## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

HORIZON THERAPEUTIC	25	IIC
HONIZON HILKALLUTIC	~ <b>D</b> ,	LLC.

Plaintiff,

v.

Civil Action No.

PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.

Defendants.

## **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Horizon Therapeutics, LLC ("Plaintiff" or "Horizon"), by its undersigned attorneys, brings this action against Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Defendants"), and hereby alleges as follows:

## **NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Par Pharmaceutical, Inc. 's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiff's pharmaceutical product RAVICTI® (glycerol phenylbutyrate oral liquid) ("RAVICTI®") prior to the expiration of United States Patent No. 8,642,012 ("the '012 patent"). A true and accurate copy of the '012 patent is attached to this complaint as Exhibit A.

### THE PARTIES

- 2. Plaintiff Horizon Therapeutics, LLC is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.
- 3. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at One Ram Ridge Road, Chestnut Ridge, New York 10977.
- 4. Upon information and belief, Par Pharmaceutical Companies, Inc. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware; (ii) alone, in concert with, and/or through its various wholly-owned subsidiaries, including defendant Par Pharmaceutical, Inc., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) alone, in concert with, and/or through its various wholly-owned subsidiaries, including defendant Par Pharmaceutical, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.
- 5. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of New York, and its principal place of business is located at One Ram Ridge Road, Chestnut Ridge, New York 10977.
- 6. Upon information and belief, Par Pharmaceutical, Inc. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware; (ii) alone, in concert with, and/or through its related parent companies and various subsidiaries, the preparation,

submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) alone, in concert with, and/or through its related parent companies and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

7. Upon information and belief, Par Pharmaceutical, Inc. is wholly owned by defendant Par Pharmaceutical Companies, Inc. Upon information and belief, Par Pharmaceutical, Inc. acts at the direction of, under the control of, and for the direct benefit of Par Pharmaceutical Companies, Inc., and is controlled and/or dominated by Par Pharmaceutical Companies, Inc. Upon information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. have at least one officer and/or director in common. *See* Endo International PLC's Form 10-K for the Year Ended December 31, 2017 at 16-17; *see also Shire-NPS Pharm., Inc. v. Ambio, Inc. et al.*, C.A. No. 17-cv-00397-RGA, D.I. 21 at ¶ 12.

## **JURISDICTION AND VENUE**

- 8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 9. This Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, upon information and belief, Par Pharmaceutical Companies, Inc. is incorporated under the laws of the State of Delaware and has a registered agent for service of process in Delaware.
- 10. This Court also has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, upon information and belief, Par Pharmaceutical Companies, Inc. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in

Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Par Pharmaceutical Companies, Inc. has continuous and systematic contacts with Delaware.

- 11. This Court also has personal jurisdiction over Par Pharmaceutical Companies, Inc. because, *inter alia*, Par Pharmaceutical Companies, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Plaintiff, a Delaware corporation.
- 12. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. is qualified to do business under the laws of the State of Delaware under File No. 6125148 and has a registered agent for service of process in Delaware. Upon information and belief, Par Pharmaceutical, Inc. is "doing business as Par Pharmaceutical." *See* Endo International PLC's Form 10-K for the Year Ended December 31, 2017 at Exhibit 21.1. Par Pharmaceutical holds an active pharmacy wholesale license for the State of Delaware under License No. A4-0002347 and an active distributor/manufacturer license for controlled substances for the State of Delaware under License No. DM-0011836. As of July 24, 2018, Par Pharmaceutical's website states that its "sales place it among the leading generic pharmaceutical companies in the United States." Par Pharmaceutical "[c]onducts manufacturing in the United States and abroad and markets and/or license more than 200 prescriptions drug products families," and has "[s]trong distribution relationships in place at top U.S. retail chains, wholesalers, distributors, managed care organizations, mail order pharmacies and group purchasing organizations." *See* http://www.parpharm.com/about/.

