IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

IN RE: AFLIBERCEPT PATENT LITIGATION **THIS DOCUMENT RELATES TO:** Civil Action Nos. 1:24-cv-39-TSK and 1:25-cv-74-TSK	MDL No.: 1:24-md-3103-TSK

REGENERON'S MEMORANDUM IN SUPPORT OF ITS
MOTION TO BIFURCATE AND STAY AMGEN'S ANTITRUST CLAIMS

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This case is complicated enough. In April 2024, the Judicial Panel on Multidistrict Litigation (JPML) centralized six cases concerning proposed biosimilar versions of Regeneron's 2 mg Eylea (aflibercept) product before this Court. ECF 1.[1] Those cases have involved dozens of patents, spanning multiple patent families and technical fields—from cell culture to downstream purification processes, from methods of administration to formulation. Beyond the MDL consolidation, the case has proceeded for years with the fact pattern of a law school civil procedure exam: this Court has presided over a multi-week bench trial and issued a lengthy post-trial decision; two additional cases have been transferred into the MDL; the Court has heard and decided three motions to dismiss for lack of personal jurisdiction and five motions for injunctive relief; five appeals ensued; and the parties thereafter briefed a sixth motion for injunctive relief, as well as a motion to dissolve one of the granted preliminary injunctions. While certain member cases have since concluded, that has not materially diminished the breadth or complexity of this MDL. The docket now contains nearly 700 entries. Meanwhile, Amgen chose to launch its biosimilar product, Pavblu, in late 2024—an act that willfully infringes numerous Regeneron patents, including the recently-issued buffer-agnostic patent (U.S. Patent No. 12,331,099) asserted in member case 1:25-cv-74-TSK. Amgen's sales of Pavblu mean that this case no longer is limited to questions of equitable relief, but now also will entail complicated issues of patent damages.

Facing the prospect of an enormous damages judgment for its willful infringement of Regeneron's patents, Amgen's goal is simple: slow things down. For almost a year, Regeneron has been proposing any number of ways to simplify this case. For example, last December, Regeneron requested Amgen's consent to amend its complaint and thereby withdraw its assertion of fifteen patents and add counts related to two newly issued patents. All other relevant Defendants

[1] Unless otherwise noted, all docket citations herein are to MDL No. 1:24-md-3103.

(Formycon, Celltrion, Samsung Bioepis) sensibly agreed to this approach. Not Amgen—Regeneron *still* is negotiating with Amgen to file its amended complaint without burdening the Court with motion practice. And just last month, Regeneron proposed an early case-narrowing plan by which it would commit to reduce the number of patents asserted from 19 (against Amgen) and 42 (against Samsung Bioepis) to just nine patents and 40 claims against each. Ex. 1 at 1-22. When the parties conferred, Samsung stated it was in favor of early narrowing. *Id.* at 2. At first, so did Amgen—before reversing its position, rejecting Regeneron's proposal, and counter-proposing a process that would require all parties to litigate all patents until June 2026 and would necessitate an extension of the Court's schedule by five months. *Id.* at 1-2 (summarizing the December 5th meet and confer), 24-33 (Amgen's counterproposal).

In its latest gambit to delay judgment, Amgen now seeks to inject a series of antitrust-related counterclaims into this already overflowing litigation. ECF 666 at 118-130. Those new claims are facially deficient and Regeneron has filed a Rule 12 motion seeking their dismissal. ECF 680. To whatever extent Amgen's new claims are permitted to continue beyond the pleadings stage, however, Regeneron respectfully requests that the Court order them bifurcated and stayed pending resolution of the patent-infringement claims at the heart of this case and MDL. As discussed in greater detail below, numerous courts have stayed antitrust counterclaims raised in patent cases in similar circumstances. And here, the reasons for applying those cases in support of a stay are simple. First, Amgen's antitrust-type claims do not apply to any other defendant in this MDL, or any still to come. Second, Amgen's antitrust-type claims largely will be extinguished if Regeneron prevails in its patent infringement suit. For example, Amgen's counterclaims depend on a finding that Regeneron's asserted patents were fraudulently procured. But this same question (*i.e.*, whether Regeneron procured its challenged patents through fraud) will be presented by

