IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER AG, BAYER INTELLECTUAL PROPERTY GMBH and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No _____
v.	)	
MAYNE PHARMA LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bayer AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") bring this Complaint for patent infringement against Defendant Mayne Pharma LLC ("Mayne") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement by Mayne of U.S. Patent No. 8,071,577 ("the '577 patent") arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and, more particularly, 35 U.S.C. §§ 271 (e)(2). This action relates to the Abbreviated New Drug Application ("ANDA") No. 202999, filed by Mayne with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Bayer's Natazia® drug product.

PARTIES

2. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

3. Plaintiff Bayer Intellectual Property GmbH ("Bayer IP") is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), formerly known as Berlex, Inc., is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

5. On information and belief, Mayne Pharma LLC is a limited liability company organized under the laws of the State of Delaware, having its principal place of business at 1240 Sugg Parkway, Greenville, North Carolina 27834. On information and belief, Mayne Pharma LLC is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market.

6. On information and belief, Mayne prepared and submitted ANDA No. 202999 to the FDA.

7. On information and belief, following any FDA approval of an ANDA, Mayne will distribute and sell Mayne's oral-contraceptive products for ANDA No. 202999 throughout the United States, including within Delaware.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Defendant Mayne by virtue of, inter alia, the fact that it regularly transacts and solicits business in Delaware and has purposefully availed itself of this forum such that it should reasonably anticipate being

haled into Court here. On information and belief, Mayne has had persistent and continuous contacts within this judicial district, including developing, manufacturing, and/or selling pharmaceutical products.

10. On information and belief, Mayne is organized under the laws of Delaware and has appointed The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801 as its registered agent for receipt and service of process.

11. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because Mayne is organized in Delaware and is a Delaware resident.

BACKGROUND

12. The patent-in-suit is United States Patent No. 8,071,577 ("the '577 patent") (attached as Exhibit A). Inventors Jan Endrikat and Bernd Düsterberg filed their application for this patent on April 15, 2005. The '577 patent was issued on December 6, 2011.

13. Plaintiff Bayer IP holds title to the '577 patent. Bayer AG has an exclusive license in the United States to use the '577 patent in in the field of women's healthcare, general medicine, and specialty medicine.

14. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 022252, for Natazia®. Natazia® contains, as active ingredients, estradiol valerate and dienogest. Natazia® tablets have been approved by the FDA to prevent pregnancy in women who elect to use an oral contraceptive, and to treat heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.

15. Natazia® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs in

the Orange Book may be used as the basis of an applicant's ANDA to obtain approval of the generic drug product under the provisions of 21 U.S.C. § 355(j).

16. The Orange Book lists patents that the NDA holder asserts cover the approved drug product. The '577 patent is listed in the Orange Book in association with Natazia®. The '577 patent claims cover Natazia®.

17. Natazia® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 2 tablets comprising 3 mg of estradiol valerate, plus 5 tablets comprising 2 mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2 mg estradiol valerate and 3 mg dienogest, plus 2 tablets comprising 1 mg estradiol valerate, plus 2 placebo tablets.

18. Bayer AG markets Natazia® in the United States under Bayer AG's exclusive license in the field of women's healthcare, general medicine, and specialty medicine.

19. On information and belief, Mayne submitted to the FDA ANDA No. 202999 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer HealthCare's Natazia® tablets.

20. On information and belief, Mayne continues to seek approval of ANDA No. 202999 from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer HealthCare's Natazia® tablets.

21. On information and belief, the composition of the product that is the subject of Mayne's ANDA is for oral contraception in a human female and is a 28-day oral contraceptive regimen that contains 2 tablets comprising 3 mg of estradiol valerate, plus 5 tablets comprising 2

mg estradiol valerate and 2 mg dienogest, plus 17 tablets comprising 2 mg estradiol valerate and 3 mg dienogest, plus 2 tablets comprising 1 mg estradiol valerate, plus 2 placebo tablets.

22. On information and belief, on or about June 16, 2017, Mayne sent a Notice Letter to Bayer, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, and stating that Mayne was seeking approval to engage in the commercial manufacture, use, or sale of its ANDA product prior to the expiration of the '577 patent.

23. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), Mayne's Paragraph IV Letter shall contain "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

24. Mayne's Paragraph IV Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '577 patent is invalid.

25. Mayne's Paragraph IV Letter does not state that the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA product would not infringe the claims of the '577 patent, if valid. Mayne's only statement of non-infringement is based on a presumed finding of invalidity.

26. On information and belief, Mayne had actual and constructive notice of the '577 patent prior to the filing of ANDA No. 202999.

27. Bayer commenced this action within 45 days of the date on which it received Mayne's Paragraph IV Letter containing Mayne's Paragraph IV certifications.

CLAIM FOR PATENT INFRINGEMENT OF
UNITED STATES PATENT NO. 8,071,577

28. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

29. On information and belief, Mayne submitted ANDA No. 202999 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mayne's ANDA product before the expiration of the '577 patent.

30. On information and belief, Mayne included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '577 patent is invalid, and unenforceable, and will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mayne's ANDA product.

31. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mayne's ANDA product before the expiration of the '577 patent, Mayne has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Mayne's ANDA product will also infringe one or more claims of the '577 patent.

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Mayne's ANDA shall be a date which is not earlier than May 13, 2026, the current expiration date of the '577 patent, or any later date of exclusivity to which Bayer becomes entitled.

33. Bayer has no adequate remedy at law to redress the infringement by Mayne.

34. Bayer will be irreparably harmed if Mayne is not enjoined from infringing, actively inducing, or contributing to the infringement of the '577 patent, either literally or under the doctrine of equivalents.

35. Further, Bayer is entitled to an award of damages for any commercial sale or use of Mayne's ANDA product, and any act committed by Mayne with respect to the subject matter claimed in the '577 patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

36. On information and belief, when Mayne filed its ANDA, it was aware of the '577 patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '577 patent constituted an act of infringement of the '577 patent.

37. This case is an exceptional one, and Bayer is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Bayer respectfully requests the following relief:

A. Judgment that Mayne has infringed, either literally or under the doctrine of equivalents, one or more claims of the '577 patent by filing its ANDA relating to Mayne's ANDA product containing estradiol valerate and dienogest;

B. Judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Mayne's ANDA No. 202999 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 date of the '577 patent, including any additional exclusivity period applicable to that patent;

C. A judgment permanently enjoining Mayne and each of its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mayne's ANDA product until the day after the expiration of the '577 patent, including any additional exclusivity period applicable to that patent, and from otherwise infringing one or more claims of the '577 patent, either literally or under the doctrine of equivalents;

D. A permanent injunction restraining and enjoining Mayne and its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mayne's ANDA product;

E. Damages from Mayne for any commercial activity constituting infringement of the '577 patent, or inducing or contributing to such infringement, pursuant to 35 U.S.C. §§ 271(a), either literally or under the doctrine of equivalents, and an accounting;

F. Judgment that this is an exceptional case under 35 U.S.C. § 285, and an award of Bayer's costs and expenses of suit, including reasonable attorneys' fees for bringing and prosecuting this action; and

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

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