

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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| | X | |
| ORTHO-MCNEIL | X | |
| PHARMACEUTICAL, INC., | X | |
| | X | |
| Plaintiff, | X | |
| | X | Civil Action Nos. 04-1689 and 06-757 |
| | X | Consolidated Cases |
| v. | X | |
| | X | OPINION |
| MYLAN LABORATORIES INC., et al., | X | |
| | X | |
| Defendants. | X | |
| | X | |

CHESLER, District Judge

This matter comes before the Court on the motion by Plaintiff Ortho-McNeil Pharmaceutical, Inc. (“Ortho”) for a preliminary injunction, pursuant to FED. R. CIV. P. 65, enjoining Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively “Mylan”) from marketing or selling topiramate products. For the reasons stated below, Ortho’s motion for a preliminary injunction is **GRANTED**.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. Plaintiff Ortho claims that, on April 23, 1985, the United States Patent and Trademark Office (“PTO”) issued United States Patent No. 4,513,006 (the “’006 patent”) to McNeilab, Inc. as assignee of inventors Bruce E. Maryanoff and Joseph F. Gardocki. (Compl. ¶ 10.) McNeilab is Ortho’s corporate predecessor. (Id.) The claims of the ’006 patent cover the drug topiramate, pharmaceutical

compositions containing topiramate, and a method of using topiramate to treat convulsions. (Id. ¶ 11.) Ortho holds an approved New Drug Application (“NDA”), under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 335(a), for topiramate tablets and topiramate capsules, which are marketed in the United States as the anticonvulsant TOPAMAX®. (Id.)

In 2001, Mylan filed an Abbreviated New Drug Application (“ANDA”), pursuant to Section 505(j) of the FFDCA, to market topiramate 25, 50¹, 100, and 200 mg tablets before the expiration of the ’006 patent. (Id. at ¶ 14.) In its ANDA, Mylan claimed that the ’006 patent is invalid and, therefore, that none of its claims would be violated by Mylan’s manufacture, use, and sale of topiramate. (Id. at ¶ 15.) On March 2, 2004, Mylan served Ortho with notice of its position and intent to seek approval to market topiramate before the expiration of the ’006 patent, triggering the running of the 30-month period staying FDA action. (Id. at ¶ 16.) Anticipating the expiration of the 30-month stay in September, 2006, on July 14, 2006, Ortho filed the instant motion for a preliminary injunction, asking that this Court preliminarily enjoin Mylan from marketing or selling topiramate. On August 1, 2006, this Court entered a Consent Order barring Mylan from marketing topiramate prior to this Court’s adjudication of this motion. On September 11, 2006, following the expiration of the 30-month stay, the FDA approved Mylan’s ANDA for 25, 100, and 200 mg topiramate tablets.

¹The Complaint filed in Civil Action No. 04-1689 alleged infringement of the ’006 patent based on Mylan’s efforts to obtain an ANDA with respect to topiramate 25, 100, and 200 mg tablets. Mylan subsequently amended its ANDA to include 50 mg tablets and Ortho filed another lawsuit to address that dosage, under Civil Action No. 06-757. On May 17, 2006, Magistrate Judge Bongiovanni entered an Order consolidating these matters. [Civil Action No. 04-1689, Docket Entry No. 129.]

As affirmative defenses to patent infringement, Mylan has asserted that the '006 patent is invalid under statutory law, based on 35 U.S.C. §§ 101, 103, and 112, and under the doctrine of inequitable conduct. Mylan has withdrawn the claim of invalidity under § 101. On May 30, 2006, this Court granted Ortho's motion for partial summary judgment on Mylan's affirmative defense of inequitable conduct. On October 3, 2006, this Court granted Ortho's motion for partial summary judgment on Mylan's affirmative defense of invalidity under § 112.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). As the moving party, a plaintiff "is entitled to a preliminary injunction if it shows: (1) a reasonable likelihood of success on the merits of its claims; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1370 (Fed. Cir. 2005). In order to demonstrate a likelihood of success on the merits on a particular claim of patent infringement, Plaintiffs must show that, in light of the presumptions and burdens that will inhere at a trial on the merits, (1) Defendants likely infringe the patent, and (2) the claims of the patent will likely withstand Defendants' challenges to validity. Id. If Defendants "raise[] a substantial question concerning either infringement or validity, *i.e.*, assert[] an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350-1351 (Fed. Cir. 2001). Thus, once the non-movant has raised a substantial

question as to infringement or validity, for the preliminary injunction to issue, the movant must prove that this question lacks substantial merit.

