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Derogatory to Professional Character? Physician Innovation and Patents as Boundary-Spanning Mechanisms

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This Article suggests that the historical evolution of physician patenting norms can be understood from a user innovation perspective. User innovator communities often eschew patenting, relying instead on reputation-based reward systems and sharing norms. While virtually all medical innovation was once the province of user innovator physicians, that is no longer the case. The rewards of reputation and use offered by the physician community are insufficient for innovations that require collaboration with outsiders. Patents, on the other hand, are a generally recognized currency for rewarding and governing innovation. I argue that physician patenting norms have evolved to track changes in the role physicians play in particular aspects of medical innovation. The resulting hypothesis that user innovator communities often will find patenting acceptable only when innovation requires collaboration with outsiders applies generally and can be tested in other technological arenas. The user innovator perspective also raises important questions about how patent law should accommodate anti-patenting norms in industries where user innovation is prevalent.

I. Introduction

Physicians have a long history of opposing medical patenting. In the nineteenth century, the organized medical community opposed medical patents of all kinds, whether on drugs, devices, or procedures. Most recently, medical associations weighed in against claims to diagnostic procedures in Mayo Collaborative Servs. v. Prometheus Labs., Inc., and claims related to naturally-occurring DNA sequences in Ass’n for Molecular Pathology v. Myriad Genetics, Inc. In Mayo, the Court, on its way to holding the claims invalid, contrasted the biotechnology industry’s support for such patents with physician opposition. In AMP, the Court made no comment about the disagreement between genetic medicine practitioners and biotech firms, though its holding essentially split the difference, invalidating isolated DNA claims, while allowing claims to complementary or “cDNA” sequences.

Despite physicians’ history of opposing patents, medical device and drug patenting were given ethical approval years ago. Physicians today are co-inventors on a sizeable fraction of important medical device patents. Several factors may have influenced the changing relationship between physicians and patents. In the 1990s, commentators argued that increased physician patenting

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1 132 S. Ct. 1289, 1304-05 (2012). Note that this author represented a group of medical associations in amicus filings in this case.
3 Mayo at 1304-05.
stemmed from economic forces that decreased physicians’ compensation for direct patient services, leading them to look elsewhere for financial rewards.5 Others have argued that physician patenting reflects the fact that health care commercialization has diminished medical professionalism.6

This Article uses the lens of “user innovation” to illuminate the relationship between physicians and patents. User innovators are motivated by their desire to use the technologies they invent, rather than to sell them to others.7 User innovation often stems from users’ experiences with the ways that technologies perform “on the ground,” including the effects (and sometimes the advantages) of accidents and serendipitous occurrences during use. Physician user innovators make significant advances in medical procedures, diagnostic tests, medical devices, surgical instruments and off-label uses of drugs.8 Physicians are motivated to innovate for use in their practices by altruistic goals of patient care, as well as self-interested career goals.

User innovators often form communities in which they discuss problems with current technology and share innovations they have made.9 Unlike competing sellers, who may have little to gain from sharing, users can benefit in at least three ways from sharing their innovations with other users even if they compete with one another in some respects. First, reciprocal sharing of innovations leads directly to benefits from using innovations shared by other community members. Second, sharing an innovation with other users allows those others to improve upon it, making its use more valuable to the original innovator. Third, sharing an innovation can boost a user’s reputation, which confers intrinsic and monetary benefits. As long as the benefits of

7 See, generally, ERIC VON HIPPEL, DEMOCRATIZING INNOVATION (2005).
8 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, Strategic Entrepreneurship J. (forthcoming 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; 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)”).
sharing are not outweighed by the benefits of a user’s exclusive use of her own innovations, she should opt in to a sharing regime as long as reciprocity can be ensured.\textsuperscript{10}

User innovator communities often develop informal norms or other private governance mechanisms to ensure sharing, relying on reputation to allocate rewards and eschewing patenting. Reputation-based rewards can be preferable for several reasons. In a context of frequent and cumulative innovation, patent exclusivity imposes transaction costs of negotiating licenses and paying licensing fees. Moreover, patents take the task of evaluating and rewarding innovative contributions out of the hands of the community, giving it to the government. The scope of legally-defined patent rights may not accord with the community’s perspective of the value of a particular innovator’s contribution. Moreover, patents can threaten the stability of a system of reciprocal sharing and community-defined rewards, encouraging free riding on the community’s efforts and providing a means to defect from the community’s allocation of rewards.

Longstanding norms of information sharing, publication and reputational rewards suggest that physicians make up a user innovator community. Unlike many user innovator communities that have been described in the literature, however, the medical community currently does not oppose patenting of all physician innovations. Physician norms permit drug and device patents. That was not always the case, however. This Article attempts to understand the evolution of physician patenting norms by studying the history of their evolution from a user innovation perspective. It argues that this history suggests that user innovator community norms are likely to permit patenting in contexts where innovation demands significant collaboration between users and outsiders.

Since the nineteenth century, physician norms about patenting have evolved in several stages. Part II describes the period from 1847, when the American Medical Association (AMA) was founded,\textsuperscript{11} through the late nineteenth century. During this period, the AMA maintained and solidified a blanket anti-patent position. So-called “regular” physicians were (or at least perceived themselves to be) the primary innovators of drugs, instruments, devices and procedures. They sought to distinguish themselves from purveyors of secret and potentially harmful “nostrums” and “patent medicines.” During this period, the anti-patenting norm survived a major controversy over the patenting of ether anesthesia.

Part III describes changes in drug innovation from the late 1880s through the 1970s. Technological changes and industrialization moved most pharmaceutical innovation out of the physician community into large chemistry-based research companies. The federal government took over the regulation of drug and device safety and efficacy, which previously had been within the physician community’s purview. During this shift away from physicians as primary

\textsuperscript{10} For more detailed discussion, see 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); Katherine J. Strandburg, User Innovator Community Norms at the Boundary Between Academic and Industrial Research, 77 Fordham L. Rev. 2237 (2009).

drug innovators, the AMA’s stand on pharmaceutical patents evolved from complete opposition to complete acceptance.

Part IV describes the more complex situation pertaining to medical devices and instruments. Physician user innovation remains vital in this arena, but industrialization and technological change have meant that collaboration between physicians and commercial firms is increasingly important. Norms have changed to allow patents to play a boundary-spanning role.

Part V describes a period during the 1990s when physicians lobbied Congress to ban patents on medical and diagnostic procedures. The catalyst for this effort was the cataract surgery patent case, *Pallin v. Singer*. Congress eventually amended the Patent Act, not to ban procedure patents, but to exempt physicians from infringement penalties.12 Physician opposition to medical procedure patents, which continues to this day, is consistent with the fact that medical procedure innovation is dominated by physicians, with little need for outsider involvement.

Part VI discusses recent controversies about patents claiming medical diagnostic procedures and genetic diagnostic tools in light of the user innovator paradigm, arguing that, despite some complexities, physician opposition to such patents also makes sense from a user innovation perspective.

Part VII describes some possible further tests of the hypothesis that the contours of physician patenting norms have their roots in physician user innovation and suggests that a similar analysis might be applied in other arenas, such as software, in which at least some innovators have opposed patenting. It concludes with some brief thoughts about possible doctrinal implications of the analysis.

II. Physician Innovators, Patents, and the Ether Controversy in the Mid-Nineteenth Century

The AMA’s first Code of Ethics, adopted at the AMA’s formation in 1847, stated that it was “derogatory to professional character” for physician to hold patents “for any surgical instrument or medicine.”13 At that time, so-called “ethical” medications were prescribed and formulated by physicians according to “pharmacopeia.”14 So-called “patent” medicines were sold directly to consumers. Most “patent” medicines actually were secret, rather than patented (for good reason, since many apparently consisted primarily of water or alcohol). The medical profession’s debate about patents was bound up with its attempts to differentiate itself from the

12 35 U.S.C. 287(c).
13 AMA, CODE OF MEDICAL ETHICS § 4 (1847).
15 See, e.g., H.R. REP. NO. 52, at 5-23, 30 (1849) (showing eighty instances between the years 1796 and 1843 where the Patent Office granted patents on medicines, most of which "combines some active known agent, disguised under colors, and heralded with a name, in many instances, as uncouth as it is insignificant or false"); Ethics and Patents, 16 AM. J. PUB. HEALTH 919, 920 (1926) (discrediting the idea that since the government granted a patent on the scarlet fever toxin/antitoxin that such a patent is justified by showing multiple examples of patents that were granted on nostrums).
purveyors of such “nostrums” by its scientific approach to medicine. These issues formed the backdrop of a notorious and influential controversy over the patenting of ether anesthesia, which left its mark on patent doctrine through the case of Morton v. New York Eye Infirmary.

A. The Ether Anesthesia Controversy

Ether anesthesia was an extremely important medical advance. In 1847, when the fledgling AMA was formed, controversy about the patenting of ether anesthesia was raging. The controversy tested the medical community’s anti-patenting norm and provides a window into the norm’s contours and justifications.

1. Morton and Jackson: Discovery, Patenting and Controversy

In the early 1840s, surgery was a horrifying experience, performed on conscious patients fortified sometimes with narcotics such as opium, but often only with courage. Death from shock was common. Ether was well known. Its ingestion, inhalation or topical application was prescribed to treat various maladies, Ether and its cousin, nitrous oxide, also were popular as what we would today call “party drugs;” indeed ether has been called the “marijuana of the 1830s,” though its use was both legal and socially acceptable at the time. When inhaled at “frolics,” ether produced euphoria and, sometimes, stupefaction. Physicians believed that inhaling enough ether to produce stupefaction was very dangerous, which apparently deterred exploration of its potential for alleviating pain. Once ether anesthesia was tested and publicized in late 1846, it was adopted very rapidly. During the Mexican-American and Civil Wars, it was used in countless battlefield operations.

The discovery of ether anesthesia was notable not only for its importance but also because of a bitter and long-running controversy over patenting and scientific credit. A patent was obtained in November 1846 by dentist, sometime medical student, and reputed con man, William T.G. Morton and Harvard lecturer Dr. Charles T. Jackson. Jackson was a highly distinguished polymath, trained in chemistry and geology, as well as medicine. Morton had studied with

16 See JAMES A. JOHNSON & WALTER J. JONES. THE AMERICAN MEDICAL ASSOCIATION AND ORGANIZED MEDICINE 5-6 (1993) (explaining that the AMA was founded in part out of a need to create standards “for effective treatment based upon the most up-to-date scientific principles”); Kara W. Swanson, Food and Drug Law as Intellectual Property Law: Historical Reflections, 2011 WIS. L. REV. 331, 353-56 (2011) (discussing how “doctors sought to distinguish themselves as experts who prescribed drugs to treat particular patients, relying on their medical knowledge to be specific, rather than offering general cure-alls”).
17 17 F. Cas. 879 (C.C.S.D.N.Y. 1862)
18 One description is given in NATHAN P. RICE, TRIALS OF A PUBLIC BENEFACTOR, AS ILLUSTRATED IN THE DISCOVERY OF ETHERIZATION 40-42 (1858) (“RICE”). The pamphlet was written in support of Morton’s claim to credit for the discovery. Nonetheless, few would dispute the essential accuracy of its vivid description of the horrors of pre-anesthesia surgery.
19 Materia medica is a Latin term commonly used to describe the physicians’ accumulated knowledge about the effects and properties of medicines.
20 How It All Began, 10 ANESTHESIA HISTORY ASS’N NEWSLETTER 3 (January 1992) reprinted from 11 M.E. J. ANESTH. 93 (June 1991).
21 RICHARD J. WOLFE, TARNISHED IDOL (2001) at 58-60. See also How It All Began.
22 U.S. Patent No. 4848 (Nov. 12, 1846).
23 WOLFE.
Jackson, even rooming in Jackson’s house, at some point prior to the ether anesthesia discovery. Later, various others, including Morton’s former mentor, dentist Horace Wells, sought credit for the discovery. Many now believe that Georgia physician Crawford Long was the first to use ether for anesthesia, in 1842. The story is fascinating, though it was ultimately tragic for its eccentric major characters. Because our interest is in the patent, we focus on Morton and Jackson.

Morton first successfully used ether anesthesia for a tooth extraction on September 30, 1846. The dispute between Morton and Jackson revolved around Jackson’s role in that first use. Though there are various versions of events, all agree that Morton and Jackson discussed the possibility of ether anesthesia shortly before Morton’s first use and that Jackson supplied the ether. Morton, however, claimed that he had had the idea of ether anesthesia before their conversation, while Jackson claimed to have instigated and directed Morton’s attempt.

Whatever the real story may have been (and there are reasons to doubt both versions), after the initial success Morton began immediately to look for ways to make money from the discovery. He advertised painless tooth extraction services (unsurprisingly, drawing quite a few takers), invited press attention, and consulted a patent attorney. He also attempted to keep the composition of the anesthetizing inhalant secret, at least in the beginning.

Morton attracted the attention of Dr. Henry J. Bigelow, a young surgeon at Massachusetts General Hospital (MGH). After observing several tooth extractions, Bigelow persuaded two senior surgeons at MGH, Drs. John Collins Warren and George Hayward, to allow Morton to attempt ether anesthesia during surgeries they performed in mid-October. The success of those attempts sparked interest in adopting ether anesthesia as a standard practice at MGH. As a prerequisite, Warren and Hayward demanded to know the composition of the anesthetic agent, so that its safety could be evaluated.

24 How It All Began, supra.
25 See, e.g., J.M. FENSTER, ETHER DAY (2002); WOLFE.
27 Report of the Committee on Surgery, in AMA TRANS. 159, 179 (1848).
29 WOLFE
31 George Hayward, Some Account of the First Use of Sulphuric Ether by Inhalation in Surgical Practice, Boston Med. and Surgical J. p. 1 (Apr. 21, 1847); One of the Surgeons of the Mass. General Hospital, Boston Med. and Surgical J. p. 1 (Mar. 24, 1847)
Morton resisted disclosing his formulation, while moving quickly to apply for a patent and to set up a network of licensing agents. On October 19, 1946, a week before submitted the patent application, Morton contacted Wells and attempted to recruit him as a licensing agent:

I have discovered a preparation, by inhaling which a person is thrown into a sound sleep; . . . the severest of surgical and dental operations may be performed, the patient not experiencing the slightest pain. I have patented it and am now sending agents to dispose of the right to use it. I have used [it] ... in over one hundred and sixty cases in extracting teeth. My object in writing you is to know if you would not like to visit New York and the other cities and dispose of rights.\(^{32}\)

Wells visited Morton the following week. He later maintained that during the visit he observed several failed attempts, found out that Morton had not yet even applied for a patent, and decided that he wanted nothing to do with the endeavor.\(^{33}\)

Jackson, whose primary interest was in scientific credit, was uncomfortable with patenting, because of the medical profession’s general disapproval of patents. He proposed initially that Morton pay him a consulting fee and patent the invention independently.\(^{34}\) Morton’s attorney, R.H. Eddy, apparently advised Morton that Jackson should be included as a co-inventor and urged Jackson to join the patent application to ensure scientific credit. Eddy assured Jackson that, while members could be expelled from the Massachusetts Medical Society for dealing in secret remedies, he could not be expelled simply for patenting.\(^{35}\) Jackson, who had been involved in an earlier credit dispute with Samuel Morse involving the telegraph patent,\(^{36}\) apparently was convinced.

Morton and Jackson filed a joint patent application on October 27. Jackson immediately assigned his rights to Morton.\(^{37}\) He was to be compensated $500 for his “professional advice,” to be paid over time at 10% of licensing revenue.\(^{38}\) On November 7, Morton reluctantly agreed to disclose the composition of his anesthetic agent to the MGH surgeons. More operations ensued.\(^{39}\)

The patent, entitled “Improvement in Surgical Operations,” issued in record time on November 12, 1846.\(^{40}\) The specification described the “discovery that the inhalation of [ether] vapors (particularly those of sulphuric ether) would produce insensibility to pain …” and the

\(^{32}\) WOLFE at _.

\(^{33}\) Horace Wells, Letter to the Editor, Boston Med. and Surgical J. p. 298 (May 12, 1847)

\(^{34}\) WOLFE at _.

\(^{35}\) Id.

\(^{36}\) Id.

\(^{37}\) Id. at 103.

\(^{38}\) Review of Dr. M. Gay's Statement of Dr. Charles T. Jackson's Claims to the Discovery of the Inhalation of Sulphuric Ether, as a preventive of Pain, Boston Med. and Surgical J. p. 1 (June 30, 1847).

