Intellectual Property Owners Association

HATCH-WAXMAN COMMITTEE NEWSLETTER

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RECENT COURT DECISIONS

TRO AGAINST GENERIC EXTENDED RELEASE DENIED

by James W. Gould (Morgan & Finnegan, LLP)

In *Abbott Laboratories v. Sandoz*, 2006, the district court denied a TRO against commercial launch of an extended release antibiotic. The patent on the immediate release drug expired in 2005. Instead, Abbott filed a complaint against Sandoz seeking a declaratory judgment of infringement of its extended release patents. In parallel actions, the court entered a stipulated TRO against Andrx and a TRO and preliminary injunction against Teva. The latter was vacated by the Federal Circuit because Teva had demonstrated a substantial question regarding validity.

In *Abbott*, the court refused to hold that the Federal Circuit's statement precluded Abbott from arguing there was no question of validity. Abbott's victory, however, was hollow because the Court gave deference to the Federal Circuit and found there was a substantial question.

The lesson here for the generic is to raise any substantial questions on the likelihood of success in the lower Court when faced with a TRO or preliminary injunction. A vacation by the Federal Circuit on any grounds raised will likely prevent any pretrial injunctive relief on remand.

Abbott Labs. v. Sandoz, Inc., No. 05 C 5373, 2006 WL 3718025 (N.D. Ill. Dec. 15, 2006).

REVERSE PAYMENT CASE APPEALED TO SUPREME COURT

by James W. Gould (Morgan & Finnegan, LLP)

The Supreme Court denied *certiorari* in the recent case involving reverse payments, *FTC v. Schering Plough*. Now another petition for *certiorari* has been filed by the plaintiffs in *In re: Tamoxifen Citrate Antitrust Litigation*. The plaintiffs are appealing the dismissal of their antitrust action.

It remains to be seen if the factual setting in

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this petition is sufficiently clear for the Solicitor General to urge grant of certiorari. What is more certain is that sooner or later the Supreme Court will take on a reverse payment case to at least resolve the split in the Circuits as to whether reverse payments are subject to a *per se* or rule of reason standard.

PRELIMINARY INJUNCTION AGAINST ANDRX AFFIRMED FOR BIAXIN XL®

by Brian Kramer (Morrison & Foerster, LLP)

In a case involving Abbott's extended release formulations of clarithromycin, marketed by Abbott as Biaxin XL®, the Federal Circuit affirmed a preliminary injunction against generic manufacturer Andrx Pharmaceuticals.

Abbott asserted various claims of U.S. Patent Nos. 6,010,718 ("'718 patent"); 6,551,616 ("'616 patent"); and 6,872,407 ("'407 patent") against Andrx, Ranbaxy, and Teva, and sought a preliminary injunction against each. Both Ranbaxy and Teva convinced the district court and Federal Circuit that certain claims of the Abbott '616 and '407 patents were likely to be held either invalid or unenforceable. However, the district court later held that in the case against Andrx, Abbott had met its burden of showing that it would likely withstand the invalidity and unenforceability arguments raised by Andrx in its case based on the same asserted claims of the '616 and '407 patents.

On appeal, Andrx argued that Abbott was collaterally estopped from seeking a preliminary injunction based on holdings in the preliminary injunction proceedings against Teva and Ranbaxy that many of the asserted claims were invalid or unenforceable. Applying Seventh Circuit law, the Federal Circuit held that Abbott was not estopped from arguing anew that it would withstand invalidity and unenforceability challenges to the same patents because collateral estoppel is implicated only when the prior decision is sufficiently final to preclude re-litigating the issue. The Federal Circuit held that the preliminary injunction rulings in the Teva and Ranbaxy cases were "expressly preliminary" and were not sufficiently final to invoke collateral estoppel. The Federal Circuit's entire analysis of the collateral estoppel issue was largely unnecessary because, even if the Court found that Abbott was collaterally estopped from re-arguing the invalidity and unenforceability issues, one claim asserted against Andrx (Claim 1 of the '718 patent) was not held to be likely invalid or unenforceable in the Teva and Ranbaxy litigations.

Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196 (Fed. Cir. 2007).

SUPREME COURT ALLOWS LICENSEE TO SEEK DECLARATORY JUDGMENT

by Craig R. Kaufman (Orrick, Herrington & Sutcliffe, LLP)

On January 9, 2007, the U.S. Supreme Court issued its long-awaited decision in *Medimmune, Inc. v. Genentech, Inc.* In *Medimmune*, the Supreme Court decided whether a licensee, who remained in good standing under its license by continuing to pay royalties, could nonetheless seek a declaratory judgment that the licensed patent was invalid or not infringed. The Federal Circuit, relying on its decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004), held that a licensee in good standing cannot establish an Article III case or contro-

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versy because the existence of the license agreement "obliterates any reasonable apprehension" that the licensee will be sued for infringement. The Supreme Court reversed the Federal Circuit, and held as follows: "[P]etitioner was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed." 127 S. Ct. at 777.

Medimmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007).

BARR PHARMACEUTICALS' MOTION TO DISMISS DENIED WHERE FTC SOUGHT TO PREVENT FUTURE ANTICOMPETITIVE CONDUCT

by Rick Williams (Vinson & Elkins, LLP)

Barr Pharmaceuticals, a co-defendant with Warner Chilcott, filed a motion to dismiss as moot the Federal Trade Commission's suit against Barr. The FTC alleged that Barr and Warner Chilcott had entered into an anticompetitive agreement, in which Barr agreed not to bring a generic version of Warner Chilcott's branded oral contraceptive, Ovcon, to market. As part of a settlement with the FTC, Warner Chilcott agreed to waive the agreement with Barr and stipulated to a permanent injunction on entering any similar agreements in the future. In its motion to dismiss, Barr argued that Warner Chilcott's settlement agreement and Barr's introduction of a generic version of Ovcon, rendered the FTC's remaining claims against Barr moot. The district court held that because the FTC sought to prevent Barr from engaging in future similar and related conduct and Barr remained free to enter into the same type of agreement again with other branded companies, the case was not moot. The court consequently denied Barr's motion to dismiss.

