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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and TAKEDA IRELAND LIMITED,

Plaintiffs,

v.

INDOCO REMEDIES LTD.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A."), Takeda Pharmaceuticals America, Inc. ("Takeda America"), and Takeda Ireland Limited ("Takeda Ireland") (collectively, "Plaintiffs") by their undersigned attorneys, and for their complaint against Indoco Remedies Ltd. ("Indoco"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Indoco's filing of Abbreviated New Drug Application ("ANDA") No. 209998 with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market generic versions of the pharmaceutical drug product Kazano® prior to the expiration of U.S. Patent Nos. 7,807,689 ("the '689 patent"), 8,173,663 ("the '663 patent"), 8,288,539 ("the '539 patent"), and 8,900,638 ("the '638 patent") (collectively, the "patents-in-suit" or the "asserted patents").

THE PARTIES

2. Plaintiff Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products.

3. Plaintiff Takeda Japan is the owner of record and assignee of all of the patents-in-suit.

4. Plaintiff Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the research, development, and marketing of pharmaceutical products.

Takeda U.S.A. is the registered holder of approved New Drug Application ("NDA") No. 203414 for Kazano®.

5. Plaintiff Takeda America is a Delaware corporation. It is a wholly owned subsidiary of Takeda U.S.A., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Takeda America has the right to sell Kazano® in the United States.

6. Plaintiff Takeda Ireland is a company incorporated under the laws of Ireland. It is a wholly owned subsidiary of Takeda Japan and maintains its registered office at Bray Business Park, Kilruddery, Co. Wicklow, Ireland. Takeda Ireland is the exclusive licensee of the patents-in-suit.

7. Upon information and belief, Indoco is a company organized under the laws of India, having its principal place of business at Indoco House, 166 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

8. Upon information and belief, Indoco is in the business of making and selling generic pharmaceutical products, which it distributes in New Jersey and throughout the United States.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Indoco because, *inter alia*, Indoco has conducted business in New Jersey, Indoco has availed itself of the rights and benefits of New Jersey law, Indoco has purposefully availed itself of the privilege of conducting business in New Jersey, Indoco intends to sell its ANDA products in the State of New Jersey upon approval of ANDA No. 209998, and Indoco has engaged in systematic and continuous contacts with the State of New Jersey.

11. Upon information and belief, (i) Indoco is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through its subsidiaries, agents, and/or alter-egos, which Indoco manufactures, distributes, markets, and sells throughout the United States and in this Judicial District; (ii) Indoco purposefully has conducted business and continues to conduct business directly, and/or through its subsidiaries, agents, and/or alter-egos in this Judicial District; and (iii) this Judicial District is likely a destination of Indoco's ANDA products that are the subject of this lawsuit.

12. Indoco has consented to personal jurisdiction before this Court in other patent cases, including in *Takeda Pharmaceutical Company Ltd., et al. v. Indoco Remedies, Ltd.*, Civil Action No. 17-7301 (SRC)(CLW), which is a related matter in which Takeda is asserting three of the patents-in-suit against Indoco. Indoco has asserted counterclaims in that matter, thus invoking the benefits and protections of this Court and this District.

13. In the alternative, this Court has jurisdiction over Indoco because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Indoco is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Indoco has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Indoco satisfies due process.

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

15. Indoco has acknowledged that this District is an appropriate venue in other patent cases, including in *Takeda Pharmaceutical Company Ltd., et al. v. Indoco Remedies, Ltd.*, Civil Action No. 17-7301 (SRC)(CLW), which is a related matter in which Takeda is asserting three of the patents-in-suit against Indoco.

THE PATENTS-IN-SUIT

16. On October 5, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '689 patent entitled, "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of the inventors Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, and Luckner G. Ulysse. A copy of the '689 patent is attached hereto as Exhibit A.

17. Takeda Japan is the owner of all right, title, and interest in the '689 patent.

18. On May 8, 2012, the USPTO duly and lawfully issued the '663 patent entitled, "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of inventors Jun Feng, Stephen L. Gwaltney, Jeffrey A. Stafford, Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, Jonathon S. Salsbury, and Luckner G. Ulysse. A copy of the '663 patent is attached hereto as Exhibit B.

19. Takeda Japan is the owner of all right, title, and interest in the '663 patent.

20. On October 16, 2012, the USPTO duly and lawfully issued the '539 patent entitled, "Dipeptidyl Peptidase Inhibitors," to Takeda Japan as assignee of inventors Jun Feng, Stephen L. Gwaltney, Jeffrey A. Stafford, Zhiyuan Zhang, Bruce J. Elder, Paul K. Isbester, Grant J. Palmer, Jonathon S. Salsbury, and Luckner G. Ulysse. A copy of the '539 patent is attached hereto as Exhibit C.

