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Chicago ■ New York ■ Washington, D.C.

December 2010

IP Strategies

The Uncertain Future of Isolated DNA Patents

Ever since the U.S. District Court for the Southern District of New York (S.D.N.Y.) issued a decision in the lawsuit brought by the American Civil Liberties Union (ACLU) against Myriad Genetics,[1] the future of isolated DNA patents has been uncertain. Not surprisingly, the S.D.N.Y. decision in *Myriad Genetics* was appealed to the Federal Circuit.[2] On 29 October 2010, the U.S. Department of Justice (DOJ) filed an amicus brief in support of the S.D.N.Y. position in *Myriad Genetics* that isolated human genomic DNA is not patentable.[3] The DOJ amicus brief sides with the ACLU on the issue of isolated DNA and with Myriad Genetics on the patentability of scientifically manipulated DNA. Specifically, the DOJ took the position that (a) human-engineered DNA molecules, such as cDNAs, are patent-eligible under 35 U.S.C. § 101, and (b) isolated, but otherwise unmodified, genomic DNA is patent-eligible subject matter under 35 U.S.C. § 101.

In the *Myriad Genetics* case, the patents in suit encompass breast cancer genes BRCA1 and BRCA2. The composition claims relate to "isolated DNA" containing human BRCA1/2 gene sequences. The method claims refer to diagnostic methods for identifying mutations in the BRCA1/2 genes by analyzing the sequences of the genes. The S.D.N.Y. ruled that DNA's existence in an "isolated" form does not transform it into something "distinctly different in character" from the nonisolated DNA contained in the human gene sequences. The S.D.N.Y. was of the belief that purifying DNA did not change the underlying characteristic of the DNA, which was to convey information to express a protein. With respect to the method claims, the S.D.N.Y. held that the claimed comparisons are abstract mental processes and thereby constitute unpatentable subject matter.

The S.D.N.Y. decision in *Myriad Genetics* on the isolated DNA claims runs counter to established Federal Circuit precedent including *Amgen v. Chugai*[4] and *Fiers v. Revel*,[5] neither of which are mentioned by the S.D.N.Y. in the *Myriad Genetics* decision or in the DOJ amicus brief. In issuing its decision in *Myriad Genetics*, the S.D.N.Y. appears to have also cast aside many cases from the Federal Circuit and Supreme Court regarding isolated biological or chemical substances, with the explanation that those cases did not relate to Section 101 of the Patent Act,[6] which sets forth what is patentable subject matter, but does not discuss or attempt to distinguish the *Amgen* and *Fiers* cases.

The *Amgen* and *Fiers* cases both relate to interfering subject matter under 35 U.S.C. § 102(g). The *Amgen* case relates to isolated DNA-encoding erythropoietin (EPO) and the *Fiers* case relates to isolated DNA-encoding human fibroblast beta-interferon. In both *Amgen* and *Fiers*, the Federal Circuit, in the context of interference proceedings, recognized that an isolated and purified DNA is invented when a complete and correct DNA sequence is provided.[7] The Federal Circuit explicitly stated in *Amgen* that "[a] gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it."[8]

In this issue...

However, as under *Amgen* and *Fiers*, isolated DNA can be conceived and reduced to practice, and can be the subject of interference proceedings under, *inter alia*, 35 U.S.C. § 102(g), since it follows *a fortiori* that it is patentable subject matter under Section 101 of the Patent Act, which is contrary to the holding by the S.D.N.Y. in *Myriad Genetics*. Likewise, in casting aside many cases from the Federal Circuit and Supreme Court regarding isolated or biological or chemical substances with the explanation that those cases did not relate to Section 101 of the Patent Act, the S.D.N.Y. may have acted erroneously. In other words, it follows from the courts' decisions in those other cast-aside cases that the subject matter at issue therein had to be patentable subject matter under 35 U.S.C. § 101; otherwise the courts' decisions in those other cases would arguably be invalid, as those courts would lack jurisdiction to have decided those issues if the subject matter claimed was not itself patentable under Section 101 of the Patent Act.

Some have argued that *Myriad Genetics* stands for the proposition that any "isolated" biological or chemical substance is not patentable under 35 U.S.C. § 101, despite the large body of Federal Circuit and Supreme Court case law that indicates that "isolated" biological or chemical substances are patentable subject matter under Section 101 of the Patent Act.

