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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PFIZER INC., PFIZER LIMITED, and
PFIZER IRELAND PHARMACEUTICALS,

Plaintiffs,

v.

TORRENT PHARMACEUTICALS
LIMITED and TORRENT PHARMA INC.

Defendants.

Civil Action No. _____

Document electronically filed.

COMPLAINT FOR PATENT INFRINGEMENT

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively “Pfizer” or “Plaintiffs”), by their attorneys, for their Complaint against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (collectively, “Torrent” or “Defendants”), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Torrent for patent infringement of United States Patent No. 6,469,012 (the "'012 patent"). This action arises out of Torrent Pharmaceuticals Limited's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's revolutionary oral treatment for erectile dysfunction, Viagra[®], prior to the expiration of the '012 patent owned by Pfizer.

THE PARTIES

2. Pfizer Inc. is a corporation organized under the laws of the State of Delaware and has its principal place of business located at 235 East 42nd Street, New York, New York. Pfizer invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

3. Pfizer Limited is a corporation organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent, England.

4. Pfizer Ireland Pharmaceuticals is a private unlimited liability company, incorporated in Ireland, having its registered office at Operations Support Group, Ringaskiddy, Co Cork, Ireland.

5. Pfizer has all right, title, and interest in the '012 patent and the right to sue for infringement thereof.

6. Upon information and belief, defendant Torrent Pharmaceuticals Limited ("Torrent Ltd.") is a corporation organized and existing under the laws of India, having its principal place of business at Torrent House, Off Ashram Road, Ahmedabad, 380009, Gujarat, India.

7. Upon information and belief, defendant Torrent Pharma Inc. (“Torrent Inc.”) is a corporation organized and existing under the laws of Delaware, having its corporate headquarters at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.

8. Upon information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

Torrent Ltd.

11. Torrent Ltd. is subject to personal jurisdiction in New Jersey due, among other things, to Torrent Ltd.’s systematic, purposeful, and continuous contacts in this district. Upon information and belief, Torrent Ltd., directly or through its wholly-owned subsidiaries (primarily Torrent Inc.), has purposefully availed itself of this forum by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Upon information and belief, this judicial district is a likely destination of Torrent Ltd. generic products, either directly or through its wholly-owned subsidiaries (primarily Torrent Inc.).

12. On multiple previous occasions, Torrent Ltd. has submitted to the jurisdiction of this Court and has availed itself of this Court by asserting counterclaims in civil actions initiated in this jurisdiction.

Torrent Inc.

13. Torrent Inc. is subject to personal jurisdiction in New Jersey due, among other things, to Torrent Inc.'s systematic, purposeful, and continuous contacts in this district. Upon information and belief, Torrent Inc. has purposefully availed itself of this forum by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

14. Upon information and belief, Torrent Ltd. and Torrent Inc. operate in the United States as a single, integrated business. Both Torrent Ltd. and Torrent Inc. share a website, www.torrentpharma.com. The website refers to Torrent Inc. as a "fully owned" subsidiary of Torrent Ltd. (http://www.torrentpharma.com/int_usa.php) and Torrent has previously admitted that Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd. (*Pfizer Inc., et al. v. Torrent Pharm. Ltd., et al.*, 11-cv-04297 (D.N.J.) (Doc. 17 ¶ 8)). Torrent's website states that Torrent Inc.'s goal is "[t]o serve the large and growing need for cost-effective high quality medicines in the USA." (http://www.torrentpharma.com/int_usa.php). Torrent's website further states that "Torrent Pharmaceuticals Limited began spreading its wings beyond India with thrust on becoming a global player in the international market" and that "Torrent Pharma's international business is segregated into five different zones," including the United States of America, for which Torrent Inc. is identified as a contact for "general inquiries," "sales" and "business development." (http://www.torrentpharma.com/int_operational.php; http://www.torrentpharma.com/int_usa.php).

15. Torrent Ltd.'s 2012-13 annual report states that Torrent has forty-three (43) ANDA approvals, that Torrent received six (6) ANDA approvals in 2012-13, and that Torrent "plans to launch 5-6 products [in the US] every year." (p. 25). Torrent Ltd.'s 2012-13 annual

report also states that “[t]he US business is expected to contribute to the growth of international business in a significant way.” (p. 25). Torrent Ltd’s 2012-13 annual report states that in the US for the 2012-13 financial year, Torrent had \$64 million in revenue, a 64% increase in revenue from the previous year. (p. 24).

16. Torrent Inc. has previously admitted that it sells generic drug products in New Jersey and throughout the United States. (*Pfizer Inc., et al. v. Torrent Pharm. Ltd., et al.*, 11-cv-04279 (D.N.J.) (Doc. 17 ¶ 7)).

17. Upon information and belief, Torrent Inc. maintains its principal place of business in Basking Ridge, New Jersey.

18. On multiple previous occasions, Torrent Inc. has submitted to the jurisdiction of this Court and has availed itself of this Court by asserting counterclaims in civil actions initiated in this jurisdiction.

