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Patents / Obviousness

KSR'd Again: Including a Keypad Is an Obvious Improvement over a Fax Machine Melody Wirz

Reversing a jury verdict that found three patents covering electronic money transfer were not obvious in view of the prior art, the U.S. Court of Appeals for the Federal Circuit held that the prior art keypad combined with a prior art electronic transaction system rendered the patents-in-suit obvious as a matter of law. *The Western Union Co. v. MoneyGram Payment Sys., Inc.*, Case No. 10-1080 (Fed. Cir., Dec. 7, 2010) (Lourie, J.).

Western Union brought a patent infringement action against MoneyGram asserting infringement of four patents, three relating to methods of sending money through a financial services institution and the fourth relating to methods for receiving transferred money. A jury concluded that MoneyGram failed to show the patents were obvious and awarded Western Union reasonable royalty damages of \$16.5 million. The district court declined to grant MoneyGram's request for judgment as a matter of law (JMOL) that the patents were obvious. MoneyGram appealed with respect to the three patents relating to methods of sending money.

The Federal Circuit first determined that MoneyGram's right to appeal based on obviousness had not been waived, despite the fact that MoneyGram's Rule 50(a) motion did not specifically set forth the prior art arguments asserted on appeal, noting at "even a cursory motion suffices to preserve an issue" so long as it alerts the court to the party's position and puts the opposing party on notice.

The claims in issue are directed to an electronic transaction system having a keypad that works over the internet. During trial, MoneyGram presented evidence as to a prior art Western Union system that used a fax machine. MoneyGram also presented testimony that keypads (missing from the fax used in prior art system) already existed at Western Union retail locations. The Federal Circuit concluded that no reasonable jury should have found the MoneyGram failed to present sufficient evidence at least demonstrating that the elements were present in the prior art.

Next, the Court analyzed whether there was a motivation to combine the prior art fax based system with a keypad. Citing the KSR "predictable results" standard, the Court found that common sense demonstrates why the combination would have been obvious, concluding that "the use of an electronic transaction device where the prior art employed a fax machine to be an unpatentable improvement at a time when such a transition was commonplace in the art." Addressing additional claim language requiring that the keypad access a database, the Federal Circuit found that when replacing a fax machine with a keypad, one "would necessarily have known how to retrieve transaction details

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from the database." Similarly, claim recitations regarding the use of internet-based communications were deemed an obvious improvement.

Finally, the Court considered whether claim recitations regarding a code stored on the database were obvious. At trial, MoneyGram presented evidence that the prior art taught invoices that had a code that could be used for tracking. In light of this evidence, the Federal Circuit determined that common sense would allow the code so generated to be used at another location, noting that a "person of ordinary skill is also a person of ordinary creativity."

Western Union argued that secondary considerations of non-obviousness supported the jury verdict. However, citing the requisite nexus between the commercial success and the claimed invention, the Federal Circuit concluded that Western Union failed to present any relevant evidence proving such a nexus. Finally, the panel noted that weak secondary considerations of non-obviousness generally do not overcome a strong *prima facie* case of obviousness.

Patents / Litigation / Venue

Venue Jurisprudence Evolves ... Win Some; Lose Some

David M. Stein

The U.S. Court of Appeals for the Federal Circuit recently issued two more mandamus opinions on motions to transfer patent cases out of the U.S. District Court for the Eastern District of Texas, one denying transfer and one granting it. *In re Vistaprint Limited and OfficeMax*, Misc. Docket No. 954 (Fed. Cir., Dec. 15, 2010), (granting *mandamus* order); *In re Acer*, Misc. Docket No. 942, (Fed. Cir., Dec. 3, 2010) (denying *mandamus* order).

In *In re Vistaprint Ltd. and OfficeMax*, the Federal Circuit declined to grant the mandamus request to transfer the case to Massachusetts. The district court weighed the various transfer factors, finding some favored transfer, but it ultimately concluded these factors did not outweigh considerations of judicial economy. The district court previously handled a case involving the same patent in suit (the only one), and it had become familiar with the technology and issued a claim construction. There also was another currently pending case before the district court with the same plaintiff and patent involving the same underlying technology and similar accused services.

