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THE BRCA PATENTS: THE GOOD, THE BAD, AND THE SCIENCE EXCERPT

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Consider these scenarios: A man on the run from a corporation who has the rights to a specific gene line in his body, and the willingness to take samples from him by force; babies genetically engineered with genes to emphasize height, strength, and intelligence, and jobs granted based on genetic testing instead of proven merit; an airborne biological weapon designed to target members of a specific ethnic group to wipe them out efficiently without worries of killing those the wielder deems worthy to inherit the earth.

Sounds like fiction?

They are. These are plot lines from Michael Crichton's novel [Next](#), the movie [Gattaca](#), and an episode of the TV show [Fringe](#). They are not taken from real world cases, but from real world fears, from the boogiemens people conjure in their minds when one says "genetic patenting," "genetic research," or "genetic engineering."

These are the fears those opposing patents on genes feed to the public to make their case against gene patents, claiming gene patents could lead to these types of scenarios, but what does the law actually allow? Are gene patents merely the first step down the slippery slope to corporations owning parts of human beings? Will we be encouraging eugenics and engineering out our children less desirable traits in the near future because scientists are encouraged to invent today? Will our research today lead to genetic weapons tomorrow?

Are the repercussions less fantastical? Something along the lines of women across America having only one company available to test them for the gene signaling a higher risk of cancer, while that company stifles new innovations in the area because they hold the patent on that specific gene sequence? [Because this scenario actually was a real problem the Supreme Court addressed this summer.](#)

While it would certainly be interesting to speculate on the wonders and horrors that could come from genetic research and gene patents, that is best left to the science fiction writers. This paper is about the law and science as it is today, explaining the real world issues away from the scary Sci Fi. This paper focuses specifically on the BRCA patents on the gene sequences that indicate a higher risk of breast and ovarian cancer, what the debate around the BRCA patents

is about, the policy implications of either allowing or disallowing that type of gene patent, and what the Supreme Court ruled this summer when it took all of this into account.

Patent Law starts with the [statute section](#) saying, “[w]hoever 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.”

This is the patentable subject matter requirement of US patent law, the gatekeeper of what one could possibly patent. In the landmark case [Diamond v. Chakrabarty](#), the Supreme Court ruled that living organisms could be within the scope of patentable subject matter, and the floodgates opened.

Inventors developed and patented biological organisms made in a lab, [new plant breeds](#), and genetic sequences within the body that signal the increased risk of a certain type of cancer, to name a few.

It seemed there was no end to what could possibly be patentable, “[anything under the sun](#)” as long as it was made by man and fulfilled the patent requirements, until the Supreme Court ruled on the [Prometheus case](#) last year. Prometheus’s patents claiming methods for calibrating proper dosage of thiopurine drugs to treat autoimmune diseases were challenged by licensees and found to be unpatentable subject matter.

This paper focuses on the case after [Prometheus](#), the case about the BRCA patents on gene sequences, [Association of Molecular Pathology v. Myriad Genetics Inc.](#), aka the Myriad Genetics case, which was decided by the Supreme Court this summer.

Myriad Genetics obtained patents on two human genes, BRCA1 and BRCA2. More specifically, the patents are for these isolated DNA sequences, which are associated with predisposition to breast and ovarian cancers. They also obtained patents on the diagnostic methods of identifying mutations in those DNA sequences. The Petitioners, Molecular Pathology, brought suit challenging the validity of those patents. The case had made it all the way up to the Supreme Court when the Court ruled on [Prometheus](#) and sent [Myriad Genetics](#) back down the Federal Circuit to be considered in light of the Supreme Court’s ruling in [Prometheus](#). The Federal Circuit considered the case and came to the same conclusion, that Myriad’s composition claims directed to “isolated” DNA molecules were valid under §101.¹¹ So the Supreme Court took up the case again, it heard the case on April 15th, 2013, and ruled in favor of the Petitioners on June 13, 2013, striking down patents on isolated genes under §101.

If patenting gene sequences were found valid, what would the consequences for research in the area have been? Since these types of patents are no longer allowed, will innovation be cooled by the lack of protection after investing millions of dollars?

This paper discusses the §101 patentable subject matter requirement as applied to biology based patents, highlighted by the Chakrabarty and Prometheus cases, what Myriad Genetics actually patented and the Federal Circuit's interpretation of the invention, the arguments for both sides in the case the Supreme Court just decided, and the possible repercussions of the Court going either way. It ends with a discussion of why the case should have come out like it did, on the side of Molecular Pathology, based on the legal merits, why their position makes sense from a scientific standpoint, and the policy rational behind ruling Myriad Genetics' patent invalid under §101.

Myriad patented the BRCA genes, whose variances signal a higher risk of breast and ovarian cancer, and methods covering the correlation between these genes and the higher risk of these cancers. Molecular Pathology and others brought suit because anyone besides the patentee could not test women for these variances without violating the gene and method patents.

The Federal Court ruled for Myriad Genetics on the issue of the gene patents, even after the Supreme Court sent the case back down, saying isolated genes were compositions of matter, irrespective of the information they coded for, because an isolated gene is something pulled from nature and made into something else that is not found in nature, not a product of nature, and that compositions of matter are patent eligible.

The Petitioners appealed to the Supreme Court again and the Court accepted the case. The Petitioners argued that the isolated genes are not markedly different than the product found in nature, and the information coded for is the same; there is not a true inventive step in isolating genes, merely discovery; and the patents claim far more than is permissible by what they contribute to the science.

The Respondents argued that isolated genes are compositions of matter, things taken from nature and changed into different molecules, and therefore fit into the patent eligible subject matter, and that the monopoly they are claiming is no different than the monopolies other patentees acquire in their inventions.

This paper argues that isolated genes by themselves should not be patent eligible subject matter, using the recent Myriad Genetics case to highlight the argument. Myriad Genetics claimed the BRCA genes, putting a monopoly on the genetic information within the bounds of the genes. The information is the same in isolated form as in nature, and no one else could isolate the gene on their own without infringing the patent, effectively putting a patent on the natural product that is the genetic information. This is why the Supreme Court ruled correctly in ruling that genes are not to be considered patentable subject matter anymore. This was a decision forged by the existing patent law, the policy underlying patent law, and the science behind isolating genes, which is truly nothing more than discovering and purifying information contained within us all.

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