IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC. and DUCHESNAY USA INC.,	)	
Plaintiff,	)	C.A. No. _____
v.	)	
MYLAN PHARMACEUTIALS INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Duchesnay Inc. and Duchesnay USA Inc. (collectively "Duchesnay"), by way of Complaint against Defendant Mylan Pharmaceuticals Inc. state as follows:

THE PARTIES

1. Duchesnay Inc. is a Canadian corporation with its headquarters at 950 Boulevard Michele-Bohec, Blainville, Quebec, Canada J7C 5E2.

2. Duchesnay USA Inc. is a corporation organized and existing under the laws of Delaware with its headquarters at 919 Conestoga Rd, Bryn Mawr, PA 19010.

3. Duchesnay is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the world.

4. 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 at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. On information and belief, Mylan Pharmaceuticals Inc. manufactures and sells various generic drug products and conducts business throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

6. This is a civil action for patent infringement of U.S. Patent No. 6,340,695 ("the '695 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. 207825, which Mylan Pharmaceuticals Inc. 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 Duchesnay's Diclegis® product, which is sold in the United States.

JURISDICTION AND VENUE

7. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

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

10. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. by virtue of the fact that, inter alia, it has committed — or aided, abetted, induced, contributed to, or participated in the commission of — the tortious act of patent infringement that has led and will lead to foreseeable harm and injury to Duchesnay USA Inc., a Delaware corporation, and to Duchesnay Inc.

11. On information and belief, Mylan Pharmaceuticals Inc. has a registered agent in Delaware (located at Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808) for the receipt of service of process.

12. On information and belief, Mylan Pharmaceuticals Inc. is registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware.

13. On information and belief, Mylan Pharmaceuticals Inc. holds current and valid "Distributor/Manufacturer CSR" (DM-00007571) and "Pharmacy-Wholesale" (A4-0001719) licenses from the Delaware Board of Pharmacy.

14. On information and belief, Mylan Pharmaceuticals Inc. has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Mylan Pharmaceuticals Inc. has previously availed itself of this forum by invoking this Court's jurisdiction by asserting counterclaims in at least 46 cases. See, e.g., AbbVie Inc. et al. v. Mylan Pharmaceuticals Inc., et al., C.A. 14-cv-01236-RGA (D. Del. Nov. 5, 2014) (Doc. 10), UCB, Inc., et al., v. Mylan Pharmaceuticals Inc., et al., C.A. 13-cv-01214-LPS (D. Del. Sept. 16, 2013) (Doc. 11), and in Teijin Limited, et al. v. Mylan Pharmaceuticals, Inc. C.A. 13-cv-01781-SLR (D. Del. Nov. 27, 2013) (Doc. 10).

15. On information and belief, Mylan Pharmaceuticals Inc., formulates, develops, markets, and sells active pharmaceutical ingredients (APIs), solid dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations (collectively "Mylan's products") that it distributes in Delaware and throughout the United States. Mylan Pharmaceuticals Inc. routinely files, and/or aids, abets, contributes to, and/or participates in the filing of, ANDAs to seek FDA approval to market its products in the United States, including in Delaware.

16. On information and belief, this judicial district is a likely destination for products that will be manufactured and sold as a result of FDA approval of Mylan's ANDA No. 207825 which is the subject of this lawsuit.

17. On information and belief, Mylan Pharmaceuticals Inc. purposefully has conducted and continues to conduct substantial business in this district, from which it has derived, directly or indirectly, substantial revenue.

18. On information and belief, Mylan Pharmaceuticals Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, inter alia, abacavir sulfate, acyclovir, alprazolam, amitriptyline hydrochloride-chlordiazepoxide, and amlodipine besylate.

19. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, inter alia: (1) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (2) its presence in Delaware including having a registered agent in Delaware; and (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute.

20. Duchesnay has initiated related litigation against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma Inc. ("Actavis") in Delaware to enforce the '695 patent against Actavis' proposed generic copy of Duchesnay's Diclegis® product, in the case styled as Duchesnay Inc. et al. v. Actavis Laboratories FL, Inc. et al., C.A. No. 1:14-cv-00912-SLR-SRF.

