Morgan Lewis
update
IP Academy Newsletter
www.morganlewis.com

October 18, 2011

Federal Circuit Reverses District Court Decision and Rules that Isolated DNA Sequences Are Patent-Eligible Subject Matter

In a recent decision, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office et al.*, No. 2010-1406 (Fed. Cir. July 29, 2011), the Federal Circuit held that isolated DNA sequences are patent-eligible subject matter under 35 U.S.C. § 101 (Section 101).

Background

On May 12, 2009, the American Civil Liberties Union (ACLU), on behalf of several medical associations, advocacy organizations, physicians, researchers, and individuals, filed a declaratory judgment lawsuit, naming the U.S. Patent and Trademark Office (USPTO) and Myriad Genetics, Inc. (Myriad) among the defendants. The ACLU challenged the validity and constitutionality of Myriad's BRCA1/2 breast cancer gene patents.

Myriad's patents, however, are not unusual or unique in view of the USPTO's present rules and practice and the courts' legal precedents. The USPTO has taken the position that isolated and purified genes are chemical compounds, albeit complex ones, and thus qualify for potential patenting as compositions of matter. Thus, the USPTO's position has been that, although a naturally occurring product (as it exists in nature) cannot be patented, naturally occurring products that have been isolated and purified should be patent-eligible subject matter. For this reason, since 1975, the USPTO has issued more than 15,000 patents with claims containing the word "gene," and current estimates are that approximately 50,000 gene patents have been issued over the years.

Accordingly, in challenging the validity of Myriad's gene patents, the ACLU attacked the legality of at least a significant part of all issued gene patents. Specifically, the ACLU disagreed with the USPTO's current practice and the courts' precedents by stating in its declaratory judgment complaint that "[e]very person's body contains human genes, passed down to each individual from his or her parents. These genes determine, in part, the structure and function of every human body. This case challenges the legality and constitutionality of granting patents over this most basic element of every person's individuality."

District Court Ruling

On March 29, 2010, the U.S. District Court for the Southern District of New York ruled in favor of the ACLU and held that Myriad's claims reciting isolated BRCA1/2 breast cancer genes were invalid.

Section 101 of the U.S. Patent Law defines the categories of statutory subject matter as "any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof." As the U.S. Supreme Court has noted, the terms in Section 101 reciting "manufacture" and "composition of matter," modified by the comprehensive "any," are "expansive terms," and "the language of Section 101 is extremely broad." Specifically, the Supreme Court previously interpreted Section 101 broadly to include "anything under the sun that is made by man." *Diamond v. Chakrabarty,* 447 U.S. 303,309 (1980). The broad reading of Section 101, however, has a limit. In interpreting Section 101, the Supreme Court has recognized three narrow categories of subject matter that fall outside the scope of Section 101: "laws of nature, physical phenomena, and abstract ideas." *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010).

In his opinion, district court judge Robert W. Sweet reasoned that Myriad's challenged claims encompass patent-*ineligible* subject matter because the underlying BRCA genes exist in nature and thus are part of the laws of nature, which are not patentable.

Federal Circuit Decision

On appeal, the Federal Circuit reversed Judge Sweet's decision and ruled that isolated DNA sequences are patent-eligible subject matter under Section 101. In reviewing the district court's decision, the Federal Circuit began by setting out the legal framework established by the Supreme Court for patent-eligible subject matter in important earlier Supreme Court decisions: *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), and *Funk Brother Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). In those cases, the Supreme Court stated that the distinction made "between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature." Relying on the Supreme Court's earlier rulings, the Federal Circuit therefore reasoned that Myriad's claims that "cover molecules that are markedly different—[that is,] have a distinctive chemical identity and nature—from molecules that exist in nature," are drawn to patent-*eligible* subject matter under Section 101.

