US Patent Laws and the Constitutional Mandate

The patent laws are in the U.S. Constitution dating back from 1790 to 1793 to promote, as articulated by one of the framers, Thomas Jefferson, and protect ‘any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof’. Although the U.S. Congress in 1952 replaced the word ‘art’ with the word ‘process’, the Congress, as well as the courts, have strived to retain the basic philosophy of the Constitutional mandate that ‘ingenuity should receive a liberal encouragement’. In accordance with such constitutional mandate, and to follow the spirit of the mandate, the U.S. Supreme Court in 1980 boldly declared in the case Diamond v. Chakrabarty (447 U.S. 303, 1980) that ‘anything under the sun that is made by man’ is patent eligible under the patent laws as long as it meets the statutory requirement of novelty (35 USC section 102), non-obviousness (section 103), detailed description for enablement (section 112) and utility (section 101/112). It is noteworthy that the framers of the Constitution not only put such language in the Constitution but to emphasize the spirit of such mandate, when the first US patent was granted to Samuel Hopkins on July 31, 1790 for 14 years, President George Washington and the Attorney General Edm. Randolph signed this issued patent followed by Secretary of State Thomas Jefferson who also signed and delivered the patent to Mr. Hopkins on the 4th of August, 1790. This was thus an exciting beginning of both the promotion of the inventive spirit, legal protection of such inventions for a period of time, and the economic development in the United States. This commentary deals with a patent eligibility issue decided by the US Supreme Court on June 13, 2013 in the case Association for Molecular Pathology, et al v. Myriad Genetics, Inc., et al (No. 12-398), where the Supreme Court held that a naturally-occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.

Patent Eligibility Issues in Recent Years

There have been contentious court cases in recent years in the US about what is a patentable invention. Two recent patent eligibility issues involve business methods, particularly computer-related methods. The Bilski v. Kappos case involved a business method of hedging commodity-associated risks on price fluctuations for energy commodities such as natural gas or electricity. In 2008, the Court of Appeals for the Federal Circuit (CAFC) set forth the criteria for subject matter eligibility for patentable process claims that must be tied to a machine or apparatus or must be involved in the transformation of a material to a different state or thing. Since the Bilski claims did not address such issues, the CAFC decided against the patent eligibility of the Bilski claims. On appeal to the Supreme Court, the Court in June 2010 affirmed the CAFC decision on the patent ineligibility of the Bilski claims as representing abstract ideas which are not patent eligible as previously decided by the Court in the case Diamond v. Diehr, 450 US 175, 182, 185 (1981)
that laws of nature, natural phenomena and abstract ideas are not patent eligible under 35 USC section 101. Myriad Genetics, Inc. (a company that computer programming in the case CSL Bank Int’l v. Alice Corporation Private Ltd. involving computer programming on risk minimization for foreign exchange and similar monetary exchange, the Federal Circuit issued diverse opinions and split decisions, holding Alice’s patents on computer methods, program and storage medium as invalid. In June 2014, the US Supreme Court issued a unanimous verdict deciding that the software patent claims were drawn to a patent ineligible abstract idea and were thus patent ineligible.

For patent eligibility issues involving diagnostic procedures and drug dosing, a recent relevant case is that of Mayo Collaborative Services v. Prometheus Laboratories. In the patents in the application filed by Prometheus Laboratories covered the use of thiopurine drugs to treat autoimmune diseases. If not to arrive at the optimum dosage of the drug. Since Mayo Collaborative Services and Mayo Clinic used such diagnostic tests on their patients, the CAFC affirmed the patent eligibility of the Prometheus patent claims as they were pertinent to the machine or transformation test, in March 2012, a unanimous Supreme Court reversed the CAFC ruling, holding that claims directed to methods of medical diagnostics and drug dosage optimization are basically a manifestation of the laws of nature and are therefore patent ineligible.

