IDEAS ON INTELLECTUAL PROPERTY LAW

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It's only natural

Supreme Court rejects patents on diagnostic test

Medical researchers are sometimes accused of playing God. But there's at least one place where they can't get away with that: in the patent arena. As the U.S. Supreme Court's recent decision in *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.* reminds us, the laws of nature — as well as some processes that purport to apply them — aren't patentable.

3-step process

Prometheus Laboratories held an exclusive license on two patents that involve the use of thiopurine drugs to treat autoimmune diseases. When ingested by a patient, the body metabolizes the drugs, producing metabolites in the bloodstream.

Because patients metabolize the drugs differently, doctors had found it difficult to determine whether a particular patient's dose was too high (which could harm the patient) or too low (which would probably be ineffective). To identify correlations between metabolite levels and the likely harm or ineffectiveness with precision, the patents used a three-step process:

1. *Administering,* which instructs a doctor to administer the drug to the patient,
2. *Determining,* which instructs the doctor to measure the resulting metabolite levels in the patient's blood, and
3. *Wherein,* which describes the metabolite concentrations above which there's a likelihood of harmful side effects and below which it's likely the dosage is ineffective. This step also informs the doctor of the need to decrease or increase dosage.

Using the patented method, Prometheus sold a diagnostic test kit to doctors and hospitals to help them determine proper dosage levels of thiopurine. Mayo Collaborative Services initially bought and used the tests but eventually announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo for infringement.

Back and forth

The district court found that Mayo's test infringed the patents but determined that the patents were invalid because they claimed unpatentable laws of nature — specifically, the correlations between metabolite levels and the toxicity and efficacy of thiopurine drugs. The Federal Circuit reversed, finding that the processes were patentable under the "machine or transformation test." The test requires either that the method in the claim be performed with a "machine" or that performance of the method transforms something in the tangible world.

But, after the Supreme Court ruled in *Bilski v. Kappos* that the machine or transformation test isn't the definitive test of patent eligibility, it remanded this case back to the Federal Circuit for reconsideration.

Ruling creates tightrope effect

The U.S. Supreme Court acknowledged that its ruling in *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.* (see main article) creates a sort of tightrope effect regarding medical research.

On the one hand, the promise of exclusive patent rights provides monetary incentives that lead to valuable discoveries. On the other, some argue that this very exclusivity can impede the flow of information that might spur invention and allow physicians to provide sound medical care.

But, the Court said, patent law must govern inventive activity in many different fields, so the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another. If more finely tailored rules are necessary, it's up to Congress to craft them.

The Federal Circuit reaffirmed its earlier conclusion, and Mayo appealed.

Entirely natural

The Supreme Court began its review by noting its longstanding position that, while laws of nature, natural phenomena and abstract ideas aren't patentable, "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." The Court, however, made clear that, to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it."

Here, the patents purported to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relationship, the relationship is a consequence of the ways in which thiopurine compounds are metabolized by the body. That's an entirely natural process.

Court defines "patentable"

The Court was, therefore, tasked with determining whether the claimed processes transformed these unpatentable natural laws into patent-eligible applications of those laws. And its answer was no.

To be patentable, the Supreme Court explained, the claimed processes must have additional features that provide practical assurance that the processes are a genuine application of the natural laws, rather than a patent-drafting tactic intended to monopolize the law of nature itself. It found that the three steps set forth in the patent claims, while not themselves natural laws, were insufficient to transform unpatentable natural correlations into patentable applications of those correlations. The steps simply told doctors to gather data from which they might draw an inference in light of the correlations.

The Supreme Court concluded that the claims merely informed a relevant audience about certain laws of nature. Any additional steps consisted of well-understood, routine, conventional activity already engaged in by the scientific community. Those steps, when viewed as a whole, added nothing significant.

