Intellectual Property Owners Association

Hatch-Waxman Committee Newsletter

August—December 2006

RECENT COURT DECISIONS

FEDERAL CIRCUIT AFFIRMS DISTRICT COURT'S CONSTRUCTION OF CLAIMS IN ONE PATENT COVERING LIPITOR®, BUT INVALIDATES DEPENDENT CLAIM OF SECOND PATENT COVERING SALT FORM OF COMPOUND

by Amy Manning (Alston & Bird LLP)

In a case involving the prescription drug Lipitor®, which is used to reduce low-density lipoprotein (LDL) cholesterol levels, the Federal Circuit upheld the district court's construction of Pfizer's U.S. Patent No. 4,681,893 ("the '893 patent"), holding that statements made during prosecution of foreign counterpart applications or other unrelated U.S. applications are irrelevant to claim construction. Further, on what appeared to be an issue of first impression, the Federal Circuit held Claim 6 of Pfizer's U.S. Patent No. 5,273,995 ("the '995 patent) invalid under 35 U.S.C. § 112, ¶ 4 for failure to further limit the scope of the claim from which it depended.

On appeal, Ranbaxy, which sought to bring a generic version of Lipitor® to market, argued that Claim 1 of the '893 patent only encompassed racemic mixtures of the claimed compound, thus excluding the specific enantiomer identified in Ranbaxy's ANDA. Ranbaxy relied on statements made during prosecution of the '995 patent and foreign counterparts to the '893 patent, and the fact that the specification only disclosed reaction schemes that produce racemic mixtures.

The Federal Circuit, however, upheld the district court's construction that Claim 1 covered all trans-form isomers of the compound, noting that the '893 patent consistently described the invention as a class of "trans" compounds, and that statements made during prosecution of foreign counterpart applications or other unrelated U.S. applications are irrelevant to claim construction.

In addition, the Federal Circuit reversed the district court's finding regarding the invalidity of Claim 6 of the '995 patent, holding that Claim 6 was invalid under 35 U.S.C. § 112, ¶ 4 because it did not narrow the scope of the claim from which it depended, Claim 2. Spe-

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cifically, Claim 2 failed to encompass salts of the recited chemical compound, whereas Claim 6 expressly claimed a salt form of the compound. Although the district court recognized that there may have been a problem with Claim 6, it declined to invalidate the claim under § 112 because it could not find any Federal Circuit precedent on the issue. In holding Claim 6 invalid, the Federal Circuit explained that such a ruling "does not exalt form over substance," and that applicants must satisfy certain requirements before obtaining a patent, some of which are more procedural or technical than others.

Pfizer Inc., et al. v. Ranbaxy Laboratories Limited, 457 F.3d 1284 (Fed. Cir. 2006).

BIOVAIL COMMENCES LEGAL ACTION TO ENFORCE CRITERIA SET FORTH IN ITS CITIZEN PETITION

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

On August 24, 2006, Biovail Corporation filed suit against the U.S. Food and Drug Administration (FDA) in the U.S. District Court for the District of Columbia. Biovail's complaint refers to its Citizen Petition filed with the FDA on December 20, 2005. Biovail asserts that it filed the Citizen Petition with the FDA to protect the public by ensuring that FDA applies "appropriate standards" when determining whether or not to approve an application to market a generic version of Wellbutrin XL® (bupropion hydrochloride extended-release tablets). The Citizen Petition also addressed the requirement that the labeling for a bioequivalent product be substantially identical to that of the approved branded product.

Specifically, Biovail stated that any Abbreviated New Drug Application for a generic version of Wellbutrin XL® must satisfy the following criteria:

a. All bioequivalence trials should calculate and evaluate the parameters based on concentrations of the parent drug and metabolites.

b. Any generic formulation should be shown, based on the above criteria, to be bioequivalent to Wellbutrin XL®, sustained-release, and immediate-release bupropion.

c. The bioequivalence studies described above should be conducted at steady-date evaluating the performance of the dosage form based on AUC, C_{max}, C_{min}.

d. Data using FDA's *in vitro* approach for evaluating the effect of alcohol on the performance of the controlled-release dosage form should be required to ensure the absence of "dose dumping" if the drug is consumed with alcohol.

Biovail sought a temporary restraining order and a preliminary injunction directing the FDA to resolve the issues raised by Biovail's Citizen Petition at least one week prior to the FDA's approval of any generic versions of Wellbutrin XL®. Biovail also sought a one-week lead time to ensure that there is a meaningful opportunity to seek judicial review of an FDA decision that does not incorporate Biovail's stated bioequivalence and labeling requirements. Biovail claimed the approval criteria set forth in its Citizen Petition would protect the public against the potentially harmful effects of generic versions that were not truly bioequivalent or misleadingly labeled.

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On June 7, 2006, the FDA informed Biovail that it would be unable to decide the Citizen Petition within the 180-day period "because it raised complex issues requiring extensive review and analysis by Agency officials."

In a related action, Biovail filed suit in December 2004 in the U.S. District Court for the Central District of California against Anchen, the first Paragraph IV generic filer for Wellbutrin XL. On August 1, 2006, Judge James Selna ruled in favor of Anchen on summary judgment holding that Anchen did not infringe Biovail's patents.

On August 23, 2006, Biovail Corporation filed a new suit against the FDA demanding that the FDA enforce the "proper criteria" for determining bioequivalence of generic versions of Wellbutrin XL. Biovail's Complaint sought a temporary restraining order and a preliminary injunction directing FDA to resolve the issues set forth in the Citizen Petition at least one week before the agency's supposed approval of a Wellbutrin XL generic product. Biovail requested the one-week lead time to ensure that there is a meaningful opportunity to seek judicial review of an FDA decision that does not incorporate Biovail's stated bioequivalence and labeling requirements.

Because of the time-sensitive nature of relief requested by Biovail, U.S. District Court Judge Ricardo Urbina expedited briefing of the issues. On September 6, 2006, the Court ruled that the FDA's "tentative response" adequately fulfilled the agencies legal obligations. Judge Urbina further concluded that although Biovail demonstrated that the marketing of generic Wellbutrin XL could potentially cause some irreparable injury, Biovail's showing of injury is inadequate to justify the extraordinary relief needed to obtain a restraining order.

By being first to file with the FDA, Anchen would receive 180 days of sales exclusivity of its generic form of Wellbutrin XL as soon as the FDA grants final approval of Anchen's ANDA.

Biovail Corporation v. U.S. Food and Drug Administration, 2006 U.S. Dist. LEXIS 62920 (D.C. 2006).

WYETH'S CLAIM OF WILLFUL INFRINGEMENT AGAINST RANBAXY DISMISSED, BUT RECOVERY OF ATTORNEYS' FEES STILL POSSIBLE

by Keith Hutchinson (Pfizer Inc.)

In Wyeth v. Ranbaxy the District Court for the District of New Jersey dismissed Wyeth's willful infringement claim in the context of ANDA litigation, but did not dismiss Wyeth's claim for attorneys' fees.

Wyeth markets ADVIL® Cold and Sinus Liqui-Gels, both of which contain a combination of the ingredients ibuprofen and pseudoephedrine hydrochloride. Wyeth also owns two patents covering this combination that are listed in the Orange Book. Ranbaxy filed an ANDA with the United States Food and Drug Administration seeking marketing approval for generic versions of tablets containing the same combination of ingredients. Thereafter, Wyeth sued Ranbaxy for infringement of both patents and alleged that Ranbaxy's act of filing an ANDA constituted willful infringement.

Ranbaxy defended the charge of willful infringement by arguing that such a claim cannot be based only on the "mere filing of an ANDA" (relying on Glaxo Group Ltd. v. Apo-

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tex, Inc.). Wyeth countered that Federal Circuit precedent in Glaxo permits a finding of willful infringement based on the filing of an ANDA under certain circumstances, such as where the alleged infringer is found to have deliberately copied a patented invention.

The District Court, in granting Ranbaxy's motion to dismiss the willful infringement claim, agreed that "the Federal Circuit has foreclosed … a finding of willful infringement based solely on the filing of an ANDA." However, the court did not dismiss Wyeth's claim for attorneys' fees, citing the Federal Circuit's reasoning in Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc. In that case, the Federal Circuit held that attorney's fees are available in an ANDA case that is exceptional, such as those that include the filing of an ANDA in combination with various types of misconduct, such as willful infringement, inequitable conduct before the United States Patent and Trademark Office, offensive litigation tactics, vexatious litigation, and frivolous filings.

Accordingly, the court dismissed the willful infringement claim since Wyeth did not allege any additional misconduct beyond Ranbaxy's filing of ANDA. But, the court did leave open the possibility that Wyeth could still receive attorneys' fees if it could provide evidence of such misconduct, thereby making the case "exceptional" under the reasoning in Yamanouchi.

Wyeth, Cardinal Health et al. v. Ranbaxy Laboratories, 2006 U.S. Dist. LEXIS 56784 (D.N.J. Aug. 11, 2006).

FIFTH CIRCUIT COURT OF APPEALS REVERSES SUMMARY JUDGMENT IN DEFECTIVE PRODUCT CASE

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

In *McNeil v. Wyeth*, the Fifth Circuit Court of Appeals faced an appeal after the district court granted summary judgment in favor of Wyeth, the manufacturer of Reglan® (metoclopramide), a drug used to treat gastroesophageal reflux disease (GERD). The plaintiff, Susan McNeil, had taken the Reglan® in accordance with two six month prescriptions followed by two months of additional prescribed use, though the Food and Drug Administration (FDA) had only approved the drug for use of no more than twelve weeks. Fourteen months after McNeil was first prescribed Reglan®, she was diagnosed with tardive dyskinesia, a serious medical condition, which was allegedly induced from the long-term use of Reglan®.

