IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS US LLC and ASTELLAS PHARMA US, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
XELLIA PHARMACEUTICALS APS and XELLIA PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Xellia Pharmaceuticals ApS and Xellia Pharmaceuticals, Inc. (collectively "Xellia"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. ("API") is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas US LLC ("AUS") is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. AUS is a subsidiary of Plaintiff API.

3. Plaintiff Astellas Pharma US, Inc. ("APUS") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APUS is a subsidiary of Plaintiff API.

4. On information and belief, Defendant Xellia Pharmaceuticals ApS ("Xellia ApS") is a corporation organized and existing under the laws of Denmark, having its corporate headquarters at Dalslandsgade 11, 2300 Copenhagen S, Denmark. On information and belief, Xellia ApS, by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

5. On information and belief, Defendant Xellia Pharmaceuticals, Inc. ("Xellia Inc.") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 8841 Wadford Drive, Raleigh, NC 27616. On information and belief, Xellia Inc., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

6. 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 U.S. Headquarters and as the sales office for Xellia in North America (U.S.A. and Canada).

7. 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.

8. On information and belief, Defendants Xellia ApS and Xellia Inc. have cooperated and assisted in the preparation and filing of Xellia's Abbreviated New Drug Application ("ANDA") No. 211713 and will be involved in the manufacture, importation, marketing, and sale of the drugs that are the subject of ANDA No. 211713 if it is approved.

NATURE OF ACTION

9. This is an action for patent infringement of United States Patent No. 6,774,104 ("the '104 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Xellia's filing of ANDA No. 211713 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over each Defendant for purposes of this civil action.

12. This Court has personal jurisdiction over Xellia ApS at least under Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Xellia ApS is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Xellia ApS has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling

pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Xellia ApS satisfies due process.

13. 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.

14. On information and belief, Xellia, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this Judicial District. On information and belief, Xellia has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Xellia's generic drug products. On information and belief, Xellia has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

15. On information and belief, Xellia ApS and Xellia Inc. are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic drug products. On information and belief, the acts of Xellia ApS and Xellia Inc. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of each other.

16. On information and belief, Xellia filed an ANDA seeking approval from the FDA to market and sell pharmaceutical products containing the compound micafungin sodium as active ingredient and containing lactose, for the treatment of fungal diseases, prior to the expiration of the '104 patent.

17. This lawsuit arises in part from Xellia sending Plaintiff APUS, a Delaware corporate entity, a letter dated October 8, 2018 purporting to be a notification entitled,

"Notification of Certification of Invalidity, Unenforceability, and/or Non-infringement for U.S. Patent No. 6,774,104 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("Notice Letter"). The Notice Letter is signed by an attorney for Xellia.

18. When the Notice Letter was sent, Xellia knew or should have known that: (i) APUS is a Delaware corporation; and (ii) Plaintiffs would file suit against Xellia within 45 days of receiving the Notice Letter.

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

FACTUAL BACKGROUND

A. The '104 Patent

20. The PTO duly and legally issued the '104 patent, entitled "Stabilized Pharmaceutical Composition in Lyophilized Form," on August 10, 2004. A copy of the '104 patent is attached as Exhibit A.

21. The '104 patent claims, *inter alia*, a stabilized pharmaceutical composition in lyophilized form comprising micafungin or its pharmaceutically acceptable salt, and lactose.

22. The '104 patent also claims, *inter alia*, an injection preparation, a commercial package, a method for stabilizing a compound, and methods and injectable compositions for treating fungal disease and pneumocystosis.

23. The '104 patent will expire on January 8, 2021.

B. Mycamine®

24. APUS holds approved New Drug Application ("NDA") No. 21506 for Mycamine® for Injection; IV Infusion (50 mg and 100 mg micafungin dosage forms), which vials contain the active ingredient micafungin sodium. The FDA approved NDA No. 21506 on

March 16, 2005 (50 mg/vial), and on June 27, 2006 the FDA approved the addition of a 100 mg/vial formulation.

25. Micafungin sodium is a salt of micafungin.

26. Mycamine® for Injection; IV Infusion is indicated for the treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses; esophageal candidiasis; and prophylaxis of *Candida* infections in hematopoietic stem cell transplant recipients.

27. The claims of the ’104 patent cover stable lyophilized pharmaceutical compositions comprising micafungin sodium and lactose, including the commercial Mycamine® for Injection; IV Infusion product.

28. API is the record owner and assignee of the ’104 patent.

29. AUS is the exclusive licensee of the ’104 patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms that contain micafungin sodium as the active ingredient in the United States.

30. APUS is the holder of NDA No. 21506. APUS markets and sells Mycamine® for Injection; IV Infusion in the United States.

C. Infringement by Xellia

31. On information and belief, Xellia submitted to the FDA ANDA No. 211713 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic micafungin sodium for injection containing 50 mg/vial and 100 mg/vial of micafungin (“ANDA Products”) and lactose as a pharmaceutical composition in an injectable dosage form for the treatment of infectious diseases prior to the expiration of the’104 patent.

32. On information and belief, Xellia intends to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Products if and when it receives FDA approval to do so.

33. The Notice Letter advised Plaintiffs that Xellia submitted ANDA No. 211713 to the FDA seeking approval to manufacture, use, offer to sell, sell, and/or import the ANDA Products prior to the expiration of the '104 patent, which included a certification under 21 U.S.C. § 355(j)(2)(B)(iv).

34. The submission of ANDA No. 211713 to the FDA constituted an act of infringement by Xellia of the '104 patent under 35 U.S.C. § 271(e)(2).

35. The Notice Letter does not allege non-infringement of any claim of the '104 patent.

36. By not identifying any non-infringement defense in the Notice Letter, Xellia admits the ANDA Products meet all limitations of the '104 patent claims.

37. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

CLAIM

CLAIM FOR RELIEF: INFRINGEMENT OF THE '104 PATENT

38. Plaintiffs incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Xellia's submission of ANDA No. 211713 to the FDA seeking approval of the ANDA Products was an act of infringement by Xellia of at least claims 1, 3, 8, and 16-18 of the '104 patent, which cover, *inter alia*, the lyophilized pharmaceutical composition of micafungin sodium and lactose that is contained in the ANDA

Products, and the commercial packages that will include the ANDA Products and Xellia's proposed label.

40. The ANDA Products and the use thereof would infringe the '104 patent under 35 U.S.C. § 271(a), including at least claim 1, 3, and 8, which cover, *inter alia*, the lyophilized pharmaceutical composition of micafungin sodium and lactose that is contained in the ANDA Products, and the commercial packages that will include the ANDA Products and Xellia's proposed label.

41. Unless Xellia is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Xellia's infringement of the '104 patent. Plaintiffs do not have an adequate remedy at law. This case is exceptional.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs API, AUS, and APUS, pray for a judgment in their favor and against Defendants Xellia, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Xellia has infringed one or more claims of the '104 patent by Xellia's filing of ANDA No. 211713 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products before the expiration of that patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products will infringe the '104 patent;

C. A judgment declaring that the '104 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Xellia and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, as

claimed in the'104 patent, until the expiration of the '104 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of ANDA No. 211713 be a date that is not earlier than the expiration of the right of exclusivity under the '104 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Xellia has committed any acts with respect to the subject matter claimed in the '104 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts;

G. A determination that this case is "exceptional" under 35 U.S.C. § 285, and an award of attorney fees;

H. An award of Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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