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

JANSSEN PRODUCTS, L.P., and JANSSEN SCIENCES IRELAND UC, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, "Janssen" or "Plaintiffs") for their Complaint against Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals") (collectively "Lupin" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 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 No. 7,126,015 (the "'015 patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Lupin's filing of amendments to an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic versions of Janssen's highly successful Prezista® (darunavir) 600 mg and 800 mg tablets (Lupin's "ANDA Products") prior to the expiration of patents owned by Janssen.

3. The '987 patent claims a crystalline hydrate form of darunavir in a range of ratios, and pharmaceutically acceptable compositions thereof. The '015 patent claims processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), which is an important component of darunavir.

THE PARTIES

4. 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.

5. Plaintiff Janssen Sciences Ireland UC is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

6. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

7. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

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

9. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. 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, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

10. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin 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, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

11. On information and belief, Lupin Pharmaceuticals is registered to do business in the State of New Jersey under Entity ID 0100953673. The State of New Jersey Long

Form Standing Certificate for Lupin Pharmaceuticals dated as of February 10, 2016 (the "Standing Certificate") states: "As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current."

12. On information and belief, Lupin Pharmaceuticals retains a registered agent for service of process in this judicial district. The Standing Certificate states that Lupin Pharmaceuticals has retained National Registered Agents, Inc. of NJ, 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for service of process in New Jersey.

13. On information and belief, Lupin Pharmaceuticals is registered as a wholesale drug and medical device distributor in New Jersey under Registration Number 5004060.

14. On information and belief, Lupin Pharmaceuticals operates and acts as the agent of Lupin Ltd. and is controlled by Lupin Ltd., particularly with respect to marketing Defendants' generic pharmaceutical products throughout the United States. Lupin Ltd.'s 2015 Annual Report describes a business in which "[t]he Company's US subsidiary, Lupin Pharmaceuticals . . . is recognized as a preferred supplier of quality generics into the United States servicing large US wholesale and retail channel partners."[1] Lupin Pharmaceuticals' 2015 financial statements contain a related-party disclosure stating that Lupin Pharmaceuticals' relationship with Lupin Ltd. is one "where control exists."[2]

15. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals have at least one officer and/or director in common. Lupin Pharmaceuticals' 2015 Financial Statements

[1] Lupin Ltd. 2015 Annual Report at 12, *available at* http://www.lupin.com/annual-reports.php.

[2] Lupin Pharmaceuticals, Inc. Audited Accounts for the Year Ended March 31, 2015 at Note 29, (the "Lupin Pharmaceuticals 2015 Financial Statements), *available at* http://www.lupin.com/pdf/LUPIN-PHARMACEUTICALS-INC,USA.pdf.

disclose a related-party relationship with "Key Management Personnel," Vinita Gupta (Managing Director). As stated in Lupin Ltd.'s 2015 Annual Report, Ms. Gupta is the Chief Executive Officer of Lupin Ltd. As stated in the Lupin Pharmaceuticals New Jersey Standing Certificate, Ms. Gupta is also the Chief Executive Officer and Secretary of Lupin Pharmaceuticals.

16. On information and belief, Lupin has a manufacturing facility in New Jersey. As stated in a July 23, 2015 Lupin press release, Lupin entered into an agreement on or around July 23, 2015 to acquire GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. ("GAVIS") in order to "Expand [Lupin's] US Generic Business." Lupin's acquisition of GAVIS's New Jersey-based manufacturing facility will become Lupin's manufacturing site in the U.S. According to the press release, New Jersey-based GAVIS had sales of $96 million in 2014 and has over 250 New Jersey-based employees. According to Lupin, "[t]he acquisition creates the 5th[-]largest portfolio of ANDA filings with the US FDA, addressing a [$]63.8 billion market."[3]

17. On January 11, 2016, counsel for Lupin sent a letter to Janssen (Lupin's "Paragraph IV letter") advising Janssen, among other things, that (i) the "FDA has received an amendment to an ANDA from [Lupin] for Darunavir Tablets, 600 mg and 800 mg," (ii) the ANDA "has been amended to contain a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Darunavir Tablets, 600 mg and 800 mg, before the expiration of" the '987 patent, and (iii) "the ANDA submitted by [Lupin] has been assigned number 202073 by FDA."

