IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENERON PHARMACEUTICALS, INC. Plaintiff, v. AMGEN INC. Defendant.	C.A. NO.: JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("**Regeneron**" or "Plaintiff") files this Complaint against Defendant Amgen Inc. ("**Amgen**" or "Defendant") and alleges, upon knowledge as to itself and otherwise upon information and belief, as follows:

NATURE OF ACTION

1. This is an antitrust case involving an effort to eliminate from the market a life-saving medicine that has served thousands of patients. Defendant Amgen is engaged in a persistent exclusionary campaign to deny patients the life-saving benefits of Plaintiff Regeneron's cholesterol-reducing medication, Praluent® (alirocumab). And the reason is simple: for years, Praluent® has been the only direct competitor to Amgen's own drug Repatha® (evolocumab) and Amgen is doing everything it can to avoid competing with Regeneron on the merits.

2. Before commencing the unlawful, anticompetitive bundling scheme challenged here, Amgen tried to enlist this Court to enter an injunction and force Praluent® off the market entirely, after Praluent® was already approved and being used by patients. Amgen did so by

enforcing overbroad patents covering millions of biologic compounds, known as antibodies. Amgen sought this injunction even though Praluent® is a novel, patented drug discovered and developed by Regeneron with an entirely different chemical structure from Repatha® and with a meaningfully differentiated efficacy and safety profile. In addition, Amgen directed its salesforce to spread misinformation about Praluent® by communicating that Praluent® would be taken off the market as a result of Amgen's patent litigation campaign. Amgen's patent challenge to Praluent® was ultimately a failure before this Court and the Federal Circuit, which concluded that Amgen's patents were invalid and tried to cover compounds (like Praluent®) that Amgen had never invented.[1]

3. Now, Amgen has pivoted to an unlawful commercial strategy to try to exclude Praluent® from the market. Amgen is engaged in an illegal, anticompetitive bundling scheme forcing key intermediaries (who cover and pay for the majority of the cost of these drugs) to jettison Regeneron's Praluent® in favor of Amgen's Repatha® in order to access substantial rebates on entirely unrelated medications in Amgen's portfolio that these intermediaries cannot avoid purchasing. Importantly, one of these unrelated medications is a monopoly product Amgen very recently acquired in a divestiture ordered by the Federal Trade Commission ("FTC"). When the value of these massive, unavoidable bundled rebates is compared to the cost of Repatha® standing alone, it becomes clear that Amgen is pricing Repatha® so that Regeneron cannot make a viable financial offer to compete.

4. This harm is not hypothetical. Amgen's misconduct has devastated a product that

[1] *See Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021); *Amgen Inc. v. Sanofi, Aventisub LLC*, 850 F. App'x 794, 796 (Fed. Cir. 2021), *petition for cert. docketed,* No. 21-757 (U.S. Nov. 22, 2021); *Amgen Inc. v. Sanofi,* No. CV 14-1317-RGA, 2019 WL 4058927, at *8 (D. Del. Aug. 28, 2019), *aff'd sub nom. Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021).

benefits thousands of patients who suffer from high cholesterol. Put simply, Amgen has made it economically unfeasible for Regeneron to continue selling Praluent®. In 2022, the brand is projected to be unprofitable, for the first time since Regeneron has marketed the product, due to the anticompetitive marketplace conditions created by Amgen. Specifically, Amgen's bundling scheme has (i) artificially suppressed Praluent® sales by heavily restricting its market access, and (ii) imposed artificial and substantially higher costs on the limited Praluent® sales where market access is not totally cut off.

5. Amgen's scheme to exclude, hobble, and permanently handicap Praluent® has caused Regeneron and the patients it serves significant injury, has harmed competition in the relevant market, and violates federal and state antitrust, unfair competition, and tort laws. Regeneron commences this action to redress these significant harms.

INTRODUCTION

6. This case is about Amgen's unlawful campaign to entrench its monopoly position in the market for a class of drugs known as PCSK9 inhibitors ("PCSK9i") that help high-risk patients lower their low-density lipoprotein cholesterol ("LDL-C")—often termed "bad cholesterol"—and thereby reduce their risk of heart attack, stroke, and cardiovascular disease. *See Amgen, Inc. v. Sanofi, Aventisub LLC*, 872 F.3d 1367, 1371 (Fed. Cir. 2017).

