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Derogatory to Professional Character?

The Evolution of Physician Anti-Patenting Norms

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Physicians have a long history of opposing medical patenting. When the American Medical Association was formed in 1847,[1] one of its first acts was to adopt a Code of Ethics stating that it was "derogatory to professional character" for physicians to hold patents "for any surgical instrument or medicine."[2] Opposition to patents on drugs and medical devices subsided in the early twentieth century and the ethical strictures against drug and device patents were removed. Indeed, physicians now are co-inventors on a sizeable fraction of important medical device patents.[3] While the ethical bans on physician patenting of drugs and devices are a thing of the past, the norm against patenting medical procedures has remained surprisingly robust. As I have described in more detail elsewhere, in the 1990s, a physician movement against medical procedure patents led to the enactment of a statutory provision exempting healthcare workers from infringement remedies for such patents.[4] More recently, medical associations weighed in against the patentability of diagnostic methods in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*[5] and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*[6]

Why is it acceptable for physicians to patent drugs and devices, but not medical procedures? This chapter hypothesizes that the evolution of physician ethical norms about patenting in the United States can be best understood through the lens of user innovation. Studies have shown that "user innovators," whose motivation for invention comes primarily from their use of a technology, often form reputation-based communities in which the norm is to share one's inventions and patenting is frowned upon.[7] There are a number of plausible reasons for this choice. First, user innovators benefit from a sharing norm because they can use

the inventions shared by other community members. Second, by sharing their inventions with the community, user innovators obtain feedback and suggestions for improvement. Third, sharing a valued innovation with a user community boosts a user innovator's reputation within the community and sometimes even among the broader public. Depending upon the particular community, a reputational boost may lead to non-pecuniary or monetary rewards (or both). Patents may be both costly and dangerous to the viability of a user innovator community with a reputation-based sharing norm. They may introduce transaction costs and deadweight loss without an offsetting increase in innovation or tempt community members to defect from the sharing regime in favor of an exclusivity-based monetary reward.

During the mid-nineteenth century, physicians were the primary innovators of drugs, devices, and procedures for use in treating their patients. Like other groups of user innovators, they formed a reputation-based community with a norm of sharing their innovations. The norm and its enforcement are illustrated by the famous dispute over the patenting of ether anesthesia. During the twentieth century, pharmaceutical companies and medical device manufacturers became major contributors to drug and device innovation. The anti-patenting norm was not enforceable against these companies, who wanted to sell, rather than use, their inventions and were not interested in the physician community's reputational rewards. The demise of the ethical ban on drug and device patents was a natural response to these developments. The robustness of the ethical norm against patenting medical and diagnostic procedures is also understandable from a user innovation perspective. Medical procedure innovation remains primarily the province of physician user innovators who can both benefit from and enforce a sharing norm.

Physician Innovators, Patents, and Ether Anesthesia

During the nineteenth century, so-called regular physicians sought to distinguish themselves from purveyors of secret and potentially harmful "nostrums" and "patent medicines."[8] At that time, so-called ethical medications were prescribed and formulated by physicians according to pharmacopeia.[9] So-called patent medicines were sold directly to

consumers. Their formulations were usually secret (and, in fact, rather rarely patented) and of questionable efficacy or even dangerous.[10] The medical profession's rejection of patenting was bound up with its attempts to differentiate itself by its scientific approach from the "quack" purveyors of such suspect nostrums.[11] Much of the debate about the ethics of patenting played out against the backdrop of a notorious and influential controversy over the patenting of ether anesthesia,[12] which solidified the anti-patenting ethical norm and left its mark on patent doctrine through the case of *Morton v. New York Eye Infirmary*.[13]

Before ether anesthesia was developed, surgery was a horrifying experience, performed on conscious patients fortified sometimes with narcotics such as opium, but often only with courage.[14] Ether was well known to physicians and was prescribed orally to treat various maladies. Ether and 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.[15] 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, however, it was adopted very rapidly. During the Mexican-American and Civil Wars, it was used in countless battlefield operations.

