IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff AbbVie Inc., by way of Complaint against Mylan Pharmaceuticals Inc., 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. ("Mylan") 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, Mylan manufactures and sells various generic drug products and regularly conducts business throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

4. This is a civil action for patent infringement of United States Patent Number 6,232,333 B1 ("the '333 patent"), United States Patent Number 7,141,593 B1 ("the '593 patent"), and United States Patent Number 7,432,294 B2 ("the '294 patent"), arising under the United States Patent Laws, Title 35, United States Code, § 100, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates 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

5. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, this Court has personal jurisdiction over Mylan.

7. On information and belief, Mylan formulates, develops, manufactures, markets, and sells active pharmaceutical ingredients ("APIs"), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations (collectively "Mylan's products"). Mylan routinely files ANDAs and seeks FDA approval to market its products in the United States.

8. On information and belief, Mylan, either directly or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation, sells

and/or distributes a substantial volume of Mylan's products in this judicial district. On information and belief, Mylan purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

9. 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.

10. On information and belief, Mylan 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 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.

11. Furthermore, Mylan 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 has also previously availed itself of this forum by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court.

12. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its 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 it has availed itself of the rights afforded in this judicial district.

13. This Court also has personal jurisdiction over Mylan by virtue of the fact that, *inter alia*, Mylan has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to AbbVie, a Delaware corporation.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

15. AbbVie 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.

16. 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"), which are generic copies of AbbVie's Norvir® capsules, in the United States.

17. On May 1, 2013, AbbVie 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 the '333, '593 and '294 patents.

18. Mylan purported to include an "Offer of Confidential Access" to AbbVie to ANDA No. 20-5024 along with its Paragraph IV Notice Letter. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(III), restrictions to an Offer of Confidential Access

must serve the purpose of protecting trade secrets and other confidential business information. Restrictions may not be made based on counsel's status as in-house. *U.S. Steel Corp. v. U.S.*, 730 F.2d 1465, 1468 (Fed. Cir. 1984); *see also Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 936 (N.D. Ill. 2010) (applying *U.S. Steel* to an Offer of Confidential Access).

19. Mylan's Offer of Confidential Access restricted disclosure to outside counsel and required that the outside counsel (a) not be involved in patent prosecution matters, either formally or informally, for AbbVie and (b) not be involved in any FDA counseling, litigation or other work before or involving the FDA. Mylan's Offer of Confidential Access was also restricted to certain unspecified information from ANDA No. 20-5024.

20. The proposed terms of Mylan's Offer of Confidential Access to AbbVie did not, *inter alia*, allow any of AbbVie's in-house litigation team members, who do not engage in patent prosecution relating to ritonavir and who are crucial decision makers in the process of filing any infringement action, access to the necessary information with which to assess the details of Mylan's proposed generic copy of AbbVie's Norvir® gel capsule product. The restrictions to other work performed by those having access to the ANDA were not directed to the purpose of protecting trade secrets and other confidential business information.

21. While Mylan and AbbVie's outside counsel have had a series of discussions attempting to reach agreement on the terms and conditions of the Offer for Confidential Access, the parties did not reach agreement. For the reasons explained above, AbbVie cannot agree to all of the restrictions Mylan continues to place on its Offer of Confidential Access, and Mylan did not provide AbbVie access to any portion of Mylan's ANDA. Thus, Mylan's Offer of Confidential Access is not on reasonable terms.

THE PATENTS-IN-SUIT

22. The ’333 patent was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on May 15, 2001. AbbVie is the owner by assignment of the ’333 patent and has the right to sue for infringement thereof. AbbVie lists the ’333 patent in the Approved Drug Products With Therapeutic Equivalence Evaluations (“Orange Book”) for NDA No. 020-945. A true and correct copy of the ’333 patent is attached as Exhibit A.

23. The ’593 patent was duly and legally issued by the PTO on November 28, 2006. AbbVie is the owner by assignment of the ’593 patent and has the right to sue for infringement thereof. AbbVie lists the ’593 patent in the Orange Book for NDA No. 020-945. A true and correct copy of the ’593 patent is attached as Exhibit B.

24. The ’294 patent was duly and legally issued by the PTO on October 7, 2008. AbbVie is the owner by assignment of the ’294 patent and has the right to sue for infringement thereof. AbbVie lists the ’294 patent in the Orange Book for NDA No. 020-945. A true and correct copy of the ’294 patent is attached as Exhibit C.

FIRST COUNT
PATENT INFRINGEMENT OF U.S. PATENT NO. 6,232,333 B1

25. Paragraphs 1–24 are incorporated herein by reference.

26. On information and belief, Mylan filed ANDA No. 20-5024 in order to obtain approval to manufacture, use, and market Mylan’s generic ritonavir capsules in the United States before the expiration of the ’333 patent. On information and belief, ANDA No. 20-5024 identifies Mylan as the manufacturer of the generic ritonavir capsules. On information and belief, Mylan filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’333 patent are purportedly invalid and/or not infringed.

