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

prices and sales. And had Amgen prevailed in its attempt to enforce patents on "millions of candidates" for future PCSK9 inhibitors, it would have effectively used the patent system to block potential new market entrants and protect Repatha® from competition. *Amgen*, 987 F.3d at 1088.

12. But after many years of litigation, the Court of Appeals for the Federal Circuit held that Amgen's patents were ***invalid*****,** thereby stopping Amgen's campaign to use the patent laws to exclude Praluent® from the market and rid Repatha® of competition. The Federal Circuit forcefully rejected Amgen's efforts to durably "suppress innovation" by attempting "to control what it has not invented"—namely, Praluent®. *Amgen*, 850 F. App'x at 796. In other words, Amgen told this Court that it was trying to keep Praluent® off the market because competition was forcing Amgen to lower prices and hurt its bottom line.

13. Amgen's efforts to control the PCSK9i market did not end in court: ***Amgen has now crossed the line in the marketplace***, implementing a multi-prong anticompetitive commercial strategy to unlawfully cement its monopoly position in the PCSK9 inhibitor market. Amgen is doing so by leveraging unrelated mega-products in its portfolio—including a recently acquired monopoly product—whose combined sales are more than 36 times that of Praluent® to coerce intermediaries who cover and pay for the majority of the cost of these drugs into eliminating competition in the much smaller PCSK9i market. Amgen's scheme prevents head-to-head competition between Repatha® and Praluent®, allowing Repatha® to maintain and deepen its monopoly position.

14. Beginning in 2020, Amgen started conditioning rebates for two of its ***dominant products in much larger, unrelated therapeutic areas*** upon exclusivity or practical exclusivity for Repatha® on the formularies of the key insurers ("Third-Party Payors"), such as pharmacy benefit managers ("PBMs"). And formulary positioning is critical for Praluent® and Repatha®,

because PCSK9i prescriptions are, in large part, ultimately paid for by Third-Party Payors, and the Payors' formularies drive which PCSK9 inhibitor—Praluent® or Repatha®—physicians will prescribe.

15. Amgen's bundled-rebate scheme represents a radical departure from the norms of competition in the PCSK9i market. Amgen and Regeneron for years had competed on the merits of Praluent® and Repatha® for formulary positioning with PBMs. But all that changed in 2020, when Amgen acquired Otezla®, an oral treatment for moderate-to-severe psoriasis that was so dominant that the FTC ordered it divested as a condition for approving the Bristol Meyers Squibb/Celgene merger. Amgen outbid other potential acquirers by paying an FTC-record $13.4 billion for Otezla®, which immediately became Amgen's third-largest product. The acquisition of this non-contestable monopoly product was key to launching Amgen's anticompetitive scheme, as Amgen quickly began using its new monopoly product—together with its other blockbuster immunology product, Enbrel®—as the core pillars of its scheme to free itself of the need to compete on price with Praluent®.

16. The difference in scale between these blockbuster products and the relatively small PCSK9i market is staggering. Praluent® generated just ***$356 million*** in total U.S. net sales for 2020 ($186 million) and 2021 ($170 million). Otezla® and Enbrel®, meanwhile, generated ***$12.8 billion*** in U.S. net sales in the same period, which is more than 36 times what Praluent® generated. Put another way, Praluent®'s U.S. net sales amount to only 2.8 percent of what Otezla® and Enbrel® generated. Therefore, the threat of paying just 3 percent more for Otezla® and Enbrel® easily overwhelms the total amount of sales generated by Praluent®, leaving Payors trapped and with ***no viable choice but to exclude Praluent®*** from their formularies.

17. Accordingly, Amgen threatens to withhold significant rebates on these blockbuster

products unless Payors accept either outright exclusivity for Repatha® or else "equal" formulary position. And "equal" is not really equal for several reasons, including the threat of an injunction against the sale of Praluent® (while Amgen's patent-litigation campaign was still pending before the Federal Circuit), and the false claims made by Amgen's sales force designed to dissuade medical providers from prescribing Praluent®. Moreover, Amgen knows full well that it can support its product with a massive sales force dedicated to Repatha® alone, as well as the huge sales force it employs to cover its much larger portfolio of more than 20 products, that Regeneron cannot possibly match. Thus even where Amgen does not achieve outright exclusivity for Repatha®, Amgen can artificially tilt the playing field to influence physicians to prescribe Repatha® over Praluent®, making even "equal" formulary position *de facto* exclusive.

18. By conditioning rebates for Otezla® and Enbrel® on ensuring Repatha® ***exclusivity or practical exclusivity*** on Third-Party Payor formularies, Amgen has unlawfully excluded Praluent® by making it virtually impossible for Regeneron to meaningfully engage in the competitive bidding process. Third-Party Payors, of course, are motivated by securing the lowest net prices—that is, including rebates—across all of the products they cover. The threat of lost rebates, and, in turn, increased prices for Otezla® and Enbrel® constitute a monetary penalty that Regeneron cannot match and that Payors cannot afford. Those are ***substantially larger products in unrelated classes*** where Regeneron markets no drugs and does not compete for the same indications. Moreover, Regeneron has a relatively limited drug portfolio with only four products that it markets, three of which are overwhelmingly not dispensed as prescription drug via pharmacies and, thus, are not subject to significant coverage or reimbursement by Third-Party Payors. So Regeneron does not have the practical ability to match Amgen's multi-product bundled rebate offer with its own multi-product bundled rebate offer.

19. Amgen's bundled rebate scheme further excludes competition by ***pricing Repatha® such that Regeneron cannot make a financially viable case for Praluent®***. Repatha® generated nearly $1.02 billion for Amgen in U.S. net sales for 2020 ($459 million) and 2021 ($557 million), which is dwarfed by the $12.8 billion in U.S. net sales generated by Otezla® and Enbrel® in that same period. Given this enormous gap in sales, and after allocating the entirety of Amgen's massive bundled rebates across these three products to Repatha®, Amgen is pricing Repatha® below its costs. Even though Amgen is pricing Repatha® below cost, Amgen is still not losing money overall, given the much larger sales associated with the other products in the bundle. Further, Amgen has increased the penalty to Third-Party Payors for deviating from its bundle by ratcheting up the pre-rebate list prices of Otezla® and Enbrel® (as well as Repatha®), thereby coercing Third-Party Payors to take the bundle and exclude Praluent® in favor of Repatha®. So unlike a "loss leader" on a competitive non-monopoly product, Amgen stands only to gain from its bundle. As Amgen's failed patent-litigation campaign to take Praluent® off the market illustrates, Amgen's purpose and intent in initiating and executing on this anticompetitive pricing and bundled rebate scheme has been to foreclose Regeneron's Praluent® from a significant share of the PCSK9i market in order to ultimately eliminate this competition for Repatha® altogether.

20. Amgen's scheme has worked, and the results of Amgen's unlawful exclusionary bundling are already substantial and will continue to grow worse. For example, at one Third-Party Payor, Praluent®'s share of PCSK9i sales has plummeted more than 60 percent in just six months. In aggregate, Praluent® has been substantially foreclosed from the PCSK9i market ***with no coverage from Third-Party Payors reimbursing 51 percent of prescriptions***. As a result of Amgen's anticompetitive practices, in 2022, Regeneron stands to lose money for the first time on the formerly profitable Praluent®. In 2020 and 2021, Regeneron took painful cost cutting measures

to eliminate its Praluent® sales force, stop future research and development for Praluent®, and significantly cut back its marketing and other expenses, in order to mitigate against Amgen's practices. Put simply, there is nothing left to cut.

21. But that is not all. At this significant level of restricted access, there are major spillover effects that will further harm Regeneron, because many physicians will simply prescribe the only product with widespread coverage. Amgen's ability to leverage its much larger sales force across its portfolio of drug products to promote Repatha®, not to mention its willingness to use outright misrepresentation to steer prescribers away from Praluent®, therefore exacerbates these spillover effects. These compounding factors have already artificially limited Praluent®'s market access and will continue to cripple Regeneron's ability to remain a viable competitor. Further, if Amgen's unlawful anticompetitive tactics remain unrestrained by the law, potential new entrants will foresee their future foreclosure and refuse to invest (unless they are one of a few giant pharmaceutical firms or have products that would not compete as a prescription drug dispensed via pharmacies).

22. The harm to competition, to Regeneron, and, especially, to patients resulting from Amgen's unlawful anticompetitive behavior is significant. Because of Amgen's exclusion of Praluent®, patients and physicians are deprived of choice in PCSK9 inhibitor treatments and competition is harmed by the diminution of competition and resultant higher prices for Repatha® in the long term. Regeneron accordingly files this suit to redress this unlawful anticompetitive behavior and harm to competition.

PARTIES

23. Plaintiff Regeneron is a corporation organized and existing under the laws of the State of New York with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron is in the business of inventing, developing,

manufacturing, and marketing a variety of innovative pharmaceutical products. Regeneron markets and distributes Praluent® in the United States.

24. Defendant Amgen is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen markets and distributes Repatha®, Enbrel®, and Otezla® in the United States.

JURISDICTION AND VENUE

25. This Court has subject matter jurisdiction over all claims asserted against Defendant pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1337(a), 15 U.S.C. § 4, 15 U.S.C. § 15, and 15 U.S.C. § 26. This Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

26. This Court has personal jurisdiction over Amgen under the U.S. Constitution and nationwide contacts under Section 12 of the Clayton Act, 15 U.S.C. § 22.

27. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. § 1391(b) and (c).

28. For personal jurisdiction and venue purposes, Amgen may be found in or transacts business in this District, including through the marketing and sale of Repatha®, Enbrel®, and Otzela®. Amgen's unlawful behavior was specifically intended to, has had, and will continue to have an anticompetitive effect and impact on Regeneron and U.S. consumers in this District, and elsewhere. Additionally, Amgen's patent litigation campaign against Regeneron was pursued in this District, including the sought-after injunction that, in turn, Amgen's sales representatives used to discourage physicians from prescribing Praluent® in favor of Repatha®.

INTERSTATE COMMERCE

29. The commercialization, development, manufacturing, marketing, sale, and

distribution of Praluent®, Repatha®, Enbrel®, and Otezla® occurs in interstate commerce.

FACTUAL BACKGROUND

A. Treatment of High Low-Density Lipoprotein Cholesterol

i. PCSK9 Inhibitors

30. High systemic levels of LDL-C or "bad cholesterol" can lead to heart attacks, strokes, and cardiovascular disease. PCSK9 inhibitors eliminate LDL-C by leveraging the body's natural way of removing LDL-C from the blood. In particular, LDL-C receptors, which are located on the surface of liver cells, are responsible for extracting LDL-C from the bloodstream. The PCSK9 protein, however, regulates this process by binding to and causing the degradation of these LDL-C receptors inside the liver cells. PCSK9 inhibitors prevent PCSK9 from binding to the LDL-C receptors, so the receptors are not degraded inside the cell. Therefore, the receptors can return to the cell surface and continue the body's natural process of removing LDL-C from the bloodstream. *See Amgen*, 987 F.3d at 1082.

31. While there are other FDA-approved treatments for lowering cholesterol, none is reasonably interchangeable with PCSK9 inhibitors. Doctors have historically treated high LDL-C levels with drugs called statins. In many cases, however, statins are not enough to bring a patient's LDL-C to a healthy level and/or may not be tolerated by patients due to side effects. In those cases, PCSK9 inhibitors are critical. PCSK9 inhibitors therefore serve a ***unique patient population***. Doctors typically prescribe only PCSK9 inhibitors for patients at a high risk for cardiovascular problems, such as individuals with familial hypercholesterolemia ("FH"), people at high risk who are unable to lower their cholesterol using other drugs, or people who are statin-intolerant. Clinical trials have shown that PCSK9 inhibitors can reduce cholesterol by 45 or 60 percent depending on the dose, and can reduce the risk of heart attack, stroke, and, in the case of Regeneron's Praluent®, unstable angina requiring hospitalization in adults with established

cardiovascular disease.[4]

a. Regeneron's Praluent®

32. In 2015, Praluent®, which Regeneron invented and brought to market, became the first PCSK9 inhibitor to obtain FDA approval. Praluent® is a monoclonal antibody that specifically targets and binds to PCSK9 and thereby effectively prevents the patient's body from stopping the degradation of bad cholesterol. Praluent® is a unique and highly effective molecule that is structurally and functionally distinct from Repatha® and offers distinctive medical benefits that Repatha® does not provide. *See Amgen*, 872 F.3d at 1372.

33. Praluent® "targets PCSK9 to prevent it from binding to and destroying" LDL-C receptors. *Id.* In this way, it permits the receptors to "extract LDL-C thereby lowering overall LDL-C levels." *Id.* Specifically, when Praluent® binds PCSK9, ***it almost entirely covers the exact region on PCSK9 to which the LDL-C receptor binds***. In 2011, the U.S. Patent and Trademark Office recognized the novelty of Praluent® and issued Regeneron a patent that covers the precise amino acid sequence of Praluent®. *Id.*; *see* U.S. Patent No. 8,062,640. The FDA approved Praluent® in July 2015, allowing Praluent® to become ***the first PCSK9 antibody*** marketed in the United States. *See Amgen*, 872 F.3d at 1372.

34. Praluent® is the only PCSK9 inhibitor that demonstrated in clinical trials a meaningful mortality benefit. This means that fewer patients died taking Praluent® than taking a placebo. As reported in the New England Journal of Medicine, Praluent® showed a 15 percent reduction in all-cause mortality and a 29 percent reduction in all-cause death for higher-risk

[4] *Regeneron Pharmaceuticals, Praluent® (alirocumab) package insert* (April 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125559s029s030lbl.pdf.

patients whose baseline LDL-C is equal to or greater than 100 mg/dL.[5] These results were so notable that the FDA allowed Regeneron to include data describing this distinguishing benefit in its label.[6]

35. Praluent® is available in two dosage options: a 75 mg low dose and 150 mg high dose. These dosage options provide doctors and patients with flexibility to choose either less LDL-C lowering with the low dose or more LDL-C lowering with the high dose. This optionality is critical. As a practical matter, doctors prefer the low dose and prescribe it more frequently than the high dose. Additionally, physicians—including members of the FDA's advisory panel for Praluent® and Repatha®—have expressed concerns about the unknown long-term effects of LDL-C levels that are too low.[7] Praluent® thus provides doctors with the option of prescribing a low dose where appropriate—*i.e.*, prescribing only as much medication as is necessary to treat the patient—and preventing any potential long-term effects that could arise from too low LDL-C levels.

b. Amgen's Repatha®

36. Amgen, too, developed a PCSK9 inhibitor and obtained FDA approval for the drug it markets as Repatha®. *Amgen*, 872 F.3d at 1371. Like Praluent®, Repatha® "targets PCSK9 to prevent it from destroying" LDL-C receptors. *Id.* Unlike Praluent®, however, Repatha® ***only minimally binds the region on PCSK9 to which the LDL-C receptor binds***.

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[5] Gregory G. Schwartz, et al., *Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome*, 379 New Eng. J. Med. 2097–2107, at Table 2 (2018).

[6] *Regeneron Pharmaceuticals, Praluent® (alirocumab) package insert*, at 21 (April 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125559s029s030lbl.pdf.

[7] *See* Response of *Amicus Curiae* Practitioners Who Currently Treat Patients with Praluent in Support of Appellants' Motion for Stay Pending Appeal, at 7, filed in *Sanofi v. Amgen, Inc.,* No. 17-1480, (Fed. Cir. Jan. 24, 2017), ECF No. 40 ("[T]he *amicus* practitioners believe that forcing patients to pursue a different and higher dosage course of treatment would be medically unnecessary.").

37. Repatha® further lacks a number of Praluent®'s key benefits. First, Repatha®'s clinical trials did not show a mortality benefit.[8] In fact, the results showed a slight ***increase*** in all-cause death and cardiovascular death in patients taking Repatha® as compared with patients taking placebo.[9]

38. Second, Repatha® is available only in higher doses—a 140 mg/mL dose and a 420mg/3.5mL dose. Therefore, unlike Praluent®, Repatha® does not provide doctors and patients with a 75 mg dose option or any other low dose equivalent.

39. Third, Repatha® is administered via a single-use prefilled syringe, a single-use SureClick autoinjector, or a single-use Pushtronex system (which is an on-body infuser with a prefilled cartridge)—each of which presents certain disadvantages not presented by Praluent®'s administration. Specifically, the Repatha® label warns latex-sensitive patients that the "needle cover of the glass single-dose prefilled syringe and the single-dose prefilled autoinjector contain dry natural rubber (a derivative of latex) which may cause an allergic reaction in individuals sensitive to latex."[10] As a result, certain practitioners believe that, "due to the risks associated with Repatha, patients with latex allergies or rubber allergies should not be started on Repatha."[11] Praluent®, on the other hand, is administered via a single-dose pre-filled pen with a "needle shield [that] is not made with natural rubber latex" and is therefore a safer option for patients with latex

[8] Marc S. Sabatine, et al., *Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease*, 376 New England J. Med. 1713–1722, at Table 2 (2017).

[9] *Id.*

[10] *Amgen, Inc., Repatha® (evolocumab) package insert*, at 3 (Sept. 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125522s029s031lbl.pdf.

[11] *See* Response of *Amicus Curiae* Practitioners Who Currently Treat Patients with Praluent in Support of Appellants' Motion for Stay Pending Appeal, at 7, filed in *Sanofi v. Amgen, Inc.,* No. 17-1480, (Fed. Cir. Jan. 24, 2017), ECF No. 40.

sensitivities.[12] Praluent®'s single-dose pre-filled pen is also faster and far easier to use than Repatha®'s single-use Pushtronex system, which requires the patient to remain still for five minutes following dosage administration.[13]

40. Fourth, Praluent®'s clinical trial data demonstrated a 39 percent reduction in unstable angina requiring hospitalizations,[14] whereas Repatha® showed no similar effect.[15] Additionally, only Praluent® has been shown to decrease the need for apheresis in patients with heterozygous familial hypercholesterolemia (HeFH) who were previously undergoing regular apheresis.[16]

41. Regeneron's founder, President, and CEO, Dr. Leonard Schleifer has testified to the differences between the two products and the value to patients of having both on the market. "[W]e're not talking about just having a simple choice where you make aspirin at a company in Delaware and another aspirin company in Virginia," Dr. Schleifer explained. PI Hearing Tr. at 93:9–11. Rather, "[t]hese are incredibly different molecules, totally different in structure, totally in their sequence, different in their label." *Id.* at 93:12–14. As a result, Dr. Schleifer added, "the effect of taking one off the market can be rather serious for patients." *Id.* at 93:14–15. This is because "there are some people who don't respond at all to one drug and who respond to the other drug," or sometimes the drugs "lose their efficacy," and "so you want [patients] to switch" to the

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[12] *Regeneron Pharmaceuticals, Praluent® (alirocumab) package insert*, at 21 (April 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125559s029s030lbl.pdf.

[13] *Amgen, Inc., Repatha® (evolocumab) package insert*, at 3 (Sept. 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125522s029s031lbl.pdf.

[14] Gregory G. Schwartz, et al., *Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome*, 379 New Eng. J. Med. 2097–2107, at Figure 2 (2018).

[15] Marc S. Sabatine, et al., *Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease*, 376 New Eng. J. Med. 1713–1722, at Table 2 (2017).