The discovery of ether anesthesia produced a bitter and long-running controversy over patenting and scientific credit. In November 1846, a patent[16] was issued jointly to dentist, sometime medical student, and reputed con man[17] 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 in medicine. Morton had studied with 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, though he did not publish his observations until 1849.[18] The story is fascinating, though it was ultimately tragic for its eccentric major characters.[19] 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.[20] The credit dispute between Morton and Jackson revolved around Jackson's role in that first use. Though there are various versions of events,[21] 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, after the initial success Morton began immediately to look for ways to make money from the discovery. He advertised painless tooth extraction services, invited press attention, and consulted a patent attorney.[22] 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, then a young surgeon at Massachusetts General Hospital (MGH).[23] After observing several tooth extractions, Bigelow persuaded MGH to allow Morton to attempt ether anesthesia during a surgery at the hospital in mid-October 1846.[24] The success of that attempt sparked interest in adopting ether anesthesia as a standard practice at MGH. As a prerequisite, MGH demanded to know the composition of Morton's anesthetic agent, so that its safety could be evaluated. Morton resisted disclosing his formulation, while moving quickly to apply for a patent.[25]

Jackson, whose primary interest was in scientific credit, was uncomfortable with patenting, reflecting the medical profession's general disapproval of patents. He proposed initially that Morton pay him a consulting fee and patent the invention independently.[26] Morton's attorney advised him that Jackson should be included as a co-inventor on any patent and urged Jackson to join the patent application to ensure that he received scientific credit. Jackson, who had been involved in an earlier credit dispute with Samuel Morse over the telegraph patent,[27] apparently was convinced. Morton and Jackson filed a joint patent application on October 27, 1846. Jackson immediately assigned his rights to Morton in exchange for a sum of $500 to be paid over time at a rate of 10% of licensing revenue.[28] Shortly thereafter, Morton disclosed the composition of his anesthetic agent to the MGH surgeons and more operations ensued.[29] The patent, entitled "Improvement in Surgical Operations" and

claiming the use of ether for anesthesia during surgery, issued in record time on November 12, 1846.[30]

After the patent was granted, Morton stepped up his commercialization efforts, viewing the patent as his ticket to great wealth.[31] He circulated a term sheet for five-year licenses to dentists, advertised licenses to surgeons for a royalty of 25% of surgical fees, and hired a number of agents to market the licenses. Somewhat ironically, those agents apparently sometimes credited Jackson with the discovery, since his reputation reassured potential licensees about the procedure's safety.[32]

Bigelow delivered 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. The paper was published in the *Boston Medical and Surgical Journal* on November 18,[33] "whereby the news of the discovery was promulgated to the world."[34] Bigelow's article also 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 anesthesia case. Bigelow contended that because ether anesthesia was "capable of abuse, and can readily be applied to nefarious ends," and was "not yet thoroughly understood," its use "should be restricted to responsible persons," which the patentee was empowered to do. He also excused Morton by suggesting 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]."

While readers of Bigelow's article immediately recognized the potential importance of ether anesthesia, his defense of the patent was less persuasive. Well-known dentist Josiah Flagg's impassioned response to Bigelow[35] noted that ether was a well-known part of the *materia medica* available to all physicians. 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. 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 advocated resistance to the patent: "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 the invention might have "slept for twenty years longer, had not Drs. Morton and Jackson demonstrated it to the public." "Suffering humanity," Bigelow suggested, could be assisted equally well by Morton and those licensed under his "reasonable terms" as by those who would disregard the patent.[36]

Flagg's position eventually prevailed. As a practical matter, the patent was widely ignored by physicians and Morton's investments in licensing it bore little fruit. The AMA's ethical prohibition on patenting was adopted soon after the ether anesthesia patent issued. In 1848, the AMA's Committee on Surgery presented an extensive report,[37] collecting the medical community's experience with anesthesia using ether and its close cousin, chloroform, and assessing its safety and efficacy. The report did not take sides in the priority dispute or mention patents explicitly, 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 a two-part article in which he ruminated at length about the nature of invention.[38] He acknowledged that nearly simultaneous discovery is commonplace because medical invention is based on shared community knowledge. He concluded, nonetheless, that Morton should be credited as 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.

An 1856 AMA Committee Report took a decidedly different view of the relative importance of individual and community contributions to improvements in medicine:[39]

> [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. . . . 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.

According to the committee, ether anesthesia could be nothing but an "arrant piece of quackery" until the medical community tested, verified, and improved it:

> Not until it had been stripped of its secrecy, and Letheon [Morton's name for his anesthetic agent] 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.[40]

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."[41] Patents 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 rewards of the vaunted

devotion and experience of adroit specialists," rather than to the efforts of the community as a whole.

