Medical Ethics and the Patenting of Medical Devices — A Call for Change to a Bright Line Rule

By

Todd Edward Marlette
B.S.E. (E.E.), August 1989, University of Michigan College of Engineering
J.D., May 1992, Case Western Reserve University School of Law
LL.M., May 2004, The George Washington University Law School

A Thesis submitted to
The Faculty of

The George Washington University Law School
in partial satisfaction of the requirements
for the degree of Masters of Laws

May 16, 2004

Thesis directed by
Martin J. Adelman
Professor of Law; Co-Director of the Intellectual Property Law Program;
Director of the Dean Dinwoody Center for Intellectual Property Studies

Table of Contents

Medical Ethics and the Patenting of Medical Devices — A Call for Change to a Bright Line Rule

I. Introduction

The medical establishment, like the legal establishment, is licensed at the state level and self regulated at the professional level. The American Medical Association (AMA) self regulates through the issuance of a *Code of Medical Ethics*.[1] The Opinions of the AMA's Council on Ethical and Judicial Affairs provide the substance of the *Code of Medical Ethics* and represent the official ethics policy of the AMA.[2] To justify the proscription of its ethical Opinions, the AMA relies upon reports published in the form of law review articles.[3]

In June of 1996, the AMA adopted Opinion 9.095, which deemed it unethical for a physician to obtain a medical procedure patent.[4] Opinion 9.095 was based on the report, *Ethical Issues in the Patenting of Medical Procedures*, adopted June 1995 and published in 1998.[5] The main justifications set forth in the published report are restricted clinical and academic access,[6] difficulties associated with patent enforcement,[7] and that disclosure may be delayed in the presence of widespread patenting.[8]

---

[1]Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Code of Medical Ethics: Current Opinions with Annotations* (2002–2003) [hereinafter AMA Annotated Opinions], *available at* http://www.ama-assn.org/ama/pub/category/2503.html (last updated Dec 22, 2003).

[2]*Id*.

[3]*See* Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Ethical Issues in the Patenting of Medical Procedures*, 53 Food & Drug L.J. 341 (1998) (justifying Opinion 9.095 — the prohibition of physicians obtaining medical procedure patents — as a published law review article) [hereinafter *Ethical Issues*]. *See generally* AMA Annotated Opinions, *supra* note 1 (published by AMA Press with annotations provided by Southern Illinois University Schools of Medicine and Law).

[4]AMA Annotated Opinions, *supra* note 1, at Opinion 9.095 (adopted June 1995, issued June 1996). *See infra* Part III.I.

[5]*Ethical Issues*, *supra* note 3.

[6]*Id*. at 344–46.

[7]*Id*. at 347.

[8]*Id*.

Since publication of the AMA report, the law has changed. U.S. law now prohibits enforcement of a medical procedure patent against a medical practitioner.[9] This legislation, known as the Ganske/Frist Amendment,[10] was attached as a rider to the *Omnibus Consolidated Appropriations Act of 1997*,[11] and deviated substantially from the much-debated prior legislation.[12] This has led to substantial criticism,[13] and prompted one commentator to opine that this dispute is "ripe for intellectual, philosophical, and ethical debate and resolution."[14]

In addition, the U.S. now has a default rule of 18 month publication,[15] in that a pending application will be made public unless the applicant otherwise makes a certified request.[16] This article proposes amendment to Opinion 9.095 in accordance with recent changes to U.S. law.

The AMA has also adopted Opinion 9.09, which provides a safe harbor for patenting surgical or diagnostic instruments.[17] The safe harbor of Opinion 9.09 was in

---

[9]Omnibus Consolidated Appropriations Act, 1997, Limitation On Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity, Pub. L. No. 104–208, § 616, 110 Stat. 3009, 3009–67 (1996) (codified as amended at 35 U.S.C. § 287(c) (2004)) [hereinafter Medical Practitioner Exemption Act].

[10]Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity, S. 2125, 104th Cong. § 1 (1996). The legislation was named after Rep. Greg Ganske and Sen. Bill Frist, a former heart transplant surgeon. 142 Cong. Rec. S12023 (1996).

[11]Omnibus Consolidated Appropriations Act, 1997, H.R. 3610, 104th Cong. (1996) (enacted).

[12]Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1996) (seeking to prohibit issuance of medical procedure patent by U.S. Patent and Trademark Office).

[13]Opposition to the Ganske/Frist Amendment included the U.S. Patent and Trademark Office, the American Bar Association, the American Intellectual Property Law Association, and the Intellectual Property Owners. 142 Cong. Rec. S11845 (1996).

[14]Scott D. Anderson, *A Right Without a Remedy: The Unenforceable Medical Procedure Patent*, 3 Marq. Intell. Prop. L. Rev. 117, 130 (1999).

[15]Intellectual Property and Communications Omnibus Reform Act of 1999, Title IV (American Inventors Protection Act of 1999), Pub. L. No. 106-113, § 4502, 113 Stat. 1501A-521, 1501A-561 (codified as amended at 35 U.S.C. § 122 (2004)).

[16]The U.S. Patent and Trademark Office offers form PTO/SB/35 for U.S. applicants not filing in a foreign country and seeking non-publication of their application, *available at* http://www.uspto.gov/web/forms/sb0035.pdf (last visited Apr. 18, 2004).

[17]AMA Annotated Opinions, *supra* note 1, at Opinion 9.09 (issued prior to Apr. 1977). *See infra* Part III.I.

response to the prior AMA *Code of Ethics*, dating from 1847,[18] that prohibited physician patenting on same. Uncountable medical devices are neither surgical nor diagnostic instruments, such as a simple bandage or crutch, a therapeutic pacemaker, or a heart valve stent. Moreover, the controversy surrounding medical procedures and their current prohibition under Opinion 9.095 provides an impetus for a bright line rule. In view of the evolving nature of medical technology, this article proposes to expand the safe harbor of Opinion 9.09 to include patenting of all medical devices.

II. Selected Historical Developments in Medical Technology[19]

The evolution of modern patent law policy for medical devices involves the interplay of technological advancement, ethical restraint by the medical community, and governmental regulation. In accordance with the following, the author seeks to re-establish the justification for patenting of medical technology through historical example, while addressing specific aberrations that have, at times, unnecessarily restrained advances in patent protection.

A. Early Developments in Medical Technology

The use of medical devices traces its history to the origin of medicine itself. Hippocrates, born circa 460 BC, is the presumed author of a number of medical treatises, known as the *Hippocratic Collection*.[20] Medical devices of the time included forceps,

---

[18]Am. Med. Ass'n, *Original Code of Medical Ethics* (1847) [hereinafter Code of 1847], *reprinted in Ethics Revolution*, *supra* note 274, app. C, *available at* http://www.ama-assn.org/ama/upload/mm/369/1847code.pdf (last visited Apr. 18, 2004).

[19]I wish to thank Christine A. Ruggere, Curator, Historical Collection, Inst. of the History of Med., Johns Hopkins Univ., for her invaluable assistance in researching the history and origin of many notable medical devices.

[20]The ancient manuscripts of Hippocrates, some seventy in all, are generally referred to as the *Hippocratic Collection*. W.H.S. Jones, *Preface* to 1 Hippocrates, at v (W.H.S. Jones trans., 1923) (consecutive series continually translating and publishing works in the *Hippocratic Collection* in vols. 1–8). *See also Translator's Note* to Jacques Joanna, *Hippocrates* (MB DeBevoise trans., Johns Hopkins Univ. Press 1999) (1992) (referring to treatises collectively as the *Hippocratic Collection*). Due to limited access to original Greek manuscripts, no definitive work collects and translates into English all treatises of the *Hippocratic Collection*. Interview with Christine A. Regur, Curator, Historical Collection, Institute of the History of Medicine, Johns Hopkins University, Baltimore, Md. (Mar. 2, 2004). The scholar is referred to the Loeb Classical Library series by W.H.S. Jones et al. *Id*.

knives, and probes, along with detailed and complex bandaging techniques.[21] The Etruscan civilization in Italy during the 6th and 7th centuries BC had developed sophisticated dental appliances including gold bridges to secure human or ox teeth to existing good teeth.[22] Indian doctors in the first millennium AD possessed over a hundred different types of surgical instruments.[23] Indian doctors were particularly gifted at reconstructing the nose — primarily because amputation was the official punishment for adultery.[24]

Medical devices in early American history, and particularly during the nineteenth century, greatly increased medical knowledge in the combat of disease. In 1884, it was observed, "If there is a single feature that, more than another, distinguishes the practice of the present from that of a former time, it is the use of numerous instruments of precision."[25] Due in part to an underdeveloped patent system and in part due to philanthropic notions of medical discovery, many early medical advances did not benefit from patent protection.

Notorious, scandalous, questionable, and outright dangerous medical devices are prevalent throughout the history of medicine.[26] The author has chosen the following

---

[21]Albert S. Lyons & R. Joseph Petrucelli, *Medicine: An Illustrated History* 199, 207 (1987) (illustrating and detailing ancient surgical, dental, and gynecological instruments; and 19th century advertisements for patent medicines).

[22]*Id*. at 232. *See also* Don Clawson, *Phoenician Dental Art, in* 1 Encyclopedia Phoeniciiana (The American Press, Beirut, 1934), *available at* http://phoenicia.org/dentstry.html (note misspelling of "dentistry" which may change at later date) (last visited Jan. 15, 2004).

[23]Jurgen Thorwald, *Science and Secrets of Early Medicine* 206 (Richard Winston & Clara Winston trans., Harcourt, Brace & World, Inc. 1963) (1962) (illustrating ancient Indian bone forceps and modern surgical instruments). The surgical text, *Susruta Samhita (Collection)*, described twenty sharp instruments and 101 blunt instruments, and provided a detailed description of cataract surgery and restoration of a nose mutilated by plastic surgery. *Id*. The surgical instruments included forceps, specular, scalpels, scissors, saws, needles, cauteries, syringes, trocars, and catheters. Lyons, *supra* note 21, at 115.

[24]Thorwald, *supra* note 23, at 208; Lyons, *supra* note 21, at 115.

[25]Norman Bridge, *The New Science of Medicine*, 2 JAMA 309, 312 (1884). Just one year earlier, the same postulate was made in Great Britain. A.T.H. Waters, *An Address Delivered at the Fifty-First Annual Meeting of the British Medical Association*, 6 Med. Rec. 141 (1883) ("[I]f I were to point to one circumstance which, in my opinion, has, probably more than any other, contributed to this result, I should say it was the introduction into our practice of instruments of precision.").

[26]*See, e.g.*, Audrey Davis & Toby Apple, *Bloodletting Instruments in the National Museum of History and Technology* (1979) (providing 124 illustrations of antique bloodletting instruments).

devices due to their revolutionary impact on contemporary medicine and their ease of technical understanding. While contemporary use of the following devices is easily taken for granted, the policy considerations underlying their acceptance underscore the need for a liberal patent system and a liberal ethical doctrine when confronted with emerging and yet untested technology.

B. The Chamberlen Obstetric Forceps: A Century of Suppression[27]

The re-invention of the obstetric forceps in the 17th century represented a critically important technical advance in the management of childbirth.[28] As stated by Alfred H. McClintock, editor of *Smellie's Treatise on the Theory and Practice of Midwifery*,[29] "This discovery of the forceps, therefore, may fairly be regarded as *the* most salient and important epoch in the history of obstetrics."[30]

The obstetric forceps for the delivery of a living child were probably known as early as the second or third century AD.[31] A marble bas-relief from that era clearly shows use of forceps during childbirth.[32] While destructive forceps were well known to

---

[27]*See generally* J.H. Aveling, *The Chamberlens and the Midwifery Forceps* (AMS Press, Inc. 1997) (1882) (providing detailed biography and critical essay on prior writings, including his own, regarding Chamberlen obstetric forceps). *See also* Kedarnath Das, *Obstetric Forceps Its History and Evolution* (1927) (providing detailed history of the obstetric forceps distinguishing the pre–Chamberlen period from the Chamberlen period).

[28]Peter M. Dunn, *The Chamberlen Family (1560–1728) and Obstetric Forceps*, 81 Archives Disease Childhood Fetal and Neonatal Edition F232 (1999) (the *Fetal and Neonatal Edition* is a supplement journal to the *Archives of Disease in Childhood*; wherein page numbers are preceded by an "F") (summarizing the development of obstetric forceps over four generations by the Chamberlen family).

[29]William Smellie, *Smellie's Treatise on the Theory and Practice of Midwifery* (Alfred H. McClintock, ed., London, New Sydenham Soc'y 1878) (first recognized treatise on practice of obstetrics).

[30]1 *id*. at 66 (praising quality of Chamberlen obstetric forceps).

[31]Harold Speert, *Iconographia Gyniatrica A Pictorial History of Gynecology and Obstetrics* 270 (1973) (detailing history of obstetric instruments).

[32]*Id*. at 281 (illustrating Roman marble bas-relief of physician using obstetric forceps, 74 cm x 55 cm, circa 2nd or 3rd century AD).

the surgeon,[33] the obstetric forceps fell into disuse and were not reintroduced into service until the advent of the Chamberlen family, toward the close of the sixteenth century.[34] Even the famous William Smellie,[35] in the second quarter of the 18th century, used a blunt hook, a crochet and a perforator for the first thirteen years of his practice.[36] Levers were sometimes used to pry the infant head from the mid or low pelvis.[37]

In the mid–seventeenth century, attempts by male physicians to practice obstetrics were met with opposition.[38] Due to the prudish nature of the times, male physicians were often forced to tie one end of a sheet to their neck, with the other end tied to the patient's neck, to protect the patient's dignity.[39] As a result of malnutrition, especially in the country and towns, many women's bones had become twisted and warped by rickets, making normal childbirth extremely dangerous.[40] If the child could not be delivered through normal birth, the only available remedies were cesarian section, an operation where the child is delivered through a cut in the woman's abdomen, or a craniotomy, by which the child was destroyed before being drawn through the birth canal.[41] Surgeons

---

[33]*Id*. at 270–75 (illustrating numerous destructive forceps throughout history). Destructive forceps for bringing forth a dead child were known from the 2nd century BC; and by 1554, various instruments were well known to the general surgeon for extraction of a dead child. Bryan M. Hibbard, *The Obstetric Forceps — A Short History and Descriptive Catalogue of the Forceps in the Museum of the Royal College of Obstetricians and Gynaecologists* 4 (1988) (Bryan M. Hibbard, Curator of Instruments). *See also* Vilhelm Møller-Christensen, *The History of the Forceps — An Investigation on the Occurrence, Evolution and Use of the Forceps from Prehistoric Times to the Present Day* (W.E. Calvert trans., 1938) (detailing history of destructive and surgical forceps from Egyptian tweezers, circa 3300–2890 BC to early twentieth century).

[34]Speert, *supra* note 31, at 270.

[35]*See* Smellie, *supra* note 29.

[36]Hibbard, *supra* note 33, at 5.

[37]*Id*.

[38]Howard W. Haggard, *Devils, Drugs, and Doctors — The Story of the Science of Healing from Medicine-Man to Doctor* 46 (1929) (detailing time period and role of Chamberlens as obstetric physicians in ch. 3).

[39]*Id*.

[40]Walter Radcliffe, *The Secret Instrument (The Birth of the Midwifery Forceps)* 4 (1947) (describing "mediæval [sic] midwifery" towards the end of the seventeenth century).

[41]*Id*.

were particularly feared by expectant mothers because all procedures were performed without anesthetic.[42]

The Chamberlens went to great lengths to maintain the secrecy of their obstetric forceps. In a massive gilt-trimmed chest borne by special carriage, they transported their instruments to their patients.[43] Reportedly, it required two people to transport this box,[44] and the patients were blindfolded during the procedure.[45] The Chamberlens then produced "peculiar noises, ringing bells, and other sinister sounds" as their secret went to work.[46] This may possibly have given rise to the phrase "bells and whistles" as indicative of obvious showmanship.[47]

The four generations of Chamberlens began their notable history in 1569 when Dr. William Chamberlen fled with his family from Paris to Southampton, England.[48] Dr. William had five children — most notably, Peter the elder and Peter the younger.[49] Peter the elder is credited with invention of the obstetric forceps.[50] In 1813 the mystery surrounding inventorship was dispelled when a box of tools were found hidden beneath a trap door in the attic of his former residence.[51] The box included three pairs of levers

---

[42]*Id*. at 5–6.

[43]Speert, *supra* note 31, at 271.

[44]Dunn, *supra* note 28, at F232.

[45]Speert, *supra* note 31, at 271.

[46]Dunn, *supra* note 28, at F233.

[47]*See* Brett G. Alten, Note, *Left To One's Devices: Congress Limits Patents on Medical Procedures*, 8 Fordham Intell. Prop. Media & Ent. L.J. 837, 837 n.2 (1998) (indicating Chamberlens as possible origin of term "bells and whistles").

[48]*See* Das, *supra* note 27, at 77.

[49]*See* Aveling, *supra* note 27, app. (illustrating pedigree chart of 5 children, 8 grandchildren, 9 great grandchildren, and 4 great-great grandchildren).

[50]Das, *supra* note 27, at 101–02 ("As far therefore as can be determined by existing evidence, Peter Chamberlen senior [the elder], may with absolute certainty have the honour [sic] conferred upon him of being the inventor of midwifery forceps.").

[51]Speert, *supra* note 31, at 273.

terminating in hooks, three pairs of crotchets terminating in hooks, three fillets, and four pairs of metal obstetric forceps.[52] The forceps were fenestrated, separable, and when viewed from the side evidenced a straight portion with a cranial curve for grasping the infant head.[53] The bearing for three of the forceps was a fixed pivot on one blade that was received into a hole in the other.[54] The fourth pair merely had holes in each blade through which a cord could be passed and wound.[55]

There is no record that Dr. Peter Chamberlen the elder attempted to patent his obstetric forceps.[56] However, one biography confirms that Peter the elder was well aware of the patent system. "It is true Dr. Peter Chamberlen [the elder] attempted to patent some mechanical contrivances, but he acknowledged that they were not of his own invention, and were of so chimerical a character, as to prove him to have been anything but a sound and practical mechanician."[57]

Dr. Peter Chamberlen the elder clearly enjoyed the political clout to obtain a patent had he desired one. Peter the elder's name appears in the Annals of the Barber Surgeon's company in 1598.[58] However, in 1612 he was condemned to the infamous Newgate prison by the Royal College of Physicians for not confining himself to the practice of surgery, i.e. practicing medicine.[59] The Archbishop of Canterbury petitioned

---

[52]Aveling, *supra* note 27, at 220–23.

[53]Dunn, *supra* note 28, at F234.

[54]*Id*.

[55]*Id*.

[56]The English patent to Dr. Peter Chamberlen in 1668–1669 for *Propelling Ships and Carriages by Wind*, was issued to the son of Peter the younger (hereinafter called Peter II), not to his brother, Peter the elder. Das, *supra* note 27, at 84, 86 (indicating Peter II as the inventor of several inventions, including "baths and stoves" for the cure of disease). Reportedly, Peter II obtained patents on his wind-impelled carriages in Sweden in 1669 and Denmark in 1670. *Id*. at 90 (citing "Scharffenberg, Norsk Mag. f. Laegevidenskaben, 1902, vol. 63, p. 419"). *See also* Aveling, *supra* note 27, at 60–79, 90–104 (describing Peter II's inventions of baths and showers, a proposal for propelling ships and carriages by wind, and advocacy of phonetic writing).

[57]Aveling, *supra* note 27, at 224–25.

[58]Das, *supra* note 27, at 77.

[59]*Id*. at 78.

to the President and Censors, at the mandate of the Queen Ann, to secure the release of Dr. Chamberlen.[60] Peter the elder had attended Queen Ann during the delivery of her child, the future King Charles I.[61]

While all generations of Chamberlens practiced obstetrics, it was the son of Peter the younger, also named Dr. Peter Chamberlen (hereinafter Peter II), who gained considerable notoriety. Peter II received his medical degree from Yale, attempted political reform in England, and produced numerous inventions in his own right. Peter II was clearly aware of patents, having obtained a number of them.[62] However, Peter II did not obtain a patent on his family's obstetric forceps, relying instead upon secrecy for protection. Peter II published a translation of a contemporary — a treatise on obstetrics, in which he wrote:

> In the 15th Chapter of this book, my author proposes the conveying of sharp instruments into the womb, to extract a head, which is a dangerous operation and may be much better done by our forementioned arts . . . .
>
> . . . .
>
> . . . I will now take leave to offer an apology for not publishing the secret I mention we have to extract children without hooks, where other artists use them, *viz*, there being my Father and two Brothers living, that practise [sic] this art, I cannot esteem it my own to dispose of nor publish it without injury to them; and think I have not been unservicable [sic] to my country, altho [sic] I do but inform them that the forementioned three persons of our family and myself, can serve them in these extremities, with greater safety than others.[63]

Had Peter the elder, Peter the younger, or Peter II published their discovery for the benefit of mankind, each "would have conferred honour [sic] on his profession and

---

[60] *Id*.

[61] *Id*.

[62] *See supra* note 56 (reporting patents to Peter II).

[63] Das, *supra* note 27, at 91–92 (quoting Dr. Peter Chamberlen (Peter II), *Preface to* Frances Mauriceau, *The Diseases of Women with Child and in Child-bed* (Peter Chamberlen trans., London 1694) (1672)).

entitled himself to everlasting gratitude as one of the greatest benefactors of the human race."[64] Contemporaries of the time were less flattering. In the notable words of de La Monte, obstetrician of Volgens, "He who keeps secret so beneficial an instrument as the harmless obstetrical forceps deserves to have a worm devour his vitals for all eternity."[65] The benefits of the obstetric forceps to women of the time were unquestionable, namely the avoidance of caesarian sections, which were often deadly to the mother, and avoidance of craniotomies, which were deadly to the infant.[66]

Thus, the story of the Chamberlen obstetric forceps underscores two fundamental policy considerations for the patenting of medical devices: First, that the benefits to society and human welfare are greatly increased through the disclosure of technology in exchange for a limited right; and second, that concerns from the established medical community and attempts at ethical restraint are better addressed through disclosure, rather than secret and misinformed criticism.

C. The Laennec Stethoscope: Private Resources in the Development of Technology

The modern stethoscope was invented in 1816 by René Théophile Hyacinthe Laënnec (R.T.H. Laennec).[67] At the brink of his monumental discovery, Laennec first attempted diagnosis of his patient by using the technique of percussion, i.e. rapping the chest with fingers and then listening to the sound.[68] Obesity and a regard for his female

---

[64]Smellie, *supra* note 29, at 66 (McClintock annotation).

[65]Haggard, *supra* note 38, at 51.

[66]Radcliffe, *supra* note 40, at 4.

[67]R.T.H. Laennec, *A Treatise on the Diseases of the Chest (Auscultation Médiate)* (John Forbes trans., Hafner Publ'g Co. 1962) (1821), *reprinted in* 1 Fredrick A. Willius & Thomas E. Keys, *Classics of Cardiology* 328–84 (1983); Jacalyn Duffin, *To See with a Better Eye — A Life of R.T.H. Laennec* 124 (1998) (prepared from dissertation in support of Ph.D.). *See also* Stanley Joel Reiser, *The Science of Diagnosis: The Sound, in* 2 Companion Encyclopedia of the History of Medicine 828 (W.F. Bynum & Roy Porter eds., 1993) (describing invention of stethoscope and effect on medical practice). *See generally* Roger Kervran, *Laennec His Life and Times* (D.C. Abrahams-Curiel trans., 1960) (providing biography and extensive bibliography).

[68]Reiser, *supra* note 67, at 828. Modern use of percussion is attributed to Leopold Auenbrugger (1722–1809). *Id*. *But cf.* Robert W. Buck, *Physical Diagnosis Prior to Auenbrugger*, 209 New Eng. J. Med. 239 (1933) (reporting Nicander as using "tympanitic dropsy," i.e. striking the abdomen to produce a drum-like sound, circa 200 BC; and the *Ebers papyrus* as referencing sounds that are "audible within the human body" in Egypt circa 1500 BC).

patient's dignity prohibited use of the Hippocratic technique of placing the ear directly to the chest.[69] At this point, as stated by Laennec:

> [I] happened to recollect a simple and well-known fact in acoustics . . . [namely] the augmented impression of sound when conveyed through certain solid bodies . . . . [I] rolled a quire [square] of paper into a sort of cylinder and applied one end of it to the region of the heart and the other to my ear, and was not a little surprised and pleased, to find that I could thereby perceive the action of the heart in a manner much more clear and distinct than I had ever been able to do by the immediate application of the ear.[70]

By February of 1818 Laennec was using a stethoscope[71] formed from a wooden cylinder about one foot long with a quarter-inch central canal, a break in the middle joined by a screw, and a funnel shaped hollow at one end.[72] The now-familiar binaural (dual ear) stethoscope did not find acceptance until the 1850s, with the first useful model including flexible gutta-percha tubes, flat ear pieces, and a chest piece including a membrane stretched over a disk.[73]

---

[69]R.T.H. Laennec, *supra* note 67, at 284. Listening to the sounds within the chest was reported in ancient medical literature, namely the Ebers Papyrus (1500 BC). Audry B. Davis, *Medicine and Its Technology — An Introduction to the History of Medical Instrumentation* 87 (1981) (providing in ch. 5 a history of the stethoscope).

