

memorANDA™

LIFE SCIENCES LITIGATION review

New FDA Requirements for Post-Marketing Studies and Clinical Trials: Patent Strategy

We are happy to bring you this edition of *memorANDA*, a quarterly newsletter providing a strategic look at Hatch-Waxman litigation in the Districts of Delaware and New Jersey.

We hope our readers find *memorANDA* to be an insightful and educational snapshot of the Hatch-Waxman docket, which will provide a deeper understanding of the current and evolving state of the law.

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

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In July 2009, the FDA released a Guidance implementing § 505(o) of the Federal Food, Drug, and Cosmetic Act, a powerful new law authorizing the FDA to require post-marketing studies and clinical trials for drug and biological products found to raise safety concerns. For pioneer drug developers, it means potentially significant new costs of doing business over which they may have little control. To recover these high costs prior to generic launch, pioneers may be well advised to look into a patent strategy.

New Post-Marketing Rules

Prior to 2007, post-marketing studies and clinical trials were something of a rarity, required only for accelerated approvals, deferred pediatric studies or approvals based on animal efficacy studies. Unlike pre-marketing trials, which are strictly regulated by FDA rules, post-approval studies were subject to less rigorous oversight, and information gathered was seldom made public. The Medicare Modernization Act of 2003 gave the FDA greater authority to monitor these trials, but did not expand FDA authority to order them.

In 2007, after several well-publicized drug withdrawals, Congress passed the FDA Administrative Amendments (FDAAA), giving the FDA broad powers to require post-marketing studies or clinical trials for any drug or biologic for which “new safety information” becomes available. The FDAAA defines “new safety information” to include any information derived from a clinical trial, an adverse event report, a post-approval study or peer-reviewed biomedical literature; data derived from a risk evaluation and mitigation strategy (REMS); or scientific data deemed relevant by FDA about a “serious risk,” or the effectiveness of a REMS. “Serious risks” are defined as those that could result in death, risk of death, hospitalization, incapacity, substantial disruption of normal life functions, or birth defects, or require medical or surgical intervention.

The FDA Guidance indicates that NDA applicants will have input on the design and conduct of all studies, however such input is purely discretionary, as the FDA is given authority to impose post-marketing requirements (PMRs) unilaterally, and can pursue legal action against non-compliant manufacturers for unapproved marketing or misbranding of drugs.

Protection for PMR Data

Manufacturers of generic drugs are unlikely to bear the costs of PMRs since most PMRs will be required at the time of NDA approval or during the statutory (usually five year) exclusivity period when generics are not yet on the market. Thus, while PMRs will serve public health, their high costs will be borne almost entirely by pioneers, leaving less money for new drug development. The challenge pioneers face is to develop a strategy for recovering these new costs ahead of generic entry. Essentially, there are two ways for a pioneer to protect information obtained from studies and clinical trials: three year data exclusivity, and patents.

Three year data (or labeling) exclusivity prevents generics from using clinical trial information added to a pioneer drug label. However, the FDA will not, as a matter of public policy, provide three year exclusivity

(cont. on page X)

Recent District of Delaware Hatch-Waxman Opinions

CONCERTA®

Alza Corp., et al. v. Andrx Pharmaceuticals, LLC, et al.

C.A. No. 05-642-JJF

March 30, 2009 Opinion and Order

Plaintiff Alza Corp. and McNeil-PPC sued Andrx for infringement of U.S. Patent Nos. 6,919,373 (“the ’373 patent”) and 6,930,129 (“the ’129 patent”), which cover CONCERTA® extended-release methylphenidate (“MPH”) tablets. Andrx denied that it infringed the patents and sought declaratory judgments that the asserted claims were invalid for obviousness and lack of enablement. Prior to trial, Plaintiffs voluntarily dismissed their claim that Andrx infringed the ’129 patent and Andrx argued that the Court nonetheless retained DJ jurisdiction over the ’129 patent counterclaims.

In a 108-page opinion, Judge Farnan held that the Court lacked subject matter jurisdiction over Andrx’s ’129 patent-related counterclaims because any potential harm to Andrx stemming from the ’129 patent was too speculative. Alza submitted its request to list the ’129 patent in the Orange Book to the FDA on August 16, 2005 – the day the patent issued. On the same day, two entities – Andrx and Impax (not a party to the litigation) – submitted Paragraph IV certifications for the ’129 patent. The order in which the FDA received the request and certifications was unknown, and, accordingly, it was uncertain whether Andrx or Impax would be entitled to a 180-day exclusivity period as first filer of a Paragraph IV for the ’129 patent.

Andrx argued that a party’s Paragraph IV certification may be invalid if received by the FDA prior to the FDA’s receipt of the NDA holder’s request to list the patent at issue in the Orange Book. However, because the timing of the submissions was unresolved at trial and because it was unclear whether the FDA would agree with Andrx’s argument regarding the invalidity of Impax’s Paragraph IV certifications based on premature filing, “the Court conclude[d] that the potential for harm to [Andrx] remain[ed] too speculative to support declaratory judgment jurisdiction.”

Andrx alternatively argued that that the Court had subject matter jurisdiction over the ’129 patent-related counterclaims because Alza had a pending patent application “that may include claims substantially identical to those in the ’129 patent” and that “may eventually pose a litigation threat.” Judge Farnan held that “this potential injury [was] also too speculative to support declaratory judgment jurisdiction over [Andrx’s] counterclaims on the ’129 patent.”

Next, Judge Farnan found that the asserted claims of the ’373 patent were not infringed and were non-obvious. Central to the infringement analysis was the claim term “ascending release rate over an extended period of time,” which was construed to require some release of MPH from the core tablet (excluding MPH liberated from the immediate-release coating) at the first measured time interval. Andrx provided evidence, which Plaintiffs did not effectively rebut, that its formulation did not release MPH from the core tablet until after the first time measurement. Thus, the Court held that Plaintiffs failed to prove infringement of the ’373 patent by a preponderance of the evidence.

Regarding obviousness, the Court found that acute tolerance to MPH was a known problem that was solved by the ’373 patent, but when the ’373 patent was filed, the problem of acute tolerance to MPH “had not gone far beyond the stage of being a hypothesis.” Although the method of “providing increasingly larger doses of the relevant drug” had been previously suggested as a solution to acute tolerance problems with other compounds, and drug formulations that could be used to achieve ascending release rates were known, “the overall scope of the prior art pertaining to overcoming acute tolerance to MPH [was] quite limited. . . . Significantly, the Court [found] no art that suggest[ed] the use of escalating release to overcome acute tolerance to MPH.” Additionally, “the secondary considerations – in particular, the long felt need of others and commercial success – favor a finding of non-

obviousness.” Thus, the ’373 patent was held to be non-obvious.