Furthermore, by casting aside many cases from the Federal Circuit and Supreme Court regarding isolated biological or chemical substances, giving the explanation that those cases did not relate to Section 101 of the Patent Act, the S.D.N.Y. may have issued a decision with unintended consequences. Some have argued that *Myriad Genetics* stands for the proposition that any "isolated" biological or chemical substance is not patentable under 35 U.S.C. § 101, despite the large body of Federal Circuit and Supreme Court case law that indicates that "isolated" biological or chemical substances are patentable subject matter under Section 101 of the Patent Act.

Examples of these arguments include the DOJ amicus brief and Judge Dyk's dissent in the *Intervet v. Merial* Federal Circuit decision.[9] In *Intervet*, Judge Dyk opined that the claim relating to an isolated DNA molecule raises substantial issues of patentable subject matter under 35 U.S.C. § 101. According to Judge Dyk, the Federal Circuit and the Supreme Court have not yet directly decided the issue of the patentability of isolated DNA. Judge Dyk admits that the Federal Circuit has upheld the validity of several gene patents (including the *Amgen* case), but he believes that none of the cases directly addresses the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101. In this instance, Judge Dyk employed the same reasoning as the S.D.N.Y. in the *Myriad Genetics* case and failed to recognize that isolated DNA had to be patentable subject matter under 35 U.S.C. § 101. Otherwise, the Federal Circuit decisions regarding gene patents would be invalid, as the Federal Circuit would have lacked jurisdiction to have decided those issues if the subject matter claimed was not itself patentable under Section 101 of the Patent Act.

The DOJ amicus brief adopts Judge Dyk's position that the mere fact that genes do not naturally occur in isolated form does not provide a basis for patent eligibility.[10] The DOJ amicus brief suggests that the process of isolating DNA from the human genome was patent-eligible when it was first conceived, but the isolated DNA remains what it was in the human body. The DOJ amicus brief further opines that the pure BRCA1 polynucleotide is structurally identical to the DNA that occurs in the human body, absent the isolation. It was the position of the DOJ that isolated DNA is a product of nature.

The arguments, as set forth in the DOJ amicus brief, that isolated DNA is a product of nature, do not make sense from a scientific standpoint. Unlike what is characterized in the DOJ amicus brief, the isolation of a gene is not necessarily a standard and routine process of extracting and amplifying a desired gene. A gene is not merely the necessary sequence to express a protein. Rather, a gene may have several components, including, but not limited to, promoters, enhancers, exons, introns and untranslated regulatory sequences that are not ultimately translated into a protein. In other words, genes are not merely products of nature that can be routinely isolated. Furthermore, an isolated gene does differ from what is naturally occurring. For example, in a naturally occurring state, DNA is often coiled and bound to DNA binding proteins, such as histones. In contrast, isolated DNA is often relaxed and free of DNA binding proteins and exists in a buffered environment. Thus, contrary to the DOJ amicus brief, isolated DNA is not structurally identical to DNA found in the human body.

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While the *Myriad Genetics* case remains pending in the Federal Circuit, what options are available to a patent practitioner? Recitation of "isolated" or "substantially pure" may raise issues during the prosecution of a gene patent, wherein the recitation of "non-naturally occurring" may be a better alternative. Furthermore, the inventive aspects of a gene patent should be stressed, especially the difficulties in isolating and characterizing the gene and the inventive characteristics thereof. The use of genes in diagnostic assays should also be emphasized, particularly in view of the *Bilski v. Kappos*[11] decision that suggests that biotech and diagnostic methods will likely pass muster as patentable subject matter. ■

1 *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, 09 Civ. 4515 (S.D.N.Y., March 29, 2010).
2 *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit.
3 Brief for the United States as Amicus Curiae in Support for Neither Party for *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit.
4 *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991).
5 *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).
6 35 U.S.C. § 101.
7 *Amgen*, 927 F.2d at 1206; *Fiers*, 984 F.2d at 1169.
8 *Amgen*, 927 F.2d at 1206.
9 *Intervet, Inc. v. Merial Ltd.*, 617 F.3d 1282, 1293-95 (Fed. Cir. 2010) (Dyk, J. concurring-in-part and dissenting-in-part).
10 Brief for the United States as Amicus Curiae in Support for Neither Party for *Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al.*, case number 2010-1406 in the U.S. Court of Appeals for the Federal Circuit.
11 *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. ___ L.Ed. ___ 3218 (2010), 2010 U.S. LEXIS 5521 at *22 (June 28, 2010).

