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

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	Civil Action No. _____ ***Electronically Filed***

COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for their Complaint against Defendant Teva Pharmaceuticals USA, Inc., hereby allege 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's submissions 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's SPRYCEL® (dasatinib) tablets prior to the expiration of United States Patent No. 7,491,725.

THE PARTIES

2. Plaintiff Bristol-Myers Squibb Company ("BMS") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

3. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b). On information and belief, Teva has a regular and established place of business in New Jersey, and because, on information and belief, Teva has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to BMS, which resides in this District, by preparing or assisting in preparing Teva's ANDA in New Jersey and/or with the intention of seeking to market ANDA No. 211094 (the "Teva ANDA") for Teva's 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg dasatinib tablets (the "Teva ANDA Products") nationwide, including within New Jersey.

6. On information and belief, Teva has been previously sued in this District and has not challenged venue. *See, e.g.*, *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, No. 19-cv-8758 (D.N.J.); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, No. 18-cv-14366 (D.N.J.); *Boehringer Ingelheim Pharma GMBH & Co., et al. v. Teva*

Pharmaceuticals USA, Inc., et al., No. 14-cv-7811 (MLC)(TJB) (D.N.J.); *Janssen Prods., L.P., et al. v . Teva Pharmaceuticals USA, Inc. et al.*, No. 13-cv-7576 (WHW)(CLW) (D.N.J.).

PERSONAL JURISDICTION OVER TEVA

7. Plaintiff realleges paragraphs 1-6 as if fully set forth herein.

8. On information and belief, Teva prepared and submitted the Teva ANDA for the Teva ANDA Products.

9. On information and belief, Teva develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this District.

10. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva has its principal place of business in this District. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100250184. On information and belief, Teva is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration Nos. 5000583 and 5003436. On information and belief, Teva purposefully has conducted and continues to conduct business in this District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva.

11. On information and belief, Teva is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of New Jersey, through its own actions and through the actions of its agents and subsidiaries. On information and belief, this District will be a destination for the generic drug product described in Teva's ANDA.

12. This Court has personal jurisdiction over Teva because, *inter alia*, Teva, on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute infringing ANDA Products to residents of this State upon approval of ANDA No. 211094, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State.

13. Teva specifically directed its notice letter to BMS's offices in Lawrence Township, NJ, in this District. Teva specifically directed BMS to direct its correspondence to Teva's office in Parsippany, NJ, also in this District.

14. On information and belief, Teva has previously been sued in this District and has not challenged personal jurisdiction. *See, e.g., Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, No. 19-cv-8758 (D.N.J.); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, No. 18-cv-14366 (D.N.J.); *Boehringer Ingelheim Pharma GMBH & Co., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-cv-7811 (MLC)(TJB) (D.N.J.); *Janssen Prods., L.P., et al. v . Teva Pharmaceuticals USA, Inc. et al.*, No. 13-cv-7576 (WHW)(CLW) (D.N.J.).

15. Teva has further availed themselves of the jurisdiction of this Court by previously initiating litigation in this District. *See, e.g., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. v. Sandoz Inc. et al.*, No. 17-cv-275 (FLW)(DEA) (D.N.J.); *Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. v. Dr. Reddy's Laboratories, Ltd.*, No. 17-cv-517 (FLW)(DEA) (D.N.J.); *Teva Neuroscience, Teva Pharmaceutical Industries Ltd., Teva Pharmaceutical USA,*

Inc., and Yeda Research and Development Co., Ltd. v. Dr. Reddy's Laboratories, Inc., et al., No. 14-cv-5672 (MAS)(TJB) (D.N.J.).

BACKGROUND

U.S. PATENT NO. 7,491,725

16. On February 17, 2009, the USPTO duly and legally issued United States Patent No. 7,491,725 ("the '725 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '725 patent is attached as Exhibit 1. The '725 patent is assigned to BMS.

SPRYCEL®

17. BMS is the holder of New Drug Application ("NDA") No. 021986 for dasatinib, for oral use, in 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg dosages, which is sold under the trade name SPRYCEL®.

18. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '725 patent is among the patents listed in the Orange Book with respect to SPRYCEL®.

19. The '725 patent covers the SPRYCEL® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '725 PATENT

20. Plaintiff realleges paragraphs 1-19 as if fully set forth herein.

21. On information and belief, Teva submitted the Teva ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Teva ANDA Products.

22. Teva has represented that the Teva ANDA refers to and relies upon the SPRYCEL® NDA, and contains data that, according to Teva, demonstrate the bioavailability or bioequivalence of the Teva ANDA Products to SPRYCEL®.

23. Plaintiff received a letter from Teva on or about February 14, 2020 stating that Teva had included a certification in the Teva ANDA that, *inter alia*, certain claims of the '725 patent are either invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Teva ANDA Products (the "Teva Paragraph IV Certification"). Teva intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Teva ANDA Products prior to the expiration of the '725 patent.

24. On information and belief, Teva does not deny that the Teva ANDA Products will satisfy all limitations of certain claims of the '725 patent, and in the Teva Paragraph IV Certification, Teva did not deny that the Teva ANDA Products will satisfy all limitations of certain claims of the '725 patent.

25. Teva has infringed at least one claim of the '725 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Teva ANDA, by which Teva seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Teva ANDA Products prior to the expiration of the '725 patent.

26. Teva has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Teva ANDA Products in the event that the FDA approves the Teva ANDA. Accordingly, an actual and immediate controversy exists regarding Teva's infringement of the '725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

27. Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Products in the United States or importation of the Teva ANDA Products into the United States during the term

of the ’725 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the ’725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

28. On information and belief, the Teva ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’725 patent either literally or under the doctrine of equivalents.

29. On information and belief, the use of the Teva ANDA Products constitutes a material part of at least one of the claims of the ’725 patent; Teva knows that the Teva ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’725 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

30. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Products would contributorily infringe at least one of the claims of the ’725 patent, either literally or under the doctrine of equivalents.

31. On information and belief, Teva had knowledge of the ’725 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’725 patent, either literally or under the doctrine of equivalents.

32. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Products by Teva would actively induce infringement of at least one of the claims of the ’725 patent, either literally or under the doctrine of equivalents.

33. Plaintiff will be substantially and irreparably harmed if Teva is not enjoined from infringing the ’725 patent.

34. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS’s reasonable attorney fees.

35. On information and belief, based on the information provided by Teva to date, the factual contentions in paragraph 21-34 have evidentiary support. On information and belief, the factual contentions in paragraphs 21-34 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Teva and for the following relief:

a. A Judgment be entered that Teva has infringed at least one claim of the ’725 patent by submitting the Teva ANDA;

b. A Judgment be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys’ fees pursuant to 35 U.S.C. § 285;

c. That Teva, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the ’725 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the ’725 patent or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva’s ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. § 355(j)) shall not be earlier than the expiration date of the '725 patent, including any extensions;

e. That Plaintiff be awarded monetary relief if Teva commercially uses, offers to sell, or sells its respective proposed generic versions of SPRYCEL® or any other product that infringes or induces or contributes to the infringement of the '725 patent, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Plaintiff with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

Dated: March 25, 2020

Respectfully submitted,

s/Christopher DeCoro

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action. This action alleges infringement of a patent at issue in the following matter: *Bristol-Myers Squibb Co. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:19-cv-18686-MAS-TJB. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: March 25, 2020

s/Christopher DeCoro

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: March 25, 2020

s/Christopher DeCoro