Fed. Trade Comm'n v. Warner Chilcott Holdings Co., No. 05-2179 (CKK), 2007 WL 158746 (D.D.C. Jan. 22, 2007).

PARTIAL SUMMARY JUDGMENT MOTION STRIKING DEFENSE OF OBVIOUSNESS GRANTED IN FAVOR OF ORTHO-MCNEIL IN LITIGATION INVOLVING ANTICONVULSANT MEDICATION TOPOMAX ®

by Marc Brassler (Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.)

In a patent infringement case brought under the Hatch-Waxman Act, Ortho-McNeil Pharmaceutical, Inc. ("Ortho") sued generic drug maker Mylan Labs. Inc. ("Mylan") for infringement of Ortho's U.S. Patent No. 4,513,006 ("the '006 patent") based on Mylan's filing of an Abbreviated New Drug Application ("ANDA"). The '006 patent covers topiramate tablets and topiramate capsules, which are marketed in the United States as the anticonvulsant TOPOMAX®.

Ortho moved for partial summary judgment to strike Mylan's defense of patent invalidity due to obviousness. The court found that Mylan's expert, Dr. Anderson, used the inventor's, Dr. Maryanoff's, motivations to structure his obviousness theories, and therefore had inappropriately incorporated hindsight into his obviousness analysis. Second, the court found that Mylan did not begin its obviousness analysis at the correct starting point. The court found that the problem facing the inven-

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tor was the problem of controlling the level of glucose in diabetic patients, not the task of formulating an FBPase inhibitor as a potential treatment for diabetes. The court found that it could not be assumed that the ordinary artisan would have had the insight that FBPase inhibitors might be used to control blood sugar of diabetics, and that none of the references cited by Mylan disclosed using an FBPase inhibitor for diabetes treatment.

Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc., Nos. 04-1689, 06-757, 06-5166, 2007 WL 432792 (D.N.J. Feb. 5, 2007).

COURT RULES IN FAVOR OF AMPHASTAR AND TEVA OVER AVENTIS IN LITIGATION INVOLVING ANTICOAGULANT MEDICATION LOVENOX® FINDING PATENT IN SUIT UNENFORCEABLE ON THE GROUND OF INEQUITABLE CONDUCT

by Marc Brassler (Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.)

Aventis Pharma S.A. and Aventis Pharmaceuticals, Inc. (collectively, "Aventis") brought suit against Amphastar Pharmaceuticals, Inc. ("Amphastar") and Teva Pharmaceuticals USA, Inc. ("Teva") for infringement of Aventis' patent, U.S. Patent No. 5,389,618, and its replacement, U.S. Reissue Patent No. 38,743 (collectively, "the '618 patent"). The case was transferred to the court for a bench trial on inequitable conduct limited to an inquiry into Aventis' and its agents' intent in failing to disclose highly material information to the United States Patent and Trademark Office ("PTO").

The '618 patent claims a range of defined low molecular weight heparin ("LMWH") mixtures. These encompass the drug formulation, enoxaparin, which is approved by the FDA as an anticoagulant in diseases featuring venous thromboses. Aventis manufactures enoxaparin under the brand name Lovenox®.

The '618 patent was sought by Aventis to protect enoxaparin in the U.S., as a successor to a European Patent 40,144 ("EP '144"). The '618 prosecution involved successive rounds of rejection and appeal. The Patent Examiner rejected the application as anticipated or, in the alternative, as obvious in light of EP '144. Aventis' strategy for overcoming the rejections was to distinguish the formulations of the '618 patent based on its purportedly superior pharmacokinetic properties – particularly, its longer plasma half-life. Aventis directed the Examiner's attention to Example 6 of the '618 patent and the half-life analysis presented therein. Aventis also submitted two expert declarations from its employee, Dr. Uzan, who was responsible for the data underlying Example 6. However, neither Aventis nor Dr. Uzan disclosed which dose of the EP '144 composition they were comparing to which dose of the '618 composition. In fact, they were comparing different doses. When identical doses were compared the mean half-life of the two compositions did not exhibit a statistically significant difference. Moreover, the only dose of the '618 composition reflecting a statistically significant difference in half-life from the EP '144 composition was the one chosen by Dr. Uzan.

Aventis argued that Dr. Uzan had scientifically valid reasons for not making his half-life comparison at equivalent doses. The court however, found that Dr. Uzan's clinical justifications were implausible under the circumstances of the prosecution of the application that resulted in the '618 patent and, in that

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context, failed to persuade the Court that the comparison of different doses was reasonable. Clearly, the court stated, Aventis was well aware of the Examiner's concern that the inventive composition was inherent in EP '144. Additionally, the court pointed out that Aventis' and Amphastar's experts agreed that a dose-ranging experimental design – e.g., comparing different doses of two chemical compositions - is inappropriate to establish that the two compositions are compositionally different.

Moreover, the court held that Aventis had failed to come forward with facts supporting a plausible explanation or excuse justifying Aventis and Dr. Uzan's highly material omissions. Although Dr. Uzan explained that the comparison analysis was inadvertent, the court found that it was not plausible for Dr. Uzan to have, in fact, been grossly negligent. Given that but for Dr. Uzan's intentional omissions the probability is high that the '618 patent would not have issued, the Court found the '618 patent to be unenforceable on the ground of inequitable conduct.

