IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
XELLIA PHARMACEUTICALS APS,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Janssen Pharmaceutica N.V. (hereinafter "Janssen" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Xellia Pharmaceuticals ApS (hereinafter "Xellia" or "Defendant"), herein alleges:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Xellia's filing of a New Drug Application ("NDA") under 21 U.S.C. § 355(b)(1)-(2) with the United States Food and Drug Administration ("FDA"), seeking approval to market Voriconazole for Injection (200 mg), prior to the expiration of United States Patent No. 6,407,079 ("the '079 patent"), which covers certain beta-cyclodextrin drug inclusion complexes.

THE PARTIES

2. Plaintiff Janssen Pharmaceutica N.V. ("Janssen") 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. Upon information and belief, defendant Xellia is a corporation organized and existing under the laws of Denmark, having its corporate headquarters at Dalslandsgade 11, 2300 Copenhagen S, Denmark.

THE PATENT-IN-SUIT

4. On June 18, 2002, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '079 patent, entitled "Pharmaceutical Compositions Containing Drugs Which Are Instable or Sparingly Soluble in Water and Methods for Their Preparation." On October 16, 2014, the USPTO issued an ex parte reexamination certificate for the '079 patent. A copy of the '079 patent, along with the ex parte reexamination certificate, is attached to this Complaint as **Exhibit A**.

5. Janssen is the lawful owner of and holds right, title, and interest in the '079 patent, including the right to sue and to recover for infringement thereof.

6. Janssen holds approved New Drug Application No. 020966 (the "Sporanox® NDA").

7. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '079 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Sporanox®.

XELLIA'S 505(b)(2) NDA

8. Upon information and belief, Xellia has submitted NDA No. 20-8562 ("Xellia's 505(b)(2) NDA") to the FDA, pursuant to 21 U.S.C. § 355(b)(2), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic injectable voriconazole product, in a 200 mg dose, injected with 1 mL of liquid ("Xellia's Product"), before the expiration of the '079 patent.

9. Xellia is the holder of Xellia's 505(b)(2) NDA.

10. Upon information and belief, Xellia's 505(b)(2) NDA refers to and relies upon the Sporanox® NDA and references data contained therein.

11. By letter to Janssen, dated May 20, 2016, Xellia stated that Xellia's 505(b)(2) NDA contained certifications, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV), that the '079 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of Xellia's Product (the "Paragraph IV Certifications"). Xellia attached a memorandum to its May 20, 2016 letter, in which it purported to allege the factual and legal bases for its Paragraph IV Certifications (the "Paragraph IV Notice Letter"). Xellia did not dispute infringement of claims 1-5, 12-16, 18-19, 23, 26-28, and 36-38 of the '079 patent.

12. Upon information and belief, if the FDA approves Xellia's 505(b)(2) NDA, Xellia plans to and will manufacture, distribute, import, offer for sale and/or sell Xellia's Product throughout the United States, including within the State of Delaware.

JURISDICTION AND VENUE

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

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

15. Upon information and belief, Xellia is subject to personal jurisdiction in the State of Delaware due to, *inter alia*, its regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, Xellia has engaged in the regular conduct of business within this judicial district.

16. This Court has personal jurisdiction over Xellia because, upon information and belief, Xellia has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Xellia has had persistent and continuous contact with this judicial district, including by developing, manufacturing, and/or selling generic pharmaceutical products that are distributed and sold in this district.

17. Upon information and belief, Xellia derives substantial revenue from selling pharmaceutical products throughout the United States, including in this judicial district.

18. This Court has exercised jurisdiction over Xellia in prior cases under the Hatch-Waxman Act, and Xellia has not contested such jurisdiction. *See, e.g.*, *Merck, Sharp & Dohme, Corp. v. Xellia Pharms. ApS*, C.A. No. 14-199-RGA (D. Del. Feb. 14, 2014).

19. This Court has personal jurisdiction over Xellia for the reasons articulated by the United States Court of Appeals for the Federal Circuit on March 18, 2016 in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 2015-1456 (Fed. Cir. March 18, 2016); *reh'g en banc denied*, 2015-1456, Dkt. No. 128 (Fed. Cir. June 20, 2016). There, the Federal Circuit held that a generic drug company such as Xellia is subject to personal jurisdiction in Delaware when it "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)." *Acorda*, slip op. at 8.

20. If Xellia commercially markets, uses, offers for sale, or sells Xellia's Product in the State of Delaware, or anywhere within the United States, before the expiration of the '079 patent, Xellia will infringe and/or actively induce or contribute to the infringement of the '079 patent, causing harm to the Plaintiff in the State of Delaware.

