

Speech Delivered to the Yorktown Bar Association
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Are Genes Patentable?

At the outset, I want to thank Mr. DePrado for giving me the opportunity to join you for breakfast this morning, and to speak to you briefly about this subject.

Rod Serling once said, "[I]t may be said with a degree of assurance that not everything that meets the eye is as it appears." Or, in my case, not everything that meets my brain is as I thought.

For, I've been laboring under the impression for years now that this was a question that had already been conclusively answered in the affirmative----yes genes *are* patentable. Now, after actually researching the subject and getting my brain out of the way of the truth, I'm not so sure.

By way of background, I started my career in intellectual property on the other side of the fence, working as a patent examiner at the United States Patent and Trademark Office. This was back in 1983, a few years after the Supreme Court's landmark decision in *Diamond v. Chakrabarty* that held, using a widely-quoted phrase, impossible to forget, that the boundaries of patentable subject matter extended to "anything under the Sun made by man."

The Patent Office apparently took this proverbial "football" and ran with it, and, about the same time that I entered the service there, began in earnest to issue patents claiming "isolated and purified DNA sequences", i.e., genes isolated from their natural environment. Being green, the new kid on the block, I more or less "drank the koolaid," and accepted, along with my coworkers, that genes claimed in isolated and purified form were, in fact, patentable subject matter. I never considered the question whether genes *should* be patentable.

A case making its way through the courts right now has brought this question to the forefront. The case is *Association for Molecular Pathology v. United States Patent and Trademark Office*, and is also known in the field as the *Myriad Genetics* case. The case was originally brought in the United States District Court for the Southern District of New York. On March 29, 2010, Judge Sweet delivered a 152-page opinion that set the patent field afire, striking down two patents held by *Myriad* as being invalid, holding that the claims to isolated and purified DNA sequences contained therein are not patentable subject matter. This decision, should it be upheld on appeal, has the potential to turn the biotechnology industry on its head, for these types of patent claims are a cornerstone of that industry.

It is perhaps appropriate that the decision was issued by Judge Sweet. Appointed to the federal bench by President Jimmy Carter in 1978, Judge Sweet, now semi-retired into senior status, has had a colorful career and has not shied away from controversy. He dismissed a suit brought by a group of teenagers who sued McDonald's, claiming the food sold by McDonald's caused their obesity, with the admonishment to the teens that "it is not the place of the law to protect them against their own excesses." He also was involved in the Judith Miller controversy, deciding that the New York Times could maintain the confidentiality of its sources. I note only in passing that he was overruled on appeal in both these controversies. He has also expressed strong opposition to the United States War on Drugs, stating at one point that the drug war is "expensive, ineffective and harmful," and even going so far as to co-author a chapter in a book entitled "How to Legalize Drugs." I won't comment further on that. The point is that he speaks his mind, and lets the chips fall where they may.

So, when the Myriad Genetics case was placed on his desk, the plaintiffs were blessed with the best of luck. For Judge Sweet not only took up their sword, he did his best to plunge it deep between the shoulder blades of the biotechnology industry.

The Myriad Genetics case was filed in federal court on May 12, 2009, but the case really began much earlier in 2003. In that year, two professors--John Conley of the University of North Carolina School of Law and Roberte Makowski of Villanova University School of Law--published an article entitled "Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents." In this article, the authors stated they were putting forth a plan--a legal plan of action--to reinvigorate the "products of nature" limitation on patent eligibility "so as to exclude discoveries of DNA sequences, proteins and biochemical mechanisms from patent protection."

What is the "product of nature" limitation? In order to receive a patent for his or her invention, the inventor must surmount four hurdles. First, the invention must be directed to patentable subject matter. Second, the invention must be of practical usefulness. Third, the invention must be novel. Finally, at the time the invention was made, the invention must not have been obvious to a person having ordinary skill in the art to which the invention pertains.

Each of these criteria is itself the subject of a speech or two or three, so I won't go into any detail. However, with respect to the requirement that the invention be directed to patentable subject matter, the courts have always carved out an exception that "laws of nature, physical phenomena and abstract ideas" are not patentable. The Chakrabarty decision mentioned earlier explains: "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of * * * nature, free to all men and reserved exclusively to none.'"

In the case of laws of nature, this extends to products of nature, i.e., the fruits of nature themselves or manufactures that are not substantially different therefrom in structure and function.