[70]R.T.H. Laennec, *supra* note 67, at 284–85, *reprinted in* Willius, *supra* note 67, at 326.

[71]Laennec preferred the term "*le cylindre,*" but finally coined the term *"stethescope* [sic]" from the Greek στῆθος (chest) and σκοπεῖυ (to examine, to explore). Duffin, *supra* note 67, at 129. "This instrument I commonly designate simply the *Cylinder*, sometimes the *Stethescope* [sic]." R.T.H. Laennec, *supra* note 67, at 286. For a side-by-side comparison of the Laennec cylindrical stethoscope, circa 1820, and a binaural stethoscope having flexible tubing for the ears, circa 1858, by Scott Alison, see The Wellcome Trust, *The Forgotten Museum of Henry Wellcome* at (Ken Arnold & Danielle Olsen eds., 2003).

[72]*Id*. For an illustration of a stethoscope dated 1819, see R.T.H. Laennec, *supra* note 67, at 437, *PLATE VIII* (describing at 437 and illustrating at PLATE VIII wooden stethoscope used by Laennec). *See also* M. Donald Blaufox, *An Ear to the Chest — An Illustrated History of the Evolution of the Stethoscope* (2002) (detailing with illustration evolution of stethoscope and binaural stethoscope).

[73]A.B. Davis, *supra* note 69, at 104 (crediting invention of the first acceptable binaural stethoscope to Dr. Arthur Leared of Dublin, Ireland in 1851). *But see* Blaufox, *supra* note 72, at 44–45, 48 (illustrating Leared binaural stethoscope, but crediting G.P. Cammann's self adjusting double stethoscope as the first truly practical binaural stethoscope).

Although by April of 1819 Laennec had reportedly sold 35,000 copies of the first two editions of his treatise, *Auscultation Médiate,*[74] and had decided to retain the publication rights for himself,[75] there is no indication that Laennec ever sought patent protection for his stethoscope. Patent protection was available in Europe at the time, as indicated by the prior patents of Dr. Peter Chamberlen (Peter II) circa 1668–1670.[76] One is left to speculate whether Laennec, a well known student of Hippocrates,[77] chose to dedicate his stethoscope to the public while earning a living from his scholarship and consultations.

The first recorded U.S. patent for the stethoscope was awarded to Nathan B. Marsh of Cincinnati, Ohio on December 16, 1851.[78] Threats of infringement soon followed, as described by Dr. George P. Cammann in his letter to the *New York Journal of Medicine*:

> Being informed that Dr. Marsh, of Cincinnati, complains of my having infringed the patent on his double stethoscope, I would state that,
> 1. Dr. Marsh's instrument and mine differ essentially one from the other both in principle and construction.
> 2. I wholly disclaim any intention of interfering with the rights and interests of Dr. Marsh. I have never received any advantage from the sale of my stethoscope, but presented it free to the profession. Dr. Marsh . . . [seems] to avail himself of [my invention] with all its improvements and adaptation to practical purpose. . . . He certainly cannot acquire the moral right to receive the benefit of other men's labors.

---

[74]R.T.H. Laennec, *supra* note 67.

[75]Duffin, *supra* note 67, at 148 (describing April 1819 letter from Laennec to his cousin).

[76]*See supra* note 56 (reporting patents to Peter II).

[77]Willius, *supra* note 67, at 325 (reporting that Laennec received his doctor degree in June 1804 for "Propositions on the doctrines of Hippocrates in regard to the practice of medicine."). *See also* Duffin, *supra* note 67, at 270 (reporting that Laennec often quoted from Hippocrates during his lectures as Professor at the Collége de France, circa 1822).

[78]U.S. Patent No. 8,591 (issued Dec. 16, 1851).

> 3. Dr. Marsh's stethoscope appears to be but a modification of other instruments long known in Europe and now in my possession.[79]

The views of Dr. Cammann reflect the prevailing view of the time, namely that physicians should neither patent nor profit from their invention. While there is no record of litigation or licensing between Drs. Marsh and Cammann, the foregoing serves to illustrate the need for defensive patenting of medical technology as an aid to bringing useful medical technology to the medical practitioner through the stream of commerce.

By the turn of the century, significant improvements to the stethoscope followed. Charles Denison chose not to patent his improvements to the stethoscope, but later regretted his decision, citing the need for quality control and maintaining reasonableness of price.[80] Perhaps by way of defensive publication, Denison published seven criteria for improved stethoscope design: (1) smooth inner calibre [sic], (2) continuous transmission of sound, (3) flexible tubes lined with smooth soft rubber, (4) acorn shaped ear endings, (5) spring attached arms to urge ear pieces toward ears, (6) bell ending of preferably one inch diameter, and (7) larger bell for use with forcible percussion.[81] As expected with the evolution of any technology, significant patent activity followed.[82]

The effects of the stethoscope on the medical profession were revolutionary.[83] First, the stethoscope contributed to understanding pathology and therapeutics of chest

---

[79]Letter from G.P. Cammann to correspondence section of the *New York Journal of Medicine* (New York, Dec. 2, 1856), *in* Blaufox, *supra* note 72, at 46.

[80]Charles Denison, *An Improved Binaural Stethoscope*, 42 Med. Rec. 494, 494–95 (1892) ("My instrument was not patented, as it should have been, for the purpose of needed regulation as to the quality of work and reasonableness of price."), *reprinted in* Blaufox, *supra* note 72, at 51–53.

[81]*Id*.

[82]*See, e.g.*, U.S. Patent No. 526,802 (issued Oct. 2, 1894) (diaphragm placed within bell); U.S. Patent No. 773,274 (issued Oct. 25, 1904) (pear shaped diaphragm); U.S. Patent No. 910,854 (issued Jan. 26, 1909) (internal bell having grooved concentric rings).

[83]Eric V.D. Luft, *René Laënnec Revolutionizes the Diagnosis of Chest Diseases with His Invention of the Stethoscope, in* 5 Science and Its Times — Understanding the Social Significance of Scientific Discovery 282 (Neil Schlager ed., 2000) ("This simple advance [the stethoscope] revolutionized the diagnosis of chest diseases and later contributed to understanding their pathology and therapeutics — that is, what they are and how to treat them.").

disease.[84] The physician was now able to determine the pathology of tuberculosis,[85] distinguish bronchitis and pneumonia,[86] and determine the pathology of asthma.[87] Second, the stethoscope encouraged physicians to be self reliant and independent, as opposed to previous reliance on patients and their family for evidence of pathology.[88] Third, the stethoscope brought reassurance to the patient that medical instruments, heretofore thought to be threatening and magical, would not cause embarrassment or pain.[89]

Laennec received financial reward for his medical innovation from publication and professional advancement. However, Laennec was able to develop his stethoscope from rather simple technology, i.e. rolled paper and shaped wood. Today, the development of modern medical innovation relies heavily on technology and instrumentation — thereby requiring substantial financial investment. To the extent that substantial financial resources are required to further the advancement of medical technology, a system for securing this financial investment is not only justified, but required.

---

[84] *Id*. While Laennec was praised for his research on the lungs, he was criticized for his research on the heart. Duffin, *supra* note 67, at 174 ("[H]istorians have criticized [Laennec's] research on the heart in different ways . . . ranging from open ridicule to bemused indulgence.").

[85] Duffin, *supra* note 67, at 155–56.

[86] *Id*. at 163.

[87] *Id*. at 166. In his treatise, Laennec described diagnosis for "peripneumony" (pneumonia), gangrene of the lungs, pulmonary apoplexy, bronchitis, dilation of the bronchia, edema of the lungs, and "hydatids" (cysts or tumors) in the lungs. R.T.H. Laennec, *supra* note 67, at 44, 51, 60, 68, 76, 97, 113.

[88] Reiser, *supra* note 67, at 831.

[89] *Id*. at 831–32.

D. The Thermometer: Forgotten in Time — Yet Patently Revolutionary

The thermometer, much like the microscope,[90] was known for many years prior to its acceptance as a medical device by the nineteenth century medical community.[91] The thermometer was chosen over the microscope for this article due to its greater use in self diagnosis and initial medical treatment. Most people are more likely to "take their temperature" at the on-set of a cold rather than microscopically view a drop of blood to determine a white blood cell count.

The concept of body temperature and fever has been known throughout recorded history.[92] The Bible, in both the old and new testaments, indicates the presence of fever.[93] From the time of *Hippocrates*,[94] the heat of the body was deemed the chief and most diagnostic sign of disease.[95] The physician Celsus, in 64 AD, described four

---

[90]For a history of medical microscope design, see Albert E. Kalderon, *The Evolution of Microscope Design from Its Invention to the Present Day*, 7 Am. J. Surgical Pathology 95 (1983). For the historical influence of the microscope on medicine, see James H. Cassedy, *The Microscope in American Medical Science, 1840–1860*, at 67 ISIS 76 (1976). For a historical article introducing the microscope to popular medicine, see C. Heitzmann, *The Aid Which Medical Diagnosis Receives from Recent Discoveries in Microscopy*, 1 Archives Med. 44 (1879), *reprinted in* Technology and American Medical Practice 1880–1930, at 65 (Joel D. Howell ed., Garland Publ'g, Inc. 1988) [hereinafter Tech. Practice].

[91]"The clinical thermometer was known three centuries ago. It was neglected till about ninety years since, and has of late grown into such favor that now it is used by the profession almost without exception. . . . [N]o man would think of reporting a case of acute sickness for a first-class medical journal without giving the records of the thermometer." Bridge, *supra* note 25, at 312.

[92]*See* Martin T. Stein, *Historical Perspective on Fever and Thermometry*, 30 Clinical Pediatrics supp. at 5 (1991) (indicating fever during Biblical times, the Middle Ages, the Great Plague of London in 1665, and the nineteenth century tuberculosis epidemics).

[93]*The Bible, Leviticus 26:14–16* (The New Oxford Annotated Bible, Oxford Univ. Press, 3d ed. 2001) (fever as biblical pronouncement — "[I]f you . . . break my commandments . . . I will bring terror on you; consumption and fever that waste the eyes and cause life to pine away."); *id* at *Deuteronomy* 28.15–22 ("[I]f you do not obey the Lord your God[,] . . . [t]he Lord will afflict you with consumption, fever, inflammation, with fiery heat and drought . . . ."); *id*. at *Mark* 1:30 ("Now Simon's mother-in-law was in bed with a fever, and they told [Jesus of Nazareth] about her at once.").

[94]Born circa 460 BC.

[95]C.A. Wunderlich, *On the Temperature in Diseases: A Manual of Medical Thermometry* §§ 1–4 (W. Bathurst Woodman trans., London, New Sydenham Soc'y 1871) (2d ed. 1870) (detailing the origin and history of the thermometer up to the beginning of the eighteenth century).

indicators of inflamation as heat, redness, pain, and swelling.[96] Aristotle postulated that all matter contained four qualities: heat, cold, dryness, and moistness.[97]

Galen, a Roman physician from the first century AD, felt that a person's "complexion" was determined from proportional combinations of the four Aristotle qualities of matter — but in a person, each tempered the other.[98] The word *temperature* was once used to describe a person's emotional disposition, while today the word *temperament* is used.[99] Temperature determinations were subjective, such that a "hot tempered" person might perceive another's temperature differently that a "cold tempered" person.[100] Physicians were therefore required to be "even tempered" in order to diagnose disease. Galen suggested a graduated scale — having end points determined by boiling water and ice, a neutral point determined by mixing boiling water and ice, and four degrees of separation between the neutral point and each end point.[101] However, Galen never constructed such an instrument.[102]

---

[96]Francis J. Ring, *Progress in the Measurement of Human Body Temperature*, IEEE Engineering in Med. and Biology Mag. July/Aug. 1998, at 19 (vol. 17(4)) (providing chronology of temperature as indication of health or disease from the early thermoscope to modern infrared imaging). *Celsus* should not be confused with *Anders Celsius* inventor of the 100° scale instrument in 1742. A.B. Davis*, supra* note 69, at 66 (generally detailing history of medical thermometry in ch. 4, at 61–85).

[97]Taylor F. Sherwood, *The Origin of the Thermometer*, 5 Annals Sci. 129, 129 (1942).

[98]*Id*. For a general review of Galen (131–201 AD) and his writings, see Joseph Walsh, *Galen's Writings and Influences Inspiring Them* 6 Annals Med. Hist. 1 (New Series, 1934). Galen was the most voluminous of the ancient medical writers, and his quotations of others formed a veritable index to all ancient medical knowledge. *Id*. at 1.

[99]Ralph L. McLaury, *A History of Clinical Thermometry*, 76 J. Okla. St. Med. Ass'n 420, 421 (1983).

[100]*Id*.

[101]Sherwood, *supra* note 97, at 130.

[102]McLaury, *supra* note 99, at 421.

Santorio Santorio is credited not only with invention of the thermometer,[103] but with its first medical application as well.[104] In 1612, Santorio in his *Commentaria in Artem Medicinalem Galeni* explained:

> I wish to tell you about a marvelous way in which I am accustomed to measure, with a certain glass instrument, the cold and hot temperature of the air of all regions and places, and of all parts of the body; and so exactly, that we can measure with the compass the degrees and ultimate limits of heat and cold at any time of day.[105]

Thus, the thermometer as we know it was specifically invented to be a medical device.

Some erroneously credit Galileo, a contemporary and friend of Santorio, with invention of the thermometer.[106] This is incorrect for two reasons. First, Galileo used a *thermoscope,* an instrument without a scale, as opposed to a *thermometer*, which includes a scale.[107] Second, the correspondence between Santorio and Galileo clearly establishes

---

[103]*Id*. at 422.

[104]Santorio Santorio, *Commentaria in Primum Fen* col. 219 (Venice 1626) (vault copy at Welch Medical Library, Johns Hopkins University, numbered by column not by page) (showing illustration of oral clinical thermometer used to take temperature), *illustration reprinted in Introduction to* Santorio Santorio, *La Medica Statica* 29 (Giuseppe Ongaro ed., Giunti 2001) (1614) (citing *Commentaria in Primum Fen* at col. 307; note that *La Medica Statica* was previous to *Commentaria in Primum Fen* but the reprint chose to include the illustration in the introduction), *and in* Lyons, *supra* note 21, at 437. *See also* Wunderlich, *supra* note 95, at § 2 ("Sanctorius [sic] . . . was the first to apply, a thermometric instrument of his own discovery and manufacture, to the determination of temperature.").

[105]W.E. Knowles Middleton, *A History of the Thermometer* 9 (1966) (quoting Santorio Santorio, *Commentaria in Artem Medicinalem Galeni,* Part III (Venice, 1612) (Imprimatur 1611)). Compass: An instrument for taking measurements and describing circles, consisting (in its simplest form) of two straight and equal legs connected at one end by a movable joint. 3 *The Oxford English Dictionary* 594, 594 n.4a. (J.A. Simpson & E.S.C. Weiner eds., 2d ed. 1989).

[106]Roger Hahn & Pierre M. Hahn, *Thermometer, in* 26 Encyclopedia Americana 656, 656 (1996) (reporting unverified observations of Galileo inventing air thermoscope in 1610, but noting that disputes of priority are numerous and cannot be settled).

[107]Middleton, *supra* note 105, at 4 ("[A] thermometer is simply a thermoscope provided with a scale."). *But see* Lyons, *supra* note 21, at 437 (incorrectly calling Galileo's non-scaled instrument a "thermometer"); *see* Sherwood, *supra* note 97, at 132 (treating early thermometer, thermoscope, calendar-glass, and weather-glass as equivalent, and having one meaning — an instrument for the measurement or detection of temperature change).

inventorship with the former.[108] Nevertheless, this is irrelevant from a medical perspective because there is no indication that Galileo ever sought to apply his thermoscope to the body.[109] The drawback to Santorio's thermometer was that it was open air, and thus sensitive to changes in barometric pressure.[110]

Contrary to popular belief, Gabriel Fahrenheit did not invent the thermometer,[111] nor did he invent the mercury thermometer.[112] Fahrenheit, a manufacturer of precision instruments, did invent the temperature scale that bears his name.[113] The Fahrenheit scale and its derivation, as observed by Middleton, is controversial. "The history of the scale known by the name of Fahrenheit has led to a very great deal of controversy, and in no other area of the subject are there so many quicksands."[114] However, the invention of the Fahrenheit scale warrants attention because, as set forth below, its origin was based on the determination of human body temperature — laying its incipient foundation for use as a medical device.

---

[108]Middleton, *supra* note 105, at 5–9 (attributing invention of air thermometer to Santorio based upon his correspondence to Galileo). *Contra* Elisabeth Bennion, *Antique Medical Instruments* 182 (1979) (incorrectly listing, without citation, Galileo as first to put scale on tube).

[109]*See* McLaury, *supra* note 99, at 422 (reporting that no mention of the thermometer exists in writings authored by Galileo).

[110]*Id*. at 423.

[111]*See, e.g.,* Bennion, *supra* note 108, at 183 (incorrectly listing, without citation, Gabriel Fahrenheit as inventor of the thermometer).

[112]*See, e.g.,* John S. Haller, *Medical Thermometry — A Short History*, 142 W. J. Med. 108, 108 (1895) (incorrectly listing, without citation, Gabriel Fahrenheit as inventor of mercury thermometer). *See also* 4 Encyclopaedia Britannica, Inc., *The New Encyclopaedia Britannica* 654 (1998) (incorrectly listing Daniel Gabriel Fahrenheit as inventor of mercury thermometer in 1714). The issue is disposed by Fahrenheit's letter of Apr. 17, 1729. *See infra* text accompanying note 115.

[113]*See* Z.C. McElroy, *The Clinical Thermometer: Its Lessons and Teachings Tentatively Expressed in Numbers*, 1 Med. World 121 (1871–1872) (reproducing Fahrenheit scale listing probable death at 108° F and 93° F), *reprinted in* Haller, *supra* note 112, at 110.

[114]Middleton, *supra* note 105, at 66.

In the first decade of the eighteenth century, Fahrenheit visited the Danish astronomer Olaf Rømer, the discoverer of the finite speed of light.[115] Rømer kept a detailed notebook of thermometer observations, the *Adversia*[116] — which recorded his creation of several identical thermometers, was given upon his death to the University Library in Copenhagen, and was revised by his successor Peter Horrebow. Upon investigation, Peter Horrebow determined the Rømer invention date to be between 1702 and 1703.[117] Rømer fixed the melting point of ice at 7.5° (Rø) (because salt water was known to freeze at a lower temperature than fresh water) and a boiling point of 60° (Rø).[118] It was only through a review of Fahrenheit's letters that derivation of the now-infamous scale from Rømer was learned.

> As to the means whereby I came to begin improving thermometers, it may be useful for you to know that it was the commerce I had with the excellent Mr. Rømer of Copenhagen in the year 1708 that first let me in this direction, for on arriving at his house one morning I found that he had several thermometers standing in water and ice, which he later placed in warm water heated to blood heat, and after he had marked these two points on them all, half of the distance found between them was added below the point of water with ice, and this whole distance was divided into 22½ parts, beginning at the bottom with 0, arriving thus at 7½ for the point of water mixed with ice, and 22½ for the point of blood heat, which scale I also used until the year 1717, with the only difference that I further divided each degree into 4 smaller ones. . . . Considering that this scale was difficult and awkward to use because of the fractions, I decided to change it and, instead of 22½ or 90, to use 96, which scale I have always used since and which, although chosen by chance, I have found to agree, if

---

[115]Middleton, *supra* note 105, at 67 (citing at n.4, 2 Kirstin Meyer, *Arch. Gesch. Naturw. Techn.* 323–49 (1910)). *See also* Daniel Gabriel Fahrenheit, *Fahrenheit's Letters to Leibniz and Boerhaave* 4 (Pieter Van Der Star ed. & trans., 1983) (reporting Rømer light speed calculations from observations of Jupiter and its satellites) (providing in Part I the life and work of Fahrenheit, and providing in Part II a line by line translation of original Dutch Fahrenheit letters).

[116]Latin for "notebook." Middleton, *supra* note 105, at 67 (citing reprint at n.6, "*Ole Rømers Adversaria . . . udgivne af det Klg. Danske Videnskaberm Selskab*, ved Thyra Eibe og Kirstine Meyer (Copenhagen, 1910)"). *See also* Fahrenheit, *supra* note 115, at 19 (indicating Rømer scale calibrated at 7.5° (Rø) and 60° (Rø)).

[117]*Id*. at 67–68.

[118]*Id*. at 68.

> not exactly, at least very closely with the thermometer which hangs in the Paris Observatory.[119]

By 1713, Fahrenheit was using mercury over alcohol in his thermometers because it was much easier to obtain pure mercury than it was to obtain pure alcohol.[120] Fahrenheit then adapted his scale to a mercury expansion of 1/120, which meant that 96° F would no longer correspond to normal body temperature.[121] By 1777 a committee of the Royal Society of London, under the chair of Henry Cavendish, specified the boiling temperature of water at a barometric pressure of 29.8 inches (=75.7 cm) of mercury at 212° F with the temperature of melting snow fixed at 32° F, as it had been by Fahrenheit.[122] Later, the average barometric pressure was changed to 760 mm of mercury, thereby raising the boiling point of water to 212.2° F.[123]

There is no indication that Fahrenheit ever tried to patent his thermometers or his temperature scale, and he never published details of his methods of manufacture.[124] The patent system was well known to Fahrenheit because he applied for and obtained a fifteen-year Dutch patent on a *Water Machine* for pumping water from polders.[125]

The difference between a mere thermometer and a *medically useful* thermometer can mean the difference between night and day. While the temperature measurements of Fahrenheit were accurate, the readings could not be held for a useful period of time before returning toward ambient temperature. In 1832, geologist John Philips separated a column of mercury by a "speck of air" to provide thermal insulation and a more accurate

---

[119]Fahrenheit, *supra* note 115, at 171. *See also*, Middleton, *supra* note 105, at 71 (reprinting relevant portions of Fahrenheit letter of Apr. 17, 1729, describing derivation of thermometer scale from Rømer, and providing minor changes of syntax from Fahrenheit translation).

[120]Fahrenheit, *supra* note 115, at 21, 26.

[121]*Id*. at 26.

[122]*Id*. at 30 (citing Cavendish, *The Report of the Committee appointed by the Royal Society* (London, 1777)).

[123]*Id*. at 31.

[124]Fahrenheit, *supra* note 115, at 18.

[125]Gabriel Fahrenheit, Netherlands patent for *Water Machine* (issued Aug. 24, 1736).

reading.[126] However, the Philips thermometer had to be retained horizontally,[127] thereby resulting in substantial inconvenience from a medical perspective. The real breakthrough came by way of the constricted bore tube, patented in England by Negretti & Zambra under British Patent No. 14,002 (issued Mar. 8, 1852).[128] The thermometer including the constricted bore was an immediate success.[129] By way of the constricted bore, the accurate temperature took a period of time to materialize, but also took a period of time to return, thereby allowing ample time for the physician to read the temperature regardless of thermometer orientation.[130] Fourteen years later,[131] the useful thermometer made an everlasting impact on medical practice.

In 1866, the use of the thermometer, popular in Germany and Great Britain, was recognized to provide accurate, reliable information about the temperature of the body.[132] Dr. C.A. Wunderlich, in his treatise, *On the Temperature in Diseases* listed two fundamental principles of temperature in relation to the body: first, that temperature is constant in healthy persons in all places and all circumstances at 98.6° F. in the well-closed axilla (and a few tenths higher in certain body orifices);[133] and second, that the

---

[126]McLaury, *supra* note 99, at 425.

[127]*Id*.

[128]British Patent No. 14,002 (issued Mar. 8, 1852), *discussed in* Middleton, *supra* note 105, at 156. *See also* A.B. Davis, *supra* note 69, at 66 (stating that mercury-based instruments, introduced in the 1600s, were abandoned until a smaller, more uniform bore could be made in the thermometer tube).

[129]Middleton, *supra* note 105, at 156.

