UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION STATE OF CALIFORNIA STATE OF ILLINOIS STATE OF MINNESOTA STATE OF NEW YORK STATE OF WASHINGTON and STATE OF WISCONSIN, *Plaintiffs*, v. AMGEN INC. and HORIZON THERAPEUTICS PLC, *Defendants*.	Case No. 1:23-cv-03053 Hon. John F. Kness

BRIEF FOR *AMICI CURIAE* INTERNATIONAL CENTER FOR LAW & ECONOMICS AND 11 SCHOLARS OF ANTITRUST LAW AND ECONOMICS IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

INTEREST OF *AMICI CURIAE* 1

INTRODUCTION 1

ARGUMENT 2

I. The FTC Seeks To Block a Conglomerate Merger That Has No Inherently Anticompetitive Effects 2

A. Antitrust Law Differentiates Between Horizontal, Vertical, and Conglomerate Mergers 2

B. The FTC Here Challenges a Likely Procompetitive Conglomerate Merger Under a Discredited Theory of Harm 4

II. The FTC's Behavioral—Not Structural—Theory of Harm Stacks Speculation Atop Speculation 8

III. Any Remedy Should Be Tailored To Prohibit the Supposed Post-Merger Anticompetitive Conduct, Not the Likely Procompetitive Merger 13

TABLE OF AUTHORITIES

Page(s)

CASES

Abraham v. Ordway,
158 U.S. 416 (1895).....11

Brown Shoe Co. v. United States,
370 U.S. 294 (1962).....1, 2, 8

Collins Inkjet Corp. v. Eastman Kodak Co.,
781 F.3d 264 (6th Cir. 2015).....13

FTC v. Great Lakes Chem. Corp.,
528 F. Supp. 84 (N.D. Ill. 1981).....2

United States v. Anthem, Inc.,
855 F.3d 345 (D.C. Cir. 2017).....3, 7

United States v. Marine Bancorp.,
418 U.S. 602 (1974).....1, 9, 11, 13

United States v. Microsoft Corp.,
253 F.3d 34 (D.C. Cir. 2001).....14, 15

STATUTES AND REGULATIONS

15 U.S.C. § 18 .....1, 8, 14

Orphan Drug Act, Pub. L. No. 97-414.....10

21 C.F.R. § 316 10

OTHER AUTHORITIES

3 P. Areeda & H. Hovenkamp, *Antitrust Law* (1996).....14, 15

H. Armour & D. Teece, *Vertical Integration and Technological Innovation*,
62 Rev. Econ. & Stat. 470 (1980).....3

B. Bolgar, *The Pharmacy Benefit vs the Medical Benefit*, Pharmacy Times (Dec.1, 2011), https://www.pharmacytimes.com/view/the-pharmacy-benefit-vs-the-medical-benefit- 6

Cong. Budget Office, *Research and Development in the Pharmaceutical Industry* (April 2021), https://www.cbo.gov/publication/57126.....5

D. Carlton, *Transaction Costs and Competition Policy*, 73 Int'l J. Indus. Org. 1 (2019) 3

Clinical Trial Information for VRDN-001, U.S. Nat'l Libr. of Med. (last updated July 27, 2023), https://classic.clinicaltrials.gov/ct2/show/NCT05176639 10

D. Crane & J. Wright, *Can Bundled Discounting Increase Consumer Prices Without Excluding Rivals?*, 5 Competition Pol'y Int'l 209 (2009) 13

Fed. Trade Comm'n, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry* (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry 12

Fed. Trade Comm'n, *Health Care Competition*, https://www.ftc.gov/news-events/topics/competition-enforcement/health-care-competition 15

J. Feng, *et al.*, *Mergers that Matter: The Impact of M&A Activity in Prescription Drug Markets*, SSRN Working Paper (July 25, 2023), https://ssrn.com/abstract=4523015 6

J. Harrington, Jr., *Evaluating Mergers for Coordinated Effects and the Role of "Parallel Accommodating Conduct*," 78 Antitrust L.J. 651 (2013) 3

D. Hosken, *et al.*, *Any Willing Provider and Negotiated Retail Pharmaceutical Prices,* 68 J. Indus. Econ. 1 (Mar. 2020) 13

T. Lambert, *Evaluating Bundled Discounts*, 89 Minn. L. Rev. 1688 (2005) 13

A. Mullard, *Parsing Clinical Success Rates*, 15 Nature Reviews Drug Discovery 447 (2016), https://www.nature.com/articles/nrd.2016.136 10

OECD, *Conglomerate Effects of Mergers – Note by the United States* (Jun. 10, 2020), https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf 4, 8

