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. 13-1674-RGA

DEFENDANTS PAR PHARMACEUTICAL, INC. AND INTELGENX TECHNOLOGIES CORP.'S ANSWER TO THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") and IntelGenx Technologies Corp. ("IGX", and together with Par, "Defendants"), answer the Third 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 Laws 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 One Ram Ridge Road, Spring Valley, New York 10977.

Answer: Defendants admit the allegations in 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 Defendants 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 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.

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.

THE DRUG APPROVAL PROCESS

21. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent

protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

Answer: Defendants admit that in 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. 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. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

Answer: Defendants state that the statute speaks for itself and that the allegations in paragraph 22 of the Complaint contain a legal conclusion to which no response is required. Defendants further state that the NDA applicant causes the patent information to be listed in the Orange Book by filing a declaration with FDA, and that FDA publishes the information in the Orange Book as a ministerial act.

23. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-

approved drug.

Answer: Defendants state that the statute speaks for itself and that the allegations in paragraph 23 of the Complaint contain a legal conclusion to which no response is required.

24. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. *See* 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.*

Answer: Defendants state that the regulation speaks for itself and that the allegations in paragraph 24 of the Complaint contain a legal conclusion to which no response is required.

25. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV certifications").

Answer: Defendants state that the statute speak for itself and that the allegations in paragraph 25 of the Complaint contain a legal conclusion to which no response is required.

26. Paragraph IV certifications can allow generic manufacturers to obtain FDA approval long before expiration of the patents listed in the Orange Book.

Answer: Defendants admit that submission of a Paragraph IV certification by an ANDA applicant may allow the applicant to obtain approval of the ANDA by FDA before the scheduled expiration of the patents subject to the Paragraph IV certification. To the extent there are any remaining allegations in paragraph 26 of the Complaint, Defendants deny them.

27. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice ("notice of Paragraph IV certification") to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed, "not later than 20 days after the date of the postmark on the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

Answer: Defendants state that the statute speaks for itself and that the allegations in paragraph 27 of the Complaint contain a legal conclusion to which no response is required.

28. The patent owner can file an infringement action within 45 days of receiving the notice of Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of the FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

Answer: Defendants state that the statute speaks for itself and that the allegations in paragraph 28 of the Complaint contain a legal conclusion to which no response is required. To the extent there are any remaining allegations in paragraph 29 of the Complaint, Defendants deny them.

29. The date of receipt of the notice of Paragraph IV certification by the patent owner affects important rights and remedies of the patent owner, including the deadline for filing an infringement action and the start and end dates of the 30-month injunction. By providing a premature notice of Paragraph IV certification to the NDA holder or patent owner, the ANDA applicant attempts to trigger the 30-month injunction earlier and to reach the market sooner than it would otherwise be permitted. In addition, there is a significant risk for the patent owner to miss the 45-day deadline for filing an infringement action, and consequently the opportunity for

a 30-month injunction, if the patent owner mistakenly relies on a premature and ineffective notice of Paragraph IV certification.

Answer: Defendants deny the allegations in paragraph 29 of the Complaint.

30. The ANDA applicant may not send the notice of Paragraph IV certification to the patent owner before the FDA "informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B)(ii)(I); *SB Pharmco Puerto Rico, Inc. v. Mut. Pharm. Co., Inc.*, 552 F. Supp. 2d 500, 508 (E.D. Pa. 2008); *Otsuka Pharm. Co. v. Par Pharm., Inc.*, Docket No. 13-1979 (D. Del. March 10, 2014) (Andrews, J.).

Answer: Defendants state that the statute and cases speak for themselves and that the allegations in paragraph 30 of the Complaint contain a legal conclusion to which no response is required.

31. Federal regulations also govern the timing of the notice of Paragraph IV certification by directing the generic manufacturer to send such notice "when it receives from FDA an acknowledgment letter stating that its [ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

Answer: Defendants state that the regulations speak for themselves and that the allegations in paragraph 31 of the Complaint contain a legal conclusion to which no response is required.

DEFENDANTS' ANDA AND NOTICES OF PARAGRAPH IV CERTIFICATION

32. Plaintiffs received a letter from Defendant Par dated July 8, 2013 (the "July 2013 Notice 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 July 2013 Notice Letter to Plaintiffs, dated

July 8, 2013, and that the July 2013 Notice 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 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 32 of the Complaint and therefore deny them.