[16] Patrick M. Moriarty, et al., *Alirocumab in patients with heterozygous familial hypercholesterolemia undergoing lipoprotein apheresis: the ODYSSEY ESCAPE trial*, 37 European Heart J. 3588–95 (2016).

other option "so they can get the benefit of a PCSK9" inhibitor. *Id.* at 93:21–25, 94:2–4. Dr. Schleifer further clarified some of the differences between the two drugs. First, Praluent® "has been clearly shown to have an effect on unstable angina." and "has in its label, in the beta section a benefit related to mortality," which if "you look at Repatha, you don't see." *Id.* at 94:6–12. Second, and "maybe this is the most important thing on the safety side," Praluent® offers "a lower dose" to avoid "lower[ing] the LDL so much that you might have a risk . . . that everybody has been concerned about." *Id.* at 94:15–20. So while the two drugs compete against one another and can serve many of the same patients, Dr. Schleifer concluded that "efficacy, safety, the details, resistance to the drug," coupled with the unique benefits Praluent® offers, are "all reasons that these two drugs really should be available to patients." *Id.* at 95:2–4.

c. Novartis's Leqvio® (inclisiran)

42. Until December 22, 2021, Praluent® and Repatha® were the only two drugs in the PCSK9i class that had been approved by the FDA—and thus the only PCSK9 inhibitors that were on the market. Very recently, the FDA approved a new PCSK9 inhibitor manufactured by Novartis Pharmaceuticals Corporation ("Novartis") called Leqvio® (inclisiran).[17]

43. Leqvio®, however, is not and cannot be a competitive constraint on Praluent® and Repatha®. Unlike Praluent® and Repatha®, which are self-administered by patients outside a medical office once every two weeks, Leqvio® will be administered ***by doctors twice a year*** through a subcutaneous injection. Due to this need for in-office administration, Leqvio® is sold to doctors through different sales channels, and is not subject to the same type of contracting and

[17] *See FDA approves Novartis Leqvio® (inclisiran), first-in-class siRNA to lower cholesterol and keep it low with two doses a year*, NOVARTIS (Dec. 22, 2021), https://www.novartis.com/news/media-releases/fda-approves-novartis-leqvio-inclisiran-first-class-sirna-lower-cholesterol-and-keep-it-low-two-doses-year.

rebating that drive patient access to Praluent® and Repatha®. Rather, Leqvio® is managed as a "medical benefit" under Medicare Part B, not a "prescription drug" benefit under Medicare Part D (as explained in more detail below).[18] Upon information and belief, Third-Party Payors administering commercial insurance will manage Leqvio® the same way, as a "medical benefit." In other words, Leqvio® is not going to be subject to the same PBM-driven payment structure as Praluent® and Repatha®, where ***patients buy the drug*** and Third-Party Payors pay a portion of the cost that is determined through contracts negotiated between manufacturers and PBMs. Instead, Leqvio® is being launched using a "buy-and-bill" payment system, which is where ***physicians and providers buy the drug*** and bill the costs after administering it to patients.[19] Under the program, physicians and providers will reportedly be reimbursed the average selling price plus 6 percent.[20]

44. Leqvio® also differs from Praluent® and Repatha® in a number of other ways. While Praluent® and Repatha® are antibody therapies that bind to the PCSK9 protein to prohibit its binding to LDL-C receptors, Leqvio® is a small interfering RNA ("siRNA") therapy that interferes with the synthesis of the PCSK9 protein itself. The prices of the drugs are different, too. The list price of Leqvio® at launch is reported to be $3,250 per injection, or $9,750 for the first year based on a schedule of three doses, and $6,500 annually for two doses per subsequent year.[21]

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[18] Angus Liu, *Novartis aims to avoid pitfalls of earlier PCSK9 launches with its new blockbuster hopeful Leqvio*, FIERCE Pharma (Dec. 22, 2021), https://www.fiercepharma.com/marketing/novartis-belated-leqvio-fda-approval-avoid-pitfalls-amgen-regeneron-pcsk9-cholesterol.

[19] *Id.*; *see also* Novartis AG, *Novartis enters into agreement to acquire The Medicines Company: Investor Presentation*, at 22 (Nov. 25, 2019), https://www.novartis.com/sites/www.novartis.com/files/novartis-agreement-acquire-medicines-company-investor-presentation.pdf (identifying flexibility of U.S. market access strategy through a "buy-and-bill" payment system).

[20] *See* Jessica Merrill, *Novartis Sees Reimbursement Advantage for PCSK9 Launch*, https://pharmaintelligence.informa.com/resources/product-content/novartis-sees-reimbursement-advantage-for-pcsk9-launch (last visited May 25, 2022).

[21] *Q4 2021 Results Investor Presentation*, NOVARTIS (Feb. 2, 2022), at slide 30 https://www.novartis.com/sites/novartis_com/files/q4-2021-investor-presentation.pdf; Michael

Praluent® and Repatha®, on the other hand, are less expensive and cost roughly $220 to $230 per injection, or $6,000 annually based on a schedule of 26 doses per year. Since its launch, sales for Leqvio® have been "not meaningful" according to Novartis.[22] Additionally, unlike Praluent® which demonstrated a meaningful mortality benefit,[23] "the effect of Leqvio® on cardiovascular morbidity and mortality has not been determined."[24] Finally, unlike Praluent®, Leqvio® is not indicated to lower dangerous cardiovascular events such as heart attack or stroke in patients with established cardiovascular disease.[25]

ii. Other Drugs for Lowering Bad Cholesterol

45. While there are other FDA-approved treatments for lowering bad cholesterol, none of these treatments has the same mechanism of action as PCSK9 inhibitors. These other treatments are also not used interchangeably with, and do not otherwise compete closely with, PCSK9 inhibitors. Additionally, most are substantially less expensive than Praluent® and Repatha®, which cost approximately $500 per month or $6,000 per year. While "[m]ost patients do not pay the list

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O'Riordan, *Pricey Inclisiran Is Rolling Out: a 'Buy-and-Bill' Model May Smooth Its Path*, tctMD (Jan. 17, 2022), https://www.tctmd.com/news/pricey-inclisiran-rolling-out-buy-and-bill-model-may-smooth-its-path.

[22] *2022 Q1 Results Presentation & Transcript*, NOVARTIS, at slide 7, https://www.novartis.com/investors/financial-data/quarterly-results/2022-q1-transcript.

[23] Gregory G. Schwartz, et al., *Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome*, 379 New Eng. J. Med. 2097-2107, at Table 2 (2018).

[24] *Novartis Pharmaceuticals Corporation, Leqvio® (package insert)*, at 1, (last visited May 25, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf

[25] *Novartis Pharmaceuticals Corporation, Leqvio® (package insert)*, at 1, (last visited May 25, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf ; *Regeneron Pharmaceuticals, Praluent® (alirocumab) package insert*, at 1 (April 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125559s029s030lbl.pdf.

price"[26] for PCSK9 inhibitors, the pricing of other FDA-approved drugs does not constrain the pricing of PCSK9 inhibitors.[27] Other FDA-approved treatments for lowering bad cholesterol include:

- ***Statins***: Statins, which were first released in 1987,[28] are HMG-CoA reductase inhibitors that work in the liver and prevent cholesterol from forming. Statins are oral medications that may be used in combination with other FDA-approved drugs to increase their effectiveness. There are several brand name and generic versions of statins available in the United States, including Atorvastatin (Lipitor®), Fluvastatin (Lescol®), Lovastatin (Mevacor®, Altoprev®), Pravastatin (Pravachol®, Livalo®, Zypitamag™), Rosuvastatin Calcium (Crestor®), and Simvastatin (Zocor®). Some generic statins cost patients less than $1 per tablet.[29]

- ***Ezetimibe***: Like statins, Ezetimibe and its brand name version, Zetia®, is a tablet that patients ingest orally. Ezetimibe lowers cholesterol by preventing its absorption in the intestines. The FDA first approved Zetia® in late 2002 and approved the generic version in December 2016.[30] The average net cost for Zetia® is about $20 per 30-day supply, while a 30-day supply of the generic version may cost less than $1 for some patients.[31]

- ***Adenosine triphosphate-citrate lyase ("ACL") inhibitors***: The FDA recently approved two types of ACL inhibitors, Nexletol® and Nexlizet®. Nexletol® is a

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[26] *See Paying for Repatha®*, (last visited May 25, 2022), https://www.repatha.com/repatha-cost; *see also Starting & Paying for PRALUENT*, (last visited May 25, 2022), https://www.praluent.com/starting-and-paying-for-praluent-rx/.

[27] While both Regeneron and Amgen reduced the list price of Praluent® and Repatha® by 60 percent from their initial launch price in response to competition from one another, Repatha® and Praluent both cost approximately $500 per month for patients without insurance copayments or other discounts, while the cost of other FDA-approved cholesterol drugs mostly range from $1-$15 per month. *See, e.g.*, *Sanofi and Regeneron offer Praluent® (alirocumab) at a new reduced U.S. list price*, (Feb. 11, 2019), https://www.news.sanofi.us/2019-02-11-Sanofi-and-Regeneron-offer-Praluent-R-alirocumab-at-a-new-reduced-U-S-list-price; *Paying for Repatha®*, (last visited May 25, 2022), https://www.repatha.com/repatha-cost.

[28] U.S. Food & Drug Admin, *Statins: A Success Story Involving FDA, Academia, and Industry*, https://www.fda.gov/media/110452/download (last visited May 25, 2022).

[29] Lauren Chase, *How much do Statins Cost?*, GoodRx® (Feb. 4, 2020), https://www.goodrx.com/blog/statin-pricing-comparison/.

[30] Ronilee Shye, *Generic Zetia for High Cholesterol Now Available*, GoodRx® (Jan. 9, 2017), https://www.goodrx.com/blog/generic-zetia-for-high-cholesterol-now-available/.

[31] *Ezetimibe Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/ezetimibe#oral-tablet-10-mg (last visited May 25, 2022).

form of bempedoic acid whereas Nexlizet® is bempedoic acide and ezetimibe.[32] Like statins, ACL inhibitors prevent the liver from producing cholesterol, but ACL inhibitors target a different part of the process. Nexletol® and Nexlizet® are taken orally and cost about $300 for a 30-day supply.[33]

- ***Bile Acid Sequestrants***: Bile acid sequestrants work by binding bile acids that contain cholesterol to an insoluble complex. Because this complex cannot be dissolved in the body, it and the cholesterol is excreted rather than being absorbed. Bile acid sequestrants may be ingested in a tablet form or by mixing a powder with water. Like statins, there are several brand and generic forms available in the United States, including Cholestyramine (Questran®, Questran® Light, Prevalite®, Locholest®, Locholest® Light), Colestipol (Colestid®), and Colesevelam Hcl (WelChol®). Bile acid sequestrants have been available to treat cholesterol since the late 1990s and may cost patients less than $1 per dose.[34]

B. The Role of Third-Party Payors in the PCSK9i Market

46. The PCSK9 inhibitor market in which Praluent® and Repatha® participate operates through several key intermediaries and meaningfully relies on pricing through negotiated rebates. After a physician prescribes Praluent® or Repatha®, patients transact with the pharmacy at which they fill their prescription, usually paying only a copayment—or "copay"—that is an amount (or a portion of the drug's list price) that is set by the plan sponsor and the insurance provider. Insurance companies, in turn, pay the pharmacy based on the drug's list price. The insurance company then receives a negotiated rebate from the manufacturer. Most insurance companies contract with an intermediary, called a PBM, to manage this interaction between the pharmacies and manufacturers.

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[32] *Cholesterol Medications*, American Heart Association, https://www.heart.org/en/health-topics/cholesterol/prevention-and-treatment-of-high-cholesterol-hyperlipidemia/cholesterol-medications (last visited May 25, 2022).

[33] Alex Evans, *FDA Approves Nexletol, a New Kind of Cholesterol Medication – Here's What You Need to Know*, GoodRx® (Mar. 13, 2020), https://www.goodrx.com/blog/fda-approves-nexletol-for-high-cholesterol/.

[34] *Cholestyramine Prices, Coupons and Patient Assistance Programs*, https://www.drugs.com/price-guide/cholestyramine#oral-powder-for-reconstitution-4-g-5-g (last visited May 25, 2022).

47. For the commercial segment of the market, PBMs handle the pharmacy benefit of all types of private group health plan sponsors, such as HMO plans, self-insured employer plans, indemnity plans, labor union plans, and plans covering public employees. Similarly, on the public side, the federal government contracts with private insurance companies to administer healthcare to Medicare beneficiaries.[35] Medicare benefits are grouped into four parts; Part D, most relevant here, provides prescription drug coverage.[36] To fulfill their contracts with the federal government, most private insurance companies responsible for administering Medicare plans contract with PBMs to manage the prescription drug benefits under Medicare Part D.[37] According to the U.S. Government Accountability Office, PBMs manage about 74 percent of Medicare Part D plans.[38]

48. Together, these PBMs and other health insurance providers are referred to as "Third-Party Payors." The significant majority of patients with prescription drug insurance coverage—whether that is through a commercial or government insurance provider—receive their benefits through a Third-Party Payor.[39]

49. Access to a Third-Party Payor's drug formulary—that is, the Third-Party Payor's

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[35] *Medicare Part D*, MEDICARE INTERACTIVE.org, https://www.medicareinteractive.org/get-answers/medicare-basics/medicare-coverage-overview/medicare-part-d (last visited May 25, 2022).

[36] The remaining parts are: Part A, which, provides medical benefit coverage for inpatient and hospital services; Part B, which, provides medical benefit coverage for outpatient services (such as regular doctor's office visits or, as described above, in-office injections of Novartis' Leqvio®); and Part C, which offers an alternative to "original" Medicare through a "Medicare Advantage Plan." *See The parts of Medicare (A, B, C, D)*, MEDICARE INTERACTIVE.org, https://www.medicareinteractive.org/get-answers/medicare-basics/medicare-coverage-overview/original-medicare (last visited May 25, 2022).

[37] *See MEDICARE PART D Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*, U.S. Government Accountability Office, (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.

[38] *Id.* at 14.

[39] *See, e.g.*, *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 115th Cong. 77 (Dec. 13, 2017) (statement of Mark Merritt, President, Pharmaceutical Care Management Association), https://docs.house.gov/meetings/IF/IF14/20171213/106730/HHRG-115-IF14-Wstate-MerrittM-20171213.pdf.

official list of covered medications, which determines how much a patient will pay for them—is critical to the success of many branded drugs, including self-administered PCSK9 inhibitors. According to a joint report on competition in the health care industry by the U.S. Department of Justice and the FTC, the formulary is the "main tool" that Third-Party Payors use to manage pharmacy benefits.[40] The amount that a patient will pay is determined based on the drug's placement on the following commonly-used formulary "tiers":

- **"Tier 1" to "Tier 3"** designate ascending rates of co-pays designed to create an incentive for the enrollee to prefer the lowest cost, yet clinically effective, alternative. Co-pays significantly influence drug utilization.

- **"Prior Authorization"** is normally reserved for drugs that treat conditions or illnesses not otherwise covered by plans, have high costs, have a high potential for abuse, or are ordered in unusual quantities.

- **"Not Covered"** requires patients to pay full retail price—without rebates—rather than a co-pay under their insurance plans.

50. Medicare Part D plans also typically use tier placement and other formulary management tools, such as prior authorization.[41] Some plans also include a "specialty tier" in addition to Tier 1, Tier 2, and Tier 3.[42] The specialty tier applies to high-cost prescription drugs (currently, the specialty tier threshold price for Medicare Part D plans must exceed $670 per

[40] U.S. Dep't of Justice & FTC, *Improving Health Care: A Dose Of Competition*, Ch. 7, IV. B (July 2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[41] U. S. Dep't of Health & Human Services: Centers for Medicare & Medicaid Services, *Your Guide to Medicare Prescription Drug Coverage*, at 28-29, (Sept. 2019) https://www.medicare.gov/Pubs/pdf/11109-Your-Guide-to-Medicare-Prescrip-Drug-Cov.pdf.

[42] *Id.*

month),[43] which may result in higher co-pays.[44] Most Medicare Part D plans initially placed PCSK9i drugs on a specialty tier, but once Regeneron and Amgen lowered prices for their respective PCSK9i drugs, the Centers for Medicare & Medicaid Services recommended that the PCSK9i class of drugs be removed from this specialty formulation tier to provide patients with easier and expanded access to these potentially life-saving drugs.[45] Now most Medicare Part D plans include PCSK9i drugs as a non-preferred drug, listed on Tier 3.[46]

51. Since Praluent® and Repatha® are distributed to individual patients and caregivers directly, rather than through hospitals or health care providers, patients receive these PCSK9 inhibitors as part of their private drug insurance coverage or through Medicare Part D. Given the cost of these PCSK9 inhibitors, which have list prices of nearly $500 per month,[47] prescribers and patients will often opt for the medication that is covered by the patient's insurance plan with the least hassle or lowest out-of-pocket costs. As just explained, those costs are substantially determined by formulary position. As a result, knowing well the influence of formulary positioning, manufacturers compete to offer Third-Party Payors attractive rebates to ensure

[43] U. S. Dep't of Health & Human Services: Centers for Medicare & Medicaid Services, *Updated Contract Year (CY) 2021 Final Part D Bidding Instructions*, at 2 (May 22, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_8.pdf.

[44] *Id.*

[45] Letter from the Centers for Medicare & Medicaid Services to Rep. Joyce Beatty, (Aug. 26, 2019), https://twitter.com/TheFHFoundation/status/1167570597930573824/photo/1.

[46] *Affordable Patient Access to PCSK9 Inhibitors Remains Challenging Across Part D Plans in 2020*, (Nov. 12, 2019), https://avalere.com/insights/affordable-patient-access-to-pcsk9-inhibitors-remains-challenging-across-part-d-plans-in-2020.

[47] *See Paying for Repatha®*, (last visited May 25, 2022), https://www.repatha.com/repatha-cost; *Information for Colorado Prescribers Provided Pursuant to Colorado House Bill 19-1131*, (last visited May 25, 2022), https://www.regeneron.com/downloads/codrugcosteducation_praluent.pdf; *see also* Complaint, at 4–5, *Pharma. Care Mgmt. Assoc. v. U.S. Dep't of Health and Human Servs.,* No. 21-cv-02161 (D.D.C. Aug. 12, 2021), ECF No. 1.

advantaged formulary positioning for the manufacturers' own products. Third-Party Payors, in turn, decide formulary positioning for comparable drugs in a way that will reduce their total net cost, taking all applicable manufacturer rebates into account. Negotiations between Third-Party Payors and competing manufacturers generate price concessions, discounts, and rebates from the nominal "list prices" at which manufacturers sell drugs, and have been recognized by some as "one of the few proven methods of lowering prescription drug prices."[48] PBMs will generally pass the savings onto the health insurance providers and plan sponsors, who can then pass on these savings to their beneficiaries.[49]

52. Importantly, Third-Party Payors primarily negotiate—and leverage competition between—those drugs that are paid for by patients. Thus, for these types of drugs, market access is determined almost entirely through contracts negotiated between manufacturers and Third-Party Payors. By contrast, most drugs that physicians administer during office visits or that are administered in the hospital are not subject to these types of rebate agreements or the Third-Party Payor-manufacturer negotiating process for formulary position. That is why, Leqvio®, which is administered through subcutaneous injection during in-office doctor visits,[50] is not and cannot be a competitive constraint or factor in the Third-Party Payor negotiations for self-administered PCSK9 inhibitors.

53. Express Scripts ("ESI"), UnitedHealthcare/OptumRx ("UHC/Optum"), and CVS Caremark ("CVS") are the three most dominant Third-Party Payors for both the Commercial and

[48] *See id.* ¶ 6.

[49] *See id.*

[50] "*Novartis receives EU approval for Leqvio®* (inclisiran), a first-in-class siRNA to lower cholesterol with two doses a year***," (Dec. 11, 2020), https://www.novartis.com/news/media-releases/novartis-receives-eu-approval-leqvio-inclisiran-first-class-sirna-lower-cholesterol-two-doses-year.

