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. 13-1461-RGA

DEFENDANTS PAR PHARMACEUTICAL, INC. AND INTELGENX TECHNOLOGIES CORP.'S ANSWER TO FIRST AMENDED COMPLAINT AND PAR PHARMACEUTICAL, INC.'S COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") and IntelGenx Technologies Corp. ("IGX", and together with Par, "Defendants"), answer the First Amended Complaint of Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") 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"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

Answer: Defendants admit that Plaintiffs purport to bring this action under the Food and Drug Law and Patent Laws of the United States. Defendants deny that Plaintiffs properly state a claim for patent infringement. Defendants further admit that Par submitted an ANDA to the FDA seeking approval to manufacture and sell a generic sublingual film containing buprenorphine hydrochloride and naloxone hydrochloride prior to the expiration of the '832 patent, the '150 patent and the '514 patent. Defendants deny the remaining allegations in paragraph 1 of the Complaint.

THE PARTIES

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

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore deny them.

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

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and therefore deny them.

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

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint and therefore deny them.

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.

Answer: Defendants admit that Par is a Delaware corporation. Defendants deny the remaining allegations of paragraph 5 of the Complaint.

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.

Answer: Defendants admit the allegations in paragraph 6 of the Complaint.

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.

Answer: Defendants state that they do not contest subject matter jurisdiction over this action.

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.

Answer: Defendants state that Par Pharmaceutical, Inc. is in the business of making and selling generic and branded pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States. To the extent there are any remaining allegations in paragraph 8 of the Complaint, Defendants deny them.

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.

Answer: Defendants state that Par has previously filed suit in 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. To the extent there are any remaining allegations in paragraph 9 of the Complaint, Defendants deny them.

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.

Answer: Defendants state that Par does not contest this Court's personal jurisdiction over Par for purposes of this action.

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.

Answer: Defendants state that 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. To the extent there are any remaining allegations in paragraph 11 of the Complaint, Defendants deny them.

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.

Answer: Defendants state that IGX's wholly-owned subsidiary IntelGenx Corp. has on a previous occasion declined to contest jurisdiction of the United States District Court for the District of Delaware by voluntarily substituting in as defendant in the patent infringement suit *Biovail Laboratories International SRL v. IntelGenx Corp.*, C.A. No. 09-605-LPS. To the extent there are any remaining allegations in paragraph 12 of the Complaint, Defendants deny them.

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.

Answer: Defendants state that IGX does not contest this Court's personal jurisdiction over IGX for purposes of this action.

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

Answer: Defendants state that they do not contest venue in this District for purposes of this action.

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.

Answer: Defendants admit that the '832 patent issued on July 2, 2013. Defendants admit that the '832 patent is entitled "Sublingual and Buccal Film Compositions." Defendants state that Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan are listed as inventors on the face of the '832 patent. Defendants deny that the '832 patent was duly and legally issued. Defendants state that Plaintiff RBP UK is listed as the assignee on the face of the '832 patent. Defendants admit that what appears to be a copy of the '832 patent is attached to the Complaint as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the Complaint and therefore deny them.

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.

Answer: Defendants admit that the '150 patent issued on September 13, 2011. Defendants admit that the '150 patent is entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." Defendants state that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '150 patent. Defendants deny that the '150 patent was duly and legally issued. Defendants state that Plaintiff MonoSol is listed as the assignee on the face of the '150 patent. Defendants admit that what appears to be a copy of the '150 patent is attached to the Complaint as Exhibit B. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 of the Complaint and therefore deny them.

17. Plaintiff Mono Sol 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.

Answer: Defendants admit that the '514 patent issued on December 10, 2013. Defendants admit that the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions." Defendants state that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '514 patent. Defendants deny that the '514 patent was duly and legally issued. Defendants state that Plaintiff MonoSol is listed as the assignee on the face of the '514

patent. Defendants admit that what appears to be a copy of the '514 patent is attached to the Complaint as Exhibit C. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 of the Complaint and therefore deny them.