The patent debate ran in parallel with controversy over scientific credit for ether anesthesia, which had begun almost before the ink on the patent application was dry. On November 13, 1846, Jackson wrote to a Parisian colleague describing "his" discovery of ether anesthesia and asking the colleague to transmit a report of the discovery to the French Academy of Sciences.[42] Jackson's letter, and his colleague's later-published report to the Academy, omitted Morton's role in the discovery entirely. The credit dispute, to some degree unresolved to this day, continued unabated for decades. Morton even took his case for credit to Congress, lobbying for official credit and compensation for the discovery's military use and drawing responsive petitions from supporters of other claimants. Congress considered the issue off and on for 25 years, but never came to any resolution.[43]

At first, many physicians, especially in Boston and New York, supported Morton's claim to credit and his petitions for compensation from Congress. They also were sympathetic to the financial plight that resulted from Morton's investments in lobbying Congress. A December 1858 letter to the editor of the *New York Times* described efforts to assist Morton financially after "years of unsuccessful application to Congress for justice."[44] A long list of members of the medical community, topped by MGH, donated to a fund created as a "National Testimonial" to Morton.[45]

All that changed when, his licensing and lobbying efforts having failed, Morton sued the New York Eye Infirmary for patent infringement, turning the tide of medical community opinion against him. Many of his supporters had relied on his representations that the patent would not be enforced.[46] Dr. Willard Parker, one of the primary movers in the "national testimonial" effort, testified at the infringement trial that the profession's efforts on Morton's behalf were premised "on the idea that he had abandoned his patent, otherwise not a thing would have been done."[47] The court invalidated the ether anesthesia patent in 1862.[48] At its June 1864 meeting, the AMA passed a resolution opposing Morton's petition for congressional compensation because 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."[49]

The opinion in the case is known for its now-classic statement of the unpatentability of natural phenomena:

> 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.[50]

Morton's attempts to monetize his patent failed long before the court got involved, however, when he violated the medical profession's sharing norm. Because his attempts to collect royalties from other members of the medical community were viewed as illegitimate, Morton never was able to collect substantial royalties for its use, though prestigious members of the community initially supported his claim to scientific credit. By suing his fellow physicians for infringement, he lost the medical community's support entirely. Morton thus 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. When the patent was invalidated, he was left without recourse.

The nineteenth-century medical profession's objections to the ether anesthesia patent reflected a view of medical innovation remarkably aligned with the user innovator community paradigm. Every claimant to the ether anesthesia discovery was a medical or dental practitioner, who developed anesthesia through and for use in his practice. As illustrated by the MGH surgeons' refusal to adopt Morton's procedure until he disclosed his chemical formulation, the community's norms enforced disclosure and punished secrecy. Physicians were expected to publish their innovations in exchange for reputational credit, which was greatly valued, as the long-standing credit controversy illustrates. The medi-

cal community was responsible for honing and testing the innovations its members shared. The 1848 AMA 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 and chloroform anesthesia. The 1856 AMA Committee Report contrasted this community-based approach 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 ether anesthesia story nicely illustrates the operation of a user innovator community's sharing norm. But it also raises the question of whether patents are important for disclosure and dissemination. Bigelow suggested that the invention of ether anesthesia might have been delayed another 20 years without Morton because "the human mind . . . runs in the channels of routine," whereas innovation may require "incredulity and rejection of authority," along with "unyielding perseverance."[51] Bigelow clearly was wrong that, without Morton, the *discovery* would have been delayed. There were several near-simultaneous discoveries of ether anesthesia. But, while Morton may not have been the first to employ ether anesthesia, his discovery certainly was the most widely publicized. Bigelow's article by which "the news of the discovery was promulgated to the world" and Jackson's letter to the French Academy were standard applications of the community's sharing norm. On the other hand, Morton's own efforts at publicizing his discovery—inviting a journalist to observe his first tooth extraction, passing out circulars in Boston, and sending agents to persuade dentists and surgeons to adopt (and license) the procedure—were motivated by the potential for patent-based profits.[52] Without Morton's attempts to drum up business it is hard to know how quickly word of the invention would have spread. Indeed, without the publicity, Bigelow might never have visited Morton to make the observations that he reported in his article.

There can certainly be barriers to disseminating a user innovation. It is unclear why Crawford Long, who apparently used ether anesthesia in his dental practice in 1842, did not publish until 1849, after he heard about Morton's patent. Maybe Long did not see himself as a member

of the publishing medical innovator community because he was a dentist, because he lacked academic connections, or for some other reason. Perhaps he was not interested in national recognition or was simply too busy with his practice to make time to publish. The experience of Morton's mentor Wells, who also later claimed credit for the discovery of anesthesia (though he focused on nitrous oxide), illustrates another potential pitfall for a reputation-based innovation system. In this instance the reputation-based system backfired, since Wells abandoned his attempts at developing anesthesia after being humiliated by a failed demonstration at MGH in 1845.[53] The issue of dissemination recently has begun to garner more attention from researchers studying user innovation, who have begun to explore the conditions under which user innovators are motivated to make the effort needed to disseminate their inventions.

