

memorANDA™

LIFE SCIENCES LITIGATION review

Countering Jurisdiction: The Effect of Negotiating a Covenant Not to Sue

memorANDA is a newsletter providing a strategic look at Hatch-Waxman litigation in the districts of Delaware and New Jersey.

memorANDA provides an insightful and educational snapshot of the Hatch-Waxman docket, which we hope will give our readers a deeper understanding of the current and evolving state of ANDA litigation.

Suggestions, comments, or ideas are welcome via email to:

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The jurisdiction of a district court to hear counterclaims on patent claims that are either not asserted by the plaintiff or are the subject of a covenant not to sue is a common issue in Hatch-Waxman litigation. Generally, a counterclaimant seeking relief under the Declaratory Judgment Act must show that the facts alleged, under all circumstances, demonstrate a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343 (Fed. Cir. 2007). This controversy “must be extant at all stages of review, not merely at the time the complaint [was] filed,” *Benitec*, 495 F.3d at 1345, and “must be evaluated on a claim-by-claim basis.” *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1398-99 (Fed. Cir. 1984). A covenant not to sue may, if properly worded, divest the court of jurisdiction, thereby eliminating such controversy. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297 (Fed. Cir. 2009). The burden to prove that a controversy exists rests with the party asserting the claim. *MedImmune*, 549 U.S. at 140 (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95 (1993)).

In light of these principles, what is the effect on the court’s declaratory judgment jurisdiction where the patentee originally alleges infringement of all the claims in a patent but

subsequently limits its infringement accusations to only a few claims? Moreover, how does a covenant not to sue (particularly a partial covenant) impact continuing subject matter jurisdiction?

There is disagreement among the district courts on the first question. Compare *Howes v. Zircon Corp.*, 992 F. Supp. 957, 959-60 (N.D. Ill. 1998) (holding there was no subject matter jurisdiction over counterclaims directed to the unasserted claims even though those claims were originally in the case); *Teradyne Inc. v. Hewlett-Packard Co.*, Civil Action No. 91-0344, 1994 WL 317560 (N.D. Cal. June 21, 1994) (same); *Therma-Tru Corp. v. Peachtree Doors Inc.*, Civil Action No. 89-73028, 1992 WL 332100 (E.D. Mich. Feb. 25, 1992), aff’d in part, rev’d in part on other grounds, 44 F.3d 988 (Fed. Cir. 1995) with *Lear Automotive Dearborn, Inc. v. Johnston Controls, Inc.*, 528 F. Supp. 2d 654 (E.D. Mich. 2007) (refusing to dismiss counterclaims despite plaintiff’s abandonment of infringement charge and covenant not to sue); *Syngenta Seeds, Inc. v. Monsanto Co.*, Civil Action No. 02-1331, 2004 WL 2790498 (D. Del. Nov. 22, 2004) (holding court had jurisdiction over counterclaims unless patentee withdrew the entire patent from controversy); *F.B. Leopold Co., Inc. v. Roberts Filter Mfg. Co., Inc.*, Civil Action No. 92-2427, 1995 WL 776945 (W.D. Pa. Aug. 2, 1995) (same).

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Selected District of Delaware Hatch-Waxman Opinions

ULTRAM®
In re Tramadol HCl Litigation
C.A. No. 07-255-KAJ
August 14, 2009 Post-Trial Opinion

Following a five-day bench trial, the Court found that the Defendant literally infringed claims of the patents-in-suit, but that the patents were invalid for obviousness. In making the case for non-obviousness, Plaintiffs argued that “it would not have been obvious for a person of ordinary skill to choose tramadol for a 24-hour controlled release formulation out of ‘scores’ of other analgesics or combinations disclosed in [a prior art reference]” However, the Court held that “Plaintiffs fail to recognize that a prior art reference’s inclusion of a claimed active agent in an undifferentiated list does not necessarily remove the reference from consideration as invalidating. The Court explained that “to the extent [Plaintiffs suggest] that the prior art must point to only a single [active] for further development efforts, that restrictive view would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in KSR [Intern. Co. v. Teleflex Inc., 550 U.S. 398 (2007)].”

The Court also rejected Plaintiffs’ argument “that the PTO allowed the claims as non-obvious even though it considered the same categories of prior art that are before [the Court] now,” finding that “Plaintiffs fail to acknowledge that [two of the references] were not before the PTO and are directly on point. Moreover, the PTO did not have the benefit of the Supreme Court’s opinion in KSR.”

The Court further rejected Plaintiff’s claim of validity based on “secondary considerations of non-obviousness, including [defendant’s] blatant copying and [the product’s] commercial success.” The Court stated that “secondary considerations for non-obviousness do not rebut a clear showing of invalidity. Moreover, a showing of copying is not compelling evidence of non-obviousness in the Hatch-Waxman context.”

CONCERTA®
UCB, Inc. et al. v. KV Pharmaceutical Co.
C.A. No. 08-223-JJF
August 18, 2009 Claim Construction Opinion

Judge Farnan construed claims of the patent-in-suit, relating to “multiparticulate pharmaceutical dosage forms that include both immediate release (“IR”) beads and extended release (“ER”) beads,” including the term “approximately.” Plaintiffs argued that the term did not require construction, while the Defendant argued that it should be construed to mean “almost exactly.” Defendant contended that “almost exactly” was its plain and ordinary meaning, according to the American Heritage College Dictionary. The Court found that the term did not require construction, despite the fact that “Defendant’s extrinsic dictionary definition clearly supports such a construction,” because nevertheless, “without some meaningful corresponding basis for it in the intrinsic record, the Court will not paraphrase the ordinary word ‘approximately’ as ‘almost exactly.’” (emphasis added)

MENTAMINE HCl
Forest Labs v. Cobalt Labs, Inc., et al.
C.A. No. 08-021-GMS-LPS
September 21, 2009 Review of Report & Recommendation

In reviewing a Report and Recommendation by Magistrate Judge Leonard P. Stark, Chief Judge Gregory M. Sleet issued an opinion construing adopting several claim terms construed in the R&R. However, the Court rejected the Defendant’s claim differentiation and other invalidity arguments, where “they couched these arguments as claim construction objections.” The Court found that “[s]uch validity arguments are not properly resolved at the claim construction stage,”

and agreed with Magistrate Judge Stark’s refusal to consider any such arguments presented by Defendants.

SENSIPAR®
Brigham and Women’s v. Teva Pharms., Inc.
C.A. No. 08-464-HB
September 24, 2009 Order

Sitting by designation in the District of Delaware, E.D. Pa. Chief Judge Harvey Bartle issued an Order limiting the total number of claims to be tried. In a case with four patents-in-suit, the Court restricted the Plaintiffs to no more than twelve representative claims, inclusive of at least one claim from each of the patents-in-suit. The Court explained, however, that the trial on the representative claims would be “without prejudice to a trial at a later point, at the request of [P]laintiffs, on any of the remaining claims of the patents.”

ENTOCORT® EC
AstraZeneca v. Barr Labs, Inc., et al.
C.A. Nos. 08-305, 08-453-GMS
October 5, 2009 Order

Chief Judge Sleet issued a Markman order interpreting claim 1 of U.S. Pat. No. 5,643,602 (“the ‘602 patent”) and claims 1, 12, 13, and 14 of U.S. Pat. No. 6,423,340 (“the ‘340 patent”). The Court found the term “about” to mean “approximately.” Plaintiffs argued that the claim 1 of the ‘602 patent could extend beyond the percentage range recited in the claim (0.5% to 30%), “so long as that percentage ‘can rate-limit release of the glucocorticosteroid,’ as required by the claim. The specification states the preferred range to be between 1% and 15%, and the examples in the specification utilize ranges between 2.05% and 7.65%. The Court noted that it was “mindful that the word ‘about’ cannot be read out of a claim that cites a numeric range,” but found that “any deviation from the recited range must be minimal” in this case due to restrictions in the prosecution history and the specification, which provided “no basis for expanding the range beyond a minimal mathematical variance on either end of the range.”

Additionally, the Court construed the term “controlled release pharmaceutical formulation” from claim 1 of the ‘340 to mean “an oral composition formulated to ensure that the active compound is released preferentially at the site of the disease to be treated.”

