

Q3 2008

Welcome!

We are happy to bring you the second edition of *memorANDA*, a quarterly newsletter that provides a strategic look at life sciences litigation in the District of Delaware, with a focus on the ever-growing docket of Hatch-Waxman litigation. We hope our readers will find this an insightful and educational snapshot of the Court's docket that will provide a deeper understanding of the current and evolving state of the law.

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Even Where There Is No Will[fulness], There Still Might Be a Way

In a recent opinion, Judge Farnan clarified that the filing of an Abbreviated New Drug Application (“ANDA”) cannot, by itself, support a cause of action for willful infringement. However, a baseless ANDA filing, coupled with other misconduct, can result in a finding that a case is exceptional and support an award of attorneys fees against an infringer.

On September 26, in the case of *Sepracor, Inc. v. Dey, L.P.*, C.A. No. 06-113, Judge Farnan granted generic defendant Dey’s motion to strike branded plaintiff Sepracor’s claims for willful infringement, but denied Dey’s motion to strike Sepracor’s allegations that the case was exceptional under 35 U.S.C. § 285.

In striking Sepracor’s willful infringement claims, Judge Farnan relied on the Court of Appeals for the Federal Circuit’s opinion in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), which he characterized as “quite clear” in holding that “the filing of an ANDA application or certification is only an artificial ‘act of infringement’ that cannot support a claim for willful infringement.”

Nevertheless, in declining to strike Sepracor’s claim to have the case declared exceptional, Judge Farnan noted that baseless filings and meritless arguments, including those asserted in Paragraph IV certifications submitted to the FDA in the context of an ANDA submission, “have always justified a finding of an exceptional case.” In so holding, Judge Farnan reinforced that, while the filing of an ANDA may not constitute willful infringement, generic companies are not free from the risk of a finding that a case is exceptional, or the remedies that flow from such a finding.

Sepracor brought the action in response to Dey’s filing of an ANDA seeking approval to market a generic version of Sepracor’s Xopenex® for the treatment of asthma. With its ANDA filing, Dey included a Paragraph IV certification stating that it believed Sepracor’s five patents covering Xopenex were either invalid or not infringed by Dey’s levalbuterol hydrochloride solutions. Sepracor’s complaint alleged that Dey’s ANDA filing constituted “deliberate and willful” infringement because Dey’s Paragraph IV certification was “devoid of an objective good faith basis in either the facts or the law.” Judge Farnan struck the willfulness allegations, observing that plaintiffs in Hatch-Waxman cases continue to make willfulness allegations when the only act of infringement is an ANDA filing, despite the Federal Circuit’s holding in *Glaxo* and the precedent of numerous district courts—including the District of Delaware—which have “repeatedly dismissed such allegations in a variety of procedural postures” following *Glaxo*.

Judge Farnan’s rebuke regarding Hatch-Waxman plaintiffs’ continued practice of alleging willfulness in spite of “clear” Federal Circuit precedent counsels against including such allegations in complaints, at least in the District of Delaware. The issue is not in dispute. In the words of the *Glaxo* court, “the mere fact that a company has filed an ANDA application or



(cont'd on page IV)

CLOSED CASES

EFFEXOR® XR: Wyeth v. Impax Laboratories, Inc.
C.A. No. 06-222-JJF

On June 15, 2008, the Court entered a consent judgment following the parties' execution of a Settlement and Release Agreement and a License Agreement. This ends a lawsuit related to Impax's filing of ANDA No. 78-057 seeking approval to market a generic version of the antidepressant EFFEXOR® XR venlafaxine hydrochloride. Wyeth patents covering venlafaxine hydrochloride include U.S. Patent Nos. 6,274,171; 6,403,120; and 6,419,958. A Wyeth press release indicates that the settlement would permit Impax to launch its capsule on or after June 11, 2011, subject to an earlier launch in limited circumstances, but in no event earlier than January 1, 2011. Impax will be required to pay Wyeth a royalty on the sales of its product. The parties have also agreed that Impax will use its sales force to promote a product to be named by Wyeth.

PRIMAXIN: Merck & Co Inc. v. Ranbaxy Inc., et al.
C.A. No. 07-229-GMS

On July 29, 2008, the parties entered into a stipulation, dismissing the case without prejudice. Merck had asserted its 5,147,868 patent against Ranbaxy following Ranbaxy's ANDA directed to imipenem/cilastatin sodium, an anti bacterial agent. Merck sells PRIMAXIN I.M. and PRIMAXIN I.V., and is the holder of NDA Nos. 50-630 and 50-587 for imipenem and cilastatin.

