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

JANSSEN PRODUCTS, L.P., and JANSSEN SCIENCES IRELAND UNLIMITED COMPANY, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., AND CADILA HEALTHCARE LTD. Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (together, "Janssen" or "Plaintiffs") for their Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Cadila Healthcare Ltd. (d/b/a/ Zydus Cadila) ("Cadila") (collectively, "Defendants" or "Zydus") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Defendants of U.S. Patent Nos. 7,700,645 (the "'645 Patent") and 8,518,987 (the "'987 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 U.S.

Patent Nos. 7,126,015 (the "'015 Patent") and 7,595,408 (the "'408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Defendants' filing of Abbreviated New Drug Application No. 214085 (the "ANDA"), supported by Drug Master File No. 033895 (the "DMF"), seeking approval to sell generic versions of Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 600 mg and 800 mg tablets (the "ANDA Products") prior to the expiration of the '645 Patent, '987 Patent, the '015 Patent, and the '408 Patent (together, the "patents-in-suit").

THE PARTIES

3. 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.

4. Plaintiff Janssen Sciences Ireland Unlimited Company is an Irish corporation having its principal place of business at Barnahely, Ringaskiddy, County Cork, Ireland.

5. On information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534. On information and belief, Zydus USA is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Zydus USA is a wholly-owned subsidiary, alter ego and agent of Defendant Cadila. On information and belief, Zydus USA is the holder of the ANDA.

6. On information and belief, Defendant Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower,

Satellite Cross Roads, Ahmedabad-380015, Gujarat, India. On information and belief, Cadila is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the U.S. market. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Cadila. On information and belief, Cadila is the holder of the DMF. On information and belief, Cadila will manufacture the API for the ANDA Products.

JURISDICTION AND VENUE

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

8. On information and belief, this Court has personal jurisdiction over Zydus USA because Zydus 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.

9. On information and belief, this Court has personal jurisdiction over Zydus USA, *inter alia*, because Zydus USA's principal place of business is in Pennington, New Jersey. Zydus USA's Paragraph IV Notice Letter states Zydus USA's address is 73 Route 31, Pennington, NJ 08534.

10. On information and belief, Zydus USA is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Zydus USA.

11. On information and belief, Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business I.D. No. 0100915422.

12. On information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003171.

13. On information and belief, Zydus USA has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

14. On information and belief and as stated in the Paragraph IV Notice Letter, Zydus USA intends to engage in the commercial manufacture, use, or sale of the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of Zydus USA will therefore cause injury to Janssen in New Jersey.

15. On information and belief, Zydus USA directly and/or through its parent company Cadila markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

16. On information and belief, Zydus USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its parent company Cadila.

17. On information and belief, Zydus USA directly and/or through its parent company Cadila has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

18. On information and belief, Zydus USA has invoked this Court's jurisdiction as Plaintiff in civil actions concerning pharmaceutical products. *See, e.g.*, *Zydus Pharms. USA, Inc., v. Eli Lilly and Co.*, Case No. 2:10-cv-05584-DMC (D.N.J. Oct. 27, 2010); *Zydus Pharms. USA, Inc. and Cadila Healthcare Ltd., v. Gilead Sciences, Inc*., Case No. 3:14-

cv-07080-FLW-LHG (D.N.J. Nov. 11, 2014); *Zydus Pharms. USA, Inc., v. Novartis Pharms. Corp., et al*., Case No. 2:19-cv-21259 (D.N.J. Dec. 10, 2019).

19. On information and belief, Zydus USA has availed itself of the protections afforded by the Court by invoking this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigations. *See, e.g., Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 3:10-cv-01723-JAP-TJB (D.N.J. Aug. 16, 2011); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 1:14-cv-03168-JBS-KMW (June 26, 2014); *Roxane Labs, Inc. v. Zydus Pharms. (USA) Inc.*, Case No. 2:14-cv-05423-SRC-CLW (D.N.J. Oct. 7, 2014); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 1:14-cv-07252-JBS-KMW (D.N.J. Dec. 12, 2014); *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 2:14-cv-7272-SDW-LDW (D.N.J. March 13, 2015).

