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

DUCHESNAY INC. and DUCHESNAY USA INC., **Plaintiffs,** **v.** **ACTAVIS LABORATORIES FL, INC., ACTAVIS, INC., and ACTAVIS PHARMA, INC.** **Defendants.**	Civil Action No.: **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Duchesnay Inc. and Duchesnay USA Inc. (collectively "Duchesnay"), by way of Complaint against Defendants Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Actavis") 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 Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories Inc. - Florida) is a corporation organized and existing under the laws of Florida having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

5. On information and belief, Defendant Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

6. On information and belief, Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a corporation organized and existing under the laws of the State of Delaware, having its

principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

7. On information and belief, Defendant Actavis, Inc. is the parent company of Actavis Laboratories FL, Inc.

8. On information and belief, Defendant Actavis, Inc. is the parent company of Actavis Pharma, Inc.

9. On information and belief, Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. manufacture and sell various generic drug products and conduct business throughout the United States, including the State of New Jersey.

NATURE OF THE ACTION

10. 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. 205811, which Actavis 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 are sold in the United States.

JURISDICTION AND VENUE

11. 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.

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

13. On information and belief, this Court has personal jurisdiction over Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc.

14. On information and belief, Actavis Laboratories FL, Inc. has its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

15. On information and belief, Actavis, Inc. has its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

16. On information and belief, Actavis, Inc. is registered to do business in New Jersey.

17. On information and belief, Actavis, Inc. holds a current and valid "Wholesale Drug & Medical Device" registration in New Jersey (5003854).

18. On information and belief, Actavis Pharma, Inc. has its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

19. On information and belief, Actavis Pharma, Inc. is registered to do business in New Jersey.

20. On information and belief, Actavis Laboratories FL, Inc. and Actavis, Inc., and Actavis Pharma, Inc. have availed themselves of this forum previously for the purpose of litigating a patent dispute. For example, Actavis Laboratories FL, Inc. and Actavis, Inc. have filed counterclaims for declaratory judgment. *See e.g., Supernus Pharmaceuticals, Inc. v. Actavis, Inc., Watson Laboratories, Inc. – Florida, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc.*, No. 13-04740-RMB (D.N.J.) (counterclaims for declaratory judgment filed

by Actavis Laboratories FL, Inc.); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.,* Civil Action No. 13-1669 (counterclaims for declaratory judgment filed by Actavis Laboratories FL, Inc.); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.,* Civil Action No. 13-3038 (counterclaims for declaratory judgment filed by Actavis Laboratories FL, Inc.); *Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida,* Civil Action No. 11-5989 (counterclaims for declaratory judgment filed by Actavis Laboratories FL, Inc.); *Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al*, Civil Action No. 10-6424 (counterclaims for declaratory judgment filed by Actavis Laboratories FL, Inc.); *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358 (counterclaims for declaratory judgment filed by Actavis, Inc.).

21. Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. have not contested personal jurisdiction in this district in, for example, *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.,* Civil Action No. 13-3038; *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *see also Supernus Pharmaceuticals, Inc. v. Actavis, Inc., Watson Laboratories, Inc. – Florida, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc*., No. 13-04740-RMB (D.N.J.); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida,* Civil Action No. 13-1669; *Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida,* Civil Action No. 11-5989; *Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al*, Civil Action No. 10-6424.

22. On information and belief, Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. operate as an integrated business.

23. On information and belief, Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. share common officers and directors and are agents of each other and/or

work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into New Jersey.

24. On information and belief, Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc., in concert, formulate, develop, market, and sell active pharmaceutical ingredients (API), solid dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Actavis's products") that it distributes in New Jersey and throughout the United States. Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc., in concert, routinely file, and/or aid, abet, contribute to, and/or participate in the filing of, ANDAs to seek FDA approval to market its products in the United States, including in New Jersey.