Managing Your Internet Traffic

Sales over the Internet are a growing source of revenue for most corporations. Websites that were once nothing more than expensive on-line brochures now serve as legitimate international sales outlets. These new portals process orders and payments, track shipments and even allow customers to report problems. More than ever, corporations must defend their on-line revenue and anticipate unfair, on-line trade practices.

Branding your products on the Internet is a double-edged sword. On-line clients rarely memorize a domain address or know the source for goods. They rely on search engines and, using a descriptive term or a brand, search for the site they want.[1] The use of brands and trademarks facilitates the digital search but is also a magnifying glass to other advertisers and competitors. Once a person types in a brand, direct competitors have located a prey who can potentially become a loyal customer. The fight over on-line traffic is ongoing, and the law recently evolved on this front.[2]

How Searching Works

Search engines offer free Internet indexing. No annual subscription is required. But in exchange, these service providers are free to raise money by selling advertising space often located next to search results. Search engines distinguish between the hits returned from the search and the advertisers placed next to the hits. Few take issue with this free business model until they realize that clients who enter a protected brand into the search engine are subsequently presented with very attractive or even deceptive ads. The practice reaches an apotheosis when the protected brand is used to benefit both the search engine and the competitor.[3]

Google generates $29 billion in annual revenue from a complex system that manages ads; Google's system is called *AdWords*.[4] AdWords is designed to divert traffic and only charges advertisers when traffic is diverted; this is the Pay-Per-Click (PPC) system. Google's revenue is collected from "diverted" clicks of searchers who entered one word in the search engine field and then click on the ad link.

The Problem

There are two ways to view this situation. Free market proponents argue that search engines are nothing more than an update of the Yellow Pages or retail store shelving where retailers are allowed to place their products to their benefit. The other view is that, once a protected brand is secured, it should not be used by search engines or competitors to divert traffic. Once again, the free market clashes head on with trademark law.[5]

Trademark law developed from a need to protect consumers as they bought goods or services. Corporations are granted certificates of registration, or common-law rights to police the marketplace, on behalf of their consumers. With the growth of the Internet, and the public's growing experience with search engines, claims of confusion diminish, favoring the free market argument. But with increased speeds and faster purchasing cycles, confusion is enhanced, thus favoring the trademark enforcement argument. It is not surprising that, absent clear congressional intent on this topic, judges are at odds as to what should prevail, the free market theory or enforcement of trademarks.

The Legal Analysis

Trademark law provides: "Any person who shall, without the consent of the registrant . . . *use in commerce* any reproduction of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive . . . shall be liable in a civil action."[6] (Emphasis added.)

The above-quoted section places liability on a competitor selecting and using a registered mark, as long as confusion, deception or mistake can be shown. The question is: can a search engine that does not sell these goods be liable under this section? Search engines argue they do not "use in commerce" the protected mark and therefore cannot be liable under this statute. The Lanham Act[7] defines how broadly the "use in commerce" must be read. "[I]n the construction of this Act, unless the contrary is plainly apparent from the context, the term 'use in commerce' means the bona fide use of a mark in the ordinary course of trade . . . [A] mark shall be deemed to be used in commerce when it is used or displayed in . . . sale or advertising . . . and the person rendering the service is engaged in commerce in connection with the services."[8] Search engines argue that they do not sell soda, cars or even banking services, they simply sell search tools and, therefore, they are not a "person rendering the services engaged in commerce with the services" and cannot be liable under the statute.