33. The July 2013 Notice 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 the commercial manufacture, use, and/or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Defendants' generic product") before expiration of the patents-in-suit.

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. To the extent that paragraph 33 of the Complaint contains additional allegations, Defendants deny them.

34. 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 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 34 of the Complaint contains additional allegations, Defendants deny them.

35. 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.

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

36. 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 36 of the Complaint.

37. 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 37 of the Complaint, Defendants deny them.

38. 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 38 of the Complaint, Defendants deny them.

39. Plaintiffs filed suit against Defendants in this judicial district on August 20, 2013 (Case No. 1:13-cv-01461-RGA), within 45 days of receiving the July 2013 Notice Letter.

Answer: Defendants admit that Plaintiffs filed Case No. 1:13-cv-01461-RGA within 45 days of the July 2013 Notice Letter. To the extent there are any remaining allegations in paragraph 39 of the Complaint, Defendants deny them.

40. Plaintiffs received another letter from Defendant Par dated February 3, 2014 ("the

'514 Notice Letter"), stating that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 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.

Answer: Defendants state that Par sent the '514 Notice Letter to Plaintiffs, dated February 3, 2014, and that the '514 Notice 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 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 40 of the Complaint and therefore deny them.

41. Plaintiffs amended their complaint in Case No. 1:13-cv-01461-RGA on February 18, 2014, within 45 days of receiving the '514 Notice Letter, to further assert the infringement of the '514 Patent under 35 U.S.C. § 271(e)(2).

Answer: Defendants admit that Plaintiffs amended the complaint in Case No. 1:13-cv-01461-RGA within 45 days of the '514 Notice Letter, and state that the complaint speaks for itself. To the extent there are any remaining allegations in paragraph 41 of the Complaint, Defendants deny them

42. On March 4, 2014, Defendants filed an answer to Plaintiffs' first amended complaint in Case No. 1:13-cv-01461-RGA, with counterclaims asserted by Par.

Answer: Defendants admit that on March 4, 2014, Defendants filed an answer to Plaintiffs' first amended complaint in Case No. 1:13-cv-01461-RGA, and state that the answer speaks for itself.

43. Plaintiffs received yet another letter from Defendant Par dated March 25, 2014 (the "March 2014 Notice Letter"), repeating that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832, '150, and '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.

Answer: Defendants state that Par sent the March 2014 Notice Letter to Plaintiffs, dated March 25, 2014, and that the March 2014 Notice 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 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 43 of the Complaint and therefore deny them.

44. The March 2014 Notice 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 the commercial manufacture, use, and/or sale of Defendants' generic product, i.e. buprenorphine hydrochloride and naloxone hydrochloride sublingual film, before expiration of the patents-in-suit.

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.

45. Unlike the earlier notices of Paragraph IV certifications (which include the July 2013 Notice Letter and the '514 Notice Letter), the March 2014 Notice Letter represents that the FDA "has received [ANDA No. 20-5854] for substantive review."

Answer: Defendants state that the July 2013 Notice Letter, the '514 Notice Letter and the March 2014 Notice Letter speak for themselves. To the extent there are any remaining allegations in paragraph 45 of the Complaint, Defendants deny them.

46. On information and belief, Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, were sent before receiving the FDA's acknowledgment letter stating that ANDA No. 20-5854 is sufficiently complete to permit a substantive review (the "FDA Acknowledgment Letter").

Answer: Defendants admit the allegations in paragraph 46 of the Complaint.

47. Recent authority from this judicial district demonstrates that Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature and ineffective to trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854. *See Otsuka Pharm. Co. v. Par Pharm., Inc.*, Docket No. 13-1979 (D. Del. March 10, 2014) (Andrews, J.).

Answer: Defendants state that the case law speaks for itself and that the allegations in paragraph 47 of the Complaint contain a legal conclusion to which no response is required. Defendants further state that the July 2013 Notice Letter and the '514 Notice Letter were sent pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II), which mandates that an ANDA applicant provide notice of Paragraph IV certification "if the certification is in an amendment or supplement to the [ANDA], at the time at which the applicant submits the amendment or supplement." Defendants still further state that it is FDA's position that a notice of Paragraph IV certification sent prior to FDA's acknowledgement letter does not trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854.

