IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff AbbVie Inc., by way of Complaint against Mylan Pharmaceuticals Inc. and Mylan Laboratories Ltd. (collectively, "Mylan"), states as follows:

THE PARTIES

1. Plaintiff AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

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

3. On information and belief, Defendant Mylan Laboratories Ltd. ("Mylan Ltd.") is a corporation organized under the laws of India, having its principal place of business at Plot No. 564/A22, Road No. 92, Jubilee Hills, Hyderabad - 500 034, Andhra Pradesh, India. On information and belief, Mylan Laboratories Ltd. was formerly known as Matrix Laboratories Ltd.

4. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. manufacture and sell various generic drug products and regularly conduct business throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

5. This is a civil action for patent infringement of United States Patent Number 8,691,878 B2 ("the '878 patent") arising under the United States Patent Laws, Title 35, United States Code, § 1 *et seq.*, in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202,. This action is related to Abbreviated New Drug Application ("ANDA") No. 20-5024, which Mylan filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of AbbVie's successful Norvir® gel capsule product that is sold in the United States.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement and declaratory judgment, arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Ltd.

8. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. formulate, develop, manufacture, market, and sell active pharmaceutical ingredients ("APIs"), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations (collectively "Mylan's products"). On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. routinely seek FDA approval to market Mylan's products in the United States through ANDA filings. Most of Mylan Ltd.'s

manufacturing facilities are FDA-approved and it focuses its marketing efforts on regulated markets such as the United States.

9. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd., either directly or through one or more of their wholly owned subsidiaries, affiliates, agents, distributors, or parent corporations, sell and/or distribute a substantial volume of Mylan's products in this judicial district. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. purposefully have conducted and continue to conduct substantial business in this judicial district, from which they have derived, directly or indirectly, substantial revenue.

10. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Mylan's ANDA No. 20-5024, which is the subject of this lawsuit.

11. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. operate as an integrated business ultimately controlled by Mylan Inc., which is not a party to this suit. For example, on Mylan Inc.'s website, http://www.mylan.com/company/about-us, the available company fact sheet indicates Mylan Inc.'s acquisition of Matrix in 2007 and further states that now "[t]he company ranks among the top five generics companies in several international markets and is one of the largest U.S.-based generics manufacturers in the world."

12. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) in the United States, including Delaware.

13. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. acted in concert to seek approval from the FDA to market generic copies of AbbVie's Norvir® gel

capsule product that are the subject of ANDA No. 20-5024 throughout the United States and in this judicial district.

14. On information and belief, Mylan Pharmaceuticals Inc. is qualified to do business in the State of Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses in Delaware. Further, on information and belief, Mylan Pharmaceuticals Inc. is registered to transact business in Delaware and has appointed a registered agent in Delaware (Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808) for service of process.

15. On information and belief, Mylan Ltd. purposefully avails itself of the privilege of selling its generic products in the State of Delaware and can, therefore, reasonably expect to be subject to jurisdiction in the Courts in Delaware. Among other things, on information and belief, Mylan Ltd., directly or through its parent and/or sister corporations, Mylan Inc. and Mylan Pharmaceuticals Inc., places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

16. Mylan Pharmaceuticals Inc. previously has availed itself of this forum by bringing suits and asserting claims arising under the Patent Laws of the United States in this Court. Mylan Pharmaceuticals Inc. and Mylan Ltd. (as Matrix Laboratories Ltd.) have also previously availed themselves of this forum by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court, including but not limited to in *AbbVie Inc. & AbbVie Deutschland GmbH & Co. KG. v. Mylan Pharmaceuticals Inc. & Mylan Labs. Ltd.*, C.A. No. 1:13-cv-01072-RGA ("the 13-1072 Case"), which is currently pending in this District.

17. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Ltd. by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district, and the fact that they have availed themselves of the rights afforded in this judicial district.

18. Mylan Pharmaceuticals Inc. and Mylan Ltd. hereinafter are referred to collectively as "Mylan."

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

20. AbbVie Inc. is the holder of approved New Drug Application ("NDA") No. 020-945 for ritonavir capsules, which AbbVie markets and sells under the trademark Norvir®. AbbVie manufactures and sells Norvir®, Ritonavir Soft Gelatin Capsules, 100 mg in the United States under NDA No. 020-945.