20. On information and belief, Zydus USA has also previously consented to personal jurisdiction in this district in Hatch-Waxman litigations. *See, e.g., AstraZeneca AB, et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila)*, Case No. 1:15-cv-07415-RMB-JS (D.N.J. Jan. 18, 2016); *Boehringer Ingelheim Pharms. Inc. v. HEC Pharm., et al*., Case No. 3:15-cv-05982-PGS-TJB (D.N.J. March 25, 2016); *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila)*, Case No. 2:16-cv-04239-SRC-CLW (D.N.J. Sept. 12, 2016); *Celgene Corporation v. Zydus Pharms. (USA) Inc., et al*., Case No. 2:17-cv-02528-SDW-LDW (D.N.J. Aug. 7, 2017).

21. On information and belief, Cadila is subject to personal jurisdiction in New Jersey because, among other things, Cadila itself and through its wholly-owned subsidiary,

Zydus USA, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

22. On information and belief, this Court has personal jurisdiction over Cadila because, *inter alia*, it: (1) intends to market, sell or distribute the ANDA Products to residents of New Jersey; (2) exercises control over Defendant Zydus USA; (3) operates through its wholly owned subsidiary Zydus USA, which is incorporated and maintains a principal place of business in New Jersey; (4) makes its generic pharmaceutical products available in New Jersey; (5) maintains a broad distributorship network within New Jersey; and (6) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey.

23. On information and belief, Cadila has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the DMF, and acting in concert with Zydus USA in the preparation and submission of the ANDA seeking FDA approval to market the ANDA Products throughout the United States, including in New Jersey, before expiration of the patents-in-suit. On information and belief, Cadila will manufacture the API for the ANDA Products.

24. On information and belief, Cadila and Zydus USA operate and act in concert as an integrated, unitary business. Cadila and Zydus USA work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey.

25. On information and belief, Zydus USA acts at the direction, and for the benefit, of Cadila, and is controlled and/or dominated by Cadila.

26. Additionally, on information and belief, Cadila has invoked this Court's jurisdiction as Plaintiff in civil actions concerning pharmaceutical products. *See, e.g., Zydus*

Pharms. USA, Inc. and Cadila Healthcare Ltd., v. Gilead Sciences, Inc., Case No. 3:14-cv-07080-FLW-LHG (D.N.J. Nov. 11, 2014).

27. On information and belief, Cadila has also availed itself of the protections afforded by the Court by invoking this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigations. *See, e.g., Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 3:10-cv-01723-JAP-TJB (D.N.J. Aug. 16, 2011); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 1:14-cv-03168-JBS-KMW (June 26, 2014); *Otsuka Pharm. Co., Ltd. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 1:14-cv-07252-JBS-KMW (D.N.J. Dec. 12, 2014); *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd*., Case No. 2:14-cv-7272-SDW-LDW (D.N.J. March 13, 2015).

28. On information and belief, Cadila has also previously consented to personal jurisdiction in this district in Hatch-Waxman litigations. *See, e.g., AstraZeneca AB, et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila)*, Case No. 1:15-cv-07415-RMB-JS (D.N.J. Jan. 18, 2016); *Boehringer Ingelheim Pharms. Inc. v. HEC Pharm., et al.*, Case No. 3:15-cv-05982-PGS-TJB (D.N.J. March 25, 2016); *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila)*, Case No. 2:16-cv-04239-SRC-CLW (D.N.J. Sept. 12, 2016); *Celgene Corporation v. Zydus Pharms. (USA) Inc., et al.*, Case No. 2:17-cv-02528-SDW-LDW (D.N.J. Aug. 7, 2017).

29. In the alternative, as to Cadila, this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, Cadila is a company organized and existing under the laws of India, with a principal place of business in Bavla, Gujarat, India.

30. Under Rule 4(k)(2), for a claim arising under federal law, jurisdiction in any federal court is proper where a defendant is: (1) not subject to jurisdiction in any state; and (2) exercise of jurisdiction is consistent with the United States Constitution and laws.

31. Cadila has availed itself of the laws of the United States by, among other things, acting in concert with Zydus USA in seeking FDA approval for the ANDA Products and other generic pharmaceutical products that are distributed throughout the United States such that this Court's exercise of jurisdiction over Cadila satisfies due process.

