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 Judge John F. Kness Date: September 11, 2023 Time: 9:00 A.M. Courtroom: 2125

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Defendants Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") (together "Defendants") respectfully submit this memorandum in opposition to the motion submitted by the Federal Trade Commission (the "FTC") and the states of California, Illinois, Minnesota, New York, Washington and Wisconsin (the "States", collectively with the FTC, "Plaintiffs") for Preliminary Injunctive Relief.

INTRODUCTION

This case concerns the merger of two biopharmaceutical companies, Amgen and Horizon, that will result in substantial benefits for underserved patients in the United States and around the world who are suffering from serious rare diseases (the "Transaction"). Relying on a speculative theory at odds with fact and law, Plaintiffs seek a preliminary injunction to block the Transaction, further delaying and likely forever preventing patients from realizing the substantial benefits it promises. But Plaintiffs' case—premised on the contention that Amgen might one day offer bundled rebates on one or more of its products to somehow exclude potential competitors to either of two Horizon products—is far too removed from reality and unmoored from decades of legal precedent to warrant such extraordinary relief.

Plaintiffs bear a significant burden to justify a preliminary injunction against the Transaction. Contrary to Plaintiffs' claims, that burden cannot be met only upon "doubts," without evidence or an "extensive analysis of the antitrust issues." (Br. at 9.) Plaintiffs must show that there is a "reasonable probability" that the Transaction will substantially lessen competition, *F.T.C. v. Meta Platforms Inc.*, No. 22-cv-04325, 2023 WL 2346238, at *22 (N.D. Cal. Feb. 3, 2023), and that the harm that would flow from a preliminary injunction is outweighed by the harm to competition. *F.T.C. v. Microsoft Corp.*, No. 23-cv-02880, 2023 WL 4443412, at *21-22 (N.D. Cal. July 10, 2023). These are rigorous standards.

Plaintiffs come nowhere close to meeting their burden to show a likelihood of success. Their case defies logic and precedent in a number of ways. Unlike every other pharmaceutical merger challenge before this one, it is not based on horizontal concerns. And unlike every other non-horizontal merger case for more than 40 years, it is not based on vertical concerns. Instead, Plaintiffs' case hinges on a theory *never before adopted* by a court: that *potential* future rivals to two Horizon products—TEPEZZA®, the only FDA-approved treatment for thyroid eye disease ("TED"), and KRYSTEXXA®, the only FDA-approved treatment for chronic refractory gout ("CRG")—may *potentially* be disadvantaged at an unspecified time in the future as a result of Amgen *potentially* offering payors a form of bundled rebates (*i.e.*, lower prices) that has never been used before (and likely is impossible to implement). No court has ever blocked a merger based on allegations that the merged firm might lower prices. And for good reason—lowering prices, including through bundled discounts—benefits consumers.

But even if that hypothesized bundling were viable in theory, Plaintiffs' case ignores an inescapable truth about this Transaction—***Amgen is not going to bundle any of its products, for any reason or at any time, with TEPEZZA® or KRYSTEXXA®***. There are numerous, independent reasons why bundling of the sort alleged by Plaintiffs is implausible.

First, Amgen has committed—including to the FTC prior to the filing of this suit, in its answer and in the sworn testimony of its executives—not to bundle TEPEZZA® or KRYSTEXXA®. Bundling is not part of the rationale or planning for the Transaction, and none of Amgen's millions of pages of documents produced in this matter suggest it would do so or has considered doing so. (*Infra* II.A.2.a.)

Second, Plaintiffs' case relies on speculative projections about potential competitors to TEPEZZA® and KRYSTEXXA® that may launch at some point in the future, or that may *never* launch, for reasons unrelated to the Transaction. In cases involving potential competitors, courts

demand a high standard of proof so as not to forestall mergers based on ephemeral possibilities of harm. Here, there is no basis to conclude that any theoretical rival will enter in the near term (if one ever enters); nor is there any reason to predict that such a rival would be harmed by the Transaction. Indeed, *not one* of the identified potential future entrants has expressed concern about the Transaction and none will show up at the evidentiary hearing. (*Infra* II.A.2.b.)

Third, there are several obstacles that would make Plaintiffs' theorized bundling extremely difficult (if not impossible) for Amgen. The Amgen products that Plaintiffs allege would be included in a bundle are patient-administered and covered under *pharmacy benefit* plans supervised by pharmacy benefit managers ("PBMs"), whereas TEPEZZA® and KRYSTEXXA® are intravenous infusions administered by healthcare providers and primarily covered under *medical benefit* plans managed by insurance payors. These are vastly different reimbursement mechanisms, with meaningful substantive differences in the biopharmaceutical industry. As a result, bundling unrelated products in contracts across pharmacy and medical benefits (*i.e.*, "cross-benefit bundling") has *never* been done by Amgen—or, as best anyone can tell, by anyone in the way Plaintiffs hypothesize—and party witnesses and [redacted] have testified it cannot feasibly be done due to differences in how pharmacy benefit and medical benefit drugs are covered, paid for and administered. Moreover, it is unclear whether a cross-benefit bundled rebate would fall within the regulatory "safe harbor" for discounts under federal anti-kickback law, creating another disincentive to engaging in such agreements. (*Infra* II.A.2.c.)

Fourth, due to regulations relating to medical benefit drug reimbursement, the type of cross-benefit bundling that Plaintiffs hypothesize would likely create a sharp downward spiral in TEPEZZA®'s and KRYSTEXXA®'s prices, eventually rendering them unprofitable and destroying the rationale for the Transaction. (*Infra* II.A.2.d.)

Fifth, rare disease medicines are ill-suited to bundling (whether cross-benefit or not) since providers choose therapies for patients suffering from debilitating rare diseases on the basis of medical considerations, and providers and patients would strongly and effectively resist any attempts to foreclose access to clinically efficacious therapies. Payors would not attempt to foreclose access to a safe, clinically efficacious new TED or CRG therapy, as doing so would risk significant consequences to their patient and provider relationships. (*Infra* II.A.2.e.)

Simply put, there is no evidence to support Plaintiffs' speculative theory that Amgen would engage in novel cross-benefit bundling to compete with products that may never come to market. Yet even if Plaintiffs were somehow able to show that some amount of such bundling were likely, that would not be enough. Among other things, Plaintiffs would still have to show that the alleged bundling—a type of price competition that is typically procompetitive—would probably harm competition. Plaintiffs cannot carry that burden either for many reasons, including because they cannot show that the alleged bundling would substantially foreclose rivals; that any alleged Amgen "donor" product has the market power required to implement an anticompetitive bundle; or that Amgen has ever entered an anticompetitive bundled contract in the past. Perhaps that is why, as the evidence indicates, no third party shares Plaintiffs' alleged concerns—not any PBMs, payors, sophisticated investors, or the potential future rivals themselves. And even setting all that aside, the flawed economic model of Plaintiffs' own expert shows that Horizon, without the Transaction, would have the same ability and incentive to act as Plaintiffs allege the combined firm would. (*Infra* II.A.3.)

On the other side of the ledger, the Transaction will produce concrete and immediate benefits for patients. TEPEZZA® and KRYSTEXXA® deliver enormous clinical value to patients: in the case of KRYSTEXXA®, the alternative may be debilitating long-term pain and/or amputation; and in the case of TEPEZZA®, the alternative may be invasive orbital surgery and/or

long term vision damage. Undisputed evidence will show that the Transaction will greatly expand patient access to Horizon therapies in the United States and globally, create research and development ("R&D") benefits that will increase the likelihood of new and better products getting to patients, and generate large cost efficiencies. Those real world benefits substantially outweigh the speculative and unsupported harms alleged by Plaintiffs and offer yet another reason to deny an injunction. (*Infra* II.B.)

In addition, Plaintiffs cannot meet their burden to show they are likely to succeed on the merits in the ongoing administrative proceeding because that process violates the Constitution many times over. Given the other flaws in Plaintiffs' case, the Court need not reach its constitutional shortcomings. But they represent alternative grounds for denying Plaintiffs' motion should the need arise. (*Infra* II.C.)

Finally, while the Court need not address the equities given the weaknesses in Plaintiffs' merits case, the balance of the equities strongly favor denying the requested injunction. If a preliminary injunction is granted, patients (now and in the future) will be denied the many benefits of the merger, even though an injunction blocking the Transaction is completely unnecessary to address Plaintiffs' speculative concerns of future bundling. (*Infra* at III.)

At bottom, Plaintiffs' case is legally unsound and far too speculative to show a likelihood of success on the merits; it also runs counter to the equities, and cannot justify scuttling a transaction that promises significant patient benefits. Plaintiffs' motion should be denied.

BACKGROUND[1]

A. Amgen, Horizon and the Transaction

Amgen was founded in 1980 in Thousand Oaks, California. Its mission is to discover, develop and deliver first-in-class and best-in-class medicines to patients suffering from serious illnesses around the world. Amgen focuses on therapeutic areas such as cancer, cardiovascular disease, osteoporosis, asthma and rheumatoid arthritis.

Horizon was founded in 2008. The company's mission is to deliver medicines for rare, autoimmune and severe inflammatory diseases and provide compassionate support. Horizon markets TEPEZZA® and KRYSTEXXA®, which treat TED and CRG, respectively, two debilitating rare diseases. As an independent business, Horizon does not have the resources to manufacture and distribute its medicines to all the patients around the world who need them.

On December 12, 2022, Amgen and Horizon announced that they had reached agreement on the terms of a cash offer for Horizon. (Ex. 22, PX5005.)

B. The Case and the Administrative Proceeding

Despite the benefits of the Transaction, the FTC has sought to block it based on hypothetical concerns that the combined company might try to disadvantage future competitors through bundled rebates with payors and PBMs that include both (i) one or more Amgen pharmacy benefit drugs and (ii) either TEPEZZA® or KRYSTEXXA®, both primarily medical benefit drugs. Although Amgen has never entered into such a cross-benefit bundle, and despite already marketing several medical benefit products and several pharmacy benefit products, the

[1] Citations herein to expert reports and declarations are given as "[Expert Surname] ¶ __". Citations herein to depositions are given as "[Witness Surname] Dep. ___:___]". The exhibits cited herein are appended to the Declaration of David Marriott and are cited as "Ex. __".

FTC has hypothesized that it might do so if a rival to TEPEZZA® or KRYSTEXXA® were to enter the market years in the future.

Because Amgen believes that the FTC's concerns are misplaced, it committed to the FTC and publicly that it would not bundle its products with TEPEZZA® or KRYSTEXXA®. Despite that, on May 16, 2023, the FTC filed its complaint (Dkt. 1), and the parties subsequently stipulated that Defendants will not consummate the Transaction until the earlier of October 31, 2023, or two business days following the Court's ruling on Plaintiffs' motion.[2] (Dkt. 60.)

On June 22, 2023, an Amended Complaint was filed, adding the states of California, Illinois, Minnesota, New York, Washington and Wisconsin.[3] (Dkt. 77.) The Amended Complaint asserts a single claim for relief under Section 7 of the Clayton Act, raising the same allegations as the FTC's initial complaint. (Dkt. 65 ¶¶ 1, 21, 91.)

On June 22, 2023, the FTC instituted an administrative proceeding against Defendants before an FTC administrative law judge ("ALJ"). By that proceeding, the FTC seeks to permanently prevent Amgen and Horizon from completing the Transaction.

On June 29, 2023, Defendants asserted counterclaims against the FTC alleging that the FTC's administrative process runs afoul of the U.S. Constitution. (Dkt. 77.) Defendants moved for summary judgment on these counterclaims on August 21, 2023. (Dkt. 125.)

[2] Many foreign antitrust authorities have reviewed the Transaction. Tellingly, none have raised concerns.

[3] None of these states conducted an independent investigation of the Transaction and each joined the complaint solely based on the FTC's allegations, not based on any underlying documents or information.