In 2005, the Second Circuit found that a pop-up ad generator, which relied on a URL to generate ads, did not qualify as engaging in "use in commerce." In that case, a trademark owner owned a web domain where the protected mark was part of the address (*1-800 Contacts*). The computer system read the URL, and therefore the mark, and in response generated a pop-up ad to divert traffic. Based on this ruling, systems were free to use protected marks to generate ads as long as the trademark was not displayed.[9]

Many lower courts and foreign jurisdictions have reached similar conclusions. In 2010, the British Columbia Supreme Court ruled that *1-800 Contacts* was good law and that search engines were free to act as they wanted.[10] Also in 2010, the European Court of Justice went one step further, finding not only that there was no "use in commerce" by the search engine, but that there was also a safe harbor provision available to the search engine, as long as the conduct was neutral, merely technical and passive.[11]

While Canada and Europe are aligning themselves with the *1-800 Contacts* decision, the Second Circuit, which had issued the *1-800 Contacts* decision back in 2005, in an *en banc* decision reversed itself.[12] In this long opinion, the Court found a strange way to keep face, and tried to distinguish the AdWords system from the pop-up generator of *1-800 Contacts*. The Court ultimately ruled that, while it was very difficult to see the search engine's conduct constituting "use in commerce" giving liability to the search engine, the Court used the introductory portion of the definition that reads, "In the construction of this Act, unless the contrary is plainly apparent from the context . . ." and found that the AdWords use by Google was plainly a use in commerce, and that a conclusion that AdWords does not use the mark was contrary to the plainly apparent context of the law.[13]

The Court explained: "Google contends its use of the trademark is no different from that of a retail vendor who uses 'product placement' to allow one vendor to benefit from a competitor's name recognition . . . Google misses the point . . . It does not follow that . . . product placement is a magic shield against liability, so that even a deceptive plan of product placement designed to confuse consumers would [not] escape liability . . . if a retail seller were to be paid by an off-brand purveyor to arrange product display and delivery in such a way that customers seeking to purchase a famous brand would receive the off-brand, believing they had gotten the brand . . . ."[14]

> While search engines may not ultimately be liable for direct trademark infringement under the Lanham Act, they may be liable under a theory of contributory trademark infringement.

Conclusion

In the shadow of the *Rescuecom* decision, trademark owners can take direct action against search engines that misuse their marks. The author routinely enforces client's marks even against search providers. However, this issue is likely to reach the Supreme Court, who must take issue with the legal reasoning of the *Rescuecom* decision.

While search engines may not ultimately be liable for direct trademark infringement under the Lanham Act, they may be liable under a theory of contributory trademark infringement. A plaintiff must simply show the search engine intentionally induced the advertiser to infringe the mark, or continued to display the ad even after knowing or having a

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reason to know the advertiser was engaged in trademark infringement. Under current law, and under the contributory liability theory, search engines must still remove problematic ads once they are given notice of them or face legal consequences.[15] ■

1 For example, a descriptive term can be "soft drink," a brand (e.g., "Coke Zero"), or a trade name like "Coca-Cola."
2 *Rescuecom v. Google*, 562 F.3d 123 (2d Cir. 2009).
3 When a person enters "Coke Zero" in the search engine, the back-end software has already auctioned off to the highest bidder this protected brand. These third parties are then able to create any ad to divert and deceive traffic with little or no control from the search engine.
4 The author encourages trademark owners to visit the AdWords program, open an account, and bid on their own marks to quantify the volume and cost of the traffic lost. Many corporations have opted to pay search engines for their own marks to recapture a portion of this lost traffic.
5 Generally, "the basic objective of the law regulating the American free market economy is the promotion and encouragement of competition." *Continental v. GTE*, 433 U.S. 562 (1977). But see "trademarks serve an important public purpose. They make effective competition possible in a complex, impersonal marketplace." *Smith v. Channel*, 402 F.2d 562 (9th Cir. 1968).
6 15 U.S.C. § 1114.
7 U.S. Trademark Law, 15 U.S.C. § 1051 et seq.
8 15 U.S.C. § 1127.
9 *1-800 Contacts, Inc. v. When U.com, Inc.*, 414 F.3d 400 (2nd Cir. 2005). The author believes that confusion is made unlikely in a pop-up ad business model, unlike a search engine, where web surfers who enter a domain know very well the invasive nature of these pop-up ads.
10 *Private Career v. Vancouver Career*, 2010 B.C.S.C. 765 (B.C. Supreme Court, 2010) ("The practice of using Keyword Advertising is no different than the time-honoured and generally accepted marketing practice of a company locating its advertisement close to a competitor's in traditional media . . .").
11 *Google France v. Louis Vuitton*, C-236/08.
12 *Rescuecom v. Google*, 562 F.3d 123 (2nd Cir. 2009).
13 15 U.S.C. § 1127.
14 *Rescuecom v. Google*, 562 F.3d 123 (2nd Cir. 2009).
15 *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982).

