Guest Post: The Myriad Ruling: 6 Points Every Biotech CEO Must Consider

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(http://massbiohq.files.wordpress.com/2013/06/linnikprofphoto6416-e1371665016155.jpg)Last week, the US Supreme Court issued a long-awaited decision in *Myriad Genetics*, which sent shockwaves through the very foundation of the biotech industry. The decision invalidated one of Myriad's patents on mutated BRCA-gene sequences associated with increased risk of breast cancer. Though widely referred to as "a gene patent," Myriad's patent, in fact, did not claim genes *per se*, but instead claimed the sequences in their "isolated" form. Such claims –"isolated XYZ substance"–have long been widely accepted as a valid approach for claiming purified or isolated substances extracted from nature (e.g., insulin, antibiotics, blood coagulation factors, to name a few). The Federal Circuit has twice considered these claims and upheld them both times. Nevertheless, the Supreme Court held that for genomic sequences "isolation" does not go far enough in distinguishing them from the genomic DNA. According to the Court, such claims are merely trying to protect "natural phenomena."

Many questions arise. How will this decision affect the biotech industry? Will it promote or impede innovation? Will it reduce the cost or increase access to medicines? Which sector of the industry will it impact the most? How large is the impact on the existing patents? How should a biotech company react to this decision?

Commentary and confusion both abound, but here are the six most salient points that every biotech executive should bear in mind in the post-*Myriad* world.

1. **A *Myriad*-type decision was anticipated, and in many cases, backup positions had already been put in place.** "Isolated" sequence claims are just one of many various types of claims that are typically drafted into a patent application or a patent portfolio. For example, Myriad itself announced shortly after the decision that it has about 500 other claims covering the BRCA test that were unscathed by the Supreme Court's decision. Industry-wide, only a small fraction of patents will turn out completely unsalvageable.

2. Beware of the position you take with respect to your competitors' patents. This dog will come back to bite you! **Your position on any third party patent should always be consistent with your view of your own patents**. In other words, you should not argue that your competitor's patents are invalid under *Myriad*, if that position would, if turned against you, undermine your own patents. United States jurisprudence has a strong tradition of relying on statements "against self interest"; to paraphrase the Miranda warning, "Anything you say may–and will–be used against you."

3. **The *Myriad* decision was only concerned with genomic DNA—*not* with other biological sequences.** Even with DNA, the Court concluded that complementary DNA (cDNA) – non-naturally occurring DNA molecules in which noncoding DNA is deleted – is patent-eligible.

Predictably, many will extend the Court's logic to claims directed to other naturally found biologic molecules, such as "isolated" antisense DNA, microRNA, siRNA, bacterial and viral nucleic acids or even sequence fragments of naturally occurring proteins, natural antibiotics, hormones, isolated stem cells, etc. You should abstain from adopting such an overreaching position. At this point, this view is just a hypothesis, and even if probable, it still presents a question for future court decisions to answer. In fact, there may be substantial differences that could weigh in favor of isolated biologic molecules other than genomic DNA. Take microRNA, for instance: 1) isolation of microRNAs is a newer and lesser developed technology than isolation of genomic DNA; 2) unlike genomic DNA, microRNAs have a functional role, and they are not purely information bearing molecules; and 3) microRNA itself can be used as a drug, akin to purified insulin or an antibiotic, whereas genetic sequences do not have such utility. It will take 5-10 years to establish the exact breadth of *Myriad* as new cases with differing fact patterns go through the courts.

4. **The *Myriad* decision leaves plenty of room for claims to chemically modified sequences and other types of claims.** For example, naturally occurring sequences that have been somehow altered by man should remain valid. Here, again, the Court did not specify what type of modification is sufficient to cross the line from merely being a "product of nature" to being a patentable invention. It is likely that a sequence will need to be modified chemically to render the molecule some new property to be patent-eligible, for example, 1) an oligonucleotide linked to a fluorescent probe for diagnostic purposes, or 2) an oligonucleotide having the phosphorothiotate backbone (which increases the oligo's resistance to nucleases). Most biologic drugs will contain chemical modifications relative to their naturally occurring forms, and if so circumscribed by the claims, they will avoid *Myriad*.

5. **The *Myriad* decision will make it more difficult–but not impossible–to protect early discoveries.** Typically, at the point of foundational discovery, very little is known about chemical modifications that will be ultimately present in the future drug. There is a concern that claiming conventional chemical modifications that are well known in the art may be viewed negatively by courts as a clever attempt to circumvent the *Myriad* holding. But at the same time, drafting narrower, more specific claims has the inherent risk that some valuable territory will remain unclaimed and open to design-arounds. Therefore, as a result of the *Myriad* ruling, more effort should be devoted to developing multiple backup strategies. Where a single sequence claim may have previously been sufficient, multiple and diverse narrower claims will be necessary to restore the commercially relevant competitive playing field to the pre-*Myriad* levels. More attention needs to be devoted now to guard against inadvertently pointing the competition to the most valuable commercial embodiments through narrowly focused claiming.

6. **The *Myriad* case has gained significant publicity, and the Supreme Court's holding is popular with various stakeholders**, ranging from research scientists and cancer patients to high level policy makers and public interest groups (such as the ACLU). Regretfully, this large contingent may view innovators as bad actors who are out to game the patent system and the "gene patents" themselves as impediments to research and discovery of new drugs. These views, while often emotionally charged, have little grounding in facts or law. Notably, the press commentary has been rife with ungrounded generalizations and poorly informed, biased interpretations. To boot, the biotech industry has been struggling to find a politically sensible way of articulating its position in the wave of strong popular anti-patent sentiment. All biotech companies should be cognizant of this public perception and strive to convey a positive message.

As a final note, the vast majority of patent experts agree that Myriad's claims did not and could not claim the genes as they are found in the human body. By weakening patent protection on the early fundamental discoveries, the Supreme Court has reduced the incentive for innovators to publicly disclose certain types of inventions. By doing so, the Court might have inadvertently thrown out the proverbial baby with the bath water. The patent system has proven again and again to be more beneficial to the technological progress than the medieval Masonic handshake. After all, a patent can enrich the inventor for a limited time, but mankind is enriched forever. And when it comes to finding cures for devastating diseases and improving people's health, we must err on the side of encouraging disclosure, not promoting trade secrecy.

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