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.

Answer: Defendants state that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for NDA No. 22-410 lists "Reckitt Benckiser" as the applicant. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 of the Complaint and therefore deny them.

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.

Answer: Defendants state that the Orange Book entry for NDA No. 22-410 lists the FDA approval date as August 30, 2010. Defendants state that the labeling for Suboxone® sublingual film currently states that Suboxone® sublingual film is "indicated for maintenance treatment of opioid dependence." Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the Complaint and therefore deny them.

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.

Answer: Defendants admit the allegations in paragraph 20 of the Complaint. Defendants further state that RBP caused the patents-in-suit to be listed in the Orange Book relative to Suboxone® sublingual film by filing a declaration with the FDA, and that the FDA published the '832, '150 and '514 patent information in the Orange Book as a ministerial act.

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.

Answer: Defendants state that Par sent the Notification Letter to Plaintiffs, dated July 8, 2013, and that the Notification Letter stated that ANDA No. 20-5854 contained a Paragraph IV certification stating 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. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21 of the Complaint and therefore deny them.

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.

Answer: Defendants admit that 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 Par's generic product before expiration of the patents-in-suit. Defendants admit that ANDA No. 20-5854 identifies Plaintiff RBP's NDA for Suboxone® sublingual film as the Reference Listed Drug pursuant to statute, and that ANDA No. 20-5854 contains data demonstrating that Par's generic product meets FDA requirements for bioequivalence with respect to Suboxone® sublingual film. To the extent that paragraph 22 of the Complaint contains additional allegations, Defendants deny them.

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, Defendants 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.

Answer: Defendants deny the allegations in paragraph 23 of the Complaint.

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

Answer: Defendants deny the allegations in paragraph 24 of the Complaint.

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.

Answer: Defendants admit that Par's generic product that is the subject of Defendant Par's ANDA No. 20-5854 includes IntelGenx Corp.'s VersaFilm™ drug delivery technology. To the extent there are any remaining allegations in paragraph 25 of the Complaint, Defendants deny them.

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.

Answer: Defendants admit that IGX filed statements with the SEC in 2013 asserting that IntelGenx Corp's "U.S. based co- development and commercialization partner" submitted an ANDA to the FDA for approval of a generic formulation of buprenorphine and naloxone sublingual film, indicated for maintenance treatment of opioid dependence. To the extent there are any remaining allegations in paragraph 26 of the Complaint, Defendants deny them.

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

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 27 of the Complaint and therefore deny them.

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.

Answer: Defendants state that Par sent the '514 Notification Letter to Plaintiffs, dated February 3, 2014, and that the '514 Notification Letter stated that ANDA No. 20-5854 contained a Paragraph IV certification stating that the '514 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. Defendants admit that ANDA No. 20-5854 identifies Plaintiff RBP's NDA for Suboxone® sublingual film as the Reference Listed Drug pursuant to statute, and that ANDA No. 20-5854 contains data demonstrating that Par's generic product meets FDA requirements

for bioequivalence with respect to Suboxone® sublingual film. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the Complaint and therefore deny them.

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

Answer: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint and therefore deny them.

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.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-29 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.

Answer: Defendants deny the allegations in paragraph 31 of the Complaint.

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).

Answer: Defendants deny the allegations in paragraph 32 of the Complaint.

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.

Answer: Defendants deny the allegations in paragraph 33 of the Complaint.

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).

Answer: Defendants deny the allegations in paragraph 34 of the Complaint.

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.

Answer: Defendants deny the allegations in paragraph 35 of the Complaint.

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.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-35 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.

Answer: Defendants deny the allegations in paragraph 37 of the Complaint.

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).

Answer: Defendants deny the allegations in paragraph 38 of the Complaint.

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.

Answer: Defendants deny the allegations in paragraph 39 of the Complaint.