- 13. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, inter alia, Par Pharmaceutical, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protection of the State of Delaware, having consented to iurisdiction in this Court, see, e.g., Shire-NPS Pharmaceuticals, Inc. v. Ambio, Inc. et al., 1:17cv-00397- RGA (D. Del. Apr. 10, 2017); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:15-cv-01050-RGA (D. Del. Dec. 4, 2015); Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc., 1:15-cv-01049-LPS (D. Del. Dec. 7, 2015); Actavis Laboratories UT, Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00886-LPS (D. Del. Dec. 1, 2015); Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00824-LPS (D. Del. Oct. 7, 2015); Ferring Pharmaceuticals Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00173-RGA (D. Del. Mar. 13, 2015); Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc., 1:15-cv-00116-LPS (D. Del. Feb. 26, 2015); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:15-cv-00078-RGA (D. Del. Jan. 30, 2015); Tris Pharma, Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00068-GMS (D. Del. Feb. 12, 2015); Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc., 1:14-cv-01573-RGA (D. Del. Jan. 26, 2015); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:14-cv-01494-RGA (D. Del. Jan. 16, 2015).
- 14. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, inter alia, Par Pharmaceutical, Inc. has previously availed itself of the rights, benefits, and privileges of this Court by asserting claims in prior Delaware actions, see, e.g., Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc., 1:18-cv-00823-VAC-CJB (D. Del. May 31, 2018); Par Pharmaceutical, Inc. et al. v. Hospira, Inc., 1:17-cv-00944-JFB-SRF (D. Del. July 13, 2017); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:15-cv-01050-RGA (D. Del. Dec. 4, 2015); Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc.,

- 1:15- cv-01049-LPS (D. Del. Dec. 7, 2015); Actavis Laboratories UT, Inc. v. Par Pharmaceutical, Inc., 1:15- cv-00886-LPS (D. Del. Dec. 1, 2015); Par Pharmaceutical, Inc. et al. v. Breckenridge Pharmaceutical, Inc., 1:15-cv-01039-SLR (D. Del. Nov. 11, 2015); Acorda Therapeutics, Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00824-LPS (D. Del. Oct. 7, 2015); Ferring Pharmaceuticals Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00173-RGA (D. Del. Mar. 13, 2015); Cosmo Technologies Ltd. v. Par Pharmaceutical, Inc., 1:15-cv-00116-LPS (D. Del. Feb. 26, 2015); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:15-cv-00078-RGA (D. Del. Jan. 30, 2015); Tris Pharma, Inc. v. Par Pharmaceutical, Inc., 1:15-cv-00068-GMS (D. Del. Feb. 12, 2015); Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc., 1:14-cv-01573-RGA (D. Del. Jan. 26, 2015); Novartis Pharmaceuticals Corp. v. Par Pharmaceuticals Corp. v. Par Pharmaceuticals Inc., 1:14-cv-01573-RGA (D. Del. Jan. 26, 2015); Novartis Pharmaceuticals Corp. v. Par Pharmaceutical, Inc., 1:14-cv-01494-RGA (D. Del. Jan. 16, 2015).
- 15. This Court also has personal jurisdiction over Par Pharmaceutical, Inc. because, *inter alia*, Par Pharmaceutical, Inc. has committed, encouraged, aided, abetted, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2)(A) that has led and/or will lead to foreseeable harm and injury to Plaintiff, a Delaware corporation.
- 16. Upon information and belief, if ANDA No. 205742 is approved, Par Pharmaceutical Inc.'s generic version of glycerol phenylbutyrate oral liquid, 1.1 gm/ml ("Par Product") will, *inter alia*, be marketed and distributed by Defendants in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.
- 17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

18. Venue is also proper in this judicial district over Defendants, because, *inter alia*, Endo International PLC's Form 10-K for the Year Ended December 31, 2017, Exhibit 21.1 identifies 19 entities incorporated in Delaware, six of which are Par entities. Notably, Par Pharmaceutical Companies, Inc. is incorporated under the laws of the State of Delaware and therefore resides in the State of Delaware for the purposes of venue under 28 U.S.C. § 1400(b).

## U.S. PATENT NO. 8,642,012

- 1. On February 4, 2014, the U.S. Patent and Trademark Office duly and legally issued the '012 patent entitled "Methods of Treatment Using Ammonia-Scavenging Drugs." At the time of its issue, the '012 patent was assigned to Hyperion Therapeutics Inc., which later changed its name to Horizon Therapeutics, Inc., and then to Horizon Therapeutics, LLC.
- 2. Horizon Therapeutics, LLC is currently the sole assignee and owner of all right, title and interest in and to the '012 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder.
  - 3. As owner of the '012 patent, Horizon is authorized to enforce the '012 patent.

