

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAYER INTELLECTUAL PROPERTY GMBH,
BAYER PHARMA AG, and
JANSSEN PHARMACEUTICALS, INC.

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED., et al.

Defendants.

Civ. A. No. 15-902 (SLR)
(Consolidated)

**DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.’S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO
COMPLAINT FILED IN C.A. NO. 16-628**

Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge” or “Defendant”), by and through its undersigned counsel, hereby responds to the separately numbered paragraphs of the Complaint filed by Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG and Janssen Pharmaceuticals, Inc. (collectively, “Bayer” or “Plaintiffs”) in Civil Action No. 16-628-SLR against Breckenridge, as follows.

NATURE OF THE ACTION

1. Breckenridge admits that Plaintiffs purport to bring this action under the patent laws of the United States, and in particular for infringement of one or more of U.S. Patent Nos. 7,157,456 (“the ’456 patent”) and 7,592,339 (“the ’339 patent”), related to, *inter alia*, Breckenridge’s Abbreviated New Drug Application seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of rivaroxaban tablets (“Breckenridge’s ANDA Products”). Breckenridge denies the remaining allegations of paragraph 1.

THE PARTIES

Plaintiffs

2. Breckenridge is without information sufficient to form a belief as to the truth of the averments in paragraph 2 and therefore denies them.

3. Breckenridge admits that, upon information and belief, Bayer Pharma AG has a place of business at Müllerstrasse 178, 13353 Berlin, Germany. Breckenridge is without information sufficient to form a belief as to the truth of the remaining averments in paragraph 3 and therefore denies them.

4. Breckenridge admits that, upon information and belief, Janssen Pharmaceuticals, Inc. has a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey. Breckenridge is without information sufficient to form a belief as to the truth of the remaining averments in paragraph 4 and therefore denies them.

Breckenridge

5. Breckenridge admits that it is a corporation organized and existing under the laws of the State of Florida and that it has a principal place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida 33487.

6. Breckenridge admits that it is engaged in, *inter alia*, the development and marketing of drug products, and that it has filed Abbreviated New Drug Applications (“ANDAs”) with the Food and Drug Administration (“FDA”) seeking approval to manufacture, use and sell generic versions of drug products, and that in one or more instances such ANDAs have included a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Except as so admitted, Breckenridge denies the allegations of paragraph 6.

7. Admitted.

8. The allegations of paragraph 8 appear to be directed to whether the Court has personal jurisdiction over Breckenridge, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit, Breckenridge does not contest personal jurisdiction over it by this Court. To the extent further averments in paragraph 8 are not addressed by the foregoing, Breckenridge denies them.

9. The allegations of paragraph 9 appear to be directed to whether the Court has personal jurisdiction over Breckenridge, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit, Breckenridge does not contest personal jurisdiction over it by this Court. To the extent further averments in paragraph 9 are not addressed by the foregoing, Breckenridge denies them.

JURISDICTION

10. Breckenridge incorporates its responses to Paragraphs 1 - 9 as if fully set forth herein.

11. Admitted.

12. Admitted.

13. The allegations of paragraph 13 appear to be directed to whether this Court has personal jurisdiction over Breckenridge, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit, Breckenridge does not contest personal jurisdiction over it by this Court. To the extent further averments in paragraph 13 are not addressed by the foregoing, Breckenridge denies them.

14. The allegations of paragraph 14 appear to be directed to whether this Court has personal jurisdiction over Breckenridge, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit,

Breckenridge does not contest personal jurisdiction over it by this Court. To the extent further averments in paragraph 14 are not addressed by the foregoing, Breckenridge denies them.

15. The allegations of paragraph 15 appear to be directed to whether this Court has personal jurisdiction over Breckenridge, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit, Breckenridge does not contest personal jurisdiction over it by this Court. To the extent further averments in paragraph 15 are not addressed by the foregoing, Breckenridge denies them.

VENUE

16. The allegations of paragraph 16 appear to be directed to whether venue is proper in this judicial district, which is a legal conclusion to which no response is required. To the extent any response is required, solely for purposes of this lawsuit, Breckenridge does not contest venue. To the extent further averments in paragraph 16 are not addressed by the foregoing, Breckenridge denies them.

FACTUAL BACKGROUND

17. Breckenridge admits that information publicly available in the records of FDA indicates that New Drug Application (“NDA”) No. 022406 is for rivaroxaban 10 mg, 15 mg, and 20 mg tablets; that the rivaroxaban tablets that are the subject of said NDA are (i) indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, (ii) for the treatment of deep vein thrombosis (DVT), and of pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; and that the trade name for said tablets is XARELTO®. To the extent that the remaining averments in paragraph 17 are not addressed, Breckenridge denies them.

18. Breckenridge admits that information publicly available in the records of FDA indicates that FDA approved NDA No. 022406 and that the owner of said application is Janssen Pharmaceuticals, Inc. To the extent that the remaining averments in paragraph 18 are not addressed, Breckenridge denies them.

The '456 Patent

19. Breckenridge admits that U.S. Patent No. 7,157,456 (“the ’456 patent”) is entitled “Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation,” and that the patent indicates on its face that it was issued on January 2, 2007. Breckenridge admits that what purports to be a copy of the ’456 patent was attached as Exhibit A to the complaint. Breckenridge denies that the ’456 patent was duly and legally issued. To the extent that the remaining averments in paragraph 19 are not addressed, Breckenridge denies them.

20. The allegations of paragraph 20 state legal conclusions to which no answer is required. To the extent any answer is required, Breckenridge denies the allegations in paragraph 20.

21. Breckenridge is without sufficient information to form a belief as to the truth of the averments in paragraph 21; however, Breckenridge admits that a search for patent assignment on the United States Patent and Trademark Office website indicates that the ’456 patent is assigned to Bayer Intellectual Property GmbH; otherwise, denied.

22. Breckenridge is without sufficient information to form a belief as to the truth of the averments in paragraph 22 and therefore denies them.

23. Breckenridge is without sufficient information to form a belief as to the truth of the averments in paragraph 23 and therefore denies them.

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