IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUNOVION PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON PHARMACEUTICALS, INC., WATSON LABORATOIRES, INC., and WATSON PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion"), by its undersigned attorneys, for its Complaint against Defendants Watson Laboratories, Inc. ("Watson Laboratories"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), and Watson Pharma, Inc. ("Watson Pharma") (collectively, "Watson"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from Watson's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic copy of Sunovion's XOPENEX HFA® Inhalation Aerosol drug product prior to the expiration of United States Patent No. 7,256,310 ("the '310 patent").

PARTIES

2. Sunovion is a corporation organized under the laws of Delaware, having its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

3. On information and belief, Watson Pharmaceuticals is a corporation organized under the laws of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

4. On information and belief, Watson Laboratories is a corporation organized under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880 and is a wholly-owned subsidiary of Watson Pharmaceuticals.

5. On information and belief, Watson Pharma is a corporation organized under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054 and is a wholly-owned subsidiary of Watson Pharmaceuticals.

JURISDICTION AND VENUE

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

7. Watson is subject to personal jurisdiction in Delaware because, among other things, Watson Pharma is incorporated in Delaware, Watson regularly transacts and/or solicits business in Delaware, has consented to jurisdiction in Delaware in cases arising out of the filing of its ANDAs, and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and counterclaims such that it should reasonably anticipate being haled into court here.

8. On information and belief, this Court has previously held that Watson Laboratories "'regularly does or solicits business' in Delaware or engages in a 'persistent course of conduct' in Delaware" and "can reasonably expect to be 'haled into court' in Delaware." *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 348-49 (D. Del. 2009).

9. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and/or Watson Pharma share common employees, officers, and directors.

10. On information and belief, Watson Pharmaceuticals organizes its operations into three distinct operating segments: Global Generics, Global Brands, and Distribution.

11. On information and belief, Watson Pharmaceutical's Global Generics segment is responsible for developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market.

12. On information and belief, Watson Laboratories and Watson Pharma are agents of Watson Pharmaceuticals and each other, and operate in concert as integrated parts of Watson Pharmaceutical's Global Generics segment.

13. On information and belief, Watson Pharmaceuticals has consolidated its activities and financial results in its most recent SEC filings with, among other subsidiaries, Watson Laboratories and Watson Pharma.

14. On information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and Watson Laboratories, distributes and sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories and/or for which Watson Laboratories submitted the underlying ANDAs.

15. On information and belief, generic pharmaceutical products that are manufactured by Watson Laboratories and/or for which Watson Laboratories submitted the underlying ANDAs are available for purchase at retail pharmacies in Delaware.

16. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 204032, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma will act in concert to distribute and sell the generic

levalbuterol tartrate inhalation aerosol product described within ANDA No. 204032 ("Watson's ANDA Product") throughout the United States and within Delaware.

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

THE PATENT-IN-SUIT

18. The '310 patent, entitled "Levalbuterol Salt" was duly and legally issued by the United States Patent and Trademark Office on August 14, 2007. Sunovion is the owner of the '310 patent, which was originally assigned to Sepracor Inc., a predecessor of Sunovion. A true and correct copy of the '310 patent is attached hereto as Exhibit A.

FACTUAL BACKGROUND

19. Sunovion is the current holder of approved New Drug Application ("NDA") No. 21-730 for XOPENEX HFA® Inhalation Aerosol, which contains, among other things, levalbuterol tartrate as its active ingredient and 1,1,1,2-tetrafluoroethane as its propellant.

20. One or more claims of the '310 patent, incorporated by reference herein, cover XOPENEX HFA® Inhalation Aerosol, and also methods of effecting bronchodilation by use of XOPENEX HFA® Inhalation Aerosol.

21. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XOPENEX HFA® Inhalation Aerosol.

22. By letter dated June 14, 2012, Watson Laboratories notified Sunovion that it submitted to the FDA ANDA No. 204032 for Watson's ANDA Product. Watson's ANDA Product is a generic version of XOPENEX HFA® Inhalation Aerosol.

23. The purpose of ANDA No. 204032 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '310 patent.

24. As part of its June 14, 2012 letter, Watson Laboratories further stated that, in connection with ANDA No. 204032, it had submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

25. As part of its June 14, 2012 letter, Watson Laboratories asserted purported grounds on which it believes that the '310 patent is invalid, unenforceable and/or not infringed.

CLAIM: INFRINGEMENT OF U.S. PATENT NO. 7,256,310

26. Sunovion incorporates by reference its responses to paragraphs 1-25 above.

27. Under 35 U.S.C. § 271(e)(2)(A), Watson's submission of ANDA No. 204032 to the FDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of Watson's ANDA Product prior to the expiration of the '310 patent constitutes an act of infringement of one or more claims of the '310 patent.

28. Upon FDA approval of ANDA No. 204032, Watson will infringe one or more claims of the '310 patent by making, offering to sell, importing, and/or selling Watson's ANDA Product, and/or by actively inducing and/or contributing to infringement by others unless this Court orders that the effective date of any FDA approval of ANDA No. 204032 shall be no earlier than the expiration date of the '310 patent.

29. On information and belief, Watson has actual notice of the '310 patent and was aware that the filing of ANDA No. 204032 and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification with respect to the '310 patent constituted an act of infringement of one or more claims of the '310 patent.

30. On information and belief, Watson's statement of the factual and legal basis for its opinion regarding the validity, enforceability, or non-infringement of the '310 patent is devoid of an objective good faith basis in either the facts or the law.

31. Sunovion will be substantially and irreparably damaged and harmed if Watson's infringement of the '310 patent is not enjoined.

32. Sunovion has no adequate remedy at law.

33. This case is an exceptional one, and Sunovion is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Sunovion prays for judgment as follows:

A. A judgment declaring that Watson has infringed the '310 patent by submitting ANDA No. 204032 to the FDA.

B. A judgment declaring that Watson's making, using, selling, offering to sell, and/or importing of Watson's ANDA Product will infringe one or more claims of the '310 patent.

C. A judgment declaring that the effective date of any FDA approval of Watson's ANDA No. 204032 should be no earlier than the expiration date of the '310 patent.

D. A permanent injunction enjoining Watson and its officers, agents, attorneys and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Watson's ANDA Product until after the expiration date of the '310 patent.

E. A judgment that this is an exceptional case and that Sunovion is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

F. A judgment awarding Sunovion costs and expenses in this action.

G. An Order granting such other and further relief as the Court deems just and equitable.

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