VIGAMOX®
Alcon, Inc., v. Teva Pharms USA, Inc.
C.A. No. 06-234-SLR
October 19, 2009 Post-Trial Opinion

Judge Sue L. Robinson issued a post-trial opinion following a bench trial held in February 2008, finding in favor of Plaintiff on both infringement and validity. The infringement analysis focused on claim construction of the term “moxifloxacin,” since the generic proposed ANDA product used moxifloxacin as the active ingredient. Defendants argued that the patentee had redefined “moxifloxacin” more narrowly than the ordinary understanding of that term in the pharmaceutical industry, due to the fact that the specification “provides an alternate meaning for the claim term ‘moxifloxacin’ in the form of the depiction of a structurally different compound.” The Court rejected this argument, as “[t]he record before the court is replete with instances in which Teva’s proposed construction is at odds with the specification of the ‘830 patent so as to cause an absence of [the level of] clarity, deliberateness and precision” needed for a finding that the patentee had acted “as his own lexicographer.”

In analyzing obviousness, defendant argued that the combination yielding moxifloxacin would have been obvious to try,

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Selected District of Delaware Hatch-Waxman Opinion, cont.

“due to both market pressure and the existence of ‘a finite number of identified, predictable solutions’ to treat ophthalmic infections.” Furthermore, Defendants contended that the person of ordinary skill in the art would have expected the combination to be successful in giving rise to a compound with desirable properties. The Court first rejected the notion that the combination would have been obvious to try, noting that “the record indicates anything but a finite number of identified, predictable solutions.” Moreover, even if the combination were obvious to try, the Court found that there was still no evidence as to “whether the prior art motivated a person of ordinary skill to even select moxifloxacin” for use in the first instance. The Court noted that “the prior art consistently taught away from the use of moxifloxacin,” on account of its toxicity in light of the intended prophylactic use, as well as its poor activity against critical pathogens.

Secondary considerations further weighed in favor of the finding of non-obviousness. The Court noted the initial skepticism by experts in the field, a long felt need for the compound as well as its unexpected properties, in addition to the fact that “it is undisputed that the commercial success of VIGAMOX® has resulted in hundreds of millions of dollars in sales.”

ALPHAGAN P®

In re Brominidine Patent Litigation

MDL Docket No. 07-MD-1866-GMS

October 23, 2009 Memorandum Opinion

Following an eight day bench trial held from March 8 to March 19, 2009, the Court issued its Opinion in In re Brominidine Patent Litigation, finding that: 1. the Defendants’ proposed ANDA products literally infringe the asserted claims of the patents-in-suit; 2. that the patents-in-suit are not invalid; 3. that the patents-in-suit are not unenforceable due to inequitable conduct. The Court also ruled on Plaintiff’s motion for judgment as a matter of law on “numerous prior art references and combinations of references that were not discussed or referred to by any witness at trial,” granting the motion, since these “references are not supported by any expert testimony.” Defendant Exela’s Rule 52(c) motion for a ruling that it does not infringe the ’834 patent was denied, as the Court “conclude[d] that Exela’s accused product literally infringes all of the asserted claims of the ’834 patent.”

VIGAMOX®

Takeda Pharm. Co., v. Teva Pharms USA, Inc.

C.A. No. 07-331-SLR

November 9, 2009

The Court granted Plaintiffs’ motion to clarify judgment in the case, which was issued on October 19, 2009. In providing clarification to the judgment, the Court found that the earliest effective date on which Defendant could launch its commercial generic product was the day after the FDA-granted six-month period of pediatric exclusivity ended on the brand product. The Court addressed the issue of “whether [plaintiff’s] 6-month period of pediatric exclusivity for [its product] ‘overlaps’ with the 180-day marketing exclusivity period to which [defendant] is entitled pursuant to 21 U.S.C. § 355(j)(5)(B)(iv) and, if so, which of these parties gets the benefit of the single day of overlap.” The Court concluded that “there should be no overlap between the expiration of a patent’s exclusivity period and the commencement of a generic’s period of marketing exclusivity; and [plaintiff] should continue to get the benefit of its exclusive rights until the day after the patent and its related period of exclusivity expires.”

AMRIX®

Eurand, Inc. et al. v. Mylan Pharmaceuticals et al.

C.A. No. 08-889-SLR-MPT

December 9, 2009 Memorandum Order

In a Memorandum Order issued December 9, 2009, Judge Thyng denied Mylan’s demand for the production of confidential lab notebooks and other documents concerning drugs other than cyclobenzaprine, the subject of Mylan’s ANDA and the patents-in-suit, finding that the documents requested were not relevant. However, Judge Thyng also held that “Mylan’s request for disclosure of the factual evidence upon which Plaintiffs may rely concerning the secondary considerations of the claimed formulation is not unreasonable,” and ordered Plaintiffs to supplement their responses to Mylan’s discovery requests regarding factual evidence supporting secondary considerations of non-obviousness.

CRESTOR®

In re Rosuvastatin Calcium Patent Litigation

MDL No. 08-1949

December 11, 2009 Report and Recommendation

In this multidistrict litigation consolidating nine patent infringement actions, Judge Stark recently issued a Report and Recommendation Regarding Motions for Summary Judgment and to Dismiss and Order on Evidentiary Motions. In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949 (D. Del. Dec. 11, 2009). One such motion was Defendant Aurobindo India’s Motion for Summary Judgment of No Personal Jurisdiction. Id. at 5. Aurobindo India argued that if it is dismissed from the case, so must be defendant Aurobindo USA because of the absence of “the necessary and indispensable Aurobindo India.” Id. However, Judge Stark agreed with Plaintiffs that under Forest Labs., Inv. v. Cobalt Labs., Inc., 2009 WL 605745 (D. Del. Mar. 9, 2009), and considering the record, id. at 6-9, there was sufficient evidence to conclude that “Aurobindo USA ‘engages in [a] persistent course of conduct’ in Delaware, thereby establishing general jurisdiction.” Id. at 9 (citing 10 Del. C. § 3104(c)(4)). Moreover, “[u]nder the alter ego and agency theories, these jurisdictional contacts of Aurobindo USA may be imputed to Aurobindo India.” Id.

A different result was reached when Judge Stark considered defendant Apotex Inc.’s Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer to the Middle District of Florida. Id. at 10. Here, Judge Stark found insufficient contacts with Delaware but that transfer was warranted. Id. Judge Stark noted that “Apotex Inc. is a Canadian corporation with a principal place of business in Canada. It has no offices, facilities, telephone listings, bank accounts, or property in Delaware. It does not have employees, or do business, in Delaware.” Id. at 11. Although plaintiffs argued that defendant Apotex Corp.’s contacts with Delaware should be imputed to Apotex Inc., the same argument that was successful with the Aurobindo defendants, here, Judge Stark found that plaintiffs failed to meet their burden. Id. “Apotex Corp. generates its own revenue, with which it purchases the products it sells. Apotex Corp. decides which of Apotex Inc.’s approved products it will market. Apotex Corp. pays Apotex Inc. for administrative services rendered by Apotex Inc. and the two companies maintain distinct books, records, financial statements, and tax returns.” Id. at 11-12. Judge Stark subsequently transferred the suit against Apotex Inc. to Florida, where Apotex Inc. conceded jurisdiction exists. Id. at 12.