ARGUMENT

I. PLAINTIFFS BEAR A SIGNIFICANT BURDEN TO JUSTIFY A PRELIMINARY INJUNCTION AGAINST THE TRANSACTION.

Plaintiffs suggest that the Court may preliminarily enjoin the Transaction on the slightest of showings. They assert that merely raising "substantial *doubts* about a transaction" unsupported by any "detailed evidence of anticompetitive effect" and without any "extensive analysis of the antitrust issues" is enough to meet their burden and justify this Court issuing a preliminary injunction. (Br. at 2-3, 9.) Plaintiffs even suggest that the Court may effectively kill the Transaction based on the mere *possibility* that it may have anticompetitive effect at some unspecified point in the future if a number of speculative events ever come to pass.

That is wrong. "[T]he issuance of a preliminary injunction prior to a full trial on the merits is an extraordinary and drastic remedy" because "the issuance of a preliminary injunction blocking an acquisition or merger may prevent the transaction from ever being consummated." *Microsoft*, 2023 WL 4443412, at *8 (citation omitted). Given the grave consequences of issuing a preliminary injunction, courts "demand[] rigorous proof to block a proposed merger" under Section 13(b). *F.T.C. v. Sysco Corp.*, 113 F. Supp. 3d 1, 23 (D.D.C. 2015); *see also F.T.C. v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 86 (N.D. Ill. 1981) ("In light of the severe adverse consequences of a preliminary injunction, the FTC has a substantial burden under Section 13(b)."). Applying that standard, "antitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future." *F.T.C. v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116-17 (D.D.C. 2004).

Plaintiffs assert a single claim for relief under Section 7 of the Clayton Act. To establish a claim under Section 7, Plaintiffs must prove that the Transaction "may lessen competition substantially or tend to create a monopoly." *F.T.C. v. Elders Grain, Inc.*, 868 F.2d 901, 902 (7th

Cir. 1989); *Arch Coal, Inc.*, 329 F. Supp. 2d at 115 (denying relief after concluding the FTC and States failed "to show a likelihood that the challenged transactions will substantially lessen competition."). To meet their "substantial burden" to obtain a preliminary injunction on their claim, Plaintiffs "must prove a 'likelihood of ultimate success'" and "must show that 'the equities' favor enjoining the transaction." *Great Lakes Chem. Corp.*, 528 F. Supp. at 86 (citations omitted). Proving a likelihood of success on the merits requires "more than mere questions or speculations," *F.T.C. v. Meta Platforms Inc.*, No. 22-cv-04325, 2023 WL 2346238, at *8 (N.D. Cal. Feb. 3, 2023), and "ephemeral possibilities" are not enough, *Arch Coal*, 329 F. Supp. 2d at 115 (citation omitted). Plaintiffs must prove "there is a 'reasonable probability' that the challenged transaction will substantially impair competition." *F.T.C. v. Staples, Inc.*, 970 F. Supp. 1066, 1072 (D.D.C. 1997) (quoting *F.T.C. v. Univ. Health*, 938 F.2d 1206, 1218 (11th Cir. 1991)); *see also Tenet Health Care Corp.*, 186 F.3d at 1051 ("A showing of a fair or tenable chance of success on the merits will not suffice . . . .") (citation omitted).[4] A court may not "simply rubber-stamp an injunction whenever the FTC provides some threshold evidence; it must 'exercise independent judgment'" and "evaluate the FTC's chance of success on the basis of all the evidence before it . . . ." *F.T.C. v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1035 (D.C. Cir. 2008) (citation omitted).

[4] In this Circuit, ultimate likelihood of success on the merits contemplates "a full administrative proceeding before the FTC, followed by judicial review . . . in one of the courts of appeals." *Elders Grain, Inc.*, 868 F.2d at 903. Because an ALJ's decision is subject to *de novo* review by the Commission, and the Commission's final order is in turn subject to judicial review by the Court of Appeals, a "favorable initial decision does not necessarily assure the FTC of ultimate success." *F.T.C. v. Simeon Mgmt. Corp.*, 532 F.2d 708, 713 (9th Cir. 1976) (affirming the denial of a preliminary injunction in a Section 13(b) proceeding involving allegations of false advertising).

Further, a Section 7 violation must be predicated on substantial harm to *competition*; harm to a *competitor* alone does not suffice. *E.g.*, *Microsoft*, 2023 WL 4443412, at *13 ("The FTC also appears to contend it need only show the combined firm would have a greater ability and incentive to foreclose *Call of Duty* from its rivals than an independent Activision. . . . This assertion, however, ignores the text of Section 7 which forbids mergers which may 'substantially . . . lessen competition.'").

When a case involves the question of whether a potential rival might enter a market, "the 'reasonable probability' standard" requires the FTC to prove "a likelihood noticeably greater than fifty percent". *Meta Platforms*, 2023 WL 2346238, at *22. Moreover, such entry must be "imminent." *United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 623 n.22 (citation omitted); *BOC Int'l., Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977) (entry in "near future"); *F.T.C. v. Steris Corp.*, 133 F. Supp. 3d 962, 978 (N.D. Ohio 2015) ("[T]o obtain injunctive relief, the FTC has to show a likelihood of proving at trial that" the rival "probably would have entered [the market] . . . within a reasonable period of time.").

To show that the balance of the equities favors granting a preliminary injunction, Plaintiffs must prove that "the harm to the parties and to the public that would flow from a preliminary injunction is outweighed by the harm to competition, if any, that would occur in the period between denial of a preliminary injunction and the final adjudication of the merits of the Section 7 claim." *F.T.C.* v. *Lab'y Corp. of Am.*, No. SACV 10-1873 AG, 2011 WL 3100372, at *21 (C.D. Cal. Feb. 22, 2011) (quotation omitted)). Courts evaluate both public and private equities when considering a claim under Section 13(b). *F.T.C. v. Freeman Hosp.*, 69 F.3d 260, 272 (8th Cir. 1995) (citing *F.T.C. v. Nat'l Tea Co.*, 603 F.2d 694, 697 (8th Cir. 1979)).

Plaintiffs cannot meet the demanding standards for a preliminary injunction here.

II. PLAINTIFFS CANNOT SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS.

Plaintiffs' case founders at the first step of the inquiry. They cannot show a likelihood of success on the merits of their claim. *First*, they cannot show that the Transaction is likely to have anticompetitive effect. (*Infra* II.A.) *Second*, even if Plaintiffs could show a likely anticompetitive effect from the Transaction, it would easily be offset by the benefits of the Transaction. (*Infra* II.B.) *Third*, the administrative proceedings in support of which Plaintiffs seek an injunction violate the Constitution.[5] (*Infra* II.C.)

A. Plaintiffs Cannot Show That the Transaction is Likely to Have Anticompetitive Effect.

Plaintiffs come nowhere close to meeting their burden for three reasons. *First*, Plaintiffs' case is predicated on mistaken legal standards. (*Infra* II.A.1.) *Second*, Plaintiffs' case is improperly based on a speculative theory that runs counter to the overwhelming weight of the real world evidence. (*Infra* II.A.2.) *Third*, even if the alleged bundling were to occur, Plaintiffs present no evidence that it would result in anticompetitive effects. (*Infra* II.A.3.)

1. Plaintiffs' case is predicated on mistaken legal standards.

Plaintiffs ask this Court to condemn the Transaction based on a non-horizontal, non-vertical, "future bundling" theory that has never been adopted by any court. Because the alleged harm that would result from the Transaction is not horizontal, Plaintiffs "cannot use a short cut to

[5] To succeed on their claim, Plaintiffs must show the Transaction may substantially lessen competition in properly defined relevant markets. 15 U.S.C. § 18. Plaintiffs allege two relevant product markets: "(1) for Tepezza, the sale of FDA approved drugs to treat TED ('TED market'), and (2) for Krystexxa, the sale of FDA-approved drugs to treat CRG ('CRG market')." (Br. at 11.) While Defendants do not believe Plaintiffs have made a sufficient showing to support Plaintiffs' alleged market definitions, Defendants assume only for purposes of this memorandum that Plaintiffs have met their burden to define the relevant markets because Plaintiffs' motion fails for myriad other reasons as discussed herein.

establish a presumption of anticompetitive effect". *Microsoft*, 2023 WL 4443412, at *8 (quoting *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019)).[6]

To meet their burden, Plaintiffs must make a "fact-specific" showing that the Transaction is likely to imminently and substantially lessen competition in the alleged relevant markets. *Id.* Plaintiffs argue they can meet their burden in this non-horizontal, non-vertical case under either of two supposedly "related, but distinct" "frameworks" (Br. at 9), an "ability-and/or-incentive" framework and an "entrenchment" framework. Neither standard reflects the law.

Plaintiffs' "ability and/or incentive" framework is not the law. Citing the FTC's own April 2023 administrative decision in *Illumina*, Plaintiffs argue that they need only show that the Transaction is "likely to increase the ability and/or incentive of the merged firm to weaken its rivals." (Br. at 17 (citing *In re Illumina, Inc.*, No. 9401, 2023 WL 2823393, at *41 (F.T.C. Mar. 31, 2023)). That framework has *never* been endorsed by any court, and it has been squarely rejected twice in the last two years—first by the FTC's own ALJ in *Illumina* (a decision the Commissioners who voted to bring the case later overturned)[7], *In re Illumina, Inc.*, No. 9401, Initial Decision (F.T.C. Sept. 9, 2022); and most recently by the federal district court that just last month rejected the FTC's challenge to Microsoft's vertical acquisition of Activision.

In *Microsoft*, the FTC pushed for the same "ability and/or incentive" framework it claims applies here, also citing the Commission's *Illumina* administrative decision. The court categorically rejected the FTC's framework, holding that the *Illumina* decision overturning the

[6] In horizontal merger cases, "the Government's path to carrying its prima facie burden is clear: by putting forward statistics to show that the proposed merger would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market, the Government triggers a presumption that the merger will substantially lessen competition." *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 192 (D.D.C. 2018).

[7] The Commission's *Illumina* decision reversing the ALJ's ruling in favor of the merging parties is pending appeal before the United States Court of Appeals for the Fifth Circuit.

ALJ's ruling "provides no authority for [that standard], nor could it" since "[u]nder Section 7, the government must show a 'reasonable *probability* of anticompetitive effect.'" *Microsoft*, 2023 WL 4443412, at *12 (citing *F.T.C. v. Warner Comm'ns. Inc.*, 742 F.2d 1156, 1160 (9th Cir. 1984)). The *Microsoft* court went on to identify two fundamental errors with the FTC's framework. First, the court held that the "and/or" standard is wrong because the FTC must establish that the merged firm will have *both* an incentive *and* an ability to foreclose rivals, reasoning: "[i]f there is no incentive to foreclose, then there is no probability of foreclosure and the alleged concomitant anticompetitive effect," and "[l]ikewise, if there is no ability, then a party's incentive to foreclose is irrelevant." *Id.* Second, the court held that, even if the FTC could show that the merger created "a greater ability and incentive to foreclose" a rival, that would not be enough to meet the FTC's burden, explaining:

> It is not enough that a merger might lessen competition—the FTC must show the merger will probably *substantially* lessen competition. That the combined firm has more of an incentive than an independent Activision says nothing about whether the combination will "substantially" lessen competition. Thus, to establish a likelihood of success on its ability and incentive foreclosure theory, the FTC must show the combined firm (1) has the ability to withhold Call of Duty, (2) has the incentive to withhold Call of Duty from its rivals, and (3) competition would probably be substantially lessened as a result of the withholding. *Id*. at *13 (citation omitted).

Plaintiffs' burden is no lower here. At a minimum, Plaintiffs must show not only that the Transaction would give Amgen an ability and incentive to foreclose any alleged (future) rival using the hypothesized bundling conduct, but also must show a reasonable probability that such foreclosure may substantially lessen competition. Plaintiffs cannot make that showing.