Case Law Review

Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.

563 F. Supp. 2d 1016 (N.D. Cal. 2008)

The United States Supreme Court has granted a petition for a writ of certiorari in a case with the potential to have a significant impact on the commercialization of technology where government funding has been provided in its development. The Supreme Court has agreed to hear docket number 09-1159, *Board of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.* The question presented in the case is: "Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party."

The Bayh-Dole Act was passed and signed into law in 1980. The Act states:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.
>
> 35 U.S.C. § 200.

The Act, among other things, requires the disclosure of inventions made subsequent to the use of federal funding at nonprofit organizations and small businesses. 35 U.S.C § 202. Nonprofit organizations, as defined by the Act, include universities and other institutions of higher learning. 35 U.S.C. § 201. The Act further provides for a process of election of rights by inventors, small businesses, nonprofit organizations, and the federal government. 35 U.S.C. §§ 202-20. The election of these rights and the role of the Bayh-Dole Act in joint University-private business technology development relationships is at issue in this case.

The background of the case is helpful to understand the question presented to the Supreme Court. The case is, at its essence, a patent infringement suit. The subject matter of the patents of the underlying suit includes methods of measuring Human Immunodeficiency Virus ("HIV") in blood samples and correlating the measurements to the effectiveness of antiretroviral drugs. The technology of the patents was developed between Stanford University and Cetus, a company involved in the development of

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biochemical measurement techniques. Roche Diagnostics Operations, Inc. ("Roche") purchased part of Cetus's business in 1992, including its agreements with Stanford and the related researchers. One researcher instrumental in the development of the patented invention is Mark Holodniy.

Holodniy joined Stanford's research laboratory as a Research Fellow in the Department of Infectious Disease in 1988. When joining the lab, Holodniy signed a copyright and patent agreement that obligated Holodniy to assign his inventions to the University. Upon beginning to work on the development of the technology of the patents, Holodniy interacted with and visited Cetus's researchers and laboratories to learn biochemical measurement techniques. Before beginning that interaction, however, Holodniy signed a visitor's confidentiality agreement with Cetus. The agreement stated that Holodniy will "assign and does hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions, and improvements" that Holodniy may devise as a consequence of the relationship. *See Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 837 (Fed. Cir. 2009).

Holodniy went on to develop the technology that resulted in four patents relating to HIV detection kits and their use. Roche, after its purchase of Cetus's interest in HIV detection, began manufacturing kits using the technology of the patents. Stanford, after applying for the patents at issue, elected under the Bayh-Dole Act to retain title to the inventions and granted the federal government a license to the technology. The election and grant of a license was required of Stanford because of the provisions under the Bayh-Dole Act for technology development that is completed, as was the case here, with the help of federal funding.

Stanford then approached Roche and asserted its ownership of the inventions and offered Roche an exclusive license. But, after four years of negotiating, talks broke down and Stanford filed suit in the Northern District of California alleging infringement of its patents. Roche counterclaimed and asserted defenses against the suit.

The District Court granted Roche's motion that the asserted claims were invalid for obviousness. *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 F. Supp. 2d 1016 (N.D. Cal. 2008). Stanford appealed the ruling, and Roche cross-appealed as to the parties' respective rights in the patents. The Federal Circuit then vacated the District Court's ruling of invalidity but, to Stanford's dismay, ordered the suit dismissed for Stanford's lack of standing, due to Roche's ownership interest in the asserted patents. *Stanford*, 583 F.3d at 849. The Federal Circuit held that the visitors confidentiality agreement between Holodniy and Cetus was an immediate grant of equitable title to Cetus of Holodniy's interest in his inventions which Roche subsequently purchased. *Id*. at 842. The Court further decided that the copyright and patent agreement between Stanford and Holodniy, in contrast, was only a "promise to assign rights in the future, not an immediate transfer of expectant interests." *Id*. at 841. With this contract language interpretation, the Court found that Roche had an ownership interest in the asserted patents, and this resulted in Stanford's lacking standing for the underlying suit. Dismissal was therefor ordered. *Id*. at 848. The Court considered the impact of the Bayh-Dole Act on the ownership interests of the parties, and it ultimately decided that the statutory scheme of the Act did not void the assignment of Holodniy's rights in the invention to Cetus and the subsequent purchase by Roche. *Id*. at 844-45.