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).

Answer: Defendants deny the allegations in paragraph 40 of the Complaint.

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.

Answer: Defendants deny the allegations in paragraph 41 of the Complaint.

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.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-41 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.

Answer: Defendants deny the allegations in paragraph 43 of the Complaint.

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).

Answer: Defendants admit that ANDA No. 20-5854 under 21 U.S.C. § 355(j) seeks approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '514 patent. Defendants deny the remaining allegations of paragraph 44 of the Complaint.

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.

Answer: Defendants deny the allegations of paragraph 45 of the Complaint.

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).

Answer: Defendants deny the allegations of paragraph 46 of the Complaint.

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.

Answer: Defendants deny the allegations of paragraph 47 of the Complaint.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief they seek in their Complaint.

AFFIRMATIVE DEFENSES

1. The claims of the '832, '150 and '514 patents are invalid under 35 U.S.C. § 1 *et seq.* and/or the doctrine of obviousness-type double patenting.

2. Par Pharmaceutical, Inc.'s filing of ANDA No. 20-5854 was not an act of infringement of any valid claim of the '832, '150 and '514 patents.

3. The manufacture, use, offer for sale, sale, marketing, distribution, or importation of the product that is the subject of Par Pharmaceutical, Inc.'s ANDA No. 20-5854 would not infringe any claim of the '832, '150 and '514 patents.

4. Par Pharmaceutical, Inc. and IntelGenx Technologies Corp. have not induced infringement of '832, '150 and '514 patents.

5. The Complaint fails to state a claim for which relief can be granted.

6. The relief requested in the Complaint is barred by the doctrines of estoppel and/or waiver.

COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") asserts the following Counterclaims against Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs"):

THE PARTIES

1. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. RBP asserts in its Complaint that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. RBP UK asserts in its Complaint that it is a corporation organized and existing under the laws of the United Kingdom, with a principal place of business at 103-105 Bath Road, Slough, UK.

4. MonoSol asserts in its Complaint that it is a Delaware corporation with a principal place of business at 30 Technology Drive, Warren, New Jersey.

NATURE OF THE ACTION

5. Par seeks a declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that United States Patent Nos. 8,017,150 (the "'150 patent"), 8,475,832 (the "'832 patent") and 8,603,514 (the "'514 patent") are invalid and not infringed, and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that Par has not misappropriated any MonoSol trade secret.

JURISDICTION

6. This Court has original and supplemental jurisdiction over the subject matter

of these claims under 28 U.S.C. §§ 1331, 1338(a), 1357, 1367, 2201, and 2202.

7. This Court has personal jurisdiction over RBP based, *inter alia*, on the filing by RBP of this lawsuit in this jurisdiction.

9. This Court has personal jurisdiction over RBP UK based, *inter alia*, on the filing by RBP UK of this lawsuit in this jurisdiction.

10. This Court has personal jurisdiction over MonoSol based, *inter alia*, on the filing by MonoSol of this lawsuit in this jurisdiction.

VENUE

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d), 1400(b), and Plaintiffs' choice of forum.

FACTUAL BACKGROUND

12. Par and IntelGenx Corp. (IntelGenx Technology Corp.'s wholly-owned subsidiary) developed a generic drug that is administered by a "sublingual film," that is, it is administered by placing it under the tongue and allowing it to dissolve. The generic drug—buprenorphine hydrochloride and naloxone hydrochloride sublingual film—is indicated for maintenance treatment of opioid dependence. Par and IntelGenx's product is bioequivalent to Suboxone® sublingual film. Par filed an ANDA seeking approval to market the buprenorphine hydrochloride and naloxone hydrochloride sublingual film product. MonoSol asserts that it provided Par with trade secret information relating to manufacture of sublingual film technology, including information described in the '150,'832 and/or '514 patents, while Par and MonoSol were in a previous commercial arrangement relating to a different pharmaceutical product. MonoSol has contended that Par wrongfully misappropriated and used the trade secret information it disclosed to Par to develop the product that is the subject of Par's ANDA. MonoSol and Par engaged in negotiations regarding an agreement to allow MonoSol the ability to inspect Par's ANDA, In those negotiations, MonoSol specifically