In her Complaint, McNeil alleged claims for marketing and design defects based on Wyeth's failure to adequately warn physicians and consumers of the increased risk of tardive dyskinesia that allegedly accompanies the long-term use of Reglan®. McNeil argued that Wyeth's failure to warn rendered the product inherently unsafe and unreasonably dangerous. McNeil further alleged that Reglan's® label was misleading as to the risk of tardive dyskinesia and failed to adequately warn about the increase in risk associated with exposure to the drug for more than twelve weeks.

The District Court for the Northern District of Texas found Reglan's® label to be "adequate as a matter of law." In granting Wyeth's motion for summary judgment, the court con-

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cluded that Reglan's® label was adequate because it explicitly mentions the symptom's of which the plaintiff complained of and specifies that the drug is intended for short-term use of twelve weeks or less. The court also found that the label adequately warned against the potential risk, albeit a "comparatively rare risk," of tardive dyskinesia and other movement disorders, and discloses that the risk of developing tardive dyskinesia increases with the duration of treatment.

On appeal, Wyeth maintained its argument that it does not have a duty to warn about risks of use longer than twelve weeks because the label clearly states that the drug is indicated for treatment for no more than that duration. Thus, not only would such a warning be superfluous, but it would also be improper, because Wyeth allegedly cannot tell a medical professional how to exercise professional judgment on whether a drug should be used longer than the period approved by the FDA.

The Court of Appeals for the Fifth Circuit, in an opinion written by Judge Smith, disagreed with Wyeth's contentions, reversed the lower court's finding of summary judgment, and remanded for case for further proceedings. The court held that genuine issues of material fact existed as to whether pharmacological evidence should have alerted Wyeth of the significantly increased risk that a patient would develop tardive dyskinesia from long-term use of Reglan®. The court also found that the widespread, long-term use of Reglan® suggested that the twelve week indication is generally disregarded in the medical community and created an issue of material fact as to whether the warning statement on the label regarding tardive dyskinesia and other movement disorders, while "comparatively rare" for short-term use was misleading and inadequate as failing to alert physicians to the magnitude of risk if the product was used over an extended term.

McNeil v. Wyeth, 2006 U.S. App. LEXIS 21499 (5th Cir. August 22, 2006).

PFIZER'S PATENT RELATING TO NORVASC® FOUND VALID AND INFRINGED

by Vickie Ford (Alston & Bird LLP)

In Pfizer v. Synthon Holdings BV, the District Court for the Middle District of North Carolina found in favor of Pfizer, holding that Synthon's proposed amlodipine besylate product would infringe Pfizer's U.S. Patent No. 4,879,303 ("the '303 patent"). Consequently, the court issued an injunction that prevents Synthon from marketing its proposed product until both the '303 patent and Pfizer's period of pediatric exclusivity have expired.

Pfizer's '303 patent covers its amlodipine besylate drug product, which it markets as Norvasc®, that is used to treat hypertension and angina. After a Markman hearing, the court construed the claim language "the besylate salt of amlodipine" as covering Synthon's proposed product, which is the monohydrate form of amlodipine besylate. Synthon asserted numerous defenses, including invalidity of the claims of the '303 patent for obviousness, lack of written description, and obviousness-type double patenting. The court, however, disagreed with Synthon and found the claims of '303 patent valid and enforceable. With respect to Synthon's argument regarding obviousness, the court found that the besylate salt

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was not obvious because one skilled in the art would not have been motivated to create the particular salt and, furthermore, the unexpected properties of the besylate salt were sufficient to overcome any prima facie case of obviousness.

Pfizer Inc. v. Synthon Holdings BV, 2006 WL 2553370 (M.D.N.C. Aug. 31, 2006).

SANOFI WINS PRELIMINARY INJUNCTION AGAINST APOTEX RELATING TO PLAVIX®

by Vickie Ford (Alston & Bird LLP)

In Sanofi-Synthelabo v. Apotex Inc., Sanofi-Synthelabo ("Sanofi") sought a preliminary injunction to prevent Apotex from making a generic version of clopidogrel bisulfate, a blood-thinning agent marketed as by Sanofi as Plavix®. Sanofi secured U.S. Patent No. 4,847,265 ("the '265 patent") which claims clopidogrel bisulfate. Apotex filed an ANDA for approval of a generic form of clopidogrel bisulfate tablets and alleged in a Paragraph IV certification that the relevant claims of the '265 patent are invalid. Sanofi filed suit against Apotex alleging infringement of the '265 patent, and Apotex defended by arguing that the claims are invalid on several grounds and unenforceable due to inequitable conduct. During the proceedings, the parties stipulated that Apotex's generic product infringed the claims of the '265 patent and so the only issue that remained for the court to resolve was whether those claims are invalid and/or unenforceable.

In particular, Apotex argued that the claims of the '265 patent are invalid as anticipated by the disclosure contained in an earlier Sanofi patent, are obvious based on various prior art references, and are unenforceable due to alleged inequitable conduct during Sanofi's prosecution of the claims. In particular, Apotex alleged that Sanofi committed inequitable conduct by falsely claiming that the therapeutic activity of clopidogrel was "unexpected" and that such argument was highly material because it was critical to overcoming an obviousness rejection during prosecution of the claims at issue.

The district court found that Apotex's argument relating to anticipation lacked substantial merit because the disclosure contained in Sanofi's earlier patent did not provide specific guidance as to the beneficial properties of clopidogrel, nor did it provide a method for separating enantiomers of the compounds. Additionally, the court found that the claims of the '256 patent were not obvious in view of the disclosure in various prior art references because the extensive resources used by Sanofi to develop the drug showed clopidogrel bisulfate refuted such a finding. The court chose not to address Apotex's double-patenting argument. Finally, the court found Sanofi did not commit inequitable conduct during prosecution of the claims at issue because Sanofi's tests concerning other compounds that are structurally close to clopidogrel did not, by itself, preclude a finding that the therapeutic properties of clopidogrel were "unexpected."

In performing the required balancing test when considering whether or not to grant a preliminary injunction, the court found that Sanofi had suffered irreparable harm; in addition to finding they had established a likelihood of success on the merits. The harm included irreversible price erosion, loss of good will, and the discontinuance of research aimed at developing other medical uses for Plavix®.

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In balancing the hardships of the parties, the court was not sympathetic to the hardships incurred by Apotex because such harms would not have existed if Apotex had waited until the successful conclusion of litigation instead of launching at risk. On balance, the court found the harms that would be suffered by Sanofi were greater than those of Apotex because Apotex's harms were preventable. Finally, the court found that the public interest favored Sanofi and the continued investment in the discovery and development of new drugs represented by pioneer drug companies. Such continued investment outweighed the public interest in accessing lower priced drugs.

Sanofi-Synthelabo v. Apotex Inc., 2006 WL 2516486 (S.D.N.Y August 31, 2006).

LIPITOR® WORLDWIDE PATENT INFRINGEMENT LITIGATION UPDATE

by Vickie Ford (Alston & Bird LLP)

A court in Norway held that Ranbaxy does not infringe two of Pfizer's Norwegian patents that cover Lipitor®. Pfizer responded, "[The ruling] has no practical effect on Pfizer's ability to protect Lipitor®" from generic competition in Norway because a different Norwegian patent covering Lipitor® was held valid and infringed last year.

Separately, a court in the Netherlands has upheld Pfizer's basic patent covering Lipitor® and ruled that it would be infringed by Ranbaxy's proposed product containing atorvastatin calcium.

PURDUE AND ENDO SETTLE OXYCONTIN PATENT CASE

by Vickie Ford (Alston & Bird LLP)

Endo Pharmaceuticals has settled a long-standing patent infringement case with The Purdue Frederick Company regarding Endo's generic equivalent of Oxycontin. Endo will continue selling its generic Oxycontin until December 31, 2006.

ALZA FAILS TO PROVE INFRINGEMENT WITH RESPECT TO MYLAN'S PROPOSED GENERIC VERSION OF DITROPAN XL® (MYLAN II)

by Vickie Ford (Alston & Bird LLP)

Alza Corp. ("Alza") owns U.S. Patent No. 6,124,355 ("the '355 patent"), which claims a once-daily, controlled-release oxybutynin formula, that is used to treat urinary incontinence. Alza markets the drug as Ditropan XL®. The benefits of once-a-day dosing include convenience, steady-dosing, and possibly reduced absorption of a metabolite that may lead to a reduced incidence of certain side effects. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan") filed two ANDAs for approval of a generic version of Alza's once-a-day oxybutynin formulation. Alza subsequently filed suit alleging infringement. At trial, the district court held that Alza failed to meet the burden of proof for infringement and that the claims of the '355 patent were invalid as both anticipated and obvious in light of the prior art. Upon appeal, the Federal Circuit affirmed the district court's holding.

