IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG and BAYER PHARMACEUTICALS CORPORATION,)
Plaintiffs,))
٧.	Civil Action No.
TEVA PHARMACEUTICALS USA, INC.,)
Defendant.)
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COMPLAINT

Plaintiffs Bayer HealthCare AG and Bayer Pharmaceuticals Corporation, 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 AVELOX® tablets, 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 Bayer Pharmaceuticals Corporation ("BPC") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of

business at 400 Morgan Lane, West Haven, Connecticut 06516.

4. 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 19454-1090.

JURISDICTION AND VENUE

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

COUNT I

- 6. BHC and BPC incorporate each of the preceding paragraphs 1-5 as if fully set forth herein.
- 7. 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.
- 8. 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.
- 9. Bayer AG has assigned the '517 patent and the '942 patent to plaintiff BHC.
 - 10. 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.

- Plaintiff BPC has been granted a license under the '517 patent and the '942 patent and holds a New Drug Application approved by the United States Food & Drug Administration ("FDA") for AVELOX® tablets. BPC will be substantially and irreparably damaged by infringement of the '517 patent and the '942 patent.
- 12. By letter dated March 7, 2007 (the "Notice Letter"), defendant Teva notified BHC and Bayer Corporation, Pharmaceutical Division, that Teva had submitted to the FDA an amended certification to an ANDA, No. 77-437. The purpose of the amended certification to ANDA No. 77-437 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 and the '942 patent.
- The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 77-437 is covered by one or more claims of the '517 patent and of the '942 patent.
- In the Notice Letter, Teva also notified BHC and Bayer Corporation,

 Pharmaceutical Division, that the amended certification was 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).
- 15. Teva's filing of an amended certification to its 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).
 - 16. 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.

17. Unless defendant Teva is enjoined from infringing the '517 patent and the '942 patent, BHC and BPC will suffer irreparable injury. BHC and BPC have 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 and United States Patent No. 5,607,942;
- (b) A preliminary and permanent injunction against any infringement by defendant Teva of United States Patent No. 4,990,517 and United States Patent No. 5,607,942 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 in 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.

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