The petitioner essentially argued for a per se rule that, when all of the convenience factors clearly favor transfer, it is necessarily an abuse of discretion to deny transfer based on judicial economy. The Federal Circuit rejected this position, noting, "[a]t the end of the day, §1404(a) balances a number of case-specific factors, not just convenience." It also reiterated that the Federal Circuit has "repeatedly rejected the use of per se rules in forum non conveniens analyses."

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The Federal Circuit also rejected the petitioners' argument that it was the magistrate judge who construed the patent claims in the earlier case, not the district judge, finding, "it was not plainly incorrect to conclude that having the same magistrate judge handle this and the co-pending case involving the same patent would be more efficient than requiring another magistrate or trial judge to start from scratch."

The Court did note, however, that it was not intending the *In re Vistaprint* holding to mean that once a patent is litigated in a particular venue, the patent owner would have a "free pass" to maintain all future litigation in that venue.

The Federal Circuit reached a different conclusion in *In re Acer*, ordering the case transferred to the U.S. District Court for the Northern District of California. In *Acer*, a plaintiff headquartered in the Northern District of California sued 12 defendants for patent infringement in the Eastern District of Texas. One of these defendants, Dell, was headquartered in Texas, though not within the Eastern District. The majority of the defendants, however, were headquartered in California, with five of them headquartered in the Northern District of California. No party was headquartered in the Eastern District of Texas.

The Federal Circuit noted that the majority of documents and witnesses would be within the Northern District of California or at least closer to it. The presence of one Texas defendant did not overcome this: "The number of Dell witnesses, even if greater than one, will be insignificant, given that the allegation of infringement against Dell is largely based on integrated software of other defendants with headquarters outside of Texas." The Federal Circuit also noted the importance of the subpoena power to compel witnesses and evidence in California, as well as the localized interest in California given that the plaintiff, most of the defendants, the inventor and the prosecuting attorneys all were located there.

The Court did not overrule the district court's position that court congestion, familiarity with governing law and conflict of law factors do not favor either venue.

Patents / Right to Appeal

Stipulation to Final Judgment Does Not Constitute Waiver of Right to Appeal

Whitney D. Brown

The U.S. Court of Appeals for the Federal Circuit rejected the contention that a party waived its right to appeal by stipulating to final judgment. *Taylor Brands LLC v. GB II Corp.* d/b/a *Columbia River Knife and Tool Co.*, Case Nos. 10-1151; -1294 (Fed. Cir., Dec. 9, 2010) (Dyk, J).

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Taylor Brands sued Columbia River Knife and Tool Company (CRKT), alleging infringement of its U.S. patent directed to "assisted opening" knives. CRKT counterclaimed, seeking declaratory judgments of non-infringement and invalidity. Before discovery commenced, CRKT counterclaimed, seeking summary judgment of non-infringement of 22 of the accused products. The parties then moved to amend their respective pleadings to add false marketing and false advertising claims. The district court granted CRKT's motion for partial summary judgment, holding that, under the court's construction, the 22 models did not infringe the asserted claims. Both parties thereupon agreed to withdraw motions to amend their pleadings and CRKT agreed to dismiss without prejudice its counterclaim for declaratory judgment of invalidity. Taylor Brands then requested that the court enter a final judgment, and both parties consented to a proposed Stipulated Final Judgment.

Taylor Brands filed a timely notice of appeal, seeking to challenge the court's grant of summary judgment of noninfringement. CRKT moved to dismiss Taylor's notice of appeal for standing, on the basis that Taylor Brands had waived its right to appeal by consenting to the entry of a final judgment.

The Federal Circuit, noting Supreme Court and appellate court precedent stating that entry of a stipulated final judgment after a dispositive ruling does not bar an appeal, disagreed. The Court drew a distinction between consenting to the substance of a judgment, "the substantive outcome of the judgment will be," as opposed to consenting to the form of a judgment. While a party that consents to the substance of a judgment is presumed to have waived its right to appeal, no waiver exists when a party consents solely to the form of a judgment, because "merely agreeing to the form of a judgment does not it itself imply that the party agrees with the judgment's substantive outcome, or intends to abandon its position on the issues."

The panel found no showing that Taylor Brands had agreed to surrender its infringement claim and noted that Taylor Brands' consent constituted a "purely ministerial act of entering a judgment pursuant to Rule 58 implementing the summary judgment decision." Thus, Taylor Brands consented to judgment only to the extent it effectuated the court's already-granted summary judgment order.