Wider implications

The Supreme Court's reasoning in this case could have wider implications. For example, it may also apply to the mathematical algorithms commonly used in software patents. But just how widely the application of *Mayo* will extend remains to be seen. ❍

Almost famous: A trademark case

The "B List" isn't just for celebrities. In *Coach Svcs., Inc. v. Triumph Learning LLC,* the U.S. Court of Appeals for the Federal Circuit essentially told a handbag maker trying to block the registration of its trademarks for use in another industry, "You're almost famous … but not quite."

Accessories and assessments

Coach Services Inc. (CSI) sells a wide variety of "accessible luxury" products. It has been using the "Coach" mark in connection with its products since at least December 1961. CSI owns 16 incontestable trademark registrations for the "Coach" mark.

Triumph publishes books and software used to assist teachers and students in preparing for standardized tests. Triumph claimed that it has used the "Coach" mark in connection with its products since at least 1986. It filed three trademark applications for the "Coach" mark in December 2004. CSI filed a notice of opposition against the applications on grounds of likelihood of confusion and dilution.

Fame for likelihood of confusion and fame for dilution are distinct concepts.

The Trademark Trial and Appeal Board (TTAB) dismissed the opposition, and CSI appealed to the Federal Circuit.

Dominant but insufficient

As that court explained, whether a likelihood of confusion exists between an applied-for mark and a prior mark is determined on a case-by-case basis by applying the 13 nonexclusive DuPont factors. CSI argued, among other things, that the TTAB had erred in applying the factors by failing to give proper weight to the fame of the "Coach" mark.

Fame is a dominant factor, the Federal Circuit said. But fame is insufficient, standing alone, to establish likelihood of confusion. CSI's "Coach" mark is famous for likelihood of confusion purposes, but the unrelated nature of the parties' goods and their different channels of trade weighed heavily against CSI and supported a finding of no likelihood of confusion.

Confusion vs. dilution

CSI also alleged that Triumph's mark would cause dilution of its own mark by "blurring." The Trademark Dilution Revision Act (TDRA) defines dilution by blurring as an "association arising from the similarity between a mark … and a famous mark that impairs the distinctiveness of the famous mark." The TTAB found that CSI couldn't succeed on its dilution claim because it failed to show that its "Coach" mark was famous for dilution purposes.

Fame for likelihood of confusion and fame for dilution are distinct concepts. While fame for dilution "is an either/or proposition" — it either exists or doesn't — fame for likelihood of confusion is a matter of degree along a continuum. A mark can acquire sufficient public recognition and renown to be famous for purposes of likelihood of confusion without meeting the more stringent requirements for dilution fame.

Under TDRA, a mark is famous only if it's "widely recognized by the general consuming public of the United States as a designation of source of the goods or services of the mark's owner." In other words, a famous mark has become a "household name."

As the Federal Circuit observed, it's well established that dilution fame is difficult to prove. This is particularly true where, as here, the mark is a common English word with different meanings in different contexts. Moreover, the owner of the allegedly famous mark must show that its mark became famous before the filing date of the trademark application or registration it opposes. And the Federal Circuit held that CSI failed to satisfy its burden.

Specifically, the court found that CSI didn't present sufficient evidence of fame for dilution. CSI's limited evidence of sales and advertising, federal trademark registrations, unsolicited media attention, and joint marketing efforts with popular brands (such as Lexus) failed to establish the requisite fame.

More evidence

Many trademark owners might assume their prominence in the marketplace is enough to show dilution or likelihood of confusion. But, as this case shows, a court may require more evidence. ❍