[130]*Id*.

[131]The Patent Act of 1790, ch. 1-7, § 2, 1 Stat. 109, 110, granted a patent term of fourteen years. The Patent Act of 1861, ch. 88, § 16, 12 Stat. 246, 249, changed the patent term to 17 years from date of issue.

[132]Austin Flint, *Remarks on the Use of the Thermometer in Diagnosis and Prognosis*, 4 New York Med. J. 81 (1866) (detailing recognition and acceptance of thermometer by American medical community in the diagnosis of disease), *reprinted in* Tech. Practice, *supra* note 90, at 1. *See also* F.W. Gibson, *On the Use of the Thermometer as a Guide in the Diagnosis of Pyrexial Diseases*, I British Med. J. 249 (1866) (vol. I for 1866 covers Jan. to June) ("[T]he day is not, I think, very far distant when the physician will consider the thermometer not less indispensable to him than the stethoscope and microscope, and when the surgeon will not neglect the observations of the temperature, since Billroth has brought forward sufficient proofs of its great importance as an assistance in the diagnosis of surgical diseases.").

[133]Wunderlich, *supra* note 95, at §§ 1–2. A normal temperature does not necessarily indicate health. *Id*. at § 4.

variation of temperature in disease deviate from the normal temperature of the healthy between 109.4° F and 91.4° F.[134] An added benefit, as observed by Wunderlich, was that temperature can neither be feigned nor falsified,[135] thereby relieving the physician from misleading impressions of the patient and family. Wunderlich did not create clinical thermometry, but rather put clinical thermometry on a scientific basis.[136] Because of his work, fever, which had previously been viewed as disease, became recognized as a clinical sign of disease.[137]

Prior to the re-introduction of the thermometer to medical practice in 1866, physicians measured body temperature by placing the hand on the body.[138] A complete record of the thermometric phenomena could then be charted during the course of a disease.[139] For example, the physician could now distinguish between typhoid and remittent fever,[140] and rule out tuberculosis meningitis[141] with reference to the thermometric evidence.[142]

---

[134]*Id*. at §§ 1, 5.

[135]Ring, *supra* note 96, at 20 (citing generally Wunderlich, *supra* note 95).

[136]Philip A. Mackowiak & Gretchen Worden, *Carl Reinhold August Wunderlich and the Evolution of Clinical Thermometry* 18 Clinical Infectious Diseases 458, 466 (1994) (historical article detailing life and dictums of C.R.A. Wunderlich). During a 20 year period, Wunderlich examined over 25,000 patients, measuring their temperature at least, and up to a dozen times each day. *Id*.

[137]*Id*.

[138]Flint, *supra* note 132, at 82.

[139]*Id*. at 83.

[140]*Id*. at 85.

[141]*Id*. at 89.

[142]*See also* Haller, *supra* note 112, at 113 (reporting tests at New York Hospital in 1866 by Dr. E. Seguin and William H. Draper distinguishing between typhus and typhoid, and remittent and intermittent fevers) (citing E. Seguin, *Medical Thermometry and Human Temperature* (New York, William Wood 1876)).

John B. Bradbury argued before the British Medical Association in 1880 that:

> The *thermometer* had done more than the microscope to place medicine on a scientific basis. The "Treatise on Medical Thermometry,"[143] by Professor Wunderlich, has done more than any other work to further the progress of scientific medicine in the last ten years. Owing to it we are able to diagnosticate [sic] diseases which before, at an early stage, were confounded as tuberculosis and typhoid fever. We can make more confident prognoses, and use our drugs with more precision.[144]

Today, the thermometer is "in use at every bedside"[145] and is a "familiar instrument to all physicians."[146] Moreover, "the thermometer remains the single most common medical instrument in use on a worldwide basis."[147] It has been shown that a relatively simply improvement in a previously known technology, namely the incorporation of a constriction in a thermometer tube, can have a revolutionary impact on medicine and the treatment of disease. Moreover, there can be shown a direct correlation between the expiration of the Negretti patent and the adoption of the thermometer into accepted medical practice by 1866. Accordingly, the history of the thermometer serves as a testament to the patent system and its contribution to the progress of science and the betterment of mankind.

---

[143]*See generally* Wunderlich, *supra* note 95 (providing history and diagnostic value of the thermometer).

[144]John B. Bradbury, Address in Medicine, *The British Medical Association Forty-eighth Annual Meeting, Modern Scientific Medicine*, 18 Med. Rec. 353 (1880) (praising use of thermometer and crediting Wunderlich treatise with advancement of science).

[145]McLaury, *supra* note 99, at 426.

[146]*Id*.

[147]Ring, *supra* note 96, at 20.

E. The X-ray Radiograph: Medical Advancement at the Speed of Light

The discovery of X-rays (Roentgen Rays) on November 5, 1895 by Wilhelm Conrad Roentgen[148] found immediate acceptance by the medical community[149] and became the subject of considerable academic study.[150] On December 22, 1895, Roentgen produced a photograph of his wife Bertha's left hand, showing her internal skeleton and external ring.[151] A few days later, and within two months of initial discovery, Roentgen published his preliminary report, *On a New Kind of Rays: A Preliminary Communication*[152] in the 1895 volume of the Proceedings of the Würzburg Physical Medical Society.[153] Two more articles were to follow.[154] However, once again, prior to

---

[148]Professor of Physics, Physical Institute of the University of Würzburg, Germany, at time of discovery. Richard F. Mould, *A History of X-rays and Radium* (1980) (providing hundreds of early X-ray radiographs, device advertisements, and anecdotal stories).

[149]Emil H. Grubbe, *X-Ray Treatment Its Origin, Birth and Early History* 20 (1949) (detailing discovery of X-rays by Roentgen on Nov. 5, 1895) (Grubbe was first to use X-rays in treatment of disease); Meyer Friedman & Gerald W. Friedland, *Medicine's 10 Greatest Discoveries* 115–32 (1998) (describing the discovery of X-rays by Wilhelm Roentgen as the sixth greatest medical discovery of all time and the only discovery related to a medical device).

[150]George Dock, *X-Ray Work from the Viewpoint of an Internist*, 8 Am. J. Roentgenology 321 (1921) (describing use of X-rays in medical practice), *reprinted in* Tech. Practice, *supra* note 90, at 281; P.F. Butler, *Methods and Problems of Medical Education* 99 (12th series, Rockefeller Found. 1929) (espousing benefits of X-rays), *reprinted in* Tech. Practice, *supra* note 90, at 276.

[151]Wilhelm C. Roentgen, *On a New Kind of Rays: A Preliminary Communication,* Annals of the Würzburg Physical Med. Soc'y, Dec. 1895, at 1, *reprinted in* Otto Glasser, *Wilhelm Conrad Röntgen and the Early History of the Roentgen Rays* 16, 25 (G.F. Barker trans., Charles C. Thomas 1934) (illustrating left hand of Bertha Roentgen bearing ring, dated Dec. 22, 1895 — original photograph plate located in the Deutsche Museum, Munich, Germany). *See also* Rolf Winau, *The Impact of Roentgen's Discovery on Medicine, in Wilhelm Conrad Roentgen 1845–1923*, at 25 (1973) (collected works illustrating photograph, this time of Bertha Roentgen's right hand also bearing ring, dated Dec. 22, 1895).

[152]Roentgen, *supra* note 151, at 16–28.

[153]Roentgen missed the December proceedings of the Physical Medical Society of Würzburg and did not submit his preliminary report to the secretary of the Society until December 28, 1895. Friedman, *supra* note 149, at 123. Journal publication of a medical discovery within one week of submission has never happened before or since. *Id*. Two informal reports were presented to the Physicalisches Institut der Universität Würzburg on Nov. 8, 1895 and Nov. 15, 1895. Grubbe, *supra* note 149, at 3, nn.4–5.

[154]Wilhelm C. Roentgen, *On a New Kind of Rays: Second Communication,* Annals of the Würzburg Physical Med. Soc'y, Mar. 1896, at 1, *reprinted in* Glasser, *supra* note 151, at 216–21; Wilhelm C. Roentgen, *Further Observations on the Properties of the X-ray,* Annals of the Würzburg Physical Med. Soc'y, May 1897, at 1, *reprinted in* Glasser, *supra* note 151, at 401–18.

its discovery, the inventor did not know what he had found and wasn't looking for it in the first place.

Roentgen's initial experiments related to Crookes tubes — evacuated glass cylinders filled with rare gases having electrodes placed at opposite ends and charged by a high voltage electric current to produce cathode rays.[155] Roentgen confirmed earlier experiments of Phillip Lenard[156] that the cathode rays would escape through an aluminum sheet covering a window of the glass tube by placing barium platinocyanide crystals (known to fluoresce in the presence of cathode rays) near the window.[157] The crystals were so placed because cathode rays were known to travel only a few inches in the air.[158] Roentgen then covered a Crookes tube with black cardboard,[159] placed the crystals nearby, turned off the lights, and turned on the current.[160] The screen of barium platinocyanide crystals continued to fluoresce, up to several feet away, and a shadow outline of the bones in Roentgen's hand shown across the crystals.[161] These "special cathode rays" could not penetrate lead or platinum but could penetrate various laboratory objects, such as a large German chemistry book, according to the object's density.[162]

---

[155]Friedman, *supra* note 149, at 117–18 (describing Roentgen's experiments with Crookes tubes). Cathode rays are electrons that travel across space in a near vacuum, such as found in a modern television tube. We now know X-rays to form a part of the electromagnetic spectrum, along with, *inter alia*, visible light, gamma rays, microwaves, radio waves, and ultra-violet light.

[156]Philipp Eduard Anton von Lenard, 1905 Nobel laureate in Physics, "For his work on cathode rays." George Thomas Kurian, *The Nobel Scientists — A Biographical Encyclopedia* 126–27 (2002) (providing short biographical sketch and bibliography of Nobel laureates).

[157]Friedman, *supra* note 149, at 118.

[158]*Id*.

[159]Most crystals that fluoresce under cathode rays also fluoresce under ultra-violet rays. Ultra-violet rays do not pass through black cardboard. Grubbe, *supra* note 149, at 19 (detailing discovery of X-rays by Roentgen).

[160]*Id*. at 20 (reporting the discovery of X-rays as the chance placement of Roentgen's hand across the barium platinocyanide crystal and relying upon a written report by Roentgen dated Nov. 6, 1895 to the Physical Institute of the University of Würzburg). *Cf.* Pino Donizetti, *Shadow and Substance The Story of Medical Radiology* 10–11 (Frank Ellis ed., Frank Ellis & Anne Ellis trans., 1967) (reporting the emission of a "strange light" on a table a short distance away).

[161]Donizetti, *supra* note 160, at 10–11.

[162]*Id*. at 13.

Thereupon, Roentgen substituted light-sensitive gelatin coated photographic plates, often used in cathode ray experiments, for the barium platinocyanide crystal sheets, and produced the world's first radiographs.[163] Roentgen coined the term *X-ray* ("X-strahlen" in German) because the nature of the rays was uncertain.[164]

Few discoveries have captured the world's imagination as did X-rays. Before the end of January 1896, others had produced X-ray photographs of the human hand showing enclosed splinters and bullets.[165] In 1896 alone, approximately fifty books and pamphlets and almost one thousand papers were published on the subject.[166] On January 23, 1896, Roentgen gave a lecture to the Physical Medical Society of Würzburg and took an X-ray photograph of the left hand of anatomist A. von Koelliker bearing two rings.[167] After this, von Koelliker suggested the new rays be called "Roentgen's rays."[168] The American General Electric Company produced equipment by autumn of 1896 and T.A. Edison introduced calcium tungstate to produce brighter images for medical diagnosis.[169] By

---

[163]*Id*. at 14.

[164]*Id*. at 186 ("For brevity's sake I shall use the expression 'rays' and to distinguish them from others of this name I shall call them 'X-rays.'"). *See also* Brian Bowers, *X-rays their discovery and applications* 10 (1970) (stating that the "X" in "X-rays" means "uncertain").

[165]Winau, *supra* note 151, at 21–24.

[166]Bowers, *supra* note 164, at 13. *See also* Mould, *supra* note 148, at 1 (reporting sensational headlines in January of 1896: "'Sensational worded story' — The Electrician, London, January 10th, 1896; 'Illuminated tissue' — New York Medical Record: January 11th, 1896; 'Searchlight of Photography' — The Lancet, January 11th, 1896; 'Photography of unseen substances' — Literary Digest: January 25th, 1896; 'Remarkable Discovery . . .' — Daily Telegraph, Sydney: January 31st, 1896.").

[167]Bowers, *supra* note 164, at 14. The photograph of Koelliker's left hand bearing two rings is the well-known photograph often associated with X-rays. Winau, *supra* note 151, at 29 (illustrating X-ray photograph of Albert von Koelliker's left hand).

[168]*Id*.

[169]*Id*. at 13–14, 16 (illustrating Edison Surgeon's X-ray Apparatus at 16). *See also* Donizetti, *supra* note 160, at 46 (reporting letter dated Mar. 17, 1896 from T.A. Edison to Lord Kelvin of a fluorescent screen of calcium *wolframate* (tungstate)).

1900 the Roentgen Ray Society of the United States was formed,[170] and in 1901 Roentgen became the first Nobel laureate for physics.[171]

The first X-ray picture literally illustrated the benefits for medical diagnosis and treatment. Roentgen, a professor of physics, recognized this fact and chose peer reviewed medical publication over scientific publication. Without the aid of the internet, computers, television or even commercial radio,[172] others began duplicating Roentgen's experiments within weeks of publication. The need for immediate protection of technological innovation cannot be better illustrated than by the flurry of activity surrounding disclosure of the X-ray radiograph.

This case also illustrates the benefits of commercial funding. Laboratories, equipment, faculty, and staff all require funding. Had Roentgen filed for patent protection prior to publication,[173] he could have secured patent protection to support, *inter alia*, funding for continued research.

F. Perkins's Metallic Tractors: Expulsion from Medicine for Obtaining a Patent

The history of patenting medical innovation traces its roots to the earliest history of the United States. The Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[174] In the first

---

[170]*The American Roentgen Ray Society 1900–1950* (Charles C. Thomas 1950) (detailing milestones in Radiology including the formation of the Society on Mar. 26, 1900).

[171]*Id*. at 15. *See also* Kurian, *supra* note 156, at 122 (providing short biographical sketch and bibliography of Wilhelm Conrad Roentgen).

[172]An experimental radio program of talk and music by Reginald A. Fessenden, of Brant Rock, Massachusetts, debuted in 1906. Fed. Communications Comm'n, *History of Wire and Broadcast Communication* (May 1993), *at* http://www.fcc.gov/cgb/evol.html (last reviewed/updated on Feb. 12, 2002). However, the telegraph was commonplace. Western Union built its first transcontinental telegraph line in 1861, and the Postal Telegraph System entered the field for economic reasons in 1881. *Id*.

[173]Unlike the United States, Germany follows a doctrine known as "absolute novelty," i.e. prior publication before application for patent destroys the patent right. *See* 2-4 Baxter, *World Patent Law & Practice* § 4.01 (listing 95 countries, including Germany, currently requiring absolute novelty as a prerequisite to patenting). The United States offers patent applicants a one year grace period following publication to apply for a patent. 35 U.S.C. § 102(b) (2004).

[174]U.S. Const. art. 1, § 8, cl. 8.

session of the House of Representatives, William Hoy petitioned that "[A]n adequate compensation may be made him for his labour [sic] and assiduity in the discovery, which in that case he will make public . . . an infallible cure for the bite of a mad dog."[175] However, no record is made that Hon. Hoy ever received a patent.

The first generally acknowledged medical device letters patent in the United States — and most historically controversial, was awarded to Dr. Elisha Perkins on February 19, 1796, for *A New and Expeditious Method of Removing Pains and Inflammations of the Human Body by the Application of Metallic Substances*, U.S. Patent No. 106x.[176] Dr. Elisha Perkins is also distinguished as the first doctor in United States history to be expelled from a medical society for obtaining a patent.[177] Containing neither drawings nor illustrations, the Perkins patent provides:

> The method which I have generally practiced, and which I have found most successful in removing pains and inflammations from the human body, though I have sometimes varied the application as the circumstances of the case might be, is by applying a pointed piece of metal to the part affected, and drawing across and from the part to some of the more muscular parts, continuing the application of the instrument a distance from the complaint; in some cases the pain is with greater facility removed by drawing the instrument from the pained part to the extremities; in some few obstinate cases it will be necessary to use friction upon the part till it produces a redness and small degree of inflammation; in bryspelas [illegible] the friction should be very light and gentle. —— In removing pains from the head the part should be free from powder and pomatum; the hair should be separated by a comb, and the instrument drawn upon the skin from the forehead to the back of the head, and down the neck; sometimes it may be removed by operating only on the forehead, back of the neck, or pit of the stomach. The head-ache which arises from

---

[175]H. Journal, 1st Cong., 1st Sess. 113 (Sept. 18, 1789).

[176]U.S. Patent No. 106x (issued Feb. 19, 1796) (typeset with manuscript number "8301" written thereon), *microformed on* Early American Imprints, First Series, No. 47880 (Readex Microprint). *Also microformed on* Early American Medical Imprints, 1668-1820, Reel 73, No. 1498 (Research Publ'ns) (typeset with manuscript number "4497"). U.S. Patent No. 106x is listed in the paper index, located in the public search room of the U.S. Patent and Trademark Office; however the physical office copy is presumed lost in the U.S. Patent Office fire of 1836. The author has now submitted his copy to the U.S. Patent and Trademark Office so that their records may be complete.

[177]*See infra* text accompanying note 199.

> drinking to excess, it does not always cure. Pains in the breast are removed by operating on the breast, or the back opposite the part afflicted, on the hip by operating on the thigh or leg; in the shoulder, by drawing the instrument from the shoulder, or arm, to the hand. In burns and strokes by lightening by drawing the instrument across the part afflicted to a distance, often changing the instruments. Where there is a soreness, and pain in consequence of motion, it does not generally relieve. The complaints in which the operation has been most useful are pains in the head, face, teeth, breast, side stomach, back, rheumatisms, burns, the effect of lightening, and some gouts. Venereal pains are apt to return and require a different treatment. It is unsafe to operate on the back during the existence of the Catamenia. The efficacy of the means is prevented by all oily or greasy substances.[178]

The patent metallic tractors sold for twenty-five dollars a pair in the United States and for five guineas a pair in England.[179] While the patent itself does not report the theory of operation, other sources report that the tractors operated by "[d]rawing off the noxious electrical fluid that lay at the root of the suffering."[180]

During the life of Elisha Perkins, the patented Metallic Tractors had an immense vogue and brought considerable wealth to their inventor.[181] Dr. Perkins traveled up and down the country lecturing and was consulted by many physicians of high standing at the time.[182] A popular satirical poem of the time, *Terrible Tractoration . . .*,[183] detailed the

---

[178]*Id*. (correcting eighteenth century English to modern English).

[179]William Snow Miller, *Elisha Perkins: His Metallic Tractors*, 8 Yale J. of Biology and Med. 41, 43 (1935–1936).

[180]James Harvey Young, *The Toadstool Millionaires* 22 n.9, 25 (1961). Young's account of Perkinism is drawn from Jacques Marc Quen, *A Study of Dr. Elisha Perkins and Perkinism* (1954) (unpublished M.D. thesis, Yale University School of Medicine) (work based, in part, on Perkins' manuscript letter book dated 1794–1799, subsequently acquired by Yale Historical Library in 1953) [hereinafter Quen I]. However, the reader is directed to Quen's published works: Quen II, *infra* note 190; and Quen III, *infra* note 185.

[181]William Read, *Some Notable Quacks,* 1 British Med. J. 1264, 1272 (1911).

[182]*Id*.

[183]T.G. Fessenden, *Terrible Tractoration!! A Poetical Petition against Galvanising Trumpery, and the Perkinistic Institution. In Four Cantos. Mostly Respectfully Addressed to The Royal College of Physicians, by Christopher Caustic, M.D., LL.D., ASS. Fellow of the Royal College of Physicians, Aberdeen, and Honorary Member of no Less than Nineteen Very Learned Societies, New York, 1804*, 123–24 (New York, Samuel Stanbury 1804) (pen name at original publication "Christopher Caustic"), *reprinted in* Miller, *supra* note 179, at 53–56.

controversy over the Metallic Tractors — and a satirical engraving by James Gillray, *Metallic Tractors*, illustrated the treatment.[184] But, despite its name and subsequent misunderstanding in the secondary historical literature, the poem is supportive of Perkins and his tractors.[185]

Before his discovery and advocacy of the Metallic Tractors, Perkins had obtained considerable reputation and popularity.[186] He would ride horseback sixty miles per day to visit his patients, sleep for three to four hours per night, and not partake of artificial stimulants or ardent spirits.[187] His acquaintance was extensive and gentlemen often visited him from different parts of the country.[188] In 1795, Elisha Perkins was Chairman of the Windham County Medical Association and was elected as a delegate to the Connecticut Medical Society.[189]

While there is no direct information on how Elisha Perkins made his discovery,[190] the invention was described by his son Benjamin Douglas Perkins in one of his pamphlets, as follows:

> The first remarkable incident that presented itself to the notice of Dr. [Elisha] Perkins, was the sudden contraction of a muscle, when he was

---

[184]*See* Henry George Bohn, *The Works of James Gillray: 582 Plates and Supplement Containing the 45 so-called "Suppressed Plates"* (B. Blom 1968) (1851), *plate available at* http://www.antiqueprints.com/Images/Cartoons/D3545_L.JPG (last visited Apr. 18, 2004). *See also* Roth, *infra* note 207, at 177 (illustrating engraving *Metallic Tractors*).

[185]*See Preface to* T.G. Fessenden, *Terrible Tractoration and Other Poems by Christopher Caustic* (Boston, Russell, Shattuck & Co., 3d ed. 1836), *microformed on* American Poetry, 1609-1900, Segment II, no. 821 (Research Publ'ns). *See also* Jacques M. Quen, *Perkinism and Terrible Tractoration*, 10 J. Hist. Med. and Allied Sci. 296 (Dorothy M. Schullian ed., 1964) (correcting misleading published accounts that *Terrible Tractoration* . . . was derogatory) [hereinafter Quen III].

[186]1 James Thacher, *American Medical Biography* 422 (Whitfield J. Bell, Jr. ed., Da Capo Press 1967) (1828) (providing short biographical essay on Elisha Perkins).

[187]*Id*.

[188]*Id*.

[189]Miller, *supra* note 179, at 43.

[190]Jacques M. Quen, *Elisha Perkins, Physician, Nostrum-Vendor, or Charlatan?*, 37 Bull. Hist. Med. 159, 162 (1963) (recounting early events in development of the Metallic Tractors) [hereinafter Quen II].

> performing a chirurgical [sic] operation. This he observed regularly took place whenever the point of the metallic instrument was put in contact with the muscle. . . . [H]e was induced to try the points of wood, and other substances; and no contractions taking place on these experiments, he thence inferred that the phenomenon could be ascribable only to the influence of metal.[191]

Perkins' letters, dated 1795, indicate the genesis of his discovery and his hope for acceptance by the medical community. In an October 20, 1795 letter addressed to his son-in-law, Dr. Perkins stated, "Last week at the medical convention in Hartford, I was complimented on the subject and requested to lay before them at our meeting in May next such discoveries as I may have made on the subject."[192] In an October 29, 1795 letter addressed to another physician in his area, he describes curing a man of "rheumatic pain in his knee before the Doctors at our county medical meeting in September and [curing] a severe pain in the foot of the Reverend William Flint of Hartford at the meeting of the Fellows of the Medical Society of Connecticut."[193]

On February 17, 1996, Elisha Perkins was granted U.S. Patent No. 106x.[194] Upon issuance of the patent, Elisha Perkins received many accolades. John Tilton, President of the Medical Society of the State of Delaware wrote a glowing letter of endorsement.[195] The Board of Managers for Almshouse hospital in Philadelphia purchased the patent rights for the Metallic Tractors for Philadelphia.[196] The Chief Justice of the United States, the Honorable Oliver Ellsworth, not only purchased a set of

---

[191]Benjamin D. Perkins, *The Influence of the Metallic Tractors on the Human Body, in Removing Various Painful Inflammatory Diseases, such as Rheumatism, Pleurisy, some Gouty Affections* . . . (London, J. Johnson and Ogilvy & Son 1798).

[192]Quen II, *supra* note 190, at 160.

[193]*Id*. at 162.

[194]*See* Patent 106x, *supra* note 176.

[195]Francis R. Packard, *The History of Some Famous Quacks*, 15 Bull. Johns Hopkins Hosp. 316, 323 (1904) (citing publication of letter in one of two pamphlets by Benjamin Douglas Perkins in 1799).