27. On information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan's generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie's Norvir® capsules.

28. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-5024 seeking approval for the commercial manufacture, use, or sale of Mylan's generic ritonavir capsules before the expiration date of the '333 patent constitutes infringement of one or more claims of the '333 patent, either literally or under the doctrine of equivalents. On information and belief, if ANDA No. 20-5024 is approved by the FDA, Mylan's commercial manufacture, use, sale, or offer to sell in, or importation into, the United States of Mylan's generic ritonavir capsules would infringe, either literally or under the doctrine of equivalents, one or more claims of the '333 patent under 35 U.S.C. § 271.

SECOND COUNT
PATENT INFRINGEMENT OF U.S. PATENT NO. 7,141,593 B1

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

30. On information and belief, Mylan filed ANDA No. 20-5024 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir capsules in the United States before the expiration of the '593 patent. On information and belief, ANDA No. 20-5024 identifies Mylan as the manufacturer of the generic ritonavir capsules. On information and belief, Mylan filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '593 patent are purportedly invalid and/or not infringed.

31. On information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan's generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie's Norvir® capsules.

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 manufacture, use, or sale of Mylan's generic ritonavir capsules before the expiration date of the '593 patent constitutes infringement of one or more claims of the '593 patent, either literally or under the doctrine of equivalents. On information and belief, if ANDA No. 20-5024 is approved by the FDA, Mylan's commercial manufacture, use, sale, or offer to sell in, or importation into, the United States of Mylan's generic ritonavir capsules would infringe, either literally or under the doctrine of equivalents, one or more claims of the '593 patent under 35 U.S.C. § 271.

THIRD COUNT
PATENT INFRINGEMENT OF U.S. PATENT NO. 7,432,294 B2

33. Paragraphs 1–32 are incorporated herein by reference.

34. On information and belief, Mylan filed ANDA No. 20-5024 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir capsules in the United States before the expiration of the '294 patent. On information and belief, ANDA No. 20-5024 identifies Mylan as the manufacturer of the generic ritonavir capsules. On information and belief, Mylan filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '294 patent are purportedly invalid and/or not infringed.

35. On information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan's generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie's Norvir® capsules.

36. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-5024 seeking approval for the commercial manufacture, use, or sale of Mylan's generic ritonavir capsules before the expiration date of the '294 patent constitutes infringement of one or

more claims of the '294 patent, either literally or under the doctrine of equivalents. On information and belief, if ANDA No. 20-5024 is approved by the FDA, Mylan's commercial manufacture, use, sale, or offer to sell in, or importation into, the United States of Mylan's generic ritonavir capsules would infringe, either literally or under the doctrine of equivalents, one or more claims of the '294 patent under 35 U.S.C. § 271.

FOURTH COUNT
DECLARATORY JUDGMENT AS TO THE '333 PATENT

37. Paragraphs 1–36 are incorporated herein by reference.

38. On information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 20-5024 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Mylan's generic ritonavir capsules in the United States before the expiration of the '333 patent.

39. On information and belief, Mylan is actively seeking approval to sell Mylan's generic ritonavir capsules for the same indications and the same dosage as the Norvir® product sold by AbbVie.

40. On information and belief, Mylan has made preparations to market, offer for sale, and sell Mylan's generic ritonavir capsules labeled for the same indications and the same dosage as the Norvir® product sold by AbbVie.

41. On information and belief, Mylan intends to commence sales of such ritonavir capsules in the United States immediately upon receiving approval from the FDA.

42. On further information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan's generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie's Norvir® capsules.

43. Thus, on information and belief, upon FDA approval of ANDA No. 20-5024, Mylan will infringe one or more claims of the '333 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Mylan's generic ritonavir capsules, 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 '333 patent and any additional periods of exclusivity.

44. AbbVie will be irreparably harmed if Mylan's threatened infringement of at least one claim of the '333 patent is not enjoined. AbbVie does not have an adequate remedy at law. Thus, pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against such infringement.

45. As a result of the foregoing facts, there is a real, substantial, definite, concrete, and continuing justiciable controversy between AbbVie and Mylan as to liability for infringement of the '333 patent. Mylan's actions have created in AbbVie a reasonable apprehension of irreparable harm and loss resulting from Mylan's threatened imminent actions.

46. Thus, under the totality of the circumstances, there is a substantial controversy between AbbVie and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan's threatened infringement of the '333 patent.

FIFTH COUNT
DECLARATORY JUDGMENT AS TO THE '593 PATENT

47. Paragraphs 1–46 are incorporated herein by reference.

48. On information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 20-5024 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Mylan's generic ritonavir capsules in the United States before the expiration of the '593 patent.

