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Attorneys for Plaintiffs Aptalis Pharma US, Inc., and Aptalis Pharma Canada ULC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US, INC. and APTALIS PHARMA CANADA ULC, Plaintiffs, vs. PHARMACEUTICAL SOURCING PARTNERS, INC., 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 Pharmaceutical Sourcing Partners, Inc. ("PSP"), 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 PSP of Abbreviated New Drug Application No. 207448 ("ANDA" or "PSP'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, U.S. Patent No. 8,217,083, and U.S. Patent No. 8,436,051.

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 registered office at 4300 Bankers Hall West, 888 – 3rd Street S.W., Calgary, Alberta, T2P 5C5, Canada.

3. Upon information and belief, Defendant PSP is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 14 Maidenhead Road, Princeton, New Jersey.

Jurisdiction and Venue

4. 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.

5. PSP is subject to personal jurisdiction in this District because, among other reasons, it is organized and exists under the laws of the State of New Jersey, with its principal place of business in New Jersey; it regularly and systematically conducts business in New Jersey; and it has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other things, the marketing, sales and/or distribution of pharmaceutical products in this District.

6. PSP is further subject to personal jurisdiction in this District because PSP filed an ANDA with the FDA and sent notice of its paragraph IV certification to Aptalis in New Jersey. PSP's act of filing its ANDA and sending

notice of its paragraph IV certification each provide sufficient minimum contacts with the State of New Jersey under a specific jurisdiction analysis.

7. 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

8. On information and belief, on or before October 30, 2015, PSP submitted its ANDA to the FDA, pursuant to 21 U.S.C. § 355(j). PSP's ANDA seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine 1000 mg rectal suppositories ("PSP's Proposed Product").

9. 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.

10. U.S. Patent No. 7,541,384 ("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.

11. U.S. Patent No. 8,217,083 ("the '083 patent") (attached as Exhibit B), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on July 10, 2012.

12. U.S. Patent No. 8,436,051 ("the '051 patent") (attached as Exhibit C), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on May 7, 2013.

13. Aptalis owns all rights, title, and interest in and to the '384, '083 and '051 patents, including the right to sue and obtain relief for past, present, and future patent infringement.

14. 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").

15. On information and belief, PSP included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in its opinion, the '083 and '051 patents are invalid, unenforceable and/or not infringed by PSP's Proposed Product. PSP sent Aptalis a notice letter stating that PSP 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.

16. PSP's notice letter contained an "Offer of Confidential Access." PSP originally appeared to offer access to its complete ANDA, but in later negotiations PSP became more restrictive and offered to provide access to only a handful of redacted pages of its ANDA while seeking to impose extensive restrictions on Aptalis and its counsel. Aptalis's counsel objected to PSP's Offer as unreasonable and requested access to PSP's ANDA according to terms similar to those that would apply if a court had entered a protective order during litigation. As of the date of this Complaint, PSP has not agreed to any reasonable, good faith proposals.

17. Based on its review of PSP's paragraph IV certification and other information, Aptalis is informed and believes PSP's ANDA infringes valid patent claims of the '384, '083, and '051 patents, and has therefore brought this action. Aptalis anticipates obtaining access to PSP's ANDA and other information during the litigation.

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

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

19. On information and belief, PSP 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 PSP's Proposed Product before the expiration of the '384 patent.

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

21. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of PSP'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).

22. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

23. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

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

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

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

28. On information and belief, PSP 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 PSP's Proposed Product, and by preparing to market and sell PSP's Proposed Product.

29. If the FDA approves PSP's ANDA and PSP is permitted to manufacture, use, sell, offer for sale, market and/or import PSP's Proposed Product into the United States, PSP 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.

30. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

31. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

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

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

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

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

37. On information and belief, PSP 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 PSP's Proposed Product before the expiration of the '083 patent.

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

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

40. The manufacture, use, offer for sale, or sale within the United States, or import into the United States of PSP'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).

41. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

42. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

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

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

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

47. On information and belief, PSP 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 PSP's Proposed Product, and by preparing to market and sell PSP's Proposed Product.

48. If the FDA approves PSP's ANDA and PSP is permitted to manufacture, use, sell, offer for sale, market and/or import PSP's Proposed Product into the United States, PSP 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.

49. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

50. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

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

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

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

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

56. On information and belief, PSP 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 PSP's Proposed Product before the expiration of the '051 patent.

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

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

59. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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).

60. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

61. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

64. If PSP is permitted to manufacture, use, sell, offer for sale, market and/or import PSP's Proposed Product into the United States, Aptalis will

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

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

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

66. On information and belief, PSP 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 PSP's Proposed Product, and by preparing to market and sell PSP's Proposed Product.

67. If the FDA approves PSP's ANDA and PSP is permitted to manufacture, use, sell, offer for sale, market and/or import PSP's Proposed Product into the United States, PSP 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.

68. On information and belief, PSP seeks approval of the indication for PSP's Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves PSP's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of PSP'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 PSP's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

69. On information and belief, PSP knows and intends that physicians, health care providers, and/or patients will use PSP's Proposed Product in accordance with PSP'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).

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

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

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

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

Prayer For Relief

Wherefore, Aptalis respectfully requests the following relief:

A. Judgment that PSP 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 PSP'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 PSP 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 PSP's Proposed Products 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 PSP's Proposed Products by PSP 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 PSP and its officers, agents, attorneys and employees, and those acting in privity or concert with PSP, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or importation into the United States, of PSP'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 PSP commercially makes, uses, sells, or offers to sell the PSP's Proposed Product within the United States, or imports PSP's 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 PSP's infringement of the '384, '083 and '051 patents based on its ANDA would be willful if PSP 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: December 13, 2015

Respectfully submitted,

By: /s David E. De Lorenzi

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