IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. APOTEX INC., APOTEX CORP., APOTEX PHARMACHEM INC. AND APOSHERM DELAWARE HOLDINGS CORPORATION, Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Apotex Inc., Apotex Corp., Apotex Pharmachem Inc. ("Pharmachem") and Aposherm Delaware Holdings Corporation ("Aposherm") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,525,057 ("the '057 patent"), 10,980,803 ("the '803 patent"), 11,154,553 ("the '553 patent"), 11,344,547 ("the '547 patent"), 11,400,087 ("the '087 patent") and 11,648,347 ("the '347 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 219381 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration

("FDA") approval to manufacture, use, import, offer to sell and/or sell aripiprazole for extended-release injectable suspension, 300 mg/vial and 400 mg/vial ("Defendants' generic products"), which are generic versions of Otsuka's ABILIFY MAINTENA® (aripiprazole), before the expiration of the patents in suit.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda-Tsukasamachi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '057, the '803, the '553, the '547, the '087 and the '347 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

7. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary and United States agent of Apotex Inc.

8. Upon information and belief, Pharmachem is a corporation organized and existing under the laws of Canada, with a principal place of business at 34 Spalding Drive, Brantford, Ontario, Canada N3T DB8.

9. Upon information and belief, Pharmachem is a wholly-owned subsidiary of Apotex Inc.

10. Upon information and belief, Aposherm is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

11. Upon information and belief, Aposherm is the ultimate corporate parent of at least Apotex Corp.

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

14. This Court also has personal jurisdiction over Apotex Inc. because it has previously been sued in this judicial district and has not challenged personal jurisdiction and/or it has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this judicial district. *See, e.g.*, *Gilead Scis., Inc. v. Apotex Inc.*, C.A. No. 22-1399-MN (D. Del.); *Horizon Meds. LLC v. Apotex Inc.*, C.A. No. 22-640-CJB (D. Del.); *Galderma Lab'ys L.P. v. Apotex Inc.*, C.A. No. 22-724-SB (D. Del.); *Bayer Healthcare LLC v. Apotex Inc.*, C.A. No. 21-1429-WCB (D. Del.); *Zogenix, Inc. v. Apotex Inc.*, C.A No. 21-1533-RGA (D. Del.); *Bial-Portela*

& CA S.A. v. Apotex Inc., C.A. No. 21-187-CFC (D. Del.); *Intercept Pharms., Inc. v. Apotex Inc.*, C.A. No. 20-1105-MN (D. Del.); *UCB, Inc. v. Annora Pharma Pvt. Ltd.*, C.A. No. 20-987-CFC (D. Del.); *Sanofi-Aventis U.S., LLC v. Actavis LLC*, C.A. No. 20-804-RGA (D. Del.); *Merck Sharp & Dohme Corp. v. Apotex Inc.*, C.A. No. 20-749-RGA (D. Del.); *Apotex Inc. v. Lupin Ltd.*, C.A. No. 15-357-LPS (D. Del.).

15. Upon information and belief, Apotex Inc., either directly or indirectly, currently sells significant quantities of generic drug products in the United States and in this judicial district. Apotex Inc.'s website states: "Our Canadian roots and broad portfolio of generic, biosimilar, and innovative branded products make us the largest Canadian-based pharmaceutical company and a health partner of choice for the Americas for pharmaceutical licensing and product acquisitions." https://www.apotex.com/global/about-us/our-purpose (accessed Aug. 29, 2024). Similarly, upon information and belief, Apotex Inc. states that "The Apotex Group of Companies is the largest Canadian-owned pharmaceutical company, providing more than 300 generic pharmaceutical products to the global healthcare market." https://www.apotex.com/ca/en/about-us/our-canadian-footprint (accessed Aug. 29, 2024).

16. Apotex Inc. states that by 2020, it was a "[t]op 10 player in the US generics market." https://www.apotex.com/global/about-us/our-story (accessed Aug. 29, 2024). Apotex Inc. also states that "In the USA, for the products which Apotex competes in, we have +30% market share." https://www.apotex.com/ca/en/business-development/north-american-business-opportunities (accessed Aug. 29, 2024).

17. Upon information and belief, Apotex Inc. regularly imports drug products into the United States. https://datadashboard.fda.gov/ora/cd/impentry-table.htm (searching manufacturer legal name: "Apotex Inc." yields 17,636 search results between Oct. 1, 2018 and Aug. 16, 2024)

(last searched Aug. 29, 2024).

