The Myriad Decision: What is the Impact?

Jun 20, 2013

Authors: Melanie Szweras and Carmela De Luca

As we reported in our previous article, the Supreme Court of the United States issued its long awaited decision in the *Myriad* case on June 13, 2013. The Court held that cDNA (at least some forms) which are DNA molecules in which non-coding regions called introns are absent, remains patent eligible although the Court rejected patent eligibility of naturally occurring genomic DNA.

The decision on cDNA is good news and brings some much needed clarity to innovative biotech industries as commercially cDNA may be the most important form of DNA used in biotechnology.

However, it would seem that uncertainty still remains for shorter segments of cDNA and other naturally occurring molecules.

It is unclear what effect the Court's decision will have on short sequences of cDNA that are useful for example for synthesizing or sequencing cDNA (e.g. primers) or for detecting specific mutations (e.g. probes) or naturally occurring microRNA, siRNA and mRNA molecules whose sequences are the same as those found in cells.

It also remains to be seen whether the Court's reasoning about isolating DNA from its surrounding environment being insufficient to distinguish DNA from a product of nature, will be extended to other types of "isolated" biomolecules, including proteins, cells, organisms and other natural products.

The United States Patent Office ("USPTO") was quick to issue its preliminary guidance based on the Myriad decision and has provided some guidance for what will be allowed in pending applications. According to the USPTO memorandum, claims clearly limited to non-naturally occurring nucleic acids such as cDNA are patent eligible.

No comment is made on short cDNA sequences or other biomolecules. It is also unclear how the USPTO will treat method claims.

Based on the Court's reasoning, chemical modifications or other human manipulations of naturally occurring biomolecules that make them different from the natural form may provide a basis for patentability. For example, engineered DNAs and/or other engineered biomolecules would appear patent eligible. What level of modification or manipulation is sufficient to render the biomolecule patentable, remains to be defined. Further, the Court stated that the "rule against patents on naturally occurring things is not without limits" and citing previous case law added "patent protection strikes a delicate balance between creating "incentives that lead to creation, invention and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention"" (p 11). Accordingly, it is conceivable that the decision's "limit" may be "isolated genes" as indicated in the Court's conclusion: "[W]e merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material" (p. 18).

The Court may have left another door open. Compositions of DNA (or other naturally occurring molecules) and specific diluents not found in nature are not "naturally occurring" and the Court clearly stated when referring to Myriad's objected to claims that "Myriad's claims are simply not expressed in terms of chemical compositions" (p. 14).

The Court was also clear to emphasize "it is important to note, what is not implicated by this decision. First there are no method claims before this Court… Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes….Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered" (pp 17-18).

It will be important going forward, that claims be drafted to include claims that differentiate DNA molecules from naturally occurring DNA. For example, claims should be directed to cDNA, vectors or other constructs, non-naturally occurring degenerate or optimized DNA sequences, or cells and perhaps compositions comprising said sequences as mentioned above. For example, claiming a protein, DNA, RNA, purified natural product as a composition of matter along with a carrier, such as a pharmaceutically acceptable carrier would arguably render the composition something different from its naturally occurring counterpart, leaving the more appropriate question of patentability, i.e. whether it is novel and obvious to be determined. Shorter DNA sequences could be claimed

with modifications such as labels, or tags to distinguish them from naturally occurring counterparts. Adding method claims, including methods of making or using the DNA, is also highly recommended.

Since proteins are typically described in terms of the identification of the amino acid sequence similar to DNA molecules being defined in terms of the nucleotide sequence, it may be useful to add claims that would further distinguish isolated proteins from the natural product. For example, in addition to the strategies mentioned above for DNA claims, use of the terms "recombinant" or "synthetic" for a protein could also be used in addition to "isolated", which is still acceptable in many jurisdictions.

In the case of naturally occurring cells, such as stem cells, there are clear arguments that they are distinguishable from the products of nature based on the fact that they would need to be grown in culture in cell media, are extensively manipulated in the culture system, and would be a purified product, which would likely be devoid of unwanted contaminants found in cells from the “natural” environment. However, in light of this decision, it would be prudent to include claims that reflect such manipulations, for example, an isolated stem cell cultured in media or a composition of cells and a carrier, such as media.

Regarding issued and allowed patents claiming "isolated DNA" and perhaps other "isolated" naturally occurring molecules, review of claims in light of the Myriad decision may be warranted. If a continuation is pending, pursuing claims limited to "cDNA" or comprising a label or tag may be a good way to hedge whether claims to "isolated DNA" that could encompass cDNA and non-cDNA molecules will remain patentable. If no continuation is pending, reissue may be an option.

As full genome sequencing has led to the disclosure of most human DNA sequences, the effects of the decision may be circumscribed if the reasoning is limited to isolated naturally occurring DNA. Identifying disease mutations however is an important and active area of biotech research and investment. One effect of the decision is that it may make patenting early-stage research identifying DNA mutations more difficult and could encourage patentees to pursue greater secrecy over those early stage discoveries.