IDEAS ON INTELLECTUAL PROPERTY LAW

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The final round

Supreme Court addresses patentability of genes

It's a case that had the biotech industry on pins and needles for years. At stake in *Association for Molecular Pathology v. Myriad Genetics Inc.* was whether naturally occurring DNA segments were patentable. In the final round, which made headlines this past June, the U.S. Supreme Court found that they were not. This finding, however, didn't apply to synthetic, man-made DNA.

Subject matter

Myriad Genetics holds seven patents related to a test for mutations in BRCA1 and BRCA2 genes. Mutations in these genes can increase an individual's risk of developing breast and ovarian cancers. In 1998, Myriad started sending demand letters to providers of clinical BRCA testing services. A broad consortium of plaintiffs — including testing services, researchers, medical organizations and patients — responded by seeking a declaratory judgment that several claims in Myriad's patents were invalid because they covered subject matter that's ineligible for patents.

The patent claims included "composition" claims related to isolated DNA sequences, which are created by extracting DNA from cells, and complementary DNA (cDNA), which is created synthetically. If valid, the patents would give Myriad the exclusive right to isolate an individual's BRCA genes and the exclusive right to synthetically create BRCA cDNA.

The district court invalidated all of the claims because they covered products of nature. The ruling sent a shock wave through the biotech community, which had long understood that such claims *were* patentable.

Delicate balance

In 2011, a three-judge panel of the Federal Circuit reversed the district court's decision. The Supreme Court subsequently vacated the Federal Circuit's decision and sent the case back for further consideration. The Federal Circuit again found both isolated DNA and cDNA patent-eligible.

Upon hearing the case yet again this year, the Supreme Court noted that laws of nature, natural phenomena and abstract ideas are basic tools of scientific and technological work that lie beyond the domain of patent protection. However, the Court said, this rule against patents on naturally occurring things has limits, because patent protection strikes a delicate balance between: 1) creating incentives for creation, invention and discovery, and 2) impeding the flow of information that might spur invention.

The Supreme Court applied this standard to determine whether Myriad's patents claim a "new and useful … composition of matter" or claim naturally occurring phenomena. It concluded that Myriad's DNA claim fell within the law of nature exception to patentability. The company's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes.

The Court further pointed out that Myriad didn't create or alter either the genetic information encoded in the genes or the genetic structure of the DNA.

The biotech company found an important and useful gene, but "groundbreaking, innovative, or even brilliant discovery" doesn't by itself satisfy the patentability test. Merely finding the location of the BRCA1 and BRCA2 genes didn't render the genes patentable new compositions of matter.

Natural vs. unnatural

The Supreme Court also found that Myriad's claims weren't saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together. The claims weren't expressed in terms of chemical composition, nor did they rely on the chemical changes resulting from the isolation of a particular DNA section. Rather, the patent claims focused on the genetic information encoded in the genes.

The Supreme Court concluded that Myriad's DNA claim fell within the law of nature exception to patentability.

Notably, the Court dismissed Myriad's argument that the Patent and Trademark Office's (PTO's) past practice of awarding gene patents was entitled to deference. Myriad cited an earlier Supreme Court case in support of this argument but, as the Court observed, in that case Congress had endorsed a PTO practice in subsequent legislation. Congress hasn't endorsed the practice of awarding gene patents.

However, the Supreme Court found that cDNA *was* patentable because it *isn't* a product of nature. According to the Court, cDNA didn't present the same obstacles to patentability as naturally occurring, isolated DNA segments because "the lab technician unquestionably creates something new when cDNA is made." cDNA retains some naturally occurring components of DNA but is distinct from the DNA from which it was derived.

Narrow decision

The Supreme Court took pains to note the narrowness of its decision in *Association for Molecular Pathology* — or "what is not implicated" by the ruling. It observed that the case before the Court didn't involve any method claims, patents on new applications of knowledge about BRCA1 or BRCA2 genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. For a specific look at one of these items, see "What about the method claims?" below. ❍

What about the method claims?

In *Association for Molecular Pathology v. Myriad Genetics Inc.* (see main article), the U.S. Supreme Court considered only Myriad's composition claims for the isolated DNA sequences and cDNA. Yet the original lawsuit also challenged a screening method claim and 11 method claims covering methods of analyzing or comparing a patient's BRCA sequence with the normal sequence to identify the presence of cancer-predisposing mutations. Those claims weren't pursued before the high court, so the Federal Circuit's earlier rulings on their validity stand.

