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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., JANSSEN R&D IRELAND, and G.D. SEARLE, LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No.
TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen"), and G.D. Searle, LLC ("Searle") (Janssen and Searle, collectively, "Plaintiffs") for their Complaint against defendants Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. ("Mylan Inc.") (collectively "Mylan"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries, Ltd. ("Teva Industries") (collectively, "Teva") (Mylan and Teva, collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. RE42,889 (the "'889 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. and for a declaratory judgment of infringement of the '889 Patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of Mylan's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of plaintiff Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs and Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of plaintiff Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 400 mg, and 600 mg products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

3. Plaintiff Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff G.D. Searle, LLC is a Delaware limited liability company having a principal place of business at 235 East 42nd Street, New York, New York 10017.

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

Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

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

7. On information and belief, Teva Industries is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Industries is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Teva USA.

8. On information and belief, Teva USA is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva USA is in the business of manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Teva USA is a wholly owned subsidiary of Teva Industries.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

11. On information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey.

12. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

13. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, its operation of offices in this district, and its filing of claims and counterclaims in this district.

14. Mylan Pharmaceuticals and Mylan Inc. have previously stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases, including in the related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (MCA).

15. On information and belief, this Court has personal jurisdiction over Teva USA because Teva USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva USA has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

16. On information and belief, this Court has personal jurisdiction over Teva Industries because Teva Industries has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva Industries has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

17. On information and belief, Teva USA and Teva Industries operate and act in concert as an integrated, unitary business. For example, Teva Industries includes within its Annual Report the activities of Teva USA, including revenue earned.

18. On information and belief, Teva USA is registered to do business in New Jersey.

19. On information and belief, Teva USA retains a registered agent in this judicial district.

20. Teva Industries and Teva USA have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases, including in the related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (MCA).

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

BACKGROUND

22. On November 1, 2011, the United States Patent and Trademark Office ("the PTO") issued the '889 Patent, entitled "α- and β-Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors." A true and correct copy of the '889 Patent is attached as Exhibit A.

23. Plaintiff Searle holds title to the '889 Patent.

24. The '889 Patent is a reissue of U.S. Patent No. 5,968,942 ("the '942 Patent").

25. The '942 Patent was filed on August 23, 1994, and issued on October 19, 1999.

26. Plaintiff Janssen R&D Ireland has an exclusive license to the '889 Patent.

27. The '889 Patent expires on October 19, 2016.

28. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA®. The period of pediatric exclusivity applicable to the '889 Patent does not expire until April 19, 2017.

29. Janssen Products, L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®. The NDA was formerly held by Tibotec Inc. The NDA was transferred to Janssen Products, L.P. on December 23, 2011.

30. PREZISTA® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

31. The FDA's "Orange Book" also lists patents associated with approved drugs. The '889 Patent, U.S. Patent Nos. 5,843,946 ("'the '946 Patent"), 6,248,775 ("'the '775 Patent"), and 7,700,645 ("'the '645 Patent") are listed in the "Orange Book" in association with PREZISTA® (darunavir). The claims of the '889, '946, '775, and '645 Patents cover PREZISTA® or its use.

32. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202-136 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of darunavir tablets in 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg dosages ("Mylan's Generic Tablets") as generic versions of the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg tablets.

33. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation, and filing of ANDA No. 202-136 for Mylan's Generic Tablets.

34. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-136.

35. Plaintiffs received letters from Mylan (the "Mylan Paragraph IV letters") stating that Mylan had submitted ANDA No. 202-136 seeking approval to manufacture, use, and sell Mylan's Generic Tablets prior to the expiration of the '946, '775, and '645 Patents.

36. The Mylan Paragraph IV letters also stated that Mylan ANDA No. 202-136 included certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946, '775, and '645 Patents are invalid and/or not infringed.

37. Plaintiffs are asserting the '946, '775 and '645 Patents against Mylan in a related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (MCA).

38. The '889 Patent had not issued at the time Mylan submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

39. The '889 Patent was listed in the "Orange Book" in association with PREZISTA® (darunavir) within thirty days of its issuance.

40. Mylan had actual and constructive notice of the '889 Patent. (*See* D.I. 116, Joint Status Letter for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA); D.I. 175, Joint Claim Construction and Prehearing Statement for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA).)

41. On information and belief, Mylan has sought or will seek approval to manufacture, use, and sell Mylan's Generic Tablets prior to the expiration of the '889 Patent.

42. On information and belief, Mylan has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Mylan's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

43. On information and belief, Mylan's actions include, but are not limited to, the development of Mylan's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

44. On information and belief, Mylan Pharmaceuticals and Mylan Inc. continue to seek approval of ANDA No. 202-136 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Mylan's Generic Tablets (including the

commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-136.

45. On information and belief, Teva Industries, itself and/or through its subsidiary, agent and alter ego, Teva USA, submitted ANDA No. 202-118 to the FDA under § 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® 75 mg, 150 mg, 400 mg, and 600 mg tablets ("Teva's Generic Tablets").