[196]Miller, *supra* note 179, at 43.

Metallic Tractors, but wrote a letter of introduction to John Marshall, the succeeding Chief Justice.[197]

Three months after issuance of the Perkins patent, in May 1796, the Connecticut Medical Society made the following pronouncement:

> VOTED, It having been represented to the Society, that one of their members had gleaned up from the miserable remains of animal magnetism, a practice of stroking with metallic Instruments the pained parts of human bodies, giving out that such strokings [sic] will radically cure the most obstinate pain to which our frame is incident, causing false reports to be propagated of the effects of such strokings [sic], especially where they have been performed on some public occasion, and on men of distinction; also that an excursion has been made abroad and a patent obtained from under the authority of the United States, to aid in such delusive quackery; that under such auspices as membership of this Society and the patent above mentioned, the delusion is progressing to the Southward, which may occasion disgrace to the Society and mischief abroad; wherefore this Society announce to the public, that they consider all such practices as barefaced imposition, disgraceful to the faculty, and delusive to the ignorant; and they further direct their Secretary to cite any member of this Society, practicing as above, before them, at their next meeting, to answer for his conduct, and render reasons why he should not be expelled from the Society, for such disgraceful practices.[198]

One year later, at the May 1797 meeting of the Connecticut Medical Society, Dr. Elisha Perkins was formally expelled:

> Whereas, Doctor Elisha Perkins, a member of this Society, having obtained a patent from under the authority of the United States, for the exclusive privilege of using and vending certain pointed metallic

---

[197]*Id*. at 44 ("Should there be cases favorable for experiments in your vicinity, [Dr. Perkins] would be ready to operate . . . .").

[198]Connecticut Medical Society, *Proceedings of the President and Fellows of the Connecticut Medical Society 1792–1829* (Hartford, Case, Lockwood and Brainard Co. 1884), *quoted in* Miller, *supra* note 179, at 44. *See also* Elisha Perkins, *Evidences of the Efficacy of Doctor Perkins's Patent Metallic Tractors* 32–33 (Philadelphia, Richard Folwell 1797) (36 pp.) (one of several redundant pamphlets by Elisha Perkins providing testimonials — the June 1797 copy is the only pamphlet reproducing the *Proceedings* and the Perkins rebuttal), *microformed on* Early American Imprints, First Series, No. 32670 (Readex Microprint).

> Instruments, pretending that they were the invention of his own; and also, that they possess inherent powers of curing many diseases, which is contrary to rules and regulations adopted by this Society, interdicting their members the use of Nostrums. Therefore,
>
> VOTED, That the said Elisha Perkins be expelled from the Medical Society of the State of Connecticut.[199]

To which, Dr. Elisha Perkins replied:

> To determine the reasonableness of attempting to load me with an opprobrium by an expulsion, on the grounds of my having obtained a patent, I appeal to those just and equitable laws of our land, which were framed for the purpose of encouraging new and useful improvements, and to that principle of moral justice, which stimulates an honest man to recompense those to whom he is indebted. While I am making these remarks, it is my duty to observe, that all the Members of the Society were not concerned in those extraordinary proceedings. Several respectable Fellows and Members of the Society, as may be observed in this publication, who have been furnished with the Instruments, have generously come forward, notwithstanding the menaces of the Society, and openly declared their sentiments in favour [sic] of the practice. Influenced by the fame worthy and philanthropic motives, other characters, of the first respectability, have published their attestations independent of that buffonery [sic], which, by interested persons, is too often exerted to discourage useful innovations.[200]

Dr. Elisha Perkins was clearly expelled from the Connecticut Medical Society for the sole reason of his having obtained a patent. The letter of Dr. Elisha Perkins dated October 29, 1795,[201] clearly indicates that expected reactions of the Society in May of 1796 were to be favorable. There was no intervening act, but for the issuance of the patent itself. Nevertheless, the words of expulsion by the Connecticut Medical Society clearly set forth an anti-patent bias, and provide so as their first grievance.

---

[199]Connecticut Medical Society, *supra* note 198, *quoted in* Miller, *supra* note 179, at 45, *also quoted in* Perkins, *supra* note 198, at 33.

[200]Elisha Perkins, *supra* note 198, at 33–34.

[201]Quen II, *supra* note 190, at 160.

The work of Dr. Elisha Perkins was continued by his son, Dr. Benjamin Douglas Perkins, who moved to London in 1799 upon the death of his father.[202] Benjamin Perkins applied for and received his own British patent for *Application of Galvanism as Curative Agent*, British Patent No. 2221, dated 1798.[203] In 1804, Benjamin Douglas established the Perkinean Institute in London for the purpose of benefitting the poor by the use of the Tractors.[204] The Institute was supported by eight professors, twenty-one regular physicians, nineteen surgeons, and twelve Doctors of Divinity.[205] In March 1802, Benjamin Perkins published successful results numbering five thousand and total operations exceeding one million five hundred thousand.[206] The venture was so successful that when Benjamin Perkins left England in 1804 he had acquired £10,000.[207]

Reportedly, George Washington owned a pair of the Metallic Tractors.[208] However, there is no direct evidence that George Washington used the Tractors himself.

---

[202]Thacher, *supra* note 186, at 424.

[203]British Patent No. 2221/1798 (issued 1798). The first page, with partial obstruction by Metallic Tractors and case is reprinted in Elisabeth Bennion, *supra* note 108, at 168. Until 1852, British patents (covering England and Wales only) were obtained through a complex medieval system which required visiting seven different offices and obtaining two signatures by the monarch. Patents granted under this system were not numbered and not published by the authorities at that time (though the details of some were printed in journals such as the Repertory of Arts). Following the modernization of the British patent law in 1852, 14,359 patents granted up to that date were given numbers of the form No. nnnn/yyyy, e.g. No. 1/1617, No. 913/1769 and published during the 1850s. The UK Patent Office, *British Patent Numbers 1617 - 1852 (Old Series),*
at http://www.patent.gov.uk/patent/history/oldnumbers/after1617.htm (last updated Apr. 10, 2002).

[204]Thacher, *supra* note 186, at 424.

[205]*Id*.

[206]*Id*. Voluminous pamphlets were published by Elisha Perkins and Benjamin Perkins, mostly repeating the same case histories. *See, e.g.*, Benjamin D. Perkins, *supra* note 191. *See also* Francis R. Packard, *supra* note 195, at 322 (citing two pamphlets published by Benjamin Douglas Perkins in 1799).

[207]Quen III, *supra* note 185, at 279. *See also* Nancy Roth, *Elisha Perkins and the 'Terrible Tractors'*, 1 Med. Instrumentation 176, 176 (1977) (translating £10,000 to $50,000 in early 1800s U.S. dollars).

[208]Miller, *supra* note 179, at 43–44 (reporting without citation, "Even the President of the United States, George Washington, purchased a set for use in his own family."). *See also* Young, *supra* note 180, at 27 (reporting without direct citation, but citing in other parts Miller, *supra* note 179, at 43, to wit "Legend has it that he [Elisha Perkins] made a customer of President George Washington himself."). *See also* Eric T. Carlson & Meribeth M. Simpson, *Perkinism vs. Mesmerism*, 6 J. Hist. Behav. Sci. 16, 16 (1970) (reporting without specific citation that Perkins had "sold a set of his metallic tractors to President George Washington," but generally citing Quen's unpublished thesis, Quen I, *supra* note 180).

J.H. Mason Knox while reporting on the extensive blood-letting practiced upon George Washington in his latter days, fails to list the Metallic Tractors as treatment for Washington, and fails to list Elisha Perkins as an advisor.[209] The writings of George Washington list a single occurrence of Dr. Elisha Perkins or his Metallic Tractors in a letter to William Pearce of Philadelphia, September 11, 1796.

> Did you receive any benefit from Doctor Perkins's metallic application. [W]hich, possibly ought to be repeated and continued for some time. I wish you well and am Your friend[, George Washington].[210]

The established medical community has historically labeled Elisha Perkins a quack.[211] Speculation has determined that the effects of the tractors were produced "not by the metal points but by the mental condition of those who used them."[212] Most authorities ascribe the "failure" of the tractors to a "double blind" experiment conducted

---

[209]J.H. Mason Knox, Jr., *The Medical History of George Washington, His Physicians, Friends and Advisers*, 1 Bull. Inst. Hist. Med. 174 (1933) (listing the attending physicians to Washington throughout his presidency and retirement, and reporting blood letting of 80 ounces through four separate bleedings during Washington's last days).

[210]1 *The Writings of George Washington from the Original Manuscript Sources 1745–1799*, at 206–07 (John C. Fitzpatrick ed., 1931) (citing "From the printed text in Conway's *George Washington and Mount Vernon*, Long Island Historical Society Memoirs (vol. 4)") (intentional stylistic deviation from *The Bluebook: A Uniform System of Citation* R. 5.1(b), at 44 (Columbia Law Review Ass'n et al. eds., 17th ed. 6th prtg. 2003)).

[211]Read, *supra* note 181, at 1272 (listing Elisha Perkins as one of several "notable quacks"). *See also* Packard, *supra* note 195, at 321 ("Among successful American quacks the name of Elisha Perkins should always hold a preeminent position . . . not only in this country, but throughout the continent of Europe."). *See also* Nancy Roth, *supra* note 207, at 176 (ascribing to Elisha Perkins the "first great American medical fraud."). *See also* Walter R. Steiner, *The Conflict of Medicine with Quackery* 6 Annals Med. Hist. 60, 69 (First Series 1924) (labeling Perkins' Metallic Tractors as blatant quackery that led to the formation of Yale Medical School in 1810 in cooperation with the Connecticut Medical Society). *But see* Joseph T. Smith, *Historical Sketch of Dr. Elisha Perkins*, 53 Md. Med. J. 166, 173 (1910) (concluding Dr. Elisha Perkins' activities as "an honest striving after knowledge with a view to benefitting mankind.").

[212]Read, *supra* note 181, at 1272.

by Dr. Haygarth, of Bath.[213] In a case study of Robert Thomas, age 43, and suffering from rheumatic affection of the shoulder, it was reported:

> The tractors I used being made of lead, I thought it advisable to lay them aside lest (being metallic points) the proof against the fraud might be less complete. Thus, much, however — was proved that the patent tractors possessed no specific power independent of simple metals.
>
> Two pieces of wood properly shaped and painted were next made use of . . . . In four minutes, the man raised his hand several inches, and he had lost also the pain in his shoulder usually experienced when attempting to lift anything. . . . [I]t must be confessed that it was more than sufficient to act upon weak minds and induce a belief that these pieces of wood and iron were endowed with some peculiar virtues.[214]

The Haygarth article, contemporaneous with Perkins and published in 1800, did not have an immediate impact on the popularity of Perkinism,[215] but rather was cited by much later articles as evidence that Elisha Perkins was a fraud.[216]

Dr. Elisha Perkins should not be labeled a quack. Even if he was mistaken in his advocacy of the Metallic Tractors, he was sincere, and undoubtedly a man of "honorable principles and character."[217] In 1799 he introduced his formulation of antiseptic to

---

[213]John Haygarth, *Of the Imagination, as a Cause and as a Cure of Disorders of the Body; Exemplified by Fictitious Tractors, and Epidemical [sic] Convulsions* (Bath, R. Cruttwell 1800) (documenting several double blind clinical trials of wooden tractors and Perkins's metallic tractors as evidence of placebo effect of Perkins's metallic tractors) (copy on file with author), *available at* http://www.jameslindlibrary.org/trial_records/19th_Century/haygarth/haygarth_tp.html (last visited Jan. 19, 2004). *See also* Quen II, *supra* note 190, at 159 (reporting Dr. John Haygarth's experiments proved "that the effectiveness of the tractors lay solely in the imagination of the patient and the observer.").

[214]Haygarth, *supra* note 213, at 8–9 (corrected for old English), *quoted in* Read, *supra* note 181, at 1272.

[215]Quen III, *supra* note 185, at 297 (refuting allegations of Fielding H. Garrison, *An Introduction to the History of Medicine* 386–87 (4th ed. 1929) that Haygarth's article had immediate impact).

[216]*See supra* text accompanying note 211.

[217]Thacher, *supra* note 186, at 425.

individuals suffering from yellow fever in New York.[218] After four weeks of attending the sick, he acquired the disease himself and died at the age of 59.[219]

At a minimum, the Perkins Metallic Tractors historically demonstrate the placebo effect, and give rise to the need for double blind studies — as now conducted during modern FDA clinical trials.[220] To date, no modern clinical trial has rigorously tested the hypotheses of Dr. Elisha Perkins. It is apparent that his techniques of applying metal across the skin are similar to the techniques of acupuncture, which today are licensed and practiced in virtually every state in the United States.[221] Moreover, as evidenced by the call for investigation of the healing power of magnetic therapy,[222] and emerging diagnostic tools based on human electrical sensitivity — such as the O-ring patent,[223] there is still much to be learned through investigation of this seemingly questionable treatment and therapy. Nevertheless, the Perkins Metallic Tractors serve as an example of ethical suppression of an emerging technology. While the Perkins Metallic Tractors may or may not have provided patient relief when properly applied, the correct forum for this determination is rigorous scientific study rather than ad hoc suppression based upon a manufactured ethical contention.

---

[218]Thacher, *supra* note 186, at 425.

[219]*Id*.

[220]John Greenway, *Galvanism as Therapeutic Agent: Perkins's "Metallic Tractors" and the Placebo Effect* (1996) (archived in subscription journal service by title, key word, and author's name) (determining doctor's role in placebo effect from study of Perkins Metallic Tractors), *at* http://www.highbeam.com (last visited Apr. 18, 2004).

[221]Most states, including the District of Columbia, license the practice of acupuncture and accept the licensing authority of the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). *See generally* National Certification Commission for Acupuncture and Oriental Medicine, *at* http://www.nccaom.org/ (last visited Mar. 12, 2004). There are 112 schools that teach acupuncture in North America. Acupuncture Schools Directory, Acupuncture.com, *at* http://www.accupuncture.com/default.htm (last visited Mar. 12, 2004).

[222]Roger M. Macklis, *Magnetic Healing, Quackery, and the Debate About the Health Effects of Electromagnetic Fields*, 118 Annals Internal Med. 376 (1993) (observing that assumptions of quackery have historically impeded scientific investigation of electromagnetism, and calling for dispassionate study of EMF effects at the cellular and molecular level).

[223]U.S. Patent No. 5,188,107 (issued Feb. 23, 1993) (for *Bi-digital O-ring Test for Imaging and Diagnosis of Internal Organs of Patient* — patent secured through demonstration to Commissioner of Patents and Trademarks that applied force in human hand shaped into O-ring changes in response to electromagnetic field of sample human organ as detected through non-invasive movement across human body).

G. *Ex Parte Brinkerhoff*[224] and the Evolution of U.S. Patent Policy

While medical and surgical methods have encountered some difficulty in gaining acceptance as patentable subject matter, medical devices have consistently been held patentable. United States inventors sought protection for their surgical inventions as early as 1846.[225] By 1862, the subject matter of U.S. Patent No. 4,848 was heralded as one of the "greatest discoveries of modern times," — the application of a sulfur ester as anesthesia to surgical patients.[226] However, U.S. Patent No. 4,848 itself disclaimed both the anesthesia and its administration. The patent disclosed as its discovery the application of sufficient quantities of anesthesia during surgery to provide an imperceptibility to pain.[227] The court in *Morton v. New York Eye Infirmary*[228] held the patent void because "the application of a well-known agent, by well-known means, to a new or more perfect use . . . is not sufficient to support a patent."[229] While concluding that application of the ether to the "art of surgery" was not patentable, the same court found that medical devices, such as a "lancet, saw, forceps, or bandage" would be patentable based upon their construction, and that application to the art of surgery could

---

[224]Ex parte Brinkerhoff, 24 Commissioner's Manuscript Decisions 349 (24 Commr's MS Decisions 349) (1883), *reprinted in* 27 J. Pat. & Trademark Off. Soc'y 797 (1945). Numerous law reviews incorrectly cite the *Official Gazette of the United States Patent Office (O.G.)*. There is no such cite. The *Commissioner's Manuscript Decisions*, "Commr's MS Decisions," should not be confused with the *Decisions of the Commissioner of Patents*, "Dec. Comm'r Pat." published yearly, 1869–1968, from cases reported in the *Official Gazette of the United States Patent Office*. *Cf.* 1 Anthony William Deller, *Deller's Walker on Patents* § 12 (2d ed. 1964) (referring to the *Decisions of the Commissioner of Patents* as the *"Commissioner's Decisions"* (C.D.) and listing 1872 as the year of the first issue of the *Official Gazette of the United States Patent Office*). Commissioner's Manuscript Decisions were typewritten, unpublished decisions of the U.S. Patent Office, that were not available to the public. Archie R. McCrady, *Patent Office Practice* § 116 (4th ed. 1958). Prior to the *Administrative Procedure Act of June 11, 1946*, ch. 324, 60 Stat. 237 (repealed and recodified by Pub. L. No. 89–554, 80 Stat. 383, at 5 U.S.C. §§ 551–559, 701–706 (2000)), such decisions were regularly cited by the U.S. Patent Office. *Id*. Current policy of the U.S. Patent and Trademark Office indicates that "the use of manuscript decisions . . . should be avoided." Patent and Trademark Office, U.S. Dep't of Commerce, *Manual of Patent Examining Procedure* § 707.06 (8th ed. 2003), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (last revised June 2003).

[225]U.S. Patent No. 4,848 (issued Nov. 12, 1846) (for an *Improvement in Surgical Operations*).

[226]Morton v. New York Eye Infirmary, 17 F. Cas. 879, 882 (No. 9,865) (S.D.N.Y. 1862).

[227]*Id*.

[228]*Id*.

[229]*Id*. at 883.

provide evidence of utility.[230] Unfortunately, dicta from *Morton* spawned the notion that methods of treating the human body were not patentable.[231]

In 1883, the Commissioner of Patents relied upon *Morton* to hold in *Ex parte Brinkerhoff*[232] that:

> [N]o particular method or mode of treatment . . . under all cases will produce the same result, and, hence to grant a patent for a particular method of treatment would have a tendency to deceive the public.[233]

However, the *Brinkerhoff* decision also observed that:

> It appears from the records of the case that applicant has had certain instruments patented to him which can only be used in the way pointed out in this application. A sale therefore, of such instruments should carry with it the right to use them.[234]

While *Brinkerhoff* had an effect on the patenting of some medical methods,[235] it clearly did not limit the patenting of medical devices. Moreover, the *Brinkerhoff* decision was not universally followed.

---

[230]*Id*.

[231]1 Donald S. Chisum, *Chisum on Patents* § 1.03[3] (2004) ("Morton had an impact on the patentability of medical methods generally. . . . The Commissioner of Patents stated categorically that the methods or modes of treatment of physicians of certain diseases are not patentable.").

[232]Ex parte Brinkerhoff, *supra* note 224.

[233]In *Ex parte Brinkerhoff*, the Commissioner of Patents rejected a claim for a method of treating piles. *Id*. (intentional stylistic deviation from *The Bluebook*, *supra* note 210, R. 5.1(b), at 44). Piles is another word for hemorrhoids. Webster's Third New International Dictionary 1715 (1993).

[234]Ex parte Brinkerhoff, *supra* note 224 (intentional stylistic deviation from *The Bluebook*, *supra* note 210, R. 5.1(b), at 44). There is no "right to use" a patented invention under current United States patent law. Studiengesellschaft Kohle mbH v. N. Petrochemical Co., 784 F.2d 351, 357 (Fed. Cir. 1986) ("The patent grant is not for the right to use the patented subject matter, but only for the right to exclude others from practice of the patented subject matter.").

[235]Claims "directed to a method of treatment of the human body" were rejected as late as 1945. *Ex Parte Appeal No. 2,648* (Case No. 181) Bd. of Pat. Appeals and Interferences (Sept. 11, 1945) (citing Ex parte Brinkerhoff).

On July 28, 1925, future Nobel Prize nominees George F. Dick and Gladys Henry Dick were awarded U.S. Patent No. 1,547,369 for *Scarlet Fever Toxin and Antitoxin and Process for Producing the Same*.[236] Scarlet fever is a serious disease that showed a mortality rate in 1911 of 8.8 per 100,000.[237] George and Gladys Dick published their findings in the *Journal of Infectious Disease* in an article dated October of 1916,[238] and the *Journal of the American Medical Association* in articles dated October 6, 1923,[239] and January 26, 1924.[240]

George and Gladys Dick successfully enforced their patent against Lederle Antitoxin Laboratories in 1930.[241] The Dick patent included claims for a process of isolating streptococci specific to scarlet fever, a composition of an antitoxin specific to scarlet fever obtained from the blood of an animal, and a process that included injecting the toxin in or through the skin of a human being.[242] In awarding judgement for George and Gladys Dick, the court found their conduct to be of the highest ethical regard. The court observed:

> [N]othing has been done by them that offended in the slightest the ethics of their profession.
>
> Their conduct in passing these patents out of their own hands and into control, one of the Presbyterian Hospital and the other of the Scarlet Fever Committee, so as to dedicate them to the benefit of the country, is

---

[236]U.S. Patent No. 1,547,369 (filed Apr. 14, 1924, issued July 28, 1925).

[237]Bureau of the Census, U.S. Dep't of Commerce, *Mortality Statistics 1911* (1913) (Bull. 112), *available at* http://www.cdc.gov/nchs/data/vsushistorical/mortstatbl_1911.pdf.

[238]George F. Dick & Gladys Henry Dick, *Immune Reactions in Scarlet Fever, II*, 19 J. Infect. Dis. 638 (1916).

[239]George F. Dick & Gladys Henry Dick, *Experimental Scarlet Fever*, 81 JAMA 1166 (1923) (reporting cause of scarlet fever in two cases by hemolytic streptococcus).

[240]George F. Dick & Gladys Henry Dick, *A Skin Test for Susceptibility to Scarlet Fever*, 82 JAMA 265 (1924) (disclosing skin test that bears a specific relation to immunity to scarlet fever).

[241]Dick et al. v. Lederle Antitoxin Lab., 43 F.2d 628 (S.D.N.Y. 1930).

[242]U.S. Patent No. 1,547,369, at claims 1, 4 and 7.

> the utmost manifestation they could make of their desire to serve mankind and to live up to the ideals of their profession.[243]

Not only did the achievements of George and Gladys Dick provide a valuable benefit to public health, but ethical enforcement of their patented product and method of treatment ensured funding in support of their continued research.

In 1954, the Board of Appeals of the United States Patent Office officially overruled *Morton v. The New York Eye and Ear Infirmary*[244] and *Ex parte Brinkerhoff*[245] in the case of *Ex parte Scherer*.[246] In that case, the applicant appealed claims related to a method of injecting medicaments by a pressure jet.[247] Claim 29 is representative and reads:

> 29. The method of injecting fluids into the human body comprising the steps of . . . displacing liquid from the jet orifice . . . to puncture the epidermis and penetrate the body tissues therebeneath, . . . and abruptly stopping the high pressure and thereafter continuing the jet at a lower pressure . . . .

The Board first held that the method claimed is of a character which would normally be regarded as within the field of patentable subject matter, except that the human body is the subject acted upon.[248] The Board then concluded that medical or surgical methods are not unpatentable merely because they involve treating the human body.[249]

---

[243]Dick v. Lederle at 638.

[244]Morton, *supra* note 226.

[245]*Supra* note 224.

[246]Ex parte Scherer, 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954) ("To the extent that *Ex parte Brinkerhoff* holds or implies that all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body, that decision is expressly overruled.").

[247]*Id*. at 108.

[248]*Id*. at 109.

[249]*Id*. at 110.

Today, medical methods are considered patentable and are judged according to a standard of utility. Article I, section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the useful arts.[250] The current Patent Act provides that patents may be granted only for new *and useful* inventions.[251] To meet this requirement of usefulness, also know as the *utility requirement*, the Supreme Court has held that a product or process must be "operable" -- that is, "capable of being used to effect the object proposed."[252] In other words, to be patentable, the medical method must actually work.

In addition to the above general utility requirement, the U.S. Patent and Trademark Office imposes a requirement of specific utility for some medical inventions.[253] For example, a general statement regarding diagnosing or treating disease is insufficient absent a disclosure of what condition can be diagnosed.[254]

III. The History of Ethical Restraint on Patenting by the Medical Profession

The origin of ethical restraint on medical patents is commonly attributed to the unscrupulous "patent medicine man" that traveled the country side selling cure-alls and elixirs of unknown and dubious origin.[255] Various concoctions included "Dr. C.V. Girard's Ginger Brandy"; "No-To-Bac" — a cure for nicotine addiction; "Hood's

---

[250]Carl Zeis Stiftung v. Reinshaw PLC, 945 F.2d 1173 (Fed. Cir. 1991) (holding a properly claimed invention valid for utility when at least one stated objective has been met).

