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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD. Plaintiffs, v. PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., and TRANSCEPT PHARMACEUTICALS, INC., Defendants.	CIVIL ACTION NO._____ *Filed Electronically*

COMPLAINT

Plaintiff s Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), by their attorneys, for their Complaint against Defendants Purdue Pharmaceutical Products, L.P., Purdue Pharma L.P., and Transcept Pharmaceuticals, Inc. (collectively, "Defendants") as follows:

THE PARTIES

1. Dr. Reddy's Laboratories, Inc. ("DRLI") is a New Jersey corporation with its principal place of business at 107 College Road East, Princeton, NJ 08540.

2. Dr. Reddy's Laboratories, Ltd. ("DRLL") is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India. (The Defendants, DRLI and DRLL, hereinafter are collectively referred to as ("DRL")).

3. Upon information and belief, Purdue Pharmaceutical Products L.P. ("Purdue Pharmaceutical") is a limited partnership organized and existing under the laws of the State of Delaware, having a principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

4. Upon information and belief, Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901. (Purdue Pharmaceutical and Purdue Pharma may hereinafter be collectively referred to as "Purdue").

5. Upon information and belief, Transcept Pharmaceuticals, Inc. ("Transcept") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1003 W. Cutting Blvd., Suite #1000, Pt. Richmond, CA 94804.

NATURE OF THE ACTION

6. DRL seeks 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 No. 7,658,945 ("the '945 Patent"), attached hereto as Exhibit A, is not infringed by DRL.

JURSDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271e(5) .

8. This Court has personal jurisdiction over Purdue Pharmaceutical, Purdue Pharma, and Transcept because, upon information and belief, they conduct substantial business in, and have regular and systematic contacts with, this judicial district including, *inter alia*, soliciting business in and deriving substantial revenue from this judicial district. Moreover, Defendants have previously submitted to, and purposefully availed themselves of, the jurisdiction of this judicial district by filing civil actions in this Court. *See, e.g., Purdue Pharmaceutical Products, L.P., Purdue Pharma L.P., and Transcept Pharmaceuticals, Inc. v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.*, Civ. No. 2:13-cv-02067-JLL-MAH.

9. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c) and 1400(b).

10. There is an actual and justiciable controversy between the parties as to infringement and enforceability of the '945 Patent.

BACKGROUND

11. The '945 Patent, entitled "Compositions for Delivering Hypnotic Agents Across the Oral Mucosa and Methods of Use Thereof," issued on February 9, 2010.

12. On information and belief, Transcept is the assignee of the '945 Patent.

13. On information and belief, Purdue Pharmaceutical and Purdue Pharma are exclusive licensees of the '945 Patent.

14. On information and belief, Purdue Pharma holds approved New Drug Application ("NDA") No. 022328 for zolpidem tartrate sublingual tablets under Section 505(b) of the Federal

Food Drug and Cosmetic Act ("FFDCA").

15. The Hatch-Waxman Amendments to the FFDCA ask NDA holders to disclose the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

16. On request from an NDA holder, the FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the "Orange Book." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are purely "ministerial." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1677 & n.2 (2012); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

17. On information and belief, Purdue Pharmaceutical, Purdue Pharma, and/or Transcept caused the '945 Patent to be listed in the Orange Book as a patent that claims the drug and/or claims a method of using such a drug for which Purdue Pharma submitted NDA No. 022328.

18. DRL filed ANDA No. 204503 to obtain FDA approval to engage in the commercial manufacture, use, and sale of zolpidem tartrate sublingual tablets in the 1.75 mg and 3.5 mg dosage strengths.

19. DRL's ANDA No. 204503 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '945 Patent is unenforceable, invalid and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in ANDA No. 204503.

20. The first drug company that files an ANDA containing a paragraph IV certification

is entitled to a 180-day period of generic marketing exclusivity before the FDA may approve any later paragraph IV ANDA based on the same NDA. 21 U.S.C. §§ 355(j)(5)(B)(iv).

21. The 180-day exclusivity period is triggered by the first ANDA filer's entry into the market. However, the first ANDA filer's 180-day exclusivity period can be forfeited under certain circumstances. For instance, if a later ANDA-filer obtains a final judgment that each of the listed drug's Orange Book patents are not infringed and/or are invalid, the first ANDA filer must market its product within 75 days of the later ANDA filer's judgment, or forfeit its period of exclusivity. 21 U.S.C. §§ 355(j)(5)(D)(i)(I).

22. DRL was not the first generic drug manufacturer to file an ANDA directed to zolpidem tartrate sublingual tablets in the 1.75 mg and 3.5 mg dosage strengths.

23. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) on February 19, 2013, DRL sent Purdue Pharma and Transcept notice of DRL's Paragraph IV certification with ANDA No. 204503 ("DRL's Notice Letter").

24. DRL's Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 204503 to each Defendant so that each could determine whether DRL's generic products would infringe any valid claim of the Orange Book-listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

25. DRL's Notice Letter initiated a 45-day statutory period during which Defendants had the opportunity to file an action for patent infringement.