Finally, the asserted claims of the ’373 patent were held invalid for lack of enablement. “[B]ecause the Court’s construction of ‘ascending release rate’ call[ed] for ‘an appropriate dissolution test,’ the Court’s construction limit[ed] the scope of the claims to dosage forms that may reasonably be subject to such a dissolution test,” including “dosage forms other than oral capsules and tablets.” Applying the seven “undue experimentation” factors articulated by the Federal Circuit in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), Judge Farnan found that the specification did not teach persons of ordinary skill in the art to “prepare non-osmotic tablets and capsules that meet the limitations of the claims without undue experimentation.” Therefore, the Court found that the asserted claims were not enabled.

Note: The Federal Circuit is slated to consider en banc the question of whether 35 U.S.C. § 112, ¶ 1 contains a written description requirement, separate and apart from that of enablement. See *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009).

CRESTOR®

In re: Rosuvastatin Calcium Patent Litigation

MDL No. 08-1949

May 4, 2009 Report and Recommendation

On May 4, 2009, Magistrate Judge Stark issued a Report and Recommendation interpreting claims 6 and 8 of U.S. Reissue Patent RE37,314 (“the ’314 patent”), which covers AstraZeneca’s rosuvastatin calcium product, CRESTOR®. The Court determined that the claim language at issue – “acid in the form of a non-toxic pharmaceutically acceptable salt thereof” – must be construed as a “unitary term” and claim 8, which depends from claim 6, was construed to include the monocalcium bis form of the claimed compound.

Defendants argued that claim 6 could not be construed as a whole. Instead they contended that three claim terms—“acid,” “a non-toxic pharmaceutically acceptable salt” and “in the form of”—each required independent construction. Magistrate Judge Stark disagreed, noting that “a careful review of [the prosecution history] reveals how the claim language came about.” The “in the form of” language was suggested by the PTO; “acid” was distinguishable from “in the form of a salt . . . thereof”; and “a non-toxic pharmaceutically acceptable salt thereof” did not include the limitation that the salt start with a particular compound and then be formed by a specific process, as Defendants posited. Magistrate Judge Stark concluded that “Defendant’s proposed construction of certain elements within Claim 6 amounts to a ‘word-by-word definition, removed from the context of the invention, [that] leads to an overall result that departs significantly from the patented invention.” As a result, claim 6 was construed as a whole.

Regarding claim 8, Defendants argued that Plaintiffs disclaimed the monocalcium bis form of the claimed compound. Originally, claim 8 was written as an independent claim explicitly covering the monocalcium bis compound. Claim 8 was subsequently amended to depend from claim 6. As part of that amendment, the “monocalcium bis” claim language was deleted; however, the prosecution history made clear that in deleting the “monocalcium bis” language, the scope of the claim was not being altered. Moreover, Magistrate Judge Stark noted that if the monocalcium bis form of the claimed compound were disclaimed, this would have resulted in Plaintiffs disclaiming a preferred embodiment of the invention. Unlike in *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1327 (Fed. Cir. 2002), where “the prosecution history require[d] a claim construction that exclude[d] some but not all of the preferred embodiments,” “[t]here [was] no indication in the record that the deletion of the ‘monocalcium bis’ designation...was motivated by a need to overcome a prior art problem.” Thus, claim 8 was interpreted to include the monocalcium bis compound.

District of Delaware Paragraph IV Litigation

Filed April through June 2009

PARTIES	C.A. NO.	DATE	BRAND DRUG	PATENT(S)
<i>Wyeth v. Cadila Healthcare Limited, et al.</i>	09-239	4/9/2009	EFFEXOR® XR	6,274,171; 6,403,120; 6,419,958
<i>Meda Pharms., Inc. v. Sun Pharm. Ind. Ltd.</i>	09-241	4/9/2009	OPTIVAR®	5,164,194
<i>Eli Lilly and Co., et al. v. Barr Laboratories, Inc.</i>	09-272	4/22/2009	ALIMTA®	5,344,932
<i>Bone Care Int'l. LLC, et al. v. Eagle Pharms, Inc.</i>	09-285	4/23/2009	HECTOROL®	5,602,116
<i>Pronova BioPharma Norge AS v. Teva Pharms. USA, Inc., et al.</i>	09-286	4/23/2009	LOVAZA®	5,502,077; 5,656,667
<i>Novartis Pharms. Corp., et al. v. Teva Pharms. USA, Inc.</i>	09-291	4/24/2009	ENABLEX®	5,502,077; 5,656,667
<i>Novartis Pharms. Corp., et al. v. Watson Pharms., Inc., et al.</i>	09-292	4/24/2009	ENABLEX®	6,106,864
<i>Novartis Pharms. Corp., et al. v. Anchen Pharms., Inc.</i>	09-294	4/24/2009	ENABLEX®	6,106,864
<i>Pronova BioPharma Norge AS v. Apotex Corp., et al.</i>	09-304	4/29/2009	LOVAZA®	5,502,077; 5,656,667
<i>Pronova BioPharma Norge AS v. Par Pharm. Inc., et al.</i>	09-305	4/29/2009	LOVAZA®	5,502,077; 5,656,667
<i>Pfizer Inc., et al. v. Teva Pharms USA Inc., et al.</i>	09-307	4/29/2009	LYRICA®	6,197,819; 6,001,876
<i>Pfizer Inc., et al. v. Alphapharm Pty Ltd., et al.</i>	09-308	4/29/2009	LYRICA®	6,001,876
<i>Pfizer Inc., et al. v. Lupin Ltd. et al.</i>	09-309	4/29/2009	LYRICA®	6,197,819; 6,001,876; 5,563,175
<i>Pfizer Inc., et al. v. Sandoz, Inc.</i>	09-310	4/29/2009	LYRICA®	6,197,819; 6,001,876; 5,563,175
<i>Pfizer Inc., et al. v. Actavis Elizabeth LLC, et al.</i>	09-311	4/29/2009	LYRICA®	6,197,819; 6,001,876; 5,563,175
<i>Pfizer Inc., et al. v. Wockhardt Limited et al.</i>	09-312	4/29/2009	LYRICA®	6,197,819
<i>Pfizer Inc., et al. v. Sun Pharma Global Inc., et al.</i>	09-313	4/29/2009	LYRICA®	6,197,819
<i>Pfizer Inc., et al. v. Cobalt Labs., Inc., et al.</i>	09-315	4/29/2009	LYRICA®	6,197,819; 5,563,175
<i>Alcon Research Ltd. v. Barr Laboratories, Inc.</i>	09-318	4/30/2009	TRAVATAN®	5,510,383; 5,631,287; 5,849,792; 5,889,052; 6,011,062
<i>Allergan Inc. v. Barr Laboratories, Inc.</i>	09-333	5/7/2009	LUMIGAN®	5,688,819; 6,403,649
<i>CIMA Labs Inc., et al. v. Barr Labs., Inc., et al.</i>	09-349	5/15/2009	FAZACLO™	6,024,981; 6,221,392
<i>Stiefel Laboratories Inc. v. KV Pharmaceutical Co.</i>	09-376	5/28/2009	DUAC®	5,466,446
<i>Medicis Pharm. Corporation v. Ranbaxy Inc., et al.</i>	09-435	6/11/2009	SOLODYN®	5,908,838
<i>Pfizer Inc., et al. v. Mylan Inc. et al.</i>	09-441	6/15/2009	LIPITOR®	5,969,156; 6,087,511; 6,274,740
<i>Dey LP, et al. v. Teva Parenteral Medicines Inc., et al.</i>	09-467	6/25/2009	PERFOROMIST®	6,667,344; 6,814,953; 7,348,362; 7,462,645
<i>Daiichi Sankyo Co. Ltd., et al. v. Apotex Inc., et al.</i>	09-470	6/26/2009	EVOXAC®	5,340,821

