry No. 24, Exhibit J; *Doctor Implores Principles of Hippocrates to Standing Ovation*, OPHTHALMOLOGY TIMES, May 1, 1994, at 28.

⁴⁹ Letters from James R. Longacre to George Neuner, Entry No. 24, Exhibit N.

⁵⁰ *Id.* at 3.

Pallin's attorneys seem to have felt that Singer's appeals for support from the physician community, like his attempts to negotiate relief for the entire community, were inappropriate. They moved to compel discovery about those activities, arguing that "[t]he defendants' public allegations of invalidity and unenforceability and activities to organize a national movement against Dr. Pallin are areas in which the plaintiff has a right to inquire."⁵¹ The court summarily denied the request, stating merely that "questions regarding defendants' funding of the litigation [are] not relevant to the pending subject matter."⁵² Pallin's attorneys were understandably frustrated by the turn of events. Singer's appeals to the physician community effectively switched the playing field from one governed by patent law to one governed by medical community norms of sharing skills and techniques. While Pallin was the plaintiff in the litigation, he became the defendant in the court of medical profession opinion.

D. Pallin's Attempt to Situate Medical Procedure Patents Within Medical Community Norms

Though Pallin's attorneys seemed nonplussed by Singer's outreach to the physician community, Pallin's actions grew out of his membership in that community. He consistently argued that he resorted to patent enforcement only in response to the community's failure to award him adequate credit for his contributions. A pleading filed on his behalf in the suit against Singer even implied that his initial decision to apply for a patent was a response to his peers' rejection of his initial submission to JCRS:⁵³

As an experienced and respected surgeon he expected to be published. Amazingly, his article was rejected. His invention was harshly criticized by his colleagues. He then retained counsel and a patent application . . . was prepared and filed in June of 1990.⁵⁴

There are reasons to doubt this implication in light of the timing of manuscript submission and patent application preparation.⁵⁵ It also appears there would have been little justification for

⁵¹ Motion to Compel at 8.

⁵² Opinion and Order at 2, Entry No. 29.

⁵³ Plaintiff's Opposition to Defendants [sic] Motion for Leave to Amend at 3. This contention was also widely reported in contemporaneous media and law review reports. *See, e.g.,* William B. Lafferty, *Statutory and Ethical Barriers in the Patenting of Medical and Surgical Procedures*, 29 J. MARSHALL L. REV. 891, 892 (1996); Joseph M. Reisman, Comment, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355, 366 (1995); Wendy W. Yang, Note, *Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion from Patentability*, 1 B.U. J. SCI. & TECH. L. 5, para 51 n. 146 (1995); Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties from Method Patents Stirs Debate*, AM. MED. NEWS, Sept. 5, 1994, at 3. *See, e.g.,* Eric M. Lee, *35 U.S.C. § 287(c)-The Physician Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 701, 701-02 (1997)

⁵⁴ Plaintiff's Opposition to Defendants [sic] Motion for Leave to Amend at 3.

⁵⁵ Pallin's Declaration filed in December 1994 makes it clear that he prepared his patent application and submitted his manuscript to JCRS at around the same time, in April 1990. Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment at ¶¶ 26-27.

perceiving JCRS's rejection of an early report of a few surgeries as a serious affront. The first peer-reviewed JCRS article about sutureless cataract surgery was authored by Gills and appeared in May 1991.⁵⁶ Gills had access to a very large patient population, as evidenced by the fact that in 1990 he published a monograph reporting 2000 sutureless surgeries.⁵⁷ JCRS did not publish another article about sutureless cataract surgery until the October 1991 special issue, in which Pallin's article appeared alongside several other articles on the topic. Thus, Pallin certainly was not alone in having to wait for publication while experience with sutureless surgery accumulated.

