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

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. BIOCON PHARMA LIMITED, Defendant.	)	Civil Action No. _____ *Electronically Filed*

COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for its Complaint against Defendant, Biocon Pharma Limited, 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 submission 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 Biocon Pharma Limited ("Biocon") is a corporation organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India.

4. On information and belief, Biocon 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.

5. On information and belief, Biocon is listed as the applicant of ANDA No. 217217 (the "Biocon ANDA") and has sent notice to BMS stating that Biocon included a certification in the Biocon ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

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

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

8. On information and belief, following FDA approval of the Biocon ANDA, Biocon, through its own actions and through the actions of its partners, agents, and subsidiaries, will manufacture, supply, market, and sell the approved generic product throughout the United States, including New Jersey.

JURISDICTION AND VENUE

9. 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).

10. Venue is proper in this Court because, among other things, Biocon 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). Moreover, Biocon has litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and has not contested venue in those cases. *See, e.g., Celgene Corporation v. Biocon Pharma Limited et al*, C.A. No. 21-11261, Dkt. 7 (D.N.J. Jun. 11, 2021); *Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd. et al*, C.A. No. 19-01979, Dkt. 56 (D.N.J. Feb. 6, 2020).

PERSONAL JURISDICTION OVER BIOCON

11. Plaintiff realleges paragraphs 1–10 as if fully set forth herein.

12. On information and belief, Biocon develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

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

of the Biocon 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 on its own and through at least one of its wholly-owned subsidiaries or agents.

14. This Court has personal jurisdiction over Biocon because, *inter alia*, Biocon, itself and through its agents, has purposefully 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, Biocon, 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, Biocon has not contested jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g., Celgene Corporation v. Biocon Pharma Limited et al*, C.A. No. 21-11261, Dkt. 7 (D.N.J. Jun. 11, 2021); *Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd. et al*, C.A. No. 19-01979, Dkt. 56 (D.N.J. Feb. 6, 2020).

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

17. In addition, this Court has personal jurisdiction over Biocon because, Biocon, through its counsel stated it will not contest jurisdiction for purposes of this action only, prior to the filing of this complaint.

BACKGROUND

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

18. On February 17, 2009, the United States Patent and 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

19. On April 24, 2018, 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®

20. 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®.

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