[251]*Id*. at 1180 (quoting 35 U.S.C. § 101 (1988)).

[252]Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1873).

[253]Patent and Trademark Office, U.S. Dep't of Commerce, *Manual of Patent Examining Procedure* § 2107.01, § I (8th ed. 2003), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (last revised June 2003). *See also* Refac Int'l v. Lotus Dev. Corp., 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996) ("The MPEP does not have the force and effect of law; however, it is entitled to judicial notice as the agency's official interpretation of statutes or regulations, provided that it is not in conflict with the statutes or regulations.").

[254]*Id*.

[255]*See* William H. Edgerton, *Medical Associations and Physicians' Patent Policies, in The Encyclopedia of Patent Practice and Invention Management* 563 (Robert Calvert ed., 1964). *See also* Eric Maple, *Magic, Medicine & Quackery* 158–59 (1968) (describing practice of quackery as a national institution, where street corner pitchmen garbed as Quakers would pitch "magic oils" and "secret remedies").

Sarsparilla"; and "Dr. James's Fever Powder" — a product composed primarily of elemental antimony.[256] Even Coca-Cola(R) began as an elixir including caffeine and cocaine, derived from the coca plant and cola (kola) nut,[257] and sold at pharmacies for the relief of headaches.[258]

However, the ethical justification for medicine's higher calling was created much earlier. The *Susruta Samhhita* declares surgery "the first and highest subdivision of the healing art, and the least susceptible to deception, transparent in itself, most noble in its application, the worthy product of heaven, the sure source of prestige upon the earth."[259]

A. *The Hippocratic Oath*

The Hippocratic Oath has for centuries provided the foundation of medical ethics and its calling to a higher purpose.[260] In European and Arabic medical traditions, the oath remains the standard against which questionable practice is often measured.[261] As of 1993, ninety-eight percent of a surveyed 150 medical schools administered an oath to

---

[256]Lyons, *supra* note 21, at 506–07, 527 (displaying and commenting on notorious patent medicines of the nineteenth century).

[257]Mark Pendergrast, *For God, Country and Coca-Cola — The Unauthorized History of the Great American Soft Drink and the Company that Makes It* 33 (1993) (reciting original advertisement claims and ingredients of Coca-Cola(R)).

[258]Coca-Cola Co. v. Koke Co. of America, 254 U.S. 143 (1920) ("Before 1900 the beginning of the good will [of Coca-Cola] was more or less helped by the presence of cocaine . . . ."). *See also* Elizabeth Candler Graham & Ralph Roberts, *The Real Ones Four Generations of The First Fammily of Coca-Cola(R)* 6 (1992) (recounting story of John G. Wilkes, pharmacy owner, accidently drinking a mixture of Coca-Cola syrup and carbonated water as a hang-over cure).

[259]Thorwald, *supra* note 23, at 206.

[260]*See generally* Steven H. Miles, *The Hippocratic Oath and the Ethics of Medicine* (2004) (providing phrase by phrase analysis of the Oath, and in contrast to Edelstein, opining that the Oath was consonant with medical practices and ethics of the day). *See also* Ludwig Edelstein, *Hippocrates The Oath or The Hippocratic Oath* (Ares Publishers Inc. 1943) (reprinting text and translation from 1 *Hippocratis Opera, Corpus Medicorum Graecorum* 4–5 (I.L. Heiberg ed., 1927)), *reprinted in Legacies in Ethics and Medicine* (Chester R. Burns ed., 1977) (providing side-by-side translation and analysis of original text, and opining that the Oath was philosophical rather than a working document for medical ethics).

[261]Robert D. Orr et al., *Use of the Hippocratic Oath: A Review of Twentieth Century Practice and a Content Analysis of Oaths Administered in Medical Schools in the U.S. and Canada in 1993*, 8 J. Clinical Ethics 377 (1997). *But see* R.M. Veatch, *The Hippocratic Ethic is Dead*, 48 New Physician 41 (1984) (arguing that subscription to *The Hippocratic Oath* is no longer relevant to modern medical practice).

their graduates,[262] while nearly half of the oaths were based on a version of *The Hippocratic Oath*.[263] The rest incorporated precepts of *The Hippocratic Oath* but were formally based on the *Declaration of Geneva*[264] and other more specific oaths.[265] *The Hippocratic Oath*[266] provides:

> OATH
>
> I swear by Apollo the Physician and Asclcepius and by Health [the god Hygieia] and Panaceia and all the gods as well as goddesses, making them judges [witnesses], to bring the following oath and written covenant to fulfillment, in accordance with my power and my judgment;
>
> to regard him who has taught me this techne [art and science] as equal to my parents, and to share, in partnership, my livelihood with him and to give him a share when he is in need of necessities, and to judge the offspring [coming] from him equal to [my] male siblings, and to teach them this techne, should they desire to learn [it], without fee and written covenant,
>
> and to give a share both of rules and of lectures, and of all the rest of learning, to my sons and to the [sons] of him who has taught me *and to the pupils who have both made a written contract and sworn by a medical convention but by no other*.
>
> And *I will use regimens for the benefit of the ill in accordance with my ability and my judgment*, but from [what is] to their harm or injustice I will keep [them]. And I will not give a drug that is deadly to anyone if

---

[262]Orr, *supra* note 261, at 379.

[263]*Id*.

[264]The *Declaration of Geneva*, in its combined forms of 1948 and 1983, was administered to 23 percent of medical school graduates. *Id*. at 380 (providing table and percentage across medical schools administering oaths). World Med. Ass'n, *Declaration of Geneva (Physician's Oath)* (1948) (adopted by the General Assembly of the World Medical Association, Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia, Aug. 1968) (silent with regard to patent or intellectual property, but also stating "THE HEALTH OF MY PATIENT will be my first consideration" and "MY COLLEAGUES will be my sisters and brothers"), *at* http://www.cirp.org/library/ethics/geneva/ (revised June 6, 2002).

[265]Orr, *supra* note 261, at 379.

[266]*The Hippocratic Oath* is an ancient Greek document dating from 400 BC and simply entitled *Oath*. Miles, *supra* note 260, at 3. There is no evidence that Hippocrates wrote it, approved of it, or even knew of it. *Id*.

> asked [for it], nor will I suggest the way to such a counsel. And likewise I will not give a woman a destructive pessary. . . .[267]

The Hippocratic Oath falls into two parts: the first specifying the pupil's obligations in transmitting medical knowledge and the second defining rules for the treatment of disease — the general and the specific.[268] The obligation of transmission of medical knowledge seeks to sustain and nurture the future of medical learning within the medical profession through the insights learned during the physician's career.[269] In accordance with the times, Greek physicians fulfilled this obligation by offering apprenticeships, providing lectures, and writing medical treatises.[270] While *The Hippocratic Oath* forms a part of the *Hippocratic Collection*,[271] scholars are in disagreement whether a coherent Hippocratic ethic can be discerned from the half-millennium collection as a whole.[272] However, one thing is clear, *The Hippocratic Oath* offers no prohibition against patenting.

B. Dr. Thomas Percival

Modern medical ethics trace their origin to the 1794 publication by Dr. Thomas Percival, *Medical Jurisprudence or a Code of Ethics and Institutes Adopted to the Professions of Physic and Surgery*.[273] The unique and revolutionary aspect of Percival's

---

[267]Miles, *supra* note 260, at xiii–xiv (emphasis added). The "ethical tradition expressed by Hippocrates" is cited in Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Code of Medical Ethics,* Opinion 9.08 (2002–2003) (stating role of physician to disclose new medical procedures to colleagues and students).

[268]Edelstein, *supra* note 260, at 4.

[269]Miles, *supra* note 260, at 36.

[270]*Id*.

[271]*See supra* text accompanying note 20.

[272]Miles, *supra* note 260, at 41 (arguing that no coherent ethic can be discerned from the *Hippocratic Collection* taken as a whole).

[273]Thomas Percival, *Medical Ethics* (Chauncey D. Leake ed., Huntington, R.E. Krieger Publ'g Co. 1975) (1927) (1803), *also reprinted in* Am. Med. Ass'n, *Percival's Code: A Chapter in the Historical Development of Medical Ethics* (Chauncey D. Leake ed., 1923) (pamphlet reprinting Leak, *infra* note 275, and Percival's *Medical Ethics* (Manchester, S. Russell 1803) without section on "Discourse on Hospital Duties").

code was that "unlike anything written previously, it severed the connection between personal and professional morality."[274] Percival's contribution was the derivation of a code that was acceptable for "authoritative enforcement, and therefore, widespread emulation."[275]

Percival sought to ground moral authority in a professional consensus because "the trustees of eighteenth-century hospital charities were not always trustworthy guardians of the profession's fiduciary responsibility."[276] The trustees were tempted to cut corners by failing to provide ventilation for hospitals or by overcrowding wards.[277] Physicians and surgeons had a professional obligation not to be restrained "from prescribing wine, and drugs even of high price, when required in diseases of extraordinary malignity and danger. . . . [N]o economy of fatal tendency ought to be admitted into institutions founded on the principles of the purest beneficence, and which, in this age and country, when well conducted, can never want contributions adequate to their liberal support."[278]

Percival did not opine on the holding of patents by physicians or surgeons, *per se*. However, he did provide in chapter 2, sections XXI, XXII:

> XXI. The use of *quack medicines* should be discouraged by the faculty, as disgraceful to the profession, injurious to health, and often destructive, even of life. Patients, however, under lingering disorders, are sometimes obstinately bent on having recourse to such as they see

---

[274]*Preface to The American Medical Ethics Revolution — How the AMA's Code of Ethics Has Transformed Physician's Relationships to Patients, Professionals, and Society* ix (Robert B. Baker et al. eds., 1999) (collected papers delivered at a sesquicentennial conference, Philadelphia, Mar. 14–15, 1997, "Ethics and American Medicine: History, Change, and Challenge," co-sponsored by the Center for Bioethics of the University of Pennsylvania, the College of Physicians of Philadelphia, and the Institute for Ethics of the American Medical Association) [hereinafter *Ethics Revolution*].

[275]Chauncey D. Leake, *Percival's Code: A Chapter in the Historical Development of Medical Ethics*, 81 JAMA 366 (1923).

[276]*Id*. at xvii.

[277]Percival, *supra* note 273, at ch. 1, § 16.

[278]*Id*. at ch. 1, § 8.

> advertised . . . . [D]iligent attention should be paid to the process of the experiment [the patient] is so unadvisedly making on himself . . . .
>
> XXII. No physician or surgeon should dispense a *secret nostrum*, whether it be his invention, or exclusive property. For it be of real efficacy, the concealment of it is inconsistent with beneficence and professional liberality. And if mystery alone gives it value and importance, such craft implies either disgraceful ignorance, or fraudulent avarice.[279]

Accordingly, Percival recognizes the proprietary nature of invention but rather chastises concealment because of the potential for a lack of efficacy. Percival's chapter 2, section XXV is more instructive on the nature of physician compensation:

> XXV. A wealthy physician should not give advice *gratis* to the affluent; because it is an injury to his professional brethren. The office of physician can never be supported but as a lucrative one; and it is defrauding, in some degree, the common funds for its support, when fees are dispensed with, which might justly be claimed.[280]

Finally, the "Notes and Illustrations" appended to Percival's code specifically address payment for services and payment between physicians:

> PECUNIARY ACKNOWLEDGMENTS
>
> The following fact, related in Dr. Johnson's Life of Addison, is applicable to the professional conduct of physicians toward their friends. . . . [Addison] made a law to himself . . . never to remit his regular fees in civility to his friends. "For," said he, "I may have a hundred friends, and if my fee be two guineas, I shall, by relinquishing my right, lose two hundred guineas and no friend gain more than two; there is therefore no proportion between the good imparted, and the evil suffered." . . .
>
> . . . .
>
> A precise and invariable modus, however, would be injurious both to the barrister and the physician, because the fees of each ought to be measured by the value of his time, the eminence of his character, and by his general rule of practice.

---

[279] *Id*. at ch. 2, §§ 21, 22 (emphasis added).

[280] *Id*. at ch. 2, § 25 (emphasis added).

Accordingly, we find from Percival, that is it the secret nature of so-called nostrums that presents the evil to the profession. Further, payment for services rendered — even between physicians, is required to maintain the financial well being of the profession as a whole.

C. AMA *Code of Ethics* of 1847[281] and 1865[282]

The American Medical Association itself and the first AMA *Code of Ethics* were created at Philadelphia in May 1847.[283] The 1847 *Code of Ethics* departed from Percival's code to represent the first recognized hostility to patents by a national organization. As set forth in chapter II. — Of the Duties of Physicians to Each Other and to the Profession at Large, article I. — Duties for the Support of Professional Character:

> 4. Equally derogatory to professional character is it, for a physician to hold a patent for any surgical instrument, or medicine; or to dispense a secret *nostrum*, whether it be the composition or exclusive property of himself or of others. For, if such nostrum be of real efficacy, any concealment regarding it is inconsistent with beneficence and professional liberality; and, if mystery alone give it value and importance, such craft implies either disgraceful ignorance, or fraudulent avarice. It is also reprehensible for physicians to give certificates attesting the efficacy of patent or secret medicines, or in any way to promote the use of them.[284]

---

[281]Code of 1847, *supra* note 18.

[282]Nathan Smith Davis, *History of Medicine with the Code of Medical Ethics* 197 (1903) (reporting full text of AMA *Code of Ethics* of 1865, including prohibition against patenting by physicians).

[283]Kenneth Warren Hamstra, *The American Medical Association Code of Medical Ethics of 1847,* at 2 (Ph.D. Thesis 1987) (reporting simultaneous formation of American Medical Association and creation of its *Code of Ethics*), *photocopied at* UMI Order No. 8717427 (Univ. Microfilms, Inc. 1988).

[284]*Id*. at ch. 2, art. I, § 4 (emphasis added).

The Introduction to the 1847 *Code of Ethics*[285] provides substantial justification against the use of secret nostrums due to the impact on public health.[286] A "host of quacks [had] infested the land" and attempted to sell "poisonous substances for food."[287] The Introduction further reports that "[t]hese delusions are sometimes manifested in the guise of a new and infallible system of medical practice — the faith in which, among the excited believers, is usually in the inverse ratio of the amount of common sense evidence in its favour [sic]." However, noticeably absent is any justification what-so-ever, for the prohibition against surgical instruments. While Kenneth Hamstra[288] reports that the prohibition on patenting drew loud complaints from innovator, J. Marion Sims,[289] he fails to report the impetus for this provision.

The term "patent medicine," which was really a misnomer, was notorious for proprietary elixirs and tonics that were really protected as trade secrets by their promoters. In a notable case, a manufacturer sold "Beecham's Patent Pills" that were not the subject of a patent.[290] The Court held "the use of the word patent to indicate medicines made by secret formulas is widespread and well known. It is mentioned in the dictionaries, and it occurs in the plaintiff's circulars. . . . [t]here is no danger that anyone would be defrauded by the form of the label on the plaintiff's box."[291]

The 1865 AMA *Code of Ethics* continued the prohibition of patenting under a heading, Of the Duties of Physicians to Each Other, and to the Profession at Large, article

---

[285]Code of 1847, *supra* note 18, at 83. *See also Ethics Revolution*, *supra* note 274, app. B.

[286]*Id*. at 319.

[287]*Id*.

[288]Hamstra, *supra* note 283.

[289]*Id*. at 45.

[290]*See e.g.* Jacobs v. Beecham, 221 U.S. 263 (1911) (recognizing widespread use of word "patent" to indicate medicines made by secret formula).

[291]*Id*. at 273.

I. — Duties for the support of professional character, section 5.[292] But for a change from section 4 to section 5, the text is identical to the 1849 *Code*. The AMA *Code* of 1865 is significant because it adopted as a bylaw that "[n]o State or Local Medical Society, or other organized institution, shall be entitled to representation in this Association that has not adopted its Code of Ethics."[293]

The 1865 requirement that state or local medical societies adopt the AMA *Code of Ethics* was a direct result of one of the first recorded ethical controversies over the patenting of medical devices. In 1855, the State Medical Society of Ohio resolved "[t]hat it is *not* derogatory to medical dignity, or inconsistent with medical honor, for medical gentlemen to take out a patent right for surgical or medical instruments."[294] The State Medical Society of Ohio was then requested by a national association of physicians to either rescind the resolution or leave the national association.[295]

D. Nineteenth Century Re-evaluation of Patenting

In 1897, Dr. F.E. Stewart, M.D., Ph.G. presented a paper at the 48th annual meeting of the American Medical Association outlining four popular arguments against patenting medical devices;[296] they are:

> 1. Higher Cost to the Consumer: Every substance used for the treatment of the sick should be free from control by secret processes and patents, so that they may be manufactured and delivered at the least expense to the consumer, i.e. the sick.
> 2. Creation of Fictitious Demand: For the purpose of creating a demand as articles of commerce, medicines must be advertised, and the

---

[292]N.S. Davis, *supra* note 282.

[293]*Id*. at 191.

[294]Edgerton, *supra* note 255, at 563 (also citing 1949 AMA resolution that "[t]he ethical physician will not receive remuneration from patents.").

[295]*Id*.

[296]F. E. Stewart, *Is It Ethical for Medical Men to Patent Medical Inventions?*, 29 JAMA 583 (1897).

> advertisements must be worded for the purpose of selling goods, thereby displacing older and well-tried drugs by medical novelties.
>
> 3. Trade Methods Destroy the Profession: The only object in patenting a medical invention is to utilize it for money-making purposes, which can only be accomplished by adopting trade methods. Physicians who patent medical inventions or offer medicines for sale enter the domain of trade and thereby cease to be professional men. The liberal professions deal exclusively in advice, not material substances, and thus must not adopt trade methods.
>
> 4. Patenting Erodes Philanthropic Nature of Medicine: the medical inventor who has a material substance for sale will unconsciously promote the sale of his goods, rather than seek to benefit his patients who purchase his goods. This would change the nature of a medical practice from a beneficent one to a distinctly commercial one. The physician's vocation is the relief of human suffering, not the acquisition of money.[297]

Dr. Stewart distinguished a physician's right to copyright, in that copyright on a book, while restraining the writing itself from general use for a limited time, does not in any way restrain the use of knowledge contained within the book.[298] The pharmacist, necessarily dealing in trade, should be allowed to patent, but only such processes, apparatus and machinery necessary to prepare medical products.[299] Dr. E.R. Squibb, founder of E.R. Squibb & Sons,[300] responded to Dr. Stewart, "I do not myself think that anything should be patented by either physician or pharmacist; I am sure the patient would not be benefitted thereby."[301]

---

[297] *Id*. at 584.

[298] *Id*.

[299] *Id*. at 585

[300] In 1856 Edward Robinson Squibb founded a pharmaceutical company in Brooklyn, New York, dedicated to the production of consistently pure medicines. In 1895 Squibb passed most of the responsibility to his sons, Charles and Edward, and the company became known as E.R. Squibb & Sons. Bristol-Myers Squibb Company, *A Brief History of Bristol-Myers Squibb*, *at* http://www.bms.com/aboutbms/content/data/ourhis.html (last updated Mar. 12, 2003).

[301] In calendar year 2001, Bristol-Myers Squibb was awarded 102 U.S. patents. Info. Products Div., U.S. Pat. and Trademark Office, *Patenting by Organizations 2001*, *at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_01.pdf.

In 1903, the American Medical Association adopted its *Principles of Medical Ethics*, wherein it maintained its prohibition against patenting.[302] The 1903 *Principles* is significant because the prohibition against patenting was now included in chapter I. — The Duties of Physicians to Their Patients. The duty was now categorized as one to patient rather than to other physicians.

E. The Effect of the *Federal Food and Drugs Act of 1906*[303]

The 1912 *Principles of Medical Ethics* continued the prohibition against patents, but once again categorized the prohibition in chapter II., article I. — Duties to the Profession.[304] This time, the prohibition changed from one against patents *per se* to one against receiving monetary reward. Section 5 of the *Principles* provided, "It is unprofessional to receive remuneration from patents for surgical instruments or medicines; to accept rebates on prescriptions or surgical appliances, or perquisites from attendants who aid in the care of patients."[305]

By 1912, the effects of the *Federal Food and Drugs Act of 1906* had begun to be realized by the organized medical profession. Protection of the public against secret nostrums, "patent medicines," and unsafe elixirs was now vested in the hands of the federal government. With the shifting of public protection from the self regulating medical profession to the federal government, the prospects for patenting were now free to be re-examined in view of the professional goals of the medical profession.

In 1914, the House of Delegates of the American Medical Association adopted the recommendation of the AMA Judicial Council:

---

[302]Am. Med. Ass'n, *Principles of Medical Ethics* (Chicago, Am. Med. Ass'n Press 1911) (1903), *reprinted in Ethics Revolution*, *supra* note 274, app. D.

[303]Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[304]Am. Med. Ass'n, *Principles of Medical Ethics* (adopted by the House of Delegates, Atlantic City, New Jersey, June 4, 1912), *reprinted in Ethics Revolution*, *supra* note 274, app. E.

[305]*Id*. at § 5.

> Resolved, That the Board of Trustees of the American Medical Association shall be permitted to accept, at their discretion, patents for medical and surgical instruments and appliances and to keep these patents as trustees for the benefit of the profession and the public; provided, that neither the American Medical Association nor the patentee shall receive remuneration from these patents.[306]

In 1916, the American Medical Association voted to accept and administer medical patents, particularly the patent application of future Nobel laureate Dr. Edward C. Kendall of the Mayo Clinic for thyroxin.[307] However, in a reversal of policy just two years later, the AMA returned the patents. The Judicial Council of the AMA declared it unethical for either the University of Minnesota or the Mayo brothers to consider patenting a medical discovery and using the commercial proceeds to finance a research fund.[308] In 1919 an editorial in the *Journal of the American Medical Association* advocated the desirability of patenting in the public interest, and in particular the patenting of medical devices.[309]

> [T]here are occasions when it is wise, if not necessary, to obtain a patent in the interest of the public and, in the case of surgical instruments and medicines, of the medical profession. In certain instances it may be absolutely necessary that the article produced shall maintain a definite standard of quality and purity and . . . sold a reasonable price. It has become practically necessary, therefore, for research workers to protect

---

[306]Morris Fishbein, *Medical Patents*, 29 Ind. & Eng. Chem. 1315, 1317 (1937) (calling for the formation of a central body, such as the AMA, to administer medical patents in the public interest).

[307]*See* Edgerton, *supra* note 255, at 563. Edward C. Kendall filed his first patent application *Thyroid Product and Process of Producing the Same* on June 7, 1916, which eventually matured into U.S. Patent No. 1,392,767 (issued Oct. 4, 1921). Edward C. Kendall filed a second patent application *Thyroid Substance and Method of Making It* on August 20, 1919, which matured into U.S. Patent No. 1,392,768 (issued Oct. 4, 1921). Dr. Kendall isolated a derivative of the thyroid gland from 6500 pounds of hog thyroid glands, and coined the term for his derivative "thyroxin." E.C. Kendal, *Isolation of the Iodine Compound Which Occurs in the Thyroid*, 39 J. Biol. Chem. 125 (1919). Edward C. Kendall et al., 1950 Nobel laureates in Medicine, "For their discoveries relating to the hormones of the adrenal cortex, their structure and biological effects." Kurian, *supra* note 156, at 298–301.

[308]*Id*. at 564.

[309]Comment, *Patenting Therapeutic Agents, Current Comment*, 73 JAMA 1219 (1919).

> their products in the interest of the public welfare and scientific medicine.[310]

In short, as medical research became more institutionalized, the need for patenting became more recognized.

F. Recognized Demands of University Research

In 1934, a special committee of the American Association for the Advancement of Science recognized the use of medical patents for purposes of: quality control, securing large scale product development, and financing additional research.[311] The Committee recognized that the strong feelings against medical patents were largely due to public exploitation by the harmful effects of "patent medicines."[312] The Committee also observed that by 1934, government regulation had virtually eliminated the misrepresentations and false claims of patent medicines and that the U.S. Patent Office had ceased issuing patents for such concoctions.[313] "The mere fact that medical patents offer the means of making profit is not a sufficient reason to condemn them entirely."[314] The Committee further recognized three distinct conditions wherein a medical professional may obtain monetary profits:

> (a) Large Scale Operation: A large scale commercial operation, involving expensive equipment and numerous personnel may be required to introduce the medical invention. In such cases, no manufacturer would be willing to undergo the expenses unless an adequate return on investment could be obtained.

