The Legal Intelligencer

Justices Take on Thorny Intellectual Property Cases

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Grey Market Deals

In 2007 and 2008, a Thai immigrant named Supap Kirtsaeng imported educational textbooks published in Thailand by Wiley Asia, a wholly-owned foreign subsidiary of the American textbook manufacturer John Wiley & Sons Inc. Kirtsaeng sold these textbooks on eBay.com and other similar websites to help finance his own education, amassing almost $100,000. Such sales are commonly referred to as "grey market" sales because of their uncertain legality.

When Wiley caught wind of the scheme, it sued Kirtsaeng for copyright infringement. Kirtsaeng countered that the textbooks had been published and purchased under a valid license in Thailand, and thus Wiley's suit was precluded under the so-called "first sale doctrine." This doctrine holds that a copyright owner's distribution rights in a given product are exhausted after an initial lawful sale or transfer. Wiley countered that the codification of the first-sale doctrine in the Copyright Act applied the doctrine only to copies "lawfully made under this title," and that such language could only be understood to apply to copies made in jurisdictions in which the title was law. The trial court and the U.S. Court of Appeals for the Second Circuit agreed.

This precise issue has come before the court before when in *Costco Wholesale v. Omega S.A.*, 131 S. Ct. 565 (2010), the court considered the validity of the first-sale doctrine as applied to imported watches. In that case, newly-confirmed Justice Elena Kagan recused herself on the basis of her work as former solicitor

general. The remaining eight justices reached a 4-4 split decision.

Understandably, all eyes were on Kagan at oral arguments this October. Kagan, however, did not show her hand, grilling both sides with tough questions. It should not surprise anyone if Kagan authors the majority opinion in this case — a common strategy of the assigning justice is to assign authorship to the most important (read: most tentative) justice in the majority as a way to solidify that justice's vote.

The Arc of a Covenant

The court also recently heard a case on an important procedural question concerning intellectual property rights. In the field of trademark law, it is common practice for an alleged trademark or patent infringer to respond to a lawsuit with a counterclaim challenging the validity of the trademark or patent at issue. In *Already v. Nike*, 663 F.3d 89 (2d Cir. 2011), cert. granted, 80 U.S.L.W. 3707 (U.S. June 25, 2012) (No. 11-982), Nike sued Already over a sneaker Already LLC manufactured. In response to Nike's lawsuit, Already challenged the validity of the relevant trademark. Apparently thinking the risk of having its trademark declared invalid outweighed any damages it might incur from Already's alleged infringement, Nike delivered a "covenant not to sue" to Already. Finding that the covenant rendered Already's counterclaim moot and thus nonjusticiable, the district court dismissed the counterclaim, and the Second Circuit affirmed. Meanwhile, however, the Ninth Circuit has issued countervailing authority on the same question.

The scope of Nike's covenant is the key issue. Because the Lanham Act gives a potential infringer a cause of action only when it has "reasonable apprehension of liability" arising from such infringement, the justices at oral argument in November pressed Already's counsel to explain what apprehension could exist once Already received the very broad protections of the covenant. Already's counsel suggested that the limitations imposed on Already by the covenant were injurious in and of themselves. Specifically, he argued that the necessity of determining which potential new sneaker designs were protected by the covenant, and which may potentially fall outside its purview, created the necessary apprehension on Already's part to keep their counterclaim alive. Justice Anthony Kennedy, for one, seemed intrigued by this argument, suggesting that the only way Already may be able to determine an answer to that question would be to consult Nike and reveal its intended future plans, a process that would be "to say the least, patronizing, and probably quite injurious, in and of itself."

Escape Hatch

In *Federal Trade Commission v. Watson Pharmaceuticals*, 677 F.3d 129 (11th Cir. 2012), cert. granted, 81 U.S.L.W. 3324 (U.S. Dec. 7, 2012) (No. 12-416), the Supreme Court will consider whether it is presumptively anticompetitive for a name-brand pharmaceutical corporation to deter potential generic-brand competitors with generous settlement payments. In 1984, Congress passed the Hatch-Waxman Act, which, among other things, allowed generic manufacturers to challenge the validity of brand-name pharmaceutical patents without incurring the costs of market entry. However, brand-name pharmaceutical companies soon found a clever way to protect against such challenges — by settling with the generic manufacturers. Unlike a typical settlement between a patent holder and a potential infringer, though, the payments provided by these settlements flowed from the patent holder to the potential infringer, thus earning the moniker "reverse payment settlements."