21. Xellia has agreed not to contest personal jurisdiction in this matter.

22. Venue is proper in the District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,407,079

23. Plaintiff incorporates each of the preceding Paragraphs 1 through 22 as if fully set forth herein.

24. Xellia has infringed one or more claims of the '079 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Xellia's 505(b)(2) NDA, by which Xellia seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Xellia's Product prior to the expiration of the '079 patent.

25. Xellia's sale, offer for sale, use, or commercial manufacture of Xellia's Product within the United States, or importation of Xellia's Product into the United States, during the term of the '079 patent would infringe, contribute to the infringement of, and/or induce the infringement of the '079 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Xellia will infringe or aid another in the infringement of at least one or more of the following claims of the '079 patent: claims 1-5, 12-16, 26-28 and 36-38.

26. Xellia's Paragraph IV Notice Letter does not dispute that Xellia's Product infringes claims 1-5, 12-16, 18-19, 26-28 and 36-38 of the '079 patent.

27. Upon information and belief, Xellia has acted with full knowledge of the '079 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '079 patent. Notwithstanding this knowledge, Xellia has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Xellia's Product with its proposed labeling immediately and imminently upon

approval of Xellia's 505(b)(2) NDA. Upon information and belief, through such activities, Xellia specifically intends infringement of the '079 patent.

28. Upon information and belief, if the FDA approves Xellia's 505(b)(2) NDA, Xellia plans and intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the '079 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

29. Upon information and belief, Xellia knows that Xellia's Product is especially made or adapted for use in infringing the '079 patent, and that Xellia's Product is not suitable for substantial noninfringing use. Upon information and belief, Xellia plans and intends to, and will, contribute to infringement of the '079 patent immediately and imminently upon approval of Xellia's 505(b)(2) NDA.

30. Plaintiff will be harmed substantially and irreparably if Xellia is not enjoined from infringing the '079 patent.

31. Plaintiff has no adequate remedy at law.

32. Plaintiff is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 6,407,079

33. Plaintiff incorporates each of the preceding Paragraphs 1 through 32 as if fully set forth herein.

34. A definite and concrete, real and substantial justiciable controversy of sufficient immediacy exists between Plaintiff and Xellia regarding infringement of the '079 patent.

35. Xellia has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use

within the United States a product patented by the ’079 patent before the expiration of the ’079 patent. If those substantial and meaningful preparations lead to Xellia’s sale, offer for sale, use, or commercial manufacture of Xellia’s Product within the United States, or importation of Xellia’s Product into the United States, during the term of the ’079 patent, then Xellia would infringe, contribute to the infringement of, and/or induce the infringement of the ’079 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. Xellia’s actions, including but not limited to the filing of Xellia’s 505(b)(2) NDA, and systematically attempting to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

37. Upon information and belief, Xellia’s manufacture, importation, use, sale and/or offer to sell Xellia’s Product prior to the expiration of the ’079 patent would infringe at least claims 1-5, 12-16, 26-28 and 36-38 of the ’079 patent under at least 35 U.S.C. § 271(a), (b), and/or (c).

38. Upon information and belief, Xellia has acted with full knowledge of the ’079 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the ’079 patent.

39. Plaintiff should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of Xellia’s Product will constitute infringement of the ’079 patent under at least 35 U.S.C. § 271 (a), (b), and/or (c).

40. Plaintiff will be harmed substantially and irreparably if Xellia is not enjoined from infringing the ’079 patent.

41. Plaintiff has no adequate remedy at law.

42. Plaintiff is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Janssen Pharmaceutica N.V. prays for a judgment in its favor and against Xellia Pharmaceuticals ApS, and respectfully requests the following relief:

A. A judgment that Xellia has infringed the '079 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment declaring that the making, using, offering to sell, selling or importing of Xellia's Product described in NDA 20-8562 would constitute infringement by Xellia of the '079 patent, or inducing or contributing to such conduct, pursuant to 35 U.S.C. § 271;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Xellia, its officers, agents, servants, and employees, and those persons in active concert with any of them, from manufacturing, using, offering to sell, or selling Xellia's Product within the United States, or importing Xellia's Product into the United States, prior to the expiration of the '079 patent, including any extensions;

D. A judgment ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 20-8562, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), shall not be earlier than the expiration of the '079 patent, including any extensions;

E. If Xellia commercially manufactures, uses, offers to sell, or sells Xellia's Product within the United States, or imports Xellia's Product into the United States, prior to the

expiration of the '079 patent, including any extensions, a judgment awarding Plaintiff monetary relief, together with interest;

F. A declaration that this case is exceptional;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other relief as the Court deems just and proper.

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