---

[310] *Id*.

[311] Fishbein, *supra* note 306, at 1315 (citing Comm. on Patents, Copyrights and Trademarks, Am. Ass'n for the Advancement of Sci., *The Protection by Patents of Scientific Discoveries* 20 (Jan. 1934) [hereinafter *Protection by Patents*]).

[312] Archie M. Palmer, *Medical Patents*, 137 JAMA 497, 499 (1948) (citing *Protection by Patents*, *supra* note 311, at 20).

[313] *Id*.

[314] *Id*.

> (b) Unusually Large Expenses: In such cases where the expenses of development are unusually large and an individual investigator or organization provides funding without public assistance, a legitimate reason arises for recoupment of research expenses. The public should be willing to pay the actual cost for what it gets.
>
> (c) Limited Organizational Funds: Where a medical invention is made at a university or similar institution having limited funds for research, patents that secure funding for future research would ultimately inure to the public welfare.[315]

In 1937, the Wisconsin Alumni Research Foundation adopted a more liberal patent policy at the request of the American Academy of Pediatrics.[316] While recognizing that medical matters vary widely in nature and that a policy should be applied on a case by case basis, the University of Wisconsin Alumni Research Foundation resolved:

> Many discoveries of a medical nature should probably be made available to the profession without any effort to patent them. Where a lack of proper control in the use of the patented article might result in undue exploitation of the public, lack of uniformity in standardization, and confusion of the public mind as to the inherent value of the product, we believe that patent consideration is preferable.[317]

In an effort to defend the Foundation policy, and thereby foster a university trend toward defensive patenting, Mr. Russell outlined a typical problem as applied to the Babcock Milk Fat Test. Dr. Babcock developed a standard test for determining the amount of fat present in milk.[318] In accordance with the prevailing attitude about patents at the time, Dr. Babcock refused to take out a patent while proclaiming, "the state of Wisconsin supported my investigation for years when the test was being perfected, and its people

---

[315] *Id*. (paraphrased for brevity).

[316] H.L. Russell, *Are Patents on Foods and Medicinals in the Public Interest*, 29 Ind. & Eng. Chem. 1322 (1937) (outlining purpose and effect of the patent policies of the Wisconsin Alumni Research Foundation on behalf of the University of Wisconsin).

[317] *Id*. at 1324.

[318] *Id*.

are entitled to receive all the benefits derived from its use."[319] Without control over this valuable dairy equipment, a number of manufacturers produced machines with uncalibrated glassware, thereby providing erroneous results and discrediting the test.[320]

In that same year, 1937, Dr. Morris Fishbein reiterated the position of the American Medical Association:

> It is unprofessional to receive remuneration from patents for surgical instruments or medicines; to accept rebates on prescriptions or surgical appliances, or perquisites from attendants who aid in the care of patients.[321]

Thus, the act of securing patents for medical discoveries is not unethical in itself, and that act does not necessarily mean that personal profits are sought. Even Dr. Fishbein recognized that a university with limited funds for research may use patents on technology developed in its laboratories to encourage further research.[322] In 1939, the American Medical Association held a conference to address the economic justification for medical patents.[323] In 1940, the *Principles of Medical Ethics* were changed, and patents on surgical instruments and procedures were treated equally, as follows:

> 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

---

[319] *Id*.

[320] *Id*.

[321] Morris Fishbein, *Medical Patents*, 29 Ind. & Eng. Chem. 1315 (1937) (calling for the formation of a central body, such as the AMA, to administer medical patents in the public interest) (intentional stylistic deviation from *The Bluebook*, *supra* note 210, R. 5.1(b), at 44).

[322] *Id*.

[323] A.W. Booth, *Report of the Conference on Medical Patents, Held Under the Auspices of the Board of Trustees of the American Medical Association March 16, 1939*, 112 JAMA 2163 (Supp. Report May 27, 1939).

> patents or copyrights either to retard or to inhibit research or to restrict the benefit of patients or the public . . . .[324]

By 1948, the medical community was beginning to realize that the ethical limitations placed on doctors were not placed on other specialized researchers, such as specialized investigators in the fields of biochemistry, physiology, and physics.[325]

The Patent Act of 1952[326] encouraged the prospects for obtaining medical procedure patents by providing for the explicit protection of processes. Unchanged to this day, 35 U.S.C. § 101 sets forth "Whoever invents or discovers any new or useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . . ."[327] Changes to medical ethics soon followed.

G. Removal of Ethical Prohibition on Patenting for Devices and Medical Procedures

In 1955, the American Medical Association adopted the following resolution:

> A physician *may* patent surgical instruments, appliances, and medicines or copyright publications, methods or *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.[328]

---

[324]Am. Med. Ass'n, *Principles of Medical Ethics* 8, § 5 (1940).

[325]Archie M. Palmer, *Medical Patents*, 137 JAMA 497, 498 (1948) (advocating the contributions of universities and professional schools to the progress of medical science though the acquisition of patents).

[326]Patent Act of 1952, ch. 950, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1–376 (2004)).

[327]35 U.S.C. § 101 (2004).

[328]Edgerton, *supra* note 255, at 564 (emphasis added).

By 1957, the reference to patents was removed from the *Principles of Medical Ethics* all together.[329] Organization and control by university funded research, coupled with the development of federal regulation of *nostrums* and elixirs, had addressed the concerns of the medical community. Self regulation in the area of patents was no longer required. However, financial concerns were still embedded in the *Principles*. No longer divided into chapters and articles, section 7 of the *Principles* provided:

> In the practice of medicine a physician should limit the source of his professional income to medical services actually rendered by him, or under his supervision, to his patients. His fee should be commensurate with the services rendered and the patient's ability to pay. He should neither pay nor receive a commission for referral of patients. Drugs, remedies or appliances may be dispensed or supplied by the physician provided it is in the best interests of the patient.[330]

Today, the general goal of increasing medical knowledge is clearly met by the patent system, while at the same time recognizing the economic requirements for practicing the art. The specific goals of protecting the patient are met through regulation of the medical profession and restraints on the unauthorized practice of medicine. Nevertheless, concerns over patenting of medical procedures have induced ethical and legal changes to the body of medical patents.

---

[329]Am. Med. Ass'n, *Principles of Medical Ethics* (1957), *reprinted in Ethics Revolution*, supra note 274, app. F, *available at* http://www.ama-assn.org/ama/upload/mm/369/1957_principles.pdf (last visited Apr. 18, 2004). In 1957, the AMA Judicial Council also issued an Official Opinion that it no longer considered medical patents necessarily unethical. Judicial Council, Am. Med. Ass'n, *Official Opinions of the Judicial Council*, 163 JAMA 1156 (1957).

[330]*Id*. at § 7.

H. *Pallin v. Singer*[331] — A Clear Controversy for Medical Procedure Patents

In 1990, Dr. Dr. Samuel L. Pallin made an upside-down V-shaped incision in the eye of a patient while removing a cataract.[332] Dr. Pallin did not stitch the incision after removal of the cataract because the patient was experiencing heart problems.[333] Two weeks later, Dr. Pallin determined that the incision had healed without suture and the patient had received far less scar tissue than normal.[334] Dr. Pallin attempted to publish his findings in the *Journal of Cataract and Refractive Surgery*,[335] but his submission was rejected.[336] Accordingly, on June 28, 1990, Dr. Pallin filed for patent protection on his invention entitled *Method of Making Self-Sealing Episcleral Incision*. Approximately nineteen months later, Dr. Samuel L. Pallin was awarded U.S. Patent No. 5,080,111 (issued Jan. 14, 1992).

Although numerous medical and surgical procedure patents had been issued between 1846 and 1993,[337] Dr. Pallin is recognized as one of the first modern physicians

---

[331]Pallin v. Singer, 1996 WL 274407 (D. Vt. 1996) (final consent order invalidating 4 of 29 claims, prohibiting enforcement of patent against any physician or health care provider, and dismissing action with prejudice).

[332]U.S. Patent No. 5,080,111 (issued Jan. 14, 1992) (Claim 1. "A method of making a substantially self-sealing episcleral incision . . . in the sclera . . . 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 . . . .").

[333]Joseph M. Reisman, Comment, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 High Tech. L.J. 355, 366 (1995) (citing Jodie Snyder, *A Patent for Eye Surgery? Court Case Arises Over the Technique*, The Phoenix Gazette, Apr. 4, 1995, at A1).

[334]*Id*.

[335]Robert L. Lowes, *Are You Stealing from Other Doctors?*, Med. Econ., Mar. 11, 1996, at 206 (vol. 73, no. 5), *available at* 1996 WL 9421717.

[336]*Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. (Oct. 19, 1995) [hereinafter Hearings H.R. 1127] (testimony of Samuel L. Pallin, M.D., Medical Director, Lear Eye Clinic) ("I was denied the opportunity to publish my writings and discovery in a traditional medical journal. I turned to the U.S. Patent Office to document what I had accomplished . . . ."), *available at* 1995 WL 615761.

[337]William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. Pat. & Trademark Off. Soc'y 651, 658–60 (1995) (listing 48 issued patents for medical procedures between 1846 and 1993).

to assert his patent rights against another physician.[338] On July 6, 1993, Dr. Pallin elected to enforce his patent and filed suit against Dr. Jack A. Singer, M.D., and the Hitchcock Clinic d/b/a/ The Hitchcock Associates of Randolph.[339] Although ultimately unsuccessful,[340] the infringement lawsuit prompted considerable debate in the medical community,[341] congressional hearings,[342] a formal ethical opinion against patenting of medical procedures,[343] and a new law prohibiting enforcement of medical procedure patents against medical practitioners.[344]

In 1995, the American Medical Association responded to Dr. Pallin with *The 1995 AMA Report of the Council on Ethical and Judicial Affairs*.[345] This report was eventually refined and published as justification for AMA Opinion 9.095.[346]

---

[338]Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. Davis L. Rev. 601, 604 (2000) (alleging Dr. Pallin to be the first doctor to sue another doctor).

[339]Pallin v. Singer, No. 93–202 (D. Vt. filed July 6, 1993).

[340]Pallin v. Singer, 1996 WL 274407 (D. Vt. 1996) (consent order invalidating 4 of 29 claims, prohibiting enforcement of patent against any physician or health care provider, and dismissing action with prejudice); Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (denying Dr. Singer's motion for summary judgment of patent validity).

[341]*See* Stephen E. Wear et al., *Patenting Medical and Surgical Techniques: An Ethical-Legal Analysis*, 23 J. Med. and Phil. 75 (1998) (arguing against blanket prohibition or wholesale acceptance of the patenting of medical or surgical techniques). *See also* Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, Wall St. J., Aug. 11, 1994, at B1.

[342]Hearings H.R. 1127, *supra* note 336 (debating proposed changes to laws defining patentable subject matter).

[343]*See infra* Opinion 9.095 accompanying note 351. Resolutions and lobbying by the medical community resulted in responsive legislative action. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. Pat. & Trademark Off. Soc'y 789 (1996) (analyzing the legislative history of statutory limitations on medical procedure patents led by the "Medical Procedure Patents Coalition" — a consortium of sixteen medical associations).

[344]35 U.S.C. § 287(c)(1) (2004) ("With respect to a medical practitioner's performance of a medical activity that constitutes [patent] infringement . . . [certain remedial] provisions . . . shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.").

[345]Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Patenting of Medical Procedures* (1994) (CEJA Report 1-A-95) (based on Substitute Resolution 2, adopted by the House of Delegates at the 1994 AMA Annual Meeting) (purporting to "vigorously condemn the patenting of medical and surgical procedures and work with Congress to outlaw this practice.").

[346]*Ethical Issues*, *supra* note 3; AMA Annotated Opinions, *supra* note 1, at 263 (denoting that Opinion 9.095 was based on the report *Ethical Issues*, *supra* note 3).

I. Current Ethical Rules and Policies

The current *Principles of Medical Ethics* were adopted by the American Medical Association in 2001.[347] While the *Principles* do not prohibit or even address patenting, they have been interpreted by the Council on Ethical and Judicial Affairs of the American Medical Association in their formal Opinions to relate to patenting. The *Principles* relied upon by the Judicial Council are:

> V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
>
> . . . .
>
> VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.[348]

The two Opinions[349] relating to patents offered by the AMA Judicial Council are the safe harbor for patenting surgical and diagnostic instruments — Opinion 9.09, and the prohibition against patenting of medical procedures — Opinion 9.095, as follows:

> 9.09 Patent for Surgical or Diagnostic Instrument
>
> 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. (V, VII).[350]

---

[347]Am. Med. Ass'n, *Principles of Medical Ethics* (adopted by AMA House of Delegates June 17, 2001), *available at* http://www.ama-assn.org/ama/pub/category/2512.html (last updated Apr. 2, 2002).

[348]*Id.*

[349]Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Code of Medical Ethics Current Opinions with Annotations* (2002–2003 ed. 2002), *available at* http://www.ama-assn.org/ama/noindex/category/11760.html (last visited Apr. 18, 2004).

[350]*Id*. at 262.

> 9.095 Patenting of Medical Procedures
>
> A physician has the ethical responsibility not only to learn from but also to contribute to the total store of scientific knowledge when possible. Physicians should strive to advance medical science and make their advances known to patients, colleagues, and the public. This obligation provides not merely incentive but imperative to innovate and share the ensuing advances. The patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures available to patients and should be condemned on this basis. Accordingly, it is unethical for physicians to seek, secure, or enforce patents on medical procedures. (V, VII).[351]

The safe harbor of Opinion 9.09 was adopted prior to April 1977, and historically serves to redress the prior AMA conflict with the State Medical Society of Ohio regarding the patenting of surgical or diagnostic instruments.[352] On the other hand, Opinion 9.095 was issued June 1996, and is officially based on the report *Ethical Issues in the Patenting of Medical Procedures*.[353]

IV. The History of Medical Device Regulation

A. The *Federal Food and Drugs Act of 1906*[354]

The history of medical device regulation by the FDA traces its roots to early government regulation of food and drugs. This government regulation of food, drugs — and now devices, has evolved, for the most part, as a reaction to a social wrong.[355] The history of food quality regulation is easily traced to the appointment in 1882 of Harvey Washington Wiley as the Chief Chemist, Bureau of Chemistry, in the U.S. Department of

---

[351] *Id*. at 263.

[352] *See supra* text accompanying note 293 (outlining conflict between the State Medical Society of Ohio and the American Medical Association over patenting of surgical or diagnostic instruments).

[353] *Ethical Issues*, *supra* note 3.

[354] Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[355] *See* Emilio Q. Daddario, *Technology Assessment — A Legislative View*, 36 Geo. Wash. L. Rev. 1044, 1053 (1968) ("[A]gain and again this country has moved to assess technology *after* some major catastrophe."). Mr. Daddario was a member of the 86th–91st Congress from the 1st Connecticut district. *Who's Who in American Law* 168 (Karen Chassie et al. eds., 13th ed. 2003).

Agriculture.[356] By 1902, Wiley had conducted a number of well publicized "poison squad" studies, which consisted of feeding various preservatives, such as formaldehyde and sulphate of copper, to healthy young men employed by the Department of Agriculture.[357] The 1906 novel, *The Jungle*,[358] intensified public concern by detailing the filthy conditions of a Chicago meat packing plant. Public response led to the passage of the *Federal Food and Drugs Act of 1906*.[359] The *1906 Act* deemed it unlawful to manufacture adulterated or misbranded food or drugs.[360] Drugs were defined with reference to the *U.S. Pharmacopoeia*[361] or the *National Formulary*,[362] or as substances intended to cure disease. While violations of the *1906 Act* were determined by the Bureau of Chemistry of the U.S. Department of Agriculture and reported to the proper United States district attorney,[363] the manufacturer was not required to test for product safety.[364] Prosecutions under the *1906 Act* were difficult because the state was required

---

[356]U.S. Food and Drug Administration, *FDA History, FDA Commissioners and Their Predecessors*, *at* http://www.fda.gov/opacom/morechoices/comm1.html#wiley (last visited Nov. 14, 2002).

[357]Harvey W. Wiley, M.D., *The History of a Crime Against the Food Law*, ch. 2 (Harvey W. Wiley, M.D., pub., 1929). *See also* Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 Law & Contemp. Prob. 3, 6 (1933) (noting that the poison squad studies were conducted for five years and reported all over the world).

[358]Upton Sinclair, *The Jungle* (1906) (depicting experiences of a Slavic immigrant working in the Chicago meat-packing industry).

[359]Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[360]*Id*. § 1.

[361]The United States Pharmacopeia ("USP") is a non-government organization that publishes the standards publication, *United States Pharmacopeia*, for drug identity, strength, and quality. United States Pharmacopeia, *News Release, The USP 25-NF . . . Becomes Official*, http://www.onlinepressroom.net/uspharm/ (last modified Jan. 2, 2002). The *U.S. Pharmacopeia* is "known as the 'bible' of the pharmaceutical industry." United States v. Bhutani, 175 F.3d 572, 575 (7th Cir. 1999).

[362]In 1975, USP purchased the standards publication, *National Formulary,* for excipients, botanicals, and similar products. The two publications remain separate, but are currently published under the same cover. *News Release,* supra note 361.

[363]Food and Drugs Act of 1906, § 4 (repealed 1938).

[364]S. Doc. No. 75–124, at 1 (1937) ("[T]he Federal Food and Drugs Act contains no provision against dangerous drugs.").

to prove intent.[365] In 1927, the Bureau of Chemistry within the U.S. Department of Agriculture was renamed the Food, Drug and Insecticide Administration,[366] and was shortened in 1931 to the Food and Drug Administration.[367]

B. The Sulfanilamide Tragedy

In 1932, German biochemist Gerhard Johannes Paul Domagk slightly changed the chemical makeup of a red dye Prontosil, created Sulfanilamide,[368] and changed the world. Mr. Domagk gave his newly created drug to his daughter and saved her from near death by streptococcal bacterial infection.[369] Sulfanilamide is the grandparent of the Sulfonamide family of drugs, popularly known today as "sulfa drugs."[370] However, in 1937 the S.E. Massengill company directed its chief chemist, Harold Cole Watkins, to create a liquid form of Sulfanilamide that would be more acceptable to children.[371] Mr. Watkins diluted Sulfanilamide with 72 percent[372] diethylene glycol (DEG), a poison

---

[365]Federal Food and Drugs Act of 1906, §§ 1–2 (repealed 1938) (defining manufacture or shipping of adulterated food or drugs as a misdemeanor). *See generally* 1 Toulmin, *The Law of Foods, Drugs and Cosmetics* § 2.3 (1963) (outlining chief differences between the Acts of 1906 and 1938, notably that intent is required for a conviction of false therapeutic claims under the 1906 Act).

[366]Act of Jan. 18, 1927, ch. 39, 44 Stat. 976, 1002 (referring to Food, Drug and Insecticide Administration by name).

[367]Act of May 27, 1930, ch. 341, 46 Stat. 392, 422 (referring to Food and Drug Administration by name).

[368]David Steinert, *World War II Combat Medic, The History of WWII Medicine*, *at* http://home.att.net/~steinert/wwii.htm (last updated Apr. 5, 2004).

[369]*Id*.

[370]*Id*.

[371]GMP Institute, *Food and Drug Legislation — The Story Behind the Law*, *at* http://www.gmp1st.com/histlaw.htm (last visited Apr. 18, 2004).

[372]Drug Store News 2 (June 16, 1997).

currently used in antifreeze[373] and as a tobacco humectant.[374] As a result, over a hundred people, mostly children, suffered a severe and painful death.[375] The *1906 Act*[376] did not require new drugs to be tested for safety, and the FDA technically lacked statutory authority to recall individual medicine bottles.[377] The S.E. Massengill Company was merely fined $26,100 for misbranding violations under the *1906 Act*[378] and Harold Watkins committed suicide.[379] In 1938, Congress passed the *Federal Food, Drug and Cosmetics Act*.[380] While excepting existing drugs subject to the *1906 Act*, the *1938 Act* prohibited delivery of any new drug unless shown to the Secretary of Agriculture to be safe for use.[381] In 1940, the FDA was transferred to the Federal Security Agency,[382] and in 1953 was merged into the Department of Health, Education, and Welfare.[383]

---

[373]Morbidity and Mortality Weekly Report, Center for Disease Control, *Fatalities Associated with Ingestion of Diethylene Glycol . . .*, Aug. 2, 1996*, available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00043194.htm (page converted Sept. 9, 1998).

[374]Philip Morris USA, *Product Facts: Ingredients in Cigarettes* (indicating by percentage amount of diethylene glycol in cigarette paper), *at* http://www.philipmorrisusa.com/our_products/ingredients/non_tobacco_ingredients.asp (last visited Apr. 20, 2004).

[375]Drug Store News, *supra* note 372.

[376]Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[377]1 James T. O'Reilly, *Food and Drug Administration* § 13.02, at 13–5 (2d ed. 1993). In fact, at the height of the effort, Massengill salesmen were uncooperative and at least one was jailed until he disclosed recipients of the elixir. S. Doc. No. 75–124, at 6 (1937).

[378]Linda Bren, *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History,* FDA Consumer Magazine, Mar.–Apr. 2001, *available at* http://www.fda.gov/fdac/features/2001/201_kelsey.html (last visited Apr. 18, 2004). Had the product been called a "solution," rather than an "elixir," no charge of violating the law could have been brought. S. Doc. No. 75–124, at 9 (1937).

[379]Bren, *supra* note 378.

[380]Federal Food, Drug and Cosmetics Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2004)).

[381]FDCA, § 505(a), 21 U.S.C. § 355(a) (2004).

[382]Reorg. Plan No. 4 of 1940, § 12, 5 Fed. Reg. 2,431 (1940), *reprinted in* 54 Stat. 1234 (1940) (approved by Act of June 4, 1940, ch. 231, § 4, 54 Stat. 231 (1940)).

[383]Reorg. Plan No. 1 of 1953, § 5, 18 Fed. Reg. 2,053 (1953), *reprinted in* 67 Stat. 631 (1953).

C. Thalidomide

In 1958, the drug thalidomide was popular in Europe for treating sleep disorders and morning sickness in pregnant women.[384] Thalidomide was available in Germany without a prescription, and the William S. Merrill Company submitted a U.S. application to the FDA for U.S. marketing.[385] Concerned about reports of tingling nerve inflammation in long time users, Ms. Frances Kelsey of the FDA did not approve the application and requested additional information from Merrill.[386]

By 1961, reportedly 5,000 German babies were born with severe birth defects as a result of thalidomide and at least 3,000 United States women had received thalidomide experimentally.[387] In fact, during pendency of the thalidomide new drug application with the FDA, the Merrill Co. had distributed over 2,500,000 tablets for investigational use by 1,270 physicians in the United States, who in turn dispensed thalidomide to 20,771 patients.[388] In response to the thalidomide tragedy of the late 1950s, Congress passed the *Drug Amendments of 1962*,[389] thereby requiring new drugs to also be proven effective, as well as safe.[390] For her efforts in minimizing the effects of thalidomide in the United

---

[384]GMP Institute, *supra* note 371.

[385]*Id*.

[386]Bren, *supra* note 378.

[387]*Id*. Public concern was enhanced by press reports of a woman having taken thalidomide during a trip abroad and being denied a U.S. abortion during her first trimester of pregnancy. *See generally* Taussig, *A Study of the German Outbreak of Phocomelia*, 80 JAMA 1106 (1962).

[388]77 Pub. Health Rep. 946 (1962) ("The 1,258 physicians interviewed in the FDA survey reported a total of 20,771 patients as having received thalidomide."). *See also* Comment, *The Food and Drug Administration: Law, Science and Politics in the Evaluation and Control of New Drug Technology*, 67 Nw. U. L. Rev. 858, 867–68 (1973).

[389]Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781–82 (codified as amended in scattered sections of 21 U.S.C.) (adding "and effectiveness" after "safety" throughout statute).

[390]Critics argue that the Congressional action was not a direct response because the efficacy proposals had been pending a number of years, and the problem with thalidomide was safety — not efficacy.