District of Delaware Paragraph IV Litigation

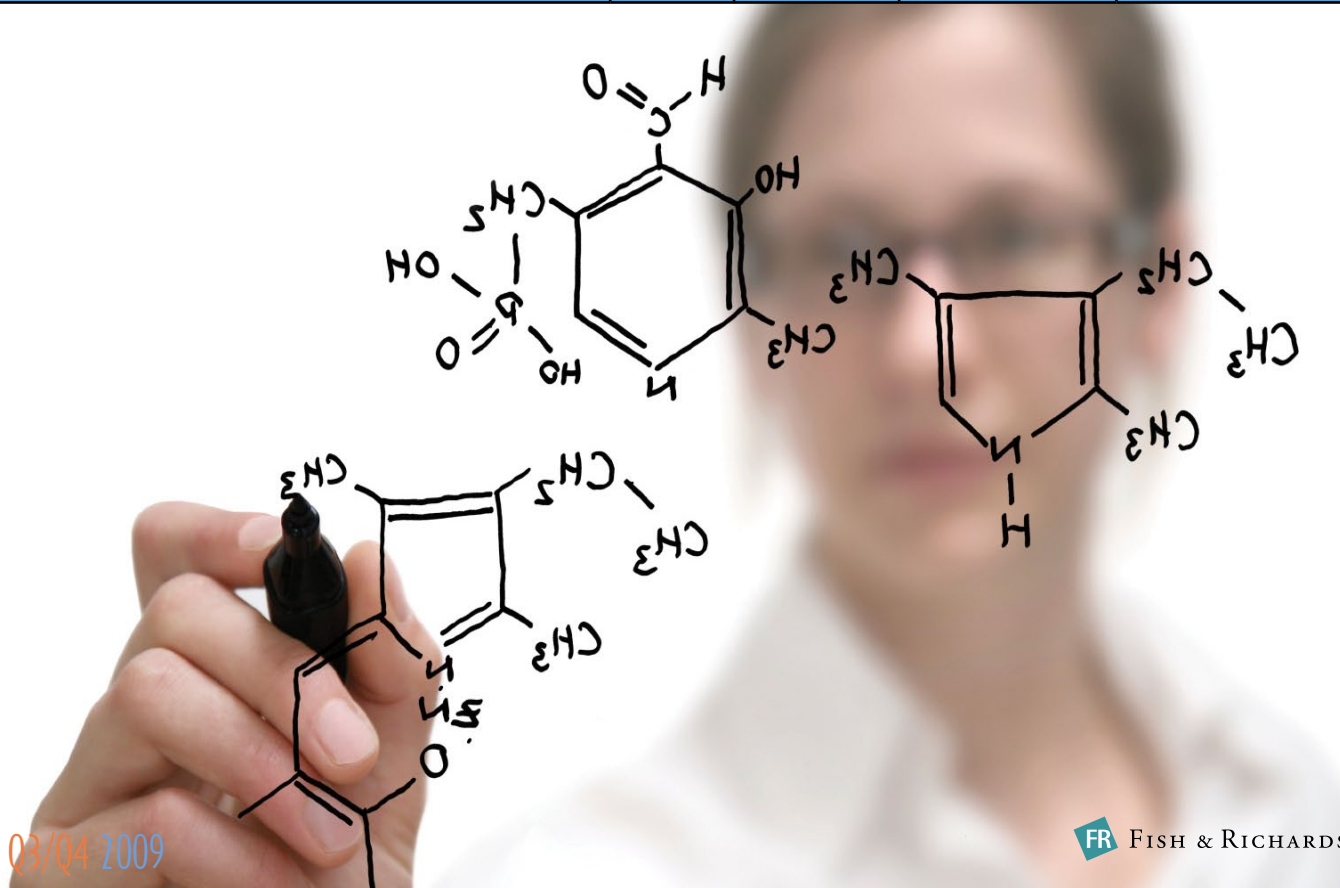
Filed July through December 2009

PARTIES	C.A. NO.	DATE	BRAND DRUG	PATENT(S)
<i>Bayer Schering Pharma AG, et al. v. Teva Pharms. USA, et al.</i>	09-480	7/1/2009	LEVITRA®	6,362,178
<i>Alcon Research, Ltd. v. Par Pharmaceutical, Inc.</i>	09-481	7/1/2009	TRAVATAN®	5,510,383; 5,631,287; 5,849,792; 5,889,052; 6,011,062
<i>Alcon Research, Ltd. v. Par Pharmaceutical, Inc.</i>	09-481	7/1/2009	TRAVATAN Z®	5,510,383; 5,889,052; 6,503,497; 6,849,253
<i>The Research Foundation of State University of New York, et al. v. Lupin Limited, et al.</i>	09-483	7/2/2009	ORACEA®	7,232,572; 7,211,267; 5,789,395; 5,919,775
<i>Takeda Pharmaceutical Co. Limited, et al. v. Torrent Pharms. Limited, et al.</i>	09-499	7/8/2009	ACTOS®	5,965,584
<i>Allergan, Inc., et al. v. Watson Pharms, Inc., et al.</i>	09-511	7/13/2009	SANCTURA XR®	7,410,978
<i>Alcon Research, Ltd. v. Barr Laboratories, Inc.</i>	09-512	7/13/2009	TRAVATAN Z®	5,510,383; 5,889,052; 6,503,497; 6,849,253
<i>Bone Care International LLC, et al. v. Sandoz, Inc.</i>	09-524	7/16/2009	HECTOROL®	5,602,116
<i>Bayer Schering Pharma AG, et al. v. Teva Pharms. USA, et al.</i>	09-536	7/24/2009	LEVITRA®	6,362,178
<i>Genzyme Corporation v. Roxane Laboratories, Inc.</i>	09-567	7/31/2009	HECTOROL®	5,602,116
<i>Baxter Healthcare Corporation, et al. v. Minrad, Inc., et al.</i>	09-582	8/6/2009	SUPRANE®	5,617,906
<i>SmithKline Beecham Corp. v. Glenmark Generics Inc., USA</i>	09-608	8/14/2009	MALARONE®	6,166,046; 6,291,488; 5,998,449
<i>Aventis Pharma S.A., et al. v. Sun Pharmaceutical Industries Ltd., et al.</i>	09-630	8/21/2009	TAXOTERE®	5,438,072; 5,698,582; 5,714,512; 5,750,561
<i>Bristol-Myers Squibb Co., et al. v. Mylan Pharms., Inc., et al.</i>	09-651	8/28/2009	SUSTIVA®	6,673,372 B1
<i>King Pharms., Inc., et al. v. Teva Parenteral Medicines, et al.</i>	09-652	8/28/2009	EPIPEN®	7,449,012 B2
<i>Hospira, Inc., et al. v. Sandoz International GmbH, et al.</i>	09-665	9/4/2009	PRECEDEX™	4,910,214; 6,716,867
<i>Purdue Pharma Products L.P., et al. v. Paddock Labs, Inc.</i>	09-666	9/4/2009	ULTRAM®	6,254,887; 7,074,430
<i>Warner Chilcott Co. v. Lupin Limited, et al.</i>	09-673	9/9/2009	LOESTRIN®	5,552,394
<i>Warner Chilcott Co. v. Lupin Limited, et al.</i>	09-672	9/9/2009	FEMCON®	6,667,050
<i>Bayer Schering Pharma AG, et al. v. Teva Pharms. USA, et al.</i>	09-682	9/15/2009	LEVITRA®	6,362,178
<i>The Research Foundation of State University of New York, et al. v. Impax Laboratories, Inc.</i>	09-703	9/18/2009	ORACEA®	7,232,572; 7,211,267; 5,789,395; 5,919,775
<i>Eurand, Inc., et al. v. Anchen Pharms., Inc., et al.</i>	09-715	9/23/2009	AMRIX®	7,387,793; 7,544,372
<i>Cephalon, Inc. v. Watson Pharms., Inc., et al.</i>	09-724	9/25/2009	ACTIQ®	6,264,981 B1
<i>Elan Pharma International Limited, et al. v. Actavis Elizabeth LLC, et al.</i>	09-744	10/6/2009	LUVOX CR®	7,465,462
<i>The Medicines Co. v. APP Pharmaceuticals, LLC, et al.</i>	09-752	10/8/2009	ANGIOMAX®	7,582,727
<i>The Medicines Company v. Teva Parenteral Meds., Inc., et al.</i>	09-750	10/8/2009	ANGIOMAX®	7,582,727
<i>The Medicines Company v. Pliva Hrvatska d.o.o., et al.</i>	09-751	10/8/2009	ANGIOMAX®	7,582,727
<i>Stiefel Res. Australia Pty. Ltd. v. Perrigo Company, et al.</i>	09-758	10/13/2009	MEN'S ROGAINE®	6,946,120 B2
<i>Shelbyzyme LLC v. Genzyme Corporation</i>	09-768	10/14/2009	FABRAZYME®	7,011,831
<i>Cephalon, Inc. v. Barr Pharmaceuticals, Inc., et al.</i>	09-794	10/22/2009	FENTORA®	6,264,981 B1
<i>Alcon Research, Ltd. v. Apotex Corp., et al.</i>	09-798	10/23/2009	TRAVATAN®	5,510,383; 5,631,287; 5,849,792; 5,889,052; and 6,011,062

District of Delaware Paragraph IV Litigation

Filed July through December 2009, cont.

