

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

U.S. Patent No. 12,168,036 to Graham
Issue Date: December 12, 2024
Title: Methods for Treating Angiogenic Eye Disorders
with High Doses of VEGF Receptor Fusion Proteins

Post Grant Review No. PGR2026-00039

**DHRUV TANEJA AFFADAVIT IN SUPPORT OF PETITIONERS'
OPPOSITION TO MOTION FOR DISCRETIONARY DENIAL**

I, Dhruv Taneja, declare as follows:

1. I have been employed by Biocon Biologics Limited (“Biocon”) since 2019.

2. My current title at Biocon is Head – Portfolio Strategy. In that role, I am responsible for identifying and selecting the Company’s product portfolio and pipeline based on several factors including patient need and access, which are core to our business. I am responsible for working with our cross-functional teams such as R&D, Clinical Development, Operations, Program Management etc. to oversee the development of the product from “lab to market.”

3. Biocon Biologics Limited is a global biosimilars company headquartered in Bengaluru, India. Biocon Biologics, Inc. is its U.S. subsidiary. Biocon Biologics, Inc. maintains its North American headquarters in New Jersey, which it opened in September 2024.

4. Biocon Biologics is one of the largest biosimilar pharmaceutical companies in the world with annual revenues of ~\$1.2B globally (FY26). We have one of the most comprehensive portfolios in the industry, which includes over 30 biosimilar products. Of these, eight (8) are already marketed in the U.S. (Trastuzumab, Pegfilgrastim, Insulin Glargine, Bevacizumab, Adalimumab, Ustekinumab, Denosumab, Insulin Aspart). The first two products—Trastuzumab and Pegfilgrastim—having garnered a market share in the U.S. by volume of over 20% (Company Analysis). Our ninth biosimilar, Aflibercept, is approved in the U.S. and will be launched later this year.

5. Through our partnership with Civica Inc, Biocon has launched private-label insulin products to expand access to affordable insulin for American patients.

6. Based on the Association for Accessible Medicines (AAM) recent publication, biosimilars have saved the US healthcare system \$55B+ since their launch in 2015. Companies like ours, Biocon Biologics, are at the forefront and play a critical role in realizing these savings and expanding access.

7. In addition to our biosimilars business, we also have a large portfolio of over 25 complex generics marketed in the U.S., such as Liraglutide, Rosuvastatin, Dasatinib and Sacubitril-Valsartan. These products span oral solids, injectables, specialty and high potent products that are difficult to develop and manufacture and we have secured some U.S. government contracts, for example, with Veteran's Affairs.

8. In fiscal year 2026 (FY26), Biocon generated over \$500M in net revenue from biosimilars sales in the United States and over \$100M in generics sales in the United States.

9. In September 2025, Biocon launched its first U.S. manufacturing facility in Cranbury, New Jersey, an investment of over \$30M. This U.S. manufacturing site is a state-of-the art oral solid dose facility with an annual capacity of up to 2 billion tablets.

10. With regard to its biosimilar aflibercept product specifically, Biocon is developing a biosimilar aflibercept product that would compete with Regeneron's Eylea® and/or Eylea HD® products. A large part of the manufacturing activities, including final testing and release, for this biosimilar product will happen in the United States through U.S. contract manufacturing organizations.

11. Biocon's affiliate, Syngene International Limited, has also invested in U.S.-based operations. In 2025, Syngene invested approximately \$36.5 million in a new facility in Baltimore, Maryland, to expand its global research and manufacturing footprint and support domestic pharmaceutical manufacturing capacity. Syngene anticipates the site will see demand from innovative U.S. monoclonal antibody developers requiring direct access for "onshore" production, as well as international innovators that want a U.S.-based manufacturing option.

12. Biocon chose to make these significant investments in U.S.-based operations with the expectation that it would be able to compete fairly in the U.S. pharmaceutical market, including by bringing affordable biosimilar alternatives to American patients.

13. Through its U.S. operations, Biocon currently employs about 230 full-time employees across its facilities in the United States. This includes teams across sales and marketing, key account management, manufacturing, quality, regulatory and other personnel.

14. Biocon as a company is committed to investing in the U.S., which is its largest market by revenue. Over the next few years, Biocon is looking to potentially invest up to ~\$250M in manufacturing and allied activities in the United States.

15. Biocon's investments in U.S.-based operations reflect the company's long-term commitment to expanding domestic pharmaceutical manufacturing capacity, creating American jobs, and ensuring that American patients have access to affordable, high-quality biologic medicines.

16. A principal reason that Biocon has invested in U.S.-based manufacturing is to support its growing biosimilar portfolio for the U.S. market. Biocon's ability to bring biosimilar products to market, including its biosimilar aflibercept product, depends on its ability to challenge patent claims that may improperly extend market exclusivity beyond the scope of legitimate patent protection.

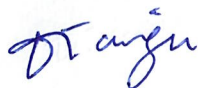
17. Biocon is committed to investing in the United States, expanding access to affordable biologic medicines for American patients, manufacturing in the United States, and creating American jobs.

18. Biocon's challenge to U.S. Patent No. 12,168,036 in this post-grant review proceeding is an important part of that commitment, as it seeks to ensure that competition in the biosimilar aflibercept market is not improperly foreclosed.

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. § 1001.

Date: July 7th 2026



Signature: _____

DHRUV TANEJA

Head- Portfolio Strategy

Biocon Biologics Limited.