SURPRISE PATENT SETBACK STUNS BIOTECH

Two recent US court decisions have important implications for patent attorney practice as well as for the biotech sector, as Paul Sutton reports.

The US Supreme Court, on March 20, unanimously invalidated a broad medical diagnostic patent owned by the Prometheus Laboratories Inc unit of Nestle SA and asserted in a patent infringement lawsuit against Mayo Collaborative Services (doing business as Mayo Medical laboratories), thereby giving a significant victory to the medical profession (*Mayo v Prometheus,* 566 US [2012]). The Prometheus patents—US patent numbers 6,355,623 and 6,680,302—include claims which cover a method for determining the proper dose of a drug used to treat autoimmune disorders. By invalidating these patents, medical providers have potentially been saved from a host of broad newly issued patents covering medical diagnostic tests. Nervous physicians in the US have been at risk of infringing such patents merely by using scientific research in arriving at patient treatment options. The court cited the provisions of the US Patent Act, which dictates that discoveries based upon the "laws of nature" cannot be patented. The court held that a process which recites a law of nature, likewise, cannot be patented, and it reversed the Federal Circuit's judgment favouring Prometheus.

Amicus curiae briefs urging the court toward its final determination were filed by a relatively broad coalition of groups including the American Association of Retired Persons (AARP), the American Civil Liberties Union (ACLU), the American Medical Association (AMA), and the Cato Institute. *Amicus* briefs supporting Mayo included associations of physicians, researchers, medical educators, healthcare service providers, several public interest groups, two clinical laboratories, and two high-tech non-life sciences companies. *Amicus* briefs supporting Prometheus included life sciences biotech companies, Pharmaceutical Research Manufacturers of America (PhRMA), the Association of University Technology Managers, and Myriad Genetics (itself at the centre of a Supreme Court decision discussed below). The Obama administration supported Prometheus and the biotech industry's position.

Vocal opponents of the expansion of patent law into the medical profession include Timothy B. Lee in his *Law & Disorder* article: "Oblivious Supreme Court poised to legalize medical patents", published within a week of oral arguments in the case. Lee quotes from the AMA's *amicus* brief: "If claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." The AMA doctors went on to argue: "Conscientious physicians will be unwilling and unable to avoid considering all relevant scientific information when reviewing test results. Thus, as medical knowledge accumulates, patent licenses increasingly will be required for physicians to conduct even well established diagnostic tests." Justice Stephen Breyer, writing the court's main opinion, obviously agreed with the doctors.

The number of patent cases accepted by the Supreme Court is relatively small and, for this reason, the patent bar takes great interest in its decisions. The court's decisions have enormous impact upon the day-to-day practice of patent attorneys. Those involved with patent prosecution are guided by the court's dictates as to what type of patent claims stand a better chance of resisting an invalidity challenge. Those whose practice includes patent litigation defences will be armed with invalidity arguments which may be bolstered by the court's decisions.

The *Mayo v Prometheus* decision surprised and disappointed the biotech industry and directly impacts on the delivery of personalised medicine, which tailors medical treatment to the genetic makeup and characteristics of individual patients. Biotech observers seemed encouraged by the oral argument in this case. Companies, have in recent years, increasingly sought to patent medical diagnostic procedures and methods which are arrived at after obtaining favourable outcomes from experimenting with the efficacy of drugs.

Drug efficacy is not the only concern. Some drugs are somewhat toxic, such that monitoring the levels of toxins in patients' bloodstream will ensure that dosage levels will not adversely

affect patients' health or risk death (see Ryan Davis's March 20, 2012 *Prometheus Blood Test Unpatentable, High Court Rules).*

Prometheus is the sole and exclusive licensee of the two patents at issue, which concern the use of thiopurine drugs to treat autoimmune diseases such as Crohn's disease and ulcerative colitis. After the drugs are ingested, the body metabolises them, producing metabolites in the bloodstream. Because patients metabolise these drugs differently, doctors have found it difficult to determine whether a particular patient's dose is too low or too high. The patent claims at issue set forth processes embodying researchers' findings that identify with precision correlations between metabolite levels and likely harm or ineffectiveness.