18. As stated in Lupin's Paragraph IV letter, Lupin sent its Paragraph IV letter to Janssen Products, L.P., a New Jersey corporation, at its offices located at 1125 Trenton-

[3] Press Release, Lupin Acquires GAVIS to Expand US Generic Business, July 23, 2015,

Harbourtown Road, Titusville, New Jersey 08560.

19. Lupin's January 11, 2016 letter to the FDA submitting the amendment to ANDA No. 202073 was provided by Lupin Pharmaceuticals as the agent of Lupin Ltd. Likewise, the form application submitted with Lupin's amendment to ANDA No. 202073 identifies Lupin Pharmaceuticals as the authorized U.S. agent of Lupin Ltd.

20. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals have been and are collaboratively engaging in activities directed toward infringement of the '987 and '015 patents by, among other things, preparing and submitting ANDA No. 202073 seeking FDA approval to market Lupin's ANDA Products before expiration of the '987 and '015 patents throughout the United States, including in New Jersey.

21. On information and belief and as stated in Lupin's Paragraph IV letter, Lupin intends to engage in the commercial manufacture, use, or sale of Lupin's ANDA Products before expiration of the '987 and '015 patents throughout the United States, including in New Jersey. Lupin's conduct therefore will cause injury to Janssen in New Jersey.

22. Lupin Ltd. and Lupin Pharmaceuticals have consented to personal jurisdiction in this district in numerous prior patent cases, and they asserted counterclaims in those cases as well. *See, e.g.*, *Horizon Pharma Ireland Ltd. et al. v. Lupin Ltd. et al.*, 15-cv-07745-NLH-AMD (D.N.J.); *Roxane Labs., Inc. v. Lupin Ltd. et al.*, 15-cv-01095-SRC (D.N.J.); *Otsuka Pharma. Co., Ltd. v. Lupin Ltd. et al.*, 14-cv-07105-JBS-KMW (D.N.J.); *Senju Pharma. Co., Ltd. et al. v. Lupin, Ltd. et al.*, 14-cv-04149-JBS-KMW (D.N.J.).

23. Lupin Ltd. and Lupin Pharmaceuticals have also availed themselves of the benefits and protections of the courts of this judicial district by bringing suit as plaintiffs in this

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available at http://www.lupin.com/july-23-2015_2.php.

judicial district. *See Lupin Ltd., et al. v. Merck, Sharp & Dohme Corp.*, 10-cv-0683-JAP-TJB (D.N.J.).

24. Lupin Ltd. and Lupin Pharmaceuticals have also consented to personal jurisdiction in this district in two related consolidated actions, *Janssen Products, L.P., et al. v. Lupin Ltd., et al.*, 10-cv-5954-WHW-CLW (D.N.J.) and *Janssen Products, L.P., et al. v. Lupin Ltd., et al.*, 13-cv-03891-WHW-CLW (D.N.J.). Those actions involve the same parties and the same patents at issue here.

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

BACKGROUND

Lupin's Tentatively Approved ANDA

26. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, had previously submitted ANDA No. 202073 for approval of Lupin's generic copies of Prezista 75 mg, 150 mg, 300 mg, 400 mg, 600 mg, and 800 mg tablets (Lupin's "Tentatively Approved ANDA").

27. The FDA tentatively approved Lupin's ANDA on Dec. 15, 2014.

28. Janssen Products, L.P. and Janssen Sciences Ireland UC (including a predecessor Janssen entity) filed several lawsuits against Lupin Ltd. and Lupin Pharmaceuticals based on Lupin's submission of its now Tentatively Approved ANDA. Many of those lawsuits were consolidated in a related action, *Janssen Products, L.P. et al. v. Lupin Ltd. et al.*, 10-cv-5954 (WHW) (CLW) (the "10-cv-5954 Action"). Janssen asserted the '015 patent (among others) against Lupin in that case. Janssen also asserted the '015 and '987 patents against Lupin's generic versions of Prezista 800 mg tablets (and the '987 patent was also asserted against other dosage strengths), as described in the Tentatively Approved ANDA, in a related consolidated

action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 13-cv-3891 (WHW) (CLW). That action is stayed pending the outcome of the 10-cv-5954 Action, which is, as described below, pending on appeal.

