



IP LITIGATION

Locke Lord's Looking Ahead 2011

Patents, DNA Sequences and *Twombly*

New Standard For Invalidity – The Supreme Court has granted *certiorari* in a case that may affect the long established clear and convincing evidence standard to invalidate patents.

In the case, *i4i v. Microsoft*, the specific issue is whether this standard, or a lower standard of preponderance of the evidence (balancing evidence on a scale) should apply to art that was not considered by the Patent Office. However a broader issue is also implicated as to whether the lower standard should apply to all art or indeed all statutory grounds for invalidating a patent, including improper inventorship, written description and enablement. While predicting the outcome of an appeal is difficult, commentators seem to think the Court will do something; otherwise it would not have granted cert. At the limits, the Court may just treat the Patent Office as any other agency of the administrative branch of the Government, entitled to no more deference than any other agency under the Administrative Procedures Act. Stay tuned for this one, as it could result in a seismic shift in the patent law.

Discovery of a purified compound is patentable subject matter even though its impure form was known and functioned the same as the natural compound

Biotech

The whole family of patents on unmodified DNA sequences may be at risk. In the first statutory subject matter challenge to such patents, Judge Sweet of the Southern District of New York in *Association for Molecular Pathology v. USPTO* granted summary judgment holding one such patent (on DNA sequence markers for risk of breast and ovarian cancer and methods of detecting genetic mutation by comparing or analyzing gene sequences) to be invalid under the product of nature doctrine. 702 F. Supp. 2d 181, 236–38 (S.D.N.Y. 2010). An appeal to the Federal Circuit should be decided in 2011, and a further appeal to the Supreme Court is likely.

At first blush, this case seems to be a departure from the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980), where it held that the discovery of new bacterium through independent genetic modification was patent eligible subject matter. Here however, according to the District Court, the claims deal with isolation of unmodified DNA, whose isolated form functions similarly to its non-isolated form. At present, the Federal Circuit has treated DNA as chemical compounds, *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991), and it is well established that the discovery of a purified compound is patentable subject matter even though its impure form was known and functioned the same as the natural compound. *In re Bergy*, 596 F.2d 952, 996 n.4 (C.C.P.A. 1979); *In re Bergstrom*, 427 F.2d 1394, 1401–02 (C.C.P.A. 1970). Therefore, appellate review of the *Molecular Pathology* decision will undoubtedly force the Federal Circuit, and possibly the Supreme Court, to reconvene on these prior holdings in their attempt to determine the fate of patent claims on unmodified DNA sequences.

The PTO May Lack the Green to Go Green

In the budget squeeze, money will likely again be taken from PTO user fees to fund other programs in 2011. This may well have an effect on the quality and timeliness of prosecution. Thus the PTO's announced plan to accelerate prosecution of "green" applications may be a zero sum game.

Grokster... should be of interest to both patent and copyright practitioners in the area of inducement of infringement of intellectual property

Indirect Infringement

On October 12, 2010, the Supreme Court granted a writ of certiorari in *Global-Tech Appliances, Inc. v. SEB S.A.* to re-review the state of mind requirement for inducement of infringement under 35 U.S.C. § 271(b). This issue will not be the first time the Supreme Court faced the legal quagmire that is inducement of infringement of intellectual property. The Court had encountered such a question in reference to copyright infringement in *MGM Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005). In fact, the Federal Circuit's current inducement of infringement practice stems from the Supreme Court's *Grokster* ruling.

As the Supreme Court prepares itself to speak on the legal standard that should apply to the Federal Circuit's current inducement practice under the patent statute, it is likely to revisit its *Grokster* decision as well. Therefore, this case should be of interest to both patent and copyright practitioners in the area of inducement of infringement of intellectual property.

Patent Damages

With Congressional gridlock on larger issues likely in 2011, passage of one of the competing patent reform bills will be problematic. The Federal Circuit started the year with a prophetic January 4, 2011 decision, *Uniloc USA, Inc. v. Microsoft Corp.* The widely used "Rule of Thumb" (patent royalties equal to 25 percent of profits) was held inadmissible under *Daubert* and the Federal Rules of Evidence, even as a starting point to be adjusted up or down by the Georgia-Pacific factors. The Court ordered a new trial on damages on this basis and it also affirmed the district court's grant of a new trial for Uniloc's violation of the Entire Market Value Rule. Since these two Rules have often been the basis for damages on small components or features of a combination, expect more *Daubert* challenges to patent damages experts who fail to present sufficient data or a rigorous methodology to determine damages in these types of cases.

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Patent and Antitrust

Another trend is the increase in antitrust counterclaims in patent cases. Some recent cases that were dismissed illustrate the impact of the *Twombly* heightened pleading standard for antitrust cases. For example, harm to competition, not just to the defendant competitor, must be shown. And for monopolization claims, support for a market definition is needed. But these dismissals in no way counter the trend of antitrust assertion. They just illustrate that such claims must be pled correctly to avoid being prematurely dismissed.

Inequitable Conduct

Another trend in Federal Circuit has been to raise the bar for the defense of inequitable conduct, which can render a patent unenforceable. In *Therasense, Inc. v. Becton Dickinson & Co.*, the Federal Circuit *en banc* asked for briefing on the proper test for this defense, resulting in a flurry of amicus briefs. Oral argument occurred on November 9, 2010, and a decision is expected in 2011. Issues in play include: what level of proof is required to show that the patent would not have issued “but for” the conduct; whether using a preponderance of the evidence standard is best to judge materiality; and to what extent would “sliding scale” usage of materiality be available to infer intent. While predicting the outcome of Federal Circuit decisions is difficult, it seems from the transcript of the oral argument that the Court is moving towards a more demanding standard for proving inequitable conduct.

International Trade Commission (“ITC”) Domestic Industry

Patent cases in the ITC require, among other things, an affected domestic industry. IP licensing can be such an industry under the statute. But to show the industry’s robustness, a non-practicing entity (“NPE”) involved in licensing would be well advised to show it follows classic business principles: (1) the cost of pursuing licensees is a business expense or investment; (2) licensing fees are revenues resulting from the expense or investment; and (3) the difference can be characterized as either an operating profit or a return on investment. A defendant facing an ITC claim by an NPE should consider discovery of these elements, even though there are no damages in the ITC. Expect to see some of these issues arise in 2011.

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