

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

_____	)	
BRISTOL-MYERS SQUIBB COMPANY,	)	
AND PFIZER INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. _____
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	
	)	
	)	
_____	)	

**COMPLAINT**

Plaintiffs Bristol-Myers Squibb Company (“BMS”) and Pfizer Inc. (“Pfizer”) (BMS and Pfizer, collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Mylan Pharmaceuticals Inc. (“Mylan”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 210128 filed by Mylan with the U.S. Food and Drug Administration (“FDA”).

2. In ANDA No. 210128, Mylan seeks approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs’ Eliquis® drug product (the “Mylan ANDA product”), prior to expiration of U.S. Patent Nos. 6,967,208 (the “’208 patent”) and 9,326,945 (the “’945 patent”) (collectively, the “patents-in-suit”).

**PARTIES**

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

4. Pfizer is a corporation organized and existing under the laws of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including treatments for thromboembolic disorders. Plaintiffs sell Eliquis<sup>®</sup> in this judicial district and throughout the United States.

6. Upon information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

7. On information and belief, Mylan is registered to do business in Delaware (File Number 4809319).

8. On information and belief, Mylan has designated its registered agent for the receipt of service of process for the State of Delaware as Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

9. On information and belief, Mylan is actively registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed “Pharmacy-Wholesale” (License No. A4-0001719) and “Distributor/Manufacturer CSR” (License No. DM-00007571).

10. On information and belief, Mylan is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

### JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has jurisdiction over Mylan because, *inter alia*, Mylan has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, both Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 210128, Mylan will make, use, import, sell, and/or offer for sale the Mylan ANDA product in the United States, including in Delaware, prior to the expiration of the patents-in-suit.

13. This Court also has jurisdiction over Mylan because, *inter alia*, this action arises from actions of Mylan directed toward Delaware, and because Mylan has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Mylan is registered to do business in Delaware (File Number 4809319), is actively registered with the Delaware Board of Pharmacy (License Nos. A4-0001719 and DM-00007571), and has designated a registered agent for the receipt of service of process in Delaware. Upon information and belief, Mylan regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Mylan derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

14. Mylan has previously been sued in this judicial district and has availed itself of Delaware courts through the assertion of claims and counterclaims in suits brought in Delaware

including *Mylan Pharms. Inc. v. Ethypharm SA*, 1-10-cv-01064, and *Mylan Pharms. Inc. v. Galderma Laboratories Inc.*, 1-10-cv-00892.

15. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Mylan is subject to personal jurisdiction in this district, as set forth above, has committed an act of infringement and will commit further acts of infringement in this judicial district, as set forth in more detail in paragraph 12 above, and, upon information and belief, has a regular and established place of business in this judicial district.

16. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue is challenged, the Court has personal jurisdiction over Mylan, and venue in this judicial district is proper.

#### **PATENTS-IN-SUIT**

17. On November 22, 2005, the U.S. Patent and Trademark Office duly and legally issued the '208 patent, titled "Lactam-Containing Compounds and Derivatives thereof as Factor Xa Inhibitors." A true and correct copy of the '208 patent is attached hereto as Exhibit A. The claims of the '208 patent are valid, enforceable, and not expired. BMS is the owner of the '208 patent and has the right to enforce it.

18. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued the '945 patent, titled "Apixaban Formulations." A true and correct copy of the '945 patent is attached hereto as Exhibit B. The claims of the '945 patent are valid, enforceable, and not expired. Plaintiffs are the joint owners of the '945 patent and have the right to enforce it.

19. BMS is the holder of New Drug Application ("NDA") No. 202155, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength apixaban tablets. Plaintiffs market apixaban tablets in the United States, under the trade name "Eliquis<sup>®</sup>." The FDA's official publication of approved drugs (the "Orange Book") includes Eliquis<sup>®</sup> together with

the patents-in-suit. Eliquis<sup>®</sup> is a factor Xa inhibitor indicated: (1) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the prophylaxis of deep vein thrombosis (“DVT”), which may lead to pulmonary embolism (“PE”), in patients who have undergone hip or knee replacement surgery; and (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. A copy of the complete prescribing information for Eliquis<sup>®</sup> approved in NDA No. 202155 is attached as Exhibit C.

### **INFRINGEMENT BY MYLAN**

20. By letter sent by Federal Express on March 2, 2017, Mylan notified Plaintiffs that Mylan had submitted ANDA No. 210128 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (“the Eliquis Notice Letter”). Plaintiffs received the Eliquis Notice Letter no earlier than March 3, 2017.

21. The Eliquis Notice Letter states that Mylan seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Mylan ANDA product before the expiration of the patents-in-suit. Upon information and belief, Mylan intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Mylan ANDA product promptly upon receiving FDA approval to do so.

22. By filing ANDA No. 210128, Mylan has necessarily represented to the FDA that the Mylan ANDA product has the same active ingredient as Eliquis<sup>®</sup>, has the same dosage form and strength as Eliquis<sup>®</sup>, and is bioequivalent to Eliquis<sup>®</sup>.

23. Upon information and belief, Mylan is seeking approval to market the Mylan ANDA product for the same approved indications as Eliquis<sup>®</sup>.

24. In the Eliquis Notice Letter, Mylan states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patents-in-suit are invalid,

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