

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

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

Plaintiffs,

v.

MACLEODS PHARMACEUTICALS LTD. and
MACLEODS PHARMA USA, 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 September 12, 2025

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

Regulatory Stay Deadline: No earlier than January 9, 2029¹

¹ 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 20, 2025

MCCARTER & ENGLISH, LLP

Of Counsel:

/s/ Daniel M. Silver

Deborah Fishman
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real,
Five Palo Alto Square, Suite 500
Palo Alto, CA 94306-3807
(650) 319-4500
deborah.fishman@arnoldporter.com

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Jeremy Cobb
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave, NW
Washington, DC 20001-3743
(202) 942-5000
jeremy.cobb@arnoldporter.com

Attorneys for Plaintiffs
Bayer HealthCare Pharmaceuticals Inc.,
Bayer Pharma AG, and Bayer AG

Abigail Struthers
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000
abigail.struthers@arnoldporter.com