Plaintiffs' "entrenchment" framework is not the law. Attempting further to lighten its burden, the FTC argues in the alternative that it can prevail if it shows that the Transaction "will entrench or extend the dominant position of the acquisition target by increasing entry barriers or switching costs, dissuading rivals from competing aggressively, or eliminating a nascent

competitive threat." (Br. at 9.) A variation on this theme was used more than 55 years ago in *F.T.C. v. Procter & Gamble Co.*, 386 U.S. 568 (1967), but the framework has not been applied by any court in decades. And in recent years even the FTC and DOJ have recognized that "[t]his approach ***is no longer viewed as valid under U.S. law or economic theory***." Conglomerate Effects of Mergers – Note by the United States, OECD, at 4 (June 10, 2020) (emphasis added).[8] The FTC's attempt to pursue a theory it has admitted is invalid should be rejected.[9]

In any event, the FTC's supposedly "distinct" entrenchment theory is really a repackaging of the same "incentive/ability" theory. Both are predicated on the hypothesis that Amgen would bundle its existing products to foreclose competition to KRYSTEXXA® and TEPEZZA®, if and when it emerges. (Br. at 27 ("The Proposed Merger will entrench monopoly positions in Tepezza and Krystexxa because the merged firm will have the ability to prevent entry by leveraging Amgen's portfolio to secure preferential formulary placement").) In

[8] Entrenchment theory was rooted in the Warren Court's concern that "the substitution of the powerful acquiring firm for the smaller, but already dominant, firm may substantially reduce the competitive structure of the industry by raising entry barriers and by dissuading the smaller firms from aggressively competing." *Procter & Gamble Co.*, 386 U.S. at 578. Although the Supreme Court has not revisited entrenchment theory since *Procter & Gamble*, its subsequent decisions confirm that antitrust law does not protect competitors from vigorous competition. *See, e.g., Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself . . . ."); *Monfort of Col., Inc. v. Cargill, Inc.*, 479 U.S. 104 (1986) ("[C]ompetition for increased market share is not actively forbidden by the antitrust laws. It is simply vigorous competition. To hold that the antitrust laws protect competitors from the loss of profits due to such price competition would, in effect, render illegal any decision by a firm to cut prices in order to increase market share. The antitrust laws require no such perverse result . . . .").

[9] Moreover, even decades ago when the FTC considered cases under an "entrenchment" framework, the FTC took the position that "the existence of possible [contractual] leverage should be a ground for barring a merger only when the evidence shows that it will probably produce significant adverse competitive effects," because "any full line forcing or tying produced by the leverage could most likely be later challenged under Section 3 of the Clayton Act or Section 1 of the Sherman Act," and thus "the anticompetitive effects that could only be eliminated by prohibiting the merger will often be both insignificant and remote." *Heublein, Inc.*, 96 F.T.C. 385 (1980). As shown below, therefore, although "entrenchment" theory is not the law, even under it, Plaintiffs' claim fails.

Microsoft, the court rejected a similar attempt by the FTC to advance an "alternative" theory that as a factual matter did "not make any new arguments." 2023 WL 4443412, at *21.

Plaintiffs must show a noticeably greater than 50 percent chance of substantial harm. In cases such as this, where the alleged "harm to competition . . . is not the loss of *present* competition but rather the loss of a *future* competitor", courts have held the FTC to a stricter burden of proof due to "the many *a priori* inferences required" with such a theory and to avoid "stray[ing] too close to the specters of ephemeral possibilities". *Meta Platforms*, 2023 WL 2346238, at *22. *Meta* is the most recent case to address the "potential competition" theory, and following the Fifth Circuit, the court required the FTC to prove the harm it alleges had a "reasonable probability" of coming to pass, meaning "a likelihood noticeably greater than fifty percent".[10] *Id.* Plaintiffs' claim combines an unprecedented bundling theory with a heightened burden of proof, making it doubly difficult for Plaintiffs to obtain a preliminary injunction here.

2. Plaintiffs' allegations regarding cross-benefit bundling are speculative and at odds with the overwhelming weight of the evidence.

Plaintiffs cannot come close to meeting their burden of proving that the Transaction is likely to have an anticompetitive effect. Their theory of harm is hopelessly speculative and completely at odds with an overwhelming amount of evidence that shows: (i) the Transaction has nothing to do with bundling, as Amgen has no plans to bundle its products with TEPEZZA® or KRYSTEXXA® and has in fact committed not to do so; (ii) it is speculative whether any

[10] Notably, the FTC has lost every potential competition case that it has brought under Section 13(b) in the last 50 years. *Meta Platforms*, 2023 WL 2346238, at *22; *F.T.C. v. Tenneco, Inc.*, 433 F. Supp. 105 (D.D.C. 1977); *F.T.C. v. Atl. Richfield Co.*, 549 F.2d 289 (4th Cir. 1977); *Steris Corp.*, 133 F. Supp. 3d 962. While these cases address allegations of lost future competition from one of the merging parties, the standard should apply equally where the alleged loss of future competition is from a third-party potential future competitor. The standard is especially apt here, since Plaintiffs' theory requires an even greater number of *a priori* inferences than a case where the alleged entrant is a merging party. Here, even if one of the alleged potential entrants successfully enters, many more events would have to happen, all of them highly speculative at best, for Plaintiffs' theory of harm to ever come to pass. (*See infra* II.A.2.b.)

potential future competitor will obtain the required approval to enter in the foreseeable future (Sensabaugh ¶¶ 78, 143); (iii) the structure of the industry impedes cross-benefit bundling and will continue to do so for the foreseeable future; (iv) even if it were possible to cross-benefit bundle, Amgen would have no financial incentive to do so (and every incentive not to) because such bundles would lead to a ruinous downward spiral in the price of the bundled Horizon product; and (v) rare disease medicines, like TEPEZZA® and KRYSTEXXA®, typically do not compete based on rebates (bundled or otherwise), and nothing about the Transaction would change that. In sum, Plaintiffs fall far short of proving there is a "noticeably greater than fifty percent" probability that the Transaction will result in an anticompetitive effect.

a. The Transaction is not premised on future bundling and Amgen has committed not to bundle TEPEZZA® and KRYSTEXXA®.

The rationale for the Transaction has been extensively documented in Amgen's normal course transaction modeling and analyses. In the enormous record in this case, not a single document suggests Amgen has ever had any plan to bundle its products with TEPEZZA® or KRYSTEXXA®. Nor is there any hint whatsoever in the record that bundling was part of the strategic rationale for the deal. The contemporaneous documents instead consistently show that [redacted]; *infra* II.B.) That is true across all of Amgen's modeling and analyses of the Transaction, including in scenarios where [redacted] In those scenarios [redacted]

[redacted]

Amgen's witnesses likewise have consistently testified, and will testify under oath at the evidentiary hearing, that there is no plan to bundle Amgen products with TEPEZZA® and KRYSTEXXA®. (*See, e.g.*, Ex. 9, Niksefat Dep. 353:20-23; Ex. 10, Bradway Dep. 33:1-23, 41:5-21, 42:10-18.) Ordinary course documents and sworn testimony tell a consistent story—bundling is simply not part of the rationale for this deal, in any way, shape or form.

The total lack of documentation supporting Plaintiffs' theory alone demonstrates its implausibility. *Cf. Microsoft*, 2023 WL 4443412, at *14 (noting "there are no internal documents, emails, or chats contradicting Microsoft's stated intent not to make *Call of Duty* exclusive to Xbox consoles. . . . [d]espite the completion of extensive discovery in the FTC administrative proceeding, including production of nearly 1 million documents and 30 depositions"). As Plaintiffs tell it, Amgen spent $28 billion to buy Horizon and somehow did not create a single document describing its supposed "real" plan to bundle its products with Horizon's. It is implausible that an acquiror in Amgen's position would not reduce to writing such a strategy if it was at all contemplated, especially given that there is nothing inherently wrong or anticompetitive with bundling, and the government has not, to Defendants' knowledge, ever before challenged a merger on the basis of bundling.

Given that Amgen has no plans to bundle TEPEZZA® or KRYSTEXXA®, it has repeatedly committed not to do so, including directly to the Chair of the FTC before the filing of the Complaint, in Defendants' Answers to the Complaint and the Amended Complaint, and in this filing. Amgen's Chairman and CEO re-affirmed that commitment in his deposition: "we won't bundle [TEPEZZA® or KRYSTEXXA®] full stop that means we won't." (Ex. 10,

Bradway Dep. 240:19-22.) Amgen has even offered to formalize that commitment in a binding consent order, a copy of which is attached hereto, and stands ready to do so. (Ex. 21.)

Plaintiffs insist that only blocking the Transaction will suffice to address the alleged concerns. (Br. at 33-34.) But the law does not allow Plaintiffs to ignore Amgen's commitment, even if Plaintiffs would prefer to do so. Companies have used similar remedies in the past to alleviate government concerns, and a remedy of this kind can be just as effective as a structural remedy if designed appropriately, which is exactly what Amgen is offering here: a remedy that is straightforward and can be effectively monitored and enforced. *See, e.g.*, *Microsoft*, 2023 WL 4443412, at *14 ("The public commitment to keep *Call of Duty* multiplatform, and the absence of any documents contradicting those words, strongly suggests the combined firm probably will not withhold *Call of Duty* from PlayStation."); (Orszag ¶ 12 n.8). If a remedy of any kind were appropriate, a behavioral remedy is particularly apt here since Plaintiffs' allegations are focused on an alleged behavioral concern (future bundling), not a change in market structure.

Other than expressing a general preference for blocking allegedly problematic mergers, the only specific concern Plaintiffs have raised to Defendants' proposed remedy is an implausible one—specifically, that Amgen could somehow enter into secret "handshake" bundled agreements with payors and PBMs to circumvent its commitment. (Kesselheim ¶¶ 229-31.) But Plaintiffs have pointed to no evidence suggesting that Amgen, a large public company, engages in "handshake" agreements, or that this practice occurs in the market more broadly, and Amgen does not in fact do so—it enters only written contracts. Further, Plaintiffs do not even attempt to explain (nor could they plausibly) why Amgen or its PBM or payor customers would accept the risk of not reducing to writing the terms of a rebate worth tens or hundreds of millions of dollars. [redacted]

[redacted].[11] Moreover, even if Amgen and its customers tried to circumvent Amgen's commitment through never-before-done handshake bundling, it would not go undetected because it would be impossible for a payor or PBM to secretly exclude the hypothetical CRG or TED competitor from its formulary.

Plaintiffs were required to address and consider the concrete offer made by Amgen in meeting their burden for injunctive relief. Instead, they rely on pie-in-the-sky "assumptions and simplifications that are not supported by real-world" facts, *Am. Booksellers Ass'n v. Barnes & Noble, Inc.*, 135 F. Supp. 2d 1031, 1041 (N.D. Cal. 2001), and that ignore economic reality, *Craftsmen Limousine, Inc. v. Ford Motor Co.*, 363 F.3d 761, 777 (8th Cir. 2004). This is yet another reason why Plaintiffs' motion should be denied.

b. Plaintiffs provide nothing more than speculation about the likelihood, timing and impact of competitor entry.

Plaintiffs admit that there are no rivals to TEPEZZA® or KRYSTEXXA® and that their theory is based on theoretical harm to potential future competitors for these products. (Br. at 7, 25.) As an initial step in any analysis of Plaintiffs' allegations, the Court must find that one or more rivals of TEPEZZA® or KRYSTEXXA® not only have a greater than 50 percent chance of making it to market, *Meta Platforms*, 2023 WL 2346238, at *22, but also that they would do so in the near future and compete with Horizon's products in a way that would give rise to Amgen's purported incentive to engage in cross-benefit bundling. Plaintiffs cannot do so. They identify four companies that are allegedly developing potential future treatments for TED (Viridian, Acelyrin, Sling and Immunovant) and one that is allegedly developing a potential future CRG

[11] [redacted]

treatment (SelectaBio/Sobi). The evidence makes clear, however, that the likelihood of imminent entry from any of these potential competitors is highly uncertain.[12]

Plaintiffs principally focus on the ongoing efforts of Viridian. Viridian's pipeline product "[redacted] (Sensabaugh ¶¶ 137-38.) [redacted][13] (*Id.* ¶¶ 126-27.)