D. Reiffen & M. Vita, *Comment: Is There New Thinking on Vertical Mergers?*, 63 Antitrust L.J. 917 (1995) 3

J. Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. Health Care L. & Pol'y 1 (2018) 5

U.S. Dep't of Justice, Antitrust Div., & Fed. Trade Comm'n, *Vertical Merger Guidelines* (2020) 3

U.S. Dep't of Justice, Antitrust Div., *Merger Remedies Manual* (Sept. 2020), https://www.justice.gov/atr/page/file/1312416/download.....14, 15

U.S. Dep't of Justice, Antitrust Div., *Submission for OECD Roundtable on Portfolio Effects in Conglomerate Mergers* (Oct. 12, 2001), https://www.justice.gov/atr/department-justice-11.....7, 13

U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.....10

D. Wainer, *Elizabeth Warren and the FTC are the Least of Amgen's Problems*, Wall St. J. (May 24, 2023), https://www.wsj.com/articles/elizabeth-warren-and-the-ftc-are-the-least-of-amgens-problems-889163a6 11

Amici Curiae respectfully submit this brief in support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction (Dkt. 130).[1]

INTEREST OF *AMICI CURIAE*

The International Center for Law & Economics ("ICLE") is a nonprofit, nonpartisan, global research and policy center aimed at building the intellectual foundations for sensible, economically grounded policy. ICLE promotes the use of law and economics methodologies, and economic findings, to inform public policy. ICLE has longstanding expertise in antitrust law, and a strong interest in the proper development of antitrust jurisprudence. ICLE thus routinely files *amicus* briefs in cases, like this one, presenting important issues of antitrust law. ICLE is joined by 11 scholars of antitrust law and economics (listed in the Appendix to this brief).

INTRODUCTION

Section 7 of the Clayton Act prohibits mergers where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. Congress used the word "may" to "indicate that its concern was with probabilities, not certainties." *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962). The government thus need not wait for anticompetitive conduct to occur before seeking relief. *Id.* at 317-18. Still, the government must show a "'*reasonable likelihood*' of a *substantial lessening* of competition in the relevant market." *United States v. Marine Bancorp.*, 418 U.S. 602, 622 (1974) (emphasis added).

But—as Yogi Berra might have paraphrased Nils Bohr—it can be "tough to make predictions, especially about the future." Enforcers and courts thus traditionally approach merger control with caution. Deciding whether to block a merger requires making predictions about its

[1] No party's counsel authored any part of this brief, and no person other than *amici* and their counsel made a monetary contribution to fund its preparation or submission.

likely impact on competition and consumers. That requires evaluating both the likely future state of the market given the transaction and the "but for" world in which it does not take place, often with limited (but nonetheless sufficiently substantial) information and imperfect (but ideally well-tested) tools.

For decades, courts and enforcers have looked to economic principles to develop a set of considerations to inform and constrain such decision-making. Three of them are especially relevant here: the distinctions among horizontal, vertical, and conglomerate mergers; the distinction between structural and behavioral threats to competition; and the distinction between structural and behavioral remedies. In challenging Amgen's proposed acquisition of Horizon, the Federal Trade Commission elides all three established distinctions. It instead seeks to block a likely procompetitive conglomerate merger based on harms supposed to arise from a chain of conjectured post-transaction events, where each link in the chain is highly speculative. It is unlikely that they will all come to pass and cause the competitive harm the FTC posits. There is no sound economic basis for blocking the merger here and forfeiting its likely procompetitive benefits. Because the antitrust theory alleged in the complaint lacks merit, the FTC cannot establish the "likelihood of success" necessary for a preliminary injunction. *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 86 (N.D. Ill. 1981).

ARGUMENT

I. THE FTC SEEKS TO BLOCK A CONGLOMERATE MERGER THAT HAS NO INHERENTLY ANTICOMPETITIVE EFFECTS

A. Antitrust Law Differentiates Between Horizontal, Vertical, and Conglomerate Mergers

Mergers can be separated into three categories: horizontal, vertical and conglomerate. *See Brown Shoe*, 370 U.S. at 317. Each type of merger has distinct implications for competition.

