IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| MAYNE PHARMA INTERNATIONAL PTY LTD., | ) | |
| Plaintiff, | ) | |
| v. | ) | C.A. No. 15-438-LPS-CJB |
| MERCK & CO., INC. and MERCK SHARP & DOHME CORP., | ) | JURY TRIAL DEMANDED |
| Defendants. | ) | |

**SECOND AMENDED COMPLAINT**

Plaintiff Mayne Pharma International Pty Ltd. ("Plaintiff" or "Mayne"), by its undersigned attorneys, for its Complaint herein against Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively "Defendants" or "Merck") alleges upon knowledge with respect to its own acts, and upon information and belief as to other matters, as follows:

**THE PARTIES**

1. Plaintiff Mayne Pharma International Pty Ltd. is organized and existing under the laws of Australia having a principal place of business at 1538 Main North Road, Salisbury South, South Australia 5106. Mayne is in the business of, among other things, selling pharmaceutical drug products.

2. Upon information and belief, Defendant Merck & Co., Inc. is a corporation organized and existing under the laws of Delaware (see Exhibit G) and has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Upon further information and belief, Merck & Co., Inc. holds itself out as being organized and existing under the laws of the State of New Jersey.

3. Upon information and belief, Defendant Merck Sharp & Dohme Corp. 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.

4. Upon further information and belief, Merck Sharp & Dohme Corp. is a wholly-owned subsidiary of Defendant Merck & Co., Inc.

## NATURE OF THE ACTION

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 101, *et seq.*

## JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the claims asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Defendants because, among other things, upon information and belief, Defendants regularly transact business within this judicial district, including sales of the infringing product in Delaware, and have committed acts of patent infringement within this judicial district.

8. On information and belief, Defendants are registered with the Delaware Department of State to transact business in Delaware, have a registered agent in Delaware, and have therefore consented to general personal jurisdiction in the State of Delaware and this judicial district.

9. On information and belief, Defendants have previously availed themselves of the United States District Court for the District of Delaware and submitted to the jurisdiction of this Court. See, e.g., Intervet Inc. and Merck & Co., Inc. v. E.I. DuPont De Nemours and Co., C.A. No. 15-607 (D. Del. Jul. 7, 2015); Merck Sharp & Dohme Corp. v. Amneal Pharmaceuticals

LLC, C.A. No. 15-250 (D. Del. Mar. 20, 2015); Bristol-Myers Squibb Co. v. Merck & Co., Inc. and Merck Sharp & Dohme Corp., C.A. No. 14-1131 (D. Del. Sep. 5, 2014).

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

**BACKGROUND**

11. United States Patent No. 6,881,745 ("the '745 patent"), entitled "Pharmaceutical Compositions for Poorly Soluble Drugs," was duly and lawfully issued by the United States Patent and Trademark Office on April 18, 2005. A copy of the '745 patent, which is valid and enforceable, is attached hereto as Exhibit A.

12. Mayne is the assignee of the '745 patent.

13. The inventors of the '745 patent are David Hayes and Angelo Mario Morella.

14. Merck markets delayed-release posaconazole tablets, 100 mg, in the United States under the tradename Noxafil® ("Merck's Noxafil® Tablets").

15. Merck Sharp & Dohme Corp. owns New Drug Application No. 205053 (the "NDA") for Noxafil (posaconazole) delayed-release tablets, 100 mg, which was first approved by the United States Food and Drug Administration ("FDA") on November 25, 2013.

16. According to the drug label, Merck's Noxafil® Tablets are "[manufactured] for: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ 08889, USA." A copy of the drug label for Merck's Noxafil® Tablets is attached hereto as Exhibit B.

17. Employees of Merck Sharp & Dohme Corp. have email addresses having a "@merck.com" domain name, which, upon information and belief, is a Merck & Co., Inc. domain name. A notice stating that "[t]his email message, together with any attachments,

contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates" appears in email correspondence between Merck and FDA regarding the approval of the NDA, including on email correspondence that is ostensibly from employees of Merck Sharp & Dohme Corp.

18. In public speaking engagements and presentations, Merck & Co., Inc. has described Noxafil® as a key antifungal product in its acute care franchise.

19. In quarterly and annual filings with the United States Securities and Exchange Commission, Merck & Co., Inc. has described Noxafil® as a pharmaceutical product in its acute care franchise and further reported sales of Noxafil, including sales made within the United States.

20. On information and belief, Merck & Co., Inc. and Merck Sharp & Dohme Corp. share a common website with domain name "www.merck.com" on which its Noxafil® Tablets are advertised and information about the Noxafil® Tablets is provided to the public.

