

Intellectual Property

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VOLUME 16, ISSUE 12 / OCTOBER 6, 2009

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Intellectual Property Litigation Reporter

Published since August 1989

Publisher: Mary Ellen Fox

Executive Editor: Jodine Mayberry

Production Coordinator: Tricia Gorman

Managing Editor: Robert W. McSherry

Editor: Deborah Nathan, Esq.

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Intellectual Property Litigation Reporter

(ISSN 1554-4052) is published biweekly by Andrews Publications, a Thomson Reuters business.

Andrews Publications, 175 Strafford Avenue, Building 4, Suite 140, Wayne, PA 19087
877-595-0449 in Pennsylvania;
Fax: 800-220-1640; www.andrewsonline.com
Customer service: 800-328-4880

Subscription Rate (26 issues)

\$1,234 Print version

For more information, or to subscribe, please call 800-328-9352.

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COMMENTARY

ANDA Litigation: The Pitfalls of the Paragraph IV Certification After *Takeda v. Mylan*

By Chandran B. Iyer, Esq., and Deboadhonyaa Sengupta

Paragraph IV Certification: The Story Thus Far

In filing an abbreviated new-drug application, generic-drug manufacturers are required to submit a certification regarding patents listed in the Food and Drug Administration's Orange Book¹ claiming the drug in question. A Paragraph IV certification is one type of certification whereby the ANDA applicant sets forth the factual and legal bases for why a listed patent is invalid or would not be infringed by the generic drug.^{2,3}

As a matter of course, Paragraph IV certifications are prepared by generic-drug manufacturers prior to litigation and without the benefit of discovery. In many ANDA actions, however, the generic-drug manufacturers prevail on theories *not asserted* in their Paragraph IV certifications and, instead, on information obtained during discovery.⁴ The U.S. Court of Appeals for the Federal Circuit's recent decision in *Takeda Chemical Industries Ltd. v. Mylan Laboratories Inc.*, however, illustrates the risks of asserting defenses not contained in a Paragraph IV certification while abandoning defenses that are contained in the certification.⁵

In *Takeda* the Federal Circuit affirmed an award of \$16.8 million in fees and expenses, with interest, against generic-drug manufacturers Mylan and Alphapharm (\$11.4 million for Mylan and \$5.4 million for Alphapharm), based on an "exceptional case" theory.

The decision was based in part on the fact that both Alphapharm's and Mylan's defenses at trial were different from the legal and factual bases set forth in their respective Paragraph IV certifications. The Federal Circuit's finding was also based on Alphapharm's "shifting theory of obviousness" (failure to explain why a specific compound

would be chosen as a lead compound, and Mylan's "frivolous" and unsupported allegation of Takeda's inequitable conduct during prosecution of the patent in suit).

After *Takeda* generic-drug manufacturers now run the risk of an "exceptional case" finding against them based in part on differences between the contents of the Paragraph IV certification and the defenses asserted at trial.⁶ In other words, *Takeda* allows plaintiffs to seek and recover attorney fees in ANDA litigation by proving an "exceptional case" based on, among other things, a deficient Paragraph IV certification.

The *Takeda* Trial: Lack of Correlation Between Paragraph IV Letters and Trial Strategy

The patent in suit (Takeda's U.S. Patent No. 4,687,777) claimed pioglitazone, a highly successful anti-diabetic drug available commercially as Actos. Alphapharm and Mylan filed individual ANDAs and corresponding Paragraph IV certifications to produce generic versions of pioglitazone.

At trial Alphapharm's main argument was that the pioglitazone patent was obvious in view of compound (b) disclosed in U.S. Patent No. 4,287,200 and in *Sohda II*.⁷ Alphapharm also argued that prior-art compound 58, taught in *Sohda II*, was a lead compound, and that further experimentation on compound 58 would have led to the discovery of pioglitazone.⁸

However, although Alphapharm identified a number of compounds in its Paragraph IV certification as rendering the patent for pioglitazone obvious, arguments concerning compounds (b) and 58 were not included in its Paragraph IV certification.⁹ In fact, at trial, Alphapharm's experts contradicted many of the arguments outlined in the Paragraph IV certification related to the compounds identified therein.

Similar to Alphapharm, Mylan, in its Paragraph IV certification, identified compound 14 of *Sohda II* in its Paragraph IV certification, but at trial relied on compound 57 of *Sohda II*, as rendering the pioglitazone patent obvious. However, Mylan's expert's testimony contradicted Mylan's reliance

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on compound 57 of Sohda II. Mylan then abandoned its obviousness theory and argued that Takeda had engaged in inequitable conduct during the prosecution of the '777 patent.

The District Court's Decision

In finding an "exceptional case" and awarding attorney fees to Takeda, the U.S. District Court for the Southern District of New York said Alphapharm's evidence fell "woefully short of demonstrating a credible claim of obviousness."¹⁰ The court said it was incumbent on Alphapharm to provide in its Paragraph IV certification a legal and factual basis as to why compound (b), the compound relied on at trial, was a lead compound and, at the very least, outline the basis for choosing compound (b) and modifying it in a manner appropriate to arrive at pioglitazone, as argued by Alphapharm at trial.¹¹

Moreover, the court held that Alphapharm changed its strategy because the arguments in its Paragraph IV certification were unsupported, especially since they were contradicted by the company's witnesses at trial.^{12,13} The court further stated that Alphapharm needlessly extended the trial with the use of its ever-changing theory of obviousness.