### **RAVICTI®**

- 4. Horizon Therapeutics, LLC is the owner of FDA-approved New Drug Application No. 203284 ("the RAVICTI® NDA") for glycerol phenylbutyrate oral liquid 1.1gm/ml, which is sold in the United States under the trademark RAVICTI®.
- 5. RAVICTI® is currently approved by the FDA for use as a nitrogen-binding agent for chronic management of adult and pediatric patients  $\geq 2$  years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.
  - 6. The use of RAVICTI® is covered by the claims of the '012 patent.

- 7. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the '012 patent is listed in the FDA publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations," ("the Orange Book") for the RAVICTI® NDA.
- 8. The '012 patent qualifies for listing in the Orange Book in connection with NDA No. 203284 because the patent claims an approved method of use of RAVICTI®.

### **BACKGROUND FACTS**

- 9. Upon information and belief, Defendants have included in ANDA No. 205742 a "paragraph IV" certification seeking approval from the FDA to engage in the commercial manufacture, use, or sale of the Par Product before the expiration of the '012 patent. And upon information and belief, upon approval of ANDA No. 205742, Defendants will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of the Par Product.
- 10. Upon information and belief, Defendants' proposed labeling for the Par Product copies the FDA-approved label for RAVICTI®. Upon information and belief, Defendants intend, conditioned upon FDA approval of ANDA No. 205742, to market the Par Product for the indication included in the approved label for RAVICTI®. Upon information and belief, Defendants also intend for medical practitioners and/or physicians to prescribe, and for patients to use, the Par Product in accordance with, and as directed by, Defendants' proposed labeling for the Par Product.
- 19. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a] detailed

statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

- 20. Hyperion Therapeutics, Inc., a partial predecessor company to Horizon, received from Par Pharmaceutical, Inc. a letter, dated March 12, 2014, stating that Par Pharmaceutical, Inc. included a certification in the Par ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV Certification"), that the '012 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the Par Product.
- 21. On April 23, 2014, suit was filed in the Eastern District of Texas, Marshall Division, by Hyperion Therapeutics, Inc. against Par Pharmaceutical, Inc., alleging infringement of the '012 patent. In response to the complaint, Par filed a motion to dismiss the complaint, asserting lack of personal jurisdiction, or in the alternative to transfer the case to New York. That motion remains on the docket, and Par has not filed an answer to the complaint. Par also has not filed any Summary Judgment motions.
- 22. On April 29, 2015, Par Pharmaceutical, Inc. petitioned the U.S. Patent Trial and Appeal Board ("PTAB") to institute an *inter partes* review ("IPR") of the validity of all claims of the '012 patent. The IPR was instituted and Par Pharmaceutical, Inc. moved the District Court for the Eastern District of Texas to stay the litigation. That motion to stay was granted on December 14, 2015.

- 23. On November 3, 2016, the PTAB issued a Final Written Decision determining that Par had not proven by a preponderance of the evidence that the claims of the '012 patent were unpatentable. *See Par Pharm., Inc. v. Horizon Therapeutics, LLC*, IPR2015-01117, Paper 53 (P.T.A.B. Nov. 3, 2016). Par subsequently filed an appeal of the PTAB Final Written Decision to the Court of Appeals for the Federal Circuit, and on March 30, 2017, the District Court, at Par Pharmaceutical, Inc.'s request, granted a continuation of the stay of the litigation until after decision of the appeal by the Federal Circuit. *See* Order, *Hyperion Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, 2:14-cv-00384-JRG-RSP, D.I. 199 (E.D. Tex. Mar. 30, 2017).
- 24. On June 7, 2018 the Federal Circuit heard oral argument and on June 18, 2018, issued a Rule 36 judgment affirming PTAB's Final Written Opinion. *See Par Pharm., Inc. v. Horizon Therapeutics, LLC*, No. 2017-1451, 727 F. App'x 688 (Fed. Cir. 2018).
  - 25. The Federal Circuit issued its mandate on July 25, 2018.
- 26. On August 9, 2018, Horizon submitted to the District Court for the Eastern District of Texas, a Rule 41(a) Notice of Voluntary Dismissal Without Prejudice of the litigation filed against Par Pharmaceutical, Inc.

# **CLAIM FOR RELIEF** (Infringement of the '012 Patent)

- 27. Plaintiff repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.
- 28. Upon information and belief, Par Pharmaceutical Companies, Inc. actively directed, controlled, and/or worked in concert with Par Pharmaceutical, Inc. to prepare, submit, and file ANDA No. 205742, and to include in ANDA No. 205742 a paragraph IV certification to the '012 patent.