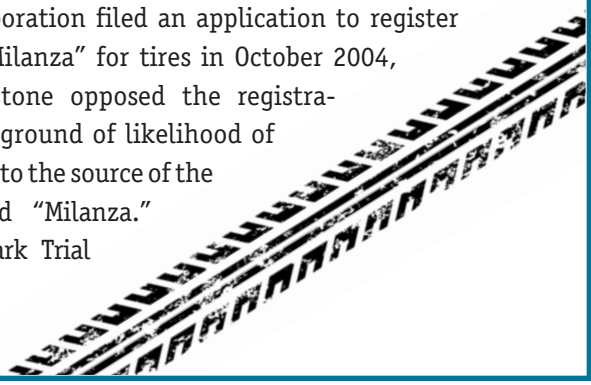
Tread marks and trademarks

What's in a name? In some circumstances, there could be enough brand strength to stop others from using even similar names for their own purposes. The U.S. Court of Appeals for the Federal Circuit had to decide whether such was the case in *Bridgestone Americas Tire Operations, LLC v. Federal Corp.*

Appealing out

Bridgestone, the widely known tire manufacturer, registered the mark "Potenza" in June 1984 and the mark "Turanza" in May 2004, both for tires. "Potenza" had been in commercial use since 1981 and "Turanza" since 1991.

Federal Corporation filed an application to register the mark "Milanza" for tires in October 2004, and Bridgestone opposed the registration on the ground of likelihood of confusion as to the source of the tires marked "Milanza." The Trademark Trial and Appeal



Board (TTAB) dismissed the opposition, finding the marks were too dissimilar. Bridgestone appealed.

Taking a spin

On appeal, Bridgestone argued that its market strength and the public's familiarity with the "Potenza" and "Turanza" marks made it likely that consumers would deem the products in question to have the same source. The company also noted the common suffix of "za," as well as the shared cadence, sound and Italian connotation.

Exact identity isn't necessary to generate confusion about the source of similarly marked products.

The Federal Circuit agreed, to some extent, that the fame — or strength — of an opposer's mark plays a dominant (but not decisive) role in determining whether a likelihood of confusion exists between one registered mark and another. It explained that "well-known marks are more likely to be associated in the public mind with the reputation of the source."

The TTAB had pointed out that the "Potenza" and "Turanza" marks are usually accompanied in advertising by the "Bridgestone" mark. It concluded that, though the marks are inherently distinctive, any market strength they have is tied to the "Bridgestone" mark.

Tracking identity

The appellate court disagreed with the TTAB, finding that the concurrent use of the "Bridgestone" mark doesn't diminish the status of the other two marks as strong marks for tires: "A unique arbitrary word mark does not lose its strength as a trademark when the manufacturer is identified along with the branded product."

The court also noted that, when goods are identical, the appearance of a mark of similar sound, appearance or connotation is more likely to cause confusion than if the goods are significantly different. Further, exact identity isn't necessary to generate confusion about the source of similarly marked products.

Previous cases have provided many examples in which registration was denied to the newcomer in view of a mark in prior use — for example, "Huggies" and "Dougies." The prior user is entitled to protection of its marks against newcomers using a confusingly similar mark for the same goods.

Throwing it in reverse

In light of the type of goods involved; lengthy prior use and strength of the marks; and similarities of the words, sounds and connotations with "Milanza," the court found a likelihood of confusion existed. Therefore, it reversed the TTAB's decision denying Bridgestone's opposition to the mark. ❍

Do not pass "Go," do not collect anything

Investment tool ruled unpatentable

Method patents continue to come under attack in the courts. In one recent case, *Fort Properties, Inc. v. American Master Lease LLC*, the U.S. Court of Appeals for the Federal Circuit ruled that a real estate investment tool was an unpatentable abstract idea.

Roll of the dice

American Master Lease (AML) owned a patent on an invention designed to enable property owners to buy and sell properties without incurring tax liability. All of the claims in the patent were method claims, though some included an additional limitation requiring a computer.

When AML threatened Fort Properties with a patent infringement lawsuit, Fort Properties filed an action asking the district court for a declaratory judgment that AML's patents were invalid. The court held that all of AML's patent claims were invalid for claiming an abstract idea.

Not in the cards

On appeal, AML contended that the involvement of real estate deeds in the process removed the invention from the realm of the abstract. This is because deeds are physical legal documents signifying real property ownership that must be publicly recorded.