The thesis put forth by Conley and Makowski was that after Chakrabarty the Patent Office had grabbed the football a little too quickly and run a bit too far with it without ever asking the question: Should it? While the Chakrabarty case involved the patentability of a microorganism that had been modified to a form that did not exist in nature and could not exist in nature and, therefore, was clearly not a natural product excluded from patent eligibility, the authors reasoned that DNA molecules, even if isolated and purified from their natural form, were still essentially the same molecules that existed in nature and, therefore, could not be patented. They suggested that instead of simply proceeding with the status quo and allowing these patents to be granted without opposition, that litigants actively take up the fight and force the courts to deal with the issue they saw as central to this dispute--that using mere "lawyers tricks" in the choice of meaningless "isolated and purified" language, we (as a society) were allowing companies to gain proprietary rights over our DNA, the very essence of ourselves as human beings, what should be the exclusive property of no man.

Their theories found welcoming ears in the Myriad plaintiffs and, as it turned out, Judge Sweet, who cites unashamedly to the Conley article in his opinion. The Conley article even targets the Myriad patents, undoubtedly for the shock value of the facts involved. There is truth in much of what they say: If you told people on the street that a company had gained a monopoly over the breast cancer gene, not a small number would be incredulous. How can they patent that? would be a common refrain. If you pointed out that breast cancer is the most frequently diagnosed cancer worldwide and the second leading cause of cancer death for women in the United States, most of them would not only be incredulous, but also angry. If you then pointed out that Myriad charged exorbitant prices for their breast cancer screening tests, and that many women in need of testing could not afford such tests, and their insurance companies were refusing to pick up the tabs, they would be furious. However, such concerns, though they sensationalize the case, and tap base public resentments generally directed against wealthy corporations, do not help us to answer the basic legal question: Are genes patentable?

Certainly, there is another question: Should genes be patentable? That is an altogether different question for that speaks to policy, to what the law should be, not what the law is. Such policy considerations attended the decision in Chakrabarty. The court's decision noted the "grave risks" and "gruesome parade of horrors" attendant their sanction of patents for genetic engineering, risks and horrors that had been brought to the court's attention by scientists, among them Nobel laureates, who had postulated genetic research posed "a serious threat to the human race," would spread "pollution and disease that might result in a loss of genetic diversity," and "depreciate the value of human life." The court declined to weigh these potential hazards in considering whether Chakrabarty's microorganisms were patentable subject matter. The court noted that "[t]he grant or denial of patents on microorganisms is not likely to put an end to genetic

research or its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all. What is more important is that we are without competence to entertain these arguments--either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination and study that the legislative bodies can provide and courts cannot."

Ultimately, that is where I think we will find ourselves regarding the patentability of genes. Are genes patentable? Under the current law--yes, I think they are. Should they be patentable? That is a question for Congress, which has so far made no movement in the direction of excluding genes from patent eligibility. And, while Judge Sweet has ceased on this moment to legislate from the bench, whether this is prudent is left to doubt.

The fact is that the genes that Myriad has patented do not occur in nature, and cannot occur in nature and, therefore, they are not natural products. Isolated and purified gene sequences differ from natural genes in at least two different respects. First, natural genes are contained on chromosomes along with other genes and in association with proteins; isolated and purified gene sequences lack this additional genetic material and the associated proteins. Second, natural gene sequences typically contain alternating coding and non-coding regions, with the collective coding regions encoding a given protein; isolated and purified gene sequences typically contain an uninterrupted coding sequence for the same protein. So, in terms of the environment and the structure, natural genes and isolated and purified gene sequences are, in fact, different. In other words, the isolated and purified gene sequence is not, in fact, a natural product, nor substantially identical thereto, but, rather, the product of human intervention. Because of the manner in which it is made, the isolated and purified gene sequence lacks the natural gene environment and the natural gene non-coding sequences and, therefore, is different structurally from the natural gene.

Moreover, the identification, isolation and purification of the gene sequence affords a functionality that is not possible using the natural gene. For example, the isolated and purified gene sequence can be used, as Myriad has done, in diagnostics testing; in biotechnical processes, for example, to produce pure protein encoded by the genes; and even in medical therapy, for example, in gene therapy. Judge Sweet considered these functionalities of the isolated and purified genes did not make them markedly different from the natural sequences, but I cannot agree with this. He focuses on the alleged overwhelming similarities, i.e., that both the isolated and purified genes and the natural genes primarily function as genetic information carriers, and ignores these aforementioned functional differences. However, this approach does not appear to be supported by the case law. Even in those cases where subject matter eligibility has

been upheld, there was always more similarity between the natural and man-made products than dissimilarity, yet it was the dissimilarities that carried the day. While it remains to be seen, I believe the fact that Myriad, in isolating and purifying the gene sequence, has made a manufacture that is clearly different from the natural gene sequence and, as a result of those differences, has functionalities that are beneficial to mankind that do not reside in the natural gene sequence. I, therefore, also believe that Myriad's isolated and purified gene sequences are patentable subject matter.