IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANESTA AG, APTALIS PHARMATECH, INC. and IVAX INTERNATIONAL GMBH, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC. and MYLAN INC., Defendants.	Civil Action No. 08-889-SLR **JURY TRIAL DEMANDED**

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DAMAGES RESULTING FROM MYLAN'S LAUNCH AT RISK

Plaintiffs Anesta AG, Aptalis Pharmatech, Inc. and Ivax International GmbH (collectively, "Plaintiffs") bring this Amended Complaint against Defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively "Mylan" or "Defendants") and in support state and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and damages under the Food and Drug and Patent Laws of the United States, Titles 21 and 35, respectively, arising from the Defendants filing of an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market generic versions of AMRIX® drug products (cyclobenzaprine HCl extended release capsules), and the Defendants subsequent manufacture, use, sale, and offers to sell generic cyclobenzaprine HCl extended release capsules prior to the expiration of United States Patent Nos. 7,387,793 ("the '793 patent") and 7,544,372 ("the '372 patent), which cover the AMRIX® drug products.

THE PARTIES

2. Plaintiff Anesta AG ("Anesta") was formerly a Swiss corporation having a principal place of business at Baarerstr 23CH-6300 Zug, Switzerland.

3. Plaintiff Ivax International GmbH ("Ivax") is a Swiss corporation having a principal place of business at Alpenstrasse 2, 8640 Rapperswil, Switzerland.

4. Effective on or about October 1, 2012, Anesta was merged into Ivax.

5. Plaintiff Aptalis Pharmatech, Inc. ("Aptalis"), formerly known as Eurand, Inc., is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office and principal place of business located at 845 Center Drive, Vandalia, Ohio 45377.

6. On information and belief, Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

7. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

8. On information and belief, Defendant Mylan Inc. is the parent company of Mylan Pharmaceuticals, and Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

9. On information and belief, Defendant Mylan Pharmaceuticals is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Mylan Pharmaceuticals. On information and belief, together, Mylan

Pharmaceuticals and Mylan Inc. collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) within the United States generally, and the State of Delaware specifically.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271.

11. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants Mylan Inc. and Mylan Pharmaceuticals.

12. Mylan Inc. and Mylan Pharmaceuticals have previously submitted to the jurisdiction of this Court in this matter and have further previously availed themselves of this Court by, for example, asserting counterclaims in this and other civil actions initiated in this jurisdiction.

13. This Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals by virtue of their systematic and continuous contacts with the State of Delaware.

14. On information and belief, this Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals by virtue of their sales and offers to sell generic cyclobenzaprine HCl extended release capsules within the State of Delaware prior to the expiration of the ’793 patent and the ’372 patent.

15. On information and belief, Mylan has at all relevant times maintained continuous and systematic contacts with the State of Delaware, including but not limited to, its

aforementioned business of preparing generic pharmaceuticals that it distributes in the State of Delaware; and Mylan plans to continue to maintain such contacts.

16. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

17. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

18. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several aspects. One provision requires innovator drug companies to submit patent information to FDA "with respect to 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 the drug." 21 U.S.C. § 355(b)(1). FDA publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

19. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 255(j). When filing an ANDA, generic drug companies are required to review the patent information that FDA lists in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to the same.

20. The generic drug company may state that it does not seek FDA approval to market its generic drug products prior to patent expiration (commonly called a "Paragraph III Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug products prior to patent expiration by stating in its ANDA that the Orange Book listed patents are "invalid or will not be infringed …" (commonly called a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

THE PATENTS IN SUIT AND NDA NO. 21-777

21. On July 17, 2008, the United States Patent and Trademark Office ("PTO") duly and legally issued the '793 patent entitled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" to Eurand, Inc. ("Eurand"). Eurand subsequently changed its name to Aptalis Pharmatech, Inc. A true and correct copy of the '793 patent is attached hereto as **Exhibit A**.

22. On June 9, 2009, the PTO duly and legally issued the '372 patent entitled "Modified Release Dosage Forms of Skeletal Muscle Relaxants" to Eurand. Eurand subsequently changed its name to Aptalis Pharmatech, Inc. A true and correct copy of the '372 patent is attached hereto as **Exhibit B.**

23. On or about August 23, 2007, Anesta obtained, via an Asset Purchase Agreement ("APA"), all right, title, and interest in approved New Drug Application ("NDA") No. 21-777 for cyclobenzaprine hydrochloride extended-release capsules, in 15 mg and 30 mg doses, both sold under the AMRIX® trademark. Under the APA, Anesta also obtained an exclusive license to the '793 and '372 patents in the United States.