In Mylan's case, the court said its Paragraph IV certification was "deeply flawed" and was not defended during discovery.¹⁴ Although Mylan argued that the change in trial strategy was necessitated by documents produced by Takeda during discovery, the court disagreed, saying Mylan's Paragraph IV certification lacked a good-faith basis because challenging the obviousness of a patent is based on prior art — information that does not change over time. The court also found that Mylan increased the burden and expenses associated with the litigation by its actions that, when taken together with the company's other misconduct (such as its unfounded claim of inequitable conduct), resulted in the finding of an exceptional case and the award of attorney fees to Takeda.¹⁵

The Federal Circuit's Affirmation of the District Court's Ruling

The Federal Circuit reviewed the District Court's finding of an "exceptional case" for clear error and the award of fees for abuse of discretion.

The Federal Circuit affirmed the District Court's decision on the basis that Alphapharm's and Mylan's Paragraph IV certifications were insufficient (*i.e.*, none of the arguments contained in their respective Paragraph IV certifications were asserted at trial).¹⁶ Although the Federal Circuit did not discuss the District Court's finding of misconduct by

Alphapharm based on the changing theory of obviousness and the failure to clearly explain the choice of compound (b) as the lead compound, the Federal Circuit agreed that Alphapharm's filing of a "baseless" Paragraph IV certification would "amount to litigation misconduct supporting an exceptional-case finding."¹⁷

With regard to Mylan, the Federal Circuit found that Mylan's Paragraph IV certification was "even more baseless than Alphapharm's."¹⁸ The court found that although in the Paragraph IV certification, Mylan asserted at trial that the pioglitazone patent was obvious based on compound 14, Mylan's expert "emphatically disagreed with this assertion."¹⁹

Moreover, the Federal Circuit said Mylan's Paragraph IV certification was filed in bad faith because it included scientific inaccuracies. The court also agreed with the District Court's finding of litigation misconduct based on Mylan's allegation (without sufficient proof), that Takeda engaged in inequitable conduct.

Looking at the totality of the circumstances, the Federal Circuit found that the District Court's finding of an "exceptional case" was meritorious. Additionally, the Federal Circuit found that the District Court did not abuse its discretion by awarding attorney fees to Takeda because of Mylan's and Alphapharm's "bad faith and vexatious litigation conduct."²⁰

Drafting a Paragraph IV Certification After Takeda

Takeda is of significant interest because it is not uncommon for trial strategies to change based on documents unearthed during the discovery phase of litigation. The issue now in light of *Takeda* is whether defendants will be penalized even if the defenses outlined in a Paragraph IV certification can be upheld but are abandoned at trial. This, in turn, raises another issue: If additional evidence as to the invalidity of a patent is unearthed during discovery, is the generic pharmaceutical company barred from asserting the defense at trial? In fact, in many cases, generic-drug manufacturers have prevailed at trial based on defenses not contained in the Paragraph IV certification and asserted for the first time at trial.²¹

Although the Federal Circuit emphasized that the decision in *Takeda* is limited to the specific facts of the case, generic-drug manufacturers now should ensure, in view of the severity of the sanctions awarded, that the defenses alleged in their Paragraph IV certification are well-supported in law and in underlying technical facts. Particularly, the generics makers should avoid broad Paragraph IV certifications that include defenses that may

not be asserted at trial, or vague assertions (such as obviousness) that are not supported by precedent. Although the finding of an “exceptional case” in *Takeda* was based only in part on the deficiencies in the Paragraph IV certifications, drafting of Paragraph IV certifications now requires more careful scrutiny and preparation. This is largely because, contrary to noninfringement or invalidity opinions, *Takeda* requires Paragraph IV certifications to anticipate most, if not all, the litigation defenses. Note, however, that *Takeda* does not exclude a party from raising a defense discovered after the suit is filed, if the defense could not have been raised earlier under Federal Rule of Civil Procedure 11.

‘Exceptional Case’: The Proper Vehicle For Recovery of Fees After *Takeda*

The Federal Circuit’s decision in *Takeda* appears to be an extension of its 2000 decision in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.*,²² where the court noted that the act of filing an ANDA is a “highly artificial act of infringement” that does not give rise to a finding of willful infringement.²³ In other words, according to *Yamanouchi*, fees in ANDA cases are properly recovered under an “exceptional case” theory, as opposed to a willful-infringement theory.

The patent at issue in *Yamanouchi* (U.S. Patent No. 4,283,408) related to inhibitors of gastric acid secretion. The lawsuit commenced after Danbury filed an ANDA application for famotidine, a stomach-acid-secretion inhibitor.

In *Yamanouchi* the Paragraph IV certification Danbury filed along with supporting affidavits contained incorrect factual assumptions directed to famotidine’s asserted obviousness. For example, one of the arguments Danbury included in the Paragraph IV certification asserted that selection of compound 44 from the patent in suit would be obvious based on its increased efficacy, as compared to cimetidine, the benchmark compound at the time of invention.

However, the trial court noted that activity was insufficient to establish obviousness because other compounds were far more effective than compound 44.

In *Yamanouchi*, as in *Takeda*, the Federal Circuit based its finding of “an exceptional case” on deficiencies in the obviousness defense set forth in a Paragraph IV certification. In upholding the District Court’s award of sanctions, the Federal Circuit noted that “the trial court need not have elevated the ANDA certification into a finding of willful infringement” and that “Danbury’s misconduct in filing a wholly unjustified ANDA certification and misconduct

during the litigation that followed” was sufficient to establish an “exceptional case” finding.²⁴

Yamanouchi was able to recover attorney fees upon the finding of an “exceptional case,” just as it could have upon a finding of willful infringement. *Takeda* and *Yamanouchi* also give rise to and validate an emerging trend in ANDA cases — the recovery of attorney fees by showing discrepancies in the arguments outlined in the Paragraph IV certification and the arguments asserted at trial. In other words, *Takeda* and *Yamanouchi* make it easier for plaintiffs to obtain attorney fees without having to prove willful infringement.

