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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US, INC. and APTALIS PHARMA CANADA ULC Plaintiffs, vs. AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Aptalis Pharma US, Inc. and Aptalis Pharma Canada ULC (collectively, "Aptalis"), by way of complaint against Defendant Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal" or the "Amneal Defendants"), allege as follows:

Nature Of The Action

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Amneal of Abbreviated New Drug Application No. 210509 ("ANDA" or "Amneal's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic mesalamine suppositories prior to the expiration of U.S. Patent No. 7,541,384 ("the '384 patent"), U.S. Patent No. 8,217,083 ("the '083 patent"), and U. S. Patent No. 8,436,051 ("the '051 patent").

PARTIES

1. Plaintiff Aptalis Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Aptalis Pharma Canada ULC is an unlimited liability corporation organized and existing under the Canada Business Corporations

Act, having a principal place of business at 4300 Bankers Hall West, 888 – 3rd Street S.W., Calgary, Alberta, T2P 5C5, Canada.

3. Upon information and belief, Defendant Amneal Pharmaceuticals LLC is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey.

4. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company with a principal place of business at 50 Horseblock Road, Brookhaven, NY 11719.

5. Upon information and belief, the Amneal Defendants work in concert with each other with respect to the regulatory approval, manufacturing, marketing, distribution, and sale of generic pharmaceutical products throughout the United States, including, without limitation, in this District.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

7. The Amneal Defendants are subject to personal jurisdiction in this District because, among other reasons, they regularly and systematically conduct business in New Jersey; they have purposefully directed their activities at New Jersey and have purposefully availed themselves of the laws of New Jersey through, among other things, direct and indirect manufacturing, marketing, sales and/or distribution of generic pharmaceutical products in this District; Amneal Pharmaceuticals LLC has its principal place of business in New Jersey; Amneal Pharmaceuticals LLC sent notice of its ANDA and paragraph IV certification from its New Jersey corporate headquarters to Aptalis in New Jersey; if permitted, the Amneal Defendants plan to conduct various release and stability testing of their generic mesalamine suppositories out of a facility in New Jersey; and if permitted, the Amneal Defendants plan to package, market, and distribute their generic mesalamine suppositories from a location in New Jersey. This District is also a likely destination for the Amneal Defendants' generic mesalamine suppositories if Amneal's ANDA is approved by the FDA.

8. For the foregoing reasons, venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 28 U.S.C. § 1400(b).

FACTUAL BACKGROUND

9. On information and belief, on or before April 28, 2017, Amneal submitted its ANDA to the FDA, pursuant to 21 U.S.C. § 355(j). Amneal's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine 1000 mg rectal suppositories ("Amneal's Proposed Product").

10. Aptalis and its affiliates manufacture and sell mesalamine 1000 mg rectal suppositories under the brand name CANASA® pursuant to New Drug Application ("NDA") No. 021252, which was approved by the FDA. CANASA® is approved for the treatment of active ulcerative proctitis.

11. The '384 patent" (attached as Exhibit A), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 2, 2009.

12. The '083 patent" (attached as Exhibit B), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on July 10, 2012.

13. The '051 patent") (attached as Exhibit C), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on May 7, 2013.

14. Aptalis owns all rights, title, and interest in and to the '384, '083 and '051 patents, including, without limitation, the right to sue and obtain relief for past, present, and future patent infringement.

15. Pursuant to 21 U.S.C. § 355(b)(1), the '083 and '051 patents are listed for CANASA® in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book").

16. On information and belief, Amneal included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in Amneal's opinion, the '083 and '051 patents are invalid, unenforceable and/or not infringed by Amneal's Proposed Product. On or about June 28, 2017, Amneal sent Aptalis a notice letter stating that Amneal had included paragraph IV certifications in its ANDA with respect to the '083 and '051 patents, and that it is seeking approval of its ANDA prior to expiration of the '083 and '051 patents.

Count I: Infringement Of U.S. Patent No. 7,541,384

17. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 16 above.

18. On information and belief, Amneal prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or

importation into the United States of Amneal's Proposed Product before the expiration of the '384 patent.

19. Under 35 U.S.C. § 271(e)(2)(A), Amneal infringed one or more claims of the '384 patent, in violation of Aptalis's patent rights, by submitting to the FDA Amneal's ANDA, which seeks approval to commercially market Amneal's Proposed Product before the expiration of the '384 patent.

20. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Amneal's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under, for example, 35 U.S.C. §271(a).

21. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '384 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

22. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed

Product in accordance with Amneal's proposed label, and it will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

23. On information and belief, Amneal was aware of the '384 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

24. Amneal's actions render this an exceptional case under 35 U.S.C. §285.

25. If Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Count II: Declaratory Judgment Of Infringement Of U.S. Patent No. 7,541,384

26. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 25 above.

27. On information and belief, Amneal has taken significant and concrete steps toward infringement of the '384 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by

submitting its ANDA for FDA approval of Amneal's Proposed Product, and by preparing to market and sell Amneal's Proposed Product.

28. If the FDA approves Amneal's ANDA and Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Amneal would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

29. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '384 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

30. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed Product in accordance with Amneal's proposed label, and will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

31. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Amneal as to liability for Amneal's infringement of the '384 patent claims. Amneal's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

32. On information and belief, Amneal was aware of the '384 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

33. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

34. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Count III: Infringement Of U.S. Patent No. 8,217,083

35. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 34 above.