Patents / Personal Jurisdiction

Court Has Personal Jurisdiction over a Foreign Company that Imports Accused Products into the District Vinod J. Mapranath

The Court of Appeals for the Federal Circuit held that the a federal district court had personal and specific jurisdiction over a Russian corporate entity that had purposely imported goods to be used by residents in the district, where the plaintiff's claims related to and accused those imported goods of patent infringement. The Court also held that it

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would be fair to exercise personal jurisdiction. *Nuance Communications v. Abbyy Software House*, Case No. 10-1100 (Fed. Cir., Nov. 12, 2010) (Rader, J.).

This case focuses on whether a district court has the jurisdiction to hold a foreign company liable for patent infringement when it imports allegedly infringing goods into the United States through a sister company. Nuance alleged that Abbyy Software, Abbyy USA and Abbyy Production infringed patent claims related to optical character recognition software. Abbyy Software is a parent company that wholly owns subsidiaries Abbyy USA and its Russian sister company, Abbyy Production. The Federal Circuit focused its reasoning on the legal theory of specific personal jurisdiction applying the three-prong test of Akro and focusing on (1) whether Abbyy Production purposely imported its software into the United States so that it would be used by residents in the district; (2) whether the claims relate to and accuse those imported goods of patent infringement; and (3) whether it would be fair to exercise jurisdiction over Abbyy Production.

First, the Federal Circuit found that Abbyy Production purposely imported its software for use by residents in the district. The Court highlighted the fact that some previous cases cited by Abbyy were decided under a different (narrower) long-arm statute and that, factually, the transactions in the cited cases occurred between unrelated entities whereas here the agreement, between Abbyy Production and Abbyy USA, was between sister companies operating under a single parent company. The Court also observed that agreement here provided that more than 95 percent of the profits would flow to Abbyy Production. In addition, the Court concluded that there was a focused effort by Abbyy Software to enter the U.S. market. As a result, the Court found that the first prong of the Akro test was met.

Second, the Court found that the cause of action for patent infringement relates to the allegedly infringing software imported into the district. Abbyy Production argued that the arrangement between Abbyy Production and Abbyy USA was simply an exchange of licensing software rights provided by Abbyy Production in return for royalty payments from Abbyy USA. The Court dismissed this argument as irrelevant, noting that Abbyy Production had made those products available through an established distribution chain and that the cause of action arose out of this distribution chain. Thus, the Court decided that the second prong of the Akro test was also met.

Finally, the Court found that extending jurisdiction over Abbyy Production would be fair because Abbyy Production for three reasons: it had established a distribution system to deliver its products; it knew the destination of its products; and it should have reasonably anticipated that it could be sued in the district.

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Patents / Patentable Subject Matter

Section 101 Eligibility Satisfied if Invention Has Specific Application to Technology Isaac Crum

Reversing a district court's finding that two digital halftoning patents were invalid as claiming patent-ineligible subject matter under 35 U.S.C. §101, the U.S. Court of Appeals for the Federal Circuit held that the RCT patents directed to digital halftoning were not "abstract ideas" and thus satisfied the requirements of §101. *Research Corporation Technologies, Inc. v. Microsoft Corp.*, Case No. 10-1037 (Fed. Cir., Dec. 8, 2010) (Rader J.).

RCT filed suit against Microsoft alleging that Microsoft infringed six of RCT's patents relating to digital halftoning. Digital halftoning is a process of simulating a wide range of colors or shades while using a limited number of colors (*i.e.*, simulating shades of gray using only black and white). One method of digital halftoning, called thresholding, involves the use of a two-dimensional array (a mask). The thresholding technique compares the gray level at each pixel against the threshold at the corresponding pixel of the mask. If the gray level exceeds the mask value, the pixel is turned on; if it does not, the pixel is left off. In order to measure the properties of halftoned images, a power spectrum can be created that graphs the relative frequency of dots at a particular gray level. This power spectrum, also known as a "blue noise" power spectrum, contains primarily high-frequency components and negligible low-frequency components.

The district court held that two of RCT's digital halftoning patents were directed to abstract ideas and were thus nonpatentable subject matter under §101. Accordingly, the district court granted summary judgment of invalidity. RCT appealed.