Aventis Pharma S.A. v. Amphastar Pharms., Inc., 475 F. Supp. 2d (C.D. Cal. 2007).

VALIDITY OF FLOMAX® PATENT UPHELD FINDING NO OBVIOUSNESS-TYPE DOUBLE PATENTING

by Victoria E. Ford (Alston & Bird LLP)

The U.S. District Court for New Jersey upheld the validity of the plaintiffs' patent on Flomax and granted plaintiffs summary judgment for its infringement action against the defendants. Astellas Pharma, Inc. and Boehringer Ingelheim Pharmaceuticals, Inc., Astellas' marketing partner in the United States (collectively "Astellas") filed an NDA for tamsulosin, marketed under the trade name Flomax, which is used to treat benign prostatic hyperplasia. On December 20, 2004, Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd. (collectively "Ranbaxy") filed an ANDA to market generic tamsulosin hydrochloride patents. After Ranbaxy's ANDA was approved, Ranbaxy provided Astellas with notice of its opinion that U.S. Patent No. 4,703,063 ("the '063 patent"), which covered tamsulosin, was invalid for, *inter alia*, double patenting over the claims of U.S. Patent No. 4,373,106 ("the '106 patent"). Astellas subsequently filed suit against Ranbaxy for patent infringement.

The '106 patent, which issued in 1983, claimed the processes for making sulfamoyl-substituted phenethylamines, including tamsulosin. The '063 patent, which issued in 1987, claimed pharmaceutical compositions and chemical compounds, including tamsulosin. While the '106 patent expired on February 4, 2001, the '063 patent does not expire until October 27, 2009.

The court clarified that obviousness-type double patenting compares what was claimed in the earlier patent with the claims in the later patent. The court found that Ranbaxy incorrectly made comparisons between the '106 and '063 patent according to the obviousness analysis under section 103, and not the limited comparisons under an obviousness-type double patenting analysis. The court was unable to find one double-patenting case where a later product claim was anticipated by an earlier process claim for making that product. Further, the court was unable to find a case where a product or the compounds comprising that product were found to be a genus antici-

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pated by the species of the earlier process claims. Moreover, the court found that the '063 patent claimed unexpectedly potent adrenergic anatognists not claimed in the earlier patent. Accordingly, the court held that the '063 claims are patentably distinct from the claims in the '106 patent.

Astellas Pharma, Inc. v. Ranbaxy Inc., No. 05-2563 (MLC), 2007 WL 576341 (D.N.J. Feb. 21, 2007).

A KIWI KABOSH TO APOTEX PATENT

by James W. Gould (Morgan & Finnegan, LLP)

A "technicality" in New Zealand not only invalidated an Apotex patent, it also resulted in Apotex paying attorney fees for asserting an invalid patent. The patent related to Cyclosporin. The "technicality" was that "plaintiff applied for a patent to which it was not entitled as a consequence of having received an identical patent in New Zealand… more than one (1) year prior to filing the application for the [U.S.] patent…." This fact came out of a colloquy during the trial, when the Judge said, after a reference to New Zealand, "Fill me in about New Zealand. I always wanted to go there". The colloquy established that the New Zealand patent issued and the U.S. case did not claim priority. (It also turned out the U.S. Examiner misstated the issue date in New Zealand, which gave the appearance of removing it as a bar.)

An alert Eon lawyer heard the colloquy and checked with the New Zealand Patent Office and discovered the true date.

Despite the inventor's and Apotex's long list of excuses, the Court ruled this was an exceptional case because of "gross negligence and a reckless indifference" and ordered Apotex to pay Eon's attorney fees. The award was reduced by 30% on an unstated comparative negligence theory because Eon did not discover the New Zealand date during five years of litigation.

The moral: if there are foreign filings relating to a U.S. patent, check them carefully, whether plaintiff or defendant.

Apotex, Inc. v. Eon Labs Mfg., Inc., Nos. 01-CV-0482, 02-CV-1604, 2007 WL 656256 (E.D.N.Y. Feb. 26, 2007).

PFIZER PATENT COVERING NORVASC® HELD INVALID FOR OBVIOUSNESS

by Brian Kramer (Morrison & Foerster, LLP)

In a case involving amlodipine besylate tablets for treating hypertension and angina and marketed by Pfizer as Norvasc®, the Federal Circuit reversed a bench trial judgment and concluded as a matter of law that Claims 1-3 of Pfizer's U.S. Patent No. 4,879,303 (the '303 patent) were invalid for obviousness.

Pfizer scientists invented amlodipine and filed a patent in 1982 that eventually issued as U.S. Patent No. 4,572,909 (the '909 patent) in 1986. Pfizer then sought to make and test other amlodipine salts in order to make a tablet of the drug that had improved stability and less stickiness. By October of 1984, Pfizer researchers had found that amlodipine besylate salt, made from amlodipine and benzene sulphonate, showed improved stability and less stickiness, making it suitable for a tablet. The '909 patent does not disclose amlodipine

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besylate.

The amlodipine besylate salt is the subject matter of the '303 patent-in-suit. Relevant prior art to the '303 patent included: (1) the '909 patent; (2) an article showing 53 FDA-approved commercially marketed anions, including benzene sulphonate, for making pharmaceutically-acceptable salts ("Berge"); (3) a 1977 U.S. patent providing an example of a pharmaceutical compound wherein the besylate form is specifically identified as the preferred embodiment ("Spiegel"); and (4) a 1974 U.S. patent which discloses that besylate salts are superior to maleate salts.

