IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
EURAND, INC., CEPHALON, INC. and ANESTA AG,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") by way of their Complaint allege the following against Defendants Eurand, Inc., Cephalon, Inc. and Anesta AG (collectively, "Defendants"):

Nature of the Action

1. This is a declaratory judgment action seeking a declaration of non-infringement, unenforceability, and/or invalidity of United States Patent No. 7,544,372 (the "'372 patent"), attached hereto as Exhibit A. Along with U.S. Patent No. 7,387,793 (the "'793 patent"), Defendants listed the '372 patent with the United Stated Food and Drug Administration (the "FDA") in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as a patent which could reasonably be asserted against anyone marketing or seeking to market a generic version of cyclobenzaprine hydrochloride extended-release capsules. Mylan Pharmaceuticals has filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market a generic version of cyclobenzaprine hydrochloride extended-release capsules ("Mylan's ANDA Products"). At the time Mylan Pharmaceuticals filed its ANDA, the '793 patent was the only patent listed in the Orange Book for cyclobenzaprine hydrochloride

extended-release capsules. As part of that application, Mylan Pharmaceuticals certified that in its opinion and to the best of its knowledge, the '793 patent is invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Products, and notified the Defendants of its certification. On November 26, 2008, Defendants filed an action in this District alleging that Mylan infringed the '793 patent by filing Mylan Pharmaceuticals' ANDA with the foregoing certification seeking approval to market Mylan's ANDA Products prior to the expiration of the '793 patent.

2. Subsequent to Mylan Pharmaceuticals' filing of its ANDA, the '372 patent was issued by the U.S. Patent and Trademark Office ("USPTO") from a divisional of the same application that led to the '793 patent. Defendants caused the '372 patent to be listed in the Orange Book along with the '793 patent for cyclobenzaprine hydrochloride extended-release capsules. Mylan Pharmaceuticals thereafter amended its ANDA to include a certification that in its opinion and to the best of its knowledge, the '372 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Products. Defendants, while having sued Mylan on the '793 patent, have not sued Mylan on the related '372 patent within 45 days after receiving notice of Mylan Pharmaceuticals' certification to the FDA. Defendants have, however, asserted the '372 patent along with the '793 patent against co-defendants, including Barr Laboratories, Inc. Because the '372 patent is listed in the Orange Book and claims substantially overlapping subject matter to that claimed in the '793 patent, Defendants' failure to initiate litigation concerning the '372 patent against Mylan may impair Mylan's ability to bring Mylan's ANDA Products to market. Mylan thus seeks a declaratory judgment that it does not infringe the '372 patent and that the '372 patent is unenforceable and invalid.

The Parties

3. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its headquarters at 781 Chestnut Ridge Road, West Virginia 26504.

4. Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. On information and belief, Defendant Eurand, Inc. is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its offices and principal place of business located at 845 Center Drive, Vandalia, Ohio 45377.

6. On information and belief, Defendant Cephalon, Inc. is a corporation, organized, existing and doing business under and by virtue of the laws of the Delaware, with its offices and principal place of business located at 41 Moores Road, Frazer, Pennsylvania 19355.

7. On information and belief, Defendant Anesta AG is a Swiss corporation having a principal place of business at Baarerstr 23CH-6300 Zug, Switzerland.

Jurisdiction and Venue

8. These claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. The Court has subject matter jurisdiction based upon 28 U.S.C. §§ 1331, 1338(a), 2201 and 2201.

10. The Court has personal jurisdiction over Defendants at least because each of the Defendants initiated the action against Mylan in this Court alleging infringement of the '793

patent based on the filing of Mylan's ANDA and thereby availed themselves of the rights and privileges of this forum by suing Mylan in this judicial district.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

Background

12. On information and belief, Anesta AG is the current owner of a New Drug Application ("NDA") No. No. 21-777 for Amrix® cyclobenzaprine hydrochloride extended-release capsules (15 mg and 30 mg), which are used for the treatment of muscle spasms.

13. NDA holders are required to file with the FDA the patent number and expiration date for any patent which claims the drug that is the subject of the NDA and for any patent which claims a method of using the subject drug for "which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of this drug." 21 U.S.C. § 355 (b)(1). These patents are then listed in the Orange Book.

14. In connection with the NDA for cyclobenzaprine hydrochloride extended-release capsules, Defendants caused the '793 to be listed in the Orange Book.

