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.

C.A. No. 1:23-cv-03053

REDACTED – PUBLIC VERSION

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

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Pharmaceutical manufacturers will do whatever they can to extend the lifetime of their monopoly products. *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136, 141-42, 144-45 (2013) (describing an anticompetitive scheme by which a branded pharmaceutical manufacturer paid over $250 million to would-be competitors in return for their agreement to delay launch of competing generic drugs). Once a drug's monopoly erodes and new competitors enter the market, profitability will diminish as competition drives prices lower. Although increased treatment options and lower prices would greatly benefit patients, for pharmaceutical manufacturers such as Amgen, this phenomenon provides an incentive to protect its monopoly profits.

Amgen Inc. proposes to acquire Horizon Therapeutics plc in a transaction valued at approximately $27.8 billion (the "Proposed Merger"). The Proposed Merger's value is primarily tied to reaping profits from a pair of Horizon's highly lucrative monopoly drugs. Facing impending competition, post-merger, Amgen will have every incentive to preserve these monopolies to maximize the return on its $27.8 billion investment. In seeking to stifle competition, Amgen will most likely turn to the strategy it already employs—leveraging its existing drug portfolio to entrench the monopoly positions of the drugs acquired through the Proposed Merger. As a result, the Proposed Merger may substantially lessen competition and tend to preserve monopolies for Amgen in two critical markets, the sale of FDA-approved drugs to treat thyroid eye disease ("TED") and chronic refractory gout ("CRG"). Lack of competition in these markets will reduce patients' access to drugs that might provide the best treatment, in favor of the merged firm's entrenched monopoly drugs, as well as insulate the merged firm's drugs from price competition.

The Federal Trade Commission ("Commission") issued an administrative complaint on June 22, 2023. The issue before the Court is the Commission's and the Plaintiff States' (collectively, "Plaintiffs") request that it preliminarily enjoin Defendants from completing the

Proposed Merger pending administrative adjudication of that complaint. Absent a preliminary injunction, Defendants can close their Proposed Merger before the administrative proceeding concludes. Pursuant to a Stipulated Order, Defendants have agreed to defer consummation of the Proposed Merger only until October 31, 2023 or two business days after a ruling by this Court on the FTC's motion. Stipulated Order at 2, ECF No. 60. Closing the Proposed Merger prior to full administrative review would harm competition and deprive the Plaintiffs of the ability to obtain relief. To preserve the status quo, the Plaintiffs respectfully request that the Court enter a preliminary injunction, under 15 U.S.C. § 53(b), to prevent Defendants from merging until the Commission can adjudicate the Proposed Merger's legality.

LEGAL STANDARDS

Section 7 of the Clayton Act prohibits mergers that "may" substantially lessen competition or "tend to" create a monopoly in any line of commerce. 15 U.S.C. § 18; *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 902 (7th Cir. 1989) ("Section 7 forbids corporate acquisitions that *may* lessen competition substantially or *tend to* create a monopoly.") (emphasis added). The Commission found "reason to believe" that the Proposed Merger may have such anticompetitive effects, and thus commenced an administrative proceeding to determine whether the Proposed Merger violates Section 7 of the Clayton Act and Section 5 of the FTC Act, 15 U.S.C. §§ 18, 45. Section 13(b) of the FTC Act enables the Commission to seek to preserve the status quo in this situation and authorizes the Court to issue a preliminary injunction pending administrative adjudication of the Proposed Merger's legality. 15 U.S.C. § 53(b); *Elders Grain*, 868 F.2d at 902. Section 16 of the Clayton Act enables the State Plaintiffs to bring this action on behalf of each respective State. 15 U.S.C. § 26.

When the Commission seeks to preserve the status quo pending administrative review of a merger challenge, the FTC need not present "detailed evidence of anticompetitive effect at this

preliminary phase," and the Court should grant preliminary relief where the FTC "raise[s] substantial doubts about a transaction." *FTC v. Advoc. Health Care*, No. 15 11473, 2017 WL 1022015, at *2 (N.D. Ill. Mar. 16, 2017) (quoting *FTC v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1074 (N.D. Ill. 2012)); *see also FTC v. Rhinechem Corp.*, 459 F. Supp. 785, 789 (N.D. Ill. 1978) (citation omitted); *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 883 (E.D. Mo. 2020) (quoting *FTC v. Freeman Hosp.*, 69 F.3d 260, 267 (8th Cir. 1995)). "A certainty, even a high probability [of anticompetitive effect], need not be shown . . . and doubts are to be resolved against the transaction." *Elders Grain*, 868 F.2d at 906. If the FTC raises such doubts, the Court should grant injunctive relief "where such action would be in the public interest," as determined by "weighing the equities." *Id.* at 902.

When weighing the equities, private considerations must give way to public concerns because "[t]he public has strong interests in the effective enforcement of the antitrust laws and in preserving [the FTC's] ability to order effective relief if it succeeds after a trial on the merits." *Advoc. Health Care*, 2017 WL 1022015 at *16 (quoting *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 61, 86 (D.D.C. 2015)). States, likewise, have a *parens patriae* interest in the economic welfare of their residents and in participating in a fair and competitive economy. *See Alfred L. Snapp Son, Inc. v. Puerto Rico*, 458 U.S. 592, 605-08 (1982). Thus, while private equities may be considered, "public equities must receive far greater weight." *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1030 (7th Cir. 1988) (quoting *FTC v. Warner Commc'ns, Inc.*, 742 F.2d 1156, 1165 (9th Cir. 1984)); *see also Elders Grain*, 868 F.2d at 903 ("[A] countershowing of private equities alone would not suffice to justify denial of a preliminary injunction barring the merger.") (citation omitted).

