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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 midst of attempts 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 proctor, 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 adopted 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 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.

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. Understanding the strengths and limitations of patents as a business tool will allow you to realize needed returns from your biomedical intellectual property.

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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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