The Federal Circuit found that the invention's "intertwinement" with deeds, contracts and real property didn't transform the abstract method into a patentable process. An investment tool — particularly a real estate investment tool designed to enable tax-free exchanges of property — is an abstract concept that can't be transformed into patentable subject matter merely because it has connections to the physical world.

The claims with the limitation requiring performance of the process using a computer had the same ties to deeds, contracts and real property, which, again, were insufficient to make those claims patent-eligible. The computer requirement also wasn't enough. The court explained that, to render an otherwise unpatentable process patentable under the theory that it's linked to a machine, the use of the machine "must impose meaningful limits on the claim's scope." The addition of the computer must be more than an insignificant postsolution activity.

AML's computer limitation didn't play a significant part in permitting the claimed method to be performed. AML itself admitted that "using a computer" merely meant "operating an electronic device that features a central processing unit." Such a broad and general limitation failed to impose meaningful limits and was simply insignificant postsolution activity.

Game still on

The debate over the patentability of method claims is far from over. Prospective patent owners will no doubt continue to submit applications with high hopes. But they should look to *Fort Properties* for some helpful guidance on what will and won't pass muster. ❍

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Patent Marking in the 21st Century: Virtual Marking

By Brian L. Stender

The Leahy-Smith America Invents Act of 2011 (AIA), signed into law on September 16, 2011, gives patent owners a new option for marking their patented products. The option is called "virtual marking" and it allows a patent holder to mark a patented product utilizing the Internet. The patent owner will still place the word "patent" or the abbreviation "Pat." on the patented product, but now, the patent number can be replaced by an Internet URL address. The URL must lead to a web page that is accessible to the public and free of charge, where the patent number is associated with the patented product.

Prior to the AIA, traditional patent marking required a patent holder to consistently fix the word "patent" or the abbreviation "Pat." together with the number of the patent on the patented product. This form of marking presented practical problems in maintaining proper patent marking, such as adding a new patent number when a new patent issued or removing a patent number when the patent expired. It takes time and money to make those changes on the patented products. These problems were exacerbated when a patented product was covered by numerous issued patents or a company had an extensive patent portfolio covering numerous patented products.

As a result of virtual marking, the URL identified on the patented product will remain the same, but a patent holder can now efficiently manage patent marking by making necessary changes to the web page as new patents issue and the patent term on existing patents expires. It also allows the patent owner to associate all relevant patents with the product because space is not an issue.

Best practice is to put the virtual marking on the product by inscription or other permanent means. If the character of the patented product does not allow such marking, the statutory marking requirements are still met when either (i) a label fixed to the patented product, or (ii) a package containing the patented product contains the required patent information.

Why Patent Marking? No Notice, No Damage Recovery.

While patent marking is not mandatory, it is advisable for a patent owner to mark its commercial products with a patent notice because a patent owner may only recover damages for infringement that occurs during a period of time in which the accused infringer had constructive or actual notice of the asserted patent. If the infringer does not receive proper notice, the patent owner is not entitled to recover damages during the period of time the infringer did not have proper notice. Both constructive notice and actual notice (e.g., a cease-and-desist letter) are dependent upon the patent owner's activities.

Patent Marking Provides Constructive Notice

Constructive notice occurs by patent marking. The marking statute serves to: (1) help avoid innocent infringement; (2) encourage patent owners to give notice to the public that the commercial product is patented; and (3) aid the public in identifying whether a product is patented. Thus, when the patented product is properly marked with the patent information, an infringer has constructive notice of the patent as of the date the patented products are consistently and continuously marked with the patent information.

Care Should Be Taken to Avoid False Patent Marking

The patent notice should be placed only on products which are in fact covered by the claims of a particular patent. Marking products with patents that do not cover the products can result in liability for false marking under 35 U.S.C. § 292. This also underscores the importance of keeping virtual marketing web pages current. Virtual marking will not only be helpful for patent owners in eliminating false marking liability, but will also help maximize the potential recovery of damages should patent infringement occur.

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