First, the Federal Circuit affirmed the district court's holding that the relevant claims of the

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'355 patent were invalid as obvious. They concluded that the district court properly analyzed the obviousness issue by (i) identifying the level of ordinary skill in the art, (ii) determining whether there was a motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine references, and (iii) examining secondary considerations of nonobviousness. Agreeing with the lower court, the Federal Circuit found that Mylan had established a strong prima facie case of obviousness, which Alza had failed to rebut by the introduction of evidence relating to secondary indicia of non-obviousness.

The Federal Circuit additionally affirmed the district court's finding of Noninfringement with respect to the claims of the '355 patent. To prove infringement, Alza had the burden of proving that Mylan's accused generic formulation exhibited an *in vivo* release profile falling within certain claimed concentration ranges at relevant times. The court found, however, that Alza had provided no direct evidence of the rate of dissolution of the accused product *in* vivo and instead had presented evidence relating only to blood plasma concentrations of the drug versus time for both the accused ANDA formulation and the marketed formulations of the drug and evidence of the *in vitro* rate of release of both formulations in the laboratory. The Federal Circuit found this evidence lacking because Alza had failed to credibly link either the blood plasma concentration or the *in vitro* dissolution rates to the rate of *in vivo* dissolution in the GI tract, which *in vivo* rates were recited as limitations in the claims at issue. The Federal Circuit agreed with the district court that Alza's evidence of *in vitro* dissolution rates was irrelevant without evidence proving the *in vitro* system was a good model of actual *in vivo* behavior. Therefore, the Federal Circuit affirmed the district court's holding of noninfringement in favor of Mylan.

Alza Corp. v. Mylan Laboratories, Inc., 464 F.3d 1286 (Fed. Cir. 2006) (*Mylan II*).

IMPAX WINS DITROPAN XL® LITIGATION IN VIEW OF HOLDING IN MYLAN II CASE (MYLAN I)

by Vickie Ford (Alston & Bird LLP)

In this case, the Federal Circuit affirmed the district court's invalidity holding with respect to claims covering Alza's Ditropan XL® product, used to treat incontinence. Impax Laboratories, Inc. ("Impax") filed an ANDA for a generic extended-release oxybutynin, and like Mylan, was sued by Alza for infringement of the '355 patent. During the litigation of this case, Alza stipulated that if the claims of '355 patent were found to be invalid during litigation against Mylan with respect to the same patent, see above, they would consent to an entry of judgment in the instant case that the same claims were invalid. The Federal Circuit held in *Mylan II* that the relevant claims of '355 patent were invalid. Therefore, the court entered a final judgment in this case in favor of Impax.

Alza Corp. v. Impax Laboratories, Inc., 193 Fed. Appx. 973 (Fed. Cir. 2006) (*Mylan I*).

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BIOVAIL FAILS TO OBTAIN TEMPORARY RESTRAINING ORDER TO PREVENT THE MARKETING OF GENERIC WELLBUTRIN XL®

by Vickie Ford (Alston & Bird LLP)

Biovail Corp. and Biovail Laboratories International SRL (collectively, "Biovail") manufacture Wellbutrin XL®, which is an extended release formulation of bupropion HCl, a drug that is used to treat depression. Anchen Pharmaceuticals, Inc. ("Anchen") is awaiting FDA approval of its generic version of Wellbutrin XL®. In December 2005, Biovail filed a citizen petition with the FDA seeking to ensure that they apply what Biovail considers the proper standards for determining whether generic versions of Wellbutrin XL® are bioequivalent. Biovail was voiced concern that some generic versions of Wellbutrin XL® may contain dangerous versions of a chemical that may cause *grand mal* seizures. Therefore, Biovail argued that allowing such generic versions of Wellbutrin XL® to be marketed would both threat public safety and damage the reputation of Wellbutrin XL® amongst patients and physicians.

Biovail subsequently filed suit against FDA seeking a temporary restraining order (TRO) and asking the court to compel the FDA to rule on its citizen petition one week prior to approving any generic versions of Wellbutrin XL®. Biovail further alleged the FDA had violated the Administrative Procedures Act ("APA"), 5 U.S.C. § 706 (providing a cause of action when an agency fails to act), and violated Biovail's right to constitutional due process when they failed to substantively respond to its citizen petition within 180 days of its filing.

The District Court for the District of Columbia denied Biovail's motion for a TRO because they failed to demonstrate that they were likely to succeed on the merits of their claims. In its ruling, the court found that the FDA had issued a tentative response to Biovail's citizen petition within 180 days of its filing, which response included an explanation as to why the agency was unable to reach a decision on the petition in such a short timeframe. Furthermore, the court disagreed with Biovail's argument that the FDA should be required to rule on a citizen petition prior to taking any on an ANDA that is subject of such a petition. Specifically, the court held that there is no legal authority to support such a proposition and that the FDA's approval of an ANDA which is the subject of an unresolved citizen's petition would necessarily lead to the marketing of an unsafe drug that would harm the public. Finally, the court held that Biovail failed to demonstrate that it was likely to succeed on the merits of its due process claim because it had not shown a protected interest in its business reputation.

Finally, the court found Biovail failed to make a showing of irreparable injury that sufficient to warrant the issuance of a TRO. Specifically, the court found the potential loss in profits to Biovail, if the FDA approved the generic version Wellbutrin XL® at issue, was insufficient to establish irreparable harm. Further, the court found the evidence supporting Biovail's argument that the generic version Wellbutrin XL® at issue may cause *grand mal* seizures and consequently harm the reputation of branded Wellbutrin XL® was similarly insufficient to satisfy the irreparable harm prong of a TRO analysis. Next, the court found that the grant of a TRO in this case could harm third parties with pending ANDAs. Finally, the

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court held that the public benefit afforded by the availability of low-priced drugs outweighed Biovail's unsupported claim that the public would be harmed by unsafe, generic drugs.

Biovail Corp. v. U.S. Food and Drug Administration, 448 F.Supp.2d 154 (D.C.C. 2006).

ORTHO-MCNEIL WINS PRELIMINARY INJUNCTION IN TOPAMAX® CASE, LOSES SUMMARY JUDGMENT IN ORTHO TRI-CYCLEN® LO

by Rick Williams (Vinson & Elkins L.L.P.)

On October 23, Judge Stanley R. Chesler for the United States District Court, District of New Jersey, issued two opinions in separate Hatch-Waxman patent infringement actions, both involving Ortho-McNeil Pharmaceuticals, Inc., a Johnson & Johnson company.

First, in the matter of Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc., the Court granted Ortho-McNeil's motion for a preliminary injunction, enjoining Mylan from marketing or selling products containing the active ingredient, topiramate. Topiramate is the active ingredient in Topamax®, an anti-convulsant drug approved for marketing in the United States by the FDA.

Judge Chesler's ruling on Ortho-McNeil's motion for a preliminary injunction follows two earlier summary judgment decisions in this case where he found that Mylan failed to present sufficient evidence to support its inequitable conduct and indefiniteness defenses. After these earlier rulings, Mylan had only a defense of obviousness to oppose Ortho-McNeil's motion for a preliminary injunction. In finding that Ortho-McNeil had satisfied the four part test for entitlement to a preliminary injunction, Judge Chesler noted that Mylan's obviousness argument failed to establish a motivation or suggestion to combine the cited prior art references, characterizing the motivation test as a "crucial" component of the obviousness analysis. *Id.* at *4.

The Court's opinion discussed at length the expert declarations offered by Mylan in support of it's obviousness defense, and found that Mylan's expert engaged in forbidden hindsight reconstruction by starting the analysis with the very problem solved by the inventor, following the path taken by the inventor and arriving at the invention. *Id*. The Court questioned the propriety of beginning the obviousness analysis by starting with the particular problem solved by the inventor of the patent in suit, absent proof that the inventor was a person of ordinary skill in the art and that the skilled artisan would have been trying to solve that particular problem. *Id.* at *5.

In addition, the Court found that Mylan failed to establish a reasonable expectation of success to support its obviousness defense. Judge Chesler stated that Mylan's expert had failed to address the issue of expectation of success, and thus, Mylan's obviousness defense was "legally insufficient" on this ground as well. *Id.* at *6. The Judge also noted that the standard under 35 U.S.C. § 103 is not an "obvious to try" standard and remarked that Mylan had nonetheless failed to satisfy this standard as well.

Finally, Judge Chesler discussed four categories of secondary evidence of non-obviousness: unexpected results, commercial success, copying and industry recognition. The Judge found that Mylan's arguments that

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the secondary considerations only related to methods of using topiramate and not to the compound itself were not persuasive, noting that upon a demonstration of commercial success, the burden of proof shifts to the challenger to show that the commercial success is due to extraneous factors and not the patented invention. *Id.* at 9.

In the second case, Ortho-McNeil Pharmaceutical, Inc. v. Barr Laboratories, Inc., a Hatch-Waxman patent infringement dispute involving the oral contraceptive Ortho Tri-Cyclen Lo. Judge Chesler denied two summary judgment motions, one filed by Ortho-McNeil (on Barr's anticipation defense) and one filed by Barr (on its obviousness defense). With respect to Barr's anticipation defense, the parties agreed that all but one of the limitations found in the asserted claims appear expressly in two prior art patents. *Id.* at *3. The only limitation not admittedly found in the prior art patents is the 25 microgram dose of ethinyl estradiol limitation. *Id.* The prior art patents do, however, disclose contraceptive dosages of ethinyl estradiol between the range of 20 micrograms to 50 micrograms. *Id.* at *4. Thus, the issue of anticipation turned on whether the recitation of this range discloses the 25 microgram ethinyl estradiol limitation as a matter of law.