29. Before trial in the 10-cv-5954 Action, Lupin stipulated that the darunavir products described in its Tentatively Approved ANDA would infringe U.S. Patent No. 7,700,645 (the "'645 patent"), which describes and claims an ethanolate solvate form of darunavir in about a 1:1 ratio, and pharmaceutically acceptable compositions thereof.

30. In the 10-cv-5954 Action, Lupin also did not dispute that it used the process claimed in the '015 patent to make the bis-THF component of the generic darunavir products described in its Tentatively Approved ANDA. This Court in the 10-cv-5954 Action granted summary judgment that Lupin's sale of darunavir, which includes bis-THF made by the patented process, would infringe the '015 patent under 35 U.S.C. § 271(g).

31. Following a bench trial on validity, the Court rejected Lupin's validity defenses and concluded that the asserted claims of the '645 and '015 patents are not invalid.

32. On August 14, 2014, this court entered an injunction against Lupin's sale of its infringing generic products described in its Tentatively Approved ANDA and by any colorable variation thereof. The injunction bars Lupin from using, selling, offering for sale, or importing into the United States any darunavir product that includes a bis-THF component made by the process used to make the product described in Lupin's Tentatively Approved ANDA, or by any colorable variation of that process. It also bars Lupin from making, using, selling, offering for sale, or importing into the United States any darunavir product described in Lupin's Tentatively Approved ANDA or any darunavir product that includes darunavir ethanolate in a darunavir/ethanol ratio of approximately 1:1, or any colorable variation of that form.

33. Lupin has appealed to the U.S. Court of Appeals for the Federal Circuit from the judgment in the 10-cv-5954 Action. That appeal, No. 2014-1842, is pending in the U.S. Court of Appeals for the Federal Circuit.

Lupin's Amended ANDA

34. On January 11, 2016, Lupin submitted amendments to its Tentatively Approved 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 generic versions of Prezista 600 mg and 800 mg tablets (Lupin's "Amended ANDA").

35. Lupin's Amended ANDA has not yet been considered or tentatively approved by FDA.

36. On or about January 12, 2016, Janssen received Lupin's Paragraph IV Letter stating that Lupin submitted an amendment to ANDA No. 202073 seeking approval to manufacture, use, and sell Lupin's ANDA Products prior to the expiration of the '987 patent.

37. The Lupin Paragraph IV letter also stated that Lupin's Amended ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '987 patent are invalid and/or are not infringed.

38. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals collaborated in the research, development, preparation, and filing of Amended ANDA No. 202073 for Lupin's ANDA Products.

39. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's ANDA Products if Amended ANDA No. 202073 is approved by the FDA.

40. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of Lupin's Amended

ANDA No. 202073.

The '987 Patent

41. The U.S. Patent and Trademark Office ("PTO") issued the '987 patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor," on August 27, 2013. A true and correct copy of the '987 patent is attached hereto as Exhibit A.

42. Janssen Sciences Ireland UC holds title to the '987 patent.

43. The '987 patent expires on February 16, 2024.

44. 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.

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

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 '987 patent is listed in the "Orange Book" in association with Prezista.

Lupin's *Inter Partes* Review Petition for the '987 Patent

48. On April 9, 2015, Lupin Ltd. filed a Petition requesting *inter partes* review by the Patent Trial and Appeal Board (the "PTAB") of claims 1-19 of the '987 patent. Lupin contended that the claims of the '987 patent were invalid as anticipated and obvious under 35 U.S.C. §§ 102 and 103.

49. On October 16, 2015, the PTAB denied Lupin's Petition and declined to institute an *inter partes* review, finding that Lupin had "not established a reasonable likelihood that it would prevail in showing the unpatentability of" any of claims 1-19 of the '987 patent under any of its theories of anticipation or obviousness.

