IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, and HETERO USA INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No.
ABBVIE INC. and NEUROCRINE BIOSCIENCES, INC.	:	
Defendants	:	

HETERO LABS LIMITED, HETERO LABS LIMITED UNIT V, AND HETERO USA, INC.'S COMPLAINT FOR DECLARATORY JUDGMENT

For their complaint against Defendants AbbVie Inc. ("AbbVie") and Neurocrine Biosciences, Inc. ("Neurocrine") (collectively, "Defendants"), Plaintiffs Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively "Hetero" or "Plaintiffs"), state as follows:

BACKGROUND AND PARTIES

1. This is an action for declaratory judgment of non-infringement and invalidity of U.S. Patent No. 12,102,637 ("the '637 patent"), a true and complete copy of which is attached to the Complaint as Exhibit A, pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the patent laws of the United States, 35 U.S.C. § 1, et seq.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)).

2. Plaintiff Hetero Labs is a company organized and existing under the laws of India, with a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

3. Plaintiff Hetero Unit-V is a company organized and existing under the laws of India, with a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Telangana, India.

4. Plaintiff Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

5. Defendant Neurocrine is a plaintiff in this judicial district in C.A. No. 22-1423 against Hetero, alleging that Hetero's ANDA No. 217690 infringes one or more claims of the patents listed in the United States Food and Drug Administration ("FDA") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for Elagolix ("the Related Litigation"), and has averred that it is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130.

6. Defendant AbbVie Inc. is a plaintiff in the Related Litigation and has averred that it is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

JURISDICTION AND VENUE

7. These claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction over these claims under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has personal jurisdiction over AbbVie Inc. and Neurocrine (collectively, "Defendants") because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing the Related Litigation; because, on information and belief, either directly or through agents, they transact business in, and derive substantial revenue from, the State of Delaware; and because AbbVie Inc. and Neurocrine have averred that each is a corporation organized and existing under the laws of the State of Delaware.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Defendants commenced the underlying action in this venue.

FACTUAL BACKGROUND

A. FDA Approval of Brand Name Pharmaceuticals

11. Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the Food and Drug Administration ("FDA"). *See* 21 U.S.C. § 355.

12. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See 21 U.S.C. § 355(b)(1),-(c)(2); 21 C.F.R. § 314.53(b)(1),-(c)(2).

13. Upon approval of the NDA, the FDA publishes patent information for the approved drug in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

14. The FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patent.

B. FDA Approval of Brand Name Pharmaceuticals

15. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

16. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

17. Among other things, an ANDA must also contain a "certification" as to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. See 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

18. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

19. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id*. If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. **NDA No. 210450 and the '637 Patent**

22. According to the Orange Book, AbbVie Inc. is the holder of New Drug Application ("NDA") No. 210450, under which the FDA granted approval for elagolix eq. 150 mg and eq. 200 mg tablets, marketed in the United States as ORILISSA® ("ORILISSA®").

23. NDA holders are required to disclose to the FDA the patent number of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

The '637 Patent

24. Upon information and belief, the United States Patent and Trademark Office ("USPTO") issued the '637 patent, titled "Pharmaceutical Formulations For Treating

Endometriosis, Uterine Fibrosis, Polycystic Ovary Syndrome or Adenomyosis" on or about October 1, 2024.

25. The '637 patent on its face lists Defendant AbbVie Inc and Neurocrine Biosciences, Inc. as the assignees. A copy of the '637 patent is attached as Exhibit A to the Complaint.

D. Hetero's ANDA No. 217690

26. Hetero USA filed Abbreviated New Drug Application ("ANDA") No. 217690 ("Hetero's ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval for elagolix oral tablets, 150 mg and 200 mg ("Hetero's ANDA Product") prior to expiration of the patents listed on the Orange Book in association with NDA No. 210450 for ORILISSA® elagolix sodium tablet eq. 150 mg base and eq. 200 mg base.

27. Hetero's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that, in Hetero's opinion and to the best of its knowledge, Hetero's ANDA Product would not infringe any valid claim of the patents listed in the Orange Book in association with NDA No. 210450 for ORILISSA® elagolix sodium tablet eq. 150 mg base and eq. 200 mg base.

