

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC.,	)	
and ALCON MANUFACTURING, LTD.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. _____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
_____	)	

**COMPLAINT**

Plaintiffs Bayer HealthCare AG, Alcon, Inc., and Alcon Manufacturing, Ltd. (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Teva Pharmaceuticals USA, Inc. ("Teva") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of VIGAMOX<sup>®</sup> ophthalmic solution, a drug product containing moxifloxacin hydrochloride, prior to the expiration of various U.S. patents.

**PARTIES**

2. Plaintiff Bayer HealthCare AG ("BHC") is a corporation organized and existing under the laws of the Federal Republic of Germany, having its principal place of business at 51368 Leverkusen, Federal Republic of Germany.

3. Plaintiff Alcon, Inc. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Bösch 69, CH-6331 Hünenberg,

Switzerland.

4. Plaintiff Alcon Manufacturing, Ltd. is a limited partnership organized and existing under the laws of the State of Texas, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

5. Except where otherwise noted, Alcon, Inc. and Alcon Manufacturing, Ltd. are referred to collectively herein as “Alcon.”

6. Upon information and belief, defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

#### **JURISDICTION AND VENUE**

7. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b).

#### **COUNT I**

8. BHC incorporates each of the preceding paragraphs 1-7 as if fully set forth herein.

9. United States Patent No. 4,990,517 (“the ’517 patent”), entitled “7-(1-Pyrrolidinyl)-3-Quinolone- and -Naphthyridonecarboxylic Acid Derivatives as Antibacterial Agents and Feed Additives” (Exhibit A hereto), was duly and legally issued on February 5, 1991 to Bayer AG, as assignee of Uwe Petersen, Thomas Schenke, Andreas Krebs, Klaus Grohe, Michael Schriewer, Ingo Haller, Karl G. Metzger, Rainer Endermann, and Hans-Joachim Zeiler.

10. United States Patent No. 5,607,942 (“the ’942 patent”), entitled “7-(1-Pyrrolidinyl)-3-Quinolone- and -Naphthyridone-Carboxylic Acid Derivatives as Antibacterial Agents and Feed Additives” (Exhibit B hereto) was duly and legally issued on March 4, 1997 to

Bayer AG, as assignee of Uwe Petersen, Thomas Schenke, Andreas Krebs, Klaus Grohe, Michael Schriewer, Ingo Haller, Karl G. Metzger, Rainer Endermann, and Hans-Joachim Zeiler.

11. Bayer AG has assigned the '517 patent and the '942 patent to plaintiff BHC.

12. Plaintiff BHC owns both the '517 patent and the '942 patent. BHC will be substantially and irreparably damaged by infringement of the '517 patent and the '942 patent.

13. By letter dated February 21, 2006 (the "Notice Letter"), defendant Teva notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that Teva had submitted an ANDA, No. 78-073, to the FDA. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and sale of a drug product containing moxifloxacin hydrochloride prior to the expiration of the '517 patent, the '942 patent, and U.S. Patent No. 6,716,830.

14. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 78-073 is covered by one or more claims of the '517 patent and of the '942 patent.

15. In the Notice Letter, Teva also notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. Teva's filing of the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product containing moxifloxacin hydrochloride before the expiration of the '517 patent and the '942 patent is an act of

infringement of each of those patents under 35 U.S.C. § 271(e)(2)(A).

17. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringement of the '517 patent and the '942 patent.

18. Unless defendant Teva is enjoined from infringing the '517 patent and the '942 patent, BHC will suffer irreparable injury. BHC has no adequate remedy at law.

## COUNT II

19. Alcon incorporates each of the preceding paragraphs 1-7 as if fully set forth herein.

20. United States Patent No. 6,716,830 ("the '830 patent"), entitled "Ophthalmic Antibiotic Compositions Containing Moxifloxacin" (Exhibit C hereto), was duly and legally issued on April 6, 2004 to Plaintiff Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

21. Plaintiff Alcon, Inc. owns the '830 patent and holds an approved New Drug Application for VIGAMOX<sup>®</sup> ophthalmic solution. Alcon, Inc. will be substantially and irreparably damaged by infringement of the '830 patent.

22. Plaintiff Alcon Manufacturing, Ltd. has been granted an exclusive license under the '830 patent. Alcon Manufacturing, Ltd. will be substantially and irreparably damaged by infringement of the '830 patent.

23. In the Notice Letter described in paragraph 13 above, defendant Teva notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that Teva had submitted ANDA No. 78-073, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of a drug product containing moxifloxacin hydrochloride

prior to the expiration of the '830 patent.

24. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 78-073 is covered by one or more claims of the '830 patent.

25. In the Notice Letter, Teva also notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

26. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringement of the '830 patent.

27. Teva's filing of the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product containing moxifloxacin hydrochloride before the expiration of the '830 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

28. Unless defendant Teva is enjoined from infringing the '830 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

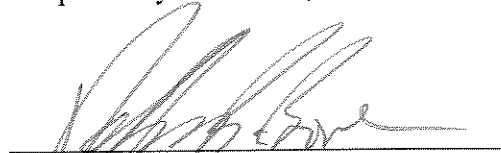
(a) A judgment providing that the effective date of any FDA approval for defendant Teva commercially to make, use, or sell moxifloxacin hydrochloride or any drug product containing moxifloxacin hydrochloride be not earlier than the latest of the expiration dates of United States Patent No. 4,990,517, United States Patent No. 5,607,942, and United States Patent No. 6,716,830;

(b) A preliminary and permanent injunction against any infringement by defendant Teva of United States Patent Nos. 4,990,517, 5,607,942, and 6,716,830 through the

commercial manufacture, use, sale, offer for sale, or importation into the United States of moxifloxacin hydrochloride or any drug product containing moxifloxacin hydrochloride;

- (c) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (d) Costs and expenses in this action; and
- (e) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,



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Dated: April 5, 2006

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