48. Plaintiffs commenced this action within 45 days of receiving the March 2014 Notice Letter, to preserve their right to a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii).

Answer: Defendants lack knowledge or information sufficient to form a belief as the truth of the allegations in paragraph 48 of the Complaint.

49. Plaintiffs received another notice of Paragraph IV certification from Defendant Par, dated April 8, 2014 (the "April 2014 Notice Letter"). The April 2014 Notice Letter states that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832, '150, and '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.

Answer: Defendants state that Par sent the April 2014 Notice Letter, dated April 8, 2014, and that the April 2014 Notice Letter stated that ANDA No. 20-5854 contained a Paragraph IV certification that the '832, '150, and '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. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 49 of the Complaint and therefore deny them.

50. Whereas the March 2014 Notice Letter states that "[t]he active ingredient, strength, and dosage form of the proposed drug product are buprenorphine hydrochloride; naloxone hydrochloride, 8 mg/2 mg (Equivalent Base), and sublingual film," the April 2014 Notice Letter adds the "2 mg/0.5 mg (Equivalent Base)" and "4 mg/1 mg (Equivalent Base)" strengths.

Answer: Defendants state that the March 2014 Notice Letter and the April 2014 Notice Letter speak for themselves and that to the extent there are any remaining allegations in paragraph 50 of the Complaint, Defendants deny them.

51. Plaintiffs commenced this action within 45 days of receiving the April 2014 Notice Letter, to preserve their right to a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii) as to the newly added "2 mg/0.5 mg (Equivalent Base)" and "4 mg/1 mg (Equivalent Base)" strengths, which 30-month stay was triggered, at the very earliest, upon Plaintiffs' receipt of the April 2014 Notice Letter.

Answer: Defendants lack knowledge or information sufficient to form a belief as the truth of the allegations in paragraph 51 of the Complaint.

52. On April 17, 2014, Plaintiffs moved to dismiss their amended complaint and Par's counterclaims in Case No. 1:13-cv-01461-RGA, without prejudice, on the basis that Par admittedly served the Paragraph IV certifications on which that action was based even though its application had not been accepted for filing when it started the litigation process.

Answer: Defendants admit that on April 17, 2014, Plaintiffs moved to dismiss their amended complaint and Par's counterclaims in Case No. 1:13-cv-01461-RGA. Defendants state that Plaintiffs' motion speaks for itself. To the extent paragraph 52 purports to allege that Plaintiffs' motion to dismiss had merit, that paragraph contains a legal conclusion to which no response is required.

53. On May 27, 2014, this Court granted Plaintiffs' motion to dismiss their amended complaint and Par's counterclaims in Case No. 1:13-cv-01461-RGA, without prejudice.

Answer: Defendants admit that on May 27, 2014, this Court granted Plaintiffs' motion to dismiss without prejudice. To the extent there are any remaining allegations in paragraph 53 of the Complaint, Defendants deny them.

54. Plaintiffs received another notice of Paragraph IV certification from Defendant Par, dated June 13, 2014 (the "June 2014 Notice Letter"). The June 2014 Notice Letter states that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832, '150, and '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.

Answer: Defendants state that Par sent the June 2014 Notice Letter, dated June 13, 2014, and that the June 2014 Notice Letter stated that ANDA No. 20-5854 contained a Paragraph IV certification that the '832, '150, and '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. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 54 of the Complaint and therefore deny them

55. Whereas the April 2014 Notice Letter states that "[t]he active ingredient, strength, and dosage form of the proposed drug product are buprenorphine hydrochloride; naloxone hydrochloride, 2 mg/0.5 mg (Equivalent Base); 4 mg/1 mg (Equivalent Base); and 8 mg/2 mg 12

(Equivalent Base), and sublingual film," the June 2014 Notice Letter adds the "12 mg/3 mg (Equivalent Base)" strength.

Answer: Defendants state that the April 2014 Notice Letter and the June 2014 Notice Letter speak for themselves and that to the extent there are any remaining allegations in paragraph 55 of the Complaint, Defendants deny them

56. Plaintiffs commenced this action within 45 days of receiving the June 2014 Notice Letter, to preserve their right to a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii) as to the newly added "12 mg/3 mg (Equivalent Base)" strength, which 30-month stay was triggered, at the very earliest, upon Plaintiffs' receipt of the June 2014 Notice Letter.