The Federal Circuit found that the methods for analyzing or comparing two gene sequences to identify mutations weren't patentable because they were only mental processes. Such diagnostic methods, the court said, essentially claim unpatentable natural laws.

But the court ruled that the method for screening potential cancer therapeutics via changes in cell growth rates *was* patentable. The method, it found, applies certain steps to a man-made, non-naturally occurring transformed cell — and the transformed, man-made nature of that cell made the claim patentable.

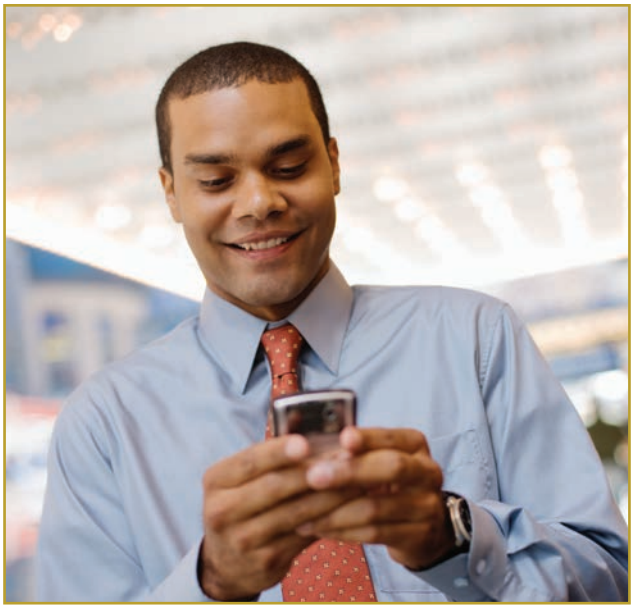
Are wireless carriers liable for user infringement?

Today's technology makes it easier than ever to infringe copyrighted material. But can the providers of that technology be found liable for its users' infringement? That was the question addressed by the U.S. Court of Appeals for the Ninth Circuit in *Luvdarts, LLC v. AT&T Mobility*.

Sent message

The defendants in *Luvdarts* are mobile wireless carriers that own Multimedia Messaging Service (MMS) networks. Mobile phones use MMS networks to send and receive messages that include multimedia content.

Luvdarts LLC sells commercial multimedia-messaging content — such as games, news, coupons and greeting cards — designed to be transmitted over MMS networks. Luvdarts attaches a notice to the content that says it may be shared only once, but there are no technical impediments to prevent users from forwarding a purchased message multiple times. Not surprisingly, users have ignored the notice and reshared content without permission or compensation.



Luvdarts sued the carriers for copyright infringement. It alleged that they vicariously infringed Luvdarts' content and induced others to infringe the content. The district court dismissed the case before trial, and Luvdarts appealed to the Ninth Circuit.

Fatal error

Vicarious infringement occurs when one profits from direct infringement while declining to exercise a right to stop or limit the infringement. The carriers would be vicariously liable here if they had both:

1. The right and ability to supervise the infringing activity, and

2. A direct financial interest in the activity.

Because the first prong wasn't satisfied, the Ninth Circuit didn't consider the second prong.

The court explained that the "right and ability to supervise" must be evaluated in the context of a system's "current architecture."

Luvdarts conceded that the carriers currently have no way of supervising the use of their networks for copyright infringement. Instead, the company alleged that the carriers could establish "a system" giving them the right and ability to supervise the infringing activity.

But, the court explained, the "right and ability to supervise" must be evaluated in the context of a system's "current architecture." Luvdarts' failure to allege that the carriers *have* the current capacity to supervise was, therefore, fatal to its vicarious liability claim.

Insufficient knowledge

Contributory infringement liability requires that the defendant induced or encouraged direct infringement. To be contributorily liable, the carriers must have:

1. Known of the direct infringement, and

2. Induced, caused or materially contributed to the infringing conduct.

The first prong, the court said, requires more than a generalized knowledge of the possibility of infringement. Luvdarts claimed that notices it had sent the carriers established actual knowledge.

The court, however, pointed out that the notices failed to notify the carriers of "any meaningful fact." The notices were 150-page lists of titles that didn't identify which titles were infringed, who infringed them or when the infringement occurred. Because Luvdarts failed to establish the necessary specific knowledge of infringement, its contributory copyright infringement claim also failed.

