

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

JANSSEN PHARMACEUTICA N.V.,
JANSSEN PHARMACEUTICALS, INC., and
JANSSEN RESEARCH & DEVELOPMENT,
LLC,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceutica N.V. (“Janssen N.V.”), Janssen Pharmaceuticals, Inc. (“Janssen Pharm.”), and Janssen Research & Development, LLC (“Janssen R&D”) (collectively, “Janssen”), by its attorneys, for its complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, in response to the submission by Apotex of Abbreviated New Drug Application No. 208481 (“ANDA No. 208481”) to the United States Food and Drug Administration (the “FDA”), seeking approval to manufacture and sell generic versions of SPORANOX® oral solution prior to the expiration of U.S. Patent No. 6,407,079 (“the ’079 Patent”).

THE PARTIES

2. Janssen N.V. is a corporation organized and existing under the laws of Belgium with its principal place of business at Turnhoutseweg 30, B-2340, Beerse, Belgium.

3. Janssen Pharm. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Janssen R&D is a corporation organized and existing under the laws of New Jersey with its principal place of business at 920 Route 202, Raritan, New Jersey 08869.

5. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its corporate headquarters at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc.

6. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings, Inc.

7. Upon information and belief, Apotex is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), and 21 U.S.C. § 355.

9. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Apotex because Apotex has consented to personal jurisdiction in this Judicial District for the limited purposes of this litigation and this matter only.

11. This Court has personal jurisdiction over Apotex because, upon information and belief, Apotex directly, or through its affiliates and agents, manufactures, exports, markets and sells drug products throughout the United States and this Judicial District.

12. This Court has personal jurisdiction over Apotex because, upon information and belief, Apotex has purposefully availed itself of the benefits and protections of New York's law by filing suit in this Judicial District in *Apotex, Inc. v. Pfizer, Inc.*, 1-04-cv-02539 (S.D.N.Y. 2004); *Apotex Inc. v. Bristol-Myers Squibb Co.*, 1-04-cv-02922 (S.D.N.Y.); *Apotex, Inc. v. Sanofi-Aventis*, 1-05-cv-03965 (S.D.N.Y.); and *Apotex Inc. v. Acorda Therapeutics, Inc.*, No. 1:11-cv-08803 (S.D.N.Y.).

13. This Court has personal jurisdiction over Apotex Corp. because, upon information and belief, Apotex Corp. is registered with the Office of Professions of the New York State Education Department as a non-resident pharmacy wholesaler (Registration No. 025806).

14. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

15. The '079 Patent, entitled "Pharmaceutical compositions containing drugs which are instable or sparingly soluble in water and methods for their preparation," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 18, 2002, naming Bernd W. Müller and Ulrich Brauns as inventors. A true and correct copy of the '079 Patent is attached to this Complaint as Exhibit A. An Ex Parte Reexamination Certificate was

duly and legally issued for the '079 Patent on October 16, 2014. A true and correct copy of the '079 Ex Parte Reexamination Certificate is attached to this Complaint as Exhibit B.

16. Janssen N.V. is the lawful owner of all rights, titles and interests in the '079 Patent, including the right to sue and to recover for past infringement thereof.

17. Janssen Pharm. currently markets prescription product SPORANOX® oral solution under the trademark SPORANOX®. SPORANOX® oral solution is covered by the claims of the '079 Patent.

18. Janssen Pharm. and Janssen R&D collaborated to get approval from the FDA for New Drug Application No. 20657 which is listed in the FDA's Orange Book as covering the drug SPORANOX® oral solution.

APOTEX'S ANDA NO. 208481

19. Upon information and belief, Apotex submitted ANDA No. 208481 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of a generic version of SPORANOX® oral solution based on SPORANOX® as the Reference Listed Drug before the expiration of the '079 Patent.

20. Upon information and belief, ANDA No. 208481 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the '079 Patent is "invalid, unenforceable and/or will not be infringed" by the commercial manufacture, use, sale, offer for sale, or importation of Apotex's proposed generic copies of SPORANOX® oral solution.

21. In a letter dated July 28, 2015 addressed to and received by Janssen on or about July 29, 2015, Apotex provided “Notice” under 21 U.S.C. § 355(j)(2)(B) with respect to its proposed generic copies of SPORANOX® oral solution and the ’079 Patent.