50. Despite the PTAB's determination that Lupin did not show a reasonable likelihood of prevailing on its assertions of invalidity for the claims of the '987 patent, Lupin has set forth many of the very same invalidity arguments concerning the '987 patent in the Lupin Paragraph IV letter here.

The '015 Patent

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

52. Janssen Sciences Ireland UC holds title to the '015 patent.

53. The '015 patent expires on June 21, 2023.

54. The '015 patent discloses and claims processes useful for the preparation of bis-THF, which is an important component of Prezista.

55. On information and belief, Lupin has 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 process patented by the '015 patent prior to the expiration of that patent.

56. On information and belief, Lupin's preparations include, but are not limited to, the development of generic versions of Prezista 600 mg and 800 mg tablets and the filing of its Amended ANDA with a Paragraph IV certification.

57. On information and belief, Lupin or its supplier intends to use processes claimed in the '015 patent to prepare the bis-THF component of Lupin's ANDA Products. That bis-THF is incorporated into and present in the drug substance in Lupin's ANDA Products. The bis-THF component of Lupin's ANDA Products is not materially changed from the bis-THF made by use of Janssen's patented processes. The bis-THF made by Janssen's patented processes is an essential component of Lupin's ANDA Products.

Janssen's Prompt and Repeated Requests to Lupin for Samples and Manufacturing Information Concerning Its Amended ANDA

58. After Janssen received Lupin's Paragraph IV letter on January 12, 2016, it promptly requested samples of Lupin's ANDA Products (both tablets and API) and information concerning its manufacturing process, so it could evaluate infringement of the '987 and '015 patents.

59. Specifically, on January 14, 2016, counsel for Janssen formally requested from Lupin tablets from each of Lupin's registration batches for each dosage form included in its Amended ANDA (600 and 800 mg), as well as the corresponding API used to produce each of the registration batches for those dosages, along with supporting analytical data. Janssen also requested manufacturing specifications and batch records describing Lupin's supposed new manufacturing process.

60. On January 19, 2016, Janssen reiterated its request for samples and manufacturing information.

61. On January 20, 2016, Lupin produced its Amended ANDA and associated Drug Master File ("DMF"), which included documents that it claimed showed its new manufacturing process. But Lupin's regulatory documents included only a schematic of the synthesis it claims to use to manufacture bis-THF on a commercial scale. Counsel for Janssen

notified counsel for Lupin that Lupin's own experts had testified that the process shown in the schematic Lupin provided to FDA could not be used to manufacture bis-THF on a commercial scale. Indeed, Lupin's own experts could not use the process shown in the schematic to even make a small amount of bis-THF.

62. Because Lupin did not provide any detailed manufacturing information, counsel for Janssen on January 21, 2015 again "request[ed] that Lupin produce all manufacturing specifications/batch records for the commercial manufacture of its bis-THF component immediately." Counsel for Janssen also requested a site inspection of the manufacturing facility where Lupin claims that the bis-THF being used for its proposed ANDA Products is produced on a commercial scale.

63. On January 21, 25, and 28, 2016, counsel for Janssen reiterated its requests for samples and for information concerning Lupin's manufacturing process.

64. By January 31, 2016, Janssen still had not received the requested samples and documentation from Lupin. On that date, counsel for Janssen wrote to counsel for Lupin and stated: "Lupin should have already produced the samples (precisely those requested now more than two weeks ago) as well as the other materials and documentation. There is no basis for further delay or not producing exactly the samples, materials and documentation that Janssen sought (all which Lupin has). Please confirm that you will produce the samples as requested and the other materials and documentation immediately. As you know, we are operating under tight deadlines under the Hatch-Waxman Act in light of Lupin's new PIV certifications and Lupin's delay has impeded appropriate testing."

65. Having not received the requested samples or documentation as of February 4, 2016, counsel for Janssen again formally requested these materials, noting that

Lupin's failure to provide the requested information was "quite serious given the tight deadlines of the Hatch-Waxman Act."

