

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

MERCK SHARP & DOHME CORP.,

PLAINTIFF,

v.

MYLAN LABORATORIES LIMITED,

DEFENDANT.

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

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Merck Sharp & Dohme Corp. (“Merck”), by and through its undersigned attorneys, for its Complaint against Defendant Mylan Laboratories Limited (“MLL”) alleges, upon knowledge with respect to Defendant’s acts and upon information and belief as to other matters, as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement of U.S. Patent Nos. 9,023,790 (the “790 Patent”) and 9,358,297 (the “297 Patent”) arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). MLL is the owner of Abbreviated New Drug Application (“ANDA”) No. 211500, (the “MLL ANDA”), which MLL filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”) for approval to engage in the commercial manufacture, use or sale of a generic version of Merck’s NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL), which is sold in the United States. The MLL posaconazole product described in the MLL ANDA is referred to herein as the “ANDA Posaconazole Product.”

### **THE PARTIES**

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

3. On information and belief, Defendant MLL is a company organized and existing under the laws of India, having a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, Telangana 500034, India. MLL develops, formulates, manufactures, markets and sells pharmaceutical drug products in the United States.

4. Upon information and belief, MLL is a wholly-owned subsidiary of and is controlled by Mylan Inc., a corporation organized and existing under the laws of Pennsylvania. Upon information and belief, Mylan, Inc. is a wholly-owned subsidiary of Mylan N.V., a corporation organized and existing under the laws of the Netherlands.

5. Upon information and belief, MLL will act in concert with Mylan, Inc., and/or other entities under the umbrella of Mylan N.V., to market and sell the ANDA Posaconazole Product if that product is approved.

### **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

7. This Court has personal jurisdiction over MLL by virtue of its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of Delaware through the marketing and sales of generic drug products within this judicial district, through the

receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its ANDA Posaconazole Product to market and sell its ANDA Posaconazole Product, if approved, in this judicial district and to residents of this judicial district. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625 (2017).

8. Although this Court has personal jurisdiction over MLL for at least the reasons set forth in Paragraph 7, in the absence of such personal jurisdiction in any single state, a foreign entity such as MLL is subject to jurisdiction throughout the United States. *See Fed. R. Civ. P. 4(k)(2); Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293-94 (Fed. Cir. 2012).

9. Venue is proper in this judicial district under 28 U.S.C. § 1391, including because MLL is a foreign company pursuant to § 1391(c)(3) and subject to personal jurisdiction in this district, as set forth *supra*. *See 3G Licensing, S.A. v. HTC Corp.*, D.I. 73 at 3-4, C.A. No. 17-83-LPS (D. Del. Dec. 18, 2017) (holding that 28 U.S.C. § 1391 governs for a foreign defendant in a patent case).

10. Alternatively, under 28 U.S.C. § 1400(b), venue is proper in this judicial district because, *inter alia*, MLL has committed an act of infringement and will commit further acts of infringement in this judicial district, and, upon information and belief, has a regular and established place of business in this judicial district. *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, D.I. 24 at 3-4, C.A. No. 17-379-LPS (D. Del. 2017).

11. As explained above, MLL is part of the family of companies owned by Mylan N.V. Upon information and belief, the Mylan family of companies includes at least 40 subsidiaries incorporated in Delaware, and products from the Mylan family of companies are

sold in Delaware by various Mylan entities. *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, D.I. 36 at 35–39, C.A. No. 17-379-LPS (D. Del. 2017).

12. In addition, upon information and belief, the Mylan family of companies has previously sued and been sued in this judicial district and has purposely availed itself of Delaware courts through the assertion of claims and counterclaims in Delaware. As this Court has noted, Mylan Pharmaceuticals, Inc. (“MPI”), another subsidiary of Mylan, Inc., “appears in front of this Court with regularity for the purpose of getting its generic drugs on the market, and when that litigation concludes in a way that is favorable for MPI, those generic drugs are distributed to and used by Delaware residents through a distribution network that has been established for that purpose.” *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, D.I. 36 at 38, C.A. No. 17-379-LPS (D. Del. 2017). Furthermore, “[f]or at least the past ten years, there has been at least one Mylan action pending in this District at any given time,” *see id.* at 36, several of which include a Mylan entity as the plaintiff or counter claimant. *See, e.g., Javelin Pharm., Inc. et al v. Mylan Labs. Ltd.*, C.A. No. 16-554-LPS (D. Del. filed 2016); *Mylan Pharm., Inc. v. Galderma Labs. Inc.*, C.A. No. 10-892-LPS (D. Del. filed 2010); *Mylan Pharm., Inc. v. Ethypharm SA*, C.A. No. 10-1064-LPS (D. Del. filed 2010); *Mylan Pharm., Inc. et al v. Eurand Inc.*, C.A. No. 10-306-SLR (D. Del. filed 2010); *Mylan, Inc. et al v. Boehringer Ingelheim Intern’l GMBH*, C.A. No. 10-244-RK (D. Del. filed 2009).