Recent Hatch-Waxman Decisions from the Federal Circuit

ACTONEL®: *Proctor & Gamble Co. v. Teva Pharms. USA, Inc.*
No. 2009-1404, -1405, -1406, May 13, 2009 Opinion

The Court of Appeals for the Federal Circuit, in a May 13, 2009 opinion by the Honorable Marilyn L. Huff of the U.S. District Court for the Southern District of California, sitting by designation, affirmed the U.S. District Court for the District of Delaware's determination that Proctor & Gamble's patent claims directed to the compound risedronate were not invalid as obvious. Explaining that even after KSR, "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound," the Federal Circuit affirmed the district court's determination that a person of ordinary skill in the art would not have had a reason to modify the prior art compound to make risedronate. The Federal Circuit also affirmed the district court's determinations that, even if Teva had established a prima facie case of obviousness, Proctor & Gamble had introduced sufficient rebuttal evidence of unexpected results, and that secondary considerations, such as long-felt need, supported a finding of non-obviousness.

The Federal Circuit also affirmed the district court's determination that the patent claims were not invalid for obvious-type double patenting, finding that Teva had not presented clear and convincing evidence of overlap between the claims of the patent-in-suit and an expired patent.

PROTONIX®: *Altana Pharma AG et al. v. Teva Pharms. USA, Inc. et al.*
No. 2009-1039, May 14, 2009 Opinion

In a May 14, 2009 opinion by the Honorable T. John Ward of the U.S. District Court for the Eastern District of Texas, sitting by designation, the Court of Appeals for the Federal Circuit affirmed the U.S. District Court for the District of New Jersey's decision denying Altana's motion for preliminary injunctive relief to prevent infringement of U.S. Patent No. 4,758,579 ("the '579 patent"), directed to the compound pantoprazole. The Federal Circuit affirmed the district court's determination that Altana had failed to establish a likelihood of success on the merits. Altana argued that the District Court applied an incorrect standard in the likelihood of success analysis by placing the burden on Altana to show that Teva's invalidity defense lacked merit, rather than placing the burden on Teva to establish a substantial question of invalidity. The Federal Circuit rejected Altana's argument, noting that "the precedent of this court holds that if the accused infringer raises a substantial question concerning validity, enforceability, or infringement (i.e. asserts a defense that [the movant] cannot show lacks substantial merit) the preliminary injunction should not issue."

The Federal Circuit went on to affirm the district court's preliminary obviousness findings and the district court's finding that Altana had failed to demonstrate irreparable harm, holding that these determinations were not clearly erroneous.

Judge Newman, writing in a concurring opinion, agreed that the discretionary weight afforded the District Court required affirmance of the denial of injunction. Judge Newman added that evidence presented to the District Court, in her view, did not establish invalidity of the '579 patent, citing the U.S. Supreme Court's opinion in *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418 (2006) for the proposition that "the burdens at the preliminary injunction stage track the burdens at trial." Notably, Judge Newman's concurrence reprises the view of the burden of proof applicable to the likelihood of success analysis that she previously expressed writing for the majority in *Abbott Labs. v. Sandoz, Inc.*, No. 2007-1300 (Fed. Cir. October 21, 2008), while Judge Gajarsa, who joined District Judge Ward in the present Opinion, dissented from the majority in *Abbott Labs.* For a more detailed discussion of the *Abbott Labs* Opinion and its potential impact on Hatch-Waxman litigation, please see the cover story of the Q4 2008 edition of *memorANDA*, available at <http://www.fr.com/memoranda>.

Recent District of Delaware Hatch-Waxman Opinions, cont.

CRESTOR®
In re: Rosuvastatin Calcium Patent Litigation
MDL No. 08-1949
April 27, 2009; May 7, 2009; May 28, 2009 Memorandum Orders

In separate Memorandum Orders, Magistrate Judge Stark denied a request to compel the production of documents and granted in part/denied in part two requests to compel the production of documents.

In an April 27, 2009 Order, Magistrate Judge Stark denied Defendants' motion to compel the production "of documents reflecting the assignment within [Plaintiffs] IP Department of each case or project number to which department members were assigned, as well as what applications within each project number they were assigned, for 1991, 1992 and 1993," because the request was broad, the production would be highly burdensome (involving translations and privilege review) and the documents were only marginally relevant.

In a May 7, 2009 Order, Defendants' motion to compel Plaintiffs to produce "all documents relating to their efforts to 'co-market' and 'co-promote' Crestor, including all due diligence communications" was granted in part and denied in part. Although finding that the Defendants' request was overbroad, Magistrate

Judge Stark accepted Plaintiffs' alternative proposal, which involved Plaintiffs' searching document repositories and documents in the possession of key senior level custodians and producing those documents: "(i) relating to communications between [Plaintiffs] and potential co-promoters or co-marketers of Crestor rosuvastatin calcium product to the extent such communications reflect the views of such third parties regarding either the clinical or pharmacological properties of Crestor or the strength of the '314 patent-in-suit; (ii) whatever due diligence documents were made available to such third parties expressing an interest in co-marketing or co-promoting Crestor ...; and (iii) any co-promotion or co-marketing agreements limited to Crestor rosuvastatin actually signed with any such third party."