In a horizontal merger, the merging firms compete in the same market. Horizontal mergers

thus necessarily reduce the number of firms engaged in head-to-head competition. That reduction can harm consumers, both by making it easier for the merged entity to raise prices unilaterally and by making it easier for remaining firms to coordinate to raise prices. *See* J. Harrington, Jr., *Evaluating Mergers for Coordinated Effects and the Role of* "*Parallel Accommodating Conduct*," 78 Antitrust L.J. 651, 652 (2013). Because horizontal mergers inherently reduce the number of competing firms, the government may be entitled to a presumption of anticompetitive effect if it shows the "transaction will lead to undue concentration in the market for a particular product in a particular geographic area." *United States v. Anthem, Inc.*, 855 F.3d 345, 349 (D.C. Cir. 2017).

Vertical mergers combine firms that operate "at different stages of the same supply chain," and thus have an upstream-downstream (*e.g.*, buyer-seller) relationship in a particular market. U.S. Dep't of Justice, Antitrust Div., & Fed. Trade Comm'n, *Vertical Merger Guidelines* 1 (2020). Vertical mergers do not decrease the number of competitors or increase concentration in a market. Whereas the first-order effect of a horizontal merger can be upward pricing pressure, the first-order effect of a vertical merger is *downward* pricing pressure. Vertical mergers typically entail the elimination of double marginalization—successive markups—at different points in the supply chain, as well as the internalization of externalities in research and development. *See* D. Reiffen & M. Vita, *Comment: Is There New Thinking on Vertical Mergers?*, 63 Antitrust L.J. 917, 920 (1995); H. Armour & D. Teece, *Vertical Integration and Technological Innovation*, 62 Rev. Econ. & Stat. 470, 470 (1980). They also create operational and transactional efficiencies. D. Carlton, *Transaction Costs and Competition Policy*, 73 Int'l J. Indus. Org. 1, 7 (2019).

Conglomerate mergers combine firms that are neither engaged in head-to-head competition nor operating in the same supply chain. Such mergers thus do not inherently reduce competition in any market. The government has explained that conglomerate mergers can produce many of

the same "procompetitive benefits" of vertical mergers if the combined firms' "production or distribution uses the same assets, inputs, or know-how." OECD, *Conglomerate Effects of Mergers – Note by the United States* 2 (Jun. 10, 2020), https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf ("*Conglomerate Effects*"). That is so "even if the merged firm will become a more effective competitor or gain [market] share." *Id.* at 2-3. The resulting economies of scope can increase consumer welfare.

The FTC claims "all mergers must be tested by the same standard." Dkt. 106 ("Mot.") at 8. But it cites outdated precedent. Today, antitrust law treats horizontal, vertical, and conglomerate mergers differently. While horizontal mergers are closely scrutinized, the same skepticism does not apply to vertical and conglomerate mergers. As the United States explains, the "presumption of harm from horizontal mergers" under Section 7 "is not applied for vertical and conglomerate mergers" because they "do not involve an increase in market concentration." *Conglomerate Effects*, *supra*, at 4. "Rather, the plaintiff must prove that the merger under review is likely to substantially lessen competition by a fact-specific inquiry into whether there is an appreciable danger of anticompetitive effects relying on sound theories of economic harm." *Id.*

B. The FTC Here Challenges a Likely Procompetitive Conglomerate Merger Under a Discredited Theory of Harm

This case concerns a conglomerate merger. Amgen and Horizon are both biotechnology companies with a mission to develop and deliver critical medicines to patients. *See* Dkt. 77 ("Answer") at 1. But there are no horizontal overlaps in their businesses: They do not compete head-to-head or produce substitutes in any given market. The FTC acknowledges that Horizon's TEPEZZA® and KRYSTEXXA® products have "*no* direct competition." Complaint ¶¶33, 57 (emphasis added). And the FTC does not allege any vertical overlaps; neither party markets an input

into the other's production. But the FTC nowhere acknowledges the conglomerate nature of the Amgen-Horizon merger, the procompetitive benefits that such mergers typically provide in the pharmaceutical industry, or the significance of the relationship between the merging parties for the FTC's claims under Section 7 of the Clayton Act.

1. Conglomerate mergers between large, established firms and smaller innovators play an important role in fostering innovation—and thus product competition—in the pharmaceutical industry. As the Congressional Budget Office explains:

> The acquisition of a small company by a larger one can create efficiencies that might increase the combined value of the firms by allowing drug companies of different sizes . . . to specialize in activities in which they have a comparative advantage. Small companies—with relatively fewer administrative staff, less expertise in conducting clinical trials, and less physical and financial capital to manage—can concentrate primarily on research. For their part, large drug companies are much better capitalized and can more easily finance and manage clinical trials. They also have readier access to markets through established drug distribution networks and relationships with buyers.

Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (April 2021), https://www.cbo.gov/publication/57126. Conglomerate mergers in the pharmaceutical industry thus can realize the procompetitive effects of vertical combinations (creating efficiencies) while avoiding the anticompetitive effects of horizontal mergers (eliminating competition).