PARTIES	C.A. NO.	DATE	BRAND DRUG	PATENT(S)
<i>Purdue Pharma Products L.P., et al. v. Sun Pharm Ind. Ltd.</i>	09-833	11/5/2009	RYZOLT®	6,254,887; 7,074,430
<i>Takeda Pharm. Co. Ltd., et al. v. Teva Pharms. USA, Inc.</i>	09-841	11/6/2009	ROZEREM®	6,034,239
<i>Allergan, Inc., et al. v. Sandoz, Inc.</i>	09-882	11/19/2009	SANCTURA XR®	7,410,978
<i>Abbott Laboratories, et al. v. Teva Parenteral Medicines, Inc., et al.</i>	09-884	11/19/2009	ZEMPLAR®	5,246,925; 5,587,497; 6,136,799
<i>Cephalon, Inc., et al. v. Teva Pharms. USA, Inc., et al.</i>	09-918	12/2/2009	NUVIGIL®	RE37,516 E; 7,297,346 B2; 7,132,570 B2
<i>Takeda Pharmaceutical Co. Ltd., et al. v. Watson Laboratories, Inc., et al.</i>	09-917	12/2/2009	ROZEREM®	6,034,239
<i>Bristol-Myers Squibb Co., et al. v. Teva Pharms., USA Inc.</i>	09-919	12/2/2009	REYATAZ®	5,849,911; 6,087,383
<i>Pfizer Inc., et al. v. Kremers Urban, LLC, et al.</i>	09-924	12/3/2009	LIPITOR®	5,969,156
<i>Cephalon, Inc., et al. v. Actavis Group, et al.</i>	09-940	12/8/2009	NUVIGIL®	RE37,516 E; 7,132,570
<i>Pfizer Inc., et al. v. Dr. Reddy's Labs. Ltd., et al.</i>	09-943	12/8/2009	LIPITOR®	5,969,156
<i>Seattle Children's Hospital, et al. v. Teva Parenteral Medicines, Inc., et al.</i>	09-949	12/10/2009	TOBI®	5,508,269
<i>Wyeth Holdings Corp., et al. v. Sandoz, Inc.</i>	09-955	12/11/2009	TYGACIL®	RE40,183
<i>Cephalon, Inc., et al. v. Mylan Pharms., Inc., et al.</i>	09-954	12/11/2009	NUVIGIL®	RE37,516 E
<i>Abbott Labs. v. Sandoz, Inc.</i>	09-972	12/18/2009	NIMBEX®	5,453,510
<i>Abbott Labs., Inc., et al. v. Apotex, Inc., et al.</i>	09-990	12/23/2009	MERIDIA®	5,436,272
<i>The Medicines Company v. Teva Parenteral Medicines, Inc.</i>	09-999	12/28/2009	ANGIOMAX®	7,598,343
<i>The Medicines Company v. Pliva Hrvatska, et al.</i>	09-1000	12/28/2009	ANGIOMAX®	7,598,343; 7,582,727



District of New Jersey Paragraph IV Litigation

Filed July through December 2009

PARTIES	C.A. NO.	DATE	BRAND DRUG	PATENT(S)
<i>Wyeth v. Orgenus Pharma, Inc., et al.</i>	09-3235	7/02/2009	EFFEXOR® XR	6,274,171; 6,403,120; 6,419,958
<i>Endo Pharmaceuticals, Inc., et al. v. Barr Laboratories, Inc.</i>	09-3224	7/02/2009	OPANA® ER	5,662,933; 5,958,456
<i>Taro Pharmaceuticals North America, Inc., et al. v. Synerx Pharma, LLC, et al.</i>	09-3569	7/20/2009	OVIDE®	7,560,445
<i>King Pharmaceuticals, Inc., et al. v. Sandoz, Inc.</i>	09-3587	7/21/2009	AVINZA®	6,066,339
<i>Paddock Laboratories, Inc. v. Ethypharm S.A.</i>	09-3779	7/30/2009	ANTARA®	7,101,574
<i>AstraZeneca LP, et al. v. Breath Limited</i>	09-4115	8/12/2009	PULMICORT RESPULES®	7,524,834
<i>Aventis Pharma S.A., et al. v. Sun Pharmaceutical Industries, Ltd., et al.</i>	09-4333	8/24/2009	TAXOTERE®	5,438,072; 5,698,582; 5,714,512; 5,750,561
<i>King Pharmaceuticals, Inc., et al. v. Sandoz, Inc.</i>	09-4513	9/1/2009	AVINZA®	6,066,339
<i>Hospira, Inc., et al. v. Sandoz International GmbH, et al.</i>	09-4591	9/4/2009	PRECEDEX®	4,910,214; 6,716,867
<i>Albany Molecular Research, Inc. v. Dr. Reddy's Laboratories, Ltd., et al.</i>	09-4638	9/09/2009	ALLEGRA®, ALLEGRA D®	7,390,906
<i>Albany Molecular Research, Inc. v. Sandoz, Inc., et al.</i>	09-4639	9/09/2009	ALLEGRA®, ALLEGRA D®	7,390,906
<i>Astellas US LLC, et al. v. Wockhardt Limited, et al.</i>	09-4654	9/10/2009	ADENOSCAN®	5,731,296
<i>Forest Laboratories, Inc., et al. v. Orgenus Pharma, Inc. et al.</i>	09-5105	10/6/2009	NAMENDA®	5,061,703
<i>Teva Women's Health, Inc. v. Lupin, Ltd., et al.</i>	09-5112	10/6/2009	SEASONALE®	RE 39,861
<i>Aventis Pharmaceuticals, Inc., et al. v. Sun Pharmaceutical Industries, Ltd., et al.</i>	09-5179	10/9/2009	ALLEGRA®	7,135,571; 6,399,632; 6,187,791; 6,037,353; 5,855,912; 6,113,942; 5,738,872
<i>Hoffmann-La Roche, Inc. v. Teva Pharmaceuticals USA, Inc., et al.</i>	09-5283	10/16/2009	XELODA®	5,472,949
<i>Astrazeneca AB, et al. v. Lupin, Ltd. et al.</i>	09-5404	10/21/2009	NEXIUM®	5,714,504; 5,877,192; 6,875,872; 6,369,085; 7,411,070
<i>Abbott Laboratories, et al. v. Impax Laboratories, Inc.</i>	09-5517	10/29/2009	TRICOR®	6,277,405; 7,037,529; 7,041,319
<i>Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc. et al.</i>	09-5531	10/29/2009	ABILIFY®	5,006,528; 6,977,257
<i>Elan Pharma International, Ltd., et al. v. Impax Laboratories, Inc.</i>	09-5541	10/29/2009	TRICOR®	5,145,684; 7,276,249; 7,320,802
<i>Medicis Pharmaceutical Corp. v. Glenmark Generics Inc, USA, et al.</i>	09-5556	10/30/2009	LOPROX®	7,018,656
<i>Novartis AG, et al. v. Apotex, Inc. et al.</i>	09-5614	11/03/2009	Myfortic7 delayed-release tablets	6,025,391; 6,172,107; 6,306,900
<i>Merck & Co, Inc., et al. v. Teva Parenteral Medicines, Inc., et al.</i>	09-6026	11/25/2009	CANCIDAS®	5,378,804; 5,514,650; 5,952,300
<i>Cephalon, Inc., et al. v. Actavis Group, et al.</i>	09-6239	12/10/2009	NUVIGIL®	RE 37,516E; 7,132,570
<i>Hoffmann-La Roche, Inc. v. Roxane Laboratories, Inc. et al.</i>	09-6335	12/15/2009	XELODA®	5,472,949
<i>Schering Corporation et al. v. Mylan Pharmaceuticals Inc., et al.</i>	09-6383	12/16/2009	VYTORIN®	RE 37,721; 5,846,966
<i>Schering Corp. v. Apotex Inc., et al.</i>	09-6373	12/18/2009	NASONEX®	5,837,699; 6,127,353; 6,723,713;
<i>Abbott Laboratories v. Sandoz, Inc.</i>	09-6402	12/21/2009	NIMBEX®	5,453,510

Selected District of New Jersey Hatch-Waxman Opinions

SEROQUEL XR®

AstraZeneca Pharmaceuticals v. Handa Pharmaceuticals, et al.
C.A. Nos. 08-3773; 08-4804; 08-5328; 08-5997; 09-0128; 09-0619
July 31, 2009 Letter Order

Magistrate Judge Bongiovanni considered defendants' request that plaintiff be compelled to produce the three inventors of the patent-in-suit for depositions prior to the close of claim construction discovery. While acknowledging that "the subjective intent of an inventor when he or she used a particular term is of little if any probative value in determining the scope of a claim" (citing *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996)), the Court nevertheless granted defendants' motion, noting that "an inventor's testimony is relevant to explain the technology at issue and what was invented and claimed" (citing *Voice Tech. Group, Inc. v. VMC Sys. Inc.*, 164 F.3d 605, 615 (Fed. Cir. 1999)).

