

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

CIVIL CASE NO. 1:23-CV-89
Judge Kleeh

JURY TRIAL DEMANDED

**DECLARATION OF DONGIK SHIN IN SUPPORT OF DEFENDANT'S MOTION TO
DISMISS FOR LACK OF PERSONAL JURISDICTION, OR ALTERNATIVELY, TO
TRANSFER VENUE**

I, Dongik Shin, declare as follows:

1. I am the head of Global Legal Department at Celltrion, Inc. I have been a Celltrion, Inc. employee since 2016. I live and work in Incheon, Korea. I submit this Declaration in support of Defendant's Motion to Dismiss for Lack of Personal Jurisdiction or Alternatively, to Transfer Venue in the above-referenced case. I have personal knowledge of the matters stated in this Declaration.

2. Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea with its principal place of business located at 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea.

3. Celltrion, Inc. was founded in 2002. It is a leading global biopharmaceutical company that focuses on the research, development, and manufacture of high-quality biosimilars and novel biopharmaceuticals. Its biosimilar medicines are marketed by local partner companies in approximately 110 countries around the world.

4. Celltrion, Inc. filed abbreviated Biologics Drug Application No. 761377 with the FDA for "CT-P42" on June 29, 2023. CT-P42's active ingredient is aflibercept and it is a proposed biosimilar to Regeneron's EYLEA® product.

5. All research, development, and manufacturing activities for CT-P42 have occurred and will continue to occur outside the United States.

6. Celltrion, Inc. is not registered to conduct business in any states, including West Virginia and does not have an agent to accept service in West Virginia. Celltrion, Inc. does not have any employees in West Virginia. Furthermore, it does not own, lease, or operate any offices, real property, or other facilities in the United States, including West Virginia.

7. Celltrion, Inc. does not design, manufacture, sell, or offer to sell any products in West Virginia. Celltrion, Inc. does not ship products to West Virginia, and it does not conduct any marketing or advertising in, or directed toward, West Virginia.

8. Celltrion, Inc. has never been a party to litigation in West Virginia.

9. Celltrion, Inc. is not and will not be responsible for the sale and distribution of CT-P42 in the United States, including in West Virginia. Upon receiving FDA approval, Celltrion USA, Inc., a separate corporate entity from Celltrion, Inc., will be solely responsible for marketing, advertising, offering to sell, selling, and distributing CT-P42 in the United States.

10. Celltrion USA, Inc. was founded in 2018. It is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at One Evertrust Plaza, Suite 1207, Jersey City, New Jersey.

11. Celltrion USA, Inc. through agreement with Celltrion, Inc., has been solely responsible for marketing, advertising, offering to sell, selling, and distributing Celltrion, Inc.'s other FDA approved products in the United States, including Vegzelma® (bevacizumab-adcd), Yuflyma® (adalimumab-aaty), and Zymfentra™ (infliximab-dyyb).

12. Celltrion, Inc. has also contracted with unaffiliated third-parties who are solely responsible for the marketing, sales, and distribution of Celltrion, Inc.'s other FDA approved products in the United States. Celltrion, Inc. contracted with unaffiliated third-party Pfizer Inc. to market, sell, and distribute Inflectra® (infliximab-dyyb). Celltrion, Inc. contracted with unaffiliated third-party Teva Pharmaceutical Industries Ltd. to market, sell, and distribute Truxima® (rituximab-abbs) and Herzuma® (trastuzumab-pkrb).

13. At the time the Complaint was filed on November 8, 2023, Celltrion USA, Inc. was a wholly-owned subsidiary of Celltrion Healthcare Co. Ltd.—also a separate corporate

entity from Celltrion, Inc. and a non-party to this case. Celltrion Healthcare Co. Ltd. is a corporation organized and existing under the laws of the Republic of Korea with its principal place of business located at 19 Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea.

14. Like Celltrion, Inc., Celltrion Healthcare Co. Ltd. is not registered to conduct business in West Virginia. Celltrion Healthcare Co. Ltd. does not own, lease, or operate any offices, real property, or other facilities in West Virginia.

15. On December 28, 2023, Celltrion, Inc. merged with Celltrion Healthcare Co. Ltd. Thereafter, Celltrion USA, Inc. became a wholly-owned subsidiary of Celltrion, Inc. but retains its status as a separate corporate entity incorporated in Delaware and with its principal place of business in New Jersey.

16. No witnesses, documents, samples, information or other potential evidence concerning the development, marketing or distribution of CT-P42 is located in West Virginia. All such witnesses and evidence either reside in the Republic of Korea or at Celltrion USA, Inc.'s corporate headquarters in New Jersey.

17. Celltrion, Inc. has approximately 2,000 employees, most of whom live in the Republic of Korea. Celltrion, Inc. does not have any employees or agents that live in West Virginia.

18. Celltrion USA, Inc. has approximately 60 employees who live in the United States. None of the Celltrion USA, Inc. employees reside nor work in West Virginia.

19. Celltrion USA, Inc. does not have any agents in West Virginia. Nor does it own, lease, or operate any offices, real property, or other facilities in West Virginia.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: January 17, 2024



Dongik Shin