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Life Science Patent Cases High Court May Review: Part 1

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It has been a busy year for patent cases at the U.S. Supreme Court. The court recently issued its opinion in Halo and Stryker cases (regarding enhanced damages) and is preparing an opinion for the Cuozzo case (regarding the broadest reasonable interpretation claim construction standard use in IPR proceedings). That said, a number petitioners are asking the Supreme Court to review additional decisions involving patent issues. In this two-part article, we review some of the key pending petitions that may impact the life sciences industry, and comment on the likely outcome of each petition.

Sequenom v. Ariosa

Sequenom Inc. v. Ariosa Diagnostics Inc., et al., No. 15-1182. Sequenom, Inc. filed a petition for certiorari asking the Supreme Court to revisit the hotly contested issue of exceptions to 35 U.S.C. § 101 for "laws of nature" after their earlier decisions in Association for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) and Mayo Collab. Servs. v. Prometheus Labs. Inc., 132 S.Ct. 1289 (2012). In both of these earlier cases, the Supreme Court struck down patent claims generally directed toward diagnostic methods for biotechnology and pharmaceutical applications holding that these claims recited laws of nature.

These cases laid out a two-part test for patent eligibility: (1) whether the claims are directed towards a patent-ineligible concept (such as a law of nature), and, if so, (2) whether the claims recite sufficient additional limitations such that they are directed to more than just the ineligible concept. One of the most significant effects of this test in the biotechnology industry has been to greatly limit patent eligibility at both the U.S. Patent and Trademark Office and in the courts for patents directed to sequences of DNA, particularly those that naturally occur in living organisms. This impact on eligibility arises because many patents seek to claim either naturally occurring DNA itself as a composition of matter (as was the case in Myriad) or methods of detecting such DNA using techniques already well known in the art.

Sequenom is the licensee of the patent-in-suit, U.S. Patent No. 6,258,540, which generally discloses and claims methods for analyzing a blood sample taken from a pregnant woman for paternal DNA. The methods may be employed to determine the risk of fetal genetic disorders (such as Down syndrome), material pre-eclampsia, fetal blood type and sex, and other useful medical information. The inventors discovered that maternal blood naturally contained a tiny amount of

"cell-free fetal DNA" (cffDNA) inherited from the father of the baby (paternally inherited cffDNA), and first disclosed this in an application that led to the '540 patent, which claims methods of detecting paternally inherited cffDNA. Sequenom sells a commercial embodiment of the invention as a diagnostic test for analysis of paternally inherited ffDNA present in a maternal blood sample. This test avoids many risks of earlier diagnostic methods and has been commercially successful.

Ariosa and its co-appellants Natera Inc. and Diagnostics Center Inc. sell or license competing diagnostic blood tests that also use paternal cffDNA taken from maternal blood. When threatened with claims of infringement, Ariosa et al. brought separate declaratory judgment actions that were related by the district court for the pretrial phase. Sequenom responded with claims of infringement. The parties filed cross motions for summary judgment regarding the validity of the claims under 35 U.S.C. § 101.

The district court found that the claims of the '540 patent were directed to the natural phenomenon of paternally inherited cffDNA, and further found that the claims did not include enough additional limitations beyond the natural phenomenon to be eligible under § 101. In particular, the district court determined that the steps of amplifying and detecting DNA were a well-understood, routine or conventional activity in 1997, when the application was filed. The district court then held that the inventors simply applied these conventional steps to the natural phenomenon of paternally inherited cffDNA. The Federal Circuit affirmed. In a concurring opinion, Judge Richard Linn noted that the broad language used by the Supreme Court in the Myriad decision compelled the holding, but that the result in this case may have been unintended by the Supreme Court. A petition by Sequenom for rehearing en banc was denied, although in denial, four additional circuit judges raised similar concerns.