[12] In other contexts, the FTC has argued that entry of a potential competitor is too remote and speculative to be counted absent evidence that the entry would be "timely"—meaning "within two years"—and "likely." *F.T.C. v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 55 (D.D.C. 1998). The potential future rivals that the FTC says the Court must credit as likely entrants do not come close to meeting the FTC's own standard for non-speculative entry.

[13] Less than two weeks ago, Viridian disclosed that it "may be several years, if ever, before [it] complete[s] pivotal clinical trials or ha[s] a product candidate approved for commercialization" and that it does "not anticipate generating revenue from product sales for the foreseeable future." (Ex. 26, Viridian Therapeutics, Inc. 10-Q (Aug. 8, 2023).)

[redacted] (*Id.* ¶¶ 131-32.) [redacted] (*Id.* ¶¶ 110, 117-18.) [redacted] (*Id.* ¶¶ 145-46, 148.).

Plaintiffs' experts do not tell a different story; nor do the declarations Plaintiffs obtained from a few doctors. [redacted] The optimism of Plaintiffs' experts, who act as principal investigators for Viridian and Selecta Biosciences, and declarants is not a substitute for actual evidence of likely and imminent entry.

Another problem for Plaintiffs' entry theory is that Plaintiffs themselves characterize all of the products in development as significantly differentiated from Horizon's products in a number of ways. [redacted] *see also* Sensabaugh ¶¶ 102, 124-25, 128, 134, 155.) Payors are unable to exclude differentiated products from a medical benefit formulary (Gan ¶ 141), and Plaintiffs have not identified a single instance in which this has happened. This is particularly true for rare diseases. Because of that differentiation, it is unlikely that Amgen could block a competitor's entry through bundled rebates. (*Infra* II.A.2.e.)

Finally, it is highly revealing that, despite having plenty of opportunity to do so, [redacted] If it were true that these companies would likely soon enter and the Transaction posed a significant

threat to their ability to enter the market, nullifying the investment they put into developing their products, it is inconceivable that [redacted] because the Transaction will not harm them, or consumers. Plaintiffs have not deposed any of these theoretical rivals, and none will testify at the evidentiary hearing to support Plaintiffs' case. The lack of any evidence of concern from these companies—whom Plaintiffs allege will be harmed, but who as market participants are much better situated to assess market-based risk—speaks volumes.

c. The market structure impedes cross-benefit bundling.

Even if a potential TED or CRG competitor successfully launched, the evidence shows that the Plaintiffs' hypothesized cross-benefit bundling of Amgen products with TEPEZZA® or KRYSTEXXA® will not happen, including because there are a number of barriers—logistical, regulatory and economic—to bundling a pharmacy benefit drug with a medical benefit drug.

Plaintiffs suggest bundling is common in the pharmaceutical space and that Amgen is a prevalent bundler, and then make the illogical leap to the conclusion that cross-benefit bundling can be done. As an initial point, the evidence will show that bundling generally is not widely used in the pharmaceutical industry, and Amgen does not have many bundled contracts. As of April 2023, Amgen had only [redacted] (none of which is cross-benefit). (Gan tbl. 4; Ex. 8, Gordon Dep. 40:3-20.) And as discussed below, there are no Amgen bundles that Plaintiffs have even alleged are anticompetitive (and the evidence shows that none is). (*Infra* II.A.3.)

But as uncommon as bundling is in the pharmaceutical industry, cross-benefit bundling as theorized by the Plaintiffs is simply unheard of. Multiple industry participants testified that [redacted]

[redacted] Plaintiffs have presented no instances of a cross-benefit bundle, with one possible (unconfirmed) exception involving [redacted] However, this alleged bundle by all accounts was a unique situation born out of nonreplicable circumstances.[14] Even if this alleged unicorn bundle existed, it does not show that cross-benefit bundling is feasible, let alone likely, today or in the foreseeable future, and there is no evidence (nor do Plaintiffs allege) that it had anticompetitive effect.

In sum, Plaintiffs cannot show that Defendants—nor any other pharmaceutical manufacturer—have engaged in the practice at the core of Plaintiffs' claim, which alone is fatal to it. *Cf. Microsoft*, 2023 WL 4443412, at *18 (finding that the FTC's "partial foreclosure theory fails" in part because "the record does not include any evidence Microsoft has engaged in [the alleged conduct] in the past"). There are a number of reasons for that dearth of evidence.

First, negotiations for pharmacy benefits and medical benefits are typically handled by different entities. Pharmacy benefit products are negotiated by PBMs, while medical benefit products are negotiated by payors. (Gan ¶ 172.) That poses significant logistical hurdles to the

[14] Although Defendants have no personal knowledge of the alleged bundle, and Plaintiffs have offered no direct evidence of its existence, the chronology of the events alleged in a complaint filed against Johnson & Johnson suggests that the Remicade® bundle may have been a holdover from a preexisting contract between Johnson & Johnson and Cigna, prior to Cigna's merger with Express Scripts in December 2018. *See Pfizer Inc.* v. *Johnson & Johnson*, 333 F. Supp. 3d 494, 499 (E.D. Pa. 2018). Prior to that merger, Cigna had its own in-house PBM that exclusively served Cigna's medical benefit customers, and as a result, there was a very high overlap between Cigna's pharmacy benefit and medical benefit customers. After the merger, the overlap between the combined firms' pharmacy and medical benefit customers was greatly reduced, and it is likely that the Remicade® bundle was simply a holdover based on Cigna's pre-merger structure.

hypothesized cross-benefit bundling. As one payor explained, due to the fact that [redacted] that payor. ([redacted]) Similarly, [redacted]

Second, contrary to Plaintiffs' allegations, the fact that some PBMs and payors have vertically integrated has not mitigated this logistical hurdle to the hypothesized cross-benefit bundling. (Lakdawalla ¶¶ 51-52; Gan ¶ 174.) For one thing, many medical benefits payors today remain independent from PBMs and account for a meaningful percentage of covered lives. For example, [redacted] For these payors, as the testimony above highlights, there is not a single entity with whom Amgen could contract a bundled discount across pharmacy and medical benefit products. And logistical hurdles exist even for integrated firms, because there is not even close to complete overlap between the patients who participate in those plans.[15]

Tellingly, even years after the "big three" PBMs vertically integrated, there is still no evidence that any cross-benefit bundling is occurring or is likely to occur in the foreseeable future. The documents and testimony Plaintiffs and their experts rely upon that mention "cross

[15] For example, Express Scripts ("ESI"), which was acquired by Cigna in 2018, covers the pharmacy benefit for [redacted] patients, but only [redacted] of those patients are also covered by Cigna's medical benefit. (Gan ¶ 174.) Likewise, Cigna's medical benefit covers [redacted] patients, but Amgen estimates that only [redacted] of those patients are also covered by ESI's pharmacy benefit plan. (Lakdawalla ¶ 51.)

benefit management" (Br. at 30-31) do not show otherwise. The evidence makes clear that those references have nothing to do with cross-benefit bundling, but rather relate to general aspirations by some PBMs to manage the utilization of the same products, or products that treat the same disease, across pharmacy and medical benefit plans. (

Third, cross-benefit bundling may also be vulnerable to challenge under the federal anti-kickback statute, which provides that prescription drug companies cannot offer inducements to promote their products but can offer discounts. (Gan ¶ 122; *see* 42 U.S.C. § 1320a-7b(b).) The statute provides a "safe harbor" for such discounts, setting forth criteria under which they are appropriately given. (Gan ¶ 123; *see* 42 C.F.R. § 1001.952.) Pharmaceutical manufacturers take care to meet these criteria in structuring their discounts and rebates in order to take advantage of the safe harbor protections. (Gan ¶ 123.) It is unclear whether a bundled discount involving a medical benefit product and a pharmacy benefit product would fall within the regulatory "safe harbor" for discounts and this uncertainty is yet another factor that makes cross-benefit bundling unattractive to manufacturers (as well as PBMs and payors).

Recognizing that their cross-benefit bundling theory is implausible, Plaintiffs argue in the alternative that subcutaneous versions of TEPEZZA® and KRYSTEXXA® are in development, and that those versions, if they ever come to market, would be self-administered and covered under the pharmacy benefit. (Br. at 30.) But the contention only adds to the speculative nature of Plaintiffs' challenge.

[redacted] Moreover, even then, the hypothesized foreclosure in this scenario would *further* require either that the potential future competitors' products be covered under a pharmacy benefit as well, or if not, coordination across benefits in a way that would be impractical and (as best anyone can tell) unprecedented—in either case rendering the whole theory even more speculative.[16]

d. Cross-benefit bundling would precipitate an ASP death spiral.

If Amgen were to enter into the cross-benefit bundle hypothesized by Plaintiffs, it would likely result in a precipitous downward spiral in the average selling price ("ASP") of TEPEZZA® and KRYSTEXXA® (an "ASP death spiral"), putting their profitability in serious jeopardy. The likelihood that a cross-benefit bundle would cause an ASP death spiral is yet another reason why Plaintiffs' theory of harm makes no sense.

[16] [redacted] White bagging is an occasional alternative to the typical way that medical benefit drugs are purchased, whereby a specialty pharmacy ships a product to a provider rather than the provider buying and stocking the product itself. (Gan app'x D.) But Plaintiffs' expert ignores the significant practical constraints that limit the prevalence of white bagging, and grossly overestimates its use with TEPEZZA® and KRYSTEXXA®. (Gan ¶¶ 224-25.)

The ASP death spiral arises from the way in which most payors reimburse providers who administer medical benefit products such as TEPEZZA® and KRYSTEXXA®. (Lakdawalla ¶ 54.) Most medical benefit products are sold to providers (*e.g.*, doctors), who pay for the products out of pocket, billing the patient's insurer (Medicare Part B or a commercial health plan) for the expense. (*Id.* ¶ 26.) The reimbursement that a provider receives for that out-of-pocket expense most often is based on a formula tied to the product's ASP. (Gan ¶ 114.) Since rebates lower a product's ASP, they also lower the provider's reimbursement on that product. (Lakdawalla ¶ 26.) When the rebate is provided to a *payor*, it lowers the product's ASP and therefore the provider's reimbursement, but it does not lower the *provider's* acquisition cost (since the provider did not get the rebate itself).[17] (*Id.*) Over time, rebates given to payors on a medical benefit product can lead to providers losing money on each prescription of that product, ultimately causing them to stop administering it. To avoid putting providers at a financial loss on each administration of a drug, the manufacturer would need to offer the provider a separate discount on the same product, but that discount would further drive down the product's ASP, leading to a downward price spiral that eventually makes the product unprofitable. (*Id.* ¶ 54.)

If Amgen were to bundle any of its so-called "blockbuster" pharmacy benefit products with TEPEZZA® or KRYSTEXXA®, it would cause a steep ASP spiral that would put the bundled Horizon product's profitability in serious jeopardy and likely render the product unprofitable—defeating the very "profit protection" purpose that Plaintiffs allege would motivate Amgen to implement such a bundle in the first place. The spiral would be particularly impactful in the circumstances alleged by Plaintiffs due to government rules relating to how bundled

[17] By contrast, where the rebate is given to the provider, the provider's cost and reimbursement fall in tandem (the rebate lowers the product's ASP and reimbursement, but the provider is getting a rebate off its acquisition cost).

discounts must be proportionally allocated to the products in the bundle. Pursuant to those rules, [redacted], causing a dramatic drop in the Horizon product's ASP, and creating a substantial gap between providers' out-of-pocket costs to acquire the product and their reimbursement for it.[18] At that point, providers would stop administering the Horizon products, or Amgen would offer more rebates to the providers to get them to start administering the product again, which would eventually render the Horizon product unprofitable.

