So Now What? Implications of the Supreme Court's Myriad Ruling

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Late last week, the United States Supreme Court issued its long-awaited decision in *Association of Molecular Pathology v. Myriad Genetics, Inc.* The Court held unanimously that full-length wild-type DNA molecules are not patent-eligible under the Patent Act, even when isolated, but are instead "products of nature" that cannot be patented. Importantly, the Court also concluded that cDNAs – DNA molecules in which the naturally occurring non-coding regions (introns) are absent – are patent-eligible. The decision is likely to have wide-ranging impact on the biotechnology industry in litigation, patent prosecution, and licensing.

The challenged claims in *Myriad* were directed to naturally occurring genes that play a role in breast cancer. The Court held that an isolated, naturally occurring gene or gene fragment was not a new "composition of matter" under § 101 of the Patent Act, because such a gene had all the same genetic information the DNA would have in the body. The Court rejected arguments made by Myriad and adopted by the Federal Circuit that isolating a DNA molecule by cleaving the chemical bonds that join it to flanking DNA sequences is enough to render the molecule patent-eligible.

In contrast, the Court held that cDNAs were patent-eligible because they were "unquestionably … something new." While the Court did not explain its rationale in detail, the justices appear to have reasoned that cDNAs are not naturally occurring and are synthesized from RNA in the laboratory. The Court's reasoning almost certainly validates the patent-eligibility of highly engineered DNAs such as those coding for humanized or chimeric antibodies.

The Court briefly addressed claims drawn to naturally occurring DNA fragments, observing that "very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA." Under this reasoning, a short fragment would not be patent-eligible if it had a wild-type DNA sequence even if it was originally created as part of a cDNA.

At oral argument, the justices evidenced some uneasiness with the finer points of molecular biology underlying the patent issues. In a separate concurring opinion, Justice Scalia expressed his own concerns and refused to join in the Court's scientific discussion, writing, "I am unable to affirm those [scientific] details on my own knowledge or even my own belief."

Because of the highly technical subject matter, the Court appears to have kept its opinion deliberately narrow. Even so, some of the Court's reasoning is less than clear. Most notably, the Court distinguished between "naturally occurring" and "synthetically created" DNAs, despite the fact that DNAs having a naturally occurring sequence can be readily synthesized in a laboratory. The Court specifically expressed no opinion as to the patent-eligibility of inventions directed to "DNA in which the order of the naturally occurring nucleotides has been altered."

The *Myriad* ruling draws on the Court's previous ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, a case that addressed the patent-eligibility of method or process claims. The two cases together expand the Court's previous holdings that "laws of nature" and "products of nature" are not patent-eligible and apply them to the life sciences.

The effects of the ruling going forward are, in a word, myriad.

For patent litigation:

While the opinion appears to hold that patent claims directed to isolated wild-type genes or gene fragments (and, by extension, other wild-type DNAs such as enhancers, promoters, etc.) are invalid, the decision presents an open field to litigate the validity of claims drawn

to:

- Purified, naturally occurring proteins synthesized in host-cell expression systems;
- Non-mutant wild-type DNA sequences that have been trivially altered in non-natural ways, such as by ligation to a known sequence, or by labeling; and
- DNAs that have been "synthetically created" but could theoretically be found in nature (such as certain types of mutant DNAs, which the Court expressly declined to consider).

More generally, the Court did not provide guidance about the extent to which a naturally occurring DNA sequence must be modified to become patent-eligible, nor did it suggest how it would rule on other purified, isolated, or synthesized materials that may have a naturally occurring counterpart. All of these issues are likely to be the subject of future patent litigation.

For patent prosecution:

It will be extremely important to draft claims that clearly differentiate between the claimed invention and any naturally occurring form of the DNA. For example, a human DNA sequence incorporated into a non-human mammalian chromosome may pass muster even if the isolated DNA itself would not (assuming that the DNA meets other requirements for patentability such as non-obviousness). Claims should be directed to plasmids, vectors, transformed host cells, or other constructs including the DNA sequence of interest to make clear that the claims do not encompass naturally occurring embodiments. Patent applicants should take advantage of the Court's ruling that cDNAs are patent-eligible by claiming those, even in isolated form. Where an invention relies on the use of intronic sequences (the sequences omitted in a cDNA), it may be beneficial to disclose and claim non-natural introns such as chimeric introns. The written description should emphasize the differences between the natural composition of matter and the claimed invention. Patent applicants with vulnerable claims should add new method claims about how to create or use the DNAs of interest and should add construct claims, as discussed above. Finally, patentees who no longer have applications pending may seek to narrow and strengthen their claims by initiating reissue proceedings.

For patent licensing:

Licensors and licensees should review licensed patent portfolios to determine if any licensed patents contain only claims drawn to wild-type DNAs, because such patents may be invalid in their entirety. While the ruling may invalidate some claims of many patents, it is unlikely to invalidate all claims in a patent. Most patents have both broad DNA claims (which may now be invalid) and claims drawn to cell lines, vectors, and chimeric or non-natural mutant DNAs (which are probably still valid).

Authors Claire Laporte and Marco J. Quina represented the Federal Circuit Bar Association (FCBA), an *amicus curiae* in the *Myriad* case, and filed an *amicus* brief in support of affirmance on behalf of the FCBA.

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