24. FDA approved AMRIX® for marketing in the United States under NDA No. 21-777, pursuant to section 505(b) of the FFDCA, 21 U.S.C. § 355(b).

25. In conjunction with NDA No. 21-777, Anesta listed the '793 and '372 patents in the Orange Book as patents "with respect to 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 the drug." 21 U.S.C. § 355(b)(1).

26. Effective on or about October 1, 2012, Anesta was merged into Ivax.

27. Ivax is the current holder of NDA No. 21-777 and is an exclusive licensee to the '793 and '372 patents in the United States.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENTS IN SUIT AND DAMAGES

28. On information and belief, the Defendants are engaged in the practice of reviewing pharmaceutical patents and challenging those patents.

29. This action arises because of the Defendants' efforts to gain approval from FDA to market generic versions of AMRIX® prior to the expiration of the '793 and '372 patents, and the Defendants subsequent manufacture, use, sales and offers to sell in the United States, including Delaware, of generic versions of AMRIX® drug products prior to the expiration of the '793 and '372 patents.

30. On information and belief, Defendant Mylan Pharmaceuticals, jointly with, and/or as the agent or alter ego of its parent Mylan Inc., submitted ANDA No. 90-738 to FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). That ANDA seeks, *inter alia*, FDA approval to commercially manufacture, use, and sell cyclobenzaprine hydrochloride extended-release capsules, 15 mg and 30 mg, ("the Mylan Generic Products"), throughout the United States including Delaware. ANDA No. 90-738 specifically seeks FDA approval to market the Mylan Generic Products prior to the expiration of the '793 and '372 patents.

31. On or about October 17, 2008, Cephalon, Inc. (on behalf of Anesta Corp.) received a letter dated October 16, 2008, signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii) with respect to the '793 patent (the "First Paragraph IV Notice Letter").

32. On or about October 21, 2008, Eurand received the First Paragraph IV Notice Letter dated October 16, 2008, signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii) with respect to the '793 Patent.

33. Mylan's First Paragraph IV Notice Letter to Eurand and Cephalon, Inc. states Mylan's intention to seek approval to market generic versions of AMRIX® cyclobenzaprine HCl extended release capsules prior to the expiration of the '793 Patent.

34. On or about November 26, 2008, Eurand, Cephalon, Inc. and Anesta filed suit against the Defendants as well as Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc. (C.A. 08-cv-889-SLR, D.I. 1), and therein alleged infringement of the '793 patent by Mylan. Count V of the complaint sought a Declaratory Judgment of infringement of the '793 patent under 35 U.S.C. § 271(a) against all the named defendants.

35. On or about February 22, 2010, Eurand received a letter dated February 19, 2010, signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21

U.S.C. § 355(j)(2)(b)(i) and (ii) with respect to the '372 patent (the "Second Paragraph IV Notice Letter").

36. On or about February 22, 2010, Cephalon, Inc. (on behalf of Anesta Corp.) received the Second Paragraph IV Notice Letter dated February 19, 2010, signed by an attorney on behalf of Mylan, purporting to be notice of Mylan's filing of an ANDA seeking to market 15 mg and 30 mg generic versions of AMRIX® cyclobenzaprine HCl extended release capsules and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii) with respect to the '372 patent.

37. Mylan's Second Paragraph IV Notice Letter to Eurand and Cephalon, Inc. states Mylan's intention to seek approval to market generic versions of AMRIX® cyclobenzaprine HCl extended release capsules prior to the expiration of the '372 patent

38. On or about September 8, 2010, Eurand, Cephalon, Inc., Anesta and Mylan filed a Stipulation and Order Regarding Mylan's Non-Infringement Defenses and Counterclaims (C.A. No. 08-cv-889-SLR, D.I. 208). Pursuant to that Stipulation and Order, Eurand, Cephalon, Inc., and Anesta withdrew their previously-filed opposition to Mylan's Motion to Amend Pleadings to Add Counterclaims Concerning the Related '372 Patent and consented to the Court's entry of Mylan's Third Amended Answer, Defenses, and Counterclaims.

39. On or about September 29 through October 7, 2010, this Court held a bench trial on, *inter alia*, the infringement of the '793 and '372 patents by Mylan and the validity and enforceability of the '793 and '372 patents.

40. On or about April 8, 2011, this Court issued an Order (C.A. No. 09-md-2118-SLR, D.I. 251), *inter alia*, enjoining Defendants from launching the Mylan Generic Products

until the Court's opinion on the infringement, validity and enforceability of the '793 and '372 patents issued.