Here, the only potential harm to private interests is delaying Defendants' ability to close

the Proposed Merger until the Commission can adjudicate the Proposed Merger's legality. In contrast, public interests would permanently and irreparably suffer if Amgen and Horizon merged sooner. Competition would be injured, and the status quo, in which Defendants are separate, would be extremely difficult—if not impossible—to restore. As the Seventh Circuit has recognized, "[i]f the acquisition seems anticompetitive, then failing to stop it during the administrative proceedings will deprive consumers and suppliers of the benefits of competition *pendente lite* and perhaps forever, for it is difficult to undo a merger years after it has been consummated." *Elders Grain*, 868 F.2d at 904; *see also id.* at 905 (stating that the "effects [of an anticompetitive merger] will be magnified if the acquisition is allowed to go forward during the period of administrative challenge, especially if that period is so protracted as to defeat the prospects for effective divestiture at the end"); *Rhinechem Corp.*, 459 F. Supp. at 787 (Section 13(b)'s "unique 'public interest' standard" reflects Congress's recognition of the difficulty of "effectuat[ing] a remedy once an acquisition is consummated") (internal citations omitted); *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 727 (D.C. Cir. 2001) ("If the merger is ultimately found to violate section 7 of the Clayton Act, it will be too late to preserve competition if no preliminary injunction has issued."). Accordingly, the Court should issue a preliminary injunction to prevent Defendants from consummating the Proposed Merger pending administrative adjudication of the Proposed Merger's legality.

STATEMENT OF FACTS

I. Prescription Drug Coverage and Reimbursement

Most individuals in the United States have insurance that covers some or all of the cost of prescription medications. Insurance coverage is provided by plan sponsors, which are often employers. Plan sponsors generally either pay a commercial health insurer to bear the financial risk of insurance claims, or else bear the financial risk themselves. Payers—commercial health insurers or the government—"bear the cost of the prescribed drug." PX9000, Expert Report of Dr.

Aaron Kesselheim (July 7, 2023) ("Kesselheim Report") ¶ 46. Drugs dispensed by retail pharmacies are covered under payers' pharmacy benefits, which are typically negotiated and managed by pharmacy benefit managers ("PBMs") on behalf of the payers; drugs injected or infused by a healthcare professional in an outpatient setting typically are covered under payers' medical benefits. PX9000 (Kesselheim Report) ¶¶ 24, 55, 183. These medical benefit policies are either negotiated directly by payers or by medical benefit managers on behalf of the payers. PX9000 (Kesselheim Report) ¶ 183; [redacted] However, "the lines between pharmacy benefit and medical benefit have increasingly blurred in recent years as payors and PBMs integrate operations." PX9000 (Kesselheim Report) ¶ 24.

For large drug manufacturers like Amgen, a core component of their business model is to increase sales or expand market share such that its drugs will be used by as many providers and patients as possible. One common method to increase sales or gain market share is through negotiations over prescription drug coverage. Payers use formularies, medical benefit policies, and a number of other tools to set out which prescription medications they will cover on behalf of their members, which in turn influences drug utilization (i.e., which prescription medications providers and patients are likely to use). Drugs with broader payer coverage allow for greater utilization by both providers and patients, which translates into increased sales and expanded market share.

Drug manufacturers, including Amgen, frequently offer rebates and other inducements that influence payers' formularies and benefit policies, and thus [redacted] When drug manufacturers face competition for a particular treatment, payers—or intermediaries such as PBMs and medical benefit managers

negotiating on the payers' behalf—can play competing manufacturers off one another, negotiating for higher rebates in exchange for more preferential coverage decisions.

Some drug manufacturers, including Amgen, also use rebates to evade direct competition on the merits through the use of cross-market bundling. Cross-market bundling involves conditioning rebates on one product in exchange for preferred coverage on other products. Rather than directly competing on the merits to provide more affordable or higher quality treatments for a given condition, cross-market bundling allows manufacturers to leverage the strength of their broader portfolio to prop up unrelated products. Such multi-product deals undermine competition by distorting how PBMs and payers make decisions about which drugs to make available to patients. To illustrate, Amgen will negotiate significant rebates on [redacted]—which can amount to [redacted] of dollars in payments to payers, PBMs, health plans, and plan sponsors—in exchange for exclusive or preferred placement for Amgen's other drugs. Amgen's ordinary course documents acknowledge this, stating, [redacted]

II. Amgen's Broad Product Portfolio

Amgen has a diverse portfolio of both pharmacy benefit and medical benefit products that includes 27 U.S. Food and Drug Administration ("FDA")-approved medicines. PX0009 at 002 (Amgen, Ltr. To Shareholders & 2022 10-K). The company earned $26.3 billion in total revenue in 2022. PX0009 at 002. Nine of Amgen's drugs generated more than $1 billion in annual net sales

each (i.e., inclusive of rebates and discounts),[1] with one product—Enbrel—comprising nearly 20% of total sales in 2021. *See* PX0009 at 077. Amgen's R&D efforts are focused primarily on three therapeutic areas: inflammation, oncology/hematology, and cardiovascular and metabolic diseases. PX0009 at 074.

III. Horizon's Drug Monopolies

Amgen is pursuing the Proposed Merger primarily for the projected profits of Horizon's products Tepezza and Krystexxa, which generated approximately $1.96 billion and $716 million in 2022 revenue, respectively. PX0002 at 008 (Horizon 2022 10-K). Tepezza treats Thyroid Eye Disease ("TED"), a rare autoimmune disease affecting over 60,000 Americans that, left untreated, can cause [redacted] Krystexxa treats Chronic Refractory Gout ("CRG"), a severe form of gout that affects patients whose symptoms are not sufficiently treated with therapies indicated to treat traditional gout. *See* PX0002 at 010 (Horizon 2022 10-K). As Amgen and Horizon acknowledge, Tepezza and Krystexxa are currently monopolies, facing no competition in the TED and CRG markets, respectively. Defs.' Answer at 2, ECF No. 77 (describing Tepezza as "the first and only FDA-approved treatment for thyroid eye disease ("TED")," and Krystexxa as "the first and only FDA-approved treatment for chronic refractory gout ("CRG")."); *see also* Argument I.A.1, *infra*. Accordingly, Horizon does not currently offer any rebates on these drugs because [redacted]. The annual revenue pools associated with these drugs are projected to grow substantially, to nearly $[redacted]

[1] These include Enbrel ($4.1 billion in 2022 worldwide sales), Prolia ($3.6 billion), Otezla ($2.3 billion), Xgeva ($2.0 billion), Aranesp ($1.4 billion), Nplate ($1.3 billion), Repatha ($1.3 billion), Kyprolis ($1.2 billion), and Neulasta ($1.1 billion).

for Tepezza and over $ [redacted] for Krystexxa, by 2031. [redacted]; *see also* Argument I.A.1, *infra* (noting high cost of these drugs).