TTFN, maybe CUL8R

The *Luvdarts* decision doesn't completely cut off the possibility of carriers being held vicariously or contributorily liable for unauthorized sharing on MMS networks. A future plaintiff that's able to satisfy the requirements for infringement may find success in court. ❍

You reap what you sow

Patent exhaustion defense doesn't stir Supreme Court

If a recent case decided by the U.S. Supreme Court is any indication, the stereotypical image of farmers as straightforward, simple folk may be misplaced. The defendant in *Bowman v. Monsanto Co.* went to great lengths to devise a complex planting and harvesting practice to evade the terms of a licensing agreement. Ultimately, however, the Court ruled that his stratagems indeed violated a seed manufacturer's patent.

Dispute is planted

Monsanto invented and patented a genetic modification that allows soybean plants to survive exposure to glyphosate, the active ingredient in many herbicides — including Monsanto's own product, "Roundup." The company markets seed containing this altered genetic material as "Roundup Ready" seed. Farmers who plant the seed can use a glyphosate-based herbicide to kill weeds without damaging their crops.

Monsanto sells the seed subject to a licensing agreement that permits farmers to plant the purchased seed in only one growing season. Farmers may either consume or sell the resulting crops, but they can't save any of the harvested soybeans for replanting.

Vernon Bowman bought Roundup Ready seed for his first crop of each growing season from a company associated with Monsanto and followed the licensing

terms. To reduce costs for his riskier late-season planting, though, he purchased soybeans intended for consumption from a grain elevator, which had purchased them from other farmers.

Bowman planted these soybeans and then treated the resulting plants with glyphosate, killing all the plants without the Roundup Ready trait. Bowman harvested the surviving soybeans and saved some to use in his late-season planting the next season. He repeated the cycle until he harvested eight crops that way.

After discovering this practice, Monsanto sued Bowman for infringing its patents. Bowman raised the "patent exhaustion" defense, which gives the purchaser of a patented article, or any subsequent owner, the right to use or resell that article. The district court, however, rejected this argument and awarded Monsanto about $84,000 in damages. The Federal Circuit Court of Appeals affirmed the ruling, and Bowman appealed to the Supreme Court.

Defense goes to seed

On review, the Court explained that, under the patent exhaustion doctrine, the initial authorized sale of a patented item terminates all patent rights to that item. In addition, the sale gives the purchaser, or any subsequent owners, the right to use or sell the item as he or she sees fit. The doctrine, however, restricts only the patentee's rights on the particular item sold; it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item.

That, according to the Supreme Court, was the situation here. By planting and harvesting Monsanto's harvested seeds, Bowman made additional copies of the patented invention, so his conduct fell outside the protection of patent exhaustion. The Court reasoned that, if this weren't so, Monsanto's patent would provide "scant benefit." That is, after the company sold its first seed, other seed companies could produce the patented seed to compete with it, and farmers would need to buy the seed only once.

The "patent exhaustion" defense gives the purchaser of a patented article, or any subsequent owner, the right to use or resell that article.

The Supreme Court also rejected Bowman's contention that patent exhaustion should apply because soybeans naturally self-replicate — meaning it was the seeds, not Bowman himself, that made copies of the patented item. It found this "blame the bean" defense "tough to credit" in light of his active role in the beans' reproduction.

Other issues may take root

The Court emphasized that its ruling in *Bowman* was limited to the situation before it. Not addressed was whether, or how, patent exhaustion might apply when a patented item's self-replication occurs outside of the purchaser's control or is a necessary but incidental step in using the item for another purpose. ❍

Case dismissed: "ibooks" mark isn't protected

A federal district court has tossed yet another lawsuit involving computer giant Apple. In *J.T. Colby & Co. Inc. v. Apple, Inc.*, a small publisher of an imprint labeled "ibooks" was informed it couldn't bring a claim for trademark infringement.

Core of the case

Two publishers launched an imprint using the unregistered trademark "ibooks" in 1999 in connection with the publication of graphic novels and science fiction, horror, and fantasy works. J.T. Colby & Co. acquired the assets of the publishers, including the ibooks imprint, in 2006. Since then, Colby has continued to publish both print books and e-books under the imprint, though print books have accounted for about 98% of the books sold.

In 2010, Apple obtained the rights to the registered trademark "iBooks" from another company. Later that year, the company announced that it would be offering e-reader software called "iBooks." Colby subsequently sued Apple, claiming the company had infringed Colby's trademark and created a likelihood of reverse confusion — meaning consumers will likely believe that Colby's books are published by or affiliated with Apple.