13. Based on these facts and causes alleged herein, and for additional reasons to be further developed through discovery, if necessary, venue is proper in this district.

**NOXAFIL®**

14. Merck is the holder of New Drug Application (“NDA”) N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells

under the registered trademark NOXAFIL® (“NOXAFIL® for Injection”). NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

15. NOXAFIL® for Injection is an embodiment of one or more claims of the '790 Patent and the '297 Patent (collectively, the “Patents-in-Suit”). The Patents-in-Suit are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for NOXAFIL®.

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

16. The '790 Patent, entitled “Posaconazole Intravenous Solution Formulations Stabilized by Substituted  $\beta$ -Cyclodextrin,” was duly and legally issued by the USPTO on May 5, 2015. The '790 Patent is set to expire on July 4, 2031. Merck is the owner of all title, right and interest in and to the '790 Patent by assignment. A copy of the '790 Patent is attached as Exhibit A.

17. The '297 Patent, entitled “Posaconazole Intravenous Solution Formulations Stabilized by Substituted  $\beta$ -Cyclodextrin” was duly and legally issued by the USPTO on June 7, 2016. The '297 Patent is set to expire on June 24, 2031. Merck is the owner of all title, right and interest in and to the '297 Patent by assignment. A copy of the '297 Patent is attached as Exhibit B.

### **MLL’S ANDA**

18. MLL filed or caused to be filed the MLL ANDA with the FDA, seeking FDA approval to market and sell within the United States the ANDA Posaconazole Product before the expiration of the Patents-in-Suit.

19. On information and belief, the MLL ANDA identified Merck’s NOXAFIL® for Injection product and included a written certification, as required by 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents-in-Suit are invalid or otherwise will not be infringed by the ANDA Posaconazole Product.

20. On or after February 14, 2018, Merck received a letter from MLL, dated February 13, 2018, stating that pursuant to § 505(j)(2)(B)(i) and (ii), MLL had submitted the MLL ANDA to the FDA.

21. In its letter to Merck, MLL stated that the claims of the Patents-in-Suit are invalid.

22. MLL does not contest that Claims 1-16 of the '790 Patent and Claims 1-14, 17-24, and 27-32 of the '297 Patent would be infringed by the manufacture, use, or sale of the ANDA Posaconazole Product, if those claims are not found to be invalid.

23. By filing or causing to be filed the MLL ANDA, MLL necessarily represented to the FDA that the ANDA Posaconazole Product has the same active ingredient as NOXAFIL® for Injection, has the same method of administration, dosage form, and strength as NOXAFIL® for Injection and is bioequivalent to NOXAFIL® for Injection.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,023,790**

24. Merck incorporates by reference Paragraphs 1-23 of this Complaint as if fully set forth herein.

25. By filing or causing to be filed the MLL ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the ANDA Posaconazole Product before the expiration of the '790 Patent, MLL committed an act of infringement under 35 U.S.C. § 271(e)(2).

26. If MLL commercially makes, uses, offers to sell or sells the ANDA Posaconazole Product within the United States, or imports the ANDA Posaconazole Product into the United States, or induces or contributes to any such conduct during the term of the '790 Patent, MLL

would further infringe the '790 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

27. MLL's commercial manufacture, use, offer to sell, or sale of the ANDA Posaconazole Product within the United States, or importation of the ANDA Posaconazole Product into the United States, during the term of the '790 Patent, would infringe the '790 Patent.