21. Takeda Japan is the owner of all right, title, and interest in the '539 patent.

22. On December 2, 2014, the USPTO duly and lawfully issued the ’638 patent entitled, “Solid Preparation Comprising Alogliptin and Metformin Hydrochloride,” to Takeda Japan as assignee of inventors Kazumichi Yamamoto and Hiroyoshi Koyama.

23. Takeda Japan is the owner of all right, title, and interest in the ’638 patent.

TAKEDA DRUG PRODUCT

24. Takeda U.S.A. holds approved NDA No. 203414 for oral tablets containing 12.5 mg/500 mg, and 12.5 mg/1 g of alogliptin benzoate and metformin hydrochloride, sold under the trade name Kazano®.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to Kazano®.

26. A number of other patents are also listed in the “Orange Book” with respect to Kazano®, but Indoco has not filed Paragraph IV certifications as to those patents.

INDOCO’S FDA SUBMISSION

27. Upon information and belief, Indoco submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 335(j) (ANDA No. 209998), seeking approval to commercially manufacture, use, and market generic versions of the pharmaceutical drug product Kazano® in the form of oral tablets containing 12.5 mg/500 mg, and 12.5 mg/1 g of alogliptin benzoate and metformin hydrochloride (“Indoco’s Alogliptin-Metformin Generic Product”), prior to the expiration of the patents-in-suit.

28. Indoco’s ANDA No. 209998 relies upon the Kazano® NDA and, according to Indoco, contains the required data demonstrating the bioavailability or bioequivalence of Indoco’s Alogliptin-Metformin Generic Product to Kazano®.

29. Takeda received a letter from Indoco, dated December 1, 2017, with an attached memorandum ("Indoco's Kazano® Notification"), stating that Indoco included a certification in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Indoco's Alogliptin-Metformin Generic Product (the "Alogliptin Paragraph IV certification"). Thus, Indoco is seeking approval of its proposed Alogliptin-Metformin Generic Product prior to the expiration of the asserted patents. Plaintiffs are filing this complaint within 45 days of receiving Indoco's Kazano® Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of Indoco's ANDA No. 209998 and Indoco's Kazano® Notification.

COUNT ONE: INFRINGEMENT OF THE '689 PATENT

30. Plaintiffs repeat and reallege the allegations of paragraphs 1–29 as though fully set forth herein.

31. Submission of ANDA No. 209998 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of oral tablets containing alogliptin benzoate and metformin hydrochloride (12.5 mg/500 mg and 12.5 mg/1 g) prior to the expiration of the '689 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

32. Unless enjoined by this Court, upon FDA approval, Indoco will induce infringement of the '689 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Indoco will intentionally encourage acts of direct infringement with knowledge of the '689 patent and knowledge that its acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval, Indoco will contributorily infringe the '689 patent under 35 U.S.C. § 271(c). Upon information and belief, Indoco has had

and continues to have knowledge that Indoco's Alogliptin-Metformin Generic Product is especially made or especially adapted for a use that infringes the '689 patent and that there are no substantial non-infringing uses for Indoco's Alogliptin-Metformin Generic Product.

34. Indoco does not contest infringement of claims 1-4, 9-15, 18, 25-27, 30-34, 39-44, and 49-50 of the '689 patent in Indoco's Kazano® Notification. If Indoco had a factual or legal basis to contest infringement of claims 1-4, 9-15, 18, 25-27, 30-34, 39-44, and 49-50 of the '689 patent, it was required by applicable regulations to state such a basis in Indoco's Kazano® Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of applicant's bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

35. Indoco's actions, including its reliance on the purported defenses and statements set forth in Indoco's Kazano® Notification regarding the '689 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems just and proper.

36. Plaintiffs will be substantially and irreparably harmed if Indoco's infringement of the '689 patent is not enjoined.

37. Plaintiffs do not have an adequate remedy at law.

COUNT TWO: INFRINGEMENT OF THE '663 PATENT

38. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

39. Submission of ANDA No. 209998 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of oral tablets containing alogliptin benzoate and metformin hydrochloride (12.5 mg/500 mg and 12.5 mg/1 g) prior to the expiration of the

'663 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

40. Unless enjoined by this Court, upon FDA approval, Indoco will induce infringement of the '663 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Indoco will intentionally encourage acts of direct infringement with knowledge of the '663 patent and knowledge that its acts are encouraging infringement.

41. Unless enjoined by this Court, upon FDA approval, Indoco will contributorily infringe the '663 patent under 35 U.S.C. § 271(c). Upon information and belief, Indoco has had and continues to have knowledge that Indoco's Alogliptin-Metformin Generic Product is especially made or especially adapted for a use that infringes the '663 patent and that there are no substantial non-infringing uses for Indoco's Alogliptin-Metformin Generic Product.