Amgen's inequitable conduct defenses to Regeneron's patent-infringement claims. If the answer to the question is "no" (as Regeneron asserts), Amgen's antitrust claims necessarily fail, and there will be no need to engage in protracted discovery or motion practice relating to the *additional* elements Amgen must prove to succeed on its antitrust claims—including that Regeneron possessed market power in a relevant market and that its assertion of the challenged patents caused cognizable antitrust injury. Those are complex questions that the Court and parties may or may not need to grapple with one day, but they certainly need not do so now, when resolution of Regeneron's infringement claims (and Amgen's inequitable conduct defenses) could dispose of most of Amgen's antitrust arguments.

A stay of the antitrust claims will promote judicial economy, spare the parties and Court the extraordinary burden presented by antitrust litigation, and present no meaningful prejudice to Amgen, which already has launched its accused product. Under these circumstances, courts routinely adopt the "standard practice" of staying antitrust counterclaims as the underlying patent litigation proceeds. *In re Innotron Diagnostics*, 800 F.2d 1077, 1084-86 (Fed. Cir. 1986) (collecting cases). The Court thus should decline Amgen's invitation to transform this already-complex *In re: Aflibercept Patent Litigation* into a wholly sprawling and unworkable "*In re: Aflibercept Patent (& Antitrust) Litigation.*"

BACKGROUND

Regeneron filed its initial patent infringement suit against Amgen in the Central District of California in January 2024. *Regeneron Pharms., Inc. v. Amgen Inc.*, Case No. 24-cv-39 (C.D. Cal. Jan. 10, 2024), ECF 1. The JPML subsequently centralized that action with five others in this MDL and transferred it to this Court. ECF 1. In June 2025, Regeneron filed a second complaint, alleging infringement of a newly-issued patent also infringed by Amgen's aflibercept product. *Regeneron Pharms., Inc. v. Amgen Inc.*, Case No. 25-cv-5499 (C.D. Cal. June 27, 2025), ECF 1.

The JPML likewise transferred that action to this Court as part of the MDL. ECF 577.

Amgen filed an answer and counterclaims in that later, 2025 case on September 12 (ECF 644) and filed a corrected answer several weeks after that (ECF 666). In its pleading, Amgen sought to raise counterclaims for, *inter alia*, alleged violation of the Sherman Act (15 U.S.C. § 2) by monopolization through *Walker Process* fraud[2] (Count 6), alleged violation of the Sherman Act (15 U.S.C. § 2) by attempted monopolization through *Walker Process* fraud (Count 7), alleged violation of California's Unfair Competition Law (Count 8), and alleged patent misuse (Count 5) (collectively, Amgen's "Antitrust Claims"). ECF 666 at 118-30.

The timing of Amgen's injection of antitrust counterclaims into this case makes clear that its concern is not a genuine one about anti-competitive behavior but rather a desire to bog down and thwart progress of the patent case, which is otherwise ready to proceed. For example, Amgen's new counterclaims belatedly plead injury that allegedly occurred when Regeneron filed its original complaint back in January 2024—even though Amgen asserted no such counterclaims in its 2024 Answer. More remarkably, Amgen's proffered antitrust "injury" is based, in part, on Amgen's ongoing "need" to defend against patents that Regeneron has been trying for nearly a year to remove from the case. Ex. 2 at 3, 5. Last December, Regeneron sought Amgen's consent to file an amended complaint that would withdraw infringement counts as to fifteen patents, many of which underlie Amgen's assertions of antitrust violations. *Id.* As recently as today, Amgen *continues* to revise the terms according to which it will stipulate to entry of Regeneron's amended complaint. Regrettably, Regeneron may need to burden the Court with motion practice to effectuate the straightforward case streamlining to which all other affected defendants readily agreed. *See* ECF 423-424 (stipulations to amend complaints against Celltrion in member case

[2] *See Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 174 (1965).

