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. _____
FRESENIUS KABI USA, LLC	)	
Defendant.	)	

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 Defendant Fresenius Kabi USA, LLC ("Fresenius"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. 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. Astellas Pharma Inc. was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas US LLC 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. Astellas US LLC is a subsidiary of Plaintiff Astellas Pharma Inc.

3. Plaintiff Astellas Pharma US, Inc. 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. Astellas Pharma US, Inc. is a subsidiary of Plaintiff Astellas Pharma Inc.

4. On information and belief, Defendant Fresenius is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

JURISDICTION AND VENUE

5. This is an action for patent infringement of United States Patent Nos. 6,107,458 ("the '458 patent") and 6,774,104 ("the '104 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Fresenius' filing of an Abbreviated New Drug Application ("ANDA") 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. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This court has jurisdiction over Fresenius. On information and belief, Fresenius is a limited liability company organized and existing under the laws of the State of Delaware, and has a registered agent for service in Delaware. On information and belief, Fresenius, 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, Fresenius has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Fresenius' generic products. On information and belief, Fresenius 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.

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

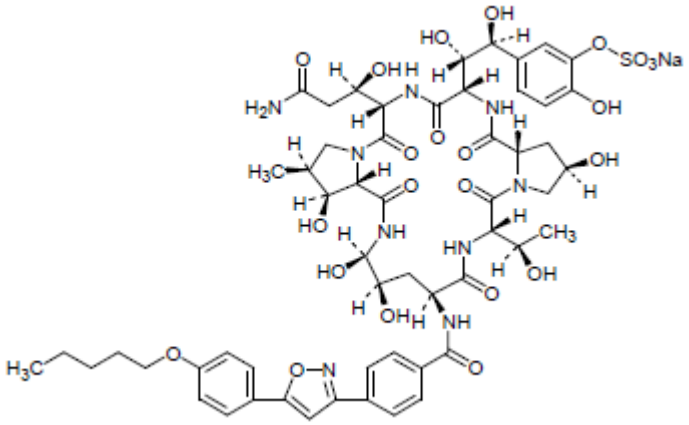
CLAIM FOR RELIEF – PATENT INFRINGEMENT

8. Astellas Pharma US, Inc. holds approved New Drug Application ("NDA") No. 021506 for Mycamine® for Injection; IV Infusion (50 mg and 100 mg dosage forms), which vials contain the active ingredient micafungin sodium. The FDA approved NDA No. 021506 on March 16, 2005 (50 mg/vial), and on June 27, 2006 the FDA approved the addition of a 100 mg/vial formulation. Astellas Pharma US, Inc. lists, *inter alia*, the '458 and '104 patents in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 021506.

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

10. The United States Patent and Trademark Office ("PTO") duly and legally, and after considering the patentability of the claimed inventions over the relevant prior art, issued the '458 patent, entitled "Cyclic Hexapeptides Having Antibiotic Activity," on August 22, 2000. A copy of the '458 patent is attached as Exhibit A.

11. The '458 patent claims, *inter alia*, micafungin or a salt thereof. Micafungin sodium, which is a sodium salt of micafungin, is known chemically as, *inter alia*, Pneumocandin A0, 1-[(4*R*,5*R*)-4,5-dihydroxy-N^2-[4-[5-[4-(pentyloxy)phenyl]-3-isoxazolyl]benzoyl]-L-ornithine]-4-[(4*S*)-4-hydroxy-4-[4-hydroxy-3-(sulfooxy)phenyl]-L-threonine]-, monosodium salt. The chemical formula of micafungin sodium may be illustrated as:



12. The ’458 patent also claims, *inter alia*, a process for the preparation of polypeptides including micafungin sodium; a pharmaceutical composition containing, e.g., micafungin sodium as an active ingredient; and a method for the therapeutic treatment of infectious diseases caused by pathogenic microorganisms comprising administering, e.g., micafungin sodium.

13. The PTO issued a Certificate Extending Patent Term Under 35 U.S.C. § 156 for the ’458 Patent for 1,265 days. The ’458 patent will expire on March 16, 2019.

14. The PTO duly and legally, and after considering the patentability of the claimed inventions over the relevant prior art, 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 B.

15. The ’104 patent claims, *inter alia*, a stabilized pharmaceutical composition in lyophilized form which comprises micafungin or its pharmaceutically acceptable salt, and lactose.

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

17. The ’104 patent will expire on January 8, 2021.

18. Astellas Pharma Inc. is the record owner and assignee of the ’458 and ’104 patents.

19. Astellas US LLC is the exclusive licensee of the ’458 and ’104 patents to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain micafungin sodium as the active ingredient in the United States.

20. Astellas Pharma US, Inc. is the holder of NDA No. 021506. Astellas Pharma US, Inc. markets and sells Mycamine® for Injection; IV Infusion in the United States.

21. On information and belief, Fresenius submitted to the FDA ANDA No. 207344 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 import of generic micafungin sodium for injection containing 50 mg/vial and 100 mg/vial of micafungin sodium as a pharmaceutical composition in an injectable dosage form for the treatment of infectious diseases prior to the expiration of the ’458 and ’104 patents.