In a May 28, 2009 Order, Magistrate Judge Stark granted in part and denied in part Plaintiffs' motion to compel production of certain research and development documents. Defendant was ordered to produce: (i) unredacted versions of research and development documents that were already provided to Plaintiffs in redacted form, (ii) unredacted versions of all responsive documents already in the possession of Defendant's counsel, and (iii) unredacted versions of documents responsive to a related subpoena. Defendant was not, however, required to conduct additional document searches unless Plaintiffs demonstrated good cause for the same.

District of New Jersey Paragraph IV Litigation

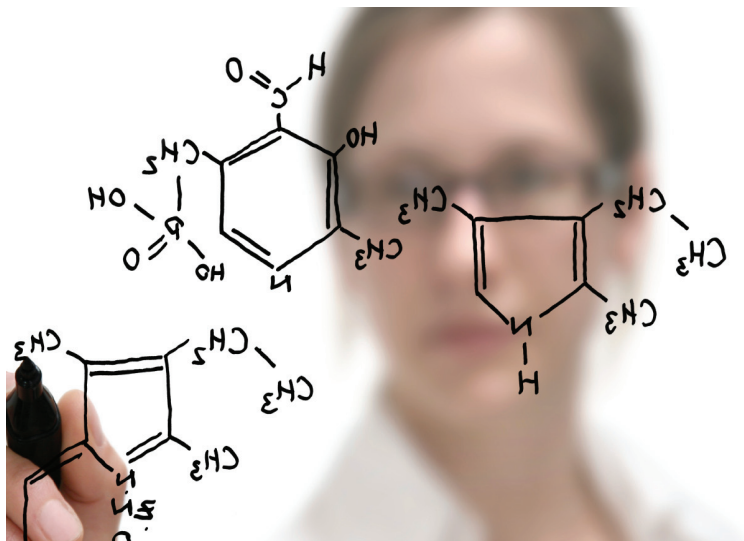
Filed April through June 2009

PARTIES	C.A. NO.	DATE	BRAND DRUG	PATENT(S)
<i>Abbott Laboratories, et al. v. Sandoz, Inc., et al.</i>	09-1587	4/2/2009	ZEMPLAR®	5,246,925; 5,587,497; 6,136,799; 6,361,758
<i>Hoffmann-La Roche, Inc. v. Mylan, Inc., et al.</i>	09-1692	4/8/2009	XELODA®	5,472,949
<i>Warner Chilcott Company, LLC, et al. v. Mission Pharmacal Co.</i>	09-2025	4/30/2009	NATAFORT®	6,521,247
<i>Warner Chilcott Company, LLC, et al. v. Midlothian Laboratories, LLC</i>	09-2026	4/30/2009	NATAFORT®	6,521,247
<i>Pfizer, Inc., et al. v. Sandoz, Inc.</i>	09-2052	4/30/2009	LYRICA®	6,197,819; 6,001,876; 5,563,175
<i>Pfizer, Inc., et al. v. Wockhardt Ltd., et al.</i>	09-2069	4/30/2009	LYRICA®	6,197,819
<i>Pfizer, Inc., et al. v. Sun Pharma Global, Inc., et al.</i>	09-2070	4/30/2009	LYRICA®	6,197,819
<i>Warner Chilcott Labs Ireland, et al. v. Mylan Pharm., Inc., et al.</i>	09-2073	5/1/2009	DORYX®	6,106,864
<i>Novo Nordisk, Inc., et al. v. Mylan Pharmaceuticals, Inc.</i>	09-2445	5/20/2009	PRANDIN®	6,677,358
<i>Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Sandoz, Inc.</i>	09-2863	6/4/2009	ORTHO TRI-CYCLEN LO®	6,214,815
<i>Medicis Pharm. Corp. v. Glenmark Generics Inc., USA, et al.</i>	09-3010	6/19/2009	VANOS®	6,765,001; 7,220,424
<i>Reckitt Benckiser, Inc., et al. v. Tris Pharma, Inc.</i>	09-3125	6/26/2009	DELSYM®	5,980,882

Recent District of New Jersey Hatch-Waxman Opinions

ARICEPT®

Eisai Co., Ltd. v. Teva Pharmaceuticals USA
 C.A. Nos. 05-05727-GEB-ES; 07-05489-HAA-ES
 April 17, 2009 Opinion and Order



Eisai brought suit against Teva in December 2005 following Teva's submission of a Paragraph IV certification alleging that Eisai's U.S. Patent No. 4,895,841 ("the '841 patent") was invalid for obviousness. The parties litigated the issue of obviousness for two years. In April 2007, Teva

stipulated that its proposed generic would infringe claims of the '841 if not found invalid or unenforceable. In December 2007, Teva amended its Answer to add the affirmative defense of unenforceability of the '841 patent due to inequitable conduct but removed all references to invalidity. At a conference before Magistrate Judge Salas in late December 2007, Teva confirmed that it was no longer asserting obviousness as a defense, and on January 2, 2008, Magistrate Judge Salas issued a letter order stating that "[p]ursuant to Defendants' Amended [Answer] and on-the-record statements, they are no longer asserting the affirmative defense of obviousness." Eisai requested that Teva sign a stipulation stating that it would not assert that the '841 patent "is invalid or fails to satisfy the requirements of patentability in this or any other litigation or proceeding." Teva, however, refused. Eisai then moved for judgment on the pleadings that the '841 patent is valid.

The Court denied Eisai's motion on the basis that it sought judgment on an issue that was no longer disputed or even raised in the case: "Eisai offers no authority for the notion that this Court may grant judgment to a plaintiff solely on an affirmative defense, particularly where the plaintiff did not file a claim for a declaratory judgment on the issue and where the defendant has explicitly withdrawn the defense. . . . This Court cannot issue judgment, or partial judgment, on an issue not presented in this case." The Court rejected Eisai's argument that statutory language of the Hatch Waxman Act places patent invalidity at issue in every case, irrespective of whether it is raised as an issue by the litigants, holding instead that "nothing in the Hatch-Waxman Act allows for judgment in a plaintiff's favor on non-existent affirmative defenses."