Where the traditional law topics of contracts and property would normally guide the decision in a case like this, the Bayh-Dole Act has injected some uncertainty and disagreement.

The Supreme Court has agreed to hear the case regarding the question concerning the Bayh-Dole Act. Where the traditional law topics of contracts and property would normally guide the decision in a case like this, the Bayh-Dole Act has injected some uncertainty and disagreement. On one side is a party such as Roche, who argues that the Bayh-Dole Act was intended to foster technology development relationships that use federal funds. This would include private organizations such as Roche. Roche argues that, if the government or the nonprofit organization such as Stanford can trump an assignment made by an inventor to that private organization, then private organizations will be reluctant to cooperate with universities, and the development of technology will suffer. *See* Appellee, Roche, Reply Brief to Fed. Cir. 23-24.

On the other side are parties such as Stanford who argue that the cost of the federal funds is a restricted right to the inventions produced by the individual inventors. The argument further states that the nonprofit organization may elect to retain rights and the individual inventor may retain rights but only subject to the provisions and outlined process of the Act. *See* Appellant, Stanford, Br.-Markman to Fed.

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Cir. 50-53. Stanford argues that individual inventors who participate in federally funded projects covered by the Bayh-Dole Act have limited rights in their inventions, and thus, when Holodniy assigned his interest, he assigned only this limited interest, which was subject to Stanford's election to retain ownership. *Id*.

While the Supreme Court will take on this issue of statutory interpretation, the real problem between the litigants arose because of unclear agreements between the parties involved in the original technology development. The Supreme Court, however, will likely act cautiously because of the influence of a decision regarding the Bayh-Dole Act on technology development relationships in the future. While sophisticated organizations will learn how to deal with the legal environment after a decision is reached in this case, existing and future technology agreements and assignments may need revision or rethinking. ■

Practice Tip:

Always clearly define and clearly state the legal rights of all parties involved in a technology development agreement. Further, whether you are involved in development projects involving federal funding or not, a review of technology agreements is likely a prudent course of action.

Sun Pharm. Indus. v. Eli Lilly & Co.

611 F.3d 1381 (Fed. Cir. 2010)

The doctrine of double patenting is intended to prevent a patentee from, in essence, extending patent rights beyond the term of an initial patent by claiming the same invention or an obvious variation of the patent in a second patent. *See In re Basell Poliolefine Italia S.PA.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008). Obviousness-type double patenting is a judicially created doctrine that prevents a later patent from covering a slight variation of an earlier patent. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). One situation in which this doctrine arises is where an initial patent is filed that claims a compound and also discusses a use for the patent in the Specification without claiming the disclosed use. The patentee then files a second patent claiming this use of the compound. This is the situation presented in *Sun Pharm. Indus. v. Eli Lilly & Co.*, and the Federal Circuit took the opportunity to clarify its position.

Sun Pharmaceutical Industries ("Sun") is a generic drug manufacturer and it filed an Abbreviated New Drug Application ("ANDA") with the FDA for approval to market a generic version of Eli Lilly's Gemzar®. Gemzar® is a drug that is marketed for the treatment of various types of cancer. As part of Sun's ANDA, Sun stated that the patents surrounding Eli Lilly's drug were invalid or not infringed. Sun then filed a declaratory judgment action against Eli Lilly desiring judgment that the patent at issue is invalid and not infringed. Eli Lilly, in turn, counterclaimed for infringement of its patents.

The patents and patent applications surrounding the dispute include U.S. Patent No. 5,464,826 ("'826 patent"), U.S. Patent No. 4,808,614 ("'614 patent"), and U.S. Patent Application Serial No. 473,883 ("'883 application"). The '614 patent issued from a divisional application as a continuation-in-part of the '883 application, which expired on May 15, 2010. In addition, Eli Lilly filed another application that issued as the '826 patent on November 7, 1995 with an expiration date of November 7, 2012. The '826 patent did not include a terminal disclaimer with respect to the '614 patent and would have expired more than two years after the '614 patent.