Selected District of Delaware Hatch-Waxman Decisions

RAZADYNE®

In re '318 Patent Infringement Litigation,
C.A. No. 05-356-SLR

Judge Robinson issued findings of fact and conclusions of law in this ANDA litigation related to Janssen's Razadyne® for the treatment of Alzheimer's disease. She found that Janssen's 4,663,318 patent was invalid for lack of enablement. The patent only contained prophetic examples, and although the patent laws do not require a patent to contain actual working examples, Judge Robinson found that the specification failed to teach one of ordinary skill in the art to use the invention without undue experimentation. Judge Robinson explained that, although the inventor ultimately received data confirming that the medication worked after the patent issued, at the time the patent was applied for, the inventor and others were unsure that the drug would work. In concluding that the patent was not enabled, Judge Robinson explained that one of skill in the art, reading the disclosure in the patent, would not have recognized that the drug would be effective in treating Alzheimer's disease.

TRICOR®

Teva Pharmaceuticals USA v. Abbott Laboratories, et al.,
C.A. Nos. 02-1512, 03-120, 05-340, 05-360-SLR

Beginning in October 2002, Abbott Laboratories filed a series of lawsuits against Teva and Impax in response to their Paragraph IV certifications of invalidity and/or noninfringement of patents covering Abbott's TRICOR®, a drug used to control high cholesterol. Teva and Impax asserted Walker Process and "sham litigation" counterclaims against Abbott. Although Abbott subsequently dropped its infringement claims and executed covenants not to sue with Teva and Impax, Teva and Impax's antitrust counterclaims remained pending.

Abbott moved for summary judgment of no "sham litigation" and no Walker Process violation. Judge Robinson granted Abbott's motions on the Walker Process claims and any "sham litigation" claims premised on fraud on the Patent Office, finding that there was insufficient evidence of inequitable conduct. But the Court denied Abbott's motion with respect to "sham litigation" claims to the extent they were based on Abbott's lack of probable cause for asserting patent infringement.

The Court's refusal to dismiss the sham litigation claims based on lack of probable cause for asserting patent infringement is noteworthy because the requirement that the claimant show that a lawsuit was baselessly filed is rarely met. Here, the Court held that Abbott could not have reasonably expected success on the merits in asserting infringement at the time it filed suit, in part because Abbott's proposed construction of one disputed claim term had previously been rejected in prior litigation, by both the district court and by the Federal Circuit on appeal. The Court sharply criticized another of Abbott's infringement arguments as "nonsensical" and "exceeding all reasonable interpretations of the

major tenets of claim construction." Holding that a jury could find Abbott's infringement allegations objectively baseless, the Court permitted the sham litigation claims based on a lack of probable cause for asserting patent infringement to survive.

The opinion illustrates the need to clearly articulate the theoretical and factual basis for all claims. With respect to the antitrust claims, the court could not ascertain which of the plaintiffs' claims were based on lack of probable cause for asserting patent infringement and thus triable in view of the Court's holdings: "[t]he parties have not delineated which of plaintiffs' claims are litigation-based, i.e., "petitioning activity" for the purposes of its sham litigation claims. The parties pretrial submissions should reflect which of plaintiffs' claims remain triable, with reference to specific paragraphs of the complaints."

ULTRAM® ER:

Purdue Pharma Products L.P., et al. v. Par Pharmaceuticals, Inc., et al.
C.A. No. 07-255-JJF

In a Memorandum Order dated August 26, 2008, Judge Farnan denied Defendants' Application for Issuance of a Letter of Request for International Judicial Assistance pursuant to the Hague Convention and granted non-party Grunenthal USA's motion to quash. Defendants had filed a letter of request seeking documents and deposition testimony from an employee of non-party Grunenthal GmbH related to Grunenthal's development of tramadol and its opposition to the European counterpart to the patent-in-suit. Judge Farnan found that Defendants could seek discovery of foreign patents and publications, which were prior art to the patent-in-suit, "on its own and without burdening the German Courts, Grunenthal, or Defendants." Judge Farnan further found that more general evidence of Grunenthal's use or knowledge of tramadol was not prior art and was too peripherally relevant to justify issuance of a letter of request under the Hague Convention.

XOPENEX®

Sepracor Inc. v. Dey, L.P., & Barr Labs, Inc.
C.A. No. 06-113-JJF (consolidated)

Defendants Dey, L.P., and Dey, Inc. ("Dey") moved to strike the willfulness allegations by Plaintiff Sepracor. Relying on the Federal Circuit's opinion in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351-52 (Fed. Cir. 2004), the Court struck Sepracor's allegations of willfulness. In Glaxo, the Federal Circuit stated that "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination" as such filing is "an artificial act of infringement for purposes of establishing jurisdiction in the federal courts . . ."