Nos. 1:24-cv-53 and 1:23-cv-89), 435 & 437 (stipulations to amend complaints against Samsung Bioepis in member case Nos. 1:23-cv-94 and 1:23-cv-106), 436 (stipulation to amend complaint against Formycon in member case No. 1:23-cv-94).

Meanwhile, Regeneron has been making other efforts to narrow the case. The Court entered a Scheduling Order in this MDL on September 29th. ECF 663. That order requires the parties to submit a joint proposal regarding case narrowing. *Id.* Regeneron proposed just such a schedule to Amgen and Samsung in the preceding weeks. Specifically, Regeneron circulated a case-narrowing proposal to Amgen on November 14th and recirculated materially the same proposal to Amgen and Samsung on November 21st. Ex. 1 at 1-2 (summarizing correspondence), 5-22 (emails to Amgen and Samsung and case-narrowing proposal). After initially refusing even to confer on the subject, Amgen suggested on a November 26th call that it was amenable to early, limited discovery that would effectuate early and substantial case narrowing—a plan consistent with Regeneron's proposal. *Id.* at 1-2. When all three parties conferred the next week on December 5th, Samsung sensibly made clear its desire for early case narrowing, but Amgen reversed itself and counter-proposed a plan that would require all parties to litigate all patents until June and necessitate a five-month extension to the Court-ordered schedule. *Id.* at 1-2 (summarizing conferral), at 24-33 (Amgen's counterproposal). Amgen offered no rationale in favor of its own proposal except to assert that it "made sense." And its complaints regarding Regeneron's proposal were self-perpetuating: Amgen first complained that Regeneron's requests for early discovery to facilitate narrowing were overbroad. When Regeneron offered to discuss the scope of those requests, Amgen declined, characterizing the situation as hopeless because the timeline was too short. Regeneron thus offered to discuss timing. Amgen demurred, insisting that any such discussion would be futile because Regeneron's requests were too broad.

Notwithstanding Amgen's circular protestations, Regeneron asked Amgen to confirm whether or not it would consider *any* mutual, early narrowing event (*e.g.*, a compromise of February 2026 instead of the January 2026 date Regeneron proposed), or whether it is committed to requiring all parties to litigate all asserted patents until June 2026. *Id.* at 2. Regeneron awaits Amgen's response.

In the interim, the parties conferred and reached impasse on another issue: whether the parties must litigate Amgen's antitrust counterclaims concurrently with Regeneron's patent claims in an MDL about patent infringement. For the reasons described below, they should not.

LEGAL STANDARD

The decision to stay some or all of a proceeding rests within the sound discretion of the trial court. *Romeo v. Antero Res. Corp.*, 2021 WL 2933176, at *3 (N.D.W. Va. July 12, 2021). This "power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). "Relevant factors for the Court's consideration include (1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party."[3] *Romeo*,

[3] Courts also evaluate requests to bifurcate and stay claims under Federal Rule of Civil Procedure 42. That Rule provides that a court may bifurcate a trial to separate issues, claims, crossclaims, counterclaims, or third-party claims "[f]or convenience, to avoid prejudice, or to expedite and economize." Fed. R. Civ. P. 42(b). Trial courts have broad discretion regarding trial management and whether to bifurcate under Rule 42(b). *Shum v. Intel Corp*., 499 F.3d 1272, 1276 (Fed. Cir. 2007). Subsumed by that discretion is the "authority to limit discovery as to any segregated issues" so as to minimize and defer "costly and possibly unnecessary discovery proceedings pending resolution of potentially dispositive preliminary issues." *Ellingson Timber Co. v. Great N. Ry. Co.*, 424 F.2d 497, 499 (9th Cir. 1970). Both Amgen member cases in this MDL were filed in the Central District of California and will not be tried before this Court unless Amgen waives its right to transfer back to that district for trial. *See Lexecon v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40 (1998). As such, Regeneron has not addressed trial bifurcation at this time and instead discusses its requested stay of Amgen's Antitrust Claims under the standard set forth by the Supreme Court in *Landis*. The analysis under either framework, however, is highly similar and yields the same result here—this Court has wide discretion to stay the Antitrust Claims for efficiency purposes.

