Liza M. Walsh
Christine I. Gannon
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Counsel for Plaintiff
Bristol-Myers Squibb Company

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. XSPRAY PHARMA AB, Defendant.	Civil Action No. _____ ***Electronically Filed***

COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for their Complaint against Defendant, Xspray Pharma AB, 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 a New Drug Application ("NDA") 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 Xspray Pharma AB ("Xspray") is a corporation organized and existing under the laws of Sweden, having a principal place of business at Råsundavägen 12, 169 67 Solna, Sweden.

4. On information and belief, Xspray 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 partners, agents and subsidiaries.

5. On information and belief, Xspray is listed as the applicant of NDA No. 216195 (the "Xspray NDA") and has sent notice to BMS stating that Xspray included a certification in the Xspray NDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV).

6. On information and belief, Xspray initially prepared and submitted the Xspray NDA for Xspray's 100 mg dasatinib tablets. BMS previously filed a lawsuit against Xspray in this District arising from Xspray's submission of the Xspray NDA for Xspray's 100 mg dasatinib tablets. *See Bristol-Myers Squibb Co. v. Xspray Pharma AB*, C.A. No. 1-22-cv-00964, Dkt. 1 (D.N.J. Feb. 23, 2022). On information and belief, Xspray subsequently amended the Xspray NDA to include five additional dosage strengths of 15 mg, 36 mg, 50 mg, 57 mg, and 70 mg tablets ("Xspray NDA Products").

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

8. On information and belief, following FDA approval of the Xspray NDA, Xspray, 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 as to Xspray because, among other things, Xspray is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(b), (c); *see also* 28 U.S.C. § 1400(b); Fed. R. Civ. P. 4(k)(2); *In re HTC Corp.*, 889 F.3d 1349 (Fed. Cir. 2018).

11. Venue is further proper in this Court as to Xspray because, among other things, Xspray 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 Xspray NDA with the intention of seeking to market the Xspray NDA Products nationwide, including within New Jersey. *See* 28 U.S.C. § 1400(b).

12. Moreover, Xspray did not contest venue, and filed counterclaims, in this District in the prior case in which BMS filed a lawsuit against Xspray arising from Xspray's submission of the Xspray NDA for Xspray's 100 mg dasatinib tablets. *See Bristol-Myers Squibb Co. v. Xspray Pharma AB*, C.A. No. 1-22-cv-00964, Dkt. 10 (D.N.J. May 5, 2022).

PERSONAL JURISDICTION OVER XSPRAY

13. Plaintiff realleges paragraphs 1–12 as if fully set forth herein.

14. This Court has personal jurisdiction over Xspray because, *inter alia*, Xspray, on information and belief: intends to market, sell, and/or distribute the Xspray NDA Products to residents of this State upon approval of the Xspray NDA, either directly or through at least one of its partners or wholly-owned subsidiaries or agents. Xspray's intent to sell its NDA Products here is sufficient to support a finding of specific personal jurisdiction. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016).

15. Alternatively, to the extent the above facts do not establish personal jurisdiction over Xspray, this Court may exercise jurisdiction over Xspray pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Xspray would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Xspray has sufficient contacts with the United States as a whole, including, but not limited to, preparing and filing NDAs with the FDA, marketing its drug product candidates, and manufacturing generic pharmaceutical products that will be distributed throughout the United States, such that this Court's exercise of jurisdiction over Xspray satisfies due process, and is consistent with the United States Constitution and Laws.

16. Upon information and belief, if the Xspray NDA is approved, Xspray's NDA Products will be marketed and distributed by Xspray in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

17. Upon information and belief, Xspray does not currently maintain a principal place of business, maintain any offices, store its products, or sell its products directly into another forum, and no other forum has a superior claim of personal jurisdiction over Xspray.

18. Moreover, Xspray did not contest personal jurisdiction, and filed counterclaims, in this District in the prior case in which BMS filed a lawsuit against Xspray arising from Xspray's submission of the Xspray NDA for Xspray's 100 mg dasatinib tablets. *See Bristol-Myers Squibb Co. v. Xspray Pharma AB*, C.A. No., Dkt. 10 1-22-cv-00964 (D.N.J. May 5, 2022)

BACKGROUND

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

19. 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

20. 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®

21. 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®.

22. 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®.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.