The Federal Circuit reviewed the evidence and held claims 1-3 of the '303 patent invalid for obviousness. Both parties agreed that all of the '303 patent claim limitations were found in the prior art. The two main issues addressed on appeal were (1) Was there a motivation to combine prior art references to achieve the claimed invention?; and (2) Was there a reasonable expectation of success in making a besylate salt of amlodipine? Regarding the motivation to combine, the Federal Circuit noted that a suggestion, teaching, or motivation does not have to be found explicitly in the prior art references sought to be combined but may be found in a number of sources such as "common knowledge, the prior art as a whole, or the nature of the problem itself."

Regarding the reasonable expectation of success, the Federal Circuit found enough evidence to show that one skilled in the art would have had a reasonable expectation of success with the besylate salt of amlodipine including: (1) testimony from a Pfizer scientist that he expected the salt to work before it was tested; (2) a strong suggestion in the prior art '909 patent that other anions would work with amlodipine; (3) Pfizer's downplaying in prior litigation of any difference between amlodipine maleate and any other acid addition salt form of amlodipine; and (4) Pfizer's FDA filings suggesting it was known that the besylate salt would work for its intended purpose.

The Federal Circuit's holding invalidating the '303 patent came three days before the '303 patent's expiration, although Pfizer was entitled to an additional six months of pediatric exclusivity. As the first ANDA filer, Mylan Laboratories launched its generic the day after the Federal Circuit's decision. However, for pre-Medicare Modernization Act ANDAs, the FDA's policy was not to allow generic exclusivity to extend beyond the term of the patent, meaning that Mylan's normal 180-day exclusivity would only last 2 days. Mylan sought injunctive relief against the FDA precluding the FDA from approving other ANDAs, including one for the prevailing party, Apotex. Eventually, the FDA announced that during Pfizer's six month pediatric exclusivity, it would only approve Apotex's ANDA, but not until the Federal Circuit issued its mandate, which happened approximately 60 days later on May 21, when the court denied Pfizer's request for rehearing en banc over three dissenting votes.

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007).

PATENT TERM EXTENSION CAN BE APPLIED TO PATENT SUBJECT TO TERMINAL DISCLAIMER

by Craig R. Kaufman (Orrick, Herrington & Sutcliffe, LLP)

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In *Merck*, the Federal Circuit considered whether the patent term extension provisions of 35 U.S.C. § 156 could be applied to a patent subject to a terminal disclaimer. The Federal Circuit concluded that the answer was yes. In *Merck*, the patent at issue had been issued after a terminal disclaimer was filed. Merck sought, and was granted, a 1233 day extension of patent term pursuant to 35 U.S.C. § 156, starting on the date that the patent would have otherwise expired because of the terminal disclaimer. The Federal Circuit rejected Hi-Tech's argument that the terminal disclaimer operated to permanently disclaim all patent term beyond the operative date of the disclaimer. Instead, after construing the statute, the Federal Circuit concluded that Section 156 does not exclude terminally disclaimed patents, and that such patents are properly the subject of patent term extension under section 156.

Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317 (Fed. Cir. 2007).

MEDIMMUNE HOLDING APPLIED TO DECLARATORY JUDGMENT ACTION

by Craig R. Kaufman (Orrick, Herrington & Sutcliffe, LLP)

In *Teva*, the Federal Circuit applied the Supreme Court's recent *Medimmune* decision to declaratory judgment actions bought by a generic company under 21 U.S.C. § 355(j)(5)(c) and 35 U.S.C. § 271(e)(5). Novartis had listed five patents in the Orange Book that it identified as covering its product Famvir®. Teva had filed an ANDA with a paragraph IV certification for all five patents. Novartis, however, filed a suit alleging infringement of only one of the five patents. In response, Teva filed a declaratory judgment action of invalidity for the remaining four patents. The district court dismissed the declaratory judgment action, based on the Federal Circuit's decision in *Teva Pharmaceuticals v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

The Federal Circuit reversed, applying the totality of the circumstances test set forth by the Supreme Court in *Medimmune*. Under this test, *Teva* has injury-in-fact and has a justiciable article III controversy. The Court found that filing an ANDA on multiple patents created a single act of infringement, and that Novartis' filing suit with respect to one patent was a present injury creating a justiciable controversy.

Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330 (Fed. Cir. 2007).

DISTRICT COURT DENIES ALL CHALLENGES TO FDA DECISION CONCERNING RIGHTS TO MARKET AND SELL GENERIC VERSIONS OF PFIZER'S NORVASC®

by Philip C. Canelli (McDermott Will & Emery, LLP)

On April 30, 2007, the U.S. District Court for the District of Columbia issued its opinion in *Mylan Labs. et al. v. Leavitt et al.*, involving generic versions of Pfizer's high blood pressure drug Norvasc (amlodipine besylate) and the availability and applicability of both 180-day generic drug exclusivity and pediatric exclusivity with respect to U.S. patent No. 4,879,303 ("the '303 patent"). Essentially the court denied all requests for preliminary injunction related to Amlodipine Besylate Tablets and supported the U.S. Food and Drug Administration's (FDA) position con-

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cerning Mylan's current status as the only approved ANDA for all strengths of this product. In the decision, the District Court confirmed the position taken by the FDA that all of the unapproved amlodipine besylate ANDAs are currently blocked from approval by pediatric exclusivity. In support of the decision, Judge Urbina addressed each of the following notable issues.