BACKGROUND

The '012 Patent

19. On October 22, 2002, the United States Patent and Trademark Office (“USPTO”) issued the '012 patent, titled “Pyrazolopyrimidinones for the Treatment of Impotence,” based on an application filed by Dr. Peter Ellis and Dr. Nicholas Kenneth Terrett. Drs. Ellis and Terrett duly and legally assigned the '012 patent to Pfizer Inc. The USPTO, during the course of reexamination proceedings, has confirmed the patentability of claims 1–23, 25, and 26 of the '012 patent over numerous prior art references. The USPTO found claim 24 not patentable. Pfizer is only asserting claims 25 and 26 of the '012 patent in this case. In *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011), the Eastern District of Virginia found claims 25 and 26 of the '012 patent valid, enforceable and infringed. A copy of the '012 patent is attached hereto as Exhibit A.

20. Pfizer Limited is the owner of a beneficial interest in the '012 patent.

21. Pfizer Ireland Pharmaceuticals is an exclusive licensee under the '012 patent.

Orange Book Listing for Viagra®

22. Pfizer holds an approved New Drug Application for treating erectile dysfunction with sildenafil citrate which Pfizer sells under the registered name Viagra®. Treatment of erectile dysfunction with Viagra® is covered by the '012 patent. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '012 patent is listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for treatment of erectile dysfunction.

23. The Orange Book lists the '012 patent's expiration date as October 22, 2019. The Orange Book lists pediatric exclusivity for the '012 patent as expiring on April 22, 2020.

Torrent's ANDA

24. By letter dated January 31, 2014 (the “Torrent Notice Letter”), Torrent Ltd. notified Pfizer Inc. and Pfizer Ireland Pharmaceuticals that it had filed ANDA No. 091448 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell, prior to the expiration of the '012 patent, 25 mg, 50 mg, and 100 mg tablets of sildenafil citrate, generic copies of Viagra®, for treatment of erectile dysfunction (“Torrent ANDA Products”).

25. The Torrent Notice Letter states that ANDA No. 091448 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that “the '012 patent is not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale” of the Torrent ANDA Products prior to the date of the expiration of the '012 patent.

26. The Torrent Notice Letter lists the applicant for ANDA No. 091448 as Torrent Ltd., whose place of business is in India. The Torrent Notice Letter fails to list the name and

address of an agent in the United States authorized to accept service of process for the applicant. Accordingly, the Torrent Notice Letter fails to comply with 21 C.F.R. § 314.95(c)(7).

27. Upon information and belief, Torrent Ltd. and Torrent Inc. collaborated and acted in concert in the decision to file and the filing of ANDA No. 091448.

28. Upon information and belief, Torrent Inc. will distribute the Torrent ANDA Products in the United States.

COUNT I
(Patent Infringement by Torrent)

29. The allegations of paragraphs 1-28 above are repeated and re-alleged as if set forth fully herein.

30. Pursuant to 35 U.S.C. § 271(e)(2)(A), Torrent Ltd.'s filing of ANDA No. 091448 seeking approval to market Torrent's ANDA Products is an act of infringement of each of claims 25 and 26 of the '012 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 091448 be a date which is not earlier than the expiration date of the '012 patent.

31. Torrent had knowledge of the '012 patent when it submitted ANDA No. 091448 to the FDA.

32. Upon information and belief, Torrent Ltd.'s actions relating to Torrent Ltd.'s ANDA No. 091448 were done with the cooperation, participation, assistance, and for the benefit of, Torrent Inc. and Torrent Ltd.

33. Upon information and belief, Torrent intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Torrent's ANDA Products with the proposed labeling. The use of Torrent's ANDA Products in accordance with and as directed by Torrent's proposed labeling would infringe each of claims 25 and 26 of the '012 patent.

34. Upon information and belief, Torrent intends to actively induce infringement of one or more claims of the '012 patent.

35. Upon information and belief, Torrent knows that the Torrent ANDA Products and the proposed labeling are especially made or adapted for use in infringing each of claims 25 and 26 of the '012 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

36. Upon information and belief, Torrent intends to contribute to the infringement of each of claims 25 and 26 of the '012 patent.

37. The foregoing actions by Torrent constitute and/or would constitute infringement of each of claims 25 and 26 of the '012 patent, active inducement of infringement of each of claims 25 and 26 of the '012 patent, and/or contribution to the infringement by others of each of claims 25 and 26 of the '012 patent.

38. Pfizer will be substantially and irreparably harmed if Torrent is not enjoined from infringing the '012 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

- A. A judgment that Torrent Ltd.'s submission of ANDA No. 091448 was an act of infringement and that Torrent's making, using, offering to sell, selling or importing the Torrent ANDA Products prior to the expiration of the '012 patent will infringe, actively induce infringement and/or contribute to the infringement of the '012 patent;
- B. A judgment that the effective date of any FDA approval for Torrent to make, use offer for sale, sell, market, distribute, or import the Torrent ANDA Products be no earlier than the expiration of the '012 patent;

- C. A permanent injunction enjoining Torrent, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing the Torrent ANDA Products, and from inducing or contributing to any of the foregoing, prior to the expiration of the '012 patent;
- D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;
- E. An award of Pfizer's costs and expenses in this action;
- F. Such further and additional relief as this Court deems just and proper.

DATED: March 17, 2014

Respectfully submitted,

s/ David E. De Lorenzi

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