IV. The Proposed Merger

Pursuant to a Transaction Agreement dated December 11, 2022, Amgen proposes to acquire Horizon in a transaction valued at approximately $27.8 billion. On June 2, 2023, the parties stipulated to, and the Court entered, an order reflecting Defendants' agreement not to consummate the Proposed Merger until the earlier of (i) October 31, 2023, or (ii) two business days after a ruling by this Court on the FTC's motion for a preliminary injunction. Stipulated Order at 2, ECF No. 60. On June 22, 2023, the Commission voted to file an administrative complaint alleging that the Proposed Merger would harm competition in the United States. The Commission also authorized staff to seek a preliminary injunction under Section 13(b) of the FTC Act, enjoining the Proposed Merger pending resolution of the administrative complaint. The administrative proceeding is scheduled to begin on October 25, 2023.

ARGUMENT

I. The Commission Is Likely to Succeed on the Merits

Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." 15 U.S.C. § 18. The Supreme Court explains that all mergers "must be tested by the same standard, whether they are classified as horizontal, vertical, conglomerate, or other." *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967). "Congress used the words '*may be* substantially to lessen competition' to indicate that its concern was with probabilities, not certainties." *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1073 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) (emphasis added)); *see also Elders Grain,* 868 F.2d at 906. Thus, "[a]ll that is necessary is that the merger create an appreciable danger

of [anticompetitive] consequences in the future." *FTC v. Advoc. Health Care Network*, 841 F.3d 460, 467 (7th Cir. 2016) (quoting *Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1389 (7th Cir. 1986)).

A merger violates Section 7 if post-merger the merged firm would possess the ability and incentive to weaken or disadvantage current or future rivals, and the merger increases the merged firm's ability and/or incentive. *See United States v. AT&T, Inc.*, 916 F.3d 1029, 1033-38 (D.C. Cir. 2019) (affirming case analyzed under ability and incentive framework); *In re Illumina, Inc.*, FTC Docket No. 9401, at 41 (Mar. 31, 2023). A related, but distinct, framework applied by the Supreme Court is to examine whether it is reasonably probable that the merger 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. *See Procter & Gamble*, 386 U.S. at 578; *United States v. Wilson Sporting Goods Co.*, 288 F. Supp. 543, 550-56 (N.D. Ill. 1968).

At this juncture, under either test, Plaintiffs meet their burden if they "raise substantial doubts about the transaction," and need not show "detailed evidence of anticompetitive effect at this preliminary phase." *Advoc. Health Care*, 2017 WL 1022015, at *2 (quoting *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1074); *see also Warner Commc'ns*, 742 F.2d at 1162; *Heinz*, 246 F.3d at 714-15. Because the issue is a "narrow one," the Court at this stage "do[es] not resolve the conflicts in the evidence, compare concentration ratios and effects on competition in other cases, or undertake an extensive analysis of the antitrust issues." *Warner Commc'ns*, 742 F.2d at 1164; *see also OSF Healthcare*, 852 F. Supp. 2d at 1073-74. It is not until the administrative proceeding, which will provide a forum for all parties to present plenary evidence regarding the likely effects of the merger with up to 210 hours of live testimony, 16 CFR § 3.4, that the FTC will exercise its

congressionally vested authority to determine, upon a full evidentiary record, the merger's legality. *Heinz*, 246 F.3d at 713-14; *FTC v. CCC Holdings, Inc*., 605 F. Supp. 2d 26, 35 (D.D.C. 2009).

A. The Proposed Merger May Substantially Lessen Competition or Tend to Create a Monopoly in the TED and CRG Markets

Although Tepezza and Krystexxa are currently monopolies, and the revenue pools associated with these drugs are projected to grow substantially in future years, the profitability of these drugs, and thus the Proposed Merger, could be threatened by rivals' products that are in late-stage development. Unlike Horizon, Amgen has a broad portfolio of blockbuster drugs that it can leverage to gain anticompetitive advantages over soon-to-be rivals. In particular, Amgen often uses cross-market bundling, which involves conditioning rebates on one of its blockbuster products in exchange for preferred formulary placements for one of Amgen's other products. In other words, Amgen pays PBMs, health plans, and plan sponsors—through rebates on its blockbuster products—to favor its less competitive drugs over a rival's potentially cheaper or better competing product. By combining Amgen's portfolio of blockbuster drugs and contracting leverage with Horizon's highly lucrative products, the deal would give the merged firm the ability and incentive to raise barriers to new entry and thereby entrench Tepezza's and Krystexxa's monopolies, depriving patients, providers, and health plans of the benefits of competition and access to new options for treating TED and CRG.

1. The Relevant Product Markets Are the Sale of FDA-Approved Drugs to Treat TED and CRG

The relevant product market is the "line of commerce" affected by a Proposed Merger. *Brown Shoe*, 370 U.S. at 324. To determine the validity of a relevant antitrust market definition, courts generally look to two types of evidence: the "practical indicia" set forth by the Supreme Court in *Brown Shoe* and testimony from experts in the field of economics regarding the Hypothetical Monopolist Test ("HMT"). Courts evaluate "practical indicia" such as "(1) the

industry or public recognition of the submarket as a separate economic entity, (2) the product's peculiar characteristics and uses, (3) unique production facilities, (4) distinct customers, (5) distinct prices, (6) sensitivity to price changes, and (7) specialized vendors." *Beatrice Foods Co. v. FTC*, 540 F.2d 303, 308 (7th Cir. 1976) (citing *Brown Shoe*, 370 U.S. at 325). Courts and the Commission may, alternatively or in addition, use the HMT to assess the relevant product market. *See Advoc. Health Care Network*, 841 F.3d at 468-69 (applying the HMT to define a relevant geographic market); *see also FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 338 (3d Cir. 2016); *FTC v. Hackensack Meridian Health, Inc.*, 30 F.4th 160, 167 (3d Cir. 2022). The practical indicia, as well as analysis performed by Plaintiff's economic expert Dr. David Sibley, including an HMT, show that the relevant product markets here are (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"). In similar scenarios, courts have routinely defined the relevant market as prescription drug treatments for a specific disease or condition. *FTC v. Shkreli*, 581 F. Supp. 3d 579, 630 (S.D.N.Y. 2022); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at *15 (E.D. Pa. Oct. 30, 2017).