First, under the Federal Food, Drug, and Cosmetic Act , 21 U.S.C. § 301 *et seq*. (1994), a brand manufacturer (here Pfizer) is entitled to a period of pediatric exclusivity if, among other things, "in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed." In addressing the parties' arguments, Judge Urbina held that since 21 U.S.C. § 355a(c)(2)(B) is silent "as to the particular court which may determine the patent dispute," the January 24, 2006 Northern District of Illinois Order in *Pfizer v. Apotex* triggered Pfizer's pediatric exclusivity and "is effective and remains so during the pendency of the appeal unless the district court's judgment is stayed or until the Federal Circuit issues its mandate."

Second, the parties disputed whether Apotex is subjected to Pfizer's period of pediatric exclusivity. Here, Judge Urbina reasoned that Section 355(a) manifests a clear Congressional intent that pediatric exclusivity not block the approval of an ANDA where the ANDA applicant has prevailed in the paragraph IV litigation. He concluded that "FDA's decision to exempt Apotex in light of its status as a prevailing party in challenging Pfizer's patent is reasonable and is not contrary to the language in Hatch-Waxman."

Next, the court turned to the FDA's ruling that Apotex is the sole beneficiary of the Federal Circuit's invalidity ruling regarding Pfizer's Norvasc patent (the '303 patent). Here, the court concurred with the FDA that because the Federal Circuit invalidated only three claims of the '303 patent and left several claims untouched, Pfizer's patent remains valid as to the remaining claims and is presumed to be properly listed in the Orange Book. Judge Urbina further agreed, that "[u]ntil Teva succeeds in its own patent litigation with Pfizer or until administrative or legal action completely de-lists Pfizer's patent from the Orange Book, the FDA's decision to withhold market approval for Teva's generic drug remains in effect."

Finally, Mylan challenged the FDA ruling that its 180-day market exclusivity does not extend beyond the '303 patent's expiration. Mylan argued that "nothing in the text or legislative history of the Hatch-Waxman Act indicates that generic exclusivity is forfeited upon patent expiration." Judge Urbina, however, held that under Hatch-Waxman, paragraph IV certifications are no longer valid upon patent expiration and must be converted to paragraph II certifications. At that time, the ANDA becomes eligible for approval.

Mylan Labs., Inc. v. Leavitt, 484 F. Supp. 2d 109 (D.D.C. 2007).

U.S. SUPREME COURT REJECTS RIGID APPLICATION OF FEDERAL CIRCUIT'S "TEACHING, SUGGESTION OR MOTIVATION" TEST FOR OBVIOUSNESS

by Philip C. Canelli (McDermott Will & Emery, LLP)

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On April 30, 2007, the U.S. Supreme Court overturned a decision of the Federal Circuit that had held Teleflex's patented invention was not obvious. The issue before the Supreme Court was whether the Federal Circuit erred in holding that a claimed invention can only be proved obvious if the prior art, the problems nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine relevant prior art teachings in the manner claimed.

In reaching its decision, the Supreme Court reaffirmed the *Graham* analysis as the objective measure for determining obviousness under 35 U.S.C. § 103, but decided the Federal Circuit's "teaching, suggestion, or motivation" (TSM) test as rigidly applied in *KSR* was improper. The Supreme Court said: "[t]here is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry . . . it errs." The Supreme Court rejected the Federal Circuit's narrow conception of the obviousness inquiry consequent in its application of the TSM test. Specifically, the Federal Circuit erred by (1) looking only at the problem the patentee was trying to solve, (2) assuming that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem, (3) concluding that a patent claim cannot be proved obvious merely by showing the combination of elements was "obvious to try," and (4) applying rigid rules to prevent hindsight that deny recourse to common sense.

The Supreme Court noted that a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Following these principles, the Court advised that when confronted with an obviousness issue, "it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art."

KSR Int'l Co. v. Teleflex Inc., No. 04-1350, 2007 WL 1237837 (U.S. Apr. 30, 2007).

PFIZER AWARDED $3.2 MILLION FOR SYNTHON'S BASELESS SUIT

by Philip C. Canelli (McDermott Will & Emery, LLP)

On April 16, 2007, Synthon IP was ordered by a federal district court to pay Pfizer $3.2 million in attorney's fees and expenses in a patent case in which Synthon accused Pfizer of infringing its patent on a process for making amlodipine, the active ingredient in Pfizer's top selling high blood pressure drug Norvasc.

During the earlier district court proceeding, the Virginia district court found that Pfizer did not infringe Synthon's amlodipine process patent, U.S. Patent No. 6,653,481 (the "'481 patent") and that the '481 patent is unenforceable due to inequitable conduct. Pfizer then filed a motion to declare the case exceptional and sought attorney's fees and expenses pursuant to 35 U.S.C. § 285.

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In the April 16 decision, Judge Ellis explained that there are many types of misconduct that may create an exceptional case for purposes of awarding fees in patent cases, including inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement. According to Judge Ellis, Synthon's inequitable conduct before the PTO, Synthon's litigation strategy, and its conduct in the course of the proceedings compel an exceptional case finding.

The court took particular issue with Synthon's prosecution of the '481 patent whereby "the record made clear that Synthon copied and sought patents on what it knew to be Pfizer's work and then, once those patents had issued, filed against Pfizer what it knew, or should have known with reasonable investigation, was a baseless suit for willful infringement of two invalid patents."

Although Judge Ellis granted Pfizer's motion for attorney fees, he reduced Pfizer's request for fees and costs by 20% due to what he called "instances of lumping multiple tasks together" under the same time entry, thereby preventing a confident assessment of the quantum and reasonableness of the time expended on each task. He also refused Pfizer's request for reimbursement of $345,000 in expert witness fees, as well as Pfizer's request for pre-judgment interest.

Synthon IP, Inc. v. Pfizer Inc., 48 F. Supp. 2d 437 (E.D. Va. 2007).