While Pallin's motivations for filing his patent application remain murky, there is little doubt that his later turn to enforcement was driven by discontent with the community's recognition of his contributions. When the patent issued in January 1992, Pallin did not run out to seek royalties. Instead, he sought community recognition by attempting to donate the patent first to the ASCRS and then to the American Academy of Ophthalmology (AAO).⁵⁸ Only after these attempts to deploy the patent to gain recognition from the community were rejected did Pallin begin to demand royalty payments. As Pallin perceived things: "The degree of resistance I encountered when I attempted to share my work with the profession at large was astounding. The arrogance with which my work was dismissed by individuals whom I had held in high regard was shocking."⁵⁹

Besides justifying his resort to patent enforcement by alleging a failure of the community's reward system, Pallin also argued repeatedly that his use of his patent was an appropriate extension of community norms. Thus, an April 20 1994 settlement offer portrayed Pallin's patent enforcement strategy as tempered by the sharing norms of the physician community:

Dr. Pallin has stated on a number of occasions that he would never seek an injunction or an unreasonable royalty from a surgeon or anyone else so you and Dr. Singer may be assured that no one will be stopped from using this incision in the future. At the most they will be asked to pay a small royalty.⁶⁰

A June 1994 settlement offer focused even more clearly on portraying Pallin's actions as consistent with the sharing norm.⁶¹ It recognized Singer's goal of "ensuring that [] the Frown remain available to everyone" and offered to accommodate the sharing norm by refraining from seeking royalties from those who were teaching the technique and foregoing injunctive relief all

⁵⁶ J.P. Gills and D. Wang, *Sutureless Closure for Exchange Surgery of Intraocular Lenses*, 17 J. CATARACT REFRACT. SURG. 383 (May 1991).

⁵⁷ JAMES GILLS AND DONALD SANDERS, *SMALL-INCISION CATARACT SURGERY* at 127 (Slack, Inc. 1990), Entry No. 42, Appx. I, Ex. 2A.

⁵⁸ Samuel L. Pallin, *Method Patents Benefit Information Dissemination*, OCULAR SURGERY NEWS, July 15, 1994, at 19.

⁵⁹ *Id.*

⁶⁰ Letters from James R. Longacre to George Neuner at 3, Entry No. 24, Exhibit N

⁶¹ Letter from James R. Longacre to George Neuner at 2-3, Entry No. 37, Exhibit C

together. Pallin also deferred to community reputational norms by offering to credit Singer for his contributions to “popularizing the frown incision.”

Pallin also presented himself as a concerned community member seeking revision of the anti-patenting norm in light of changed circumstances. Thus, the June 1994 settlement letter emphasized that Pallin strongly believed that he was “doing the right thing” and “pioneering the way for others to follow.” It also asserted that the USPTO Official Gazette reflected increasing numbers of procedure patents in ophthalmology and other surgical specialties so that inventors were “watching this debate.” Pallin also acknowledged Singer’s “goals of embracing a political debate within the profession” and offered to debate him at a professional meeting. Similarly, in a debate with Singer published in a July 1994 AAO newsletter,⁶² Pallin argued that the journal publication process was “too easily corrupted by politics and special interests” and that patents therefore might sometimes be the only way for the true inventor to be recognized. For his part, Singer distinguished medical procedures from devices and drugs, arguing that procedure innovations are incentivized by “the foundation of good medical practice” and generally do not require substantial financial investments that must be recouped through patents. Pallin contended that the growth of managed care would shrink physicians’ intrinsic incentives to invent new procedures, which would have to be replaced by the “recognition and small profit” available from patenting. He also disputed Singer’s distinction between devices and procedures, arguing that both device and procedure patents should be ethically acceptable as long as royalties were not too expensive (and thus, by implication, did not interfere with the sharing norm).

In the end, the 1994 settlement negotiations failed for reasons that make sense in light of the ongoing battle over the norms of the physician community. Though Pallin eventually went so far as to offer the defendants a royalty-free license,⁶³ on top of the concessions discussed above, and even attempted to grant such a license unilaterally, Singer refused to settle.⁶⁴ Singer demanded nothing less than dedication of the patent to the public or something of equivalent effect,⁶⁵ while Pallin was equally adamant that he would not give up his patent. It was time for the court to weigh in.

D. *Pallin v. Singer* in Court

In October 1994, Singer moved for summary judgment of noninfringement and of invalidity in light of the work of Gills, Singer, and McFarland.⁶⁶ The summary judgment motion moved the

⁶² John Hayes, *The War Over Patents*, ARGUS, July 1994, at 8.

⁶³ Reply Brief on Behalf of Pallin, Feb. 1996, at 8, Entry No. 81.

⁶⁴ Letter from James R. Longacre to George Neuner at 1, Entry No. 37, Exhibit E.