41. On or about April 17, 2011, the 30-month stay of FDA approval of ANDA No. 90-738 expired.

42. On or about April 18, 2011, FDA granted final approval of ANDA No. 90-738.

43. On or about May 12, 2011, this Court issued a Memorandum Opinion (C.A. No. 09-md-2118-SLR, D.I. 254) finding, *inter alia*, that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent, but that those claims were invalid as obvious. On that same day, the Court entered a Judgment in a Civil Case (C.A. No. 09-md-2118-SLR, D.I. 255), wherein the Court, *inter alia*, "ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of plaintiffs Eurand, Inc. and Anesta AG and against defendants Mylan Pharmaceuticals, Inc. and Barr Laboratories, Inc. as to infringement of U.S. Patent Nos. 7,387,793 and 7,544,372."

44. On or about May 13, 2011, Defendants began offering for sale and selling the Mylan Generic Products to various buyers in the United States.

45. On or about May 15, 2011, Plaintiffs filed a motion for a temporary restraining order ("TRO"), seeking, *inter alia*, to enjoin Defendants' sales and offers for sale of the Mylan Generic Products (C.A. No. 09-md-2118-SLR, D.I. 256).

46. On or about May 20, 2011, this Court issued an Order granting Plaintiffs' TRO motion (C.A. No. 09-md-2118-SLR, D.I. 273). Defendants subsequently filed a motion for reconsideration (C.A. No. 09-md-2118-SLR, D.I. 275), which this Court denied (C.A. No. 09-md-2118-SLR, D.I. 289).

47. On or about May 24, 2011, this Court converted its May 20, 2011 temporary restraining order to an injunction pending appeal (the "Injunction Order") (C.A. No. 09-md-2118-SLR, D.I. 290), which, *inter alia*, enjoined Defendants from manufacturing, using, offering for sale, selling and/or importing into the United States the Mylan Generic Products, and required Defendants to take reasonable steps to recall their generic cyclobenzaprine products from the United States market and issue recall letters. (*Id.* ¶ 3.)

48. On or about May 24, 2011, Defendants filed an emergency motion in the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") seeking to stay this Court's TRO Order and Injunction Order (C.A. No. 09-md-2118-SLR, D.I. 294).

49. On or about May 24, 2011, Defendants filed a notice of appeal in the Federal Circuit of, *inter alia*, this Court's Injunction Order, but Defendants did not appeal this Court's May 12, 2011 ruling that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent.

50. On or about May 25, 2011, the Federal Circuit issued an Order granting Defendants' motion for a temporary stay of the Court's TRO Order and Injunction Order, pending full consideration of Defendants' motion for a stay. On information and belief, Defendants resumed sales of the Mylan Generic Products immediately upon the Federal Circuit's granting of the motion for a temporary stay.

51. On or about May 25, 2011, Plaintiffs filed a notice of appeal in the Federal Circuit of this Court's ruling that claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent were invalid as obvious.

52. On or about July 7, 2011, after receiving full briefing on the merits of the appeal and the motion for a stay, the Federal Circuit issued an order lifting, in part, its May 25, 2011

Order. Upon issuance of that Order, Defendants were again enjoined from manufacturing, using, offering for sale, or selling and/or importing into the United States the Mylan Generic Products, but were not required to recall products already in the market. On information and belief, Defendants took no steps to recall products already in the market after the Federal Circuit's July 7, 2011 order.

53. On September 7, 2011, a panel of the Federal Circuit heard oral argument on the parties' respective appeals.

54. On or about April 16, 2012, the Federal Circuit issued a precedential opinion, *inter alia*, reversing this Court's finding that claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent were invalid as obvious.

55. On or about October 23, 2012, Defendants filed a Petition for a Writ of Certiorari (the "Petition") in the Supreme Court of the United States (the "Supreme Court"). The Supreme Court denied the Petition on or about January 14, 2013.

56. On or about April 2, 2013, the parties filed in this Court a Stipulated Dismissal of Counterclaims, Final Judgment and Permanent Injunction (the "April 2, 2013 Stipulation") (C.A. No. 09-md-2118-SLR, D.I. 429), which, *inter alia*, set forth the parties' agreement that final judgment should be entered that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent, and that claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent are not invalid and are not unenforceable.