49. On information and belief, Mylan is actively seeking approval to sell Mylan's generic ritonavir capsules for the same indications and the same dosage as the Norvir® product sold by AbbVie.

50. On information and belief, Mylan has made preparations to market, offer for sale, and sell Mylan's generic ritonavir capsules labeled for the same indications and the same dosage as the Norvir® product sold by AbbVie.

51. On information and belief, Mylan intends to commence sales of such ritonavir capsules in the United States immediately upon receiving approval from the FDA.

52. On further information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan's generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie's Norvir® capsules.

53. Thus, on information and belief, upon FDA approval of ANDA No. 20-5024, Mylan will infringe one or more claims of the '593 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Mylan's generic ritonavir capsules, 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 '593 patent and any additional periods of exclusivity.

54. AbbVie will be irreparably harmed if Mylan's threatened infringement of at least one claim of the '593 patent is not enjoined. AbbVie does not have an adequate remedy at law. Thus, pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against such infringement.

55. As a result of the foregoing facts, there is a real, substantial, definite, concrete, and continuing justiciable controversy between AbbVie and Mylan as to liability for

infringement of the ’593 patent. Mylan’s actions have created in AbbVie a reasonable apprehension of irreparable harm and loss resulting from Mylan’s threatened imminent actions.

56. Thus, under the totality of the circumstances, there is a substantial controversy between AbbVie and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan’s threatened infringement of the ’593 patent.

SIXTH COUNT
DECLARATORY JUDGMENT AS TO THE ’294 PATENT

57. Paragraphs 1–56 are incorporated herein by reference.

58. On information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 20-5024 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Mylan’s generic ritonavir capsules in the United States before the expiration of the ’294 patent.

59. On information and belief, Mylan is actively seeking approval to sell Mylan’s generic ritonavir capsules for the same indications and the same dosage as the Norvir® product sold by AbbVie.

60. On information and belief, Mylan has made preparations to market, offer for sale, and sell Mylan’s generic ritonavir capsules labeled for the same indications and the same dosage as the Norvir® product sold by AbbVie.

61. On information and belief, Mylan intends to commence sales of such ritonavir capsules in the United States immediately upon receiving approval from the FDA.

62. On further information and belief, in its ANDA No. 20-5024, Mylan has represented to the FDA that Mylan’s generic ritonavir capsules are pharmaceutically and therapeutically equivalent to AbbVie’s Norvir® capsules.

63. Thus, on information and belief, upon FDA approval of ANDA No. 20-5024, Mylan will infringe one or more claims of the '294 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Mylan's generic ritonavir capsules, 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 '294 patent and any additional periods of exclusivity.

64. AbbVie will be irreparably harmed if Mylan's threatened infringement of at least one claim of the '294 patent is not enjoined. AbbVie does not have an adequate remedy at law. Thus, pursuant to 35 U.S.C. § 283, AbbVie is entitled to a permanent injunction against such infringement.

65. As a result of the foregoing facts, there is a real, substantial, definite, concrete, and continuing justiciable controversy between AbbVie and Mylan as to liability for infringement of the '294 patent. Mylan's actions have created in AbbVie a reasonable apprehension of irreparable harm and loss resulting from Mylan's threatened imminent actions.

66. Thus, under the totality of the circumstances, there is a substantial controversy between AbbVie and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan's threatened infringement of the '294 patent.

PRAYER FOR RELIEF

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

a. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-5024 to obtain approval for the commercial manufacture, use, offer for

sale, or sale in, or importation into, the United States of Mylan's generic ritonavir capsules before the expiration of the '333 patent was an act of infringement of the '333 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 infringement of the '333 patent;

c. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-5024 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir capsules before the expiration of the '593 patent was an act of infringement of the '593 patent;

d. 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 infringement of the '593 patent;

e. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-5024 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir capsules before the expiration of the '294 patent was an act of infringement of the '294 patent;

f. 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 infringement of the '294 patent;

g. ordering that the effective date of any FDA approval of Mylan's generic ritonavir capsules shall be no earlier than the expiration date of the '333 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

h. ordering that the effective date of any FDA approval of Mylan's generic ritonavir capsules shall be no earlier than the expiration date of the '593 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

i. ordering that the effective date of any FDA approval of Mylan's generic ritonavir capsules shall be no earlier than the expiration date of the '294 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

j. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir capsules within the United States or importing into the United States Mylan's generic ritonavir capsules, until the expiration of the '333 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

k. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir capsules within the United States or importing into the United States Mylan's generic ritonavir capsules, until the expiration of the '593 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

l. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir capsules within the United States or importing into the United States Mylan's generic ritonavir capsules, until the expiration of the '294 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

m. 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 ’333 patent, and any additional periods of exclusivity;

n. 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 ’593 patent, and any additional periods of exclusivity;

o. 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 ’294 patent, and any additional periods of exclusivity;

p. 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 and 271(e)(4)(C); and

q. awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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