In both *Takeda* and *Yamanouchi*, the Federal Circuit found “exceptional cases” based on Paragraph IV certifications filed by the generic-drug manufacturers. That is, it found that the Paragraph IV certifications were frivolous and the arguments included in the letters could not be supported at trial. In fact, although *Yamanouchi* requested and prevailed on a finding of “willful infringement” in the District Court, the Federal Circuit found that the facts did not support willful infringement, but a finding of an “exceptional case.”

In view of *Takeda* and *Yamanouchi*, the recovery of fees by proving an “exceptional case,” may be an easier task because deficiencies in Paragraph IV certifications are now considered a separate basis for a finding that a case is exceptional. For this reason, we believe a Paragraph IV certification should not only be well supported both in law and in underlying technical facts, but should also anticipate litigation defenses.

Notes

¹ “Approved Drug Products With Therapeutic Equivalence Evaluations” (Orange Book), available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>.

² 21 U.S.C. § 355(j)(2)(A)(viii) requires that “an ANDA filer must file a certification for each patent claims the new drug, that in the opinion of the ANDA filer (I) the patent information has not been filed, (II) the patent has expired, (III) the date on which the patent will expire or, (IV) the patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA drug.” This commentary will only deal with subsection (IV), also referred to as a Paragraph IV certification.

³ 21 U.S.C. § 355(j)(2)(B)(iv)(II).

⁴ Brief of *amicus curiae* The GPhA, 4-15.

⁵ *Takeda Chem. Indus. v. Mylan Labs.*, 549 F.3d 1381 (Fed. Cir. 2008).

⁶ 35 U.S.C. § 285.

⁷ T. Sohda et al., *Studies on Antidiabetic Agents II, Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl] thiazolidine-2,4-dione (ADD-3878) and its Derivatives*, 30 CHEM. PHARM. BULL. 3580 (1982).

⁸ *Id.*

⁹ Alphapharm's Paragraph IV certification identified compounds 11 and 14 of Sohda II, compounds 16, 40 and 42 of the '200 patent, and ciglitazone of the '200 patent, the '777 patent and Sohda II.

¹⁰ *Takeda Chem. Indus. v. Mylan Labs.*, 459 F. Supp. 2d 227, 244 (S.D.N.Y. 2006).

¹¹ *Id.* at 238.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 245.

¹⁵ *Id.* at 251.

¹⁶ *Takeda*, 549 F.3d at 1389.

¹⁷ *Id.* at 1388.

¹⁸ *Id.* at 1389.

¹⁹ *Id.*

²⁰ *Id.* at 1393.

²¹ Brief of *amicus curiae* The GPhA, 10-15, citing cases such as *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001), and *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006), where strategies changed at trial.

²² *Yamanouchi Pharm. Co. v. Danbury Pharmacal*, 231 F.3d 1339 (Fed. Cir. 2000).

²³ *Id.* at 1347.

²⁴ 35 U.S.C. § 271(e)(2).

PATENT INFRINGEMENT

Treatment Patents Are Valid, Fed. Cir. Rules

***Prometheus Laboratories Inc. v. Mayo Collaborative Services et al.*, No. 2008-1403, 2009 WL 2959888 (Fed. Cir. Sept. 17, 2009).**

The U.S. Court of Appeals for the Federal Circuit has ruled that methods for treating diseases are not natural phenomena and therefore are patentable.

The decision reverses a California federal judge's ruling that the method described in two patents held by Prometheus Laboratories described natural phenomena that cannot be patented.

"*Prometheus* is significant because it states that patent claims directed to treatment methods are always transformative and thus always constitute patent-eligible subject matter when a drug is administered to a patient to address a certain condition of the patient," **Thomas C. Meyers** and **Robert J. Tosti**, partners in the IP group at **Brown Rudnick**, said about the decision. They are not involved in the case.

"Prometheus is significant because it states that patent claims directed to treatment methods are always transformative and thus always constitute patent-eligible subject matter when a drug is administered to a patient to address a certain condition of the patient," the panel said.

"The transformation is the effect on the patient's body after metabolizing the artificially administered drug. While the administered drug is metabolized as a result of natural processes inside the body, treating the patient by administering the drug "is itself not a natural process," Meyers and Tosti said.

Prometheus owns U.S. Patent Nos. 6,355,623 and 6,680,302.

Both patents claim methods for calibrating the proper dosage of drugs to treat gastrointestinal and non-gastrointestinal autoimmune diseases.

In 2004 Prometheus sued Mayo Collaborative Services and the Mayo Clinic in the U.S. District Court for the Southern

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District of California, alleging infringement of the two patents.

Mayo challenged the patents' validity, asserting that they were unpatentable subject matter.

Judge John A. Houston agreed.

He concluded that the each patent involved three steps: administering a drug to a patient, determining the metabolite levels and warning when an adjustment in dosage may be necessary.

The first two steps merely were "data-gathering" steps, while the third merely was a mental step, Judge Houston said.

