IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

CIMA LABS, INC., AZUR PHARMA LIMITED, and AZUR PHARMA INTERNATIONAL III LIMITED,	:	
Plaintiffs,	:	Civil Action No.: _____
vs.	:	
MYLAN PHARMACEUTICALS INC,	:	
Defendant.	:	

COMPLAINT FOR PATENT INFRINGEMNT

Plaintiffs CIMA LABS, INC. ("CIMA"), Azur Pharma Limited and Azur Pharma International III Limited (jointly with Azur Pharma Limited, "Azur") (collectively with CIMA, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant"), allege as follows:

THE PARTIES

1. Plaintiff CIMA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 7325 Aspen Lane, Brooklyn Park, Minnesota 55428.

2. Plaintiff Azur Pharma Limited is a limited company organized and existing under the laws of Ireland, having a principal place of business at 45 Fitzwilliam Square, Dublin 2, Ireland.

3. Azur Pharma International III Limited is a limited liability company organized and existing under the laws of Bermuda, having a principal place of business at Clarendon House, 2 Church Street, Hamilton, Bermuda HM11.

4. Upon information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia, 26505. Upon information and belief, Mylan can be served with process through its West Virginia registered agent for service of process, Corporation Service Company, 209 West Washington Street, Charleston, West Virginia, 25302.

NATURE OF THE ACTION

5. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

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. Upon information and belief, Mylan is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its incorporation under the laws of the State of West Virginia, and its maintenance of its principal place of business in the State of West Virginia. Accordingly, upon information and belief, Mylan has availed itself of the privileges of doing business in West Virginia, and has maintained systematic and continuous contacts with the State of West Virginia, such that Mylan is subject to jurisdiction of this Court.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and/or (c) and/or 1400(b).

ACTS GIVING RISE TO CLAIMS FOR PATENT INFRINGEMENT

9. On February 15, 2000, the United States Patent and Trademark Office issued U.S. Patent No. 6,024,981, entitled "Rapidly Dissolving Robust Dosage Form" (the "'981 patent"). A

copy of the '981 patent is attached as Exhibit A.

10. An *ex parte* reexamination of the '981 patent was requested on or about August 22, 2005 (Control No. 90/007,684), and reexamination was ordered on or about October 7, 2005. A second *ex parte* reexamination of the '981 patent was filed on or about September 7, 2006 (Control No. 90/008,133), and reexamination was ordered on or about September 28, 2006. The two *ex parte* reexaminations of the '981 patent were consolidated on or about January 8, 2007.

11. With respect to the '981 reexamination, a final Office Action was issued by the patent examiner on July 6, 2007. CIMA filed a response to that Office Action on September 6, 2007. On December 5, 2007, CIMA filed a Notice of Appeal and supporting brief traversing the patent examiner's final office action. The patent examiner filed an Answer to CIMA's brief on March 20, 2008, and CIMA filed its Reply brief on May 20, 2008. A decision from the Patent and Trademark Office ("PTO") Board of Appeals and Interferences ("BPAI") on the patentability of the '981 patent was issued on September 28, 2009. The BPAI upheld the Examiner's decision rejecting all claims of the '981 patent. On November 25, 2009, CIMA filed a Request for Rehearing before the BPAI, which is pending.

12. By way of assignment from the original inventors, CIMA owns all rights, title and interest in and to the '981 patent, including the right to sue and recover for patent infringement.

13. On April 24, 2001, the United States Patent and Trademark Office issued U.S. Patent No. 6,221,392, entitled "Rapidly Dissolving Robust Dosage Form" (the "'392 patent"). A copy of the '392 patent is attached as Exhibit B.

14. An *inter partes* reexamination of the '392 patent was filed on July 28, 2006 (Control No. 95/000,160) by KV Pharmaceutical, and reexamination was ordered on or about September 13, 2006.

15. With regard to the *inter partes* reexamination of the '392 patent, the patent examiner issued an office action on September 18, 2007. On October 18, 2007, CIMA responded to the examiner's office action and subsequently, on November 23, 2007, KV Pharmaceutical filed an additional response. On April 10, 2008 the patent examiner issued a Right of Appeal Notice**.** On May 29, 2008, CIMA filed a Notice of Appeal, and on July 29, 2008, CIMA filed its Appeal Brief, and on August 29, 2008, KV Pharmaceutical filed its Respondent Brief. On November 26, 2008, the Board of Patent Appeals returned CIMA's Appeal Brief to allow CIMA to address an issue regarding citation to evidence that was not in the administrative record. On December 18, 2008, CIMA filed a corrected Appeal Brief. On January 22, 2009, KV filed its Respondent Brief in response to CIMA's corrected Appeal Brief. On April 1, 2009 an Examiner's Answer was filed and on May 1, 2009 CIMA filed its Rebuttal Brief. Oral argument before the BPAI is anticipated, but no oral hearing has yet been scheduled.

16. By way of assignment from the original inventors, CIMA owns all rights, title and interest in and to the '392 patent, including the right to sue and recover for patent infringement.