SIXTH CIRCUIT COURT OF APPEALS AFFIRMS SUMMARY JUDGMENT IN WYETH'S FAVOR HOLDING NO ANTITRUST VIOLATIONS

By Victoria E. Ford (Alson & Bird LLP)

Plaintiffs, wholesale and retail purchasers of pharmaceutical drugs, sued Wyeth-Ayerst Laboratories, Inc. ("Wyeth") for antitrust violations related to Wyeth's drug, Premarin. Premarin is a form of estrogen replacement therapy ("ERT") used to treat women who have undergone hysterectomies and whose bodies no longer produce estrogen. Premarin was approved for marketing in the United States in 1942 and until 1999 was the only ERT available. In March 1999, Duramed Pharmaceuticals' drug, Cenestin, became the second branded conjugated ERT drug on the market. Plaintiffs alleged that Wyeth engaged in certain conduct that resulted in higher prices of Premarin: 1) Wyeth emphasized the differences between Premarin and Cenestin, 2) Wyeth limited Cenestin distribution, and 3) Wyeth limited Duramed's contracting opportunities in the ERT markets—all in violation of Section 2 of the Sherman Act.

It is undisputed that Wyeth developed a Premarin Preemptive Plan. Plaintiffs pointed out that Wyeth limited the distribution of Cenestin by entering in restrictive contractual arrangements with pharmacy benefit managers and managed care organizations ("MCOs"). As of January 1, 2000, Wyeth had rebate contracts with 74 MCOs, of which 31 contained sole conjugated estrogen clauses preventing the MCO from including on its formulary (listing of medications for which an MCO provides coverage) any other conjugated estrogen therapy.

The Sixth Circuit reviewed the district court's grant of summary judgment *de novo*. The

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district court noted that there was no evidence showing that Wyeth's activities in the MCO market caused a price increase for Premarin. The Sixth Circuit agreed that the evidence in the record did not create a genuine issue of material fact as to the causal relationship between the Premarin Preemptive Plan and an increase in the price of Premarin. While Plaintiffs offered Wyeth documents concerning pricing practices, expert testimony, a governmental study allegedly supporting the view that increased competitor market share imposes a price restraint in the pharmaceutical market, and "concessions" by Wyeth's expert witnesses, the Sixth Circuit did not find such evidence convincing so as to create a genuine issue of material fact. Accordingly, the court affirmed the district court's grant of summary judgment.

J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc., 485 F.3d 880 (6th Cir. 2007).

SECTION 353(A) OF TITLE 21 DOES NOT EXCUSE COMPLAINCE WITH NDA

by Victoria E. Ford (Alston & Bird LLP)

Genendo imported sixty boxes of prescription Lipitor containing 10 mg tablets, and forty-eight boxes containing 20 mg tablets. While Lipitor is manufactured by Pfizer, Inc., Genendo purchased the Lipitor in Brazil in order to import it into the United States. Before importing the drug, Genendo sought a declaratory judgment that its importation was permissible under the Federal Food, Drug & Cosmetic Act (FDCA). Upon the motion of the United States, the action was dismissed on ripeness grounds. Genendo proceeded with the importation months later and the Lipitor was seized by the government.

At issue in this case was whether the seized Lipitor is an "unapproved new drug." The NDA sought by Pfizer and approved by the FDA specified the manufacture and packaging of Lipitor. However, the Lipitor imported by Genendo deviated from the NDA because it was packaged at an unapproved facility and its packaging was not consistent with the specifications set forth in the NDA. Genendo believed that the drug still qualified as an approved drug because all labeling and packaging requirements in the FDCA, including NDA requirements, are excused under 21 U.S.C. § 353(a) if the drug that is en route to or being held at an authorized drug repackager. At the time the drug was seized, it was en route to an FDA-registered repacker and labeler in Illinois. In contrast, the corresponding regulation, 21 C.F.R. § 201.150 sets forth specific labeling and packaging requirements that are exempt if a drug is en route to a repackager.

The district court found Genendo's expansive reading of § 353(a) too broad and that it would "eviscerate the protections afforded by the new drug approval process." The court held that the labeling and packaging requirements referred to in § 353(a) applied to general labeling and packaging, but not the detailed requirements for packaging set forth in the NDA, which the court ruled were not affected by § 353(a).

Given that the question was one of statutory interpretation, the Seventh Circuit conducted a *de novo* review. Under Chevron, the Seventh Circuit did not find the FDA's interpretation to be arbitrary, capricious or manifestly contrary to the statute. Rather, the court noted that 21 C.F.R. § 201.150 explicitly enumerates the particular labeling and packaging require-

RECENT COURT DECISIONS, CONT'D:

ments from which drugs in transit are exempt, and the NDA requirements are notably not included in that list. The court further found that such an interpretation is consistent with earlier precedent supporting the "congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs at issue." In affirming the district court, the Seventh Circuit held that the exemption in § 353(a), as implemented by § 201.150, does not excuse compliance with an FDA-approved NDA and thus the seized Lipitor was an unapproved drug.

U.S. v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007).

30-MONTH STAY OF APPROVAL DENIED WHERE SUIT NOT INITIATED WITHIN STATUTORY 45-DAY TIME PERIOD

By Thomas J. Parker and Victoria E. Ford (Alston & Bird LLP)

The United States District Court for the Southern District of New York denied the motion of Purdue Pharma, L.P., P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively "Purdue") which requested a thirty month stay of Mallinckrodt's ANDA. The court denied the motion because the action was not commenced within the 45-day statutory time period.