The test for whether a claimed process can be patented is whether the claimed process is tied to a particular machine or apparatus or whether it transforms a particular article into a different state or thing, the Federal Circuit said.

The judge also found that the correlations between the metabolite levels and the dosages' therapeutic efficacy and toxicity were natural phenomena. The inventors did not "invent" the correlation; rather it was the product of the drugs' natural metabolizing, he said.

The inventors merely were observers of the relationship between the naturally produced metabolites and the therapeutic efficacy and toxicity, Judge Houston said.

The Federal Circuit disagreed.

Citing its decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), the panel said that although it agreed that natural phenomena are not patentable, applying a law of nature to a known structure may be deserving of patent protection.

Bilski articulates a test to determine whether a claimed process is tied to a particular machine or apparatus or whether it transforms a particular article into a different state or thing.

The Federal Circuit applied the test to Prometheus' patents and concluded that they fell within the realm of patentability because they transformed an article into a different state or thing. The court further found that the transformation was central to the purpose of the claimed process.

The panel rejected the District Court's characterization of the steps in the claimed process as mere "data gathering."

It concluded that the steps were part of a treatment protocol and thus were transformative.

 **See Document Section A (P. 19) for the opinion.**

PATENTS

Court Stays Injunction Against Microsoft Word Pending Appeal

***i4i Ltd. v. Microsoft Corp.*, No. 2009-1504, 2009 WL 2873909 (Fed. Cir. Sept. 3, 2009).**

An injunction barring sales of Microsoft's popular Word software with key patent-infringing components will be stayed pending appeal, the U.S. Court of Appeals for the Federal Circuit has ruled.

The ruling followed Toronto, Ontario-based i4i Technologies' victory against the software giant in a patent infringement lawsuit.

Last May a Texas federal jury found in favor of i4i on its claims that Microsoft willfully infringed its patent on using extensible markup language, or XML, to format the structure of a document independently of the document's text.

Later, Microsoft was ordered to pay i4i more than \$300 million in damages and was enjoined from selling versions of its Word software that used i4i's technology. The Federal Circuit's ruling stays the injunction while the appeal is heard.

According to published reports, Microsoft has vowed to appeal the rulings and maintains that the patent at issue is invalid.

Because of Microsoft's substantial investment in XML, however, it is widely believed that the company eventually will settle out by licensing i4i's patent.

XML is an outgrowth of standard generalized markup language. SGML was developed in the 1980s as a standardized document-exchange format. Its intended use mainly was for large law projects and in academia. As a simplified subset of SGML, XML has grown into much broader use than its predecessor.

The case began in March 2007, when i4i sued Redmond, Wash.-based Microsoft in the U.S. District Court for the Eastern District of Texas. It alleged the defendant willfully infringed U.S. Patent No. 5,787,449 for a "method and system for manipulating the architecture and the content of a document separately from each other."

The Eastern District of Texas is seen by some as a plaintiff-friendly jurisdiction. It is regularly featured on the American Tort Reform Association's list of "judicial hellholes."

In 2003 Microsoft began using XML in its Office document formats for better interoperability across its product lines.

In the past only Microsoft's Office programs, such as Word and Excel, could read and write those programs' files. Using XML as a format, rather than proprietary binary formats as before, allows non-Office software to read and generate Office documents.

Microsoft also has submitted its XML Word document format, known as Office Open XML, to the International Standards Organization to be adopted as an international standard for such documents. The standard would be known as ISO 29500.

The lawsuit alleged that Microsoft's use of XML codes known as "metacode maps" to format the layout of a document, as opposed to the document's text, violates the patent.

Following an eight-day trial the jury agreed that Microsoft willfully infringed i4i's patent.

U.S. District Judge Leonard Davis later issued an injunction barring the sale of versions of Word using i4i's patented technology. Microsoft still may sell versions of Word that do not infringe the patent.

The judge also ruled that i4i presented sufficient evidence that Microsoft's infringement was willful. As a result, he awarded the company an additional \$40 million in damages.

The Federal Circuit has agreed to give Microsoft's appeal an expedited hearing.

To retrieve the order (2009 WL 2873909), visit westlaw.com.

PATENT INFRINGEMENT

EpiPen Maker Sues to Block Teva's Generic

***King Pharmaceuticals Inc. et al. v. Teva Parenteral Medicines Inc. et al.*, No. 1:09-cv-652, complaint filed (D. Del. Aug. 28, 2009).**

King Pharmaceuticals has filed a declaratory judgment suit in Delaware federal court, seeking to block Teva Pharmaceuticals' plan to sell a generic version of the popular EpiPen allergy treatment device before the patent lapses in 2025.

Tennessee-based King seeks relief in the U.S. District Court for the District of Delaware after Teva subsidiary Teva Parenteral Medicines Inc. petitioned the Food and Drug Administration for approval to sell its own epinephrine injection device.

King says the plan would infringe U.S. Patent No. 7,449,012, issued to subsidiary Meridian Medical Technologies Inc. in November 2008, for the EpiPen, used to inject epinephrine during severe allergic reactions.

King alleges that TPM's abbreviated new drug application to the FDA was prepared with the assistance of Teva USA and Teva Ltd. Teva USA is based in North Wales, Pa., while TPM's headquarters are in Irvine, Calif.

TPM and Meridian are both incorporated in Delaware.

Any attempt by TPM to make and sell its own epinephrine injector device would constitute infringement under one or more claims of the '012 patent, King says.

The company wants a court order validating its infringement claims and a permanent injunction barring the Teva companies from producing such a product before the EpiPen's 2025 patent expiration.

