IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC., MYLAN INC., MATRIX LABORATORIES LIMITED and MATRIX LABORATORIES INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Endo Pharmaceuticals Inc. ("Endo"), by its attorneys, for its complaint against Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals"), Mylan Inc., Matrix Laboratories Limited, and Matrix Laboratories Inc. (collectively "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 5,464,864; 5,637,611; and 5,827,871 (collectively, the "Patents-in-Suit") arising under the patent laws of the United States of America, 35 U.S.C. §§ 100 *et seq.*

THE PARTIES

2. Endo is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 100 Endo Blvd., Chadds Ford, Pennsylvania 19317.

3. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the State of West Virginia, having its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. On information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

5. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the United States, alone or through its parent Mylan Inc. and sister corporations Matrix Laboratories Limited and Matrix Laboratories Inc.

6. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly-owned subsidiaries and agents, Mylan Pharmaceuticals, Matrix Laboratories Limited and Matrix Laboratories Inc.

8. On information and belief, Matrix Laboratories Limited is a corporation organized under the laws of India, with its principal place of business located at 1-1-151/1, IV Floor, Sairam Towers, Alexander Road, Secunderabad 500 003, India.

9. On information and belief, Matrix Laboratories Limited is a wholly-owned subsidiary of Mylan Inc.

10. On information and belief, Matrix Laboratories Limited is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for importation in the United States, alone or through its parent Mylan Inc. and sister corporations Mylan Pharmaceuticals and Matrix Laboratories Inc.

11. On information and belief, Matrix Laboratories Inc. is a corporation organized under the laws of the State of Delaware.

12. On information and belief, Matrix Laboratories Inc. is a subsidiary and the U.S. agent of Matrix Laboratories Limited.

13. On information and belief, Matrix Laboratories Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the United States, alone or through its parent corporations Mylan Inc. and Matrix Laboratories Limited and its sister corporation Mylan Pharmaceuticals.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331; 1338(a); and 2201.

15. This Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here, including by registering to do business in Delaware, and appointing a registered agent for service of process.

16. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, *inter alia*, its persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, including through its parent Mylan Inc. and sister companies Matrix Laboratories Limited and Matrix Laboratories Inc.

17. This Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

18. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, including through its subsidiaries and agents Mylan Pharmaceuticals, Matrix Laboratories Limited and Matrix Laboratories Inc.

19. This Court has personal jurisdiction over Matrix Laboratories Limited because Matrix Laboratories Limited has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

20. This Court has personal jurisdiction over Matrix Laboratories Limited by virtue of, *inter alia*, its persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, including through its parent Mylan Inc., sister corporation Mylan Pharmaceuticals and subsidiary and agent Matrix Laboratories Inc.

21. This Court has personal jurisdiction over Matrix Laboratories Inc. because Matrix Laboratories Inc. is a Delaware corporation and has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

22. This Court has personal jurisdiction over Matrix Laboratories Limited by virtue of, *inter alia*, its persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, including through its parent corporations Mylan Inc. and Matrix Laboratories Limited and its sister corporation Mylan Pharmaceuticals.

23. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PATENTS-IN-SUIT

U.S. Patent No. 5,464,864

24. On November 7, 1995, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,464,864 ("the '864 Patent"), entitled "Use of Tetrahydrocarbazole Derivatives As $5HT_1$ Receptor Agonists." A true and correct copy of the '864 Patent is attached hereto as Exhibit A.

25. The '864 Patent was granted a Patent Term Extension under 35 U.S.C. § 156 on February 10, 2006 such that its term is extended up to and including at least November 7, 2015.

26. Endo is the assignee of the '864 patent pursuant to an assignment from Vernalis Development Limited.

U.S. Patent No. 5,637,611

27. On June 10, 1997, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,637,611 ("the '611 Patent"), entitled "Medicaments." A true and correct copy of the '611 Patent is attached hereto as Exhibit B.

28. The term of the '611 Patent is up to and including at least June 10, 2014.

29. Endo is the assignee of the '611 patent pursuant to an assignment from Vernalis Development Limited.

U.S. Patent No. 5,827,871

30. On October 27, 1998, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,827,871 ("the '871 Patent"), entitled "Medicaments 1,2,3,4,-Tetrahydrocarbazoles ad 5-HT_1 Agonist Use Thereof." A true and correct copy of the '871 Patent is attached hereto as Exhibit C.

31. The term of the '871 Patent is up to and including at least October 27, 2015.

32. Endo is the assignee of the '871 patent pursuant to an assignment from Vernalis Development Limited.

FACTS COMMON TO THE INFRINGEMENT OF ALL THE PATENTS-IN-SUIT

Frovatriptan tablets

33. On November 8, 2001, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 021006 for 2.5 mg frovatriptan tablets.

34. Endo is the holder of NDA No. 021006. Pursuant to that NDA, it sells a product containing the equivalent of 2.5 mg frovatriptan, specifically containing 3.91 mg of frovatriptan succinate, ("2.5 mg frovatriptan tablets") under the trademark FROVA®.