32. Furthermore, Cadila has availed itself of the laws of the United States by, among other things, filing the DMF seeking FDA approval to manufacture API for the ANDA Product and other generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cadila satisfies due process.

33. Litigating in the District of New Jersey would not burden Cadila unduly. Among other things, on information and belief, Cadila has consented to personal jurisdiction in the District of New Jersey on numerous occasions. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Janssen has a substantial interest in obtaining convenient and effective relief for violations of its property interests. In addition, the states have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

34. Venue is proper in this district for Zydus USA pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Zydus USA is a corporation organized and existing under the laws of New Jersey, has committed and will commit acts of infringement in this judicial district and has a regular and established place of business at its headquarters in Pennington, New Jersey, located within this judicial district.

35. Venue is proper in this district for Cadila pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cadila is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

BACKGROUND

36. On April 20, 2010, the U.S. Patent and Trademark Office ("PTO") issued the '645 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '645 Patent is attached hereto as Exhibit A.

37. Janssen Sciences Ireland Unlimited Company holds title to the '645 Patent.

38. The '645 Patent expires on December 26, 2026.

39. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '645 Patent does not expire until June 26, 2027.

40. On August 27, 2013, the PTO issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit B.

41. Janssen Sciences Ireland Unlimited Company holds title to the '987 Patent.

42. The '987 Patent expires on February 16, 2024.

43. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

44. Janssen Products, L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®.

45. Janssen Products, L.P. sells Janssen's PREZISTA® in the United States.

46. 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).

47. The FDA's "Orange Book" also lists patents associated with approved drugs. The '645 and '987 Patents are listed in the "Orange Book" in association with PREZISTA®. The claims of the '645 and '987 Patents cover PREZISTA®.

48. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit C.

49. Janssen Sciences Ireland Unlimited Company holds title to the '015 Patent.

50. The '015 Patent expires on June 21, 2023.

51. On September 29, 2009, the PTO issued the '408 Patent, entitled "Method for the Preparation of (3R,3aS,6aR) Hexhydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit D.

52. Janssen Sciences Ireland Unlimited Company holds title to the '408 Patent.

53. The '408 Patent expires on May 6, 2025.

54. The '015 Patent and the '408 Patent claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), an essential component of darunavir.

55. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a processes patented by the '015 and '408 Patents prior to their expiration.

56. On information and belief, Defendants' preparations include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

57. On information and belief, Defendants intend to use the processes claimed in the '015 and '408 Patents to prepare the bis-THF component of the ANDA Products.

58. On information and belief, that bis-THF is incorporated into and present in the drug substance (darunavir) in the ANDA Products intact and without material change from the bis-THF made by use of Janssen's patented processes.

59. On information and belief, the bis-THF resulting from Janssen's patented processes is an essential component of the ANDA Products.

60. Immediately after receiving Zydus's Paragraph IV Notice Letter, on December 19, 2019, Janssen contacted Zydus and asked for information documenting the process that has been and will be used to manufacture bis-THF for the ANDA Products so that Janssen could evaluate infringement of, *inter alia*, the '015 and '408 Patents. Janssen requested Zydus's ANDA, DMF, executed batch records, and samples of the API and tablets for each dosage form of the ANDA Products. Despite repeated requests, Zydus has not provided Janssen with the needed information.

61. In Zydus's Paragraph IV Notice Letter, Zydus purported to offer confidential access to portions of the ANDA, and no other materials, on terms and conditions set

forth in Zydus's Offer of Confidential Access ("OCA"). Zydus's OCA contained unreasonable restrictions that would limit Janssen's access to Zydus's ANDA "for the sole purpose of determining whether an infringement action . . . may be brought with respect to the '645 and '987 patents" and would not allow to Janssen to sue on other patents that were infringed, including patents that Janssen asserted against other generic manufacturers.