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

FACTUAL BACKGROUND

22. Duchesnay Inc. is the holder of approved New Drug Application ("NDA") No. 021876 for the manufacture and sale of doxylamine succinate and pyridoxine hydrochloride

delayed-release tablets, 10 mg/10 mg, which Duchesnay markets and sells under the trademark Diclegis®.

23. The ’695 patent was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on January 22, 2002. Duchesnay Inc. is the owner by assignment of the ’695 patent and has the right to sue for infringement thereof. Duchesnay Inc. lists the ’695 patent in the Approved Drug Products With Therapeutic Equivalence Evaluations (“Orange Book”) for NDA No. 021876. A true and correct copy of the ’695 patent is attached as Exhibit A.

24. Duchesnay USA Inc. holds a license under the ’695 patent. Duchesnay USA Inc. distributes Diclegis® in the United States.

25. On information and belief, Mylan Pharmaceuticals Inc. (“Mylan”) filed or caused to be filed with the FDA ANDA No. 207825 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market generic doxylamine succinate, 10 mg, and pyridoxine hydrochloride, 10 mg, delayed-release tablets (“Mylan’s Generic Product”), which are generic copies of Duchesnay’s Diclegis® tablets, in the United States prior to the expiration of the ’695 patent.

26. ANDA No. 207825 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the ’695 patent are invalid or would not be infringed by Mylan’s Generic Product.

27. On April 14, 2015, Duchesnay received a letter on behalf of Mylan, dated April 13, 2015, purporting to be a “Notification of Paragraph IV Certification” for ANDA No. 207825 (“Mylan’s Notice Letter”) pursuant to section 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Mylan’s Notice Letter notified Duchesnay that Mylan

had filed ANDA No. 207825, seeking approval to market Mylan's Generic Product prior to the expiration of the '695 patent.

28. The submission of ANDA No. 207825 with a Paragraph IV Certification to the FDA constitutes infringement by Mylan of the '695 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Mylan's Generic Product would infringe the '695 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Mylan knows and intends that physicians will prescribe and/or administer, and patients will take, Mylan's Generic Product for which approval is sought in ANDA No. 207825 and therefore, will infringe at least one claim of the patent-in-suit.

30. Mylan had knowledge of the patent-in-suit and by its promotional activities associated with Mylan's Generic Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the patent-in-suit, either literally or under the doctrine of equivalents.

31. Mylan plans to make, use, sell, offer to sell, and/or import Mylan's Generic Product for uses that will infringe the patent-in-suit. Mylan's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

32. Duchesnay commenced this action within 45 days of receiving Mylan's April 13, 2015 Notice Letter.

COUNT I

(INFRINGEMENT OF UNITED STATES PATENT NO. 6,340,695 B1)

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

34. On information and belief, Mylan filed ANDA No. 207825 in order to obtain approval to manufacture, use, and market Mylan's Generic Product in the United States before the expiration of the '695 patent. On information and belief, ANDA No. 207825

identifies Mylan as the manufacturer of the generic doxylamine succinate and pyridoxine hydrochloride delayed-release tablets. 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 '695 patent are purportedly invalid and/or not infringed.

35. On information and belief, in its ANDA No. 207825, Mylan has represented to the FDA that Mylan's Generic Product is pharmaceutically and therapeutically equivalent to Duchesnay's Diclegis® tablets.

36. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 207825 seeking approval for the commercial manufacture, use, or sale of Mylan's Generic Product before the expiration date of the '695 patent, constitutes infringement, either literally or under the doctrine of equivalents.

37. Upon FDA approval of ANDA No. 207825, Mylan will infringe one or more claims of the '695 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Generic Product, and by actively inducing infringement by others under § 271(b) and /or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 207825 shall be no earlier than the expiration of the '695 patent and any additional periods of exclusivity.

38. On information and belief, Mylan knows and intends that physicians will prescribe and parties will take Mylan's Generic Product for which approval is sought in ANDA No. 207825, and therefore will infringe at least one claim in the '695 patent.