The ether anesthesia story also resonates with current debates about the balance between innovation and safety in medicine. At the time Morton conducted his experiments, there was widespread belief that inhaling ether was too dangerous for medical use. Morton went ahead despite those concerns, but at what risk to his patients? Bigelow noted 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 equal clearness, that insensibility produced death."[54] Morton plunged ahead nonetheless, using the technique on "twenty or more" dental patients before convincing the MGH surgeons to attempt its use. Bigelow generously attributed Morton's 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.[55] More damning complaints about Morton's practices eventually surfaced from dentist Nathaniel Keep, who later became the first dean of Harvard's dental school. Keep 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 claimed 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."[56]

The balance between the risks and benefits of medical innovation is a perennial subject of policy debate. Deciding whether Morton is best viewed as a daring patent-spurred innovator unconstrained by the conservative norms of the professional community or as a lucky money-grabber who advanced the dissemination of ether anesthesia only at considerable risk to his patients may be as difficult as fixing that balance.

The Decline of the Norm against Patenting Drugs and Devices

Eventually, technological changes and industrialization moved most pharmaceutical innovation into large chemistry-based research companies and the federal government took over the regulation of drug safety and efficacy. During this shift away from physicians as primary drug innovators, the AMA's stand on pharmaceutical patents evolved from complete opposition to complete acceptance. Physicians continue to play an important role in the invention of medical devices, but regulation and technological change have meant that they rarely work alone. Collaboration between physicians and device manufacturing firms is increasingly important and norms have adjusted to permit device patenting.

By the end of the nineteenth century, developments in both science and industry were planting the seeds of change to the medical profession's patenting norms. The rise of a scientifically based chemical industry, along with the forces of industrialization, eventually moved the locus of drug innovation out of the physician's office and into the commercial laboratory, where the emphasis shifted away from formulations based on the *materia medica* to developing new molecules. In addition, government gradually assumed responsibility for vetting drug safety and efficacy. As drug development became dominated by companies seeking monetary profits, rather than reputational credit, 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 retreat from the anti-patenting position that the organization had held for more than a hundred years. In 1955, the AMA's ethical principles were revised to permit the patenting of drugs and medical devices, though the principles maintained that the "use of such patents . . . or the receipt of remuneration from them which retards or inhibits research or restricts the benefits derivable therefrom is unethical."[57] In 1957, the principles were substantially simplified and no longer addressed patenting explicitly. The newly permissive rule about patenting was, however, included in a compilation of sections from the 1955 principles deemed "included within the spirit and intent of the language of the 1957 edition."[58] Nowadays, the AMA's Council on Ethical and Judicial Affairs issues ethics opinions, which, together with the pared down principles, make up what is currently called the Code of Medical Ethics.[59] Not only is drug patenting no longer banned, but, consistent with the shift in the ecosystem of pharmaceutical innovation, no current ethics opinion of the AMA even addresses the patenting of drugs by physicians.

While the 1955 amendments to the AMA principles also permitted patenting of medical devices, the device patenting issue did not fade so quickly from the ethical debate. Physicians continue to play an important role in device innovation. In 1957, an ethics opinion based on the newly revised principles approved medical device patenting, but with significant caveats:

> 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.[60]

By 1977, however, the AMA Judicial Council had trimmed away the caveats, in an opinion that 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.[61]

From a user innovation perspective, medical device innovation is complicated because a physician innovator seeking to design a device often needs collaborators with skills in electrical, material, mechanical, or software engineering. During the nineteenth century, physicians generally were able to design instruments and devices independently (and sometimes owned factories to produce them). Nowadays, medical devices often are technologically complex and subject to significant regulatory requirements. Thus, physicians and device industry engineers must often collaborate to invent medical devices. Patents provide a mechanism by which both physician innovators and industry engineers can be rewarded for their inventive contributions.

The Continuing Persistence of the Norm against Patenting Medical Procedures

During the 1980s and '90s, patenting in the United States seemed to be on a path of virtually limitless expansion. Consistent with the AMA's revised view of drug and device patents, optimism about the potential for patents to facilitate medical advances, particularly through the emerging field of biotechnology, was high. The USPTO, which in 1883 had denied a patent because "[t]he methods or modes of treatment of physicians of certain diseases are not patentable,"[62] reversed its rule against medical procedure patents in 1954.[63] While medical procedure patents apparently remained rare (or at least rarely enforced),[64] it would have been reasonable to assume that the medical profession's aversion to patenting had finally been laid completely to rest.

Seeds of resistance to the continued expansion of patenting in medicine began to be sown in the 1980s, however, when some patentees began to attempt to collect royalties for physicians' use of controversial reproductive medicine procedures. In 1984, the AMA adopted an

opinion about medical procedures which, though it did not mention patents, reinforced the norm that "[p]hysicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. . . . [while] [t]he 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."[65] Perhaps surprisingly, the eventual catalyst for a major physician-led movement against medical procedure patents was a patent in the relatively mundane arena of lens-replacement surgery for treating cataracts. Physician opposition to medical procedure patents eventually led to the passage, in 1996, of 35 U.S.C. §287(c), which exempts physicians from remedies for infringement of medical procedure claims.