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

ARICEPT®

Eisai Co., Ltd. v. Teva Pharmaceuticals USA

C.A. Nos. 05-05727-GEB-ES; 07-05489-HAA-ES

June 26, 2009 Opinion and Order

After initially asserting the defense of obviousness of Eisai's '841 patent, Teva moved in May 2007 to amend its answer to allege inequitable conduct based on Eisai's nondisclosure to the PTO of four families of co-pending patent applications. Magistrate Judge Salas permitted Teva to allege inequitable conduct based on Eisai's failure to disclose one family of co-pending applications – collectively, “the ‘459 application” – but denied Teva's motion to allege inequitable conduct for failure to disclose three other families of applications on grounds that they were not material. Teva's amended answer did allege inequitable conduct for failure to disclose the ‘459 application, but also included allegations that non-disclosure of the other three families of applications evidenced a “pattern of non-disclosure,” probative of intent to deceive the PTO. Teva did not allege that the three other families were material. Eisai moved to strike Teva's allegations regarding the three other families.

Magistrate Judge Salas reasoned that Teva was required to plead intent to deceive to PTO with particularity under Federal Rule of Civil Procedure 9(b). This, in turn, required Teva to allege that the undisclosed references were material because “without alleging materiality, Teva ha[d] no basis upon which to assert that the co-pending applications should have been disclosed to the patent examiner.” Because Teva did not allege materiality of the three other families, the Magistrate Judge granted Eisai's motion to strike, and Teva appealed.

In an Opinion and Order dated June 26, 2009, Judge Ackerman reversed the order granting Eisai's motion to strike, stating that “[i]n asserting prior non-disclosures solely to help show intent, a party need not allege those prior non-disclosures were material.” The Court reasoned that under Rule 9(b) “intent . . . and other conditions of a person's mind may be alleged generally” and that “[c]ourts have only applied a particularity standard to the materiality element.” Additionally, although the Court observed that Eisai's alleged pattern of nondisclosure alone was unlikely to show intent to deceive, at the pleading stage, Teva's alleged “pattern of non-disclosure” was not “so irrelevant to intent that pleadings regarding that evidence should have been stricken.”

Note: the Court issued an Amended Opinion and Order on July 6, 2009. The Amended Opinion and Order differed from the original Opinion and Order issued on June 26 only in its identification of prior Orders issued by the Magistrate Judge.

Note: the Federal Circuit's opinion in Exergen Corp. v. Wal-Mart Stores, Inc., issued on August 4, 2009, provides additional guidance on the pleading standards for inequitable conduct allegations, including the particularity requirements applicable to the intent element of inequitable conduct pleadings.

DETROL®

Pfizer Inc. v. Ivax Pharmaceuticals, Inc.

C.A. No. 07-00174-DMC-MF

June 29, 2009 Opinion

Judge Cavanaugh's June 29, 2009 Opinion in this matter recounts a series of tragic events not commonly seen in Hatch-Waxman litigation. Teva retained pharmacologist John P. Long, Ph.D. as an expert witness in this matter. Dr. Long provided opening and reply reports

on the obviousness of Pfizer's U.S. Patent No. 5,382,600 (“the ‘600 patent”), and was deposed by Pfizer in November, 2006. Unfortunately, Dr. Long passed away on June 10, 2007. Teva notified Pfizer of Dr. Long's passing twenty months later, on February 9, 2009. Pfizer retained Rodney A. Appell, M.D. as a testifying expert witness and served his report upon Teva on January 27, 2006. Unfortunately, Dr. Appell passed away on January 19, 2009. Pfizer notified Teva of Dr. Appell's passing days later.

Pursuant to the scheduling order entered in this matter, the close of expert discovery occurred on April 7, 2008. In March 2009, Teva proposed a stipulation permitting the admission of the reports and deposition testimony of the late Drs. Long and Appell at trial, which would obviate the need to retain new experts with little time remaining before trial, then scheduled for June 16, 2009. Pfizer agreed and the parties executed the stipulation on April 21, 2009.

On April 24, Teva submitted a curriculum vitae and confidentiality declaration (signed on February 25, 2009) to Pfizer for one Dr. Cannon, and on May 4, Teva provided Pfizer with a preliminary trial witness list which included Dr. Cannon. On May 8, Teva sought leave to present live testimony of Dr. Cannon at trial – in addition to the stipulated admission of Dr. Long's expert report – and served Pfizer with an expert report from Dr. Cannon which consisted of “revisions” to the report previously submitted by Dr. Long. On the same day, Pfizer moved for a protective order seeking to preclude Dr. Cannon's access to Pfizer's confidential information.

Judge Cavanaugh rejected Teva's request to present live testimony from Dr. Cannon at trial, characterizing the identification of Dr. Cannon as a proposed expert nearly two years after Dr. Long's death, more than one year after the close of expert discovery, and only five weeks before the original trial date as a “flagrant disregard” of the scheduling order, warranting denial of the relief sought. Rather than rely solely on judicial discretion, however, the Court also evaluated the four factor test for precluding testimony under the Third Circuit standard announced in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 55 F.3d 894 (3d Cir. 1977) (1) prejudice to party against whom testimony is offered, 2) ability to cure prejudice, 3) disruption of orderly and efficient trial, 4) bad faith or willfulness in failing to comply with a court order). The Court found that Pfizer would be prejudiced if forced to rely solely on the reports and deposition testimony of the deceased Dr. Appell while Teva was permitted to introduce live testimony from Dr. Cannon, and that allowing Dr. Cannon to intercede in this action would interfere with Pfizer's trial preparation and presentation. While stopping short of finding that Teva acted in bad faith, the Court concluded that “the inequity of the untimely disclosure of Dr. Cannon precludes the grant of leave [to admit his testimony] by this Court.”

ELOXATIN®

Sanofi-Aventis U.S. LLC v. Sandoz, Inc. et al.

C.A. No. 07-02762-JAP-DEA (consolidated)

June 18, 2009 Opinion

Multiple defendants in this consolidated proceeding moved for summary judgment of non-infringement of U.S. Patent No. 5,338,874 (“the ‘874 patent”) and Sanofi-Aventis cross-moved for summary judgment of infringement. By an Opinion issued on June 18, 2009, the Court granted the defendants' motions for summary judgment and denied Sanofi-Aventis' cross-motion.

