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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEXCEL PHARMA TECHNOLOGIES LTD., *Plaintiff,* v. TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC. *Defendants.*	Civil Action No. 16-04957-MLCLHG

AMENDED COMPLAINT

Dexcel Pharma Technologies Ltd. ("Dexcel") by its undersigned attorneys, for its Complaint against Defendants Takeda Pharmaceutical Company Limited, Takeda

Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda" or "Defendants") alleges as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 of the United States Code. Dexcel seeks a declaration of noninfringement of U.S. Patent No. 6,328,994 ("the '994 patent") ("the patent-in-suit").

THE PARTIES

2. Plaintiff Dexcel is a corporation organized and existing under the laws of Israel, having a principal place of business at 1 Dexcel Street Or-Akiva, Israel 3060000.

3. Upon information and belief, Defendant Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

4. Upon information and belief, Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

5. Upon information and belief, Defendant Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

6. Upon information and belief, Takeda consented to personal jurisdiction or venue in the District of New Jersey and purposefully availed itself of the jurisdiction in this district by filing suit in this Court in at least *Takeda Pharmaceutical Company, Ltd. et al. v. Wockhardt Bio AG, et al.,* No. 3:13-cv-06427; *Takeda Pharmaceutical Company, Ltd. et al. v. Sun Pharma Global FZE, et al.,* No. 3:14-cv-04616; *Takeda Pharmaceutical Company Ltd., et al. v.*

Aurobindo Pharma Ltd., et al., No. 3:15-cv-07635; *Takeda Pharmaceutical Company Ltd., et al. v. Lupin Limited, et al.,* No. 3:12-cv-07333; *Takeda Pharmaceutical Company Ltd., et al. v. Zydus Pharmaceuticals (USA) Inc., et al*., No. 3:10-cv-1723; and *Takeda Pharmaceutical Company Ltd., et al. v. Mylan Inc., et al.,* No. 3:11-cv-02506.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, Title 35 of the United States Code, with specific remedies sought based upon the laws authorizing actions for declaratory judgment in the courts of the United States, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because this action involves an actual controversy concerning Dexcel's alleged infringement of Takeda's '994 patent.

8. This Court has personal jurisdiction over Takeda by virtue of, *inter alia*, Takeda having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being "haled into court" in this judicial district, previously consenting to personal jurisdiction in this Court, and previously availing itself of the jurisdiction of this Court, including through repeated enforcement activities of the '994 patent against multiple other parties in at least *Takeda Pharmaceutical Company, Ltd. et al. v. Wockhardt Bio AG, et al.,* No. 3:13-cv-06427; *Takeda Pharmaceutical Company, Ltd. et al. v. Sun Pharma Global FZE, et al.,* No. 3:14-cv-04616; *Takeda Pharmaceutical Company Ltd., et al. v. Aurobindo Pharma Ltd., et al*., No. 3:15-cv-07635; *Takeda Pharmaceutical Company Ltd., et al. v. Lupin Limited, et al.,* No. 3:12-cv-07333; *Takeda Pharmaceutical Company Ltd., et al. v. Zydus Pharmaceuticals (USA)*

Inc., et al., No. 3:10-cv-1723; and *Takeda Pharmaceutical Company Ltd., et al. v. Mylan Inc., et al.,* No. 3:11-cv-02506.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because, upon information and belief, Takeda is subject to the court's personal jurisdiction with respect to this action as described above and thus is deemed to reside in this judicial district.

THE PATENT-IN-SUIT

10. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 patent, entitled "Orally Disintegrable Tablets." At the time of its issue, the '994 patent was assigned to Takeda Chemical Industries, Ltd., which later assigned the patent to Takeda Pharmaceutical Company Limited. Takeda Japan is the sole current assignee of the '994 patent, which discloses and claims, *inter alia*, an orally disintegrable tablet comprising lansoprazole. A true and correct copy of the '994 patent is attached hereto as Exhibit A.

FACTUAL BACKGROUND

11. Dexcel is the holder of the approved New Drug Application ("NDA") No. 208025 ("the Dexcel NDA"), under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), for lansoprazole delayed-release orally disintegrating tablets, 15 mg ("the Dexcel NDA product"). Dexcel's NDA product is the first lansoprazole delayed-release orally disintegrating tablets (15 mg) approved by the FDA for marketing over-the-counter ("OTC").

12. On June 7, 2016, Dexcel received a letter from the Food and Drug Administration ("FDA"), granting approval of NDA No. 208025.