\(^{39}\) WOLFE at 80. Report of the Committee on Surgery, in AMA TRANS. 159, 180 (1848); J. Mason Warren, Inhalation of Ether: One of the Surgeons of the Mass. General Hospital, Boston Med. and Surgical J. p. 1 (Mar. 24, 1847); George Hayward, Some Account of the First Use of Sulphuric Ether by Inhalation in Surgical Practice, Boston Med. and Surgical J. p. 1 (Apr. 21, 1847)

\(^{40}\) U.S. Patent No. 4848 (Nov. 12, 1846).
“invention” of “combining [the discovery] with or applying it to any operation of surgery for the
purpose of alleviating animal suffering, as well as of enabling a surgeon to conduct his operation
with little or no struggling or muscular action of the patient and with more certainty of success.”
It claimed “the hereinbefore-described means by which we are enabled to the above highly-
important improvement in surgical operations — viz. by combining therewith the application of
ether or the vapor thereof — substantially as above specified.” In other words, the patent
claimed the use of ether for anesthesia during surgery, with a “preference” for sulphuric ether.

The credit controversy began before the ink on the patent application was dry. Henry Bigelow
publicized the discovery by delivering a paper describing his observations of Morton’s cases to
the American Academy of Arts and Science and the Boston Society of Medical Improvement in
early November 1846. Bigelow’s paper was published in the Boston Medical and Surgical
Journal on November 18, “whereby the news of the discovery was promulgated to the world.”
Jackson reacted immediately. On November 13, he wrote to a Parisian colleague describing
“his” discovery of ether anesthesia and asking the colleague to transmit a report of “Jackson’s”
discovery to the French Academy of Sciences. Jackson’s letter, and his colleague’s later-
published report to the Academy, omitted Morton’s role in the discovery entirely.

The credit dispute continued unabated for decades (in fact, the question is to some degree
unresolved to this day).

2. Morton’s Attempts to Monetize the Patent

After obtaining the patent, Morton stepped up his commercialization efforts, anticipating that
the patent would lead to great wealth. He advertised that he would furnish trained individuals
to provide anesthesia during surgery, circulated a term sheet for five-year licenses to dentists and
advertised licenses to surgeons for a royalty of 25% of surgical fees. Those who refused to take
out licenses sometimes were threatened with litigation. Morton hired a number of agents to sell
the licenses. Somewhat ironically, those agents apparently sometimes credited Jackson with the
discovery, since his reputation reassured potential licensees about the procedure’s safety.

41 Id. at 2.
42 Id. Morton, with co-inventor Augustus Gould, also patented an apparatus for ether inhalation a year later. U.S.
Pat. No. 5365.
43 Henry J. Bigelow, Insensibility During Surgical Operations Produced by Inhalation, Boston Med. and Surgical J.
p. 1 (Nov. 18, 1846).
45 WOLFE at 120-121
46 WOLFE at 105.
47 Id. at 106.
48 Id. One purchaser presaged today’s disputes about “patent trolls” by stating later that his lawyer strongly doubted
the patent’s validity and “advised him not to pay anything for the license unless he should be inclined to do so on the
ground that it was preferable to pay a small sum rather than run the risk of being troubled by Dr. Morton for alleged
violation of his patent.”
49 Id. at 107.
Morton also invested heavily in lobbying Congress for official credit and compensation for the discovery in light of its military use.\textsuperscript{50} Morton's petitions drew responsive petitions from supporters of other claimants. Morton's efforts continued on and off for 25 years.\textsuperscript{51} For several years, many physicians, especially in Boston and New York, supported Morton's petitions and were sympathetic to the financial difficulties he suffered after devoting his time and money in patent licensing and lobbying efforts, to the neglect of his dental practice. A December 1858 Letter to the Editor described efforts to assist Morton after "twelve years of bitter and relentless persecution" had resulted in "professional prospects destroyed, health ruined and years of unsuccessful application to Congress for justice."\textsuperscript{52} The letter named a long list of medical community supporters, topped by MGH, along with amounts donated to a fund for a "National Testimonial" to Morton. An "Appeal to the Public by Members of the Medical Profession"\textsuperscript{53} solicited subscriptions to the fund.

Eventually, when his licensing and lobbying efforts failed, Morton filed the lawsuit\textsuperscript{54} against New York Eye Infirmary that resulted in the ether patent's invalidation in 1862.\textsuperscript{55} Morton's resort to litigation turned the tide of medical community opinion against him. Many of his supporters had relied on his representations that the patent would not be enforced.\textsuperscript{56} Dr. Willard Parker, one of the primary movers in the "national testimonial" effort, testified at the trial:

I had a conversation with Morton about it, and he said that he had abandoned the patent, and was now throwing himself upon the humanity of the world; I then took him cordially by the hand and introduced him to a large number of gentlemen in the profession; he made a statement at a meeting we had of what he had gone through with, and of his purpose with regard to the patent, and explained about a suit which had been commenced against the Chelsea Hospital; measures were taken by the profession here to raise funds for him; the New-York Hospital paid him $500, and Bellevue $1,500; I went down to South-street and raised


\textsuperscript{51} See JAMES GREGORY MUMFORD, A NARRATIVE OF MEDICINE IN AMERICA 422-24 (1903); RICE AT 457-58; Stephanie Browner, Ideologies, supra at 111.

\textsuperscript{52} John Watson, Letter to the Editor, The Invention of Anaesthesia-National Testimonial to Dr. Wm. T. G. Morton, N.Y. TIMES, Dec. 3, 1858, at 2.

\textsuperscript{53} APPEAL TO THE PUBLIC BY MEMBERS OF THE MEDICAL PROFESSION (1859)

\textsuperscript{54} See JAMES GREGORY MUMFORD, A NARRATIVE OF MEDICINE IN AMERICA 422-24 (1903); RICE AT 457-58; Stephanie Browner, Ideologies, supra at 111.

\textsuperscript{55} Morton v. New York Eye Infirmary, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

\textsuperscript{56} New Eng. J. Med. (Sept. 16, 1858); New Eng. J. Med. (Sept. 23, 1858); New Eng. J. Med. (Sept. 30, 1858); Law Reports, N.Y. Times (Jan. 31, 1862)
several hundred dollars for him on the ground that he was a benefactor to the world; that was done on the idea that he had abandoned his patent, otherwise not a thing would have been done.57 (Emphasis added.)

The Morton v. New York Eye Infirmary opinion is known for its classic statement of the difference between patentable inventions and unpatentable scientific discoveries:58

[The principles of patent law] secure to the inventor a monopoly in the manufacture, use, and sale of very humble contrivances, of limited usefulness, the fruits of indifferent skill, and trifling ingenuity, as well as those grander products of his genius which confer renown on himself, and extensive and lasting benefits on society. But they are inadequate to the protection of every discovery, by securing its exclusive control to the explorer to whose eye it may be first disclosed. A discovery may be brilliant and useful, and not patentable. No matter through what long, solitary vigils, or by what importunate efforts, the secret may have been wrung from the bosom of Nature, or to what useful purpose it may be applied. Something more is necessary. . . . Neither the natural functions of an animal upon which or through which it may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential parts of the combination, however they may illustrate and establish its usefulness.59

In the end, Congress also did nothing. Ironically, Morton’s patent was partly responsible for this result. Opponents of legislative compensation repeatedly argued that Morton’s proper recourse was to sue individual army surgeons for infringement. As one senator put it, "If the principle is to be recognized that we are to extinguish patent rights whenever an important invention is made, the Patent Office will cease to be of any benefit whatever, and you may as well abolish it, and repeal all the patent laws at once."60 In essence, many in Congress apparently believed that, having chosen to cast his lot with the patent system, rather than the system of scientific honors, Morton was stuck with that choice.

3. Medical Community Reaction to the Ether Patent

Despite support for Morton’s claim to credit, the ether patent itself provoked immediate controversy in the medical and dental communities. Bigelow’s November 18th article attempted a preemptive defense of the patent, acknowledging that “discoveries in medical science” have generally been rewarded “indirectly by fame, honor, [and] position,” but arguing that special circumstances excused patenting in the ether case. Bigelow contended that ether anesthesia was “capable of abuse, and can readily be applied to nefarious ends,” was “not yet thoroughly

60 32 Congress 2nd. Sess. Cong. Globe 1003 1853
understood, and therefore “should be restricted to responsible persons.” He also suggested that the medical norm against patenting was not shared by practitioners of “the mechanical art of dentistry.” Finally, Bigelow argued that the patent would not hamper medical treatment because the patentees’ intentions were “extremely liberal with regard to the medical profession generally” and “so soon as necessary arrangements can be made for publicity of the process, great facilities will be offered to those who are disposed to avail themselves of [it].”

Bigelow’s efforts to nip opposition in the bud were unsuccessful. Well-known dentist Josiah Flagg’s impassioned response to Bigelow noted that ether was a well-known part of the “material medica,” available to all physicians, which he himself had “administered to patients hundreds of times,” “often swallowed,” and “inhaled til [he] was all but lost in sleep.” Foreshadowing the rationale of the Morton v. New York Eye Infirmary court, he doubted the patentability of a “natural effect” such as “the operation of a well-known medicinal agent.” Flagg scoffed at Bigelow’s arguments that special circumstances excused the patent, doubting that a profit seeking patent holder would best protect society from anesthesia’s potential dangers: “If the right is to be sold, and every opportunity is to be improved to make money of it, and all may buy who please, I do not see how the abuses to which it may possibly be put by evil-minded persons are to be restricted by such a patent.” Rather, Flagg argued: “Who are the most responsible persons to be trusted with this agent? … [I]n three words, regular physicians, surgeons and dentists.” Flagg also hotly disputed Bigelow’s contention that dentistry’s norms were more permissive of patenting than the norms of medicine. He advocated resistance: “I shall not obtain and use it as a secret medicine—I shall not purchase and use it as a patent medicine. If it is simply sulphuric ether, and it will produce the desired effect, I shall use it, and so will others who wish to do so.”

Bigelow replied that the discoverers of an “inestimable boon” to humanity such as ether anesthesia deserve a “substantial return in some shape or other,” and argued that there was “no evidence that the invention would not have slept for twenty years longer, had not Drs. Morton and Jackson demonstrated it to the public.” He derided “the tribe of ex post facto inventors, who always settle like parasites upon every recent invention of any pecuniary value.” “Suffering humanity,” he suggested, could be assisted equally well by Morton and those licensed under his “reasonable terms” as by those who would disregard the patent.

Flagg’s position that attempting to “prevent the free use of any article of discovery which would be of universal benefit in relieving human … suffering, is derogatory to the character of an enlightened liberal profession” prevailed. The AMA, which held its first meeting in May 1847, adopted a Code of Ethics adopted Flagg’s position that medical patenting was “derogatory to professional character.” The following year, the Association’s Committee on Surgery presented an extensive report on ether anesthesia, which included a scientific paper by none other than Henry Bigelow. The report

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61 Bigelow, Insensibility, supra.
63 Id.
64 Id.
66 WOLFE at 110.
67 Id. at 176-224.
collected the medical community’s experience with ether and its close cousin, chloroform, and assessed their safety and efficacy for surgical anesthesia. The report did not take sides in the priority dispute or mention patents, but “regret[ed] that the early history of the discovery is encumbered with angry disputes amongst rival claimants for the honour, and that attempts were made by those most intimately interested in the claim, to render their private interests paramount to those higher considerations which should animate the disinterested love of truth.”

Bigelow continued to engage the issues of patenting and credit along with the science. Just before the 1848 AMA meeting, he published “Etherization—A Compendium of its History, Surgical use, Dangers, and Discovery” in The Boston Medical and Surgical Journal. There he retreated from his earlier defense of the patent, claiming that he had “vainly endeavored, as far as [his] very humble influence might weigh, to prevent the final measures for procuring it.” And conceding that “[i]t does not harmonize with our better impulses, that a great invention in the art of relieving human suffering should be in any way conditional.” He had, he said, predicted that “an invention may be so valuable as to be worthless to the patentee in a pecuniary point of view. In other words, the encroachment of the multitude may become too formidable for the resistance of an individual.”

Nonetheless, Bigelow lamented that overly fastidious attitudes toward patenting had delayed its adoption and argued that considerations such as “quackery and professional etiquette … should fall before a question of this magnitude.” He ruminated at length about the nature of invention, acknowledging that nearly-simultaneous discovery is commonplace because of shared community knowledge: “[t]he world, whether in science or art, is built up to a certain point, by the easy and wide transmission of knowledge, and upon this elevation stand a multitude of philosophers, engaged, often, in identical researches, and who will be possessed of much information upon the subject to which a discoverer first gives utterance.” Yet Bigelow emphasized the importance of “the true inventor’s mind,” characterized by “an invincible determination to compel the world to recognize the reality and value of its invention.” He thus concluded that Morton was the “real discoverer” of ether anesthesia because he “verifie[d] the suggestion, from whatever source it emanated,” “made and modified the experiments at his own discretion,” and “assumed the responsibility of danger” in experimenting with it. Credit belonged, in Bigelow’s view, to the one who publicized a discovery: “The world has always honored that individual among such discoverers who presented his discovery to them.”

An 1856 AMA Committee Report took a different view of the relative importance of individual and community contributions to improvements in medicine. Considering the advisability of Congressional forays into assigning credit and compensation for medical discoveries in light of the ether controversy, it concluded that Congress lacked the expertise to decide who deserved

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68 Id.
69 Report of the Committee on Surgery, in AMA TRANS. 159, 178 (1848).
71 Id., Pt. II.
72 Id., Pt. II at 1.
73 Joshua B. Flint, Report of the Best Mode of Rendering the Patronage of the National Government Tributary to the Honor and Improvement of the Profession, in AMA TRANS. 531, 542 (1856)
Congressional action also was inappropriate because “Congress undertook to compliment and reward, for an alleged improvement in medical science and practice, an individual instead of the profession.” Far from being due to individual luck or effort, the report argued:

> [E]very real improvement in medicine, every contribution to its curative resources which time and scrutiny have sanctioned—all have been results of patient and prolonged investigation, conducted by a succession of cooperative laborers, with every advantage which the light of science and methodical habits of study could supply. Never have there been, properly speaking, discoveries nor revelations, but always inductions—not the production and property of an individual, however fortunate or sagacious, but the legitimate fruits of the common efforts and devotion of a venerable and progressive calling.

Morton’s actions, which for Bigelow had exemplified the importance of the individual who delivers an invention to the world, served instead to illustrate the futility of individualistic approaches to medical advancement. Morton’s patented procedure was nothing but an “arrant piece of quackery” until it was subjected to the testing, verification, and improvement functions of the medical community:

> Not until it had been stripped of its secrecy, and Letheon had become sulphuric ether, under the demands of the profession; not until the principles of medical science had been applied to the administration of its vapor by inhalation, by the profession; not until the conditions of safety for this administration had been investigated and approximately determined by the profession, did anaesthetic etherization become a boon to humanity, or anything else than a seductive and dangerous nostrum. We submit, then, that whatsoever debt of gratitude the world has incurred in this behalf was due to the medical profession, and not to Dr. Morton, nor to either of his competitors.

Consistent with its community theory of invention, the report strongly criticized medical patenting, concluding that “it is very plain that no good has come, or can come to [the progress of the healing art and the true character of the profession] from the patronage of the Patent-office. Patents even give “indirect discouragement [to] legitimate medicine” by attributing medical progress to “fortuitous events in the practice of lucky doctors, or inspirations vouchsafed to favored ones; lucky hits of some bold experimenter, or rightful

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74 This issue also was at the forefront of the Congressional debate, prompting an ultimately unsuccessful legislative proposal to have the credit issue determined by a district court. See 32 Congress 2nd. Sess. Cong. Globe 1057 1853; 32 Congress 2nd. Sess. Cong. Globe 1003 1853; 33rd Congress 1st Session Cong. Globe 943 1854; 33rd Congress 1st Session Cong. Globe 1854. Stephanie Browner, Ideologies, supra at 111.

75 Id.

76 Id. at 537.

77 Id. at 542.

78 Joshua B. Flint, Report of the Best Mode of Rendering the Patronage of the National Government Tributary to the Honor and Improvement of the Profession, in 9 AMA TRANS. 531, 534, 537 (1856) (emphasis in original).
rewards of the vaunted devotion and experience of adroit specialists,” rather than to the efforts of the community as a whole.