Although the Court struck Sepracor's allegation of willful infringement, it refused to strike Sepracor's claim that the case was exceptional, and carefully tailored its order to leave the exceptional-case allegation intact.

District of Delaware Paragraph IV Litigation

Filed June through September 2008

Parties	C.A. No.	Date Filed	Branded Drug	Patent(s)
<i>Cephalon Inc., et al. v. Watson Pharms. Inc., et al.</i>	08-330	6/2/2008	FENTORA®	6,200,604, 6,974,590
<i>Eli Lilly & Co., et al. v. Teva Parenteral Medicines, Inc.</i>	08-335	6/5/2008	ALIMTA®	5,344,932
<i>Forest Labs., Inc., et al. v. Apotex Inc.</i>	08-336	6/5/2008	NAMENDA®	5,061,703
<i>Lannett Company Inc. v. KV Pharmaceuticals, et al.</i>	08-338	6/6/2008	PRIMACARE ONE®	6,258,846, 6,576,666
<i>Takeda Pharm. Co. Ltd., et al. v. Barr Pharmaceuticals, Inc.</i>	08-339	6/9/2008	PREVACID SOLUTAB®	5,464,632, 6,328,994
<i>Ethypharm, S.A. v. Barr Laboratories, Inc., et al.</i>	08-344	6/9/2008	PREVACID SOLUTAB®	5,464,632
<i>Sanofi-Aventis, et al. v. Apotex Inc., et al.</i>	08-347	6/23/2008	UROXATRAL®	4,661,491
<i>Sanofi-Aventis, et al. v. Sun Pharma. Indus. Ltd., et al.</i>	08-350	6/11/2008	UROXATRAL®	4,661,491
<i>Apotex, Inc. v. AstraZeneca Pharms. LP</i>	08-358	6/20/2008	CRESTOR®	6,316,460
<i>AstraZeneca Pharms. LP, et al. v. Aurobindo Pharma Ltd., Inc.</i>	08-359	6/24/2008	CRESTOR®	RE 37,314
<i>Dey LP, et al. v. Sepracor Inc.</i>	08-372	6/20/2008	XOPENEX®	6,451,289
<i>Eli Lilly & Co., et al. v. APP Pharmaceuticals, LLC</i>	08-384	6/25/2008	ALIMTA®	5,344,932
<i>Wyeth v. Biovail Corporation, et al.</i>	08-390	6/26/2008	EFFEXOR XR®	6,274,171, 6,403,120, 6,419,958
<i>AstraZeneca Pharms LP, et al. v. Teva Pharmaceuticals USA</i>	08-426	7/10/2008	CRESTOR®	RE 37,314
<i>AstraZeneca LP, et al. v. Mylan Pharms., Inc.</i>	08-453	7/22/2008	ENTOCORT EC®	6,423,340, 5,643,602
<i>Cephalon, Inc., et al. v. Barr Pharmaceuticals, Inc., et al.</i>	08-455	7/22/2008	FENTORA®	5,698,558, 6,974,590
<i>Novartis Corporation, et al. v. Teva Parenteral Medicines Inc.</i>	08-459	7/24/2008	ZOMETA®, RECLAST®	4,939,130
<i>Endo Pharmaceuticals Inc., et al. v. Impax Laboratories Inc.</i>	08-463	7/25/2008	OPANA®ER	5,662,933, 5,958,456
<i>Brigham & Women's Hospital Inc., et al. v. Teva Pharms USA Inc., et al.</i>	08-464	7/25/2008	SENSIPAR®	6,211,244, 6,313,146 6,011,068, 6,031,003
<i>Aventis Pharma S.A., et al. v. Apotex, Inc., et al.</i>	08-496	8/8/2008	TAXOTERE®	5,714,512, 5,750,561
<i>Janssen Pharma. N.V., et al. v. Sandoz, Inc.</i>	08-511	8/14/2008	RAZADYNE®	4,663,318
<i>Purdue Pharma Prod., L.P. v. Impax Labs., Inc.</i>	08-519	8/15/2008	ULTRAM® ER	6,254,887
<i>CIMA Labs, Inc. v. Barr Labs., Inc., et al.</i>	08-531	8/21/2008	FAZACLO®	6,024,981
<i>Endo Pharms., Inc., et al. v. Sandoz, Inc.</i>	08-534	8/22/2008	OPANA ER®	5,958,456
<i>Glaxo Group Ltd., et al. v. Lupin LTD et al.</i>	08-551	8/29/2008	COMBIVIR®	5,859,021