13. On June 10, 2016, shortly after the FDA's publication of its approval of the Dexcel NDA, Dexcel received correspondence from counsel representing Takeda, requesting information concerning the FDA approval process for the Dexcel NDA. Takeda also sought information about the formulation of Dexcel's NDA product and a "detailed statement as to why Dexcel believes (if it does)" that its NDA product avoids infringement of Takeda's '994 patent. Takeda's June 10, 2016, correspondence requested a response from Dexcel by June 14, 2016, "[g]iven the urgency of this matter from Takeda's perspective."

14. Upon information and belief, Takeda America is a wholly-owned subsidiary of Takeda U.S.A., which is a wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Japan. Upon information and belief, based upon the Takeda corporate structure and the joint submission of the June 10, 2016 letter and subsequent correspondence on behalf of all defendants, Takeda U.S.A. and Takeda America are controlled by their parent, Takeda Japan, and all three entities have acted in concert as to the enforcement activities related to the patent-in-suit discussed below.

15. In two letters dated June 14 and 16, 2016, Dexcel promptly provided Takeda with information concerning the FDA's approval process for the Dexcel NDA, including sharing a copy of the June 7, 2016, FDA approval letter. Dexcel also provided Takeda with a description of its bases for non-infringement of the '994 patent. In its June 16, 2016, correspondence, Dexcel additionally offered to share limited confidential information relevant to these positions, provided an appropriate confidentiality agreement could be reached.

16. In correspondence dated June 22, 2016, Takeda indicated that it could not accept Dexcel's bases for non-infringement as stated, and requested Dexcel to send "a form of confidentiality agreement that Dexcel deems appropriate." On June 23, 2016, Dexcel provided a

proposed offer of confidential access ("OCA") agreement to Takeda to facilitate the provision of confidential Dexcel information relevant to its noninfringement positions, which included a 30-day period in which to consider whether to file suit against Dexcel after provision of relevant confidential Dexcel information.

17. Over a month later, in its July 29, 2016 correspondence, Takeda rejected Dexcel's proposed OCA but indicated a desire to engage in dialogue with Dexcel "in the hope of avoiding patent litigation, if possible." Takeda, in what appears to be an attempt to delay resolution of matters to the detriment of Dexcel, requested additional confidential Dexcel information irrelevant to Dexcel's stated noninfringement positions for the '994 patent together with a 90-day review period to allegedly "properly evaluate whether to file suit."

18. In correspondence dated August 3, 2016, Dexcel renewed its offer to provide relevant confidential information, sufficient to allow Takeda to conclude that the Dexcel NDA product does not infringe the patent-in-suit, under the OCA as originally presented. Dexcel additionally provided further description of the type of information that would be provided under the OCA.

19. In its August 3, 2016 correspondence, Dexcel requested Takeda to respond within a week, as to whether, in view of this additional information from Dexcel, Takeda would agree to proceed under the OCA as originally presented. As of the filing of this complaint, no response to Dexcel's August 3, 2016 correspondence has been received.

20. Upon information and belief, Takeda has previously engaged in a pattern of initiating lawsuits against other parties alleging infringement of the patent-in-suit, in which Takeda has ultimately not been successful in obtaining a judgment of infringement, including at least *Takeda Pharmaceutical Company Ltd., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*,

No. 3:10-cv-1723; *Takeda Pharmaceutical Company, Ltd. et al. v. Sun Pharma Global FZE, et al.,* No. 3:14-cv-04616; *Takeda Pharmaceutical Company Ltd., et al. v. Lupin Limited, et al.,* No. 3:12-cv-07333; and *Takeda Pharmaceutical Company Ltd., et al. v. Mylan Inc., et al.,* No. 3:11-cv-02506.

21. Upon information and belief, Takeda U.S.A. has previously alleged infringement of patents owned by that subsidiary against at least one other party that had filed an NDA under Section 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), with the goal of obtaining a temporary restraining order ("TRO") or preliminary injunction from the district court in order to prevent the launch of the Section 505(b)(2) NDA product upon FDA approval, including in at least *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp., et al.,* No. 14-cv-01268 (D. Del.).

22. Upon information and belief, Takeda U.S.A. was successful in obtaining injunctive relief via a TRO issued against the Section 505(b)(2) NDA holder, substantially delaying the launch of the product that was the subject of the already FDA-approved Section 505(b)(2) NDA. *See Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp., et al.*, No. 14-cv-01268 (D. Del.), at D.I. 5, 72 and 79.