28. Hetero previously complied with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 3 l4.95(c)(6) with respect to providing notice to each patent owner and to the holder of the approved application in connection with NDA N210450 for ORILISSA (Elagolix Sodium) Tablets; Oral, Eq. 150 mg base and Eq. 200 mg base ("Hetero's Prior Notice Letters").

29. Defendants initiated the Related Litigation against Hetero on October 27, 2022, alleging that Hetero's ANDA infringes one or more claims of patents listed in the Orange Book for Elagolix.

30. Defendants subsequently listed the '637 patent in the Orange Book. Hetero thereafter complied with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 3 l4.95(c)(6) with respect to providing notice to each patent owner of the '637 patent and to the holder of the approved application in connection with NDA N210450 for ORILISSA (Elagolix Sodium) Tablets; Oral, Eq. 150 mg base and Eq. 200 mg base ("Hetero's '637 Notice Letter"). In Hetero's '637 Notice Letter, Hetero provided notice to each patent owner of the '637 patent that Hetero's ANDA Product would not infringe any valid claim of the '637 patent.

31. As a consequence of the foregoing, there is an actual and justiciable controversy between Defendants and Hetero as to whether Hetero's ANDA infringes the '637 Patent, or whether the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product would infringe the '637 Patent.

COUNT I

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 12,102,637)

32. Hetero restates and realleges each of the foregoing paragraphs 1-31 of the Complaint as if fully set forth herein.

33. Hetero seeks a declaration that Hetero's filing of ANDA No. 217690 does not infringe the '637 patent and that the manufacture, use, offer for sale, sale or importation of Hetero's ANDA Product would not infringe the '637 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,102,637)

34. Hetero restates and realleges each of the foregoing paragraphs 1-33 of the Complaint as if fully set forth herein.

35. Hetero seeks a declaration that the '637 Patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Hetero respectfully request that this Court enter a judgment in its favor and against Defendants as follows:

a. Declaring that the filing of Hetero's ANDA did not infringe any valid and enforceable claim of the asserted '637 patent;

b. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and enforceable claim of the asserted '637 patent, either literally or under the doctrine of equivalents;

c. Declaring that the claims of the '637 patent are invalid;

d. Declaring this case exceptional in favor of Hetero pursuant to 35 U.S.C. § 285;

e. Awarding costs and attorneys' fees to Hetero; and,

f. Awarding Hetero such other and further relief the Court may deem just and proper.

Dated: April 7, 2025

By: /s/*Andrew J. Koopman*

Andrew J. Koopman (#5288)
Geoffrey G. Grivner (#4711)
Kody M. Sparks (#6464)
BUCHANAN INGERSOLL & ROONEY PC
500 Delaware Avenue, Suite 720
Wilmington, Delaware 19801
Tel. (302) 552-4200
Facsimile (302) 552-4295
Email: geoffrey.grivner@bipc.com
Email: kody.sparks@bipc.com
Email: andrew.koopman@bipc.com

Matthew L Fedowitz (*pro hac vice)*
S. Lloyd Smith (*pro hac vice)*
Karima Tawfik Thompson (*pro hac vice)*
BUCHANAN INGERSOLL & ROONEY PC
1700 K St. N.W., Suite 300
Washington, DC 20006-3807
Tel.: (202) 452-7306
Email: matthew.fedowitz@bipc.com
Email: lloyd.smith@bipc.com
Email: karima.tawfik@bipc.com

Andrew Cheslock (*pro hac vice*)
Grant Shackelford (*pro hac vice*)
Patrick C. Keane (*pro hac vice*)
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Tel.: (703) 836-6620
Fax: (703) 836-2021
Email: andrew.cheslock@bipc.com
Email: grant.shackelford@bipc.com
Email: patrick.keane@bipc.com

Maxwell C. Ruocco (*pro hac vice*)
BUCHANAN INGERSOLL & ROONEY PC
Carillon Tower
227 West Trade Street, Suite 600
Charlotte, NC 28202-2601
Tel.: (704) 444-3365
Email: maxwell.ruocco@bipc.com

Erin A. Napoleon (*pro hac vice*)
BUCHANAN INGERSOLL & ROONEY PC

Two Liberty Place
50 S. 16th Street, Suite 3200
Philadelphia, PA 19102-2555
Tel.: (215) 665-5328
Email: erin.napoleon@bipc.com

Attorneys for Defendants, Hetero Labs Limited, Hetero Labs Limited Unit-V and Hetero USA Inc.