21. According to the drug label for Merck's Noxafil® Tablets, "Noxafil is an azole antifungal agent available as concentrated solution to be diluted before intravenous administration, delayed-release tablet or suspension for oral administration." (Ex. B at 20.) The drug label also identifies posaconazole as the active pharmaceutical ingredient in Merck's Noxafil® Tablets and states that "posaconazole is an azole antifungal agent." (Id. at 20-21.)

22. The drug label for Merck's Noxafil® Tablets states that "[e]ach delayed-release tablet contains the inactive ingredients: hypromellose acetate succinate, microcrystalline cellulose, hydroxypropylcellulose, silicon dioxide, croscarmellose sodium, magnesium stearate, and Opadry® II Yellow (consists of the following ingredients: polyvinyl alcohol partially

hydrolyzed, Macrogol/PEG 3350, titanium dioxide, talc, and iron oxide yellow)." (See Ex. B at 20-21.)

23. The drug label for Merck's Noxafil® Tablets reports pharmacokinetic parameters for Merck's Noxafil® Tablets, including for example, AUC ("area under the plasma concentration-time curve from time zero to 24 hr") and $C_{max}$ ("maximum observed concentration") under fasting conditions. (See Ex. B at 22-23.) The drug label for Merck's Noxafil® Tablets further states that "Noxafil delayed-release tablets exhibit dose proportional pharmacokinetics after single and multiple dosing up to 300 mg." (See Ex.t B at 22.)

24. According to dosing information contained in the drug label, the "loading dose" for Merck's Noxafil® Tablets is "300 mg (three 100 mg delayed-release tablets) twice a day on the first day." (See Ex. B at 5.) The "maintenance dose" for Merck's Noxafil® Tablets is "300 mg (three 100 mg delayed-release tablets) once a day, starting on the second day." (Id.)

25. The drug label, as revised in November 2015, identifies N.V. Organon as the manufacturer Merck's Noxafil® Tablets. (See Ex. B at 33.) The drug label, as of November 2013, also identified N.V. Organon as the manufacturer Merck's Noxafil® Tablets. A copy of the November 2013 drug label is attached hereto as Exhibit C.

26. Upon information and belief, Merck Sharp and Dohme Corp. has received and continues to receive shipments into the United States of Merck's Noxafil® Tablets that have been manufactured by N.V. Organon.

27. After a reasonable opportunity for further investigation or discovery, there will likely be evidentiary support that Merck & Co., Inc., alone or by and through an agent or alter ego, including, without limitation, Merck Sharp & Dohme Corp., has received and continues to

receive shipments into the United States of Merck's Noxafil® Tablets that have been manufactured by N.V. Organon.

28. Upon information and belief, Merck Sharp and Dohme Corp. currently makes, uses, sells, offer for sale or imports Merck's Noxafil® Tablets in the United States.

29. After a reasonable opportunity for further investigation or discovery, there will likely be evidentiary support that Merck & Co., Inc., alone or by and through an agent or alter ego, including, without limitation, Merck Sharp & Dohme Corp., makes, uses, sells, offer for sale or imports Merck's Noxafil® Tablets in the United States.

30. Upon information and belief, Schering-Plough Corporation was renamed Merck & Co., Inc. in or around November 2009.

31. Upon information and belief, Merck & Co., Inc. (formerly Schering-Plough Corporation) filed U.S. Patent Application No. 12/937,881 ("the '881 patent application") on October 14, 2010, which was filed as a U.S. national phase application of International Patent Application No. PCT/US2009/040653, which was filed on April 15, 2009. A copy of the '881 patent application is attached hereto as Exhibit D.

32. Upon information and belief, Merck & Co., Inc. (formerly Schering-Plough Corporation) filed U.S. Patent Application No. 12/999,547 ("the '547 patent application") on December 16, 2010, which was filed as a U.S. national phase application of International Patent Application No. PCT/US2009/040652, which was filed on April 15, 2009. A copy of the '547 patent application is attached hereto as Exhibit E.

33. Upon information and belief, attorneys representing Merck & Co., Inc. actively participated in the '881 and '547 patent applications.

34. The "Background of the Invention" portions of each of the specifications of the '881 and '547 patent applications state that "U.S. Patent No. 6,881,745 (the '745 patent) issued April 19, 2005 to Hayes et al., generally describes compositions comprising an azole antifungal compound and a polymer." (See, e.g., Ex. D at ¶ 0008.)

