



# THE SURGE IN MEDICAL PATENT ACTIVITY

## Paul Sutton examines the arguments for and against patenting medical and surgical procedures.

While a great deal of attention has been focused on President Barack Obama's March 23, 2010 signing into law of the landmark US healthcare reform bill, the general public is not nearly as aware of the increasing role that patents play in the delivery of improved medical and dental technologies to patients. Patents directed to the clinical diagnoses and treatments of patients teach promising inventions in the field of personalised medicine. Similarly, the fruits of significant improvements in the dental arts are in use and were on display at the 2009 International Dental Show in Cologne, Germany.

### Human gene and business method patents:

US patent law relating to the eligible scope of protection available for human genes and business-related methods is not as yet fully settled. We are awaiting final decisions in the *ACLU v. Myriad* and *Bilski* cases currently before the courts. A Supreme Court decision in *Bilski* and its effect upon business method patents is expected soon. District Judge Sweet's more recent invalidation of gene patents in *Myriad* will work its way up through the appeals process.

**Patent proliferation:** Until legislative efforts to limit the scope of patent protection are signed into law, there can be little doubt that there will be a continuing proliferation of patents granted by the US Patent and Trademark Office (USPTO) covering, by way of limited examples only, clinical diagnostic and therapeutic methods and apparatus, medical and dental hardware, software, surgical methods and techniques, dental appliances, laser eye treatments and surgeries, and stents and procedures involving their use.

Medical procedures include those for diagnosis and treatment, whether or not the condition constitutes a disease. Recent methods that have been patented include techniques and procedures for administering insulin, transferring surrogate embryos, diagnosing and treating heart problems, grafting skin, determining the gender of a foetus using ultrasound and combining various drugs.

**Opposition to medical patents:** Historically, many physicians have rejected the idea of patents covering medical inventions as contrary to the philanthropic nature of their practice. The American Medical Association (AMA) voted in 1994 to oppose the practice of medical and surgical procedure patents as unethical and in conflict with the spirit of the Hippocratic Oath, which calls upon physicians to share their expertise freely and to teach their colleagues for the benefit of patients. AMA delegates have viewed such patents as contrary to the medical tradition of open exchanges of information without the expectation of financial reward. They have been of the belief that the pursuit of such patents might have a chilling effect on medical practice and education. Similar concerns have been shared by the American Academy of Ophthalmology. Many foreign countries have banned medical procedure patents.

**Support for medical patents:** A contrary view is held by many, including representatives of biotech companies. They observe that the US patent system has its origins in the US Constitution, where the mandated goal is to promote "the progress of science and the useful arts". Congress adopted this directive with the belief that the patent system serves the public interest by creating economic incentives for the development and, more importantly, the disclosure of new technology, and for investment and innovation. The argument favouring the grant of a patent monopoly is that many procedures would never have been developed but for patents and their use in attracting financial and research investments. Prior to 1954, the USPTO only rarely granted patents for medical and surgical procedures. Since then, medical and dental patents have regularly been granted and examples of patents of a variety of meaning and scope abound.

**Patent wings clipped:** Not all granted patents survive post-issuance challenges to their presumptive validity in patent

infringement litigation and/or by way of re-examination proceedings. Even where such patents do survive these challenges, the lawful scope of their claims may be greatly narrowed or limited, thereby defeating their use against accused infringers. An example of such a narrowing of the scope of claims during re-examination proceedings can be seen in US Patent No. 6,066,160 entitled *Passive Knotless Suture Terminator For Use In Minimally Invasive Surgery And To Facilitate Standard Tissue Securing*, assigned to Quickie LLC. The claims ultimately issued by the USPTO were of greatly different scope and effectiveness than those originally granted.

**Personalised medicine:** When it comes to the practice of personalised medicine, physicians will employ diagnostic tests to assess the therapeutic value versus the possible harm to patient candidates for specific therapies. As discussed by author Tracy Muller in a *National Law Review* article, “[s]uch tests often rely upon the presence of certain characteristics, for example, biomarkers, variant gene sequences, or alternate forms of a protein, that differ among individuals or groups of people. These differences may affect how a therapeutic drug or biological molecule is processed by the body and the presence of certain biomarkers may be useful in predicting the patient response.”