2021 WL 2933176, at *3 (quotation and citation omitted).

ARGUMENT

I. THE COURT SHOULD STAY THE ANTITRUST CLAIMS PENDING RESOLUTION OF THE PATENT CLAIMS AND RELATED DEFENSES.

Amgen's Antitrust Claims largely depend on the success of its defenses to Regeneron's patent infringement allegations. As detailed in Regeneron's pending Motion to Dismiss, those claims are predicated on alleged fraud in the procurement of three families of patents asserted by Regeneron in this MDL. ECF 680-1 at 17-24. Amgen also has alleged that patents in each of those families are unenforceable under the doctrine of inequitable conduct due to this supposed fraud. Thus, resolution of Regeneron's patent infringement claims may dictate the continued viability (if any) of Amgen's Antitrust Claims. If Amgen's inequitable conduct arguments are rejected, its Antitrust Claims likewise must fail. *See FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987) ("failure to establish inequitable conduct precludes a determination that [claimant] had borne its greater burden of establishing the fraud required to support its *Walker Process* claim"); *Walter Kidde Portable Equip., Inc. v. Universal Sec. Instruments, Inc.*, 2009 WL 10682454, at *3 (D. Md. Apr. 5, 2009) (explaining that antitrust counterclaims based on "enforcement of a fraudulently procured patent . . . rise and fall with the court's determination vis-à-vis patent validity/enforceability.").

This dynamic hardly is unique: it has been "standard practice" for decades to bifurcate and stay such antitrust counterclaims pending resolution of patent infringement claims. *In re Innotron*, 800 F.2d at 1084-86 (collecting cases). Indeed, courts repeatedly have recognized the dependency of such responsive antitrust claims on the merits of the underlying patent infringement allegations. *See, e.g.*, *Iptronics v. Avago Technologies U.S., Inc.*, 2015 WL 5029282, at *8 (N.D. Cal. Aug. 25, 2015); *Walter Kidde*, 2009 WL 10682454, at *3; *ASM Am., Inc. v. Genus, Inc.*, 2002 WL 24444,

at *7 (N.D. Cal. Jan. 9, 2002). As a result, courts have bifurcated and stayed antitrust claims in patent cases both for purposes of trial, *e.g.*, *Audio MPEG, Inc. v. Dell Inc.*, 254 F. Supp. 3d 798, 806–08 (E.D. Va. 2017) ("resolution of the patent infringement claims could resolve one or more of the antitrust claims"), as well as at the pretrial stage to avoid the potential needless expenditure of judicial and litigant resources, *e.g.*, *Walter Kidde*, 2009 WL 10682454, at *3; *Fitbit, Inc. v. Aliphcom*, 2016 WL 7888033, at *3 (N.D. Cal. May 27, 2016) ("[A]llowing discovery to proceed with respect to the antitrust counterclaim would be unnecessary and burdensome."); *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 659–60 (D.N.J. 2015) ("[R]esolution of the patent infringement issues may render Torrent's antitrust Counterclaim moot, thereby serving the interests of judicial economy."); *Affymetrix, Inc. v. PE Corp. (N.Y.)*, 219 F. Supp. 2d 390, 398 (S.D.N.Y. 2002) ("[F]ull discovery of the antitrust claims would significantly slow the discovery process and impede the progress of this case.").