In 1999, Purdue sued four generic drug companies for infringement of its patents relating to OxyContin. In its suit against Endo Pharamceuticals, Inc., the court found the patents invalid due to inequitable conduct before the U.S.P.T.O. and enjoined Purdue from further enforcement of the OxyContin patents. In the other OxyContin cases, this court granted summary judgment for the defendants based on collateral estoppel.

Mallinckrodt filed an ANDA to seek approval to manufacture and sell a generic version of OxyContin. Purdue received Mallinckrodt's Paragraph IV notice on October 4, 2005. Given the court's previous rulings, Purdue did not file suit against Mallincrokdt. On February 1, 2006, the Federal Circuit withdrew it's affirmance of the lower court's invalidity decision. Thus, on March 29, 2006, the district court vacated its order enjoining Purdue from enforcing its patents. Instead of promptly moving to vacate the summary judgment orders in the related cases, Purdue filed stipulations in two of the cases and filed a consent judgment in the other case, all in October 2006. On November 9, 2006, before final vacating orders were issued, Purdue filed suit against Mallincrokt under the Hatch-Waxman Act. Purdue moved the court to apply the doctrine of equitable tolling or to invoke its inherent powers to issue a thirty-month stay.

The court denied Purdue's motion. The court found that even if it were to apply equitable tolling, Purdue's suit against Mallincrokdt was still untimely. On March 29, 2006 the court vacated its order enjoining Purdue from enforcing its OxyContin patents; however, Purdue did not bring suit within 45 days of that decision—instead waiting until November 9, 2006. The court was not convinced that the other summary judgment orders precluded Purdue from bringing suit and noted that Purdue could have moved promptly to vacate the orders after the Federal Circuit's mandate. The court declined to exercise any "inherent authority" because the clear statutory provisions were binding.

RECENT REGULATORY ACTIVITIES

DOJ Comments on Potential Antitrust Issues during Standard Setting Process

by Rick Williams (Vinson & Elkins, LLP)

These comments address how standards setting organizations and related intellectual property rights holders might navigate potential antitrust issues during the standard setting process. The basic problem in this area is that when an industry standard is selected, if the standard infringes a patent right, the right holder may be in a position to "hold up" the standard, inefficiently demanding higher royalty rates than it might have otherwise received. The paper outlines three basic approaches to avoiding this problem: reasonable and nondiscriminatory licensing commitments; pre-disclosure; and *ex ante* licensing. The paper looks favorably on *ex ante* licensing, which requires standard setting participants holding related patent rights to state—before the standard is selected—what maximum royalty rate and other terms they would demand if the standard would infringe their rights.

DRAFT GUIDANCE FOR INDUSTRY ON THE CONTENT AND FORMAT OF THE DOSAGE AND ADMINISTRATION SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS

By Rick Williams (Vinson & Elkins, LLP)

The FDA announced the availability of a draft guidance for labeling. The guidance provides recommendations for selecting and organizing information to be included in the "Dosage and Administration" section of the label. Comments may be submitted.

72 FR 17561 (April 9, 2007).

RECENT LEGISLATIVE ACTIVITY

FDA NEWS:

PRESCRIPTION DRUG USER FEE ACT (PDUFA IV)

by Thomas J. Parker and Victoria E. Ford

(Alston & Bird LLP)

The FDA is proposing various recommendations to the Prescription Drug User Fee Act (PDUFA) which intend to ensure strong pre-market review and transform the post-market safety system.

To enhance pre-market review, the recommendations propose to increase resources and staffing so that the FDA can maintain current review goals for applications, develop a review plan for each application, and communicate the planned review timeline to the sponsor in the "74-day letter" to increase the transparency of the review system. Further, the FDA hopes to expedite drug development by publishing for comment new draft guidelines to clarify current FDA thinking on certain critical trial design issues and attempt to clarify regulatory pathways.

The proposals also include improving the information technology infrastructure. Such improvements would allow for electronic applications with automated cross-links to previously submitted data and information so that information only has to be submitted once.

The proposals to the PDUFA additionally intend to modernize and transform the post-market drug safety system. The recommendations include new scientific approaches and better utilization of existing tools for the detection, evaluation, prevention, and mitigation of adverse events. Among other things, the FDA would also produce guidance in critical areas, increase pre- and post-market staff interactions, expand databases for analyses of new drug safety data, and maximize risk management and risk communication tools and programs.

CONGRESSIONAL HEARINGS:

SENATE HEARINGS RE: FOLLOW-ON BIOLOGICS (GENERIC BIOTECH DRUGS)

by James W. Gould (Morgan & Finnegan, LLP)

The Senate recently weighed in on the issue of generic biologic drugs by holding a hearing. The panel of experts set forth the tension between rising biologic drug costs in the absence of generics and the need for patient safety in determining substitutability. This will surely not be the last such political debate in this election year.

LEGISLATION:

S. 3546 (109th Congress) – AMENDMENT TO DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG AND CONSUMER PROTECTION ACT

by Thomas J. Parker and Victoria E. Ford

(Alston & Bird LLP)

At the end of the 109th Congress, legisla-

RECENT LEGISLATIVE ACTIVITY, CONT'D:

tion to amend the Federal Food, Drug, and Cosmetic Act was passed and signed into law on December 22, 2006 (Pub. Law No. 109-462). The law addresses the reporting of serious adverse events for dietary supplements and nonprescription drugs.

The legislation adds Section 760 to Title 21 of the United States Code, which requires that the manufacturer, packer or distributor whose name appears on the label of a dietary supplement or nonprescription drug marketed in the U.S. to submit to the Secretary of the FDA any report of a serious adverse event associated with the supplement or drug. A retailer whose name appears on the label can authorize the manufacturer or packer to submit the required reports as long as the retailer directs all adverse events to the manufacturer or parker. The report must be submitted within 15 business days of any report of a serious adverse event associated with the drug or supplement in the US, and within 15 business days the responsible party must submit any related medical information that is received within one year of the initial report.