Federal Circuit Review of Hatch-Waxman Decisions

RISPERDAL®: Janssen Pharmaceutica, N.V., et al. v. Apotex, Inc., No. 2008-1062 (Fed. Cir. September 4, 2008)

On appeal from D. N.J. C.A. No. 06-1020, the Court of Appeals for the Federal Circuit affirmed the trial court's dismissal of Apotex's declaratory judgment action for non-infringement against Janssen as lacking a justiciable Article III controversy. The Court held that Apotex's exclusion from the market because of a prior ANDA filer's entitlement to a period of market exclusivity did not present a justiciable Article III controversy. The Court distinguished this case from its recent opinion in Caraco Pharm. Labs. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008), stating that unlike Caraco, Apotex could not claim at the time of the district court's dismissal that it was being excluded from selling a non-infringing product, because it had previously stipulated to the validity of the '663 patent. The Court also held that a possible future delay of a prior Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction.

RILUTEK®: Impax Labs., Inc. v. Aventis Pharms., Inc., No. 2007-1513 (Fed. Cir. October 3, 2008)

On appeal from D. Del. C.A. 02-00581, the Court of Appeals for the Federal Circuit affirmed the trial court's holding that U.S. Patent No. 5,236,940 (the '940 patent) does not qualify as an enabling prior art reference and thus does not anticipate claims 1-5 of U.S. Patent No. 5,527,814 (the '814 patent). In affirming, that the Court pointed to the district court's factual findings that the '940 patent's dosage guidelines are broad and general, the alleged prior art contained no working examples, and that nothing in the '940 patent would have led a skilled artisan to identify riluzole as a treatment for ALS.

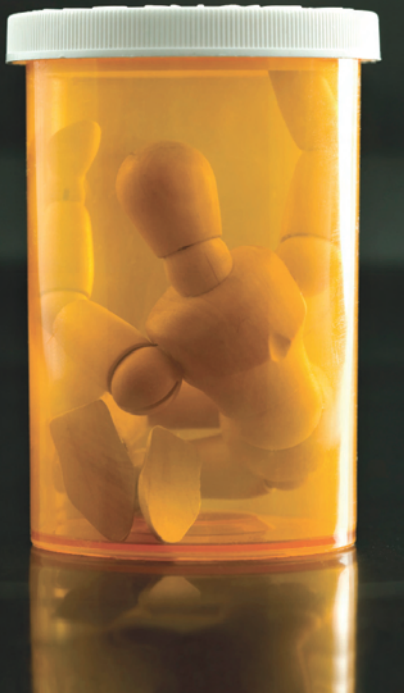
certification cannot support a finding of willful infringement for purposes of awarding attorneys' fees pursuant to 35 U.S.C. § 271(e)(4)."

Branded pharmaceutical companies are not without recourse if confronted with baseless ANDA filings and Paragraph IV certifications, however. To the contrary, Judge Farnan explicitly left Sepracor's exceptional case allegations intact. Section 285 of the Patent Act provides that courts, in "exceptional cases," may award attorneys' fees to the prevailing party. Although willful infringement is commonly considered sufficient to justify a determination that a case is exceptional, as the *Glaxo* court itself noted, "[a] myriad of factual circumstances may give rise to a finding that a case is exceptional."

Misconduct is often the basis of a finding of misconduct under § 285. Types of misconduct that have supported an exceptional case finding include vexatious or unjustified litigation and frivolous filings. Such misconduct has justified exceptional case findings in the context of Hatch-Waxman litigation. For example, in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000), the Federal Circuit affirmed an award of attorneys' fees where the generic company had submitted numerous baseless filings regarding patent invalidity in support of a meritless Paragraph IV certification.

One purpose of the Hatch-Waxman Act is to give patent holders the opportunity to bring suit against generic companies upon the filing of a Paragraph IV certification, despite the fact that the generic companies' only acts of infringement fall within the safe harbor of § 271(e)(2). Although the filing of an ANDA cannot be an act of willful infringement, ANDA filers must nevertheless have good-faith, non-frivolous, and non-vexatious bases for their submission of Paragraph IV certifications. Generic competitors' failure to contest validity, enforceability, or infringement of branded pharmaceutical patents in good faith may result in a finding of exceptional case and an award of attorneys' fees to the patentee.

- Gregory Booker & Kyle Wagner Compton



LIFE SCIENCES LITIGATION review

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