Specifically, with respect to the isolated DNA sequences, the Federal Circuit majority pointed out that these molecules no longer retain the chemical bond that the naturally occurring genes would have with other genetic materials, stating that the "covalent bonds in this case separate one chemical species from another." The Federal Circuit majority further emphasized that "the PTO has issued patents directed to DNA molecules for almost thirty years," and noted that any change in the law to exclude DNA inventions from the broad scope of Section 101 would have to come from Congress, not the courts.

While reversing the district court's decision on the patentability of isolated DNA sequences, however, the Federal Circuit affirmed the district court's decision on the patentability of some of Myriad's diagnostic method claims. Specifically, the Federal Circuit found that the claims directed to the methods of comparing or analyzing sequences only cover abstract mental processes and therefore fell outside Section 101 in view of the Supreme Court's famous *Bilski* decision.

Based on this decision by the Federal Circuit, isolated DNA sequences remain patent-eligible subject matter. The Federal Circuit, however, affirmed the district court's finding that the diagnostic method claims that are not tied to a machine or a transformative step are invalid.

A copy of the opinion can be found at http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf.

On Remand from the Federal Circuit, the District Court in *Lucent v. Microsoft* Rules Lucent Again Failed to Properly Apply the Entire Market Value Rule

In another chapter of the long saga of the *Lucent Technologies, Inc. v. Microsoft* litigation, the U.S. District Court for Southern District of California (Judge Huff) (Case No. 07-CV-2000) in July granted in part and denied in part Microsoft's motion in limine challenging Lucent's supplemental expert report on damages. The opinion can be found at *Lucent Techs., Inc. v. Microsoft Corp.*, 2011 WL 2728317 (July 13, 2011). The district court excluded the opinions of Lucent's damages expert to the extent they were based on the entire market value of the accused software products. However, the district court stated it would revisit this ruling at trial if Lucent meaningfully apportions the per-unit price of the accused product.

Background

Lucent sued Gateway alleging infringement of "the Day patent," which the Federal Circuit has described as "generally directed to a method for entering information into fields on a computer screen without using a keyboard." Microsoft voluntarily joined the lawsuit and a jury trial was held in the U.S. District Court for the Southern District of California. At trial, Lucent alleged that four Microsoft products indirectly infringed the Day patent. Lucent sought reasonable royalty damages of $561.9 million "based on an 8% royalty [on sales of] the accused software products" and Microsoft countered that "a lump-sum payment of $6.5 million" adequately compensated Lucent. The jury returned a verdict awarding Lucent a lump-sum royalty payment of more than $350 million dollars. Microsoft appealed, arguing that the verdict was based on an improper application of the entire market value rule and was not supported by "substantial evidence." On September 11, 2009, the Federal Circuit issued its opinion in *Lucent Techs. v. Gateway, Inc.*, 580 F.3d 1301, vacating the $350 million dollar award against Microsoft and remanding for a new trial solely on the issue of damages because it found that the original verdict was not supported by substantial evidence.

Valuation of Damages

Upon remand to the district court, the parties submitted new damages reports in light of the Federal Circuit's opinion. On December 7, 2010, each of the parties filed motions in limine to challenge the damages report of the other party. However, while the district court was considering these motions, the Federal Circuit issued its opinion in *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011).

In *Uniloc*, the Federal Circuit clarified that to be able to use the entire market value of the product, it is not enough to simply assert a low enough royalty rate without showing that the patented feature is the basis—or a substantial basis—for consumer demand. *See Uniloc*, 632 F.3d at 1319–20. Accordingly, the Federal Circuit rejected the argument that "the base used in a running royalty calculation can always be the value of the entire commercial embodiment, as long as the magnitude of the rate is within an acceptable range as determined by the evidence." *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1338–39 (Fed. Cir. 2009). If the patentee cannot meet the test for the entire market value rule, then "the patentee . . . must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features." *Uniloc*, 632 F.3d at 1318. In other words, unless a party satisfies the entire market value test, a patentee seeking damages for a component cannot use the entire market value of the larger product as a royalty base.

