IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC, Plaintiff, v. ETHYPHARM S.A. and ETHYPHARM USA CORP., Defendants.	)	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Mylan Pharmaceuticals Inc. ("MPI"), by and through its counsel, respectfully submits this Complaint for Declaratory Judgment against Defendants Ethypharm S.A. and Ethypharm USA Corp. (collectively, "Defendants" or "Ethypharm"). In support thereof, Plaintiff alleges as follows:

NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code. MPI brings this action for a declaratory judgment of noninfringement under, *inter alia,* the Declaratory Judgment Act and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

THE PARTIES

2. Plaintiff MPI is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

3. Upon information and belief, Defendant Ethypharm S.A. is a corporation organized and existing under the laws of France, having a principal place of business at 21 Rue Saint Mathieu 78550, Houdan, France.

4. Upon information and belief, Defendant Ethypharm USA Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1500 Market Street, 12th Floor, East Tower, Philadelphia, PA 19102. Ethypharm USA Corp. may be served with process through its registered agent Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808.

JURISDICTION AND VENUE

5. This action arises under, *inter alia,* the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 21 U.S.C. § 355(j)(C)(i) and 35 U.S.C. § 271(e)(5).

6. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338 because it involves claims arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq,*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because there is an actual controversy concerning the infringement of U.S. Patent No. 6,106,861 ("the '861 patent"); and under the MMA, 21 U.S.C. § 355(j)(C)(i) and 35 U.S.C. § 271(e)(5), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

7. There exists a substantial and continuing actual, justiciable case or controversy between MPI and Ethypharm regarding infringement of the '861 patent.

8. This Court can and should declare the rights and legal relations of the parties regarding noninfringement of the '861 patent pursuant to, *inter alia,* the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 21 U.S.C. § 355(j)(C)(i) and 35 U.S.C. § 271(e)(5).

9. MPI has a statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over MPI's claims pursuant to 35 U.S.C. § 271(e)(5).

10. This Court has personal jurisdiction over Ethypharm S.A. because, upon information and belief, Ethypharm S.A. is in the business of, among other activities, manufacturing pharmaceutical products for importation into and sale throughout the United States and promotes the importation and sale of such products, including in the State of Delaware and this judicial district. Furthermore, Ethypharm S.A. has previously submitted to the jurisdiction of this Court and availed itself of the jurisdiction of this Court by filing lawsuits in the United States District Court for the District of Delaware.

11. This Court has personal jurisdiction over Ethypharm USA Corp. because, upon information and belief, Ethypharm USA Corp. is a corporation organized and existing under the laws of Delaware and is in the business of, among other activities, manufacturing pharmaceutical products for sale throughout the United States and promotes sale of such products, including in the State of Delaware and this judicial district.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and/or 1400.

BACKGROUND

I. Statutory Scheme For Approval Of New And Generic Drugs

13. The approval of new and generic drugs is governed by the applicable provisions of the FDCA, 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman Act"), and amended again by the MMA (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

A. New/previously-unapproved drugs and patent listing requirements

14. Before marketing an original new or previously-unapproved drug in the United States, the FDCA, as amended by Hatch-Waxman Act and the MMA, requires that an applicant submit, and that the FDA approve, a New Drug Application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug and labeling relating to the use of the drug for which approval is requested.

15. An NDA applicant is required to submit information regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

16. The FDA publishes patent information submitted by an NDA-holder in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book").

17. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent version of the NDA drug before patent expiration.

18. Thus, the NDA-holder/patent owner necessarily puts prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

19. Such conduct by the NDA-holder/patent owner gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

B. Generic drugs and patent certification requirements

20. The FDCA, as amended by Hatch-Waxman Act and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously approved brand-name or NDA drugs on an expedited basis.

21. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

22. Instead of repeating the clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

23. An ANDA applicant also is required to address each patent properly listed in the Orange Book in connection with the approved NDA drug. In particular, with certain exceptions not applicable here, the Hatch-Waxman Act requires an ANDA applicant to submit one of four types of patent certifications for each properly listed patent: (I) that the NDA-holder/patent owner has not submitted any patent information to the FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date; or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent.

24. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent. 21 U.S.C. § 355(j)(2)(B). This notice contains a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

25. The submission of a paragraph IV certification for a listed patent constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

26. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

27. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within 45 days of receiving such notification. Such a suit automatically delays the FDA from issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii). An ANDA applicant is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder/patent owner may bring suit after receiving notification of the ANDA and paragraph IV certification. *Id.*

28. If the NDA-holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, as explained below, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

II. Congress Explicitly Mandated That An ANDA-Filer May Bring And Maintain A Declaratory Judgment Action When Not Sued For Infringement

29. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

30. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code], bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

31. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access is accepted.

32. The declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings.

III. The '861 Patent

33. Upon information and belief, on or about August 22, 2000, the United States Patent and Trademark Office issued the '861 patent, entitled "Multiparticulate Tablet

Disintegrating In Less Than 40 Seconds In the Mouth." As per the face of the patent, the inventors of the subject matter claimed in the '861 patent are Charles Chauveau, Edouard Gendrot, Alain Gilles Demichelis and Nourreddine Nouri. A true and correct copy of the '861 patent is attached hereto as Exhibit A.

34. The '861 patent purports to claim a rapidly disintegratable multiparticulate tablet.

35. Upon information belief, Ethypharm S.A. purports and claims to own, and to have the right to enforce, the '861 patent.

36. Upon information and belief, Ethypharm USA Corp. has a license to the '861 patent and is able to assert rights under the '861 patent in the United States.

37. The '861 patent is listed in the Orange Book as covering FazaClo®, clozapine orally disintegrating tablets in 12.5 mg, 25 mg and 100 mg dosages. Also listed as covering FazaClo® are U.S. Patent Nos. 6,024,981 ("the '981 patent") and 6,221,392 ("the '392 patent"), which are purportedly owned by CIMA LABS, Inc.

38. Upon information and belief, Azur Pharma International III Limited, holder of NDA 21-590, markets and sells FazaClo® pursuant to a license to the '861 patent from Ethypharm.

39. By listing the '861 patent in the Orange Book, it is purportedly represented to the world that the '861 patent claims FazaClo® tablets or a method of using that drug, and that an infringement suit could be alleged against any generic ANDA applicant, including MPI, that attempts to seek approval for, and market, a generic version of clozapine orally disintegrating tablets before patent expiration.

IV. MPI's ANDA For Clozapine Orally Disintegrating Tablets

40. MPI is engaged in the research, development and manufacture of generic pharmaceutical products.

41. MPI submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of a generic version of clozapine orally disintegrating tablets in 12.5 mg, 25 mg and 100 mg dosages ("MPI's ANDA products").

42. MPI's ANDA was accepted for filing by the FDA and assigned No. 201824.

43. Upon information and belief, MPI's ANDA products do not infringe the claims of the '861 patent.

44. MPI's ANDA included a paragraph IV certification to the '861 patent, among others, stating that, in MPI's opinion and to the best of its knowledge, the '861 patent is invalid, unenforceable and/or will not be infringed by the manufacture, importation, use, offer for sale and/or sale of MPI's ANDA products.

45. MPI's submission of a paragraph IV certification purportedly constitutes an artificial act of patent infringement putting MPI at considerable risk of being sued by Ethypharm both before and after market entry. Indeed, this regulatory submission created the purported subject matter jurisdiction for CIMA LABS Inc., Azur Pharma Limited and Azur Pharma International III Limited to sue MPI for alleged infringement of the '981 and '392 patents in the United States District Court for the District of Delaware, Civil Action No. 10-625-LPS.

46. In accordance with 21 U.S.C. § 355(j)(2)(B), on or about June 15, 2010, MPI provided Ethypharm, among others, the requisite notice that it submitted an ANDA and a paragraph IV certification to the '861 patent. That notice included a detailed statement setting forth the factual and legal bases why the '861 patent is invalid, unenforceable and/or will not be

infringed by the manufacture, importation, use, offer for sale and/or sale of MPI's ANDA products for which MPI seeks FDA approval.

