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*OTSUKA PHARMACEUTICAL CO., LTD.*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| OTSUKA PHARMACEUTICAL CO., LTD.<br><br>Plaintiff,<br><br>v.<br><br>APOTEX CORP.<br><br>and<br><br>APOTEX INC.<br><br>Defendants. | Civil Action No.: 3:08-cv-04958 |

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex") alleges as follows:

**THE PARTIES**

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Weston, Toronto, Ontario, Canada M9L 1T9.

## NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Number 5,006,528 ("the '528 patent"), 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 Apotex Corp.'s filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market generic pharmaceutical products ("Apotex Corp.'s generic products").

## JURISDICTION AND VENUE

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

6. This Court has jurisdiction over Apotex Corp. Apotex Corp. directly, or indirectly, 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 Apotex Corp.'s generic products. Apotex Corp. has previously submitted to the

jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. This Court has jurisdiction over Apotex Inc. 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 through its wholly-owned subsidiaries (primarily Apotex Corp.), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Apotex Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

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

**FIRST COUNT FOR PATENT INFRINGEMENT**

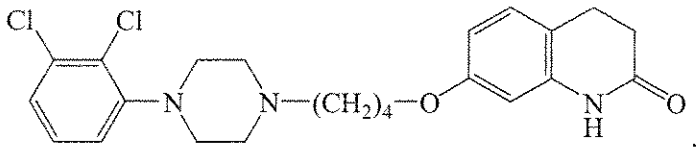
9. The U.S. Patent and Trademark Office ("PTO") issued the '528 patent on April 9, 1991, entitled "Carbostyril Derivatives." A copy of the '528 patent is attached as Exhibit A.

10. The '528 patent is assigned to Otsuka. Otsuka is the owner of the '528 patent as recorded by the PTO at Reel 014402, Frame 0284.

11. The PTO issued a Patent Term Extension under 35 U.S.C. §156 on October 12, 2005. The '528 patent expires on October 20, 2014. A copy of the Patent Term Extension for the '528 patent is attached as Exhibit B.

12. The PTO issued a Reexamination Certificate for the '528 patent on June 13, 2006. A copy of the Reexamination Certificate for the '528 patent is attached as Exhibit C.

13. The '528 patent claims, *inter alia*, aripiprazole. The chemical structure for aripiprazole is:




14. Otsuka is the holder of New Drug Application ("NDA") No. 02-1436 for aripiprazole, which the FDA approved on November 15, 2002. Otsuka lists the '528 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 02-1436.

15. Otsuka manufactures and sells various dosage strengths of aripiprazole in the United States under the trademark Abilify®.

16. Upon information and belief, Apotex Corp. filed with the FDA ANDA No. 78-583, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

17. Upon information and belief, Apotex Corp.'s ANDA No. 78-583, as originally filed, sought FDA approval to sell in the United States generic products containing 5, 10, 15, 20 and 30 mg of aripiprazole ("Apotex Corp.'s 5, 10, 15, 20 and 30 mg generic products").

18. Apotex Corp.'s 5, 10, 15, 20 and 30 mg generic products, and Otsuka's claims that these products will, if approved and marketed, infringe at least one claim of the '528 patent, are the subject of Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000.

19. Upon information and belief, Apotex Corp. has amended its ANDA No. 78-583, to now seek FDA approval to sell in the United States, in addition to Apotex Corp.'s 5, 10, 15,

20 and 30 mg generic products, a generic product containing 2 mg of aripiprazole ("Apotex Corp.'s 2 mg generic product").

20. Otsuka received a letter from Apotex Inc., on behalf of Apotex Corp., dated August 22, 2008, purporting to be a Notice of Certification for an amendment to ANDA No. 78-583 ("Apotex's 78-583 amendment letter") under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(c).

21. Apotex's 78-583 amendment letter alleges that Apotex has submitted to the FDA an amendment to Apotex Corp's ANDA No. 78-583 to add a 2 mg strength tablet and that the active ingredient in Apotex Corp.'s generic products for which it seeks approval, including Apotex Corp.'s 2 mg generic product, is aripiprazole.

22. Upon information and belief, Apotex Corp.'s 2 mg generic product will, if approved and marketed, infringe at least one claim of the '528 patent.

23. Under 35 U.S.C. § 271(e)(2)(A), Apotex Corp. has infringed at least one claim of the '528 patent by submitting, or causing to be submitted to the FDA, an amendment to ANDA No. 78-583 ("Apotex's ANDA amendment") seeking approval for the commercial marketing of Apotex Corp.'s 2 mg generic product before the expiration date of the '528 patent.

24. Upon information and belief, Apotex Corp.'s actions relating to Apotex Corp.'s ANDA No. 78-583 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of, Apotex Inc.

**SECOND COUNT FOR WILLFUL INFRINGEMENT**

25. Otsuka realleges, and incorporates in full herein, paragraphs 9-24.

**A. Apotex Knowingly and Deliberately Copied the '528 Patent**

26. On information and belief, Apotex knowingly and deliberately copied the teachings of the '528 patent in formulating Apotex Corp.'s 2 mg generic product.