Because of the spiral, Amgen's incentives post-Transaction are exactly the opposite of what Plaintiffs allege and must show to prove their case. Amgen plainly has every incentive to avoid an ASP death spiral on Horizon's products, and so has every incentive *not* to engage in payor rebating on Horizon's products, much less any cross-benefit bundling of its products with Horizon's products. That is clearly a problem for Plaintiffs' theory, yet Plaintiffs have no serious answer for it. Their only response is to assert that the spiral is "hardly a foregone conclusion." (Br. at 32.) But contemporaneous Amgen and Horizon documents make clear that [redacted].[19] And the evidence shows that [redacted]

[18] Specifically, because an Amgen pharmacy benefit product like Enbrel® has much higher revenue than TEPEZZA®, [redacted]

[19] Plaintiffs point to Amgen's past medical benefit rebates as evidence that the spiral can be avoided. (Br. at 32.) But they show the opposite. For example, [redacted] Since biosimilars are by definition undifferentiated from the branded product, in both contexts, [redacted] (Lakdawalla ¶ 55 & exh. 2.) In these narrow circumstances, [redacted] contrary to Plaintiffs' unsupported claims. (*Id.*)

[redacted]

Moreover, the spiral need not be a "foregone conclusion" to be a serious risk that constrains Amgen's post-Transaction incentives. And Plaintiffs, who have the burden of proof, do nothing to explain why or under what circumstances Amgen would have the financial incentive to risk an ASP death spiral on either TEPEZZA® or KRYSTEXXA®, both products whose profitability, according to Plaintiffs, is the driver of the Transaction. Nor do Plaintiffs identify any example of a manufacturer triggering an ASP spiral to foreclose a competitor.

Plaintiffs' theory that Amgen would risk a death spiral on either drug is all the more implausible given that Amgen has many non-price tools to respond to any new TED or CRG market entrant, such as using differentiating medical evidence to inform provider usage, using its resources to educate providers and expand patient access and ensure the products are available to "every patient, every time," as well as investing in product development programs to improve the efficacy, safety, tolerability and/or convenience of these products to attract additional patients. Those non-price tools would not put TEPEZZA®'s or KRYSTEXXA®'s profitability at risk in the way the death spiral surely would. Plaintiffs have no explanation as to why Amgen would eschew them in favor of a strategy that would likely render the Horizon products unprofitable. Plaintiffs have done no analysis to show that, of all the multitude of options available to grow sales and compete, Plaintiffs' hypothesized bundling theory would be the most profit-maximizing approach. Their theory simply does not add up.[20]

[20] Moreover, even if (counterfactually) Amgen were economically irrational enough to precipitate an ASP spiral *and* somehow could still maintain patient access to the Horizon drug, that would only mean that consumers are benefitting, since the lower ASP would mean lower costs to health plans and lower out-of-pocket costs to patients, without any impact on patient access.

e. Rare disease medicines are ill-suited to bundling.

Even if the obstacles to cross-benefit bundling were somehow overcome, that would not make Plaintiffs' theory plausible. Among other problems, their theory also depends on the assumption that payors and PBMs would restrict patient access to a newly launched rare disease treatment just to secure a bundled rebate. But that is not how the industry works. And, tellingly, Plaintiffs cite no example of a payor or PBM restricting patient access to a rare disease treatment just to get a rebate. Indeed, when asked by interrogatory [redacted] Thus, along with cross-benefit bundling (which, by all accounts, has never happened in the way hypothesized by Plaintiffs), all evidence indicates that yet another assumption core to Plaintiffs' theory does not happen in the real world.

Plaintiffs' theory about bundling rare disease products ignores real-world distinctions. Specifically, in treatment areas where there are multiple medications indicated to treat the same disease, and not any meaningful differentiation between them, payors sometimes use protocols called "utilization management" to steer patients to the cost-effective medication (*e.g.*, requiring the patient to try Product A before trying Product B, both of which treat the same illness in the same way with the same degree of efficacy and safety, because Product A is cheaper). (Lakdawalla ¶¶ 97-99.) Where the products are undifferentiated and preferencing can be done without affecting patient outcomes, a drug's cost can play a role in these payor decisions. (*Id.*)

But these examples have nothing to do with Plaintiffs' theory of harm, which assumes future entry by one or more treatments that Plaintiffs' own experts predict will be differentiated from Horizon's products in the treatment of serious rare diseases. In that context, Plaintiffs' assumption that payors might restrict patient access to obtain a rebate has no basis in reality.

First, as payors and PBMs affirmed, when it comes to formulary and coverage decisions, safety and clinical efficacy come first. As one payor explained, [redacted][21]

Second, physicians, patients and patient advocacy groups have strong preferences about therapeutic options for rare diseases, for which the choice between alternatives can have life-altering consequences. Those preferences are driven by medical reasons relating to the needs of the particular patient. (*See* Gan ¶ 117.) In that context, choosing the right treatment for the particular patient based on medical reasons is essential, and it is implausible and unheard of that a payor might foreclose access to what is medically best for the patient for reasons relating to cost. (*Id.*) Payors are incentivized to keep providers in network, not chase them away with restrictions that harm suffering patients. And providers (who bear the financial burden of any lack of reimbursement for a therapy they administer) would have no interest in being part of a network that will not reimburse them for therapies that are best for their patients.[22]

Third, payors also have no financial incentive to inappropriately restrict access to beneficial rare disease treatments because the payor generally bears the cost of less effective therapies, which could lead to expensive surgical interventions with many more side effects. (Lakdawalla ¶ 97.) It would not make economic sense for a payor to limit patient access to a

[21] [redacted]

[22] Plaintiffs point to a handful of third-party declarations from doctors who treat TED and CRG as support for their claims, but those declarations merely make the unremarkable point that having additional treatments for these debilitating diseases would be good for patients. They do more to undercut Plaintiffs' claim than support it, as those strong payor and patient preferences are one of the (many) dynamics that make it implausible a payor would exclude a clinically efficacious rare disease drug just to get a bundled rebate.

therapy that could avoid such interventions in order to get a rebate. Nor would it make financial sense for the payor to risk driving providers out of its network by forcing the provider to choose between reimbursement and administering the most effective therapy for the suffering patient. (*Id.*) [redacted]

Fourth, new treatments for rare diseases are generally differentiated from incumbent treatments, and all evidence indicates that the potential future entrants, if they ever launch, would be differentiated from TEPEZZA® and KRYSTEXXA®. (Lakdawalla ¶¶ 100-01.) The potential future entrants to TEPEZZA® have different mechanisms of action, different levels of receptor antagonism, different dosing regimens and routes of administration, and/or different clinical trial populations, each of which would be expected to result in different clinical outcomes (good or bad) vis-à-vis the Horizon products. [redacted]. This too strongly cuts against Plaintiffs' theory.

A differentiated new product will be better or worse across each of a multitude of attributes than the incumbent. In neither case would bundling make sense or be effective. If the new entrant is worse, then the incumbent wins on the basis of its clinical superiority. If the new entrant is better, even for just a subset of patients, it is improbable, and indeed unheard of, that a payor would deny patient access to such a treatment just to get a rebate on the incumbent product. (*See* Lakdawalla ¶ 99.) As noted, providers and patients would revolt. And doing so would cut against the clear financial interests of the payor, which has every incentive not to restrict access to therapies that might avoid unnecessary and costly interventions and could drive providers from its network. For all these reasons, the restrictions Plaintiffs hypothesize, though

fundamental to their theory, simply do not happen in the real world and will not happen as a result of the Transaction.

* * *

When all is said and done, Plaintiffs' theory of this case depends on multiple layers of speculation and requires ignoring the real world in which pharmaceutical companies operate. Plaintiffs ask this Court to make, at least, the following assumptions:

1) Amgen will pursue a strategy that it never contemplated;

2) Amgen will disregard its commitment, made publicly and to this Court, not to bundle its products with TEPEZZA® or KRYSTEXXA®;

3) Alleged potential rivals of Horizon will enter the market in the near term with undifferentiated substitutes for TEPEZZA® and KRYSTEXXA®;

4) Amgen will be able to convince a sufficient number of counter-parties to bundle a medical benefit product with a pharmacy benefit product to foreclose access to another medical benefit product that treats a rare disease;

5) Payors, over the objection of patients and their physicians, would disregard their mandate to construct formularies and make coverage decisions that include the safest and most effective medications for their members, putting the health of members at risk, potentially causing them to have to incur avoidable and costly interventions, and risking driving providers out of the payor's network;

6) Amgen will risk an ASP spiral for TEPEZZA® and KRYSTEXXA®, despite its prior experience and the likely destruction of the deal value it would cause;

7) Amgen will (at some unspecified future point) discount its most successful products, which face intense competition, to attempt to foreclose competitors (that do not today exist) in a way that would be highly unlikely to succeed;

8) Payors would act [redacted], inviting provider and patient push back and financial downside, just to get an incremental rebate on Amgen products (*e.g.*, Enbrel®) for which there are many substitutes and more to come.

This is not an exhaustive list of the conditions for Plaintiffs' theory of harm, but it is illustrative of the speculative nature of their case. While there is very little chance any of these conditions will be met, there is essentially no chance that all will. Assuming for the sake of discussion that the likelihood of each hypothetical event is 50 percent (which is a significant overstatement of the probability for any of them), the likelihood that the *entire* sequence of events were to occur is less than half of 1 percent.[23] This falls far short of Plaintiffs' burden to show that the alleged harm is probable. Indeed, Plaintiffs' theory is against all odds. Similar to a number of recent cases that the FTC has litigated and lost, Plaintiffs have alleged a series of "ephemeral possibilities," not proven an anticompetitive effect is likely as the law requires. *Meta Platforms*, 2023 WL 2346238, at *22; *see Microsoft*, 2023 WL 4443412, *13. Thus, Plaintiffs cannot establish a likelihood of success on the merits of their claim.

3. Plaintiffs have not shown that the alleged cross-benefit bundling would have anticompetitive impact.

Even if Plaintiffs were able to show that all of the above scenarios would transpire at some unknown point in the future (and they cannot), that would not automatically mean that the Transaction is likely to substantially lessen competition. Among other things, Plaintiffs would also have to show that the alleged bundle would be likely to have anticompetitive impact. But Plaintiffs cannot make that showing, including because (i) bundling is pervasive in the economy (although not in the biopharma industry) and typically procompetitive, (ii) Plaintiffs cannot show

[23] The probability of eight independent events, each of which carries a 50% probability, all occurring is equal to 50% x 50% x 50% x 50% x 50% x 50% x 50% x 50% = 0.39%.

that the hypothesized bundle would substantially foreclose any TED or CRG rival; (iii) Plaintiffs cannot show that the alleged Amgen "donor" products have the degree of market power required to sustain an anticompetitive bundle; (iv) Plaintiffs do not and cannot contend that Amgen has ever entered into an anticompetitive bundled contract, and the evidence shows Amgen has not done so; and (v) the reaction to the Transaction by sophisticated investors to the Transaction indicates knowledgeable market participants do not share Plaintiffs' speculative foreclosure concerns. For all these reasons, Plaintiffs' assertion that the hypothesized bundle would harm competition, though a necessary element of Plaintiffs' claim, is just more baseless speculation.

First, there is in fact nothing inherently anticompetitive about bundled discounting. (Orszag ¶ 44.) To the contrary, the law recognizes that "[b]undled discounts are pervasive, and examples abound" across the economy, and they "generally benefit buyers because the discounts allow the buyer to get more for less." *Cascade Health Sol. v. PeaceHealth*, 515 F.3d 883, 894-95 (9th Cir. 2008). The Government has itself acknowledged that bundling is often procompetitive. *See, e.g.*, U.S. Amicus Curiae Br. at 12, *3M Co. v LePage's Inc.*, 542 U.S. 953 (2004) ("Bundled rebates are widespread and are likely, in many cases, to be procompetitive."). So too has Plaintiffs' expert, Dr. Sibley. David S. Sibley et. al., Tying and Bundled Discounts: An Equilibrium Analysis of Antitrust Liability Tests, 13 Berkeley Bus. L.J. 149, 153-54 (2016) ("Bundling can therefore increase total welfare; both buyers and sellers can gain from the practice.").

Indeed, "cutting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 749 (5th ed. 2023) ("[T]he great majority of discounting practices are procompetitive."). For that reason, it is well understood that bundled discounting is often

procompetitive and can harm competition in only limited circumstances. *See, e.g.*, *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 271 (6th Cir. 2015).

