IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

JOHNSON MATTHEY INC. d/b/a JOHNSON MATTHEY PHARMACEUTICAL MATERIALS and JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, INC. d/b/a JOHNSON MATTHEY PHARMA SERVICES,

Plaintiffs,

v.

PFIZER, INC., PFIZER LIMITED, and PFIZER IRELAND PHARMACEUTICALS,

Defendants.

Civil Action No. 2:15-cv-14 (AWA)

JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Johnson Matthey Inc. d/b/a Johnson Matthey Pharmaceutical Materials and Johnson Matthey Pharmaceutical Materials, Inc. d/b/a Johnson Matthey Pharma Services (collectively "JM") hereby brings this action for declaratory relief against the above named Defendants Pfizer, Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively "Pfizer"), and states as follows:

THE PARTIES

1. Johnson Matthey Inc. d/b/a Johnson Matthey Pharmaceutical Materials is a corporation organized under the laws of the Commonwealth of Pennsylvania and has a place of business at 2003 Nolte Drive, West Deptford, NJ 08066.

2. Johnson Matthey Pharmaceutical Materials, Inc. d/b/a Johnson Matthey Pharma Services is a corporation organized under the laws of the state of Delaware and has a place of business at 25 Patton Road, Devens, MA 01434.

3. On information and belief, Pfizer Inc. is a corporation organized under the laws of the State of Delaware and having its principal place of business located at 235 East 42nd Street, New York, New York 10017. On information and belief, U.S. Patent No. 6,124,363 ("the '363 patent") is assigned to Pfizer Inc. A copy of the '363 patent is attached hereto as Exhibit 1.

4. On information and belief, Pfizer Limited is a company organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent CT13 9NJ, England.

5. On information and belief, Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland.

JURISDICTION AND VENUE

6. This is an action for declaratory relief regarding the noninfringement and invalidity of the '363 patent.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. On information and belief, this Court has personal jurisdiction over Pfizer, Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively "Pfizer") because of Pfizer's continuous and systematic contacts with the Commonwealth of Virginia. On information and belief, Pfizer intentionally markets and directs its products to the Commonwealth, maintains a broad distributorship network within the Commonwealth, and enjoys substantial income from sales in the Commonwealth.

9. On information and belief, Pfizer maintains a facility in the Commonwealth at 1211 Sherwood Avenue, Richmond, Virginia 23220 and is therefore present in this judicial

district. On information and belief, Pfizer is registered to do business in Virginia, including its appointment of a registered agent in Virginia for the receipt of service of process.

10. This Court also has personal jurisdiction over Pfizer because of its purposeful availment of this forum previously for the purpose of civil litigation. See Pfizer Inc., et al v. Teva Pharmaceuticals USA, Inc., No. 2:10-cv-00128-RBS-FBS; Pfizer Inc. et al v. Tiger Pharmaceuticals, LLC, No. 1:14-cv-01501-AJT-TRJ; Pfizer Inc. et al v. Tiger Pharmaceuticals, LLC, No. 2:14-cv-00633-AJT-TRJ.

11. Venue in this Judicial District is proper under 28 U.S.C. §§ 1391 and 1400(b).

AN ACTUAL AND JUSTICIABLE CONTROVERSY EXISTS

12. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is an actual and justiciable controversy within the Court's jurisdiction.

13. On November 10, 2014, Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals sued Tiger Pharmaceuticals, LLC ("Tiger"), for allegedly infringing the '363 patent. Pfizer brought that litigation after Tiger notified Pfizer that it had filed an Abbreviated New Drug Application ("Tiger's ANDA") with the FDA seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell generic versions of Pfizer's Tikosyn capsules, 0.125 mg, 0.25 mg, and 0.50 mg dofetilide capsules (collectively, "Tiger's ANDA Products"), prior to the expiration of the '363 patent. See Pfizer Inc. et al v. Tiger Pharmaceuticals, LLC, No. 1:14-cv-01501-AJT-TRJ ("the Tiger Action").

14. Pfizer claims to be the owner of all legal rights, title and interest in the '363 patent, including the right to enforce the '363 patent. The claims of the '363 patent are directed to, among other things, substantially pure, crystalline, dofetilide polymorph P162, P162a and P143, and methods for making the same.