⁶⁵ Letter from Peter J. Manus to James R. Longacre, *Pallin v. Singer*, Entry No. 37, Exhibit G; *see also* Rochelle Nataloni, *Pallin vs. Singer Still at Stalemate; Offer Made, Refused*, OCULAR SURGERY NEWS, Sept. 15, 1994, at 23 (explaining some of the inner workings of the settlement negotiations and how they came to an impasse).

⁶⁶ *See* Order, Entry No. 43 (granting Singer's request to submit a summary judgment motion in October, which was after the timeframe allotted in the court's rules).

focus from the terrain of community norms and ethics back to the technical patent law issues, at least temporarily. The arguments centered on whether the preamble term “substantially self-sealing” limited the claim and on how that term and the “wherein” clause describing the incision shape should be construed. On May 1, 1995, the court denied the motion, without resolving any of the claim construction issues, holding that “complex factual disputes” existed in the case.⁶⁷ At that point, it seemed that the case was on track for trial. Fate intervened, however. Judge Franklin Billings, who had been presiding over the case, had taken senior status in September 1994. In September 1995, he reassigned his pending cases, including *Pallin v. Singer*, to newly appointed Judge William Sessions. Singer’s attorneys asked the new judge to resolve the claim construction issues and grant summary judgment in light of intervening changes in the law.⁶⁸

Judge Sessions held the requested hearing on March 26, 1996.⁶⁹ The hearing must not have gone well for Pallin. Two days later, the court issued a Consent Order declaring the patent claims invalid and noninfringed and ordering Pallin not to make any further enforcement attempts.⁷⁰ The *Pallin v. Singer* litigation thus ended, having resulted in no pathbreaking ruling on the patentability of medical procedures (or anything else, for that matter).

The result was widely reported in the medical and mainstream media as a defeat for medical procedure patenting.⁷¹ Pallin did not acknowledge defeat, stating that “My goal from the beginning of this controversy and in this litigation was to demand and achieve recognition for a contribution, which I made to the profession in early 1990. . . . I am satisfied this goal has now

⁶⁷ Order and Opinion at 7, Entry No. 57. No one seems to have noticed that the Federal Circuit had just held, in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996), that claim construction is a matter of law for the court to decide.

⁶⁸ The intervening change was, of course, the *Markman* decision, which had been a basis for reconsideration by several other district courts by that time. See *Am. Permahedge, Inc. v. Barcana, Inc.*, 901 F. Supp 155 (S.D.N.Y. 1995), *aff’d*, 105 F.3d 1441 (Fed. Cir. 1997), and *Elf Atochem N. Am., Inc. v. Libbey-Owens-Ford Co.*, 894 F. Supp 844 (D. Del. 1995) respectively.

⁶⁹ Defendants’ Motion for Summary Judgment, Entry No. 74.

⁷⁰ Consent Order, *Pallin v. Singer*, 1996 WL 274407 (D. Vt. Mar. 28, 1996). Because the case was resolved by settlement, the order does not reflect any rationale for these declarations. See also *Pallin Patent Claims Invalidated; Physicians free to perform cataract surgery without threat of infringement litigation*, PR NEWSWIRE (March 29, 1996).

⁷¹ See, e.g., Carolyn Lederman, *Pallin Patent is Invalidated*, OPTHALMOLOGY TIMES, June 1, 1996, at 10; *Court Rules against Patent on Surgical Procedure*, ARGUS, May 1996, at 8; Greg Borzo, *Method Patent Fails; Court: Surgeon Doesn’t Have to Pay Royalties*, AM. MED. NEWS, Apr. 15, 1996, at 1; *Eye Surgeon Loses Effort to Enforce His Patent*, N.Y. TIMES, Apr. 3, 1996, at D20; *Judge Rejects Patent for Eye Surgery*, CHI. TRIB., Apr. 2, 1996, at 12; Editorial, *Patently Ridiculous*, TULSA WORLD, Apr. 4, 1996, at A12;; *Inside the Industry – Surgical Patents: Judge Dismisses Bellwether Case*, AM. HEALTHLINE, Apr. 2, 1996, http://newlive.nationaljournal.com/cgi-bin/ifetch4?ENG+AMERICAN_HEALTHLINE-_-POLL_TRACK-_-AD_SPOTLIGHT+7-ahindex+1405937-REVERSE+0+0+12710+F+6+6+1+bellwether+AND+judge; *Patenting Knowledge* (PBS television broadcast Apr. 23, 1996), available at http://www.pbs.org/newshour/bb/health/jan-june96/patent_04-23.html (transcribing the broadcast).