22. The subjects of ANDA No. 207344 are referred to as “Fresenius’ ANDA Products.”

23. On information and belief, Fresenius’ ANDA Products contain micafungin sodium as their active ingredient.

24. On information and belief, Fresenius’ ANDA Products contain micafungin sodium and lactose.

25. Micafungin sodium is a salt of micafungin.

26. Fresenius submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import of Fresenius' ANDA Products before the expiration of the '458 and '104 patents.

27. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import of Fresenius' ANDA Products before the expiration of the '458 and '104 patents, Fresenius committed acts of infringement under 35 U.S.C. § 271(e)(2) with respect to each of those patents.

28. On information and belief, when Fresenius filed its ANDA, it was aware of the '458 and '104 patents and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '458 and '104 patents was an act of infringement of each of those patents.

29. On information and belief, Fresenius made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '458 and '104 patents are invalid, unenforceable, and/or will not be infringed.

30. On December 16, 2014, Astellas Pharma Inc. received a letter from Fresenius dated December 12, 2014, purporting to be a Notification of Certification for ANDA No. 207344 under Section 505(j)(2)(B) of the Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(c). The notification letter states that it is addressed to the Chief Executive Officer of Astellas Pharma Inc.; the Chief Executive Officer of Astellas Pharma US, Inc., c/o Astellas Pharma Global Development, Inc.; and Oblon, Spivak, McClelland, Maier & Neust. The letter was not addressed to Astellas US LLC.

31. In its notification letter, Fresenius does not dispute that Fresenius' ANDA Products would be literally within the scope of one or more claims of the '458 patent.

32. In its notification letter, Fresenius does not dispute that Fresenius' ANDA Products would be literally within the scope of one or more claims of the '104 patent.

33. In its notification letter, Fresenius does not allege that any claim of the '458 patent is invalid for lack of novelty.

34. In its notification letter, Fresenius does not allege that any claim of the '104 patent is invalid for lack of novelty.

35. In its notification letter, Fresenius asserts that the claims of the '458 patent are invalid for obviousness based on prior art that was cited in the prosecution of that patent.

36. In its notification letter, Fresenius asserts that the claims of the '104 patent are invalid for obviousness based on prior art that was cited in the prosecution of that patent.

37. On information and belief, at the time it prepared and served its notification letter and submitted its ANDA, Fresenius understood that the commercial sale of its proposed products would infringe one or more claims of the '458 patent.

38. On information and belief, at the time it prepared and served its notification letter and submitted its ANDA, Fresenius understood that the commercial sale of its proposed products would infringe one or more claims of the '104 patent.

39. On information and belief, at the time it prepared and served its notification letter and submitted its ANDA, Fresenius did not have a good faith belief that it would prevail on its argument that the relevant claims of the '458 patent would be held invalid for obviousness.

40. On information and belief, at the time it prepared and served its notification letter and submitted its ANDA, Fresenius did not have a good faith belief that it would prevail on its argument that the relevant claims of the ’104 patent would be held invalid for obviousness.

41. The commercial manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products will infringe one or more claims of each of the ’458 and ’104 patents.

42. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 207344 be a date that is not earlier than the expiration dates of the ’458 and ’104 patents, including any extension(s).

43. Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products and any act committed by Fresenius with respect to the subject matter claimed in the ’458 and ’104 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

44. On information and belief, Fresenius has made, and continues to make, substantial preparation in the United States towards the commercial manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products, including seeking approval of those products under Fresenius’ ANDA No. 207344.

45. On information and belief, Fresenius continues to seek approval of ANDA No. 207344 and intends to engage in the commercial manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products.

46. There is a substantial and immediate controversy between Plaintiffs and Fresenius concerning the ’458 and ’104 patents. Plaintiffs are entitled to declaratory judgment

under 28 U.S.C. §§ 2201 and 2202 that Fresenius will infringe and/or induce infringement of one or more claims of the ’458 and ’104 patents.

47. This is an exceptional case and Plaintiffs are entitled to an award of their reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc., pray for a judgment in their favor and against defendant Fresenius, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Fresenius has infringed one or more claims of the ’458 and ’104 patents by Fresenius’ filing of ANDA No. 207344 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products before the expiration of the ’458 and ’104 patents;

B. A judgment that the manufacture, use, offer for sale, sale, and/or import of Fresenius’ ANDA Products will infringe the ’458 and ’104 patents;

C. A judgment declaring that the ’458 and ’104 patents remain valid and enforceable;

D. A permanent injunction restraining and enjoining Fresenius 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 import, of Fresenius’ ANDA Products, as claimed in the ’458 and ’104 patents, until the expiration of both of the ’458 and ’104 patents, 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. 207344 be a date that is not earlier than the expiration of the right of exclusivity under both of the '458 and '104 patents, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Fresenius has committed any acts with respect to the subject matter claimed in the '458 and/or '104 patents, 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. Costs and expenses in this action; and

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

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