While concluding that inventor testimony may be relevant to claim construction, the Court explicitly called out the limitations of such testimony, adding that "[t]he Court will not . . . allow a creative reconstruction of the invention at issue through such extrinsic evidence. Therefore, while the Court believes that it is appropriate for the inventors to be deposed, the District Court may consider their testimony with a healthy degree of skepticism, recognizing that their testimony is 'less reliable than the patent and its prosecution history in determining how to read claim terms'" (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005)).

Note: The Magistrate Judge's holding was affirmed on appeal by Order dated September 3, 2009.

CARDENE I.V.®

PDL Biopharma, Inc., et al. v. Sun Pharmaceutical Industries, Ltd.
C.A. No. 07-1788 (KSH)
July 31, 2009 Opinion

In an Opinion dated July 31, 2009, Judge Hayden denied defendant Sun's motion for reconsideration of the Court's March 31, 2009, Opinion finding that Sun's ANDA product infringed PDL's '405 patent. Sun argued that the Court erred because i) it compared the ANDA product to the commercial product instead of comparing the ANDA product to the claims of the '405 patent; ii) the Court impermissibly "adopted a theory of literal infringement" despite Plaintiffs' representations, in an email between counsel, that they would abandon their theory of literal infringement; and iii) the Court erroneously adopted a construction of the '405 patent claims that incorporated material expressly disclaimed during prosecution. Judge Hayden addressed each contention in turn and denied Sun's motion.

First, Judge Hayden noted that in the March 30 Opinion, "the Court recited the proper legal standard in observing that the patent claims alone vest the patent holder's right to exclude and that a finding of infringement requires that the accused product contains every limitation as outlined in the patent claims. (D.E. 190.) And the Court properly focused on whether Sun's ANDA product met every limitation in the '405 claims." Op. at 2-3. Judge Hayden then cited several pages from the March 30 Opinion that compared the accused ANDA product to the claims of the '405 patent.

Analyzing Sun's third argument second, Judge Hayden held that the Court's construction of the '405 patent was correct. Sun argued that its formulation contained less than 1.0 mg/ml of the active ingredient nicardipine and that during prosecution Plaintiffs expressly disclaimed a concentration of nicardipine below this level. Judge Hayden found, however, that Sun was improperly comparing a diluted form of its formula to the claims of the '405 patent. The formula described in Sun's ANDA contained a concentration of nicardipine above 1.0 mg/ml and thus fell within the scope of the '405 patent.

Addressing Sun's second argument, Judge Hayden stated that "[t]he email cited by Sun in its Reconsideration Motion brief does not have bearing on the issues before the Court because it was not filed on the docket, was not part of a stipulation, was not approved by the Court, and was not before the Court on the summary judgment motion. Rather, the email was an informal communication between counsel and did not act as a waiver of any rights." Op. at 5-6.

NAROPIN®

Abraxis Biosci., Inc. v. Navinta, LLC,
C.A. No. 07-1251 (JAP)
August 3, 2009 Opinion

In an order dated August 3, 2009, and after an eight-day bench trial, Judge Pisano found that Navinta's ANDA for a generic version of an injectable form of the anesthetic Naropin® infringed three of Abraxis's patents, U.S. Patent Nos. 4,870,086; 5, 670,524; and 5,834,389.

Naropin is sold in concentrations of 0.2%, 0.5% 0.75% and 1.0% by weight ropivacaine hydrochloride, whose chemical name is (S) (-)-1-propyl-2',6'-pipercolyxylidide hydrochloride. Ropivacaine exists as enantiomers; however, the S-enantiomer is more stable than is the R-enantiomer.

One goal of the '086 patent was to obtain a substantially pure S-enantiomer of ropivacaine. Optical activity measures how enantiomerically pure a given composition is, and examples in the '086 report an S-enantiomer having optical purity greater than or equal to 99.5%. Another goal of the '086 patent was to obtain a compound with a defined water content, e.g., a monohydrate, which increased stability and shelf life.

In the claim construction phase of the case, the parties' main dispute was whether claims covered all physical forms of ropivacaine hydrochloride or just its crystalline form, as the Defendant argued. The parties asked the court to construe these terms from claim 1: "(S)(-)-1-propyl-2',6'-pipercolyxylidide hydrochloride, where in the compound is in the form of its monohydrate"; "(S)(-)-1-propyl-2',6'-pipercolyxylidide hydrochloride"; and "the compound according to claim 1."

The Court adopted Plaintiffs' proposed construction for the first term and did not limit the claims to ropivacaine hydrochloride monohydrate in solid form. The words of the claims did not specify a physical state; the patent applicant never disclaimed ropivacaine hydrochloride in solution, and the other claims supported the conclusion that claim 1 was not limited to a solid. The Court also construed "(S) (-)-1-propyl-2',6'-pipercolyxylidide hydrochloride" to mean a compound with an (S)-enantiomer with an optical purity of more than 99.0%. And the Court construed "the compound according to claim 1" to refer to the optically pure compound of claim, not the monohydrate of that compound.

In reaching the infringement determination, the Court relied on, among other evidence, statements from Navinta's Package Insert, certificates of analysis submitted to the FDA regarding the optical purity of Navinta's ropivacaine hydrochloride, and Navinta's manufacturing documents. From this evidence, the Court concluded Navinta's ANDA Products contain (S)(-)-1-propyl-2',6'-pipercolyxylidide hydrochloride with more than 99% optical purity.

The Court then reviewed Plaintiffs' testing of Navinta's ANDA Products designed to verify the presence of ropivacaine hydrochloride monohydrate. In particular, Plaintiffs and their experts had Aptuit, Inc.,

(cont. on next page)

Selected District of New Jersey Hatch-Waxman Opinions, cont.

perform X-ray powder diffraction testing on these three sample sets: samples of 0.2%, 0.5% and 1.0% Naropin; samples of 0.2%, 0.5% and 1.0% Navinta's ANDA Products; and samples 0.2%, 0.5% and 1.0% solutions generated by Aptuit by simulating the critical steps of the manufacturing process used to prepare the ANDA Products. The test results confirmed the presence of ropivacaine hydrochloride in all three of these sample sets. Plaintiffs' expert also undertook Raman spectroscopy of 1.0% samples of Naropin and the ANDA Product, which likewise confirmed the presence of ropivacaine hydrochloride monohydrate in both sample sets. Importantly, the Court noted at the outset of the order that it accorded the Plaintiffs' experts more weight, largely because of their experience, manner of testimony and the reasons given in support of their opinions.

The Court further explained that Naropin practiced the claims of the '086 patent, and that Navinta stated in its ANDA submissions, and through testimony, that its ANDA Products are equivalent to Naropin. The Court pointed out that Navinta chose to use USP-defined terms in its Labeling, which showed that Navinta intended its ANDA Products to be consistent with the USP definitions, which specifically refer to ropivacaine hydrochloride monohydrate.