15. On October 17, 2008, Mylan Pharmaceuticals Inc., in accordance with 21 U.S.C. § 355(j)(2)(B)(i) and (ii), notified Defendants that it had filed ANDA No. 90-738 with the FDA seeking approval to manufacture and sell Mylan's ANDA Products before the expiration of the '793 patent, and that Mylan Pharmaceuticals had certified to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (hereinafter "Paragraph IV Certification"), that Mylan's ANDA Products would not infringe any claim of the '793 patent. The notice provided the factual and legal bases that the '793 patent would not be infringed, either literally or under the doctrine of equivalents,

by the commercial manufacture, use or sale of Mylan's ANDA Products, and offered confidential access to Mylan's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

16. On November 26, 2008, Defendants filed a lawsuit against Mylan in the United States District Court for the District of Delaware (the "'793 Complaint") alleging infringement of the '793 patent.

17. On June 9, 2009 the USPTO issued United States Patent No. 7,544,372 (the "'372 patent"), entitled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" to Defendant Eurand. Defendants thereafter caused the '372 patent to be listed in the Orange Book along with the '793 patent in connection with approved New Drug Application No. 21-777 for cyclobenzaprine hydrochloride extended-release capsules.

18. On February 19, 2010, in accordance with 21 U.S.C. § 355(j)(2)(B)(i) and (ii), Mylan Pharmaceuticals notified Defendants that it had filed ANDA No. 90-738 with the FDA seeking approval to manufacture and sell Mylan's ANDA Products before the expiration of the '372 patent, and that Mylan had certified "that in Mylan's opinion and to the best of its knowledge, the '372 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation" of Mylan's ANDA Products. The notice provided the factual and legal bases that the '372 patent would not be infringed, either literally or under the doctrine of equivalents, by the commercial manufacture, use or sale of Mylan's ANDA Products and that the claims of the '372 patent are invalid and unenforceable, and offered Defendants confidential access to Mylan's ANDA.

19. Plaintiffs did not, within 45 days of receiving Mylan Pharmaceuticals' notice of Paragraph IV Certification, file a lawsuit alleging Mylan infringed the '372 patent. Because the '372 patent is listed in the Orange Book for cyclcobenzaprine hydrochloride extended-release

capsules along with the '793 patent, and because the '372 patent claims subject matter that substantially overlaps with the subject matter claimed in the '793 patent, Defendants' failure to initiate litigation concerning the '372 patent may impair Mylan's ability to bring Mylan Pharmaceuticals' generic version of cyclobenzaprine hydrochloride extended-release capsules to market. Mylan thus seeks a declaratory judgment of non-infringement, invalidity and unenforceability of the '372 patent.

The Presence of a Case or Controversy

20. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission of the Paragraph IV Certification to the FDA constitutes a "technical" act of infringement for subject matter jurisdiction purposes for each patent listed in the Orange Book. Furthermore, 35 U.S.C. § 271(e)(5) specifically provides that the Court shall have subject matter jurisdiction under section 2201 of title 28 for a declaratory judgment that an unasserted Orange Book patent is invalid or not infringed.

21. Because Defendants filed their '793 Complaint alleging that Mylan has infringed the '793 patent, Defendants have demonstrated an intent to enforce the Orange Book patents concerning cyclobenzaprine hydrochloride extended-release capsules. In addition, Defendants have already asserted both the '793 and '372 patent against other parties that served Paragraph IV Certifications with respect to both patents.

22. Defendants have never disavowed an intent to assert that Mylan infringes the '372 patent, and continue to assert infringement of the related '793 patent based on the filing of Mylan Mylan Pharmaceuticals' ANDA.

23. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, sell and offer to sell Mylan's ANDA Products.

24. Because Defendants have caused the '372 patent to be listed in the Orange Book but did not assert that patent against Mylan within 45 days after Mylan Pharmaceuticals notified Defendants of Mylan's Paragraph IV Certification to the '372 patent, even though the '372 patent covers the same technology and shares substantial content with the '793 patent, Mylan has a reasonable apprehension that Defendants will sue Mylan for infringement of the '372 patent.

25. An actual justiciable controversy exists between the parties as to the infringement, invalidity, and/or unenforceability of the '372 patent.

26. To avoid legal uncertainty and to protect its substantial investment (and anticipated future investment) in Mylan's ANDA Products, Mylan has brought these declaratory judgment claims against the '372 patent.

Count I
Declaratory Judgment of Non-Infringement
U.S. Patent No. 7,544,372

27. Mylan restates and realleges each of the foregoing paragraphs of its Complaint as if fully set forth herein.

28. A case or controversy exists between Defendants and Mylan concerning the non-infringement of the '372 patent, which requires a declaration of rights by this Court.