18. This Court has personal jurisdiction over Apotex Corp. Apotex Corp. is incorporated in the State of Delaware. Additionally, upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Corp. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

19. Upon information and belief, Apotex Corp. has an active pharmacy wholesale license in the State of Delaware with the license number A4-0001921 and an active controlled substances distributor/manufacturer license in the State of Delaware with the license number DM-0008873.

20. Upon information and belief, Apotex Corp. regularly imports drug products into the United States. https://datadashboard.fda.gov/ora/cd/impentry-table.htm (searching manufacturer legal name: "Apotex Corp." yields 125 search results between Oct. 25, 2018 and Dec. 13, 2023) (last searched Aug. 29, 2024).

21. Upon information and belief, Apotex Corp. is a generic pharmaceutical company that, in coordination with or at the direction of Apotex Inc. and Aposherm, develops, manufactures, markets, imports and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

22. Upon information and belief, Apotex Corp. is responsible for distributing and selling generic products in the United States on behalf of Apotex Inc. *See, e.g.*, Press Release,

Apotex Corp., "Apotex Corp. Launches Brimonidine Tartrate Ophthalmic Solution, 0.1% in the United States" (Sept. 5, 2023), https://www.apotex.com/us/about-us/press-center/2023/09/05/apotex-corp.-launches-brimonidine-tartrate-ophthalmic-solution-0.1-in-the-united-states (accessed on Aug. 29, 2024) ("Apotex Corp. is a US based company, headquartered in Weston, Florida. It and its global affiliates are leaders in generic pharmaceuticals and biosimilars and are committed to supplying patients with a broad portfolio of high-quality, affordable medicines covering all major therapeutic areas.").

23. Upon information and belief, and consistent with its role with respect to other of Apotex Inc.'s generic products, Apotex Corp. is the United States agent for Defendants' generic products that are the subject of ANDA No. 219381. *See, e.g.*, *Otsuka Pharm. Co., Ltd. v. Apotex Inc.*, C.A. No. 19-2006-LPS (D. Del.); *Pfizer Inc. v. Apotex Inc.*, C.A. No. 24-00621-CFC (D. Del.); *H. Lundbeck A/S v. Apotex Inc.*, C.A. No. 18-00088-LPS (D. Del.); *cf. Eagle Pharms., Inc. v. Apotex Inc.*, C.A. No. 24-00064-JLH (D. Del.).

24. Upon information and belief, Kiran Krishnan is presently Apotex Inc. and/or Apotex Corp.'s Senior Vice President of Global Regulatory Affairs, and "leads the company's efforts to develop top-level regulatory strategies, supporting the launch and commercialization of key products across the specialty, biosimilar, and generic portfolios." https://www.apotex.com/ca/en/about-us/our-leadership (accessed Aug. 29, 2024). Upon information and belief, Dr. Krishnan's LinkedIn page states that he is the "Senior Vice President [of] Global Regulatory & Medical Affairs" at Apotex Corp. in Weston, Florida. https://www.linkedin.com/in/kirankrishnanki20 (accessed Aug. 29, 2024). Upon information and belief, Dr. Krishnan handles communications with the FDA on behalf of Apotex Corp. and Apotex Inc. with respect to Defendants' regulatory filings including ANDAs. *See, e.g.*, Jan. 9, 2024 Letter

to Kiran Krishnan, PhD, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/211195Orig1s000ltr.pdf (accessed Aug. 29, 2024); Jan. 5, 2024 Letter to Kiran Krishnan, PhD, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/203640Orig1s000ltr.pdf (accessed Aug. 29, 2024).

25. This Court has personal jurisdiction over Pharmachem. Upon information and belief, Pharmachem is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Pharmachem directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Pharmachem purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

26. This Court also has personal jurisdiction over Pharmachem because it has previously been sued in this judicial district and has not challenged personal jurisdiction. *See, e.g.*, D.I. 11 at ¶ 15, *Otsuka Pharm. Co., Ltd. v. Apotex Inc.*, C.A. No. 1:19-cv-2006-LPS (D. Del. Mar. 13, 2020).

27. Upon information and belief, Pharmachem is the holder of FDA Drug Master File ("DMF") No. 19957 for aripiprazole USP.