When Morton renewed his efforts to obtain compensation from Congress after the patent was invalidated in 1862, the medical community apparently had had enough. At its June 1864 meeting, the AMA passed a resolution opposing those efforts on grounds of “his unworthy conduct, also because of his unwarrantable assumption of a patentable right to anesthesia; and, further, because private beneficence in Boston, New York, Philadelphia, and other places, has already sufficiently rewarded him for any claims which he may justly urge.” In the long run, Morton’s attempt to buck the medical profession’s anti-patenting norm was unsuccessful, in part because many in the medical community refused to acknowledge the legitimacy of his patent long before it was held to be invalid as a legal matter.

C. Ether Anesthesia and the Anti-Patent Norm from a User Innovator Community Perspective

The AMA’s patenting ban in the latter half of the 19th century reflected not only an attempt to distinguish reputable physicians from charlatans and quacks, but also a particular theory of medical innovation. That theory, expressed perhaps most eloquently in the 1856 AMA Committee Report, held that medical progress is best promoted by sharing information about medicines and treatments among physicians, thus providing a basis for cumulative discovery and permitting the community’s expertise to be brought to bear in assessing the worth of new treatments and medicines. Under this community-based system, rewards for success are most appropriately bestowed by the community, in the form of reputation. The 1856 Report contrasted this system with the individualistic “old vulgar idea, according to which valuable improvements in the treatment of disease have originated … as fortuitous events in the practice of lucky doctors, or inspirations vouchsafed to favored ones; lucky hits of some bold experimenter, or rightful reward of the vaunted devotion and experience of adroit specialists.”

The perspective articulated in the 1856 AMA report and elsewhere during the ether patent dispute is remarkably aligned with the prototypical user innovator community approach to innovation. The assumption was that important medical innovations arise out of the combined expertise and experience of physician users. Indeed, every claimant to the discovery was a medical or dental practitioner, who developed anesthesia through and for use in his practice. Reciprocally sharing medical innovations provided physicians with the direct benefits of use, improving their ability to treat their patients and, presumably, helped “regular” physicians to compete with proprietary medicine purveyors and practitioners of other healthcare approaches. The community honed and tested the innovations its members shared. The 1848 Committee on Surgery Report illustrates this user innovator community function, pooling physicians’ experiences with the safety, efficacy, range of applicability, and so forth, of ether anesthesia and chloroform. The fight over credit testifies to the value of the reputational rewards bestowed by the community. As illustrated by the MGH surgeons’ refusal to adopt Morton’s procedure until

79 Id.
80 15 AMA TRANS. 53 (1865).
81 Jackson is a slight exception, in that he apparently was not practicing as a physician in 1846. However, he was clearly a part of the academic medical community at Harvard Medical School.
he disclosed his chemical formulation, the community’s norms enforced disclosure and punished secrecy.

The events following Morton’s patenting of ether anesthesia illustrate patenting’s’ potential to disrupt the physician user innovator community, while simultaneously demonstrating the community’s enforcement of the anti-patent norm. It is certainly possible that there would have been a dispute about credit for such a monumental discovery regardless of patenting (particularly since Jackson was involved). Nonetheless, the patent appears to have disrupted the process of assigning credit in several ways. First, the patent did not provide the legitimacy that might have attached to the community’s collective assignment of credit, presumably prolonging the dispute. Second, the patent introduced a winner-take-all element into the assigning credit that would not have been necessary under medical community norms. Because reputational rewards are more nuanced than the assignment of patent claims to particular inventors, they more easily accommodate overlapping and shared credit. Third, patenting appeared to provide a means to defect from the community reward system in favor of patent-based, rather than reputation-based, monetary rewards. Finally, the patent was seen as comparably problematic with secrecy, since patent-based disclosure did not give the community the right to use and evaluate the discovery.

Why did Morton violate the anti-patenting norm? Was he a defector from the medical community’s reputational reward system or an innovative outsider who needed the patent system to stake his claim? Morton’s position was complicated. He was a dentist, not a doctor, though he had begun medical training. Whether the anti-patenting norm was well-established among dentists is unclear, as evidenced by the dispute on this subject between Bigelow and Flagg. Data on patenting collected in 1866 by an AMA Committee on Patenting and Medical Men at least suggest that patenting was more tolerated in dentistry than in medicine.82 Flagg himself drew a distinction between dental devices and the ether anesthesia process. It seems likely that dentistry’s norms were in flux at the time. Nonetheless, events do not suggest that Morton was an outsider to the reputational reward system. Despite his reportedly shady past and the fact that he did not come from a well-connected family, by 1846 he seems to have had good connections in the medical community. He was given the opportunity to demonstrate ether anesthesia to the most important Boston physicians of the day. Despite Jackson’s attempt to leverage his well-established reputation, many respected members of the medical community took up Morton’s claim for reputational credit, petitioning Congress on his behalf and arranging a fund to honor his work. Morton’s troubled history suggests that he was not averse to violating norms and legal rules in pursuit of financial gain. There is probably no need for a more complicated explanation of his decision to violate the anti-patenting norm.

Though it did not keep Morton from seeking the patent, the community’s anti-patenting norm prevailed in the end. It is interesting to consider why. First, Morton was not such an outsider to the medical community that he could afford to thumb his nose at it entirely. Since he was limited in the number of patients he could anesthetize himself, he needed cooperation from the medical community for his business plans to succeed. He needed to convince surgeons to try his method. He needed the community’s vetting to show that ether anesthesia was safe and effective. He relied on Jackson’s name and reputation in licensing his patent. Another factor

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key to the community’s ability to enforce the anti-patenting norm was the difficulty Morton would have faced in detecting widespread infringement of the patent and obtaining relief in court. As Bigelow put it, “the encroachment of the multitude may become too formidable for the resistance of an individual,” especially when the multitude views ignoring the patent as moral behavior aimed at patient welfare and preserving community norms. Finally, Morton failed in his attempt to have it both ways, by accumulating both reputational credit and patent royalties. Eventually, both Congress and the medical community adopted a “live by the sword, die by the sword” attitude: by relying on the patent, Morton was seen to have opted out of the reputational reward system.

A more difficult question is the one raised by Henry Bigelow: Did Morton succeed in developing ether anesthesia because he disregarded the anti-patenting norm? Did the physician community innovation system fail? Bigelow suggested that the invention might have been delayed another twenty years without Morton because others did not “discern the value of the toy which had attracted the attention of so many” and because “the human mind …runs in the channels of routine,” whereas innovation may require “incredulity and rejection of authority,” along with “unyielding perseverance.” Bigelow clearly was wrong that, without Morton, the discovery would have been delayed twenty years. There were several near-simultaneous “discoveries” of ether anesthesia. Indeed, Georgia surgeon Crawford Long, who in 1849 published a credible report of trials of ether anesthesia beginning in 1842, is now widely believed to have been the first to perform surgery using ether anesthesia.

But one should not be too quick to dismiss Bigelow’s view. While Morton may not have been the first to employ ether anesthesia, his discovery was certainly the most widely publicized. The publicity given to Morton’s demonstration of ether anesthesia’s effectiveness almost certainly advanced its widespread use. Did Morton’s commercially-inspired promotion efforts beat out the medical community’s publication-based diffusion methods? It is difficult to say for sure. From the outset, Morton shamelessly promoted his discovery, inviting a journalist to observe his first tooth extraction, passing out circulars in Boston, and sending out agents to persuade dentists and surgeons to adopt (and license) the procedure. This self-promotion may or may not have affected the rapidity of diffusion of knowledge about ether anesthesia, since it cannot be separated from the effects of Bigelow’s article and Jackson’s letter in November 1846. Still, it is notable that Wells, who also claimed credit for the discovery of anesthesia (though he focused on nitrous oxide) abandoned his attempts to publicize it after a failed demonstration, while Long seems simply not to have gotten around to publishing his use of sulphuric ether until 1849.

What undoubtedly held many back from experimenting with ether anesthesia was the risk such experiments posed to patients. Bigelow himself notes that Morton’s initial experiments, on himself and on one dental patient, were “insufficient for the most hasty generalization” and said nothing about the “question of danger,” given that “two or three previous cases showed, with

83 Bigelow, Dec. 9 Letter to the Editor, supra.
85 WOLFE at 72-74, 103-109.
86 WOLFE at 92.
equal clearness, that insensibility produced death.” Morton plunged ahead nonetheless, using the technique on “twenty or more” dental patients before convincing the MGH surgeons to attempt its use. Bigelow is generous to Morton in attributing his actions to “unyielding perseverance.” Others did not view this trait so favorably. A December 12, 1846, report by a committee of dentists opposed to patenting described disturbing results of some of Morton’s uses of ether anesthesia and recommended that the safety of ether anesthesia be investigated by the Massachusetts Medical Society before its wide adoption. More damning complaints about Morton’s practices came later from dentist Nathaniel Keep, who entered into what was to have been a ten-year partnership with Morton in late November 1846, only to withdraw from it one month later. Keep, who later became the first dean of Harvard’s dental school, wrote in support of Jackson’s claim to credit in 1847, claiming that many of the operations under Morton’s supervision “were unsuccessful and much distress and suffering ensued” and that Morton’s approach to administering ether made inadequate provision for oxygen supply. According to Keep, Morton “was not at all well acquainted with the nature, properties, and safe and proper application of the vapor ether, and [was] reckless in its use, expressing the most perfect unconcern with its effects upon the subjects of his practice, provided they were only made insensible.” The balance between the risks and benefits of medical innovation is a perennial subject of public debate. Deciding whether Morton is best viewed as a daring patent-spurred innovator unconstrained by the conservative norms of the profession or as a lucky money-grabber who advanced the dissemination of ether anesthesia only at considerable risk to his patients is as difficult as fixing that balance.

III. Outsiders and Twentieth Century Pharmaceutical Innovation

In 1883 the patent office reinforced medical norms against patenting by denying a patent in *Ex Parte Brinkerhoff* on the grounds that “[t]he methods or modes of treatment of physicians of certain diseases are not patentable.” By that time, however, developments in both science and industry were laying the seeds of change in the profession’s patenting norms. Nineteenth century “ethical medicine” norms dictated that new treatments be published, vetted by the medical community, and then, if approved, included in authoritative sources, such as the Pharmacopoeia of the United States of America (USP) and the Dispensatory of the United States of America. The nineteenth century world of pharmaceutical manufacturers was divided into “ethical manufacturers,” who supplied physicians and pharmacists with materials listed in the official sources, and proprietary manufacturers, who produced secret nostrums and patented drugs for sale to consumers. Ethical manufacturers eschewed patenting.

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87 Bigelow, Etherization, supra.
88 Id. at 117-18.
89 WOLFE at 110-11.
90 Id. at 118.
93 See, e.g., PETER TEMIN, *TAKING YOUR MEDICINE* (1980) at 3; Gabriel, *supra* at 144.
By the mid-twentieth century, two societal changes had upset this status quo. Scientific advances, along with the forces of industrialization, moved the locus of drug innovation into the commercial laboratory and out of the physician’s office. In addition, government gradually took over responsibility for vetting new drugs. As a result, the role of physician user innovation of drugs receded (though not entirely), and the anti-patenting norm eventually disappeared.

A. The Rise of the Pharmaceutical Industry

In Europe, particularly in Germany, the 1860s saw the birth of a thriving chemical industry, based in part on the discovery that coal-tar could be used to produce mauve.\textsuperscript{95} Chemical companies routinely patented the chemicals they invented. When they began to apply chemistry to drug innovation, they continued that practice.\textsuperscript{96} In 1900, for example, the German Bayer company sought to patent its improved version of the well-known remedy, acetylsalicylic acid, which it branded Aspirin.\textsuperscript{97} Some United States drug manufacturers also began to sponsor research, primarily into the medicinal potential of plants.\textsuperscript{98} Parke-Davis & Co., one of the “ethical manufacturers,” was an early example, provoking controversy among physicians by promoting remedies its sponsored researchers had discovered.\textsuperscript{99} These companies later formed relationships with universities and in general began to turn themselves into research enterprises.\textsuperscript{100}

In the late 19\textsuperscript{th} century, medical norms generally came under pressure. Some favored radical revision of the AMA Code of Ethics to make it more relevant to changing times.\textsuperscript{101} The debate revolved mostly around the Code’s prohibition on consultation with homeopathic practitioners, which many physicians saw as archaic in light of homeopathy’s increasingly scientific approach. The New York Medical Society split with the AMA over these issues for twenty years beginning in 1882.

In the early 1890s, an AMA committee was tasked with proposing revisions to the Code.\textsuperscript{102} While the anti-patenting rule was not the central focus of debate, revisions to the ban on patenting were considered as part of this process. The proposed revisions would have removed the prohibition on patenting “mechanical appliances used in medicine or surgery,”\textsuperscript{103} leaving the drug patent ban in place. The changing face of the pharmaceutical industry did not go unremarked during the year-long debate, however. Even the AMA’s president, Henry O. Marcy, who opposed the revisions, commented that “[i]n the patenting of medicines, where modern

\begin{footnotes}
\item[95] Id.
\item[97] DUTFIELD.
\item[98] Id.; Gabriel, supra.
\item[99] Gabriel, supra.
\item[100] Beauchamp, supra.
\item[101] Lester S. King, The AMA Gets a New Code of Ethics, 249 JAMA 1338, 1340-41 (March 11, 1983).
\item[102] PROC. 43\textsuperscript{rd} ANN. MTG. AMA, 181 JAMA 797, 802 (June 25, 1892)
\item[103] PROC. 44\textsuperscript{th} ANN. MTG. AMA, 182 JAMA 679, 692 (June 24, 1893)
\end{footnotes}
chemistry is doing so much for our profession, this question is still open to discussion.”

The movement to revise the Code fizzled at the 1894 meeting. When the Code issue returned to the fore in 1902, the AMA adopted what were now denominated Principles of Medical Ethics, which mended bridges with the New York association and generally gave greater authority to the state associations. This time around, modification of the patenting ban no longer was on the table. In fact, as part of its ongoing campaign against proprietary “nostrums,” the AMA joined forces with a coalition of reformers and ethical manufacturers to advocate a legal ban on pharmaceutical product patents, allowing patents on manufacturing processes only. At the time, Europeans so dominated the chemical industry that the idea that American companies might benefit from pharmaceutical product patents was inconceivable to the bill’s sponsor.

However, even as that bill was being debated, the tide was turning. The clash between the old paradigm of “ethical manufacturers” producing ingredients for formulations developed and vetted by physicians and the new paradigm of company-based drug research played out in the famous 1911 patent case, Parke-Davis & Co. v. H.K. Mulford Co. Both plaintiff and defendant were “ethical manufacturers,” both portrayed themselves as scientifically advanced. H.K. Mulford was particularly known for its strong stance against the patenting of medicinal compounds. Parke-Davis, on the other hand, had broken with the anti-patenting norm by obtaining patents relating to adrenaline in 1904.

104 Henry O. Marcy, Letter to the Editor, JAMA 680 (May 5, 1894) (considering, but rejecting the patenting of instruments, but noting that the question was open for discussion “in the patenting of medicines, where modern chemistry is doing so much for our profession”).

105 PROC. 45th ANN. MTG. AMA, JAMA 943, 952 (June 5, 1894)

106 PROC. 53rd ANN. MTG. AMA, JAMA 1639, 1649-53 (June 21, 1902)

107 PROC. 54th ANN. MTG. AMA, JAMA 1364, 1379-81 (May 16, 1903). The change from Code to Principles was intended to delegate more authority to the state medical societies.

108 See, e.g., S. Doc. No. 56-20 at 31-32 (1898); Hearings before the Committee on Patents of the House of Representatives on H.R. 13679 (1904); H.R. Bill No. 11967, 64th Cong., 1st sess. (1916). See also Swanson at 370-72.

109 Between 1900 and 1902, U.S. inventors were responsible for only 2.1% of patents on “carbon dyes” and 9.9% of patents on “carbon compounds,” the category most closely associated with pharmaceuticals. Id. at 31-32. See, e.g., id. at 15-16, 39-40, Comments of Rep. Mann, sponsor of the bill. (“The patent laws have been in place long enough to demonstrate whether our people are going to go largely into the business of obtaining patents on drugs. They have not done it thus far. It is not likely they will in the future to any great extent.”).


111 Beauchamp, supra.

112 See, e.g., JONATHAN LIEBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY 63-64 (1987) (explaining that the leadership of H.K. Mulford & Co. vowed to eliminate patent monopolies and viewed the pharmaceutical industry as members of the medical profession bound by its ethical principles); Beauchamp, supra (claiming that of all of the pharmaceutical companies "H.K. Mulford went [the] furthest to accommodate the anti-patent norm").