DEFINING A PRODUCT OF NATURE: THE DEVIL IS IN THE DETAILS

The Supreme Court’s verdict that BRCA1 and BRCA2 genes are not patent eligible because they are products of nature raises an interesting question: what is a product of nature? On the surface, a product of nature is something that is found in nature and can be isolated from the original DNA strand. The mRNA is then transcribed by the physical removal of the introns, the introns in the DNA molecule. The pre-RNA is then "spliced" by the physical removal of the introns, giving rise to a strand of messenger RNA (mRNA) that contains nucleotides corresponding only to the exons from the original DNA strand. The mRNA is then translated to the BRCA1 and BRCA2 proteins, which become products of nature. However, the BRCA1 and BRCA2 genes are a product of nature because it can be isolated from the human body or various tissues as is and not being a tiny integral part of the body or tissue. A nucleus from a human cell can be isolated as is and thus is a product of nature, as are the chromosomes present in the nucleus. However, a chro- mosome usually harbors a few hundred genes which are integral parts of the chromosome and are not freely pres- ent in the nucleus. BRCA1 and BRCA2 genes are parts of the chromosomes and can be viewed as products of nature in the sense that human cells have produced them from parent DNA, but they have no separate existence as independent entities. As the Supreme Court pointed out in its decision, the human genome consists of approxi- mately 22,000 genes packed into 23 pairs of chromo- somes. BRCA1 and BRCA2 genes are on chromosome 17 and 13. BRCA1 gene does not exist as a continuous stretch of functional gene. It has 24 exons of varying length on chromosome 17q21.31 while BRCA2 has a few more exons than BRCA1 spanning 84 kilobases (kb) of genomic DNA on chromosome 13q12.3 (1, 2). BRCA1 forms a complex with mRNA-splicing machinery to regulate pre-mRNA splicing and encodes a nuclear protein involved in gene expression.

ISOLATED DNA OF HUMAN BRCA1/BRCA2 GENES, PRODUCT OF NATURE ISSUE AND PATENT ELIGIBILITY OF BRCA1/BRCA2 GENES

An interesting case involving patent eligibility of isolated and purified DNA of the human BRCA1 and BRCA2 genes, where specific mutations confer susceptibility to breast and ovarian cancers in women (and breast and prostate cancer in men, but with a lower frequency) that is that of The Association for Molecular Pathology v. Myriad Genetics, Inc. During the period 1995 – 2000, the University of Utah Research Foundation and a com- pany Myriad Genetics filed several patent applications to the US Patent and Trademark Office (USPTO) to cover the role of two genes BRCA1 and BRCA2 where certain mutations led to a high incidence of breast and ovarian cancers in women. Myriad Genetics quickly developed a sophisticated screening test for the detection of such mutations in the DNA isolated from the blood of women with family history of breast and ovarian cancers. Since Myriad Genetics owned the patents, the company was allowed to charge high fees for conducting such tests and prevent other clinicians in the United States to conduct such tests, leading to extreme frustrations among such clinicians and their vulnerable patients. A similar situation occurred in Europe where similar, parallel patents were issued in several countries and split decisions, holding Myriad’s patents on the BRCA1 patent 5,693,473 and claims 1, 6 and 7 of the US patent 5,837,492. These claims basically assert a patent on ‘an isolated DNA coding for a BRCA1 polypeptide with the sequence of 1863 amino acids shown in EP 203 SEQ ID No: 2’. Another claim concerns ‘the isolated DNA with a nucleo- tide sequence shown in SEQ ID No: 1’. Another claim concerns ‘an isolated DNA having at least 15 nucleotides of the BRCA1 gene shown in SEQ ID No: 1’.

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In June 2010, Myriad appealed the district Court ruling to the CAFC for reversal, arguing that the iso- lated and purified BRCA1/BRCA2 DNA isolated were not products of commerce. In March 2010, Judge Robert Sweet of the District Court in Manhattan granted a Summary Judgment in favor of the plaintiffs, revoking the Myriad patents.