been achieved.”⁷² He also claimed a moral victory, in that his case had made physicians aware that medical procedures are patentable,⁷³ and continued to defend medical procedure patenting.⁷⁴

Pallin was wrong, however. Singer’s view had prevailed in the court of physician community opinion and the norm against medical procedure patenting had, if anything, been reinforced. Indeed, Singer’s 1994 speech to the ASOS had ignited an assault on medical procedure patents in the halls of Congress, which also came to a head in 1996.

III. Negotiating the Boundary Between Physician Innovation Norms and the Patent System

A. The Physician Movement Against Medical Procedure Patents

Even before Singer’s ASOS speech, Pallin’s attempt to enforce his patent seems not to have gone over well with his fellow eye surgeons. In a March 15, 1994 interview, for example, Michael McFarland dismissed the idea that patents could replace or supplement the medical community’s assessment of credit by documenting “originality.” He explained that “traditionally in ophthalmology we’ve always documented innovation of a new procedure, technique or piece of equipment through our literature, so that will continue to be the way that we document who does what first.” He also rejected the notion that patent licenses and royalties could be means to share innovations with fellow surgeons. To McFarland, collecting royalties from another physician was “[u]ndoable, if not unthinkable”:

It’s hard for me to conceptualize why anybody would want to bring this whole royalty scheme into ophthalmology and to introduce the legalities involved and to bring lawyers into the picture and file lawsuits against our colleagues We ought to get back to trying to figure out better ways to fix folks and to share that with our colleagues for the benefit of the patients.⁷⁵

Singer’s ASOS meeting speech painted medical procedure patenting as a threat to medical community sharing norms:

An insidious virus has been threatening to destroy the foundation of good medical care in the United States since 1954. The virus is method patents for medical and surgical procedures. If allowed to proliferate this will effectively block the timeless way of sharing medical and surgical knowledge, and perhaps more

⁷² *Court Rules Against Patent on Surgical Procedure*, ARGUS, May 1996, at 8.

⁷³ Greg Borzo, *Method Patent Fails; Court: Surgeon Doesn’t Have to Pay Royalties*, AM. MED. NEWS, Apr. 15, 1996, at 1.

⁷⁴ *Patenting Knowledge* (PBS television broadcast Apr. 23, 1996), available at http://www.pbs.org/newshour/bb/health/jan-june96/patent_04-23.html (transcribing the broadcast).

⁷⁵ *Sutureless Takes Firm Hold On Cataract Surgery: Interview with Mike S. McFarland*, 12 OCULAR SURGERY NEWS, March 15, 1994, at 1, 21-32.

importantly will inhibit the interdependent free exchange of information that is the foundation of good medical care. Other victims of medical and surgical method patents include physician autonomy, the doctor-patient relationship, openness in medical research, and free exchange of medical and surgical knowledge.⁷⁶

During the spring of 1994, following Singer's letters and speech, the physician movement to oppose medical procedure patenting took on a life of its own, first among ophthalmologists and then throughout the broader medical community.⁷⁷ Dr. Herve Byron, an intraocular lens pioneer, fanned the flames of community outrage in a colorfully written OSN column in June 1994. Byron depicted the *Pallin v. Singer* case as a "monumental battle," emphasizing that its "ultimate impact" should be determined on ethical, rather than legal, grounds.⁷⁸ He described Singer as "the beleaguered general of all of surgery's ethical war," warned of "devastating and mind-boggling consequences" of a loss in court, and questioned why individual ophthalmologists and medical organizations had not reacted more strongly to the threat "of a plane flying overseas with a potential hydrogen bomb ready to explode." Byron also, however, deplored the potential negative consequences for Pallin if he should lose the lawsuit and end up "despised and [] permanently outlawed from the ophthalmic community by his peers." He urged that steps be taken to bring Pallin back into the fold and warned that failure to effect a dignified reconciliation would result in an outcome "similar to the Vietnamese war—no winners and all losers."