The Court found that with respect to Barr's anticipation defense, Ortho-McNeil had misread *In re Petering*. 301 F.2d 676 (C.C.P.A. 1962). Judge Chessler noted that *Petering* did not hold that a genus may anticipate a species *only* upon a showing that preferences in the prior art produce a limited class, but rather the *Petering* court only required *some* description in the prior art identifying a limited class such that a person could at once envision each member of the class. *Id.* at *4. Ultimately, however, the Court ruled that a genuine issue of material fact existed with regard to whether or not the prior art patents disclosed the 25 microgram ethinyl estradiol limitation and, thus, denied Ortho-McNeil's motion for summary judgment on Barr's anticipation defense.

The Court's opinion next turned to the issue of obviousness and to Barr's motion for partial summary judgment that the two key prior art patents rendered the critical claims *prima facie* obvious. The Court denied Barr's motion citing *In re Rinehart* (531 F.2d 1048 (C.C.P.A 1976)) for the proposition that the obviousness analysis should not be fragmented by a finding that *prima facie* obviousness should be treated as an established conclusion and other evidence evaluated for its knockdown power against that conclusion. *Id.* at *5. Rather the ultimate finding of obviousness must be based on all of the facts, uninfluenced by earlier decisions. *Id.* The Court stated that there was no benefit to finding a *prima facie* case of obviousness had been established since the final determination at trial would require reconsideration of everything previously considered in light of all additional facts. *Id.* at *6. The Court also noted that granting summary judgment of *prima facie* obviousness could lend excessive weight to that determination, thus improperly segmenting the obviousness analysis contrary to the decision in *In re Rinehart*. *Id.*

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories Inc., 2006 U.S. Dist. LEXIS 74842 (D.N.J. Oct. 23, 2006); Ortho-McNeil Pharmaceutical, Inc. v. Barr Laboratories, Inc., 2006 U.S. Dist. LEXIS 76991 (D.N.J. Oct. 23, 2006).

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FEDERAL CIRCUIT DENIES REHEARING IN LIPITOR SUIT

by Rick Williams (Vinson & Elkins L.L.P.)

On October 23, 2006, the Federal Circuit denied Ranbaxy's request for rehearing in the appeal of the patent infringement case related to the blockbuster drug Lipitor. The Federal Circuit previously invalidated one of Pfizer's patents but upheld the basic patent on the active ingredient (atorvastatin) in Lipitor. Barring a request for review of the Federal Circuit's decision by the Supreme Court, it appears Lipitor will remain under patent until 2010. According to IMS Health, Lipitor generated $ 8.4 billion in sales in 2005.

Pfizer Inc. v. Ranbaxy Laboratories Limited, 2006 U.S. Dist. LEXIS 28925 (Fed. Cir. October 23, 2006).

FEDERAL CIRCUIT INVALIDATES ABBOTT SEVOVFLURANE PATENT ON APPEAL

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

In Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., Abbott appealed from a judgment of noninfringement of U.S. Patent No. 5,990,176 ("the '176 patent") by Baxter, and Baxter cross-appealled the district court's determination that the asserted claims were valid and a finding of no inequitable conduct.

The '176 patent contains composition and method claims related to protecting sevoflurane from degradation in the presence of Lewis acids. Sevoflurane is a fast-acting, highly effective inhalation anesthetic. According to Abbott, prior to the filing of the patent application that matured into the '176 patent, it was not known in the art that Lewis acids could potentially degrade sevoflurane. Abbott's solution to the problem was to mix sevoflurane with water such that the added water would bind to the Lewis acids and thereby prevent the degradation of the product. Further according to Abbott, this solution ran counter to the conventional wisdom at the time because prior to this time manufacturers sought to minimize the water content in formulations of sevoflurane.

A prior art patent, U.S. Patent No. 5,684,211 ("the '211 patent"), taught saturating sevoflurane with water, but did not teach the advantageous feature of making a composition in this way. The court found that saturating the sevoflurane necessarily meant that the water was in sufficient quantity to protect sevoflurane from degradation. Case law, the court noted, has consistently held that a reference may anticipate a claim even when relevant properties of the thing disclosed were not appreciated at the time. Moreover, the court stated that the district court had misapplied the decision of Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., which states that "[n]ewly discovered results of known processes directed to the same purposes are not patentable because such results are inherent." According to the Federal Circuit, the district court had incorrectly found that invention taught in the disclosure of the prior art '211 patent was for a different purpose than the '176 patent and was not, therefore, applicable to an anticipation analysis with respect to the claims of the '176 patent. Instead, the Federal Circuit noted that the distinction in Bristol-Myers Squibb is applicable only to process

RECENT COURT DECISIONS, CONT'D:

claims. The court found that all of the steps of the '176 patent are disclosed in the '211 patent and the steps are peformed for the same purpose: the delivery of safe and effective sevoflurane as an anesthetic. Therefore, the Federal Circuit concluded that the claims of the '176patent at issue inherently were inherently anticipated by the disclosure found in the prior art '211 patent.

Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 2006 U.S. App. LEXIS 27734, 80 U.S.P.Q.2d 1860 (Fed. Cir., November 9, 2006).

DISTRICT COURT INVALIDATES TWO PATENTS COVERING MEGESTROL ACETATE FORMULATIONS FOR FAILING TO SATISFY THE ENABLEMENT REQUIREMENT

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

In Pharmaceutical Resources, Inc. v. Roxane Laboratories, Inc., plaintiffs Pharmaceutical Resources, Inc. filed a patent infringement action against defendants Roxane Laboratories, Inc. alleging infringement of U.S. Patent No. 6,593,318 ("the '318 patent") and U.S. Patent No. 6,593,320 ("the '320 patent") relating to the sale of products containing megestrol acetate. The products sold by both Pharmaceutical Resources and Roxane are generic versions of Bristol-Myers Squibb's ("BMS") drug Megace® (megestrol acetate), a drug which is used to stimulate the appetite of patients suffering from severe weight loss. Large doses of megestrol acetate are typically required to be administered to patients in order to achieve significant appetite stimulation. These large doses are administered to patients in liquid form, preferably in a stable flocculated suspension in water, in order to increase patient comfort and compliance with the dosing regimen. Such stable flocculated suspension are suspensions of the active ingredient that resist caking and are redispersible after settlement occurs.

Prior to the instant action, Pharmaceutical Resources were sued by BMS for infringement of U.S. Patent No. 5,338,732 ("the '732 patent"), which patent contains claims covering Megace®. Pharmaceutical Resources prevailed on a motion for summary judgment of non-infringement in that case and that decision was affirmed on appeal. They prevailed in that earlier suit because the product they developed was bioequivalent to BMS' Megace® product, but utilized different components than were required by the claims of the '732 patent. Furthermore, they successfully argued that the '732 patent taught that stable suspensions of megestrol acetate could be created only by using formulations with specific excipients in limited ranges. BMS's Megace® flocculated suspension product contains, and the '732 patent's claims recite, a surfactant, polysorbate, a wetting agent, polyethylene glycol, and several other excipients. In contrast, Pharmaceutical Resources' generic megestrol acetate product utilizes docusate sodium as a surfactant and glycerin as a wetting agent.

In connection with their work to develop their own stable megestrol acetate product, Pharmaceutical Resources filed several patent applications of their own, including applications that matured into the '318 and '320 patents at issue in this case. The '318 patent contains composition claims and the '320 patent contains method claims.

RECENT COURT DECISIONS, CONT'D:

The district court found the claims of the '318 and '320 patents did not meet the enablement requirement of 35 U.S.C. § 112, second paragraph, because they encompass every possible megestrol acetate flocculated suspension made with any surfactant, in any amount, in combination with any of a number of recited wetting agents. In partial support of its decision, the district court took note of evidence indicating that Pharmaceutical Resources were unable to formulate stable flocculated suspensions with several common surfactants.

Because the court granted Roxane's motion for summary judgment of invalidity, it did not address the other alleged grounds of invalidity of the claims at issue.

Pharmaceutical Resources, Inc. v. Roxane Laboratories, Inc., 2006 U.S. Dist. LEXIS 81628 (D.N.J., Nov. 8, 2006).

SCHWARZ PHARMA FILES PETITION WITH FDA TO STAY APPROVAL OF ANDA RELATING TO PRODUCTS CONTAINING MOEXIPRIL

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

On October 26, 2006, Schwarz Pharma, Inc. ("Schwarz") filed a petition with the FDA requesting a stay of approval for Paddock Laboratories' ("Paddock") ANDA relating to moexipril hydrochloride tablets. Moexipril hydrochloride is the active ingredient of Univasc® and Uniretic® tablets, both of which are used to treat hypertension and congestive heart failure. On November 1, 2006, the FDA noted acceptance of Schwarz' petition as a procedural matter but stated that the agency had not yet reached a decision on its substantive merits.

In its petition, Schwarz argued that, although the United States District Court for the District of Minnesota granted a motion for summary judgment holding that Paddock's product does not infringe Schwarz' patent, approval of Paddock's ANDA should nevertheless be stayed. Schwarz noted that it had filed a letter with the district court expressing its intent to request reconsideration of the court's order. Furthermore, Schwarz filed a Rule 59(e) motion with the court, seeking a withdrawal of the court's summary judgment finding of non-infringement, based on alleged errors of law and the improper determination of genuine issues of material facts.