The Federal Circuit reversed, concluding that "the subject matter is a 'process' for rendering a halftone image. As a process, the subject matter qualifies under both the categorical language of §101 and the process definition in §100." Because the claimed subject matter qualified as a process, the Court went on to consider whether the patents were directed to "abstract ideas" so as to render the claimed subject matter unpatentable. In holding that the patents were not directed to abstract ideas, the Court noted that "inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act." The Federal Circuit also observed that the "invention presents functional and palpable applications in the field of computer technology." In light of these observations, the Court found that there was nothing abstract about the claimed subject matter.

In this appeal, the Federal Circuit also considered whether two of RCT's other patents were entitled to claim priority based on an earlier filed application. The Federal Circuit held that because Microsoft had come forward with

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intervening prior art, the burden was on RCT to establish entitlement to priority under §120. The Court ultimately upheld the district court on one of the patents (which shared the same 1991 vintage specification as the other patents in suit), finding that the asserted claims of that patent, which were not limited to a blue noise mask, were broader than the blue noise mask invention disclosed in the parent application and, thus, not entitled to claim priority. However, the Federal Circuit found that the asserted claim of the other patent, which did create a blue noise mask, was entitled to priority because it was a pure apparatus claim and not limited to any particular process of making the blue noise mask.

Patents / Standing

License to Sue? It Depends on Standing

Hasan Rashid

Considering the issue of licensee standing to sue, the U.S. Court of Appeals for the Federal Circuit held that a licensee lacked sufficient patent rights to be sued for declaratory judgment where it had only a field of use limited exclusive license. *A123 Sys., Inc. v. Hydro-Quebec*, Case No. 10-1059 (Fed. Cir., Nov. 10, 2010) (Lourie, J.).

Hydro-Quebec (HQ) is the exclusive licensee in certain fields of use to two patents assigned to The University of Texas System (UT). After HQ sent an infringement notice letter to A123 Systems (A123), A123 filed a declaratory judgment action in the U.S. District Court for the District of Massachusetts. HQ moved to dismiss the case because it lacked sufficient patent rights to be sued instead of or without UT, which enjoys 11th Amendment sovereign immunity. HQ and UT later filed an infringement suit in the U.S. District Court for the Northern District of Texas. The Texas case was stayed and the Massachusetts case was dismissed pending reexamination of the patents.

After reexamination, A123 moved to reopen the Massachusetts case. HQ opposed, citing its previously filed motion to dismiss. The district court declined to reopen the case, noting that HQ's insufficient rights in the patents rendered UT a necessary party, and that UT's 11th Amendment sovereign immunity precluded joinder. The district court also observed that A123 had an adequate remedy as a counterclaimant in the Texas action. A123 appealed.

The Federal Circuit affirmed the dismissal, concluding that UT was a necessary party even though HQ was an exclusive licensee, because its rights were limited to certain fields of use. The Court had little trouble with A123's argument that HQ had asserted it had all substantial patent rights in its infringement letter to A123 as a "unilateral representation" that cannot alter UT's rights in the patents for the purposes of standing. Echoing the district court, the Federal Circuit also concluded that since UT is an arm of the State of Texas, it must waive its 11th Amendment sovereign immunity to be sued and that a waiver for the Texas action does not apply to the Massachusetts action, even though the same patents and parties were involved. Rather, the Court found, a separate waiver is necessary.

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Finally, even though the Massachusetts district court did not consider whether UT was an indispensable party under Fed. R. Civ. P. 19, the Federal Circuit concluded that the factual record permitted it to hold that UT was indispensable, noting that UT's and HQ's interests are not completely aligned due to the field of use carve-outs, because UT could not otherwise defend the patents' validity and because UT could bring suit against A123 under a different field of use, risking multiple lawsuits and inconsistent relief. Importantly, A123 had an alternate forum in the Northern District of Texas.

Practice Note: Whether a licensee thinks or asserts that it has all substantial patent rights is irrelevant to whether it actually has standing to sue—only the license agreement can tell.

Patents / Non-Infringement

Patent Holders Cannot Reclaim Scope of Invention Disclaimed During Prosecution

Charles J. Hawkins

In one of a series of long-standing patent disputes between the parties, the U.S. Court of Appeals for the Federal Circuit agreed with the district court's prosecution disclaimer based claim construction and consequent holding of non-infringement. *ERBE Elektromedizin GmbH v. Canady Tech. LLC*, Case No. 08-1425; -1426 (Fed. Cir., Dec. 9, 2010) (Prost, J.) (Newman, J., concurring-in-part, dissenting-in-part). The Court also affirmed the district court's summary judgment that there was no protectable color mark.