The patents at issue in the case resulted from the research of Jokichi Takamine, an agricultural chemist and former Acting Chief of Japan’s Bureau of Patents and Trademarks. Takamine married an American woman and moved to the United States. He became an important cultural ambassador between the countries, arranging Japan’s gift of the famous Washington D.C. cherry trees at around the same time as the adrenaline patent litigation. Takamine’s relationship with Parke-Davis had begun when the company licensed his patent on an enzyme developed for use in brewing, hoping to market the enzyme as an indigestion remedy.

Parke-Davis asked Takamine to work on purifying adrenaline, which was obtained as an extract from animal adrenal glands. Adrenaline’s medical promise was undercut by serious side effects associated with impurities. Takamine’s research resulted in the two patents asserted by Parke-Davis against H.K. Mulford. The patents claimed not only manufacturing processes, but also adrenal extracts “substantially free” of impurities. Parke-Davis introduced a purified adrenaline product, under the trade name “Adrenalin.” Other ethical manufacturers, consistent with earlier practice, introduced competing purified products.

In 1905, breaking with tradition, Parke-Davis sued. In the litigation, Parke-Davis argued that it needed patents on pharmaceutical compounds to compete with German chemical companies. Judge Learned Hand conducted the ensuing trial, issuing an opinion that became the primary basis for patents on natural products, including, much later, “isolated” human DNA. Judge Hand upheld the patents, taking a remarkably different view of medical innovation than had been evident in the Morton opinion. Hand emphasized the discontinuity between Takamine’s work and earlier efforts, and focused on the practical improvement Takamine had achieved:

Before Takamine’s discovery the best experts were trying to get a practicable form of the active principle. The uses of the gland were so great that it became a part of the usual therapy in the best form which was accessible. As soon as Takamine put out his discovery, other uses practically disappeared . . . . All this ought to count greatly for the validity of the patent, and Takamine has a great start, so to speak, from such facts . . . . [H]e has been author of a valuable invention and has succeeded where the most expert have failed.

As the ethical manufacturers adopted patenting, the movement to prohibit patents on pharmaceutical compounds lost momentum. Though the reform effort resurged briefly when there were problems obtaining the patented anti-syphilis drug Salvarsan during World War I, during the war, shortages pushed up prices of this indispensable drug as much as 1000%. Patricia Spain Ward, "The American Reception of Salvarsan," 36 J. HIST. MED. & ALLIED SCI. 44, 60-61 (1981). During the six months the

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114 For further details regarding Takamine’s background, see Harkness at 369-73. For even more details, see William Shurtleff and Akiko Aoyagi, Jokichi Takamine (1854-1922) and Caroline Hitch Takamine (1866-1954): Biography and Bibliography, available at http://www.soyinfocenter.com/books/155.
115 Beauchamp, supra; Harkness, supra.
118 Beauchamp, supra.
119 Remarkably, until the Supreme Court’s recently issued AMP opinion, which struck down patents on isolated DNA and undercut the authority of Judge Hand’s opinion, there was no appellate precedent on this issue.
121 During the war, shortages pushed up prices of this indispensable drug as much as 1000%. Patricia Spain Ward, "The American Reception of Salvarsan," 36 J. HIST. MED. & ALLIED SCI. 44, 60-61 (1981). During the six months the
Congress solved that problem by permitting the abrogation of patents controlled by enemy forces, rather than by banning pharmaceutical product patents.  

B. The Era of FDA Regulation

Eventually, the rationale for the AMA’s stance against drug patenting also was undermined by the profession’s diminishing role in vetting drug safety and efficacy. The AMA’s vetting efforts had evolved into an extensive quality assurance program, involving laboratory testing, which continued into the 1950s. The Food and Drugs Act of 1906 did not disturb the profession’s role, since it focused entirely on regulating mislabeling and intentionally misleading advertising. For a few years, the association flirted with the idea of acquiring and managing patents as a means of quality control. The approach foundered, however. Though the AMA took over a patent on thyroxin in 1918, it refused a patent on a scarlet fever antitoxin in 1924. In 1937, Morris Fishbein, the editor of the AMA’s journal, advocated the establishment of a not-for-profit corporation to hold and manage medical patents, along the lines of the Research Corporation, which had been established for university patents. Fishbein’s proposal went nowhere. The AMA officially abandoned its (non-existent) patent management activities in 1952, citing the German drug was unavailable, a biological variant discovered by American researchers. Salvarsan’s representative made it clear that he would bring suit if distribution of the domestic variant continued once the German drug was again available. Jay Frank Schamberg, Letter to the Editor, Status of Arsenobenzol, 67 JAMA 1776, 1776-77 (1916). These events prompted numerous calls to change the patent laws. See, e.g., Ward at 60 (recounting how JAMA ran editorials about "our infernal-please excuse the expression-and absurd patent laws"); Current Comment, 63 JAMA 585, 586 (1914) (exclaiming that "[w]e may reckon some gain along with the loss [of the drug-supply] if the war leads to a scrutiny with a view to revision of the United States patent laws").

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123 The AMA established a Council on Pharmacy and Chemistry to evaluate drugs. Approved drugs would be published in NEW AND NONOFFICIAL REMEDIES, which was updated yearly, unlike the official pharmacopeia, which were updated only once a decade. Drugs that did not meet the Council’s requirements risked being exposed in JAMA or in one of two AMA publications dedicated to exposing improper remedies: NOSTRUMS AND QUACKERY, geared toward the public, and PROPAGANDA FOR REFORM IN PROPRIETARY MEDICINES, aimed at the medical profession. See JAMES BORDLEY III & A. MCGEE HARVEY, TWO CENTURIES OF AMERICAN MEDICINE 1776-1976 366-67 (1976); FRANK D. CAMPION, THE AMA AND U.S. HEALTH POLICY SINCE 1940 470-74 (1984); Austin Smith, The Council on Pharmacy and Chemistry and the Chemical Laboratory, in MORRIS FISHBEIN, A HISTORY OF THE AMERICAN MEDICAL ASSOCIATION 1847 TO 1947 865, 872-74 (1947). In 1929, the Council instituted a seal of acceptance program, which permitted accepted drugs use the AMA seal in advertising. This program ended in 1955, whereafter JAMA’s advertising revenue skyrocketed. See TEMIN, SUPRA (suggesting that it was no coincidence that “JAMA pages devoted to drug company ads doubled in the mid-1950s” and that increased ad revenue was the true motivation behind the dropping the seal of acceptance program).

124 Proc. Atlantic City Session, 63 JAMA 73, 106 (1914) (ownership of patents for medical devices “for the benefit of the profession and the public”); Proc. Detroit Session, 66 JAMA 2079, 2080 (1916) (ownership of patents on “anything whatsoever that may be used in the treatment of disease or infirmity”)


127 Id. at 51.
complexity of the patent management business, fear of antitrust litigation, and potential conflicts between professional standards and patent management.\textsuperscript{128}

In any event, in 1938 the federal government had begun to take a much more serious approach to drug regulation under the Food Drug and Cosmetics Act, mandating pre-marketing safety assessment. Efficacy regulation began in 1962. Through academic clinicians often are contracted to run clinical trials, the medical profession’s role in drug quality control was significantly diminished.

C. New Norms for a New Innovation Paradigm

During the early twentieth century the paradigm for pharmaceutical innovation shifted. Drug development outgrew the physician’s laboratory and came to be seen as the purview of industrial R&D. The ethical manufacturers’ turn to laboratory-based drug development remained true to the scientific attack on secret proprietary nostrums, but was deeply inconsistent with the traditional physician user innovation paradigm. Rather than benefit from reciprocal sharing of their drug inventions, pharmaceutical companies simply competed for market share. As drug development became seller innovation, a clash with the medical profession’s anti-patenting norm was virtually inevitable. Moreover, once physicians ceased their dominant role in drug innovation and quality assurance, the medical community’s anti-drug patenting norm became essentially a dead letter: community norms can only hope to govern community members.

The eventual result was a dramatic turnaround in the profession’s norms about drug patenting. In 1940, the AMA softened the prohibition against medical patenting to some degree, but this first revision had little practical effect, since it prohibited most uses of patents:

\begin{quote}
It is unprofessional to receive remuneration from patents or copyrights on surgical instruments, appliances, medicines, foods, methods or procedures. It is equally unprofessional by ownership or control of patents or copyrights either to retard or to inhibit research or to restrict the benefit to patients or to the public to be derived therefrom.\textsuperscript{129}
\end{quote}

The patent question then lay dormant for a time, as the AMA grappled with more pressing concerns, including antitrust litigation related to its opposition to Depression-inspired proposals for health care reform,\textsuperscript{130} and controversies over its leadership and its very identity.\textsuperscript{131} The Second World War also intervened.

\textsuperscript{128} Reports of Officers, 150 JAMA 888, 889 (1952); Organization Section, 150 JAMA 1676, 1684 (1952). The short-lived thyroxin experience was the AMA’s sole foray into patent management. Morris Fishbein, supra at 294.

\textsuperscript{129} Organizational Section Proc. New York Session, 114 JAMA 2557, 2567 (1940).

\textsuperscript{130} The AMA was found guilty of conspiracy to restrain trade with respect to its treatment of doctors associated with Group Health Association, a prepayment insurance company with salaried doctors on staff, having threatened to expel GHA doctors from medical societies and impeded them from being granted privileges at area hospitals. Am. Med. Ass'n v. United States, 317 U.S. 519 (1943). See Fishbein, supra at 534-50, for an account of the case.

\textsuperscript{131} See Frank D. Campion, The AMA and U.S. Health Policy Since 1940 113-204 (1984), for an account of the strife within the AMA at this time.
The AMA returned to the patent issue shortly after the Patent Act of 1952 was enacted, approving revised language in 1955:

A physician may patent surgical instruments, appliances, and medicines or copyright publications, methods, and procedures. The use of such patents or copyrights or the receipt of remuneration from them which retards or inhibits research or restricts the benefits derivable therefrom is unethical.

Though the revision was justified in public-regarding terms, it was a dramatic retreat from the anti-patenting position that the organization had held for over a hundred years:

In and of itself, the act of obtaining a patent . . . is not unethical. . . . However, when a . . . patent operates in such a manner as to withhold or retard the benefits of an invention from the very patients whose ills it is designed to alleviate, then the owner of that patent . . . clearly is in a position at variance with ethical conduct.

Excessive royalties from the products of an invention are regarded with disfavor, because they may tend to stifle research and limit the dissemination of its uses and its benefits. Considerations of humanitarian import must not suffer in the interests of financial reward. Scientific and medical educational institutions should be permitted to own patents . . . and receive royalties from them without exposure to invidious criticism, because the monies thus involved accrue to the benefit of the public in the form of the enhancement of medical education and research and in the stimulation of charitable works.

In 1957, the AMA overhauled the Principles of Medical Ethics, reducing the number of principles and making them much less specific. The new Section 2 stated that “[p]hysicians should strive continually to improve medical knowledge and skill, and should make available to their patients and colleagues the benefits of their professional attainments.” The Principles no longer addressed patenting explicitly, though the patent provision was included in a compilation of sections from the 1955 Principles purportedly “included within the spirit and intent of the language of the 1957 edition.”

Since 1957, the AMA has revised the Principles only twice. Instead, the AMA’s Council on Ethical and Judicial Affairs issues ethics Opinions, which, together with the Principles, make up what is currently called the Code of Medical Ethics. Some of these opinions address patents but, consistent with the shift in the ecosystem of pharmaceutical

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136 ID.
innovation, no current ethics opinion of the AMA addresses the patenting of drugs by physicians.

IV. Medical and Surgical Instruments and Cross-Community Collaboration

Though the AMA’s official position on medical device patenting shifted simultaneously with its acceptance of drug patenting, controversy about the norm against device patenting has much deeper roots. An Ohio delegate to the AMA’s 1854 meeting advocated unsuccessfully that patenting of surgical instruments should be allowed. While the distinction between drug and device patents garnered some support, the Ohioans’ stance appears to have drawn the ire of most physicians, who feared that allowing any medical patents would open “the floodgates of quackery” and erase the boundary between “charlatanry and scientific medicine.” The AMA issued an ultimatum: rescind the resolution or be ejected from the AMA. The Ohio Society quickly rescinded, attempting to distance itself from the resolution by claiming that it had been proposed by someone who was “not a practitioner of medicine” and passed at a time when most members had gone home. Its decision was lauded by other state societies.

The debate about the Ohio resolution revolved around whether patented instruments could be distinguished from the odious “patent medicines.” Proponents of allowing instrument patenting emphasized the need to compensate inventors for “skill, time and labor [expended in the production and perfection of instruments]” and argued that patents on medical instruments did

138 7 MINUTES OF THE SEVENTH ANN. MTG. AMA, in AMA TRANS. 9, 30 (1854).
139 11 MED. EXAMINER 348, 367 (1855).
140 See, e.g., Celsius, Letter to the Editor, On the Propriety of Holding Patents for Medical and Surgical Instruments, 16 W. LANCET 346 (1855) (adamantly arguing that the medical profession has incorrectly conflated justifiably disfavored patent medicines with patented devices and that "[e]very member [of the medical profession] is entitled to all the knowledge of any other member, but he is not entitled to all the emoluments arising from such knowledge") (emphasis in original).
141 Editorial, The Ohio Medical Society and Patents, 8 N.J. MED. REP. 274, 274-75 (1855) (exclaiming that the Ohio resolution is "so palpably in conflict not only with the code of ethics of the American Medical Association, but of every medical organization in the land, and with professional sentiment everywhere" and warning that "[t]he system of ratiocination that would declare it not derogatory to professional dignity to hold patents for surgical and dental instruments would open upon us the floodgates of quackery") (emphasis in original).
142 Medicus, Letter to the Editor, Patent Surgical and Medical Instruments, 16 W. LANCET 270, 271, 273-74 (1855) (decreeing that "if the medical profession is to be looked upon as learned, enlightened and liberal, then every member of that profession is entitled to all of the knowledge held by any other member without paying anything for it." and warning that if these patents were allowed it would "lead us [] just upon the ground where quacks have, do, and always will stand. The boundary between us and them would be undefinable. . . . Once take this step, and who can distinguish between charlatanry and scientific medicine?").
143 11 MED. EXAMINER 348, 368 (1855).
144 Proceedings of Societies, 16 W. LANCET 411, 419 (1855) (reprinting the Ohio resolution to rescind, which claims that the person who proposed the earlier resolution is not "a practitioner of medicine" and that he offered it "at a time when many members of the Society had left for their homes, and [it] was not, therefore, the sense of this Society").
145 See, e.g., Miscellanea, 15 N.Y. J. MED. 158, 159-60 (1855) (exclaiming that "our readers and the profession generally will rejoice with this demonstration of the fact that there is sufficient conservatism in its ranks to stay the truant wanderings of young physic") (emphasis in original).
146 Supra note 23 at 270-271 (explaining the arguments advanced by proponents of instrument patents).
not pose the same danger of quackery as patents on medicines. Opponents responded that “[i]f it is right to [patent] an instrument, then it is right to do the same by any other species of medical knowledge,” which also might be obtained by the “devotion of days and sleepless nights.”

Medical advances, according to opponents of patenting, should be compensated by the intrinsic rewards from “ameliorating the suffering of mankind” and the reputational rewards of “professional merit,” while physicians should feel themselves “bound to contribute to the general stock of knowledge,” and thus “impart freely and receive freely, in the spirit of true science.”

The choice was between a “profession of learning and liberality” and a “mere trade.” Patenting threatened to lead to “the ground where quacks have, do, and always will stand,” leaving “the boundary between us and them … undefinable.” Apart from the elitism evident in the comparison between a profession and a “mere trade,” the case against patenting was notable for two implicit assumptions: that medical innovations of all stripes would come from members of the medical profession and that the norm of sharing medical knowledge was threatened by the availability of patents.

In 1866, the debate about medical patenting was revived temporarily by a lengthy report of an AMA Committee on Patents and Medical Men. The report recommended amending the Code of Ethics to permit physicians to patent medical instruments and devices, arguing that since it was not considered unethical to use a patented apparatus, “it should be regarded as no less honorable to obtain a patent for one’s own invention.” Though its recommendation was not adopted, the report’s arguments resonate with today’s debates: 1) patents on medicinal compositions would be preferable to the secrecy that characterized the “patent medicine” business, 2) patent rights could be deployed to guarantee quality, 3) patents provide incentives for the refinement and commercialization of medical inventions, and 4) patents allow those with limited resources to promote their discoveries. The report also alluded to the role of outsiders, noting the need for “employment of skilled mechanics” in producing new instruments and devices.