The prospect of such mergers, moreover, drives innovation ex ante. Smaller companies can focus on innovation because they know that, if they succeed, a large pharmaceutical company may acquire them, providing the resources necessary to bring their innovation to market. Potential acquisition thus spurs competition to develop and market life-saving medicines. "Today, most drug innovation originates . . . in biotech companies and smaller firms, where a culture of nimble decision-making and risk-taking facilitates discovery and innovation." J. Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. Health Care L. & Pol'y 1, 1 (2018).

That is not to say conglomerate mergers can *never* lead to higher prices. Recent research on bargaining models indicates it is *possible* for cross-market acquisitions to facilitate a price increase. Such models do not, however, suggest that is a *likely* result. Instead, empirical research indicates that "cross-market acquisitions by larger companies do not have a significant effect on price." J. Feng, *et al.*, *Mergers that Matter: The Impact of M&A Activity in Prescription Drug Markets*, SSRN Working Paper, 6 (July 25, 2023), https://ssrn.com/abstract=4523015. Moreover, the "theory" of harm posited holds only "as long as" the parties' "products have common customers." *Id.* at 5-6. That condition is not met here, where Amgen's customers are *pharmacy* benefit plans, and Horizon's are *medical* benefit plans.[2]

The conglomerate merger between Amgen and Horizon here appears likely to yield substantial procompetitive benefits. The combined firm would benefit from Amgen's experience in commercial operations, providing global manufacturing expertise and distribution networks for Horizon's TEPEZZA® and KRYSTEXXA® products that Horizon could not match on its own. Answer 40, ¶12. And Amgen's greater capital, biologics expertise, and expertise in the FDA-approval process significantly increase the chances that Horizon's other pipeline products eventually reach the market. *Id.* 41, ¶13. The FTC makes the conclusory allegation that "Defendants cannot show cognizable, merger-specific efficiencies that would offset" the alleged "competitive harm resulting from the Proposed Acquisition." Complaint ¶15. But it never addresses the significant efficiencies or other procompetitive benefits likely to result from the merger, or the benefits to patients from having increased access to Horizon's medicines for treating serious rare diseases.

[2] Pharmacy benefit plans reimburse medications administered by the patient at home, while medical benefit plans reimburse medications administered by a care provider in an outpatient setting. *See* B. Bolgar, *The Pharmacy Benefit vs the Medical Benefit*, Pharmacy Times (Dec. 1, 2011), https://www.pharmacytimes.com/view/the-pharmacy-benefit-vs-the-medical-benefit-.

2. More important, because Amgen and Horizon are not competitors, the FTC cannot allege that the merger "transaction will lead to undue concentration," *Anthem*, 855 F.3d at 349—indeed, *any* further concentration—in the markets for "the sale of FDA-approved drugs to treat" TED and CRG, Complaint ¶¶29, 38. Instead, the FTC seems to challenge the merger on the grounds that Amgen is "too big" for the FTC's liking. The FTC states that Amgen is "one of the largest biopharmaceutical companies in the world," *id.* ¶2, with "$24.8 billion" in sales in 2022, *id.* ¶25. It notes that Amgen previously executed a "$16 billion acquisition of Immunex Corporation," and a "$13.4 billion acquisition" to acquire the drug Otezla. *Id.* ¶2. It goes on to state that the "proposed acquisition of Horizon, valued at $27.8 billion," would be Amgen's largest. *Id.* The FTC never suggests that any of these transactions actually did, or would, eliminate one of Amgen's competitors. It instead implies that Amgen's size and clout as a successful biopharmaceutical company will allow it to "entrench its dominant positions" and "entrench Tepezza's and Krystexxa's monopolies." *Id.* ¶¶59, 74.

The FTC thus invokes a now discredited—and previously abandoned—antitrust theory called "entrenchment." Mot. 26-29. As the DOJ has explained, entrenchment theory is more of a bias than an economic theory. Embodying "the 'big is bad' logic" of an earlier era, it condemns conglomerate mergers if they provide "an already dominant firm access to a broader line of products or greater financial resources." U.S. Dep't of Justice, Antitrust Div., *Submission for OECD Roundtable on Portfolio Effects in Conglomerate Mergers* (Oct. 12, 2001) ("*Portfolio Effects*"), https://www.justice.gov/atr/department-justice-11. But providing a dominant firm a broader line of products does not itself imply economic harm.