asked for the right to inspect for any evidence supporting its trade secret claim. Despite those negotiations, no agreement was reached. Plaintiffs have now filed an Amended Complaint alleging that Par and IntelGenx Technologies Corp. (IntelGenx's parent company) infringe the '150, '832 and '514 patents in connection with Par's ANDA. There remains an existing dispute relating to alleged trade secret misappropriation relating to Par's ANDA. No resolution of MonoSol's trade secret claim has been reached, and MonoSol has not presently asserted that claim in this action.

Development of Par's ANDA Product

13. Par is engaged in the business of developing, manufacturing, marketing and selling both generic and branded pharmaceutical products.

14. IntelGenx is engaged in the business of developing oral drug delivery products. IntelGenx has developed novel drug delivery technologies including oral controlled-release products and rapidly disintegrating delivery systems.

15. Upon information and belief, MonoSol is engaged in the business of developing drug oral thin-film products.

16. IntelGenx is a competitor of MonoSol.

17. Par entered into an agreement with IntelGenx regarding the development and commercialization of an oral thin film product containing buprenorphine hydrochloride and naloxone hydrochloride that is bioequivalent to Suboxone® sublingual film ("Par's ANDA product").

18. The formulation of Par's ANDA product, including the composition and the manufacturing process in the ANDA, was developed using IntelGenx's novel drug delivery technologies and information in the public domain, and in no way relies on or incorporates any confidential, proprietary or trade secret information of MonoSol.

Par's Relationship With MonoSol

19. In and around June 2008, Par and MonoSol entered into a relationship and commercialized a single pharmaceutical product, Zuplenz® (odansetron) oral film.

20. On July 2, 2010, the New Drug Application ("NDA") for Zuplenz® was approved by FDA. At that time, Par was the holder of the NDA for Zuplenz®.

21. Subsequently, Par and MonoSol agreed to terminate their relationship and Par transferred all rights to the NDA for Zuplenz® to MonoSol.

22. On information and belief, MonoSol alleges that aspects of the formulation for Zuplenz® is covered by one or more patents owned by MonoSol.

23. On information and belief, MonoSol alleges that aspects of the process to manufacture Zuplenz® is covered by one or more patents owned by MonoSol.

24. MonoSol disclosed to the public information on the formulation of oral thin films by filing patent applications with the U.S. Patent and Trademark Office ("PTO") directed to formulation of oral thin films. MonoSol also disclosed to the public information on the process to manufacture oral thin films by filing patent applications with the PTO. MonoSol knew that by filing patent applications with the PTO, the contents of the patent applications would be published.

Filing of Par's ANDA

25. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," issued on September 13, 2011.

26. The '832 patent, entitled "Sublingual and Buccal Film Compositions," issued on July 2, 2013.

27. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," issued on December 10, 2013.

28. On information and belief, MonoSol is the assignee of the '150 and '514

patents.

29. On information and belief, RBP UK is the assignee of the '832 patent.

30. On information and belief, RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film. In connection with NDA No. 22-410, RBP caused the FDA to list the '150, '832 and '514 patents in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

31. Par submitted Abbreviated New Drug Application ("ANDA") No. 205854 for Par's ANDA product ("Par's ANDA") to obtain regulatory approval to engage in the commercial manufacture, use, or sale of generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film, before the expiration of the '150, '832 and '514 patents. As required by statute for a generic drug, Par's proposed drug product is bioequivalent to Suboxone® sublingual film and has the same active ingredient, strength, dosage form, and route of administration. Par made certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '150, '832 and '514 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the buprenorphine hydrochloride and naloxone hydrochloride sublingual film products that are the subject of Par's ANDA.

