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.: JURY TRIAL DEMANDED **COMPLAINT**

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

[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.

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.

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

[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.

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 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***

[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.

USPTO examiner that was reviewing the application for the '631 patent.

9. Further unknown to Regeneron, Novartis and Vetter were vying to control the patent application underlying the '631 Patent. Using this dispute as a pretense, Novartis and Vetter entered into an anticompetitive conspiracy around 2013 to unreasonably restrain competition in anti-VEGF PFS treatments for ophthalmic diseases. Novartis effectively used the settlement process for the then-pending application that would become the '631 Patent to obtain control and influence over Vetter's PFS filling services so as to inhibit anti-VEGF rivals like Regeneron. This "settlement" provided Vetter with a "co-exclusive" license to what would become Novartis's fraudulently procured '631 Patent and the exclusive right to grant sublicenses. The *quid pro quo* was that Novartis extracted a lucrative economic interest in Vetter's PFS filling services in the form of Vetter's assent to place onerous and anticompetitive restrictions on Novartis's rivals—like Regeneron—that had been working with Vetter all along. This anticompetitive agreement co-opted Vetter and enabled Novartis to exert influence over Vetter's current and future customer relationships so that Novartis could undermine competitors' efforts to develop and sell competing anti-VEGF PFS drugs. As for Vetter, it stood to benefit from this agreement by becoming the sole filler for all anti-VEGF PFS drugs—since Novartis would wield its fraudulently procured '631 Patent against any company that tried to compete by using a different PFS filler.

10. Immediately following its "settlement" with Novartis, and despite the approximately eight year long collaboration with Regeneron to commercialize an EYLEA PFS, Vetter did just as Novartis had intended. Vetter abruptly reversed course with Regeneron in 2013. Vetter chose the path of illicit profits by colluding with Novartis to control the supply of anti-VEGF PFS treatments. Specifically, Vetter contacted Regeneron in October 2013, claimed that Novartis had a pending patent application, and demanded that Regeneron take a sublicense to the

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.