15. JM has an approved Drug Master File on file with the FDA for its dofetilide active pharmaceutical ingredient ("API") ("JM's DMF"). JM maintains its DMF and manufacturing operations regarding its dofetilide API in confidence and does not allow third parties access to the same. Tiger has not been permitted to review or otherwise access JM's complete DMF or manufacturing operations relating to its dofetilide API. Accordingly, the information concerning JM's DMF and its methods of manufacturing dofetilide API are solely within the control of JM.

16. Tiger's ANDA lists JM as Tiger's only supplier of the dofetilide API contained in Tiger's ANDA Products, and refers to JM's DMF.

17. On December 12, 2014, in the Tiger Action, Pfizer issued subpoenas seeking production of JM's DMF, which specifies the confidential manufacturing process JM uses to produce its dofetilide API, and samples of the material produced according to JM's DMF, including samples of intermediary products that are not for commercial sale and are never provided to Tiger.

18. By a response to an interrogatory in the Tiger Action, on December 31, 2014, Pfizer has admitted "[t]he analytical testing by Pfizer's experts of the samples of the API used in making Tiger's ANDA products does not indicate infringement of any claim of the '363 patent." Pfizer also stated that "[t]he experts' initial analytical testing of the samples of Tiger's ANDA products has been inconclusive with respect to the dofetilide polymorph(s) contained in Tiger's ANDA products." Pfizer further stated that "Pfizer will supplement its response after it has received the requested third party discovery and tested the samples requested from the third party manufacturer." The "requested third party discovery" in Pfizer's interrogatory response referred to documents from JM including JM's DMF, and the "third party manufacturer" referred to in

the interrogatory response is JM. A copy of Pfizer's interrogatory response is attached hereto as Exhibit 2.

19. On January 7, 2015, in an email from Pfizer's counsel, Mr. Aaron Stiefel, to Tiger's counsel, Pfizer admitted that "the samples provided by Tiger did not indicate infringement." Also in that email, Pfizer's counsel reiterated that "Pfizer is awaiting production by Tiger's supplier of the Drug Master File for the API used in making Tiger's dofetilide products as well as manufacturing samples . . . and will supplement our interrogatory response at that time." A copy of Mr. Stiefel's January 7, 2015 email is attached hereto as Exhibit 3.

20. On January 9, 2015, in an email from Pfizer's counsel, Mr. Aaron Stiefel, to Tiger's counsel, Pfizer clarified "the samples" that testing revealed were non-infringing referenced in Mr. Stiefel's January 7, 2015 email were Tiger's "ANDA product." Also in that email, Pfizer's counsel reiterated "[w]e continue to expect that we will receive the Drug Master File and samples from [JM] shortly and that we will then be in a position to respond further with respect to our infringement contentions." A copy of Mr. Stiefel's January 9, 2015 email is attached hereto as Exhibit 4.

21. Pfizer thus has stated that it intends to use information learned from the JM subpoenas about JM's manufacturing process and intermediates to assert an infringement claim in the Tiger Action.

22. Pfizer, through its interrogatory response and counsel's correspondence, has stated that its infringement contentions in the Tiger Action will be based on JM's actions relating to its manufacture and supply of its dofetilide API. Thus, there is a substantial risk that Pfizer will also allege that JM infringes one or more claims of the '363 patent.

23. In the absence of a patent infringement action because Pfizer has been unable to prove infringement with respect to Tiger's ANDA, ANDA products or dofetilide API, there would be no patent-related impediment to FDA approval of Tiger's ANDA.

24. On information and belief, Tiger's ANDA is being reviewed and will continue to be reviewed by FDA on an expedited basis.

25. Upon FDA approval of Tiger's ANDA, JM will manufacture and supply Tiger with dofetilide active ingredient for Tiger's ANDA products.

26. The dofetilide active ingredient JM will supply to Tiger will be manufactured in accordance with JM's DMF that Pfizer has stated will be the basis for any infringement claim that it brings against Tiger.

27. Because Pfizer has stated in its correspondence with Tiger's counsel that any infringement will be based on the DMF and because Pfizer has subpoenaed JM documents, this is tantamount to accusing JM of infringement and JM has a reasonable apprehension that it will be sued.

28. JM denies that it infringes Pfizer's '363 patent, including during the manufacture of its dofetilide API in accordance with its DMF and through its supply of dofetilide API to Tiger for Tiger's ANDA products. JM also denies that the '363 patent is valid.