32. On July 8, 2013, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Par notified each of Plaintiffs of Par's paragraph IV certifications with respect to the '150 and '832 patents filed with its ANDA. Par also provided to each of Plaintiffs an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) (the "Offer"). Par provided the Offer to each of Plaintiffs offering to provide access to Par's ANDA for the sole purpose of determining whether an action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) for infringement of the '150 and '832 patents should be brought.

33. On July 29, 2013, Plaintiffs objected to the terms of the Offer. Plaintiffs proposed modifying the Offer to permit access to Par's ANDA for the purpose of evaluating whether each of Plaintiffs will bring suit against Par alleging infringement of any patent.

34. On July 31, 2013, Par provided to each of Plaintiffs a modified Offer that permits access to Par's ANDA for the purpose of evaluating whether each of Plaintiffs will bring suit against Par alleging infringement of any patent owned or exclusively licensed to each of Plaintiffs. Par also informed Plaintiffs that the Offer of July 8, 2013 remained open.

35. On August 2, 2013, Plaintiffs again objected to the Offer. Plaintiffs proposed additional modifications to the Offer. Plaintiffs stated:

> [. . .] MonoSol needs to be able to consider trade secret issues in addition to patent issues under the [Offer] and requests that [the Offer] expressly so provide for purposes of clarity.

36. On August 13, 2013, Par provided to each of Plaintiffs a second modified Offer that permits MonoSol access to Par's ANDA for the purpose of evaluating whether MonoSol will bring suit against Par alleging misappropriation of any trade secret owned by MonoSol. The modified Offer further provided that before MonoSol could access Par's ANDA pursuant to the Offer, MonoSol must first identify with reasonable particularity in writing to outside counsel for Par the matter(s) MonoSol alleges constitute a trade secret. Par also informed Plaintiffs that Par's Offers of July 8, 2013 and July 31, 2013 remained open.

37. On or about August 16, 2013, Plaintiffs sent a letter to Par informing Par that "it appears to us that the parties have been and are unable to reach an agreement on the terms of [the Offer]."

38. On August 19, 2013, Par sent a letter to Plaintiffs informing Plaintiffs that Par's Offers of July 8, 2013, July 31, 2013 and August 13, 2013 were still open.

39. On August 20, 2013, Plaintiffs filed its Complaint in the instant action alleging infringement of the '150 and '832 patents.

40. In the Complaint, Plaintiffs did not allege misappropriation of any trade secret.

41. Plaintiffs did not accept Par's Offers of July 8, 2013, July 31, 2013 or August 13, 2013, and did not obtain or review a copy of Par's ANDA before filing this action.

COUNT ONE

(Declaratory Judgment that Par Has Not Misappropriated Any Trade Secret of Monosol)

42. Par realleges paragraphs 1-41 of the Counterclaims as if fully set forth herein.

43. MonoSol asserts that it owns trade secrets, including protected proprietary rights to technical information, relating to the formulation and manufacture of oral thin film products.

44. On August 2, 2013, MonoSol communicated to Par that MonoSol provided Par with technical information and "know how" over which MonoSol had proprietary trade secret rights and that Par's ANDA, which delineates the formulation and manufacturing processes for Par's ANDA product, contains evidence that Par misappropriated MonoSol's proprietary rights to such technical information.

45. Par reasonably believes that MonoSol intends to bring suit against Par alleging misappropriation of trade secrets.

46. Under governing trade secret law, MonoSol is not entitled to access Par's confidential technical information to evaluate or formulate an allegation of trade secret misappropriation prior to identifying with reasonable particularity the identity of such alleged trade secret(s).

47. Par reasonably believes that absent a court order preventing such access and use, MonoSol may use Par's confidential technical information obtained during the course of discovery in this patent-infringement action to formulate and bring MonoSol's allegations of trade secret misappropriation against Par.