21. AbbVie Inc. is the holder of NDA No. 022-417 for ritonavir tablets, 100 mg, which AbbVie also markets and sells under the trademark Norvir®. AbbVie manufactures and sells Norvir®, Ritonavir tablets, 100 mg in the United States under NDA No. 022-417.

22. Mylan filed with the FDA ANDA No. 20-5024 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market generic Ritonavir Gel capsules 100 mg ("Mylan's generic ritonavir capsules"), as generic copies of AbbVie's Norvir® capsules, in the United States.

23. ANDA No. 20-5024 is also the subject of the 13-1072 Case currently pending in this District.

24. On May 1, 2013, AbbVie Inc. received a letter on behalf of Mylan, dated April 20, 2013, purporting to be a "Notification of Paragraph IV Certification" for ANDA No. 20-5024

("Mylan's Notice Letter") pursuant to sections 505(j)(2)(B)(i)–(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Mylan's Notice Letter notified AbbVie that Mylan had filed ANDA No. 20-5024, seeking approval to market Mylan's generic ritonavir capsules prior to the expiration of certain of AbbVie's patents. This proposed marketing would also be prior to the expiration of the '878 patent.

25. Upon information and belief, Mylan intends to capture some of the market for Norvir® products with Mylan's generic ritonavir capsules, so as to induce healthcare providers who currently prescribe Norvir® products and patients who currently take Norvir® products, to switch to Mylan's generic ritonavir capsules.

THE PATENT-IN-SUIT

26. The '878 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 8, 2014. AbbVie is the owner by assignment of the '878 patent and has the right to sue for infringement thereof. AbbVie lists the '878 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417 for Norvir® tablets. A true and correct copy of the '878 patent is attached as Exhibit A. The '878 patent expires on August 25, 2024, with a pediatric exclusivity that extends to February 25, 2025.

27. The '878 patent claims priority to the same provisional application, No. 60/498,412, filed on August 28, 2003, as U.S. Patent Nos. 8,399,015 ("the '015 patent") and 8,268,349 ("the '349 patent"), both of which are at issue in the 13-1072 Case, which is currently pending in this District. True and correct copies of the '015 and '349 patents are attached as Exhibits B and C, respectively.

28. The '878 patent is at issue in each of the following two litigations, both of which are currently pending in this District: *AbbVie Inc. & AbbVie Deutschland GmbH & Co. KG v.*

Hetero USA Inc. & Hetero Labs Ltd., C.A. No. 13-852-RGA (consolidated); and *AbbVie Inc. v. Aurobindo Pharma Limited & Aurobindo Pharma USA, Inc.*, C.A. No. 14-959-RGA ("the Aurobindo Litigation"). Pleadings from the Aurobindo Litigation, which include a copy of the '878 Patent, have been produced to Mylan in the 13-1072 Case. AbbVie has also produced to Mylan, in the 13-1072 Case, AbbVie's NDA No. 20-945 for Norvir® capsules, AbbVie's current FDA approved package insert (*i.e.*, labeling) that accompanies its Norvir® capsules is publically available online. AbbVie's NDA No. 20-945 describes the composition and method of making of Norvir® capsules, as well as the indication for which Norvir® capsules are approved. AbbVie has also produced to Mylan, in the 13-1072 Case, AbbVie's NDA No. 22-417 for Norvir® tablets, AbbVie's current FDA approved package insert (*i.e.*, labeling) that accompanies its Norvir® tablets is publically available online. AbbVie's NDA No. 22-417 describes the composition and method of making of Norvir® tablets, as well as the indication for which Norvir® tablets are approved.

FIRST COUNT FOR PATENT INFRINGEMENT
AS TO THE '878 PATENT

29. Paragraphs 1-28 are incorporated herein by reference.

30. On information and belief, Mylan filed and has maintained ANDA No. 20-5024 in order to obtain FDA approval to market Mylan's generic ritonavir capsules in the United States prior to the expiration of the '878 patent.

31. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. acted in concert to seek FDA regulatory approval for Mylan's generic ritonavir capsules. On information and belief, Mylan Ltd. actively and knowingly induced, aided and abetted, and specifically intended the acts of Mylan Pharmaceuticals Inc. in the filing of ANDA No. 20-5024. On

information and belief, Mylan Pharmaceuticals Inc. actively and knowingly induced, aided and abetted, and specifically intended the acts of Mylan Ltd. in the filing of ANDA No. 20-5024.

32. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-5024 seeking approval for the commercial marketing of Mylan's generic ritonavir capsules before the expiration date of the '878 patent constitutes infringement of one or more claims of the '878 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Mylan is aware and has actual knowledge of the '878 patent, at least by virtue of the fact that AbbVie has provided a copy of the '878 patent to Mylan in the 13-1072 Case, and that the '878 patent is listed in the Orange Book for AbbVie's related Norvir® tablet product.

34. On information and belief, at least by its proposed package insert for Mylan's generic ritonavir capsules, Mylan knows that it will aid and abet another's direct infringement of at least one of the claims of the '878 patent, either literally or under the doctrine of equivalents. On information and belief, Mylan's proposed package insert is identical to the FDA-approved package insert for AbbVie's Norvir® capsules, except for, for example, information specific to Mylan's generic ritonavir capsules, such as the manufacturer and specific formulation components. The FDA-approved package insert for AbbVie's Norvir® capsules states and instructs that "NORVIR is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection," that "NORVIR is administered orally in combination with other antiretroviral agents," that "NORVIR is a prescription anti-HIV medicine used with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection," and that a patient should "[t]ake NORVIR exactly as prescribed by your doctor." *See* Exhibit D. On

information and belief, Mylan's proposed package insert contains the same or substantially similar language and instructions to the reader.

35. On information and belief, Mylan has actual knowledge that its generic capsule products have been alleged by AbbVie to infringe at least one claim of each of the '349 and '015 patents, both of which are in the same family as the '878 patent. Both the '349 and '015 patents are at issue in the 13-1072 Case, which pertains to the same Mylan generic ritonavir capsule that is at issue here. AbbVie has provided Mylan with infringement contentions for the '349 and '015 patents in that litigation. Whereas the '349 and '015 patents are generally directed to certain ritonavir compositions, the '878 patent is generally directed to methods of treating HIV comprising the administration to a patient of certain ritonavir compositions, such as one or more of the compositions claimed in the '349 and/or '015 patents. Upon information and belief, Mylan is actively seeking to market its generic ritonavir capsule product prior to February 25, 2025, the expiration date (including pediatric exclusivity) of the '878, '349, and '015 patents. On information and belief, Mylan has actual knowledge that its generic ritonavir capsule products will be used by healthcare professionals and by patients for the treatment of HIV, at least by virtue of its proposed package insert that will accompany its generic ritonavir capsule products.

36. On information and belief, Mylan has actual knowledge, at least by virtue of its application to the FDA for approval to market a generic version of AbbVie's Norvir® product, and its possession and knowledge of AbbVie's Norvir® NDAs, that healthcare professionals (such as, for example, physicians and pharmacists) treating patients with human immunodeficiency virus (HIV) will use Mylan's generic ritonavir capsules according to the instructions in Mylan's proposed package insert in a way that directly infringes at least one of the

claims of the ’878 patent (i.e., for treating HIV), either literally or under the doctrine of equivalents.

37. On information and belief, Mylan has actual knowledge, at least by virtue of its application to the FDA for approval to market a generic version of AbbVie’s Norvir® product, and its possession and knowledge of AbbVie’s Norvir® NDAs, that patients in need of treatment for HIV will use Mylan’s generic ritonavir capsules according to the instructions in Mylan’s proposed package insert in a way that directly infringes at least one of the claims of the ’878 patent (i.e., for treating HIV), either literally or under the doctrine of equivalents.

38. On information and belief, at least by the directions in its proposed package insert for its generic ritonavir capsules, including the direction to healthcare professionals and to HIV patients to administer Mylan’s generic ritonavir capsule product for the treatment of HIV, Mylan intends for healthcare professionals and/or patients to use its generic ritonavir capsules in a way that directly infringes at least one of the claims of the ’878 patent, either literally or under the doctrine of equivalents. On information and belief, Mylan had at least this information regarding its proposed package insert and its generic ritonavir capsule products prior to the filing of this complaint, such that Mylan knew and continues to know that the acts of healthcare professionals and/or patients would constitute infringement of the ’878 patent.

39. On information and belief, if FDA approves ANDA No. 20-5024 and Mylan is permitted to make, use, sell, offer to sell, and/or import its generic ritonavir capsules in or into the United States, Mylan will actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the ’878 patent, either literally or under the doctrine of equivalents. Mylan’s submission of ANDA No. 20-5024 therefore constitutes infringement under 35 U.S.C. § 271(e)(2).

40. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic ritonavir capsules in or into the United States, and is not enjoined from doing so and also from actively inducing infringement of at least one claim of the '878 patent. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 20-5024 for Mylan's generic ritonavir capsules be a date which is not earlier than the date of expiration of the '878 patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT AS TO THE '878 PATENT

41. Paragraphs 1-40 are incorporated herein by reference.

42. On information and belief, and in accordance with at least their proposed package insert, Mylan is actively seeking FDA approval to sell Mylan's generic ritonavir capsules labeled for the same indication, and same dosage and methods of use, as the Norvir® capsule product sold by AbbVie.

43. Under 35 U.S.C. § 271(b), by the filing of ANDA No. 20-5024 with directions that encourage patients and healthcare professionals to use Mylan's generic ritonavir capsule products in a manner that directly infringes the '878 patent, Mylan has an affirmative intent to actively induce infringement by others, such as healthcare professionals and/or patients, of one or more claims of the '878 patent, either literally or under the doctrine of equivalents.

44. Upon FDA approval of ANDA No. 20-5024, Mylan Pharmaceuticals Inc. and Mylan Ltd. will each infringe one or more claims of the '878 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) by actively inducing infringement by healthcare professionals and/or patients, unless this Court orders that the effective date of any

FDA approval of ANDA No. 20-5024 shall be no earlier than the expiration date of the '878 patent and any additional periods of exclusivity.

45. On information and belief, Mylan intends to commence sale of Mylan's generic ritonavir capsules immediately upon receiving approval from the FDA.

46. On information and belief, and in accordance with at least their proposed package insert, Mylan Pharmaceuticals Inc. and Mylan Ltd. intend to make, use, sell, offer to sell, and/or import Mylan's generic ritonavir capsules for uses that will infringe the '878 patent.

47. On information and belief, Mylan has knowledge of the '878 patent and will knowingly induce infringement of the '878 patent, if the FDA approves ANDA No. 20-5024 before the expiration of the '878 patent. On information and belief, if the FDA approves ANDA No. 20-5024, Mylan will import into the United States its generic ritonavir capsules, despite an objectively high likelihood that Mylan's importation into the United States, and Mylan's marketing, offering for sale, and sale, of Mylan's generic ritonavir capsules in the United States will constitute inducing infringement of a valid patent. On information and belief, this risk is either known or should be known to Mylan.

48. If the FDA approves ANDA No. 20-5024, the import into the United States of Mylan's generic ritonavir capsules by Mylan to market, offer for sale, and sell in the United States before the expiration of the '878 patent will actively induce infringement by others (such as healthcare professionals and/or patients) under 35 U. S.C. § 271(b) of one or more claims of the '878 patent, either literally or under the doctrine of equivalents.

49. Mylan's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its generic ritonavir capsules will infringe one or more claims of the '878 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Ltd. acted in concert to seek FDA regulatory approval for Mylan's generic ritonavir capsules.

51. The offering to sell, sale, making, and/or importation of Mylan's generic ritonavir capsules would actively induce infringement of at least one of the claims of the '878 patent, either literally or under the doctrine of equivalents.

52. In view of the foregoing, there exists a substantial controversy between AbbVie and Mylan, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

(a) declaring that Mylan's submission of ANDA No. 20-5024 to the FDA was an act of infringement of the '878 patent;

(b) declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Mylan's generic ritonavir capsules would constitute induced infringement of the '878 patent;

(c) declaring that Mylan would induce infringement of one or more claims of the '878 patent under 35 U.S.C. §§ 271(b) and/or 271(e)(2)(A) by its manufacture, use, offer to sell, and sale in, and importation into the United States, of Mylan's generic ritonavir capsules prior to expiration of the '878 patent, and any additional dates of exclusivity;

(d) enjoining Mylan, and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-5024 until the expiration of the '878 patent, and any additional periods of exclusivity;

(e) declaring the '878 patent valid and enforceable;

(f) finding this to be an exceptional case and awarding AbbVie its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. § 285;

(g) awarding AbbVie its costs and expenses in this action; and

(h) awarding AbbVie any further and additional relief as this Court deems just and proper.

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September 25, 2014
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