

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and)
BAYER HEALTHCARE)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
)
v.) C.A. No. 13-978 (RGA)
)
WATSON LABORATORIES, INC.,)
)
Defendant.)

~~PROPOSED~~ **FINAL JUDGMENT**

This action, having come to trial before the Court from May 18 through May 21, 2015, Honorable Richard G. Andrews, District Judge presiding, the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 14 day of September, 2015, for the reasons set forth in the Order Regarding Infringement and Claim Construction of U.S. Patent No. 6,441,168 dated February 19, 2014 (D.I. 38) and the Court's Trial Opinion dated August 31, 2015 (D.I. 115) that:

1. Judgment is entered in favor of Plaintiffs Merck & Cie, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs") and against Defendant Watson Laboratories, Inc. ("Watson") on the claim in Plaintiffs' Complaint for Patent Infringement dated June 4, 2013 (D.I. 1), that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic version of Bayer HealthCare's Safyral® combined oral contraceptive that is the subject of Watson's Abbreviated New Drug Application ("ANDA") No. 203594 would infringe Claim 4 of U.S. Patent No. 6,441,168 ("the '168 patent").

2. Judgment is entered in favor of Plaintiffs and against Watson on the counterclaim of invalidity in Watson's Answer to Complaint, Defenses, and Counterclaims dated August 2, 2013 (D.I. 11). Specifically, that Claim 4 of the '168 patent is not invalid for having been on sale in this country, more than one year prior to the date of application for the patent under 35 U.S.C. § 102(b), not invalid as anticipated under 35 U.S.C. § 102, not invalid for obviousness under 35 U.S.C. § 103, and not invalid for lack of written description under 35 U.S.C. § 112.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") is ordered to make the effective date of any final approval of Watson's ANDA No. 203594 to be a date that is not earlier than the date of expiration of the '168 patent (April 17, 2020).

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Watson 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, Watson's proposed generic version of Bayer HealthCare's Safyral® combined oral contraceptive that is the subject of Watson's ANDA No. 203594 during the term of the '168 patent.

Sept 14, 2015
DATED

Richard G. Andrew
UNITED STATES DISTRICT JUDGE