“[I]nfringement and validity analyses must be performed on a claim-by-claim basis.” Id. at 1351. “[I]n cases involving multiple patent claims, to demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer.” Id.

II. Validity

In Amazon, the Federal Circuit stated the standard for a validity challenge in the context of an application for a preliminary injunction:

Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial. The test for invalidity at trial is by evidence that is clear and convincing. . . . In resisting a preliminary injunction . . . one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself. . . . When moving for the extraordinary relief of a preliminary injunction, a patentee need not establish the validity of a patent beyond question. The patentee must, however, present a clear case supporting the validity of the patent in suit.

Amazon, 239 F.3d at 1358-1359 (citations omitted).

III. Non-obviousness

To patent an invention, the subject matter must be non-obvious:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a).

“It is well-settled that obviousness is a legal question based on underlying factual determinations.” Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004) (quotation omitted).

[F]actual determinations relevant to the obviousness inquiry include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any, such as commercial success, unexpected results, copying, long-felt but unresolved need, and the failure of others to develop the invention.

Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005).

The Federal Circuit emphasizes the importance of eliminating the influence of hindsight in the obviousness inquiry through application of the “motivation-suggestion-teaching” test.

In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006).

[T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999) (citations omitted). Moreover, “an obviousness determination requires not only the existence of a motivation to combine elements from different prior art references, but also that a skilled artisan would have perceived a reasonable expectation of success in making the invention via that combination.” Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006).

ANALYSIS

I. Plaintiff has demonstrated a likelihood of success in establishing that Mylan would infringe the '006 patent.

The parties have agreed that, based on this Court's claim construction set forth in the Opinion of July 18, 2005, Mylan's proposed use and sale of topiramate products would infringe claims 1, 2, 4 through 8, 11 and 12 of the '006 patent. (Final Pretrial Order 10 ¶ 33.)

II. Plaintiff has demonstrated that the infringed claims of the '006 patent will likely withstand Defendants' challenges to validity.

This Court has granted summary judgment in Ortho's favor on Mylan's validity challenges based on inequitable conduct, non-enablement, and indefiniteness. (Opinion of May 30, 2006; Opinion of October 3, 2006.) Mylan has only one remaining challenge to the patent's validity, based on obviousness.

This Court addressed issues of obviousness in ruling on the motion for summary judgment on Mylan's affirmative defense of inequitable conduct. Mylan had argued, inter alia, that, after the patent examiner issued a § 103 rejection, but for the applicant's misrepresentations and omissions, the applicant would have been unable to overcome the rejection. (Opinion of May 30, 2006 at 9.) Among other arguments, Mylan relied on Dr. Anderson's opinion in contending that the prior art work of Jenkins and Shuman taught that the sulfamoylation of fructose derivatives would be "easy to accomplish." (*Id.* at 19.) This Court rejected Mylan's arguments, holding that a prior art teaching that a step is "easy to accomplish" is insufficient to meet the Federal Circuit's "motivation-suggestion-teaching" test. (*Id.* at 20-21.) Although Mylan has further developed its obviousness arguments in opposing the instant motion, as will be discussed below, its position still does not succeed under this crucial test.

Claim 1 of the '006 patent is the only independent claim, and claims topiramate. In arguing that claim 1 is invalid as obvious, Mylan relies entirely on the expert opinion of Dr. Laurens Anderson. (Defs.' Opp. Br. 10-11.) Dr. Anderson sets forth his opinion about the obviousness of claim 1 in two documents: 1) the Expert Report of April 27, 2005 ("Anderson 1") (Exhibit A to Anderson 2); and 2) the Declaration of August 23, 2006 ("Anderson 2"). These statements of opinion propose two theories of obviousness which differ in important ways.

