

**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.

FERA PHARMACEUTICALS, LLC,

Defendant.

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 Defendant Fera Pharmaceuticals, LLC (“Fera”), alleges 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 of Abbreviated New Drug Application No. 202762 (“the ANDA”) to the United States Food and Drug Administration (“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, Fera is a limited liability company organized and existing under the laws of the state of New York, having its corporate headquarters at 134 Birch Hill Road, Locust Valley, New York 11560.

**JURISDICTION AND VENUE**

6. 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.

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

8. This Court has personal jurisdiction over Fera because, upon information and belief, *inter alia*, Fera has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Fera does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Fera directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products,

including generic drug products within and directed to the United States, this State, and this Judicial District specifically. Further, this Court has personal jurisdiction over Fera because, upon information and belief, *inter alia*, Fera is registered as a domestic limited liability company (DOS ID #: 3606407) in the State of New York by the New York State Department of State, Division of Corporations. Furthermore, Fera is registered as a Pharmacy Establishment (Registration No. 029519) in the State of New York by the New York State Department of Education, Office of the Professions. In addition, upon information and belief, Fera is actively preparing to make its proposed generic copies of SPORANOX® oral solution that are the subject of the ANDA, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

#### **THE PATENT-IN-SUIT**

10. 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.

11. 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.

12. 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.

13. Janssen Inc. 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.

#### **FERA'S ANDA**

14. Upon information and belief, Fera submitted the ANDA 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.

15. Upon information and belief, the ANDA 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 Fera's proposed generic copies of SPORANOX® oral solution.

16. In a letter dated June 17, 2015 addressed to and received by Janssen Inc. on or about June 18, 2015, Fera 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.

17. Upon information and belief, if the ANDA is approved by the FDA before the expiration of the '079 Patent, Fera 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 SUBMISSION**

18. Janssen incorporates each of the preceding paragraphs 1–17 as if fully set forth herein.

19. Fera's submission of the ANDA 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).

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

21. Upon information and belief, Fera'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.

22. Upon information and belief, unless enjoined by this Court, Fera plans and intends to, and will, infringe one or more claims immediately following approval of the ANDA.

23. Upon information and belief, Fera 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.

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

25. The acts of infringement by Fera 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**

26. Janssen incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

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

28. 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.

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

30. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Fera'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.

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

32. Janssen is entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Fera'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 Fera 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 FDA approval of ANDA No. 207608 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 Fera 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. 206790 until the expiration of the '079 Patent;
- D. Issue a permanent injunction restraining and enjoining Fera 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. 206790 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. 206790 would constitute infringement of the '079 Patent, or inducing or contributing to such conduct, by Fera 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: July 30, 2015

/s/ Robert A. Johnson  
Robert A. Johnson  
rajohnson@akingump.com  
Akin Gump Strauss Hauer & Feld LLC  
One Bryant Park  
New York, NY 10036-6745  
(212) 872-1000

*Of Counsel:*  
Barbara L. Mullin\*  
[bmullin@akingump.com](mailto:bmullin@akingump.com)  
Jonathan Underwood\*  
[junderwood@akingump.com](mailto: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*