The claims of the '524 and '429 patents are directed to methods for treating pain, and the Court determined that a person of skill in the art of those patents was an anesthesiologist or physician with experience in pain management. Specifically, the asserted claims were directed to administering ropivacaine at a concentration of less than 0.25% by weight, and compositions of ropivacaine at concentrations lower than 0.25% and 0.5% by weight for use in pain management with minimal motor blockade. Generally speaking, ropivacaine at low concentrations, such as 0.2% or less, avoids motor blockade but still provides pain relief. The Court considered how physicians used Naropin in practice. The Court found that practitioners regularly dilute or mix higher concentrations of ropivacaine to lower concentrations for pain management, and that physicians would do the same with the ANDA Products. The Court also found that the ANDA Package Insert and Labeling encouraged the use of diluted ANDA Products. For example, those documents suggest Naropin for use in pain management during labor and delivery, and 0.2% Naropin is an appropriate concentration for those conditions. Market research and expert testimony supported this conclusion.

In total, the Court found that Navinta's ANDA Products infringed claims 1-3 and 6 of the '086 patent, claims 1 and 9 of the '524 patent, and claim 1 of the '429 patent.

RESTORIL®

Tyco Healthcare Group LP v. Mutual Pharmaceutical Company

C.A. No. 07-1299 (SRC)

August 4, 2009

Plaintiffs Tyco and Mallinckrodt moved for a preliminary injunction to prevent defendant Mutual from launching a generic version of temazepam upon the expiration of the 30-month stay of approval of Mutual's ANDA. Applying *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), Judge Chesler denied the motion, finding that Tyco was unlikely to succeed on its infringement claims. The Court reasoned that, under *Elan*, where a patentee alleges infringement per 35 U.S.C. § 271(e)(2)(A) (i.e., infringement based on an ANDA filing), and the ANDA specification defines the compound in a manner that directly addresses infringement, the infringement question should

focus on whether the product as described in the ANDA infringes and not whether a physical sample of the product infringes. Judge Chesler concluded that because Tyco based its infringement argument primarily on a physical analysis of Mutual's compound and not on the product specifications described in the ANDA, Tyco was not likely to succeed in proving infringement and therefore a preliminary injunction was inappropriate.

Mallinckrodt owns U.S. Patent No. 5,211,954 (the '954 patent,) which is directed to temazepam and expires in May 2010. Tyco holds an FDA-approved supplement to a new drug application for Restoril® temazepam capsules. Tyco asserted only claim 2 of the '954 patent, which provides that the compound's specific surface area is 0.65-1.1 m²/g. It was undisputed that Mutual's ANDA specification provided a specific surface area of 2.2 m²/g. Experts for both Tyco and Mutual testified regarding the testing they had performed to measure the specific surface area of Mutual's compound.

In denying Tyco's motion, the Court reasoned that, under *Elan*, to show a likelihood of success on proving infringement as required for a preliminary injunction, Tyco was required to show that it was likely to prove by a preponderance of the evidence that either (1) Mutual's ANDA specification does not define the compound in a manner that directly addresses infringement and, therefore, the Court must analyze infringement based on other evidence that corresponds to what Mutual is likely to market if its application is approved; or (2) the ANDA specification defines the compound in a manner that directly addresses infringement and defines it as infringing.

Mutual offered evidence that the ANDA specification defines the compound in a manner that directly addresses infringement. Tyco did not rebut this evidence. Rather, Tyco primarily argued that *Elan* did not apply and that Mutual's product, when properly tested, does not meet the ANDA specifications. The Court held that *Elan* did apply and that, based on Mutual's evidence that the ANDA specification directly addresses infringement, as well as the fact that the specific surface area described in the ANDA differed from the specific surface area in claim 2 of the '954 patent, Tyco was unlikely to prove infringement. Reiterating the rationale of *Elan*, the Court pointed out that "if, in fact, Mutual markets a temazepam product with a [specific surface area] that does not conform to the ANDA, it risks serious consequences with the FDA."

The Court also found that even if, as Tyco argued, infringement is properly based on product samples and not the ANDA specification, Tyco was still unlikely to prove infringement due to factual issues regarding the testimony of its expert. Tyco's expert, as well as Mutual's expert, measured the specific surface area of Mutual's temazepam using "outgassing" analysis. The experts performed their analyses at different temperatures from one another, thereby raising a factual dispute about which method was appropriate. The Court found that Mutual's expert raised substantial questions about the strength of Tyco's infringement case and, accordingly, could not conclude that Tyco was likely to show by a preponderance of the evidence that its testing method was appropriate.

Finally, Mutual moved for judgment on partial findings under Fed. R. Civ. P. 52(c) that claim 2 did not infringe pursuant to 35 U.S.C. § 271(e)(2)(A). The Court granted the motion.

Selected District of New Jersey Hatch-Waxman Opinions, cont.

SINGULAR®

Merck Sharp & Dohme Pharms., SRL v. Teva Pharms. USA, Inc.,
C.A. No. 07-1596 (GEB) (DEA)
August 19, 2009 Findings of Fact and Conclusions of Law

In a written opinion containing its Findings of Fact and Conclusions of Law, the Court concluded that Teva failed to prove either that Merck Sharp & Dohme's (MSD) patent covering montelukast sodium (the active ingredient in Singulair®) was obtained through inequitable conduct or that the asserted claims were obvious.

Teva argued that the prosecuting attorney committed inequitable conduct when he (i) made a misrepresentation of material fact to the PTO, and (ii) withheld a material reference from the PTO with the intent to deceive. The Court rejected both arguments. The Court concluded that a statement made by the prosecuting attorney to the PTO regarding the differences between the claims and the prior art was consistent with the testimony of both parties' witnesses and therefore was "not an affirmative misrepresentation of material fact for purposes of inequitable conduct." In addition, although the Court found that the prosecuting attorney failed to disclose a material reference, it found that the attorney did not intend to deceive the PTO. In so doing, the Court acknowledged evidence that the attorney had reviewed the reference but found that such evidence did not justify an inference of an intent to deceive.

With respect to obviousness, the Court found that Teva's expert had not identified an actual lead compound (or starting point) in the prior art. Instead, Teva's expert chose "a concept for a compound." The Court further found that Teva had not provided sufficient evidence of motivation to have led one of skill in the art to perform the 11 distinct structural modifications required to transform Teva's hypothetical lead structure into the claimed montelukast sodium. Finally, the Court concluded that the secondary considerations of commercial success, long-felt but unsolved need, unexpected results, failure of others, and copying by Teva all supported a conclusion of non-obviousness.

FENOFIBRATE Products

Elan Pharm Int'l, Ltd., et al. v. Teva Pharms. USA, Inc.
C.A. No. 08-1085 (JAG)
August 19, 2009 Letter Order

In a Letter Order dated August 19, 2009, Magistrate Judge Arleo granted in part and denied in part defendant Teva's motion to consolidate *Elan Pharm Int'l, Ltd., et al. v. Teva Pharms. USA, Inc.*, C.A. No. 08-1085 (JAG), with *Abbott Labs., et al. v. Teva Pharms. USA, Inc.*, C.A. No. 08-5869 (SDW). Both actions stemmed from Teva's filing an ANDA seeking approval to market generic 145 mg fenofibrate products, but Elan's and Abbott's patents covered different technologies. Elan's patents related to the use of surface modified drug nanoparticles in drug formulations, while Abbott's patents related to pharmaceutical compositions containing micronized fenofibrate that dissolve at different rates. Reasoning that discovery from Teva would be the same in both actions and that pre-trial consolidation would promote efficiency, Magistrate Judge Arleo granted Teva's motion to consolidate the two actions for discovery purposes. Because of "the technical nature of these two actions and the multiple patents and plaintiffs involved," Magistrate Judge Arleo denied Teva's motion to consolidate for purposes of trial.

OPANA ER®

Endo Pharmaceuticals v. Impax Laboratories, et al.
C.A. Nos. 09-0831; -0832; -0833; -0836; -0838 (KSH)
August 25, 2009 Order
September 30, 2009 Order

In an Order dated August 25, 2009, Magistrate Judge Schwartz discusses the obligation, in accordance with L. Civ. R. 34.1, to log documents that have been redacted as privileged. Although L. Civ. R. 34.1 does not explicitly require production of privilege logs, it does require that a party asserting privilege "identify the nature of the privilege (including work product) which is being claimed." Citing the Rule as authority, the Magistrate Judge ordered the defendant, in conjunction with its production of redacted documents, to produce a log consistent with the following criteria:

The log shall set forth the document, the author and recipients of the document, the page on which a redaction appears, and the privilege that it claims supports the redaction. If [the producing party] is relying upon the work product rule, then it shall identify the purpose for which the document was created and, if it was created in anticipation of litigation, then it shall identify the anticipated litigation.