62. Beginning with correspondence on December 19, 2019, outside counsel for Janssen negotiated in good faith with counsel for Zydus in an attempt to reach agreement on reasonable terms of confidential access to the ANDA. Zydus continued to insist on unreasonable restrictions on access to the ANDA, which prohibited Janssen from asserting infringement of the process patents (i.e. the '015 and '408 Patents) used to commercially manufacture PREZISTA® (including its essential bis-THF component). Janssen explained to Zydus that it has litigated against eight other generic darunavir manufacturers and asserted process patents against all of them. Janssen also stressed that it was in both parties interests for Janssen to receive information important to infringement of the Orange Book patents and process patents (i.e., Zydus's ANDA, DMF, samples of the API and tablets for the exhibit batches for each dosage form and executed batch records), and that "[i]f Zydus has a basis to contest infringement, it is in Zydus's interest to provide these materials rather than withhold them." Nonetheless, Zydus refused to allow Janssen access to the ANDA, or any of the requested materials showing the process that has been used and will be used to manufacture Zydus's ANDA Products. Zydus's withholding of needed manufacturing information has impeded Janssen's ability to evaluate infringement of the '015 and '408 Patents.

63. Zydus's unreasonable OCA terms which restrict Janssen from asserting infringement of the '015 and '408 Patents, and Zydus's failure to produce manufacturing

information for its ANDA Products, is consistent with the conclusion that the processes invented by Janssen and protected by the ’015 and ’408 Patents will be used to manufacture bis-THF for Zydus’s ANDA Products.

64. On information and belief, Zydus has not contested infringement of Janssen’s patents and continues to withhold its manufacturing information because the bis-THF component of the ANDA Products is made using the processes claimed in Janssen’s ’015 and ’408 Patents and the importation, use, sale, and/or offer for sale of the ANDA Products would infringe the ’015 and ’408 Patents.

65. The processes claimed in the ’015 and ’408 Patents are important for the commercial-scale manufacture of bis-THF. These processes have been infringed by numerous generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the ’015 and ’408 Patents. *See* Consent Judgment and Order against Teva Defendants (Dkt. No. 804), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the ’015 and ’408 Patents); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the ’015 and ’408 Patents); Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the ’015 Patent); Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34), *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*, Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018) (judgment as to the ’015 and ’408 Patents); Amended Consent Judgment and Order against Hetero Defendants (Dkt. No. 55), *Janssen Prods., L.P. et al. v. Hetero Labs, Ltd. et al.*,

Case No. 2:13-cv-01444-WHW-CLW (D.N.J. Oct. 9, 2018) (judgment as to the '015 and '408 Patents); Consent Judgment and Order against Amneal Defendants (Dkt. 21), *Janssen Prods., L.P. et al. v. Amneal Pharms., LLC., et al.*, Civil Action No. 2:18-cv-17585-WHW-CLW (D.N.J. May 1, 2019) (judgment as to the '015 and '408 Patents).

66. On information and belief, Zydus USA submitted the ANDA to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the ANDA Products. Zydus's ANDA has been assigned ANDA No. 214085.

67. On information and belief, Zydus USA and Cadila collaborated in the research, development, preparation and filing of the ANDA and DMF for the ANDA Products.

68. The Paragraph IV Notice Letter was signed by Zydus USA and stated that the ANDA was submitted by Zydus USA.

69. On information and belief, Cadila is the holder of the DMF.

70. On information and belief, Defendants have acted in concert in seeking approval of the DMF and ANDA, prior to expiration of the patents-in-suit.

71. On or about December 17, 2019, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company respectively received Zydus's Paragraph IV Notice Letter stating that Zydus has submitted ANDA No. 214085 to the FDA, seeking approval to manufacture, use, and sell Zydus's ANDA Products prior to the expiration of the '645 and '987 Patents.

72. Zydus's Paragraph IV Notice Letter stated that Zydus's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '645 and '987

Patents are not infringed. Zydus does not dispute that the claims of the '645 and '987 Patents are valid.

73. Upon receiving Zydus's Paragraph IV Notice Letter, Janssen promptly and repeatedly requested that Zydus produce its ANDA, DMF, executed batch records, and samples of the API and tablets of the exhibit batches for each dosage form of the ANDA Products, in order to evaluate infringement of Janssen's patents protecting PREZISTA®. Janssen informed Zydus that it was in both parties' interest for Zydus to provide Janssen with the information necessary for Janssen to evaluate infringement of Janssen's patents. Janssen first requested the production of these materials on December 19 and repeated this request on at least December 20, December 30, January 3, and January 8. However, despite repeated requests for Zydus to provide the necessary information, Zydus has not produced any of the materials which has impaired Janssen's ability to evaluate infringement of the '645 and '987 Patents.

