October 2011: Appellate Litigation Update

Overview of Intellectual Property Cases Before the Supreme Court in the October 2011 Term: In keeping with its recent trend, the Supreme Court has so far agreed to hear one copyright and several patent cases during the October 2011 Term.

Golan v. Holder, No. 10-545, was argued October 5, 2011, and addressed a copyright law issue. It concerns the constitutionality of Section 514 of the Uruguay Round Agreements Act ("URAA"). Congress enacted the URAA in 2004 to implement Article 18 of the Berne Convention for the Protection of Literary and Artistic Works, which requires that member countries afford the same copyright protection to foreign authors as they provide to their own authors. Because certain works by foreign authors had already entered the public domain in the United States by virtue of failures to comply with prior U.S. copyright formalities, lack of subject matter protection, or lack of national eligibility, Section 514 of the URAA restored the authors' copyrights in those foreign works (with certain time-limited protections afforded to persons, called "reliance parties," who were exploiting the foreign works in the United States). In other words, works that were in the public domain would now become subject to U.S. copyright protection.

A group of persons who have relied on public domain works for their livelihoods (including orchestra conductors, educators, performers, publishers, film archivists, and motion picture distributors) brought suit in the U.S. District Court for the District of Colorado, challenging Section 514 of the URAA as unconstitutional under the Copyright Clause of the U.S. Constitution, *see* U.S. Const., art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"), and the First Amendment. The district court ruled in favor of the government, and the Tenth Circuit affirmed in a 2007 decision as to the Copyright Clause and a 2010 decision as to the First Amendment. Among the governmental interests cited by the Tenth Circuit in rejecting the First Amendment challenge was that U.S. protection of foreign works is necessary to ensure that other countries extend the protection of their copyright laws to U.S. works.

The Supreme Court granted certiorari on both the Copyright Clause issue and the First Amendment issue. The case has attracted the attention of numerous *amici curiae* on both sides. A decision is expected by June 2012.

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, No. 10-844, scheduled for oral argument on December 5, 2011, involves the interpretation of the counterclaim provision of the Hatch-Waxman Act. The Hatch-Waxman Act, as described by the Federal Circuit, seeks to balance the goal of encouraging the development of new drugs and methods with the potentially conflicting goal of facilitating introduction of low-cost generic copies of those drugs and methods. The Act provides a streamlined approval process, known as an abbreviated new drug application ("ANDA") for generic manufacturers, which allows the generic manufacturer to rely on the safety and efficacy studies of an already-approved drug upon a showing of bioequivalence between the approved drug and generic drugs. The ANDA process includes a certification by the generic manufacturer that the approved drug is not covered by a patent, the approved drug is covered by a patent that has expired or will expire, or, as relevant here, the patent is invalid or will not be infringed by the proposed generic drug. The last option, if invoked by the generic manufacturer, is deemed an act of patent infringement and allows the patent owner to file suit, and in turn allows the generic manufacturer to file a counterclaim challenging the accuracy of the "patent information" submitted to the FDA.

The scope of the counterclaim provision is at issue. Novo owns a patent that claims one of the three methods for using repaglinide to treat type 2 diabetes. Caraco, the generic manufacturer, submitted an ANDA asserting that Caraco was not seeking approval for the method claimed by Novo's patent, and the FDA indicated that it would approve Caraco's proposed drug label carving out the Novo method. Novo then asked the FDA to broaden Novo's use code narrative for its patent so that it would no longer be specific to the one method claimed by Novo; that in turn led the FDA to change its initial position and reject Caraco's carve-out label. Without the carve out, Caraco's product would infringe Novo's patent. Caraco counterclaimed, alleging that the new use code narrative was overbroad because it improperly suggested that Novo's patent covered all three approved methods of using repaglinide to treat type 2 diabetes. The district court granted summary judgment in favor of Caraco on its counterclaim. A panel of the Federal Circuit reversed, over the dissent of Judge Dyk. The majority reasoned that the statute limits counterclaims to those alleging that the "patent does not claim … an approved method of using the drug." The majority held that Novo's method was "an approved method" and that the alleged overbreadth of the use code narrative was irrelevant. Judge Dyk argued that the majority's approach left the generic manufacturer without a remedy and was contrary Congress' purpose in ending the law.

Several *amici curiae* have filed briefs in support of Caraco, including the United States, Representative Henry Waxman, and the Generic Pharmaceutical Association.