a. The Sale of FDA-Approved Drugs to Treat TED is a Relevant Product Market

Tepezza is the "[f]irst and only FDA approved treatment for TED." PX3029 at 005 (Horizon presentation). Tepezza has been designated an "orphan drug" by the FDA, which reflects a determination that there are no reasonably interchangeable substitutes for Tepezza for the treatment of TED, and that before Tepezza's approval, no adequate drug to treat TED had been developed. *See* PX0010 (FDA News Release, Jan. 2020); Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049; *see also* PX9000 (Kesselheim Report) ¶ 22. The primary other treatments physicians may use to try to treat "disruptive or disabling" TED include the off-label use of steroids

or immunosuppressive agents such as rituximab, orbital radiation therapy, and surgery. PX9003, Expert Report of Dr. Kimberly P. Cockerham (July 7, 2023) ("Cockerham Report") ¶ 46. However, as Defendants' ordinary course documents recognize, these treatments are not reasonable substitutes for Tepezza. For example, one Horizon document highlights that Tepezza is different from other TED treatments because it [redacted] Tepezza's safety and efficacy likewise differentiate it from non-drug treatments. [redacted]

Physicians who treat TED confirm that they prescribe Tepezza (if covered by insurance) instead of steroids or surgery because Tepezza is "more efficacious" at curtailing inflammation than both steroids and surgery and is also less invasive and less risky than surgery. PX7012 ¶ 2 (Tamhankar, Decl.). Similarly, Dr. Cockerham, an expert in treating TED, explained that Tepezza "is the only FDA approved treatment indicated for the treatment of TED. Although there are other treatments currently used to reduce some of the inflammation caused by TED, these treatments do not address the autoimmune response that is the root of, and which causes the various symptoms, associated with TED." PX9003 (Cockerham Report) ¶ 45.

Tepezza also has distinct customers and pricing. Horizon's Executive Director, Access Strategy & Marketing, testified that steroids are [redacted] Tepezza's pricing is likewise distinct from other treatments for TED. *Compare* [redacted]; PX9003 (Cockerham Report) ¶ 13 ("TEPEZZA's cost is at least $350,000 for eight infusions."), *with* Shreya Ashish Shah et al., *Comparison of treatment cost and quality-of-life impact of thyroid eye disease therapies*, 63 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 4002 (2022) (estimating average price for treating TED with intravenous methylprednisolone at approximately $4,000 and orbital radiotherapy at approximately $4,300).

Voluminous documents and testimony confirm that Defendants and industry participants consider Tepezza to be the only drug that is approved to treat TED. Amgen's own ordinary course documents that analyze the [redacted] Horizon, in its 2022 10-K, admits that Tepezza "does not face direct competition." PX0002 at 010. These factors confirm that the sale of FDA-approved drugs to treat TED is the relevant market for Tepezza as there are no other reasonably interchangeable substitutes. Relying on the testimony of Dr. Cockerham, an expert in the treatment of TED, Dr. David Sibley, Plaintiff's economic expert, similarly concluded that the sale of FDA-approved drugs to treat TED is a relevant product market because "there are currently

no alternative treatments that are reasonably interchangeable" for Tepezza. PX9001, Expert Report of David Sibley, Ph.D. (July 7, 2023) ("Sibley Report") ¶ 92; *see also* PX9001 § 3.1b.i.

Alternatively or in addition to these practical indicia, courts often consider the HMT, which asks whether a hypothetical firm that controls the entire candidate product market could "raise prices profitably a bit above competitive levels," also referred to as a small but significant non-transitory increase in price ("SSNIP"). *Advoc. Health Care Network*, 841 F.3d at 465 (quoting U.S. Dep't of Justice & FTC, *Horizontal Merger Guidelines* (2010) § 4.1.1 ("*Horizontal Merger Guidelines*")). As Dr. Sibley and the Commission have recognized, a traditional SSNIP test may not be applicable where a party already has monopoly power in a market or incomplete data exists. *See* PX9001 (Sibley Report) ¶¶ 76, 79, 93, 114; *see also In re Illumina, Inc*., FTC Docket No. 9401, at 29 n.15 (noting that "markets can be delineated using other evidence when the HMT cannot be run," particularly in markets where competing products have not yet been commercialized). As the Commission explained, "[t]he ultimate goal is to determine whether a merger may substantially lessen competition, *Horizontal Merger Guidelines* § 4.1.3, and the Commission uses the data and tools that are available for that inquiry." *In re Illumina, Inc*., FTC Docket No. 9401, at 29 n.15. Here, to perform the SSNIP test, Dr. Sibley considered whether "current prices [for monopolist Tepezza are] higher than the prices that we would expect following entry (the prices we expect absent the transaction)," and determined they are, providing another basis on which conclude that the sale of FDA-approved treatments for TED is a relevant antitrust market. PX9001 (Sibley Report) ¶¶ 93-98.

b. The Sale of FDA-Approved Drugs to Treat CRG is a Relevant Product Market

Krystexxa is "the first and only FDA-approved treatment for" CRG, and, like Tepezza, received orphan drug designation from the FDA. Defs.' Answer, ECF No. 77 at 2, 23. Krystexxa

has biosimilar exclusivity until [redacted] and patent exclusivity until [redacted].[2] [redacted] Although other treatments exist for conventional gout, they are not functional substitutes for Krystexxa, which is prescribed to patients who have not seen results from conventional gout treatments. [redacted] In addition to the distinct patient base and lack of reasonable substitutes, the cost of Krystexxa is significantly higher than the standard treatments available for gout. [redacted]

Dr. Herbert S. B. Baraf, an expert in the treatment of CRG, explained that CRG patients are those that have not responded to traditional therapies, such as uric acid lowering drugs, and that these traditional therapies "do not directly treat gout flares." PX9002, Expert Report of Dr. Herbert S. B. Baraf (July 7, 2023) ("Baraf Report") ¶¶ 33-34. Based on economic theory and the expert opinion of Dr. Baraf, Plaintiff's economic expert Dr. Sibley similarly concluded that the sale of FDA-approved treatments for CRG, currently including only Krystexxa (pegloticase), is a relevant product market because there are currently no reasonably interchangeable substitutes for Krystexxa, and because current prices are "higher than the prices that we would expect following

[2] Krystexxa [redacted]

entry (the prices we expect absent the transaction)." PX9001 (Sibley Report) ¶ 113; § 3.1.c. Accordingly, the sale of FDA-approved drugs to treat CRG is a relevant product market.