- 29. Upon information and belief, Par Pharmaceutical Companies, Inc. will actively direct, control, and/or work in concert with Par Pharmaceutical, Inc. to commercially manufacture, use, sell, offer for sale, and/or import the Par Product.
- 30. Upon information and belief, Par Pharmaceutical Companies, Inc. is jointly and severally liable for Par Pharmaceutical, Inc.'s infringement of one or more claims of the '012 patent.
- 31. Upon information and belief, Defendants have submitted ANDA No. 205742 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Par Product—the methods of use of which are claimed in the '012 patent—before the expiration of the '012 patent.
- 32. Upon information and belief, Defendants included in ANDA No. 205742 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of the Par Product before the expiration of the '012 patent.
- 33. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Par Product upon, or in anticipation of, FDA approval.
- 34. The submission of ANDA No. 205742 and including in ANDA No. 205742 a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Par Product before the expiration of the '012 patent was an act of infringement by Defendants of one or more claims of the '012 patent under 35 U.S.C. § 271(e)(2)(A).
- 35. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Par Product would indirectly

infringe one or more claims of the '012 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

- 36. Upon information and belief, the sale or offer for sale of the Par Product by Defendants would induce and/or contribute to third-party infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).
- 37. Defendants knew of the existence of the '012 patent, as evidenced by Defendants' including in ANDA No. 205742 a paragraph IV certification specifically referencing the '012 patent.
- 38. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States the Par Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will knowingly encourage, advise, instruct, urge, aid, and otherwise induce third parties (*e.g.*, wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to use products in a manner that infringes the claims of the '012 patent. Upon information and belief, Defendants intend such infringement by third parties, as Defendants are in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Defendants know that their actions will induce acts that constitute direct infringement of claims of the '012 patent by, *e.g.*, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.
- 39. Upon information and belief, Defendants will include within the packaging of the Par Product, or will otherwise make available to prospective subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists upon FDA approval, a label, package insert, and/or medication guide that instructs and encourages subjects, patients, caretakers,

medical practitioners, physicians, and/or pharmacists to perform one or more of the methods claimed in the '012 patent.

- 40. Upon information and belief, the use of the Par Product by subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists according to the instructions included in the labeling, package insert, and/or medication guide will constitute an act of direct infringement of one or more of the methods claimed in the '012 patent.
- 41. Upon information and belief, through the labeling, package insert, and/or medication guide for the Par Product, Defendants will market the Par Product with the specific intent, and/or with the desire to actively encourage, advise, instruct, urge, aid, and otherwise induce infringement of the '012 patent. Upon information and belief, Defendants know that their conduct will induce acts that constitute infringement.
- 42. Upon information and belief, by offering for sale or selling within the United States or importing into the United States the Par Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Defendants will contribute to infringement of claims of the '012 patent by third parties because: (i) the Par Product constitutes a material part of the methods of treatment claimed in the '012 patent; (ii) Defendants know or should know that the Par Product will be made for uses that directly infringe the methods of treatment claimed in the '012 patent; and (iii) the Par Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.
- 43. Defendants' infringement of the '012 patent will cause Plaintiff to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Plaintiff has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '012 patent.

44. At least as of the date of the Notice Letter, Defendants were aware of the existence of the '012 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not infringe one or more valid claims of the '012 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 205742 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Par Product before the expiration of the '012 patent constitutes an act of infringement of the '012 patent by Defendants;
- B. A Judgment declaring that, pursuant to 35 U.S.C. §§ 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the Par Product before the expiration of the '012 patent would directly and indirectly infringe the '012 patent;
- C. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Par Product shall be no earlier than the expiry of the '012 patent, including any regulatory extensions;
- D. Injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) precluding Defendants from manufacturing, using, selling, offering to sell, or importing the Par Product prior to the date on which the '012 patent has expired, including any regulatory extensions;
- E. A Judgment awarding Plaintiff damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer for

sale, and/or import any product that is the subject of ANDA No. 205742 that infringes the '012 patent;

- F. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiff its attorneys' fees;
- G. A Judgment awarding Plaintiff its costs under Fed. R. Civ. P. 54(d) and 28 U.S.C § 1920; and
  - H. Such other and further relief as this Court may deem just and proper.

Date: August 10, 2018 BARNES & THORNBURG LLP

/s/ Chad S.C. Stover

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