22. Upon information and belief, if ANDA No. 208481 is approved by the FDA before the expiration of the ’079 Patent, Apotex will begin manufacturing, using, importing, offering for sale and/or selling its proposed generic copies of SPORANOX® oral solution.

COUNT I: INFRINGEMENT OF THE ’079 PATENT — ANDA NO. 208481

SUBMISSION

23. Janssen incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Apotex’s submission of ANDA No. 208481 was an act of infringement of the ’079 Patent under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, Apotex’s proposed generic copies of SPORANOX® oral solution are covered by one or more claims of the ’079 Patent.

26. Upon information and belief, Apotex’s commercial manufacture, importation, use, sale, and/or offer for sale of its proposed generic copies of SPORANOX® oral solution before the expiration of the ’079 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’079 Patent.

27. Upon information and belief, unless enjoined by this Court, Apotex plans and intends to, and will, infringe one or more claims immediately following approval of ANDA No. 208481.

28. Upon information and belief, Apotex has been aware of the existence of the '079 Patent, and has no reasonable basis for believing that its proposed generic copies of SPORANOX® oral solution will not infringe the '079 Patent.

29. This case is exceptional, as that term is used in 35 U.S.C. § 285.

30. The acts of infringement by Apotex set forth above will cause Janssen irreparable harm for which it has no adequate remedy at law, and will continue to cause such harm unless enjoined by this Court.

COUNT II: INFRINGEMENT OF THE '079 PATENT — DECLARATORY JUDGMENT

31. Janssen incorporates each of the preceding paragraphs 1–30 as if fully set forth herein.

32. Janssen brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

33. There is an actual case or controversy such that the Court may entertain Janssen's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

34. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Apotex's proposed generic copies of SPORANOX® oral solution before the expiration of the '079 Patent.

35. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic copies of SPORANOX® oral solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '079 Patent.

36. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Janssen and Apotex as to liability for the infringement of the '079 Patent claims. Apotex's actions have created for Janssen a reasonable apprehension of irreparable harm and loss resulting from Apotex's threatened imminent actions.

37. Janssen is entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic copies of SPORANOX® oral solution will constitute infringement of one or more claims of the '079 Patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests for this Court to grant the following relief:

- A. Enter a judgment that Apotex has infringed the '079 Patent under 35 U.S.C. § 271(e)(2)(A);
- B. Issue an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 208481 by the FDA is not earlier than the expiration date of the '079 Patent, or any later expiration of exclusivity for the '079 Patent to which Janssen is or becomes entitled;
- C. Issue a preliminary injunction restraining and enjoining Apotex and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 208481 until the expiration of the '079 Patent;
- D. Issue a permanent injunction restraining and enjoining Apotex and its officers, agents, servants, and employees, and those persons in active concert or participation with any of

them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 208481 until the expiration of the '079 Patent;

E. Enter a declaratory judgment that making, using, selling, offering to sell, or importing the product described in ANDA No. 208481 would constitute infringement of the '079 Patent, or inducing or contributing to such conduct, by Apotex pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

F. Award Janssen its costs incurred in this action;

G. Find that this is an exceptional case under 35 U.S.C. § 285 and award Janssen its reasonable attorneys' fees, and disbursements (including expert fees) incurred in this action; and

H. Award Janssen such other relief as the Court determines just and proper.

Dated: September 10, 2015

Respectfully submitted,

/s/ Robert A. Johnson

Robert A. Johnson

rajohnson@akingump.com

AKIN GUMP STRAUSS HAUER & FELD LLP

One Bryant Park

New York, NY 10036-6745

(212) 872-1000

Of Counsel:

Barbara L. Mullin*

bmullin@akingump.com

Jonathan Underwood*

junderwood@akingump.com

Two Commerce Square

2001 Market Street, Suite 4100

Philadelphia, PA 19103-7013

(215) 965-1200

Attorneys for Plaintiffs

Janssen Pharmaceutica N.V.

Janssen Pharmaceuticals, Inc.
Janssen Research & Development, LLC

**Pro hac vice applications forthcoming*