2. The United States Is the Relevant Geographic Market

The relevant geographic market is the area where a potential buyer "can practicably turn" for the goods or services sought. *Advoc. Health Care*, 2017 WL 1022015, at *3. The geographic market "must correspond to the commercial realities of the industry." *Advoc. Health Care*, 841 F.3d at 468 (quoting *Brown Shoe*, 370 U.S. at 336) (internal quotation marks omitted). Here, the relevant geographic market is the United States. Drugs to treat TED and CRG are regulated and approved by the FDA. [redacted] Accordingly, products sold outside the United States, but not approved for sale in the United States, do not provide viable alternatives for customers. The *Brown Shoe* practical indicia also support the conclusion that the United States is the relevant geographic market. For example, Defendants' internal documents and testimony discuss different approval processes and business development strategies for Tepezza and Krystexxa in the United States and in other countries, indicating that Defendants recognize the United States as a distinct geographic market. [redacted] Dr. Sibley similarly concluded that the relevant geographic market is the United States. PX9001 (Sibley Report) § 3.2.

3. There is a Reasonable Probability the Proposed Merger Will Substantially Lessen Competition or Tend to Create a Monopoly

Under both the ability and incentive framework and entrenchment framework, the evidence justifies the requested temporary relief. Under either framework, the evidence "raises substantial doubts" regarding whether the Proposed Merger creates a reasonable probability of substantially

lessening competition or tending to create a monopoly in the relevant markets. *See Advoc. Health Care*, 2017 WL 1022015, at *2.

a. Amgen Will Have the Ability and Incentive to Foreclose TED and CRG Rivals Post-Merger

A merger violates Section 7 if post-merger the merged firm would possess both the ability and incentive to weaken or disadvantage current or future rivals and the transaction is likely to increase the ability and/or incentive of the merged firm to weaken its rivals. *See In re Illumina, Inc.*, FTC Docket No. 9401, at 41; *see also, e.g.*, *id.* at 47-49; *United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 243-46 (D.D.C. 2018) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors). Post-merger, the merged firm will combine Amgen's portfolio of blockbuster drugs and Horizon's monopoly positions with Tepezza and Krystexxa. With those monopoly positions threatened by rival drugs in development, the Proposed Merger will provide the combined firm with a strong incentive to protect Tepezza's and Krystexxa's market dominance and the ability to do so by leveraging the merged firm's large portfolio of blockbuster drugs.

i. Ability to Leverage Its Drug Portfolio

Amgen's diverse portfolio of products—with nine different drugs generating more than $1 billion in annual net sales each—may increase the merged firm's ability to maintain monopolies for Tepezza and Krystexxa. The most likely tactic Amgen could employ to maintain these monopolies is leveraging its broad portfolio of products to secure preferred access for Tepezza and Krystexxa without competing on the merits of the drugs.

Amgen commonly refers to the bargaining leverage it possesses based on its diverse portfolio as its "portfolio leverage," and it has relied on "portfolio contracting" or "cross-market bundling" to distort how PBMs and payers make decisions about which drugs to make available

to patients. In other words, Amgen conditions valuable rebates on one or more products in exchange for preferred access for its other products at the expense of rivals' drugs. [redacted] An email from Amgen's Executive Director/General Manager, National Accounts explained the strategy as an [redacted] which included [redacted] and [redacted]

Amgen's ordinary course documents explain the effectiveness of its portfolio leverage over payers and PBMs. In one email, Amgen's Executive Director, Inflammation Payer Contracting and Pricing requested that a colleague [redacted]

Since at least 2020, Amgen has entered [redacted] separate contracts for multi-product drug bundles with multiple payers and the [redacted]

[redacted] Many of these bundle contracts use [redacted] one of Amgen's most successful products, as leverage. [redacted] In fact, in the context of previous acquisitions, such as Amgen's 2022 acquisition of ChemoCentryx, Amgen analyzed how it could [redacted]

One cross-market bundle which Amgen negotiated with [redacted] Amgen's conduct in this instance prompted a private lawsuit alleging distinct, but similar, violations of the antitrust laws. [redacted] Regeneron filed a May 2022 federal complaint alleging that such bundling was an anticompetitive means to foreclose its product from competing with Amgen's Repatha. Compl. at ¶¶ 8, 19, *Regeneron Pharms., Inc. v. Amgen Inc.*,

1:22-cv-00697-UNA (D. Del. May 27, 2022). The federal court overseeing that lawsuit concluded that Regeneron had plausibly stated a claim, denying Amgen's motion to dismiss. *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 22-697-RGA, 2023 WL 2587809 (D. Del. Mar. 21, 2023). Post-merger, Amgen will be able to employ the same tactic to maintain exclusivity for Tepezza and Krystexxa. And while payers and PBMs may enjoy the financial benefit of a rebate on [redacted] the patients who rely on Tepezza and Krystexxa will not benefit from that rebate and will be left with an entrenched monopolist controlling the drugs they so desperately need.

Payers dislike bundles because [redacted] With Amgen, however, it may be particularly difficult for payers to resist cross-market bundles because blockbuster drugs like [redacted] are among the most highly rebated drugs and most predictable and consistent sources of revenue for payers and PBMs. Amgen's Vice President of Global Commercial Integration estimated that the company pays [redacted] dollars in [redacted] rebates each year to payers. [redacted] Internal Amgen documents show that [redacted] rebates paid to [redacted] alone totaled $[redacted] in one year. [redacted] This degree of rebating, and Amgen's large portfolio, [redacted] and provide Amgen with significant leverage in negotiating formulary coverage for the rest of its portfolio. [redacted]

[redacted] And even if smaller, rival manufacturers could offer similar dollar amounts of rebates, rebates on drugs such as [redacted] provide other incentives to payers including predictability, guarantees, and payment timing that are difficult to match. *See, e.g.*, [redacted] PX9000 (Kesselheim Report) ¶ 154.