26. The Hatch-Waxman Amendments to the FFDCA authorize an ANDA filer to initiate a declaratory judgment action with respect to Orange Book listed patents that the patent holder does not assert within 45 days of receipt of the ANDA filer's Paragraph IV notice letter. 21 U.S.C. § 355(j)(5)(C).

27. Defendants did not file an action against DRL for infringement of the '945 Patent within the 45-day statutory period, or at any time.

28. Rather, on or about April 19, 2013, Defendants tendered a covenant "not to sue [DRL] under any patent claim of" the '945 Patent in connection with DRL's ANDA seeking approval to manufacture, use and sell a generic version of Intermezzo®. Defendants' covenant does not contain any language suggesting that the '945 Patent is invalid or not infringed by DRL. In fact, the covenant specifically states that it "does not . . . constitute an admission by [Purdue and/or Transept] . . . as to the scope or interpretation of, the infringement of, the validity of, or the enforceability of, any patent (including but not limited to [the '945 Patent])."

29. Notwithstanding the covenant not to sue, the '945 Patent is an impediment to DRL's entry into the market. As a subsequent ANDA filer, DRL's ANDA for zolpidem tartrate sublingual tablets in the 1.75 mg and 3.5 mg dosage strengths cannot be approved by the FDA until the first ANDA filer's 180-day exclusivity period is either forfeited or runs out.

30. One of the ways that DRL may trigger the first ANDA filer's exclusivity period so as to precipitate its own entry into the market is by obtaining a final favorable judgment in all Orange Book-listed patents in connection with NDA No. 022328, including the '945 Patent.

31. Accordingly, the tendering of a covenant not to sue does not negate jurisdiction over a Hatch Waxman declaratory judgment action because "even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs.*, 527 F.3d 1278, 1296-97 (Fed. Cir. 2008) (citation omitted).

32. This District Court previously held that the Defendants' grant of a covenant not to

sue under the '945 Patent did not negate jurisdiction over a Hatch Waxman declaratory judgment action. *See Purdue Pharmaceutical Products, L.P. et al. v. Actavis Elizabeth, LLC et al.*, Civ. No. 2:12-cv-05311-JLL-JAD (D.N.J.) (Apr. 9, 2014), Dkt. 152 ("Indeed, the binding principles the Federal Circuit set forth in *Dey* and *Caraco* compel this Court to conclude that Plaintiffs' covenant not to sue TWi on the '945 and '628 patents does not moot TWi's counterclaims seeking declaratory judgment that these patents are not infringed.") .

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '945 PATENT

33. DRL incorporates by reference the answers to the allegations set forth in paragraphs 1 to 32 above by reference as if fully set forth herein.

34. This claim arises 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 and 2202, and seeks a declaration that no claim of the '945 Patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of DRL's ANDA product.

35. The submission of ANDA No. 204503 does not infringe any claim of the '945 Patent.

36. The manufacture, use, offering for sale, or importation of the zolpidem tartrate sublingual tablets that are the subject of ANDA No. 204503 will not infringe, directly or indirectly, any claim of the '945 Patent.

37. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the zolpidem tartrate sublingual tablets that are the subject of ANDA No. 204503 will infringe the '945 Patent.

38. DRL is entitled to a judicial declaration that it has not infringed and does not

infringe directly, by inducement, or by contribution of any claim of the '628 Patent.

DRL'S PRAYER FOR RELIEF

WHEREFORE, DRL prays that the Court enter judgment in its favor and against Defendants as follows:

a. Declaring that the filing of DRL'S ANDA No. 204503 has not infringed, and does not infringe, any claim of the '945 Patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of DRL's products that are the subject of ANDA No. 204503 do not, and will not, infringe any claim of the '945 Patent;

c. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding DRL its costs and attorneys' fees in this action; and

d. Awarding such other and further relief as this Court deems just and proper.

Dated: May 20, 2014

By: /s/ Harry D. McEnroe

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Dr. Reddy's Laboratories, Ltd.

NOTICE OF OTHER ACTION PURSUANT TO L. CIV. R. 11.2 AND L. CIV. R. 40.1

Pursuant to L. Civ. R. 11.2 and L. Civ. R. 40.1(c) , counsel certifies that a separate ANDA action, *Purdue Pharmaceutical Products, L.P. et al. v. Actavis Elizabeth, LLC et al.*, Civ. No. 2:12-cv-05311-JLL-JAD (D.N.J.), also involving zolpidem tartrate sublingual tablets, is presently pending before this Court and assigned to Judges Linares and Dickson.

Counsel states that infringement of the '945 Patent is at issue in *Purdue Pharmaceutical Products, L.P. et al. v. Actavis Elizabeth, LLC et al.*, Civ. No. 2:12-cv-05311-JLL-JAD (D.N.J.), but as to a different ANDA and product as compared to this action.

Dated: May 20, 2014

By: /s/ Harry D. McEnroe
Harry D. McEnroe, Esq.