A. Dr. Anderson's Expert Opinion of April 27, 2005

In Anderson 1, Dr. Anderson proposes a theory of how Dr. Maryanoff came up with topiramate. Essentially, Dr. Anderson states that Dr. Maryanoff followed a series of steps, each of which would have been obvious to one of ordinary skill in the art, arriving at topiramate at the end. The steps in Dr. Anderson's theory of may be summarized as follows: 1) Dr. Maryanoff sought to develop a pharmaceutical treatment for diabetes. (Anderson 1 at ¶ 11.) 2) Because it was well-known that FBPase is a key enzyme involved in glucose production in the body, Dr. Maryanoff decided that a pharmaceutical inhibitor of FBPase might be useful as a diabetes treatment. (Id.) 3) Dr. Maryanoff saw the discovery by Thomas that the replacement of the phosphate group by a sulfamate group in 5'-AMP produced nucleocidin, a powerful antibiotic. (Id. at ¶ 12.) 4) Dr. Maryanoff saw that Jenkins had used a reaction with sulfamoyl chloride ("sulfamoylation") to generate nucleocidin. (Id. at ¶ 16.) 5) Dr. Maryanoff selected a well-known fructose derivative, DPF, reacted it with sulfamoyl chloride, and produced topiramate. (Id. at ¶ 17.)

The approach espoused in Anderson 1 has significant problems that lead this Court to conclude that, in relying on it, Mylan has not raised a substantial question of obviousness. To

begin with, as Ortho contends, Dr. Anderson has merely followed the path of development that Dr. Maryanoff claims to have followed. (See New Product Conception Record, Harth Conf. Decl. Ex. Q.) Dr. Anderson begins with the problem he believes Dr. Maryanoff was attempting to solve, follows the path he believes Dr. Maryanoff took, and ends up with topiramate. This is a hindsight-based obviousness analysis. The Federal Circuit has made clear that the inventor's chosen path is irrelevant: "[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute. . . [T]his inquiry, as a matter of law, is independent of the motivations that led the inventors to the claimed invention." Life Techs., Inc. v. Clontech Lab., Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000). Rather, § 103 requires that the obviousness inquiry must be performed from the perspective of one of ordinary skill in the art. 35 U.S.C. § 103(a).

Because the obviousness inquiry must be independent of the motivations that led Dr. Maryanoff to the invention, and must instead follow the perspective of one of ordinary skill in the art, this Court questions the appropriateness of beginning with the particular problem that Dr. Maryanoff was facing, that of developing a new treatment for diabetes. Dr. Anderson provides no basis to infer that Dr. Maryanoff was one of ordinary skill in the art, nor that one of ordinary skill in the art would have been looking for a new diabetes treatment. See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1322 (Fed. Cir. 2005) (considering whether the problem could be found in "knowledge generally available" to those of ordinary skill in the art). Moreover, even if Mylan could establish that people of ordinary skill in the art were generally aware of this problem, as Ortho's expert Dr. Danishefsky points out, Dr. Anderson provides no basis to conclude that one of ordinary skill in the art would find it obvious to think of solving it by searching for FBPase inhibitors. (Danishefsky Decl. ¶ 6.)