17. Azur Pharma Limited is the exclusive licensee to the '981 and '392 patents for clozapine orally disintegrating tablets in the United States. Under the exclusive license, CIMA manufactures FAZACLO™, a clozapine product, for Azur. As the licensee of the '981 and '392 patents with regard to products containing various amounts of clozapine, Azur Pharma Limited has standing to sue Mylan for patent infringement.

18. The '981 and '392 patents (sometimes collectively referred to as the "patents in suit") are listed, by Azur Pharma International III Limited, holder of NDA No. 21-590, in a publication known as the Orange Book (formally entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*) as covering FAZACLO™, clozapine orally disintegrating

tablets in 12.5 mg, 25 mg and 100 mg dosages. As holder of NDA No. 21-590 covering FAZACLO™, clozapine orally disintegrating tablets in 12.5 mg, 25 mg and 100 mg dosages, Azur Pharma International III Limited has standing to sue Mylan for patent infringement.

19. Upon information and belief, Mylan submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 201824 under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). Through this ANDA, Mylan seeks the approval of the FDA necessary to engage in the commercial manufacture, use, offer for sale and sale of generic versions of clozapine orally disintegrating tablets in 12.5 mg, 25 mg and 100 mg dosages. ANDA No. 201824 specifically seeks FDA approval of the proposed generic versions prior to the expiration of the patents in suit.

20. No earlier than June 16, 2010, Plaintiffs received a letter from Mylan notifying them that ANDA No. 201824 containing a Paragraph IV Certification had been submitted to the FDA ("Paragraph IV Notice Letter"). The Paragraph IV Notice Letter and, upon information and belief, ANDA No. 201824, allege that the '981 patent and the '392 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the generic versions of clozapine orally disintegrating products for which Mylan seeks FDA approval.

21. Plaintiffs have commenced this action within forty-five (45) days of receipt of the Paragraph IV Notice Letter.

COUNT ONE

INFRINGEMENT OF THE '981 PATENT

22. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

23. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant's

submission of ANDA No. 201824 to the FDA constitutes infringement of the '981 patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant's manufacture, use, offer for sale and/or sale (including in West Virginia) of its proposed generic versions for which Defendant seeks approval from the FDA under ANDA No. 201824 will infringe, contribute to the infringement of and induce the infringement of one or more of the claims of the '981 patent.

25. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant was aware at the time of submission of ANDA No. 201824 and continues to be aware that the proposed generic versions for which Defendant seeks approval from the FDA under ANDA No. 201824, if approved, will be made, used and/or sold (including in West Virginia) in contravention of Plaintiffs' rights in and to the '981 patent.

26. Upon information and belief and subject to F.R.C.P. 11(b)(3), the conduct by Mylan renders this case "exceptional" as described in 35 U.S.C. § 285.

27. Plaintiffs will be irreparably harmed if the infringing activities of Mylan in relation to the '981 patent are not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT TWO

INFRINGEMENT OF THE '392 PATENT

28. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

29. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant's submission of ANDA No. 201824 to the FDA constitutes infringement of the '392 patent under

35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant's manufacture, use, offer for sale and/or sale (including in West Virginia) of its proposed generic versions for which Defendant seeks approval from the FDA under ANDA No. 201824 will infringe, contribute to the infringement of and induce the infringement of one or more of the claims of the '392 patent.

31. Upon information and belief and subject to F.R.C.P. 11(b)(3), Defendant was aware at the time of submission of ANDA No. 201824 and continues to be aware that the proposed generic versions for which Defendant seeks approval from the FDA under ANDA No. 201824, if approved, will be made, used and/or sold (including in West Virginia) in contravention of Plaintiffs' rights in and to the '392 patent.

32. Upon information and belief and subject to F.R.C.P. 11(b)(3), the conduct by Mylan renders this case "exceptional" as described in 35 U.S.C. § 285.

33. Plaintiffs will be irreparably harmed if the infringing activities of Mylan in relation to the '392 patent are not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendant has infringed the patents in suit by submission of ANDA No. 201824 and that the manufacture, use, offer for sale or sale of the generic versions proposed by Defendant to the FDA in ANDA No. 201824, if marketed, would infringe, induce or contribute to the infringement of the patents in suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing the effective date of any approval of ANDA No. 201824 be subsequent to the date of the last to expire of the patents in suit;

C. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) prohibiting Mylan, its officers, agents, attorneys, and employees and those acting in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale or importation of the generic versions proposed by Defendant to the FDA in ANDA No. 201824 or any other product that infringes, induces or contributes to the infringement of one or more of any of the claims in the patents in suit prior to expiration, including any extensions;

D. Monetary relief and damages, including damages for willful infringement, pursuant to 35 U.S.C. § 284, if the Defendant commercially manufacture, use, offer for sale or sell the generic versions proposed by Defendant to the FDA in ANDA No. 201824 or any other product that infringes, induces or contributes to the infringement of one or more of any of the claims in the patents in suit prior to expiration, including any extensions;

E. A declaration that this case is exceptional under 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 285 and an award of attorneys' fees, costs and expenses to Plaintiffs;

F. Such other and further relief as this Court may deem just and proper.

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Dated: July 28, 2010