The 1866 report provides a window into the frequency of medical patenting at the time. The review found only 38 patents granted on medical compounds from 1862-64 (out of 11,640 patents issued), confirming that the so-called “patent medicines” rarely were patented. Similarly, “[i]n Chemistry and Pharmacy, few patents are applied for – secrecy being regarded as a better protection than patents which would reveal the nature of the processes.” Medical apparatus patents were only somewhat more common, with a total of 157 granted, most commonly for dentists’ apparatus (24 patents), artificial legs and attachments to them (33 patents), and miscellaneous surgical instruments (17 patents).

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147 Supra note 21 at 347 (arguing that the profession had become “hyper-sensitive on the subject of patents” and that there is “no parallel between the patent of a surgical instrument and that of a secret medicine, for while the one can be safely and conscientiously used by the honest and candid physician, the other can never be so.”)

148 Supra note 23 at 271.

149 Id. at 274.

150 Id. at 273-74.

151 David Prince & Thomas Antisell, Patent Rights Among Medical Men, in 17 AMA TRANS. 519 (1866).

152 Id. at 527.

153 Id. at 524-25.
At the AMA’s first post-Civil-War meeting in 1870, its newly-elected president strongly re-affirmed the blanket prohibition on patenting, arguing that physicians should feel bound to “contribute to the general stock of knowledge” and thereby “to impart freely and receive freely.” He warned that “[a] false step once taken will involve us in a labyrinth of inconsistencies, and bring dishonor to our beloved profession.”

In 1894, the AMA again revisited the ban on patenting “mechanical appliances used in medicine or surgery.” Advocates of lifting the ban maintained that medical instrument patenting by physicians was already commonplace. One thread of argument attempted to characterize patents on medical instruments as forms of “instruction” in line with traditional knowledge sharing norms. Supporters of the ban hotly (and more convincingly) disputed the comparison. A second thread focused on the role played by non-physicians in developing and distributing medical apparatus in an increasingly industrialized era, questioning whether the ban on physician patenting made sense in that light. One ophthalmologist recounted that when he approached a “very prominent manufacturer of optical apparatus” about an ophthalmoscope he had invented, the manufacturer desired a patent to prevent rival manufacturers from copying the new instrument, proposing to pay the inventor a 10 per cent royalty, as had been its arrangement with others.

The ban on medical apparatus patenting finally fell with the 1955 revision to the Principles of Medical Ethics, which stated that “[a] physician may patent surgical instruments, appliances, and

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154 Address of George Mendenhall, M.D., President of the Association, in 21 AMA TRANS. 77, 95 (1870).
155 PROC. 44th ANN. MTG. AMA, 182 JAMA 679, 692 (June 24, 1893)
156 See, e.g., Harmony, Letter to the Editor, JAMA 718 (May 12, 1894) (comparing patents favorably to copyrights); Leartus Connor, Letter to the Editor, JAMA 854 (June 2, 1894) (comparing patents to copyrights); Edward Jackson, Letter to the Editor, JAMA 544 (May 13, 1893); A.C. Simonton, Letter to the Editor, JAMA 678, 679 (May 5, 1894).
157 Editors, Two Wrongs Do Not Make One Right, MEDICAL NEWS 551, 552-53 (May 19, 1894) (rebuttering the comparison between copyright and patents); Editors, Am. Ass’n Genito-Urinary Surgeons 669, 669-70 (June 16, 1894) (same); Editor, The Report of the Committee on Revision of the Code, MEDICAL NEWS 693 (June 24, 1893) (arguing that “the true parallel is that between patented medicines and patented instruments; not between patented instruments and copyrighted books,” that patents “have a tendency to unduly increase the cost of an instrument, to restrict its application, and to prevent its improvement,” and that, if patents are permitted the profession can expect a “delightful time” as “Professor Biggun hauls Doctor Greathead into court for [infringement]”); Editors, Attenuated Quackery, MEDICAL NEWS 498 (May 5, 1894)(noting the receipt of an advertisement for a medical instrument that included a copy of the inventor’s paper on the subject and opposing revision of the code as likely to lead to more of the same); N.S. Davis, Letter to the Editor, JAMA 556, 558 (April 14, 1894).
158 Compare A.C. Simonton, Letter to the Editor, JAMA 678, 679 (May 5, 1894) (noting that “all physicians use patented instruments and appliances” and that it is considered “perfectly honorable to use a patented instrument, but not honorable to hold patent for an instrument!”); A.C. Simonton, Letter to the Editor, JAMA 460 (April 22, 1893) (call ridiculous the fact that “all admit that it is proper and legitimate to use a patented instrument, provided it was invented by some one outside the profession”) with Editors, Stand by the Code, Occidental Medical Times 201, 203 (April 1894) (disfavoring patents but seeing no great harm from permitting patenting on the assumption that “the greatest number of appliances, and the most valuable, will still be devised by the leaders in the profession, and it is fair to assume that they would not go into the patent rights business, but that it would still be confined to the person who peddle inferior apparatus of their own device at an exhorbitant price”); E.D. Ferguson, Letter to the Editor, JAMA 758, 759 (May 19, 1894) (arguing that “if the invention is likely to be more profitable than the honors and rewards of strictly professional work, then let the inventor cease to practice medicine and surgery, patent his ‘machine’ and enter upon the strictly business methods belonging to its manufacture and sale”);
159 Edward Jackson, Letter to the Editor, JAMA 544 (May 13, 1893).
It is not unethical for a physician to patent a surgical or diagnostic instrument he has discovered or developed. Our laws governing patents are based on the sound doctrine that one is entitled to protect his discovery. Medicine, recognizing the validity of our patent law system, accepts it, but in the interest of the public welfare and the dignity of the profession insists that once a patent is obtained by a physician for his own protection, the physician may not ethically use his patent right to retard or inhibit research or to restrict the benefits derivable from the patented article. Any physician who obtains a patent and uses it for his own aggrandizement or financial interest, to the detriment of the profession or the public, is acting unethically.\(^{161}\)

At some time before 1977, however, the AMA Judicial Council issued a more permissive opinion, which remains in force today:

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.\(^{162}\)

The situation for physician device inventors became even more complex – and more intertwined with industry -- when regulatory controls were tightened in 1976. Before then, medical devices were regulated only post-market. Beginning in 1976, some classes of devices required pre-market FDA approval, substantially increasing the cost of bringing them to market, presumably only increasing the emphasis that manufacturers placed on patenting.

From a user innovation perspective, the difficulty in establishing workable norms for instrument and device patenting arises from the fact that, while physician user innovation of instruments and devices is common, it frequently, and increasingly, requires collaboration with outsiders. While physicians often were able to design instruments and devices independently during the 19th century (and sometimes owned factories to produce them), collaboration with engineers at medical device firms was a routine part of device innovation by the mid-twentieth century. In sum, industrialization, along with the increasing technological complexity of medical devices, resulted in a shift toward joint development of medical devices by physicians and device manufacturers. The relationship between physician inventors and device manufacturers is fraught because of the potential for ethical conflicts of interest, which have been the subject of much


\(^{161}\) Official Opinions of the Judicial Council, 163 JAMA 1156, 1157 (1957).

discussion. From the innovation theory perspective, the loosening of the anti-patenting norm reflected the increasing need to collaborate with outsiders in medical device innovation.

V. Medical Procedure Patenting: The Re-awakening of the Physician Innovator Community

During the 1980s and 90s, patenting in the United States seemed to be on a path of virtually limitless expansion. Optimism about the potential for patents to facilitate medical advances, particularly through the emerging field of biotechnology, was high. In 1980, the Supreme Court approved the patenting of living organisms in *Diamond v. Chakrabarty*, which was seen as giving the green light to biotechnology patenting. That same year, passage of the Bayh-Dole Act was premised on the assumption that patents would facilitate the commercialization of neglected fruits of academic research, particularly in the biomedicines. The pharmaceutical industry played a major role in lobbying for the negotiation and adoption of the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which established minimum standards of intellectual property protection internationally. The Federal Circuit Court of Appeals, which had been established in 1982 largely because of Congress’s sense that the courts were insufficiently friendly to patenting, continued to expand the terrain of patentable subject matter. At this time, and in light of the AMA’s endorsement of device patenting, it would have been natural to assume that the medical profession’s aversion to patenting had finally been laid to rest.

In the mid-1990s, however, something surprising happened – a physician-led movement against medical procedure patents that resulted in the passage of 35 U.S.C. § 287(c), exempting physicians from the enforcement of medical procedure patent claims that did not involve patented drugs or devices. This fight against procedure patenting erupted not over a controversial reproductive technology related to the biotechnology boom, but over a patent in the relatively mundane arena of cataract surgery. This Part tells the story of that patent, the lawsuit brought by Dr. Pallin against Dr. Singer to enforce it, and the resulting movement for legislative reform.

A. Medical Procedures at the Patent Office

Despite its many debates over patenting, the AMA never seriously questioned its ban on physician patenting of medical procedures. The USPTO, however, apparently without fanfare, reversed its longstanding practice of rejecting such claims in 1954. As mentioned above, the patent office had opined in 1883 that “[t]he methods or modes of treatment of physicians of

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167 See, e.g., S. REP. NO. 97-275, at 2, 5-6 (1981), reprinted in 1982 U.S.C.C.A.N. 11, 12, 15-16 (explaining that the creation of the Federal Circuit Court of Appeals is designed to create uniformity in patent decisions and thereby remove the uncertainty and unnecessary costs that has been hindering patents and stifling innovation).

168 See, e.g., *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373-75 (Fed. Cir. 1998) (patents available as long as there is a “useful, concrete, and tangible result”
certain diseases are not patentable.” That rule apparently was alive and well in 1951, when a district court noted, in Martin v. Wyeth Inc.:

Instances 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. . . . Doctors and surgeons have seldom thought it desirable to try to patent their new procedures for human relief. . . . The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage. In this respect it would seem also that public interest is here involved.

In 1954, however, the Patent Office Board of Patent Appeals and Interferences reversed position. A patent examiner had rejected Scherer’s claims to a method of “injecting fluids into the human body” by a pressure jet because they were directed to treatment of the human body, relying on Brinkerhoff and Morton to interpret the 1952 Patent Act’s subject matter provision. On appeal, the Board reconsidered “whether methods in which the subject matter treated is the human body and the object of the method is some medical or surgical purpose are within the field of subject matter capable of being patented” and held that such methods were patent eligible.

Thus, unlike in Europe, where the 1973 Patent Convention precluded patents on methods of medical treatment and diagnosis, medical procedure patents have been available in the United States since 1954. Nonetheless, such patents seem to have been rare (or at least rarely enforced) during the next few decades, most likely because of physician norms. In 1984, the AMA adopted an opinion reinforcing the norm of sharing new medical procedures which, though it did not mention patents, became important in the later debate:

New Medical Procedures: In the ethical tradition expressed by Hippocrates and continuously affirmed thereafter, the role of the physician has been that of a healer who serves patients, a teacher who imparts knowledge of skills and techniques to colleagues, and a student who constantly seeks to keep abreast of new medical knowledge.

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170 96 F. Supp. 689, 694-95 (D. Md. 1951), aff’d, 193 F.2d 58 (4th Cir. 1951).
173 Scherer, supra. The dissenter also distinguished two earlier cases involving “testing method[s]”: Dick v. Lederle Antitoxin Labs., 43 F.2d 628 and Ellis v. Coe, No. 5149, 1941 WL 9598 (D.D.C Mar. 31, 1941) and cited In re Saunders, 154 F.2d 693 (C.C.P.A. 1946).
175 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).
Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. . . . This tradition enhances patient care, leads to the early evaluation of new technologies, and permits the rapid dissemination of improved techniques.

The intentional withholding of new medical knowledge, skills and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.

Prompt presentation before scientific organizations and timely publication of clinical and laboratory research in scientific journals is an essential element of good medical care.176

Seeds of controversy began to be sown in the 1980s, with controversial patents on reproductive medicine procedures. In 1978, Latorre obtained a patent directed to a “Method of Effecting and Enhancing an Erection,”177 which his heirs sold to Men’s Health Resources, Inc., which began demanding royalties from urologists in 1994. Ronald Ericsson, former pharmaceutical biologist and consultant, obtained patents related to procedures for determining fetal gender in 1977 and 1982178 and founded Gametrics, Ltd. as a licensing vehicle. In 1989, Mark Bogart patented a method for pre-natal testing for Down syndrome based on statistical correlations he had observed between HCG hormone level and the syndrome.179 The test suffered from a high false positive rate. In 1988, other researchers published a more effective test, combining measurements of three chemical markers, including HCG. Bogart outraged many doctors by demanding royalties from laboratories that were using the triple screen test. In 1989, John Buster and James Simon of UCLA Medical Center patented the surrogate embryo transfer procedure (SET).180 The SET patent is frequently cited in support of medical procedure patenting because its $500,000 development costs were funded by private investors after the National Institutes of Health (NIH) denied funding, perhaps because of the controversial nature of the research. In 1991, John Stephens patented a method of determining fetal gender from ultrasound images,181 outraging many physicians, one of whom likened it to a method of telling the right hand from the left.182 Stephens’s marketing to particular ethnic communities, viewed as facilitating the preferential abortion of female embryos, added to the disapproval.183

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183 See Kathleen Kenna, Couples Wanting Only Boys Flock to MD for Fender Test, TORONTO STAR, Dec. 10, 1990, at B1, for an account of Dr. Stephens unapologetically explaining his targeted advertising and of the public backlash.

The eventual catalyst for the 1990s physician movement against medical procedure patents was a lawsuit brought by Dr. Samuel Pallin, who had patented a technique in cataract surgery, against fellow eye surgeon Jack Singer. The movement eventually led to the passage of 35 U.S.C. § 287(c), which exempts physicians from remedies for infringement of medical procedure claims. The story illustrates the persistence of sharing norms for procedure innovations, despite widespread and accepted device and pharmaceutical patenting.

1. The Origins of Sutureless Cataract Surgery

Human beings have suffered from, and treated, cataracts (opacity of the optic lens) for millennia. Modern treatment generally involves removing the lens. The early twentieth century saw improved removal methods, yet removal left patients with rather poor vision. In the 1940s, physician Harold Ridley revolutionized treatment by developing an artificial replacement lens. When improved removal methods permitted smaller incisions, flexible replacement lenses, which could be folded for insertion, were developed.

Surgeons sought to minimize trauma to their patients’ eyes by improving incision technique. 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. A surgeon employing the scleral tunnel technique would make an incision partway through the sclera at some distance from the cornea, “tunnel” through the sclera to the anterior chamber, remove the defective lens and insert the artificial replacement through the tunnel, and suture the wound. Sutures were problematic, however, because they could induce astigmatism. Dr. John Shepherd developed a technique for closing the wound with a single, loose stitch, thus mitigating, but not entirely solving, these problems.

In March 1990, the trade journal *Ocular Surgery News (OSN)* described a sutureless cataract surgery technique developed by Dr. Michael McFarland, an Arizona ophthalmologist. McFarland performed his first sutureless surgery in January 1990. Shortly afterward, he phoned Dr. Paul Ernest, a clinical professor at Wayne State University, to discuss his procedure. Ernest replicated McFarland’s technique in February, 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 this “corneal lip” was critical to safe sutureless surgery. Singer visited Ernest during this time and observed the procedure.

At around the same time, Dr. Steven Siepser, a Pennsylvania ophthalmologist, developed another sutureless technique, which he reported at the March 1990 meeting of the American Society of Cataract and Refractive Surgery. Siepser’s film of his sutureless surgery received an award at the meeting’s regular “film festival.”

Siepser’s film and OSN’s report of McFarland’s technique generated both excitement and skepticism, 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 sealing the wound safely and 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.

Dr. Gills had specialized almost exclusively in cataract surgery for nearly twenty years. Though he was not the first to achieve sutureless cataract surgery, Pallin recalled Gills suggesting the possibility of sutureless surgery sometime in the late 1980s. Gills described his incision shape, which he first tested on March 19, 1990, as an “inverted V.” He published a photo of the healed wound from that surgery in an August 1990 monograph, which became a critical piece of prior art in Pallin v. Singer. Though in 1990 Gills believed that incision shape was important, by 1992 he no longer held that view.

Singer first tried what he called a “frown incision” on March 20, 1990 and published a videotape of the surgery in the Audiovisual Journal of Cataract and Implant Surgery. 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.

2. Samuel Pallin’s Patented Chevron Incision

Pallin’s patented “Method of Making Self-Sealing Episcleral Incision” was developed after he saw the McFarland and Siepser reports. He was interested in using hard replacement lenses, but found their techniques unworkable for that purpose. He conceived the idea of a “chevron” incision on April 16, 1990, and performed his first sutureless chevron incision surgery the next day. Pallin’s 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.”

