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IP Newsflash

03.25.16

SUPREME COURT CASES

Sequenom Seeks Supreme Court Review of Diagnostic Claims Held Invalid Under § 101

On Monday, March 21, 2016, Sequenom, Inc. filed a petition for writ of certiorari in *Sequenom, Inc. v. Ariosa Diagnostics, Inc., et al.*, No. 14-1139 (Fed. Cir. June 12, 2015). The question posed to the Supreme Court centers around the patentability of diagnostic claims applied to newly-discovered natural phenomena.

The claimed work dates back to 1996, when two doctors discovered paternal cell-free fetal DNA (cffDNA) in maternal blood serum and plasma. With that discovery, the doctors developed a method of testing fetal DNA to determine, among other things, the risk of certain birth defects in a manner far less invasive than conventional techniques, which required DNA samples to be taken directly from the fetus or placenta. The doctors obtained U.S. Patent No. 6,258,540 covering the methods.

Sequenom filed an infringement suit against Ariosa. The district court granted Ariosa's motion for summary judgment that asserted claims were invalid for failure to claim patentable subject matter under 35 U.S.C. § 101. A panel of the Federal Circuit affirmed. The Federal Circuit applied the two-part test set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and held that (1) the asserted claims were directed to naturally occurring phenomena, and (2) the practice of the claimed method did not transform that natural phenomenon into patent-eligible subject matter. Judge Linn concurred, explaining that *Mayo* compelled such an outcome, even though the patent at issue claimed a meritorious invention. The Federal Circuit denied rehearing *en banc* with several judges authoring opinions.

In its petition, Sequenom presents a single issue to the Supreme Court:

> Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery.

Sequenom explains that the doctors did not try to patent cffDNA itself or preempt all uses of it by others. Instead, the doctors claimed an application of their discovery and taught others new combinations and techniques that are now available. According to Sequenom, the Federal Circuit reads *Mayo* so broadly that the only solution is Supreme Court intervention. Sequenom argues that multiple judges and *amici* agree that the result in this case is untenable and that, in light of *Mayo*, only the Supreme Court can fix the problem.

Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, et al., No. 15-__ (Mar. 21, 2016).

- Author: Jason Weil

DISTRICT COURT CASES

Allegedly Cumulative Prior Art Does Not Create An Estoppel Under 35 U.S.C. 315(e)(2)

Clearlamp, LLC filed a patent infringement action against LKQ Corporation (LKQ), who, in turn, counterclaimed seeking declaratory judgments of noninfringement and invalidity. During the pendency of this case, the parties participated in an *inter partes* review (IPR), during which the Patent Trial and Appeal Board found that several claims of the patent-at-issue were unpatentable as obvious in view of three prior art references. In the instant opinion, the Court grants LKQ's motion for summary judgment on invalidity and denies the parties' remaining motions on validity and noninfringement. The key issue addressed by the Court in deciding these summary judgment motions was whether LKQ was estopped under 35 U.S.C. § 315(e)(2) from combining the datasheet of

a prior art product, which was not raised during the IPR proceeding, with the three prior art references used to invalidate other patent claims.

The Court examined the language of § 315(e)(2) and interpreted the phrase "reasonably could have been raised" to mean that the scope of estoppel applies to "prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover." However, rather than establishing that a skilled search would have found the product's datasheet, Clearlamp argued that a skilled search would have found cumulative pieces of prior art. The Court rejected Clearlamp's argument and found that cumulative prior art does not invoke § 315(e)(2) estoppel. Therefore, LKQ could rely on the product's datasheet combined with the three prior art references to establish the asserted claims were obvious.

Clearlamp, LLC v. LKQ Corp., No. 12-cv-2533 (N.D. Ill. Mar. 18, 2016).

- Author: Melissa Gibson

INTERNATIONAL TRADE COMMISSION

ITC ALJ Holds That the Presumption of Validity Does Not Apply to Section 101 Challenges

In granting a summary determination motion, ALJ Lord found that the patent owner's (Owner) patents were directed to ineligible subject matter under 35 U.S.C. § 101. This was the first successful challenge to patentability under Section 101 at the International Trade Commission (ITC) since the Supreme Court's decision in *Alice Corporation Pty. Ltd. v. CLS Bank International*.

Owner's patents were directed to (1) a system for providing feedback for an individual's weight-loss goals, including a wearable sensor that has a processing unit for balancing the wearer's caloric intake and activity levels; and (2) a method and device for setting and modifying targets, such as health and activity targets. In holding that Owner's patents were directed to unpatentable abstract ideas, ALJ Lord applied the two-step test set forth in the Supreme Court's *Mayo* decision: (1) are the claims directed to an abstract idea, and, if so, (2) do the claims "transform that abstract idea into a patent-eligible application." For the first step, the ALJ found that Owner's patents were directed to the abstract idea of collecting and recording information related to weight loss and general health programs. For the second step, the ALJ found that the recited generic sensors and processors did not add sufficient meaningful limitations to the claims. Thus, the ALJ held that the claims are directed to ineligible subject matter.

ALJ Lord stated that, "[f]or the purposes of deciding whether the claims meet the demands of section 101, no presumption of eligibility applies." This is the first time that an ITC ALJ has held that there is no presumption of validity in a Section 101 challenge. Further, ALJ Lord cited to a district court case holding the same, which in turn cited Judge Mayer's concurrence in *Ultramercial*. Judge Mayer's concurrence stated: "Although the Supreme Court has taken up several Section 101 cases in recent years, it has never mentioned — much less applied — any presumption of eligibility. The reasonable inference, therefore, is that while a presumption of validity attaches in many contexts, no equivalent presumption of eligibility applies in the section 101 calculus." (Internal citations omitted). As a result of ALJ Lord's holding, more respondents are likely to challenge patentability under Section 101 at the ITC.

Certain Activity Tracking Devices, Systems, and Components Thereof, Inv. No. 337-TA-963, Order No. 40 (March 3, 2016), Initial Determination Granting Respondents' Motion for Summary Determination that the '546 and '257 Patents Are Directed to Ineligible Subject Matter (ALJ Lord).

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