

FRESENIUS MEDICAL CARE  
HOLDINGS, INC.,  
  
Plaintiff,  
  
v.  
  
ZYDUS PHARMACEUTICALS USA INC.,  
  
Defendant.

Plaintiff Fresenius Medical Care Holdings, Inc. (“FMCH”) for its Complaint against Zydus Pharmaceuticals USA Inc. (“Zydus”) alleges as follows:

1. FMCH is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

2. Zydus is a New Jersey corporation having its principal place of business at 73 Route 31 North, Pennington, NJ 08534.

3. This is a civil action for declaratory and injunctive relief against Zydus for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Zydus's submission of Abbreviated New Drug Application ("ANDA") No. 20-2315 to the Food and Drug Administration ("FDA") for approval to market a generic copy of FMCH's PhosLo® GelCaps calcium acetate drug product.

## **JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Specifically, Zydus included in ANDA No. 20-2315 a certification under Paragraph IV of Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the “Hatch-Waxman Act”), with respect to United States Patent No. 6,576,665 (the “’665 patent”). *See* 21 U.S.C. § 355(j)(2)(A)(vii). Under the Hatch-Waxman Act, Zydus’s filing of a so-called “Paragraph IV certification” with respect to a patent constitutes an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law over which the Court has exclusive subject matter jurisdiction.

5. This Court has personal jurisdiction over Zydus at least by virtue of the fact that Zydus conducts business in the Commonwealth of Massachusetts, has availed itself of the rights and benefits of Massachusetts law, and has engaged in substantial and continuing contacts with the Commonwealth.

6. Zydus is in the business of selling drug products in the United States.

7. Zydus conducts business in the Commonwealth of Massachusetts and sells various drug products in the Commonwealth of Massachusetts.

8. Venue is proper in this jurisdiction under 28 U.S.C. §§ 1391 and 1400(b).

## **ZYDUS’S INFRINGEMENT OF FMCH’S ’665 PATENT**

9. FMCH is the assignee of the ’665 patent and holder of New Drug Application (“NDA”) No. 21-160, upon which Zydus’s ANDA No. 20-2315 is based. A copy of the ’665 patent is attached as Exhibit A.

10. Zydus’s submission of ANDA No. 20-2315 constitutes infringement of the ’665 patent. Zydus included within its ANDA a Paragraph IV certification to the effect that the ’665

patent is invalid or would not be infringed by Zydus's proposed generic copy of FMCH's PhosLo® GelCaps calcium acetate drug product. Zydus's submission of this certification constitutes an act of infringement of one or more claims of the '665 patent under the Hatch-Waxman Act and the Patent Act. *See* 35 U.S.C. § 271(e)(2)(A).

11. By letter dated December 7, 2010, Zydus provided notice to FMCH of the ANDA filing and Paragraph IV certification alleging that no valid claim of the '665 patent would be infringed by Zydus's proposed generic calcium acetate drug product.

12. Upon information and belief, Zydus intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

13. Upon FDA approval of Zydus's ANDA No. 20-2315, Zydus will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling Zydus's proposed generic calcium acetate drug product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

14. FMCH has the right and standing to enforce the '665 patent and bring this action.

15. Zydus had notice of the '665 patent at the time of its infringement. Zydus's infringement has been, and continues to be, willful and deliberate.

16. FMCH will be substantially and irreparably damaged and harmed if Zydus's infringement is not enjoined. FMCH does not have an adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, FMCH respectfully requests the following relief:

- (a) A judgment declaring that Zydus has infringed the '665 patent, and that Zydus's making, using, selling, offering to sell, or importing of its generic calcium acetate drug product will infringe the '665 patent;
- (b) A judgment providing that the effective date of any FDA approval for Zydus to make, use or sell Zydus's generic calcium acetate drug product be no earlier than the date on which the '665 patent expires;
- (c) A judgment permanently enjoining Zydus from making, using, selling, offering to sell, or importing its generic calcium acetate drug product until after the expiration of the '665 patent;
- (d) If Zydus engages in the commercial manufacture, use, offer to sell, or sale of its generic calcium acetate drug product prior to the expiration of the '665 patent, a judgment awarding FMCH damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;
- (e) Attorney's fees in this action pursuant to 35 U.S.C. § 285;
- (f) Costs and expenses in this action; and
- (g) Such further and other relief as the Court may deem just and proper.

FRESENIUS MEDICAL CARE  
HOLDINGS, INC.

By its attorneys,

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*Fresenius Medical Care Holdings, Inc.*

Dated: January 21, 2011