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

The '874 patent claims "optically pure [oxaliplatin]," which is a levorotatory enantiomer. The specification of the '874 patent teaches a method of separating oxaliplatin from a racemic mixture also including the undesired dextrorotatory enantiomer using High Performance Liquid Chromatography ("HPLC"). The Court construed the claims as product-by-process claims limited to optically pure oxaliplatin produced through the use of the HPLC method recited in the specification. Although the claims of the '874 patent are not facially limited to optically pure oxaliplatin produced through the use of HPLC, the Court concluded that repeated attribution of the claimed optically pure oxaliplatin to the recited HPLC process, as well as the prosecution history of the '874 patent and positions that Sanofi-Aventis took in litigation, made clear that the recited HPLC process was an essential part of the claimed invention. Because there was no dispute that the oxaliplatin products that are the subject of the defendants' ANDAs were produced using methods other than HPLC, the Court granted summary judgment of non-infringement.

Note: Final judgment in this matter was entered on June 30, 2009, and Sanofi-Aventis filed notice of appeal to the Federal Circuit on the same day.

Note: the Federal Circuit's opinion in *Abbot Labs. v. Sandoz, Inc.*, issued on May 18, 2009, provides additional guidance on the construction of product-by-process claims.

ELOXATIN®

Sanofi-Aventis U.S. LLC v. Sandoz, Inc.

C.A. No. 07-02762-JAP-DEA (consolidated)

July 1, 2009 Opinion

On June 18, 2009, the Court entered summary judgment of non-infringement of U.S. Patent No. 5,338,874 against plaintiff Sanofi-Aventis. Sanofi-Aventis then moved to delay entry of judgment, which the Court denied on June 25. At the hearing on the motion to delay entry of judgment, Sanofi-Aventis orally moved to stay entry of Final Judgment pending appeal pursuant to Federal Rule of Appellate Procedure (8)(a)(1)(A). Following an expedited briefing schedule, the Court, by a July 1 Opinion, denied that motion as well.

The Court first noted that the relief requested by Sanofi-Aventis is properly sought under Fed. R. Civ. P. 62(c) rather than Fed. R. App. P. 8, but that the standards under either rule were the same. The burden of meeting the Rule 62(c) standard for injunctions pending appeal is a "heavy one," involving evaluation of four factors: (1) a strong showing of likely success on the merits, (2) irreparable injury absent a stay, (3) injury to other interested parties, and (4) public interest.

With respect to the first factor, the Court found that Sanofi-Aventis relied on the same arguments in showing a strong likelihood of success on the merits that the Court found insufficient so defeat summary judgment of non-infringement, and accordingly that the first factor weighed against entry of a stay. The Court found no likelihood of injury that supported entry of the requested stay. Finally, the Court found that the intent of the Hatch-Waxman Act to bring less expensive generic products to market earlier favored denial of Sanofi-Aventis' request.

FAMVIR®

Novartis Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.

C.A. No. 08-03853-DMC-MF

April 28, 2009 Opinion

Roxane filed an ANDA seeking approval to market a generic version of Novartis' FAMVIR® product and Novartis brought an infringement suit against Roxane asserting U.S. Patent No. 5,246,937 ("the '937 patent"), demanding trial by jury and requesting that the Court find the case exceptional. Roxane moved to strike Novartis' demand for jury trial and its exceptional case pleadings.

Novartis had previously filed suit against Teva, asserting the '973 patent in response to Teva's having filed an earlier ANDA for FAMVIR®. *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, C.A. No. 05-01887 (DNJ April 8, 2005). In opposing Roxane's motion to strike its request for jury trial, Novartis argued that Roxane intended to seek consolidation of the present case with the co-pending Teva case, which was scheduled for trial by jury on the issue of the '937 patent's invalidity. The Court granted Roxane's motion with respect to Novartis' jury trial demand, noting that Novartis' sole remedy against Roxane under the Hatch-Waxman act is injunctive relief and citing the "well settled" proposition that "a patentee seeking only injunctive relief does not have a right to a trial by jury." The court further noted that, because the present case had not in fact been consolidated with the co-pending Teva action, any argument relying on such consolidation was premature.

In support of its motion to strike Novartis' exceptional case pleadings, Roxane argued that the mere filing of an ANDA is insufficient to support a claim for willful infringement, citing *Glaxo Group Ltd. V. Apotex Inc.*, 376 F.3d 1339 (Fed. Cir. 2004). However, the Court denied Roxane's motion, relying on the Federal Circuit's opinion in *Yamanouchi Pharm. Co. Ltd. v. Danbury Pharm., Inc.*, 231 F.3d 1286 (Fed. Cir. 2000), which upheld a patentee's claims for attorney fees following a showing that a defendant's ANDA filing was "wholly unjustified," and that the defendant had committed misconduct. The Court noted that "further litigation in this case may produce proofs showing that [Roxane's] ANDA certification was baseless or exposing some other litigation misconduct supporting [Novartis'] claim."

Note: For a discussion of the treatment of exceptional case and willful infringement pleadings in Hatch-Waxman litigation in the District of Delaware, please see the cover story of the Q3 2008 edition of *memorANDA*, available at <http://www.fr.com/memoranda>.

FLOXIN OTIC®

Daiichi Sankyo, Inc. v. Apotex Inc.

C.A. No. 03-00937-SDW-MCA

May 18, 2009 Opinion

Daiichi brought suit against Apotex for infringement of U.S. Patent No. 5,401,741 ("the '741 patent") in March 2003, and Apotex counterclaimed for invalidity, non-infringement, unenforceability due to inequitable conduct, monopolization, attempted monopolization, and tortious interference with a prospective business relation. In September 2005, Apotex's counterclaims for monopolization, attempted

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

monopolization, and tortious interference were severed and stayed pending trial. Issues of infringement, invalidity, and unenforceability of the '741 patent were tried in November 2005 during a nine-day trial. In a written opinion dated August 2, 2006, the Court found the '741 patent valid and infringed, and held that Daiichi had not committed inequitable conduct.

On September 12, 2007, the Federal Circuit reversed the Trial Court, holding the '741 patent invalid as obvious and stating that "we need not reach Apotex's arguments that the '741 patent was anticipated or procured through inequitable conduct." *Daiichi v. Apotex*, 501 F.3d 1254 (Fed. Cir. 2007). Following the Federal Circuit's decision on appeal, Apotex filed amended counterclaims alleging monopolization, attempted monopolization, tortious interference, and unjust enrichment. Daiichi moved to dismiss all of Apotex's counterclaims pursuant to Fed. R. Civ. P. 12(b)(6).