Furthermore, applying the “motivation-suggestion-teaching” test, this Court finds significant gaps in the path Dr. Anderson follows: 1) Dr. Anderson implies that knowledge of Thomas “inspired” the idea of substituting a sulfamate group for a phosphate group. (Anderson 1 at ¶ 12.) This leaves unexplained, however, how knowledge that replacing a part of 5'-AMP with a sulfamate group produces an antibiotic would motivate the idea of sulfamoylation of a fructose derivative to produce a FBPase inhibitor. Furthermore, Dr. Danishefsky contends that the research on 5'-AMP and nucleocidin should not be considered to be part of the analogous prior art. (Danishefsky Decl. ¶ 19.) Even if it were shown to be relevant prior art, Dr. Anderson does not explain how knowledge of modifications to produce antibiotic potency would motivate modifications to produce gluconeogenic enzyme inhibition. 2) Dr. Anderson states that Dr. Maryanoff selected the “well-known” 2,3:4,5-di-isopropylidene fructose (“DPF”). (Anderson 1 at ¶ 17.) Dr. Anderson gives no explanation of what would have suggested DPF to one of ordinary skill in the art. Dr. Anderson states that Dr. Maryanoff “suggested that the desired inhibitory properties might be present in fructose derivatives . . .” (Id. at ¶ 12.) Dr. Anderson’s statement that it was Dr. Maryanoff himself, and not something in the prior art, that suggested researching fructose derivatives for enzyme inhibitors raises the inference that Dr. Anderson’s ideas in this regard may have been original and inventive. Certainly, Dr. Anderson has not pointed to anything that would have suggested the use of fructose derivatives to Dr. Maryanoff. This is a crucial gap in the theory, since Dr. Anderson proposes that by choosing a particular fructose derivative (DPF), and then choosing to sulfamoylate it, one ends up with topiramate. There is no basis to infer that one of ordinary skill in the art would have been motivated to select DPF to sulfamoylate.

This year, the Federal Circuit applied the “motivation-suggestion-teaching” test in reversing the decision of the Board of Patent Appeals and Interferences in In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006): “When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used hindsight to conclude that the invention was obvious.” This statement applies equally well to Dr. Anderson’s theories.

B. Dr. Anderson’s Expert Declaration of August 23, 2006

In the Expert Declaration of August 23, 2006, Dr. Anderson offers a second version of his theory. Again, Dr. Anderson traces the steps he believes Dr. Maryanoff took, which may be summarized as follows: 1) Dr. Maryanoff sought to develop a treatment for diabetes. (Anderson 2 at ¶ 4.) 2) Dr. Maryanoff sought to formulate an inhibitor of FBPase as a potential diabetes treatment. (Id.) Dr. Maryanoff knew that Benkovic had designed FBPase inhibitors. (Id. at ¶ 5.) 3) It was common in the art to design enzyme inhibitors by making isosteric analogs of an enzyme’s substrate. (Id. at ¶ 6.) The most important natural substrate of FBPase is D-fructose 1,6-bisphosphate (FBP). (Id. at ¶ 7.) 4) It would be obvious to make an isosteric analog in which sulfur replaced phosphorus, such that a sulfate replaced a phosphate group. (Id.) 5) It would also be obvious that the analog with a sulfate group would not be suitable as a pharmaceutical because of the ionic charge. The analog would have to be modified to eliminate the ionic charge. (Id. at ¶ 8.) It would have been obvious that this could be done by using a sulfamate group instead of a sulfate group. (Id. at ¶ 9.) Shuman taught that, for some chemicals with phosphate groups, replacement of the phosphate groups with sulfamates produced antibiotics. (Id. at ¶ 9.) 6) A person of ordinary skill would have known to use as a starting material for synthesis a

fructose derivative modified with temporary protecting groups at all positions except for position 1, and DPF would be obvious to choose. (Id. at ¶ 10.) Reacting DPF with sulfamoyl chloride produces topiramate. (Id.)

Dr. Anderson's second theory differs in important ways from his first: the second theory adds in the ideas of creating an isosteric analog of the enzyme's substrate and of eliminating the ionic charge by substituting a sulfamate for a sulfate group. Mylan offers no acknowledgment of or explanation for these changes. The fact that Dr. Anderson revised his theory significantly when he offered his opinion on August 23, 2006 indicates that he himself no longer finds his first theory adequate. This Court finds that this raises the inference that the first theory was insufficient. Moreover, Dr. Anderson's unexplained modification of his theory raises this Court's concern about the extent to which Dr. Anderson's expert opinion is the product of reliable principles and methods, or is the product of reliable application of such principles to the facts of the case. FED. R. EVID. 702(2-3).