29. Mylan's cyclobenzaprine hydrochloride extended-release capsules would not, if commercially manufactured, sold or offered for sale in the United States, infringe any claim of the '372 patent.

Count II
Declaratory Judgment of Invalidity
U.S. Patent No. 7,544,372

30. Mylan restates and realleges each of the foregoing paragraphs of its Complaint as if fully set forth herein.

31. A case or controversy exists between Defendants and Mylan concerning the invalidity of the '372 patent, which requires a declaration of rights by this Court.

32. The claims of the '372 patent are invalid under one or more provisions of Title 35, United States Code, including at least §§ 102, 103 and 112 thereof.

Count III
Declaratory Judgment of Unenforceability
U.S. Patent No. 7,544,372

33. Mylan restates and realleges each of the foregoing paragraphs of its Complaint as if fully set forth herein.

34. A case or controversy exists between Defendants and Mylan concerning the unenforceability of the '372 patent, which requires a declaration of rights by this Court.

35. Under the patent laws and regulations, each individual associated with the filing and prosecution of a patent application before the United States Patent and Trademark Office ("the USPTO") has a duty of candor and good faith in dealing with the USPTO which includes a duty to disclose to the Examiner responsible for examination of the application all information known to be material to patentability. This duty of candor includes a duty to disclose prior art that may be material to the patentability of any pending patent application.

36. The claims of the '372 patent are unenforceable because of the failure of, *inter alia*, both Gopi Venkatesh (one of the named inventors of both the '372 patent and of Eurand's earlier-filed '793 patent) and the prosecuting attorneys of the '793 patent to disclose Eurand's prior art U.S. Patent No. 6,344,215 (the "'215 patent") to the USPTO during prosecution of the related '793 patent.

37. The application leading to the '793 patent was filed on November 14, 2003. The application leading to the '372 patent, a divisional application of the application that issued as

the '793 patent, was filed on February 6, 2008. Thus both applications were filed after the February 5, 2002 issue date of the '215 patent and the '215 patent is prior art to both the '793 patent and the '372 patent under 35 U.S.C. § 102(b).

38. Moreover, the claims of the '793 and '372 patents are directed to the use of identical formulations. Nevertheless, the inventors and prosecuting attorneys prosecuting the '793 patent never disclosed the '215 patent to the USPTO in connection with the prosecution of that patent. Instead, the inventors and prosecuting attorneys for the '372 patent disclosed the '215 patent (along with a large amount of other material) for the first time in the application leading to the '372 patent in an information disclosure statement ("IDS") filed on or about December 12, 2008. This IDS, which was filed after a notice of allowance issued for the '372 patent, was submitted only after Barr Pharmaceuticals Inc. cited the '215 patent in a notice of paragraph IV certification challenging the validity of the '793 patent and after Eurand had sued both Mylan and Barr for infringement of the '793 patent based on their filing of Paragraph IV certifications.

39. The '215 patent discloses the use of Eurand's DIFFUCAPS® controlled release technology, the same technology disclosed and claimed in the '793 patent. Moreover, the '215 patent discloses the use of the same polymers and plasticizers and the same manufacturing process that is described in the '793 patent. *Compare* '215 patent at 3:22-39 *with* '793 patent at 5:51-67. The inventors of the '793 patent merely substituted a different active ingredient into the extended-release technology disclosed in the '215 patent.

40. The '215 patent additionally discloses the same method of measuring the desired release profile as is disclosed and claimed in the '793 patent, *i.e.,* using USP apparatus 2, Paddles @ 50 rpm. *Compare* '215 patent at 2:1-4 *with* '793 patent at 4:29-33. The release rates shown

in the Examples of the '215 patent fall within the release profile disclosed and claimed in the '793 patent. *Compare* '215 patent at 5:14-24 (Table 1) and 6:14-23 (Table 2) *with* '793 patent, claim 1.

41. Because the '215 patent discloses the precise extended-release technology and dissolution profile that is claimed as novel in the '793 patent, and the named inventors of the '793 patent claimed a formulation in which they substituted one active ingredient for that of the '215 patent, a reasonable examiner would have found the '215 patent to be material to the patentability of the claims of the '793 patent. Indeed, when Eurand first submitted the '215 patent to the U.S. Patent Office in connection with the prosecution of related U.S. Application No. 12/026,882 ("the '882 application"), well after the '793 patent issued, the Examiner (the same examiner who examined the '793 patent) found the '215 patent sufficiently material to the patentability of the '882 application claims to require rejection of the pending claims. '882 Prosecution History, October 16, 2009 Office action at 4-8. The claims of the '882 application which the examiner rejected over the '215 patent are virtually identical to the '793 patent claims, with the exception that the rejected '882 application claims do not require a plasticizer in the extended-release layer as required in the '793 patent claims. Specifically, the Examiner noted that "[t]he simple substitution of one drug of '228 or Razaghi et al (cyclobenzaprine hydrochloride) for the drug of the '215 patent is within the purview of the skilled artisan and would yield predictable results." *Id.* at 7. Thus, the examiner's rejection of nearly identical claims confirms that a reasonable examiner would have considered the '215 patent material to the patentability of the '793 patent claims.