The Court granted Daiichi's motion to dismiss, noting that all of Apotex's counterclaims were based on the same factual allegations of fraud and misrepresentation that Apotex previously asserted as a basis for a finding of inequitable conduct. Because the Trial Court previously determined that Daiichi had not committed inequitable conduct, and because that determination was not overturned on appeal, the Court relied on Federal Circuit case law holding that Apotex's monopolization claims could not survive. *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987) ("failure to establish inequitable conduct precludes a determination that [plaintiff] had borne its greater burden of establishing the fraud required to support its [monopolization] claim").

The Court rejected Apotex's argument that nothing in the Trial Court's opinion survived because the Federal Circuit reversed "the judgment of the District Court." Noting that the Federal Circuit opinion explicitly "did not reach Apotex's arguments that the '741 patent was anticipated or procured through inequitable conduct," the Court concluded that "to hold that the Federal Circuit's reversal eviscerates the inequitable conduct portion of that decision – even though it expressly declined to reach it – exceeds the bounds of reason."

LEVAQUIN®

Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharmaceutical, Inc.

C.A. No. 06-04999-GEB-TJB

May 1, 2009 Memorandum Opinion

By a memorandum opinion issued on May 1, 2009, Judge Brown discussed the interplay between the USPTO and the FDA in patent term extensions, and provided guidance on deference owed administrative decisions to extend patent terms.

On December 28, 1990, the FDA approved plaintiff Daiichi Sankyo's application to market ofloxacin, a racemic mixture of two constituent enantiomers, which was then covered by U.S. Patent No. 4,382,892, issued on May 10, 1983. During the early development of ofloxacin, Daiichi researchers unsuccessfully attempted to separate the mixture into its constituent enantiomers. However, in 1985, Daiichi scientists succeeded in synthesizing the levorotatory enantiomer of ofloxacin – known as levofloxacin – in its pure form using novel synthetic methods. Research with levofloxacin showed that it was less toxic and twice as active as ofloxacin. Daiichi applied for and eventually obtained U.S. Patent No. 5,053,407 ("the '407 patent") covering levofloxacin, and on December 20, 1996, the FDA approved levofloxacin for use in

the U.S. Although the '407 patent would have expired, at the time of its issuance, on October 1, 2008, Daiichi was granted a term length extension pursuant to 35 U.S.C. § 156. The term extension granted by the USPTO was 810 days, which moved the expiration date from October 1, 2008 to December 20, 2010.

On July 14, 2006, Lupin submitted an ANDA seeking approval to market a generic equivalent of Daiichi's levofloxacin product (licensed and sold in the U.S. by Ortho-McNeil under the name LEVAQUIN®), certifying that it would not infringe the '407 patent when marketed after October 1, 2008, which Lupin understood to be the '407 patent's expiration date. Ortho-McNeil then brought suit for infringement of the '407 patent pursuant to the Hatch-Waxman Act.

The parties stipulated to the validity, enforceability, and infringement of the '407 patent by Lupin's proposed generic levofloxacin product and contested only the validity of the term length extension. Lupin moved for summary judgment that the term length extension of the '407 patent was invalid, and Ortho-McNeil cross-moved for summary judgment that the extension was valid.

The Court, first acknowledging the "great deference" to which the USPTO's decision on entitlement to a term length extension is afforded, and the clear and convincing evidence required to invalidate a term length extension, noted that Lupin's sole argument for invalidating the term length extension was that the USPTO, acting in concert with the FDA, had improperly determined that levofloxacin was a "product" within the meaning of 35 U.S.C. § 156. Noting further that the USPTO and FDA had consistently determined that enantiomers were "products" within the meaning of § 156 in numerous other cases, the Court rejected Lupin's argument that the USPTO had "uniformly misapplied that statute." The Court denied Lupin's motion and granted Ortho-McNeil's cross motion, declaring the '407 patent's term length extension valid.



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

PROTONIX®

Altana Pharma AG v. Teva Pharms. USA

C.A. No. 04-02355-JLL-CCC

June 19, 2009 Letter Order

Plaintiff Altana requested that the Court permit it to substitute a new gastroenterology expert, Dr. Sloan, for a previously-designated expert, Dr. Elfant, on the ground that Dr. Elfant would be unavailable at trial due to a confidential legal obligation. The Court, in its discretion, and finding that Altana had shown good cause, granted its application to substitute Dr. Sloan for Dr. Elfant.

Although Dr. Elfant had previously prepared an expert report in the case, the Court ordered that Dr. Sloan would be permitted to submit a report limited to the same subject matter as Dr. Elfant's report, but permitting Dr. Sloan to add additional supplemental testimony regarding reduced risk of drug-drug interactions. Although Dr. Sloan's proposed supplemental testimony pertained to the results of a recently-completed study, the Court held that Dr. Elfant's report made reference to drug-drug interactions, Dr. Sloan's supplemental data would merely provide additional empirical support for previously disclosed theories, and thus would not prejudice the Defendants.

PULMICORT RESPULES®

AstraZeneca LP v. Apotex, Inc.

C.A. No. 09-01518-RMB-AMD

May 14, 2009 Opinion, May 22, 2009 Supplemental Opinion

In an opinion dated May 14, 2009 and a supplemental opinion and order dated May 22, 2009, the Court granted AstraZeneca's motion for a preliminary injunction preventing Apotex from marketing its generic version of AstraZeneca's PULMICORT RESPULES®. AstraZeneca had filed suit against Apotex earlier this year alleging that the sale of Apotex's generic product would directly infringe AstraZeneca's product claims covering budesonide inhalation suspension "kits" with instructions for once-daily dosing and would indirectly infringe AstraZeneca's claims covering methods of treatment that employ once-daily dosing.

The District Court found that Apotex raised a substantial question concerning the validity of AstraZeneca's product ("kit") claims. According to the Court, the only difference between those claims and prior art budesonide products was the inclusion of an instruction for once-daily dosing, which was insufficient to impart patentability. The District Court rejected Apotex's argument that it had raised a substantial question concerning the validity of AstraZeneca's method claims, finding that the prior art did not disclose once-daily dosing of a "budesonide composition" within the meaning of the claims.