The Federal Trade Commission quickly became suspicious of such settlements, alleging that their primary function was to dissuade potential generic manufacturers from entering the market and producing generic drugs. The FTC charged that such settlements should be regarded as prima facie evidence of anticompetitive behavior.

Courts were not so sure. After all, the patent holder held a legitimate patent, and thus patent law itself granted the holder a monopoly on the market. As long as the settlement between the name-brand and generic manufacturers did not exceed the scope of this patent, did such settlements really introduce any cognizable injury to the market that would be subject to antitrust review? This reasoning has persuaded several courts.

The FTC, meanwhile, argued that this line of reasoning rests on a critical assumption that may prove faulty: that the patent holder in fact holds a valid patent. Rather than take the patent at face value, the FTC has argued, courts should scrutinize the patent itself when evaluating whether reverse payment settlements are anticompetitive. In fact, because there is always a certain probability that a given patent will be declared invalid, the patent's scope should be evaluated in terms of its "expected value." To do otherwise allows the patent holder to buy out potential infringers before they even have a chance to challenge the validity of the patent. As the Third Circuit has suggested, this approach "nominally protects intellectual property, not on the strength of a patent holder's legal rights, but on the strength of its wallet."

If the Supreme Court sides with the FTC and invalidates the use of reverse payment settlements, a significant level of generic competition may soon be introduced to the pharmaceutical market, which indeed was Congress' purpose in enacting the Hatch-Waxman Act in the first place.

A Blueprint For DNA Patenting?

The Supreme Court has also turned its attention to a question that has concerned not only court watchers, but also journalists, politicians, biologists, philosophers, theologians and more: Can human DNA be patented?

The question has come to the Supreme Court in a scenario that is increasingly common. Over the course of decades, Myriad Genetics, in conjunction with the University of Utah, developed a technique for isolating and sequencing genes in the human genome known as BRCA1 and BRCA2. BRCA1 and BRCA2 help produce proteins that are capable of repairing chromosomal damage in unhealthy cells. Researchers have identified hundreds of mutations in the BRCA1 and BRCA2 genes, many of which are predictive of an increased risk of cancer. Myriad used its technique for isolating and sequencing the gene to produce a highly effective test for determining women's risk of certain breast and ovarian cancers. Relying on a patent for this technique, Myriad has successfully marketed its cancer screening test, and by 2012 was generating over $500 million in revenue per year.

The Association for Molecular Pathology, along with researchers at various universities interested in studying the isolated gene, sued Myriad. The lawsuit claimed that the patent over an isolated gene was an invalid attempt to patent what was essentially a law of nature, which under Supreme Court precedent is unpatentable. The Supreme Court accepted certiorari and docketed the case, but then remanded the case in light of its early 2012 decision of *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012). After the Federal Circuit issued a nearly identical decision on remand, the Supreme Court again accepted certiorari and docketed the case for oral arguments.

The petitioners in *Association for Molecular Pathology v. Myriad Genetics*, 689 F.3d 1303 (Fed. Cir. 2012), cert. granted, 81 U.S.L.W. 3305 (U.S. Nov. 2012) (No. 12-398), had found some hope in *Mayo*. In that case, the Supreme Court held that a method of determining the proper dosage of a certain drug was not patentable. In doing so, the court held that the process identified by the patent holder simply identified a law of nature concerning how certain drugs were metabolized by the human body, and then instructed physicians to apply that law to determine the correct dosage of the relevant drug. The court held that such instructions did not sufficiently transform "unpatentable natural correlations into patentable applications of those regularities."

The Federal Circuit, however, agreed with Myriad that its process was sufficiently distinct from the one examined in *Mayo*. The court held instead that "isolated DNA molecules are distinct from their natural existence as portions of larger entities," and that the process used to evaluate such molecules was thus not simply an application of a law of nature.

In its petition for certiorari, the petitioners asserted that DNA found in nature and isolated DNA do not have "markedly different characteristics" inasmuch as they contain the same protein-coding materials. Moreover, the petitioners asserted that the process of isolating DNA, and the process used for reading such DNA, is the same across all such molecules and one that is commonly used. As such, the only concept claimed within Myriad's patents were the DNA codes for the BCRA proteins — something found in nature, albeit in a

slightly different form.

In the end, the Supreme Court will be faced, as it often is in patent cases, with a conflict between incentivizing innovation and allowing access to new and vital technologies. However the court resolves the complicated technical, scientific, ethical and legal principles at stake in the case, it is clear that its decision, if it in fact addresses the merits of the case, will have enormous repercussions: To date, there are more than 2000 isolated human genes that have been patented in the United States. •

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