King is represented by Steven Balick, John Day and Tiffany Lydon of Ashby & Geddes in Wilmington, Del., and Kevin Collins, Natalie Derzko and Allison Kerndt of Covington & Burling in Washington.

To retrieve the complaint (2009 WL 2849496), visit westlaw.com.

PATENTS

Fed. Cir. Overturns \$358 Million Verdict Against Microsoft

***Lucent Technologies Inc. et al. v. Gateway Inc. et al.*, Nos. 2008-1485, 2008-1487 and 2008-1495, 2009 WL 2902044 (Fed. Cir. Sept. 11, 2009).**

The U.S. Court of Appeals for the Federal Circuit has vacated a \$358 million damages award against Microsoft Corp. for infringing two patents held by Alcatel-Lucent.

The court said the award lacked evidentiary support. At the same time, the court affirmed the verdict that the patents at issue were valid and infringed by Microsoft.

"We are pleased that the court vacated the damages award, and we look forward to taking the next step in the judicial process," Microsoft spokesman Kevin Kutz said in a statement.

On behalf of Alcatel-Lucent, representative Mary Ward said in an e-mailed statement, "While we are disappointed that the court did not affirm the jury's decision on damages, we look forward to an upcoming proceeding to determine the compensation to which Alcatel-Lucent is entitled based on the court's finding that Microsoft did use our patented invention."

Lucent filed suit in the U.S. District Court for the Southern District of California in 2002, alleging Microsoft infringed a whole host of its patents.

Microsoft countersued, saying the patents were invalid for various reasons. U.S. District Judge Rudi M. Brewster ruled that the disputes should be grouped into five separate cases based on the type of technology at issue.

In this case, the jury concluded that Microsoft infringed two of Alcatel's patents, U.S. Patent Nos. 5,347,295 and 4,763,356.

The patents relate to stylus-based computer operating systems, such as those for tablet PCs and personal digital assistants, that allow dates to be entered into calendars.

In its verdict the jury found that Microsoft had willfully infringed the '295 and '356 patents but rejected Lucent's claim that Microsoft had infringed two other patents. It awarded Lucent a lump sum of \$358 million.

On appeal, the Federal Circuit noted that at trial, Lucent had asked for a damages award based on a running royalty, while Microsoft told the jury that damages should be a lump-sum royalty payment of \$6.5 million.

Writing for the court, Chief Judge Paul Michel explained the difference between the two types of royalties.

Under a running royalty license, the amount of money payable to the owner of a patent is tied directly to how often the licensed invention is later used or incorporated into products by the licensee.

With a running royalty, licensing risks shift to the licensor because he does not receive a guaranteed payment and because royalties are dependent on the level of sales or usage, which the licensee can control.

By contrast, a lump-sum royalty benefits the patent holder because it enables a company to raise money quickly and removes any risk that the licensee will underreport, and therefore underpay, for a license.

Observing that Lucent's own expert argued for damages based solely on a running royalty rate, the appeals court rejected Lucent's defense of the jury's verdict on appeal.

"We are left with the unmistakable conclusion that the jury's damages award is not supported by substantial evidence, but is based mainly on speculation or guesswork," the Federal Circuit said.

The evidence did not sustain a finding that Microsoft and Lucent would have agreed to a lump-sum royalty payment amount, the court said.

 **See Document Section B (P. 28) for the opinion.**

PATENTS

Judge Dishes Out \$90M In Contempt Sanctions To Dish Network

***TiVo Inc. v. Dish Network Corp. et al.*, No. 04-CV-01-DF, 2009 WL 2900039 (E.D. Tex., Marshall Div. Sept. 4, 2009).**

Finding that Dish Network violated an injunction against further use of Tivo's patented digital video recorder technology, a federal judge in Texas has ordered the satellite TV provider to pay \$90 million in contempt damages on top of \$110 million in damages, interest and attorney fees already awarded.

The recent award followed TiVo's motion for contempt sanctions against EchoStar, Dish Network's parent company. TiVo alleged EchoStar willfully ignored an injunction entered last year against use of its patent relating to DVR software.

TiVo originally sought a total of \$1 billion in contempt sanctions.

Both companies said they were happy with the ruling, but for different reasons.

"We are pleased that the District Court rejected TiVo's request to award a billion dollars in sanctions and that it found that any violation of the injunction was not willful," Dish Network said in a statement on its Web site. "[T]he decision confirms our belief that we designed around TiVo's patent in good faith."

In its own statement TiVo said it was pleased with the sanctions and the court's decision to award TiVo its attorney fees and costs incurred during the contempt proceedings.

TiVo originally sued EchoStar and four subsidiaries in the U.S. District Court for the Eastern District of Texas, alleging two of the defendants' DVR models infringed U.S. Patent No. 6,233,389.

The suit concerns the "time-shifting" of television broadcasts, which allows users to pause a live broadcast and scan backward and forward through it. Users also can record a show to the DVR's internal hard drive while watching a different show.

TiVo's patent relates to software for receiving and tuning broadcast signals and recording, storing and playing back shows on the DVRs.

EchoStar had argued that the patent's claims reference four kinds of software "objects." Since there is no evidence that the software in EchoStar's DVR devices was written in an object-oriented language like C++, it could not have infringed the patent, the company said.

The jury sided with TiVo, awarding it \$41 million in lost profits and \$32 million in royalties for past use.

U.S. District Judge David J. Folsom permanently enjoined EchoStar from using TiVo's technology.