Dr. Anderson's second theory repeats the problems found in the first. The theory is still based on the perspective of Dr. Maryanoff, rather than one of ordinary skill in the art. Dr. Anderson again provides no basis to conclude that one of ordinary skill in the art would find it obvious to think of using FBPase inhibitors to treat diabetes. Again, application of the "motivation-suggestion-teaching" test shows that there are now some old and some new gaps in the theory: 1) Dr. Anderson does not explain what would have motivated one of ordinary skill in the art to apply Shuman's teaching about producing antibiotics by replacing phosphate groups with sulfamates to a FBPase inhibitor for the treatment of diabetes. 2) Dr. Anderson does not explain what would have motivated one of ordinary skill in the art to replace the phosphorus in

FBP with sulfur, instead of some other element. 3) Dr. Anderson does not explain what would have motivated one of ordinary skill in the art to eliminate the ionic charge by substituting a sulfamate group for the sulfate group, instead of some other group that also eliminated the ionic charge. 4) Again, crucially, Dr. Anderson finds DPF to be the obvious, “ideal” choice as a starting material, but gives no explanation for what would have suggested this to one of ordinary skill in the art. (Anderson 2 at ¶ 10.)

Examining the second theory as a whole highlights the significance of the missing DPF link. The theory begins with a focus on using FBP as an inhibitor for FB Pase, and proceeds to the idea that the FBP should be transformed into an isosteric analog, which should also be transformed so as to eliminate the ionic charge. At this point, the trail ends, and Dr. Anderson abruptly states, without explanation, that it is obvious and ideal to sulfamoylate DPF, not FBP. This leaves a gap at a crucial point in the theory.

Dr. Danishefsky also questions Dr. Anderson’s second theory’s reference to Benkovic: Dr. Danishefsky states that Benkovic teaches away from using compounds like topiramate to inhibit FB Pase, teaching that a FB Pase inhibitor should contain two phosphate groups, while topiramate contains no phosphate groups. (Suppl. Danishefsky Decl. ¶ 6c.)

C. Issues Common to Both Theories

As discussed, neither of Dr. Anderson’s theories explains what would have provided a motivation or suggestion to one of ordinary skill in the art to choose DPF for sulfamoylation to produce topiramate. Furthermore, even if Dr. Anderson had pointed to the source of motivation or suggestion, he would then needed to have shown “that a skilled artisan would have perceived a reasonable expectation of success in making the invention.” Medichem, 437 F.3d at 1165. Dr.

Anderson does not address issues of expectation of success at all. Thus, Dr. Anderson's theories are legally insufficient to raise a substantial question of obviousness for this reason as well.

On the present record, this appears to be what Wigley has referred to as the classic "needle in a haystack" situation. See David E. Wigley, Evolution of the Concept of Non-Obviousness of the Novel Invention: From a Flash of Genius to the Trilogy, 42 Ariz. L. Rev. 581, 600 (2000). Dr. Danishefsky observes that FBPase is but one of hundreds of enzymes involved in sugar metabolism in the human body. (Suppl. Danishefsky Decl. ¶ 6a.) Dr. Danishefsky also states that the chapter in "Enzyme and Metabolic Inhibitors" cited by Dr. Anderson as supporting the proposition that it was well-known in the art to replace a phosphate group with a sulfate group, discussing the group of enzymes that includes FBPase, actually suggests replacing the phosphate with arsenate, silicate, carboxylates, tartrate, glycerate, fluoride dimer, and malate.² (Anderson 2 at ¶ 7; Suppl. Danishefsky Decl. ¶ 8.) Furthermore, Dr. Danishefsky contends that the path to topiramate includes a choice of which group to replace.³ Considering the hundreds of possible enzymes involved in sugar metabolism, the question of which group to replace, and the many possibilities for what new group might be substituted for the old one, this alone suggests a very large number of possible modified sugar metabolism enzyme inhibitors. From the present record, topiramate appears to have been the needle in the

² Moreover, Dr. Danishefsky states that this reference actually teaches away from the path leading to topiramate, teaching that, to create an inhibitor for the class of enzymes that includes FBPase, it is better to replace a phosphate group with a group other than a sulfamate. (Suppl. Danishefsky Decl. ¶ 8.)