The story leading up to the enactment of §287(c) begins in 1990, when Dr. James McFarland reported that he had successfully performed sutureless cataract surgery, which alleviated the risk that sutures would distort the replacement lens during healing.[66] Following McFarland's announcement, many surgeons, including Dr. Samuel Pallin and Dr. Jack Singer, worked to duplicate and perfect the sutureless technique. Unlike the others, Pallin applied for a patent, which was directed to a particular shape of the incision through which the replacement lens was inserted. Pallin then attempted to collect royalties from other surgeons who he believed to be infringing his patent.

The response of the medical community is strikingly reminiscent of its response to the ether anesthesia patent. Dr. Jack Singer was one recipient of a demand letter from Pallin. Singer was so outraged by Pallin's royalty demand that he, like Josiah Flagg 150 years earlier, not only refused to pay, but took a very public stand on the patenting issue. He argued at an April 1994 ophthalmology meeting that medical procedure patenting, which he called an "insidious virus," threatened to destroy the medical community's sharing norms:

> 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 relation-

> ship, openness in medical research, and free exchange of medical and surgical knowledge.[67]

Pallin's royalty demands and eventual suit against Singer raised the hackles of many other physicians as well. In a March 1994 interview, for example, McFarland argued:

> 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.[68]

While a lively and sometimes blistering debate about medical procedure patenting ensued, the debate was one-sided, with medical associations urging support of Singer's defense and forming the Medical Procedure Patent Coalition to lobby Congress to make medical and diagnostic procedures unpatentable.

Legislation that would have banned medical procedure patents attracted a bipartisan group of co-sponsors in 1995. Opposition from the biopharmaceutical industry eventually resulted in the 1996 compromise that became 35 U.S.C. §287(c).[69] Though §287(c)'s passage was widely (though not always accurately) celebrated in the medical press as heralding the end of medical procedure patents, the provision is significantly weaker than the medical community's original proposal. Rather than precluding medical procedure patents or providing a defense to infringement liability, §287(c) only eliminates *remedies against medical practitioners and related health care entities*. Because medical practitioners can still be infringers (even though there are no remedies against them), §287(c) leaves the door open to suits against third parties, such as testing laboratories, for contributing to or inducing their infringement.

After §287(c) passed, the medical procedure patent issue receded. In the wake of the *Pallin v. Singer* uproar, physician innovators, who invent most new medical and diagnostic procedures, likely have been unwilling to risk community opprobrium by pushing the limits of the exemption

in suits against other physicians. Indeed, §287(c) was not considered in a single published opinion until 2008, when it came up in *Emtel, Inc. v. Lipidlabs, Inc.*,[70] which remains the only opinion interpreting the scope of §287(c).[71] The silence likely results from the fact that the medical community's norm against patenting medical procedures sweeps more broadly than the statutory provision, which has several carve-outs. In 1995, AMA Ethics Opinion 9.095 made clear in no uncertain terms that "the use of patents . . . to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical."[72]

The persistence of the norm against patenting medical procedures was evident again in recent medical association opposition to the patentability of medical diagnostic procedures. The AMA and other medical associations filed amicus briefs opposing patent eligibility in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*[73] and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*[74] Rather than sue physicians for direct infringement, which probably would have been futile in light of §287(c), the plaintiffs in these cases brought secondary liability suits against test laboratories that provided measurements used by physicians in patented medical diagnostic methods. Unlike *Morton* and *Pallin*, *Mayo* and *LabCorp* did not involve physicians suing other physicians for infringement. Instead, the plaintiffs were commercial firms and the defendants were medical laboratories.

Does the medical profession's continued opposition to these patents after the passage of §287(c) make sense? The hypothesis of this chapter, based on the historical evolution of the physician anti-patenting norm and the insights from studies of user innovation, is that the medical community will oppose patents on the types of inventions that can be made by community members without significant collaboration with outsiders. The opposition stems not only from resistance to paying royalties, but also from concern about the survival of the sharing norm.