74. Zydus's failure to produce the requested materials is consistent with the conclusion that it has and will infringe Janssen's '645 and '987 Patents.

75. On information and belief, Zydus continues to withhold, *inter alia*, the ANDA, DMF, executed batch records, and samples of its API and tablets due to infringement of the '645 and '987 Patents.

76. On information and belief, the ANDA Products infringe one or more claims of the '645 and '987 Patents.

77. The '645 and '987 Patents have been infringed by other generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '645 and '987 Patents. *See, e.g.*, Consent Judgment and Order against Teva Defendants (Dkt. No. 13), *Janssen Prods., L.P.*

et al. v. Teva Pharms. USA, Inc. et al., Case No. 2:13-cv-07576-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '987 Patent); Consent Judgment and Order against Teva Defendants (Dkt. No. 804), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '645 Patent); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the '987 and '645 Patents); Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the '645 Patent); Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34), *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al*., Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018) (judgment as to the '987 and '645 Patents); Consent Judgment and Order against Amneal Defendants (Dkt. 21), *Janssen Prods., L.P. et al. v. Amneal Pharms., LLC., et al.*, Civil Action No. 2:18-cv-17585-WHW-CLW (D.N.J. May 1, 2019) (judgment as to the '987 Patent).

78. On information and belief, Defendants had actual and constructive notice of the '645, '987, '015 and '408 Patents prior to the filing of the ANDA seeking approval of Zydus's ANDA Products, including through judgments in Janssen's favor against other generic manufacturers in this Court.

79. On information and belief, Defendants have made and continue to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import Zydus's ANDA Products prior to the expiration of the '645, '987, '015 and '408 Patents.

80. On information and belief, Defendants' actions include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

81. On information and belief, Defendants continue to seek FDA approval of the ANDA and intend to collaborate in the commercial manufacture, marketing and sale of the ANDA Products (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves the ANDA.

82. Plaintiffs commenced this lawsuit within 45 days of the date they received Zydus's notice of ANDA No. 214085 containing a Paragraph IV certification.

COUNT I

Infringement of the '645 Patent by Defendants under 35 U.S.C. § 271(e)(2)(A)

83. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 82 hereof, as if fully set forth herein.

84. Under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '645 Patent by submitting ANDA No. 214085 with a Paragraph IV certification and seeking FDA approval of ANDA No. 214085 to market the ANDA Products prior to the expiration of the '645 Patent.

85. On December 19, 2019, Janssen requested that Zydus produce the ANDA, DMF, samples of API and tablets for the exhibit batches for each dosage form of the ANDA Products, among other information, in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '645 Patent. Janssen repeated this request on at least December 20, December 30, January 3, and January 8. To date, Zydus has not produced any of the requested information or samples, which has impaired Janssen's ability to evaluate infringement of the '645 Patent.

86. On information and belief, including Zydus's failure to produce the requested samples and information, Defendants' commercial manufacture, importation, use, sale

and/or offer for sale of the ANDA Products prior to the expiration of the '645 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '645 Patent either literally or under the doctrine of equivalents.

87. Zydus's Paragraph IV Notice Letter does not dispute that the '645 Patent is valid.

88. Defendants had actual and constructive notice of the '645 Patent prior to the filing of ANDA No. 214085 seeking approval of the ANDA Products.

89. Janssen has no adequate remedy at law to redress the infringement by Defendants.

90. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

COUNT II

Infringement of the '987 Patent by Defendants under 35 U.S.C. § 271(e)(2)(A)

91. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 90 hereof, as if fully set forth herein.

92. Under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '987 Patent by submitting ANDA No. 214085 with a Paragraph IV certification and seeking FDA approval of ANDA No. 214085 to market the ANDA Products prior to the expiration of the '987 Patent.