Having performed a successful sutureless cataract surgery (perhaps serendipitously), Pallin pursued two avenues for obtaining recognition: publication and patenting. Pallin submitted a manuscript to the Journal of Cataract and Refractive Surgery (JCRS) shortly after April 17, which was rejected in July. Pallin’s work was, however, reported in August in Ocular

187 Declaration of James P. Gills, M.D. at ¶ 7; Deposition of Dr. James P. Gills at 9.
188 JAMES GILLS AND DONALD SANDERS, SMALL-INCISION CATARACT SURGERY (Slack, Inc. 1990), Entry No. 42, Appx. I, Ex. 2A.
189 Declaration of Jack A. Singer, M.D. in Support of Motion for Summary Judgment of Invalidity at ¶ 8.
190 This appeared in the third issue of the journal’s sixth volume in 1990. Id. at ¶ 9.
191 Id. at ¶ 18.
193 Pallin Decl. at ¶¶ 18-21.
194 Id. at ¶ 27.
Surgery News, the trade journal that had announced McFarland’s sutureless surgery.\textsuperscript{195} Pallin also published a Letter to the Editor in JCRS in November 1990 describing his technique, its applicability to hard lenses, and results from 150 surgeries.\textsuperscript{196} In April 1991, Pallin presented a paper and film entitled “Chevron Sutureless Closure for Rigid Lenses: A Preliminary Report” at an ASCRS symposium.\textsuperscript{197} Finally, in October 1991, JCRS published articles by Pallin, Siepser, Gills, Ernest, Singer, and seventeen others in a volume devoted to sutureless cataract surgery.\textsuperscript{198}

Concurrently, Pallin sought a patent. By April 29, 1990, he had obtained counsel and begun drafting his application, which was filed on June 28.\textsuperscript{199} Pallin’s patent issued on January 14, 1992.\textsuperscript{200} 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
   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 no lack of relevant medical literature,\textsuperscript{201} the examiner considered only seven prior art references, all of which were patents on ophthalmic surgery devices. Pallin did not disclose any references to the patent office and later testified that he did not think that publications such as the McFarland report would have been relevant to his application. The examiner’s failure to cite relevant publications suggests unfamiliarity with the medical literature, perhaps because medical procedure patenting was rare.

3. Pallin’s Resort to Litigation

On June 4, 1993, Pallin’s attorneys sent a cease and desist letter to Singer, alleging that Singer’s frown incision infringed Pallin’s patent and that Singer induced infringement by his “active encouragement and teaching” of the technique. Pallin offered a license in exchange for a “reasonable royalty” and an agreement that Singer would cite Pallin’s patent when promoting the frown incision.\textsuperscript{202} After informal discussions failed to resolve the matter, Pallin sued Singer and the Hitchcock Clinic where he practiced. Settlement negotiations ensued, during which,

\begin{itemize}
\item \textsuperscript{195} See Deposition of Samuel L. Pallin, M.D. Volume II at 210-212.
\item \textsuperscript{196} S. L. Pallin, \textit{Chevron Incision For Cataract Surgery}, 16 J. CATARACT REFRACT. SURG. 779 (Nov. 1990).
\item \textsuperscript{197} Curriculum Vitae Samuel Lear Pallin, M.D., F.A.C.S. at 5, Entry No. 42, App. D, Exhibit 1.
\item \textsuperscript{199} Pallin Decl. at ¶ 26.
\item \textsuperscript{200} U.S. Patent No. 5,080,111 (filed June 28, 1990).
\item \textsuperscript{201} Deposition of Dr. James P. Gills at 6, Pallin v. Singer, No. 2:93-cv-202 (D. Vt. Mar. 28, 1996) (testifying that he read at least ten publications monthly to stay abreast of developments in the field).
\item \textsuperscript{202} Complaint at ¶ 15, Letter from John M. White to Jack L. Singer, Entry No. 1, Exhibit B.
\end{itemize}
according to Singer, Pallin proposed a “graduated royalty of $2,500 - $10,000 per year, which can be increased annually at [his] discretion.” Settlement negotiations during the fall of 1993 were unfruitful.

Before discussing the ensuing events, it is worth pausing to consider why Pallin decided to break with tradition and sue for patent infringement. Pallin’s reasons for obtaining the patent are obscure. According to a pleading, “[a]s 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 patent application . . . was prepared and filed in June of 1990. Media reports repeated the claim that Pallin turned to patenting because his attempts to publish were thwarted. However, according to Pallin’s Declaration filed in December 1994, his patent application and rejected manuscript were prepared at around the same time, certainly before the July 1990 rejection.

Regardless of why he applied for a patent, was Pallin justified in perceiving the rejection of his April 1990 submission as a slap in the face? Perhaps the reviewers were particularly harsh, but Pallin’s expectation that JCRS would publish the article seems to have been quite unrealistic. OSN reports, like those published about McFarland’s technique in March 1990 and Pallin’s chevron incision and Singer’s frown incision in August, were the typical avenue for early reporting of new techniques. As Dr. Howard Fine 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.” In the early summer of 1990, JCRS peer reviewers likely were skeptical of claims of sutureless cataract surgery and inclined to demanded substantial evidence of success. McFarland reported that, because some ophthalmologists thought he “must be some kind of quack or crook,” he hosted some “couple hundred” to observe his technique during the subsequent year. Because sutureless cataract surgery was so novel, Pallin’s April 1990 manuscript simply may have had insufficient data to get past the JCRS reviewers.

Indeed, Gills and a co-author seem to have published the first JCRS article about sutureless cataract surgery in May 1991. Gills served a very large patient population (a 1990 monograph

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203 Singer 2/17/94 Letter to Fellow Ophthalmologists, at 1, Entry No. 24, Ex. B.
204 Plaintiff’s Opposition to Defendants Motion for Leave to Amend at 3.
206 Pallin Decl. at ¶¶ 26-27.
207 Deposition of I. Howard Fine, M.D. at 40.
reported 2000 sutureless surgeries),\textsuperscript{210} which may explain his relatively early JCRS publication. Otherwise, the first JCRS publications about sutureless cataract surgery appeared, alongside Pallin’s, in the October 1991 special issue. Siepser first published there, as did Singer. McFarland seems never to have published his technique in JCRS. Whatever Pallin’s subjective reaction to JCRS’s July 1990 rejection, his publication experience seems to have been unexceptional.

The idea that the litigation was motivated by the July 1990 rejection also is in tension with Pallin’s delay in enforcing his patent after it issued in January 1992. Initially, Pallin sought to donate the patent, first to the ASCRS, then to the American Academy of Ophthalmology (AAO), and finally to a charitable organization. In March 1992, the ASCRS rejected the proffered donation on grounds that the patent was “either invalid or politically sensitive.” The AAO also demurred. Donation to a third organization fell through because Pallin did not want the patent enforced by a “nonmedical agency, which would have little sensitivity to the needs of ophthalmologists.”\textsuperscript{211}

Perhaps, the primary impetus for Pallin’s lawsuit against Singer was these associations’ rejection of his proffered donation or his sense that his contribution was inadequately recognized in other ways. Or perhaps by 1993 the profession was coalescing around an “origin story” for sutureless surgery that did not recognize Pallin’s work. Whatever the immediate trigger, Pallin’s resort to litigation appears to have been motivated more by a desire for recognition by the medical community than by a desire to turn a profit.

4. Singer Takes The Case to the Physician Community

Though Singer may have been only one of “what we expect is a rather long line of people” to be approached for a license,\textsuperscript{212} his reaction to the failure of the initial settlement negotiations was out of the ordinary. Singer and his clinic decided to use the lawsuit as a vehicle for fighting what they believed was a dangerous trend toward medical procedure patenting. In February 1994, Singer sent a mass mailing to fellow ophthalmologists:

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.\textsuperscript{213}

\textsuperscript{210}JAMES GILLS AND DONALD SANDERS, SMALL-INCISION CATARACT SURGERY at 127 (Slack, Inc. 1990), Entry No. 42, Appx. I, Ex. 2A.
\textsuperscript{211}Samuel L. Pallin, Method Patents Benefit Information Dissemination, OCULAR SURGERY NEWS, July 15, 1994, at 19.
\textsuperscript{212}Id.
\textsuperscript{213}Letter from Jack A. Singer and John C. Collins at 1, Entry No. 24, Exhibit B.
The letter sought contributions to defray the costs of the litigation, promising that any surplus contributions would be used “toward efforts to change the patent laws to exclude ‘pure method’ patents for medical and surgical procedures (i.e. those not involving an innovative device or apparatus which is central to the claim).”214 The letter also requested information about potential prior art. OSN published a similar letter in April.215 To cap things off, Singer delivered an impassioned speech, entitled “Free Exchange of Surgical Knowledge,” at an April meeting of the American Society of Ocular Surgeons and received a standing ovation.216

Suddenly, Pallin’s attempt to garner a few thousand dollars per year of royalties had become a cause celebre. Pallin clearly had not expected such a much more conciliatory settlement offer.217 Recognizing that Singer’s “fundamental objection is not to the Pallin patent alone, but to the present availability of method patents on surgical techniques,” 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.” Unappeased, Singer pressed Pallin to disclaim all further enforcement of his patent in exchange for Singer’s acceptance of the settlement proposal. Pallin’s attorney’s response nicely illustrates the culture clash between the patent system’s emphasis on individual entitlements and the medical profession’s community-based approach to innovation. He expressed frustration and some incredulity that Singer insisted on relief for the medical community at large rather than settled the dispute for a small sum:

[A] paid up license allows the defendants in this lawsuit to operate under the patent without any further payments. . . . Further, why would your client want to be the only infringer in the world who has taken a license? In my experience infringers want to be assured that all others in their situation are treated similarly.218

The response also attempted to align Pallin’s actions with medical community norms:

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.219

Pallin’s attorneys viewed Singer’s appeals for support from the medical community as inappropriate. They sought discovery into “[t]he defendants’ public allegations of invalidity and unenforceability and activities to organize a national movement against Dr. Pallin.”220 The court denied the request, stating merely that “questions regarding defendants’ funding of the litigation

214 Id. at 2.
216 Physicians Program at 52, Entry No. 24, Exhibit J; Doctor Implores Principles of Hippocrates to Standing Ovation, OPHTHALMOLOGY TIMES, May 1, 1994, at 28.
217 Letters from James R. Longacre to George Neuner, Entry No. 24, Exhibit N.
218 Id. at 3.
219 Id. at 3.
220 Motion to Compel at 8.
are] not relevant to the pending subject matter."

Pallin’s attorneys’ frustration is understandable. Singer’s appeals to the medical community effectively switched the playing field from one governed by patent law to one governed by medical norms. Though Pallin was the plaintiff in the litigation, he became the defendant in the court of physician opinion, which mattered a great deal to him.

In June 1994, as the public debate intensified, Pallin sent another settlement offer, which represented him as a norm entrepreneur to the medical community. The letter emphasized Pallin’s belief that he was “doing the right thing” and “pioneering the way for others to follow,” asserting that the USPTO Official Gazette reflected increasing numbers of medical procedure patents and that inventors were “watching this debate.” Acknowledging Singer’s “goals of embracing a political debate within the profession” and of “ensuring that [] the Frown remain available to everyone,” Pallin offered to 1) forego injunctive relief entirely, 2) forego any claim based on teaching or espousing the frown technique, 3) debate Singer about medical procedure patenting at a professional meeting; 4) credit Singer for his contributions to popularizing the frown incision; and 5) leave Singer “free to speak his mind with regard to this subject” as long as he stopped short of slander. Pallin’s attorney evidently was uncomfortable with this proposal, writing “somewhat reluctantly” for fear that Singer would conclude that Pallin was “close to throwing in the towel.”

Eventually, Pallin went so far as to offer the defendants a royalty-free license. When that offer was rebuffed, he informed Singer that he had decided to “proceed and grant the license . . . unilaterally,” and that there was no remaining jurisdiction for the suit. Singer spurned this attempt to move back onto the patent system playing field, demanding nothing less than dedication of the patent to the public or something of equivalent effect.

In the end, the parties were unable to come to terms. Despite Pallin’s offer of virtually complete surrender in the particular case and his willingness to make some concessions about his future enforcement plans and despite the significant litigation expenses, neither party was willing to back down on the patent validity question. In October 1994, Singer moved for summary judgment of noninfringement and of invalidity in light of the work of Gills, Singer, and McFarland. It was time for the court to weigh in.

5. Pallin and Singer Face Off Before the Court

The summary judgment arguments centered on questions of claim construction: Did the preamble term “substantially self-sealing” limit the claims? How should that term and the clause describing the incision shape be construed? In May 1995 the court denied the motion, leaving

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221 Opinion and Order at 2, Entry No. 29.
222 Letter from James R. Longacre to George Neuner at 2-3, Entry No. 37, Exhibit C
224 Letter from James R. Longacre to George Neuner at 1, Entry No. 37, Exhibit E.
225 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).
226 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).
these questions unresolved, on grounds that they involved “complex factual disputes.”

(No one seems to have noticed that the Federal Circuit had just held, in Markman v. Westview Instruments, Inc. that claim construction is a matter of law for the court to decide.) It seemed that the case was on track for trial.

Fate intervened, however. Judge Billings, who had been presiding, had taken senior status in September 1994. In September 1995, he reassigned his pending cases to newly appointed Judge William Sessions. On November 15, 1995, Singer’s attorneys requested a hearing on claim construction based on the Markman decision. Around this time, Singer retained the Chicago litigation firm, Jenner & Block, which also represented a newly-formed coalition of medical associations opposed to medical procedure patenting.

Judge Sessions scheduled a Markman hearing for March 1996. In February, Singer moved for summary judgment in anticipation of the claim construction rulings. The hearing did not go well for Pallin. On March 28, the court issued a consent order declaring all of the patent claims invalid and noninfringed and ordering Pallin not to take any enforcement actions. The result was widely reported in the medical and mainstream media. Pallin, however, did not acknowledge defeat, maintaining 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 been achieved.” He continued to defend medical procedure patenting in the media and expressed satisfaction that the case had publicized their patent eligibility.

The Pallin v. Singer litigation ended in March 1996 without generating any pathbreaking ruling on the patentability of medical procedures (or anything else, for that matter). Both doctors

227 Order and Opinion at 7, Entry No. 57.
229 Defendants’ Motion for Summary Judgment, Entry No. 74. Pallin’s response to the motion is notable because the brief argues that Markman’s rule about claim construction applies only to infringement and not to validity, an argument that could only have been made at a time when Markman hearings were not yet a routine part of patent litigation. Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid at 21, Pallin v. Singer, No. 2:93-cv-202 (D. Vt. Mar. 28, 1996), Entry No. 83.
230 See Pallin Patent Claims Invalidated; Physicians free to perform cataract surgery without threat of infringement litigation, PR NEWSWIRE (March 29, 1996).
continued their careers in ophthalmological surgery. As recently as July 2006, EYEWORLD published a report by Singer about newfound uses for the frown incision. Singer passed away in 2011. Pallin published a report on “Smooth versus Rough Incisions” in JCRS in July 1998 and in 2004 authored a chapter describing both his chevron incision and Singer’s frown incision in the book, PHACOEMULSIFICATION, where he continued to argue that the geometry of the tunnel, rather than Ernest’s “corneal flap,” was the critical factor in sutureless cataract surgery.

C. The Physicians’ Movement against Medical Procedure Patenting and the Passage of 35 U.S.C. § 287(c)

While Pallin v. Singer ended without leaving any mark on patent jurisprudence, the physician movement against medical procedure patenting had taken on a life of its own.

1. The Medical Community Reacts to the Pallin Suit

Pallin’s suit against Singer raised the hackles of many physicians. In a March 1994 interview, for example, McFarland dismissed the suggestion that patents could document “originality,” contending 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.” 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.

Singer’s April 1994 ASOS meeting speech, which Ophthalmology Times described as having brought “the ghost of Hippocrates” into the room, argued that procedure patenting threatened 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 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,

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239 Id.

openness in medical research, and free exchange of medical and surgical
knowledge.241

Singer bolstered his ethical argument against medical procedure patents with reference to the
AMA’s Ethics Opinion on New Medical Procedures.242

Dr. Herve Byron, an intraocular lens pioneer, fanned the flames of outrage in a melodramatic
emphasizing that its “ultimate impact” should be determined on ethical, rather than legal,
grounds.243 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, the American College of Surgeons, and “that omnipotent
organization called the American Medical Association” had not reacted more strongly to the
threat “of a plane flying overseas with a potential hydrogen bomb ready to explode.” He urged
ophthalmologists to contribute to Singer’s defense, professional associations to become involved,
and the Academy to take a firm ethical stand against procedure patents.

