IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC. Plaintiff, v. NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, NOVARTIS PHARMACEUTICALS CORPORATION, VETTER PHARMA INTERNATIONAL GMBH Defendants.	CASE NO. 1:20-cv-05502-AJN JURY TRIAL DEMANDED **FIRST AMENDED COMPLAINT** **SUBJECT TO PROTECTIVE ORDER; CONTAINS CONFIDENTIAL INFORMATION**

Plaintiff Regeneron Pharmaceuticals, Inc. ("**Regeneron**") files this Complaint against Defendants, Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, "**Novartis**") and Vetter Pharma International GmbH ("**Vetter**"), and alleges, upon knowledge as to itself and otherwise upon information and belief, as follows:

NATURE OF ACTION

1. Plaintiff Regeneron's EYLEA® (aflibercept) injection ("**EYLEA**") is an innovative biologic drug for the treatment of a variety of severe eye diseases.

2. Defendant Novartis developed and recently launched BEOVU® (brolucizumab-dbll) injection ("**BEOVU**"), which competes against EYLEA to treat a certain eye disease. Novartis, together with Genentech, Inc. ("**Genentech**"), also co-developed LUCENTIS® (ranibizumab) injection ("**LUCENTIS**"), which competes against EYLEA to treat most of the same eye diseases. Novartis markets LUCENTIS outside of the United States, and benefits from the sales of LUCENTIS in the United States through its significant financial stake in Roche Holding AG ("**Roche**"), the parent company of Genentech, which markets LUCENTIS in the

United States.[1] Defendant Vetter is an essential supply chain provider of drug "filling" services and is the exclusive filler for Novartis's LUCENTIS prefilled syringe ("**PFS**") product. Upon information and belief, Vetter will be the filler for Novartis's BEOVU PFS once it launches in the United States. Vetter also has a longstanding relationship with Regeneron, both as a filler for EYLEA vials and as a prior development partner for an EYLEA PFS.

3. Defendant Novartis, unwilling to compete on the clinical merits of LUCENTIS or BEOVU against EYLEA, has done everything in its power to try to stop EYLEA through anticompetitive means. BEOVU's launch has been riddled with serious safety issues, and LUCENTIS is a less effective treatment than EYLEA for certain diabetic eye diseases ***and*** requires more frequent injections (per the FDA-approved label) at a time when in-patient trips to medical doctors are difficult with the COVID-19 pandemic.[2] Novartis has therefore resorted to various unlawful means, including the enforcement of a fraudulently procured United States patent and an anticompetitive licensing and settlement agreement with Vetter, all as part of a scheme to attempt to monopolize the market and/or unreasonably restrain competition for PFS ophthalmic drug treatments. Defendants' purpose and intent throughout this scheme has been to prevent, deter, or at least delay the competitive launch of EYLEA PFS for years, to artificially inflate Regeneron's costs of entry, and now to stop Regeneron altogether from competing in the U.S. market with EYLEA PFS. In addition to Regeneron, physicians and patients have been the victims of this scheme because Novartis's and Vetter's actions are aimed at limiting the availability of the most effective and convenient ophthalmic PFS drug treatment—EYLEA PFS.

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[1] All references to LUCENTIS refer to the product that was co-developed by Novartis and is marketed by Novartis outside the United States and by Genentech inside the United States.

[2] *Compare* U.S. Food and Drug Administration, Lucentis® (ranibizumab injection), "Highlights of Prescribing Information, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125156s111lbl.pdf *with* U.S. Food and Drug Administration, Eylea® (aflibercept), "Highlights of Prescribing Information, *available at* https://www.regeneron.com/sites/default/files/EYLEA_FPI.pdf.

4. By this action for injunctive relief and damages, Regeneron seeks to stop Defendants Novartis and Vetter from continuing their illegal conduct in violation of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2.

INTRODUCTION

5. Regeneron's EYLEA and Novartis's LUCENTIS and BEOVU are competing drugs that treat certain eye diseases involving overproduction of a naturally occurring protein in the body called vascular endothelial growth factor ("**VEGF**"). This VEGF overproduction can cause vision loss and even blindness, and many millions of patients suffer from VEGF-related eye diseases.

