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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. EUGIA PHARMA SPECIALTIES, LTD., Defendant.	Civil Action No. 21-20409 ***Electronically Filed***

COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for their Complaint against Defendant, Eugia Pharma Specialties, Ltd. hereby alleges 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 Nos. 7,491,725 and/or 8,680,103.

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 Eugia Pharma Specialties, Ltd. ("Eugia") is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad - 500038, Telangana, India. On information and belief, Eugia 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.

4. On information and belief, Eugia is listed as the applicant of ANDA No. 216547 (the "Eugia ANDA") and has sent notice to BMS stating that Eugia included a certification in the Eugia ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

5. On information and belief, Eugia prepared and submitted the Eugia ANDA for Eugia's 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg dasatinib tablets ("Eugia ANDA Products").

6. On information and belief, Eugia prepared and submitted the Eugia ANDA for the Eugia ANDA Products, which was done for the direct benefit of Eugia.

7. On information and belief, following FDA approval of the Eugia ANDA, Eugia will manufacture, supply, market, and sell the approved generic product throughout the United States, including New Jersey.

JURISDICTION AND VENUE

8. 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).

9. Venue is proper in this Court as to Eugia because, among other things, Eugia is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c); *see also* 28 U.S.C. § 1400(b).

10. Venue is further proper in this Court as to Eugia because, among other things, Eugia has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to BMS by filing the Eugia ANDA with the intention of seeking to market the Eugia ANDA Products nationwide, including within New Jersey. 28 U.S.C. § 1400(b).

11. Moreover, Eugia has not contested venue in New Jersey in other cases arising out of the filing of an ANDA. *See, e.g.*, *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 20 Civ. 315 (D.N.J. Mar. 27, 2020), ECF No. 14; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 19 Civ. 5799 (D.N.J July 1, 2019), ECF No. 15; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 19 Civ. 143 (D.N.J. Jan. 18, 2019), ECF No. 10; *Boehringer Ingelheim Pharma, Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 17 Civ. 7887 (D.N.J. Dec. 11, 2017), ECF No. 9; *Celgene Corp. v. Hetero Labs Ltd.*, No. 17 Civ. 3387 (D.N.J. Sept. 15, 2017), ECF No. 79.

PERSONAL JURISDICTION OVER EUGIA

12. Plaintiff realleges paragraphs 1-11 as if fully set forth herein.

13. This Court has personal jurisdiction over Eugia because, *inter alia*, Eugia, 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 the Eugia ANDA Products to residents of this State upon approval of the Eugia ANDA, 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.

14. This Court has personal jurisdiction over Eugia because, *inter alia*, Eugia, itself, and through its agents purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Eugia itself, and through its agents, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to BMS's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

15. On information and belief, Eugia has not contested jurisdiction in New Jersey in other cases arising out of the filing of an ANDA, and has filed counterclaims in some cases. *See, e.g.*, *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 20 Civ. 315 (D.N.J. Mar. 27, 2020), ECF No. 14; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 19 Civ. 5799 (D.N.J July 1, 2019), ECF No. 15; *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 19 Civ. 143 (D.N.J. Jan. 18, 2019), ECF No. 10; *Boehringer Ingelheim Pharma, Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 17 Civ. 7887 (D.N.J. Dec. 11, 2017), ECF No. 9; *Celgene Corp. v. Hetero Labs Ltd.*, No. 17 Civ. 3387 (D.N.J. Sept. 15, 2017), ECF No. 79.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Eugia, this Court may exercise jurisdiction over Eugia pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Eugia would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Eugia has sufficient contacts with the United

States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Eugia satisfies due process, and is consistent with the United States Constitution and Laws.

BACKGROUND

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

17. On February 17, 2009, the United States Patent & Trademark Office ("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.

U.S. PATENT NO. 8,680,103

18. On March 25, 2014, the USPTO duly and legally issued United States Patent No. 8,680,103 ("the '103 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 '103 patent is attached as Exhibit 2. The '103 patent is assigned to BMS.

SPRYCEL®

19. BMS is the holder of New Drug Application ("NDA") No. 029186 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®.

20. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '725 and '103 patents are among the patents listed in the Orange Book with respect to SPRYCEL®.

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