Ignoring these well-established precedents, Plaintiffs contend that bundled rebates somehow "evade direct competition on the merits" and "undermine competition." (Br. at 6.) To the extent Plaintiffs suggest that bundled rebates are always or typically anticompetitive, this is contrary to black letter law. In any event, there is no basis to conclude, and Plaintiffs cannot show, that the alleged bundled discounts—which will not come about for all the reasons explained—would be the rare form of competition-reducing price cutting.

Second, a bundled discount cannot harm competition unless (among other things) it substantially forecloses an equally efficient competitor from the market. *See ZF Meritor, LLC v. Eaton Corp*., 696 F.3d 254, 281-83 (3d Cir. 2012). Plaintiffs cannot come close to showing that the hypothesized bundles would have such an effect. Plaintiffs baldly assert that the hypothesized bundling could "prevent entry" and "maintain exclusivity for TEPEZZA and KRYSTEXXA". (Br. at 20, 27). Simply saying it does not make it true. In actuality, it is inconceivable, in light of real-world industry dynamics, that the bundling about which Plaintiffs speculate could substantially foreclose competition from any entrant in the TED or CRG market. In addition to all the reasons explained in Section II.A.2 above, Plaintiffs cannot make their required showing of likely substantial and imminent harm to competition because:

- It is not possible for a bundled rebate to completely exclude a TED or CRG rival for the simple reason that not all health insurance plans allow for exclusive coverage. For example, Medicare Part D prescription drug plans are required to cover at least two drugs in a therapeutic category, formulary restrictions are not permitted for medical benefit drugs covered by Medicare Part B, and State Medicaid agencies are required to cover almost all FDA-approved drugs.

(Lakdawalla ¶ 113.) Thus, at a minimum, a new TED or CRG entrant would not be foreclosed from competing for the [redacted] percent of TEPEZZA® patients and [redacted] percent of KRYSTEXXA® patients that receive health coverage from a government payor. (*Id.*)

- There are numerous commercial health plans and formularies.[24] Thus, even if it were assumed (contrary to all evidence) that some might accept the hypothesized bundled rebate and choose not to cover a new TED or CRG entrant, it is not remotely plausible, and Plaintiffs do not even attempt to argue, that *all* commercial payors across *all* formularies and plans would do so. Indeed, as noted, [redacted] There is thus no basis to conclude that *any* payor or PBM would accept the hypothesized bundle, much less enough of them to deprive a new entrant of competitive scale.
- It also is not plausible that any TED or CRG rival that emerged would not be able to, and would in fact not, offer its own competitive inducements to obtain coverage on at least some formularies. Plaintiffs assert that a new entrant would be likely to launch at a significant discount as compared to Horizon's products. (*E.g.*, Br. at 24.) It is inconceivable that a clinically efficacious TED or CRG product priced lower than Horizon's product would not gain traction in the market.

[24] For example, KRYSTEXXA® and TEPEZZA® are each reimbursed by over [redacted] payors, the vast majority of which are not consolidated with a Big 3 PBM. (Orszag ¶ 16.)

- Patients and providers can and do regularly access pharmaceutical products that are not on the formulary used by the patient's health plan. For example, when Amgen's Repatha® was not preferred on CVS's formulary, up to approximately [redacted] percent of the patients covered by CVS's plan continued to use Amgen's product over the covered rival. (*See* Gan ¶ 138.) As one PBM explained, [redacted]

Given these industry dynamics, even if it were assumed that some payors would agree to the hypothesized bundle, it is implausible that any entrant would be substantially foreclosed from competing on the merits of its product. Indeed, as noted above, Plaintiffs have not identified a single example of a rare disease medicine that was blocked from the market as a result of an incumbent's rebating strategy. (*See* Gan ¶ 14 ("In my decades of experience in the pharmaceutical industry, I am not aware of a single competitor that has obtained FDA approval but was foreclosed from entering the market because of a bundled contracting strategy employed by the incumbent firm.").

Third, a bundle cannot harm competition unless the "donor" product in the bundle (*i.e.*, the product on which the conditional rebate is offered) has significant market power. *See, e.g.*, *Inline Packaging, LLC v. Graphic Packaging Int'l, LLC*, 962 F.3d 1015, 1030 (8th Cir. 2020) (holding in a "discount-bundling" case that plaintiff must "establish that [defendant] is a monopolist or, at the very least, holds sufficient market power in the relevant or leveraging market"). Yet Plaintiffs do not even attempt to show that any of Amgen's so-called "blockbusters" has sufficient market power to sustain an anticompetitive bundle today, much less

at the unspecified time in the future when bundling would occur under their theory.

The reason Plaintiffs do not even attempt to show monopoly power of the Amgen donor products is obvious: it doesn't exist. Plaintiffs' allegations focus on Enbrel®, which has less than a [redacted] share in any conceivable market and operates in a therapeutic class with many options that is growing more competitive by the day. (Orszag ¶¶ 56-60.)[25] Upcoming policy changes, such as the Inflation Reduction Act ("IRA"), make Enbrel®'s position in the market even more tenuous as it will likely be subject to a significantly reduced price ("Maximum Fair Price" or "MFP") set by CMS, and it is not expected that products with a MFP would be subject to further contracted price concessions for Medicare Part D or any other commercial payors that adopt MFP-based reimbursement. (Bell ¶¶ 48-50.) These market facts easily refute any notion that Enbrel® could serve as an "anchor" to an anticompetitive bundle today, much less years into the future when any TED or CRG alternative might launch.

Fourth, Plaintiffs do not and cannot contend that any of Amgen's past bundles (none of which was cross-benefit) was or is anticompetitive. Plaintiffs suggest that Amgen "already employs" a strategy to "entrench . . . monopoly positions", while asserting that Amgen has a "historic practice of bundling" that is supposedly "instructive" about how Amgen would behave post-Transaction with respect to Horizon's products. (Br. at 1, 21.) Plaintiffs also point to unproven allegations by an Amgen rival (Regeneron Pharmaceuticals) as supposed evidence that Amgen might try to use bundling to exclude a TEPEZZA® or KRYSTEXXA® future rival. (*Id.*) Yet when Defendants asked the FTC by interrogatory to [redacted]

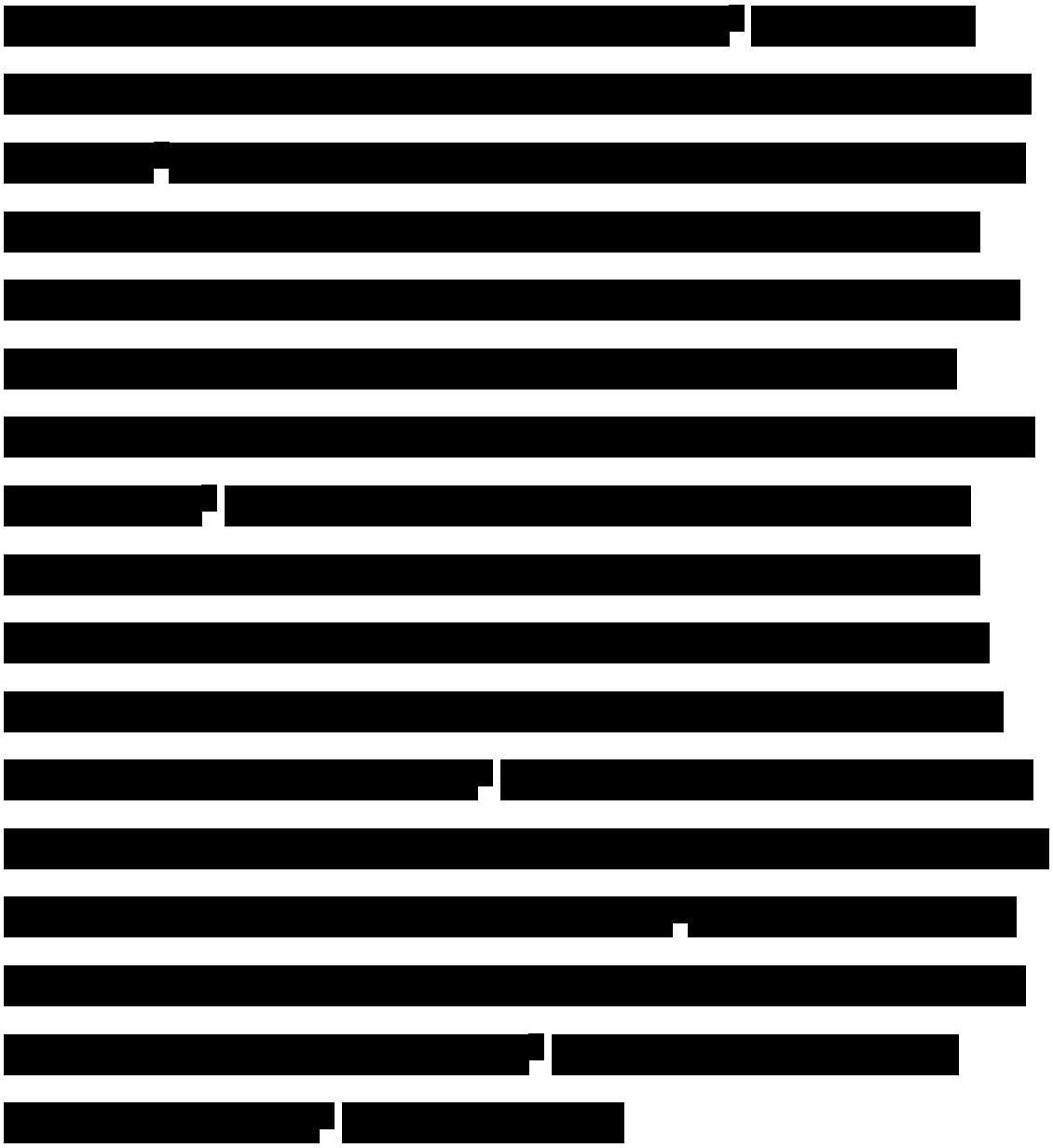
[25] *See also* [redacted]

[redacted] Similarly, when Defendants asked by interrogatory if [redacted]

The evidence will show that none of Amgen's past bundles—none of which was cross-benefit—was or is anticompetitive. In particular, it will show that Amgen has entered into only [redacted] (Ex. 8, Gordon Dep. 40:3-20), and in every case, for the procompetitive purpose of maintaining patient access to Amgen's products. Specifically:

- [redacted] which plainly is procompetitive.
- [redacted]

  These bundles are not exclusionary and ultimately result in more choice for patients.
- [redacted]



In sum, Amgen's few past bundles share key characteristics: (a) they bundled products covered under the same benefit scheme; (b) they were designed to maintain patient access to Amgen products in the face of competition from clinically undifferentiated products; and (c) they offered payors the opportunity to earn modest, single-digit incremental discounts on one product in the bundle, in addition to other, much larger, standalone rebates available for each product in the bundle. Moreover, none resulted in foreclosure of any competitor from the market. Directly to the contrary, in the case of Praluent (the only example of a rival that has faced a 1-of-1

contract), its sales have significantly *increased* since the bundles were put in place. (Lakdawalla ¶ 123.) None of these bundles bears any resemblance to the cross-benefit bundles Plaintiffs hypothesize; none resulted in competitive harm (and Plaintiffs do not contend otherwise); and they provide no support whatsoever for Plaintiffs' speculative theory.

Fifth, no market participant—not a single payor, PBM, potential future entrant or analyst—has indicated any concern about the Transaction; [redacted][26]; and sophisticated investors do not appear to share Plaintiffs' concern, as reflected in the stock prices of those companies. (Lakdawalla ¶¶ 117-18.) If Plaintiffs' foreclosure theory were right, highly informed and knowledgeable investors would surely foresee the risk that the Transaction posed to these potential future entrants, and the expected result would be a significantly negative stock price reaction to the Transaction. (*Id.* & n.54). Instead, the opposite occurred. (*Id.*) Nor have Plaintiffs identified any concerns by analysts that follow any of these entrants, or anyone else for that matter—including, as noted, the companies themselves. According to one analyst, the Transaction is a positive for potential future entry, not a negative, precisely because of its ability to expand patient access to Horizon therapies; that analyst emphasized: [redacted]

Finally, the evidence will show that, even assuming (counter-factually) that Amgen could bundle to foreclose potential future entrants into the TED and CRG markets, Plaintiffs would still lose because—***under the Plaintiffs' own analysis***—standalone Horizon could obtain the

[26] *See, e.g.*, [redacted]

exact same hypothesized competitive effects without any Amgen products and without any bundling. (Gilbert § VI.F.) This is yet another, independent reason that their case fails.

