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

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

MYLAN LABORATORIES LIMITED, MYLAN PHARMACEUTICALS INC., and MYLAN INSTITUTIONAL LLC,

Defendants.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)



Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendants Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals"), and Mylan Institutional LLC ("Mylan Institutional") (collectively "Defendants" or "Mylan"), hereby allege as follows:

NATURE OF THE ACTION

- This is a civil action for infringement of United States Patent No.
 9,439,906 (the "'906 Patent").
- 2. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") by Mylan to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent.

THE PARTIES

- JPI is a corporation organized and existing under the laws of the
 Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
- 4. JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.
- 5. On information and belief, Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, 500034, Hyderabad, India. Upon information and belief, Mylan Labs is an agent or affiliate of Mylan Pharmaceuticals and Mylan Institutional.
- 6. On information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781



Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is an agent or affiliate of Mylan Labs and Mylan Institutional.

- 7. On information and belief, Mylan Institutional is a limited liability company organized and existing under the laws of Delaware, having a place of business at 4901 Hiawatha Drive, Rockford, Illinois 61003. Upon information and belief, Mylan Institutional is an agent or affiliate of Mylan Labs and Mylan Pharmaceuticals.
- 8. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.
- 9. On information and belief, Mylan Labs, Mylan Institutional, and Mylan Pharmaceuticals are wholly-owned subsidiaries of Mylan Inc., a corporation organized under the laws of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
- 10. On information and belief, Mylan Inc. is a wholly-owned subsidiary of Mylan N.V., a corporation organized under the laws of the Netherlands, with a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire AL10 9UL, England.
- 11. On information and belief, Mylan Labs is acting on behalf of itself and on behalf of Mylan Pharmaceuticals and Mylan Institutional with respect to Mylan's ANDA No. 213124.

JURISDICTION AND VENUE

12. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.



- 13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and § 1400(b).

Mylan Labs

- 15. This Court has personal jurisdiction over Mylan Labs because, *inter alia*, Mylan Labs 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 New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 213124, Mylan Labs will, directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Institutional, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Sustenna® brand products in the United States, including in New Jersey, prior to the expiration of the '906 Patent.
- 16. Exercising personal jurisdiction over Mylan Labs in this district would not be unreasonable given Mylan Labs' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.
- Labs has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Mylan Labs regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Mylan Pharmaceuticals and Mylan Institutional—including by selling pharmaceutical products in New Jersey. On information and belief, Mylan Labs derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.



- 18. On information and belief, Mylan Labs, either directly or indirectly through Mylan Institutional or Mylan Pharmaceuticals, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.
- 19. This Court also has personal jurisdiction over Mylan Labs because, *inter alia*, this action arises from the actions of Mylan Labs directed toward New Jersey. For example, Mylan Labs' counsel sent a letter dated June 28, 2019 to JPI, a corporation with its principal place of business in this Judicial District, stating that Mylan Labs had submitted ANDA No. 213124 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. If Mylan Labs succeeds in obtaining FDA approval, it would sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, either directly or through its affiliates Mylan Pharmaceuticals and/or Mylan Institutional, causing injury to Plaintiffs in New Jersey.
- 20. Mylan Labs has conceded that venue is proper over Mylan Labs in patent cases in this Judicial District in at least the following District of New Jersey action: *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals, Inc.*, Civil Action No. 18-cv-14305.
- 21. Mylan Labs has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals, Inc. et al.*, Civil Action No. 2:15-cv-8180; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 1:14-cv-7094; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No.



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