Apparently medical organizations were not as blind to the procedure patent issue as Byron had thought. Only two weeks later, the AMA passed a resolution, sponsored by the AAO, to "vigorously condemn the patenting of medical and surgical procedures and work with Congress

⁷⁶ *Doctor Implores Principles of Hippocrates to Standing Ovation*, OPTHALMOLOGY TIMES, May 1, 1994, at 28.

⁷⁷ See, e.g., Ely Jay Crary, Letter to the Editor, *Payment and Credit Due to Dr. Pallin*, ARGUS, Nov.-Dec. 1996, at 10; Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1; H. Dunbar Hoskins, Jr., Letter to the Editor, *Doctors Group Opposes Medical Method Patents*, WALL ST. J., Sept. 6, 1994, at A13; John S. Jarstad, Letter to the Editor, *Shared Guilt*, OCULAR SURGERY NEWS, Dec. 1, 1994, at 3; James R. Longacre, *Pallin Action No Indication of Method Patent Avalanche*, OCULAR SURGERY NEWS, Dec. 1, 1994, at 4; Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties from Method Patents Stirs Debate*, AM. MED. NEWS, Sept. 5, 1994, at 3; Mike S. McFarland, Letter to the Editor, *McFarland Responds*, OCULAR SURGERY NEWS, Sept. 15, 1994, at 3; Rochelle Nataloni, *AAO's Patent Position Made Public in the National Press*, OCULAR SURGERY NEWS, Dec. 1, 1994, at 1; Samuel L. Pallin, Letter to the Editor, *An Unethical Objection to My Surgical Patent*, WALL ST. J., Oct. 24, 1994, at A15; Samuel L. Pallin, Letter to the Editor, *Incision Reference*, OCULAR SURGERY NEWS, Sept. 15, 1994, at 3; Samuel L. Pallin, Letter to the Editor, *Pallin Responds*, OCULAR SURGERY NEWS, Nov. 15, 1994, at 4; Jack A. Singer, Letter to the Editor, *Patent Suit*, OCULAR SURGERY NEWS, Nov. 15, 1994, at 4.

⁷⁸ Herve M. Byron, *Is This Déjà Vu?*, OCULAR SURGERY NEWS, June 1, 1994, at 13.

to outlaw this practice.”⁷⁹ In 1995, an AMA report on medical procedure patenting concluded that it is unethical for physicians to “seek, secure or enforce patents on medical procedures.”⁸⁰

The AAO’s executive vice president, H. Dunbar Hoskins, spearheaded efforts to lobby Congress against medical procedure patents.⁸¹ The Medical Procedure Patent Coalition, which eventually included the AMA, the American College of Surgeons, and the Association of American Medical Colleges, along with the ophthalmology associations and others, sought legislation that would render medical procedures and diagnostic methods unpatentable. Eventually, after several bills were introduced and debated, the lobbying efforts resulted in the enactment of 35 U.S.C. §287(c) in 1996. Senator Frist, himself a physician, introduced the final version of the bill.⁸²

In §287(c), the physicians got some, but not all, of what they had wanted, which was to exclude medical procedures from patentable subject matter. The proposed ban on medical procedure patents was opposed by the biopharmaceutical industry and by the USPTO. The provision that eventually emerged reflects a compromise. Rather than eliminating medical procedure patents, § 287(c) eliminates *remedies, including injunctive relief, against medical practitioners and health care entities only* for infringement of pure procedure patents. By eliminating remedies against physicians, the legislation made it pointless to sue them directly for infringing pure medical procedure patents. However, §287(c) preserved the value of lawsuits against third parties for inducing or contributing to physician infringement, by allowing the USPTO to continue issuing medical procedure patents and subjecting medical practitioners to technical liability for infringing them. Moreover, the §287(c) remedy exemption does not apply to all medical procedures. Many claims to medical procedures involving patented devices or drugs fall outside of its scope, as do biotechnology patents.

Despite its limitations, the legislation’s passage was widely (though sometimes not entirely accurately) celebrated in the medical press.⁸³ Singer responded to the bill’s passage by stating that “this may be the most important contribution to healthcare that I make during my career.”⁸⁴

⁷⁹ American Medical Association, *Resolutions*, 1994 PROC. AM. MED. ASS’N ANNUAL MEETING 388, 390, available at <http://www.ama-assn.org/ama/pub/about-ama/our-history/ama-historical-archives/the-digital-collection-historical-ama-documents.page>.