States, President John F. Kennedy subsequently presented Ms. Frances Kelsey with the *President's Award for Distinguished Federal Civilian Service*.[391]

D. *Drug Amendments of 1962*

Before passage of the *Drug Amendments of 1962*, there were thousands of generic drugs, often called "me-too" drugs, being marketed without FDA approval in reliance on prior "pioneer" drug applications.[392] According to the *Drug Amendments of 1962*, *all* drugs were now required to show effectiveness, and the generic drugs were given a two year grace period to present such evidence to the FDA.[393] To handle the considerable burden of reviewing all marketed drugs for efficacy, the FDA retained the National Academy of Sciences-National Research Council (NAS–NRC) to create expert review panels.[394] This procedure was known as the *Drug Efficacy Study Implementation (DESI)*.[395] The *DESI* review of drug products produced monographs[396] responding to approximately 16,500 claims made for approximately 4000 pre–1962 drugs.[397]

---

[391]Remarks Upon Presenting the President's Awards for Distinguished Federal Civilian Service, 1962 Pub. Papers § 323 (Aug. 7, 1962). The *President's Award for Distinguished Federal Civilian Service* is often confused with the *Presidential Medal of Freedom*, authority for both deriving from the same statute. 5 U.S.C. § 4504 (2004).

[392]Weinberger v. Hynson, Estcott & Dunning, Inc., 412 U.S. 609, 614 (1973) ("'[M]e-toos,' are similar to or identical with drugs with effective NDA's and are marketed in reliance on [a prior] 'pioneer' drug application approved by FDA.").

[393]Drug Amendments of 1962, Pub. L. No. 87–781, § 107(c)(2), 76 Stat. 780, 788 (proclaiming approval of drug applications that were effective before passage of 1962 Act); *id*. § 107(c)(3)(B)(i), at 789 (withdrawing approval of drug applications two years after passage of 1962 Act if not shown effective).

[394]*Hynson*, 412 U.S. at 614 (confirming NAS–NRC expert panels to review efficacy of every approved drug).

[395]*See generally* National Academy of Sciences, *Drug Efficacy Study: Final Report to the Commissioner of Food and Drugs* (1969).

[396]A monograph is a scientific report describing a class of drugs and making certain findings regarding safety and effectiveness. O'Reilly, *supra* note 377, § 13.07.

[397]*Id*.

E. *DESI* Review 1962–1969

During the *DESI* review process conducted 1962–1969, the FDA concluded that each drug product was in fact a "new drug" that required an approved new drug application (NDA) before it could be legally marketed.[398] In 1968, the FDA revoked earlier advisory opinions that drugs could be marketed without prior FDA clearance.[399] By 1969, the FDA created an abbreviated new drug application (ANDA) to provide for regulatory approval of generic drugs marketed before the 1962 Act.[400] The FDA initially permitted marketing by generic drug manufacturers while the ANDA was pending, however this practice was enjoined in 1975 as a violation of the Drug Amendments of 1962.[401] The FDA has not permitted the filing of 1962 ANDAs for generic drugs corresponding to pioneer drugs approved on or after October 10, 1962.[402]

F. The Cooper Committee of 1969

Formal regulation of medical devices by the FDA traces back to 1969, when Dr. Theodore Cooper, Director of the National Heart and Lung Institute, headed a panel to review the need for additional medical device legislation.[403] Once again, government regulation responded to a well publicized social wrong. The Cooper Committee searched

---

[398]United States v. Generix Drug Corp., 460 U.S. 453 (1983) (holding a generic drug product is a *drug* within the meaning of section 201(g)(1) of the Federal Food, Drug, and Cosmetics Act, thereby requiring the filing of a new drug application under section 505 of the Act).

[399]33 Fed. Reg. 7,758 (May 28, 1968) (codified as amended at 21 C.F.R. § 310.100(d) (2004)) (revoking all previous opinions by the FDA that an article is "not a new drug" or is "no longer a new drug").

[400]34 Fed. Reg. 2,673 (Feb. 27, 1969) (defining regulations for filing and content of abbreviated new drug applications); 35 Fed. Reg. 11,273 (July 14, 1970) (requiring generic drug manufacturer without approved NDA to submit full or abbreviated NDA).

[401]Hoffmann-LaRouche, Inc. v. Weinberger, 425 F. Supp. 890 (D.D.C. 1975) (requiring FDA to prohibit marketing of generic drugs during NDA approval phase); Office of Regulatory Affairs, U.S. Food and Drug Admin., *Compliance Policy Guide Manual*, § 448.100 (implementing Hoffmann-LaRouche court order through FDA Compliance Program 7332.26), *at* http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg448-100.html (revised Mar. 1995).

[402]54 Fed. Reg. 28,872, 28,873 (July 10, 1989).

[403]Study Group on Med. Devices, Dep't of Health, Education & Welfare, *Medical Devices: A Legislative Plan* (1970) [hereinafter Cooper Committee Report]. *See also* Cooper, *Device Legislation*, 26 Food Drug Cosm. L.J. 165 (1971) (summarizing Cooper Committee Report).

the scientific literature for accounts of injuries from medical devices and discovered some 10,000 recorded injuries, of which 731 resulted in death.[404] For example, 186 injuries were related to heart pacemakers, while 10 deaths and 8,000 injuries were related to intrauterine devices, most notably the Dalkon Shield.[405]

G. *Medical Device Amendments of 1976*

In 1976, Congress passed the *Medical Device Amendments of 1976*[406] to further distinguish medical devices from drugs, solidify FDA authority over medical devices, establish different classes of medical devices, and mandate premarket approval for devices in need of additional information.[407] Prior to passage of the *1976 Amendments*, the FDA bore the burden of proving that a medical device in the stream of commerce was unsafe or misbranded.[408] Now, for the first time, the *1976 Amendments* gave the FDA comprehensive regulatory authority over medical devices.[409] In general, the medical device applicant must submit to a complicated and lengthy premarket approval process,[410]

---

[404]S. Rep. No. 94-33, at 6 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1076.

[405]H.R. Rep. No. 94–853, at 8 (1976), *reprinted in An Analytical Legislative History Of The Medical Device Amendments Of 1976*, app. III (Daniel F. O'Keefe & Robert Spiegel eds., 1976). House Report No. 94–853 is considered by scholars to be "the best source of legislative history on the Medical Device Amendments of 1976." Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J. Law & Tec. 1, 84 n.11 (1989).

[406]Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.). *See generally*, H.R. Rep. No. 94–853, *supra* note 405 (providing legislative history of the *Medical Device Amendments of 1976*).

[407]*See generally* Jennifer Salvatore O'Connor, *The Impact of Lohr v. Medtronic on the First Circuit's Application of the Medical Device Amendments*, 3 Suffolk J. Trial & App. Adv. 157 (1998) (reporting on the Supreme Court's detailed analysis of the Medical Device Amendments of 1976 in *Lohr v. Medtronic*, 518 U.S. 470 (1996)).

[408]*See* Leflar, *supra* note 405, at 2.

[409]Slater v. Optical Radiation Corp., 961 F.2d 1330, 1331 (7th Cir. 1992) (quoting H.R. Rep. No. 94–853, at 6–13 (1976)).

[410]FDCA, § 515(b)(1), 21 U.S.C. § 360e(b)(1) (2004) (requiring premarket approval for Class III devices); 21 C.F.R. pt. 814 (2004) (providing procedures for the premarket approval of medical devices intended for human use).

or show that the device is substantially equivalent to a device existing prior to enactment of the *1976 Amendments*.[411]

H. The *Hatch-Waxman Act*[412]

While seemingly unrelated, the next legislative change to significantly affect medical device regulation was the *Drug Price Competition and Patent Term Restoration Act of 1984*,[413] also known as the *Hatch-Waxman Act*.[414] The *Hatch-Waxman Act* primarily sought to quicken the approval process for generic drugs and extend patent life of pioneer drugs to compensate for regulatory delay.[415] The *Hatch-Waxman Act* had a number of effects, notably: to establish a statutory abbreviated new drug application (ANDA) for generic drugs,[416] to establish patent term extensions for delays in the approval of products regulated by the FDA,[417] to exempt submission of information under a federal law which regulates drugs from patent infringement,[418] and to provide for a

---

[411]*Id.* § 513(f)(1), 21 U.S.C. § 360c(f)(1) (designating a device as a Class III device unless substantially equivalent to a Class I or II device).

[412]The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2004); 21 U.S.C. §§ 301 note, 355, 360cc (2004); 28 U.S.C. § 2201 (2004); 35 U.S.C. §§ 156, 271, 282 (2004)).

[413]*Id*.

[414]*See generally* Ann K. Wooster, *Construction and Application of Hatch-Waxman Act*, 180 A.L.R. Fed. 487 (2002) (reporting application of the Hatch-Waxman Act in particular circumstances).

[415]*See generally* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187 (1999) (reconstructing the legislative history of the *Hatch-Waxman Act* as relating to drug discovery and development, drug patent protection, and generic drug competition). Hon. Mossinghoff is a former Commissioner of Patents and Trademarks, Patent and Trademark Office, U.S. Dep't of Commerce, and a former President of the Pharmaceutical Manufacturers Association (predecessor organization of the Pharmaceutical Researchers and Manufacturers of America).

[416]Hatch-Waxman Act, sec. 101, § 505(j) (codified as amended at 21 U.S.C. § 355(j) (2004)) (defining contents of abbreviated new drug application).

[417]*Id*. § 201 (codified as amended at 35 U.S.C. § 156(a) (2004)) (extending patent term of product subject to regulatory review).

[418]*Id*. § 202 (codified as amended at 35 U.S.C. § 271(e) (2004)) (exempting from infringement making, using or selling a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates drugs).

number of technical clarifications relating to patent infringement and regulatory approval. For example, constructive patent infringement was established for the manufacture and sale of generic drug copies prior to patent expiration,[419] while the drug approval process itself was statutorily exempted from infringement.[420]

On the other hand, interpretation of the *Hatch-Waxman Act* as applied to medical devices has relied heavily on judicial interpretation. In the 1990 case of *Eli Lilly v. Medtronic*,[421] the Supreme Court interpreted section 202 of the *Hatch-Waxman Act*[422] with respect to medical devices. That portion provides, in pertinent part:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.[423]

The Supreme Court specifically determined that "a Federal law which regulates . . . drugs"[424] refers to the entire *Federal Food, Drug, and Cosmetics Act*,[425] thereby exempting medical devices from infringement during uses solely related to obtaining regulatory approval. In *Eli Lilly*, the Supreme Court left unanswered whether all classes

---

[419]*Id*. sec. 102, § 505(b) (codified as amended at 21 U.S.C. § 355(b) (2004)) (requiring the applicant to file patent number and expiration date of patent claiming drug).

[420]*Id*. § 201 (codified as amended at 35 U.S.C. § 271(e)(1) (2004)) (exempting from infringement activities reasonably related to development and submission of information under a federal law which regulates drugs).

[421]Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

[422]Hatch-Waxman Act, sec. 101, § 202, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e)(1) (2004)).

[423]*Id*.

[424]*Id*.

[425]21 U.S.C. §§ 301–399 (2004).

of medical devices and hence all forms of FDA regulation would suffice for the exemption.[426]

In *Abtox, Inc. v. Exitron Corp.*,[427] the U.S. Court of Appeals for the Federal Circuit clarified that all classes of medical devices fall within the plain meaning, and hence the infringement exception of section 271(e)(1).[428] It has been observed by one scholar that change in this area seems likely.[429] Activities such as displaying devices at medical conferences,[430] continuing clinical trials after submission of an initial application to the FDA,[431] and shipping to a foreign affiliate to evaluate alternative manufacturing procedures,[432] were held within the exemption.[433] On the other hand, shipment of samples to a foreign agency exclusively for obtaining foreign regulatory approval,[434]

---

[426]*Eli Lilly* involved an implantable ventricular defibrillator — a Class III device requiring lengthy and substantial FDA review for safety and effectiveness.

[427]Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997)

[428]*Id*. at 1029 ("This Supreme Court reasoning creates the rub for this case. As the Supreme Court reasoned, Class III devices are eligible for a patent term extension under section 156, and therefore application of the section 271 infringement shield to these devices creates a convenient statutory symmetry. Title 35 both giveth and taketh away.").

[429]Edward V. Filardi, *Patent Issues that Both Regulatory Affairs Personnel and Patent Attorneys Should Understand*, 54 Food Drug L.J. 215 (1999) (speculating that the exemption from patent infringement under section 271(e)(1) for acts solely related to obtaining regulatory approval for Class I and II devices will ultimately change).

[430]Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1523–25 (Fed. Cir. 1992) (holding demonstrations at medical conferences exempt from infringement because selection of qualified investigators was reasonably related to securing clinical data under an FDA Investigational Device Exemption).

[431]Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1282–83 (N.D. Cal. 1991) (holding *inter alia* that section 271(e)(1) analysis turns on a party's actual uses — which could lead to submission of information to the FDA — and not an ultimate objective, such as securing foreign regulatory approval), *aff'd mem.,* 991 F.2d 808 (Fed. Cir. 1993).

[432]Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 109 (D. Mass 1998) (holding that tests unacceptable to the FDA for determining safety and effectiveness may still be related to obtaining FDA approval) ("The inference to be drawn that the Defendants had other purposes in mind when conducting these studies [related to purity standards and not related to safety and effectiveness], even if accepted as true, is statutorily irrelevant.").

[433]*See generally* Brian D. Coggio & Francis D. Cerrito, *The Application of The Patent Laws to the Drug Approval Process*, 4 No. 1 Andrews Intell. Prop. Litig. Rep. 3 (Aug. 6, 1997) (listing otherwise infringing activities held exempt under section 271(e)(1)).

[434]NeoRx Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 207 (D.N.J. 1994) ("The court agrees with plaintiff that making the Products in the United States then shipping them abroad to regulatory agencies is not reasonably related to the submission of data to the FDA and as such is a nonexempt infringing activity.").

testing with an intent unrelated to obtaining FDA approval,[435] and stockpiling[436] have been considered non-exempt, and therefore infringing activity. On at least one occasion, the courts have attempted to defer to the FDA for a determination whether activity is reasonably related to obtaining regulatory approval.[437] However, the FDA specifically declined this invitation,[438] thereby resulting in confusion and additional litigation.[439]

V. International Ethical and Legal Standards

Throughout the world, with the exception of the United States, ethical and legal standards for patenting medical devices and procedures form a close relationship to guide medical practitioners. The requirement of industrial utility inherent in many foreign patent statutes has necessarily removed the prospect of obtaining medical procedure patents. However, regardless of the differing standards, the global relationship between ethical and legal standards on a country-by-country basis remains remarkably consistent.

A. United States Medical Patent Practice

On September 30, 1996 as part of the *Omnibus Consolidated Appropriations Act of 1997*, Congress passed in Division A, Title VI, section 616, *Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity —*

---

[435]*Id*. (holding an explicit understanding of non-intent from a researcher "that, 'it had never been his understanding that the results of these studies were intended for subsequent submission to the FDA,'" as defeating an exemption from infringement).

[436]Biogen, Inc. v. Schering AG, 954 F. Supp. 391, 396–97 (D. Mass. 1996) (holding that expenditures exceeding twenty-four million dollars to stockpile and prepare for marketing were not reasonably related to obtaining FDA approval).

[437]Nexell Therapeutics v. Amcell Corp., 143 F. Supp. 2d 407, 423 (D. Del. 2001) ("The court will not resolve the issue of whether AmCell's activities are protected by section 271(e)(1). Rather, the court will defer to the FDA. The FDA can resolve the issue and define for AmCell what activities are reasonably related to the development and submission of information necessary to obtaining pre-market approval for its device.").

[438]The FDA declined to determine whether alleged activities fell within the section 271(e)(1) exemption. "[A]ccording to the FDA, 'there is no reason to assume any direct correlation between [the] FDA's evaluation of AmCell's submissions and the appropriate construction of section 271.'" Nexell Therapeutics v. Amcell Corp., 199 F. Supp. 2d 197, 202 (D. Del. 2002) (quoting private FDA letter dated July 11, 2001).

[439]"[I]t is apparent that the parties have two vastly different readings of the court's opinion. The ostensible ambiguity in the opinion is also apparent from the response of the FDA." *Id*.

the *Medical Practitioner Exemption Act*.[440] United States patent law does *not* prohibit the patenting of medical procedures, but rather prohibits enforcement against medical practitioners.

> 35 U.S.C. § 271(a)[441] provides:
> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.
>
> 35 U.S.C. § 287(c)(1)[442] provides:
> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

A medical practitioner is a state licensed practitioner or subordinate performing a medical activity,[443] and a health care entity has a professional affiliation with the medical practitioner for performance of the medical activity, such as a hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.[444] The definition of "medical activity" provides three exceptions to the general exemption from infringement, including:

> (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent,
> (ii) the practice of a patented use of a composition of matter in violation of such patent, or

---

[440] *See* Medical Practitioner Exemption Act, *supra* note 9.

[441] 35 U.S.C. § 271(a) (2004).

[442] 35 U.S.C. § 287(c)(1) (2004).

[443] 35 U.S.C. § 287(c)(2)(B) (2004).

[444] § 287(c)(2)(C) (2004).

(iii) the practice of a process in violation of a biotechnology patent.[445]

Most notably, medical procedures using patented products are not immune from infringement.[446] Unlike the relationships between law and ethics found in other countries, § 287(c) is clearly inconsistent with AMA Opinion 9.095, *infra* Part III.I., which prohibits physician patenting in the first instance.

B. European and British Medical Patent Practice

European patents are issued in accordance with the patent rules of the contracting states, known as the European Patent Convention (EPC).[447] Article 52(1) of the EPC defines patentable invention as those "susceptible of industrial application, which are new and which involve an inventive step."[448] However, article 52(4) addresses methods of medical treatment and relates to article 52(1) as follows:

> (4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised [sic] on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.[449]

---

[445]§ 287 (c)(2)(A) (2004).

[446]Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. Davis L. Rev. 601, 638 (2000) (interpreting the exemption to include patents that claim both a product and a process, and recognizing doctor liability for use of non-licensed products).

[447]Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199, 13 I.L.M. 268 (text as amended by the act revising EPC article 63 of Dec. 17, 1991 and by decisions of the Administrative Council of the European Patent Organisation of Dec. 21, 1978, Dec. 13, 1994, Oct. 20, 1995, Dec. 5, 1996, and Dec. 10, 1998) (also known as the European Patent Convention) [hereinafter EPC], *available at* http://www.european-patent-office.org/legal/epc/e/ma1.html (last updated Mar. 2004).

[448]*Id*. art. 52(1).

[449]*Id*. art. 52(4).

While at least one commentator has criticized article 52(4) as an outright exclusion rather than a statement on industrial application,[450] article 52(4) nevertheless has been consistently upheld.[451] Medical treatment has been held to include cosmetic, experimental, and research based treatment, but is limited in scope to living bodies.[452] Even if one step of a claim falls within article 52(4), the claim is unpatentable.[453]

Member countries of the European Patent Convention are generally in accord with article 52(4).[454] For example, the *United Kingdom Patents Act of 1977*, section 4(1), (2) corresponds to EPC article 52(1), (4) as follows:

> (1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.
> (2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised [sic] on the human or animal body shall not be taken to be capable of industrial application.[455]

---

[450]Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. Pat. & Trademark Off. Soc'y 381, 390 (2000) (declaring EPC article 52(4) as perpetuating a fiction that methods of medical treatment are incapable of industrial application).

[451]*See* In Re Eisai Co., Ltd. (Bayer AG), 1983 O.J. EPO 266 (Case number G 0005/83-EBA, EPO Enlarged Board of Appeal, Dec. 5, 1984) (holding European patent use may not be granted for the use of substance or composition for treatment of human or animal body by therapy, but a claim to the use of a product for the manufacture of a medicament for a specified new and inventive medical use could be permitted — "Swiss type" (second medical use) claim), *available at* http://www.european-patent-office.org/dg3/g_dec/pdf/g830005.pdf. *See also* In Re Georgetown University, 10/2000 O.J. EPO 477 (Case number T 0035/99, EPO Technical Board of Appeal, Sept. 29, 1999) (holding catheterisation [sic] as part of a medical process to be a "method for treatment of the human or animal body by surgery" which is not regarded as susceptible of industrial application), *available at* http://www.european-patent-office.org/epo/pubs/oj000/10_00/10_4470.pdf.

[452]*See* In Re See/Shell Biotechnology, Inc., 1994 O.J. EPO 641 (Case number T 0182/90, EPO Technical Board of Appeal, July 30, 1993) (holding method including surgical step on living animal in combination with a step of sacrificing the animal not to be a method of surgery within article 52(4) and hence patentable), *available at* http://legal.european-patent-office.org/dg3/pdf/t900182ex1.pdf.

[453]*See* In Re Hoffmann-La Roche, 1984 O.J. EPO 164 (Case number T 0128/82, EPO Technical Board of Appeals, Jan. 12, 1984) (the fact that a specific use is disclosed in the specification does not call for a restriction of the purpose-limited product claim to that use).

[454]The validity of Swiss-type claims (second medical use claims), i.e. use of a substance or composition for the manufacture of a medicament for a new and inventive therapeutic application, while allowable before the EPO, varies between members of the EPC. The U.K., Sweden, Germany, and Switzerland accept Swiss-type claims, while the Dutch and French are more restrictive. Martin, *supra* note 450, at 399.

[455]United Kingdom Patents Act of 1977, ch. 37, § 4(1), (2) (Eng.).

Due to a well established requirement of industrial utility, the United Kingdom has a long history of non-patentability for medical methods.[456]

The British Medical Association is a professional association of doctors, representing their interests and providing services for its 128,000 members.[457] Registration and discipline of U.K. doctors is provided by the General Medical Council.[458] The Medical Ethics Committee of the British Medical Association provides ethical guidance to its members and publishes a handbook on ethical principles.[459] Neither the General Medical Council, the British Medical Association, nor the handbook *Medical Ethics Today* . . . identifies any prohibition on any aspect of patenting by its members.[460]

C. Canadian Medical Patent Practice

The Canadian *Patent Act* itself is silent with regard to medical procedure patents,[461] and is "not modeled on the British [Patent] Act."[462] In particular, the Canadian *Patent Act* defines the term *invention*:

---

[456]*See* C & W's Application, 31 R.P.D. & T.M. Cas. 235 (1914) (denying patent for method of medical treatment). *See also* Eli Lilly & Co.'s Application, 1975 R.P.D. & T.M. Cas. 438, 438 ("It has long been established that claims to methods of medical treatment should not be accepted.").

[457]British Med. Ass'n, *About the BMA*, *at* http://www.bma.org.uk/ap.nsf/Content/About+the+BMA+-+Introduction (last visited Apr. 18, 2004).

[458]General Medical Council, *The Duties of a Doctor Registered with the General Medical Council*, *at* http://www.gmc-uk.org/standards/default.htm (last visited Apr. 18, 2004) (summarizing general duties of registered doctor, which do not include prohibitions on patenting).

[459]Med. Ethics Dep't, British Med. Ass'n, *Medical Ethics Today — The BMA's Handbook of Ethics and Law* (Patricia Fraser & Fenella Overinrton eds., 2d ed. 2004) (summarizing duties of doctor in over 800 pages and a searchable CD Rom).

[460]The BMA website does not provide access to its Ethical Briefs 1–64. The BMA supports the EC Directive on the Legal Protection of Biotechnological Inventions (98/44/EC), adopted by the European Parliament in July 1998. *See* British Med. Ass'n, *Gene Patenting: A BMA Discussion Paper* (July 2001), *at* http://www.bma.org.uk/ap.nsf/Content/Gene+patenting+paper (last visited Apr. 18, 2004).

[461]Patent Act, R.S.C., ch. P-4 (2004) (Can.).

[462]Comm'r of Patents v. Winthrop Chem. Co., [1948] S.C.R. 46.

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.[463]

The Supreme Court of Canada interpreted the Canadian *Patent Act* in *Tennessee Eastman Co. et al. v. Commissioner of Patents*[464] to decide whether a new use for surgical purposes of a known substance can be claimed as an invention. However, at that time, the Canadian Supreme Court relied upon section 41(1) of the *Patent Act* (repealed), which required that "the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described in the claim or by their obvious equivalents."[465] The Canadian Supreme Court held "this necessarily implies that, with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself."[466]

Despite the repeal of section 41 of the Canadian *Patent Act*, subsequent Canadian court decisions have retained its rule. In *Imperial Chemical Industries Ltd. v. Commissioner of Patents*,[467] the court held:

> [T]his is a clear and unequivocal statement that "methods of medical treatment are not contemplated in the definition of 'invention' as a kind of 'process' . . .". That was the sole issue before the Court and it is here answered in unmistakable and unambiguous language. Accordingly, in my view, the force of that pronouncement cannot be restricted merely to factual situations where subsection 41(1) of the Act applies. It follows, therefore, that the Commissioner did not err in considering himself bound by the *ratio* of *Tennessee Eastman*.[468]

---

[463]R.S.C., ch. P–4, § 2(6).

