

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS SOLUTIONS)
INC., BAYER INTELLECTUAL PROPERTY)
GMBH, and BAYER PHARMA AG,)
)
Plaintiffs,)
) C.A. No. 14-1422 (SLR) (SRF)
v.)
)
CUSTOPHARM, INC.,)
)
Defendant.)

[PROPOSED] AMENDED FINAL JUDGMENT

This action, having come to trial before the Court from September 26 through September 29, 2016, and the Court having issued its Opinion and Order on February 10, 2017 (D.I. 85, 86) and a Judgment having been entered on February 10, 2017 (D.I. 87):

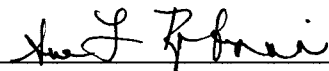
IT IS HEREBY ORDERED AND ADJUDGED this ~~28th~~ day of February, 2017, for the reasons set forth in the Memorandum Opinion dated February 10, 2017 (D.I. 85) that:

1. Judgment is entered in favor of Plaintiffs Endo Pharmaceuticals Solutions Inc., Bayer Intellectual Property GmbH, and Bayer Pharma AG (collectively “Plaintiffs”) and against Defendant Custopharm, Inc. (“Custopharm”) on the claim in Plaintiffs’ Complaint dated November 20, 2014 (D.I. 1), and on the counterclaim of non-infringement (Counterclaim Count III) in Custopharm’s Answer and Counterclaims dated December 23, 2014 (D.I. 11), that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic version of Plaintiffs’ Aveed® drug product that is the subject of Custopharm’s Abbreviated New Drug Application (“ANDA”) No. 207583 would infringe Claim 2 of U.S. Patent No. 7,718,640 (“the ’640 patent”) and Claim 18 of U.S. Patent No. 8,338,395 (“the ’395 patent”).

2. Judgment is entered in favor of Plaintiffs and against Custopharm on the counterclaims of invalidity (Counterclaim Counts I and II) in Custopharm's Answer and Counterclaims dated December 23, 2014 (D.I. 11). Specifically, that Claim 2 of the '640 patent and Claim 18 of the '395 patent are not invalid under any provision of 35 U.S.C. §§ 101, 102, 103, or 112, or any other judicially-created bases for invalidation.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") is ordered to reset the effective date of the approval of Custopharm's ANDA No. 207583 to be a date that is not earlier than the date of expiration of the '640 patent inclusive of the patent term adjustment awarded to Plaintiffs under 35 U.S.C. § 154(b) (currently March 14, 2027) or the expiration of the '395 patent inclusive of the patent term adjustment awarded to Plaintiffs under 35 U.S.C. § 154(b) (currently February 27, 2026), whichever is later.

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Custopharm and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby permanently enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Custopharm's proposed generic version of Plaintiffs' Aveed® drug product that is the subject of Custopharm's ANDA No. 207583 during the terms of the '640 and '395 patents.



Senior United States District Judge
2/20/17