⁸⁰ American Medical Association, *Reports of Council on Ethical and Judicial Affairs*, 1995 PROC. AM. MED. ASS’N ANNUAL MEETING 200, available at <http://www.ama-assn.org/ama/pub/about-ama/our-history/ama-historical-archives/the-digital-collection-historical-ama-documents.page>.

⁸¹ Editorial, *What the Academy is Doing to Oppose Method Patents ... and What You Can Do*, ARGUS, July 1994, at 14.

⁸² Pub. L. No. 104-208, § 616, 110 Stat. 3009-67 (codified as amended at 35 U.S.C. § 287(c)).

⁸³ See, e.g., Julie Rovner, *Congress Moves to Restrict Medical-Procedure Patents*, 348 LANCET 1025 (1996); *Legislative Success in ‘96*, ARGUS, Nov.-Dec. 1996, at 30; Greg Borzo, *Royalty Relief: Procedure Patents Not Enforceable*, AM. MED. NEWS, Oct. 21, 1996, at 3; Chet Scerra, *Medical Patent Bill Gives Doctors New Protections*, OPHTHALMOLOGY TIMES, Jan. 15, 1997, at 28, 30.

⁸⁴ Chet Scerra, *Medical Patent Bill Gives Doctors New Protections*, OPHTHALMOLOGY TIMES, Jan. 15, 1997, at 28, 30.

B. Viewing the Physician Community's Opposition to Medical Procedure Patents through a User Innovation Lens

No doubt, a number of factors have contributed to the changing relationship between physicians and patents. Commentators often attribute the softening of the profession's absolute anti-patent stance to a spiral of increasing healthcare commercialization and decreasing medical professionalism over time.⁸⁵ The *Pallin v. Singer* story does not fit into that picture. During the heyday of enthusiasm for the patent system's potential for medical innovation generally and at a time when the patentability of methods was otherwise expanding, the physician community resoundingly rejected medical procedure patenting. Physicians took this stand despite their support for physician patenting of medical devices. The lens of "user innovation" suggests a possible explanation of the line the physician community has drawn between procedure and device patenting.

Because they are users, physician innovators benefit directly from the norm of sharing medical procedure inventions: it gives them access to the collective inventive output of the community for use in treating their patients. The sharing norm also allows physician innovators to build upon and improve one another's innovations. Of course, physicians, like many other types of user innovators, also compete with one another to some extent and seek rewards for their inventive efforts. This interplay between the drive for credit and the drive for access likely explains why user innovator communities so often eschew the exclusivity and inflexibility of legally-defined intellectual property rights in favor of tailored reputation rewards and sharing norms.⁸⁶ Formal IP rights can threaten these norms-based governance regimes. Exclusive IP rights may allow community members to defect from the community's reward system by holding the community up for rewards that are excessive in relation to the credit the community has allocated. If the number of such defections begins to rise, these internal governance mechanisms may be destabilized.⁸⁷ User innovator community norms against patenting help to stabilize the reputation-based reward system and associated sharing norms. Of course, doing away entirely with intellectual property rights that provide the tools for defection is an even more effective stabilization mechanism.

The user innovator perspective comports with physician opposition to medical procedure patents. Physicians and other medical caregivers are the primary users of medical procedures and also are likely to be the primary innovators. They have strong common interests in effective patient care, which motivate the community norms of disclosure and sharing. The physician community

⁸⁵ See, e.g., Jane Applegate, *Surgery: The Mother of Invention*, L.A. TIMES, Apr. 5, 1991, at 3; Arnold S. Relman, *Medical Professionalism in a Commercialized Health Care Market*, 75 CLEV. CLINIC J. MED. S33 (2008).

⁸⁶ For further discussion of this point, see Katherine J. Strandburg, *Intellectual Property at the Boundary*, in FESTSCHRIFT FOR ERIC VON HIPPEL, Karim Lakhani and Dietmar Harhoff, eds., (forthcoming 2014), available at http://www.pbs.org/newshour/bb/health/jan-june96/patent_04-23.html.