In January 2011, the US Supreme Court held that isolated BRCA1 and BRCA2 genes are naturally occurring DNA segments without any modifications and are not patent eligible. Thus, the Supreme Court upheld the CAFC decision that the isolated BRCA1 and BRCA2 genes are naturally occurring DNA segments without any modifications and are not patent eligible. The main issues considered by the Supreme Court involved several Myriad patents and several claims such as claims 1, 2, 6, 7, 11 and 16 of the US patent 5,693,473 and claims 1, 6 and 7 of the US patent 5,837,492. These claims basically assert a patent on ‘an isolated DNA coding for a BRCA1 polypeptide with the sequence of 1863 amino acids shown in EP 203 SEQ ID No: 2’. Another claim concerns ‘the isolated DNA with a nucleo- tide sequence shown in SEQ ID No: 1’. Another claim concerns ‘an isolated DNA having at least 15 nucleotides of the BRCA1 gene shown in SEQ ID No: 1’.

The Southern District of New York against the USPTO alleging that the USPTO should not have issued the patents to Myriad since human genes such as BRCA1/CA2 genes are products of nature, connected to methods of chemical and biological processes and should not be the products of commerce. In March 2010, Judge Robert Sweet of the District Court in Manhattan granted a Summary Judgment in favor of the plaintiffs, revoking the Myriad patents.

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The Supreme Court’s verdict that BRCA1 and BRCA2 genes are not patent eligible because they are products of nature raises an interesting question: what is a product of nature? On the surface, a product of nature is something that is found in nature and can be isolated from the original DNA strand. The mRNA is then transcribed by the physical removal of the introns, giving rise to a strand of messenger RNA (mRNA) that contains nucleotides corresponding only to the exons from the original DNA strand. The mRNA is then translated to the BRCA1 and BRCA2 proteins, which become products of nature. However, the BRCA1 and BRCA2 genes are a product of nature because it can be isolated from the human body or various tissues as is and not being a tiny integral part of the body or tissue. A nucleus from a human cell can be isolated as is and thus is a product of nature, as are the chromosomes present in the nucleus. However, a chro- mosome usually harbors a few hundred genes which are integral parts of the chromosome and are not freely pres- ent in the nucleus. BRCA1 and BRCA2 genes are parts of the chromosomes and can be viewed as products of nature in the sense that human cells have produced them from parent DNA, but they have no separate existence as independent entities. As the Supreme Court pointed out in its decision, the human genome consists of approxi- mately 22,000 genes packed into 23 pairs of chromo- somes. BRCA1 and BRCA2 genes are on chromosome 17 and 13. BRCA1 gene does not exist as a continuous stretch of functional gene. It has 24 exons of varying length on chromosome 17q21.31 while BRCA2 has a few more exons than BRCA1 spanning 84 kilobases (kb) of genomic DNA on chromosome 13q12.3 (1, 2). BRCA1 forms a complex with mRNA-splicing machinery to regulate pre-mRNA splicing and encodes a nuclear protein involved in gene expression.
many naturally occurring products such as antibiotics and bacterial anticancer proteins (5). The USPTO is, however, in the process of issuing fresh guidelines as of July 30, 2015, following its 2014 Interim Guidance on the patent eligibility issue involving 35 USC section 101 involving the product of nature claims following the CAFC and Supreme Court decisions. An interesting area of such patent eligibility issues is the patent eligibil-

CONCLUDING REMARKS

The interfacing of science and law is an important subject as articulated in the past by the organiza-
tion Einstein Institute for Science, Health and the Courts, and more recently by the Advanced Science & Technology Adjudication Resource Center (ASTAR, www.astarcourts.net). Thus science in the courtroom and science education to judges are an important goal of the Department of Justice. Indeed, the inter-

REFERENCES


ACKNOWLEDGEMENT

I would like to thank Dr. Teri Aldrich of ZymoGenetics, a Bristol-Myers Squibb company at Seattle and Professor Bellor Prabhabak, Head, Department of Microbiology & Immunology, University of Illinois College of Medicine at Chicago, for their helpful comments and suggestions.

I would like to thank Dr. Teri Aldrich of ZymoGenetics, a Bristol-Myers Squibb company at Seattle and Professor Bellor Prabhabak, Head, Department of Microbiology & Immunology, University of Illinois College of Medicine at Chicago, for their helpful comments and suggestions.