Amgen's historic practice of bundling is instructive about how it may behave after acquiring Horizon's highly lucrative products. It also reveals the tendency of the industry to be vulnerable to the types of bundles that the merged firm would have the ability and incentive to implement. Emerging market dynamics make bundling even more likely here, as vertical integration of health plans and PBMs will further facilitate bundling of rebates for products such as Tepezza and Krystexxa. [redacted]

Plaintiff's expert Dr. Kesselheim explained that Amgen's "documents indicate that Amgen believes [cross-benefit bundles] are feasible" and that "Amgen's contemplation of these so-called cross-benefit bundles appears to be motivated in part by incoming competition or the loss of exclusivity for its current products." PX9000 (Kesselheim Report) ¶ 175; *see also* PX9000 ¶¶ 176-82. Multiple payers agreed that Amgen could bundle in response to future competitive threats. [redacted]

[redacted]

ii. Incentive to Protect Its Monopolies

Post-Acquisition, Amgen will be incentivized to leverage its portfolio to bias decisions about drug coverage to protect the value of its newly acquired monopoly products. Amgen's ordinary course documents analyzing the Proposed Merger highlight that Amgen's valuation of the deal is [redacted]

In particular, Amgen's vice president and head of commercial integration for Horizon wrote in an internal message that [redacted] Documents from both Defendants and other market participants project that the total addressable market for TED is approximately [redacted]

Multiple rivals are developing competitors to Tepezza, threatening this massive profit pool. Horizon recognizes that the [redacted] and numerous Horizon documents [redacted]

Amgen similarly identified these same firms as future Tepezza competitors. [redacted] For example, an Amgen competitive intelligence document showed that [redacted] Amgen is particularly focused on Viridian, noting it is expected to launch in [redacted] One Amgen executive responsible for competitive intelligence remarked: [redacted] The threat of entry by these companies is not mere speculation—just months before the Proposed Merger, Horizon estimated the probability that Viridian (VRD-001) and Immunovant would achieve technical regulatory success as [redacted] Separately, Amgen's vice president and the head of the global commercial integration for Horizon Therapeutics estimated that Viridian had a [redacted] likelihood of entry. [redacted]

Krystexxa's dominant position in the CRG market may also soon be challenged, as Selecta Bio's SEL-212 could enter the market as soon as [redacted] Both Horizon and Amgen ordinary course documents, as well as testimony from a

Horizon executive, confirm Selecta is developing a competitive product. [redacted] Horizon expects that once SEL-212 is approved, it would [redacted]

Party executives have acknowledged that this competitive entry could lead to competition on the merits, with payers leveraging drugs off one another to secure lower prices. [redacted] This scenario is not unlikely, as [redacted] Other Horizon documents recognize that [redacted]

Not only do Defendants' documents recognize looming competition for Tepezza and Krystexxa, but the deal documents specifically analyze the financial benefit of any delay from Tepezza's rivals. For instance, a May 2022 Amgen Business Development plan outlined several [redacted] to acquiring Horizon's Tepezza. [redacted] One value upside focused on a [redacted] In November 2022, a separate Business Development plan modeled both a [redacted] and a [redacted] of the Proposed Merger. [redacted] According to the [redacted] model, there are several "key sensitivities" impacting valuation, including [redacted]

Thus, the merged firm will have an incentive to leverage Amgen's blockbuster drugs to defend the monopoly share of the Tepezza and Krystexxa markets and profit pools that Amgen, acting independently prior to the merger, does not. Like in *In re Illumina Inc.*, FTC Docket No. 9401, at 49-59, post-merger Amgen's economic motivations will change with respect to the acquired firm's markets. Further, because the acquired firm's competitors pose a threat, the acquiring firm will develop a strong incentive to pursue a strategy to weaken rivals. *Id.* at 47-52. Indeed, just three days after the Proposed Merger was announced, Amgen's SVP of Finance emailed Amgen's EVP and CFO: [redacted]—the very

drug which Amgen has previously sought to protect through the use of a cross-market bundle.

[redacted]

***

If the Proposed Merger is permitted to proceed, a combined Amgen/Horizon will possess the ability and incentive to entrench Tepezza's and Krystexxa's monopoly positions, thus causing rival drug treatments to be weakened or disadvantaged. This substantial lessening of competition in the markets for the sale of FDA-approved TED and CRG treatments is likely to result in decreased patient choice and/or access to competitive alternatives to Tepezza and Krystexxa—even where a competing drug might be clinically preferred—as well as higher prices than would exist but for the Proposed Merger. For example, Dr. Baraf, an expert in the treatment of CRG, explained that his ability to prescribe Krystexxa is often constrained by a patient's health plan coverage due to the high cost of the drug. PX9002 (Baraf Report) ¶ 57. Plaintiff's expert Dr. Cockerham similarly explained that although other treatments such as surgery do not treat TED's underlying symptoms, she will perform surgery on patients if they are unable to access the preferred drugs through their insurance coverage. PX9003 (Cockerham Report) ¶¶ 45, 57.

b. The Proposed Merger Has a Reasonable Probability of Extending or Entrenching Tepezza's and Krystexxa's Monopoly Positions

Section 7 also prohibits acquisitions that pose a reasonable probability of substantially entrenching the acquired company's (i.e., the "target company's") dominant position in the relevant market. In *Procter & Gamble,* the Supreme Court held 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." 386 U.S. at 578. Courts have identified several factors to determine whether an acquisition may entrench the dominant firm: (1) the structure of the relevant market,

including concentration and barriers to entry; (2) the target firm's dominance in the relevant market; (3) whether the acquisition would create substantial competitive disparities in the relevant market; and (4) whether the acquisition would increase barriers to entering the relevant market or dissuade competition generally. *See, e.g.*, *id.* at 578, 579; *General Foods Corp. v. FTC*, 386 F.2d 936, 945-46 (3d Cir. 1967); *Wilson Sporting Goods Co.*, 288 F. Supp. at 550-56.

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. Each factor listed above militates in favor of preliminarily enjoining the Proposed Merger. *First*, the relevant markets are highly concentrated, with Tepezza and Krystexxa each accounting for 100% of their respective markets. By comparison, in *Procter & Gamble*, the Court emphasized that the relevant market was characterized by six firms that together held nearly 80% of the market. 386 U.S. at 571; *see also Allis-Chalmers Mfg. Co. v. White Consol. Indus., Inc.*, 414 F.2d 506, 517, 518 (3d Cir. 1969) (four firms held 80% of market, with the target holding 20%; court held, "[t]he potential entrenchment of the market power of a merged [firm] . . . is an example of 'product extension' consequences which may be anticompetitive and violative of § 7"); *cf. United States v. General Dynamics Corp.*, 415 U.S. 486, 497 (1974) (quoting *United States v. Aluminum Co. of Am.*, 377 U.S. 271, 279 (1964)) ("[I]f concentration is already great, the importance of . . . preserving the possibility of eventual deconcentration is correspondingly great.").