25. On information and belief, Actavis Pharma, Inc. is a wholly owned subsidiary of Actavis, Inc. On information and belief, Actavis Pharma, Inc., acting either alone or in concert with Actavis, Inc. and/or Actavis Laboratories FL, Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

26. On information and belief, Actavis Pharma, Inc. distributes and/or sells in the United States market generic pharmaceutical products made by Actavis Laboratories FL, Inc. or for which Actavis Laboratories FL, Inc. is the applicant of an approved ANDA.

27. On information and belief, Actavis Laboratories FL, Inc. is a wholly owned subsidiary of Actavis, Inc. On information and belief, Actavis Laboratories FL, Inc., acting either alone or in concert with Actavis, Inc. and/or Actavis Pharma, Inc., either directly or

through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

28. On information and belief, Actavis, Inc. directs, authorizes, cooperates, participates, and/or assists Actavis Pharma, Inc. and Actavis Laboratories FL, Inc. with the marketing, selling, and/or distributing of a substantial volume of its pharmaceutical products in New Jersey. On information and belief, the acts of Actavis Pharma, Inc. and Actavis Laboratories FL, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Actavis, Inc.

29. 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 Actavis's ANDA No. 205811 which is the subject of this lawsuit.

30. On information and belief, Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis Pharma, Inc. have 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 Duchesnay.

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

32. On information and belief, this Court has personal jurisdiction over Actavis Laboratories FL, Inc. by virtue of, *inter alia:* (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable

harm in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute.

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

34. On information and belief, this Court has personal jurisdiction over Actavis Pharma, Inc. by virtue of, *inter alia:* (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute.

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

FACTUAL BACKGROUND

36. 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®.

37. 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.

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

39. On information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 205811 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market generic doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, 10 mg/10 mg ("Actavis's Generic Product"), which are generic copies of Duchesnay's Diclegis® tablets, in the United States.

40. ANDA No. 205811 contains certifications 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, unenforceable, and/or would not be infringed by Actavis's Generic Product.

41. On June 2, 2014, Duchesnay received a letter on behalf of Actavis, dated May 30, 2014, purporting to be a "Notification of Certification" for ANDA No. 205811 ("Actavis'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. Actavis's Notice Letter notified Duchesnay that Actavis had filed ANDA No. 205811, seeking approval to market Actavis's Generic Product prior to the expiration of the '695 patent.

42. The submission of ANDA No. 205811 with a Paragraph IV Certification to the FDA constitutes infringement by Actavis of the '695 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Actavis's Generic Product would infringe the '695 patent under 35 U.S.C. § 271(a), (b), and/or (c).

43. Actavis knows and intends that physicians will prescribe and/or administer, and patients will take, Actavis's Generic Product for which approval is sought in ANDA No. 205811 and therefore, will infringe at least one claim of the patent-in-suit.

44. Actavis had knowledge of the patent-in-suit and by its promotional activities associated with Actavis'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.

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

46. Duchesnay commenced this action within 45 days of receiving Actavis's May 30, 2014 Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 6,340,695 B1

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

48. On information and belief, Actavis, through Actavis Laboratories FL, Inc., filed ANDA No. 205811 in order to obtain approval to manufacture, use, and market Actavis's Generic Product in the United States before the expiration of the '695 patent. On information and belief, ANDA No. 205811 identifies Actavis as the manufacturer of the generic doxylamine succinate and pyridoxine hydrochloride delayed-release tablets. On information and belief, Actavis 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.

49. On information and belief, in its ANDA No. 205811, Actavis has represented to the FDA that Actavis's Generic Product is pharmaceutically and therapeutically equivalent to Duchesnay's Diclegis® tablets.

50. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 205811 seeking approval for the commercial manufacture, use, or sale of Actavis's Generic Product before the expiration date of the '695 patent, constitutes infringement, either literally or under the doctrine of equivalents.

51. The filing of the ANDA by Defendants through Actavis Laboratories FL, Inc. constituted direct infringement under 35 U.S.C. § 271(e).

52. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), defendants Actavis, Inc. and Actavis Pharma, Inc. induced the infringement of the '695 patent by actively and knowingly

causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 205811 to the FDA knowing that the submission of ANDA No. 205811 would constitute direct infringement of the '695 patent. Defendants Actavis, Inc. and Actavis Pharma, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 205811, knowing that its submission would constitute direct infringement, constitutes induced infringement of the '695 patent.

53. Upon FDA approval of ANDA No. 205811, Actavis 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 Actavis'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. 205811 shall be no earlier than the expiration of the '695 patent and any additional periods of exclusivity.

54. On information and belief, Actavis knows and intends that physicians will prescribe and parties will take Actavis's Generic Product for which approval is sought in ANDA No. 205811, and therefore will infringe at least one claim in the '695 patent.

55. On information and belief, Actavis had knowledge of the '695 patent and, by its promotional activities and proposed package insert for Actavis'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.

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

57. The offering to sell, sale, making, and/or importation of Actavis'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. Actavis has knowledge and is aware of Duchesnay Inc.'s '695 patent, as evidenced by Actavis Laboratories FL, Inc.'s May 30, 2014 Notice Letter.

58. On information and belief, if ANDA No. 205811 is approved, Actavis intends to and will offer to sell, sell, and/or import in the United States Actavis's Generic Product.

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

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

61. Duchesnay will be irreparably harmed if Actavis 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 FOR DECLARATORY JUDGMENT AS TO THE '695 PATENT

62. Paragraphs 1-61 are incorporated herein by reference.

63. On information and belief, Actavis, through Actavis Laboratories FL, Inc., filed or caused to be filed with the FDA ANDA No. 205811 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Actavis's Generic Product in the United States before the expiration of the '695 patent.

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

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

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

67. On further information and belief, in its ANDA No. 205811, Actavis has represented to the FDA that Actavis's Generic Product is pharmaceutically and therapeutically equivalent to Duchesnay's Diclegis® product.

68. On information and belief, Actavis has knowledge of the '695 patent and will knowingly induce infringement of the '695 patent, if the FDA approves ANDA No. 205811 before the expiration of the '695 patent. On information and belief, if the FDA approves ANDA No. 205811, Actavis Laboratories FL, Inc., in concert with Actavis, Inc. and Actavis Pharma, Inc., will market, offer for sale, sell, and/or import Actavis's Generic Product in the United States, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '695 patent. On

information and belief, that marketing, offering for sale, and sale will occur with Actavis, Inc. and Actavis Pharma, Inc.'s specific intent and encouragement, and will be conduct that Actavis, Inc. and Actavis Pharma, Inc. knows or should know will occur. On information and belief, Actavis, Inc. and Actavis Pharma, Inc. will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of Duchesnay's rights under the '695 patent.

69. If the FDA approves ANDA No. 205811, the market, offer for sale, and sale in the United States of Actavis's Generic Product by Actavis 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 Actavis of one or more claims of the '695 patent, either literally or under the doctrine of equivalents.

70. Duchesnay will be irreparably harmed if Actavis'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.

71. As a result of the foregoing facts, there is a real, substantial, definite, concrete, and continuing justiciable controversy between Duchesnay and Actavis as to liability for infringement of the '695 patent. Actavis's actions have created in Duchesnay a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

72. Thus, under the totality of the circumstances, there is a substantial controversy between Duchesnay and Actavis having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Actavis'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 Actavis, through Actavis Laboratories FL, Inc.'s submission of ANDA 205811 was an act of infringement and that Defendants making, using, offering to sell, selling or importing Actavis'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) A judgment that defendants Actavis, Inc. and Actavis Pharma, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA 205811 knowing that its submission would constitute direct infringement and/or induced infringement of United States Patent No. 6,340,695;

d) The effective date of any FDA approval of Actavis'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);

e) Defendants, and all persons acting in concert with Defendants shall be enjoined from commercially manufacturing, using, offering for sale, or selling Actavis's Generic Product within the United States, or importing Actavis'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;

f) 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);

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

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

Respectfully submitted,

Dated: July 11, 2014

By: s/ John F. Brenner

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