IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC,	)	
Plaintiffs,	)	CA. No.
v.	)	
PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP") and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendants Par Pharmaceutical, Inc. ("Par"), and IntelGenX Technologies Corp. ("IGX") (collectively "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement related to United States Patent Nos. 8,900,497 ("the '497 patent") and 8,906,277 ("the '277 patent") (collectively, "the patents-in-suit") arising under the Patent Laws of the United States, Title 35 of the United States Code.

THE PARTIES

2. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff MonoSol is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

4. Defendant Par is a Delaware corporation having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

5. Defendant IGX is a Delaware corporation having a principal place of business at 6425 Abrams, Ville St-Laurent (Quebec), Canada.

JURISDICTION AND VENUE

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

7. On information and belief, Par is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in Delaware and throughout the United States.

8. Par has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example, by bringing the patent infringement suit *Par Pharmaceutical Inc. v. Breckenridge Pharmaceutical Inc.*, C.A. No. 13-1114-SLR, and by submitting to jurisdiction in *Reckitt Benckiser Pharmaceuticals Inc. et. al. v. Par Pharmaceutical, Inc. and Intelgenx Technologies Corp.*, Civil Action No. 1:14-cv-00422-RGA ("C.A. 14-422").

9. This Court has personal jurisdiction over Par because of, *inter alia*, Par's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of this judicial district, and its marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

10. On information and belief, IGX is a holding company that owns one or more wholly owned subsidiaries that are focused on the development of oral controlled-release products as well as rapidly disintegrating delivery systems.

11. IGX, directly or through its affiliates, has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example in *Reckitt Benckiser Pharmaceuticals Inc. et. al. v. Par Pharmaceutical, Inc. and Intelgenx Technologies Corp.*, C.A. 14-422.

12. This Court has personal jurisdiction over IGX because of, *inter alia*, IGX's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, and its previous submission to the jurisdiction of this judicial district.

13. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

SUBOXONE® SUBLINGUAL FILM

14. Plaintiff RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

15. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

THE PENDING ANDA LITIGATION BETWEEN THE PARTIES

16. Plaintiffs and Defendants (collectively "Parties") are involved in ongoing litigation in this District, C.A. 14-422.

17. C.A. 14-422 relates to Defendant Par's submission of an Abbreviated New Drug Application No. 20-5854 ("ANDA No. 20-5854") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of three of Plaintiffs' patents, listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

18. The patents at issue in C.A. 14-422 include Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the'514 patent").

19. Par's ANDA No. 20-5854 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832, '150, and the '514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

20. Plaintiffs commenced C.A. 14-422 within 45 days of receiving the relevant notice letters from Defendant Par, to preserve their right to a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

THE PATENTS-IN-SUIT

21. This current action relates to the '497 and '277 patents.

22. Plaintiff Monosol is the lawful owner of the '497 patent, and Plaintiff RBP is an exclusive licensee of the '497 patent. The '497 patent, entitled "Process for Making a Film Having a Substantially Uniform Distribution of Components," duly and legally issued on December 2, 2014, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '497 patent is attached hereto as Exhibit A.

23. Plaintiff Monosol is the lawful owner of the '277 patent, and Plaintiff RBP is an exclusive licensee of the '277 patent. The '277 patent, entitled "Process for Manufacturing a Resulting Pharmaceutical Film," duly and legally issued on December 9, 2014, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '277 patent is attached hereto as Exhibit B.

DEFENDANTS' INFRINGING GENERIC PRODUCT

24. Plaintiff Par has submitted ANDA No. 20-5854 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of

buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Defendants' generic product") before expiration of the patents-in-suit.

25. Defendant IGX has entered into a co-development and commercialization agreement with Defendant Par for the commercial manufacture, use, and/or sale of Defendants' generic product.

26. ANDA No. 20-5854 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

27. On information and belief, Defendants' generic product will be produced using a method protected by the patents-in-suit.

COUNT I
(Declaratory Judgment of Infringement of the '497 Patent Under 35 U.S.C. § 271)

28. Plaintiffs reallege paragraphs 1-27 above as if fully set forth herein.

29. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product immediately following approval of ANDA No. 20-5854.

30. On information and belief, Defendants' commercial manufacture of Defendants' generic product before the expiration of the '497 patent would infringe one or more claims of the '497 patent under 35 U.S.C. § 271.

31. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

COUNT II
(Declaratory Judgment of Infringement of the '277 Patent Under 35 U.S.C. § 271)

32. Plaintiffs reallege paragraphs 1-31 above as if fully set forth herein.

33. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product immediately following approval of ANDA No. 20-5854.

34. On information and belief, Defendants' commercial manufacture of Defendants' generic product before the expiration of the '277 patent would infringe one or more claims of the '277 patent under 35 U.S.C. § 271.

35. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A declaratory judgment that Defendants' commercial manufacture within the United States of Defendants' generic product would infringe the patents-in-suit under 35 U.S.C. § 271;

B. Preliminary and permanent injunctions, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from infringement of the patents-in-suit;

C. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

D. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or imports into the United States, Defendants' generic product before the expiration of each patent-in-suit that Defendants are found to infringe, including any extensions; and

E. Any and all other relief as the Court deems just and proper.

Dated: December 31, 2014.

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Respectfully submitted,

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