The FTC and DOJ have repeatedly acknowledged that entrenchment "is no longer viewed

as valid under U.S. law or economic theory." *Conglomerate Effects*, *supra*, at 4. "Critical reflection" on enforcement practices since the 1960s has led the agencies to "increase economic rigor in antitrust analysis," "place greater emphasis on consumer welfare and efficiency," and "discard[ ]" entrenchment as a theory of anticompetitive harm. *Id.* at 5. Accordingly, the DOJ and FTC "have not brought in modern times any challenges to mergers of unrelated products that rely on 'conglomerate' theories outside the horizontal and vertical frameworks." *Id.* at 6. Today, market power—not size—is the cornerstone of antitrust policy, including merger control. Insofar as the FTC relies on an antiquated theory to block a conglomerate merger—in an industry that depends on combining large and small firms to realize procompetitive efficiencies—that alone counsels strongly against the relief the FTC seeks. Consumers should not be denied the efficiencies and increased availability of medicines that such mergers provide based on an outmoded theory.

II. THE FTC'S BEHAVIORAL—NOT STRUCTURAL—THEORY OF HARM STACKS SPECULATION ATOP SPECULATION

Section 7 of the Clayton Act looks to the likely effect of the transaction itself. It prohibits mergers where "the *effect of such acquisition* may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18 (emphasis added). Section 7 is concerned with "[m]ergers with a probable anticompetitive effect." *Brown Shoe*, 370 U.S. at 323. Nowhere does the FTC allege that the likely effect of the transaction *itself* will be to "lessen competition" or "create a monopoly." Because Horizon and Amgen do not compete, the merger does not decrease the number of competitors or increase concentration in any market. To the contrary, the FTC acknowledges that Horizon's TEPEZZA® and KRYSTEXXA® *already* enjoy "monopolies" in alleged markets for FDA-approved treatments for TED and CRG, respectively. Complaint ¶ 74. There is no allegation that Amgen's mere acquisition of Horizon would itself confer greater or more durable market power on either of those products. Nor is there any allegation that any of Amgen's

(unrelated) products will acquire greater market power by dint of the transaction.

The FTC's theory of anticompetitive harm is thus behavioral, not structural—the FTC posits that the merger will create an *opportunity* for Amgen to engage in anticompetitive *conduct*. The FTC posits that Amgen could somehow exploit the monopoly power Horizon enjoys for treatment of TED (with TEPEZZA®) and CRG (with KRYSTEXXA®). Complaint ¶7. The FTC alleges that new treatments may "emerg[e]" so as to threaten TEPEZZA®'s and KRYSTEXXA®'s power in the markets for TED and CRG treatment, *id.* ¶9, and that the emergence of those threats will give Amgen an "incentive" to "entrench" TEPEZZA®'s and KRYSTEXXA®'s "monopolies" and suppress competition, *id.* ¶6. The FTC posits that the "most likely strategy through which Amgen could accomplish that goal is by leveraging its existing portfolio of blockbuster drugs in multi-product contracts" with pharmacy benefit managers ("PBMs"). *Id.* ¶10. Amgen would supposedly "provide[] cross-market bundles or bundled rebates" to PBMs on Amgen's "blockbuster products," such as Enbrel®, in exchange for "favorable formulary placement" for TEPEZZA® and KRYSTEXXA®, *id.* ¶4, and/or "denying coverage to, or otherwise disfavoring," any "potential rivals" to TEPEZZA® and KRYSTEXXA® that might emerge, *id.* ¶10.

It is the FTC's burden to show there is a "'*reasonable likelihood*' of a *substantial lessening* of competition." *Marine Bancorp.*, 418 U.S. at 622 (emphasis added). Section 7 "deals in 'probabilities,' not 'ephemeral possibilities.'" *Id.* at 622-23. Yet the FTC here offers nothing but speculation that any one—much less all—of the events it posits will come to pass. There are ample reasons to believe they will not. Indeed, Amgen has offered to *commit to forgo* the bundling practices on which the FTC's entire theory of harm is premised.

A. The FTC's theory requires speculation from its first step to its last. First, the FTC

must speculate a future competing medication that might be excluded. TEPEZZA® and KRYSTEXXA® currently have "no direct competition." Complaint ¶¶33, 57. As a result, there is no "competition" for Amgen to "suppress." *Id.* ¶10. There is not even a possibility of anticompetitive conduct unless competitor drugs someday "successfully enter" the market. *Id.* ¶9. But there are good reasons to doubt that they will.