Second, high entry barriers exist in both markets due to lengthy drug development timelines and FDA approval requirements. Further, the target firm, Horizon, holds monopoly positions in both relevant markets. *See, e.g.*, *Ekco Products Co. v. FTC*, 347 F.2d 745, 751 (7th Cir. 1965) ("The fact that a large corporation purchases a corporation with a virtual monopoly in

its field . . . may subject the merger to careful scrutiny to determine if additional facts exist from which a violation may be found.").

Third, the Proposed Merger would create substantial competitive disparities between the merged firm and Horizon's competitors. Currently, Horizon has only three prominent on-market drugs focused on small patient populations with rare diseases. The merged firm, however, would have Amgen's large portfolio of blockbuster drugs, which Tepezza and Krystexxa's soon-to-be competitors lack, allowing the merged firm to leverage its portfolio to entrench its monopoly positions. *See, e.g.*, *General Foods,* 386 F.2d at 945; *Ekco Products,* 347 F.2d at 747.

Fourth, the Proposed Merger would increase the already high barriers to entering the relevant market. Post-merger, Amgen could leverage its portfolio to promote sales of Horizon's drugs. And as established, it will have the ability and incentive to thereby entrench Tepezza's and Krystexxa's market positions. *See Allis-Chalmers Mfg.*, 414 F.2d at 518. As a result, any manufacturer developing a rival drug to Tepezza or Krystexxa would need a similar portfolio of highly utilized and rebated blockbuster drugs to compete for payer coverage in the TED and CRG markets. *See id.* When, as here, a merger bestows increased power to secure preferential treatment from input suppliers or distributors, this factor weighs especially heavily against the merger. *See, e.g.*, *FTC v. Consol. Foods Corp.*, 380 U.S. 592, 597 (1965); *Procter & Gamble Co.*, 63 F.T.C. 1465, 1565 (1963), *aff'd*, 386 U.S. 568 (1967). This dynamic is especially concerning here, where entrants may provide not only price competition, but also alternative and potentially superior treatments for patients.

In sum, by expanding the Horizon portfolio—which is dominant but narrow—with Amgen's broad and powerful drug portfolio, the Proposed Merger may "raise[] barriers to new entry," and may dissuade smaller firms "from aggressively competing with the newly formed,

giant competitor," thereby entrenching and extending Tepezza's and Krystexxa's monopolies. *United States v. First Nat'l State Bancorp.*, 499 F. Supp 793, 816 (D.N.J. 1980) (citing *Procter & Gamble*, 386 U.S. at 577-79; *cf. Wilson Sporting Goods*, 288 F. Supp. at 556 ("[C]ompetition in the industry will be lessened because of the adverse psychological effects the merger will engender among . . . smaller rivals, and upon potential new entrants into the market."). The effect of this Proposed Merger "may be substantially to lessen competition, or to tend to create a monopoly" and it is precisely the type of situation that requires curtailing anticompetitive harm in its incipiency. *Chicago Bridge & Iron Co. NV v. FTC*, 534 F.3d 410, 422-23 (5th Cir. 2008) (citing *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 355 (1963)); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 351 (2d Cir. 1979) (Congress wished to "nip anticompetitive practices in the bud.").

B. Defendants Cannot Rebut the Strong *Prima Facie* Case

Defendants' likely rebuttal arguments do not hold up to scrutiny. Particularly at this stage, where the court faces only the narrow issue of preliminary relief and does "not resolve the conflicts in the evidence, compare concentration ratios and effects on competition in other cases, or undertake an extensive analysis of the antitrust issues," *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1082 (quoting *Warner Commc'ns.,* 742 F. 2d at 1165, Defendants' speculative claims do not justify denying the temporary relief the Plaintiffs seek.

Defendants may claim that it would be logistically difficult for Amgen to implement a cross-market bundle involving Tepezza or Krystexxa because those drugs are currently covered under payers' medical benefits, whereas Amgen's most successful products are covered under payers' pharmacy benefits. Defs.' Answer at 4, ECF No. 77. However, internal Horizon documents indicate that some payers already cover Horizon's drugs under the pharmacy benefit. [redacted]

[redacted]

[redacted] PX9001 (Sibley Report) ¶ 158. Horizon's Executive Director of Market Access Reimbursement Strategy acknowledged that prescribers [redacted] Horizon's documents also show that self-administered Krystexxa would [redacted] Self-administered Tepezza likewise may be covered under payers' pharmacy benefits as early as [redacted]

Moreover, even if Tepezza or Krystexxa continue to be covered under the medical benefit, cross-benefit bundling—where a manufacturer implements a bundle that includes drugs managed by a health plan's medical benefit with drugs managed by its pharmacy benefit—is feasible and growing. [redacted] An internal Amgen document from February 2023 likewise lists cross-benefit management as a [redacted] for [redacted]

[redacted] Amgen will have billions of dollars in financial incentives to find a way to protect its new acquisitions, including through cross-benefit bundling.

To the extent Defendants claim that discounting and formulary positioning do not drive utilization for drugs like Tepezza and Krystexxa, *see* Defs.' Answer at 4-5, ECF No. 77, they do so only by disregarding the real-world dynamics of how patients obtain drug treatments through their insurance. It is inconceivable that a health plan's coverage of Tepezza and Krystexxa would not affect utilization and access to these drugs, which cost hundreds of thousands of dollars per treatment. Dr. Cockerham, an expert in the treatment of TED, explained that "many of [her] patients still struggle to obtain affordable access to" Tepezza, and that affordable access is often dependent on the type of insurance the patient has. PX9003 (Cockerham Report) ¶¶ 39-40. Dr. Baraf, an expert in the treatment of CRG, similarly acknowledged that his "ability to prescribe and administer Krystexxa to patients with CRG is often influenced by insurance coverage and utilization management tools health plans have in place." PX9002 (Baraf Report) ¶ 57. Defendants' own documents acknowledge this reality. In one Horizon presentation, market research on [redacted]

Defendants may also claim that they would not use cross-benefit bundles to protect Tepezza or Krystexxa because rebates applied to medical benefit products would lead to a gradual lowering of drug prices through what Defendants have described as the Average Sales Price ("ASP") "Death Spiral." *See* Defs.' Answer at 5, ECF No. 77. But this is hardly a foregone conclusion. Numerous manufacturers, including Amgen, already provide rebates for medical benefit drugs today; the strategy is demonstrably possible. [redacted] Moreover, the effect of gradually lower pricing could be avoided by, among other things, payers negotiating different reimbursement terms with providers or implementing alternative distribution systems.