66. Between February 4 and February 8, 2016, Lupin provided limited samples of its proposed ANDA Products to Janssen. But Lupin did not provide samples from 10 of 12 registration batches that Lupin had provided to FDA and Janssen had requested. Counsel for Janssen again formally requested samples from the missing registration batches on February 8 and February 12, 2016.

67. On February 19, 2016, 39 days after Lupin provided its Paragraph IV letter to Janssen and 37 days after Janssen had initially requested them, Lupin finally provided the samples Janssen had requested. Lupin's prolonged and unexcused delay in providing these materials has impeded Janssen's ability to analyze them.

68. Meanwhile, as of the filing of this Complaint, Lupin still has not produced the requested detailed manufacturing information about its synthesis process for making the bis-THF component of its ANDA Products. For example, after Lupin produced additional documents on February 6, 2016, counsel for Janssen wrote as follows to counsel for Lupin on February 8, 2016: "We have reviewed the documents Lupin produced this weekend but they did not include any of the documents and information requested nearly a month ago, including the batch records and manufacturing specifications we requested. Lupin's agreements with its supplier . . . make clear that such documentation is in Lupin's possession, custody and control. We again request that Lupin immediately produce all batch records and manufacturing specifications for the manufacture of the bis-THF in Lupin's products . . ., and all corresponding certificates of analysis." Janssen also reiterated its demand for a factory inspection and requested samples of bis-THF. When Janssen received no response, counsel for Janssen again on February

12 and February 19, 2016 requested the manufacturing information and samples.

69. None of the documents Lupin has produced as of the date of the filing of this Complaint have contained the requested manufacturing information. Lupin also has not responded to Janssen's request for a factory inspection or bis-THF samples. Janssen does not know whether Lupin has requested the information and materials from its supplier.

Lupin's ANDA Products Infringe Claims of the '987 Patent

70. Lupin contends that its Amended ANDA seeks approval for a form of darunavir that supposedly does not contain hydrate crystals.

71. After Lupin's served its Paragraph IV letter on Janssen, Lupin produced limited documents supposedly showing how it prepares its particular form of darunavir.

72. The '987 patent generally covers darunavir hydrate in which the ratio of compound to water is about 1:0.5 to about 1:3, and pharmaceutically acceptable compositions thereof.

73. Lupin's ANDA Products contain a crystalline form of darunavir and significant levels of water. On information and belief, the crystalline form of darunavir in Lupin's ANDA Products is darunavir hydrate in claimed ratios.

74. On information and belief, Lupin's ANDA products infringe one or more claims of the '987 patent, including claims 1, 3-5, and 19 of the '987 patent.

75. Lupin had actual and constructive notice of the '987 patent prior to the filing of Amended ANDA No. 202073 seeking approval of Lupin's ANDA Products.

76. Plaintiffs commenced this lawsuit within 45 days of the date they received Lupin's Paragraph IV Notice of Amended ANDA No. 202073 seeking approval to market Lupin's ANDA Products.

Lupin's ANDA Products Infringe Claims of the '015 Patent

77. Lupin's Amended ANDA seeks approval for ANDA Products that Lupin contends are made by a process unlike the one described in Janssen's '015 patent.

78. On information and belief, the process Lupin uses to manufacture its ANDA products infringes at least claim 1 of the '015 patent.

79. The DMF supporting Lupin's Amended ANDA indicates that bis-THF for its darunavir products is being manufactured overseas. The only information Lupin has provided with respect to its allegedly new process is a one-page schematic that supposedly shows the process being used to make bis-THF.

80. The process depicted in the schematic that Lupin provided to the FDA is not suitable for commercial manufacture. Indeed, in prior proceedings, Lupin's own expert testified that the process described in the schematic could not be used on a commercial scale. In fact, Lupin's experts, in sworn declarations, stated that they were unable to use that process to make even miniscule amounts of bis-THF. Accordingly, on information and belief, whether Lupin is aware of it or not, the process depicted in the schematic to make bis-THF will not actually be used by Lupin's supplier.

