

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS, INC. and BIOCON BIOLOGICS LIMITED,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: PGR2026-00039
U.S. Patent No. 12,168,036

Declaration of Daniel Van Plew

I, Daniel Van Plew, declare as follows:

1. I have been employed by Regeneron Pharmaceuticals, Inc. (“Regeneron”) since 2007.
2. My current title at Regeneron is Executive Vice President & General Manager, Industrial Operations and Product Supply (“IOPS”). I have served as General Manager of IOPS since July 2007. In that role, I am responsible for overseeing Regeneron’s commercial manufacturing activities for all of its products, including Eylea® and Eylea HD®.
3. Regeneron is an American company. Regeneron was founded in New York (1988), is incorporated under the laws of New York, and its headquarters are in Tarrytown, New York. As Regeneron has grown from a start-up biotechnology company to one of the leading developers of innovative life-altering and life-saving medicines in the world, its location and identity as an American company has not changed.
4. Regeneron is one of the largest manufacturers of biologic drug products in the world, with at least 11 FDA-approved products that it invented or developed, approved for manufacture in the United States of America.
5. Regeneron sells its Eylea® and Eylea HD® products in the United States, and outside the United States in collaboration with Bayer. Eylea® and Eylea HD® are biopharmaceutical products used to treat patients in the United States with serious ophthalmic disorders, including disorders that if left untreated can lead to blindness.
6. In fiscal year 2025, Regeneron sold approximately \$2.7 billion of Eylea® in the United States and approximately \$1.6 billion of Eylea HD® in the United States.
7. Eylea® and Eylea HD® both contain the protein aflibercept as their active ingredient.
8. Regeneron manufactures the aflibercept protein as Drug Substance Intermediate (“DSI”). Regeneron then further processes aflibercept DSI to make aflibercept Formulated Drug Substance (“FDS”).

Aflibercept FDS is the form of the aflibercept protein that Regeneron uses as the active ingredient (i.e., the API) in Eylea® and Eylea HD®.

9. Regeneron manufactures the aflibercept in its Eylea® and Eylea HD® products at its manufacturing facilities in Rensselaer, New York and in Ireland.

10. In 2026, Regeneron expects to manufacture the majority of its aflibercept DSI batches for use in product sold in the U.S. at its manufacturing facility in Rensselaer, New York.

11. To make its Eylea HD® product, Regeneron uses filling, labeling, and sterilization facilities in the Midwest region of the United States—including in Indiana, Michigan, Pennsylvania and others.

12. Regeneron has announced and been recognized for its investments in new and expanding Regeneron-owned manufacturing and research facilities in New York State (totaling approximately \$7 billion). For example, in 2025, Regeneron announced a significant expansion of its manufacturing capacity in the United States, including an up to \$2 billion investment by Regeneron in a new manufacturing facility in Saratoga Springs, New York, in the United States.

13. Regeneron's new Saratoga Springs manufacturing facility will allow Regeneron to nearly double its existing manufacturing capacity in New York State. The project is expected to support approximately 500 short-term design and construction jobs and should create as many as 1,000 - - and possibly more - - full-time, permanent jobs.

14. Regeneron chose to invest billions of dollars in its new manufacturing facility in Saratoga Springs, New York, with the expectation that Regeneron would enjoy ongoing demand for Regeneron products, including Eylea HD®.

15. The Saratoga Springs manufacturing facility is currently expected to be filed for GMP-use as soon as approximately 2029 for the first of several production areas that will be incorporated into its manufacturing capacity planning and capabilities. Along with its other facilities in New York State, Regeneron intends to leverage the capacity of its new Saratoga Springs facility in order to increase its total

available bulk API capacity so that products, including aflibercept DSI and/or FDS, can continue to be reliably manufactured in the U.S.A.

16. Regeneron is spending more than \$3 billion over a 10-year term at a bulk manufacturing facility in North Carolina that is owned and operated by a third party. Under this arrangement, Regeneron has secured and is enabling additional significant bulk API biopharmaceutical manufacturing output at a newly constructed facility in the U.S.A.

17. In 2021, Regeneron announced an investment to expand its R&D campus and headquarters in Westchester County, NY. Regeneron is investing in excess of \$3 billion to expand its research and preclinical manufacturing facilities.

18. In 2017, Regeneron first announced plans to construct a new, state-of-the-art fill/finish manufacturing facility in Rensselaer, New York, in the United States. Regeneron is investing approximately \$1 billion in constructing this new manufacturing site and bringing the fill/finish facility online.

19. A principal reason that Regeneron chose to invest in its new fill/finish manufacturing facility in Rensselaer, New York, was to maintain and expand its total capacity (i.e., internal and external/CMO) to make its product portfolio for use in product sold in the U.S., with the expectation that Regeneron can satisfy ongoing patient demand for all our products.

20. The Rensselaer fill/finish manufacturing facility is currently expected to be GMP-approved for commercial product operations by 2027; the Tempel Lane site (fill/finish, warehouse and laboratories) has over 1,000 full-time employees.

21. By January 2029, subject to usual and customary regulatory approvals and certain capital investment projects, Regeneron expects to manufacture in U.S. facilities the majority of bulk formulated drug substance batches for U.S. commercial drug product (i.e., drug product intended to be sold in the United States).

22. Consistent with these plans, Regeneron expects that its imports of formulated drug substance for Regeneron-branded pharmaceutical products will decrease significantly.

23. Regeneron has a strong commitment to developing innovative products in the U.S. from “bench” to “first-in-human innovative product.” This includes not only research and development activities in Regeneron’s Tarrytown, NY campus but also complex technology transfers and manufacturing supporting clinical programs that take place in Regeneron’s expanding manufacturing footprint in upstate New York.

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I understand that willful false statements are punishable by fine or imprisonment or both. See 18 U.S.C. § 1004.

Date: 08JUNE2026



Daniel Van Plew
Executive Vice President & General Manager
Industrial Operations and Product Supply
Regeneron Pharmaceuticals, Inc.