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

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	:	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG (hereinafter "Plaintiffs"), for their Complaint herein against defendants Mylan Pharmaceuticals Inc. and Mylan Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. On information and belief, Mylan Inc. is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

6. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Inc., and the acts of Mylan Pharms complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Mylan Inc. On information and belief, Mylan Pharms and Mylan Inc. have officers or directors in common.

7. Mylan Pharms and Mylan Inc. hereinafter are referred to collectively as "Mylan."

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. Mylan Pharms is incorporated under the laws of the State of West Virginia, and maintains its principal place of business in the State of West Virginia. Mylan has submitted to jurisdiction in this judicial district in numerous patent cases in the last six years. On information and belief, Mylan directly or indirectly manufactures, markets and sells drug products throughout the United States and in this judicial district.

10. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, the above-mentioned facts.

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

CLAIM FOR RELIEF – PATENT INFRINGEMENT

12. Plaintiff Novartis Pharmaceuticals Corporation holds an approved new drug application ("NDA") NDA No. 21-192 for Lescol® XL extended release oral tablets (80 mg), which tablets contain the active ingredient fluvastatin sodium. Lescol® XL extended release oral tablets were approved by the United States Food and Drug Administration ("FDA") to reduce elevated total cholesterol, low-density lipoprotein C, triglyceride and apolipoprotein B levels and to increase high-density lipoprotein C in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson Type IIa and IIb). The FDA has also approved Lescol® XL extended release oral tablets as an adjunct to diet to reduce total cholesterol, low-density lipoprotein C and apolipoprotein B levels in adolescent boys and girls. Lescol® XL extended release oral tablets further are FDA-approved for patients with coronary heart disease to reduce the risk of undergoing coronary revascularization procedures. Finally, Lescol® XL extended release oral tablets are FDA-approved to slow the progress of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower total and low-density lipoprotein cholesterol to target levels.

13. Novartis AG is the owner of United States Letters Patent No. 6,242,003 ("the '003 patent"). The '003 patent was duly and legally issued on June 5, 2001. A true copy of the '003 patent is attached hereto as Exhibit A.

14. The '003 patent claims color-stable sustained release tablets comprising granules comprising fluvastatin and a hydroxypropyl methyl cellulose polymer, and methods of preparing color-stable sustained release oral dosage compositions comprising fluvastatin and a hydroxypropyl methyl cellulose polymer.

15. Mylan Pharms submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic fluvastatin sodium extended release oral tablets 80 mg (hereinafter "Mylan's Fluvastatin Sodium Product").

16. Mylan submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's Fluvastatin Sodium Product before the expiration of the '003 patent.

17. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's Fluvastatin Sodium Product before the expiration of the '003 patent, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's Fluvastatin Sodium Product for which Mylan seeks approval in its ANDA will also infringe one or more claims of the '003 patent.

18. Mylan made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) ("Paragraph IV certification") that, in its opinion, the '003 patent is invalid and that Mylan does not infringe certain claims of the '003 patent. As to the remaining claims of the '003 patent, Mylan did not allege non-infringement, nor did Mylan allege unenforceability of the '003 patent in its Paragraph IV certification.

19. Mylan's Fluvastatin Sodium Product, if approved, will be stored at a relative humidity not exceeding 75% and at a temperature of 25° C to 40° C, which storage constitutes direct infringement of the '003 patent. This will occur at Mylan's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Mylan will

actively induce, encourage, aid and abet others to practice this storage method with the knowledge that it is in contravention of Plaintiffs' rights under the '003 patent.

20. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mylan's Fluvastatin Sodium Product be a date which is not earlier than the October 13, 2020 expiration of pediatric exclusivity for the '003 patent, or any later date of exclusivity to which Plaintiffs are or become entitled. Further, Plaintiffs are entitled to an award of damages for any commercial sale or use of Mylan's Fluvastatin Sodium Product, and any act committed by Mylan with respect to the subject matter claimed in the '003 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

21. On information and belief, when Mylan filed its ANDA, it was aware of the '003 patent, and that the filing of its ANDA with the request for its approval prior to the expiration of that patent was an act of infringement.

22. This is an exceptional case, and Plaintiffs are entitled to an award of reasonable attorneys fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Mylan has infringed one or more claims of the '003 patent by filing the aforesaid ANDA relating to Mylan's Fluvastatin Sodium Product;

B. A permanent injunction restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mylan's Fluvastatin Sodium Product;

C. An Order that the effective date of any approval of the aforementioned ANDA relating to Mylan's Fluvastatin Sodium Product be a date which is not earlier than the later of the expiration of the right of exclusivity under the '003 patent, or any later right of exclusivity to which Plaintiffs are or become entitled;

D. Damages from Mylan for any commercial activity constituting infringement of the '003 patent;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs are entitled to the costs and reasonable attorney fees in this action; and

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

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