28. Upon approval of the MLL ANDA, and the commercial marketing of the ANDA Posaconazole Product, MLL would actively induce and/or contribute to infringement of the '790 Patent. At least in light of the prescribing instructions MLL proposes to provide in connection with the ANDA Posaconazole Product, MLL will induce health care professionals, resellers, pharmacies, and end users of the ANDA Posaconazole Product to directly infringe one or more claims of the '790 Patent. MLL will encourage acts of direct infringement with knowledge of the '790 Patent and knowledge that it is encouraging infringement.

29. MLL had actual and constructive knowledge of the '790 Patent prior to filing the MLL ANDA, and was aware that the filing of the MLL ANDA with the request for FDA approval before the expiration of the '790 Patent would constitute an act of infringement of the '790 Patent.

30. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

**COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,358,297**

31. Merck incorporates by reference Paragraphs 1-23 of this Complaint as if fully set forth herein.

32. By filing or causing to be filed the MLL ANDA with the FDA under 21 U.S.C.

§ 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the ANDA Posaconazole Product before the expiration of the '297 Patent, MLL committed an act of infringement under 35 U.S.C. § 271(e)(2).

33. If MLL commercially makes, uses, offers to sell or sells the ANDA Posaconazole Product within the United States, or imports the ANDA Posaconazole Product into the United States, or induces or contributes to any such conduct during the term of the '297 Patent, MLL would further infringe the '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

34. MLL's commercial manufacture, use, offer to sell, or sale of the ANDA Posaconazole Product within the United States, or importation of the ANDA Posaconazole Product into the United States, during the term of the '297 Patent, would infringe the '297 Patent.

35. Upon approval of the MLL ANDA, and the commercial marketing of the ANDA Posaconazole Product, MLL would actively induce and/or contribute to infringement of the '297 Patent. At least in light of the prescribing instructions MLL proposes to provide in connection with the ANDA Posaconazole Product, MLL will induce health care professionals, resellers, pharmacies, and end users of the ANDA Posaconazole Product to directly infringe one or more claims of the '297 Patent. MLL will encourage acts of direct infringement with knowledge of the '297 Patent and knowledge that it is encouraging infringement.

36. MLL had actual and constructive knowledge of the '297 Patent prior to filing the MLL ANDA, and was aware that the filing of the MLL ANDA with the request for FDA approval before the expiration of the '297 Patent would constitute an act of infringement of the '297 Patent.



37. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment in its favor and against Defendant and respectfully requests the following relief:

- A. A judgment that Defendant has infringed one or more claims of the '790 Patent under 35 U.S.C. § 271(e)(2) by submitting the MLL ANDA;
- B. A judgment that Defendant has infringed one or more claims of the '297 Patent under 35 U.S.C. § 271(e)(2) by submitting the MLL ANDA;
- C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the '790 Patent, including the product described in the MLL ANDA, prior to the expiration of the '790 Patent, including any extensions;
- D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from working in active concert or participation with any other entities, including but not limited to Mylan, Inc. and other entities under the umbrella of Mylan N.V., from making, using, selling, offering to sell, or importing any product that infringes the '790 Patent, including the product described in the MLL ANDA, prior to the expiration of the '790 Patent, including any extensions;
- E. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and

permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from making, using, selling, offering to sell, or importing any product that infringes the '297 Patent, including the product described in the MLL ANDA, prior to the expiration of the '297 Patent, including any extensions;

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, from working in active concert or participation with any other entities, including but not limited to Mylan, Inc. and other entities under the umbrella of Mylan N.V., from making, using, selling, offering to sell, or importing any product that infringes the '297 Patent, including the product described in the MLL ANDA, prior to the expiration of the '297 Patent, including any extensions;

G. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the MLL ANDA, or inducing or contributing to such conduct, would constitute infringement of the '790 Patent by Defendant pursuant to 35 U.S.C. § 271;

H. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the MLL ANDA, or inducing or contributing to such conduct, would constitute infringement of the '297 Patent by Defendant pursuant to 35 U.S.C. § 271;

I. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the MLL ANDA be a date that is not earlier than the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

J. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the MLL ANDA be a date that is not earlier than the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

K. If Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the MLL ANDA prior to the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

L. If Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, or those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the MLL ANDA prior to the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

M. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

N. Such other and further relief as the Court deems just and proper.

Dated: March 23, 2018

MCCARTER & ENGLISH, LLP

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