The case involved competitors—ERBE Elektromedizin GmbH and Canady Technology LLC—that make gasenhanced electrosurgical products. ERBE alleged that Canady's endoscopic probes infringed its U.S. patent directed to a surgical tissue coagulator and certain of its trademarks. Canady countered with sham litigation antitrust claims.

The district court, after a *Markman* hearing, construed the term "low flow rate" to mean "a rate of flow less than about 1 liter/minute and producing flow velocities less than 19km/hour such that the gas exiting through the distal end opening forms a non-laminar inert gas temperature." In doing so, the district court relied on the applicant's disclaimer during prosecution to overcome prior art. Based on its claim construction, the district court granted summary judgment of non-infringement as to the asserted claims.

The district court also granted summary judgment as to ERBE's trademark claims, finding that ERBE failed to establish a genuine issue of material fact that the blue tube portion of its products had acquired a secondary meaning. Finally, the district court granted ERBE's motion for summary judgment as to Canady's antitrust counterclaims. The parties timely appealed.

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On appeal, the Federal Circuit considered ERBE's challenge of the district court's claim construction and consequent grant of summary judgment of non-infringement. ERBE argued that the district court's construction of the term "low flow rate" violated several established principles of claim construction, namely the failure to give the term its ordinary and customary meaning, ignoring the doctrine of claim differentiation and erroneously importing quantitative limitations from the specification.

The Federal Circuit rejected these arguments, relying primarily on the prosecution history, in which the applicant distinguished its invention from the prior art to obtain allowance. In particular, after an Office Action rejecting nearly all pending claims as obvious, the applicant responded that the low gas flow rate of its invention allows the device to operate so as to reduce patient injuries. As the applicant, ERBE distinguished its device from the prior art by specifically referring the higher flow rate ranges in those references. Based on this distinction, the examiner allowed the claims. Viewing the prosecution history as disclaimer, the Federal Circuit affirmed the lower court's construction and rejected the argument that the lower court improperly imported quantitative limitations into the claim term from the specification.

Since ERBE failed to present evidence that the accused device exhibited a "low flow rate" as defined by the Court, the Federal Circuit affirmed the summary judgment of non-infringement.

ERBE's color mark was only on the Supplemental Register and so was not entitled to a presumption of validity. The Federal Circuit, applying the law of the regional circuit, found that ERBE failed to rebut the challenger's proof that its color mark was invalid. Specifically, the Court found that ERBE failed to create a genuine issue of material fact that the color blue, as applied the tube portion of its probes, was not functional. Alternatively, the Federal Circuit found that ERBE failed to make a showing that its mark had a secondary meaning.

Finally, addressing Canady's cross-appeal on antitrust, the Federal Circuit rejected Canady's argument that the series of litigations between the parties should be analyzed under a different standard than the traditional PRE sham litigation analysis.

Judge Newman, dissenting from the majority's ruling regarding ERBE's trademark allegations, argued that the majority departed from established law and precedent in analyzing the functionality of the asserted mark and in discounting testimony as to the visibility, during surgery, of other colors.

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CERT ALERT

There's Trouble Right Here in River City

Paul Devinsky

The U.S. Supreme Court granted Microsoft's petition for certiorari in *Microsoft Corp. v i4i*. The Court will now consider whether an accused infringer that challenges patent validity based on prior art not considered by the U.S. Patent and Trademark Office (USPTO) during prosecution must overcome the 35 U.S.C. §282 presumption of validity by "clear and concurring evidence" or whether some lower standard of proof will suffice. *Microsoft v. i4i Limited Partnership*, Case No. 10-290 (Supr. Ct., Dec. 1, 2010).

The "clear and concurring" standard of proof has been used by the U.S. Court of Appeals for the Federal circuit since 1984. (See *American Hoist & Derrick v. Sowa & Sons.*) Prior to the 1982 establishment of the Federal Circuit, most of the regional courts of appeal applied the less differential "preponderance" standard to the issue, but the Federal Circuit, in setting its rule, took note of the "the deference that is due to a qualified government agency presumed to have properly done its job."