28. Upon information and belief, Pharmachem is treated as a "division of Apotex" and is "Canada's largest producer of active pharmaceutical ingredients." https://www.apotex.com/ca/en/about-us/press-center/2020/05/26/canada-s-largest-pharmaceutical-manufacturer-donates-thousands-of-bottles-of-hand-sanitizer-to-hospitals-across-quebec (accessed Aug. 29, 2024). Upon information and belief, Apotex Inc.'s website formerly

included a page titled "Apotex Pharmachem Inc (API), Brantford, ON, Canada," which was removed from Apotex's website in early August 2024. https://www.apotex.com/global/api-sales/manufacturing-facilities/api-brantford-canada (last accessed July 29, 2024) (webpage now displaying "file or directory not found"); *see also* https://web.archive.org/web/20240419162722/https://www.apotex.com/global/api-sales/manufacturing-facilities/api-brantford-canada (archived Apr. 19, 2024; accessed Aug. 29, 2024). Upon information and belief, Apotex Inc. described Pharmachem as "the centre of excellence for API R&D with cGMP API manufacturing capabilities for the Apotex group of companies." https://web.archive.org/web/20240419162722/https://www.apotex.com/global/api-sales/manufacturing-facilities/api-brantford-canada (archived Apr. 19, 2024; accessed Aug. 29, 2024). Upon information and belief, Apotex Inc. further described Pharmachem as a "key strategic component to Apotex's supply chain." *Id.*

29. This Court has personal jurisdiction over Aposherm. Aposherm is incorporated in the State of Delaware. Additionally, upon information and belief, Aposherm is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Aposherm directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Aposherm purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendants' generic products.

30. Upon information and belief, since September 2021, Aposherm has been identified by Apotex Inc. and/or Apotex Corp. as a real party-in-interest in proceedings before the Patent Trial and Appeal Board ("PTAB") involving Apotex Inc. and/or Apotex Corp. as petitioner(s).

See, e.g., *Apotex Inc. v. Novo Nordisk A/S*, IPR2024-00631, Paper No. 1 (PTAB Mar. 1, 2024); *Apotex Inc. v. Celgene Corp.*, IPR2023-00512, Paper No. 1 (PTAB Feb. 10, 2023); *Apotex Inc. v. Regeneron Pharms., Inc.*, IPR2022-01524, Paper No. 1 (PTAB Sept. 9, 2022), IPR2022-00298, Paper No. 1 (PTAB Dec. 9, 2021), IPR2022-00301, Paper No. 1 (PTAB Dec. 9, 2021); *Apotex Inc. & Apotex Corp. v. Auspex Pharms., Inc.*, IPR2021-01507, Paper No. 2 (PTAB Sept. 8, 2021).

31. Upon information and belief, Aposherm has been identified as a parent company, and as having "direct or indirect interests in companies that develop, manufacture, and/or sell generic drugs and therefore [as being] interested in the issues identified," in federal lobbying reports filed by Apotex Corp. *See, e.g.*, Apotex Corp. Lobbying Report regarding "HR 938, the Bringing Low-cost Options and Competition while Keeping Incentives for new Generics (BLOCKING) Act of 2019, provisions relating to the Hatch-Waxman Acts 180-day exclusivity framework," https://lda.senate.gov/filings/public/filing/047446ee-2adc-4235-919f-da43fcca0e3a/print/ (accessed Aug. 29, 2024).

32. Upon information and belief, Apotex Holdco Inc., an active corporation registered under the laws of Ontario, Canada as of March 20, 2024, has been identified as a corporate parent of at least Apotex Inc. in Rule 7.1 statements filed by Apotex Inc. and Apotex Corp. in litigation in this District. *See, e.g.*, D.I. 14, *Pfizer Inc. v. Apotex Inc.*, C.A. No. 24-00621-CFC (D. Del.); D.I. 7, *Apotex Inc. v. Boehringer Ingelheim Pharms. Inc.*, C.A. No. 24-00577 (D. Del.); D.I. 13, *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc.*, C.A. No. 24-549-JLH (D. Del.). At various points in time, other entities including Apotex Pharmaceutical Holdings Inc. (formerly incorporated in Ontario, Canada and inactive as of April 1, 2024) and Apotex Holdings Inc. (formerly incorporated in Ontario, Canada and inactive as of April 1, 2022) have also been identified as a corporate parent of at least Apotex Inc.; and in 2023, SK Capital Partners, LP