³ Dr. Danishefsky does not state how many possible choices exist for groups that one might possibly replace by sulfamoylation, but his statement implies at least two (the "primary OH group" and "some other group"). (Danishefsky Decl. 8.)

haystack that Dr. Maryanoff found.

At best, Dr. Anderson has pointed to a few clues that might have been helpful to one of ordinary skill in the art in searching the haystack. This does not even reach the level of showing that it would have been obvious to try sulfamoylating DFP. In In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988), the Federal Circuit repeated the maxim that "obvious to try" is not the standard under § 103, and discussed situations like the present one:

The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Id. The instant case appears to be like the first situation, in that Mylan has not shown that the prior art gave more than a few hints as to which of the many possible choices was likely to be successful. Mylan has not even raised a substantial question of whether the choices leading to topiramate were obvious to try, much less whether such choices were obvious under § 103.

In response to Dr. Anderson, Ortho offers the expert opinions of Dr. Danishefsky who, in conclusion, states that the claimed invention would not have been obvious to one of ordinary skill in the art at the time of application. (Danishefsky Decl ¶ 19.) Furthermore, Ortho argues that this conclusion is supported by four categories of objective evidence of non-obviousness:

1. Unexpected results: Ortho expert Dr. Kupfergerg states that one of ordinary skill in the art would not have predicted topiramate's anticonvulsant properties from its physical structure in the 70's and 80's. It was structurally unique compared to other anticonvulsants. (Kupfergerg Decl. ¶ 4.) It was 38% oxygen, and a level this high had not been seen before in an anticonvulsant. (Id. ¶ 5.)

2. Commercial success: Topamax® is the top-selling branded neurology product in the US. (Fischer Decl. ¶ 4.) Sales have grown at a compound annual rate of 60% from its release in 1997 to 2005. (Id. ¶ 5.)
3. Copying: The FDA presently (as of 10/3/06) has received nine ANDA applications for topiramate formulations. (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=TOPIRAMATE>)
4. Industry recognition: Ortho claims that Dr. Maryanoff has received three awards for his work on topiramate. The first, the R.W. Johnson Medal for Research & Development in 1997, is not from a source independent of his employer. Ortho has presented no evidence that the second two, awarded by the American Chemical Society, have any connection to topiramate.

Mylan argues, in opposition, that these secondary considerations relate only to claims 6-8, for use of topiramate as an anticonvulsant, not claim 1. This is unpersuasive:

When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention. If a patentee makes the requisite showing of nexus between commercial success and the patented invention, the burden shifts to the challenger to prove that the commercial success is instead due to other factors extraneous to the patented invention, such as advertising or superior workmanship.

J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997) (citation omitted). Because the successful product is the composition of claim 1, it is presumed that the compound of claim 1 has achieved commercial success.

Mylan argues as well that the evidence of unexpected results comes from a litigation expert, not an independent source. Mylan does not, however, counter this evidence by offering independent evidence that the results were expected.

Ortho notes that the fact that Mylan is willing to spend millions of dollars in litigation expenses to gain the right to make and sell topiramate is powerful evidence of copying and an

important objective indication itself of nonobviousness.

This Court finds that Ortho has shown a likelihood of success in demonstrating that the objective evidence of non-obviousness supports a conclusion of non-obviousness.

D. Claims 6, 7, and 8

Mylan contends that claims 6, 7, and 8 are obvious, and offers the expert opinions of Dr. Supuran in support. Because this Court concludes that Mylan has not raised a substantial question as to the validity of claim 1, the patentee has met its burden of showing a likelihood of success on the merits on at least one claim, claim 1: the parties have stipulated as to the likelihood of showing infringement on claim 1, and claim 1 will also likely withstand the validity challenge presented by the accused infringer. Because Mylan has shown a likelihood of success as to claim 1, this Court need not reach the issues of the obviousness of claims 6, 7, and 8.