46. On information and belief, Teva Industries and Teva USA collaborated in the research, development, preparation and filing of ANDA No. 202-118 for Teva's Generic Tablets.

47. On information and belief, Teva Industries participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 202-118.

48. Plaintiffs received a letter from Teva (the "Teva Paragraph IV letter") stating that Teva had submitted ANDA No. 202-118 seeking approval to manufacture, use, and sell Teva's Generic Tablets prior to the expiration of the '946, '775, and '645 Patents.

49. The Teva Paragraph IV letter also stated that Teva ANDA No. 202-118 included certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946, '775, and '645 Patents are invalid and/or not infringed.

50. Plaintiffs are asserting the '946, '775, and '645 Patents against Teva in a related consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (MCA).

51. The '889 Patent had not issued at the time Teva submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

52. Teva had actual and constructive notice of the '889 Patent after it issued. (*See* D.I. 116, Joint Status Letter for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA); D.I. 175, Joint Claim Construction and Prehearing Statement for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA).)

53. On information and belief, Teva intends to seek approval to manufacture, use, and sell Teva's Generic Tablets prior to the expiration of the '889 Patent. Teva has stated that it will file a Paragraph IV certification with respect to the '889 Patent. (*See* D.I. 116, Joint Status Letter for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA); D.I. 175, Joint Claim Construction and Prehearing Statement for *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW) (MCA).)

54. On information and belief, Teva has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Teva's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

55. On information and belief, Teva's actions include, but are not limited to, the development of Teva's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

56. On information and belief, Teva Industries and Teva USA continue to seek approval of ANDA No. 202-118 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Teva's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-118.

COUNT I

Infringement of the '889 Patent by Mylan under 35 U.S.C. § 271(e)(2)(A)

57. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 56 hereof, as if fully set forth herein.

58. Mylan Pharmaceuticals and Mylan Inc. have infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-136 and seeking FDA approval of ANDA No. 202-136 prior to patent expiry.

59. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

60. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '889 Patent.

COUNT II

Infringement of the '889 Patent by Teva under 35 U.S.C. § 271(e)(2)(A)

61. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 60 hereof, as if fully set forth herein.

62. Teva Industries and Teva USA have infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-118 and seeking FDA approval of ANDA No. 202-118 prior to patent expiry.

63. Plaintiffs have no adequate remedy at law to redress the infringement by Teva.

64. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of the '889 Patent.

COUNT III

Declaratory Judgment of Infringement by Mylan of the '889 Patent Under 35 U.S.C. § 271(a), (b), or (c)

65. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 64 hereof, as if fully set forth herein.

66. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Mylan regarding infringement of the '889 Patent.

67. Mylan has made and will continue to make substantial preparation manufacture, offer to sell, sell and/or import Mylan's Generic Tablets.

68. Mylan's actions, including, but not limited to, the filing of ANDA No. 202-136, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-136, and engaging in litigation to manufacture, offer to sell, sell and/or import Mylan's Generic Tablets prior to the expiration of patents listed in the Orange Book in association with PREZISTA®, indicate a refusal to change its course of action.

69. Any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

70. Plaintiffs are entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

COUNT IV

Declaratory Judgment of Infringement by Teva of the '889 Patent Under 35 U.S.C. § 271(a), (b), or (c)

71. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 70 hereof, as if fully set forth herein.

72. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Teva regarding infringement of the '889 Patent.

73. Teva has made and will continue to make substantial preparation to manufacture, offer to sell, sell and/or import Teva's Generic Tablets.

74. Teva's actions, including, but not limited to, the filing of ANDA No. 202-118, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-118, and engaging in litigation to manufacture, offer to sell, sell and/or import Teva's Generic Tablets prior to the expiration of patents listed in the Orange Book in association with PREZISTA®, indicate a refusal to change its course of action.

75. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

76. Plaintiffs are entitled to judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '889 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Defendants have infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Mylan ANDA No. 202-136 and Teva ANDA No. 202-118 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '889 Patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-136 and ANDA No. 202-118 would constitute infringement of the '889 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-136 and ANDA No. 202-118 until the day after the expiration of the period of pediatric exclusivity applicable to the '889 Patent;

(e) a declaration that this case is exceptional;

(f) an award of Plaintiffs' costs, expenses, reasonable attorneys fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(g) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: June 13, 2012

s/John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action involves the same Plaintiffs and patent as in *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 12-cv-2840-WHW-MCA. Further, this action involves the same Plaintiffs, four of the same Defendants, and two of the same ANDAs as in *Janssen Products L.P., et al. v. Lupin Limited, et al.*, D.N.J., 10-cv-5954-WHW-MCA. Lastly, this action involves the same Plaintiffs as in *Tibotec Inc., et al. v. Hetero Drugs, Ltd., Unit III, et al.*, D.N.J. 11-cv-1696-WHW-MCA. These actions all relate to generic versions of Plaintiff Janssen's PREZISTA® products.

Dated: June 13, 2012

Respectfully submitted,

s/John E. Flaherty

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