The subject matter of the '614 patent and the '826 patent includes the active ingredient of Gemzar®, gemcitabine. The '883 application described gemcitabine's use for antiviral purposes. The '614 patent added the use of gemcitabine in the treatment of cancer. Included in the Specification of the '614 patent is a specific description of the usefulness of gemcitabine as a "preferred compound" for the treatment of cancer. The '614 patent, however, only claims a class of nucleosides that includes gemcitabine and a dependent claim directly solely to gemcitabine. The '614 patent does not include a method claim regarding the treatment of cancer. The '826 patent, in contrast, is directed to a method for the treatment of cancer with a class of nucleosides that includes gemcitabine.

The U.S. District Court for the Eastern District of Michigan ruled, on Sun's motion for summary judgment, that the claims directed toward a method of gemcitabine's use for the treatment of cancer were invalid because of obviousness-type double patenting over the earlier '614 patent. *Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*, 647 F. Supp. 2d 820 (E.D. Mich. 2009). Eli Lilly appealed the decision to the U.S. Court of Appeals for the Federal Circuit, and the Federal Circuit affirmed the decision.

The Federal Circuit affirmed the decision, citing to two previous decisions of the court. It stated that obviousness-type double patenting prevents an applicant from claiming

Sun Pharm. Indus. v. Eli Lilly & Co.
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an invention that is not patentably distinct from claims in a commonly owned earlier patent. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003) and *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008). The Court clarified its position regarding obviousness-type double patenting, stating that "the holding of Geneva and Pfizer, that a 'claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use,' extends to any and all such uses disclosed in the specification of the earlier patent." *Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*, 611 F.3d 1381, 1387 (Fed. Cir. 2010).

This clarification was made in response to Eli Lilly's unsuccessful attempt to argue that Geneva and Pfizer limited an obviousness-type double patenting rejection to situations in which the earlier patent discloses a single use for a claimed compound. The Court rejected Eli Lilly's argument and stated that all uses disclosed in the specification can render a later-claimed method obvious. *Id*.

The Court further considered Eli Lilly's argument that the district court erred in considering the specification of the issued '614 patent rather than the more limited disclosure of the original '833 application specification. The Court did not find the argument persuasive, however, and stated that claim terms must be "construed in light of the entire issued patent." *Id*. at 1388. After these considerations, the Federal Circuit affirmed the decision of the district court that the asserted claims of the '826 patent are invalid for obviousness-type double patenting over the '614 patent. *Id*. at 1389. ■

Practice Tip:

Care should be taken in formulating IP strategies for the protection of technology, including the development of patent families surrounding particular technology. If further patent protection is sought, the Specifications of patents in patent families should be carefully considered and written to fully disclose and enable the subject matter of a claimed invention without disclosing potential valuable uses for the technology.

Specialized Seating, Inc. v. Greenwich Indus., L.P.
616 F.3d 722 (7th Cir. 2010)

In general, trademark law provides a system of law by which parties may protect those attributes and markings of its products that identify the source of the goods or services. Probably the best known method of achieving this is by a mark such as the name of a brand of a business or a pictorial logo of the brand or business. Another way of identifying the source of goods or services is through trade dress. Trade dress is the design, assembly of features, or presentation of a good or service that distinctly identifies the source of that good or service.

The protection of trade dress, however, is difficult to obtain because an applicant must prove that the design has a secondary meaning to consumers. It is further limited by what is known as the functionality doctrine. One purpose of the functionality doctrine is to prevent an organization or individual from obtaining the unlimited term-length of trademark protection for a functional design that normally would be protected by the limited-term patent system. For this reason and others, functional designs do not receive trade dress protection. The line between functional design and trade dress is difficult to draw, but the Seventh Circuit addressed the interaction of patent and trademark protection in *Specialized Seating, Inc. v. Greenwich Indus., L.P.*

In that case, Specialized Seating, Inc. ("Specialized") sought declaratory judgment that its design does not violate Greenwich Industries, L.P.'s ("Greenwich") rights under the Lanham Act. Greenwich, in turn, counterclaimed for an injunction.