47. In its notice letter, MPI provided Ethypharm an Offer of Confidential Access to MPI's ANDA.

48. Ethypharm did not sue MPI for infringement of the '861 patent within the 45-day period for instituting an infringement action under 21 U.S.C. § 271(e). Ethypharm, however, still retains the ability to do so.

V. There Is A Substantial And Continuing Justiciable Controversy Between MPI And Ethypharm Regarding Infringement Of The '861 Patent

49. There is a substantial and continuing actual, justiciable case and controversy between MPI and Ethypharm regarding infringement of the '861 patent.

50. By preparing and filing MPI's ANDA, MPI has substantially prepared to make generic clozapine orally disintegrating tablets.

51. By submitting its ANDA and filing a paragraph IV certification to the '861 patent, among others, MPI has committed an alleged artificial act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) and Article III of the Constitution.

52. By listing the '861 patent in the Orange Book, it has been affirmatively represented to the world, including MPI, that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). That is, Ethypharm, as owner of the '861 patent, necessarily maintains that an infringement claim on the patent-in-suit could be alleged against MPI.

53. Ethypharm did not sue MPI for infringement of the '861 patent within 45 days of receipt of MPI's notice of its paragraph IV certification. In compliance with 21 U.S.C.

§ 355(j)(5)(C), MPI granted Ethypharm an Offer of Confidential Access to MPI's ANDA for generic clozapine orally disintegrating tablets. As such, MPI is statutorily entitled to institute, and this Court has constitutional authority to adjudicate, a declaratory judgment action against Ethypharm under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

54. Upon information and belief, Ethypharm also has not asserted infringement of the '861 patent against Barr Laboratories, Inc. ("Barr") and Novel Laboratories, Inc. ("Novel") based on their ANDA filings.

55. Upon information and belief, Barr is alleged to be the first applicant to file an ANDA on the 25 mg and 100 mg dosage strengths of clozapine orally disintegrating tablets, and Novel is alleged to be the first applicant to file an ANDA on the 12.5 mg dosage strength of clozapine orally disintegrating tablets.

56. Upon information and belief, Ethypharm's listing of the '861 patent in the Orange Book effectively denies MPI an economic opportunity to enter the marketplace, unless MPI can obtain a judgment that the '861 patent is invalid or not infringed by the MPI ANDA products.

57. Therefore, upon information and belief, MPI's injury-in-fact is redressable only by a declaratory judgment that the '861 patent is not infringed. A favorable judgment here would clear the path to FDA approval of MPI's ANDA that Ethypharm's actions could otherwise deny MPI. Thus, a favorable judgment in this action would eliminate the potential for Ethypharm's failure to assert the '861 patent to exclude MPI from the market.

58. Based upon the facts asserted herein, there is a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

59. MPI is statutorily entitled to file and maintain this declaratory judgment action against Ethypharm pursuant to the MMA in order to obtain patent certainty.

60. Absent the exercise of jurisdiction by this Court and such declaratory relief, Ethypharm's actions potentially exclude MPI from the market without ever subjecting Ethypharm's '861 patent to a court determination of its scope.

61. As a result of such exclusion, MPI and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of lower-priced clozapine orally disintegrating tablets.

CAUSE OF ACTION

62. MPI hereby incorporates by reference its allegations contained in paragraphs 1 through 62 of this Complaint as though fully set forth herein.

63. There is an actual, substantial, and continuing justiciable case or controversy between MPI and Ethypharm regarding noninfringement of the '861 patent.

64. The manufacture, use, sale, offer for sale, or importation of MPI's ANDA products have not infringed, do not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '861 patent.

65. MPI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of MPI's ANDA products have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '861 patent.

JURY DEMAND

MPI hereby demands a trial by jury as to all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, MPI prays for a declaratory judgment against Ethypharm as follows:

A. Judgment against Ethypharm declaring that the manufacture, use, sale offer for sale or importation of MPI's ANDA products have not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '861 patent.

B. A declaration that MPI's case against Ethypharm is an exceptional case within the meaning of 35 U.S.C. § 285, and an award of MPI's reasonable attorney fees and costs; and

C. Such other and further relief as the Court deems just and reasonable.

Respectfully submitted,

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