The U.S. Court of Appeals for the Federal Circuit upheld the jury's finding of liability and the damages award, rejecting EchoStar's argument that the judge misconstrued the patent's claims.

The three-judge panel noted that the term "object" has a broader meaning in the software context than the defendant's proposed interpretation.

An object-oriented computer language like C++ encapsulates data to be manipulated with the procedures for doing so in a group, or object, called a class. Non-object-oriented languages, such as C, have separate groups of data or procedures.

Because an "object" can be data, procedures or both, depending on the programming language used, Judge Folsom's construal was not overbroad, the appeals court held.

The U.S. Supreme Court denied EchoStar's petition for review last October.

In a sealed motion for contempt sanctions, TiVo had argued that EchoStar was still willfully infringing the '389 patent despite claiming to have engineered around it.

EchoStar had argued that it relied in good faith on the advice of its lawyers and engineers and that any continued infringement was therefore not willful.

Judge Folsom ruled that while EchoStar did continue to infringe, it was not willful. He relied on the testimony of EchoStar's CEO, Charles Ergen, that he believed in good faith that his company's engineering work-arounds were successful. For this reason, the judge declined to award the \$1 billion in sanctions sought by TiVo.

In doing so, however, the judge warned that EchoStar may not get off so lightly next time.

"[If] EchoStar ... continues to disregard this court's orders, the court will seriously entertain the award of enhanced sanctions," he wrote.

TiVo is represented by Seth P. Waxman, Edward C. DuMont, Lauren Fletcher and Daniel S. Volchok of Wilmer, Cutler, Pickering, Hale & Dorr in Washington.

EchoStar is represented by Donald R. Dunner, Don O. Burley and Andrew J. Vance of Finnegan, Henderson, Farabow, Garrett & Dunner in Washington.

To retrieve the opinion (2009 WL 2900039), visit westlaw.com.

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COPYRIGHT INFRINGEMENT

Bratz Maker Survives 'Brats' Attack

Art Attacks Ink LLC v. MGA Entertainment Inc. et al., No. 07-56110, 2009 WL 2950659 (9th Cir. Sept. 16, 2009).

MGA Entertainment, manufacturer of the popular Bratz dolls, has successfully defeated claims that it infringed the Spoiled Brats dolls marketed by a small California company.

The 9th U.S. Circuit Court of Appeals affirmed judgment in MGA's favor against Art Attacks Ink LLC.

Art Attacks has been in business since 1993. A small, family-run air brush business, its designs include a Spoiled Brats image collection featuring cartoonish female characters with big eyes, large heads and feet, and bare midriffs.

According to the appeals court opinion, Art Attacks sells its wares primarily at county fairs in California and at Wal-Mart stores in Arizona. The company has maintained a Web site since 1996.

MGA began selling the Bratz dolls in 2001. They share many of the same characteristics as the Spoiled Brats collection.

"A plaintiff can show access either through a chain of events or by showing that a copyrighted work had been widely disseminated, but there must be more than a 'bare possibility' that an infringer had a chance to view the protected work," the 9th Circuit said.

Art Attacks sued MGA in 2004 in the U.S. District Court for the Southern District of California, alleging copyright, trademark and trade dress infringement. A jury ruled in MGA's favor on the trademark claim but could not reach a verdict on the remaining claims. U.S. District Judge Rudi Brewster subsequently granted MGA's motion for judgment as a matter of law.

Art Attacks appealed, and the 9th Circuit first considered whether the court had jurisdiction because MGA had filed

its motion beyond the 10-day period allowed by Federal Rule of Civil Procedure 50.

The panel said several courts have concluded that the time restrictions set forth in procedural rules are nonjurisdictional and can be waived or forfeited. Since Art Attacks never objected to MGA's motion before the District Court, the 9th Circuit held that it had forfeited any timeliness objection on appeal.

On the merits of Art Attacks' copyright claim, the appeals court said the company failed to show that MGA had access to the Spoiled Brats collection.

Art Attacks could demonstrate access either through a chain of events or by showing that the work had been widely disseminated. In either case, the panel cautioned, it must show more than a "bare possibility" that an alleged infringer had an opportunity to view the protected work.

Art Attacks argued that an MGA decision-maker could have attended one of the county fairs where it exhibited the Spoiled Brats collection, but the panel said that possibility was insufficient to demonstrate access.

The panel likewise rejected Art Attacks' assertion that its collection was widely disseminated.

The panel noted that although the company only sold 2,000 T-shirts annually with its signature imaging on it, no evidence suggested that a significant number of passersby saw Spoiled Brats displays at the county fairs.

"Art Attacks cannot demonstrate that its Spoiled Brats designs were widely disseminated to the extent necessary to create more than a 'bare possibility' that MGA had access to the designs," the 9th Circuit held.

 **See Document Section C (P. 53) for the opinion.**

COPYRIGHT INFRINGEMENT

James Joyce Estate to Pay \$240K Attorney Fee To End Copyright Fight

The long-running copyright dispute between a Stanford University professor and author James Joyce's estate has ended with the estate's agreement to pay \$240,000 of the professor's attorney fees.

The estate accused professor Carol Loeb Shloss of infringement when she quoted some of Joyce's papers in her biography of his daughter Lucia.

"I think it's fair to say that Professor Shloss and all her counsel are pleased to see an end to this dispute, particularly one that reflects the efforts that the situation required," said attorney **Bernard Burk** of **Howard Rice Nemerovski Canady Falk & Rabkin**, who joined members of Stanford Law School's Fair Use Project in representing Shloss.