acquired at least the former Apotex Pharmaceutical Holdings Inc. *See, e.g.*, D.I. 15, *Vanda Pharms. Inc. v. Apotex Inc.*, C.A. No. 21-282-CFC (D. Del.); D.I. 9, *Eagle Pharms., Inc. v. Apotex Inc.*, C.A. No. 24-00064-JLH (D. Del.); Press Release, SK Capital completes acquisition of Apotex, a global leader in affordable pharmaceuticals, Apr. 3, 2023, https://www.apotex.com/ca/en/about-us/press-center/2023/04/03/sk-capital-completes-acquisition-of-apotex-a-global-leader-in-affordable-pharmaceuticals (accessed Aug. 29, 2024). The extent and details of Apotex Holdco Inc.'s corporate relationship with the aforementioned entities and with Defendants Apotex Inc., Apotex Corp., Pharmachem and Aposherm is not clear at this time based on publicly available information.

33. Upon information and belief, Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district and including for Defendants' generic products that are the subject of ANDA No. 219381.

34. Upon information and belief, Apotex Inc. represents that it is "a vertically integrated company, with experience in active pharmaceutical ingredients (API) and finished product." https://www.apotex.com/mx/en/business-development/benefits-of-associating-with-apotex (accessed Aug. 29, 2024).

35. Defendants' ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Defendants' intent to market and sell Defendants' generic products in this judicial district.

36. Defendants have taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon

information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Defendants intend to direct sales of their generic drugs in this judicial district, among other places, once Defendants receive the requested FDA approval to market their generic products. Upon information and belief, Defendants will engage in marketing of their proposed generic products in Delaware upon approval of their ANDA.

37. Upon information and belief, Defendants have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 219381 and intend to benefit from the ANDA.

38. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apotex Inc. is incorporated in Canada and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

39. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apotex Corp. is incorporated in Delaware.

40. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Pharmachem is incorporated in Canada and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

41. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Aposherm is incorporated in Delaware.

FACTUAL BACKGROUND

The NDA

42. Otsuka is the holder of New Drug Application ("NDA") No. 202971 for ABILIFY MAINTENA® (aripiprazole for extended-release injectable suspension) in strengths of 300 mg and 400 mg vials and pre-filled syringes.

43. The FDA approved NDA No. 202971 on February 28, 2013.

44. ABILIFY MAINTENA® is a prescription drug approved for the treatment of schizophrenia and maintenance monotherapy treatment of bipolar I disorder. Aripiprazole is the active ingredient in ABILIFY MAINTENA®.

The Patents in Suit

45. The United States Patent and Trademark Office ("PTO") issued the '057 patent on January 7, 2020, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '057 patent is attached as Exhibit A.

46. Otsuka owns the '057 patent through assignment as recorded by the PTO at Reel 033071, Frame 0910.

47. The '057 patent expires on March 8, 2034, by virtue of 165 days of patent term adjustment granted to the '057 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit B.

48. The '057 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 202971 for ABILIFY MAINTENA®.

49. The PTO issued the '803 patent on April 20, 2021, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '803 patent is attached as Exhibit C.

50. Otsuka owns the '803 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

51. The '803 patent expires on September 24, 2033.

52. The '803 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

53. The PTO issued the '553 patent on October 26, 2021, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '553 patent is attached as Exhibit D.

54. Otsuka owns the '553 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

55. The '553 patent expires on September 24, 2033.

56. The '553 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

57. The PTO issued the '547 patent on May 31, 2022, titled "Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function." A true and correct copy of the '547 patent is attached as Exhibit E.

58. Otsuka owns the '547 patent through assignment as recorded by the PTO for the '057 patent at Reel 033071, Frame 0910.

59. The '547 patent expires on September 24, 2033.

60. The ’547 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

61. The PTO issued the ’087 patent on August 2, 2022, titled “Method of Providing Aripiprazole to Patients Having Impaired CYP2D6 or CYP3A4 Enzyme Function.” A true and correct copy of the ’087 patent is attached as Exhibit F.

62. Otsuka owns the ’087 patent through assignment as recorded by the PTO for the ’057 patent at Reel 033071, Frame 0910.

