

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

What two recent Supreme Court rulings say and don't say

Just one month after it issued a ruling in *Bowman v. Monsanto*, the US Supreme Court issued another decision on a genetic patent in *Association for Molecular Pathology et. al. v. Myriad Genetics, Inc. et.al.* (http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf).

In the *Bowman* case, the court ruled that Vernon Bowman's theory of patent exhaustion—he purchased soybeans at a local elevator and argued that the patent on these soybeans, many of which contained the Roundup Ready gene, had been exhausted in the original sale—was without merit and Bowman had violated Monsanto's patent (see our column <http://agpolicy.org/weekcol/672.html>).

In the *Myriad* case, issued June 13, 2013, the Supreme Court with Justice Thomas writing for a unanimous court (with a minor caveat by Justice Scalia declaring that he was not affirming the science described in the first part of the court's decision) ruled that Myriad's patents on two breast cancer genes known as BRCA1 and BRCA2 were invalid.

The reasoning for the decision was that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it had been isolated.” At the same time it ruled that the patents on the complementary DNA (cDNA) for these two genes were valid “because [the cDNA] is not naturally occurring” but is a new creation of the lab technician.

It is unclear to us, however, how the work of the lab technician who severed the genes from the surrounding genes (patent ineligible) is somehow different from the work of the lab technician who eliminates part of the DNA to create the cDNA (patent eligible) since the sequence of chemicals of both the DNA and the cDNA are determined by nature.

In both cases (*Bowman* and *Myriad*), the decision was unanimous even to the limits-of-reach of the decisions. In *Bowman*, Kagan wrote, “our holding today is limited—addressing the situation before us, rather than every one involving a self-replicating product. We recognize that such inventions are becoming ever more prevalent, complex, and diverse. In another case,

the article's self-replication might occur outside the purchaser's control. Or it might be a necessary but incidental step in using the item for another purpose... We need not address here whether or how the doctrine of patent exhaustion would apply in such circumstances.”

In *Myriad*, Thomas wrote, “It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents.... Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes.”

In explaining the basis of the court's decision in *Myriad*, Thomas wrote “As we have recognized before, 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.’... We must apply this well-established standard to determine whether Myriad's patents claim any ‘new and useful... composition of matter’... or instead claim naturally occurring phenomena.”

In these two decisions, it seems to us, the court may be signaling that the incentives that are needed to continue “creation, invention, and discovery” in the field of genetics are not what they were in the 1990s and some limits may be needed to overcome current impediments to “the flow of information that might permit, indeed spur, invention.”

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