Schwarz argued in its petition that the effect the Rule 59(e) motion is that the district court's order does not constitute a final judgment, and will not constitute such a judgment unless and until the court rules on the motion. Schwarz further argued that under 21 U.S.C. § 355(j)(5)(B)(I)(aa), the Court's order does not qualify as an effective judgment on which an approval can be based prior to the expiration of the 30 month period described in 21 U.S.C. § 355(j)(5)(B). Additionally, Schwarz argued that it will suffer irreparable harm if Paddock's ANDA is approved. Last, they argued that public policy supports the requested stay because it is required by statute and will further the processes by which issues of patent infringement relating generic drugs are resolved. Finally, Schwarz stated that the requested stay will not harm the public interest in having generic drugs available to the public.

RECENT COURT DECISIONS, CONT'D:

RANBAXY AND IVAX SUE FDA SEEKING RE-LISTING OF MERCK PATENTS IN ORANGE BOOK

by Keith Hutchinson (Pfizer Inc.)

Generics producers Ranbaxy Laboratories Ltd. and Ivax Pharmaceuticals, Inc. had petitioned the FDA to re-list two Merck patents covering Zocor (simvastatin) in the FDA's Orange Book. The patents were delisted by the patent owner, Merck, in response to a Paragraph IV certification filed by Ranbaxy and Ivax. FDA denied the petitions and deprived Ranbaxy and Ivax of the 180-day period of exclusivity because Merck had not sued them for patent infringement. Ranbaxy and Ivax then filed suit against FDA, seeking re-listing of the Merck patents. The district court granted summary judgment in Ranbaxy's favor and the FDA appealed to the Court of Appeals for the District of Columbia.

The DC Circuit Court of Appeals affirmed, holding that the FDA's action under the *Chevron* test violated the Federal Food, Drug and Cosmetic Act (21 USC § 301 et. seq.). The *Chevron*, two-step analysis first requires a determination as to whether Congress has directly addressed the specific issue. Second, if the statute is silent or ambiguous as to the specific issue, then one must determine whether the agency's action is based on a permissible construction of the statute.

Disposing of the case under *Chevron* step one, the Court rejected the FDA's attempt to add a requirement to the exclusivity statute that is conditioned upon litigation success. Further, in addressing the FDA's delisting of Merck's patents from the Orange Book, the Court provided that "the FDA may not … change the incentive structure adopted by Congress," and held unlawful the FDA policy requiring the ANDA-paragraph IV filer to be sued in order to preserve its statutory exclusivity.

Accordingly, the Court held that the FDA policy of conditioning an ANDA applicant's period of exclusivity upon a patent infringement suit by the NDA holder against the generic manufacturer was contrary to statute.

Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120 (D.C. Cir. 2006).

ABRAXIS WINS INFRINGEMENT SUIT AGAINST MAYNE UNDER DOCTRINE OF EQUIVALENTS

by Keith Hutchinson (Pfizer Inc.)

In Abraxis Bioscience, Inc. v. Mayne Pharma Inc., the Federal Circuit addressed the alleged infringment of Mayne's proposed generic version of DIPRIVAN®, a drug used for patient anesthesia and sedation. Mayne filed an ANDA for a generic version of DIPRIVAN® that contained a paragraph IV certification relating to a patent owned by Abraxis that allegedly covered the formulation for which Mayne was seeking approval. The district court found that Mayne's proposed product literally infringed the claims at issue and Mayne appealed to the Federal Circuit. On appeal, the Federal reversed the district court's claim construction order as well as its finding of literal infringement, but found infringement under the doctrine of equivalents.

The key issue on appeal was construction of the term "edetate" that is found in the claims of the Abraxis patent. The district court construed the term such that structural analogs of EDTA were encompassed by it. In contrast,

RECENT COURT DECISIONS, CONT'D:

the Federal Circuit adopted a more narrow definition of "edetate" as EDTA and derivatives of EDTA, such as salts, but not including structural analogs. Using this construction of the term, the Federal Circuit found that Mayne's proposed product did not literally infringe the asserted claims in the Abraxis patent.

The Federal Circuit, however, upheld the district court's finding of infringement under the doctrine of equivalents. In this respect, the court found that the calcium trisodium DTPA found in Mayne's proposed product performed "substantially the same function in substantially the same way to achieve the same result as edetate." In fact, Mayne stated they had specifically chosen calcium trisodium DTPA because of its structural similarities to edetate and the likelihood that it would match the product characteristics and stability profile of Abraxis' improved DIPRIVAN® formulation. Furthermore, the court found that the use of DTPA in place of EDTA in these formulations was unforeseeable at the time Abraxis filed the patent application that matured into the patent they asserted against Mayne. Notably and ironically, Mayne had acknowledged the unforeseeability of using DTPA in these formulations during the prosecution of their own patent applications covering the proposed formulation.

Abraxis Bioscience, Inc. v. Mayne Pharma Inc., 467 F.3d 1370 (Fed. Cir. 2006),

CONSUMER LOSES SUIT AGAINST ORTHO-MCNEIL AND WATSON OVER ALLEGED MISREPRESENTATION AND CONCEALMENT

by Keith Hutchinson (Pfizer Inc.)

Plaintiff Adamson sued Ortho-McNeil and Watson, asserting intentional misrepresentation and concealment by defendants that Ortho's Tri-Cyclen and Tri-Nessa oral contraceptives are identical drugs. Specifically, Adamson alleged that she and other "brand loyalists" overpaid for Tri-Cyclen because the identical drug, TriNessa, the authorized generic, was available at a reduced price. The District Court for the District of New Jersey granted Ortho's motion to dismiss for failure to state a claim under Fed. Rule of Civ. Pro. 12(b)(6).

Ortho's subsidiary contracted with Watson to market an authorized generic version of Ortho's Tri-Cylen, under the trade name Tri-Nessa. Watson issued press releases disclosing the agreement between Ortho and Watson for the sale and distribution of Tri-Nessa. Notably, at least one press release indicated TriNessa was the equivalent of Ortho Tri-Cyclen. Further, a subsequent Watson press release identified TriNessa as "the authorized brand equivalent of the oral contraceptive Ortho Tri-Cyclen, marketed by Ortho-McNeil Pharmaceutical, Inc."

Plaintiff asserted that she, and others similarly situated, suffered a financial loss when they purchased Tri-Cyclen because TriNessa, the identical drug, was available at a lower price and that Watson "never disclosed in any fashion that its authorized generic, TriNessa, was in fact the same drug as Ortho Tri-Cyclen."

The plaintiff's consumer fraud allegation,

RECENT COURT DECISIONS, CONT'D:

which was based on the defendant's marketing materials as allegedly misleading consumers as to equivalence of TriCyclen and TriNessa, was rejected by the court as being only sales "puffery" at most. In addition, the court held there was no obligation to inform the public that TriCyclen and TriNessa are identical and the plaintiff had cited no cases to support this assertion. Finally, the court noted that it is not the law that competitors have a duty with respect to selling or advertising a competitor's products.

Adamson v. Ortho-McNeilPharm., Inc., 2006 U.S. Dist. LEXIS 83473 (D.N.J. 2006).

UNITED STATES GOVERNMENT SEEKS AND OBTAINS PERMANENT INJUNCTION AGAINST VITA-ERB

by Keith Hutchinson (Pfizer Inc.)

In United States v. Vita-Erb, Ltd., the United States government moved for summary judgment regarding alleged violation of various provisions of the Food, Drug, and Cosmetic Act, by Vita-erb and requested a permanent injunction against its continued manufacture and distribution of drug products. Defendant Vita-Erb manufactured, *inter alia*, medicated shampoos, pain relieving gels, antimicrobial handcleaners, and herbal-extract drug products.

The government alleged that over a 9-year period, FDA inspections of Vita-Erb's operations found significant and continuing cGMP (current good manufacturing practice) violations, resulting in the issuance of at least two warning letters to Vita-Erb. The FDA also allegedly conducted undercover purchases of unapproved products which Vita-Erb produced and sold in the United States, including a prostate-specific antigen (PSA)-reducing compound purportedly contained in the Vita-Erb "Cell Revitalizer".

Based on the repeated cGMP violations and the manufacture and distribution of unapproved drug products in the United States, the government sought to enjoin Vita-Erb's further activities. The District Court for the District of Missouri granted the government's summary judgment motion and entered a permanent injunction against Vita-Erb. Specifically, the court found that that Vita-Erb had violated the Federal Food, Drug and Cosmetic Act (21 USC §§ 301-397) by introducing, selling and shipping adulterated, misbranded and unapproved drugs in interstate commerce.

United States v. Vita-Erb, Ltd., 2006 U.S. Dist. LEXIS 82968 (D.Mo. 2006).

APOTEX CHALLENGES FDA'S REFUSAL TO ACKNOWLEDGE AN ALLEGED "COURT DECISION" TRIGGER RELATING TO THEIR ONDANSETRON ANDA FILING

by Keith Hutchinson (Pfizer Inc.)

Apotex filed a declaratory action in the District Court for the District of Columbia on November 6, 2006, challenging the FDA's refusal to approve Apotex's ANDA for generic Zofran® (ondansetron HCl) tablets. Apotex alleged that FDA's refusal was a violation of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 301 et seq.).