[464]Tenn. Eastman Co. v. Comm'r of Patents, [1974] S.C.R. 111 (holding invalid a patent for a surgical method for joining incisions or wounds by applying certain compounds).

[465]*Id*. at ¶ 14 (quoting Patent Act, R.S.C., ch. P-4, § 41(1) (1969) (Can.) (repealed)).

[466]*Tenn. Eastman*, [1974] S.C.R. 111, at ¶ 14.

[467]Imperial Chem. Indus. Ltd. v. Comm'r of Patents, [1986] 3 F.C. 40.

[468]*Id*. at ¶ 11.

The *Shell Oil* decision was upheld by implication in *Apotex Inc. v. Wellcome Foundation Ltd.*,[469] although the claims in *Apotex* related to a product for oral administration — and were hence held patentable. Thus, the common law of Canada currently holds that methods of medical treatment are not considered an invention within the meaning of the Canadian *Patent Act*.[470]

The Canadian Medical Association has accepted responsibility for delineating the standard of ethical behavior expected of Canadian physicians and has developed and approved the *CMA Code of Ethics* as a guide for physicians.[471] The Office of Ethics of the Canadian Medical Association does not have a specific position paper with regard to the patenting of medical devices or procedures by its members.[472] CMA members may generally look to the *CMA Code*, paragraphs 36, 38, and 40–41 for guidance:

> 36. Teach and be taught.
> . . . .
> 38. Be willing to participate in peer review of other physicians and to undergo review by your peers.
> . . . .
> 40. Avoid promoting, as a member of the medical profession, any service (except your own) or product for personal gain.
> 41. Do not keep secret from colleagues the diagnostic or therapeutic agents and procedures that you employ.[473]

---

[469]Apotex Inc. v. Wellcome Found. Ltd., [2002] 4 S.C.R. 153, ¶ 48–50 (holding that claims for a pill embodying AZT did not seek to "fence in" an area of medical treatment, but rather sought to provide AZT as a commercial offering), *available at* http://www.canlii.org/ca/cas/scc/2002/2002scc77.html.

[470]Patent Act, R.S.C., ch. P-4 (2004) (Can.).

[471]Bd. of Dirs., Canadian Med. Ass'n, *CMA Code of Ethics* (2004) [hereinafter CMA Code], *available at* http://www.cma.ca/staticContent/HTML/N0/l2/discussion_papers/professionalism/pdf/appendix_a.pdf.

[472]Electronic letter from Jeff Blackmer, Executive Dir., Office of Ethics, Canadian Med. Ass'n, to the author (Apr. 16, 2004) (copy on file with author) ("I've searched through our policies and we don't have anything in this area [patenting of medical devices or procedures].").

[473]CMA Code, *supra* note 471, at ¶¶ 36, 38, 40, 41.

The CMA also publishes a thirty-one page pamphlet, *Professionalism in Medicine*, regarding physician ethics. The pamphlet does not address patenting by CMA members.[474] In short, the Canadian Medical Association does not prohibit patenting of any kind by its members.

D. Japan Medical Patent Practice

The first sentence of Japanese Patent Law Section 29(1) reads: "Any person who has made an industrially applicable invention may obtain a patent therefore . . . ."[475] The terms "industrially applicable" have been interpreted by the Japanese Patent Office to not include medical acts.[476] Medical acts include methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.[477] While an instrument for use in such methods has industrial applicability, a method for treating the human body using such instrument does not.[478] In this case, the Japanese rule is more restrictive than the EPO rule in that Swiss type claims or "second method claims" are not allowed.

The *Principles of Medical Ethics* adopted by the Japan Medical Association (JMA) do not prohibit patenting by physicians.[479] Paragraph 6 of the JMA *Principles* proscribes that "[t]he physician will not engage in medical activities for profit-making motives."[480] However in this case, medical acts are prohibited from obtaining Japanese

---

[474]CMA Series of Health Care Discussion Papers, Canadian Med. Ass'n, *Professionalism in Medicine* (2001), *available at* http://www.cma.ca/staticContent/HTML/N0/l2/discussion_papers/professionalism/pdf/professionalism.pdf.

[475]Japan Patent Office, *Examination Guidelines for Patent and Utility Model*, pt. 2, ch. 1 (Dec. 28, 2000), *available at* http://www.jpo.go.jp/quick_e/index_tokkyo.htm (last visited Apr. 18, 2004).

[476]*Id*. at ch. 2.1.

[477]*Id*.

[478]*Id*.

[479]Japan Med. Ass'n, *Principles of Medical Ethics*, *available at* http://www.med.or.jp/english/2_princi.html (last visited Apr. 18, 2004).

[480]*Id*. at ¶ 6.

patent protection. In short, the Japanese *Principles* allow physicians to obtain full patent protection for their inventions in accordance with Japanese patent law.

E. World Medical Association

The World Medical Association (WMA) is an international organization, founded in 1947, with an aim to represent physicians.[481] The WMA was created to ensure the independence of physicians, and to work towards the highest possible standards of ethical behavior and care by physicians.[482] The WMA has published a number of works, including the *International Code of Medical Ethics*.[483]

While medical procedure patents are not prohibited by the *International Code*, the WMA has published a *Statement on Medical Process Patents*,[484] discouraging their acquisition. The *Statement* in paragraph 3 provides:

> The purpose of patents is to encourage private investment in research and development. However, physicians, particularly those who work in research institutions, already have incentives to innovate. . . . These incentives include professional reputation, professional advancement, and ethical and legal obligations to provide competent medical care. Physicians are already paid for these activities, and . . . [t]he argument that patents are necessary to spur invention of medical procedures, and that without process patents there would be fewer beneficial medical procedures for patients, is not particularly persuasive when these other incentives and financing mechanisms are available.[485]

---

[481]World Med. Ass'n, *What is the WMA?*, *at* http://www.wma.net/e/about/index.htm (last visited Apr. 18, 2004).

[482]*Id*.

[483]World Med. Ass'n, *International Code of Medical Ethics* (adopted by the 3rd General Assembly, WMA, London, England, October 1949, amended by the 22nd World Medical Assembly Sydney, Australia, August 1968, and the 35th World Medical Assembly Venice, Italy, October 1983), *available at* http://www.wma.net/e/policy/c8.htm (last visited Apr. 18, 2004).

[484]World Med. Ass'n, *World Medical Association Statement on Medical Process Patents* (adopted by the 51st World Medical Assembly, Tel Aviv, Israel, October 1999) [hereinafter *WMA Statement*], *available at* http://www.wma.net/e/policy/m30.htm (last visited Apr. 18, 2004).

[485]*Id*. at ¶ 3.

The *Statement* in paragraph 5 distinguishes medical devices from medical procedures:

> Whether or not it is ethical to patent medical devices does not bear directly on whether it is ethical for physicians to patent medical procedures. Devices are manufactured and disseminated by companies, whereas medical processes are "produced and disseminated" by physicians. Physicians have ethical or legal obligations to patients and professional obligations towards each other, which companies do not have. Having particular ethical obligations is part of what defines medicine as a profession.[486]

The conclusions of the WMA are embodied in paragraph 13 of the *Statement* as follows:

> The World Medical Association:
> 1. states that the patenting of medical procedures poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients.
> 2. considers that the patenting of medical procedures is unethical and contrary to the values of professionalism that should guide physicians' service to their patients and relations with their colleagues. However, in light of the differences between medical procedures and medical devices discussed above, the patenting of medical devices is acceptable;
> 3. encourages national medical associations to make every effort to protect physicians' incentives to advance medical knowledge and develop new medical procedures.

While the World Medical Association seeks to proscribe higher ideals for member conduct, the WMA does not specifically relate to the patent laws of various countries.

---

[486] *Id*. at ¶ 5.

F. The *Patent Cooperation Treaty*[487]

The *Patent Cooperation Treaty (PCT)*[488] makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by first filing a standardized international patent application.[489] Under the *PCT*, an International Searching Authority will conduct a search of the international patent application.[490] However, *PCT* Rule 39.1(iv) does not require the International Searching Authority to search an international application for methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.[491] Accordingly, inventors seeking patent protection for medical procedures do not routinely seek protection through a *PCT* international application.

G. The *North American Free Trade Agreement (NAFTA)*[492]

The *North American Free Trade Agreement (NAFTA)*[493] does not present a conflict with the later enacted *Medical Practitioner Exemption Act*[494] codified at 35 U.S.C. § 287(c).[495] Like *PCT* Rule 39.1(iv), *NAFTA* article 1709 proscribes rules for member nations with regard to patents:

---

[487]Patent Cooperation Treaty (PCT), June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

[488]*Id*.

[489]World Intellectual Prop. Org. (WIPO), *Patent Cooperation Treaty ("PCT") (1970)*, *at* http://www.wipo.int/pct/en/treaty/about.htm (last visited Apr. 18, 2004).

[490]PCT, *supra* note 487, art. 17, *available at* http://www.wipo.int/pct/en/texts/articles/a17.htm (last visited Apr. 18, 2004).

[491]*Id*. at R. 39, *available at* http://www.wipo.int/pct/en/texts/rules/r39.htm (last visited Apr. 18, 2004).

[492]North American Free Trade Agreement (NAFTA), Dec. 8-17, 1992, 31 U.S.T. 4919, 32 I.L.M. 605, (1993). *See also* North American Free Trade Implementation Act, Pub. L. No. 103-182, 107 Stat. 2057 (1993) (codified at 19 U.S.C. §§ 3301-3473 (2004)).

[493]NAFTA, *supra* note 492.

[494]*See* Medical Practitioner Exemption Act, *supra* note 9.

[495]35 U.S.C. § 287(c) (2004).

> Article 1709: Patents
> 1. [E]ach Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application . . . .
> . . . .
> 3. A Party may also exclude from patentability:
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals . . . .[496]

Accordingly, the *North American Free Trade Agreement* leaves the issue of patenting medical methods to the discretion of each member country.

H. *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*[497]

Like the *PCT* and *NAFTA*, the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*[498] proscribes rules for its members with regard to intellectual property rights. Article 27 defines patentable subject matter:

> 1. [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. . . .
> . . . .
> 3. Members may also exclude from patentability:
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals . . . .[499]

Accordingly, *TRIPS* leaves the issue of patenting medical methods to the discretion of each member country.

---

[496]NAFTA, *supra* note 492, art. 1709(1), (3).

[497]Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 I.L.M. 1197, 1994 WL 761483 (1994). *See also* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified in scattered sections of 15, 17, 19, 26, and 35 U.S.C.) (U.S. legislation implementing TRIPS).

[498]*Id*.

[499]*Id*. art. 27(1), (3)(a).

VI. Call for Change to AMA Opinions 9.09, 9.095

A. Need for a Bright Line Rule Related to Patenting of Medical Devices

Today, medical devices extend much beyond surgical or diagnostic instruments.[500] While existing AMA Opinion 9.09 provides a safe harbor for these instruments, other medical devices are not covered, such as bandages, crutches, prosthetics, or implantable therapeutic devices. Due to the confusion surrounding acceptable patentability of medical technology, there is a need for a bright line rule. Even the restrictive ethical policies set forth by the World Medical Association delineate the need for patenting "medical devices."[501] Accordingly, the AMA should clarify that the safe harbor for physician patenting may be extended to the patenting of all medical devices.

Moreover, patents for medical technology provide for multiple claiming strategies. For example, in *Burroughs Wellcome Co., v. Barr Laboratories, Inc.*,[502] the plaintiffs sought enforcement of patents related to Zidovudine (commonly known as AZT), U.S. Patent Nos. 4,724,232 (the '232 patent),[503] 4,828,838 (the '838 patent),[504] 4,833,130 (the '130 patent),[505] 4,837,208 (the '208 patent),[506] 4,818,538 (the '538 patent),[507] and 4,818,750 (the '750 patent).[508] All patents claimed priority of the original

---

[500]The safe harbor of AMA Opinion 9.09 currently extends only to patenting of surgical or diagnostic instruments. *See supra* Part III.I.

[501]*See WMA Statement*, *supra* note 486, at ¶ 5.

[502]Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223 (Fed. Cir. 1994).

[503]U.S. Patent No. 4,724,232 (issued Feb. 9, 1988).

[504]U.S. Patent No. 4,828,838 (issued May 9, 1989).

[505]U.S. Patent No. 4,833,130 (issued May 23, 1989).

[506]U.S. Patent No. 4,837,208 (issued June 6, 1989).

[507]U.S. Patent No. 4,818,538 (issued Apr. 4, 1989).

[508]U.S. Patent No. 4,818,750 (issued Apr. 4, 1989).

disclosure,[509] but incorporated a variety of different claiming strategies. The '232, '130, '208 patents claimed a medical *method*, for example:

> 1. A method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syndrome treatment amount of 3'-azido-3'-deoxythymidine to said human.[510]

On the other hand, the '838 patent claimed a medical *product*:

> 1. A pharmaceutical preparation comprising a capsule containing 5 to 500 mg of 3'-azido-3'-deoxythymidine.[511]

The '538 patent claimed a medical *device*, namely a container:

> 1. A sealed container including a pharmaceutical composition in unit dosage form comprising 5 to 500 mg of 3'-azido-3'-deoxythymidine together with a pharmaceutically acceptable solid carrier.[512]

The '750 patent claimed the effect of a pharmaceutically active medical substance on a human:

> 1. A method of increasing the number of T-lymphocytes in a human infected with the HTLV III virus comprising administering to said human an effective amount of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable alkali metal, alkaline earth or ammonium salt thereof.[513]

---

[509]According to U.S. patent law, a single patent application can give rise to a number of separately issued patents.

[510]U.S. Patent No. '232, claim 1.

[511]Patent No. '838, claim 1.

[512]Patent No. '538, claim 1.

[513]Patent No. '750, claim 1.

The different claiming strategies set forth above may appear formal rather than substantive. In fact during litigation, all parties, including the Federal Circuit and the initial district court treated the patents collectively as covering the particular use of AZT as a treatment for AIDS and its symptoms.[514] However, the ethical effect is striking. Unlike the parade of horribles suggested by the *Statement on Medical Process Patents* of the World Medical Association,[515] namely that medical method patents are enforceable against medical practitioners, the AZT patents were enforced against a company. Thus, even though the AZT patents were generally treated as medical method patents, the price of enforcement was incorporated into the product — just like in a medical device patents.

If the inventors of the patented AZT technology were members of the American Medical Association and followed Opinions 9.09 and 9.095, the prescribed course of conduct would be uncertain. First, the product patent '838 and the device patent '538 would not fall within the safe harbor of Opinion 9.09. Second, in spite of the research and development costs associated with safety and effectiveness testing required to obtain FDA approval, members following Opinion 9.095 would not have sought patent protection for the medical method patents '232, '130, '208. In this case it would be doubtful that corporations seeking to develop this kind of technology would look first to inventors limited by Opinion 9.095, thereby resulting in discrimination.[516]

---

[514]*Burroughs Wellcome*, at 40 F.3d 1223, 1224 n.1.

[515]*See supra*, text accompanying note 486.

[516]Pallin, the inventor of the controversial eye surgery patent, was himself advised to characterize his invention in terms of a device rather than a method of treatment. Hearings H.R. 1127, *supra* note 336. *See also* Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 St. John's L. Rev. 329, 353 n.151 (1997) (observing that medical professionals are encouraged to patent a medical device rather than a medical method).

B. Medical Procedures with Non-medical Applications

Advances in medical technology may often have non-medical applications. The United States patent acquisition process has evolved for over 200 years to be the envy of the world.[517] In fact, for over a century, U.S. patent practitioners have refined their techniques for creatively drafting claims in view of the law.[518] However, U.S. patent law also requires that practitioners get it right the first time. Disclosed but unclaimed subject matter in a patent is dedicated to the public — known to patent practitioners as the "disclosure dedication rule."[519] Thus, medical technology patents that are directed to a device will disclose an associated method of use to the public if the subject matter is not claimed. This problem is easily envisioned for medical technology having non-medical applications. Using the Selected Historical Developments in Medical Technology set forth *supra*, in Part II., some non-medical applications of medical technology are explored.

1. The Chamberlen Obstetric Forceps

The Chamberlen Forceps set forth *supra*, in Part II.B, were secretly used in the aid of delivery of a human fetus. Had Dr. Peter Chamberlen the elder sought to patent his instrument, such action would be allowed under AMA Opinion 9.09. However, the use of forceps for the non-destructive delivery of any mammalian fetus was also a new invention at the time. Under AMA Opinion 9.095, Peter the elder could not patent his method.

---

[517]Hearings H.R. 1127, *supra* note 336 (testimony of Donald R. Dunner, Chair, Section of Intellectual Property Law, American Bar Association) (1995 WL 615780) ("Our patent system and the premises upon which it is based have been tested. That testing has gone on for more than 200 years, and has produced results which are the envy of the world.").

[518]*See* John R. Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 J. Marshall J. Computer & Info. L. 219 (1998) (describing claim drafting techniques used by practitioners to protect intellectual property and noting "Swiss-type claims" used before the EPO).

[519]*See* PSC Computer Prods. v. Foxconn Int'l, 355 F.3d 1353, 1357 (Fed. Cir. 2004) (describing "disclosure dedication rule" in that disclosed but unclaimed subject matter in a patent is dedicated to the public).

Understandably, humans are not the only mammals that may benefit from the use of instruments in the aid of delivery.[520] On the other hand, it is easy to imagine that forceps used in the delivery of a bovine mammal would differ in mechanics from human obstetric forceps, while the method of use would generally remain the same. In this regard, U.S. Patent No. 4,136,679 ('679) (issued Jan. 30, 1979) for a *Process for the Rotation of Fetal Head During Childbirth* is instructive. The '679 patent illustrates a pistol grip spatula in figs. 5–8. Claim 1 sets forth:

> 1. A process for rotation of the fetal head during childbirth, comprising the steps of: using a force through the agency of spatulas . . . ; rotating the head by applying the force . . .; and utilizing as the axis of rotation, the rotation axis of the head passing through the junction of the cervical column with the fetal occiput.

In accordance with AMA Opinions 9.09 and 9.095, the inventors could patent the pistol grip spatulas of figs. 5–8 but could not patent the method of fetal head rotation. While the form and nature of the spatulas may be changed as applied to veterinary practice, the method of fetal head rotation would not. Because this subject matter would hence go unclaimed, under the disclosure dedication rule, this matter would be dedicated to the public, thereby depriving the inventors of their rights under the law. AMA members following Opinion 9.095 would thereby dedicate to the public subject matter far beyond human medical application.

2. The X-ray Radiograph

A second example that may be familiar to the practicing physician is the X-ray radiograph, set forth *supra*, in Part II.E. The classic photograph of Bertha Roentgen's right hand showed an internal skeleton and a ring.[521] Had Roentgen sought to patent his invention, he would have many avenues for protection. Under AMA Opinion 9.09,

---

[520] *See e.g.* U.S. Patent No. 3,516,406 (issued June 23, 1970) (entitled *Apparatus and Method for Replacing a Prolapsed Uterus*, for use with a cow).

[521] *See supra* text accompanying note 151.

Roentgen could have patented the X-ray apparatus, however literal infringement of such patent would have been limited to his disclosed mechanism, namely a machine incorporating Crookes tubes.[522] In fact, it was the Jackson spherical focus tube, having differently shaped anodes and cathodes surrounded by a spherical bubble in an elongated glass cylinder, that became the standard pattern for X-ray tubes for many years.[523]

An X-ray apparatus may be used to examine biological material, such as Bertha Roentgen's hand skeleton, for medical diagnosis. However, the exact same apparatus may be used to examine non-biological material, such as Bertha Roentgen's ring. U.S. Patent No. 5,247,559 (issued Sept. 21, 1993) for a *Substance Quantitative Analysis Method* related to X-rays is instructive. Claims 1–2 provide:

> 1. A method for substance quantitative analysis which uses radiation with two or more energy levels or bands and obtains radiation transmission information by passing the radiation through an object being analyzed,
>
> performs a subtraction calculation process using the obtained transmission information . . ., and
>
> simultaneously determines or quantifies the constituent substances of the object . . . .
>
> 2. The method for substance quantitative analysis according to claim 1 wherein the object being analyzed is the human body . . . .

In the above example, claim 1 broadly covers a medical method and a non-medical method, regardless of the mechanical structure of the X-ray apparatus. Claim 1 would cover quantitative analysis of either Bertha Roentgen's skeleton, her ring, or her skeleton and ring taken together. On the other hand, claim 2 particularly relates only to quantitative analysis on a human being, in other words, a medical method.

Analysis of the above scenario illustrates an absurd result. Wilhelm Roentgen, if governed by the AMA *Code of Ethics*, would be prohibited under Opinion 9.095 from obtaining broad patent claims, such as claim 1 or claim 2 above. Any claim broad

---

[522] *See supra* text accompanying note 155.

[523] Grubbe, *supra* note 149, at 12–13, fig. 9.

enough to cover medical application to a human being, regardless of other applications, would be unethical. However, all patentable methods could have some abstract medical application. Thus, Opinion 9.095 does not serve merely to limit medical procedures, but all patentable procedures. The physician's only alternative is to solely rely upon apparatus claims, such as the quickly obsolete Crookes tube exemplified above.

C. Evolving Ethical and Legal Standards

The U.S. patent system is unforgiving. While a patent is in force for twenty years from the date of application, critical decisions regarding patentability must be made during the application process, lest the full right be lost. Accordingly, patents must be some-what predictive, as exemplified by the multiple claiming strategies found in most contemporary patents.

Substantive U.S. patent law may also change. Countless law review articles trace the refinement of U.S. patent law on a year-by-year basis, primarily following the latest pronouncements from the Federal Circuit Court of Appeals. On the other hand, patents are entitled to a life of twenty years from date of application. A broad availability of patent claims at the outset allows the physician inventor the best chance for long term protection.

Even ethics have changed. As evidenced by the history of the AMA *Code of Ethics*, set forth *supra*, in Part III, the evolution of medical ethics is far from certain. By seeking to limit physician patenting at the outset, Opinion 9.095 affects physician inventions for at least twenty years. On the other hand, patent enforcement is always present tense. By changing Opinion 9.095 in accordance with current U.S. patent law, physician patent rights may be preserved while current ethical goals maintained. Should the law change in the next twenty years, physician inventions will not be placed at a commercial disadvantage.

Finally, although 35 U.S.C. § 287(c) has been the law of the land since 1996, its constitutionally has not been tested. At least one commentator has opined that § 287(c) renders medical procedure patents worthless, and is therefore an improper regulatory

taking under the Fifth Amendment, and hence unconstitutional.[524] In that case, medical practitioners may find themselves the subject of patent infringement without having had an opportunity to participate in the patent process.

VII. Proposed Language for New AMA Ethical Opinions

A. Opinion 9.09 — Patent for Medical Device

A physician may patent a medical device he or she has invented or co-invented. The laws governing patents are based on the sound policy that one is entitled to protect one's invention. (V, VII).

B. Opinion 9.095 — Enforcement of Medical Procedure Patent

In accordance with respect for the rules necessary in an orderly society, it is unethical for a physician to seek pecuniary gain in violation of the law. Accordingly, it is unethical to enforce a patented medical procedure against a medical practitioner in violation of the laws governing patents. (V, VII).

VIII. Conclusion

The patenting of medical devices serves not only to protect one's discovery but also to further research and development of new technology. Due to the complexities surrounding the patenting of medical technology, and the often blurred line between devices and procedures, the American Medical Association should adopt a bright-line rule providing a safe harbor for the patenting of all medical devices.

Likewise, the debate surrounding the patenting of medical procedures continues. Many commentators have argued that the patenting of medical procedures will serve the

---

[524]Anderson, *supra* note 14, at 141–42 (listing factors for determining that governmental action has gone beyond regulation and becomes a taking as including: the character of the governmental action, the economic impact of the regulation, and its interference with reasonable investment-backed expectations.). *Cf* Joel J. Garris, Note and Comment, *The Case for Patenting Medical Procedures,* 22 Am. J. L. and Med. 85, 104 n.193 (opining that S. 1334, 104th Cong., 1st Sess. (1995) — like 35 U.S.C. § 287(c) (2004) — exempted medical practitioners from liability for infringement, and would not violate the Due Process Clause of the Fifth Amendment because it does not create a suspect class).

long-range goals of the medical profession by clearly placing patented procedures into the public domain after patent expiration. While ethics related to the patenting of medical procedures will continue to evolve, the scope of an issued patent will not. By changing the ethical prohibition to one of enforcement against a medical practitioner, rather than one of patenting in the first instance, the American Medical Association will not only serve its stated goals in accordance with the rules of law, but will also avoid discrimination against its members in the patenting process by placing them on the same footing as other patent applicants.