Medicare Part D segments of the PCSK9i market and collectively account for more than three quarters of all prescriptions filled in the United States.[51]

54. As this description of the role of formularies in driving patient and provider decision-making makes clear, adverse formulary treatment can dramatically restrict patient access. If a particular PCSK9i drug is blocked from a formulary and listed as "Not Covered" or "Prior Authorization" ("NC" or "PA"), patients will not have access to that drug, or at best will have access only in special cases where their provider has obtained prior authorization from the health plan before prescribing the drug. According to the U.S. General Accounting Office, drugs are normally listed as PA only when they "treat conditions or illnesses not otherwise covered by plans, have high costs, have a high potential for abuse, or are ordered in unusual quantities."[52] As the FTC has recognized, "[g]etting favorable placement on a PBM's formulary can be the key to success for a drug product" because "[i]f a drug maker's product is not on [a PBM's] formulary, patients cannot use their insurance to cover the costs of the drug."[53]

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[51] *See* Statement of David E. Mitchell, Founder, Patients for Affordable Drugs, Hearing Before Subcomm. on Competition Policy, Antitrust, and Consumer Rights, *"A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets*", 117th Cong. 13 (July 13, 2021), https://www.judiciary.senate.gov/imo/media/doc/David%20Mitchell%20Written%20Testimony%20.pdf. At least some of the power PBMs exert over the market can be attributed to increased consolidation that has "has essentially created an oligopoly of integrated healthcare companies." Letter from Alliance for Pharmacy Compounding, et al. to FTC and DOJ Antitrust Division re: Federal Trade Commission and Department of Justice's Draft Vertical Merger Guidelines (Feb. 26, 2020) at 2, https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/02-26-20_joint_pharmacy_stakeholder_comments_-_ftc_doj_draft_vertical_merger_guidelines.pdf. The three Third-Party Payors that dominate the PCSK9i market are no exception: "In the past two years alone, CVS Health (which was already both the single largest pharmacy chain in the country and the second largest PBM) acquired Aetna (the third-largest health insurance company in the country); and Cigna (another of the so-called 'big-five' health insurers) acquired Express Scripts (the largest PBM). The third major PBM (OptumRx) is already affiliated with the single largest health insurer in the country (UnitedHealthcare)." *Id.* at 1–2

[52] U.S. General Accounting Office, "*Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*", at 13 (Jan. 2003), http://www.gao.gov/new.items/d03196.pdf.

[53] Federal Trade Commission, "*Statement of Commissioner Rohit Chopra Regarding the Commission's Report on Pharmacy Benefit Manager Rebate Walls*", at 1 (May 28, 2021),

55. Regeneron's own experiences illustrate the degree to which formulary positioning severely impacts sales. Since Praluent® has been excluded from ESI Commercial's formulary effective January 1, 2021 (as explained in more detail below), its share of PCSK9i sales for ESI Commercial's covered patients has plummeted in six months from about 24 percent to about 5 percent—a precipitous decline of almost 80 percent.

C. Amgen's 2020 Acquisition of Monopoly Product Otezla®

56. Otezla® "is the ***most popular*** oral product approved to treat moderate-to-severe psoriasis in the United States" and faces little to no competition from other, "older oral generic products" approved to treat psoriasis that are only "occasionally used."[54]

57. Otezla®'s market position is so dominant that the FTC required its divestment upon the merger of BMS and Celgene Corporation ("Celgene") after the FTC found in its Analysis of Agreement Containing Consent Orders to Aid Public Comment that Celgene—the pharmaceutical company that originally marketed Otezla®—"is ***currently the market leader*** and BMS would likely be the next entrant into the market"[55] and that, as a result, the merger would harm consumers in the U.S. market for treatments taken orally for moderate-to-severe psoriasis by eliminating future competition to Otezla®.[56]

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ftc.gov/system/files/documents/public_statements/1590528/statement_of_commissioner_rohit_chopra_regarding_the_commissions_report_on_pharmacy_benefit_manager.pdf.

[54] Federal Trade Commission, "*Analysis of Agreement Containing Consent Orders to Aid Public Comment*" at 2 (Nov. 15, 2019), https://www.ftc.gov/system/files/documents/cases/bms-celgene_aac.pdf. Although Bristol-Myers Squibb Company ("BMS") is currently developing a new product in this area, that product has not yet been approved for use in any country. BMS, "*Bristol Myers Squibb Presents Positive Data from Two Pivotal Phase 3 Psoriasis Studies Demonstrating Superiority of Deucravacitinib Compared to Placebo and Otezla® (apremilast)*," (April 23, 2021), https://news.bms.com/news/details/2021/Bristol-Myers-Squibb-Presents-Positive-Data-from-Two-Pivotal-Phase-3-Psoriasis-Studies-Demonstrating-Superiority-of-Deucravacitinib-Compared-to-Placebo-and-Otezla-apremilast/default.aspx.

[55] *Id.* at 2–3.

[56] Federal Trade Commission, "*FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to*

58. In January 2020, Amgen capitalized on the opportunity created by the FTC's complaint and paid over $13.4 billion to acquire Otezla®, outbidding several other interested buyers, in the largest divestiture sale ever ordered in a merger enforcement matter.[57] After spending this record-breaking sum to acquire a new monopoly product, Amgen wasted no time in putting it to work to benefit a smaller drug in Amgen's portfolio—Repatha®—much to the detriment of Regeneron's Praluent® and competition in the PCSK9i market.

D. Amgen's Intent to Exclude Praluent®

59. Since prior to the FDA's approval of Praluent® in 2015, Amgen has tried to block Praluent® from competing in the PCSK9i market. Before commencing the challenged illegal anticompetitive bundled rebate scheme, Amgen sought to exclude Praluent® as a competitor to Repatha® through a patent-infringement lawsuit in this Court seeking an injunction to stop the sales of Praluent® outright. But, after many years of costly litigation, this effort failed with this Court and the Court of Appeals for the Federal Circuit holding Amgen's patents invalid and criticizing Amgen for trying "to control what it has not invented"—namely, Praluent®. *Amgen*, 850 F. App'x at 796.

60. Amgen's patent infringement campaign began even before FDA approved the Praluent® Biologics License Application. In October 2014, Amgen filed a complaint in this Court alleging that Praluent® infringed two Amgen patents. Critically, the asserted Amgen patents did not specifically disclose Praluent® or a drug structurally similar to Praluent®. Rather, Amgen

Divest Psoriasis Drug Otezla as a Condition of Acquisition," (Nov. 15, 2019), https://www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation.

[57] Federal Trade Commission, "*FTC Approves Final Order Requiring Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition*," (Jan. 13, 2020), https://www.ftc.gov/news-events/press-releases/2020/01/ftc-approves-final-order-requiring-bristol-myers-squibb-company.

sought to claim with its patents' exclusive rights to millions of undisclosed PCSK9-inhibiting antibodies—including Praluent®—and thereby effectively close the PCSK9i market to Praluent® and any future entrants.

61. As part of its litigation strategy, Amgen took the aggressive step of asking for an injunction to stop the manufacture and sale of Praluent®, even though Praluent® has an entirely different chemical structure from Repatha® with a distinctive clinical profile, and required its own separate clinical trials to obtain approval. Amgen's requested injunction would have denied Praluent® even to the patients, who, as Regeneron's Dr. Schleifer testified, "don't respond at all to [Repatha®] and who respond to [Praluent®]," as well as the many patients who stand to benefit from the many distinctive advantages that Praluent® has that Repatha® lacks. PI Hearing Tr. at 94:3–4.

62. Amgen was clear as to its aim in seeking an injunction: to prevent Praluent® from competing with Repatha® in the PCSK9 inhibitor market. As Amgen told this Court, "direct competition in this two-supplier market is causing Amgen to suffer price erosion, reputational harm, lost sales, and lost market share," and, if allowed to continue, such competition "threatens to disrupt the very business model on which Amgen depends for the long-term, autonomous operation of its business." PI Motion at 6. In so arguing, Amgen recognized the significance of rebates given to Third-Party Payors as a key driver of competition in the PCSK9i market. The competition between Repatha® and Praluent®, Amgen explained, allowed Payors "to pit the parties against each other to extract larger and larger rebates and other concessions as a condition to being included (even in a parity position) on national formularies." *Id.* This "head-to-head competition" between the two products—in which "a sale to defendant is the loss of sale to plaintiff"—"triggered competitive contracts for exclusive formulary position" and "forced Amgen to give []

unprecedented concessions." *Id.* at 7, 9 (citation omitted). And Amgen had "every reason to believe this will continue over the term of the patents." *Id.* at 7. The effects of this competition, Amgen added, could be dire for Amgen, as "[w]ithout an injunction, Amgen will be unable to fully recoup its investment in Repatha®" and "Amgen's future ability to invest in innovation as an autonomous enterprise will be compromised." *Id.* at 11.

63. Amgen was initially successful in obtaining an injunction before this Court—notwithstanding this Court's own conclusion, after noting Praluent®'s unique low-dose option, that the ***public interest counsels against an injunction*** because "[t]he public generally is better served by having a choice of available treatments." *See* Memorandum Order at 6, *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, (D. Del. Jan. 5, 2017), ECF No. 392. But the Federal Circuit stayed the injunction pending appeal and ultimately vacated it wholesale, explaining that a court may not issue an injunction in this context when ***doing so disserves the public interest***. *See Amgen*, 872 F.3d at 1381. Amgen was thus stymied in its attempt to use the courts to take Praluent® off the market completely, and the competition with Repatha® that Amgen sought to eliminate persisted.

64. Nevertheless, Amgen's litigation strategy still succeeded in decreasing Praluent®'s market share. Even though Praluent® remained on the market, the looming injunction order created uncertainty that Praluent® could be removed from the market at any moment.[58] This

[58] Mary Caffrey, *"Judge Won't Stay Injunction of Praluent Sales During Appeal,"* AJMC The Center for Biosimilars (Jan. 10, 2017), https://www.ajmc.com/view/judge-wont-stay-injunction-of-praluent-sales-during-appeal ("This ruling means that barring a settlement or a reversal on appeal, ***Sanofi and Regeneron could be forced to stop selling Praluent within 6 weeks.***"); Tracy Staton, *"Sanofi, Regeneron avoid Praluent disaster as appeals court stays injunction in PCSK9 patent case,"* FiercePharma (Feb. 8, 2017), https://www.fiercepharma.com/pharma/sanofi-regeneron-avoid-praluent-disaster-as-appeals-court-stays-injunction-pcsk9-patent-case ("Regeneron and Sanofi won't have to pull Praluent off the market after all—***at least not yet***."); Sue Setter, *"PCSK9 Patent Case: Praluent Injunction Vacated, But May Well Return,"* Medtech Insight (Oct. 5, 2017), https://medtech.pharmaintelligence.informa.com/PS121706/PCSK9-Patent-Case-Praluent-Injunction-Vacated-But-May-Well-Return.

caused a chilling effect that allowed Amgen's Repatha® to emerge as the market leader. After the district court issued its injunction order, Praluent®'s market share began to steadily decline. By early 2018, Praluent® had lost, and Repatha® had gained, almost 15 points in market share with the overhang of the patent litigation and possible injunction.[59]

65. Even though Amgen was unable to ultimately secure an injunction taking Praluent® off the market, it nonetheless succeeded in starting to erode Praluent®'s market share. Amgen continued its quest for an injunction by pursuing its patent litigation on appeal, where the Federal Circuit rejected Amgen's overbroad patents as invalid. Amgen, the panel explained, was not merely defending Repatha® but was instead trying to "control what it has not invented" and thereby "suppress innovation" in the PCSK9i market. *Amgen*, 850 F. App'x at 795.

E. Amgen's Misinformation Blitz

66. Regeneron learned in 2019 that, as part of Amgen's effort to exclude Praluent®, Amgen utilized its sales force to disseminate misleading facts regarding the safety and availability of Praluent®. Amgen's sales representatives promoted Repatha® with false claims to nurses, physicians, and other medical practitioners that Praluent® would be removed from the market based on Amgen's patent lawsuit. The intended effect of these misrepresentations was to mislead medical professionals into switching patients' treatments from Praluent® to Repatha®.

67. And these misrepresentations indeed had their intended chilling effect. For example, an Amgen sales representative in Lexington, Kentucky, told a physician (inaccurately) that Praluent® was "being discontinued and to stop writing it." This misrepresentation reasonably and predictably led the doctor to believe—and to inform at least three patients—that he needed to switch his patients from Praluent® to Repatha®. Upon information and belief, other Amgen sales

[59] *See infra* Section C.

representatives made similar misleading statements to physicians to get them to switch their PCSK9i prescriptions from Praluent® to Repatha®. All said, by January 2020, Amgen's misinformation campaign had clawed a significant amount of additional market share away from Praluent®.

AMGEN'S EXCLUSIONARY CONDUCT

A. Amgen Is Engaged in an Anticompetitive Bundled Rebate Scheme to Corner the PCSK9i Market for Repatha®

68. Amgen's patent-litigation scheme and misinformation blitz made transparent Amgen's intent to insulate Repatha® from competition. That effort has continued with Amgen's illegal scheme to impair competition from Praluent® by offering and entering into illegal, anticompetitive bundled rebate agreements that leverage the market position of two unrelated mega-drugs in Amgen's portfolio to limit competition in the much smaller PCSK9i market. This unlawful scheme started shortly after Amgen acquired the blockbuster drug Otezla® in 2020, when Amgen began to leverage this new monopoly product, along with the long-running blockbuster drug Enbrel® (also from an unrelated therapeutic area), to illegally block and hinder Regeneron's access for Praluent® with Third-Party Payor formularies. By doing so, Amgen has offered Third-Party Payors an offer they cannot refuse, and one that Regeneron cannot match.

69. Since Praluent® launched in 2015, Third-Party Payors had solicited rebate offers only within the PCSK9 inhibitor market during negotiations for formulary access. Prior to June 2020, Regeneron understood from Third-Party Payors that bundled rebates across a portfolio of unrelated products was not an accepted practice in the PCSK9i class. (Amgen effectively admitted as much in its April 2016 motion for an injunction in its patent-infringement lawsuit, by focusing only on the pressures of head-to-head competition that Praluent® imposed on the prices for Repatha® rather than on Amgen's broader product portfolio. *See* PI Motion at 6–9.)

70. As a result, despite Amgen's other efforts to impair Praluent®'s market position, Regeneron nevertheless was able to maintain its presence in the PCSK9i market by virtue of Praluent®'s distinctive benefits and by competing on the merits to provide better patient access, economic terms, and other benefits with Third-Party Payors, plan sponsors, and beneficiaries. For example, Regeneron's 2018 collaboration with ESI resulted in significant net price reductions and the removal of artificial barriers to give patients streamlined access to PCSK9i therapy with Praluent®. At the time, ESI touted the collaboration publicly as indicative of its commitment to "making value-based care a reality" by bringing access to "innovative therapies" to its members with an innovative "payment model[]."[60] ESI also highlighted the benefits that Praluent® brings to certain high-risk patients by meaningfully reducing the risk of death for those patients by 29 percent.[61] These incentives to prescribe and improve patient access to Praluent® were the product of fair competition—Regeneron did not tie the rebates to other, unrelated products in different therapeutic classes, nor did Regeneron price the products below-cost to drive out competition. The procompetitive benefit of such incentives have been recognized by Third-Party Payors who cover and pay for the majority of the cost of prescription drugs. For example, ESI considers "[c]linical appropriateness of the drug" to be the first and foremost consideration" in formulary development and "ensures that each drug is considered individually on its own merits."[62]

71. But all that changed in 2020, after Amgen's $13.4 billion acquisition of monopoly product Otezla® in the FTC-ordered divestiture sale. After acquiring Otezla®, Amgen began

[60] *E.g.*, *PCSK9 Therapy: An Example of Value-Based Care*, Express Scripts (May 1, 2018), https://www.express-scripts.com/corporate/articles/pcsk9-therapy-example-value-based-care.

[61] *See id.*

[62] *See White Paper: Formulary Development at Express Scripts*, Express Scripts (last visited May 25, 2022), https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf.

purposefully and knowingly bundling its sales of Otezla®, Enbrel®, and Repatha® to require that Third-Party Payors provide exclusivity to Repatha®—and exclude Praluent®—in order to obtain highly valuable product rebates on Otezla® and Enbrel®. Notably, Otezla® and Enbrel® are major products in unrelated therapeutic classes where Regeneron does not offer any competing products. Amgen's massive bundled rebates therefore cannot be matched by any similar package from Regeneron's current portfolio, which, as Amgen knows, lacks products covered as pharmacy benefit prescription drugs (as opposed to in-office, administered medical benefit prescription drugs) to make such a strategy feasible. By exploiting its combined leverage from blockbuster drugs Otezla® and Enbrel®, Amgen was able to leverage its market power to hinder and artificially limit competition from Praluent® in the PCSK9i market.

72. Amgen's anticompetitive conduct, designed and intended to entrench its monopoly in the PCKS9i market, has had the purpose and effect of foreclosing Regeneron from the formularies at the key Third-Party Payors. Amgen has done so by offering significant and coercive rebates for products that Regeneron could not contest, thus making it impossible for Regeneron to compete on the merits. Additionally, Amgen's rebates render the effective price of Repatha® below cost. Such below-cost bundled rebates, where a package of two or more products are sold at lower prices than they would be had they been provided separately, have the potential to exclude equally efficient competitors or competitors offering a product with unique advantages, such as Regeneron's Praluent®.

73. Amgen's anticompetitive bundle has already been successful in limiting Praluent®'s access to the PCSK9i market and the Pharmacy-dispensed PCSK9i sub-market—and the effects will only continue to grow worse. For example, prior to June 2020, Praluent® had at least access to the patients under nine out of the ten major Commercial Third-Party Payors in the

United States. Since June 2020, and the onset of Amgen's bundling practices, Praluent® now has access to only five of the ten. Similarly, prior to June 2020, Praluent® had access to the patients under six out of eight major Medicare Part D Third-Party Payors in the United States. Due to the impact of Amgen's bundling practices, Praluent® now has access to only three out of eight. Amgen has thus deprived Praluent® of significant marketplace access.

74. This push by Amgen to use bundled rebates across different therapeutic classes in its negotiations with Third-Party Payors has broken the competitive process in the PCSK9i market, which had previously provided greater access, lower prices, and more choices for physicians and patients. Amgen is well-aware of the consequences of its strategy, and accordingly recognizes in its Global Corporate Compliance Policy on Antitrust and Unfair Competition that representatives "should exercise caution" before "[s]elling multiple Amgen products together for a discounted rate (i.e., bundling)."[63] Nonetheless, Amgen has doubled down on this strategy to bundle its blockbuster products with Repatha® to exclude competition from Praluent®.[64]

75. Amgen's bundling practices at two major Third-Party Payors, ESI and United Healthcare/OptumRx vividly illustrate the nature and impact of Amgen's anticompetitive conduct. And those two Third Party Payors are just the beginning, as Amgen is engaged in similar negotiations to leverage its bundled rebate scheme to further exclude Praluent® from formulary coverage at additional Third-Party Payors.

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[63] *Amgen Global Corporate Compliance Policy, Antitrust and Unfair Competition*, AMGEN, at 2–3 (July 15, 2020), https://www.amgen.com/-/media/Themes/CorporateAffairs/amgen-com/amgen-com/downloads/policies/antitrust_unfair_competition_policy.pdf.