In seeking certiorari, Sequenom argued that the lower courts have adopted an overly broad interpretation of Mayo and Myriad to the detriment of patents claiming combinations of laws of nature with conventional techniques. The petition asserted that the court should clarify that a new combination of a law of nature with conventional techniques is patentable. Sequenom also argued that the claims of the '540 patent recite methods of applying the discovery of paternally inherited cffDNA, something that has always been patent-eligible, rather than the natural law of the existence of such cffDNA itself. Finally, Sequenom pointed out that its claims do not preempt all uses of paternally-inherited cffDNA, which has been viewed by the court as an indicator of an eligible claim.

Ariosa and Natera responded by adopting the viewpoint of the Federal Circuit, further emphasizing that the claims simply recite a natural law and then add words that amount to nothing more than a simple application of that law. Their briefs in opposition explained that such claims have already been ruled ineligible in Mayo. Moreover, both respondents argued that earlier Supreme Court precedent supports a finding of ineligibility because Sequenom's claims broadly preempt other uses of the discovery of paternally inherited cffDNA, and that court precedent does not require every use to be preempted.

Given the significance of the earlier case law, large number of amicus briefs filed, public policy arguments raised by the parties, and general lack of clarity around the breadth of the holdings in Mayo and Myriad (which themselves purport to be narrow decisions), there is a reasonable likelihood that the court will grant certiorari. A grant of certiorari in this case could also have a significant impact on the USPTO, which has been attempting to guide both applicants and its examiner corps through issuance of guidance and examples of eligible subject matter.

Life Technologies v. Promega

Life Technologies Corp., et al. v. Promega Corp., No. 14-1538. This case involves infringement under 35

U.S.C. § 271(f)(1), which states that it is an act of infringement to "suppl[y] ... in or from the United States all or a substantial portion of the components of a patented invention, ... in such manner as to actively induce the combination of such components outside the United States." In the case below, Promega Corporation alleged that Life Technologies was liable for infringement under § 271(f)(1) because LifeTech manufactured Taq polymerase, a single component of a genetic testing kit, in the United States and shipped it to a LifeTech facility in the United Kingdom, where the kits were manufactured and sold worldwide. At trial, a jury returned a verdict for Promega. The district court then granted judgment as a matter of law to LifeTech, and the Federal Circuit reversed that decision. In its divided decision, the Federal Circuit made two holdings. First, it held that § 271(f)(1) does not require a defendant to induce a third party entity to combine the components. Second, it held that a defendant may be found liable for supplying a single component of a patented invention. LifeTech is asking the Supreme Court to address both of these holdings.

With respect to the first holding, whether an entity can induce itself, LifeTech principally argued in its petition that the Federal Circuit misread the plain text of the statute because the ordinary meaning of "induce" is to "influence" or "persuade," an action that is inherently directed to a third party. LifeTech pointed out that "induce" has that precise meaning in another section of the statue, § 271(b). In response, Promega argued that "induce" has another meaning, which is to "bring about" or "cause" something and that the Federal Circuit correctly applied that meaning to § 271(f)(1). Promega argued that this broader definition is correct because the object of "induce" in § 271(f)(1) is an activity — "the combination" — and not a person, as occurs elsewhere in the statute, such as in § 271(b). As a result, only the broader "cause" meaning makes sense. In addition, Promega argued that multinational corporations typically act through local subsidiaries or affiliates, so components exported abroad will seldom be combined abroad by the same legal entity. Finally, Promega argued that policy considerations – namely the enactment of § 271(f)(1) in response to the Supreme Court's decision in Deepsouth Packing Co., v. Laitram Corp., 406 U.S. 518 (1972) (holding that a company did not violate § 271(a) by manufacturing all of the component parts of a patented machine in the U.S. and then shipping those parts overseas for final assembly by a customer) — also supported the broader interpretation. At the invitation of the Supreme Court, the United States recently filed an amicus brief and in it, the United States agreed with Promega that the court should not address this first holding for essentially the same reasons as Promega.

LifeTech also asked the Supreme Court to review the Federal Circuit's second holding, relating to whether the supply of a single component can lead to infringement. LifeTech argued that a single component could not be the basis of infringement since the "substantial portion" referenced in §271(f)(1) refers to quantity, not the subjective importance. LifeTech pointed out that § 271(f)(2) specifically relates to infringement for the supply of a single component, but it requires that the single component be "especially made or especially adapted for use in the invention and not a staple article or commodity of commerce." LifeTech also argued that the Federal Circuit's rule would constitute a problematic extraterritorial extension of § 271(f)(1).