Answer: Defendants admit that Plaintiffs moved to amend the Complaint as to the newly added "12 mg/3 mg (Equivalent Base)" strength within 45 days of the June 2014 Notice Letter. To the extent there are any remaining allegations in paragraph 56 of the Complaint, Defendants deny them.

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

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

Answer: Defendants repeat and reallege their answers to paragraphs 1-56 as if fully set forth herein.

58. 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 58 of the Complaint.

59. 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 59 of the Complaint.

60. 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 60 of the Complaint.

61. 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 61 of the Complaint.

62. 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 62 of the Complaint.

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

63. Plaintiffs reallege paragraphs 1-62 above as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-62 as if fully set forth herein.

64. 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 64 of the Complaint.

65. 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 65 of the Complaint.

66. 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 66 of the Complaint.

67. 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 67 of the Complaint.

68. 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 68 of the Complaint.

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

69. Plaintiffs reallege paragraphs 1-68 above as if fully set forth herein.

Answer: Defendants repeat and re-allege their answers to paragraphs 1-68 as if fully set forth herein.

70. 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 70 of the Complaint.

71. 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 in paragraph 71 of the Complaint.

72. 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 72 of the Complaint.

73. 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 in paragraph 73 of the Complaint.

74. 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 74 of the Complaint.

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") and IntelGenx Technologies Corp. ("IGX", and together with Par, "Defendants") assert 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. IntelGenx Technologies Corp. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6425 Abrams, Ville St-Laurent (Quebec), Canada.

3. 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.

4. 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.

5. 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

6. Defendants seek 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.

JURISDICTION

7. 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.

8. 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)-(c), 1400(b), and Plaintiffs' choice of forum.

BACKGROUND

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

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

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

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

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

17. 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").

18. 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.

19. On July 8, 2013, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(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.

20. On July 29, 2013, Plaintiffs objected to the terms of the Offer.

21. On August 20, 2013, Plaintiffs filed their Complaint in Case No. 1:13-cv-01461-RGA alleging infringement of the '150 and '832 patents by Par and IGX.

22. On February 3, 2014, based on Plaintiffs' listing of the '514 patent in the Orange Book after the filing of Par's ANDA and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II), Par notified each of Plaintiffs of Par's paragraph IV certifications with respect to the '150, '832 and '514 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, '832 and '514 patents should be brought.

23. On February 18, 2014, Plaintiffs filed their Amended Complaint in Case No. 1:13-cv-01461-RGA alleging infringement of the '150, '832 and '514 patents.

24. On March 25, 2014, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), Par notified each of Plaintiffs of Par's paragraph IV certifications with respect to the '150, '832 and '514 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, '832 and '514 patents should be brought.

25. On April 4, 2014, Plaintiffs filed their Complaint in the instant action alleging infringement of the '150, '832 and '514 patents.

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

26. Defendants reallege paragraphs 1-25 of the Counterclaims as if fully set forth herein.

27. 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.

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

29. 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.

30. An actual and justiciable controversy exists between the parties with respect to the '150 patent, and Defendants are entitled to a declaratory judgment that the '150 patent is invalid

and not infringed.

31. This is an exceptional case, and Defendants are entitled to their costs and reasonable attorneys' fees.

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

32. Defendants reallege paragraphs 1-31 of the Counterclaims as if fully set forth herein.

33. 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.

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

35. 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.

36. An actual and justiciable controversy exists between the parties with respect to the '150 patent, and Defendants are entitled to a declaratory judgment that the '832 patent is invalid and not infringed.

37. This is an exceptional case, and Defendants are entitled to their costs and reasonable attorneys' fees.

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

38. Defendants reallege paragraphs 1-37 of the Counterclaims as if fully set forth herein.

39. 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.

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

41. 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.

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

43. This is an exceptional case, and Defendants are entitled to their costs and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court enter judgment in their favor and against Plaintiffs and grant the following relief:

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

B. 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;

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

D. 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;

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

F. 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;

G. Award Defendants their costs and reasonable attorneys' fees; and

H. Award Defendants such other and further relief as the Court deems just and proper.

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Dated: August 21, 2014

/s/ Steven J. Fineman

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