35. Merck & Co., Inc. also identified the '745 patent to the United States Patent and Trademark Office ("PTO") in an Information Disclosure Statement ("IDS") that it submitted in connection with the prosecution of the '881 and '547 patent applications.

36. In a December 4, 2012 Office Action, the PTO rejected pending claim 1 of the '881 patent application "under 35 U.S.C. 102(b) as being anticipated by Hayes et al. (US 6,881,745, IDS)" and stated that "Hayes et al. teach a pharmaceutical composition of a practically insoluble drug, such as, itraconazole, wherein the drug is dispersed in a polymeric carrier having acidic function, particularly, hydroxypropyl methylcellulose acetate succinate."

37. Thus, the named inventors of the '881 and '547 patent applications had knowledge of the '745 patent.

38. Table I of the '547 patent application presents, for example, a "Comparison of PK Parameters Observed After Administering 100 mg Dose of Posacaonazole," including pharmacokinetic parameters under "fasted" conditions for tablets "prepared from a composition of the invention comprising hydroxypropylmethylcellulose acetate succinate (HPMC-AS, M grade) and posaconazole free base." (See Ex. E at ¶ 0045, Table 1.)

39. At least certain of the named inventors of the '547 patent application, including, for example, Gopal Krishna, contributed to the development of Merck's Noxafil® Tablets, conducted clinical studies on Merck's Noxafil® Tablets and/or had knowledge of the formulation and pharmacokinetic profile of Merck's Noxafil® Tablets. See, e.g., Krishna et al.,

"Single-Dose Phase I Study to Evaluate the Pharmacokinetics of Posaconazole in New Table and Capsule Formulations Relative to Oral Suspension," Antimicrobial Agents and Chemotherapy, August 2012, 56:8 p. 4196-4201.

40. The drug label for Merck's Noxafil® Tablets (Ex. B at 20-21) and the '547 patent application (Ex. E at ¶ 0045, Table I) describe a tablet containing that azole antifungal drug posaconazole and the polymer having acidic functional groups hypromellose acetate succinate.

41. On or around August 30, 2012, the '881 and '547 patent applications were assigned to Merck Sharp & Dohme Corp.

42. Based on the disclosures and/or the prosecution of the '881 and '547 patent applications, Merck & Co., Inc. had knowledge of the '745 patent and its relevance to Merck's posaconazole tablet product at least as early as October 14, 2010.

43. Based on the disclosures and/or the prosecution of the '881 and '547 patent applications, Merck Sharp & Dohme had knowledge of the '745 patent and its relevance to Merck's posaconazole tablet product at least as early as August 30, 2012.

44. Based on at least the disclosures and/or prosecution of the '547 and '881 patent applications, Defendants knew or should have known that Merck's Noxafil® Tablets would practice each element of one or more claims of the '745 patent.

45. Furthermore, the disclosures and/or prosecution of the '547 and '881 patent applications created an objectively high likelihood that Defendants' actions constituted infringement.

46. Upon information and belief, named inventor Gopal Krishna was an employee of Merck Sharp & Dohme Corp.

47. Upon information and belief, Merck Sharp & Dohme Corp. funded the "Single-Dose Phase I Study to Evaluate the Pharmacokinetics of Posaconazole in New Table and Capsule Formulations Relative to Oral Suspension."

48. After a reasonable opportunity for further investigation or discovery, there will likely be additional evidentiary support that Merck Sharp & Dohme Corp. had knowledge of the '745 patent and its relevance to Merck's Noxafil® Tablets.

49. After a reasonable opportunity for further investigation or discovery, there will likely be additional evidentiary support that Merck Sharp & Dohme Corp. knew or should have known that Merck's Noxafil® Tablets would practice one or more claims of the '745 patent application.

50. Mayne has had discussions about Merck's alleged infringement of the '745 patent with representatives of Merck that identify themselves as being affiliated with "Merck," "Merck Research Laboratories" and/or "Merck & Co., Inc."

51. Upon information and belief, representatives of Merck & Co., Inc. have been intimately involved in discussions regarding Merck's Noxafil® Tablets and the '745 patent, which further demonstrates that Merck & Co., Inc. and Merck Sharp and Dohme Corp. are intertwined with respect to at least Merck's Noxafil® Tablets.

52. On August 15, 2014, Mayne sent a letter to Merck regarding the '745 patent and Merck's Noxafil® Tablets.

53. Mayne's August 15, 2014 letter stated that Mayne owns the '745 patent.

54. Mayne's August 15, 2014 letter stated expressly that Mayne considered Merck's Noxafil® Tablets relevant to the '745 patent.