In light of the *Uniloc* opinion, the district court permitted the parties to update their damages experts' reports. On May 13, 2011, after the parties submitted their revised experts' reports in light of the *Uniloc* decision, the parties filed another set of motions in limine challenging the damages reports of each party. On June 16, 2011, the district court issued an order denying in part and granting in part the motions. In its order regarding Lucent's damage calculations, the court stated that "[i]n summary, the Court concludes that Lucent fails to properly apportion its damages calculation to separate between the patented features and unpatented features of Microsoft Outlook. Lucent must perform an additional apportionment in order to introduce a proper royalty base for its damages calculation or meet the three factored test for the entire market value rule if it seeks to use all revenue from infringing copies of Outlook as its base." On June 23, 2011, Lucent's damages expert supplied his supplemental expert report. Microsoft again brought a motion in limine to challenge the Lucent expert's supplemental report in violation of *Daubert* and the entire market value rule.

The district court noted that "[t]he entire market value rule allows a patentee to assess damages based on the entire market value of the accused product only where the patented feature creates the 'basis for customer demand' or 'substantially create[s] the value of the component parts,'" *Uniloc*, 632 F.3d at 1318, or where the patented feature was of "such paramount importance that it substantially created the value of the component parts," *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549 (Fed. Cir. 1995). Microsoft alleged that Lucent's supplemental expert report still failed to properly apportion. The district court agreed with Lucent. Lucent's supplemental damages report purports to do a per-unit analysis rather than basing the analysis on the entire product revenue. Nevertheless, the district court stressed that unless the patentee can show that the component was the basis or a substantial basis for consumer demand, then "the patentee . . . must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features." *Uniloc*, 632 F.3d at 1318.

The district court found that Lucent's per-unit analysis still relied solely on the whole per unit price of Outlook—$67.39—without apportioning this to account for all the other unpatented features that consumers use besides the Day patent technology even when consumers invoke the Day patent methods. Lucent contented that it should be allowed to introduce the entire market value of Outlook because such consideration is rooted in Microsoft's license practices. The district court, however, noted that while these licenses may be relevant to several of the *Georgia-Pacific* factors used to determine a reasonable royalty, Lucent still needed to further apportion by some measure to separate between the patented and unpatented features, as tied to the facts of the case and economic realities. The district court concluded that Lucent had failed to apportion by any further measure, and therefore excluded portions of Lucent's damages expert's report for failure to apportion.

For more information on the issues discussed in this Newsletter, please contact any of the following Morgan Lewis attorneys:

Houston

C. Erik Hawes	713.890.5165	ehawes@morganlewis.com
David J. Levy	713.890.5170	dlevy@morganlewis.com

Washington, D.C.

Robert W. Busby	202.739.5970	rbusby@morganlewis.com
Robert J. Gaybrick	202.739.5501	rgaybrick@morganlewis.com

About Morgan Lewis's Intellectual Property Practice
Morgan Lewis's Intellectual Property Practice consists of more than 150 intellectual property professionals. We represent and advise clients concerning all aspects of intellectual property: patents, trademarks, and copyrights; intellectual property litigation; intellectual property licensing; intellectual property enforcement programs; trade secret protection; related matters involving franchises, the Internet, advertising, and unfair competition; outsourcing and managed services; and the full range of intellectual property issues that arise in business transactions.

About Morgan, Lewis & Bockius LLP
With 22 offices in the United States, Europe, and Asia, Morgan Lewis provides comprehensive transactional, litigation, labor and employment, regulatory, and intellectual property legal services to clients of all sizes—from global Fortune 100 companies to just-conceived startups—across all major industries. Our international team of attorneys, patent agents, employee benefits advisors, regulatory scientists, and other specialists—nearly 3,000 professionals total—serves clients from locations in Beijing, Boston, Brussels, Chicago, Dallas, Frankfurt, Harrisburg, Houston, Irvine, London, Los Angeles, Miami, New York, Palo Alto, Paris, Philadelphia, Pittsburgh, Princeton, San Francisco, Tokyo, Washington, D.C., and Wilmington. For more information about Morgan Lewis or its practices, please visit us online at www.morganlewis.com.