

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

BAYER HEALTHCARE PHARMACEUTICALS  
INC.; BAYER PHARMA  
AKTIENGESELLSCHAFT; and BAYER  
AKTIENGESELLSCHAFT,

Plaintiffs,

v.

AUROBINDO PHARMA LTD.; AUROBINDO  
PHARMA U.S.A., INC.,

Defendants.

Case No. \_\_\_\_\_

**SUPPLEMENTAL INFORMATION FOR PATENT CASES  
INVOLVING AN ABBREVIATED NEW DRUG APPLICATION (ANDA)**

Plaintiffs Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma Aktiengesellschaft (“Bayer Pharma AG”), and Bayer Aktiengesellschaft (“Bayer AG”) (collectively, “Bayer” or “Plaintiffs”) hereby provide the information below with respect to the deadlines set forth in 21 U.S.C. § 355(j):

Date Patentee(s) Received Notice: No earlier than August 28, 2025

Date of Expiration of Patent: July 29, 2035 (U.S. Patent No. RE49,826)

Regulatory Stay Deadline: No earlier than January 9, 2029<sup>1</sup>

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<sup>1</sup> The stay preventing approval of the proposed generic products expires no earlier than January 9, 2029 (seven and one-half years from the new chemical entity approval on July 9, 2021). See 21 U.S.C. § 355(j)(5)(F)(ii).

Dated: October 9, 2025

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