Microsoft was supported in its certiorari petition by 11 *amici* representing major corporations, law professors and trade associations. Most of the *amici* faulted the deference given to the USPTO examiners who have limited time and resources to the examination of any particular application, who examine applications on a strictly *ex parte* basis, and who only infrequently consider non-patent prior art publication or prior products. The *amici* also note that juries already tend to give undue deference to the decision of USPTO in issuing a patent, especially in cases where the technology is complex.

Predictably, Microsoft and the *amici* characterized the Federal Circuit rule as inflexible; another "bright line" test—a characterization that has resulted in the reversal of several Federal Circuit rulings in recent history, including the KSR obviousness case, in which the Supreme Court, in dicta, noted that the rational for showing deference to the USPTO was "much diminished" where the prior art in issue was not before the examiner.

Chief Justice Roberts recused himself from consideration of the petition.

Practice Note: The Supreme Court has now granted certiorari in two other patent cases and one copyright case this term. The copyright case *Costco v. Omega* was recently decided. (See *IP Update*, this issue). The other two patent cases *are Stanford University v. Roche Molecular Systems, Inc.*, Case No. 09-1159 (Supr. Ct., November 1, 2010) (See *IP Update, Vol. 13, No. 11*) (to decide the issue whether, under the Bayh-Dole Act, inventors may assign

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their rights in patents resulting from federally funded research) and *Global-Tech v. SEB*, Case No. 10-6 (certiorari granted October 12, 2010) (to decide the proper standard to use to support a finding of inducement to infringe).

FDA / New Chemical Entity Exclusivity

Derivative Drugs Having Covalent, Non-Ester Modifications of a Previously Approved Drug Are Entitled to New Chemical Entity Exclusivity

Cynthia Chen, Ph.D.

The U.S. Court of Appeals for the District of Columbia Circuit affirmed a summary judgment from the D.C. District Court in favor of the U.S. Food and Drug Administration (FDA), holding that the FDA's interpretation of "new chemical entity" under 21 U.S.C. § 355(j)(5)(F)(ii) was reasonable. *Actavis Elizabeth LLC v. U.S. Food and Drug Administration*, Case No. 10-5066 (D.C. Cir., Nov. 9, 2010) (Randolph, J.).

The drug at issue was lisdexamfetamine dimesylate (Vyvanse®) for treating ADHD. Lisdexamfetamine consists of a portion of lysine (a common amino acid) that is covalently linked to dextroamphetamine via an amine bond. After lisdexamfetamine enters the body, it breaks apart to produce dextroamphetamine. In 2007, the FDA awarded "new chemical entity status" to lisdexamfetamine under § 355(j)(5)(F)(ii). The FDA had previously approved at least one application for dextroamphetamine.

Under § 355(j)(5)(F), a "new chemical entity" drug, *i.e.*, a drug with a previously unapproved active ingredient, enjoys five years of market exclusivity. If a drug contains previously approved active ingredients, then a three-year exclusivity period is awarded to the sponsor that provides new clinical investigations that are essential to the approval. Accordingly, Actavis sued the FDA, arguing that only three years of exclusivity should be granted for lisdexamfetamine because it had the same "active ingredient" as the previously approved dextroamphetamine. The FDA's position was that lisdexamfetamine was a new active ingredient, independent of previously approved dextroamphetamine. The FDA noted that "drug derivatives containing non-ester covalent bonds are, on the whole, distinct from other types of derivative drugs such that the former are uniquely deserving of 'new chemical entity' status and the resulting five-year exclusivity."

The D.C. Circuit, agreeing with the district court and the FDA, held that the FDA's interpretation of its regulations was entitled to judicial deference. Because the FDA had concluded that, for certain types of prodrugs, the entire preingestion molecule should be deemed responsible for the drug's activity and because Congress gave no indication, either in the statute itself or in the legislative history, as to what molecules or portions thereof constitute distinct "active ingredients," the court concluded that FDA's interpretation of "active ingredients" must stand if it was reasonable. The court cited the FDA's "longstanding experience" that "even minor covalent structural changes are

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capable of producing not only major changes in the activity of a drug but changes that are not readily predicted," and held that the FDA's view should not be second-guessed when it was based on "the agency's evaluations of scientific data within its area of expertise."