GlaxoSmithKline's (GSK's) patent infringement suit against Apotex regarding Apotex's filing of an ANDA for approval of a generic

RECENT COURT DECISIONS, CONT'D:

version of ondansetron HCl, which alleged infringement of United States Patent 5,344,658, was dismissed and GSK conceded that Apotex's ondansetron tablets did not infringe GSK's '658 patent. The FDA issued an administrative order ruling on November 3, 2006 in which it refused to treat the dismissal order as a "court decision trigger" under the FFDCA because it believed that Dr. Reddy's Laboratories was entitled to a 180-day exclusivity period for generic ondansetron because it had earlier filed a Paragraph IV certification with regard to its product and another GSK patent covering Zofran®, United States Patent No. 4,753,789.

GSK's pediatric exclusivity with respect to the '789 patent expires December 24, 2006 and Apotex asserted it was entitled to approval of its ANDA as of that date. Accordingly, Apotex asserted in its suit that it will be unlawfully denied access to the ondansetron market and thus seeks immediate declaratory and injunctive relief from the district court.

FEDERAL CIRCUIT DENIES COMBINED PETITION FOR REHEARING AND EN BANC REVIEW OF RULE THAT CLAIM CONSTRUCTION IS SOLELY A MATTER OF LAW

by William R. Boudreaux (Pfizer Inc.)

In a split decision, with several dissenting and concurring opinions published separately, the Federal Circuit denied a combined petition for panel rehearing and *en banc* review of the holding in Amgen Inc. v. Hoechst Marion Roussel, Inc. At issue in the petition filed by Amgen was the rejection by an earlier panel of the Federal Circuit of the district court's construction of the term "a therapeutically effective amount" in claims relating to a genetically engineered erythropoietin (EPO).

In a dissenting opinion authored by Judges Michel and Rader, rehearing the case *en banc* would have enabled the Federal Circuit to reconsider the rule of *de novo* review of claim construction set forth in Cybor Corp. v. FAS Techs., Inc. The current standard affords no deference to the trial court's claim construction findings and "rests upon the premise that claim construction is always a purely legal exercise, devoid of factual content." Relating that, "[w]e have likened claim construction to statutory construction," Judges Michel and Rader assert that such an analogy is open to question. In interpreting a statute, a judge asks, "What does the disputed term mean to me, the judge, as an artisan in the law?" In contrast, with claim construction, the judge is supposed to inquire, "How would the average artisan in the relevant field of technology understand the disputed claim terms in the context of the rest of the patent, the prosecution history, and the prior art?" Judges Michel and Rader submit that judges must necessarily make factual conclusions in construing claim terms that that trial judges are better situated to weigh the evidence when making these determinations.

In separate opinions, Judges Newman, Moore, Gajarsa, Linn, and Dyk all express a willingness to reconsider Cybor's rule, at least on a limited basis, provided that such reconsideration takes place in an appropriate case.

Amgen Inc. v. Hoechst Marion Roussel, Inc., 469 F.3d 1039 (Fed. Cir. 2006).

RECENT COURT DECISIONS, CONT'D:

SPECIFICALLY DISCLAIMED COMPOUND CAN BE A BASIS FOR ANTICIPATION OF METHOD OF TREATMENT CLAIMS, EVEN WITHOUT PROOF OF EFFICACY

by William R. Boudreaux (Pfizer Inc.)

In a November 20, 2006 decision, a panel of the Court of Appeals for the Federal Circuit vacated and remanded a district court's finding that a prior art reference lacked enablement and therefore could not anticipate Aventis' patent claiming the use of riluzole to treat patients with amyotrophic lateral sclerosis ("ALS"). The panel also affirmed the district court's finding that the defendants failed to prove the patent in suit unenforceable for inequitable conduct.

Impax Laboratories, Inc. ("Impax") sued Aventis Pharmaceuticals Inc. ("Aventis") for a declaratory judgment that Impax did not infringe, induce infringement of, or contribute to the infringement of U.S. Pat. No. 5,527,814 ("'814 patent"). Impax had filed an ANDA seeking authorization from the FDA to market riluzole tablets for the treatment of patients with ALS. As part of its suit, Impax alleged that the '814 patent was unenforceable for inequitable conduct and was invalid as anticipated by U.S. Pat. 5,236,940 ("'940 patent") and French Application No. 2,640,624 ("'624 application") from which the '940 patent claims priority.

Regarding the alleged anticipation issue, the '940 patent, which is owned by Aventis, is directed to a genus of compounds that would cover riluzole, except that riluzole is specifically exempted as it was not new at the time of the patent application filing. The '940 patent taught that the compounds of are useful in treating medical conditions associated with the effects of glutamate such as ALS. The '940 patent claims priority from the '624 application, which has a disclosure similar to that of the '940 patent, except that it does not exempt riluzole from the dislcosed compounds.

The district court found that the generic formulae contained in the '940 patent embraced riluzole, but concluded that the claims of '814 patent were not anticipated on this basis. Specifically, the court found that the disclosure of the '940 patent embraces a large number of compounds, riluzole is not listed as one of the "especially advantageous" compounds, riluzole was not "meaningfully discussed" in the '940 patent, and the '940 patent demonstrated that there was "substantial uncertainty regarding the effectiveness of treating ALS with glutamate inhibiting compounds." Therefore, the district court held that even though the generic structures of the '940 patent embraces riluzole, it did not anticipate the '814 patent because it did not disclose riluzole as being effective in treating ALS and was therefore not enabling. The district court also concluded that the '624 application was equally deficient since it contained a similar disclosure and the parties asserted virtually identical arguments with respect to the two disclosures. Impax appealed these findings to the Federal Circuit.

The Federal Circuit, citing Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325-26 (Fed. Cir. 2005), reversed and remanded the district court holding that proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. Rather, the proper issue is whether the prior art reference is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to

RECENT COURT DECISIONS, CONT'D:

carry out the invention.

The Federal Circuit drew a distinction between the two prior art references in that the '940 patent named riluzole by name (even in disclaiming it) while the '624 application did not. In the '624 application, riluzole is just one of hundreds of compounds included in formula I. The Federal Circuit, citing In re Petering, 49 C.C.P.A. 993, 301 F.2d 676, 681 (C.C.P.A.1962), related that when a reference discloses a class of compounds, i.e. a genus, a person of ordinary skill in the art should be able to "at once envisage each member of th [e]…class" for individual compounds to enabled. Here, with the large number of compounds included in formula I and no specific identification of riluzole by the '624 application, the '624 application does not disclose riluzole, and therefore cannot enable treatment of ALS with riluzole. Therefore, the '624 application cannot anticipate any of the claims of '814 patent.

In an opinion concurring-in-part, Judge Rader disagreed with the majority on the anticipation issue. Judge Rader agreed that anticipation does not require proof of utility but believed that the district court has demonstrated that even beyond the efficacy question, the '940 patent does not even disclose the necessary suggestion to enable one of ordinary skill in the art to look to riluzole for the treatment of ALS in the first place.

Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc., 468 F.3d 1366 (Fed. Cir. 2006).

FDA REGULATIONS AND OPINIONS DO NOT IMMUNIZE NOVARTIS FROM TORT LIABILITY

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

The Supremacy Clause of the United States Constitution preempts any state law that conflicts with the exercise of federal power. Federal law will override state law under the Supremacy Clause when (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes.

In the recent case of *Weiss v. Fujisawa Pharmaceutical Co.*, Defendant, Novartis Pharmaceuticals Corp. argued that the third and final form of preemption, namely conflict preemption, would preempt a plaintiff's claims that Novartis failed to warn that its Elidel® eczema drug could cause cancer and other serious respiratory diseases. Specifically, Novartis alleged that the FDA has stated in both regulatory and judicial contexts that such failure-to-warn claims conflict with and frustrate the FDA's exercise of its statutory responsibility to secure a proper balance of public health considerations in the labeling of prescription drugs. As such, Novartis asserted that the plaintiff's failure-to-warn claims are preempted by the FDA regulatory scheme and must be dismissed.

U.S. Judge James M. Hood of the Eastern District of Kentucky said that because the FDA's position on preemption of failure-to-warn claims has not been consistent, it is entitled to "only the most limited level of deference." Judge Hood further stated that "[e]ven though it represents FDA's formal position on a matter and obligates the agency to follow it

RECENT COURT DECISIONS, CONT'D:

until amended or revoked, an advisory opinion is entitled only to limited deference because it is not subject to notice and comment procedures."

Applying "limited deference," Judge Wood denied Novartis' Motion to Dismiss and held that a state law requirement to provide an additional warning would not conflict with federal regulations. He further noted that at the time Elidel® was prescribed for the plaintiff, the FDA had not made a conclusive finding regarding a link between the use of topical calcineurin inhibitors and increased cancer risk. In addition, Novartis could conceivably have possessed information not available to the FDA that could have been communicated to the FDA, to healthcare providers, or to patients, consistent with FDA regulations. Finally, Judge Hood concluded that state law failure-to-warn claims would not disrupt the FDA's regulatory scheme because FDA's regulations specifically provide avenues by which pharmaceutical companies may strengthen warnings following approval of the original label.

Weiss v. Fujisawa Pharmaceutical Co. et al., 2006 U.S. Dist. LEXIS 82372 (E.D. Ky. 2006).

FEDERAL CIRCUIT UPHOLDS PRELIMINARY INJUNCTION AGAINST APOTEX WITH RESPECT TO GENERIC PLAVIX®

by Vickie Ford (Alston & Bird LLP)

The Federal Circuit affirmed the decision of the United States District Court for the Southern District of New York, finding that a preliminary injunction against Apotex, Inc. and Apotex Corp. (collectively "Apotex") with regard to the further manufacture and sale of clopidogrel bisulfate was warranted.