The FTC acknowledges that TEPEZZA® and KRYSTEXXA® have been granted "Orphan Drug designation by the FDA." Complaint ¶¶33, 41. By definition, they treat small populations of patients with rare conditions—fewer than 200,000 people in the United States—which limits firms' incentives to invest in these products. Orphan Drug Act, Pub. L. No. 97-414; *see also* 21 C.F.R. §316. The number of drugs in development to treat these conditions is limited, and none of the handful of potential competitors the FTC cites has yet completed a Phase 3 clinical trial. *See* Complaint ¶¶51, 53, 56, 58. Viridian is the only potential TED treatment entrant in the next several years. That product is currently undergoing a Phase 3 clinical trial expected to be completed in May 2025. *See* Clinical Trial Information for VRDN-001, U.S. Nat'l Libr. of Med. (last updated July 27, 2023), https://classic.clinicaltrials.gov/ct2/show/NCT05176639. But that does *not* mean that Viridian will enter in 2025. The Phase 3 trial could easily take longer than anticipated. And a significant share of drugs in Phase 3 clinical trials—somewhere between 40% and 50%—fail to gain approval entirely. *See* A. Mullard, *Parsing Clinical Success Rates*, 15 Nature Reviews Drug Discovery 447, 447 (2016), https://www.nature.com/articles/nrd.2016.136. The FDA approval process will add 6-10 months to the timeline, *even if* the Phase 3 trials are successful. U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective. The FTC thus speculates the approval of a competing drug

that likely cannot enter the market before 2026, if at all.

B. Even if competitors were to gain approval, there is no basis to think Amgen would employ the FTC's alleged "bundling" rebate scheme to exclude competitors. To the contrary, Amgen has offered to enter into a "binding consent order" in which it commits that it will *not* engage in "bundling its products with TEPEZZA® and KRYSTEXXA®." Answer 2-3. That alone forecloses a "reasonable likelihood" of the alleged harm. *Marine Bancorp.*, 418 U.S. at 622. The FTC cannot *create* a hypothetical risk by refusing to accept that offer and then demand that courts order *more intrusive* relief to prevent that risk of the FTC's own making. Courts of equity will "decline to extricate the plaintiff from the position in which [it] has inexcusably placed [it]self." *Abraham v. Ordway*, 158 U.S. 416, 420 (1895).

There are myriad other reasons why the FTC's supposition about potential bundling is not plausible—and certainly not substantially likely. First, Amgen would have no incentive to bundle TEPEZZA® and KRYSTEXXA® with its other drugs unless doing so would increase Amgen's profits overall. The FTC nowhere shows that whatever profits Amgen might gain from suppressing competition for orphan drugs like TEPEZZA® and KRYSTEXXA® would surpass the cost of offering rebates on a "blockbuster drug[ ]" like Enbrel® that generated "over $4 billion in global sales" in 2022. Complaint ¶4.

Second, the FTC offers no convincing explanation of how Amgen could leverage its existing drugs—which face significant competition—to coerce pharmacy benefits managers into granting TEPEZZA® and KRYSTEXXA® favorable formulary status. *See* D. Wainer, *Elizabeth Warren and the FTC are the Least of Amgen's Problems*, Wall St. J. (May 24, 2023), https://www.wsj.com/articles/elizabeth-warren-and-the-ftc-are-the-least-of-amgens-problems-889163a6. The FTC singles out Enbrel®, calling it a "blockbuster." Complaint ¶4. But it never explains how

Enbrel®'s less-than-20% market share provides Amgen with adequate market power to insist on exclusion. That is particularly problematic given that PBMs and health plans themselves enjoy substantial leverage. The FTC has described PBMs as "powerful middlemen" that wield "enormous influence on which drugs are prescribed to patients"—so powerful that the FTC has launched investigations into their practices. Fed. Trade Comm'n, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry* (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

Third, the FTC fails to offer a plausible explanation of how Amgen could "cross-bundle" its products like Enbrel®, which are *pharmacy* benefit products, with TEPEZZA® and KRYSTEXXA®, which are *medical* benefit products. That would entail not just cross-market bundling but, as noted above, *cross-plan* bundling across distinct markets with distinct customers. The complaint states that there is a "trend toward consolidation between pharmacy and medical benefit managers." Complaint ¶72. And it speculates that this "*may* . . . facilitate Amgen's ability to implement cross-benefit bundles." *Id.* (emphasis added). But it provides no example of Amgen—or anyone else—ever actually doing so.[3]

Finally, even if Amgen had both the incentive and the ability to cross-bundle its pharmacy benefit products with medical benefit products like TEPEZZA® and KRYSTEXXA®, the FTC simply assumes bundling is anticompetitive. But bundling is not inherently anticompetitive. To the contrary, discounted bundling arrangements benefit consumers—they are the very price competition the FTC should encourage. An "above-cost bundled discount *always* provides some *procompetitive* benefit . . . and *always* provides some immediate *consumer benefit* (lower prices)."