The submission of any adverse event report, under the new law, will not be construed as an admission that the nonprescription drug or supplement involved or contributed to the adverse event. Further, if a nonprescription drug or dietary supplement does not include a domestic address or phone number for the reporting of a serious adverse event, it will be deemed misbranded.

S. 993, "PEDIATRIC RESEARCH IMPROVEMENT ACT"

by Rick Williams (Vinson & Elkins, LLP)

Introduced by Sen. Clinton (D-NY) on March 27, 2007, at the beginning of the 110th Congress, this legislation would amend Section 505B(a) of the Federal Food, Drug, and Cosmetic Act to change a number of the provisions regarding pediatric drug formulations, particularly reporting requirements for safety and efficacy studies. The bill also creates an internal FDA committee to review all of the assessments and waiver and deferral requests.

S. 1024, "SAFER DRUG ASSESSMENT TECHNOLOGY ADVANCEMENT ACT"

by Rick Williams (Vinson & Elkins, LLP)

Two days later, on March 29, 2007, Sen. Gregg (R-NH) introduced S.1024, which would amend Section 505B of the Federal Food, Drug, and Cosmetic Act to include provisions for a new postmarket risk identification and analysis system. Generally, the bill requires implementation of a system that will monitor adverse events from Federal health-related data, such as Medicare and Department of Veterans Affairs programs, and private sector health-related data, such as pharmaceutical purchase data and health insurance claims data. The bill also provides requirements for disseminating that information to the public.

H.R. 1902, "PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2007"

by Marc Brassler (Caesar, Rivise, Bernstein,

RECENT LEGISLATIVE ACTIVITY, CONT'D:

Cohen & Pokotilow, Ltd.)

Introduced by Rep. Bobby Rush (D-IL) on April 17, 2007, H.R. 1902 would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market. As introduced, the bill would make it "unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which – (1) an ANDA filer receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market or sell for any period of time the drug that is to be manufactured under the ANDA involved and is that subject of the patent infringement claim."

Exempt however is resolution or settlement of a patent infringement claim in which the value received by the ANDA filer includes no more than – (1) the right to market the drug before expiration of the patent or any other statutory exclusivity that would prevent the marketing of the drug; and (2) the waiver of a patent infringement claim for damages based on prior marketing of such drug.

Furthermore, the Federal Trade Commission may exempt certain agreements if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers.

H.R. 2273, FOOD & DRUG ADMINISTRATION IMPROVEMENT ACT OF 2007

by Victoria E. Ford (Alston & Bird LLP)

Introduced by Rep. Hinchey (D-NY) on May 10, 2007, H.R. 2273 seeks to meet four main objectives: 1) provide for the deposit in the general fund of the Treasury of fees that are collected from manufacturers of drugs under chapter VII of such Act, 2) terminate the authority of the FDA to negotiate with manufacturers on particular uses of the fees, 3) establish a Center for Postmarket Drug Safety and Effectiveness, and 4) establish additional authorities to ensure the safe and effective use of drugs.

The Center for Postmarket Drug Safety and Effectiveness would be headed by a Director appointed by the Secretary and would be established as a separate center at the organizational level, immediately below the Office of the Commissioner. The Director of the Center would report directly to the Commissioner and assist in regulating approved drugs, other than with respect to section 501, which includes administering enforcement authorities, administering section 502, administering requirements for studies that were required for conditions for the approval of applications under section 505, administering authorities under sections 505D and 505E, and monitoring approved drugs to determine whether there are any issues regarding safety and effectiveness.

RECENT LEGISLATIVE ACTIVITY, CONT'D:

S. 1082, THE PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

by Thomas J. Parker and Victoria E. Ford (Alston & Bird LLP)

The Prescription Drug User Fee Amendments of 2007, S.1082, was introduced by Sen. Kennedy (D-MA) on April 10, 2007. On May 9, 2007, the bill was passed by the Senate by a vote of 93-1 and was received by the House on the following day. No further actions have been taken on the bill.

The Act seeks to amend the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees, among other things, thereby reauthorizing the Prescription Drug User Fee Act, which is to expire on September 30, 2007, until 2012. The fees are intended to be dedicated to expediting the drug development process, the process for review of human drug applications and postmarket drug safety. Under this Act, pharmaceutical companies would pay more in user fees in 2008 than in 2007.

The Act additional requires that the Secretary annually set the fee for advisory review based on the number of direct-to-consumer advertisements that the Secretary will review in the next fiscal year. The Secretary must also create a Direct-to-Consumer Advisory Review Operating Reserve in the FDA salaries and expenses appropriation account in the event the fees collected in any subsequent fiscal year do not generate the fee revenue amount established for that fiscal year. The program is to be terminated if the Secretary fails to receive a certain amount of advisory review fees and operating reserve fees.

The Act further includes provisions addressing drug safety. Such provisions include establishing standards for monitoring postmarket data, provides for risk evaluation and mitigation strategies, requirement that new drug holder notify Secretary of new safety information that should appear on the label, creation of website with comprehensive drug safety information, the creation of a computerized network to scan insurance and pharmacy records for indications of safety issues with new medications, among other things.

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Intellectual Property Owners Association (IPO), established in 1972, is a trade association for owners of patents, trademarks, copyrights and trade secrets. IPO is the only association in the U.S. that serves all intellectual property owners in all industries and all fields of technology.

The association advocates effective and affordable IP ownership rights and provides a wide array of services to members. It concentrates on: supporting members interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the general public on the importance of intellectual property rights.

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