42. Because the claims of the '372 patent claim the use of the same formulation claimed in the '793 patent, the '215 patent is equally material to the claims of the '372 patent.

43. Gopi Venkatesh, a Eurand employee, and the attorneys who filed and prosecuted the '793 patent were well aware of the '215 patent, and the subject matter disclosed therein, before and during the prosecution of the '793 patent. Gopi Venkatesh is a named inventor of the '215 patent as well as both the '793 and '372 patents, and the same prosecuting attorney and law firm filed and prosecuted both the '793 patent and the undisclosed '215 patent on behalf of Mr. Venkatesh and Eurand.

44. At the very least, the intent to deceive can be inferred from the fact that, on February 2, 2004, during prosecution of the '793 patent, Mr. Venkatesh and his prosecuting attorneys disclosed to the USPTO every issued patent listing Mr. Venkatesh as a named inventor, other than the '215 patent. *See* Information Disclosure Statement dated Feb. 2, 2004 (listing U.S. Patent Nos. 6,663,888; 6,627,223; 6,500,454; 6,451,345).

45. The disclosed Venkatesh patents relate to technologies that are of far less relevance than the '215 patent to the extended-release formulations disclosed and claimed in the '793 patent. For instance, U.S. Patent No. 6,451,345 ("the '345 patent"), entitled "Functional Coating of Linezolid Microcapsules for Taste-Masking and Associated Formulation for Oral Administration," discloses and claims formulations that are designed for taste masking and rapid release in the upper intestinal tract. The withheld '215 patent, in contrast, discloses and claims formulations that are identical in many respects to those disclosed and claimed in the '793 patent.

46. Given the high materiality of the '215 patent in comparison to the prior art that was submitted to the Examiner, and as further discovery is expected to reveal, Mr. Venkatesh and/or his prosecuting attorneys withheld information concerning the '215 patent with an intent to deceive the USPTO in violation of their duty of candor and good faith required under, *inter alia*, 37 C.F.R. § 1.56.

47. Mr. Venkatesh's and the '793 patent prosecuting attorneys' withholding of information material to the patentability of the claims of the '793 patent constitutes inequitable conduct that renders the '793 patent unenforceable.

48. At a minimum, the inequitable conduct committed in connection with the '793 patent further renders the claims of the '372 patent unenforceable. The claims of the '372 patent are directed to the use of the exact same formulation claimed in the '793 patent for the administration of the same skeletal muscle relaxants and therefore the issued claims of both the '793 patent and the '372 patent are closely related to the omitted prior art. Thus, the omission of the '215 patent extends to the '372 patent.

49. Eurand's eventual belated submission of the '215 patent -- along with a large amount of other material after a notice of allowance issued for the '372 patent and only after the '215 patent was cited against the '793 patent in a paragraph IV certification -- does not cure the intentional failure to disclose the '215 patent in connection with the '793 patent prosecution. Accordingly, all claims of the '372 patent are unenforceable, at a minimum, based on the inequitable conduct during the prosecution of the '793 patent.

50. The claims of the '372 patent are also unenforceable due to inequitable conduct based on the submission of a false Declaration during the prosecution of the '372 patent. On December 12, 2008, during the prosecution of the '887 application which issued as the '372 patent, Applicant's attorney submitted an Information Disclosure Statement (IDS) under 37 C.F.R. § 1.97(d) after the mailing date of the Notice of Allowance. In its submission, in order to have prior art references considered by the Examiner so far along in the prosecution, Applicant certified under 37 C.F.R. § 1.97(e)(2) that none of the references submitted were known to the

inventors or to anyone else having a duty under 37 C.F.R. § 1.56 more than three months prior to the filing of the IDS. *Id.* at 3.