57. On or about April 4, 2013, the April 2, 2013 Stipulation was entered as an order by this Court.

COUNT I

(Infringement of the '793 patent Under 35 U.S.C. § 271(e)(2))

58. Paragraphs 1 to 57 are incorporated herein as set forth above.

59. The Defendants, acting jointly, submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Products. By submitting the application, the Defendants, individually and collectively, have committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

60. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Products. By submitting the application, Mylan Pharmaceuticals has committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

61. When Mylan Pharmaceuticals submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of the Mylan Generic Products throughout the United States, including Delaware, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit the application and/or causing its agent or alter ego to submit the application, Mylan Inc. has committed an act of infringement with respect to the '793 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT II

(Infringement of the '793 patent Under 35 U.S.C. § 271(a)-(c))

62. Paragraphs 1 to 61 are incorporated herein as set forth above.

63. On or about April 4, 2013, this Court entered its order on the April 2, 2013 Stipulation. Pursuant to that order, final judgment was entered in favor of Plaintiffs and against

Mylan with respect to Plaintiffs' claims that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent; final judgment was entered in favor of Plaintiffs and against Mylan with respect to Mylan's declaratory judgment counterclaims of invalidity and unenforceability and all such counterclaims were dismissed with prejudice; and it was declared that claims 1-6, 9, 11-12, and 19 of the '793 patent are not invalid and not unenforceable. This Court's final judgment that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent, and that claims 1-6, 9, 11-12, and 19 of the '793 patent are not invalid and not unenforceable, is finally adjudicated and not subject to further appeal.

64. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now infringing directly one or more claims of the '793 patent under 35 U.S.C. § 271(a). The Defendants' acts of infringement have injured and damaged Plaintiffs.

65. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now inducing infringement of one or more claims of the '793 patent under 35 U.S.C. § 271(b). The Defendants have intentionally encouraged acts of direct infringement by, for example, wholesalers, pharmacies, physicians, patients and others, with knowledge of the '793 patent and knowledge that their acts constitute infringement. The Defendants' acts of infringement have injured and damaged Plaintiffs.

66. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now contributing to infringement of one or more

claims of the '793 patent under 35 U.S.C. § 271(c). The Defendants have had and continue to have knowledge that the Mylan Generic Products are especially adapted for a use that infringes the '793 patent and that there is no substantial non-infringing use for the Mylan Generic Products. The Defendants' acts of infringement have injured and damaged Plaintiffs.

67. The Defendants acts of infringing the '793 patent have caused and will continue to cause substantial and irreparable damage and harm to Plaintiffs, for example, by virtue of the fact that AMRIX® products are commercial embodiments of the '793 patent, and the Defendants acts of infringing the '793 patent have caused lost sales of AMRIX® products.

68. Defendants' manufacture, having manufactured, use, offer for sale, sale and/or importation into the United States of the Mylan Generic Products subsequent to the Federal Circuit's issuance of its April 16, 2012 opinion has been and continues to be willful infringement of the '793 patent. At least as of that date, there was no objective basis to believe that the '793 patent was not invalid or not infringed, and Defendants subjectively were reckless in permitting any further sales of the Mylan Generic Products.

COUNT III

(Infringement of the '372 Patent Under 35 U.S.C. § 271(e)(2))

69. Paragraphs 1 to 68 are incorporated herein as set forth above.

70. The Defendants, acting jointly, submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Products. By submitting the application, the Defendants, individually and collectively, have committed an act of infringement with respect to the '372 patent under 35 U.S.C. § 271(e)(2)(A).

71. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the

commercial manufacture, use, or sale throughout the United States, including Delaware, of the Mylan Generic Products. By submitting the application, Mylan Pharmaceuticals has committed an act of infringement with respect to the '372 patent under 35 U.S.C. § 271(e)(2)(A).

72. When Mylan Pharmaceuticals submitted ANDA No. 90-738 to FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of the Mylan Generic Products throughout the United States, including Delaware, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit the application and/or causing its agent or alter ego to submit the application, Mylan Inc. has committed an act of infringement with respect to the '372 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT IV

(Infringement of the '372 patent Under 35 U.S.C. § 271(a)-(c))

73. Paragraphs 1 to 72 are incorporated herein as set forth above.

74. On or about April 4, 2013, this Court entered its order on the April 2, 2013 Stipulation. Pursuant to that order, final judgment was entered in favor of Plaintiffs and against Mylan with respect to Plaintiffs' claims that the Mylan Generic Products infringe claims 1-6, 9, 11, 19, and 21 of the '372 patent; final judgment was entered in favor of Plaintiffs and against Mylan with respect to Mylan's declaratory judgment counterclaims of invalidity and unenforceability and all such counterclaims were dismissed with prejudice; and it was declared that claims 1-6, 9, 11-12, 19, and 21 of the '372 patent are not invalid and not unenforceable. This Court's final judgment that the Mylan Generic Products infringe claims 1-6, 9, 11-12, 19, and 21 of the '372 patent, and that claims 1-6, 9, 11-12, 19, and 21 of the '372 patent are not invalid and not unenforceable, is finally adjudicated and not subject to further appeal.

75. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now infringing directly one or more claims of the '372 patent under 35 U.S.C. § 271(a). The Defendants' acts of infringement have injured and damaged Plaintiffs.

76. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now inducing infringement of one or more claims of the '372 patent under 35 U.S.C. § 271(b). The Defendants have intentionally encouraged acts of direct infringement by, for example, wholesalers, pharmacies, physicians, patients and others, with knowledge of the '372 patent and knowledge that their acts constitute infringement. The Defendants' acts of infringement have injured and damaged Plaintiffs.

77. By making, having made, using, offering to sell, and/or selling within the United States and/or importing into the United States the Mylan Generic Products without license or authority, the Defendants have been and are now contributing to infringement of one or more claims of the '372 patent under 35 U.S.C. § 271(c). The Defendants have had and continue to have knowledge that the Mylan Generic Products are especially adapted for a use that infringes the '372 patent and that there is no substantial non-infringing use for the Mylan Generic Products. The Defendants' acts of infringement have injured and damaged Plaintiffs.

78. The Defendants acts of infringing the '372 patent have caused and will continue to cause substantial and irreparable damage and harm to Plaintiffs, for example, by virtue of the fact that AMRIX® products are commercial embodiments of the '372 patent, and the Defendants acts of infringing the '372 patent have caused lost sales of AMRIX® products.

79. Defendants' manufacture, having manufactured, use, offer for sale, sale and/or importation into the United States of the Mylan Generic Products subsequent to the Federal Circuit's issuance of its April 16, 2012 opinion has been and continues to be willful infringement of the '372 patent. At least as of that date, there was no objective basis to believe the '372 patent was not invalid or not infringed, and Defendants subjectively were reckless in permitting any further sales of the Mylan Generic Products.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That, because it has been finally adjudicated, and final judgment has been entered by this Court that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent, and that claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent are not invalid and are not unenforceable, judgment be entered that the Defendants, individually and/or collectively, have been and are continuing to infringe one or more claims of the '793 and '372 patents under 35 U.S.C. § 271(a) by manufacturing, having manufactured, using, selling, offering to sell, and/or importing the Mylan Generic Products prior to patent expiry.

b. That, because it has been finally adjudicated, and final judgment has been entered by this Court that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent, and that claims 1-6, 9, 11, and 19 of the '793 patent and claims 1-6, 9, 11, 19, and 21 of the '372 patent are not invalid and are not unenforceable, judgment be entered that the Defendants, individually and/or collectively, have been and are continuing to induce infringement under 35 U.S.C. § 271(b) of one or more claims

of the ’793 and ’372 patents by manufacturing, having manufactured, using, offering for sale, selling, and/or importing the Mylan Generic Products prior to patent expiry.

c. That, because it has been finally adjudicated, and final judgment has been entered by this Court that the Mylan Generic Products infringe claims 1-6, 9, 11, and 19 of the ’793 patent and claims 1-6, 9, 11, 19, and 21 of the ’372 patent, and that claims 1-6, 9, 11, and 19 of the ’793 patent and claims 1-6, 9, 11, 19, and 21 of the ’372 patent are not invalid and are not unenforceable, judgment be entered that the Defendants, individually and/or collectively, have been and are continuing to contribute to infringement under 35 U.S.C. § 271(c) of one or more claims of the ’793 and ’372 patents by manufacturing, having manufactured, using, offering for sale, selling, and/or importing the Mylan Generic Products prior to patent expiry.

d. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(C) as appropriate;

e. That judgment be entered against the Defendants for money damages sufficient to compensate Plaintiffs for the Defendants’ infringement of the ’793 and ’372 patents in an amount to be determined at trial, including lost profits, disgorgement, and/or a reasonable royalty;

f. That pursuant to 35 U.S.C. § 284, money judgment as a result of any willful nature of the Defendants’ infringement be trebled;

g. For an accounting for any infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

h. That this Court award such other and further relief as it may deem just and proper.

JURY DEMAND

Plaintiffs request trial by jury.

Respectfully submitted,

Dated: May 15, 2013

By: */s/ Susan M. Coletti*

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