Physician opposition to the patents in *Mayo* and *LabCorp* is consistent with this hypothesis. The diagnostic procedures claimed in *Mayo* and *LabCorp* not only could have been, but were, invented by members of the academic medical community acting in their normal capacity. The claims at issue in these cases were based on statistical studies of correlations between biological indicators and clinically relevant con-

ditions. These studies were conducted by medical academics. In *LabCorp*, the inventors were "three university doctors,"[75] who published the results of their study in peer-reviewed journals the same year that their patent issued.[76] Plaintiff Metabolite Laboratories, founded by one of the doctors,[77] operated out of a university laboratory.[78] In *Mayo*, the inventors were a gastroenterologist and a pharmacologist at a university-affiliated hospital in Canada, who published the results of their research shortly after submitting their patent application.[79] Plaintiff Prometheus Laboratories was a later licensee.[80]

In both of these cases, physicians were routinely capable of using the published results to diagnose their patients without relying on the patents. While it is true that the test laboratories contributed to a physician's *practice* of the diagnostic procedures claimed in *Mayo* and *LabCorp*, the laboratory's technicians were not collaborators in *inventing* the procedures, any more than a scalpel manufacturer is a collaborator in the invention of a new surgical procedure. Thus, unlike the development of modern medical devices, the development of diagnostic procedures of the sort involved in *LabCorp* and *Mayo* can take place entirely within the bounds of the medical community and can be rewarded through its system of reputational and sharing norms.

Conclusion

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 must be compensated by something other than use and community reputation. Drug innovation, at one time the province of physicians, is now squarely the province of pharmaceutical companies, with physicians taking a subsidiary or collaborative 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. Medical procedure innovation continues to be primarily the province of physicians, who are compensated with the rewards of reputation and use. Physician opposition to patenting of medical

and diagnostic procedures is thus a typical user innovator community response.

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. Other factors almost certainly are at play, and there may be important differences between different areas of medical practice. 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 also deserve more attention. 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 also are of interest, since physicians do not need to collaborate with drug manufacturers or obtain FDA approval to prescribe off label.

Moreover, if the hypothesis of this chapter is correct, technological changes, such as the increasing incorporation of information technology into the delivery of medical care illustrated by *Emtel*,[81] and regulatory changes, such as potential tightening of regulations for medical procedures and the increased influence of payers on medical practice, may lead to further changes in physician patenting norms. *Emtel*, for example, involved claims in the field of telemedicine. The defendants had contracted with physicians and remote medical facilities to provide videoconferencing for telemedicine. Telemedicine and other IT-based medical procedures increasingly may require that physicians collaborate with software engineers to invent new procedures. As we have seen with medical device innovation, the need for such boundary-spanning collaborations strains, and may destabilize, community anti-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.

NOTES

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1 *The Founding of the AMA*, http://www.ama-assn.org/ama.

2 American Medical Association, *Code of Medical Ethics* §4 (1847).

3 Aaron K. Chatterji, Kira R. Fabrizio, Will Mitchell, and Kevin A. Schulman, "Physician-Industry Cooperation in the Medical Device Industry, When Physician-Inventors Team Up with Industry, Is It Collaborative Innovation or Conflict of Interest?" *Health Affairs* 27 (2008): 1532, 1535, 1537–1538 (approximately 20% of medical device patents have at least one physician inventor).

4 Katherine J. Strandburg, "Legal But Unacceptable: *Pallin v. Singer* and Physician Patenting Norms," in Rochelle C. Dreyfuss and Jane C. Ginsburg, eds., *Intellectual Property at the Edge: The Contested Contours of IP* (Cambridge: Cambridge University Press, 2014), 321–342.

5 *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.* 548 U.S. 124 (2006). See Brief of Amici Curiae AMA et al., *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.* (No. 04–607), http://www.ama-assn.org. (Filed on behalf of six medical associations.)

6 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* 132 S. Ct. 1289 (2012). See Brief of Amici Curiae American College of Medical Genetics et al., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (No. 10–1150), http://www.ama-assn.org/resources. (Filed on behalf of eleven medical associations.)

7 See, e.g., Eric von Hippel, *Democratizing Innovation* (Cambridge, MA: MIT Press, 2005), 77–92.

8 Kara W. Swanson, "Food and Drug Law as Intellectual Property Law: Historical Reflections," *Wis. L. Rev*. (2011): 331, 354–355 (explaining the differences between proprietary medicines and "ethical" medicines).

9 See, e.g., Lewis C. Beck, *Adulterations of Various Substances Used in Medicine and the Arts, with the Means for Detecting them: Intended as a Manuel for the Physician, the Apothecary, and the Artisan* (New York: Samuel S. and William Wood, 1846).

10 See, e.g., H.R. Rep. No. 52 (1849): 5–23, 30 (showing 80 instances of patents on medicines between 1796 and 1843, most of which "combine some active known agent, disguised under colors, and heralded with a name, in many instances, as uncouth as it is insignificant or false").

11 See James A. Johnson and Walter J. Jones, *The American Medical Association and Organized Medicine* (New York: Routledge, 1993): 5–6 (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"); Swanson at 331, 353–56 (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").