[3] The FTC alleges that Amgen may not need to engage in cross-benefit bundling because a subcutaneous version of TEPEZZA® is in development and someday *may* be approved and *may* be covered by pharmacy benefit plans. Complaint ¶73. That only introduces yet more speculation.

T. Lambert, *Evaluating Bundled Discounts*, 89 Minn. L. Rev. 1688, 1726 (2005) (emphases added). Indeed, the entire purpose of PBMs is to "employ bundled discounts," "committing to trade variety" of drugs available to members in exchange "for lower prices." D. Crane & J. Wright, *Can Bundled Discounting Increase Consumer Prices Without Excluding Rivals?*, 5 Competition Pol'y Int'l 209, 217 (2009). Research indicates that selective contracting and the ability to steer patients to certain products or providers tends to give plans additional leverage in negotiating *lower* prices. *See* D. Hosken, *et al.*, *Any Willing Provider and Negotiated Retail Pharmaceutical Prices*, 68 J. Indus. Econ. 1, 2, 37 (Mar. 2020).

Bundling is only anticompetitive under certain conditions, such as where a product is priced below cost and sold at a loss. *See, e.g.*, *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 268 (6th Cir. 2015). It defies logic to think Amgen would discount the "blockbuster drugs" that are its lifeblood to the point of loss, Complaint ¶10, to suppress non-existent, purely hypothetical competition for two "Orphan Drugs," *id.* ¶¶33, 41.

The DOJ has warned that proving a merger "facilitates bundling" in an anticompetitive fashion requires "making guesses about the future conduct of the merged firm, its customers and its rivals that are beyond the capability of even the most prescient competition authority." *Portfolio Effects*, *supra*. The FTC here takes those guesses to an extreme, making suppositions "considerably closer to 'ephemeral possibilities' than to 'probabilities.'" *Marine Bancorp.*, 418 U.S. at 623.

III. ANY REMEDY SHOULD BE TAILORED TO PROHIBIT THE SUPPOSED POST-MERGER ANTICOMPETITIVE CONDUCT, NOT THE LIKELY PROCOMPETITIVE MERGER

The sheer implausibility of the bundling scheme alleged in the complaint is ample grounds for denying the FTC's requested relief. The mismatch between the structural relief the FTC seeks under Section 7 of the Clayton Act—blocking a merger—and its purely behavioral theory of harm should preclude it too. There is no basis in law or logic for the broad structural remedy of enjoining

the Amgen-Horizon merger to address theoretical and wholly isolable post-merger conduct. The FTC acknowledges that the bundling practices it speculates could be remedied by other means—*if* they ever happen. *See* Complaint ¶¶5, 64 (describing Sherman Act suit by Regeneron challenging Amgen "rebating strategy" for Repatha® as "anticompetitive").

Under Section 7, remedies must be "tailored to fit the wrong creating the occasion for the remedy." *United States v. Microsoft Corp*., 253 F.3d 34, 107 (D.C. Cir. 2001).[4] Where the government seeks the drastic remedy of "structural relief," the law requires a "'clear[ ] indication of a *significant causal connection*'" between the relief sought and the "'conduct'" by which the defendant is alleged to have "'creat[ed] . . . the market power.'" *Id.* at 106 (quoting 3 P. Areeda & H. Hovenkamp, *Antitrust Law* 91-92, ¶653(b) (1996)). "Absent such causation, the antitrust defendant's unlawful behavior should be remedied by 'an injunction against continuation of'" the allegedly wrongful conduct. *Id.* (quoting *Antitrust Law* 67, ¶650a). That makes economic sense. Courts should not block a merger, and deny consumers its procompetitive benefits, when a more targeted remedy would address competitive concerns. *Merger Remedies Manual*, *supra*, at 2.

The relief the FTC seeks here defies those principles. As explained above (at 8-9), the complaint does not allege that "the effect of" Amgen's "acquisition" of Horizon *itself* would be "substantially to lessen competition," or to "create a monopoly." 15 U.S.C. §18. Nor is there a "significant causal connection," *Microsoft*, 253 F.3d at 106, between the merger and the alleged anticompetitive conduct. While the merger might make the bundling scheme theoretically possible, it cannot *cause* the scheme to happen. For that matter, it is unclear whether or how Amgen's

[4] The Antitrust Division concurs: "Any remedy must be . . . related to the identified competitive harm. *Tailoring* the remedy to address the violation is the best way to ensure that the relief obtained cures the competitive harm." U.S. Dep't of Justice, Antitrust Div., *Merger Remedies Manual*, at 2 (Sept. 2020), https://www.justice.gov/atr/page/file/1312416/download (emphasis added).

merger with Horizon increases either firm's incentives to offer bundled rebates of this sort that are not already present with respect to their existing products. That further undermines any notion that the FTC's theory of harm is merger-specific.