Moreover, since claims 6, 7, and 8 are all dependent on claim 1, those claims cannot be shown to be obvious in the absence of showing claim 1 to be obvious. See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“dependent claims are nonobvious if the independent claims from which they depend are nonobvious”). Because this Court has found that Mylan has not raised a substantial question as to the nonobviousness of claim 1, Mylan cannot succeed with an obviousness attack on the claims which depend on it.

III. Plaintiff has shown that the preliminary injunction factors weigh in its favor.

This Court finds that Mylan has not raised a substantial question of the validity of the '006 patent; its obviousness challenge lacks substantial merit. Ortho has demonstrated that, in light of the presumptions and burdens that will inhere at a trial on the merits, Mylan likely infringes one or more claims of the '006 patent, and one or more of such claims will likely

withstand Mylan's challenges to validity. Therefore, Ortho has met its burden of showing a reasonable likelihood of success on the merits in its action for infringement of the '006 patent.

“[A] district court should presume that a patent owner will be irreparably harmed when . . . a patent owner establishes a strong showing of likely infringement of a valid and enforceable patent.” Pfizer, Inc. v. Teva Pharms.USA, Inc., 429 F.3d 1364, 1381 (Fed. Cir. 2005). Ortho has established the showing necessary to raise the rebuttable presumption of irreparable harm.

“[W]hen the presumption of irreparable harm attaches, the burden is on the likely infringer to produce evidence sufficient to establish that the patent owner would not be irreparably harmed by an erroneous denial of a preliminary injunction.” Id. Rather than address this burden, Mylan has chosen to ignore it, merely arguing that Ortho's losses may be adequately compensated by money damages. Mylan has not produced evidence sufficient to establish the absence of irreparable harm. This factor weighs in favor of the grant of the preliminary injunction.

As to the balance of hardships, Mylan contends that, if an injunction issues, it will suffer the harm of delay in receiving a return on its investment in marketing generic topiramate. In Glaxo Group Ltd. v. Apotex, Inc., 64 Fed. Appx. 751, 756 (Fed. Cir. 2003), the Federal Circuit considered the same argument and rejected it. As in Glaxo, Ortho here stands to “lose the value of its patent,” while Mylan “would only lose the ability to go on to the market and begin earning profits earlier.” Id. The balance of hardships factor favors the grant of the preliminary injunction.

As to the public interest, Mylan argues that the public would benefit from the increased competition in the pharmaceutical market that would come with denial of the injunction. Again,

the Federal Circuit has considered and rejected this argument: “Selling a lower priced product does not justify infringing a patent.” Pfizer, 429 F.3d at 1382 (quoting Payless Shoesource, Inc. v. Reebok Int’l Ltd., 998 F.2d 985, 991 (Fed. Cir. 1993)). The public interest favors enforcing a valid patent against an infringer, and weighs in favor of granting the preliminary injunction.

CONCLUSION

For the reasons stated above, this Court finds that all four factors in the preliminary injunction analysis weigh in favor of granting Ortho’s motion for a preliminary injunction. To show an overall likelihood of success on the merits, Ortho needed to demonstrate a likelihood of success in showing that Mylan would infringe one or more claims of the ’006 patent, and that one or more of such claims will likely withstand Mylan’s challenges to validity. Because Mylan has not disputed that it would infringe claim 1 of the ’006 patent, and Mylan failed to raise a substantial question of claim 1’s validity, Ortho has demonstrated a likelihood of success on the merits. Having established a likelihood of success on the merits, Ortho is entitled to a presumption of irreparable harm, which Mylan has not rebutted. The balance of hardships and public interest factors also weigh in favor of Ortho. Because all four factors weigh in favor of granting the injunction, Ortho’s motion for a preliminary injunction, pursuant to 35 U.S.C. § 283, is granted.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: October 23, 2006