

Breast Cancer DNA Strain Patents Are Invalid

By: Shannon V. McCue, Esq.

Reminiscent of the race to the moon, molecular biologists have long sought to be the first to uncover the secrets locked in our DNA. From the perspective of the United States Patent and Trademark Office (USPTO), the winner of the pursuit to isolate DNA sequences BRCA1 and BRCA2 (which indicate the likelihood that an individual will develop breast cancer) was a company called Myriad Genetics. Myriad obtained patents covering 1) isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence, and 2) methods for comparing or analyzing these sequences to identify the presence of mutations correlating with a predisposition for developing breast or ovarian cancer. Having planted its flag, Myriad used its patent powers to exclude others from using the isolated BRCA DNA and from performing BRCA analysis to test for genetic mutations. Myriad provided these services exclusively, and charged \$3,000 to perform the testing.

Groups from the medical and scientific communities - along with patients unable to pay for Myriad's tests - cried foul, and asked that Myriad's patents be declared invalid. The central issue to their argument was whether Myriad's patents covered "patentable subject matter."

Whether an invention comprises patentable subject matter is a threshold issue and can bar someone from obtaining a patent even if the invention meets the other requirements for patentability (i.e. utility, novelty, and non-obviousness). In general, laws of nature, physical phenomena, and abstract ideas are not patentable. The rationale for excluding these categories of subject matter is that they are the basic tools of scientific and technological work such that to vest exclusive rights in them would impede the progress of science rather than promote it, as intended by Congress. This is precisely the position advanced against Myriad's patents. Myriad's accusers argued that Myriad's "patents and position as the sole provider of BRCA1/2 testing has hindered the ability of patients to receive the highest-quality breast cancer testing, and impeded the development of improvements" in such testing. The judge hearing the matter agreed.

The judge reasoned that the isolated DNA was not patentable subject matter because it was a product of nature that was not markedly different from its naturally occurring form. To be patentable, a product of nature must possess a new or distinctive form, quality, or property. Myriad's isolated DNA did not possess a new or distinctive form, quality, or property in the court's eyes; to that end, the isolated DNA's trueness to the native DNA from which it was derived was in fact a critical feature in its ability to be tested and compared for the sake of identifying the genetic mutations which indicate a predisposition for cancer. Failing to demonstrate a marked difference between the isolated DNA and native DNA, Myriad's claims to the isolated DNA were ruled by the court as unpatentable.

As in Myriad's case, patent applications relating to biotechnology and computer science are increasingly scrutinized to determine whether they encompass patentable subject matter. Since many treatment-related patents involve the isolation, fragmentation, or purification of naturally occurring elements, the Myriad decision may have far-reaching effects in the biotechnology and pharmaceutical industries. It is therefore likely that the Myriad decision will be appealed and the standard for patentable subject matter will continue to evolve.

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Shannon V. McCue is an associate with Hahn Loeser's Cleveland office. He has significant experience representing corporations of varying size in complex commercial cases in state and federal trial and appellate courts. Shannon has also worked on litigation matters that have involved a wide variety of legal issues such as contracts, trademark infringement, unfair competition, copyright infringement, patent infringement, franchise law, and business torts.