In March 2002, Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., Bristol-Meyers Squibb, and Sanofi Pharmaceuticals Holding Partnership (collectively "Sanofi") sued Apotex claiming that Apotex's ANDA infringed Sanofi's Patent No. 4,847,265 (the "'265 patent") which covers clopidogrel bisulfate, the active ingredient the blood-thinning drug Plavix®. Apotex counterclaimed arguing the patent was invalid and unenforceable. After the ANDA was approved and settlement agreements failed due to non-approval by the FTC and various state's attorneys general, Apotex launched its generic clopidogrel bisulfate product on August 8, 2006. Sanofi responded by filing a motion for a preliminary injunction on August 15, 2006. The district court granted the preliminary injunction but denied a recall of a six-month supply of product that Apotex had already shipped to distributors in the United States. In its analysis of the request for injunctive relief, the district court applied the well-known four-factor test. The court found Sanofi had a likelihood of success on the merits because Apotex conceded that its product infringed claim 3 of the '265 patent. Further, the court found that Apotex had failed to prove a likelihood of proving that the claims of the '265 patent are invalid based on anticipation, obviousness and obviousness-type double patenting invalidity defenses. The court also found that Apotex did not raise a substantial question as to whether the '265 patent was unenforceable due to inequitable conduct. The remaining three factors were found to be in Apotex's favor.

RECENT COURT DECISIONS, CONT'D:

The Federal Circuit reviewed the district court's grant of a preliminary injunction under a clear error standard of review. In its decision, the Federal Circuit first addressed whether Sanofi had indeed proven they that were likely to succeed on the merits at trial. Apotex had stipulated that its product infringed the '265 patent so that the only issue regarding the merits of the case was whether the relevant claims of the '265 patent are valid and enforceable. Apotex argued that Sanofi's earlier U.S. Patent No. 4,529,596 (the "'596 patent") inherently anticipated claim 3 of the '265 patent, which claims the d-enantiomer of the bisulfate salt of clopidogrel, because the '596 patent described racemic clopidogrel in free base form. The Federal Circuit agreed with the district court that claim 2 of the '596 patent does not inherently disclose the bisulfate salt of clopidogrel because generally disclosing a bisulfate salt of a large genus of compounds was not sufficient to disclose the bisulfate salt of a single enantiomer of a specific compound. The Federal Circuit also found that clopidogrel bisulfate is not a species of any genus in claim 2 of the '596 patent. Continuing its evaluation under the first factor, the Federal Circuit considered Apotex's assertion that claim 2 of the '265 patent was invalid as obvious. The Federal Circuit found the district court did not clearly err in finding there "was nothing obvious about arriving at clopidogrel bisulfate by separating the enantiomers of [MATTPCA] and preparing the dextrorotatory [enantiomer] as a bisulfate salt." Further, the expenditure of extensive time and money by Sanofi was considered to be persuasive, secondary evidence of non-obviousness. The Federal Circuit additionally rejected Apotex's argument that the district court erred by not separately addressing its double patenting defense. The Federal Circuit found that Apotex failed to raise a substantial question as to the validity of claim 3 based on that defense and its argument of inequitable conduct.

The Federal Circuit next addressed whether Sanofi would suffer irreparable harm if the injunction was not granted. The district court had applied a presumption of irreparable harm because Sanofi had earlier established a likelihood of success on the merits. But, the district court also considered other evidence of irreparable harm offered by Sanofi, including irreversible price erosion, loss of good will, potential employee layoffs and the discontinuance of clinical trials supporting other uses of clopidogrel. The Federal Circuit affirmed district court's finding of irreparable harm noting the district court did not clearly err in evaluating the evidence of price erosion.

Applying the third factor which includes a balancing of the hardships between the parties, the Federal Circuit agreed with the district court that this factor favored Sanofi. According to the Federal Circuit, Apotex took a "calculated risk" when it decided to launch its product and trigger the 180-day exclusivity period before the infringement case was finally decided on the merits.

Finally, the Federal Circuit found no clear error with the district court's finding that the public interest factor tipped in favor of Sanofi. Specifically, the district court found that the public interest in encouraging pharmaceutical research and development outweighs the loss of potentially cheaper generic drugs being available for patients as well as consumer confusion based on Apotex's product being no longer available after the supply already on pharmacy shelves ran out.

RECENT COURT DECISIONS, CONT'D:

Finally, the Federal Circuit found that the district court did not abuse its discretion in deciding to exclude evidence from Apotex that allegedly demonstrated unclean hands on the part of the patentee. The evidence in question was based on the conduct of the parties that allegedly took place during earlier negotiations between them. The district court refused to allow Apotex to introduce this evidence because it found that alleged conduct taking place during settlement negotiations does not affect the validity of the patents at issue and is, therefore, irrelevant in a preliminary injunction determination.

Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006).

RECENT REGULATORY ACTIVITIES

ASTRAZENECA TO LIST PATENTS DIRECTED TO DRUG DELIVERY SYSTEMS IN FDA'S ORANGE BOOK

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

On August 10, 2006, AstraZeneca requested an advisory opinion from the United States Food and Drug Administration (FDA) as to whether patents directed to drug delivery systems, such as inhalation devices, that do not recite the approved active ingredient or formulation, should be listed in the FDA's Orange Book. AstraZeneca's position is that such patents should be available for listing because doing so would further the goals of the Hatch-Waxman Amendments, such as providing notice to competitors of patents that cover a marketed product. AstraZeneca stated that GlaxoSmithKline had submitted a similar request to FDA in January 2005, but the FDA had never publicly responded or provided further guidance. AstraZeneca stated that it will continue to list such patents absent guidance from FDA that such listings are improper.

HARMONIZATION OF DEVELOPING AND REGISTERING NEW MEDICINAL PRODUCTS IN EUROPE, JAPAN AND THE UNITED STATES

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

On August 17, 2006, the FDA announced an October 2, 2006 public meeting entitled "Preparation for ICH meetings in Chicago, Illinois." The purpose of the meeting is to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Chicago. The ICH was established to identify and reduce the differences in various technical requirements for the development and registration of medical products in Europe, Japan, and the United States. It is hoped that such harmonization will increase the efficiency and speed with which medical products can be brought to market in these jurisdictions.

RECENT REGULATORY ACTIVITIES, CONT'D:

FDA PUBLISHES DRAFT GUIDANCE ON ANNUAL REPORTS FOR APPROVED PREMARKET APPROVAL APPLICATIONS

by Rick Williams (Vinson & Elkins L.L.P.)

The FDA published a draft guidance for industry regarding annual reports submitted under 21 C.F.R. § 814.84(b). This guidance outlines the information required in the annual report and provides FDA recommendations regarding the level of detail necessary for the report. Additionally, this guidance summarizes the procedures followed by the CDRH and CBER for evaluating these annual reports.

PFIZER FILES PETITION REQUESTING THAT FDA REVOKE AND DENY APPROVAL OF GENERIC LUMIGAN® AND TRAVATAN®

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

On November 1, 2006, Pfizer submitted a Citizen's Petition to FDA seeking (1) revocation of the approval of Allergan's supplemental NDA relating to first-line use of Lumigan® (bimatoprost) and (2) denying approval of a supplemental NDA submitted by Alcon Inc. for a first-line indication of Travatan® (travoprost). On November 2, 2006, the FDA acknowledged acceptance of the petition as a procedural matter but stated that the agency had not yet reached a decision on its substantive merits.

As background for its petition, Pfizer stated that in 2001 the FDA approved Lumigan® and Travatan® for second-line treatment of elevated intraocular pressure ("IOP") in patients with open-angle glaucoma and/or ocular hypertension. Another Pfizer drug product, Xalatan® (latanoprost), was approved as a second-line treatment of elevated IOP in open-angle glaucoma and ocular hypertension in 1996. In 1999, Pfizer submitted a supplemental NDA to the FDA seeking to expand the indication for Xalatan® to a first-line treatment for elevated IOP in open-angle glaucoma and ocular hypertension. After initially denying Pfizer's request for a first-line indication of Xalatan® because of safety concerns, the FDA approved the drug for first-line use in 2002, due to the results of long-term studies and investigations conducted by Pfizer.

In its petition, Pfizer argues that Allergen and Alcon are attempting to use the information Pfizer acquired in obtaining first-line use of Xalatan® to get first-line use approval of Lumigan® and Travatan®. Pfizer notes there are at least three reasons argues why such uses of its information should not be permitted. First, the FDA does not have authority to approve the Allergen or Alcon supplemental NDA based on confidential, non-public information contained in the Xalatan® NDA and any such reliance of the information would constitute a "taking," as well as an impermissible use of Pfizer's trade secrets. Second, even assuming that Allergan and Alcon were authorized to rely on data contained in the Xalatan® NDA, the data and information in that NDA do not provide substantial evidence establishing that Lumigan® and Travatan® are appropriate for first-line use. Third, Pfizer argues that it would be arbitrary and capricious for the FDA to approve Lumigan® and Travatan® as first-line therapies in the absence of clinical data substantiating the safety of those products for such uses, especially

RECENT REGULATORY ACTIVITIES, CONT'D:

given that the FDA required Pfizer to submit data supporting the use of Xalatan® as first-line therapy.