7. Until recently, Regeneron's Praluent® and Amgen's Repatha® were the ***only two***[2] PCSK9 inhibitors approved by the U.S. Food and Drug Administration ("FDA") available in the United States. Although they work on the same overall therapeutic pathway—and neither is interchangeable with other cholesterol-lowering medications like statins—Praluent® and Repatha® are very different drugs both in terms of their chemical structures and their safety and efficacy

[2] Emphasis is added in bold, italics, or underline, unless otherwise noted herein.

profiles. As Regeneron's founder, President, and Chief Executive Officer ("CEO"), Dr. Leonard Schleifer, MD, PhD, has testified, "[t]hese are incredibly different molecules, totally different in structure, totally in their sequence, different in their label," meaning that "the effect of taking one off the market can be rather serious for patients." Preliminary Injunction Hearing Transcript, at 93:12-15, *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA (D. Del. Aug. 8, 2019), ECF No. 1043 ("PI Hearing Tr."). Among the many unique medical benefits of Praluent® relative to Repatha® are: Praluent®'s demonstrated meaningful ***mortality benefit*** in clinical trials; Praluent® is available in a ***low-dose option*** preferred by doctors; Praluent® can be administered to patients with latex allergies; Praluent® has been shown to reduce unstable angina requiring hospitalizations; and Praluent® has been shown to decrease the need for apheresis (a technique for separating blood components to treat certain illnesses). Given these benefits, Praluent® would take significant share from Repatha® in the PCSK9i market[3] if allowed to compete on its medical merits without the exclusionary commercial barriers that Amgen has erected.

8. Since the FDA's approval of Praluent®, Amgen has sought by hook or by crook to exclude Praluent® from the market in order to entrench Repatha®'s monopoly position. Amgen first pursued an injunction against the sale of Praluent® through a patent litigation campaign in this Court. But that strategy failed. So Amgen turned to an anticompetitive bundling scheme designed to leverage sales of unrelated multibillion-dollar drugs in Amgen's portfolio to artificially raise the effective cost of Praluent® for key intermediaries. That illegal scheme is now having its intended effect, depriving Praluent® of a critical mass of market share so that it is no longer a financially viable competitor to Repatha®. Of course, the scheme also deprives patients of a unique

[3] Unless otherwise noted, all references to the PCSK9i market refer to both the PCSK9i market and, in addition and in the alternative, to the Pharmacy-dispensed PCSK9i sub-market. *See infra* ¶¶ 102–108.

medication that neither Amgen nor anyone else other than Regeneron can provide.

9. Amgen's patent-enforcement campaign against Praluent® in this Court was based on excessively broad patents claiming ownership of millions of antibodies—including Praluent®—that Amgen had never invented. To be sure, Amgen has a patent that specifically covers Repatha®. *Amgen*, 850 F. App'x at 796 (citing U.S. Patent 8,030,457). But Praluent® is vastly different from Repatha® and, accordingly, Amgen's Repatha® patent does not cover Praluent®. *See id.* So Amgen instead resorted to obtaining and attempting to enforce patents that cover "millions of candidates claimed with respect to multiple specific functions," even though "it is clear that the claims are far broader in functional diversity than the disclosed examples" Amgen provided. *Amgen*, 987 F.3d at 1087–88. Amgen pursued litigation against Regeneron that went far beyond merely protecting its patent on Repatha® from infringement; it instead sought to exclude Praluent®.

10. Further illustrating Amgen's intent in pursuing its patent claims, Amgen did not merely seek damages from Regeneron. Amgen instead sought an injunction against the sale of Praluent®, trying to take Praluent® off the market and out of the hands of the patients who needed it. Amgen was clear about its motivation for seeking an injunction, alleging that Praluent®'s "direct competition in this two-supplier market [was] causing Amgen to suffer price erosion, reputational harm, lost sales, and lost market share." Opening Br. in Support of Motion for Permanent Injunctive Relief at 6, *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, (D. Del. Apr. 27, 2016), ECF No. 340 ("PI Motion"). To further supplement this patent-litigation campaign, Amgen's sales representatives misleadingly promoted Repatha® with false claims to nurses, physicians, and other medical practitioners that Praluent® would soon be removed from the market.

11. Had Amgen obtained the injunction it requested, Repatha® would have become the monopoly PCSK9 inhibitor product on the market, leaving Amgen with complete control over

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