63. The ’087 patent expires on September 24, 2033.

64. The ’087 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

65. The PTO issued the ’347 patent on May 16, 2023, titled “Medical Device Containing a Cake Composition Comprising Aripiprazole as an Active Ingredient, and a Cake Composition Comprising Aripiprazole as an Active Ingredient.” A true and correct copy of the ’347 patent is attached as Exhibit G.

66. Otsuka owns the ’347 patent through assignment as recorded by the PTO at Reel 030905, Frame 0822.

67. The ’347 patent expires on April 6, 2034, by virtue of 257 days of patent term adjustment granted to the ’347 patent under 35 U.S.C. § 154(b). A true and correct copy of the patent term adjustment is attached as Exhibit H.

68. The ’347 patent is listed in the Orange Book in connection with NDA No. 202971 for ABILIFY MAINTENA®.

The ANDA

69. Upon information and belief, Defendants submitted ANDA No. 219381 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the manufacture, use, and/or sale in the United States of aripiprazole for extended-release injectable suspension, 300 mg/vial and 400 mg/vial (defined above as "Defendants' generic products"), which is a generic version of Otsuka's ABILIFY MAINTENA® (aripiprazole).

70. Upon information and belief, ANDA No. 219381 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Defendants' generic products.

71. Otsuka received a letter sent by Defendants, dated July 17, 2024, purporting to be a "Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement" for an ANDA, ("Defendants' Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Defendants' Notice Letter identified Defendants' ANDA as "ANDA No. 219381." Defendants' Notice Letter included an enclosure purporting to be a detailed factual and legal basis for Apotex's paragraph IV certification that the patents in suit are invalid, unenforceable, and/or will not be infringed.

72. Defendants' Notice Letter states that Defendants had filed ANDA No. 219381 seeking "to obtain approval to engage in the commercial manufacture, use or sale" of Defendants' generic products before the expiration of the patents in suit.

73. Plaintiffs commenced this action within 45 days of receiving Defendants' Notice Letter.

COUNT I

(INFRINGEMENT OF THE '057 PATENT)

74. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

75. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '057 patent.

76. Upon information and belief, Defendants 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 alleging that the claims of the '057 patent are invalid, unenforceable and/or not infringed.

77. Upon information and belief, Defendants concede infringement of at least one claim of the '057 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement.

78. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

79. Defendants have actual knowledge of the '057 patent, as evidenced by Defendants' Notice Letter.

80. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '057 patent by submitting, or causing to be submitted, to the FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '057 patent.

81. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '057 patent under § 271(a), either literally or under the doctrine

of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '057 patent and any additional periods of exclusivity.

82. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 219381, and therefore will infringe at least one claim of the '057 patent.

83. Upon information and belief, Defendants have knowledge of the '057 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '057 patent, either literally or under the doctrine of equivalents.

84. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '057 patent.

85. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

86. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

87. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

88. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '803 PATENT)

89. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

90. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '803 patent.

91. Upon information and belief, Defendants 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 alleging that the claims of the '803 patent are invalid, unenforceable and/or not infringed.

92. Upon information and belief, Defendants concede infringement of at least one claim of the '803 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement.

93. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

94. Defendants have actual knowledge of the '803 patent, as evidenced by Defendants' Notice Letter.

95. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '803 patent by submitting, or causing to be submitted, to the

FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '803 patent.

96. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '803 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '803 patent and any additional periods of exclusivity.

97. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 219381, and therefore will infringe at least one claim of the '803 patent.

98. Upon information and belief, Defendants have knowledge of the '803 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '803 patent, either literally or under the doctrine of equivalents.

99. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '803 patent.

100. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

101. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

102. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

103. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '553 PATENT)

104. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

105. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '553 patent.

106. Upon information and belief, Defendants 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 alleging that the claims of the '553 patent are invalid, unenforceable and/or not infringed.

107. Upon information and belief, Defendants concede infringement of at least one claim of the '553 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement.

108. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

109. Defendants have actual knowledge of the '553 patent, as evidenced by Defendants' Notice Letter.

110. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '553 patent by submitting, or causing to be submitted, to the FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '553 patent.

111. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '553 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '553 patent and any additional periods of exclusivity.

112. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 219381, and therefore will infringe at least one claim of the '553 patent.

