IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARAGON PHARMACEUTICALS, INC. JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. HETERO LABS LIMITED UNIT V, and HETERO USA, INC. Defendants.	Civil Action No. 2:22-cv-03212 (SRC)(LDW) closed

CONSENT JUDGMENT AND ORDER

WHEREAS Civil Action Nos. 2:22-cv-03212(SRC)(LDW) has been brought by Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., The Regents of the University of California and Sloan-Kettering Institute for Cancer Research (collectively "Plaintiffs") against Hetero Labs Limited Unit V and Hetero USA, Inc. ("Hetero") alleging infringement of United States Patent Nos. 8,445,507, 9,481,663, 9,884,054, RE49,353, 10,702,508, and 10,849,888 (collectively, "the Patents-in-Suit");

WHEREAS Plaintiffs currently market in the United States pursuant to New Drug Application No. 210951, a drug product containing Apalutamide under the trade name ERLEADA® ("Erleada Product");

WHEREAS Hetero filed or caused to be filed Abbreviated New Drug Application ("ANDA") No. 217185 seeking FDA approval to make, sell, offer for sale, use, and/or import in or for the United States a pharmaceutical product asserted to be bioequivalent to the Erleada Product ("Hetero ANDA Product");

WHEREAS, in the Action, the Parties entered into a Stipulation dated July 29, 2024 with respect to United States Patent Nos. 9,884,054, RE49,353, 10,702,508, and 10,849,888 because Hetero amended ANDA No. 217185;

WHEREAS Plaintiffs and Hetero have resolved this litigation for the remaining Patents-in-Suit as to Hetero for good cause and valuable consideration recognized by Plaintiffs and Hetero;

WHEREAS Plaintiffs and Hetero respectfully request that the Court terminate the pending litigation as between Plaintiffs and Hetero by the entry of this Judgment and Order; and

WHEREAS Plaintiffs and Hetero now consent to this Judgment and Order.

IT IS ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties.

2. Hetero admits that the claims of the Patents-in-Suit are valid and enforceable with respect to products containing Apalutamide (the active pharmaceutical ingredient in the Hetero Product) as the sole active ingredient that are sold, offered for sale, or distributed under an Abbreviated New Drug Application that refers to the product sold pursuant to NDA No. 210951 as the reference-listed drug, and that the claims of the Patents-in-Suit would be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Hetero Product in the United States prior to the expiration of the Patents-in-Suit.

3. Hetero and its affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Hetero ANDA Product until the expiration of the Patents-in-Suit, including any patent term extensions and/or patent term adjustments and during the period of any associated pediatric exclusivity, other than as authorized by Plaintiffs.

4. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Plaintiffs against Hetero and its affiliates, or by Hetero and its affiliates against Plaintiffs, in this litigation solely with respect to the Patents-in-Suit as asserted against the Hetero ANDA Product are hereby dismissed with prejudice.

5. Plaintiffs and Hetero shall bear their own fees and costs in connection with this litigation, including attorneys' fees.

6. Plaintiffs and Hetero waive all right to appeal or otherwise move for relief from this Judgment and Order.

7. This Court shall retain jurisdiction of this litigation and over Plaintiffs and Hetero for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED this 15th day of OCTOBER 2024

s/Stanley R. Chesler, U. S. D. J.
HONORABLE STANLEY R. CHESLER
UNITED STATES DISTRICT JUDGE

Dated: October 14, 2024

We hereby consent to the form and entry of this Order:

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