B. The Alleged Harm is Easily Offset by Merger-Specific Efficiencies.

Even if Plaintiffs could show likely, substantial and imminent anticompetitive effect, it would easily be offset by the Transaction's benefits. Although efficiencies may not "immunize" an illegal merger, they can demonstrate that a merger is not illegal, because Section 7 forbids only those mergers that are likely to substantially lessen competition, taking into account a transaction's likely harms *and* benefits.[27] The Transaction will generate significant, merger-specific benefits to patients suffering from debilitating rare diseases, including TED and CRG.

1. The Transaction will greatly expand patient access to Horizon medicines.

Amgen will make Horizon's products available to far more patients, far sooner and more reliably, than Horizon could on its own, generating significant patient benefits. (*See* Ex. 19, Bloomgarden Decl. ¶ 5.) Such increased consumer access to a merging party's products is a well-recognized procompetitive effect. *See, e.g.*, *Microsoft*, 2023 WL 4443412, at *19 ("First, the merger has the procompetitive effect of expanding access to [Activision's gaming content]."). Amgen will achieve this procompetitive benefit in myriad ways, including increasing provider awareness of Horizon's products and the rare diseases they treat, providing greater market access resources, utilizing real-world evidence and data generation, leveraging Amgen's reliable manufacturing network to ensure greater continuity of supply and expanding the reach of Horizon's products to new regions around the globe. (Bell ¶ 83.)

[27] *See, e.g.*, *Microsoft*, 2023 WL 4443412, at *19 ("Whether an acquisition would yield significant efficiencies is an important consideration in predicting whether the acquisition would substantially lessen competition." (quoting *F.T.C. v. Univ. Health, Inc.*, 938 F.2d 1206, 1222 (11th Cir. 1991)); *see also New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020).

Increased provider awareness of ***Horizon's products and the rare diseases they treat***. Amgen has a history of working with providers who treat rare diseases addressed by Horizon's treatments. (Ex. 9, Niksefat Dep. 94:6-96:19.) Horizon's experience does not run as deep. "[T]here is still a lack of awareness" among providers that they have the ability to treat these debilitating illnesses "after multiple decades in the field of medicine where they haven't had any treatments" for them. (*Id.* at 99:21-100:3; 108:2-20.) The scope of Amgen's promotional infrastructure and its presence in provider offices that treat diseases addressed by Horizon's products will result in many more providers knowing about and being comfortable prescribing those products, and many more patients having access to them. (*Id.*; Ex. 24, PX9007-001; Ex. 8, Gordon Dep. 144:9-145:20 (explaining that [redacted] Amgen has a highly effective centralized digital marketing group, developed over years. (Ex. 8, Gordon Dep. 146:18-147:3.) Amgen can use this group to vastly improve Horizon's product marketing and promotional initiatives, thereby accelerating patient and provider awareness of Horizon's products, leading to greater patient access. (Ex. 24, PX9007-001.) Amgen also has a larger presence at medical congresses, providing greater opportunity for promotion of Horizon's products. (Ex. 8, Gordon Dep. 148:17-149:23.) Reflecting the increased patient access anticipated by the Transaction, [redacted] (Ex. 9, Niksefat Dep. 102:21-109:21.)

Greater market access resources. Amgen has significantly more market access experience and resources than Horizon, which will lead to both greater and better coverage and

access for patients to Horizon products and pipeline developments when approved in the U.S. (Ex. 24, PX9007-001; Ex. 9, Niksefat Dep. 94:6-95:2.) Amgen's expansive payor-facing customer team ensures that Amgen's drugs are accessible to providers and thus their patients.

Real world evidence ("RWE") and data generation. Amgen has developed sophisticated techniques to utilize RWE data to uncover valuable insights that can broaden patient access and improve patient outcomes. (Bell ¶ 85.) [redacted] (*Id.* ¶ 100.) Amgen expects that, post-close, it will use its experience and resources in RWE generation to uncover insights into patients in need of Horizon's treatments, including TEPEZZA®, and KRYSTEXXA®, further broadening access and improving patient outcomes. (Ex. 24, PX9007-001; Ex. 9, Niksefat Dep. 109:7-15 ([redacted])

More resilient, reliable manufacturing network, ensuring greater continuity of supply. Today, [redacted] (*See, e.g.*, Ex. 23, PX5032-010.) As one example of the patient access issues that Horizon's reliance on such manufacturers can cause, one of its manufacturers "was taken offline to manufacture COVID therapeutics, thereby halting the supply of TEPEZZA for months." (PX5026 at 4.) Amgen is "an industry leader in biologics manufacturing" and can vastly improve the supply chain resilience and reliability of Horizon's products, ensuring patients do not lose access to the products they need to relieve their suffering from the rare diseases Horizon's products treat. (*Id.*; Bell ¶ 103.) Consistent with its "every patient, every time" motto, Amgen is one of only two biopharmaceutical companies in the U.S. market that has never had a supply disruption resulting in a product shortage, meaning that it has

always been able to manufacture and deliver medicines to patients without interruption. (Ex. 24, PX9007-002; Ex. 9, Niksefat Dep. 131:7-132:2.)

Global expansion will benefit patients around the world and in the U.S. Amgen can successfully market Horizon's treatments in new regions where patients do not currently have access, utilizing its global sales, marketing and regulatory teams to bring Horizon's treatments to these markets more effectively than Horizon could on its own, given that today Horizon predominantly sells its products in the United States. (Bell ¶¶ 107-09.) These efforts will benefit not only patients abroad, but also patients in the United States by generating more data from diverse patient populations, which may provide useful insights about the products applicable to those patients. (*Id.* ¶ 113; Ex. 24, PX9007-003.) The more patients that are served around the world, the more evidence Amgen can accumulate about the benefit and risk profiles of its drugs. (Ex. 10, Bradway Dep. 144:5-15.) Amgen can then use that evidence to help target the right patients, satisfying regulatory requirements regarding the continued safety and efficacy of its products. (*Id.*)

2. The Transaction will create R&D benefits that will improve patient lives.

In addition to expanding patient access to important Horizon's medicines, the combination of Amgen and Horizon will create R&D benefits that will improve patient lives.

Pipeline advancement and genetic insights. Amgen has expertise in many areas that will allow it to increase the probability and speed of bringing Horizon's pipeline drugs to market as compared to Horizon on its own. (Bell ¶¶ 94-95; Ex. 24, PX9007-003; Ex. 23, PX5032-010.) For example, Amgen will leverage the resources [redacted] (Bell ¶ 100.)

Combination products. Horizon is exploring more patient-friendly delivery options for its drugs, such as a subcutaneous injection of TEPEZZA®, but has no experience developing new drug-device combinations. (Bell ¶ 96.) Amgen has deep experience with "combination products," which combine a drug and a device, such as an auto-injector. (*Id.* ¶ 99.) The Transaction will increase the likelihood of a subcutaneous injection version of TEPEZZA® obtaining approval. [redacted], such a device will enable more providers to administer the drug in a more patient-friendly way, improving access to therapy and patient lives. (Ex. 24, PX9007-004; Ex. 9, Niksefat Dep. 154:6-19 ([redacted]).)

3. The Transaction will generate large cost efficiencies.

The Transaction will also allow the combined company to operate more efficiently than Horizon can on its own. For example, Amgen has projected efficiencies [redacted] (Ex. 24, PX9007-004; Bell ¶ 82; Ex. 9, Niksefat Dep. 159:13-174:6.)

The cost efficiencies will enable Amgen to reinvest in R&D to address serious, unmet medical needs and to continue its commitment to ensuring broad access to novel therapies at lower costs by providing drugs to low-income individuals for free. (Ex. 24, PX9007-005; Ex. 9, Niksefat Dep. 143:14-21.) These cost savings also will be invested in awareness efforts that will ensure more patients can benefit from Amgen's products. (Ex. 9, Niksefat Dep. 143:1-8.) And

they will be used to "better understand the product [and] better understand the patients who are served". (Ex. 10, Bradway Dep. 216:24-217:22.)

4. The efficiencies are merger specific and corroborated by experience.

The Transaction's efficiencies are merger specific: they are likely to be achieved as a result of the Transaction and are unlikely to be achieved absent it. Amgen would not and could not feasibly make its sales, marketing, distributional and manufacturing capabilities available to Horizon absent the Transaction, and Horizon would be unable to build those capabilities and scaled resources on its own within any foreseeable time frame, if ever; indeed—Amgen itself has done so only with enormous, risky investment over the course of years. (*E.g.*, Ex. 8, Gordon Dep. 146:14-147:12; Ex. 9, Niksefat Dep. 94:6-96:19.)

Amgen has achieved similar merger-specific efficiencies in the past, including with its recent acquisition of ChemoCentryx, whose product, Tavneos, is a rare disease treatment [redacted] (Ex. 8, Gordon Dep. 126:14-127:3.) Amgen greatly accelerated provider and patient awareness and utilization of Tavneos using the same resources that it will bring to bear to expand patient access to Horizon's treatments. (*Id.*; Ex. 24, PX9007-005; Ex. 9, Niksefat Dep. 179:18-183:14.) Since Amgen acquired ChemoCentryx in October 2022, over [redacted] patients have received access to Tavneos as compared to around [redacted] prior to the acquisition. (Bell ¶¶ 86-88; Ex. 9, Niksefat Dep. 182:3-21.) Amgen's track record of expanding patient access with merger-specific efficiencies provides powerful evidence that such efficiencies

are verifiable and likely here. *See, e.g.*, *Deutsche Telekom*, 439 F. Supp. 3d at 213 ("[E]fficiency claims substantiated by analogous past experience are those most likely to be credited.").

5. Plaintiffs' counter-arguments are misplaced.

Plaintiffs argue that efficiencies are legally irrelevant in a Clayton Act case, and even if they were relevant, should be subjected to an impossibly high legal standard. (Br. at 32.) Plaintiffs are wrong on both counts. Whether an acquisition yields significant efficiencies "is an important consideration in predicting whether the acquisition would substantially lessen competition." *Microsoft*, 2023 WL 4443412, at *19 (quoting *Univ. Health, Inc.*, 938 F.2d at 1222). And although Plaintiffs argue they can meet their burden to show supposed harm based on scant evidence, while evidence of efficiencies must be tested by a "rigorous standard" of proof, this hostility toward merger efficiencies has no place in the Clayton Act. This is particularly true where the challenged transaction is not a horizontal one and the FTC's case hinges on a speculative bundling theory never before adopted by a court.

C. Plaintiffs' Administrative Process Runs Afoul of the Constitution.

Even if Plaintiffs could show that the Transaction will substantially lessen competition (which they cannot) and even if there were no offsetting efficiencies (which there are), Plaintiffs cannot show a likelihood of success and meet their burden to obtain a preliminary injunction because the relief they seek is predicated on the outcome of an administrative proceeding that runs afoul of multiple provisions of the U.S. Constitution. As described in Defendants' counterclaims (Dkt. 77) and pending motion for summary judgment on those counterclaims (Dkt. 125), the FTC's administrative process violates multiple provisions of the U.S. Constitution:

- The FTC's unbounded discretion to initiate proceedings before an administrative tribunal or federal court violates constitutional limits on delegation of Article I power;

- The for-cause restrictions on removal of the FTC Commissioners who voted to bring the administrative complaint and the FTC ALJ who will hear the case violate the "Take Care" clause of Article II;
- The FTC's multiple roles as investigator, prosecutor and judge violate the Due Process Clause of the Fifth Amendment; and
- The process by which responsibility for this matter was assigned to the FTC as opposed to the Department of Justice—an assignment that subjects Defendants to a materially disadvantageous administrative process—lacks a rational basis and thus violates the Equal Protection Clause of the Fifth Amendment.