Specialized and Greenwich are in the business of supplying folding chairs to auditoriums, stadiums, and other venues that require a large number of seats. Clarin is a company that has participated in this industry for over 80 years. Clarin was subsequently purchased by Greenwich in 1993. Specialized, on the other hand, is a relatively new entrant to the folding chair industry, and it was founded in 1999 by the son of the former general manager of Clarin. Specialized became a competitor in Greenwich's principal folding chair market. After the filing of the declaratory action by Specialized, the Northern District of Illinois held a bench trial and ruled that Greenwich's mark is functional and was obtained fraudulently, thus ruling in Specialized's favor. *Specialized Seating, Inc., v. Greenwich Indus.*, L.P., 472 F. Supp. 2d 999 (N.D. Ill. 2007). Greenwich then appealed to the Court of Appeals for the Seventh Circuit.

The interaction between patent protection and trademark or trade dress protection is apparent from the background of

Specialized Seating, Inc. v. Greenwich Indus., L.P.
continued from page 8

the case. Clarin applied for a trademark for its x-frame chair design. The U.S. Patent and Trademark Office issued Registration No. 2,803,875. The mark is reproduced below, and the registration describes the mark as "a configuration of a folding chair containing an x-frame profile, a flat channel flanked on each side by rolled edges around the perimeter of the chair, two cross bars with a flat channel and rolled

edges at the back bottom of the chair, one cross bar with a flat channel and rolled edges on the front bottom, protruding feet, and a back support, the outer sides of which slant inward." U.S. Trademark Reg. No. 2,803,875 (registered Jan. 13, 2004).

Clarin had also previously applied for and was issued patents on its folding chair designs. U.S. Patent No. 1,943,058 was issued in 1934, No. 1,600,248 was issued in 1926, No. 2,137,803 was issued in 1938, and No. 3,127,218 was issued in 1964. The '058 patent was disclosed during the trademark prosecution, but Clarin did not tell the examiner of the other three patents.

The Seventh Circuit agreed with the finding of the District Court that the design described in the trademark application was functional and was disclosed by the four Clarin patents, except for one feature that was deemed functional as well. *Specialized Seating, Inc., v. Greenwich Indus., L.P.*, 616 F.3d 722, 726 (7th Cir. 2010). In affirming the District Court's decision, the Seventh Circuit did agree with Clarin that a product whose overall appearance is distinctive may be protected under trademark laws even though most of the product's elements serve some function. *Id*. at 727. The Court recognized some instances where the design of a functional product can be protected but the examples cited by the Court included at least some non-functional element that was distinctive. *Id*. The Court went on to clarify and stated that, in order to be protectable under trademark law, all the elements of a product cannot be functional and the distinctive feature of the design or product must be non-functional. *Id*. at 727-28. ■

Practice Tip:

While trade dress protection of elements of a product design is possible, the applicant must demonstrate that the element is distinctive and non-functional. Further, with the consultation of IP professionals at early stages of development, owners may maximize the protection of inventions and designs through all means available without conflict.

Intellectual Property Group Welcomes Six East Coast Additions

Vedder Price is pleased to announce that Thomas J. Kowalski and Deborah L. Lu, Ph.D., have joined the firm as Shareholders in its New York Intellectual Property Group and that Rebecca Goldman Rudich has joined as a Shareholder in its Washington, D.C., Intellectual Property Group. Associate Heidi E. Lunasin, M.S.P.H., and Patent Agents Smitha B. Uthaman, Ph.D., and Jane Kiselgof, Ph.D., have also joined the firm in our New York office.

The New York team significantly expands the firm's expertise in pharmaceuticals and biotechnology, particularly in the areas of bioinformatics, biomedical engineering, molecular biology, immunology, virology and plant genetics. Rudich's arrival marks a continued expansion of the firm's capabilities in the electrical and mechanical arts, specifically with regard to liquid crystal display devices, semiconductors, computer software, cellular telephone systems, laser devices and audio amplifiers. ■

Chris Moreno Named One of the "100 Most Influential Hispanics"

Intellectual Property Group Shareholder Chris Moreno was recently named one of the United States' "100 Most Influential Hispanics" by *Hispanic Business* in the magazine's October 2010 edition. Moreno was honored alongside educators, politicians, social workers and business professionals nationwide for his intellectual property work on behalf of high-technology companies. *Hispanic Business* magazine is an industry-leading publication that has been featuring members of the Hispanic community for over 25 years. ■

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We welcome your input for future articles. Please call any member of the Intellectual Property Group with suggested topics, as well as other questions or comments concerning materials in this newsletter.

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