In a second Order dated September 30, 2009, Magistrate Judge Schwartz denied defendants' request to compel the plaintiffs to include opinions about secondary considerations of non-obviousness in the plaintiffs' affirmative expert report, explaining that the appropriate method for defendants to provide responses to plaintiffs' expert opinions regarding secondary considerations is through defendants' experts' deposition testimony. The Order does not provide detailed reasons for the holding, referring instead to the record of a September 29 hearing, but it is noteworthy that the denial of defendants' request to compel plaintiffs to provide initial expert opinions on secondary considerations of non-obviousness further evidences the Court's skepticism regarding requests that would effectively permit defendants to address obviousness—an issue as to which they bear the burden of proof—responsively rather than affirmatively.

In a previous opinion, *Sanofi-Aventis v. Barr Laboratories, C.A. No. 07-1605 (WJM) (D.N.J. Feb. 20, 2009)*, Magistrate Judge Falk denied defendants' request to address secondary considerations of non-obviousness in a reply expert report responsive to plaintiffs' expert report on the subject rather than in the defendants' affirmative expert reports. Observing that "the party bearing the burden of proof on a particular issue should fully address the issue in its opening expert report," and that "[d]efendants' burden of proving invalidity—and in this case, obviousness—remains intact throughout the litigation," Magistrate Judge Falk held that "[d]efendants are hereby directed to address all issues related to those on which they bear the burden of proof in their opening report, namely invalidity and obviousness."

Note: For a more thorough discussion of the *Sanofi-Aventis v. Barr* opinion, see the Q1 2009 edition of *memorANDA*, available at <http://www.fr.com/memoranda>.

NEURONTIN®

In re Gabapentin Patent Litigation
"Purepac Opinion"

MDL Docket No. 1384, Master Civil Action No. 00-2931
C.A. Nos. 00-CV-2931 (FSH), 00-CV-3522 (FSH)
August 27, 2009 Opinion

On August 27, 2009, Judge Hochberg granted in part and denied in part plaintiff Warner-Lambert's Motion to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims of Purepac Defendants. Warner-Lambert had previously sued Purepac for infringe-

Selected District of New Jersey Hatch-Waxman Opinions, cont.

ment of its '476 and '479 patents in June 1998 (ANDA covering a gabapentin capsule formulation) and December 1999 (ANDA covering a gabapentin tablet formulation). The '476 and '479 patents cover gabapentin monohydrate and gabapentin anhydrous, respectively. In these prior suits, Purepac asserted antitrust and unfair competition counterclaims, alleging that Warner-Lambert fraudulently included the '476 and '479 patents in its NDA for gabapentin anhydrous, which led to the '476 and '479 patents being improperly listed in the Orange Book. Warner-Lambert unsuccessfully moved to dismiss the counterclaims and also unsuccessfully moved for summary judgment on the counterclaims.

In the instant case, Warner-Lambert sued Purepac for infringement of the '482 patent, which also covers gabapentin products. Because it was issued later, the '482 patent was not listed in the Orange Book until April 2000. Purepac filed a Paragraph IV certification against the '482, and Warner-Lambert initiated the instant infringement suit in June 2000. In its answer, Purepac asserted unclean hands and patent misuse as affirmative defenses and also sought declaratory judgments that the '482 was unenforceable because of Warner-Lambert's alleged unclean hands and patent misuse. Purepac additionally asserted counterclaims that Warner-Lambert engaged in i) monopolization and attempted monopolization in violation of Section 2 of the Sherman Act, and ii) common-law unfair competition. Purepac based its defenses and counterclaims on allegations that Warner-Lambert engaged in an "overall scheme to forestall, preclude, and delay generic competition" for its gabapentin products by i) intentionally withholding material prior art from the PTO during prosecution of the '482 patent, ii) improperly certifying that the '476 and '479 patents covered Neurontin®, and iii) filing objectively baseless infringement suits against Purepac for the '476 and '479 patents.

Incorporating her reasoning from a contemporaneously issued opinion in the same case (the "Teva Opinion," also covered in this issue), Judge Hochberg granted Warner-Lambert's motion to strike Purepac's unclean hands defense, reasoning that Purepac needed to, but did not, demonstrate a sufficient connection between Warner-Lambert's alleged misconduct and the patent rights or the cause of action at issue. Also referring to the Teva Opinion, Judge Hochberg denied Warner-Lambert's motion to strike Purepac's misuse defense, reasoning that preserving the patent misuse defense at such an early stage of litigation required only allegations that Warner-Lambert impermissibly extended the protection from competition afforded by the '482 patent, and Purepac made such allegations.

Given that Warner-Lambert's unclean hands defense was stricken, Judge Hochberg dismissed Purepac's counterclaim for declaratory judgment of unenforceability based on unclean hands. In dismissing Purepac's request for declaratory judgment, Judge Hochberg, citing *Aptix Corp. v. Quickturn Design Sys., Inc.*, noted that unclean hands cannot form the basis for a declaration of unenforceability of a patent as a matter of law. 296 F.3d 1369, 1378 (Fed. Cir. 2001). Again citing *Aptix*, Judge Hochberg denied Warner-Lambert's motion to dismiss Purepac's counterclaim for declaratory judgment of unenforceability based on patent misuse, noting that the Federal Circuit indicated in that case that patent misuse based on allegations of inequitable conduct—such as those pled by Purepac—could form the basis for a declaratory judgment of unenforceability. *Id.* at 1376.

Judge Hochberg next denied Warner-Lambert's motion to dismiss Purepac's antitrust counterclaims. First, quoting *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, Judge Hochberg noted that "the existence of antitrust injury is not typically resolved through motions

to dismiss." 113 F.3d 405, 417 (3d Cir. 1997). Then, citing *Biovail Corp. Int'l v. Hoechst AG*, Judge Hochberg explained that while Purepac may not have been injured by any individual action taken by Warner-Lambert, the relevant inquiry is whether Purepac suffered any injury from the overall monopolization scheme; and Purepac alleged that it was injured because Warner-Lambert's scheme delayed the launch of Purepac's generic product. 49 F. Supp. 2d 750, 767 (D.N.J. 1999). Moreover, Judge Hochberg cited *Zenith Radio Corp. v. Hazeltine Research, Inc.*, to emphasize that Purepac need not allege that Warner-Lambert's monopolization scheme was the sole cause of its injury. 395 U.S. 100, 114 n.9 (1969). Judge Hochberg further noted that in its initial pleadings, Purepac need not discredit all possible intervening causes of its delayed launch. Finally, Judge Hochberg explained that "Judge Lifland has already determined that Purepac sufficiently alleged antitrust injury and the requisite causal connection" and that the law of the case doctrine prevented re-litigation of these issues.

Addressing Purepac's claims that Warner-Lambert engaged in an "overall scheme" of monopolization, Judge Hochberg held that Purepac adequately pled antitrust counterclaims even though the "three underlying elements" of Warner-Lambert's scheme—withholding material prior art from the PTO during prosecution of the '482 patent, listing the '476 and '479 patents in the Orange Book, and filing suit against Purepac for infringement of the '476 and '479 patents—might not violate the antitrust laws individually. Judge Hochberg explained that Purepac's counterclaims were sufficient because "Purepac has alleged in detail how Warner-Lambert engaged in a comprehensive multifaceted scheme to monopolize the market for gabapentin anhydrous and how that scheme was designed to obtain more market exclusivity for Neurontin than the patent laws allow, thereby constituting the willful acquisition or maintenance of otherwise allowable monopoly power." *Op.* at 32.