48. Par intends to seek a protective order in this action to prevent MonoSol from

accessing and using Par's confidential technical information to formulate and bring any allegation of trade secret misappropriation against Par prior to MonoSol identifying with reasonable particularity MonoSol's alleged trade secret(s).

49. Par's ANDA product was developed without using any MonoSol technical information.

50. Par denies MonoSol's allegations of trade secret misappropriation, and that MonoSol has lost any proprietary protection it might have had by knowingly and intentionally filing patent applications, including the patent applications that issued as the '150 and '832 patents, disclosing technical information.

51. Par has not misappropriated any trade secret in the development of Par's ANDA product and will not misappropriate any trade secret in the manufacture or sale of Par's ANDA product.

52. By filing suit for infringement of the '150 and '832 patents, Plaintiffs placed into dispute the soundness of Par's ANDA and Par's ability to market Par's ANDA product.

53. By filing suit for infringement of the '150 and '832 patents, Plaintiffs demonstrated a willingness to protect their technology.

54. Without a determination of the parties' actively contested legal rights over the alleged trade secrets, Par risks a delay in resolution of this litigation (and the associated termination of the 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii)), as well as having to defend against later requests by Monosol for an injunction and damages.

55. An actual and justiciable controversy exists between the parties with respect to the rights MonoSol and Par have over the technical information relied upon for the formulation of Par's ANDA product and the process of manufacture for Par's ANDA product, and Par is entitled to a declaratory judgment that Par did not and does not use any MonoSol proprietary information for the formulation of Par's ANDA product or the

manufacture thereof.

COUNT TWO

(Declaratory Judgment regarding U.S. Patent No. 8,017,150)

56. Par realleges paragraphs 1-55 of the Counterclaims as if fully set forth herein.

57. The claims of the '150 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

58. Par's filing of Par's ANDA did not infringe any valid claim of the '150 patent.

59. The commercial manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '150 patent.

60. An actual and justiciable controversy exists between the parties with respect to the '150 patent, and Par is entitled to a declaratory judgment that the '150 patent is invalid and not infringed.

61. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

COUNT THREE

(Declaratory Judgment regarding U.S. Patent No. 8,475,832)

62. Par realleges paragraphs 1-61 of the Counterclaims as if fully set forth herein.

63. The claims of the '150 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

64. Par's filing of Par's ANDA did not infringe any valid claim of the '832 patent.

65. The commercial manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '832 patent.

66. An actual and justiciable controversy exists between the parties with respect to

the '150 patent, and Par is entitled to a declaratory judgment that the '832 patent is invalid and not infringed.

67. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

COUNT FOUR

(Declaratory Judgment regarding U.S. Patent No. 8,603,514)

68. Par realleges paragraphs 1-67 of the Counterclaims as if fully set forth herein.

69. The claims of the '514 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

70. Par's filing of Par's ANDA did not infringe any valid claim of the '514 patent.

71. The commercial manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '514 patent.

72. An actual and justiciable controversy exists between the parties with respect to the '514 patent, and Par is entitled to a declaratory judgment that the '514 patent is invalid and not infringed.

73. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that the Court enter judgment in its favor and against Plaintiffs and grant the following relief:

A. Declare that MonoSol has no protected proprietary interest in the information relied upon for the formulation or manufacturing processes used by or in Par's ANDA product or the manufacture thereof;

B. Declare that the claims of the '150 patent are invalid;

C. Declare that the manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '150 patent;

D. Declare that the claims of the '832 patent are invalid;

E. Declare that the manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '832 patent;

F. Declare that the claims of the '514 patent are invalid;

G. Declare that the manufacture, use, offer for sale, sale, or importation of Par's ANDA product would not infringe any valid claim of the '514 patent;

H. Award Par its costs and reasonable attorneys' fees; and

I. Award Par such other and further relief as the Court deems just and proper.

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Dated: March 4, 2014

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