55. By letter dated September 11, 2014, Merck responded to Mayne's August 15, 2014 letter and acknowledged the '745 patent.

56. On or about September 30, 2014, representatives of Mayne and Merck had discussions regarding the alleged infringement of the '745 patent by Merck's Noxafil® Tablets.

57. In October 2014, representatives of Mayne and Merck had further discussions regarding the alleged infringement of the '745 patent by Merck's Noxafil® Tablets.

58. On November 19, 2014, Mayne sent a letter to Merck notifying Merck of the alleged infringement of the '745 patent by Merck's Noxafil® Tablets.

59. In December 2014, representatives of Mayne and Merck corresponded about Merck's alleged infringement of the '745 patent.

60. On May 28, 2015, counsel for Mayne and Merck had a telephone discussion regarding Merck's alleged infringement of the '745 patent.

61. Upon information and belief, based on at least Mayne's August 15, 2014 and November 19, 2014 letters, Merck has decided to make, use, offer for sale, sell or import Merck's Noxafil® products despite knowing that Merck's Noxafil® Tablets infringe at least one claim of the '745 patent.

62. Furthermore, Mayne's August 15, 2014 and November 19, 2014 letters created an objectively high likelihood that Merck's actions constituted infringement.

## COUNT ONE
## INFRINGEMENT OF UNITED STATES PATENT NO. 6,881,745

63. Mayne incorporates each of the preceding paragraphs of this Complaint as if fully set forth herein.

64. In violation of 35 U.S.C. § 271(a), Defendants have infringed and continue to infringe the '745 patent by making, using, offering for sale or selling within the United States

and/or importing into the United States products that infringe one or more claims of the '745 patent, including but not limited Merck's Noxafil® Tablets.

65. Merck's Noxafil® Tablets practice each and every limitation of at least one or more claims of the '745 patent because, according to the drug label, Merck's Noxafil® Tablets: (1) contain 100 mg of posaconazole; (2) contain at least one polymer having acidic functional groups, including but not limited to hypromellose acetate succinate; and (3) provide a pharmacokinetic profile that satisfies the recited $C_{max}$ and AUC thresholds. An exemplary infringement chart is attached hereto as Exhibit F.

66. Upon information and belief, Defendants have been aware of the '745 patent since at least October 14, 2010 when Merck & Co., Inc. cited the '745 patent in the '881 patent application.

67. Upon information and belief, Defendants have known or should have known that Merck's Noxafil® Tablets practice at least one claim of the '745 patent since at least as early as December 16, 2010 when Merck & Co., Inc. cited the '745 patent in the '547 patent application, and, in no event, later than August 15, 2014 when Mayne sent Merck a letter regarding the '745 patent and Merck's Noxafil® Tablets.

68. Defendants' continued manufacture, importation, use, offers to sell, and/or selling of Merck's Noxafil® Tablets, despite its knowledge of the '745 patent, constitutes at least reckless disregard of the '745 patent. As a result, Defendants' infringement after becoming aware of the '745 patent has been willful.

69. Plaintiff has suffered and will continue to suffer damages and irreparable injuries unless Defendants' infringement of the '745 patent is enjoined.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. A judgment that Defendants have infringed and are infringing the '745 patent directly in violation of 35 U.S.C. § 271;

B. A judgment that Defendants' infringement of the '745 patent has been willful;

C. An order, pursuant to 35 U.S.C. § 283, enjoining Defendants and all persons in active concert or participation with Defendants from any further infringement of the '745 patent;

D. An order, pursuant to 35 U.S.C. § 284, awarding Plaintiff damages adequate to compensate for Defendants' infringement of the '745 patent;

E. An order, pursuant to 28 U.S.C. § 1961 and 35 U.S.C. § 284, awarding to Plaintiff interest on the damages and its costs incurred from this action;

F. An order, pursuant to 35 U.S.C. § 284, trebling all damages awarded to Plaintiff based on Defendants' willful infringement of the '745 patent;

G. A declaration that this case is exceptional and an award of Plaintiff's reasonable attorneys' fees and costs in bringing its claims, pursuant to 35 U.S.C. § 285;

H. An order directing Defendants to recall from distribution and destroy its entire stock of infringing products within the United States; and

I. Such other and further relief as the Court may deem just and proper.

## JURY DEMAND

In accordance with Fed. R. Civ. P. 38 and 39, Plaintiff assert its rights under the Seventh Amendment to the United States Constitution and demands a trial by jury on all issues that may be so tried.

Respectfully submitted,

/s/ *David M. Fry*

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