93. On December 19, 2019, Janssen requested that Zydus produce the ANDA, DMF, and samples of API and tablets for the exhibit batches for each dosage form of the ANDA Products, among other information, in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '987 Patent. Janssen repeated this request on at least

December 20, December 30, January 3, and January 8. To date, Zydus has not produced any of the requested information or samples, which has impaired Janssen's ability to evaluate infringement of the '987 Patent.

94. On information and belief, including Zydus's failure to produce requested samples and information, Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '987 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '987 Patent either literally or under the doctrine of equivalents.

95. Zydus's Paragraph IV Notice Letter does not dispute that the '987 Patent is valid.

96. Defendants had actual and constructive notice of the '987 Patent prior to the filing of ANDA No. 214085 seeking approval of the ANDA Products.

97. Janssen has no adequate remedy at law to redress the infringement by Defendants.

98. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '987 Patent.

COUNT III

Declaratory Judgment of Infringement of the '015 Patent by Defendants under 35 U.S.C. § 271(g)

99. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 98 hereof, as if fully set forth herein.

100. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '015 Patent.

101. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

102. Defendants' actions, including, but not limited to, the filing of ANDA No. 214085 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 214085 indicate a refusal to change its course of action.

103. On December 19, 2019, Janssen requested production of Zydus's ANDA, DMF and executed batch records, among other information, in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '015 Patent. Janssen repeated this request on at least December 20, December 30, January 3, and January 8. To date, Zydus has not produced the requested information. Zydus also has not contested infringement of the '015 Patent.

104. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '015 Patent, Defendants' importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '015 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '015 Patent under 35 U.S.C. § 271(g).

105. On information and belief, Defendants had actual and constructive notice of the '015 Patent prior to the filing of ANDA No. 214085 seeking approval of the ANDA Products.

106. On information and belief, Defendants' infringement of the '015 Patent is willful.

107. Janssen has no adequate remedy at law to redress infringement by Defendants.

108. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT IV

Declaratory Judgment of Infringement of the '408 Patent by Defendants under 35 U.S.C. § 271(g)

109. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 108 hereof, as if fully set forth herein.

110. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '408 Patent.

111. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

112. Defendants' actions, including, but not limited to, the filing of ANDA No. 214085 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 214085, indicate a refusal to change its course of action.

113. On December 19, 2019 Janssen requested production of Zydus's ANDA, DMF and executed batch records, among other information, in order to evaluate infringement of

Janssen's patents protecting PREZISTA®, including the '408 Patent. Janssen repeated this request on at least December 20, December 30, January 3, and January 8. To date, Zydus has not produced the requested information. Zydus also has not contested infringement of the '408 Patent.

114. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '408 Patent, Defendants' importation, use, sale and/or offer for sale of Zydus's ANDA Products prior to the expiration of the '408 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '408 Patent under 35 U.S.C. § 271(g).

115. On information and belief, Defendants had actual and constructive notice of the '408 Patent prior to the filing of ANDA No. 214085 seeking approval of Zydus's ANDA Products.

116. On information and belief, Defendants' infringement of the '408 Patent is willful.

117. Janssen has no adequate remedy at law to redress infringement by Defendants.

118. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(a) a judgment that Defendants have infringed the '645 and '987 Patents 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 Zydus's ANDA No. 214085 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 '645 and '987 Patents, including any additional exclusivity period applicable to the patents;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 214085 would constitute infringement of the '645 and '987 Patents, 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. 214085, or any colorable variations thereof, until the day after the expiration of the '645 and '987 Patents, including any additional exclusivity period applicable to the '645 and '987 Patents, and from otherwise infringing one or more claims of the '645 and '987 Patents;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA No. 214085 would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(g);

(f) a declaration that Defendants' infringement of the '015 and '408 Patents is willful;

(g) 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 importing, selling, offering for sale, or using the generic darunavir tablets described in in ANDA No. 214085, or any darunavir product that includes a bis-THF component made by any colorable variation of the processes used to make the ANDA Products, until after the expiration of the '015 and '408 Patents, and from otherwise infringing one or more claims of the '015 or '408 Patents;

(h) a declaration that this case is exceptional;

(i) an award of Janssen's 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

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

Respectfully submitted,

s/ John E. Flaherty

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Dated: January 23, 2020

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.

Respectfully submitted,

s/ John E. Flaherty

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Dated: January 23, 2020