⁸⁷ Id. See also Jonathan Barnett, *The Illusion of the Commons*, 25 BERKELEY TECH. L. J. 1751 (2010).

relies on an internally-governed system of publication credit and other reputational mechanisms for allocating rewards for procedure inventions and thus sees medical procedure patents as unnecessary, cumbersome, and threatening to the sharing norm. Physician opposition to medical procedure patents makes sense as an attempt to protect the medical community's norms-based innovation system.

Medical device innovation is different. Modern medical device innovation generally requires extensive collaboration with commercial firms. Device development often requires expertise in non-medical fields, such as electrical engineering and materials science, and an understanding of manufacturing processes. Device commercialization demands expertise regarding the regulatory approval process. Internal community norms cannot effectively allocate rewards when physician innovators must find their collaborators on the other side of the boundary between industry and the physician community. For medical device inventions, patents provide a shared currency for allocating rewards across community boundaries, while contracts and licenses, rather than norms, govern collaborative relationships.

The *Pallin v. Singer* story can be read against this user innovator community backdrop. The physician community viewed Pallin as a defector from the anti-patenting norm. Pallin, on the other hand, claimed that he resorted to patent enforcement because the community's reward system failed to give him enough credit for his contributions. Whether or not Pallin was justified in his view, the story highlights the fact that all systems of allocating rewards for invention are imperfect. Reputation systems can turn into old boys' networks that are difficult for outsiders without the right contacts and pedigrees to penetrate. Patent systems impose deadweight loss, while overburdened patent examiners cannot compete with the domain-specific expertise reflected in allocations of credit by expert communities. From society's perspective, whether user innovator community norms are desirable replacements for intellectual property in particular arenas depends on factors such as the way in which community membership is determined, the patent office's level of expertise, the relative transaction costs of the IP- and norms-based systems, and the importance of inventive contributions by outsiders to the community.

VI. The Aftermath

Since its passage, § 287(c) has been invoked only rarely. It has been the subject of only one published opinion, issued in 2008.⁸⁸ The provision's dormant status seems surprising in light of the many statutory interpretation issues that would seem to tempt patentees to test the provision's boundaries. Perhaps this situation reflects the law's effectiveness at deterring suits against physicians for infringing medical procedure patents. Or perhaps the main effect of the *Pallin v. Singer* episode was to clarify and reaffirm the norm against medical procedure patenting. That

⁸⁸ *Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811 (S. D. Tex. 2008).

norm, rather than the technicalities of § 287(c)'s language, sets the boundary of acceptable physician behavior.

While the scope of § 287(c)'s exemption for suits against physicians has not been tested, the issue of medical procedure patenting has come to the fore once again in cases, such as *Mayo v. Prometheus*,⁸⁹ involving secondary liability premised on physician infringement of medical diagnostic method claims. The patentees in these cases have sued the laboratories that measure metabolite blood levels, sequence and interpret DNA samples, and so forth. Physicians have argued that these patents cover unpatentable subject matter.⁹⁰ Many of their arguments about the dangers such patents pose to the medical community are similar to those made by physicians during the *Pallin v. Singer* controversy. As both medical science and medical practice continue to evolve, the boundary between the realm of community-based user innovation norms and the patent system will no doubt continue to be contested. In medical innovation, intellectual property truly does live “at the edge.”

⁸⁹ *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289 (2012) (invalidating diagnostic procedure claims as drawn to unpatentable natural phenomena in suit against laboratory for inducing physician infringement).

⁹⁰ See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1304-1305 (2012) (quoting amicus brief of numerous medical associations opposing patentability of certain medical diagnostic procedures); Brief of Amici Curiae American Medical Association et al. in Support Of Petitioners, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S. S. Ct. 2013) (opposing patents on human genes and genetic tests); Brief of American Medical Association et al in Support of Petitioner, *Lab. Corp. v. Metabolite Labs., Inc.*, No. 04-607 (U.S. S. Ct. 2004) (opposing patentability of certain medical diagnostic procedures); Opinion 9.095, Code of Medical Ethics of the AMA (1996, 2008), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.page> (last visited Feb. 21, 2013) (“The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical.”). Note that this author represented the amici medical associations in *Mayo v. Prometheus*.