113. Upon information and belief, Defendants have knowledge of the '553 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '553 patent, either literally or under the doctrine of equivalents.

114. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants'

generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '553 patent.

115. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

116. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

117. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

118. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '547 PATENT)

119. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

120. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '547 patent.

121. Upon information and belief, Defendants 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 alleging that the claims of the '547 patent are invalid, unenforceable and/or not infringed.

122. Upon information and belief, Defendants concede infringement of at least one claim of the '547 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement.

123. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

124. Defendants have actual knowledge of the '547 patent, as evidenced by Defendants' Notice Letter.

125. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '547 patent by submitting, or causing to be submitted, to the FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '547 patent.

126. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '547 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '547 patent and any additional periods of exclusivity.

127. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 219381, and therefore will infringe at least one claim of the '547 patent.

128. Upon information and belief, Defendants have knowledge of the '547 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '547 patent, either literally or under the doctrine of equivalents.

129. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '547 patent.

130. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

131. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

132. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

133. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '087 PATENT)

134. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

135. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '087 patent.

136. Upon information and belief, Defendants 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 alleging that the claims of the '087 patent are invalid, unenforceable and/or not infringed.

137. Upon information and belief, Defendants concede infringement of at least one claim of the '087 patent because Defendants' Notice Letter did not provide non-infringement allegations addressing induced infringement.

138. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

139. Defendants have actual knowledge of the '087 patent, as evidenced by Defendants' Notice Letter.

140. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '087 patent by submitting, or causing to be submitted, to the FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '087 patent.

141. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '087 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '087 patent and any additional periods of exclusivity.

142. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 219381, and therefore will infringe at least one claim of the '087 patent.

143. Upon information and belief, Defendants have knowledge of the '087 patent and, by their proposed package insert for Defendants' generic products, know or should know that it will induce direct infringement of at least one claim of the '087 patent, either literally or under the doctrine of equivalents.

144. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '087 patent.

145. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

146. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

147. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

148. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '347 PATENT)

149. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

150. Upon information and belief, Defendants filed ANDA No. 219381 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '347 patent.

151. Upon information and belief, Defendants 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 alleging that the claims of the '347 patent are invalid, unenforceable and/or not infringed.

152. Upon information and belief, in their ANDA No. 219381, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's ABILIFY MAINTENA®.

153. Defendants have actual knowledge of the '347 patent, as evidenced by Defendants' Notice Letter.

154. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '347 patent by submitting, or causing to be submitted, to the FDA ANDA No. 219381, seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '347 patent.

155. Upon information and belief, if ANDA No. 219381 is approved, Defendants will infringe one or more claims of the '347 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or 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. 219381 shall be no earlier than the expiration of the '347 patent and any additional periods of exclusivity.

156. Upon information and belief, if ANDA No. 219381 is approved, Defendants intend to and will manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States.

157. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219381 complained of herein were done by and for the benefit of Defendants.

158. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

159. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '057 patent through Defendants' submission of ANDA No. 219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '057 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '057 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '057 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '057 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants'

generic products into the United States, until the expiration of the '057 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '057 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '803 patent through Defendants' submission of ANDA No. 219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '803 patent;

G. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '803 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '803 patent under 35 U.S.C. § 271(a), (b) and/or (c);

H. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '803 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

I. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '803 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '803 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '553 patent through Defendants' submission of ANDA No. 219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '553 patent;

L. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '553 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '553 patent under 35 U.S.C. § 271(a), (b) and/or (c);

M. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '553 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

N. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '553 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining

approval of the ANDA until the expiration of the '553 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '547 patent through Defendants' submission of ANDA No. 219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '547 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '547 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '547 patent under 35 U.S.C. § 271(a), (b) and/or (c);

R. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '547 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

S. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '547 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

T. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '547 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '087 patent through Defendants' submission of ANDA No. 219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '087 patent;

V. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '087 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '087 patent under 35 U.S.C. § 271(a), (b) and/or (c);

W. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '087 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

X. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '087 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Y. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '087 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Z. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '347 patent through Defendants' submission of ANDA No.

219381 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '347 patent;

AA. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the '347 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '347 patent under 35 U.S.C. § 271(a), (b) and/or (c);

BB. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the '347 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

CC. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the '347 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DD. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons and entities acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '347 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

EE. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

FF. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

GG. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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