Ma*yo Collaborative Servs. v. Prometheus Labs., Inc.,* No. 10-1150, scheduled for argument on December 7, 2011, was initially decided by the Federal Circuit in 2009. The Supreme Court then vacated that decision and remanded it to the Federal Circuit for further consideration in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). In *Bilski*, the Court held that the "machine-or-transformation" test is not the sole, definitive test for determining the patentability of a process under 35 U.S.C. § 101. (The machine-or-transformation test deems a process eligible for patent protection if it (1) is tied to a particular machine or apparatus; or (2) transforms a particular article into a different state or thing.) Instead, the Court resolved *Bilski* by resorting to the principle, established by its earlier decisions, that abstract ideas are not patentable. Mayo was re-decided by the Federal Circuit following the remand and is now back before the high court.

Prometheus is the exclusive licensee of patents that claim methods for determining the optimal dosage of thiopurine drugs used to treat autoimmune diseases. The claimed methods involve administering a drug to a patient and then determining the levels of the drug's metabolites in the subject. The measured metabolite levels are then compared to pre-determined metabolite levels, allowing the level of drug to be corrected to minimize toxicity and maximize treatment efficiency in the particular patient. The patents were not directed to the drugs, or to any novel diagnostic test kit. Instead, Prometheus marketed a test that relied upon the levels of drug metabolites found in the human body. Mayo purchased that test for a time, but then announced that it would use its own test, which measured the same metabolites but looked to different benchmark levels to determine toxicity. Prometheus sued Mayo for patent infringement, and Mayo responded by arguing that the technology was not patentable under § 101 because the patents claimed natural phenomena involving the correlation between drug metabolite levels, on the one hand, and efficacy and toxicity, on the other.

The district court accepted Mayo's argument and granted summary judgment that the patents were invalid. The Federal Circuit initially reversed, applying the machine-or-transformation test and finding that the administering-of-the-drug and determining-of-metabolite-levels steps were transformative and not merely data-gathering steps, and holding the claims did not wholly preempt the use of the recited correlations between metabolite levels and drug efficacy or toxicity. On remand after *Bilski*, the Federal Circuit adhered to its pre-*Bilski* decision, explaining this time that it would not rely solely on the machine-or-transformation test, but additionally on the fact that the claims at issue did not preempt every use of the natural correlations between drug metabolites and efficacy/toxicity, but rather utilize them in a series of specific steps that involve particular methods of treatment. The Federal Circuit also found transformation in that the administered drug is transformed by the human body into its metabolites; even though this is a natural phenomenon, it is preceded by the administration of a drug, which is not a natural phenomenon.

The United States has filed an *amicus* brief arguing that the Federal Circuit correctly held that the subject matter is patentable, but that the patents are likely invalid because they fail the novelty and nonobviousness requirements of 35 U.S.C. §§ 102 and 103. Quinn Emanuel has filed an *amicus* brief on behalf of two leading blood testing laboratories, ARUP and LabCorp, arguing that the subject matter is not patentable; specifically, Quinn Emanuel's brief argues that the patents cross the line in patenting natural phenomena by asserting exclusive rights over the process of providing a medicine and observing the results – a biochemical reaction that occurs in the human body.

Kappos v. Hyatt, No. 10-1219, presents the questions (1) whether a plaintiff who files a civil action in federal district court against the Director of the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. § 145 may introduce new evidence that could have been presented to the PTO; and (2) whether, if the plaintiff is allowed to introduce new evidence under Section 145, the district court may decide de novo the factual questions to which the evidence pertains, without giving deference to the PTO's decision.

A patent applicant who is dissatisfied with a PTO decision may appeal the decision to the Federal Circuit or file an action in federal district court to determine whether the applicant "is entitled to receive a patent for his invention … as the facts in the case may appear." 35 U.S.C. § 145. An *en banc* Federal Circuit majority concluded that there is no limitation on an applicant's right to introduce new evidence in district court (apart from the evidentiary limitations applicable in all civil actions). The majority further held that the district court may consider whether the new evidence is inconsistent with any evidence or proceedings before the PTO in determining what weight to give it. The majority additionally held that if the applicant does not introduce new evidence that was not before the PTO, the district court should apply the Administrative Procedure Act's deferential "substantial evidence" standard.

Judge Newman concurred as to the holding that an applicant may introduce new evidence in the district court, but dissented from the holding that if an applicant does not introduce new evidence, the "substantial evidence" standard of review applies. Instead, Judge Newman argued that the district court should decide the case *de novo*.

Judges Dyk and Gajarsa dissented, arguing that a Section 145 proceeding allows only for introduction of live testimony that was presented in written form in the PTO, not to any other introduction of new evidence. Further, the dissenters argued that the deferential "substantial evidence" standard applies in all Section 145 cases.

Intel Corp. and Verizon Communications Inc. have filed *amicus* briefs in support of petitioner, the Director of the PTO (who is represented by the Solicitor General's Office); several *amicus* briefs in support of neither party, including one by the Intellectual Property Owners Association, have also been filed. The respondent's brief is due October 31st with the amicus briefs supporting the respondent to follow shortly thereafter.