51. Applicant's certification was not, however, a proper one. Two of the references listed on the IDS – the '215 patent and the '974 patent – were indeed known to the inventors. First, Gopi Venkatesh, one of the inventors of the '372 patent, is also an inventor of the '215 patent. Second, the '974 patent was described in U.S. Publication No. 2004/0126427, which relates to extended release dosage forms. In a communication dated March 6, 2009, the Examiner herself noted the fact that the '974 patent was cited in this published application. In addition, the '974 patent was cited on the face of the '215 patent. Therefore, the certification that none of the references submitted were known to the inventors or to anyone else having a duty under 37 C.F.R. § 1.56 more than three months prior to the filing of the IDS was a false statement.

52. The '215 patent issued on February 5, 2002, the '974 patent issued on July 28, 1992, and U.S. Publication No. 2004/0126427, which mentioned the '974 patent in its specification, was published on July 1, 2004. Therefore, on December 1, 2008, the mailing date of the Notice of Allowance in the '887 application, inventor Gopi Venkatesh clearly had had knowledge of both the '215 patent and the '974 patent for more than three months before the mailing date of the notice of allowance.

53. Nevertheless, in Applicant's December 12, 2008, submission of the Information Disclosure Statement (IDS) under 37 C.F.R. § 1.97(d), Applicant's attorney certified that no item on the IDS was known to anyone with a duty under 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS:

> Pursuant to 37 C.F.R. § 1.97(e)(2), Applicants state that no item of information in this information disclosure statement was cited in a

> communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this certification, after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this information disclosure statement.

54. Under 37 C.F.R. § 10.18, any paper submitted to the Patent Office during prosecution of an application is a certification and the signer agrees that the statements made are true and that violations may result in invalidity of any resulting patent. Applicant's submission of the false statement that no one with a duty had knowledge of the references submitted resulted in the Examiner accepting the IDS and issuing the '372 patent. If Applicant's attorney had not certified that the references on the IDS were not known to anyone with a duty under 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS, she would have had to file a continuing application (or possibly a Request for Continued Examination under 37 C.F.R. § 1.114) and thus would have delayed issuance of the '887 application.

55. The certification was made that "to the knowledge of the person signing this certification, after making reasonable inquiry" inventor Gopi Venkatesh had no knowledge of his own patent. Under Patent Office rules, the certification cannot be made if the inventor of the reference submitted is also a named inventor on the application. MPEP (Revision 7, July 2008) at 600-159. Therefore, Applicant's attorney knew or should have known of the materiality of the IDS certification and an inference of intent to mislead may be drawn from the fact that the false certification was made, as well as based on the high materiality of the false certification.

56. The named inventors of the '793 and '372 patent, Gopi Venkatesh and James Clevenger, also failed to disclose other highly material information to the USPTO in connection with the prosecution of those patents that renders the '372 patent unenforceable for inequitable

conduct. Specifically, the named inventors (1) failed to disclose to the USPTO during prosecution of the applications that led to the '793 and '372 patents information that was known to them concerning the administration of the extended-release dosage forms claimed in the '793 and '372 patents in clinical trials conducted more than one year before the applications' effective filing date, and (2) failed to disclose the inventors' preferred method of making and using the inventions claimed in the '793 and '372 patents, *i.e.*, preferences for certain process parameters for making the claimed formulations, which the inventors held at the time the applications that led to the patents were filed, in violation of the best mode requirement of 25 U.S.C. § 112, ¶ 1. The intent to deceive the USPTO in violation of the duty of candor and good faith required under, *inter alia*, 37 C.F.R. § 1.56, can be inferred based on the high materiality of this withheld information. This withholding of information material to the patentability of the claims of the '793 and '372 patents with deceptive intent constitutes inequitable conduct that renders all claims of the '372 patent unenforceable.

* * * * *

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully requests that this Court enter a Judgment and Order:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of Mylan's ANDA No. 90-738 have not infringed, do not infringe and would not, if marketed, used, sold, offered for sale, or imported, directly infringe any valid claim of the '372 patent, either literally or under the doctrine of equivalents, by inducement of infringement or otherwise;

(b) Declaring that the claims of the '372 patent are unenforceable;

(c) Declaring that the claims of the '372 patent are invalid;

(d) Permanently enjoining Plaintiffs, their officers, agents, directors, servants, employees, subsidiaries, and assigns, and all those acting under the authority of or in privity with any of them, from asserting or otherwise seeking to enforce the '372 patent against Mylan;

(e) Awarding Mylan the costs incurred by it in this action;

(f) Declaring this case exceptional under 35 U.S.C. § 285 and awarding Mylan its attorneys' fees, costs and expenses; and

(g) Awarding Mylan such other and further relief as the nature of the case may require and as the Court may deem just, proper, and equitable.

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By: /s/

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