UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

APTALIS PHARMA US, INC. and APTALIS PHARMA CANADA ULC, Plaintiffs, vs. DELCOR ASSET CORPORATION, RENAISSANCE PHARMA, INC., and RENAISSANCE ACQUISITION HOLDINGS, 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 Defendants Delcor Asset Corporation, Renaissance Pharma, Inc., and Renaissance Acquisition Holdings, LLC (collectively, "Defendants") allege as follows:

Nature of the Action

This is an action for patent infringement under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201-2202 and 35 U.S.C. §271(a),

(b), and (c), that arises out of the filing by Defendants of Abbreviated New Drug Application No. 208362 ("ANDA" or "Defendants' 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, NJ 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. On information and belief, Defendant Delcor Asset Corporation ("Delcor") is a corporation organized and existing under the laws of Delaware, having a principal place of business in Lake Forest, Illinois.

4. On information and belief, Defendant Renaissance Pharma, Inc. ("Renaissance Pharma"), is a corporation organized and existing under the laws of Delaware, having a principal place of business in Newtown, Pennsylvania. On information and belief, Renaissance Pharma is an affiliate and agent of Delcor, and manufactures, markets, and sells prescription drugs in this District and throughout the United States.

5. On information and belief, Defendant Renaissance Acquisition Holdings, LLC ("Renaissance Holdings") is a corporation organized and existing under the laws of

Delaware, having a principal place of business in Lake Forest, Illinois. On information and belief, Renaissance Holdings operates through and has substantial control over its subsidiaries and affiliates, including Renaissance Pharma and Delcor, to manufacture, market and sell prescription drugs in this District and throughout the United States.

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. Defendants are subject to personal jurisdiction in this District because, on information and belief, among other things, they are organized and exist under the laws of the State of Delaware; they regularly and systematically conduct business in Delaware; and they have purposefully directed their activities at Delaware and purposefully availed themselves of the laws of Delaware through, among other things, the marketing, sales and/or distribution of pharmaceutical products in this District.

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

General Averments

9. Aptalis and its affiliates manufacture and sell 1000 mg mesalamine 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 U.S. 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, Delcor and Renaissance Pharma, in concert with, at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Renaissance Holdings, prepared Defendants' ANDA and on or before November 10, 2015, submitted Defendants' ANDA to the FDA, pursuant to 21 U.S.C. § 355(j). Defendants' ANDA seeks FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine 1000 mg rectal suppositories ("Defendants' Proposed Product").

16. On information and belief, Renaissance Pharma, in concert with, at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Renaissance Holdings, has acted, and continues to act, as the agent of Delcor

with regard to Defendants' ANDA, and will provide information and materials to the FDA in connection with Defendants' ANDA.

17. On information and belief, Defendants included in Defendants' ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") asserting that, in Defendants' opinion, the '083 and '051 patents are invalid, unenforceable and/or not infringed by Defendants' Proposed Product. On information and belief, Defendants sent Aptalis a notice letter stating that Defendants had included a paragraph IV certification in Defendants' ANDA with respect to the '083 and '051 patents, and that Defendants are seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Defendants' Proposed Product prior to the expiration of the '083 and '051 patents.

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, Defendants prepared, submitted, and filed Defendants' 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 Defendants' Proposed Product before the expiration of the '384 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Defendants 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 Defendants' 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 Defendants' 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, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' 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 Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

23. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with the label proposed in Defendants' ANDA, which instructs patients to perform one or more of the methods claimed in the '384 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent.

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

25. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market Defendants' Proposed Product and make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '384 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '384 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '384 patent.

26. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

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

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

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

29. On information and belief, Defendants have 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 Defendants' ANDA for

FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

30. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants 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.

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

32. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, which instructs patients to perform one or more of the methods claimed in the '384 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

33. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Defendants as to liability for Defendants'

infringement of the '384 patent claims. Defendants' actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

34. On information and belief, Defendants were aware of the '384 patent prior to filing their ANDA seeking authorization for Defendants to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

35. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market Defendants' Proposed Product and make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '384 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '384 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '384 patent.

36. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

37. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

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

38. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 37 above.

39. On information and belief, Defendants prepared, submitted, and filed Defendants' ANDA with the FDA under § 505(j) of the 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 Defendants' Proposed Product before the expiration of the '083 patent.

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

41. Under 35 U.S.C. § 271(e)(2)(A), Defendants 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 Defendants' Proposed Product before the expiration of the '083 patent.

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

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

44. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, which instructs patients to perform one or more of the methods claimed in the '083 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

45. On information and belief, Defendants were aware of the '083 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

46. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market Defendants' Proposed Product and Defendants make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '083 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '083 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '083 patent.

47. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

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

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

49. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 48 above.

50. On information and belief, Defendants have 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 Defendants' ANDA for FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

51. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants 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.

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

53. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, which instructs patients to perform one or more of the methods claimed in the '083 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

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

55. On information and belief, Defendants were aware of the '083 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

56. On information and belief, Defendants have or will have knowledge that, if Defendants were to receive approval from the FDA to market Defendants' Proposed Product and Defendants make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '083 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had

knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '083 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '083 patent.

57. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

58. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

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

59. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 58 above.

60. On information and belief, Defendants prepared, submitted, and filed Defendants' ANDA with the FDA under § 505(j) of the 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 Defendants' Proposed Product before the expiration of the '051 patent.

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

62. Under 35 U.S.C. § 271(e)(2)(A), Defendants 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 Defendants' Proposed Product before the expiration of the '051 patent.

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

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

65. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, which instructs patients to perform one or more of the methods claimed in the '051 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

66. On information and belief, Defendants were aware of the '051 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

67. On information and belief, Defendants have or will have knowledge that, if Defendants were to receive approval from the FDA to market Defendants' Proposed Product and Defendants make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '051 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '051 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '051 patent.

68. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

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

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

70. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 69 above.

71. On information and belief, Defendants have 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 Defendants' ANDA for FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

72. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants 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.

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

74. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' Proposed label, which instructs patients to perform one or more of the methods claimed in the '051 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

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

76. On information and belief, Defendants were aware of the '051 patent prior to filing their ANDA seeking authorization for Defendants to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

77. On information and belief, Defendants have or will have knowledge that, if Defendants were to receive approval from the FDA to market Defendants' Proposed Product and Defendants make Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '051 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '051 patent. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Defendants' Proposed Product before patent expiration will, therefore, constitute an act of contributory infringement of the '051 patent.

78. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

79. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Relief Requested

Wherefore, Aptalis respectfully requests the following relief:

A. Judgment that Defendants have 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 Defendants' 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 Defendants would infringe one or more claims of the '384, '083 and/or '051 patents if they manufacture, use, sell, offer to sell, market and/or import into the United States Defendants' 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 Defendants' Proposed Product by Defendants 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 Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with Defendants, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or importation into the United States, of Defendants' 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 Defendants commercially make, use, sell, or offer to sell Defendants' Proposed Product within the United States, or import Defendants' 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 Defendants' infringement of the '384, '083 and '051 patents based on Defendants' ANDA would be willful if Defendants commercially manufacture, use, sell, offer to sell and/or import 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 27, 2015

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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* *pro hac vice* motion to follow