Byron also deplored the possibility that Pallin might lose the lawsuit and end up “despised and []
permanently outlawed from the ophthalmic community by his peers.” He urged
ophthalmologists to encourage Pallin to terminate the case, assuring him that he would be
“welcomed back to the community of which he has been and will again be an important and
valuable member,” and suggested that the ASCRS delegate “one, two or three individuals who
are Sam’s surgical peers and possess the insight, the compassion and the diplomacy to convince
him of the desirability of terminating this no-win battle for all concerned.” In a final burst of
purple prose, Byron warned that failure to effect a dignified reconciliation would result in an
outcome “similar to the Vietnamese war—no winners and all losers.”

The AMA was not as oblivious to the procedure patent issue as Byron suggested. Only two
weeks later, it passed a resolution to “vigorously condemn the patenting of medical and surgical
procedures and work with Congress to outlaw this practice.”244

A lively and sometimes blistering debate about medical procedure patenting ensued among
physicians, and ophthalmologists in particular.245 In July 1994, the AAO’s ARGUS newsletter

242 Supra note __
243 Herve M. Byron, Is This Déjà Vu?, OCULAR SURGERY NEWS, June 1, 1994, at 13.
244 Resolutions, 1994 PROC. AMA ANNUAL MEETING 388, 390.
245 See, e.g., Editorial, Patently Unwise: The Patenting of Medical and Surgical Techniques is Wrong Way to Go,
AM. MED. NEWS, July 5, 1994, at 21.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
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
devoted an issue to the “War Over Patents,” with Pallin and Singer contributing to a “Counterpoint” debate. Singer focused on distinguishing medical procedure patents from the well-accepted patents on medical devices and drugs. He argued that procedure innovations are incentivized by “the foundation of good medical practice” rather than by patents, and generally do not require substantial financial investments. He noted that other nations, including members of the European Patent Convention, prohibit medical method patents. He also pointed to the risks of biasing research, compromising the independent judgment of physicians through financial pressures and jeopardizing the free and open exchange of ideas among physicians.

Pallin disputed the distinction between device patents and procedure patents, arguing that both were ethically acceptable as long as royalties were reasonable. He argued that the journal publication process was “too easily corrupted by politics and special interests” and that patents might sometimes be the only path to recognition for the true inventor, claiming that this concern had “figured in his decision to patent the chevron incision.” Pallin also contended that incentives for inventing new procedures would shrink due to the growing importance of managed care, thus increasing the importance of the “recognition and small profit” available from patenting.

Though ARGUS gave space to Pallin’s perspective, the Academy’s opposition to medical procedure patents was evident. An editorial entitled “What the Academy is Doing to Oppose Method Patents … and What You Can Do” discussed the Academy’s sponsorship of the AMA resolution condemning method patents. It provided members with a list of talking points for calls to Congress opposing medical procedure patents, such as added costs, conflict with medical traditions of sharing knowledge, the distinction between patents on methods and patents on drugs and devices, and the fact that many other nations do not permit method patents and highlighted the Academy’s efforts to promote a medical association coalition against medical procedure patents.

2. The Legislative Compromise

The profession’s lobbying bore its first fruit in August 1994, when Rep. Bryant placed a statement in the Congressional Record encouraging the Judiciary Committee to look into the matter. In early March 1995, Representatives Ganske and Wyden introduced H.R. 1127, which would have eliminated patent eligibility for processes for “surgical or medical procedure[s], administering a surgical or medical therapy, or making a medical diagnosis” while

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247 Id. at 14.
248 Editorial, What the Academy is Doing to Oppose Method Patents ... and What You Can Do, ARGUS, July 1994, at 14.
249 See Pallin Patent Claims Invalidated; Physicians Free to Perform Sutureless Cataract Surgery Without Threat of Infringement Litigation, PR NEWSWIRE, Mar. 29, 1996 (“ARCRS leads a coalition of fifteen medical specialty societies that is actively supporting this legislative effort [to ban medical procedure patents].”).
allowing patents on associated machines, manufactures or compositions of matter. A flurry of media attention followed. The legislation attracted a bipartisan group of co-sponsors.

In June 1995, the AMA issued a detailed report about “medical process patents,” concluding that it is unethical for physicians to “seek, secure or enforce patents on medical procedures.” The Medical Procedure Patent Coalition, which now included the AMA, the American College of Surgeons, and the Association of American Medical Colleges, among others, held a briefing for congressional staff later that month.

The House Judiciary Subcommittee on Courts and Intellectual Property scheduled a hearing on the Ganske-Wyden bill for October 1995. By that time, the biopharmaceutical industry had weighed in to oppose the bill. Just before the hearing, Senator and physician Frist introduced a compromise. Rather than eliminating medical procedure patents entirely, S. 1334 would have provided an infringement exemption for physicians and other health care providers who “use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis.”

Representatives of the medical community, the biopharmaceutical industry, the patent bar, and the USPTO testified at the hearing on the Ganske-Wyden bill. Industry representatives argued that exempting medical procedures from patenting would undermine the recently concluded TRIPS Agreement (though the Agreement specifically permitted such an exemption), and “would be an invitation to our trading partners around the world to further compromise already anemic regimes for the protection of biotechnology inventions . . .” The USPTO also opposed the legislation, contending that proper application of the non-obviousness standard would solve any problems.

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Following the hearing, the legislation’s backers and opponents attempted unsuccessfully to find a compromise. Representative Ganske proposed an amendment to the appropriations bill forbidding the use of federal funds to issue medical procedure patents. Ganske’s amendment easily passed the House, but was stripped from the bill in Senate committee.

Senator Frist then introduced what became 35 U.S.C. § 287(c), which was signed into law by President Clinton in September 1996. § 287(c)’s passage was widely (though sometimes not entirely accurately) celebrated in the medical press. Singer stated that “this may be the most important contribution to healthcare that I make during my career,” while Pallin continued to defend his decision to enforce his patent. § 287(c) is significantly weaker than the medical community’s prior proposals, however. Rather than precluding patenting or eliminating infringement liability, § 287(c) eliminates remedies against medical practitioners for infringement of medical procedure patents. By preserving infringement liability, it left the door open to suits against third parties, such as testing laboratories, for contributing to or inducing medical practitioner infringement.

Various other provisions also limit § 287(c)’s scope. § 287(c) covers only “medical activity,” defined as “the performance of a medical or surgical procedure on a body,” leaving some ambiguity as to whether it encompasses methods of diagnosis. Moreover, the definition of “medical activity” has three explicit carve-outs. The first, of “the use of a patented machine, manufacture, or composition of matter in violation of such patent” merely clarifies that 287(c) does not disturb infringement remedies for patented products. The second, of “biotechnology patents,” aims to protect the biotech industry, leaving remedies intact for patents on medical procedures involving biological materials that “have been manipulated ex vivo at the cellular or molecular level.”

The third carve-out, of “patented use of a composition of matter,” is the most difficult to parse because it has a kind of counter-carve-out for claims “where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.” Though its interpretation is complicated, the third carve-out seems intended to protect the pharmaceutical and biotechnology industries, thus leaving remedies intact for patented “novel uses of drugs, novel uses of … reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs, novel methods for combining drug therapies, and novel methods for providing . . . biological materials to a patient (including gene therapies.)” The Conference Committee Report thus explains that “a novel anesthetic or a novel dosing method” used in a

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259 See, e.g., Reginald W. Rhein, Jr., BIO, AMA Clash Over Bill to Shield Health Pros from Suits Over Procedures, BIOTECHNOLOGY NEWSWATCH, Nov. 20, 1995, at 4.
261 Pub. L. No. 104-208, § 287(c).
heart transplantation process would “directly contribute to achievement of the objective” of the process, meaning that the § 287(c) exemption would not apply. Use of a conventional anesthetic in a heart transplantation process, one the other hand, would not, meaning that the exemption would apply.267

Stepping back from the statutory interpretation complexities, one can observe the fit between § 287(c)’s coverage and the realm of physician user innovation. The first two carve-outs from exempted “medical activity” correspond to innovation arenas dominated by industry. The third is more interesting. The line it draws seems aimed at preserving infringement remedies for the kinds of innovative uses of compositions of matter that are likely to come from industry. The innovative uses of compositions of matter remaining within §287(c)’s scope, such as the use of a conventional anesthetic in heart transplantation, seem likely to result from physician user innovation. The definition of medical activity seems to define the scope of the exemption from infringement penalties to encompass the arena in which physician innovation is most likely to dominate. § 287(c) thus reinforces the community norm against medical procedure patenting. The correspondence is not perfect, however. Physician user innovation and industry research both can lead to the discovery of novel uses of drugs, reagents, and so forth. Patents on such innovations remain enforceable both by and against physicians.

D. Whatever Happened to § 287(c)?

After § 287(c) passed, the medical procedure patent issue receded. §287(c) was not considered in a single published opinion until 2008, when it came up in Emtei, Inc. v. Lipidlabs, Inc.,268 which remains the only opinion interpreting §287(c).269 In light of the provision’s complexity, and the fact that it appears to leave open the possibility of physician infringement suits against other physicians, this is surprising. Where are the lawsuits pushing the boundaries of the exemption? Perhaps the answer resides in the medical community’s patenting norms. As AMA Ethics Opinion 9.095 puts it, “the use of patents … to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical.” The report accompanying this opinion’s original version in 1995 applied it to “pure medical process patents, including patents for diagnoses, imaging techniques, off-label uses of a pharmaceutical, and methods of administering a biomedical therapy,” while only “medical process patents which involve the patenting of a procedure in conjunction with a device or drug” were outside its scope. The ethical norm against patenting medical procedures thus sweeps more broadly than § 287(c)’s exemption. Perhaps, in the wake of the Pallin v. Singer uproar, physician innovators were unwilling to risk community opprobrium by pushing the limits of the exemption. Physician community norms do not completely explain §287(c)’s absence from the case law, however. Industry patentees might have tested its limits. That has not happened. Instead, more recent battles have played out primarily in litigation brought against third parties for secondary liability.

267 Id.
269 Justice Breyer referred to the provision in passing in his dissent from the dismissal of certiorari in LabCorp. Beyond that, there is simply silence.
Emtel270 arose out of telemedicine, a context unanticipated in the 1990s. The defendants had contracted with physicians and remote medical facilities to provide videoconferencing for telemedicine. The patented process included some steps relating to video-conferencing set-up and others relating to diagnosis and treatment.271 The court decided that the patented methods constituted “performance of a medical or surgical procedure on a body,” despite the physician’s remote location. It also concluded that the services providers were “related health care entities” eligible for exemption under the statute. The court nonetheless denied the claim to immunity. The § 287(c) exemption applies only to “performance of a medical activity that constitutes an infringement.” The court held that because certain claim steps relating to video-conferencing set-up were not “medical activity,” § 287(c) did not apply. In a final twist, the court nonetheless granted summary judgment to the defendants, holding that they had not infringed because a single party did not “direct or control” the actions of all of those involved in completing the claimed steps.272 The Federal Circuit recently changed the joint infringement rule, however, making it possible to prove secondary liability without demonstrating that all steps of a method were “performed by a single entity.”273 Today, a secondary liability claim would probably be viable in a case like Emtel.

Further litigation and debate over patents on telemedicine and other IT-based medical procedures that reflect collaboration between physicians and “outsiders” seem likely. It will be interesting to see whether physician patenting norms evolve in response.

VI. Physician Opposition to Diagnostic Procedure and Gene Patents

Recently, medical associations once again have become involved in the patent debate, filing amicus briefs opposing the patent eligibility of medical diagnostic procedures in Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.274 and Mayo Collaborative Servs. v. Prometheus Labs., Inc.275 and of genetic markers for breast cancer in Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office.276

A. Diagnosis as Medical Procedure

Rather than sue physicians for direct infringement, the plaintiffs in Mayo and LabCorp brought secondary liability suits against test laboratories that provided measurements used in patented medical diagnostic methods. The claims at issue were based on statistical studies of correlations

271 Id. at 816.
272 Id. at 828 (applying the standard that the Federal Circuit set in BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007).
273 Akamai Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301, 1306 (Fed. Cir. 2012) (en banc)
276 Brief Amici Curiae of AMA et al (No. 12-398), available at
between biological indicators and clinically relevant conditions. *LabCorp* involved correlations between blood levels of the hormone homocysteine and vitamin B-12 deficiency. 277 *Mayo* involved correlations between blood levels of particular drug metabolites and the toxicity and efficacy of the drugs. In each case, the heart of the claimed invention was the statistical study, rather than its diagnostic application, which was straightforward. As the Supreme Court explained in its opinion invalidating the claims at issue in *Mayo*, “the claims inform a relevant audience about certain [correlations]; any additional steps consist of well understood, routine, conventional activity …”278

The claims in these cases were rooted in both academic research and clinical practice. In *LabCorp*, the inventors were “three university doctors,”279 who published the results of their study in peer-reviewed journals in the year that their patent issued.280 Plaintiff Metabolite Laboratories, founded by one of the doctors,281 operated out of a university laboratory.282 In *Mayo*, the inventors were a gastroenterologist283 and a pharmacologist284 at a university-affiliated hospital in Canada, who published the results of their research shortly after submitting their patent application.285 Plaintiff Prometheus Laboratories was a later licensee.286

Physician opposition to diagnostic method patents is longstanding. During the controversy over medical procedure patents in the 1990s, for example, medical associations appear to have made no distinction between diagnostic methods and medical procedures, opposing both. Some of the patents that excited physician outrage in the 1990s were diagnostic procedure patents.287 The community’s 1995 legislative proposal would have precluded patenting both medical procedures

277 Id. at 128; U.S. Patent No. 4,940,658 (June 10, 1990), cl. 13;
278 Mayo, supra.
279 LabCorp at 128 (Breyer, J.) (dissenting from dismissal of certiorari).
281 See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004) (patent in suit is U.S. Patent No. 4,940,658); Riezler v. Allen, 2010 U.S. Dist. LEXIS 97853 (D. Colo. Sept. 16, 2010) at *4 (“Commercialization of the technology of the '658 Patent was the reason Metabolite was formed.”)
283 http://muhc.ca/research/entity/researchers/s.
284 http://www.pharmacologie.umontreal.ca/professeurs Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1309 (Fed. Cir. 2012); chercheurs/theoret/index.html.
286 See http://www.prometheuslabs.com/About_Contact.asp (website of Prometheus Laboratories).
287 See discussion supra __.
and “making a medical diagnosis.” Medical association amicus briefs in LabCorp and Mayo again made no distinction, relying on the obligations imposed by AMA ethics Opinion 9.08 entitled “New Medical Procedures.” Opinion 9.08 obligated physicians to “to share their knowledge and skills and to report the results of clinical and laboratory research” so as to promote “early evaluation of new technologies” and “rapid dissemination of improved techniques.” The arguments made in these briefs implicitly assume that physicians are both users and innovators of diagnostic procedures. As the LabCorp brief phrases it, “[d]iscovery of a basic scientific principle – one that could be useful to others in devising any number of useful medical applications or to a physician in reaching a diagnosis and treating a patient – is a quintessential example of the kind of medical knowledge that physicians are obliged freely to share.” These ethical arguments would have little purchase if physicians were not understood to be acting as innovators of these diagnostic methods.

That said, Mayo and LabCorp are not quite like Morton and Pallin. Most obviously, these cases did not involve physicians suing other physicians for infringement. Instead, the plaintiffs were commercial firms and the defendants were medical laboratories. In the shadow of §287(c), physician opposition to these patents seems not to have been premised primarily on fear of liability. Additionally, while most of these inventors were physicians, they performed their studies in an academic context, bringing both medical and academic norms into play and raising questions about whether user innovation or academic research is the most appropriate paradigm. The involvement of diagnostic laboratories begs an additional boundary question.

The basic hypothesis of this Article is that user innovator communities will tend to oppose patenting of types of innovations that usually are made by community members without significant collaboration with outsiders. The medical community has a long history of studying the causes and symptoms of medical conditions and of evaluating medical treatments, as evidenced by the 1848 report to the AMA on ether anesthesia discussed earlier. The statistical studies underlying the claims in LabCorp and Mayo are within that tradition. Medical procedures continue to be invented and evaluated primarily by the medical community, partly through publications and partly through the AMA’s CPT code system, which is used by insurance companies to determine reimbursement. Moreover, the correlation studies underlying the patents in LabCorp and Mayo involved relatively small numbers of individuals, were performed during the course of medical treatment, and did not involve complex statistical methodology. Thus, while such correlations would not be uncovered as a by-product of ordinary medical practice, they appear not to have required the significant input from outsiders that is involved in most modern-day drug and device innovation.