12 The definitive scholarly treatment of Morton's role in the invention of ether anesthesia is Richard J. Wolfe, *Tarnished Idol: William Thomas Green Morton and the Introduction of Surgical Anesthesia* (San Anselmo, CA: Norman, 2001). For general overviews of the controversy, see "How It All Began," *Anesthesia History Ass'n Newsletter* (January 1992), reprinted from 11 *Middle East Journal of Anesthesiology* (June 1991); J. M. Fenster, *Ether Day: The Strange Tale of America's Greatest Medical Discovery and the Haunted Men Who Made It* (New York: Harper Collins, 2002).

13 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

14 A vivid description is given in Nathan P. Rice, *Trials of a Public Benefactor, as Illustrated in the Discovery of Etherization* (Pudney and Russell, 1858): 40–42.

15 "How It All Began," 93.

16 U.S. Patent No. 4848 (Nov. 12, 1846).

17 *Tarnished Idol*, 8–26.

18 "How It All Began."

19 For an overview, see *Ether Day*; *Tarnished Idol*.

20 See, e.g., Report of the Committee on Surgery, in *Transactions of the American Medical Association* (1848): 159, 178. (Hereinafter, *AMA Trans*.)

21 See, e.g., *Tarnished Idol*, 57–74; "Massachusetts Medical College—Dr. Jackson's Remarks," *Boston Medical and Surgical Journal* (Mar. 31, 1847): 80; "Letter to the Editor," *Boston Medical and Surgical Journal* (May 7, 1847): 297; "Priority of Discovery of the Use of Ether Vapor," *Boston Medical and Surgical Journal* (May 26, 1847): 333; J.B.S. Jackson, "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 Medical and Surgical Journal* (June 30, 1847): 1; J. Mason Warren, "Inhalation of Ether: One of the Surgeons of the Mass. General Hospital," *Boston Medical and Surgical Journal* (Mar. 24, 1847): 1; John C. Warren, "Inhalation of Ethereal Vapor for the Prevention of Pain in Surgical Operations," *Boston Medical and Surgical Journal* (Dec. 9, 1846): 375.

22 *Tarnished Idol*, 57–119.

23 Bigelow went on to practice surgery at MGH for 40 years and became well known for his contributions to the field. Oliver Wendell Holmes, Reginald H. Fitz, and Arthur T. Cabot, *A Memoir of Henry Jacob Bigelow* (Boston: Little Brown, 1894).

24 J. Mason Warren, "Inhalation of Ether: One of the Surgeons of the Mass. General Hospital," *Boston Medical and Surgical Journal* (Mar. 24, 1847): 1, John C. Warren, "Inhalation of Ethereal Vapor for the Prevention of Pain in Surgical Operations,"

Boston Medical and Surgical Journal (Dec. 9, 1846): 375; George Hayward, "Some Account of the First Use of Sulphuric Ether by Inhalation in Surgical Practice," *Boston Medical and Surgical Journal* (Apr. 21, 1847): 1.

25 *Tarnished Idol*, 77–80.

26 Ibid., 99–101.

27 Ibid.

28 "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 Medical and Surgical Journal* (June 30, 1847): 1.

29 *Tarnished Idol*, 80.

30 U.S. Patent No. 4848 (Nov. 12, 1846).

31 *Tarnished Idol*, 103–109.

32 Ibid., 107.

33 Henry J. Bigelow, "Insensibility During Surgical Operations Produced by Inhalation," *Boston Medical and Surgical Journal* (Nov. 18, 1846): 1.

34 "Report of the Committee on Surgery," in *AMA Trans*. (1848): 159, 181.

35 J. F. Flagg, "Letter to the Editor," *Boston Medical and Surgical Journal* (Dec. 2, 1846): 356.

36 Henry J. Bigelow, "Letter to the Editor," *Boston Medical and Surgical Journal* (Dec. 9, 1846): 1.

37 "Report of the Committee on Surgery," *AMA Trans*. (1848): 176–224.

38 Henry J. Bigelow, "Etherization—A Compendium of its History, Surgical Use, Dangers, and Discovery," *Boston Medical and Surgical Journal* (April 19 & April 26, 1848).

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40 Ibid., 542.

41 Ibid., 534–537.

42 *Tarnished Idol*, 120–121.

43 See, e.g., H.R. Rep. No. 114, 30 Cong. 2nd Sess. (Feb. 23, 1849); 30 Cong. 2nd Sess. Cong. Globe 642 (March 1, 1849); 42nd Congress 2nd Session Cong. Globe 310 (Jan. 9, 1872); 42nd Congress 2nd Session Cong. Globe 377 (Jan. 15, 1872).