**Patentability test:** Under 35 U.S.C. §101, the Federal Circuit has applied what is known as a mandatory ‘machine or transformation’ test in determining the patentability of method claims, including those directed to diagnostic methods. This test was set forth in the Federal Circuit’s 2008 *In re Bilski* decision, which was heard by the US Supreme Court. A decision is expected at any time. This test requires a method claim to either be tied to a particular machine or include a transformation of a particular article into a different state or thing. In addition, the involvement of the machine or transformation must impose meaningful limits on claim scope and must not be merely insignificant ‘extra solution’ activity. In a September 2009 decision with great implications for the biotechnology and pharmaceutical industries, the Federal Circuit in *Prometheus Laboratories Inc. v. May Collaborative Services* held as patentable, claims directed to optimising the therapeutic efficacy of a treatment. This decision bodes well for those seeking patents covering medical diagnostic and related treatment methods. However, patent applicants would do well to ensure that their claim language clearly states a transformation, using the language of this decision as a guide.

**Doctor inventors:** Physicians and scientists continue to make important contributions as inventors. Innovation-seeking companies work closely with doctors and scientists under mutually beneficial arrangements, which may include an

“WHILE THE MEDICAL COMMUNITY IS WEARY OF THIS TREND, INVESTORS IN CLINICAL RESEARCH AND DEVELOPMENT WILL INEVITABLY SEEK TO ENFORCE VALUABLE INTELLECTUAL PROPERTY RIGHTS AGAINST INFRINGERS WHO COPY WITHOUT HAVING MADE SUCH INVESTMENTS.”

assignment or licensing of patent rights by the physician to the company for commercialisation purposes. There are also incidents where physicians will obtain patents and assert them against companies that either refuse to cease accused infringing activities or refuse to accept a royalty-bearing licence. Dr. Harry Schanzer of the Mount Sinai School of Medicine is a prolific inventor. On October 28, 1986, Schanzer was granted US Patent No. 4,619,641 entitled *Coaxial Double Lumen Arteriovenous Grafts*, directed to a coaxial double lumen tube for use in haemodialysis. In the dental arts, counterparts to medical inventions abound. On November 14, 1995, Noritake Company was granted US Patent No. 5,466,285, entitled *Dental Porcelain Material Preventing Yellow Coloration and Method for Producing Same*.

**Doctor versus doctor:** While rare, there have been circumstances where physicians have asserted their patent rights against colleague physicians, creating a predictable firestorm in the medical community. A newsworthy patent infringement lawsuit was commenced in 1990 by Dr. Samuel Pallin, medical director of the Lear Eye Clinic in Sun City, Arizona, against Dr. Jack Singer, a Dartmouth College assistant professor of ophthalmology of Randolph, Vermont. Pallin’s patent involved a medical method directed to self-healing cataract removal surgery without the need for sutures. Singer’s defence included a claim that he and others had published the patented procedure prior to Pallin’s patent filing date. Pallin deflected criticism by claiming that he was not driven by the prospect of financial reward as much as an effort to receive professional credit

for his contribution. He claimed that his demand for royalties was motivated more by a desire for recognition among his peers than for personal financial gain. This litigation was concluded with the court’s invalidation of Pallin’s patent claims and an order of the court that precludes Pallin from enforcing the patent. If the court had not invalidated Pallin’s patent claims, Singer along with thousands of physicians would have been potentially responsible for the payment of millions of dollars a year in royalties.

**The inevitable litigation:** Since innovation is the lifeblood of the medical device and medical supply industry, it is no surprise that the proliferation of therapeutic and diagnostic method patents has given rise to an increase in threats of infringement, licensing activity and, where disputes are not amicably resolved, patent infringement litigation. While the medical community is weary of this trend, investors in clinical research and development will inevitably seek to enforce valuable intellectual property rights against infringers who copy without having made such investments. Hopefully, the importance of care for the patient will not be forgotten during this jockeying for power and money.

---

*Paul J. Sutton is a founding partner of Sutton Magidoff. He can be contacted at: paul@suttonmagidoff.com*



**Paul J. Sutton**, with a juris doctor degree, “AV Preeminent” highest Martindale-Hubbell rating, and four decades of intellectual property law counselling and litigation strategy experience, was selected by *Super Lawyers* magazine in 2006, 2007, 2008 and 2009, and is listed in Strathmore’s *Who’s Who*. He is adjunct professor of law at the Polytechnic Institute of New York University. Prior to practising law, while an engineer at Douglas Aircraft’s Missiles & Space Systems Division, he was a member of the team that designed the Apollo Saturn third-stage booster rocket structure, which carried the first US astronauts to the Moon.