[64] *See* Eric Sagonowsky, *Amgen's psoriasis pill Otezla thrives amid pandemic against injectable rivals*, FIERCE Pharma (July 29, 2020), https://www.fiercepharma.com/pharma/amgen-s-otezla-helps-drive-growth-despite-covid-19.

i. Amgen's Bundling Practices at ESI

76. Prior to June 2020, Regeneron and ESI had collaborated to bring patients greater access to PCSK9 inhibitors. As described above, Regeneron's May 2018 collaboration with ESI on Praluent® resulted in significant net price reductions and the removal of artificial barriers to give patients streamlined access to Praluent®. For more than two years, ESI's more than 75 million members had uninterrupted access to Praluent®, including after ESI added Repatha® to the main National Formulary in 2019.

77. Amgen recognized the competitive threat posed by Praluent® and the inroads it had made with ESI, which considered Praluent® to have distinctive advantages that Repatha® lacked.[65] In light of the growing industry recognition of Praluent®'s benefits, Amgen quickly moved to suppress competition and, with Otezla® safely within its drug portfolio after the 2020 acquisition, offered a bundled rebate to ESI that Regeneron would be unable to match with Praluent® alone.

78. In June 2020, Regeneron was advised by ESI that Amgen had offered substantial rebates totaling ***$210 million*** over two years and four months for Enbrel®, Otezla®, and Repatha®. (This massive rebate represents close to half of the $459 million that Repatha® generated for Amgen in *total U.S. net sales* for 2020.) ESI acknowledged to Regeneron that Amgen had tied rebates for the three drug products together and conditioned these rebates on exclusivity for Repatha® on ESI Commercial's National Preferred Formulary. For example, Regeneron was informed by ESI on a June 2020 call attended by senior level executives that Amgen's offer for Repatha® included "other products that would provide much more financial incentives to ESI." As a result, Regeneron was informed that Praluent® would be excluded from ESI Commercial's

[65] As detailed above, ESI publicly described its relationship with Regeneron as a proud moment for ESI, providing an "innovative therap[y]" to its members with an innovative "payment model[]."

National Preferred Formulary unless it could match this $210 million rebate.

79. Amgen's conduct foreclosed Praluent® from accessing ESI Commercial's approximate 15% share of the PCSK9i market for a value of only approximately $110.62 million. To match Amgen's offer of at least $210 million in rebates, Regeneron would have had to make unprofitable sales of Praluent® for patients covered by ESI Commercial when factoring in Regeneron's other costs to manufacture and sell the product. Matching Amgen's rebates would therefore have made no economic sense for Regeneron and rejecting Amgen's rebates would have made no economic sense for ESI—and Amgen specifically designed and structured its bundled rebate offer to ensure that outcome. Nor is Regeneron able to match Amgen's bundled rebate by offering an equivalent bundle across its portfolio, which lacks the massive products subject to PBM rebating that could offset Amgen's coercive rebates for Otezla® or Enbrel®. Amgen purposely and knowingly bundled Otezla®, Enbrel®, and Repatha® together to offer an impossible-to-match rebate to ESI Commercial, a never-before-seen practice in the market for PCSK9 inhibitors.[66]

80. As a predictable and intended result of Amgen's bundled rebate, Praluent® was excluded from ESI's Commercial's National Preferred Formulary list, despite ESI having acknowledged Praluent® to be a PCSK9 inhibitor with distinctive benefits.[67] Notably, and unlike when ESI chose Praluent® as its preferred PCSK9 inhibitor and touted its clinically proven medical benefits as noted above, ESI has not made any public comments regarding the medical benefits of Repatha® over Praluent® since Amgen coerced ESI to exclude Praluent® on its 2021 Commercial

[66] Regeneron sent Amgen a letter on August 21, 2020 regarding Amgen's bundled rebate terms with ESI Commercial. Amgen did not deny the existence of the bundled rebate in its response.

[67] *See PCSK9 Therapy: An Example of Value-Based Care*, Express Scripts (May 1, 2018), https://www.express-scripts.com/corporate/articles/pcsk9-therapy-example-value-based-care.

National Preferred Formulary on August 12, 2020. Since January 1, 2021 and through at least January 1, 2023, Amgen has secured an exclusive position with ESI Commercial's National Preferred Formulary that limits patient choice and allows only Repatha® to be covered for consumers whose plans follow ESI Commercial's National Preferred Formulary.

81. Upon information and belief, Amgen's conduct directed at ESI Commercial drove ESI's Part D formulary decision to exclude Praluent® as well. For Third-Party Payors with commercial and Part D plans, including specifically ESI, formulary access decisions for those two segments are generally made on a consistent or uniform basis in the interest of administrative convenience and efficiency. To that end, ESI announced that Repatha® would be moved to an exclusive position for ESI Part D shortly after it made that announcement for ESI Commercial.

ii. Amgen's Bundling Practices at UnitedHealthcare/OptumRx

82. Amgen's bundling practices at UHC/Optum tell a similar story. Amgen has made a similar bundled rebate offer in its negotiations with UHC/Optum Commercial to secure exclusive access to UHC/Optum's formulary list that similarly results in a below-cost bundled rebate. Optum is a division of UnitedHealthcare's parent company, UnitedHealth Group. Optum operates as a PBM and manages multiple Third-Party Payor formulary lists, including UnitedHealthcare's formulary list.

83. Similar to Regeneron's positive working relationship with ESI, Regeneron also previously had a positive working relationship with UHC/Optum to provide Praluent® to UHC/Optum's Commercial customers. Praluent® had secured a parity position on UHC/Optum's Commercial formulary that allowed members covered by UHC/Optum to be prescribed either Repatha® or Praluent®.

84. However, that too has changed due to Amgen's misconduct. Starting on September 1, 2021, UHC Commercial moved to an exclusive relationship with Repatha®, and, starting on

January 1, 2022, Optum Commercial also moved to an exclusive relationship with Repatha®. Upon information and belief, Amgen opted to structure its rebate offer to UHC/Optum similar to its offer to ESI Commercial, using a portfolio of drugs across multiple therapeutic drug classes to secure Repatha®'s exclusive position, where the effective price of Repatha® in the bundle was below cost. Regeneron was also informed by UHC/Optum in May 2021 during negotiations for formulary access that there were further negotiations happening behind the scenes with Amgen.

85. As a result, UHC/Optum Commercial's many members no longer have any access to Praluent®.

iii. Amgen's Bundling Practices at Other Third-Party Payors

86. Moreover, it appears that ESI Commercial and UHC/Optum are just the beginning, as Regeneron has been told in current negotiations with other Third-Party Payors that Amgen made a broad portfolio offer for Repatha® that would allow for a higher absolute rebate value with the anti-inflammatory therapeutic class, *i.e.*, Otezla® and Enbrel®. Amgen then reported declines in post-rebate, net selling prices for both Otezla® and Enbrel® in its FY 2021 public financial disclosures, which is the logical and intended result of conditioning rebates on these larger products with exclusivity for Repatha®.[68] More importantly, Amgen is powering its bundling scheme by repeatedly increasing the pre-rebate, gross selling price of Otezla®. In particular, according to GoodRx, Amgen has increased the list price for Otezla® "***just shy of 94 percent*** from 2020 to 2022"—the largest increase for any drug treatment during that time.[69] By doing so, it

[68] *See Amgen Reports Fourth Quarter and Full Year 2021 Financial Results*, AMGEN (Feb. 7, 2022), https://investors.amgen.com/static-files/cc04ca13-faef-4672-a85a-3fd7c1df3c35. Amgen also noted that the net selling price for Enbrel® is expected to decline further.

[69] Paul Schloesser, *A new report tracks hundreds of new drug price hikes, along with a look at the top 10*, ENDPOINTSNEWS, (Feb. 18, 2022); *see also* Noah Higgins Dunn, *Merck, Amgen adopt double-digit price hikes in test to Big Pharma's unofficial annual limits: analyst*, FIERCE Pharma, (August 31, 2021),

makes the bundled rebate even more powerful, as Payors would have to cover ever-rising costs of Otezla® and Enbrel® (along with Repatha®) if they do not comply with Amgen's concurrent demand for Repatha® exclusivity. Amgen is thus purposely and knowingly continuing to bundle Otezla®, a monopoly product, and Enbrel®, another very powerful product that PBMs cannot exclude from their formularies, together with formulary positioning for Repatha®, to coerce PBMs into excluding Praluent® with an impossible-to-match conditional rebate.

B. Amgen's Anticompetitive Bundle Results in Below-Cost Prices For Repatha®

87. The FTC has recognized that certain rebating practices can harm competition and constitute "rebate walls." Here, Amgen's multi-product rebate offer involving Otezla®, Enbrel®, and Repatha® constitutes a bundled rebate—where a package of two or more products sell at lower price than the prices at which the products would have otherwise been provided separately. Conditional rebates like the ones Amgen has structured are commonly referred to as "rebate walls" because they insulate a product from competition by dramatically escalating the net cost to a Payor to switch to a competitive drug, in this case Praluent®. According to the FTC, rebate walls "can squelch out competitors" because Payors "cannot afford to pay the full list price when the drug manufacturer stops paying the rebate."[70]

88. Courts have applied a variety of standards to determine the exclusionary effect of bundling practices. *See, e.g.*, *LePage's, Inc. v. 3M Co.*, 324 F.3d 141, 156–67 (3d Cir. 2003) (en banc) (the anticompetitive effects of bundling practices can be determined by analyzing "the

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https://www.fiercepharma.com/pharma/merck-amgen-adopt-double-digit-price-hikes-test-to-pharma-s-drug-cost-limits-analysts.

[70] Federal Trade Commission, *Statement of Commissioner Rohit Chopra Regarding the Commission's Report on Pharmacy Benefit Manager Rebate Walls*, (May 28, 2021), ftc.gov/system/files/documents/public_statements/1590528/statement_of_commissioner_rohit_chopra_regarding_the_commissions_report_on_pharmacy_benefit_manager.pdf.

increase in the defendant's market share, the effects of foreclosure on the market, benefits to customers and the defendant, and the extent to which customers felt they were precluded from dealing with other manufacturers"); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978) (finding that Defendant insulated its competitive product from price competition in violation of Sherman Act Section 2 by bundling rebates for that product with rebates for monopoly products on which it "faced no competition"); *cf. Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 903 (9th Cir. 2008) ("[T]he exclusionary conduct element of a claim arising under § 2 of the Sherman Act cannot be satisfied by reference to bundled discounts unless the discounts result in prices that are below an appropriate measure of the defendant's costs"). For example, whether a bundled rebate results in below-cost pricing can be determined using the discount attribution test. *See, e.g.*, *Cascade Health*, 515 F.3d at 907. Under that test, a bundled rebate is below cost if the rebate given to purchasers for the bundle, when applied entirely to the competitive product in the bundle, results in that product being sold at a price below an appropriate measure of that product's costs.[71]

89. Upon information and belief, Amgen is pricing Repatha® below cost with the bundled rebate that leverages Otezla® and Enbrel® in order to secure exclusivity for Repatha® on ESI Commercial's formulary. As noted above, during Regeneron's negotiations with ESI Commercial, Regeneron was informed that Amgen conditioned rebates of $210 million over two years and four months—approximately $90 million per year—on a three-product bundle consisting of Otezla®, Enbrel® and Repatha®.

90. When this $90 million annual rebate is attributed to PCSK9i sales covered by ESI

[71] In the pharmaceutical industry, the appropriate measure of costs include industry-specific costs, such as R&D costs required to develop and launch the product, regulatory approval and compliance with the FDA, and marketing, promotional and sales force expenses.

Commercial, Amgen is pricing Repatha® below an appropriate measure of its costs. By way of example, for 2020, assuming Amgen paid its bundled rebates for the entire year, Amgen's net revenue on Repatha® from ESI Commercial, once the bundled rebates are considered would be at most, just north of $20 million. Specifically, based upon an analysis of Amgen's publicly reported earnings and other market data, Repatha®'s estimated gross sales at ESI Commercial would have been $110.62 million in 2020 if Repatha® had all of ESI Commercial's PCSK9i share. After attributing the entirety of the $90 million bundled rebate to Repatha®, and assuming that Repatha® had all of ESI Commercial's PCSK9i share, Amgen thus would have generated net revenue of $20.62 million in 2020 through ESI Commercial.

91. This $20.62 million revenue figure is far lower than any appropriate estimate of Amgen's corresponding costs. Specifically, using Amgen's own financial disclosures to estimate its costs for Repatha® suggests that Amgen incurred significant losses on ESI-covered Repatha® sales through the use of its illegal bundle.[72] Based on Amgen's public reporting of costs of goods sold and distribution costs, Amgen's approximate cost in 2020 for Repatha® totaled $224.91 million.[73] And the share of these costs attributable only to ESI Commercial was at least an estimated $42.73 million.[74] Thus, by way of example, with an annual net revenue of $20.62

[72] To be sure, Amgen has kept secret its commercial interactions and agreements with Third-Party Payors, such as ESI Commercial. However, Regeneron can estimate the range of Amgen's costs by reviewing Amgen's publicly available financial information and by analyzing market data associated with the PCSK9i market, in which there were only two products—Repatha® and Praluent®—prior to December 2021.

[73] *See Amgen Reports Fourth Quarter And Full Year 2020 Financial Results*, AMGEN (Feb. 2, 2021), https://investors.amgen.com/node/30746/pdf (estimating Amgen's costs by multiplying full year net sales for Repatha® of $459 million in 2020 by 49 percent, the overall share of Amgen's total cost of sales (25.4 percent) and selling, general, and administrative expenses (23.6 percent) across total net sales of its drug portfolio). Based on Amgen's reported disclosure and Regeneron's knowledge of the pharmaceutical industry, there is no reason to believe this margin is not generally applicable to Repatha® sales to make it more defensible using a metric across the Amgen portfolio.

[74] The share of the costs attributable only to ESI Commercial can be calculated by identifying what share of Repatha®'s total U.S. net sales are attributable to ESI Commercial (19 percent, based on Repatha®'s

million for Repatha® at a minimum, ***in 2020 Amgen would have lost approximately $22.11 million on ESI Commercial-covered Repatha® net sales*** through the use of its illegal bundle.

92. Estimating costs based on Regeneron's own analogous costs for Praluent® likewise shows that Amgen's bundled rebates cause it to incur significant losses on ESI-covered Repatha® sales. Based on either of these estimates, Amgen's bundled price for Repatha® with ESI Commercial under the discount attribution test was well below cost using any reasonable estimate of its cost.

93. This is true for 2021 as well. Based upon an analysis of Amgen's publicly reported earnings and other market data, Repatha®'s estimated gross sales at ESI Commercial would have been $134.24 million in 2021 if Repatha® had all of ESI Commercial's PCSK9i share. After attributing the entirety of the annual $90 million bundled rebate to Repatha®, and assuming that Repatha® had all of ESI Commercial's PCSK9i share, Amgen thus would have generated net revenue of $44.24 million in 2021 through ESI Commercial. Using Amgen's publicly reported costs of goods sold and distribution costs, Amgen's approximate cost in 2021 for Repatha® totaled $271.26 million.[75] And the share of these costs attributable only to ESI Commercial is at least an estimated $51.54 million. Thus, with an annual net revenue of $44.24 million for Repatha®, at a minimum, ***in 2021 Amgen would have lost approximately $7.3 million on ESI Commercial-***

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estimated gross sales at ESI Commercial of $110.62 million in 2020 if Repatha® had all of ESI Commercial's PCSK9i share out of total estimated 2020 Repatha® gross sales of $582.2 million) and applying that percentage to the costs (approximately totaling $224.91 million in 2020).

[75] *See Amgen Reports Fourth Quarter and Full Year 2021 Financial Results*, AMGEN (Feb. 7, 2022), https://investors.amgen.com/static-files/cc04ca13-faef-4672-a85a-3fd7c1df3c35 (estimating Amgen's costs by multiplying full year net sales for Repatha® of $557M in 2021 by 48.7 percent, the overall share of Amgen's total cost of sales (26.6 percent) and selling, general, and administrative expenses (22.1 percent) across total net sales of its drug portfolio).

covered Repatha® net sales through the use of its illegal bundle.

94. On information and belief, Amgen has offered this same pricing scheme and below-cost bundle to other Payors, including UHC/Optum Commercial, meaning that the losses it incurs on Repatha® through those Payors are likely to be comparable to those it incurs through ESI Commercial. Upon further information and belief, the penalty imposed by Amgen on Third-Party Payors for not excluding Praluent® has grown significantly because rebates are typically based on a percentage discount off the list price. As alleged herein, Amgen has increased the list price of Repatha®, Otezla®, and Enbrel® since 2020.

C. Amgen's Anticompetitive Bundle Substantially Forecloses the PCSK9i Market to Praluent®

95. Amgen has foreclosed Praluent® from a substantial portion of the PCSK9i market by leveraging bundled rebates on Otezla® and Enbrel®. As discussed above, Otezla® and Enbrel® are two substantially larger products from unrelated classes where Regeneron has no drugs that compete for the same indications. Otezla® and Enbrel® generated a combined $12.8 billion in U.S. net sales in 2020 ($6.64 billion) and 2021 ($6.16 billion), ***over 12 times more*** than the $1.02 billion generated by Repatha® in 2020 ($459 million) and 2021 ($557 million). Or, put another way, offering a mere 8 percent rebate on Otezla® and Enbrel® would have the same top-line impact to Amgen as offering Repatha® completely for free. Amgen's scheme leverages this enormous gap in sales to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron and that is structurally capable of excluding from the market other hypothetical rivals who make products that cannot match the significant market power of the bundled products.

96. As explained above, Amgen has conditioned significant rebates for Enbrel® and Otezla® upon Repatha® exclusivity to exclude Praluent® from the formulary at ESI Commercial

and ESI Part D in June 2020, and at UHC/Optum Commercial in July 2021. And on information and belief, Amgen has offered similar rebates to other Third-Party Payors—ESI Commercial (15.27 percent), ESI Part D (7.7 percent), and UHC/Optum Commercial (7.05 percent)—that together account for over 30 percent of the total PCSK9i market by prescriptions covered. Amgen's rebate strategy took advantage of, and dramatically increased, the Third-Party Payors not covering Praluent®. Combined with the formularies of other, relatively smaller Third-Party Payors in the PCSK9i market who covered Repatha® exclusively, such as Humana, Cigna, and Prime, Praluent® is "not covered" on formularies of Payors accounting for ***at least 50 percent*** of the total prescriptions in the PCSK9i market as of January 2022.

97. Amgen's conduct leaves these Payors with no commercially viable option but to accept Amgen's demands for Repatha® formulary coverage in the much smaller PCSK9i market in order to avoid paying higher prices on Amgen's much larger drugs Enbrel® and Otezla®. Even if Regeneron offered a lower net price for Praluent® with competitive single-product rebate offers, as it has done in the past, those savings could not offset the artificial prices for Otezla® and Enbrel® that Amgen leverages to block such competitive single-product offers. As a result, Praluent® is economically unable to avoid foreclosure at the formularies of ESI Commercial, ESI Part D and UHC/Optum Commercial. Due to Amgen's practices, U.S. net sales for Praluent® fell by almost 10 percent from 2020 ($186 million) to 2021 ($170 million).[76] By contrast, with its unlawful multi-product bundle at work, Amgen's U.S. net sales for Repatha® have increased by over 21

[76] *Regeneron Reports Fourth Quarter and Full Year 2021 Financial and Operating Results*, REGENERON (Feb. 4, 2022), https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2021-financial.

percent in that same period—from $459 million in 2020 to $557 million in 2021.[77] The detrimental effect is clear, significant, and ongoing.