In response, Promega argued that the bright-line rule put forth by LifeTech — that a single component can never give rise to liability — is not warranted. Promega acknowledged that "substantial" had different meanings, but it argued that the qualitative meaning applied here. Promega argued that what constituted a "substantial portion" of the invention was a question of fact, and in this case, one of the LifeTech witnesses had conceded that the Taq polymerase was a "main" or "major" component of the kits. Promega also argued that LifeTech's analysis would lead to absurd results, including liability for shipment of two unimportant components of an invention, but no liability for shipping one particularly important component.

In its amicus brief, the United States agreed with LifeTech that the Federal Circuit's holding was incorrect and argued that it subjects domestic exporters to the threat of liability for supply a single staple article abroad. Although the United States acknowledged that "substantial" has both qualitative and quantitative meanings, it argued that the quantitative meaning applies to § 271(f)(1). Significantly, the term "substantial" is used in connection with the term "all," which also has a quantitative meaning. The United States also repeated LifeTech's other arguments regarding § 271(f)(2) and extraterritoriality.

We expect that the court, as the United States suggests, will not review the first question, but will review the second. In light of the history of § 271(f)(1) and its enactment after Deepsouth, the Federal Circuit's determination that an entity may be liable for inducing (or causing) itself or an affiliate to combine components of an invention abroad is reasonable and supported by sound statutory interpretation principles. In contrast, the Supreme Court will likely be troubled by the fact that Federal Circuit's "single component" rule might subject distributors of a single staple article to worldwide liability. Congress expressly addressed that situation in § 271(f)(2) and determined that it would not result in liability.

WesternGeco v. ION

WesternGeco LLC v. ION Geophysical Corporation, No. 15-1085. WesternGeco filed a petition for certiorari asking the Supreme Court to reverse the Federal Circuit's decision relating to reasonable royalties. WesternGeco said that the decision "vaporiz[ed]" 90 percent of the judgment WesternGeco obtained at trial. The Federal Circuit's decision affirmed the district court's award of a reasonable royalty based on infringement under 35 U.S.C. § 271(f), but reversed the award of lost profits resulting from foreign use. The petition raises the question of whether damages based on "foreign lost profits" are unavailable in cases of patent infringement under § 271(f).

This long-running dispute centers on four patents held by WesternGeco used in geological surveys to search for oil and gas on an ocean floor. WesternGeco commercialized its inventions with the surveying system "Q-Marine." ION Geophsyical Corporation created a similar system, "DigiFIN," which it sells to companies for marine oil field exploration.

In its petition for certiorari, WesternGeco argued that Congress did not intend to limit the remedies available under § 271(f) and that the Federal Circuit's decision renders this section "largely toothless." "It is counterintuitive, to the say the least, that such a 'combination outside the United States' is part of the definition of infringement, yet the presumption against extraterritoriality forbids damages flowing directly from that combination," the petition states.

In opposition, ION argued that the Federal Circuit's decision is consistent with the Supreme Court's decision in Microsoft v. AT&T, 550 U.S. 437 (2007), and that the "presumption against extraterritoriality applies with 'particular force' to patent laws, including § 271(f)." The petition argued that if the presumption against extraterritoriality were not applied, "all infringers could be liable for any damages anywhere in the world where the patent owner can trace some connection between the acts in the United States and claim for damages in other countries."

Given the long application of the presumption against extraterritoriality, as discussed by ION, it seems unlikely that the Supreme Court will review the case. Further, as addressed by ION in its response, four of the five patent claims supporting the lost profits have been held invalid by the Patent Trial and Appeal Board. While not dispositive of the case, this likely counsels against the petition being granted. However,

if the Supreme Court decides to review the case, it could have an impact on life sciences patent litigation involving foreign sales of a product, which frequently occurs for pharmaceutical and biotechnology products.

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