289 ACMG Brief, Mayo, supra at 17 n. 5. As I represented the medical associations in their amicus filing in Mayo, this point might seem a bit suspect. However, I was completely uninvolved in the amicus briefing in LabCorp. On this topic, the Mayo brief essentially reiterates the arguments framed in LabCorp.
291 Id.
292 Id.
293 AMA Brief, LabCorp, supra at 14.
294 The reverse need not be true – it need not be the case that all or most users are innovators.
Nonetheless, one of the inventors on the patents asserted in *Mayo* was a Ph.D. clinical pharmacologist, rather than a physician and such collaborations undoubtedly are desirable. Are patents needed to incentivize and reward such “outsiders”? Probably not. Unlike drug and device manufacturers, these non-MD clinical researchers publish in the same journals and attend the same conferences as academic physicians. The reputational rewards associated with those activities provide a common currency.

The diagnostic procedures at issue in *Mayo* and *LabCorp* also require the participation of the laboratories to which physicians send biological samples for testing. The laboratories’ involvement does not raise boundary issues of the sort identified in the drug and device contexts, however, any more than a physician’s purchase of a scalpel makes the scalpel manufacturer a collaborator in her invention of a new surgical procedure. Allocating rewards among collaborating innovators is complicated by the difficulty in assessing the value of the invention—and of a particular individual’s contribution—in advance. Like scalpels, routine lab tests have known market values.

It thus makes sense from a user innovation perspective that the medical community sees medical diagnostic patents similar to those in *LabCorp* and *Mayo* as akin to medical procedure patents and opposes their patentability. The stories behind the claimed inventions in *LabCorp* and *Mayo* support the view that physician norms are sufficient to motivate discovery and dissemination of such correlations. The results of the studies were published in medical journals, after which physicians were capable of using those results in diagnosing their patients. The patents were obtained after the fact. There is nothing to suggest that the research would have been derailed if patents had been unavailable in these cases.

B. Claims to Naturally-Occurring DNA Sequences and Related cDNA Sequences

In *AMP*, a group of plaintiffs, including genetic research and clinician associations, patient advocacy groups and individual genetic scientists and patients sought to have claims to DNA indicators of heightened susceptibility to breast cancer declared invalid. Though the patents at issue belong to biotech company Myriad Genetics, they have roots in academic research. By the early 1990s, a worldwide effort to discover genetic signatures of breast cancer susceptibility had localized a breast cancer mutation to “a region of chromosome 17.” A race to sequence this “BRCA1” mutation ensued.

Myriad was founded in 1991 to obtain private financing for the efforts of a group primarily located at the University of Utah, which had been passed over by the NIH in favor of Francis Collins, then at the University of Michigan. The Myriad group won the race and obtained a patent claiming isolated human DNA incorporating the BRCA1 sequence, complementary or

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295 The Federal Circuit held that “at least one” of the plaintiffs had standing under the Declaratory Judgment Act. Ass’n for Molecular Pathology v. United States PTO, 689 F.3d 1303, 1308-09 (Fed. Cir. 2012).
298 Id. at *50.
299 Id. at *51–*52. See also Skolnik Decl., AMP v. USPTO, at ¶¶ 14-16.
“cDNA” sequences and methods of diagnosing breast cancer susceptibility by comparing a patient’s DNA to the BRCA1 sequence. Myriad later obtained similar claims to another breast cancer-related mutation, known as BRCA2. Myriad’s patents were immediately controversial. A 1994 Nature editorial, for example, pointed out that the effort to find and sequence the breast cancer markers included “many other groups, mostly at academic institutions.” It worried that gene patents could result in “deceleration of the pace of research in molecular genetics.” A responding letter from an academic geneticist emphasized that “[u]ntil now, work has proceeded as a large-scale, collaborative exercise involving the general public with some notion of general benefit” and that it was “not clear that those who have participated would be happy for their diverse contributions to be used by others for commercial gain.” Both patents also were subject to disputes with former collaborators.

In the wake of the BRCA patent controversy and in light of the Human Genome Project, medical associations debated the ethics of gene patenting. In 1997-98, the AMA’s Council on Ethical and Judicial Affairs issued a report and ethical opinion on gene patents. Despite stating rather confusingly that “patent descriptions should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question,” the policy did not oppose gene patents. Instead, it directed patent holders to “structure licensing agreements [so] as to encourage the development of better medical technology.” Moreover, the report expressly distinguished gene patents from medical procedure patents, emphasizing the importance of commercial investment in biotechnology and arguing that patents might be needed to provide necessary return on investment.

By contrast, the American College of Medical Genetics, an organization of medical geneticists, genetic counselors and related health care professionals, took the position in 1999 that “[g]enes and their mutations are naturally occurring substances that should not be patented.” The College of American Pathologists adopted a similar policy in 2000. ACMG emphasized the implications for the medical genetics community, arguing that gene patenting affects “the training of the next generation of medical and laboratory geneticists, physicians, and scientists” and “retards the usually very rapid improvement of a test that occurs through the addition of new mutations or the use of new techniques by numerous laboratories.” While CAP and the ACMG pushed the AMA to adopt a stronger stance against gene patents, the AMA continued to focus primarily on the problems caused by exclusive licensing. In 2010, the AMA finally adopted a resolution opposing “patents on human genes and their naturally-occurring mutations.”

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301 Alistair D. Stewart, Letter to the Editor, Patenting of Human Genes, 373 NATURE 185 (January 19, 1995).
303 AMA Ethics Opinion 2.105.
Does the physician user innovator community paradigm apply to the claims at issue in *AMP*? Certainly, some physicians are *users* of the claimed sequences and methods in that they order the tests for their patients. And many of those who research the relationship between genetic mutations and disease are physicians. In his declaration in the litigation, for example, one of the physician plaintiffs, Dr. Harry Ostrer, emphasized that DNA patents interfere both with treatment because “[t]ests from different labs can ensure that the information [patients] are using to make [medical] decisions is accurate with regard to test performance and interpretation” and with research because they limit research into the clinical implications of “variants of unknown significance.”

The link from medical practice to genetic diagnostic claims is less obvious than the link to the claims in *Mayo* and *LabCorp*, however, even though the claims result from conceptually similar research involving two steps: laboratory testing of a biological sample and correlating the measurement with a disease or condition. Unlike the routine blood analysis involved in *Mayo* and *LabCorp*, the isolation and sequencing of the BRCA mutations required “considerable work” and “ingenuity.” Though “the [gene sequencing] process and techniques used were well understood, widely used, and fairly uniform” among “scientists engaged in the search for a gene,” gene sequencing was a research tool, not a routine laboratory test. That distinction is fading, however. Gene sequencing is now, or soon will be, a routine and relatively cheap exercise. The correlation step, however, demands not only expertise in genetics, but also specialized statistical expertise and access to large data sets of both disease and genealogical information. Research of this sort is not complementary to medical practice in the ordinary sense of user innovation, in which innovation is based on “sticky knowledge” derived from experience.

The story of the BRCA patents illustrates this point. Of course, many of those involved in the BRCA research were physicians, including Frances Collins, now director of NIH, and Michael Stratton, who many credit with scientific priority for the BRCA2 discovery. However, all but one of the fourteen inventors on Myriad’s BRCA patents were Ph.D. researchers or students, two with degrees in informatics or biostatistics, while only two had M.D. degrees. The Myriad team relied on databases obtained from the Utah Genealogical Society and Utah Cancer Registry to identify individuals for testing. Identifying the genetic mutations correlated with breast cancer was not innovation in the course of medical practice.

Why, then, did the ACMG and CAP take early stances opposing genetic diagnostic patents and why did the AMA and other medical associations eventually follow? Myriad’s Skolnik argues that their motives are economic, first because they want to free ride on Myriad’s efforts and

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307 Ostrer Decl., AMP v. USPTO, at ¶¶ 11-12. See also Declarations of Mildred Cho, Wendy Chung, Jeffrey Kant, Roger Klein, David Ledbetter, Debra Leonard, Robert Nussbaum, Elizabeth Swisher, Michael Watson
308 AMP v. USPTO at *55*-*56.
310 See Declarations of Donna Shattuck at ¶¶ 4, 9-14; Mark Skolnik at ¶¶ 7-10 in AMP v. USPTO.
311 See, e.g., VON HIPPEL, DEMOCRATIZING INNOVATION, supra.
312 Goldgar (biostatistics) and Swenson (informatics).
313 Miki (M.D., Ph.D.) and Weber (M.D.).
314 Skolnik Decl. at ¶¶ 7-10; Shattuck Decl. at ¶¶ 9-14.
second because Myriad’s activities threaten the “monopoly of academia” in the genetic diagnostic area. The free riding argument is basic to patent theory, but is unconvincing in this context because it assumes, essentially, that these associations’ members are primarily users, but not innovators, of genetic diagnostics. While that is the case for many physicians, pathologists, and geneticists, these organizations also represent many researchers. Moreover, many preeminent genetic researchers strongly opposed gene patents.

Skolnik’s argument about the threat to academia’s “monopoly” is more interesting. Until now, this Article has treated physicians as an undifferentiated community defined by the medical degree. That is an over-simplification. Individuals belong to, and are influenced by, overlapping groups. Physicians are divided into overlapping sub-communities by factors such specialty, type of practice and location. Moreover, medical communities are not composed only of physicians. The ACMG, tellingly, describes its constituency, which is not limited to physicians, as the “medical genetics profession.” With respect to uncovering correlations of the sort underlying the Myriad patents, the “medical genetics profession” has much in common with a user innovator community, even if the “physician community” does not. Its members have a common interest in producing and using genetic diagnostics and treatments to serve patients. This interest is economic in part, but also is grounded in altruism and professional ethics. Clinician-researchers also produce and use data correlating DNA sequences with disease susceptibility and samples of those sequences as research tools. Medical genetics research simultaneously advances multiple goals of members of the medical genetics profession, including increased scientific understanding and improved patient health.

The disadvantages of patents on naturally-occurring human DNA sequences for the medical genetics profession are evident. Because genetic research is highly cumulative, a patent on a sequence containing a particular mutation (or on its associated cDNA) not only provides exclusive rights to the patentee’s discovery, such as the connection between cancer risk and the mutation, but also burdens research aimed at uncovering additional correlations involving the patented sequence. Moreover, as the Myriad example demonstrates, exclusive rights to DNA sequences also lead to proprietary accumulations of data, which also can slow the development of accurate diagnostics. In sum, DNA patents threaten high transaction costs and delay for medical genetics research, with resultant delay in meeting the goals of the medical genetics profession.

Of course, such costs are standard byproducts of patenting. The important question is whether patents nonetheless are needed to incentivize the sorts of innovations covered by DNA patents.

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315 Skolnik Decl. at ¶¶ 19-24.
316 The ACMG’s Mission Statement, for example, takes as its basic goal “to improve health through medical genetics.” See also, e.g., Leonard Decl. at ¶¶ 13-14, 21 (Pathologists are the diagnostic detectives for clinicians who directly take care of patients. Physicians in laboratory medicine do not require the incentives of gene patents to develop and provide genetic tests based on the published medical and scientific literature. … The driving force for those in the clinical laboratory is the need of the patient.”)
317 See, e.g., Strandburg, supra; von Hippel, Dominant Role, supra (discussing researchers as user innovators of research tools)
Past experience suggests they are not. For example, the Myriad team’s research began at the University of Utah and was privatized to gain advantage in a race with publicly-funded researchers. That decision worked out well for Myriad, but there is little evidence of public benefit. Myriad won the race, but not by much -- certainly not by enough to outweigh the costs of twenty years of exclusive rights. Patents also are of dubious benefit for knowledge sharing in this arena. Publication norms of the research community effectively induce disclosure of research results without the social costs imposed by exclusive rights. Patents are of no help with the more difficult issue of data sharing; indeed, they encourage data secrecy by removing the threat that other researchers will develop equivalent data. Consistent with the user innovator perspective, the genetics research community has a history of developing community-based solutions to the data sharing issue.

Genetic diagnostic innovation also does not seem to call for patents as boundary-spanning mechanisms. Research collaborators are members of the medical genetics community, who can be compensated by its publication and reputation-based reward system. While that system faces challenges in rewarding and incentivizing contributions to data management and sharing, patents do not address those challenges. There is also no need to enlist outsiders in taking these diagnostic innovations from “lab to market” (as there might be with DNA-based therapeutics). They are immediately usable.

Patenting does, however, threaten the stability of the sharing regime, by providing a mechanism for defecting from its norms-based reward system. Patenting by some can trigger defensive patenting by others. In this sense, Skolnik was right to argue that medical genetics associations opposing these patents are trying to protect an academic “monopoly” and to maintain “control” of the system of rewards for research. The public policy question is whether prohibiting patents in order to protect that system would be “tragic,” as Skolnik argues, or a boon for the public health. The ACMG’s early opposition to patents on naturally occurring DNA sequences reflected a user innovator community view – emphasizing the advantages of sharing innovations. The AMA, on the other hand, struggled for years with the concern that the efforts of outsiders – biotechnology companies – might be critical for progress before adopting its current position opposing patentability.

Unfortunately, but unsurprisingly, the AMP opinion did not grapple with these institutional issues, remaining mired in a rather 19th century discourse about what is “natural.” The Court thus drew the patentability line between “isolated” DNA and cDNA because cDNA is made in the lab

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320 See, e.g., SAGCHS Report at 91-92.
321 Sulston Decl. at ¶32
322 Skolnik Decl. at ¶¶21-24.
and was unmoved by the fact that cDNA is made routinely for the very purpose of mirroring a
natural sequence.  

VII. Conclusions and Hypotheses

The history recounted here is consistent with earlier user innovation literature in that physicians
oppose the patenting of innovations produced and used within the physician community. It
suggests, however, that patenting is likely to be deemed acceptable for innovations that require
significant collaboration with outsiders, who need to be compensated by something other than
use and community reputation. Medical procedure innovation is performed and disseminated by
physicians, who are compensated with the rewards of reputation and use. By eschewing
procedure patents, the community avoids their costs. Drug innovation, while once the province
of physicians, is now largely undertaken by pharmaceutical companies, with physicians taking a
subsidiary role. While physician user innovation is still a major source of medical instrument
and device innovation, over time it has come to require extensive cross-boundary collaboration
with engineers and manufacturers. Consistent with this evolution, physician norms against
patenting of drugs and devices have faded. Recent controversies over patents claiming
diagnostic procedures and medically significant DNA sequences also are understandable from a
user innovation perspective.

Of course, this historical story does not prove that medical community norms about patenting are
determined by the interplay between user innovation and the need for cross-boundary
collaboration. Further empirical work is required to test and potentially refine the user innovator
community hypothesis for physician patenting norms. Norms regarding instrument and device
patenting deserve more attention, for example. Though AMA ethical rules formally permit
device and instrument patenting, the user innovator perspective might lead one to expect more
complexity in the norms on the ground. For example, one might expect a norm against patenting
innovations that can be accomplished by tweaks of existing products and do not require
regulatory review. Norms about the patenting of new uses of existing drugs are of interest, since
physicians do not need to collaborate with drug manufacturers or obtain FDA approval to
prescribe off label. If the hypothesis of this Article is correct, technological changes, such as the
increasing incorporation of information technology into the delivery of medical care illustrated
by Emtel, will raise new issues and may lead to changes in physician patenting norms.

The hypothesis that user innovator community patenting norms will be tailored to the need for
collaboration with outsiders depends on general theoretical arguments and therefore is testable
outside of the medical arena as well. Industries such as tax, business methods, and software, in
which there has been significant resistance to patenting, are promising areas to study.

The user innovation perspective developed here also raises normative questions for patent
document. The basic normative question is the one the AMA grappled with regarding patents on
human DNA sequences. How should the law react when an innovative community resists
patenting? There is no simple answer to this question. On the one hand, patents have the
potential to disrupt effective and socially beneficial norms-based innovation systems, as appears
to have been the case with medical procedure patents. On the other hand, there is no guarantee

323 AMP at 16-17.
that a user innovator community has society’s best interests at heart. A group’s patenting norms sometimes may reflect a desire to control or direct innovation, rather than to innovate for society’s maximum benefit. The medical profession’s opposition to drug patents presumably facilitated physician innovation, but it also may well have reflected the profession’s resistance to the move toward chemistry-based drug research and development. Focusing on “natural phenomena” and “abstract ideas,” as patentable subject matter doctrine currently does, will not provide answers to these questions.