Finding that Apotex had failed to raise a substantial question concerning the validity of AstraZeneca's method claims, the Court then concluded that AstraZeneca had shown a likelihood that Apotex would induce infringement of those claims under 35 U.S.C. § 271(b). Although Apotex had removed all express references to "once-daily" dosing from its label, the label stated that "[o]nce the desired clinical effect is achieved, consideration should be given to tapering to the lowest effective dose," which the Court found could, in some circumstances, result in dosing once daily. The Court rejected Apotex's argument that it lacked the specific intent to cause direct infringement because the FDA required inclusion of the downward titration language. In so doing, the Court found that Apotex had not exhausted all of its avenues for appealing the FDA's decision to require that language. However, the Court noted that its finding of specific intent to cause infringement might have been different if Apotex "had done everything it could have done to dispute the

FDA's decision and was still unable to create a label that both complied with the FDA requirements and respected AstraZeneca's patent."

The Court then found that AstraZeneca made a sufficient showing of irreparable harm in certain incalculable damages, an adverse effect on employees, and a loss of goodwill. The Court also found that the balance of the hardships tipped in favor of AstraZeneca, since AstraZeneca would have a difficult time restoring its pre-generic launch market position if the injunction was not granted. After finding the public interest did not favor either side, the Court granted the preliminary injunction.

STALEVO®

Orion Corp. v. Sun Pharmaceutical Industries, Ltd.,

C.A. Nos. 07-05436-MLC-DEA; 08-05545-MLC-DEA

June 12, 2009 Memorandum Opinion and Order

In a Memorandum Opinion, the Court denied Plaintiff/Counterclaim Defendant Orion's motion to disqualify Sun's expert. Sun's proposed expert had previously been employed by Orion for sixteen years and Orion argued that, while he was an employee, he received confidential information that was relevant to the litigation. The Court denied Orion's motion, applying a two part test for determining whether an expert who had a prior relationship with a party should be disqualified. The first part of the test requires a factual finding that the moving party had an objectively reasonable belief that a confidential relationship existed between itself and the proposed expert. The Court found that Orion had an objectively reasonable belief of a confidential relationship because the proposed expert had entered into a written confidentiality agreement with Orion during his employment. The second part of the test requires a factual finding that the proposed expert actually received confidential information "directly relating to or impacting the litigation in issue." The Court found that Orion failed to establish that the proposed expert actually received information regarding the specific pharmaceutical products at issue in the litigation. It therefore denied Orion's motion.

STRATTERA®

Eli Lilly & Co. v. Actavis Elizabeth, LLC et al.

C.A. No. 07-03770-DMC-MF

May 21, 2009 Opinion

Eli Lilly brought suit against multiple defendants for their submission of ANDAs seeking approval of generic versions of Lilly's STRATTERA® product. Lilly alleged that the defendants would infringe U.S. Patent No. 5,658,590 ("the '590 patent") under 35 U.S.C. §§ 271(a), (b), and/or (c) should the FDA at some point approve the ANDAs. Because all of the claims of the '590 patent are method of use claims requiring that atomoxetine be administered to a patient in need of treatment and in an effective dose, the defendants moved for partial summary judgment of no direct infringement under 35 U.S.C. § 271(a).

The Court, by a May 21, 2009 Opinion, granted the defendants' motion. Citing Federal Circuit precedent from Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003) which considered patent claims covering "administering a therapeutically effective amount" of a drug, the Court noted that "the activities of pharmaceutical manufacturers are fundamentally different than prescribing physicians and, therefore, pharmaceutical companies cannot directly infringe such method of treatment claims." Accordingly, the Court held that the defendants would not, merely by selling a product, directly infringe Lilly's method of treatment claims requiring "administering to a patient in need of ADHD treatment an effective amount of [a]tomoxetine" under 35 U.S.C. § 271(a).

Post-Marketing: Patent Strategy *(cont'd from page 1)*

for any labeling information that deals with drug safety, a term that broadly includes warning, contra-indications, precautions and adverse drug reactions. As a practical matter, this means that data exclusivity will not be available for most PMR information added to the label because PMR trials are expected to focus mainly on safety investigations.

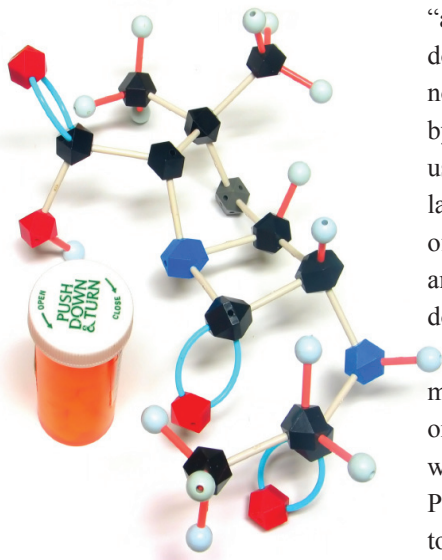
Patents, on the other hand, protect new discoveries for up to 21 years from the date a provisional patent application is filed with the US Patent Office, and are available to protect novel and non-obvious methods of using a drug, including those dealing with safety. However, when a discovery is made during trials, it is not always clear who the inventors are, thus it is important to include assignment or license provisions in agreements with medical professionals performing clinical studies or trials in which patents may be desired.

Even if effective patent protection is obtained, protected labeling language may be susceptible to being “carved out” by generics seeking to avoid infringement. FDA regulations generally require a generic drug label to be identical to the pioneer label, except where

“aspects of the [pioneer] labeling are protected by patent or by exclusivity and such differences do not render [the generic drug] less safe or effective than the [pioneer] drug for all remaining non-protected conditions of use.” Generics often attempt to circumvent pioneer method patents by seeking FDA approval to delete, or “carve out,” label instructions pertaining to the protected use, and will typically succeed when carving out new indications that are added to a pioneer’s label. However, when evaluating a generic “carve out” request, the FDA considers whether any of the protected language is needed to make the generic “as safe and effective as the pioneer” for any of the conditions of use that are on the generic label. For this reason, the carve-out strategy does not work when the protected use deals with safety or efficacy of the drug.

As noted above, patentable discoveries impacting safety or efficacy and drafted as method claims can appear on drug labels in the form of warnings, precautions, contraindications or adverse drug reactions and possibly even in the dosage/administration instructions. Pioneers who are cognizant of these rules will see the opportunity for patent protection when designing PMR trials. However, this means that patent counsel and clinical trial designers must work together with the regulatory department to determine what ultimately will go on the drug label.

-- Terry Mahn is a Principal at Fish & Richardson P.C.



LIFE SCIENCES LITIGATION *review*



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