In support of its first argument, Pfizer cited prior Pfizer Citizens' Petitions which it argued that the FDA does not have authority to rely on confidential, unpublished data in an innovator's NDA in order to approve a third-party's section 505(b)(2) NDA. Section 505(b)(2), Pfizer argues, only authorizes the use of publicly available reports of investigations to establish the safety of a drug and further that Congress did not intend that a 505(b)(2) applicant could rely on non-public, proprietary data in a competitor's NDA. Furthermore, Pfizer argues that the Constitution prohibits the government from taking protected property without providing just compensation and prior due process. Notably, Pfizer argues that an inherent property right in safety and effectiveness data filed as part of an NDA has long been recognized by the courts and FDA.

In support of its argument, Pfizer argues that the FDA's decision to approve the Allergan supplemental NDA, and its consideration of the Alcon supplemental NDA, appears to reflect a improper judgment that Allergan's product is safe and effective as first-line therapy because it belongs to the same chemical class (prostaglandins) as Xalatan®. As support for this argument, Pfizer provided examples allegedly illustrating that the performance and safety of a given product cannot be simply be assumed to be the same as other products within the same therapeutic or chemical class.

STRIDES INC. SUBMITS A CITIZEN PETITION REQUESTING THAT FDA PERMIT THE FILING OF AN ABBREVIATED NEW DRUG APPLICATION

by Philip Canelli (McDermott, Will & Emery, LLP

New Jersey based Strides Inc. has filed a Citizen Petition requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application (ANDA) for a proposed drug product that has the same route of administration, the same dosage form, the same strength of one of the active ingredients in a combination drug, and is expected to have the same therapeutic effect as that of reference product in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs with respect to one of the active ingredients in a combination drug.

Strides' request seeks permission to submit an ANDA based on Advil Cold and Sinus® in which the proposed new drug product would substitute phenylephrine hydrochloride for pseudoephedrine hydrochloride. In its petition, Strides states that phenylephrine hydrochloride and pseudoephedrine hydrochloride are equally safe and effective when used within the dosage limits established for each ingredient, therefore, no additional investigations must be conducted for the proposed drug product.

According to Nehru Gaddipati, president of Strides, Inc., a benefit to the proposed new drug product is that unlike pseudoephedrine hydrochloride, the substituted active ingredient phenylephrine hydrochloride is not a chemical precursor used in the illicit manufacture of methamphetamine and methcathinone. As such, the proposed drug product is further advantageous to public health.

RECENT REGULATORY ACTIVITIES, CONT'D:

Strides is currently awaiting a determination from the Commissioner of FDA as to whether its application to market a drug product with a change to the active ingredient is still suitable for an ANDA submission.

RECENT LEGISLATIVE ACTIVITY (109TH CONGRESS)

S. 4016 PROPOSES STATUTORY SCHEME RELATING TO THE APPROVAL OF GENERIC BIOLOGICAL PRODUCTS

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

Introduced on September 29, 2006, S. 4016 would amend the Public Health Service Act, with corresponding amendments to the Patent Act, to permit the licensing of "comparable biological products" ("CPB"). In effect, the proposed statute provides a scheme for the approval of "generic" biologic products. The act provides for two types of approval: "comparable biologic products" and "interchangeable comparable biological products" ("interchangeable CBP"). The difference between the two is that the latter can be labeled as "interchangeable with the biological reference product to which the sponsor of the comparable biological product application has demonstrated comparability to the reference compound."

A finding of such "interchangeability" triggers several provisions of the statute. First, it limits approval of a second CBP application until the earlier of: (a) 180 days after first commercial marketing of the first approved interchangeable biologic; or (b) one year after either a final court decision in a patent infringement suit, or a dismissal with or without prejudice of a patent infringement suit instituted under section 16(c) of the act; (c) 36 months after approval of the first CBP, if litigation under paragraph 16(c) is on-going; or (d) one year after approval, in the event the first approved interchangeable applicant has not been sued pursuant to paragraph 16(C). These provisions do not apply if the sponsor of the CBP elects to have the product approved as a "non-interchangeable" CBP.

Paragraph 16 would govern litigation under the proposed statute. These provisions under this paragraph differ from those under the Hatch-Waxman Act in a number of respects. First, the applicant for the CBP may, at any time, send a written request to the holder of the approved application for the reference product requesting patent information. The holder of the approved application must provide the applicant or prospective applicant a list of all patents that cover the reference product within a 60-day period, whether owned by or licensed to the holder of the approved product registration. This includes patents covering methods of making and using the approved biologic product. For a pe-

RECENT REGULATORY ACTIVITIES, CONT'D:

riod of two years after the initial request, the holder of the approved registration must update the list of relevant patents within 30 days after either (1) a new patent issues that covers the approved reference biologic product; or (2) a new patent covering the approved reference product comes under the control of the holder of the approved registration through a license.

After the CBP application is filed, the applicant may send a letter to the holder of the approved application for the reference product and the owner of the patent, which letter must include a detailed statement of the factual and legal bases for the applicant's belief that the patents included in the notice letter are either invalid or not infringed by the CBP. The letter must also include the judicial district or districts in which the applicant will consent to suit. The applicant does not, apparently, have to include all patents identified by the holder of the approved application in this letter. Upon receipt of the letter, the patent owner may bring a patent infringement action solely with respect to the patent(s) identified in the notice and such an action may be brought only in the districts identified in the letter. The patent holder may not bring a declaratory judgment action for infringement for any patent not identified in the letter sent by the CBP applicant. The applicant for a CBP may not be compelled to institute any of these procedures.

Limitations on patent suits: (1) it a patent holder receives a notice letter from the patent holder and fails to bring suit within 45 days, but later brings suit, the exclusive remedy for any infringement finding is limited to a reasonable royalty; and (2) a patent holder may not bring suit for infringement of a patent that was not timely identified in response to a request for patent information by the CBP applicant.

(Postscript: A companion House Bill, H.R. 6257, was also introduced by Rep. Waxman on October 2, 2006.)

H.R. 5418 – ESTABLISHES A PILOT PROGRAM IN CERTAIN DISTRICT COURTS TO DEVELOP EXPERTISE IN HEARING PATENT CASES

by William R. Boudreaux (Pfizer Inc.)

House Bill H.R. 5418, passed by the House September 28, 2006, was referred to the Senate Judiciary Committee on November 13, 2006. Its purpose is to establish a pilot program in certain U.S. district courts to encourage enhancement of expertise in patent cases among district court judges. As passed by the House, the bill requires the Director of the Administrative Office of the United States Court to designate within six months of enactment not less than five (5) United States district courts in at least three (3) different judicial circuits to implement the pilot program. The Director is also required to make such a designation from among the fifteen (15) district courts in which the largest number of patent cases were filed in the most recently ended calendar year, provided the court has at least ten district judges are authorized to be appointed by the President and at least three judges of the court have volunteered to be designated for the program.

As part of the program, judges may request to hear patent cases and will be designated by the chief judge to hear those cases. Patent cases will still be randomly assigned among all the judges, whether designated specially to hear patent cases or not. However, the non-designated judges may decline to accept patent cases at which time the case would be

RECENT LEGISLATIVE ACTIVITY, CONT'D:

randomly reassigned to a designated judge. Senior judges of a district court may be designated if at least one judge of the court in regular active service is also designated.

There is a ten-year termination provision built into the bill and the program would apply only to cases commenced on or after the date of the designation of the district court. Further provisions of the bill include a requirement that the Director of the Administrative Office of the U.S. Courts file reports to the House and Senate Judiciary Committees at roughly the mid-point and end of the ten year term. The reports will be made in consultation with the chief judge of each of the designated district courts and the Director of the Federal Judicial Center. The reports shall include (a) an analysis of the extent to which the program succeeded in developing patent expertise among the judges; (b) an analysis of the extent to which the program improved the courts' efficiency; (c) a comparison of designated versus non-designated judges in their rates of reversal and time for completion of patent cases; (d) the extent of forum-shopping created by the program; and (e) an analysis of whether the pilot program should be extended and made permanent. There is also an authorization and funding provided for the training of the designated judges and compensation for technically-skilled law clerks.

(Postscript: This Bill was reintroduced and passed by the House as H.R. 34 in the 110th Congress and is now pending in the Senate.)

H.R. 4742 PROPOSED TO ALLOW DIRECTOR OF PATENT AND TRADEMARK OFFICE TO WAIVE CERTAIN STATUTORY PROVISIONS DURING EMERGENCIES

by Vickie Ford (Alston & Bird LLP)

H.R. 4742 was approved in the House on December 5, 2006 and on December 6, 2006 was received in the Senate. The bill proposes to amend 35 U.S.C. § 2 by adding a new section allowing the Director of the Patent and Trademark Office to waive statutory provisions governing patents and trademarks in certain emergencies. The bill, sponsored by Rep. Berman of California and Rep. Goodlatte of Virginia, gives the Director the ability to waive provisions regarding filing, processing, renewal, maintenance of patents, trademark registrations, and applications for those persons affected by an emergency or major disaster. The Director's decision not to exercise this waiver authority is not subject to judicial review.

(Postscript: At the end of the 109th Congress, this bill had not been voted on by the Senate and failed to pass into law.)

Note: Short descriptions of the above bills and links to the full text of proposed legislation can be found on the IPO website at www.ipo.org.

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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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