27. On information and belief, Apotex also knowingly and deliberately copied the teachings of the '528 patent in formulating Apotex Corp.'s 5, 10, 15, 20 and 30 generic products that are at issue in Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000.

**B. Apotex's Objectively Baseless 78-583 amendment letter**

28. Apotex's 78-583 amendment letter contains unsupported, conclusory, and legally and scientifically deficient arguments.

29. Under FDA law, Apotex was required to provide Otsuka a certification containing "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

30. Apotex's detailed statement was required to include the following:

> (i) For each claim of a patent alleged not to be infringed, a ***full*** *and detailed explanation* of why the claim is not infringed.
>
> (ii) For each claim of a patent alleged to be invalid or unenforceable, a ***full*** *and detailed explanation* of the grounds supporting the allegation.

21 C.F.R. § 314.95(c)(6) (emphasis added).

31. Apotex's 78-583 amendment letter contains the identical arguments previously provided concerning Apotex Corp.'s 5, 10, 15, 20 and 30 generic products that are at issue in Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000.

32. Apotex's 78-583 amendment letter does not allege non-infringement of the claims of the '528 patent.

33. Apotex's 78-583 amendment letter alleges invalidity of all claims of the '528 patent for obviousness under 35 U.S.C. § 103(a). The only references cited in support of these allegations of invalidity, however, are references already considered and specifically addressed by the Examiner during reexamination of the '528 patent. Given that, during reexamination proceedings, the claims of the '528 patent were found to be patentable over all references cited in Apotex's 78-583 amendment letter, these allegations are conclusory and meritless.

34. Apotex's 78-583 amendment letter alleges that the Declaration under 37 C.F.R. § 1.132 by Tsuyoshi Hirose ("the Hirose Declaration") submitted during reexamination proceedings is not sufficient to establish unexpected results. Given that the Examiner reviewed the Hirose Declaration during the reexamination of the '528 patent and concluded that the Hirose Declaration was sufficient to establish unexpected results, Apotex's allegation is conclusory and meritless.

35. Despite criticizing the Hirose Declaration, Apotex's 78-583 amendment letter acknowledges that the claimed compounds tested in the Hirose Declaration "were shown to be more active" in the anti-apomorphine assay than the prior art compounds against which they were compared.

36. Apotex's 78-583 amendment letter argues that the claimed compounds tested are no better than "some of the unclaimed compounds of the prior art." Yet Apotex's 78-583 amendment letter also concedes that the DA receptor antagonistic activity $ED_{50}$ values of the claimed compounds are "generally nominally greater than those exhibited by non-claimed compounds." Apotex's 78-583 amendment letter also provides no evidence that these "non-

claimed compounds" it alleges should have been compared against the claimed compounds were in fact disclosed in the prior art.

37. Given that Apotex's 78-583 amendment letter provides unfounded and contradictory assertions in alleged support of its invalidity position, Apotex's allegation of invalidity is superficial, objectively baseless, and conclusory.

38. Apotex's 78-583 amendment letter fails to provide "a detailed statement of the factual and legal basis of the opinion of the applicant" concerning the alleged unenforceability of the claims of the '528 patent.

39. Apotex's 78-583 amendment letter states that "the failure of the patentee to disclose [Banno et al., *Chem. Pharm. Bull.*, 36(11): 4377-4388 (1988) ("the Banno article")] to the examiner during the original prosecution and the lack of disclosure of [Oshiro et al., *J. Med. Chem.* 41: 658-667 (1998) ("the Oshiro article")] to the Examiner during the reexamination may result in a finding of inequitable conduct on the part of the patentee." (emphasis added) Apotex provides no valid argument in support of this qualified assertion; therefore, this qualified allegation is superficial, baseless, and conclusory.

40. The analysis in Apotex's 78-583 amendment letter is so superficial, conclusory and internally inconsistent that, on information and belief, this document was not prepared by persons knowledgeable in the relevant technical fields to which the '528 patent is directed.

41. The allegations in Apotex's 78-583 amendment letter are objectively baseless.

### C. Apotex's Objectively Baseless Answer and Counterclaims in Related Litigation Concerning Apotex's ANDA 78-583

42. Apotex's Answer and Amended Answer in a related litigation concerning Apotex's ANDA 78-583, Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000, contain unsupported, conclusory, and legally and scientifically deficient arguments.

43. Apotex's Answer and Amended Answer in this related litigation allege in the First Additional Defense that the '528 patent is invalid for "failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 12, 103, and/or 112." Apotex provides absolutely no basis for its assertion; therefore, this allegation is superficial, baseless, and conclusory.

44. Apotex's Answer and Amended Answer in this related litigation allege in the Second Additional Defense unenforceability of the '528 patent due to inequitable conduct for failure to cite allegedly material information to the PTO during the original prosecution and reexamination of the '528 patent.

45. Apotex's Second Additional Defense alleges that the Banno article is material prior art; however, Apotex has presented no valid explanation for this assertion.