Practice Note: An ester derivative of a previously approved drug is entitled to three years of exclusivity if new and essential clinical investigations are provided, whereas derivative drugs having covalent, non-ester modifications of a previously approved drug are entitled to five years of exclusivity. While Actavis offered evidence that some non-ester, covalent modifications do not alter the basic properties of the drug in question, the court held that the FDA is allowed to "employ bright-line rules for reasons of administrative convenience, so long as those rules fall within a zone of reasonableness and are reasonably explained." Pharmaceutical companies may want to consider whether it would reduce R&D costs to develop new drugs that are modified from previously approved drugs.

Trademark / Remedies

Seventh Circuit Sets Own Standard for "Exceptional" Cases Justifying Attorneys' Fees Under the Lanham Act

Rita Weeks

Addressing the commercial reality that many Lanham Act suits are brought against competitors for the purpose of gaining a competitive advantage independent of the outcome of the case, the Seventh Circuit Court of Appeals, in an opinion written by Judge Richard A. Posner, held that "abuse of process" is the proper standard for determining that a case is "exceptional," warranting an award of attorneys' fees to the prevailing party. *Nightingale Home Healthcare Inc. v. Anodyne Therapy LLC*, Case No. 10-2327 (7th Cir., Nov. 23, 2010) (Posner, J.).

Plaintiff Nightingale Home Healthcare sued the defendant, Anodyne Therapy, under the Lanham Act and corresponding state law for alleged false representations made concerning the defendant's products, which are infrared lamps intended to relieve pain and improve circulation. The plaintiff had purchased several lamps from defendant and alleged that the defendant's sales representative had falsely represented that the lamp had been approved by the U.S. Food and Drug Administration for the treatment of peripheral neuropathy. While the defendant's lamps were not FDA-approved to treat that condition, the lamps had in fact been approved by the FDA for other treatment purposes. Further, the fact that the FDA had not approved the lamps for peripheral neuropathy did not preclude a healthcare provider, such as the defendant, from prescribing the device to treat that condition as an off-label usage. The district court granted summary judgment to the defendant and found that the plaintiff had made its claim in an attempt to coerce a price reduction from the defendant. Pursuant to the Lanham Act's provision permitting the award of attorneys' fees to the prevailing parties in "exceptional" cases, the court awarded Anodyne \$72,747. Nightingale appealed the award of attorneys' fees.

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The 7th Circuit held that the district court did not err in awarding the defendant its attorneys' fees as the prevailing party, because the underlying facts showed that the plaintiff had engaged in abuse of process. The court explained that abuse of process is the use of litigation for an improper purpose, regardless of whether the claim is colorable, often designed to force the opposing party to yield on a mater not involved in the suit. Nightingale was found to have engaged in abuse of process because it had brought its claims solely in an attempt to force Anodyne to offer its products at a lower price. After reviewing precedent from other circuits, the court announced its own standard that a case under the Lanham Act is "exceptional" so as to warrant an award of attorneys' fees when: (1) the defendant prevails and plaintiff is found to have engaged in abuse of process; or (2) the plaintiff prevails and the defendant has no defense but persists in its trademark infringement or false advertising in order to impose costs on its opponent.

Trademark / Licensing

FREECYCLE Marks Recycled to the District Bin

Rita Weeks

Considering whether a local chapter of a national non-profit could escape liability for infringement of the national organization's trademarks, the U.S. Court of Appeals for the Ninth Circuit affirmed the grant of summary judgment to the local chapter, finding that the national group had abandoned its FREECYCLE trademarks by engaging in "naked" licensing. *FreecycleSunnyvale v. The Freecycle Network*, Case No. 08-16382 (9th Cir., Nov. 24, 2010) (Callahan, J.).

The Freecycle Network is a national non-profit organization dedicated to promoting and facilitating the reuse of unwanted items by gifting them to others, rather than disposing of them. The plaintiff permits local sub-groups to use its FREECYCLE trademarks upon request. A group calling itself "FreecycleSunnyvale," formed independently, requested permission to use the marks. The national organization agreed so long as the FREECYCLE marks were not used for commercial purposes. Subsequently a dispute arose between the parties concerning use of the marks. FreecycleSunnyvale brought a declaratory judgment action against the national organization to protect itself from potential claims of trademark infringement.