"If they [authors and literary estates] don't pay attention to the rights of scholars, authors and researchers, they may end up paying, just as the Joyce estate did," professor Carol Loeb Shloss said.

Burk explained that the Joyce estate repeatedly threatened to sue Shloss if she used material from the author's papers or Lucia's medical records in her 2003 book, "Lucia Joyce: To Dance in the Wake."

Initially, Shloss cut a substantial part of the material from her book in response to the threats.

However, she filed a declaratory judgment action in 2006 in the U.S. District Court for the Northern District of California to establish her right to publish the excised material.

The case settled in 2007, when the estate agreed to allow publication of the material in the United States.

Shloss asked the District Court to order the estate to pay her more than \$400,000 in attorney fees. The court awarded her \$326,000 in May, but the estate appealed the order to the 9th U.S. Circuit Court of Appeals.

The Fair Use Project announced Sept. 28 that the estate has dropped its appeal and agreed pay Shloss \$240,000.

"I'm really proud of what we accomplished here," Shloss said in a statement. "We vindicated my rights as a scholar, and we also demonstrated that authors and literary estates need to be careful. If they don't pay attention to the rights of scholars, authors and researchers, they may end up paying just as the Joyce estate did."

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\$2.5M Award Against SCO Group Stands; Copyright Case Goes to Trial

SCO Group Inc. v. Novell Inc., No. 08-4217, 2009 WL 2581735 (10th Cir. Aug. 24, 2009).

A \$2.5 million award against the embattled SCO Group will stand but the issue of whether it owns the copyright to the Unix operating system will go to trial, the 10th U.S. Circuit Court of Appeals has ruled.

The long-anticipated ruling may mean a new chance for the embattled firm to prove the Linux operating system infringes its copyrights. That decision, however, will not be made by SCO's management but by a soon-to-be appointed Chapter 11 bankruptcy trustee.

"We are pleased that the court has reversed material aspects of the District Court's 2007 summary judgment against SCO," the company said in a press release on its Web site. "Importantly, the court remanded the case for jury trial. Obviously, we are very pleased with this decision."

Novell also reacted to the ruling.

"Novell is carefully studying the decision," the company said in a posting on its PR blog. "Precisely what will happen next in the lawsuit remains to be seen, especially in light of the pending SCO bankruptcy and the recent court decision to appoint a Chapter 11 trustee to take over the business affairs of the company."

"Novell intends to vigorously defend the case and the interests of its Linux customers and the greater open-source community," the company said. "We remain confident in the ultimate outcome of the dispute."

The dispute before the 10th Circuit stems from a 1995 asset-purchase agreement in which SCO claimed that predecessor Santa Cruz Operations Inc. acquired from Novell all rights, including the copyrights and trademarks, to the Unix and UnixWare operating systems.

The case grabbed the tech industry's attention in recent years because SCO claims the open-source Linux operating system contains proprietary Unix code it owns. SCO has sued Novell, IBM and other industry heavyweights for billions of dollars in licensing fees for Linux products they developed.

At the same time, SCO began a "Linux licensing" program in 2003, promising not to sue any Linux user that paid a license fee of about \$699 for each computer using the technology.

Novell sought a court ruling that SCO did not own the copyrights at issue and demanded the return of the money SCO earned from its licensing program.

Novell alleged that SCO wrongfully withheld \$26 million in license fee payments due under the asset-purchase agreement and instead spent the money on its barrage of Linux-related lawsuits.

SCO filed for Chapter 11 bankruptcy protection soon after losing the copyright fight. Later, U.S. Bankruptcy Judge Kevin Gross ruled that Novell's claims against SCO could proceed notwithstanding the bankruptcy.

SCO insisted that it owned the Unix and UnixWare copyrights, but U.S. District Judge Dale Kimball concluded that the company had ignored a provision in the deal that specifically excluded certain assets, including the copyrights, from being transferred outright.

Under its deal with Novell, SCO obtained a license to the Unix and UnixWare copyrights and would own the copyrights only for whatever products it developed using that technology, the judge said.

Last July Judge Kimball ruled that only \$2.5 million of the \$26 million in license fees was traceable to Novell products. He agreed with SCO that it was entitled to the remainder of the money because it came from products SCO developed using the licensed technology.

On appeal the 10th Circuit ruled that the clause Judge Kimball relied on was sufficiently ambiguous to entitle SCO to a trial.

"This case, involving a complicated, multimillion-dollar business transaction involving ambiguous language about which the parties offer dramatically different explanations, is particularly ill-suited to summary judgment," the panel wrote.

SCO's victory on appeal, however, may turn out to be hollow. In July Judge Gross ruled that the company's management would be ousted and that a Chapter 11 trustee would take over the company day-to-day operations. He ruled that SCO had abandoned rehabilitation and instead had bet the company on winning big in its Linux litigation.

In his ruling, Judge Gross said the Chapter 11 trustee will be responsible for determining whether continuing the

litigation is in the best interest of SCO and its creditors. If it is not, the judge indicated that SCO could be forced into an involuntary Chapter 7 liquidation.

SCO is represented by Stuart Singer, Boies, Schiller & Flexner in Fort Lauderdale, Fla.

Novell is represented by Michael Jacobs of Morrison & Foerster in San Francisco.

To retrieve the opinion (2009 WL 2581735), visit westlaw.com.

