IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP., Defendants.	)	C.A. No. 13-1461-RGA

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Amended Complaint against Defendants Par Pharmaceutical, Inc. ("Par"), and IntelGenX Technologies Corp. ("IGX") and allege as follows[1]:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant Par's submission of an Abbreviated New Drug Application ("ANDA") 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 United States Patent Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

[1] Pursuant to Federal Rule of Civil Procedure 15(a)(2), Defendants have provided written consent to Plaintiffs' filing of this pleading.

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 RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

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

5. On information and belief, Defendant Par is a Delaware corporation having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

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

JURISDICTION AND VENUE

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

8. On information and belief, Par is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

9. 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.

10. 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.

11. On information and belief, IGX is a drug delivery company focused on the development of oral controlled-release products as well as rapidly disintegrating delivery systems.

12. 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 by voluntarily substituting in as defendant in the patent infringement suit *Biovail Laboratories International SRL v. IntelGenx Corp.*, C.A. No. 09-605-LPS.

13. 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.

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

THE PATENTS-IN-SUIT

15. Plaintiff RBP UK is the lawful owner of the '832 patent, and Plaintiff RBP is an exclusive licensee of the '832 patent. The '832 patent, entitled "Sublingual and Buccal Film Compositions," duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '832 patent is attached hereto as Exhibit A.

16. Plaintiff MonoSol is the lawful owner of the '150 patent, and Plaintiff RBP is an exclusive licensee of the '150 patent. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '150 patent is attached hereto as Exhibit B.

17. Plaintiff MonoSol is the lawful owner of the '514 patent, and Plaintiff RBP is an exclusive licensee of the '514 patent. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '514 patent is attached hereto as Exhibit C.

SUBOXONE® SUBLINGUAL FILM

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

19. 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.

20. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

DEFENDANTS' ANDA

21. Plaintiffs received a letter from Defendant Par dated July 8, 2013 (the "Notification Letter"), stating that ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

22. The Notification Letter further states that Defendant Par 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. On information and belief, 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.

23. On information and belief, ANDA No. 20-5854 was prepared and submitted with the active cooperation, participation, and assistance of, and at least in part for the benefit of, Defendant IGX. On information and belief, if ANDA No. 20-5854 is approved, IGX will actively participate in manufacturing, marketing, and/or selling Defendants' generic product.

24. On information and belief, IGX designed Defendants' generic product that is the subject of Defendant Par's ANDA No. 20-5854.

25. On information and belief, Defendants' generic product that is the subject of Defendant Par's ANDA No. 20-5854 includes IGX's VersaFilm™ drug delivery technology.

26. IGX filed statements with the SEC in 2013 asserting that IGX's "U.S. based co-development and commercialization partner" submitted an ANDA to the FDA for approval of a generic formulation of Plaintiff RBP's Suboxone® sublingual film, indicated for maintenance treatment of opioid dependence.

27. Plaintiffs commenced this action within 45 days of receiving the Notification Letter.

28. Plaintiffs received another letter from Defendant Par dated February 3, 2014 (the "'514 Notification Letter"), stating that ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '514 patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic product

proposed in the ANDA. On information and belief, 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.

29. Plaintiffs filed this Amended Complaint within 45 days of receiving the '514 Notification Letter.

COUNT I
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

30. Plaintiffs reallege paragraphs 1-29 above as if fully set forth herein.

31. On information and belief, Defendants' generic product is covered by one or more claims of the '832 patent.

32. By filing ANDA No. 20-5854 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '832 patent, Par has committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

33. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

34. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

35. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT II
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

36. Plaintiffs reallege paragraphs 1-35 above as if fully set forth herein.

37. On information and belief, Defendants' generic product is covered by one or more claims of the '150 patent.

38. By filing ANDA No. 20-5854 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '150 patent, Par has committed an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

39. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

40. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

41. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter *alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '150 patent, including any extensions of that date.

COUNT III
(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

42. Plaintiffs reallege paragraphs 1-41 above as if fully set forth herein.

43. On information and belief, Defendants' generic product is covered by one or more claims of the '514 patent.

44. ANDA No. 20-5854 under 21 U.S.C. § 355(j) seeks to obtain approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior

to the expiration of the '514 patent. Therefore, Par's maintenance of this filing constitutes an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

45. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

46. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

47. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '514 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Defendants have infringed each of the patents-in-suit under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA No. 20-5854;

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 engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

C. An order that the effective date of any approval of ANDA No. 20-5854 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

D. 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;

E. 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 import 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

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

Dated: February 18, 2014

Respectfully submitted,

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
Dana K. Severance (#4869)
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
(302) 252-4320
(302) 252-4330 (Fax)
mbourke@wcsr.com
dseverance@wcsr.com

Attorneys for Plaintiffs

Of Counsel:

Daniel A. Ladow
James M. Bollinger
Timothy P. Heaton
TROUTMAN SANDERS LLP
405 Lexington Avenue
New York, NY 10174
(212) 704-6000
(212) 704-6288 (Fax)
Daniel.ladow@troutmansanders.com
James.bollinger@troutmansanders.com
Timothy.heaton@troutmansanders.com

Troy S. Kleckley
Puja R. Patel
TROUTMAN SANDERS LLP
600 Peachtree Street, NE
Suite 5200
Atlanta, GA 30308
(404) 885-3000
(404) 885-3900 (Fax)
Troy.kleckley@troutmansanders.com
Puja.patel@troutmansanders.com

Attorneys for Plaintiff Reckitt Benckiser

Pharmaceuticals, Inc. & RB Pharmaceuticals Limited

James F. Hibey
Timothy C. Bickham
Houda Morad
Stephanie L. Sconewald
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington DC 20036
(202) 429-3000
(202) 429-3902 (Fax)
jhibey@steptoe.com
tbickham@steptoe.com
hmorad@steptoe.com
sschonew@steptoe.com

Attorneys for Plaintiff MonoSol Rx, LLC

CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on February 18, 2014, upon the following individuals via electronic mail:

Daniel G. Brown
Jennifer R. Saionz
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200
(212) 751-4864 (Fax)
Daniel.brown@lw.com
Jennifer.saionz@lw.com

James K. Lynch
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111-6536
(415) 391-0600
(415) 395-8095 (Fax)
Jim.lynch@lw.com

Attorneys for Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corp.

Emily C. Melvin
LATHAM & WATKINS LLP
233 S. Wacker Drive, Suite 5800
Chicago, IL 60606
(312) 876-7700
(312) 993-9767 (Fax)
Emily.melvin@lw.com

Steven J. Fineman
Katharine C. Lester
RICHARDS LAYTON & FINGER, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
(302) 651-7701 (Fax)
fineman@rlf.com
lester@rlf.com

Attorneys for Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corp.

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
Telephone (302) 252-4320
mbourke@wcsr.com

31948400