35. FROVA® 2.5 mg frovatriptan tablets have been approved by the FDA for the acute treatment of migraine attacks with or without aura in adults at a recommended initial dose of one 2.5 mg frovatriptan tablet.

Infringement of the Patents-In-Suit

36. The Patents-in-Suit are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (also known as the "Orange Book") for FROVA®.

37. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202931 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage *inter alia* in the commercial manufacture, use, offer for sale, importation and sale of 2.5 mg frovatriptan tablets ("Mylan Generic Product").

38. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 202931.

39. On information and belief, Matrix Laboratories Limited participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 202931.

40. On information and belief, Matrix Laboratories Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 202931.

41. On information and belief, Mylan Pharmaceuticals and/or Mylan Inc. filed ANDA No. 202931 on behalf of and for the benefit of themselves and Matrix Laboratories Limited and/or Matrix Laboratories Inc.

42. On information and belief, the Mylan Generic Product contains 2.5 mg frovatriptan as the active ingredient and also contains other ingredients such as a physiologically acceptable carrier.

43. On information and belief, ANDA No. 202931 seeks approval to commercially market the Mylan Generic Product for use as a treatment for migraines, specifically for the Mylan Generic Product to be administered to a subject diagnosed with acute migraine and in need of migraine treatment.

44. On information and belief, ANDA No. 202931 specifically seeks FDA approval to market Mylan Generic Product prior to the expiration of the Patents-in-Suit.

45. Endo received a letter dated July 1, 2011 ("the Mylan Paragraph IV Letter") from Mylan Pharmaceuticals notifying Endo that ANDA No. 202931 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in Mylan's opinion, the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of the Mylan Generic Product.

46. Endo commenced this action within forty-five days of the date Endo received notice of Mylan Pharmaceutical's Paragraph IV Certification in ANDA No. 202931.

COUNT I

INFRINGEMENT OF THE '864 PATENT

47. Endo repeats and realleges each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

48. Defendants have infringed the '864 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202931 and/or causing and inducing the submission of ANDA No. 202931 with a Paragraph IV Certification seeking FDA approval for the commercial manufacture, use and sale of 2.5 mg frovatriptan tablets prior to the expiration of the '864 Patent.

49. Moreover, if Defendants commercially manufacture, use, offer to sell, sell, or import Mylan Generic Product, or induce or contribute to any such conduct, they would further infringe the '864 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

50. Defendants were aware of the '864 Patent prior to filing ANDA No. 202931.

51. Endo has no adequate remedy at law to redress the infringement by Defendants.

52. Endo will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '864 Patent.

COUNT II

INFRINGEMENT OF THE '611 PATENT

53. Endo repeats and realleges each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

54. Defendants have infringed the '611 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202931 and/or causing and inducing the submission of ANDA No.

202931 with a Paragraph IV Certification seeking FDA approval for the commercial manufacture, use and sale of 2.5 mg frovatriptan tablets prior to the expiration of the '611 Patent.

55. Moreover, if Defendants commercially manufacture, use, offer to sell, sell, or import Mylan Generic Product, or induce or contribute to any such conduct, they would further infringe the '611 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

56. Defendants were aware of the '611 Patent prior to filing ANDA No. 202931.

57. Endo has no adequate remedy at law to redress the infringement by the Defendants.

58. Endo will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '611 Patent.

COUNT III

INFRINGEMENT OF THE '871 PATENT

59. Endo repeats and realleges each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

60. Defendants have infringed the '871 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202931 and/or causing and inducing the submission of ANDA No. 202931 with a Paragraph IV Certification seeking FDA approval for the commercial manufacture, use and sale of 2.5 mg frovatriptan tablets prior to the expiration of the '871 Patent.

61. Moreover, if Defendants commercially manufacture, use, offer to sell, sell, or import Mylan Generic Product, or induce or contribute to any such conduct, they would further infringe the '871 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

62. Defendants were aware of the '871 Patent prior to filing ANDA No. 202931.

63. Endo has no adequate remedy at law to redress the infringement by the Defendants.

64. Endo will be irreparably harmed if the Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '871 Patent.

PRAYER FOR RELIEF

WHEREFORE, Endo prays for judgment as follows:

A. That Defendants have infringed the Patents-in-Suit;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202931 shall not be earlier than the expiration date of all of the Patents-in-Suit, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing the proposed generic version of the FROVA® product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, prior to the expiration of any of the Patents-in-Suit, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Endo be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Endo be awarded such other and further relief as this Court deems just and proper.

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