The Court *need not* reach Defendants' constitutional affirmative defense and counterclaims to rule on the FTC's motion. The Court can and should deny the preliminary injunction because the FTC's speculative future cross-benefit bundling theory lacks any basis in modern legal standards or real-world facts—including, among many others, the fact that Amgen has repeatedly committed not to engage in the exact hypothesized conduct described in the Amended Complaint. But the unconstitutionality of the FTC's administrative process provides additional and alternative bases for denying the preliminary injunction.

III. THE EQUITIES WEIGH AGAINST A PRELIMINARY INJUNCTION.

Because Plaintiffs cannot demonstrate a likelihood of ultimate success on the merits, the Court can deny their motion without balancing the equities. *Herrera v. Raoul*, No. 23 CV 532, 2023 WL 3074799, at *13 (N.D. Ill. Apr. 25, 2023) (balancing equities not required when Court determines Plaintiff has not demonstrated a likelihood of success on the merits). This Court should find, however, "that even if the FTC had met its burden, the balance of the equities do not fall in its favor." *Microsoft*, 2023 WL 4443412, at *21. "[T]he balancing of equities is not a pointless exercise", as Plaintiffs would lead this Court to believe. *Id.* Even if the Court were to

conclude that there were evidence in favor of Plaintiffs' theory (and it should not) there is no question that there is also at least "conflicting evidence on the anticompetitive effects of the merger", *id.* at 22, such as the absence of any complaining third parties, the absence of any corroborating documents, and the completely novel and unprecedented nature of the conduct Plaintiffs claim would occur. On such a record, the law is clear that "the FTC cannot point to beneficial economic effects as a public equity." *Id.* Moreover, the "public equities may include beneficial economic effects and pro-competitive advantages for consumers", which Defendants will show are well established on the record. *Id.* at *21 (quoting *Warner*, 742 F.2d at 1165). In sum, and for the reasons below, "the balanc[ing] of equities is a separate, independent reason the FTC's motion must be denied". *Id.* at *22.

A. A Preliminary Injunction Would Likely Kill This Beneficial Transaction.

Preliminary injunctive relief is inappropriate if it gives to a plaintiff "the actual advantage which would be obtained in a final decree." *Harlem Algonquin LLC v. Canadian Funding Corp.*, 742 F. Supp. 2d 957, 962 (N.D. Ill. 2010) (quoting *W.A. Mack, Inc. v. Gen. Motors Corp.*, 260 F.2d 886, 890 (7th Cir. 1958)) ("This adage applies to the balance of equities, because granting a plaintiff final relief at the outset of the case would completely undercut the protections due a defendant. Not only would the plaintiff receive final relief without meeting his burden, but the defendant would often suffer a harm that cannot be undone.").

Granting Plaintiffs' motion would in all likelihood kill the Transaction because the Transaction Agreement contains a "Drop-Dead Date" of December 12, 2023. (Ex. 22, PX5005-014.[28]) There is no prospect the administrative proceeding will be completed by then, given that the hearing does not begin until November 8, 2023. Under the applicable statutory framework,

[28] Pursuant to the Transaction Agreement, a preliminary injunction would also trigger Amgen's obligation to issue a Reverse Termination Payment to Horizon of $974,415,054. (Ex. 22, PX5005-092-93.)

the Commission could not rule until well into 2024. 16 C.F.R. § 3.51 (providing that the ALJ "shall file a recommended decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order pursuant to § 3.46"). Thus, a preliminary injunction is not a mere hold on the Transaction until the Part III administrative proceeding plays out as Plaintiffs suggest. Here, a preliminary injunction would effectively be a permanent injunction scuttling the Transaction and the patient benefits it otherwise will deliver.

Plaintiffs argue that "[i]f Defendants are permitted to merge immediately and begin sharing proprietary information and integrating their complex workstreams, it would be extremely difficult, if not impossible, to unwind the damage and return to the status quo, and Plaintiffs would be thwarted from ever obtaining full relief." (Br. at 35.) But Plaintiffs cite nothing merger-specific to support their argument. These generalized allegations of harm are insufficient to tip the balance in Plaintiffs' favor. *Microsoft*, 2023 WL 4443412, at *22. This is especially true here since, if there were a legal and evidentiary basis, the FTC could fashion a remedy through its administrative process that prevents Amgen from bundling its products with TEPEZZA® and KRYSTEXXA® (*supra* II.A.2.a), so there would be no need to "unwind" Defendants' integration.

B. <u>The Requested Remedy is Extreme and Unnecessary.</u>

Enjoining the Transaction would forego the numerous benefits it will produce in the near term to avoid imagined harms that are not only years away at the soonest, but that could easily be addressed by a less intrusive remedy. If (hypothetically) Amgen ever engaged in activity unlawful under the antitrust laws, the FTC could file suit at that time under the Sherman Act and Section 5 of the FTC Act. There is simply no good reason, and no legal basis under Section 7 of the Clayton Act, to prevent the consummation of a highly complementary Transaction, and to forestall the benefits it will deliver to patients in need, when the alleged conduct not only is

entirely unfounded, but also addressable under the antitrust laws if, hypothetically (and contrary to Amgen's commitment not to engage in such conduct), it ever occurred in the future.[29] (Gilbert § VII.)

The equities are especially against an injunction here because, as discussed, Amgen has made an explicit binding commitment not to engage in the alleged conduct, making the supposed harm all the more remote and implausible. *See Cassell v. Snyders*, 990 F.3d 539, 549 (7th Cir. 2021). Moreover, the alleged harm to potential entrants to the TED or CRG markets is, at the earliest, several years away (if it ever occurs). Thus, even under Plaintiffs' theory, there will be no harm before the ALJ is able to rule on the permanent injunction.[30] *Cf. Microsoft*, 2023 WL 4443412, at *22 ("By pre-existing contract, Call of Duty will remain on PlayStation through the end of 2024. There will be no foreclosure of Call of Duty pending the ALJ's decision.").

C. Granting Plaintiffs' Motion Would Harm Patients.

Patients will be harmed if the injunction is granted. Courts routinely assign great weight to harm to patients when balancing the equities. *See Roudachevski v. All-Am. Care Ctrs., Inc.*, 648 F.3d 701, 707 (8th Cir. 2011) (upholding district court's determination that "any potential harm . . . is outweighed by the likely injury to patient care and order").[31]

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[29] *See City of Chicago v. Barr*, 961 F.3d 882, 930 (7th Cir. 2020) (granting "narrowest [injunctive] relief that will redress the injury"); *City of Chicago v. Barr*, 513 F. Supp. 3d 828, 837 (N.D. Ill. 2021) ("Injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."); *see also Tolentino v. Baker*, 679 F. App'x 503, 504 (7th Cir. 2017) ("granting the injunction would violate [the] requirement that injunctive relief be narrowly drawn, not more than necessary, and the least intrusive means to correct harm warranting relief").

[30] Thus, the FTC's lead cases for why a preliminary injunction is required to preserve competition are inapplicable. (*E.g.*, Br. at 4 (citing *Elders Grain* for the proposition that failing to grant the preliminary injunction "will deprive consumers and suppliers of the benefits of competition" while the administrative trial is pending)). Here, the hypothesized effects are not at all possible for years into the future.

[31] *See also Commonspirit Health v. Emerge Clinical Sols., LLC*, No. 3:22-CV-2750-L, 2022 WL 17903800, at *2 (N.D. Tex. Dec. 23, 2022) ("the threatened harm to Plaintiff and its many patients outweighs any threatened harm to Defendant"); *Little Rock Fam. Plan. Servs. v. Jegley*, 549 F. Supp. 3d

Here, Amgen can and will use its manufacturing, distribution, marketing, promotional and medical expertise and capabilities to increase patient access to Horizon's rare disease products more efficiently and reliably than Horizon could on its own, including by getting the products to underserved communities in the United States in ways that will greatly ease the suffering of patients who are dealing with the debilitating illnesses that Horizon's products are indicated to treat. (Ex. 24, PX9007-002.) The evidence also demonstrates Amgen's commitment and ability to innovate with Horizon's products and pipeline to make its treatments more accessible to more patients. Enjoining the Transaction will deprive patients suffering from debilitating illnesses from these important benefits. (*See* Ex. 10, Bradway Dep. 58:9-62:25.) This Court should protect patients and their access to the therapies they need. The equities here overwhelmingly favor denying Plaintiffs' requested preliminary injunction.

D. Enjoining the Transaction Would Chill Innovation Well Beyond This Case.

Another reason the equities cut against an injunction is the chilling effect it would have on innovation beyond this case. Entering a preliminary injunction on the flimsy theory and dearth of evidence presented by Plaintiffs here would not only kill the Transaction, but it would also discourage others in the pharmaceutical industry from developing new drugs and expanding access to existing drugs.[32] Further, granting a preliminary injunction under Plaintiffs' novel

922, 936 (E.D. Ark. 2021) ("After balancing the relative injuries and the equities . . . the Court concludes that greater . . . harm [would result] to plaintiffs and their patients than to the State."); *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 501 (D. Md. 2020) ("The interests of affected patients . . . certainly may be considered in weighing the balance of equities and the public interest.").

[32] Misplaced enforcement chills innovation. Dave Michaels & Joseph Walker, *FTC Moves to Block Amgen's $27.8 Billion Deal for Horizon Therapeutics*, WSJ, May 16, 2023 ("The agency's aggressiveness could chill company deal making."); Editorial Board, *Antitrust Gone Wild Against Amgen*, WSJ, May 18, 2023 ("Investors fund start-ups on the expectation they will be acquired. Ms. Khan's lawsuit will disrupt their calculations and hamper investment and innovation".); Sean Reyes, *The DOJ and FTC's Antitrust Policy Will Kill Tech Innovation*, Wash. Exam'r, June 28, 2023 ("The [FTC's] approach . . . has upended decades of relatively stable antitrust enforcement standards and has had a

theory would lead to confusion in the business community about which mergers, if any, are lawful in Plaintiffs' eyes. For this additional reason, the Court should find that the equities weigh against an injunction. *See TP Grp.-Ci, Inc. v. Smith*, No. 16-C-7463, 2016 WL 6647947, at *18 (N.D. Ill. Nov. 10, 2016) (it "is true" that "[t]he public interest favors innovation and competition"); *iQuartic, Inc. v. Simms*, No. 15-13015, 2015 WL 5156558, at *6 (D. Mass. Sept. 2, 2015) ("creating innovation incentives are in the public interest"); *Wagner Aeronautical, Inc. v. Dotzenroth*, No. 21-CV-0994, 2022 WL 6837701, at *10 (S.D. Cal. Oct. 7, 2022) ("Preserving and protecting innovation . . . is clearly in the public's interest.").

E. The Equities Favor Upholding the Constitution.

Finally, the equities favor denying the injunction for the independent reason that granting it would further an administrative process that violates several of Defendants' constitutional rights, as outlined in Defendants' motion for summary judgment. (Dkt. 125.) By contrast, denying the motion would "uphold[] the constitutional rights" of Defendants which "serves the public interest." *Joelner v. Vill. of Wash. Park, Ill.*, 378 F.3d 613, 620 (7th Cir. 2004); *see also G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23. F.3d 1071, 1079 (6th Cir. 1994) ("[I]t is always in the public interest to prevent the violation of a party's constitutional rights.").

CONCLUSION

For the foregoing reasons, Amgen and Horizon respectfully request that the Court deny Plaintiffs' motion for a preliminary injunction.

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chilling effect in several economic sectors."); Ted Love, *New Attacks On The Drug Industry Would Have Made My Breakthrough Sickle Cell Treatment Impossible*, STAT, July 31, 2023 ("If the FTC clamps down on mergers, it will push companies to build duplicate global distribution systems, which is inefficient at best and simply unaffordable for smaller businesses. Mergers like the Amgen-Horizon deal expand global access to medicines, plain and simple.").

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New York, New York

Respectfully submitted,

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