A Myriad Conversation with Pandora Genomics

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To patent or not to patent? That was the question, when it came to naturally occurring DNA. The answer came from the Supreme Court in June.

Understanding the human genome is as important as it is challenging. While it has long been understood that there are 23 pairs of chromosomes that make up the human genome, unraveling how the genetic code relates to genetic disorders and human disease has been the mission of many companies. With each breakthrough, the ability to enhance the quality of a person's or a patient's life increases. A significant breakthrough came when Myriad cloned two genes which, when containing certain mutations, increase the likelihood of a woman developing breast cancer. For a disease in which early detection has long been known to be important, this discovery accelerates a patient's decision-making timeline. Specifically, individual patients can start to make quality of care decisions even before getting the disease.

Genetics also plays a role in determining how well one's body responds to specific medications. Knowing whether DNA variations in an individual's genes are present, and where, may help avoid prescribing medicine that has harmful side effects. Pandora Genomics is an informatics company working in the biotechnology field. It has developed statistical algorithms and a bioinformatics software platform that analyzes a specific patient's DNA and determines which drugs will be effective and which drugs will interfere with a proposed treatment plan.

On the road to personalized medicine, there is no question that discoveries in understanding the human genome are important. The question was whether all such discoveries are patentable. We now know from the Supreme Court's Myriad decision that, without more, isolated naturally occurring DNA is not patent eligible, while non-naturally occurring DNA, and methods or processes of using naturally occurring DNA, are patent eligible.

What we don't know is how the Myriad ruling will affect the biotech industry's motivation to innovate, which is one of the purposes of patent protection. Will companies continue to innovate in this area even though patent protection has now been limited? If innovation will continue, which path will it take?

To help understand the impact of the Myriad ruling on the biotechnology industry, I talked to Philip Arlen, President and Chief Scientific Officer of Pandora Genomics:

Joshua Rothman: What did you think of the patentability of isolated genes before the Myriad decision came down?
Philip Arlen: Generally speaking, I am not a proponent of patenting genes, regardless of whether the sequences are naturally occurring. The gene sequences themselves are irrelevant; it's the information that comes out of the genome – RNA, proteins, phenotypes – that is important, and I believe this information is a product of nature. Myriad found a relationship between mutations in the BRCA genes, which are responsible for DNA repair, and susceptibility to a variety of

cancers, including breast and ovarian. I believe Myriad should have the right to seek patent protection for their processes for isolating the BRCA sequences, as well as the test itself, but not the sequences.
While directly a patenting issue, there is also a moral aspect, which is exactly what got Myriad into trouble in the first place. Myriad's patented BRCA test, while useful, was both expensive and restrictive, in terms of who could access the basic information relating to a patient's own genetic code. As a society we have a collective goal of realizing cures for cancer; hence the immense public support cancer research has received over the past 40 years. (Needless to say, much of the work identifying the BRCA mutations was also funded by the public through government grants.) Yet Myriad alone stood to profit from knowledge of the patient's genetic code: Its patent monopoly enabled Myriad not only to exclusively profit from the BRCA test, but also to create a database of BRCA mutations that it maintained as a trade secret, a strategy that ultimately violates the spirit of publicly funded research. Moreover, many patients were unable to access the test because of its cost, and researchers and start-up companies found themselves as litigants in suits brought by Myriad because of patent infringement. These outcomes were both stifling to innovation from a business and progress standpoint and not conducive to bettering human health from a moral standpoint.

What do you think of the Myriad decision? How does it affect Pandora Genomics' business?
I agree with the decision as it relates to the patentability of naturally occurring DNA sequences; as naturally occurring substances, they should belong in the public domain. I hold this perspective despite the fact that my company is one whose ownership of specific gene sequences would be of tremendous benefit, enabling us to control regions of the genome as they relate to impacting treatment responses, and profit accordingly from the products and services we generate.
But here's the flipside: Freedom to operate. Pandora Genomics can now freely use any portion of the genome to assess whether patients are good candidates for particular medications. No entity should have a claim of ownership over any of the sequences, which are important to human health.

How do you think the decision will affect other companies?
Pharma should be ambivalent about the decision. As I understand it, genetics plays a minor role, if any, during drug discovery. If anything, the FDA's push for companies to identify which patients will respond to a particular treatment in order to receive drug approval indicates that the process for generating gene-based companion diagnostics ought to proceed more smoothly. As for those companies solely involved in gene-based tests not linked to a medication, the investment landscape will likely be a bit bleaker.

Will biotech companies continue to evaluate the human genome?
Yes, but mainly in the realm of companion diagnostics, as I mentioned before. The development of these tests will foster advances in understanding the genome and how it affects health. Companies will still see a return on research expenditures through sales of these tests. As long as patents are awarded on the basis of patentable testing methods or applications, there is great profit potential, particularly given the recent FDA push in this direction.

Do you need that innovation to continue so that you can perform your proprietary analyses?

Innovation drives this industry and benefits all companies; it also encourages competition between companies, which will ultimately benefit the patient. I firmly believe research in the area of genetics and human health will continue; publicly funded research is what provides us most of the data upon which we base our analyses.

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Discovering novel genes and their functions may no longer be enough to recoup the cost of such research efforts. Rather, innovators may have to discover novel genes and then take the second step of inventing patent eligible subject matter related to that discovery, in efforts to protect a source of revenue crucial for funding the next research effort.