36. On information and belief, Amneal prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or

importation into the United States of Amneal's Proposed Product before the expiration of the '083 patent.

37. On information and belief, Amneal included in its ANDA a paragraph IV certification that, in its opinion, the '083 patent is invalid, unenforceable and/or not infringed by Amneal's Proposed Product.

38. Under 35 U.S.C. § 271(e)(2)(A), Amneal infringed one or more claims of the '083 patent, in violation of Aptalis's patent rights, by submitting to the FDA Amneal's ANDA, which seeks approval to commercially market Amneal's Proposed Product before the expiration of the '083 patent.

39. The manufacture, use, offer for sale, or sale within the United States, or import into the United States of Amneal's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under, for example, 35 U.S.C. § 271(a).

40. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '083 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or

more claims of the '083 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

41. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed Product in accordance with Amneal's proposed label, and it will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

42. On information and belief, Amneal was aware of the '083 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

43. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

44. If Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Count IV: Declaratory Judgment Of Infringement Of U.S. Patent No. 8,217,083

45. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 44 above.

46. On information and belief, Amneal has taken significant and concrete steps toward infringement of the '083 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Amneal's Proposed Product, and by preparing to market and sell Amneal's Proposed Product.

47. If the FDA approves Amneal's ANDA and Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Amneal would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

48. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '083 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '083 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

49. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed

Product in accordance with Amneal's proposed label, and will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

50. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Amneal as to liability for Amneal's infringement of the '083 patent claims. Amneal's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

51. On information and belief, Amneal was aware of the '083 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

52. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

53. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Count V: Infringement Of U.S. Patent No. 8,436,051

54. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 53 above.

55. On information and belief, Amneal prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic

Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or import into the United States of Amneal's Proposed Product before the expiration of the '051 patent.

56. On information and belief, Amneal included in its ANDA a paragraph IV certification that, in its opinion, the '051 patent is invalid, unenforceable and/or not infringed by Amneal's Proposed Product.

57. Under 35 U.S.C. § 271(e)(2)(A), Amneal infringed one or more claims of the '051 patent, in violation of Aptalis's patent rights, by submitting to the FDA Amneal's ANDA, which seeks approval to commercially market Amneal's Proposed Product before the expiration of the '051 patent.

58. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under, for example, 35 U.S.C. § 271(a).

59. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '051 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce the

infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '051 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

60. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed Product in accordance with Amneal's proposed label, and it will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

61. On information and belief, Amneal was aware of the '051 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

62. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

63. If Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Count VI: Declaratory Judgment Of Infringement Of U.S. Patent No. 8,436,051

64. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 63 above.

65. On information and belief, Amneal has taken significant and concrete steps toward infringement of the '051 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Amneal's Proposed Product, and by preparing to market and sell Amneal's Proposed Product.

66. If the FDA approves Amneal's ANDA and Amneal is permitted to manufacture, use, sell, offer for sale, market and/or import Amneal's Proposed Product into the United States, Amneal would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

67. On information and belief, Amneal seeks approval for Amneal's Proposed Product to be used to treat the indication claimed in the '051 patent. Accordingly, if the FDA approves Amneal's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or

more claims of the '051 patent by users of Amneal's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

68. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal's Proposed Product in accordance with Amneal's proposed label, and will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

69. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Amneal as to liability for Amneal's infringement of the '051 patent claims. Amneal's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

70. On information and belief, Amneal was aware of the '051 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Proposed Product in the United States.

71. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

72. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Amneal is enjoined by this Court.

Prayer For Relief

WHEREFORE, Aptalis respectfully requests the following relief:

A. Judgment that Amneal has infringed or will infringe one or more claims of the '384, '083, and '051 patents;

B. Judgment that the claims of the '384, '083, and '051 patents are valid and enforceable;

C. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Amneal's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

D. A declaratory judgment that Amneal would infringe one or more claims of the '384, '083 and/or '051 patents if it manufactures, uses, sells, offers to sell, markets and/or imports into the United States Amneal's Proposed Product prior to the expiration of the '384, '083 and '051 patents, including any extensions or exclusivities;

E. A declaratory judgment that the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Amneal's Proposed Product by Amneal would induce and/or contribute to third-party infringement of the '384, '083 and '051 patents;

F. Pursuant to 35 U.S.C. § 271(e)(4)(B), an injunction restraining and enjoining Amneal and its officers, agents, attorneys and employees, and those acting in privity or concert with Amneal, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or importation into the United States, of Amneal's Proposed Product as claimed in one or more claims of the '384, '083 and/or '051 patents, until the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

G. If Amneal commercially makes, uses, sells, or offers to sell the its Proposed Product within the United States, or imports its Proposed Product into the United States, prior to the expiration of any one of the '384, '083 and '051 patents, including any extensions or exclusivities, that Aptalis be awarded monetary damages for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

H. Judgment that Amneal's infringement of the '384, '083 and '051 patents based on its ANDA would be willful if Amneal commercially manufactures, uses, sells, offers to sell and/or imports any products that are the subject of its ANDA prior to the expiration of the '384, '083 and '051 patents.

I. Judgment that this is an exceptional case and that Aptalis is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. The costs and expenses of this action; and

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

Dated: August 11, 2017

Respectfully submitted,

By: /s David E. De Lorenzi

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