Client Alert.

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Sound the Alarm?—The Supreme Court's Renewed Interest in Life Sciences Patents Could Create Additional Hurdles Across the Field

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First, there was *Mayo v. Prometheus*,[1] where the Supreme Court found the medical diagnostic methods at issue were not patentable subject matter. Then, the Court sent *Myriad*[2] back to the Federal Circuit, for further consideration of whether isolated DNA sequences are patentable. It could soon hear that case again—a petition for *certiorari* is currently pending. More recently, the Supreme Court granted review in *Bowman v. Monsanto*[3] on whether patent exhaustion applies to self-replicating plant seed technologies. And now a new petition is pending before the Supreme Court in *Beineke*[4] regarding whether discovered plants are patentable. Are life sciences inventions under assault?

A LOT HAS HAPPENED IN 2012

On March 20, 2012, the Supreme Court delivered its unanimous opinion in *Mayo*. Prometheus's claims in that case involved methods of determining the levels of thiopurine drug metabolites in patients with autoimmune disorders and comparing those levels to threshold values that indicate the drug's efficacy or toxicity. Mayo purchased and used diagnostic tests based on Prometheus's patents, but in 2004, Mayo decided to try to develop and market its own version of the test. Prometheus sued for infringement, and while the district court found the patents were infringed, it granted Mayo's motion for summary judgment that the claims covered subject matter that is not patent-eligible. The Federal Circuit reversed, but that decision was vacated and remanded by the Supreme Court for reconsideration in light of *Bilski*.[5] On remand, the Federal Circuit again sided with Prometheus, spurring a second petition to the Supreme Court, which was granted. In its unanimous opinion, the Supreme Court noted that Prometheus's claims sat at the intersection between those that encompass non-patentable "laws of nature, natural phenomena, and abstract ideas," and those that describe a patent-eligible "application of a law of nature or mathematical formula to a known structure or process." The Court viewed the claims as applying natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage would be ineffective or would induce harmful side-effects. The Supreme Court found the claims invalid because the act of correlating that they covered was either conventional or obvious over the natural laws themselves, *i.e.*, the application was not the point of novelty. The Court concluded that a claimed process must do more than simply instruct users to apply a natural law, but it was vague as to what exactly constitutes a patent-eligible application of such a law.

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[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, __ U.S. __ (March 20, 2012).

[2] *Association for Molecular Pathology v. Myriad Genetics, et al.*, __ U.S. __ (March 26, 2012).

[3] *Bowman, Vernon H. v. Monsanto Co., et al.*, No. 11-796, cert. granted (Oct. 5, 2012).

[4] *Beineke, Walter F. v. USPTO*, No. 12-580, petition for writ of cert. (Nov. 5, 2012).

[5] *Bilski v. Kappos*, 561 U. S. __ (2010).

Mayo put the fate of the DNA sequence patents in the then-copending *Myriad* case in doubt. The claims at issue in *Myriad* include both composition claims directed to isolated DNA sequences—specifically, the sequences for the BRCA-1 and BRCA-2 genes that have been tied to breast cancer—and method claims directed to screening for the presence of mutations in those genes. Instead of deciding that case, the Supreme Court issued a one paragraph grant, vacate, and remand order for further proceedings consistent with *Mayo.* Since then, the Federal Circuit panel has re-affirmed its prior ruling, finding that the claims directed to isolated DNA sequences were patentable because the act of cleaving covalent bonds to isolate the DNA changed its chemical identity. The panel once again also found that certain methods of comparing the patient's sequence with an isolated sequence were not patentable, though it supplemented its prior analysis with the Supreme Court's reasoning in *Mayo*. However, the panel rejected the argument that all of *Myriad's* method claims were indistinguishable from the claims found invalid in *Mayo*, explaining that some of them involved applying mental steps to "transformed cells that … are a product of man, not of nature," and thus were patent-eligible. But the panel's opinion is already the subject of a new petition for *certiorari*, and to date seven *amici* have written briefs in support of that petition. Many commentators believe the Supreme Court will grant review.