98. And while this impact is severe, these figures still do not reflect the full effect of Amgen's anticompetitive conduct, due to significant "spillover" effects at both the Payor and prescriber levels that further entrench Repatha®'s market position. On the Payor side, Praluent® has been foreclosed from the formularies at key Payors accounting for at least 50 percent of total prescriptions in the PCSK9i market as of January 2022. In addition to artificially suppressing Praluent®'s current level of access in the PCSK9i market, this exclusion diminishes Regeneron's future ability to compete for formulary access because other Payors are less incentivized to include Praluent® on their formularies at this significant level of restricted access. Amgen's exclusionary strategy is thus broadly eroding the competitiveness of Praluent®, the only PCSK9i alternative to Repatha® for years, and now the only one covered as a pharmacy benefit prescription drug, which, in turn, further reduces the pressure on Amgen to offer favorable terms to Payors. Furthermore, having secured exclusivity at a number of key Third-Party Payors, including two of the largest in the country, Amgen knows it is finishing off Praluent® by leveraging its much larger Repatha® sales force across its portfolio of drug products to make even comparable formulary coverage at the few remaining other Payors of a meaningful size a form of *de facto* exclusivity for Repatha®.

99. The exclusionary effect of Amgen's conduct is also amplified by negative spillover effects at the prescriber level. Many doctors, who know that a significant number of their patients have health insurance coverage with formularies that exclude Praluent®, will instead prescribe

[77] *Amgen Reports Fourth Quarter and Full Year 2021 Financial Results*, AMGEN (Feb. 7, 2022), https://investors.amgen.com/static-files/cc04ca13-faef-4672-a85a-3fd7c1df3c35 ("Repatha sales increased 8% year-over-year for the fourth quarter and 26% for the full year. Volume growth of 35% for the quarter and 40% for the full year was partially offset by lower net selling price").

Repatha®, even despite the unique benefits Praluent® offers. This is because physicians are often unable to take the extra time to inquire into which health plan covers which patient and whether Praluent® is available on each patient's plan. If a physician is aware that Repatha® is not foreclosed from any specific formulary, then the physician often defaults to Repatha® for all patients, despite the potential benefits associated with Praluent®. In addition, for patients who may have access to Praluent® through formularies only if they receive prior authorization from a physician, many physicians will not take the necessary extra steps to authorize patients for Praluent® if Repatha® is available without prior authorization requirements, even if the physician prefers Praluent®.

100. This additional spillover pressure from Payors and prescribers means that the effects of Amgen's anticompetitive actions are already greater than they appear when measured only by the Third-Party Payors who have accepted Amgen's bundled rebates to date. And the impact on Praluent® from Amgen's conduct will only continue to compound: as Praluent®'s market share shrinks, Regeneron will be unable to offer Third-Party Payors even the levels of rebates it is currently offering to try to maintain the small access it currently has, which will likely have adverse net price impact for those Third-Party Payors and, as a result, further reduce competitive pressure on Amgen.

101. The end result of Amgen's anticompetitive conduct is to artificially suppress and accelerate Praluent®'s already declining PCSK9i market share below a critical-mass level of 20 percent. Already, Regeneron has been unable to compete viably in the PCSK9i market with Third-Party Payors being forced to take Amgen's bundled rebate. Now, starting in 2022, Regeneron will no longer even be able to make a profit selling Praluent®. Already, that is not a sustainable business model, and only promises to deteriorate further in the face of Amgen's anti-competitive practices as Praluent®'s market access and market share both continue to fall.

AMGEN HAS MONOPOLY OR MARKET POWER IN THE RELEVANT MARKETS

A. The PCSK9i Market or The Pharmacy-Dispensed PCSK9i Sub-Market

102. PCSK9 inhibitors approved by the FDA to treat certain cardiovascular conditions by reducing low-density lipoprotein cholesterol (LDL-C) constitutes a relevant market—the "PCSK9i market."

103. Other products are not reasonable substitutes for, and not functionally interchangeable with, PCSK9 inhibitors. As explained above, PCSK9 inhibitors have unique characteristics, including a novel mechanism of action for reducing LDL-C levels, and are used for a unique population. Furthermore, PCSK9 inhibitors do not compete against other, much cheaper cholesterol lowering products on price. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

104. Within the PCSK9i market, there also is a sub-market for PCSK9i inhibitors that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Leqvio® is not dispensed through pharmacies, not covered by PBM formularies, and therefore does not compete with Praluent® and Repatha® for formulary positioning, rebates, or spillover sales. It therefore does not impact the price that PBMs pay for pharmacy-dispensed PCSK9 inhibitors, Repatha® and Praluent®. The Supreme Court has held that "[t]he boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe, Co. v. United States*, 370 U.S. 294, 325 (1962).

105. Until very recently, there were only two PCSK9 inhibitors approved in the United States, Repatha® and Praluent®.[78] As previously explained, Praluent® and Repatha® are both dispensed through pharmacies, and market access for these drugs operates through Commercial and Medicare Part D Third-Party Payors.[79] In December 2021, Novartis obtained FDA approval for another PCSK9 inhibitor called Leqvio®, which is now available through "specialty distributors" since January 2022.[80] For the reasons discussed above, however, Leqvio® is not expected to meaningfully compete with Praluent® or Repatha® due to several particular characteristics. Unlike Praluent® and Repatha®, which are ***self-administered by patients*** once every two weeks outside a medical office through subcutaneous injection, Leqvio® is ***administered by doctors*** twice a year through a subcutaneous injection. As a result, ***Leqvio® is not and will not be subject to the PBM contracting and rebating that drive patient access to Praluent® and Repatha®***. While Praluent® and Repatha® are managed and reimbursed as a "prescription drug" benefits under Medicare Part D, Leqvio® will instead be managed and reimbursed as a "medical benefit" under Medicare Part B. Upon information and belief, Third-Party Payors administering commercial insurance will manage Leqvio® the same way as a "medical benefit." Consistent with

[78] As explained above, *see supra* ¶¶ 42–44, and in this section, Novartis recently obtained FDA approval for another PCSK9 inhibitor called Leqvio®, but Leqvio® is not going to meaningfully compete with Praluent® or Repatha®.

[79] *See supra* ¶¶ 45–51. For PCSK9 inhibitors that are dispensed through pharmacies, there are no practically available alternative means of distribution or specialized selling channels through which to make sales.

[80] *See Q42021 Results Investor Presentation*, (Feb. 2, 2022), https://www.novartis.com/sites/novartis_com/files/q4-2021-investor-presentation.pdf at 30 (noting that Leqvio® is "available from specialty distributors since early January.").

industry recognition and other practical indicia, Novartis itself considers Leqvio® to be very different from Praluent® and Repatha®.[81]

106. Leqvio®'s distribution and pricing also substantially differ from those of Praluent® and Repatha®. Leqvio® has been launched using a "buy-and-bill" payment system where physicians and providers buy the drug and bill the costs to Medicare after administering it to patients.[82] By contrast, Praluent® and Repatha® use a PBM-driven payment structure in which PBMs negotiate rebates and formulary positioning for the drug on behalf of Third-Party Payors and their plan beneficiaries. Additionally, the list price of Leqvio® at launch is reported to be $3,250 per injection, or $9,750 for the first year based on a schedule of three doses, and $6,500 annually for two doses per subsequent year. That is over 60 percent more than the current list prices for Praluent® and Repatha® for the first year of treatment, and nearly 10 percent more for subsequent years.

107. Further, Leqvio®'s particular mechanism of action is distinct from the two pharmacy-dispensed PCSK9 inhibitors. While Praluent® and Repatha® are antibody therapies that bind to the PCSK9 protein to prohibit it from binding to LDL-C receptors, Leqvio® is a small interfering RNA ("siRNA") therapy that interferes with the synthesis of the PCSK9 protein itself.[83]

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[81] Angus Liu, *Novartis aims to avoid pitfalls of earlier PCSK9 launches with its new blockbuster hopeful Leqvio*, FIERCE Pharma (Dec. 22, 2021), https://www.fiercepharma.com/marketing/novartis-belated-leqvio-fda-approval-avoid-pitfalls-amgen-regeneron-pcsk9-cholesterol (Novartis's Head of U.S. Pharmaceuticals: "While Praluent and Repatha are injections that patients can give themselves at home, Leqvio is administered by a healthcare professional. That means Leqvio's reimbursement will be routed through the medical benefit pathway, where drug utilization isn't as restrictive as the pharmacy benefit side.").

[82] Jonathan Gardner, *Novartis wins FDA approval for new heart drug, but faces uphill sales battle*, BIOPHARMADIVE (Dec. 22, 2021), https://www.biopharmadive.com/news/novartis-leqvio-inclisiran-fda-approval-cholesterol-heart/611170/.

[83] *See id.; see also Novartis delivers mid single digit sales growth, margin expansion and advancement of robust pipeline,* NOVARTIS (Feb. 2, 2022), https://www.novartis.com/sites/novartis_com/files/q4-2021-

As a result, the manufacturing and production equipment and processes for Praluent® and Repatha® differ from Leqvio®. And unlike the FDA-approval process for Praluent® and Repatha®, Leqvio®'s clinical trials "were conducted exclusively with healthcare provider administration."[84]

108. Leqvio® is therefore not a reasonable substitute for pharmacy-dispensed PCSK9 inhibitors like Praluent® and Repatha®. Assuming there are no issues with the launch of Leqvio®, the substantially different method of payment, location and frequency of administration, customers and vendors, pricing, and drug mechanism for the product does not allow Leqvio® to place meaningful competitive constraints on Praluent® or Repatha®. Importantly, Leqvio® does not compete against Praluent® or Repatha® on price. In response to a small but significant and non-transitory increase in the price of pharmacy-dispensed PCSK9 inhibitors, PBMs and Payors cannot switch to Leqvio® because it is managed as a Part B medical benefit with no involvement in the PBM contracting and rebating that drive patient access to Praluent® and Repatha®. Upon information and belief, U.S. physicians and patients would not meaningfully switch to Leqvio® due to the materially distinct characteristics described above.

109. The United States is the relevant geographic market for PCSK9 inhibitors. In order to be sold in the United States, PCSK9 inhibitors must be approved by the U.S. FDA, a process that is difficult, expensive, and time consuming. As a result, U.S. Third-Party Payors and

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media-release-en.pdf at 5 (noting that Leqvio was "[a]pproved in the US as the first and only (siRNA) therapy for LDL-C reduction."). Additionally, unlike Praluent, which demonstrated a meaningful mortality benefit and is indicated to lower dangerous cardiovascular events in patients with established cardiovascular diseases, "the effect of LEQIVO® on cardiovascular morbidity and mortality has not been determined." *See* Novartis Pharmaceuticals Corporation, Leqvio® (package insert), at 1, (last visited May 25, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf.

[84] Jonathan Gardner, *Novartis wins FDA approval for new heart drug, but faces uphill sales battle*, BIOPHARMADIVE (Dec. 22, 2021), https://www.biopharmadive.com/news/novartis-leqvio-inclisiran-fda-approval-cholesterol-heart/611170/.

physicians cannot turn to products that are not approved for sale in the United States as an alternative, and would not be able to even if the price of PCSK9 inhibitors were to increase by a small, but significant and non-transitory amount.

110. From at least September 2017 until now, Amgen possessed monopoly power in the PCSK9i market with Repatha®. Specifically, Repatha® has had a durable and increasing share crossing 60 percent of the PCSK9i market in September 2017 and is now nearly 80 percent and will only increase as Amgen continues to undermine the only historical competitor to Repatha®, and the only one marketed as a pharmaceutical benefit drug namely, Praluent®. Significant and substantial commercial, developmental, regulatory, and other barriers insulate the PCSK9i market from new entry and expansion.

111. Repatha®'s monopoly power is further evidenced by its high and increasingly durable share of the PCSK9i market. Thus, Amgen's continued use of bundled rebates to attain even simple access to formulary lists at a parity position would further foreclose Regeneron's Praluent® from the market.

112. The unlawful actions described in this Complaint were committed by Amgen for the purpose of maintaining and increasing Repatha®'s monopoly power in the PCSK9i market. Repatha®'s market dominance will continue to grow if Amgen is allowed to offer its bundled rebates to Third-Party Payors and substantially foreclose the rest of the PCSK9i market to Praluent®.

B. Moderate-to-Severe Psoriasis Market (Otezla®)

113. Amgen also has monopoly power in the moderate-to-severe psoriasis market—power Amgen is leveraging to further cement its monopoly position in the unrelated market for PCSK9 inhibitors.

114. Oral drug products approved by the FDA to treat moderate-to-severe psoriasis in

the United States constitute a relevant market—the "moderate-to-severe psoriasis market."

115. The United States is the relevant geographic market for oral drug products used to treat moderate-to-severe psoriasis. In order to be sold in the United States, oral drug products used to treat moderate-to-severe psoriasis must be approved by the U.S. FDA, a process that is difficult, expensive, and time consuming. As a result, U.S. physicians and patients cannot turn to products that are not approved for sale in the United States as an alternative, and would not be able to even if the price of oral drug products used to treat moderate-to-severe psoriasis were to increase by a small, but significant and non-transitory amount.

116. According to the FTC, "Otezla® is the most significant oral product [] approved to treat moderate-to-severe psoriasis in the United States."[85] It is currently ***the only*** orally consumed treatment widely prescribed by doctors to treat moderate-to-severe psoriasis. All other moderate-to-severe psoriasis treatments widely marketed are administered by injection or are applied topically. Although other, older oral medications exist, the FTC concluded that "doctors now prescribe agents that have better efficacy, better safety, or a more favorable side effect profile for patients with moderate-to-severe psoriasis who desire an oral treatment."[86]

117. Otezla® has possessed durable monopoly power in the moderate-to-severe psoriasis market at all relevant times since its initial FDA approval in 2014. As Amgen explained in its press release describing its Q2 2021 financial results: "In the U.S., Otezla® continued to maintain

[85] Complaint at 2, *In the Matter of Bristol-Meyers Squibb Company and Celgene Corp.*, No. C-4690 (FTC, Nov. 15, 2019), https://www.ftc.gov/system/files/documents/cases/191_0061_c4690_bms_celgene_complaint_0.pdf.

[86] *Id.*

first-line share leadership in psoriasis."[87] Otezla®'s monopoly power facilitates Amgen's ability to raise prices for Otezla® without any loss in sales. In fact, despite Amgen's list price increases of 7.4 percent for Otezla®[88] in 2020—which would account for increased revenue of over $130 million on Otezla®'s $1.79 billion 2020 U.S. net sales, an increase equivalent to about half of Praluent®'s total 2020 net sales—the number of prescriptions filled has not decreased but rather ***increased*** by 13 percent in 2020 alone.[89] In particular, according to GoodRx, Amgen has increased the list price for Otezla® "***just shy of 94 percent*** from 2020 to 2022"—the largest increase for any drug treatment during that time.[90] Notwithstanding this massive price increase, the number of Otezla® prescriptions filled increased by another 2 percent in 2021, demonstrating Amgen's monopoly power.[91] Otezla® has dominated the moderate-to-severe psoriasis market because many patients believe that Otezla® is the most convenient way to treat their psoriasis. Since acquiring Otezla®, Amgen has capitalized on the high demand for safe, oral anti-psoriasis drugs, generating

[87] *See Amgen Reports Second Quarter 2021 Financial Results*, AMGEN, at 3 (Aug. 3, 2021), https://investors.amgen.com/news-releases/news-release-details/amgen-reports-second-quarter-2021-financial-results.

[88] *THIS IS THE WAY … TO ANALYZE CHANGES TO BRAND DRUG LIST PRICES*, 46brooklyn, https://www.46brooklyn.com/branddrug-boxscore (choose "Amgen Inc" from Select Drugmaker (this filter applies to all Stat Boxes) dropdown; then scroll to "Stat Box #8: WAC Changes on Top Medicaid Brand Name Drugs").

[89] *See Amgen Q4 2020 Earnings Call*, at 22 (Feb. 2, 2021), https://investors.amgen.com/static-files/35869c22-d9f4-4be2-bae1-a8ea6462e94d.

[90] *See* Paul Schloesser, *A new report tracks hundreds of new drug price hikes, along with a look at the top 10*, ENDPOINTSNEWS, (Feb. 18, 2022).

[91] *Amgen Reports Fourth Quarter and Full Year 2021 Financial Results*, AMGEN, at 3 (Feb. 7, 2022), https://investors.amgen.com/static-files/cc04ca13-faef-4672-a85a-3fd7c1df3c3.

around $2.2 billion in global sales in both 2020[92] and 2021[93]. This multi-billion-dollar-a-year drug consistently maintains high net product sales each year: $1.279 billion in 2017,[94] $1.608 billion in 2018,[95] and $1.607 billion in 2019[96].

118. Otezla®'s monopoly power is also durable, as evidenced by the absence of any new entrants into its market. There have been no recent entrants into orally administered treatments for moderate-to-severe psoriasis. Otezla®'s durability is one of the reasons why Amgen was able to justify paying a record amount (more than $13 billion) for the drug in connection with the FTC-ordered divestiture sale. As explained above, the FTC ordered Otezla®'s divestiture because of the absence of competitive alternatives to Otezla® and Amgen acquired Otezla® through the largest divestiture sale ever ordered by the FTC to settle the agency's complaint that the BMS-Celgene merger would harm consumers in the moderate-to-severe psoriasis market by eliminating future

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[92] *Amgen Reports Fourth Quarter and Full Year 2020 Financial Results*, AMGEN, at 2 (Feb. 2, 2021), https://investors.amgen.com/node/30746/pdf. This figure is particularly notable given the disruption caused from COVID-19, decreasing patient interactions with their doctors and decreasing the number of new-to-brand patients. *See id.* at 1–2.

[93] *Amgen Reports Fourth Quarter and Full Year 2021 Financial Results*, AMGEN, at 7–9 (Feb. 7, 2022), https://investors.amgen.com/static-files/cc04ca13-faef-4672-a85a-3fd7c1df3c3.

[94] Celgene Reports Fourth Quarter and Full Year 2018 Operating and Financial Results, Celgene, at 13 (Jan. 31, 2019), https://ir.celgene.com/press-releases-archive/press-release-details/2019/Celgene-Reports-Fourth-Quarter-and-Full-Year-2018-Operating-and-Financial-Results/default.aspx.

[95] *Id.*

[96] Because Amgen's acquisition of Otezla® was finalized on November 21, 2019, this figure combines the data from Celgene's First through Third Quarters financial reporting and Amgen's Fourth Quarter financial reporting. *See Celgene Reports First Quarter 2019 Operating and Financial Results*, Celgene (Apr. 25, 2019), https://s24.q4cdn.com/483522778/files/doc_financials/2019/q1/Q1-2019-Earnings-Press-Release_FINAL_FINAL_04_25_19.pdf; *Celgene Reports Second Quarter 2019 Operating and Financial Results*, Celgene (July 30, 2019), https://s24.q4cdn.com/483522778/files/doc_financials/2019/q2/Q2-2019-Earnings-Press-Release_FINAL_with-tables.pdf; *Celgene Reports Third Quarter 2019 Operating and Financial Results*, Celgene (Oct. 31, 2019), https://s24.q4cdn.com/483522778/files/doc_downloads/Q3-2019-Earnings-Press-Release_FINAL_APPROVED_with-rec-tables.pdf; *Amgen Reports Fourth Quarter And Full Year 2020 Financial Results*, AMGEN (Feb. 2, 2021), https://investors.amgen.com/node/30746/pdf.

competition. While the FTC cited BMS's development product, BMS 986165, as a potential future competitor to Otezla®, BMS 986165 has not been approved by the FDA, having encountered difficulties in the approval process, and is not approved for use in any other country. Even if BMS 986165 is approved by the FDA and is available, it would be the only other oral treatment for moderate-to-severe psoriasis and is unlikely to significantly erode Otezla®'s dominance, particularly if Amgen continues to offer Otezla® in multi-product cross-class bundles, as Amgen is wont to do, as reflected by its conduct here and its prior settlement of another antitrust dispute involving bundling.[97]

C. Rheumatoid Arthritis Market (Enbrel®)

119. Finally, Amgen has market power in the rheumatoid arthritis market. And as with its monopoly power in the moderate-to-severe psoriasis market, Amgen is likewise using its market power in the rheumatoid arthritis market to further cement its monopoly position in the unrelated market for PCSK9 inhibitors.