Further, although Defendants may argue that potential post-merger efficiencies can rebut the prima facie case, no court has held that such evidence could immunize an otherwise anticompetitive merger. *See Hershey*, 838 F.3d at 348; *Advoc. Health Care*, 2017 WL 1022015 at *12 (explaining an efficiencies "defense has never been sanctioned by the Supreme Court"). Even assuming that it could, Defendants cannot meet the "rigorous standard" of showing that any of these claimed efficiencies are "merger specific, verifiable, and . . . arise from any anticompetitive reduction in output or service." *Hershey*, 838 F.3d at 349. Amgen acknowledges that the merger is [redacted]

Contrary to Defendants' assertion, the proposed solution they "stand ready" to accept would not "fully resolve" the Plaintiffs' concerns. *See* Defs.' Answer at 3, ECF No. 77. At the preliminary injunction stage, "doubts are to be resolved against the transaction." *Elders Grain*, 868 F.2d at 906. A bare commitment to not bundle Krystexxa or Tepezza with Amgen drugs fails to even offer any detail that would dispute the substantial doubts raised by the Commission and therefore fails to "'bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]'" *In re Illumina, Inc.*, FTC Docket No. 9401, at 61 (quoting *FTC v. Staples, Inc*., 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016)); *accord In re Otto Bock*, FTC Docket No. 9378, at 61 (Nov. 1, 2019); *United States v. Aetna, Inc*., 240 F. Supp. 3d 1, 60 (D.D.C. 2017) (requiring defendant to show that the proposed divestiture would replace the competitive intensity lost as a result of the merger); *Sysco*, 113 F. Supp. at 72-73. Here, Defendants propose a behavioral remedy rather than a structural remedy. But "behavioral remedies have long been disfavored in merger cases" and the "default remedy for a Section 7 violation is a full stop injunction of the merger . . . ." *In re Illumina,* FTC Docket No. 9401, at 66 (citing *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 573 (6th Cir. 2014) ("[O]nce a merger is found illegal, an undoing of the acquisition is a natural remedy") (internal quotation omitted)); *see also California v. Am. Stores Co*., 495 U.S. 271, 280-81 (1990) ("[I]n Government actions divestiture is the preferred remedy for an illegal merger or acquisition."). In addition, "[b]ehavioral remedies provide only temporary protection, allowing the threat inherent in the merger to persist," *In re Illumina*, FTC Docket No. 9401, at 67 (citing *Steves and Sons, Inc. v. JELD-WEN, Inc*. 988 F.3d 690, 720 (4th Cir. 2021)), and "usually impose greater monitoring costs than divestiture remedies. *In re Illumina*, FTC Docket No. 9401, at 67 (citation omitted); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 793 (9th Cir. 2015)). Further, behavioral remedies

are disfavored in Section 7 cases because they "risk excessive government entanglement in the market." *Saint Alphonsus.*, 778 F.3d at 793. Moreover, as Plaintiff's expert economist Dr. Sibley recognized, "[a]s compared with conduct remedies, structural remedies are relatively clean and certain. Importantly, they avoid ongoing government entanglement in the market. Conduct remedies suffer from a number of potentially substantial costs that structural remedies such as divestitures can in principle avoid." PX9001 (Sibley Report) ¶ 193.

Consistent with courts' skepticism of behavioral remedies, Plaintiff's expert Dr. Kesselheim further elucidates why Defendants' proposed solution would not resolve the Plaintiffs' concerns about the Proposed Merger. For example, Amgen could circumvent an outward commitment not to bundle its products with Horizon's by entering into "handshake" agreements with PBMs/GPOs, or by simultaneously negotiating separate contracts for its products and Horizon's but offering implicit rebates on [redacted] in exchange for a favorable formulary position for Tepezza or Krystexxa. PX9000 (Kesselheim Report) ¶¶ 229-30. "[G]iven the implicit nature of the agreements" in these examples, "it would be difficult, if not impossible, to monitor and enforce Amgen's promise[.]" PX9000 (Kesselheim Report) ¶ 231. Further, Amgen's proposed solution could "grow stale" as negotiations and contracts in the pharmaceutical industry evolve. PX9000 (Kesselheim Report) ¶ 232. An order that preliminarily enjoins the Proposed Merger until the administrative complaint can be adjudicated is therefore the appropriate relief here.

II. The Equities Favor a Preliminary Injunction

"No court has denied relief to the FTC in a [Section] 13(b) proceeding in which the FTC has demonstrated a likelihood of success on the merits." *FTC v. ProMedica Health Sys., Inc.*, 2011 WL 1219281, at *60 (N.D. Ohio Mar. 29, 2011). "The public has strong interests in the effective enforcement of the antitrust laws and in preserving [the Commission's] ability to order effective relief if it succeeds after a trial on the merits. These interests are plainly served by entering an

injunction." *Advoc. Health Care*, 2017 WL 1022015, at *16. This "was Congress's specific 'public equity consideration' in enacting" Section 13(b). *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1035 (D.C. Cir. 2008) (Brown, J.) (quoting *Heinz*, 246 F.3d at 726); *see also FTC v. Lifewatch Inc.*, 176 F. Supp. 3d 757, 778 (N.D. Ill. 2016) ("[I]n balancing th[e] equities, while private concerns may certainly be considered, public equities must receive far greater weight.") (quoting *World Travel Vacation Brokers*, 861 F.2d at 1028-29). In contrast, private equities are "subordinate to public interests and cannot alone support the denial of preliminary relief." *FTC v. Illinois Cereal Mills, Inc*., 691 F. Supp. 1131, 1146 (N. D. Ill. 1988) (citation omitted).

If the Court concludes that the FTC has raised the requisite "substantial doubts" going to the merits, *Advoc. Health Care*, 2017 WL 1022015, at *2, then the most appropriate relief at this stage is a preliminary injunction prohibiting Defendants from consummating their transaction pending the FTC's administrative merits trial. There would be significant harm to the public if the Court were to allow the Proposed Merger to close before resolution of the administrative complaint. Combining Defendants' operations into a single company would reshape the marketplace in an anticompetitive way. If 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.

CONCLUSION

For the reasons stated above, the Plaintiffs respectfully request that the Court issue a preliminary injunction by October 31, 2023, to prevent Defendants from closing the Proposed Merger pending adjudication of the Commission's administrative complaint.

Dated: July 7, 2023

Respectfully submitted,

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