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., INTELGENX TECHNOLOGIES CORP., and LTS LOHMANN THERAPY SYSTEMS CORP., Defendants.	)	C.A. No.

COMPLAINT

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

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") (collectively, "the patents-in-suit").

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.

7. On information and belief, Defendant LTS is a Delaware corporation having a principal place of business at 15 Henderson Drive, West Caldwell, New Jersey.

JURISDICTION AND VENUE

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

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. On information and belief, LTS is in the business of developing and producing transdermal therapeutic systems as well as oral active ingredient films.

16. LTS, 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 bringing the patent infringement suits: *Novartis Pharmaceuticals Corporation v. Par Pharmaceutical Inc.*, C.A. No. 11-1077-RGA; *Novartis Pharmaceuticals Corporation v. Watson Laboratories Inc.*, C.A. No. 11-1112-RGA; *LTS Lohmann Therapie-Systeme AG v. Watson Laboratories Inc.*, C.A. No. 12-778-RGA; *Novartis Pharmaceuticals Corporation v. Alvogen Pine Brook Inc.*, C.A. Nos. 13-52-RGA and 13-370-RGA; *Novartis Pharmaceuticals Corporation v. Actavis Inc.*, C.A. No.

13-371-RGA*; Novartis Pharmaceuticals Corporation v. Noven Pharmaceuticals Inc.*, C.A. No. 13-527-RGA.

17. This Court has personal jurisdiction over LTS because of, *inter alia*, LTS' 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.

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

THE PATENTS-IN-SUIT

19. Plaintiff RBP UK is the lawful owner 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.

20. 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.

SUBOXONE® SUBLINGUAL FILM

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

22. 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.

23. The ’832 and ’150 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as covering Suboxone® sublingual film.

DEFENDANTS’ ANDA

24. 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.

25. 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.

26. 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, Defendants IGX and LTS. On information and belief, if ANDA No. 20-5854 is approved, IGX and LTS will actively participate in manufacturing, marketing, and/or selling Defendants’ generic product.

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

28. 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.

29. On information and belief, LTS is the exclusive manufacturer for IGX's VersaFilm™ drug delivery technology that is the subject of Par's ANDA No. 20-5854.

30. IGX filed statements with the SEC in 2010, 2011, and 2012 describing IGX's "strategic alliance" with LTS for the exclusive manufacturing of products developed using IGX's drug delivery technology.

31. 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.

32. On information and belief, LTS will manufacture the Defendants' generic product without authority and/or import Defendants' generic product into the United States and/or sell it to IGX or Par within the United States for subsequent commercial sale by Par under ANDA No. 20-5854.

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

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

34. Plaintiffs reallege paragraphs 1-33 above as if fully set forth herein.

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

36. 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).

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

38. IGX and LTS'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).

39. 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
(Declaratory Judgment of Infringement of the '832 Patent Under 35 U.S.C. § 271(a-c))

40. Plaintiffs reallege paragraphs 1-39 above as if fully set forth herein.

41. On information and belief, unless enjoined by this Court, Par plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product with its proposed labeling immediately following approval of ANDA No. 20-5854.

42. On information and belief, Par's commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '832 patent would infringe one or more claims of the '832 patent under 35 U.S.C. § 271(a)-(c).

43. On information and belief, by seeking approval to distribute Defendants' generic product with its proposed labeling, Par intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Par knows will infringe one or more claims of the '832 patent.

44. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, actively induce infringement of one or more claims of the ’832 patent immediately following approval of ANDA No. 20-5854.

45. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, contribute to the infringement of one or more claims of the ’832 patent immediately following approval of ANDA No. 20-5854.

46. On information and belief, Par knows that Defendants’ generic product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’832 patent, and that Defendants’ generic product and its proposed labeling are not suitable for any substantial noninfringing use.

47. IGX’s or LTS’ commercial manufacture, use, offer for sale, or sale of Defendant’s generic product within the United States will further infringe the’832 patent under 35 U.S.C. § 271(a).

48. IGX’s or LTS’ importation of Defendants’ generic product into the United States will further infringe the ’832 patent under 35 U.S.C. § 271(a).

49. 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 III
(Infringement of the ’150 Patent Under 35 U.S.C. § 271(e)(2))

50. Plaintiffs reallege paragraphs 1-49 above as if fully set forth herein.

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

52. 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).

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

54. IGX and LTS'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).

55. 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 IV
(Declaratory Judgment of Infringement of the '150 Patent Under 35 U.S.C. § 271(a))

56. Plaintiffs reallege paragraphs 1-55 above as if fully set forth herein.

57. On information and belief, unless enjoined by this Court, Par plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product with its proposed labeling immediately following approval of ANDA No. 20-5854.

58. On information and belief, Par's commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '150 patent would infringe one or more claims of the '150 patent under 35 U.S.C. § 271(a).

59. IGX's or LTS' commercial manufacture, use, offer for sale, or sale of Defendant's generic product within the United States will further infringe the'150 patent under 35 U.S.C. § 271(a).

60. IGX's or LTS' importation of Defendants' generic product into the United States will further infringe the '150 patent under 35 U.S.C. § 271(a).

61. 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 judgment that Defendants have infringed the '832 and '150 patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 20-5854;

B. A declaratory judgment that the Defendants' commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' generic product would infringe each of the patents-in-suit under 35 U.S.C. § 271(a);

C. A declaratory judgment that Par's commercial offer to sell or sale within the United States of Defendants' generic product would infringe the '832 patent under 35 U.S.C. § 271(b-c);

D. 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;

E. 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;

F. 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;

G. 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

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

Dated: August 20, 2013

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
TROUTMAN SANDERS LLP
405 Lexington Avenue
New York, NY 10174
(212) 704-6000
(212) 704-5929 (Fax)
daniel.ladow@troutmansanders.com
james.bollinger@troutmansanders.com

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

Attorneys for Plaintiffs
Reckitt Benckiser Pharmaceuticals, Inc.
and RB Pharmaceuticals Limited

Of Counsel:

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

Attorneys for Plaintiff
MonoSol Rx, LLC