42. Indoco does not contest infringement of claims 1, 4, 6-8, 10, 12, 15-17, 19-21, 27 and 29 of the '663 patent in Indoco's Kazano® Notification. If Indoco had a factual or legal basis to contest infringement of claims 1, 4, 6-8, 10, 12, 15-17, 19-21, 27 and 29 of the '663 patent, it was required by applicable regulations to state such a basis in Indoco's Kazano® Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of applicant's bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

43. Indoco's actions, including its reliance on the purported defenses and statements set forth in Indoco's Kazano® Notification regarding the '663 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

44. Plaintiffs will be substantially and irreparably harmed if Indoco's infringement of the '663 patent is not enjoined.

45. Plaintiffs do not have an adequate remedy at law.

COUNT THREE: INFRINGEMENT OF THE '539 PATENT

46. Plaintiffs repeat and reallege the allegations of paragraphs 1–45 as though fully set forth herein.

47. Submission of ANDA No. 209998 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of oral tablets containing alogliptin benzoate and metformin hydrochloride (12.5 mg/500 mg and 12.5 mg/1 g) prior to the expiration of the '539 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. Unless enjoined by this Court, upon FDA approval, Indoco will induce infringement of the '539 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Indoco will intentionally encourage acts of direct infringement with knowledge of the '539 patent and knowledge that its acts are encouraging infringement.

49. Unless enjoined by this Court, upon FDA approval, Indoco will contributorily infringe the '539 patent under 35 U.S.C. § 271(c). Upon information and belief, Indoco has had and continues to have knowledge that Indoco's Alogliptin-Metformin Generic Product is especially made or especially adapted for a use that infringes the '539 patent and that there are no substantial non-infringing uses for Indoco's Alogliptin-Metformin Generic Product.

50. Indoco does not contest infringement of claims 1-3, 5-7, 9, 11, 14-16, 22-23, 29 and 31 of the '539 patent in Indoco's Kazano® Notification. If Indoco had a factual or legal basis to contest infringement of claims 1-3, 5-7, 9, 11, 14-16, 22-23, 29 and 31 of the '539 patent, it was required by applicable regulations to state such a basis in Indoco's Kazano®

Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of applicant's bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

51. Indoco's actions, including its reliance on the purported defenses and statements set forth in Indoco's Kazano® Notification regarding the '539 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

52. Plaintiffs will be substantially and irreparably harmed if Indoco's infringement of the '539 patent is not enjoined.

53. Plaintiffs do not have an adequate remedy at law.

COUNT FOUR: INFRINGEMENT OF THE '638 PATENT

54. Plaintiffs repeat and reallege the allegations of paragraphs 1–53 as though fully set forth herein.

55. Submission of ANDA No. 209998 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of oral tablets containing alogliptin benzoate and metformin hydrochloride (12.5 mg/500 mg and 12.5 mg/1 g) prior to the expiration of the '638 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

56. Unless enjoined by this Court, upon FDA approval, Indoco will induce infringement of the '638 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Indoco will intentionally encourage acts of direct infringement with knowledge of the '638 patent and knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval, Indoco will contributorily infringe the '638 patent under 35 U.S.C. § 271(c). Upon information and belief, Indoco has had and continues to have knowledge that Indoco's Alogliptin-Metformin Generic Product is especially made or especially adapted for a use that infringes the '638 patent and that there are no substantial non-infringing uses for Indoco's Alogliptin-Metformin Generic Product.

58. Indoco does not contest infringement of any claim of the '638 patent in Indoco's Kazano® Notification. If Indoco had a factual or legal basis to contest infringement of the '638 patent, it was required by applicable regulations to state such a basis in Indoco's Kazano® Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of applicant's bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

59. Indoco's actions, including its reliance on the purported defenses and statements set forth in Indoco's Kazano® Notification regarding the '638 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

60. Plaintiffs will be substantially and irreparably harmed if Indoco's infringement of the '638 patent is not enjoined.

61. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Takeda Japan, Takeda U.S.A., Takeda America, and Takeda Ireland respectfully request the following relief:

A. A Judgment be entered that Indoco has infringed the asserted patents;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Indoco, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering to sell, or selling Indoco's Alogliptin-Metformin Generic Product within the United States, or importing Indoco's Alogliptin-Metformin Generic Product into the United States, prior to the expiration of the asserted patents;

C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 209998 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the asserted patents, including any extensions;

D. If Indoco commercially manufactures, uses, offers to sell, or sells Indoco's Alogliptin-Metformin Generic Product within the United States, or imports Indoco's Alogliptin-Metformin Generic Product into the United States, prior to the expiration of the asserted patents, including any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: January 3, 2018

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned, *Takeda Pharmaceutical Company Ltd., et al. v. Torrent Pharmaceuticals Ltd., et al.*, Civil Action No. 17-3186 (SRC)(CLW) and *Takeda Pharmaceutical Company Ltd., et al. v. Indoco Remedies, Ltd.*, Civil Action No. 17-7301 (SRC)(CLW), are related to the matter in controversy because they involve the same Plaintiffs, some of the same patents and, with respect to Civil Action No. 17-7301, the same Defendant.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 3, 2018

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