In support of non-infringement, FreecycleSunnyvale alleged that the national Freecycle organization had abandoned its rights to the FREECYCLE marks by engaging in naked licensing. A trademark owner has a duty to monitor and control the quality of goods and services sold under its mark, including those sold by licensees, so that the public may safely rely on the mark as an indicia of a certain level of quality. A trademark owner who fails to exercise such quality control when its mark is used by others engages in "naked" licensing, which can result in abandonment of the trademark. The trial court agreed granted summary judgment to FreecycleSunnyvale, agreeing that the national organization abandoned its FREECYCLE marks by failing to exercise sufficient quality control.

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The 9th Circuit noted several factors weighing towards naked licensing in affirming the trial court's determination that the national organization had abandoned its marks. First, the parties had not entered into any agreement containing restrictions on the local group's use of the marks or provisions for monitoring and inspecting the goods or services offered under the marks. Second, requiring its sub-groups to comply with the group's vague and unevenly applied standard, "Keep it Free, Legal, and Appropriate for all Ages," did not demonstrate that the national group possessed actual control over its licensees. Finally, the court found that the national organization did not maintain a sufficiently close working relationship with FreecycleSunnyvale to justify reliance on the sub-group's quality control measures. Toward this factor, the court found it significant that the only communications existing between the parties were two emails concerning the request to use the marks and the demand to cease use of the marks.

Practice Note: While other jurisdictions require a showing of naked licensing *plus* a demonstration that the mark has lost its trademark significance to find abandonment, the 9th Circuit did not require both elements here (the court declined to consider whether loss of trademark significance is required because the trademark owner raised it for the first time on appeal). Accordingly, trademark owners in the 9th Circuit should be especially careful to institute adequate quality control measures to avoid licensee challenges to their marks based upon abandonment. Trademark license agreements should contain, at a minimum, restrictions toward a licensee's permitted use of the mark and provisions toward the trademark owner's monitoring and inspection of the quality of goods and services offered under the mark.

Copyright / First-Sale Doctrine

Supreme Court Deadlock Leaves in Place Ninth Circuit Decision Denying First-Sale Doctrine Defense to Resale of Foreign-Made Copyrighted Items

Paul Devinsky and Rita Weeks

In a rare 4-4 decision that disappointed many copyright practitioners who were hoping for a resolution of the tension between section 109 (first sale exhaustion) and section 602 (importation) of the Copyright Law, the Supreme Court punted the issue, effectively upholding a U.S. Court of Appeals for the Ninth Circuit decision that the "first-sale doctrine" does not apply to the importation of copyrighted works that are manufactured abroad. *Costco v. Omega*, Case No. 08-1423 (Supr. Ct., Dec. 13, 2010). The 9th Circuit's decision was reported in IP Update at Vol. 11, No. 10, October 2008.

Omega makes its watches in Switzerland, incorporating a design protected by a U.S. copyright registration. The copyrighted work in question is a small design on the back of the watch. The underlying dispute arose when Costco legitimately acquired Omega brand watches through a New York company that bought and imported the watches from overseas—at much lower prices than Costco would have paid. Omega had authorized the initial foreign sale of

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the watches, but did not authorize their importation into the United States or their resale by Costco. Ordinarily, under the first-sale doctrine a domestic (U.S.) sale of a copyrighted work exhausts the copyright owner's copyright and a purchaser can freely resell its copy.

Omega sued Costco for copyright infringement for the unauthorized importation of copyrighted works. At the trial court level, Costco successfully defended on the basis of the first-sale doctrine. The 9th Circuit reversed, reiterating its general rule that the first-sale doctrine provides no defense where unauthorized imports were genuine copies that were foreign-made and not previously sold in the United States with the authority of the copyright owner. In effect, the 9th Circuit held that because of the territorial nature of copyrights, the first-sale doctrine does not apply to sales overseas, such that Costco's resale of Omega watches was the first sale of the copyrighted items in the United States and thus requiring Omega's authorization.

The split resulted from the recusal of Justice Elena Kagan, who filed an *amicus* brief in the case in her previous position as solicitor general. While the Supreme Court's decision upholds the 9th Circuit's decision, the ruling is only binding on the 9th Circuit. Nonetheless, the Supreme Court's decision is significant in that at least within the 9th Circuit, the unauthorized resale of genuine copyrighted items acquired overseas may lead to copyright infringement liability if the items were not made or first sold in the United States with the authority of the copyright owner.

The case now returns to the district court to be tried on Costco's other defenses and counter-claims.

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