There are a host of issued and unexpired patents with claims similar to those in the Prometheus patents. Mayo, in 2004, began using and marketing a test to determine optimal thiopurine dosages. The court observed this phenomenon and concluded that to hold valid patents with Prometheus-type claims would have the effect of hindering future innovation. The court reasoned that such patents pose a threat to the development of more refined treatment recommendations.

Ryan Davis quotes Dr Robert M. Wah, chairman of the board of trustees of the AMA, who called this decision a clear legal victory for doctors and patients that will ensure scientific data will remain widely available. According to Dr Wah: "Medical innovations that provide insight into natural human biology must remain freely accessible and widely disseminated. Blocking this information from physicians and researchers inhibits future discoveries."

This decision will have another effect, namely, the financing of startup companies who focus upon personalised medicine. These companies need to attract venture capital funding. By the court's weakening of patent protection for innovations in this area, venture investment sensitive to risk is likely to be discouraged. On the other hand, parties aligned with Mayo believe that the court's decision will have the effect of lowering health care costs for patients, by permitting companies to offer competing diagnostic tests.

Molecular Pathology v Myriad Genetics

The US Supreme Court, only days after its decision in *Mayo v Prometheus,* reversed and threw out a Federal Circuit decision allowing BRCA1 and BRCA2 gene patents, and remanded the case of *Association for Molecular Pathology, et al v Myriad Genetics, Inc, et al* back to the lower court for further consideration in light of its unanimous *Prometheus* rationale.

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Justice Breyer, as in the *Prometheus* case, wrote the court's opinion. Interestingly, the court's decision conforms to the decision of Judge Robert W. Sweet of the US District Court for the Southern District of New York, who in March of 2010 issued a summary judgment opinion invalidating both composition of matter patent claims directed to these genes and methods of detecting breast cancer-related mutations in these genes. Women who test positive using Myriad's gene test have an 82 percent higher risk of breast cancer and a 44 percent higher risk of ovarian cancer in their lifetimes. Such tests are believed to help determine therapy treatments.

The fact that the Supreme Court reversed and remanded the case does not necessarily spell doom for Myriad's patents. The *Prometheus* and *Myriad* cases and their underlying facts are not identical. Unlike the Prometheus patents, the Myriad patents include product claims. Furthermore, in the event the Federal Circuit should invalidate Myriad's patents, it will have an opportunity to appeal such a ruling to the Supreme Court.

Amicus curiae briefs were filed by, among others, Cancer Council Australia, the AMA, National Women's Health Network, Kaiser Permanente, Knowledge Ecology International, AARP, Society Project at Yale Law School, Canavan Foundation, Association for Molecular Pathology, and academics in law, medicine health policy and clinical genetics.

Some believe that an ultimate ruling against Myriad will not upend the biotech industry. Michael Yee, a biotech analyst for RBC Capital Markets, is quoted by James Vicini in his March 26, 2012 *Reuters* article: "Biotechs have patents and intellectual property for proteins, antibodies, chemical entities and other composition of matter patents that support development of drugs."

The case against Myriad was initiated by the Public Patent Foundation and the American Civil Liberties Union, as well as the Association for Molecular Pathology, claiming that patents covering natural phenomena are invalid and, if held valid, would hinder genetics research. Myriad in its opposing argument holds the position that its patent has not, in fact, hindered science or research. *GenomeWeb Daily News* in its March 26, 2012 article, quotes Daniel Ravicher, executive director of PUBPAT and co-counsel in Myriad: "Nobody 'invents' genes, so no-one should be able to claim ownership of them. We are not talking about a new drug or a new tool to fight cancer. We are talking about a genetic marker that occurs naturally in the human body. That cannot, and should not, be patented."

Clearly, the biotech industry is watching this case closely. The ultimate outcome remains uncertain, and the Supreme Court's decision not to rule on the merits but to ask the Federal Circuit to reconsider its ruling will mean a further delay before there is a conclusion in the case. Patent attorneys who are drafting patent claims will be best advised to recite claim language which adheres to the court's dictates and reasoning. ■

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