23. Upon information and belief, the TRO obtained by Takeda U.S.A. was subsequently vacated by the Federal Circuit, and the District Court of Delaware ultimately found no infringement of Takeda U.S.A.'s patents. *See id.*, at D.I. 97 and 121.

24. Because Dexcel has already obtained FDA approval of its NDA product, the first lansoprazole delayed-release orally disintegrating tablets (15 mg) approved by the FDA for OTC marketing, substantial preparations, including the manufacture of commercial product, are already underway in anticipation of a launch during the first quarter of 2017. As such

preparations represent substantial financial investment, there is a strong likelihood that Takeda will seek to disrupt Dexcel's planned launch through a TRO or preliminary injunction, and thus cause serious financial hardship to Dexcel.

25. Takeda's series of correspondence with Dexcel, as detailed above, coupled with its repeated pattern of enforcement activities alleging infringement by third parties of the '994 patent against other parties in this jurisdiction, and its previous conduct of filing at least one lawsuit alleging infringement against a Section 505(b)(2) NDA holder in order to obtain a TRO or preliminary injunction to prevent the launch of the Section 505(b)(2) NDA product, creates a reasonable apprehension and substantial likelihood that Takeda will sue Dexcel for the alleged infringement of the '994 patent, in an attempt to disrupt Dexcel's plans for the launch of its FDA-approved NDA product.

COUNT I
DECLARATION OF NONINFRINGEMENT OF THE '994 PATENT

26. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-25 of this Complaint as if fully set forth herein.

27. Upon information and belief, Takeda Japan is the current record owner of the '994 patent.

28. The manufacture, use, offer to sell, importation, or sale of Dexcel's NDA product does not, and would not if marketed, infringe any valid or enforceable claim of the '994 patent, either directly or indirectly, and either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) and/or (c).

29. Dexcel requires a court decision of noninfringement of the '994 patent to prevent it from risking infringement liability of this patent if (and when) it begins marketing its Dexcel

NDA product before this patent expires. This harm can be alleviated through a declaration of patent certainty on noninfringement from this Court of the '994 patent.

30. Dexcel also requires a court decision of noninfringement of the '994 patent to avoid an intentionally delayed lawsuit initiated by Takeda just before the planned launch of the Dexcel NDA product in order to disrupt the launch to the detriment of Dexcel, in accordance with Takeda's demonstrated pattern of conduct against other alleged infringers. This harm can be alleviated through a declaration of patent certainty on noninfringement from this Court of the '994 patent.

31. Dexcel thus seeks a judicial declaration that Dexcel's lansoprazole delayed-release orally disintegrating tablets as described in NDA No. 208025 do not, and would not if marketed, infringe any valid and enforceable claim of the '994 patent.

32. There is an actual and substantial case or controversy as to the noninfringement of the '994 patent within the meaning of 28 U.S.C. § 2201 between Dexcel and Takeda, and this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The requested declaratory judgment will resolve the controversy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dexcel Pharma Technologies Ltd. prays for a judgment in its favor against Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. and respectfully requests the following relief:

A. A judgment declaring that the manufacture, use, sale, offer for sale and/or importation of Dexcel's lansoprazole delayed-release orally disintegrating tablets as

described in NDA No. 208025 do not, and would not if marketed, infringe any valid and enforceable claim of the '994 patent;

B. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: January 4, 2017

s/ Keith J. Miller

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff Dexcel Pharma Technologies Ltd. by its undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy, to the extent that it is directed to allegations of infringement of the '994 is the subject of the following pending actions, which involve different defendants and different Abbreviated New Drug Applications ("ANDAs"):

- *Takeda Pharmaceutical Company Ltd. et al. v. Wockhardt Bio AG, et al.,* No. 3:13-cv-06427 (D.N.J.);
- *Takeda Pharmaceutical Company Ltd. et al. v. Sun Pharma Global FZE, et al.,* No. 3:14-cv-04616 (D.N.J.);
- *Takeda Pharmaceutical Company Ltd., et al. v. Aurobindo Pharma Ltd., et al*., No. 3:15-cv-07635 (D.N.J.);
- *Takeda Pharmaceutical Company Ltd. et al. v. Teva Pharmaceuticals U.S.A., Inc., et al.,* No. 1:16-cv-00246 (D. Del.)

Respectfully submitted,

Dated: January 4, 2017

s/ Keith J. Miller

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