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

JANSSEN PRODUCTS, L.P. and  
JANSSEN R&D IRELAND,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and  
MYLAN INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen"), for their Complaint against defendants Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively "Mylan"), allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for a declaratory judgment of infringement of U.S. Patent No. 8,153,829 B2 ("the '829 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. and 28 U.S.C. §§ 2201 and 2202. This action arises out of Defendants' filing

of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic versions of plaintiff Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products and Mylan's efforts to import, use, offer for sale, and/or sell those generic products prior to the expiration of the '829 Patent.

### **THE PARTIES**

2. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

3. Plaintiff Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the state of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

5. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary and agent, Mylan Pharmaceuticals.

**JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

8. On information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey.

9. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

10. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, its operation of offices in this district, and its filing of claims and counterclaims in this district.

11. Mylan Pharmaceuticals and Mylan Inc. have previously stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases as well as in the

related action *Janssen Products, L.P., et al v. Lupin, Ltd., et al*, 10-cv-5954 (WHW) (CLW) ("the Related Action").

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **FACTS**

13. On April 10, 2012, the PTO issued the '829 Patent, entitled "Methods for the Preparation of Hexahydrofuro[2,3-b]furan-3-ol." A true and correct copy of the '829 Patent is attached hereto as Exhibit A.

14. The '829 Patent expires on January 4, 2029.

15. Janssen R&D Ireland holds title to the '829 Patent.

16. The '829 Patent claims processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("Bis-THF"), an essential component of darunavir.

17. Darunavir is the active pharmaceutical ingredient in PREZISTA®.

18. Janssen Products, L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA® (darunavir). The NDA was formerly held by Tibotec Inc. The NDA was transferred to Janssen Products, L.P. on December 23, 2011.

19. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202-136 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of the PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg tablets ("Mylan's Generic Tablets").

20. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation, and filing of ANDA No. 202-136 for Mylan's Generic Tablets.

21. On January 18, 2013 Janssen asserted U.S. Patent No. 7,772,411 ("the '411 Patent") against Mylan in the Related Action.

22. The '411 Patent covers methods for the manufacture of darunavir and expires on February 22, 2027.

23. Mylan filed counterclaims asserting that the '411 Patent is invalid and not infringed.

24. In March 2014, the Court granted Janssen's motion for summary judgment of infringement and held that Mylan infringed the '411 Patent.

25. In March and April of 2014, the Court held a trial on the validity of the '411 Patent. A decision is pending.

26. After the deadline in the Related Action for Janssen to amend its complaint had passed, Mylan produced documents evidencing infringement of the '829 Patent.

27. Mylan has not disputed that these documents showed that it synthesizes the Bis-THF component of darunavir according to the processes of the '829 Patent.

28. On information and belief, Mylan uses processes covered by the claims of the '829 Patent to prepare the Bis-THF in Mylan's Generic Tablets.

29. The Bis-THF is incorporated into and present in the active pharmaceutical ingredient (darunavir) in Mylan's Generic Tablets, intact and without material change from the Bis-THF resulting from Janssen's patented processes.

30. The Bis-THF resulting from Janssen's patented processes is an essential part of Mylan's Generic Tablets.

31. Mylan would not agree to amend the discovery confidentiality order in the Related Action to allow Janssen to sue Mylan for infringement of the '829 Patent.

32. Janssen moved to amend the discovery confidentiality order in the Related Action in order to permit the filing of this case. The Court granted Janssen's motion on July 1, 2014.

33. On information and belief, Mylan seeks to use, offer to sell, sell and/or import Mylan's Generic Tablets prior to the expiration of the '829 Patent.

34. On information and belief, Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '829 Patent prior to its expiration.

35. On information and belief, Mylan's preparations include, but are not limited to, the development of Mylan's Generic Tablets, the filing of ANDA No. 202-136, and engaging in litigation, including the filing of counterclaims, to use, offer to sell, sell and/or import Mylan's Generic Tablets.

36. On information and belief, Mylan had actual and constructive notice of the '829 Patent.

### **COUNT I**

#### **Declaratory Judgment of Infringement by Mylan of the '829 Patent Under 35 U.S.C. § 271(g)**

37. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

38. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Mylan regarding infringement of the '829 Patent.

39. Mylan has made and will continue to make substantial and meaningful

preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '829 Patent prior to its expiration.

40. Mylan's actions, including, but not limited to, the filing of ANDA No. 202-136, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-136, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Mylan's Generic Tablets prior to the expiration of the '829 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

41. Any importation into the United States or offer for sale, sale, and/or use in the United States of Mylan's Generic Tablets prior to the expiration of the '829 Patent will constitute infringement of the '829 Patent.

42. On information and belief, Mylan's infringement of the '829 patent is willful.

43. Janssen is entitled to a judicial declaration that the importation into the United States or offer for sale, sale, and/or use in the United States of Mylan's Generic Tablets will constitute infringement of the '829 Patent.

44. Janssen has no adequate remedy at law to redress infringement by Mylan.

45. Janssen will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '829 Patent.

### **PRAYER**

WHEREFORE, Janssen respectfully requests relief and judgment as follows:

(a) a judgment declaring that importing, offering to sell, selling, or using the generic darunavir tablets described in ANDA No. 202-136 would constitute infringement of the

'829 Patent, or inducing or contributing to such conduct, by Mylan pursuant to 35 U.S.C. § 271(g);

(b) a judgment permanently enjoining Mylan and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, offering for sale, selling, or using the generic darunavir tablets described in ANDA No. 202-136 until after the expiration of the '829 Patent;

(c) a declaration that this case is exceptional;

(d) a declaration that Mylan's infringement of the '829 patent is willful;

(e) an award of Janssen's costs, expenses, reasonable attorney's fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 285; and

(f) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Dated: July 18, 2014



**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. The matter in controversy is related to the subject matter of:

- *Janssen Products L.P., et al. v. Lupin Limited, et al.*,  
Civil Action No. 10-cv-5954-WHW-CLW (D.N.J.).

Respectfully submitted,

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Dated: July 18, 2014