Lastly, Judge Hochberg addressed Warner-Lambert's claim that it was immune to antitrust liability under the Noerr-Pennington doctrine for some of the acts alleged by Purepac. The Noerr-Pennington doctrine limits the scope of the Sherman Act for activities in which a party petitions the government to act in a way that is beneficial to the petitioner and harmful to the petitioner's competitors. This doctrine has been expanded to include litigation to protect patent rights. See *Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). Judge Hochberg explained that there is an exception to the Noerr-Pennington doctrine for "sham litigation," and, citing *Hoffmann-La Roche, Inc. v. Genpharm, Inc.*, Judge Hochberg stated that it is inappropriate to resolve the sham litigation issue via motions to dismiss when, as here, determining the issue depends on the resolution of disputed facts. 50 F. Supp. 2d 367, 380 (D.N.J. 1999). Regarding Warner-Lambert's claim that the Noerr-Pennington doctrine immunized its conduct during prosecution of the '482 patent, Judge Hochberg noted that although Purepac did not plead a Walker Process claim, Purepac alleged sufficient facts to support "a more generalized 'sham' or 'sham petitioning' exception to Noerr-Pennington immunity." *Op.* at 42. Judge Hochberg further explained that "[f]raudulently delaying the issuance of a patent could lead to anticompetitive effects in the relevant market, if such delays were intended to obtain control over or exclude competitors from such market. Such abuse of the Patent Office's administrative and regulatory process itself is not entitled to immunity." *Op.* at 46. Accordingly, Judge Hochberg denied Warner-Lambert's motion to dismiss Purepac's antitrust counterclaims.

Selected Hatch-Waxman Decisions from the Federal Circuit

GALANTAMINE: In re '318 Patent Infringement Litigation Nos. 2008-1594, 2009-1070, 2009-1088, September 25, 2009

Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc. (collectively, "Janssen") filed suit against several generic drug companies alleging infringement of Janssen's '318 patent, which claimed methods of treating Alzheimer's disease by administering galanthamine. The '318 patent specification was only one page in length and it provided short summaries of six scientific papers in which galanthamine had been administered to humans or animals, but did not provide any analysis connecting the results of the six papers to galanthamine's potential to treat Alzheimer's disease. The specification did not contain any test results demonstrating galanthamine's ability to treat Alzheimer's disease in humans or animal models.

The defendants conceded infringement. After a bench trial, the district court found that the '318 patent was invalid for lack of enablement because (1) relevant animal testing experiments were not finished by the time the '318 patent was allowed by the PTO and (2) the specification did not teach one of skill in the art how to use the claimed method because it "only surmised how the claimed method could be used." Janssen appealed.

The Federal Circuit affirmed. It held that animal test results involving the use of galanthamine to treat Alzheimer's disease could not be used to meet the utility requirement (closely related to the enablement requirement) since they were not available "at the time of the application." The Court also rejected Janssen's argument that utility could be demonstrated "by analytic reasoning," stating the analytic steps relied on by Janssen were "nowhere in the specification" and that there was no evidence "that someone skilled in the art would infer galanthamine's utility from the specification, even if such inferences could substitute for an explicit description of utility." The Court characterized the specification as merely the statement of a hypothesis, which is not sufficient to establish utility sufficient to meet the enablement requirement.

Judge Gajarsa dissented. He would have remanded for the district court to make a specific fact finding on the issue of whether a person of skill in the art reading the patent would understand it to reveal a credible utility for the invention.

Selected District of New Jersey Hatch-Waxman Opinions, cont.

NEURONTIN®

In re Gabapentin Patent Litigation

"Teva Opinion"

MDL Docket No. 1384, Master Civil Action No. 00-2931

August 27, 2009 Opinion

On August 27, 2009, Judge Hochberg granted in part and denied in part plaintiff Warner-Lambert's Motion to Strike Certain Affirmative Defenses of the Teva, IVAX and Eon Defendants. Warner-Lambert sued all three defendants for infringement of the '482 patent, which is listed in the Orange Book as covering Neurontin® gabapentin products. Teva, IVAX and Eon each asserted affirmative defenses of unclean hands, and IVAX and Teva additionally asserted patent misuse. Warner-Lambert moved to strike both affirmative defenses.

Judge Hochberg granted Warner-Lambert's motion to strike the unclean hands defense, noting that although courts have discretion in applying the unclean hands doctrine, "in exercising such discretion, 'the primary principle guiding application of the unclean hands doctrine is that the alleged inequitable conduct must be connected, i.e., have a relationship, to the matters before the court for resolution.'" Op. at 14 (quoting *In re New Valley Corp.*, 181 F.3d 517, 525 (3d Cir. 1999) (internal citations omitted)). Given that Teva, IVAX and Eon based their unclean hands defenses on Warner-Lambert's off-label marketing activities only, Judge Hochberg reasoned that these defendants failed to demonstrate a connection between the alleged conduct and the patent infringement matters before the court.

Judge Hochberg also denied Warner-Lambert's motion to strike Teva's and IVAX's patent misuse defense. While Teva and IVAX did not allege per se patent misuse, they did allege that Warner-Lambert intentionally withheld material prior art from the PTO during prosecution of the '482 patent in order to delay issuance of the '482 patent so that they could obtain a subsequent 30-month stay of litigation when this patent was listed in the Orange Book for Neurontin®, and the current Neurontin® ANDA holders were forced to certify against it. Judge Hochberg held that this "alleged manipulation of the patent prosecution process, for the purpose of forestalling generic competition, is conduct that if proven could conceivably persuade a rational fact-finder applying a rule of reason that patent misuse has been established." Op. at 22 (citing *Bausch & Lomb, Inc. v. Allergan, Inc.*, 136 F. Supp. 2d 166, 171 (W.D.N.Y. 2001)).



Countering Jurisdiction, *cont. from page 1*

On December 9, 2009, in *Hoffmann-La Roche, Inc. v. Mylan, Inc., et al.*, Civil Action No. 2:09-cv-01692, 2009 WL 4796736 (D.N.J. Dec. 9, 2009) – a Hatch-Waxman case concerning the oral chemotherapy drug XELODA® – Judge William J. Martini granted Roche’s motion to dismiss Mylan’s defenses and counterclaims related to the unasserted claims of the patent-in-suit and reconciled the above rulings. In so doing, he stated:

This Court understands the Federal Circuit to mean that when a claimant alleges infringement with regard to a claim within a patent, and litigates that claim, its infringement claim creates a live case or controversy under the Declaratory Judgment Act so that a counterclaimant could assert invalidity or noninfringement in regard to that particular patent claim. . . . A counterclaimant seeking a declaratory judgment for invalidity or noninfringement can bring a counterclaim in regard to a particular patent claim even if the claimant does not allege infringement in regard to that particular claim, if and only if the counterclaimant could otherwise establish jurisdiction in regard to that particular patent claim.

Roche, 2009 WL 4796736 at *5 (citing *Webb*, 742 F.2d at 1399 n.8) (first emphasis in original). Judge Martini held that a patentee’s unilateral decision to limit its infringement contentions to certain claims does not, standing alone, divest a court of jurisdiction over the counterclaimant’s declaratory judgment relating to the unasserted claims. However, “once the claimant changes its litigation position, the counterclaimant cannot go forward with its declaratory judgment action in regard to the unasserted claims unless it shows the existence of a live case or controversy.” Judge Martini concluded that Mylan had failed to make the requisite showing as to unasserted claims 1 through 5 of the patent-in-suit after Roche had limited its infringement contentions to claim 6, in accordance with the scheduling order in the case and the newly enacted New Jersey Local Patent Rules.

In addition, Judge Martini, apparently in a case of first impression, held that a partial covenant could divest a court of jurisdiction over counterclaims directed to patent claims covered by the covenant. *Roche*, 2009 WL 4796736 at *7. Judge Martini noted that even though “Federal Circuit authority does not specifically address partial covenants,” Mylan “put forward no principled reason for distinguishing a partial covenant and a covenant covering an entire patent.” *Id.* (citing *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000, 1008 (C.D. Cal. 2008) (“The Federal Circuit has not suggested that a different rule should apply where partial covenants are involved.”)).

Therefore, once a covenant not to sue is provided for any claim, the district court should find that it is divested of jurisdiction. This can be an effective tool for branded manufactures to streamline their case, as well as discovery.

LIFE SCIENCES LITIGATION *review*



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