120. Drug products that are approved by the FDA treat moderate-to-severe rheumatoid arthritis constitute a relevant market—the "rheumatoid arthritis market."

121. The United States is the relevant geographic market for drug products used to treat moderate-to-severe rheumatoid arthritis. In order to be sold in the United States, drug products used to treat moderate-to-severe rheumatoid arthritis must be approved by the U.S. FDA, a process that is difficult, expensive, and time consuming. As a result, U.S. physicians and patients cannot turn to products that are not approved for sale in the United States as an alternative, and would not be able to even if the price of drug products used to treat moderate-to-severe rheumatoid arthritis

[97] *See* Deena Beasley, Mark Porter & Gary Hill, *Amgen to pay J&J $200 million to settle antitrust suit*, REUTERS, (July 11, 2008), https://www.reuters.com/article/us-amgen-jj-lawsuit-idUSN1136149420080711.

were to increase by a small, but significant and non-transitory amount.

122. Enbrel® possesses market power in the rheumatoid arthritis market. Enbrel® was deemed "one of the world's most profitable drugs" by the U.S. House of Representatives Committee on Oversight and Reform in an October 2020 staff report describing Amgen's uninhibited price increases for Enbrel® and Sensipar® (the "Staff Report"). According to the Staff Report, Enbrel® was priced at $5,556 per month as of October 2020—***a 457 percent increase*** from the date Amgen acquired the drug in 2002.[98] While Enbrel® began losing market share to Humira® starting in 2017, it is still Amgen's largest product by U.S. net sales, generating ***$4.85 billion*** in 2020 and ***$4.35 billion*** in 2021.[99]

123. Enbrel®'s market power is evidenced by Amgen's ability to increase prices without losing sales. According to the Staff Report, "Amgen's price increases for Enbrel® have contributed to billions of dollars in net revenue for the company,"[100] and the same is true for Amgen's price increases for Otezla®.[101] As illustrated by Figures 1 and 3 from the Staff Report, Enbrel's annual net sales steadily grew from $1.25 billion in 2003 to a peak of $5.72 billion in 2016 despite

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[98] *Drug Pricing Investigation: Amgen—Enbrel and Sensipar*," Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, at 5 (October 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.

[99] *Id.*; *Amgen's Letter to Shareholders*, at F-17 (2021), https://investors.amgen.com/static-files/35869c22-d9f4-4be2-bae1-a8ea6462e94d.

[100] *Drug Pricing Investigation: Amgen—Enbrel and Sensipar*," Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, at 12 (October 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.

[101] Amgen's list price for Otezla® has increased 7.4 percent since acquiring the drug, *see THIS IS THE WAY ... TO ANALYZE CHANGES TO BRAND DRUG LIST PRICES*, 46brooklyn, https://www.46brooklyn.com/branddrug-boxscore (choose "Amgen Inc" from Select Drugmaker (this filter applies to all Stat Boxes) dropdown, then scroll to "Stat Box #8: WAC Changes on Top Medicaid Brand Name Drugs"), which would account for increased revenue of over $130 million on Otezla®'s $1.79 billion 2020 U.S. net sales, all while the number of prescriptions filled has increased by 13 percent in 2020 alone. *See Amgen's Q4 2020 Earnings Call Presentation*, at 22 (Feb. 2, 2021), https://investors.amgen.com/static-files/35869c22-d9f4-4be2-bae1-a8ea6462e94d.

repeated and significant price increases during that time[102]:

Figure 1: Enbrel Price Increases

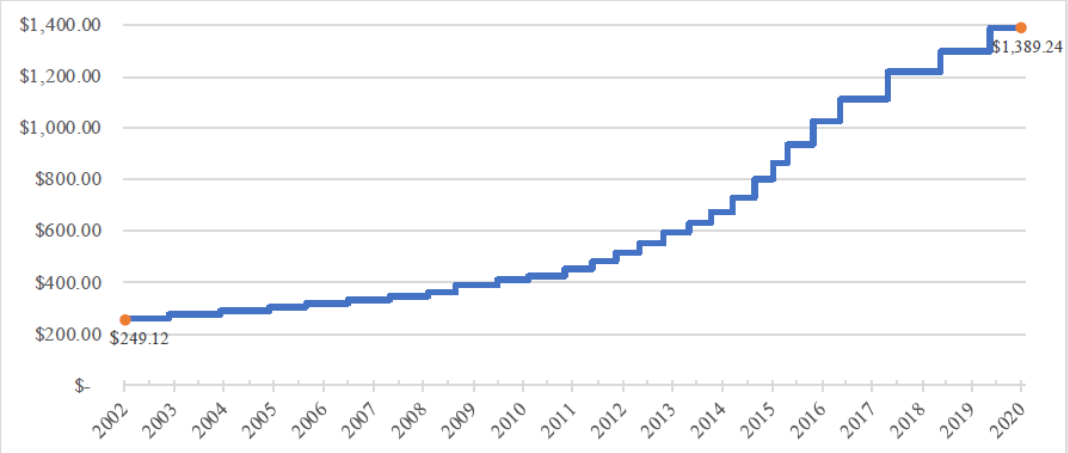
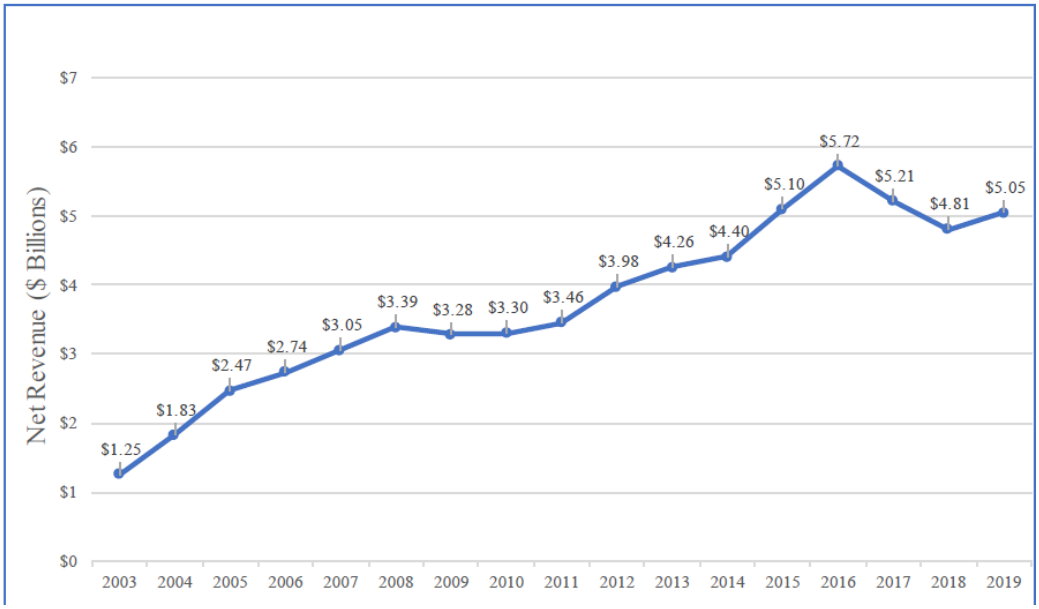


Figure 3: Amgen Net U.S. Revenue for Enbrel



BARRIERS TO ENTRY

124. The pharmaceutical industry in general and the relevant markets in particular are characterized by substantial barriers to entry.

[102] *Drug Pricing Investigation: Amgen—Enbrel and Sensipar*, Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, at 2, 4 (October 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.

125. A number of factors together create significant barriers to entry in the pharmaceutical industry. First, branded products are patent-protected, which protects them from copies until the patents have run (for example, Otezla®'s patents run through 2024). And, as described above, even when patents do not protect a product, a company like Amgen can use the patent system to try to keep a rival product off the market, delay its entry, and hobble its launch.

126. Second, a company must invest substantial time and money into research and development of a new drug. It takes years to identify a new drug and assess whether it has the potential to safely treat a condition. For example, one study analyzed 63 new drugs and biologics approved by the FDA between 2009 and 2018, accounted for the cost of failed trials, and found that the estimated median research and development investment to bring a drug to market was $985.3 million and that the estimated mean research and development investment was $1335.9 million.[103] In addition, research and development costs for drugs that successfully yield FDA approval have continued to increase over the last twenty to twenty-five years.[104]

127. Third, even if a new drug shows promise in pre-clinical studies, it is then subject to years of clinical trials, during which it is tested on large cohorts of patients to determine its safety and efficacy. Clinical trials typically occur in three phases. During Phase 1, researchers determine the drug's basic properties and safety profile in humans using healthy individuals; during Phase 2, efficacy trials begin on a group of volunteers who are part of the drug's target population; during

[103] Olivier J. Wouters, Martin McKee & Jeroen Luyten, Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018, JAMA, at 5 (Mar. 3, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054832/?report=reader.

[104] Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 31 (2016) https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/12742/DiMasi-Grabowski-Hansen-RnD-JHE-2016.pdf.

the most expensive and time-consuming stage, Phase 3, human testing continues after meeting with the FDA and discussing any concerns.[105] For a chronic condition like cardiovascular disease, clinical trials "tend to involve complex and expensive testing, large numbers of patients, and long timeframes," which all lead to higher costs associated with the clinical trials.[106] Unsurprisingly, a large majority of drugs fail during clinical trials. A recent study measuring the clinical development success rates from 2011 to 2020 concluded that likelihood that a drug that treats cardiovascular disease will progress from Phase 1 clinical trials to approval is 4.8 percent.[107] Indeed, in 2016, Pfizer discontinued its Phase 3 clinical trials for its investigational PCSK9 inhibitor, bococizumab.[108] Although the cost of clinical trials range based on the number of patients enrolled and the type of drug, one study found that each clinical trial cost between $12.2 million and $33.1 million.[109]

128. Finally, even if these trials are successful, the drug company must compile the data and submit a new drug application to the FDA, which can take a year or more to process, and often takes considerably longer if the FDA finds deficiencies in the data or application. New Drug

[105] Aylin Sertkaya, Anna Birkenbach, Ayesha Berlind & John Eyraud, *Examination of Clinical Trial Costs and Barriers for Drug Development*, at 1–2 (July 25, 2014), https://aspe.hhs.gov/sites/default/files/private/pdf/77166/rpt_erg.pdf.

[106] *Id.* at 2–4.

[107] *Clinical Development Success Rates and Contributing Factors 2011-2020*, PharmaIntelligence Informa, at 10–11 (Feb. 2021), https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2021/files/reports/2021-clinical-development-success-rates-2011-2020-v17.pdf

[108] *Pfizer Discontinues Global Development of Bococizumab, Its Investigational PCKS9 Inhibitor*, Pfizer (Nov. 1, 2016), https://www.pfizer.com/news/press-release/press-release-detail/pfizer_discontinues_global_development_of_bococizumab_its_investigational_pcsk9_inhibitor.

[109] Thomas J. Moore, Hanzhe Zhang, Gerard Anderson & C. Caleb Alexander, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA Internal Med. 1451, 1457 (Sept. 24, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6248200/#!po=68.7500.

Applications are detailed and "must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics."[110] The FDA's stated goal is to process a New Drug Application within ten months. However, as demonstrated by the delay in FDA-approval of Novartis' new drug Leqvio®, the process may take much longer.[111] All told, the average development time for a new drug from conception to approval on average takes 12 years, and in the vast majority of attempts result in failure.

129. **The PCSK9i Market and Pharmacy-Dispensed PCSK9i Sub-Market**: In addition to the barriers above, unique barriers to entry exist in the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market. PCSK9 inhibitors are a novel treatment and were first marketed in 2015. Although PCSK9 inhibitors are a critical new drug for a high-risk population, that population is relatively small. While about 25 percent of Americans over 40 years old take a statin to lower their cholesterol,[112] the high-risk population who would be candidates to take a PCSK9 inhibitor includes about just one in every 250 Americans.[113] These disincentives to enter the market, especially the Pharmacy-dispensed PCSK9i sub-market, are compounded by the tight control that Third-Party Payors—including, in particular, the three main PBMs that contract on behalf of nearly 80 percent of covered prescriptions in the Pharmacy-dispensed PCSK9i sub-market—exert by requiring that beneficiaries first fail other treatments and then using formulary

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[110] *New Drug Application (NDA),* Drugs@FDA Glossary, FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=glossary.page.

[111] *See Novartis receives complete response letter from U.S. FDA for inclisiran*, NOVARTIS (Dec. 18, 2020), https://www.novartis.com/news/media-releases/novartis-receives-complete-response-letter-from-us-fda-inclisiran.

[112] Qiuping Gu, Ryne Paulose-Ram, Vicki L. Burt & Brian K. Kitel, *Prescription Cholesterol-lowering Medication Use in Adults Aged 40 and Over: United States, 2003–2012*, NCHS Data Brief No. 177, (Dec. 2014), https://www.cdc.gov/nchs/data/databriefs/db177.pdf.

[113] *Familial Hypercholesterolemia*, CDC (Feb. 10, 2022), https://www.cdc.gov/genomics/disease/fh/FH.htm.

positioning to limit coverage to exclusive or preferred drugs within the class. Thus, it is difficult for potential entrants to justify high research and development, regulatory, and intellectual property costs given the high risk and limited sales opportunities in the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market.

130. **Moderate-to-Severe Psoriasis Market**: Unique barriers to entry also exist in the moderate-to-severe psoriasis market, the market in which Amgen's Otezla® is sold. As explained previously, Otezla® has dominated the oral medication moderate-to-severe psoriasis market. The FDA first approved Otezla® to treat psoriasis in 2014; seven years later, even the most likely apparent competitor has not yet entered the market. In addition, only recently have scientists learned more about the role the immune system plays on targeting and treating psoriasis. All of these factors make it difficult for potential new competitors to enter this market.

131. **The Rheumatoid Arthritis Market**: Unique barriers to entry similarly exist in the rheumatoid arthritis market, the market in which Amgen's Enbrel® is sold. The rheumatoid arthritis market has a high concentration of biosimilar drugs. A biosimilar is a drug that is a "highly similar" drug without "clinically meaningful differences" in a drug's safety and effectiveness.[114] Although having a high number of biosimilar drugs may suggest that fewer barriers to entry exist, biosimilar drugs face increased regulatory and patent challenges, delaying the path to the market and increasing overall costs.

132. In particular, marketing biosimilar drugs is associated with a flurry of patent litigation. For example, adalimumab (more commonly known as Humira®), a competitor of Enbrel®, has over a hundred patents, most of which were filed after adalimumab's launch. As one

[114] *See Biosimilar and Interchangeable Products*, (last visited May 25, 2022), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products.

doctor explained in a recent FDA and FTC workshop: "So you just think about that and think about the barrier to having a biosimilar for that particular medication, or any others into the marketplace, it's certainly a lot more complicated to wade through that patent thicket."[115] According to the Staff Report, Amgen has wielded the patent thicket to its advantage in this market: the Staff Report concluded that "Amgen exploited the U.S. patent system to limit biosimilar competition for Enbrel®."[116] Amgen's primary patent covering Enbrel® was filed in 1990 and expired in 2010.[117] But Amgen has filed a total of 57 patent applications for Enbrel®, and, as of 2018, 19 of those were active patent applications or granted patents.[118] Amgen stands to retain exclusivity until 2029.[119] This means that Amgen has and will enjoy decades of exclusivity since Enbrel® was first approved in 1998.[120]

133. Biosimilar drugs also face immense skepticism from patients and prescribers. Prescribers are hesitant to switch patients from an existing treatment to a new drug, even if it is FDA-approved as a biosimilar.

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[115] *FDA/FTC Workshop on a Competitive Marketplace for Biosimilar*, at 50:11–17 (Mar. 9, 2020), https://www.ftc.gov/system/files/documents/public_events/1568297/fda-ftc_biosimilars_workshop_transcript_3-9-20.pdf.

[116] *Drug Pricing Investigation: Amgen—Enbrel and Sensipar*, Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, at 22 (October 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report %2010-1-20.pdf.

[117] *Overpatented, Overpriced Special Edition Enbrel*, I-MAK, at 3 (2018), https://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf

[118] *Id.*

[119] *Id.*

[120] *Id.*

ANTITRUST INJURY IN THE PCSK9i MARKET AND PHARMACY-DISPENSED PCSK9i SUB-MARKET

134. Amgen's conduct has already harmed and, if left unaddressed, will continue to harm competition in the U.S. PCSK9i market and Pharmacy-dispensed PCSK9i sub-market. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®, including (as described above) the tens of millions of dollars ordinarily required to fund clinical trials.

135. Competition in the PCSK9i market has been harmed by Amgen's below-cost pricing and bundled conditional rebate scheme. Amgen has reduced patient choice in the PCSK9i market by leveraging its largest (Enbrel®) and third-largest (Otezla®) products by U.S. sales—two substantially larger products than Repatha® from unrelated classes where Regeneron has no drugs that compete for the same indications—to exclude or restrict access for Praluent® through the formularies of key Third-Party Payors. As explained above, Amgen's bundle results in a price for Repatha® that is below any appropriate measure of Amgen's costs.

136. The threat of increased prices for Otezla® and Enbrel® leaves these Payors with no commercially reasonable choice but to accept Amgen's demands for Repatha® in the much smaller PCSK9i market, lest they be forced to pay higher prices on Enbrel® and Otezla®, and thereby incur much greater aggregate net costs across these three products. This is a classic example of a "rebate wall" under the definition authored by the FTC to refer to a situation "in which a ***dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third-party payors to maintain market power***, by giving its products preferred status in drug formularies, and to prevent

sales of competing products."[121] According to the FTC, Third-Party Payors will not turn to rival drugs in this situation, because they cannot afford to pay the full list price when the drug manufacturer stops paying the rebate.[122] So even when Regeneron has offered a lower price with competitive single-product rebate offers—as it has done—those savings do not offset the much higher prices for Otezla® and Enbrel® given their sales volumes that Amgen is leveraging to block competitive single-product offers.

137. As a result of Amgen's conduct, as of January 2022, Praluent® has been foreclosed from ***at least 50 percent*** of the PCSK9i sales that are covered by the Third-Party Payors who have been coerced to cover Repatha® exclusively on their formularies. As explained above, because of negative spillover effects, the degree of foreclosure resulting from Amgen's conduct is even greater than the portion of the market from which Praluent® has been expressly foreclosed. This is fatal to Praluent®—which now stands to lose money in 2022—forcing Regeneron to consider investing its resources elsewhere with an exit from the market altogether. There is a large addressable segment of the U.S. population at risk for high cholesterol and for which PCSK9 inhibitors are the best treatment, and Amgen's conduct will prevent the expansion of this drug class to meet the needs of those patients.

138. Amgen's below-cost pricing and conditional bundled rebate scheme is already pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market. Unless stopped, Regeneron's exit

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[121] *See Federal Trade Commission, Report on Rebate Walls*, at 1 (May 28, 2021), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

[122] *Id.* at 2–3.

would leave Amgen as the dominant player in the PCSK9i market, and the only player in the Pharmacy-dispensed PCSK9i sub-market, with ample opportunity to make up for any losses it incurred and continues to incur through its below-cost pricing and bundled rebate schemes. Without Praluent® as a viable competitor, patients will be worse off with reduced choice in PCSK9i inhibitors and increased prices for Repatha®.