46. Apotex's Second Additional Defense alleges that the Oshiro article is a material reference; however, Apotex has again presented no valid explanation for this assertion.

47. Apotex's allegation of unenforceability is superficial, objectively baseless, and conclusory. Apotex's pursuit of this defense is unjustified and needlessly raised the costs and complexity of this related litigation.

48. Count I of Apotex's Counterclaims in this related litigation alleges invalidity of the claims of the '528 patent in view of alleged prior art references. Among the alleged prior art references, Apotex includes references already considered and specifically addressed by the Examiner during reexamination of the '528 patent. The Examiner found the claims of the '528 patent to be patentable over these references; therefore, Apotex's invalidity allegation is conclusory and meritless.

49. Apotex's allegation of invalidity is superficial, objectively baseless, and conclusory. Apotex's pursuit of this counterclaim is unjustified and needlessly raised the costs and complexity of this related litigation.

50. The additional allegations in Apotex's Answer, Amended Answer, and Counterclaims are equally without merit and needlessly raised the costs and complexity of this related litigation.

51. The allegations in Apotex's Answer, Amended Answer, and Counterclaims in this related litigation are objectively baseless.

52. The additional allegations in Apotex's proposed Second Amended Answer and Counterclaims in this related litigation are objectively baseless.

53. In light of the objectively baseless allegations in this related litigation, Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000, Apotex's continued infringement in amending its ANDA 78-583 to add a 2 mg product is unreasonable and reckless.

**D. Apotex's Litigation Misconduct in Related Litigation Concerning Apotex's ANDA 78-583**

54. During the course of related litigation concerning Apotex's ANDA 78-583, Civil Action No. 3:07-cv-01346, now consolidated into Civil Action No. 3:07-cv-01000, Apotex has repeatedly thwarted Otsuka's requests for discovery but at the same time has demanded overbroad, excessive, and unnecessary discovery from Otsuka. Apotex's actions have needlessly increased the cost and complexity of this related litigation and, accordingly, needlessly increased the cost and complexity of the present litigation, which will rely in substantial part on the same discovery record.

55. Apotex has served overly broad document requests seeking excessive document discovery from Otsuka in this related litigation.

56. Despite having demanded excessive document discovery from Otsuka, Apotex argued that it was only required to produce its final ANDA concerning aripiprazole and refused to produce any additional documents by the April 1, 2008 deadline, as required under the Second Pretrial Scheduling Order.

57. Apotex's conduct in failing to timely produce court-ordered discovery has prejudiced Otsuka's ability to obtain needed discovery in this related litigation.

58. Apotex served overbroad and excessive written discovery requests on Otsuka in this related litigation.

59. Apotex has demanded an excessive number of depositions from Otsuka and from third-party witnesses in this related litigation.

60. Despite having demanded excessive depositions from Otsuka in this related litigation, Apotex has refused to timely make their own witnesses available for deposition.

**E. Apotex's Actions In Deliberately Infringing the '528 Patent Have Been Unreasonable and Objectively Reckless**

61. On information and belief, Apotex knew or should have known that its amendment to its ANDA No. 78-583 to add its 2 mg generic product infringed one or more claims of the '528 patent and that the allegations in Apotex's 78-583 amendment letter and in its defenses asserted in related litigation concerning ANDA No. 78-583 were objectively baseless. Apotex nevertheless has continued to pursue its ANDA No. 78-583, amending it to add an additional product strength, while refusing to withdraw its certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and/or change that certification to one pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III). Apotex has also continued to pursue its counterclaims against Otsuka.

62. Apotex's pursuit of ANDA approval, despite the deficiencies in Apotex's 78-583 amendment letter and in its defenses in related litigation, has been unreasonable and objectively reckless.

63. Apotex's conduct in related litigation concerning ANDA No. 78-583 has been improper, unwarranted and vexatious.

64. Apotex's conduct constitutes knowing and willful infringement of the '528 patent.

**WHEREFORE**, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Apotex Corp. and Apotex Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '528 patent through Apotex Corp.'s submission of ANDA No. 78-583 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex Corp.'s 2 mg generic product before expiration of the '528 patent;

2) order that the effective date of any approval by the FDA of Apotex Corp.'s 2 mg generic product be a date that is not earlier than the expiration of the '528 patent, or such later date as the Court may determine;

3) enjoin Apotex from the commercial manufacture, use, import, offer for sale and/or sale of Apotex Corp.'s 2 mg generic product until the expiration of the '528 patent, or such later date as the Court may determine;

4) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Corp.'s ANDA No. 78-583, including Apotex's ANDA amendment, until expiration of the '528 patent;

5) find Apotex's infringement of the '528 patent to have been willful and award Otsuka enhanced damages for this willful infringement;

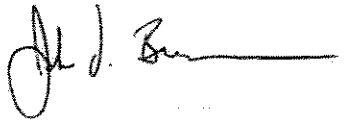
6) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

7) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: October 22, 2008

PEPPER HAMILTON LLP
Attorneys for Plaintiff Otsuka Pharmaceutical Co. Ltd.



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