RIGHT OF PUBLICITY

Retired Players Sue NFL Over Use of Images

***Dryer et al. v. National Football League*, No. 09-2182, complaint filed (D. Minn. Aug. 20, 2009).**

National Football League Hall of Famer Elvin Bethea and five other retired players are suing the league for allegedly profiting off their names, images and likenesses without permission.

The players from the 1960s and 1970s say the NFL and its filmmaking arm, NFL Films, are exploiting retired players in films, highlight reels and memorabilia to market the league's "glory days."

The proposed class action says the league made more than \$6.9 billion in 2008 alone off retired players by misappropriating their identities.

Bob Stein, an eight-year NFL veteran and attorney representing the players, said the evolution of television and channels like ESPN and the NFL Network has brought the issue front and center.

"Retired players who helped build the league and are being used to promote it today deserve to be paid for what they have contributed to generate money for the NFL," Stein said in a statement.

According to the complaint, filed in the U.S. District Court for the District of Minnesota, the NFL's exploitation of the retired players is "not only prolific, it is blatant."

One need look no further than the league's NFL Films Web site to see the names of more than 450 retired players being used to advertise and sell videos promoting the league, the suit says.

Many of the retired players suffer debilitating injuries from their playing days and are struggling financially "while the NFL reaps record-breaking revenues," the suit says.

Other former player plaintiffs are Fred Dryer, Dan Pastorini, Joe Senser, Ed White and Jim Marshall.

The plaintiffs have asked U.S. District Judge Paul Magnuson to certify the case as a class action.

The complaint alleges unjust enrichment, false endorsement and violation of the players' right of publicity.

The plaintiffs seek unspecified damages.

To retrieve the complaint (2009 WL 2762335), visit westlaw.com.

TRADEMARK INFRINGEMENT

Abercrombie Turns Up Nose at Beyonce's 'Fierce' Perfume

***Abercrombie & Fitch Co. et al. v. Knowles*, No. 09-0807, complaint filed (S.D. Ohio Sept. 15, 2009).**

Abercrombie & Fitch has filed a lawsuit alleging that pop diva Beyonce Knowles will infringe the retailer's "Fierce" trademark with her upcoming perfume, "Sasha Fierce."

Beyonce's insistence on using that name for the fragrance, set to go on sale next year, will infringe Abercrombie's long-standing trademark and likely confuse consumers, the complaint alleges.

Abercrombie, an Ohio-based retailer since 1892, says it has been using the Fierce trademark for a men's cologne since November 2002.

The company says it regularly disperses the Fierce fragrance in all of the high-end chain's 350 stores because it wants all garments that leave the store to have the scent attached to them.

According to the complaint, filed in the U.S. District Court for the Southern District of Ohio, Beyonce released an album in November titled "I am ...Sasha Fierce," referring to her on-stage alter ego.

She has since filed trademark applications for the Sasha Fierce mark, including one to be used for a fragrance.

Abercrombie says that in response to its cease-and-desist request, Beyonce disputed that there would be any confusion as to the source of the products bearing the Sasha Fierce mark.

Abercrombie disagrees and is seeking injunctive relief and damages against the pop star.

The complaint includes causes of action for trademark infringement, unfair competition and deceptive trade practices.

Abercrombie is represented by Marion H. Little Jr. of Zeiger, Tigges & Little in Columbus, Ohio.

 **See Document Section D (P. 59) for the complaint.**

TRADEMARK/COPYRIGHT INFRINGEMENT

Cell Phone Infringers Face \$5 Million Damage Award

***TracFone Wireless Inc. v. Tropical Export Inc. et al.*, No. 09-21523, 2009 WL 3055386 (S.D. Fla. Sept. 25, 2009).**

A company that bought large quantities of TracFone prepaid wireless phones and repackaged them must pay at least \$5 million in damages, a Florida federal judge has ruled.

Judge James Lawrence King of the U.S. District Court for the Southern District of Florida said Tropical Export Inc. and owner Ibrahim El-Zaatari and several unnamed people and companies infringed TracFone's trademarks and copyrights.

The defendants were engaged in a bulk-resale scheme in which they bought TracFone prepaid phones and disabled their software that enabled access to the company's wireless network. Tampering with the software allowed the phones to be used with other service providers.

Because the defendants sold the altered phones in trademarked TracFone packaging, buyers were unaware that they were getting phones that would not work with the network.

Judge King issued a permanent injunction against all the defendants but retained jurisdiction over the case. He

also ordered the defendants to pay TracFone jointly and severally \$5 million in compensatory damages.

Any defendant that violates the injunction will have to pay the greater of \$5 million or \$5,000 in additional damages for each phone that is altered, shipped and/or sold, according to the order.

To retrieve the opinion (2009 WL 3055386), visit westlaw.com.

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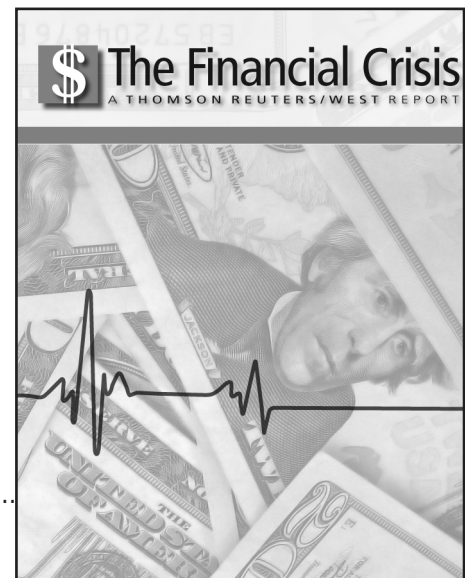
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