Court picks Apple

Apple asked the district court to dismiss Colby's claims before trial. After reviewing the case, the court agreed to do so. The district court held that Colby had failed to present sufficient evidence to show that its "ibooks" mark was entitled to trademark protection or that its mark was likely to suffer from reverse confusion with Apple's "iBooks" mark.

The court noted that Colby had presented no evidence that "ibooks" was anything other than descriptive of "books available for sale on the Internet." A descriptive mark is entitled to trademark protection

only if it has acquired and maintained secondary meaning among consumers.

Secondary meaning is acquired when the primary significance of a mark to consumers is to identify the source of the product, rather than the product itself. The court, however, found that no reasonable jury could conclude that, as of Apple's 2010 announcement, a substantial segment of consumers in Colby's market associated the "ibooks" mark with a single source.

The trademark claim also failed because of a lack of confusion. Apart from the fact that both parties use marks with a variation of the word "ibooks," the court found little evidence suggesting that consumers would mistakenly believe Colby's books originate from, are sponsored by or are affiliated with Apple.

Another bite

This certainly isn't the first lawsuit faced or filed by Apple — and it won't be the last. In fact, *J.T. Colby* itself apparently isn't over. As of this writing, the plaintiff was planning an appeal. ❍

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Work Sharing Is Bringing the Patent World Closer Together

By Jay Erstling

Patenting is no longer the domain of a few wealthy countries; today it is a global affair. In 2011, the latest year for which statistics were available, applicants filed more than 2,140,000 patent applications, and patent offices worldwide granted almost 1,000,000 patents. All told, about 7,880,000 patents were in force in 2011. Not only has the patent world expanded, it has also taken a definite turn toward Asia. Among the five countries in which US applicants most frequently file patent applications, China, Japan and Korea come in second, third, and fifth place, respectively (with Europe and Canada coming in first and fourth). And to the surprise of many, the State Intellectual Property Office of China has surpassed the US Patent and Trademark Office as the largest patent office in the world, while the patent offices of Japan and Korea fill the third and fourth slots. These developments have helped to open markets and have created tremendous commercial advantages for the creators of technology, but they have also made patenting decisions and patent prosecution that much more complex.

Fortunately, as patent activity has intensified across the globe, so have the efforts of national and regional patent offices and the World Intellectual Property Organization (the UN specialized agency dedicated to improving respect for intellectual property) to make the patent process more rational and efficient. Particularly important has been the work of the US, European, Japanese, Korean, and Chinese offices, which collaborate together as the "IP 5" and have recently promoted the notion of patent office work sharing—of communicating information about patent applications pending in more than one office and attempting to avoid unnecessary duplication in the search and examination process. Work sharing is a truly welcome development, especially since it benefits both patent applicants and patent offices. It makes patenting faster and more predictable, it generally lowers the cost of prosecution, and it helps to decrease the huge patent application backlogs that have plagued large patent offices everywhere. As work sharing initiatives proliferate and assume an increasingly prominent place in the patenting arena, patent applicants seeking protection both at home and abroad stand to be the major beneficiaries.

The most important work sharing effort to date is the **Patent Prosecution Highway (PPH)**, an initiative first proposed by the Japan Patent Office. PPH has its legal basis in a web of bilateral agreements that link the different patent offices (the USPTO has agreements in place with over 30 offices), and those agreements have achieved greater success than any single office could have imagined. PPH is designed for patent applicants who want patent protection for their invention in more than one country, and who receive a favorable opinion on patentability from one of the offices that has examined their application. Under PPH, applicants can take advantage of that opinion to expedite examination in other offices in which they have filed a related application. When PPH was first rolled out, a favorable opinion (which, in the context of PPH, means a determination that the application contains at least one allowable claim) had to come from the patent office in which the application was first filed (known as the Office of First Filing, or OFF). PPH programs have since become less dependent on the OFF, however. In an initiative known as PCT-PPH, an applicant who files a PCT application can use the favorable results of an international search report and written opinion to receive PPH treatment. And in the most recent version of PPH, called PPH Mottainai, the OFF has been replaced by any patent office that has carried out a favorable, earlier examination of the application.

Taking advantage of PPH programs can result in faster examination and increase the likelihood of patent grant. It is a work sharing success story well worth considering.

For more information on international patent protection, contact Jay Erstling at (612) 349-5740 or Erstling@ptslaw.com.

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