81. There is no reason to describe incorrectly the process used to manufacture bis-THF except to avoid admitting infringement of Janssen's '015 patent. These facts, coupled with Lupin's failure to produce manufacturing batch records and detailed synthesis information for the bis-THF component in its ANDA Products despite Janssen's repeated requests, strongly supports the conclusion that the commercial process that Lupin's supplier will actually use to create the bis-THF for Lupin's ANDA Products is the process that was invented by Janssen and is covered by the '015 patent.

82. Lupin had actual and constructive notice of the '015 patent prior to the filing of Amended ANDA No. 202073 seeking approval of Lupin's ANDA Products.

83. On information and belief, Lupin has made, and continues to make substantial preparation in the United States to offer to sell, sell, use, and/or import Lupin's ANDA Products prior to the expiration of the '015 patent.

84. On information and belief, Lupin's actions include, but are not limited to, the development of Lupin's ANDA Products and the filing of Amended ANDA No. 202273 with a Paragraph IV certification.

85. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to seek approval of the Amended ANDA No. 202073 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Lupin's ANDA Products (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves Amended ANDA No. 202073.

COUNT I

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

86. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 85 hereof, as if fully set forth herein.

87. Lupin Ltd. and Lupin Pharmaceuticals have infringed the '987 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amended ANDA No. 202073 with a Paragraph IV certification and seeking FDA approval of Amended ANDA No. 202073 to market Lupin's ANDA Products prior to the expiration of the '987 patent.

88. Upon information and belief, Lupin's commercial manufacture, importation, use, sale and/or offer for sale of Lupin's 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, including at least claims 1, 3-5, and 19.

89. Lupin had actual and constructive notice of the '987 patent prior to the filing of Amended ANDA No. 202073 seeking approval of Lupin's ANDA Products.

90. Janssen has no adequate remedy at law to redress the infringement by Lupin.

91. Janssen will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '987 patent.

COUNT II

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

92. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 85 hereof, as if set forth fully herein.

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

94. Lupin had actual and constructive notice of the '015 patent prior to the filing of Amended ANDA No. 202073 seeking approval of Lupin's ANDA Products.

95. Lupin has 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.

96. Lupin's actions, including, but not limited to, the filing of Amended ANDA No. 202073, systematically attempting to meet the applicable regulatory requirements for approval of Amended ANDA No. 202073, and engaging in litigation to offer to sell, sell, use,

and/or import Lupin's generic products prior to the expiration of the '015 patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

97. Upon information and belief, Lupin's importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's ANDA Products will constitute infringement of claim 1 of the '015 patent under 35 U.S.C. § 271(g).

98. On information and belief, Lupin's infringement of the '015 patent is willful.

99. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's ANDA Products will constitute infringement of the '015 patent by Lupin under 35 U.S.C. § 271(g).

100. Janssen has no adequate remedy at law to redress the infringement by Lupin.

101. Janssen will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '015 patent.

PRAYER FOR RELIEF

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

(a) a judgment that Lupin has infringed the '987 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 Lupin's Amended ANDA No. 202073 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 '987 patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in Amended ANDA No. 202073 would constitute infringement of the '987 patent, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Lupin and each of its 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 Amended ANDA No. 202073, or any colorable variations thereof, until the day after the expiration of the period of pediatric exclusivity applicable to the '987 patent;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in Amended ANDA No. 202073 would constitute infringement of the '015 patent, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(g);

(f) a judgment permanently enjoining Lupin and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from selling or offering for sale in the United States, using, or importing into the United States the generic darunavir tablets described in Amended ANDA No. 202073, or any darunavir product that includes a bis-THF component made by any colorable variation of the process used to make Lupin's ANDA Products, until after the expiration of the '015 patent;

(g) a declaration that this case is exceptional;

(h) a declaration that Lupin's infringement of the '015 patent is willful;

(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: February 23, 2016

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. The matter in controversy is related to the subject matter of the following consolidated actions:

- *Janssen Products L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-cv-05954-WHW-CLW (D.N.J.); and
- *Janssen Products L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 13-cv-03891-WHW-CLW (D.N.J.).

Respectfully submitted,

*s/*John E. Flaherty

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