44 John Watson, "Letter to the Editor, The Invention of Anaesthesia-National Testimonial to Dr. Wm. T. G. Morton," *New York Times* (Dec. 3, 1858): 2.

45 *Appeal to the Public by Members of the Medical Profession* (1859).

46 See Letters to the Editor in *New England. Journal of Medicine* (Sept. 16, 1858), *New England. Journal of Medicine* (Sept. 23, 1858), *New England. Journal of Medicine* (Sept. 30, 1858); "Law Reports," *New York Times* (Jan. 31, 1862).

47 "The Patent for Sulphuric Ether," *New York Times* (Jan. 31, 1862): 6.

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

49 *AMA Trans*. 15 (1865): 53.

50 17 F. Cas. at 883–84.

51 Bigelow, *Etherization*, 254.
52 *Tarnished Idol*, 72–74, 103–109.
53 Ibid., 50–52.
54 Bigelow, *Etherization*.
55 *Tarnished Idol*, 110–111.
56 Ibid., 118.
57 "Report of Council on Constitution and Bylaws," *Proc. AMA Clinical Meeting* (1955): 111.
58 *Principles of Medical Ethics 1957* §2 (1958), http://www.ama-assn.org.
59 See http://www.ama-assn.org.
60 "Official Opinions of the Judicial Council," *JAMA* 163 (1957): 1156–1157.
61 "Opinions on Professional Rights and Responsibilities," in *Code of Medical Ethics: Current Opinions with Annotations* (1996–1997 ed. 1996): 150.
62 *Ex Parte Brinkerhoff*, 24 Dec. Comm'r 349 (1883), reprinted in *New Decisions*, 27 *Journal of The Patent & Trademark Office Society* (1945): 793, 798.
63 *Ex Parte* Scherer, 103 U.S.P.Q. (BNA) 107 (B.P.A.I July 23, 1954).
64 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).
65 "Opinions on Professional Rights and Responsibilities," in *Code of Medical Ethics: Current Opinions with Annotations* (1996–1997 ed. 1996): 149–150.
66 For a more detailed discussion of these events, see Strandburg, "Legal but Unacceptable."
67 "Doctor Implores Principles of Hippocrates to Standing Ovation," *Ophthalmology Times* (May 1, 1994): 28.
68 "Sutureless Takes Firm Hold on Cataract Surgery: Interview with Mike S. McFarland," 12 *Ocular Surgery News* 12 (March 15, 1994): 21–32.
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70 *Emtel, Inc. v. Lipidlabs, Inc.* 583 F. Supp. 2d 811 (S. D. Tex. 2008).
71 The provision also was at issue in *Lamson v. U.S.*, 117 Fed. Cl. 755 (2014), but the only disputed issue was whether the exemption was available to the government.
72 Opinion 9.095, *Code of Medical Ethics of the AMA* (1996, 2008).
73 Brief of Amici Curiae AMA et al., *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.* (No. 04–607), http://www.ama-assn.org. (Filed on behalf of six medical associations.)
74 Brief of Amici Curiae American College of Medical Genetics et al., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (No. 10–1150), http://www.ama-assn.org. (Filed on behalf of eleven medical associations.)
75 LabCorp at 128 (Breyer, J.) (dissenting from dismissal of certiorari).
76 See, e.g., J. Lindenbaum , D. G. Savage, S. P. Stabler, and R. H. Allen, "Diagnosis of Cobalamin Deficiency: II. Relative Sensitivities of Serum Cobalamin, Methylmalonic Acid, and Total Homocysteine Concentrations," *American Journal of Hematology* 34 (1990): 99; R. H. Allen, S. P. Stabler, D. G. Savage, and J. Lindenbaum,

"Diagnosis of Cobalamin Deficiency I: Usefulness of Serum Methylmalonic Acid and Total Homocysteine Concentrations," 34 *American Journal of Hematology* (1990): 90–98.

77 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.").

78 *Riezler v. Allen*, 2010 U.S. Dist. LEXIS 97853 (D. Colo. Sept. 16, 2010) at *3—*7 (describing Metabolite's relationship to the University of Colorado).

79 Compare, e.g., U.S. Patent No. 6,680,302, Fig. 1, Examples I and II with M. C. Dubinsky, S. Lamothe, H. Y. Yang, S. R. Targan, D. Sinnett, Y. Theoret, and E. G. Seidman, "Pharmacogenomics and Metabolite Measurement for 6-Mercaptopurine Therapy in Inflammatory Bowel Disease," *Gastroenterology* 118 (Apr. 2000): 705, Figs. 2 and 5.

80 For information about Prometheus Laboratories, see http://www.prometheuslabs.com.

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