29. Based on the foregoing, there is a substantial, immediate, actual and justiciable controversy between JM and Pfizer as to infringement and validity of the '363 patent.

FIRST COUNT

Declaration that the '363 Patent Is Not Infringed

30. JM repeats and re-alleges paragraphs 1-29 of this Complaint above.

31. An actual and justiciable controversy exists between JM and Pfizer regarding infringement of the '363 patent.

32. Pfizer has sued non-party Tiger for patent infringement of the '363 patent, and has stated in that litigation that its infringement contentions will be based on JM's DMF and samples of intermediates in the manufacture of dofetilide API in accordance with JM's DMF. Thus, there is a substantial risk that Pfizer will also allege that JM infringes one or more claims of the '363 patent.

33. JM has not, does not, and will not infringe any valid claim of the '363 patent, directly or indirectly, literally or under the doctrine of equivalents because, by way of example, JM does not make, use, sell, offer for sale in the United States or import into the United States substantially pure dofetilide polymorphs as required by the claims of the '363 patent.

34. JM is entitled to a declaration that it does not infringe, directly or indirectly, any claim of the '363 patent.

SECOND COUNT

Declaration that the '363 Patent Is Invalid

35. JM repeats and re-alleges paragraphs 1-34 of this Complaint above.

36. An actual and justiciable controversy exists between JM and Pfizer regarding the validity of the '363 patent.

37. In its litigation against Tiger, Pfizer has maintained that the claims of the '363 patent are valid.

38. Each of the claims of the '363 patent is invalid by reason of its failure to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and 112.

39. By way of example, the prior art render the claims of the '363 patent invalid as obvious under 35 U.S.C. § 103. A number of prior art publications describe crystalline dofetilide, dofetilide's ability to form different polymorphs, and dofetilide's therapeutic

properties including without limitation U.S. Patent No. 4,959,366 ("the '366 patent"), European Patent Pub. Nos. EP 0245997 and EP 0898964, and H.S. Rasmussen, Dofetilide, A Novel Class III Antiarrythmic Agent, 20 J. Cardiovascular Pharmacol. S96-S105 (Supp. 2, 1992). Highly pure crystalline drugs (at least about 98% pure) were known in the prior art, such as, without limitation, WO 96/31492 (1996) and R.J. Mesley Infrared Identification of Pharmaceutically Important Sulphonamides with Particular Reference to the Occurrence of Polymorphism, 19 J. Pharm. Pharmac. 295-304 (1967) ("Mesley). Because conducting a polymorph screen for a drug product is routine, if not required by FDA, one of ordinary skill in the art at the time of the alleged invention of the '363 patent would have investigated and characterized the different polymorphs of dofetilide using routine methods that are known in the art as reflected in, for example, L. Borka, Crystal Polymorphism of Pharmaceuticals, 40 Acta Pharm. Jugosl. 71-91 (1990), S. Byrn, Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations, 12 Pharm. Rees. 945-54 (1995) ("Byrn"), P.E. Cross, Selective Class III Antiarrythmic Agents, 33 J. Med. Chem. 1151-55 (1990), R.J. Mesley Infrared Identification of Pharmaceutically Important Sulphonamides with Particular Reference to the Occurrence of Polymorphism, 19 J. Pharm. Pharmac. 295-304 (1967), T.L. Threlfall, Analysis of Organic Polymorphs A Review, 120 Analyst 2435-60 (1995) and WO 96/31492 (1996). And the most common methods to analyze and characterize polymorphs include powder X-ray diffraction, differential scanning calorimetry and infrared spectrometry as explained by the prior art such as, without limitation Byrn and Mesley. The claims of the '363 patent are therefore nothing more than the routine, predictable and obvious result of following the prior art and therefore are invalid as obvious.

40. JM is entitled to a declaration that the '363 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, JM demands judgment in its favor and against Pfizer and respectfully requests that this Court:

(a) Adjudge the claims of the '363 patent not infringed;

(b) Adjudge the claims of the '363 patent invalid;

(c) Preliminarily and permanently enjoin Pfizer, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Pfizer from asserting or otherwise seeking to enforce the '363 patent against JM or anyone in privity with JM;

(d) Declare this case to be exceptional under 35 U.S.C. § 285;

(e) Award JM its attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court; and

(f) Award JM such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

In accordance with Fed. R. Civ. P. 38 and 39, and Local Civ. R. 38, JM asserts 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,

Dated: January 13, 2015

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