An appropriately tailored remedy (if any were warranted) would be "'an injunction against'" the allegedly wrongful "'conduct.'" *Microsoft*, 253 F.3d at 106 (quoting *Antitrust Law* 67, ¶650a). The court could easily craft an injunction prohibiting Amgen from "provid[ing] cross-market bundles or bundled rebates" to PBMs on Amgen's products in exchange for "favorable formulary placement" for TEPEZZA® and KRYSTEXXA®. Complaint ¶4. Indeed, Amgen has already offered to enter into a "binding consent order" to that effect. Answer 2-3. Such a tailored remedy would also "preserve the efficiencies created by [the] merger," *Merger Remedies Manual*, *supra*, at 2, including giving patients increased access to Horizon's medicines for treating serious rare diseases. The FTC cannot justify the intrusive relief of blocking an otherwise likely procompetitive merger by refusing more targeted relief that would eliminate the risk of harm.

Nothing in the complaint suggests that such an injunction or consent decree would be inadequate to prevent any of the merger's supposed anticompetitive effects. Nor should the FTC be heard to complain about difficulties in monitoring compliance. For one thing, that is the FTC's job. *See* Fed. Trade Comm'n, *Health Care Competition*, https://www.ftc.gov/news-events/topics/competition-enforcement/health-care-competition. For another, if competitors to TEPEZZA® and KRYSTEXXA® ever enter the relevant markets, and if and when Amgen engaged in the prohibited conduct, those competitors would have every incentive to bring that violation to the FTC's attention, and to file antitrust suits of their own. *See* Complaint ¶64. There is no basis for the FTC to block what is likely a procompetitive conglomerate merger based on speculation about a post-merger bundling scheme that is singularly unlikely to arise, and could be forestalled in any case.

Dated: August 24, 2023

Respectfully submitted,

/s/ Megan Cunniff Church
Megan Cunniff Church
MOLOLAMKEN LLP
300 North LaSalle Street
Chicago, IL 60654
mchurch@mololamken.com
(312) 450-6700 (telephone)
(312) 450-6701 (fax)

Jeffrey A. Lamken (*pro hac vice* pending)
Michael G. Pattillo Jr. (*pro hac vice* pending)
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
(202) 556-2000 (telephone)
(202) 556-2001 (fax)

Mark W. Kelley (*pro hac vice* pending)
Alexandra C. Eynon (*pro hac vice* pending)
MOLOLAMKEN LLP
430 Park Avenue
New York, NY 10022
(212) 607-8160 (telephone)
(212) 607-8161 (fax)

Counsel for Amici Curiae

Appendix: List of *Amici Curiae*

Alden F. Abbott
Former General Counsel, Federal Trade Commission

Brian Albrecht
Chief Economist, International Center for Law & Economics

Donald J. Boudreaux
Professor of Economics, George Mason University

Daniel J. Gilman
Senior Scholar, International Center for Law & Economics
Former Attorney Advisor, Office of Policy Planning, Federal Trade Commission

Justin (Gus) Hurwitz
Senior Fellow, University of Pennsylvania Carey Law School
Director, Law & Economics Program, International Center for Law & Economics

Thomas A. Lambert
Wall Family Chair in Corporate Law and Governance, University of Missouri School of Law

Geoffrey A. Manne
President and Founder, International Center for Law & Economics
Distinguished Fellow, Northwestern University Center on Law, Business & Economics

Jeffrey T. Prince
Professor and Chair of Business Economics and Public Policy, and Harold A. Poling Chair of Strategic Management, Kelley School of Business, Indiana University

Paul H. Rubin
Samuel Candler Dobbs Professor of Economics Emeritus, Emory University Department of Economics and Law School
Former Chief Economist, U.S. Consumer Product Safety Commission
Former Director of Advertising Economics, Federal Trade Commission

Vernon L. Smith
George L. Argyros Endowed Chair in Finance and Economics, Chapman University Argyros School of Business and Economics
Nobel Laureate in Economics (2002)

Michael E. Sykuta
Associate Professor of Economics, University of Missouri Division of Applied Social Sciences