IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. 14-199 (RGA)
XELLIA PHARMACEUTICALS APS and XELLIA PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. (hereinafter "Merck"), for its Amended Complaint against Xellia Pharmaceuticals ApS (hereinafter "Xellia ApS") and Xellia Pharmaceuticals, Inc. (hereinafter "Xellia Inc."), alleges as follows:

THE PARTIES

1. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc., and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

3. On information and belief, Xellia ApS is a corporation organized and existing under the laws of Denmark, having its corporate headquarters at Dalslandsgade 11, 2300 Copenhagen S, Denmark.

4. On information and belief, Xellia ApS is in the business of developing, manufacturing and supplying active pharmaceutical ingredients (APIs) and finished dosage

forms (FDFs), including generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

5. On information and belief, Xellia ApS assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application ("ANDA") No. 205923 (hereinafter "Xellia ApS ANDA") concerning a proposed generic drug product, caspofungin acetate injectable, IV (infusion), 50 mg and 70 mg ("the Xellia ApS Products").

6. On information and belief, Xellia ApS assembled and caused to be filed with the FDA Drug Master File No. 27156 concerning caspofungin acetate manufacturing.

7. On information and belief, Xellia Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 34121 North Highway 45, Suite 207, Grayslake, IL 60030.

8. On information and belief, Xellia Inc. and Xellia ApS belong to the same corporate family. On information and belief, Xellia Inc. and Xellia ApS share the common website www.xellia.com, where Xellia Inc. is listed as the Xellia Sales Office for North America (USA and Canada).

9. On information and belief, Xellia Inc. is a subsidiary of Xellia ApS. On information and belief, Xellia ApS and Xellia Inc. have at least some overlapping directors and officers.

10. On information and belief, upon approval of the Xellia ApS ANDA, Xellia Inc. will be involved in the manufacture, sale, distribution, and/or marketing of the Xellia ApS Products.

11. On information and belief, Xellia Inc. is listed in the Xellia ApS ANDA as the U.S. agent for FDA Drug Master File No. 27156 concerning caspofungin acetate manufacturing.

12. Xellia ApS and Xellia Inc. are referred to hereinafter, collectively, as "Xellia."

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Xellia ApS at least under Federal Rule of Civil Procedure 4(k)(2).

15. This Court has personal jurisdiction over Xellia Inc. at least because Xellia Inc. is a corporation organized and existing under the laws of the State of Delaware.

16. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

CANCIDAS®

17. Merck holds approved new drug application ("NDA") 21-227 for CANCIDAS®, the active ingredient of which is caspofungin acetate. CANCIDAS® is approved for the treatment of certain types of fungal infections.

18. Merck is the owner of U.S. Patent No. 5,952,300 ("the '300 patent") (Attached as Exhibit A).

19. CANCIDAS® is an embodiment of one or more claims of the '300 patent.

XELLIA APS ANDA

20. On January 6, 2014, Merck & Co., Inc. received from Wendy M. Ward, Esq. of Merchant & Gould P.C. a letter, dated January 3, 2014 (the "January 3 letter"), stating that Xellia ApS had submitted to the FDA an ANDA, assigned as No. 205923, seeking approval to market caspofungin acetate injectable, IV (infusion), in 50 mg and 70 mg dosage forms.

21. The January 3 letter stated that the Xellia ApS ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '300 patent would not be infringed by the manufacture, use, or sale of the Xellia ApS Products, and/or that the claims of the '300 patent are invalid or unenforceable.

22. The Xellia ApS ANDA refers to and relies upon the Merck NDA for CANCIDAS®.

INFRINGEMENT OF U.S. PATENT NO. 5,952,300

23. Plaintiff repeats and realleges paragraphs 1-22 above as if fully set forth herein.

24. By filing its ANDA No. 205923 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Xellia ApS Products before the expiration of the '300 patent, Xellia ApS committed an act of infringement under 35 U.S.C. § 271(e)(2).

25. If Xellia commercially makes, uses, offers to sell, or sells the Xellia ApS Products within the United States, or imports the Xellia ApS Products into the United States, or induces or contributes to any such conduct during the term of the '300 patent, it would further infringe the '300 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Merck will be irreparably harmed if Xellia is not enjoined from infringing the ’300 patent. Merck does not have an adequate remedy at law.

27. Xellia ApS’s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’300 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests:

A. Judgment that Xellia Pharmaceuticals ApS has infringed one or more claims of the ’300 patent by filing ANDA No. 205923 relating to Xellia ApS’s generic caspofungin acetate products;

B. A permanent injunction restraining and enjoining Xellia Pharmaceuticals ApS and Xellia Pharmaceuticals, Inc., and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic caspofungin products as claimed in the ’300 patent;

C. An order that the effective date of any approval of ANDA No. 205923 relating to Xellia ApS’s generic caspofungin acetate products be a date that is not earlier than the expiration date of the ’300 patent plus any other regulatory exclusivity to which Plaintiff is or becomes entitled;

D. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Brian V. Slater
Jason A. Leonard
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

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