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"Under the Knife" - Patenting Surgical Procedures

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Patentable Subject Matter

Federal Statute 35 U.S.C. §101 establishes the patentability of inventions, stating that, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." So a surgical procedure is a process, and is patent eligible in the United States. Simple enough, and there have been many patents issued in the United States for surgical and medical procedures. But in the mid 90's, a surgeon attempting to collect license fees for "no stitch" cataract surgery created shock waves in the field of patent law that went all the way to Congress and the President.

The Outcry from Dr. Samuel L. Pallin's Cataract Surgery Patent

Dr. Pallin was awarded United States Patent 5,080,111, entitled "Method Of Making Self-Sealing Episcleral Incision" on January 14, 1992. Dr. Pallin then assumed the role of medical practitioner profiteer, and attempted to license the procedure for $4 per operation, according to the web site of Ladas and Parry, a well known patent law firm. His efforts to profit from this surgical procedure were met with some opposition. To further his attempts to enforce and profit from his patent, Dr. Pallin eventually sued Dr. Jack A. Singer alleging infringement of the '111 patent. The lawsuit ended in a consent order signed on March 28, 1996 that invalidated four of the twenty-nine claims of the Pallin patent and further enjoined him from enforcing any aspects of his patent. This court case and Dr. Pallin's licensing efforts brought the issue of patenting surgical procedures up through the American Medical Association and Congress, and eventually created a new public law signed by the President amending the U.S. Patent Laws to deal with the issue.

The American Medical Association's Position

At its September 1994 annual meeting, The American Medical Association's House of Delegates took a strong stand on this issue, and unanimously adapted a resolution that the AMA "Vigorously condemn the patenting of medical and surgical procedures and work with Congress to outlaw this practice." A coalition of medical associations that was led by the American Society of Cataract and Refractive Surgery (ASCRS) took the charge to Congress. It should be noted that the AMA Board of Directors continues to reaffirm this statement, and has done so in September 1999, October 2004, and October 2008.[1]

House and Senate Actions

A change to Federal Statute 35 U.S.C. 101 that defines what is patentable would have been a big deal, to say the least. So on March 3, 1995, Congressman Ganske (R-Iowa/4th), a surgeon in Des Moines, introduced H.R. 1127[2] entitled "Medical Procedures Innovation and Affordability Act." The House of Representatives' actions attempted to prevent issuance of patents for surgical or medical procedures without altering 35 U.S.C. 101. Later this Act was amended to limit the use of funds available to the Patent and Trademark Office to issue patents related to surgical and medical procedures.

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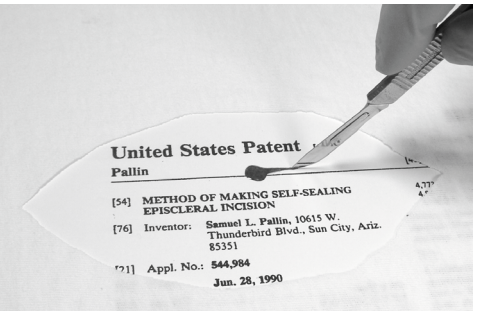

Later, in October of 1995 Senator Bill Frist (R-Tenn.), a heart and lung transplant surgeon, introduced S.1334 that again did not attempt to change 35 U.S.C. 101, but rather sought to amend 35 U.S.C. 271, the section of the Patent Laws entitled "Infringement of Patent" by essentially exempting a patient, physician, licensed healthcare practitioner, or a healthcare entity from infringement of a patented medical or surgical procedure, therapy, or diagnosis.

After lengthy discussions and negotiations, it was decided that modifications to the law should not be in the area of what is patentable under 35 U.S.C. 101, or what constitutes an infringement under 35 U.S.C. 271; but rather modifications to the law should be in 35 U.S.C. 287, relating to remedies available to patent owners. One concern was that any changes to the Patent Laws should not have an adverse affect on research and development at U.S. pharmaceutical, biotechnology or medical diagnostic industries.

The Resulting Amendment to The U.S. Patent Laws

So what was ultimately enacted into law was an amendment to 35 U.S.C. 287 that added a new subsection (c). Essentially, this amendment deprives a patentee of its infringement remedies (civil trial, injunction, damages, attorney's fees) where a medical practitioner or a related healthcare entity performs a patented medical activity. The statute defines a medical activity as "the performance of a medical or surgical procedure on a body, but shall not include (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 (iii) the practice of a process in violation of a biotechnology patent." The term "body" is defined as a human body, organ, or cadaver or a non-human animal used in medical research or instruction directly relating to the treatment of humans. A "related healthcare entity" is for example a hospital, health maintenance organization, or nursing home with which the medical practitioner has a professional affiliation. The term "patented use of a composition of matter" relates to pharmaceutical products and does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter, where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

In summary, the resulting statute does not prevent one from obtaining a patent for a surgical or medical procedure, but rather, impacts the way in which any resulting patent can be enforced. It is important to fully understand 35 U.S.C. §287 before setting out to patent a surgical or medical procedure, or a medical device that may require a surgical or medical procedure. Understanding the strengths and limitations of patents as a business tool will allow you to realize needed returns from your biomedical intellectual property.

1. Website of the American Urological Association www.auanet.org.
2. H.R. 1127, 104th Congress, 1st Session.

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