139. Since Praluent® launched in 2015, Regeneron has been a disruptive force to drive net prices lower with creative access arrangements. As explained above, in arguing for an injunction that would have taken Praluent® off the market outright, Amgen acknowledged that Praluent®'s presence in the PCSK9i market "***erod[ed] Amgen's net price for Repatha***" by enabling Third-Party Payors to "extract larger and larger rebates and other concessions as a condition to being included (even in a parity position) on national formularies." PI Motion at 6. Amgen's below-cost pricing and bundled rebate scheme is thus designed to rid Repatha® of the procompetitive, price-lowering competition Praluent® brings to the marketplace. Based on Amgen's public financial disclosures, Repatha®'s net price ***has not been lowered*** due to the bundled rebates offered to Third-Party Payors.[123]

140. Moreover, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®.[124] Practitioners have expressed concerns

[123] *See Amgen Reports Second Quarter 2021 Financial Results*," AMGEN, at 2–3, 5 (Aug. 3, 2021) https://investors.amgen.com/static-files/b9db54f1-427b-4266-817a-5451ed692c09 (highlighting lower net selling price for Repatha® only "as a result of an increase in the number of U.S. Medicare Part D patients receiving Repatha and entering the coverage gap").

[124] The medical risks and costs associated with switching patients to Leqvio® are not yet known, but Praluent® provides benefits to patients that have not been demonstrated with respect to Leqvio®, including all-cause mortality and reduction of risk of heart attack and stroke. Regeneron Pharmaceuticals, Praluent® (alirocumab) package insert (April 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125559s029s030lbl.pdf; Novartis Pharmaceuticals Corporation, Leqvio® (package insert), at 1, (last visited May 25, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf.

that switching patients to Repatha® would require lengthy and extensive review by insurance companies, which would disrupt any treatment for patients awaiting approval.[125] Switching patients to Repatha® would also deny them and their doctors the option of using Praluent®'s 75mg low dose, which currently accounts for the majority of ESI's PCSK9 inhibitor utilization. Additionally, practitioners have explained that for certain patients, Repatha® simply does not work.[126] And certain high-risk patients may suffer the most because Praluent® is the only PCSK9 inhibitor associated with an observed reduction in all-cause mortality and reduced the risk of death for those patients by 29 percent.[127]

141. Moreover, Amgen's bundling of Otezla® and Enbrel® to block access for Praluent® sets a dangerous precedent for competition in the pharmaceutical industry. Allowing this conduct will encourage large pharmaceutical companies like Amgen to exclude smaller, innovative entrants by bundling larger products from unrelated classes where a new entrant offers no competitive product and cannot offer an alternative competitive bundle. This type of exclusionary bundling has already reduced, and will continue to reduce, consumer choice in the PCSK9i market and the Pharmacy-dispensed PCSK9i sub-market to the detriment of patients. And it will have the same harmful anticompetitive effects across countless other therapeutic classes if left unchecked.

[125] *See* Response of *Amicus Curiae* Practitioners Who Currently Treat Patients with Praluent in Support of Appellants' Motion for Stay Pending Appeal at 8, filed in *Sanofi v. Amgen, Inc.,* No. 17-1480 (Fed. Cir. Jan. 24, 2017), ECF No. 40.

[126] *E.g., id.* at 7 ("[T]here is a lack of any reliable research indicating that their patients taking Praluent will actually respond to Repatha").

[127] *See PCSK9 Therapy: An Example of Value-Based Care*, Express Scripts (May 1, 2018), https://www.express-scripts.com/corporate/articles/pcsk9-therapy-example-value-based-care.

CLAIMS FOR RELIEF

Count One: Monopolization of the PCSK9i Market and Pharmacy-Dispensed PCSK9i Sub-Market Through Bundling in Violation of Section 2 of the Sherman Act

142. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

143. Section 2 of the Sherman Act prohibits the monopolization of any part of the trade or commerce among the several States. 15 U.S.C. § 2.

144. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two such PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a meaningful competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

145. From at least September 2017 until now, Amgen possessed monopoly power in the PCSK9i market and the Pharmacy-dispensed PCSK9i sub-market with Repatha®. Repatha®'s share of the PCSK9i market by total prescriptions is almost 80 percent as of February 2022. Significant and substantial commercial, developmental, regulatory, and other barriers insulate the PCSK9i market, and especially the Pharmacy-dispensed PCSK9i sub-market, from new entry and expansion.

146. Amgen unlawfully maintained and entrenched its monopoly power in the PCSK9i

market through an anticompetitive bundling scheme. Specifically, Amgen purposely and knowingly bundled its sales of Otezla®, Enbrel®, and Repatha® to require that Third-Party Payors exclude Praluent® in order to obtain highly valuable and lucrative product rebates on the wholly unrelated Otzela® and Enbrel® products, which possess monopoly power and market power, respectively, in the relevant markets. Amgen leverages these unrelated and much larger products from its portfolio to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel®, and is unable to match Amgen's rebates given the relatively more limited size of Regeneron's product portfolio and the distribution channels for those products.

147. By conditioning rebates for its combination of blockbuster drugs Otezla® and Enbrel® upon Repatha® exclusivity or *de facto* exclusivity on Third-Party formularies, Amgen was able to hinder and artificially limit competition in the PCSK9i market from Praluent®. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market. The degree of foreclosure resulting from Amgen's conduct is even greater due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the Third-Party Payors' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

148. Given that Repatha®'s net price has not been lowered due to the bundled rebates offered to Third-Party Payors, Amgen's pricing for Repatha® is not the clearly predominant means by which it forecloses competition in the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market. Amgen forecloses competition by bundling Repatha® with Otezla® and Enbrel®—substantially larger products from unrelated classes where Regeneron has no drugs that compete

for the same indications and no way to match Amgen's rebates given Regeneron's current and future drug portfolio and distribution channels. Amgen's anticompetitive conduct is designed and intended to cement its existing monopoly in the PCKS9i market and Pharmacy-dispensed PCSK9i sub-market by leveraging significant and coercive rebates for Otezla® and Enbrel® that Payors must take, thereby leaving Payors with no viable choice but to exclude Praluent® from their formularies.

149. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property and harmed competition in the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market. The anticompetitive effect of Amgen's scheme is amplified by spillover effects at the Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its much larger portfolio of drug products to make even equal formulary coverage achieved by subsidizing PCSK9i rebates using Otezla® and Enbrel® *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

150. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 2 of the Sherman Act. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[128] Additionally, there are serious medical risks and

[128] *See* PI Motion at 6–9.

costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

151. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Count Two: Attempted Monopolization of the PCSK9i Market and Pharmacy-Dispensed PCSK9i Sub-Market Through Bundling in Violation of Section 2 of the Sherman Act

152. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

153. Section 2 of the Sherman Act prohibits the monopolization of any part of the trade or commerce among the several States. 15 U.S.C. § 2.

154. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." For many years, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

155. Amgen's bundled rebate scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Specifically, Amgen purposely and

knowingly bundled its sales of Otezla®, Enbrel®, and Repatha® to require that Third-Party Payors provide exclusivity to Repatha®—and exclude Praluent®—in order to obtain highly valuable and lucrative product rebates on the wholly unrelated Otzela® and Enbrel® products. By exploiting its leverage from the combination of blockbuster drugs Otezla® and Enbrel®—which possess monopoly power and market power, respectively, in the relevant markets—Amgen was able to hinder and artificially limit competition in the PCSK9i market from Praluent®. Amgen leverages these unrelated and much larger products from its portfolio to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel®, and is unable to match Amgen's rebates given the relatively more limited size of Regeneron's product portfolio and the distribution channels for those products.

156. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection of coverage of Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

157. Given that Repatha®'s net price has not been lowered due to the bundled rebates offered to Third-Party Payors, pricing for Repatha® is not the clearly predominant means by which Amgen's bundled rebate scheme forecloses competition in the PCSK9i market and the Pharmacy-dispensed PCSK9i sub-market. Amgen forecloses competition by bundling Repatha® with Otezla® and Enbrel®—substantially larger products from unrelated classes where Regeneron has no drugs that compete for the same indications and no way to match Amgen's rebates given Regeneron's current and future drug portfolio and distribution channels. Amgen's anticompetitive

conduct is designed and intended to cement its existing monopoly in the PCKS9i market by leveraging significant and coercive rebates for Otezla® and Enbrel® that Payors must take, thereby leaving Payors with no viable choice but to exclude Praluent® from their formularies.

158. Amgen has acted with the specific intent to monopolize the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Since Praluent®'s and Repatha®'s U.S. launches in 2015, Amgen has repeatedly attempted to block Praluent® from competing in the PCSK9i market, including by trying, and failing, to exclude Praluent® from the market under U.S. patent law and utilizing its sales force to spread misleading facts about Praluent®. Having failed in its previous attempts to rid Repatha® of competition from Regeneron's Praluent®—the only competition Amgen faces in the Pharmacy-dispensed PCSK9i sub-market—Amgen has turned to an unlawful bundled rebate scheme to cement its monopoly position.

159. There is a dangerous probability that Amgen will succeed in monopolizing the PCSK9i market and the Pharmacy-dispensed PCSK9i sub-market by eliminating competition from Praluent®. Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i market. If Amgen coerces another key Third-Party Payor to exclude Praluent® from its formulary, foreclosure will be well above 50 percent and it could be fatal to Praluent®, forcing Regeneron to consider investing its resources elsewhere with an exit from the PCSK9i market altogether or some other significant scaling back of the product.

160. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property. The anticompetitive effect of Amgen's scheme is amplified by spillover

effects at the Third-Party Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its portfolio of drug products to make even equal formulary coverage achieved by subsidizing PCSK9i rebates using Otezla® and Enbrel® *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

161. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[129] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

162. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Count Three: Monopolization of the PCSK9i Market and Pharmacy-Dispensed PCSK9i Sub-Market Through Below-Cost Pricing in Violation of Section 2 of the Sherman Act

163. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

[129] *See* PI Motion at 6–9.

164. Section 2 of the Sherman Act prohibits the attempted monopolization of any part of the trade or commerce among the several States. 15 U.S.C. § 2.

165. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

166. From at least September 2017 until now, Amgen possessed monopoly power in the PCSK9i market with Repatha®. Repatha®'s share of the PCSK9i market by total prescriptions is approximately 80 percent as of February 2022. Significant and substantial commercial, developmental, regulatory, and other barriers insulate the PCSK9i market from new entry and expansion.

167. Amgen unlawfully maintained and entrenched its monopoly power in the PCSK9i market by using a below-cost offer for Repatha® to secure exclusivity, or *de facto* exclusivity, for Repatha® and exclude Praluent® from the formularies of Third-Party Payors. For example, Amgen conditioned rebates of $210 million over two years and four months—about $90 million per year—on a three-product bundle consisting of Otezla®, Enbrel® and Repatha®. As explained in more detail above, after allocating the entirety of Amgen's bundled rebates to Repatha®, Amgen is

pricing Repatha® below an appropriate measure of its costs. Upon information and belief, Amgen has used and is using a below-cost offer for Repatha® to secure exclusivity or *de facto* exclusivity for Repatha®, and exclude Praluent® from the formularies of other Third-Party Payors. Amgen's below-cost prices cannot be matched by Regeneron unless it sells Praluent® below cost.

168. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

169. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property, and harmed competition by foreclosing Regeneron from at least 50 percent of the PCSK9i market. The anticompetitive effect of Amgen's scheme is amplified by spillover effects at the Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its portfolio of drug products to make even equal formulary coverage achieved by subsidizing PCSK9i rebates using Otezla® and Enbrel® *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®.

170. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable. This has the effect of entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the

Pharmacy-dispensed PCSK9i sub-market, with no constraint on Amgen's ability to control and raise prices going forward, as well as allowing Amgen to recoup its investment from its anticompetitive bundling scheme.

171. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[130] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

172. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Count Four: Attempted Monopolization of the PCSK9i Market and Pharmacy-Dispensed PCSK9i Sub-Market Through Below-Cost Pricing in Violation of Section 2 of the Sherman Act

173. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

174. Section 2 of the Sherman Act prohibits the attempted monopolization of any part of the trade or commerce among the several States. 15 U.S.C. § 2.

175. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the

[130] *See id.*

"Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

176. Amgen's below-cost pricing scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the PCSK9i market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Specifically, Amgen conditioned rebates of $210 million over two years and four months—about $90 million per year—on a three-product bundle consisting of Otezla®, Enbrel® and Repatha®. As explained in more detail above, after allocating the entirety of Amgen's bundled rebates to Repatha®, Amgen is pricing Repatha® below an appropriate measure of its costs. Upon information and belief, Amgen has used and is using a below-cost offer for Repatha® to secure exclusivity or *de facto* exclusivity for Repatha® and exclude Praluent® from the formularies of other Third-Party Payors. Amgen's below-cost prices cannot be matched by Regeneron unless it sells Praluent® below cost.

177. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

178. Amgen has acted with the specific intent to monopolize the PCSK9i market and Pharmacy-dispensed PCSK9i sub-market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Since Praluent®'s and Repatha®'s U.S. launch in 2015, Amgen has repeatedly attempted to block Praluent® from competing in the PCSK9i market. First, Amgen attempted, and failed, to exclude Praluent® from the market under U.S. patent law. Amgen then utilized its sales force to spread misleading facts regarding Praluent®'s safety and availability. Having failed in its previous attempts rid Repatha® of competition from Regeneron's Praluent®—the only competition Amgen faces in the PCSK9i market—Amgen next turned to an unlawful bundled rebate scheme to cement its monopoly position.

179. There is a dangerous probability that Amgen will succeed in monopolizing the PCSK9i market by eliminating Praluent®. Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market. If Amgen coerces another key Payor to exclude Praluent® from its formulary, foreclosure will be well above 50 percent and it could be fatal to Praluent® forcing Regeneron to consider investing its resources elsewhere with an exit from the PCSK9i market altogether or some other significant scaling back of the product.

180. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property. The anticompetitive effect of Amgen's scheme is amplified by spillover effects at the Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its portfolio of drug products to make even equal formulary coverage achieved by subsidizing PCSK9i rebates using Otezla® and Enbrel® *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property,

including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market, with no constraint on Amgen's ability to control and raise prices going forward, as well as allowing Amgen to recoup its investment from its anticompetitive bundling scheme.

181. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[131] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

182. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Count Five: Unreasonable Restraint of Trade in Violation of Section 1 of the Sherman Act

183. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

184. Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States."

[131] *See* PI Motion at 6–9.

15 U.S.C. § 1.

185. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

186. Amgen has entered into agreements with at least ESI Commercial, ESI Part D, and UHC/Optum Commercial, whereby Amgen has conditioned and tied the availability of rebates for Otezla® and Enbrel® upon exclusive or *de facto* exclusive formulary coverage for the purchase Repatha®. These three products are separate and sold in distinct markets, and doctors prescribe each of them to treat different medical conditions and serve different patient preferences. Each agreement between Amgen and the Third-Party Payors that tied rebates for Otezla® and Enbrel® to Repatha® is an unreasonable restraint of trade that was entered into in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

187. Specifically, Amgen used a three-product bundle consisting of Otezla®, Enbrel®, and Repatha® to condition drug formulary exclusivity for Repatha®. Amgen's conduct unlawfully excluded Praluent® from competing for formulary access in the PCSK9i market by tying Repatha® exclusivity to coercive rebates for much larger products in other drug classes where Regeneron

has no drugs that compete for the same indications.

188. Otezla® possesses monopoly power in the U.S. market for orally ingested drug products approved by the FDA for the treatment of moderate-to-severe psoriasis. Enbrel® is Amgen's largest product and possesses market power in the rheumatoid arthritis market. Amgen's scheme excludes Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel®, and is unable to match Amgen's rebates.

189. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the Third-Party Payors' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

190. The threat of increased prices for Otezla® and Enbrel® leaves Third-Party Payors like ESI, CVS and UHC/Optum with no choice but to accept Amgen's demands for favorable formulary positioning for Repatha®. Even if Regeneron offered a lower price for the PCSK9i market with competitive single-product rebate offers, as it has done, those savings do not and cannot offset the increased prices for Otezla® and Enbrel® that Amgen leverages to block such competitive single-product offers.

191. Amgen's unlawful agreements have directly and proximately caused injury to Regeneron's business and property. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup

the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

192. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[132] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

193. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

Count Six: Sale on Condition to Exclude Praluent®
in Violation of Section 3 of the Clayton Act

194. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

195. Section 3 of the Clayton Act prohibits the sale or contract for sale of goods on the condition, agreement or understanding that the purchaser shall not use or deal in the goods of a competitor of the seller "where the effect of such lease, sale, or contract for sale or such condition, agreement, or understanding may be to substantially lessen competition or tend to create a

[132] *See* PI Motion at 6–9.

monopoly in any line of commerce." 15 U.S.C. § 14.

196. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

197. Amgen has entered into agreements with at least ESI Commercial, ESI Part D, and UHC/Optum Commercial, whereby Amgen has conditioned and tied the availability of rebates for Otezla® and Enbrel® upon exclusive, or *de facto*, exclusive formulary coverage for the purchase of Repatha®. These three products are separate and sold in distinct markets, and doctors prescribe each of them to treat different medical conditions and serve different patient preferences. Each agreement between Amgen and the Third-Party Payors that tied rebates for Otezla® and Enbrel® to Repatha®, is a contract for sale of goods on the condition, agreement or understanding that the purchaser shall not use or deal in the goods of a competitor of the seller and was entered into in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14.

198. Specifically, Amgen used a three-product bundle—consisting of Otezla®, Enbrel®, and Repatha®—to condition drug formulary exclusivity for Repatha®. Amgen's conduct unlawfully excluded Praluent® from competing for formulary access in the PCSK9i market by

tying Repatha® exclusivity to coercive rebates for much larger products in other drug classes where Regeneron has no drugs that compete for the same indications. Amgen's agreements with Third-Party Payors govern the terms of sale for Otezla®, Enbrel® and Repatha®, to consumers and thus relate to the sale of goods under Section 3 of the Clayton Act, 15 U.S.C. § 14.

199. Otezla® possesses monopoly power in the U.S. market for orally ingested drug products approved by the FDA for the treatment of moderate-to-severe psoriasis. Otezla® is Amgen's third largest product, generating $1.79 billion in 2020. Enbrel® is Amgen's largest product with $4.85 billion in U.S. net sales in 2020, and possesses market power in the rheumatoid arthritis market. By comparison, Repatha® generated $459 million in U.S. net sales in 2020. Amgen's scheme leverages this enormous gap in sales to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron.

200. The effect of Amgen's conduct has been to substantially lessen competition or tend to create a monopoly in the PCSK9i market by foreclosing Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection of certain coverage of Repatha® over Praluent® chooses for patients and providers whether Praluent® is available as an option.

201. The threat of increased prices for Otezla® and Enbrel® leaves Third-Party Payors with no choice but to accept Amgen's demands for favorable formulary positioning for Repatha®. Even if Regeneron offered a lower price for the PCSK9i market with competitive single-product rebate offers, as it has done, those savings would not offset the increased prices for Otezla® and

Enbrel® that Amgen leverages to block such competitive single-product offers.

202. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property. The anticompetitive effect of Amgen's scheme is amplified by spillover effects at the Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its portfolio of drug products to make even equal formulary coverage *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

203. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[133] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

204. Regeneron seeks injunctive relief, actual damages, trebled, plus interest, as well as attorneys' fees and costs under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

[133] *See id.*

Count Seven: Violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*

205. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

206. California Business and Professions Code Section 17200, which is part of California's Unfair Competition Law, prohibits any person engaged in business in California from engaging in "any unlawful, unfair or fraudulent business act or practice."