Thus, it seemed likely that *Myriad* would be the next case the Supreme Court would hear on life sciences patents. But the Supreme Court surprised many when, on October 5, 2012, it granted review in *Bowman* against the advice of the Solicitor General. That case involves Mr. Bowman's use of seeds for Monsanto's "Roundup Ready®" soybean variety with a transgenic gene for resistance to the herbicide glyphosate. While Mr. Bowman made regular, authorized purchases of seeds containing Monsanto's patented technology, starting in 1999 he also began purchasing commodity seeds (*e.g.*, soybeans sold for feed or industrial use) from a grain elevator to plant some of his yearly crop. As the majority of soybean seeds sold into commodity markets in his home state of Indiana were grown from seeds containing Monsanto's Roundup Ready® technology, Mr. Bowman found that the commodity seeds he had purchased were resistant to glyphosate as well. Accordingly, he began saving seeds from subsequent crop generations and replanting them to grow additional yearly crops. Monsanto investigated and later sued, obtaining summary judgment of infringement from the district court. On appeal, Mr. Bowman argued that exhaustion applied to the authorized sale into commodity markets of the seeds he purchased and to any downstream product of those seeds that "substantially embodies" the same characteristics, including the subsequent generations he was using for his plantings. The Federal Circuit disagreed and found the doctrine of patent exhaustion was inapplicable, explaining that "[e]ven if Monsanto's patent rights in the commodity seeds are exhausted, such a conclusion would be of no consequence because once. . .the next generation of seed develops, the grower has created a newly infringing article." Moreover, the Federal Circuit cautioned that "[a]pplying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder." The Supreme Court's decision to grant *certiorari* and review the Federal Circuit's decision despite the Solicitor General's recommendation not to do so is not uncommon, but it does suggest that the Court is unhappy with the Federal Circuit's articulation of the law in this area.

Another petition has now been filed in the *Beineke* case, this one raising the issue of whether "discovered" plants are patentable under the plant patent statute. That statute provides that "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant" may be eligible for a plant patent. Mr. Beineke observed 100 year-old white oak trees that appeared to have superior genetic traits, planted acorns from the trees, and asexually reproduced the progeny. When the progeny ran "true to type"—meaning they showed the same traits—he concluded that he had discovered two new and distinct varieties and applied for plant patents on both trees. The Federal Circuit found that Mr. Beineke's discoveries were not patent-eligible because the plants were not "created in [their] inception by human activity." Mr. Beineke argues in his petition that "[h]undreds of issued plant patents on trees and pending and future applications

are now subject to validity challenges because 'creation' was not previously required by the Patent Office and is not required by the statute." He also notes that he cultivated the trees to confirm they were true to type "through asexual reproduction, which oak trees do not achieve in nature." This human activity is not unlike the act of cleaving covalent bonds that was required to isolate the DNA for the BRCA-1 and BRCA-2 genes in *Myriad*. Thus, while the Federal Circuit's finding in *Beineke* appears limited to eligibility for plant patents, it could have implications for other life sciences inventions that are arguably discovered and isolated from nature, including patents on isolated DNA sequences. This makes *Beineke* worth watching even though it is not yet clear whether the Supreme Court is inclined to grant review.

HOW WILL THE COURT DECIDE?

If the Supreme Court's *Mayo* opinion is any indication, biotechnology companies may have good reason to be wary of the direction the Court might take in the *Bowman*, *Myriad*, and *Beineke* cases. Any further restrictions on patent-eligibility for products isolated from nature, or expansion of the doctrine of patent exhaustion for self-replicating technologies, could have unforeseen consequences far broader than the fact scenarios under which these cases may be decided. Thus, companies in the business of developing, selling, or licensing life sciences inventions will want to watch these cases closely, and work with counsel to prepare for the potential impact on the marketability of these kinds of inventions. Companies with more substantial investments in these technologies may also want to consider filing *amicus* briefs with the Court, to make the Court aware of how particular outcomes may impact their industries.

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