39. On information and belief, Mylan had knowledge of the '695 patent and, by its promotional activities and proposed package insert for Mylan's Generic Product, knows or

should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

40. On information and belief, Mylan is aware and/or has knowledge that healthcare professionals and/or patients will use Mylan's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '695 patent.

41. The offering to sell, sale, making, and/or importation of Mylan's Generic Product would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents. Mylan has knowledge and is aware of Duchesnay Inc.'s '695 patent, as evidenced by Mylan's April 13, 2015 Notice Letter.

42. On information and belief, if ANDA No. 207825 is approved, Mylan intends to and will offer to sell, sell, and/or import in the United States Mylan's Generic Product.

43. Mylan has had and continues to have knowledge that Mylan's Generic Product is especially adapted for a use that infringes the '695 patent.

44. On information and belief, Mylan has had and continues to have knowledge that there is no substantial non-infringing use for Mylan's Generic Product.

45. Duchesnay will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing infringement of at least one claim of the '695 patent. Pursuant to 35 U.S.C. § 283, Duchesnay is entitled to a permanent injunction against further infringement. Duchesnay does not have an adequate remedy at law.

COUNT II

(DECLARATORY JUDGMENT AS TO THE '695 PATENT)

46. Paragraphs 1–45 are incorporated herein by reference.

47. On information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 207825 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture,

use, and sale of Mylan's Generic Product in the United States before the expiration of the '695 patent.

48. On information and belief, Mylan is actively seeking approval to sell Mylan's Generic Product for the same indications and the same dosage as the Diclegis® product sold by Duchesnay.

49. On information and belief, Mylan has made preparations to make, market, offer for sale, sell, and/or import Mylan's Generic Product labeled for the same indications and the same dosage as the Diclegis® product sold by Duchesnay.

50. On information and belief, Mylan intends to commence sales of Mylan's Generic Product in the United States immediately upon receiving approval from the FDA.

51. On further information and belief, in its ANDA No. 207825, Mylan has represented to the FDA that Mylan's Generic Product is pharmaceutically and therapeutically equivalent to Duchesnay's Diclegis® product.

52. On information and belief, Mylan has knowledge of the '695 patent and will knowingly induce infringement of the '695 patent, if the FDA approves ANDA No. 207825 before the expiration of the '695 patent. On information and belief, if the FDA approves ANDA No. 207825, Mylan will market, offer for sale, sell, and/or import Mylan's Generic Product in the United States, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '695 patent.

53. If the FDA approves ANDA No. 207825, the marketing, offer for sale, and sale in the United States of Mylan's Generic Product by Mylan before the expiration of the '695 patent will actively induce infringement by others under 35 U.S.C. § 271(b) and/or contribute to

infringement under § 271(c) by Mylan of one or more claims of the '695 patent, either literally or under the doctrine of equivalents.

54. Duchesnay will be irreparably harmed if Mylan's threatened infringement of at least one claim of the '695 patent is not enjoined. Duchesnay does not have an adequate remedy at law. Thus, pursuant to 35 U.S.C. § 283, Duchesnay 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 Duchesnay and Mylan as to liability for infringement of the '695 patent. Mylan's actions have created in Duchesnay 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 Duchesnay and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan's threatened infringement of the '695 patent.

PRAYER FOR RELIEF

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

A. United States Patent No. 6,340,695 remains valid and is enforceable;

B. A judgment that Mylan's submission of ANDA 207825 was an act of infringement and that Defendants making, using, offering to sell, selling or importing Mylan's Generic Product prior to the expiration of United States Patent No. 6,340,695 will infringe, actively induce infringement and/or contribute to the infringement of United States Patent No. 6,340,695;

C. The effective date of any FDA approval of Mylan's Generic Product shall be no earlier than the expiration date of United States Patent No. 6,340,695 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. Mylan, and all persons acting in concert with Mylan shall be enjoined from commercially manufacturing, using, offering for sale, or selling Mylan's Generic Product within the United States, or importing Mylan's Generic Product into the United States, until the expiration of United States Patent No. 6,340,695, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. This is an exceptional case and Duchesnay should be awarded its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

F. Duchesnay is entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

G. Duchesnay is entitled to any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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