207. Amgen is engaged in business in California, and has provided or offered to provide bundled rebates of its products to customers at below-cost prices to customers in the United States for the purposes of injuring Regeneron, destroying fair competition in the PCSK9i market, and maintaining monopoly power.

208. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

209. From at least September 2017 until now, Amgen possessed monopoly power in the PCSK9i market with Repatha®. Repatha®'s share of the PCSK9i market by total prescriptions is approximately 80 percent as of February 2022. Significant and substantial commercial,

developmental, regulatory, and other barriers insulate the PCSK9i market from new entry and expansion.

210. Amgen unlawfully maintained and entrenched its monopoly power in the PCSK9i market though an anticompetitive bundling scheme. Specifically, Amgen purposely and knowingly bundled its sales of Otezla®, Enbrel®, and Repatha® to require that Third-Party Payors exclude Praluent® outright in order to obtain highly valuable and lucrative product rebates on the wholly unrelated Otzela® and Enbrel® products. By conditioning rebates for its combination of blockbuster drugs Otezla® and Enbrel® upon Repatha® exclusivity or *de facto* exclusivity on Third-Party formularies, Amgen was able to hinder and artificially limit competition in the PCSK9i market from Praluent®.

211. Otezla® possesses monopoly power in the U.S. market for orally ingested drug products approved by the FDA for the treatment of moderate-to-severe psoriasis. Otezla® is Amgen's third largest product by U.S. net sales, generating $1.79 billion in 2020. Enbrel® is Amgen's largest product with $4.85 billion in U.S. net sales in 2020, and possesses market power in the rheumatoid arthritis market. Amgen leverages these unrelated and much larger products from its portfolio to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel® and is unable to match Amgen's rebates given the relatively more limited size of Regeneron's product portfolio and distribution channels for those products.

212. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve

as the gateway for distribution and sale of PCSK9 inhibitors to patients, the Third-Party Payors' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

213. The threat of increased prices for Otezla® and Enbrel® leaves Third-Party Payors like ESI, CVS and UHC/Optum with no choice but to accept Amgen's demands for favorable formulary positioning for Repatha®. Even if Regeneron offered a lower price for the PCSK9i market with competitive single-product rebate offers, as it has done, those savings do not and cannot offset the increased prices for Otezla® and Enbrel® that Amgen leverages to block such competitive single-product offers.

214. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property and harmed competition by foreclosing Regeneron from at least 50 percent of the PCSK9i market. The anticompetitive effect of Amgen's scheme is amplified by spillover effects at the Payor and prescriber levels, as well as Amgen's ability to leverage its much larger sales force across its portfolio of drug products to make even equal formulary coverage achieved by subsidizing PCSK9i rebates using Otezla® and Enbrel® *de facto* exclusive for Repatha®. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

215. Regeneron's injuries are of the type that the U.S. and California antitrust and competition laws are intended to prohibit, flow directly from Amgen's anticompetitive conduct,

and is an illegal business practice under the unfair and unlawful prongs in violation California's Unfair Practices Act, Cal. Bus. & Prof. Code § 17200 *et seq*. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[134] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

216. Amgen's conduct was a substantial factor in causing Regeneron harm.

217. This conduct is unfair and unlawful as an illegal business practice in violation of California's Unfair Competition Law.

218. As a result of Amgen's continuing violation of California's UCL, Regeneron has been and will continue to be damages through the date of trial, for which Regeneron intends to seek monetary relief (disgorgement and/or restitution) and injunctive relief as permitted by applicable law.

Count Eight: Violation of California's Unfair Practices Act ("UPA"), Cal. Bus. & Prof. Code § 17043 *et seq.*

219. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

220. California Business and Professions Code Section 17043, which is part of California's UPA, prohibits any person engaged in business in California from selling or offering to sell "any article or product at less than the cost thereof to such vendor, or to give away any article or product, for the purpose of injuring competitors or destroying competition." California

[134] *See* PI Motion at 6–9.

enacted the UPA "to safeguard the public against the creation or perpetuation of monopolies and to foster and encourage competition, by prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." Cal. Bus. & Prof. Code § 17001.

221. Amgen is engaged in business in California, and has provided or offered to provide bundled rebates of its products to customers at below-cost prices to customers in the United States for the purposes of injuring Regeneron, destroying fair competition in the PCSK9i market, and maintaining monopoly power.

222. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

223. From at least September 2017 until now, Amgen possessed monopoly power in the PCSK9i market with Repatha®. Repatha®'s share of the PCSK9i market by total prescriptions is approximately 80 percent as of February 2022. Significant and substantial commercial, developmental, regulatory, and other barriers insulate the PCSK9i market from new entry and expansion.

224. Amgen unlawfully maintained and entrenched its monopoly power in the PCSK9i market by using a below-cost offer to secure exclusivity or *de facto* exclusivity for Repatha® and exclude Praluent® from the formularies of Third-Party Payors. Specifically, Amgen conditioned rebates of $210 million over two years and four months—about $90 million per year—on a three-product bundle consisting of Otezla®, Enbrel® and Repatha®. As explained in more detail above, after allocating the entirety of Amgen's bundled rebates to Repatha®, Amgen is pricing Repatha® below an appropriate measure of its costs. Amgen has purposely structured its multi-product bundled rebate so that Regeneron cannot match it, or even compete with it, unless Regeneron sells Praluent® for a loss.

225. The purpose of Amgen's conduct was to injure Regeneron and destroy competition in the PCSK9i market in violation of Section 17403 of California's UPA. Since Praluent®'s and Repatha®'s U.S. launch in 2015, Amgen has repeatedly attempted to block Praluent® from competing in the PCSK9i market. First, Amgen attempted, and failed, to exclude Praluent® from the market under U.S. patent law. Amgen then utilized its sales force to spread misleading facts regarding Praluent®'s safety and availability. Having failed in its previous attempts to rid Repatha® of competition from Regeneron's Praluent®—the only competition Amgen faces in the PCSK9i market—Amgen next turned to an unlawful bundled rebate scheme to cement its monopoly position.

226. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection

of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

227. Amgen's conduct was a substantial factor in causing Regeneron harm.

228. This conduct is unlawful as an illegal business practice in violation of California's Unfair Practices Act.

229. As a result of Amgen's continuing violation of California's UPA, Regeneron has been and will continue to be damages through the date of trial, for which Regeneron intends to seek damages, trebled, and injunctive relief as permitted by applicable law.

Count Nine: Violation of California's Cartwright Act, Cal. Bus. & Prof. Code §§ 16720, 16727

230. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

231. California Business and Professions Code Section 16700 *et seq.*, which is part of California's Cartwright Act, prohibits any person engaged in business in California from "leas[ing] or mak[ing] a sale or contract for the sale of goods, merchandise, machinery, supplies, commodities for use within the State, or [] fix[ing] a price charged therefor, or discount from, or rebate upon, such price, on the condition, agreement or understanding that the lessee or purchaser thereof shall not use or deal in the goods, merchandise, machinery, supplies, commodities, or services of a competitor or competitors of the lessor or seller, where the effect of such lease, sale, or contract for sale or such condition, agreement or understanding may be to substantially lessen competition or tend to create a monopoly in any line of trade or commerce in any section of the State." Cal. Bus. & Prof. Code § 16727.

232. Amgen is engaged in business in California, and has provided or offered to provide bundled rebates of its products to customers at below-cost prices to customers in the United States

for the purposes of injuring Regeneron, destroying fair competition in the PCSK9i market, and maintaining monopoly power.

233. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

234. Amgen has entered into agreements with at least ESI Commercial, ESI Part D, and UHC/Optum Commercial, whereby Amgen has conditioned and tied the availability of rebates for Otezla® and Enbrel® upon exclusive or *de facto* exclusive formulary coverage for Repatha®. These three products are separate and sold in distinct markets, and doctors prescribe each of them to treat different medical conditions and serve different patient preferences. Each agreement between Amgen and the Third-Party Payors that tied rebates for Otezla® and Enbrel®, to Repatha®, is an unreasonable restraint of trade that was entered into in violation of California's Cartwright Act, Cal. Bus. & Prof. Code § 16700 *et. seq*.

235. Specifically, Amgen used a three-product bundle—consisting of Otezla®, Enbrel®, and Repatha®—to condition drug formulary exclusivity for Repatha®. Amgen's conduct unlawfully excluded Praluent® from competing for formulary access in the PCSK9i market by

tying Repatha® exclusivity to coercive rebates for much larger products in other drug classes where Regeneron has no drugs that compete for the same indications.

236. Otezla® possesses monopoly power in the U.S. market for orally ingested drug products approved by the FDA for the treatment of moderate-to-severe psoriasis. Otezla® is Amgen's third largest product by U.S. net sales, generating $1.79 billion in 2020. Enbrel® is Amgen's largest product with $4.85 billion in U.S. net sales in 2020, and possesses market power in the rheumatoid arthritis market. Amgen leverages these unrelated and much larger products from its portfolio to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel® and is unable to match Amgen's rebates given the relatively more limited size of Regeneron's product portfolio and distribution channels for those products.

237. The effect of Amgen's conduct has been to foreclose Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the Third-Party Payors' selection of coverage for Repatha® over Praluent® forces patients and providers to choose Repatha® over Praluent®.

238. The threat of increased prices for Otezla® and Enbrel® leaves Third-Party Payors like ESI, CVS and UHC/Optum with no choice but to accept Amgen's demands for favorable formulary positioning for Repatha®. Even if Regeneron offered a lower price for the PCSK9i market with competitive single-product rebate offers, as it has done, those savings do not and cannot offset the increased prices for Otezla® and Enbrel® that Amgen leverages to block such

competitive single-product offers.

239. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

240. Regeneron's injuries are of the type that the U.S. antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct and is an illegal business practice in violation of California's Cartwright Act, Cal. Bus. & Prof. Code § 16700 *et. seq*. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market.[135] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

241. Amgen's conduct was a substantial factor in causing Regeneron harm.

242. This conduct is unlawful as it an illegal business practice in violation of California's Cartwright Act.

243. As a result of Amgen's continuing violation of the California's Cartwright Act, Regeneron has been and will continue to be damages through the date of trial, for which Regeneron

[135] *See* PI Motion at 6–9.

intends to seek damages, trebled, and injunctive relief as permitted by applicable law.

Count Ten: Violation of New York's Donnelly Act, § 340 of New York's General Business Law ("GBL")

244. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

245. FDA-approved PCSK9 inhibitors that treat certain cardiovascular conditions by reducing LDL-C constitute a relevant product market—the "PCSK9i market"—for which the United States is the relevant geographic market. Within the PCSK9i market, there is a sub-market for PCSK9i inhibitors approved by the FDA that are dispensed through pharmacies—the "Pharmacy-dispensed PCSK9i sub-market." Historically, there were only two PCSK9 inhibitors approved in the United States: Repatha® and Praluent®. While a third PCSK9 inhibitor was approved by the FDA in December 2021 (Leqvio®), it is not a competitive constraint on Repatha® and Praluent®. In response to a small but significant and non-transitory increase in the price of PCSK9 inhibitors, U.S. physicians and patients would not meaningfully switch to any other product or treatment.

246. Amgen has entered into agreements with at least ESI Commercial, ESI Part D, and UHC/Optum Commercial, whereby Amgen has conditioned and tied the availability of rebates for Otezla® and Enbrel® upon exclusive or *de facto* exclusive formulary coverage for the purchase Repatha®. These three products are separate and sold in distinct markets, and doctors prescribe each of them to treat different medical conditions and serve different patient preferences. Each agreement between Amgen and the Third-Party Payors that tied rebates for Otezla® and Enbrel® to Repatha®, is an unreasonable restraint of trade that was entered into in violation of New York's Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq*.

247. Specifically, Amgen used a three-product bundle—consisting of Otezla®, Enbrel®,

and Repatha®—to condition drug formulary exclusivity for Repatha®. Amgen's conduct unlawfully excluded Praluent® from competing for formulary access in the PCSK9i market by tying Repatha® exclusivity to coercive rebates for much larger products in other drug classes where Regeneron has no drugs that compete for the same indications.

248. Otezla® possesses monopoly power in the U.S. market for orally ingested drug products approved by the FDA for the treatment of moderate-to-severe psoriasis. Otezla® is Amgen's third largest product by U.S. net sales, generating $1.79 billion in 2020. Enbrel® is Amgen's largest product with $4.85 billion in U.S. net sales in 2020, and possesses market power in the rheumatoid arthritis market. Amgen's scheme leverages this enormous gap in sales to exclude Praluent® through a bundled rebate offer to Third-Party Payors that cannot be matched by Regeneron, which lacks comparable products to Otezla® and Enbrel®, and is unable to match Amgen's rebates given the relatively more limited size of Regeneron's product portfolio and distribution channels for those products.

249. The effect of Amgen's conduct has been to substantially lessen competition in the PCSK9i market by foreclosing Praluent® from at least 50 percent of the PCSK9i market. The degree of foreclosure resulting from Amgen's conduct is even greater than the absolute portion of the market from which Praluent® has been foreclosed due to negative "spillover" effects at the Payor and prescriber levels. Because Third-Party Payors serve as the gateway for distribution and sale of PCSK9 inhibitors to patients, the purchasers' selection of certain coverage of Repatha® over Praluent® chooses for patients and providers whether Praluent® is available as an option.

250. The threat of increased prices for Otezla® and Enbrel® leaves Third-Party Payors with no choice but to accept Amgen's demands for favorable formulary positioning for Repatha®. Even if Regeneron offered a lower price for the PCSK9i market with competitive single-product

rebate offers, as it has done, those savings would not offset the increased prices for Otezla® and Enbrel® that Amgen leverages to block such competitive single-product offers.

251. Amgen's conduct has directly and proximately caused injury to Regeneron's business and property. As a result, Regeneron has suffered and will continue to suffer injury to its business or property, including lost sales, business opportunities, and ability to recoup the significant investments spent on the development and U.S. commercialization of Praluent®. Most harmful of all, Amgen's conduct is pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable, thereby entrenching Repatha® as the dominant product in the PCSK9i market, and the only product in the Pharmacy-dispensed PCSK9i sub-market.

252. Regeneron's injuries flow directly from Amgen's anticompetitive agreements in violation of N.Y. Gen. Bus. Law § 340 *et seq*. Amgen has acknowledged that competition between Repatha® and Praluent® is a key driver of pricing in the PCSK9i market, allowing Payors to "pit the parties against each other to extract larger and larger rebates" and "forc[ing] Amgen to give [] unprecedented concessions."[136] Additionally, there are serious medical risks and costs of forcing tens or even hundreds of thousands of Praluent® patients to switch to Repatha®, which does not offer a lower 75mg dosage like Praluent® and lacks other key benefits of Praluent®. Certain high-risk patients will suffer the most because Praluent® is the only PCSK9i inhibitor associated with an observed reduction in all-cause mortality and meaningfully reduced the risk of death for those patients by 29 percent. Without Praluent® as a viable competitor, patients would be worse off with reduced choice in the PCSK9i market and increased prices for Repatha®.

253. It is appropriate to bring this action under N.Y. Gen. Bus. Law § 340 *et seq*.

[136] *See* PI Motion at 6–9.

Amgen's illegal conduct has substantially affected New York commerce by harming Regeneron, a business headquartered in New York with its principal place of business in New York.

254. Regeneron seeks actual damages, trebled, plus interest, as well as attorneys' fees and costs under NY Gen. Bus. Law § 340(5).

255. As a result of Amgen's continuing violation of the NY Gen. Bus. Law § 340 *et seq.*, Regeneron has been and will continue to be damages through the date of trial, for which Regeneron intends to seek damages and injunctive relief as permitted by applicable law.

256. Plaintiffs have complied with the notice requirements of New York's Donnelly Act by sending a letter alerting the state's Attorney General of this action contemporaneous with the filing of this Complaint. N.Y. Gen. Bus. Law § 340 *et seq.*

Count Eleven: Tortious Interference with Prospective Business Relations

257. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

258. At all relevant times, Amgen has had knowledge of Regeneron's prospective business relations with the Third-Party Payors. Amgen has competed against Praluent® for formulary access in the PCSK9i market since Praluent® launched in 2015. Until December 2021, Repatha® and Praluent® were the only two PCSK9 inhibitors approved in the United States, so they were the only two PCSK9 inhibitors that Third-Party Payors could possibly be referencing in contract negotiations. Amgen thus had knowledge of Regeneron's business relations with Third-Party Payors.

259. By engaging in the anticompetitive practices set forth above, including negotiating and contracting with Third-Party Payors to achieve below-cost pricing, bundling, and tying, and by engaging in other unfair and deceptive practices, Amgen knowingly, intentionally, and unjustifiably interfered with actual and identifiable prospective business relations between

Regeneron and third-party business partners. Specifically, Amgen acted with a wrongful purpose by bundling its sales of Otezla®, Enbrel®, and Repatha® through coercive rebates designed to rid the PCSK9i market of Amgen's competition. Amgen's significant rebates that rendered the effective price of Repatha® below cost made it impossible for Regeneron to compete on the merits. In addition, Amgen acted with dishonest, unfair, or improper means by utilizing its sales force to spread misleading facts regarding Praluent®'s safety and availability.

260. But for Amgen's interference, Regeneron would have received or would receive the expected economic advantage from its business relations with Third-Party Payors. For example, prior to Amgen's wrongful and anticompetitive conduct, Regeneron had contracts with ESI and UHC/Optum that included Praluent® on their formularies. ESI acknowledged Praluent® to offer distinctive clinical benefits and described its relationship with Regeneron as a proud moment for ESI, providing an "innovative therapy" to its members with an "innovative payment model." But for Amgen's interference, Regeneron's business relationship would have continued.

261. Amgen's interference with Regeneron's relationships with Third-Party Payors has caused and continues to cause damage to Regeneron, including, but not limited to, lost revenues, profits, and business volume.

262. Amgen's interference with these relationships causes harm to consumers, depriving them of a choice between PCSK9 inhibitors and of access to Praluent®.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Regeneron prays:

A. For judgment that:

(i) Defendant Amgen's conduct as stated in this Complaint violates Section 1 of the Sherman Act, 15 U.S.C. § 1;

(ii) Defendant Amgen's conduct as stated in this Complaint violates Section 2 of the Sherman Act, 15 U.S.C. § 2;

(iii) Defendant Amgen's conduct as stated in this Complaint violates Section 3 of the Clayton Act, 15 U.S.C. § 14;

(iv) Defendant Amgen's conduct as stated in this Complaint violates California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 *et seq*.; California's Unfair Practices Act, Cal. Bus. & Prof. Code § 17000, *et. seq*. California's Cartwright Act, Cal. Bus. & Prof. Code § 16700 *et seq.*; and New York's Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.*;

(v) Defendant Amgen's conduct as stated in this Complaint constitutes tortious interference with prospective business relations;

B. For injunctive relief restraining and enjoining Defendant Amgen from continuing its unlawful conduct;

C. That Defendant Amgen be required to pay to Plaintiff Regeneron:

(i) three times the actual damages sustained by Plaintiff as a result of Defendant's Sherman Act and certain state law violations complained of herein;

(ii) additional forms of monetary relief, including punitive damages, sustained by Plaintiff as a result of Defendant's state law violations complained of herein;

(iii) Plaintiff's costs, disbursements, expenses, and reasonable attorneys' fees in bringing this action; and

D. For any such other relief that this Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Regeneron demands a trial by jury on all issues triable by jury.

Dated: May 27, 2022
Wilmington, Delaware

By: */s/ David E. Wilks*

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