6. As "anti-VEGF" drugs, EYLEA, LUCENTIS, and BEOVU must be injected with regular frequency into a patient's eye. The frequency, manner, and safety of injection are important factors in the success of treatment, and the method of administration is therefore significant. In that regard, EYLEA and LUCENTIS were historically sold only in vial form and ultimately loaded into a separate needle or syringe for injection. Recently, however, the market for anti-VEGFs has converted from vial to PFS, which is a more accurate and more convenient method of administration that carries a lower risk of introducing foreign particles into the eye, which can cause severe complications such as endophthalmitis. LUCENTIS and EYLEA are by far the primary approved anti-VEGF PFS available in the United States.[3]

7. There are numerous challenges associated with commercializing a PFS with a complex biologic drug such as EYLEA or LUCENTIS. For example, there are a limited number of companies that can fill the syringe with the drug in accordance with the required sterile conditions, and the existing "fillers" have limited capacity. Vetter is the leading PFS filler and is

[3] While Macugen received FDA approval in 2004 for a prefilled syringe to treat one VEGF-related eye disease only, it is also an older, less effective treatment that is rarely prescribed anymore, if at all.

the exclusive PFS filler for Novartis's LUCENTIS PFS. Regeneron and Vetter also have had a long-standing relationship. For many years, Vetter has provided non-exclusive filling services to Regeneron for EYLEA in vial form. More specifically, starting in 2005, Regeneron and Vetter also embarked on a collaboration to commercialize an EYLEA PFS. This successful collaboration led to regulatory approval for EYLEA PFS in Australia in 2012.

8. Unbeknownst to Regeneron, however, as Regeneron and Vetter were jointly working to commercialize an EYLEA PFS, Novartis was pursuing its own mission in 2013 to fraudulently procure a United States patent claiming a PFS containing ***any*** anti-VEGF drug, including EYLEA, which Novartis and Vetter would soon use to unreasonably restrain Regeneron's ability to compete. Given that the prior art already described and disclosed such a PFS, Novartis could secure its patent only by ensuring that the U.S. Patent and Trademark Office ("**USPTO**") was not aware of that prior art. And Novartis did just that. By ***deliberately*** withholding material prior art from the USPTO, Novartis succeeded in obtaining a patent—U.S. Patent No. 9,220,631 (the "**'631 Patent**")—broadly claiming a PFS with ***any anti-VEGF***, including EYLEA.[4] As pled in detail below, specific Novartis employees involved in the prosecution of the '631 Patent knew of the omitted prior art and also knew the omitted prior art was material because of multiple decisions by a set of USPTO examiners in a separate patent application covering overlapping subject matter that Novartis ultimately abandoned. In order to gain allowance of the '631 Patent, the Novartis employees made a deliberate decision to withhold the prior art from the ***different*** USPTO examiner that was reviewing the application for the '631 patent.

9. The '631 Patent is additionally and independently unenforceable because Novartis deliberately withheld material information from the USPTO showing that at least one Vetter

[4] The '631 Patent specifically identifies EYLEA and states that "[a]flibercept is the preferred non-antibody VEGF antagonist for use with the invention." '631 Patent at Col. 6, ll. 42-43.

employee should have been named as an inventor of the '631 Patent. Novartis's inventorship deception was revealed to Regeneron for the first time in this case on December 23, 2020, through Vetter's first document production.[5] These documents include agreements between Vetter and Novartis that were not previously made available to Regeneron or to Regeneron's counsel in the SDNY case, and reveal, among other things, [redacted] The Novartis patent family [redacted] includes U.S. Patent Application No. 13/750,032, which was issued by the USPTO on December 29, 2015, as the '631 Patent. Novartis and Vetter also knew that 35 U.S.C. § 116 requires that when a claimed invention is made by two or more persons jointly, they ***must*** apply for a patent jointly, and ***each inventor must*** submit the required oath of inventorship to the USPTO. Novartis and Vetter also knew, consistent with § 116, that USPTO regulations ***require each*** individual who is a joint inventor of a claimed invention to ***execute and submit*** an oath or declaration identifying that individual as a

[5] Facts regarding Novartis's inventorship deception were revealed in this case for the first time on December 23, 2020, through Vetter's first document production. Although Vetter produced these Novartis-Vetter agreements and documents in the ITC case on September 21, 2020, the documents are barred from use in any other judicial proceedings, including this SDNY action, under the ITC Protective Order. Regeneron had repeatedly requested that Novartis re-produce its ITC production in this case, but Novartis refused. Therefore, this is the first possible opportunity for Regeneron to amend its antitrust complaint based on the Novartis-Vetter agreements revealed in newly produced discovery as Regeneron was unable to plead facts relating to the inventorship deception before December 23, 2020.

Furthermore, despite being denied a request to stay discovery on November 2, 2020, Novartis and Vetter continue to withhold production of thousands of documents that have already been produced in the ITC litigation that are relevant to this inventorship deception. Regeneron would be able to plead its amended claims with even greater specificity if Novartis and Vetter were not improperly withholding documents from production in this case.

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