IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS PHARMA U.S., INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA EUROPE LTD.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
CIPLA LIMITED,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Pharma U.S., Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Europe Ltd. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Cipla Limited ("Cipla"), 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. 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 Pharma U.S., Inc. ("Astellas US") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062-6111. Astellas US is a subsidiary of Plaintiff Astellas Pharma Inc.

3. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff Astellas Pharma Inc.

4. Plaintiff Astellas Pharma Europe Ltd. ("APEL") is a corporation organized and existing under the laws of England, having its principal place of business at 2000 Hillswood Drive, Chertsey, KT16 0RS, England. APEL is a subsidiary of Plaintiff Astellas Pharma Inc.

5. On information and belief, Defendant Cipla is a corporation organized and existing under the laws of India, having its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013. On information and belief, Cipla, 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, Defendant Cipla has filed Abbreviated New Drug Application ("ANDA") No. 209839 and will be involved in the manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209839 if it is approved.

NATURE OF ACTION

7. This is an action for patent infringement of United States Patent No. 6,017,927 ("the '927 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Cipla's filing of ANDA No. 209839 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

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

9. This Court has personal jurisdiction over Cipla. On information and belief, Cipla, 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, Cipla has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Cipla's generic drug products. On information and belief, Cipla 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.

10. On information and belief, Cipla filed an abbreviated new drug application seeking approval from the FDA to market and sell pharmaceutical products containing the compound solifenacin succinate as active ingredient, for the treatment of overactive bladder, prior to the expiration of the '927 patent.

11. This lawsuit arises in part from Cipla sending Plaintiffs, one of which is a Delaware corporation, a letter dated April 25, 2018 purporting to be a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act" ("Notice Letter"). The Notice Letter is signed by an attorney for Cipla.

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

13. In the alternative, this Court has jurisdiction over Cipla because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Cipla because, *inter alia*, this action arises from actions of Cipla directed toward Delaware, and because Cipla has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Cipla

regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. On information and belief, Cipla derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

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

FACTUAL BACKGROUND

A. The ’927 Patent

15. The United States Patent and Trademark Office duly and legally issued the ’927 patent, entitled “Quinuclidine Derivatives and Medicinal Composition Thereof,” on January 25, 2000. A true and correct copy of the ’927 patent is attached as Exhibit A.

16. The ’927 patent claims, *inter alia*, solifenacin succinate and salts thereof, and pharmaceutical compositions containing them.

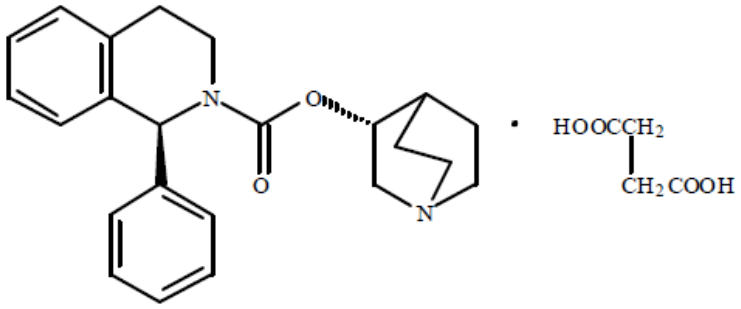
17. The Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration date of the ’927 patent as November 19, 2018,with pediatric exclusivity until May 19, 2019.

B. VESIcare®

18. Astellas Pharma U.S., Inc. holds approved New Drug Application (“NDA”) No. 21518 for VESIcare® tablets in 5 mg and 10 mg strength tablet dosage forms, which contain the active ingredient solifenacin succinate. The FDA approved NDA No. 21518 on November 19, 2004 for both the 5 mg and 10 mg strength tablet dosage forms.

19. Solifenacin succinate is a salt of solifenacin and butanedioic (succinic) acid and can be referred to chemically as, *inter alia*, butanedioic acid, compounded with (1*S*)-(3*R*)-1-azabicyclo[2.2.2]oct-3-yl 3,4-6 dihydro-1-phenyl-2(1*H*)-isoquinolinecarboxylate (1:1) having an

empirical formula of $C_{23}H_{26}N_2O_2 \cdot C_4H_6O_4$. Solifenacin succinate can be depicted as, *inter alia*, the following formula:



20. VESIcare® is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

21. API is the record owner and assignee of the ’927 patent.

22. AICL and APEL are exclusive licensees of rights under the ’927 patent.

C. Infringement by Cipla

23. On information and belief, Cipla submitted to the FDA ANDA No. 209839 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 solifenacin succinate 5 mg and 10 mg tablets (“ANDA Product”), as a pharmaceutical composition in an oral dosage form for the treatment of overactive bladder prior to the expiration of the ’927 patent.

24. On information and belief, Cipla holds Drug Master File (“DMF”) No. 29489 for solifenacin succinate.

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

26. The Notice Letter advised Plaintiffs that Cipla submitted ANDA No. 209839 to the FDA seeking approval to manufacture, use, offer to sell, sell, and/or import the ANDA Product prior to the expiration of the ’927 patent. The Notice Letter advised Plaintiffs that Cipla’s ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Cipla’s opinion, the claims of the ’927 patent are invalid, unenforceable and/or not infringed.

27. The submission of ANDA No. 209839 to the FDA constituted an act of infringement by Cipla of the ’927 patent under 35 U.S.C. § 271(e)(2).

28. 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 FOR RELIEF

29. Plaintiffs incorporate by reference and reallege paragraphs 1 through 28 above as though fully restated herein.

30. Pursuant to 35 U.S.C. § 271(e)(2), Cipla’s submission of ANDA No. 209839 to the FDA seeking approval of the ANDA Product was an act of infringement by Cipla of at least claims 1-7 of the ’927 patent, which claim solifenacin and its salts.

31. The ANDA Product and the use thereof would infringe the ’927 patent under 35 U.S.C. § 271(a), including at least claims 1-7, which cover, *inter alia*, solifenacin and its salts.

32. Unless Cipla is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Cipla’s infringement of the ’927 patent. Plaintiffs do not have an adequate remedy at law.

33. On information and belief, Cipla has no reasonable basis to believe that FDA will approve its ANDA prior to the expiration of the '927 Patent.

34. On information and belief, Cipla is aware that Teva Pharmaceuticals USA Inc. holds first filer marketing exclusivity for solifenacin succinate, which prevents FDA from approving Cipla's ANDA prior to the expiration of the '927 Patent.

35. On information and belief, Cipla was aware of the ‘927 patent and its infringement of that patent when it filed ANDA No. 209839.

36. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs API, Astellas US, AICL, and APEL pray for a judgment in their favor and against Defendant Cipla, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Cipla has infringed one or more claims of the ’927 patent by Cipla’s filing of ANDA No. 209839 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of those patents;

B. A judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product will infringe the ’927 patent;

C. A judgment declaring that the ’927 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Cipla 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 Product, as claimed in the ’927 patent, until the expiration of the ’927 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. 209839 be a date that is not earlier than the expiration of the right of exclusivity under the ’927 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Cipla has committed any acts with respect to the subject matter claimed in the '927 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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