Courts routinely stay not only claims for monopolization and attempted monopolization, but also related claims under state unfair competition laws (like Amgen's California UCL claims) and claims for patent misuse when they are based on the same underlying allegations of fraudulent procurement. *See, e.g.*, *Audio MPEG, Inc.*, 254 F. Supp. 3d at 808 ("The Court finds that it is appropriate to bifurcate Dell's patent misuse defense along with Dell's antitrust claims because of the significant overlap in alleged facts and legal arguments."); *Implant Innovations, Inc. v. Nobelpharma AB*, 1996 WL 568791, at *3 (N.D. Ill. Oct. 2, 1996) (granting motion to stay discovery on "antitrust and unfair competition claims pending resolution of the patent issues").

This case fits squarely within these well-established models. As explained below, each of the relevant factors set forth by this Court in *Romeo*—"(1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to

the non-moving party," 2021 WL 2933176, at *3—militate in favor of staying Amgen's Antitrust Claims until the patent infringement disputes at the center of this already-complex MDL can be resolved.

A. Staying the Antitrust Claims Would Promote Judicial Economy.

The "interests of judicial economy . . . weigh heavily" in favor of staying the Antitrust Claims pending resolution of the underlying patent-infringement dispute, because resolution of the latter "will have a material effect on the outcome of" the former. *Romeo*, 2021 WL 2933176, at *3–5. To be clear, Amgen's Antitrust Claims suffer from severe deficiencies that warrant dismissal under Rule 12. ECF 680-1 at 17-24. But, even assuming *arguendo* that they somehow are able to survive the pleadings stage, the ultimate success of those claims is contingent on Amgen prevailing first in the patent litigation and on its inequitable conduct defenses. *FMC Corp.*, 835 F.2d at 1417; *Walter Kidde*, 2009 WL 10682454, at *3. This dependent relationship presents a clear opportunity to preserve court and party resources by appropriately sequencing this litigation. If Amgen's inequitable conduct defenses proceed first and fail, the Court need never address most of Amgen's Antitrust Claims or the additional antitrust-specific issues they present. *See, e.g.*, *Iptronics*, 2015 WL 5029282, at *8; *ASM Am.*, 2002 WL 24444, at *7. And in the unlikely event that Amgen's inequitable conduct claims survive and succeed, "the litigation of inequitable conduct will have provided a sturdy legal and factual foundation for any future rulings as to the [stayed] derivative antitrust counterclaims." *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2017 WL 2213123, at *4 (D.N.J. Mar. 19, 2017).

The potential judicial economy benefits of a stay here are particularly significant, given the complexity of antitrust litigation and the propensity of such litigation to drain judicial and party resources. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (collecting authority). The outsized *judicial* burden specifically is reflected, for example, in the Federal Judicial Center's

weighted-filing system, which assigns weights to proceedings based on the average amount of a judge's time such a case is expected to occupy. Ex. 3 at 5. The 2003 rubric assigns antitrust filings a weight of 3.45, higher than all but four (non-criminal and non-death penalty) matter types. *Id.* (Underscoring the complexity of this MDL even before Amgen's antitrust counterclaims, patent filings are assigned a weight of 4.72. *Id.*). Amgen's Antitrust Claims would demand the Court's attention in various ways. For example, Amgen points to its legal fees supposedly spent defending against Regeneron's allegedly "fraudulently-procured patents" as its claimed antitrust injury. ECF 666 at 125. Not only will that theory compel the parties to engage in complicated antitrust damages analyses should these claims proceed at this time, but the discovery it demands will consume disproportionate judicial resources. Regeneron would be forced to seek discovery delving into Amgen's legal expenses and the nature, basis for, and timing of its litigation work, topics presenting a host of privilege questions that almost certainly will spur disputes before the Court.

B. Proceeding on the Antitrust Claims Would Cause Significant Hardship to Regeneron.

Permitting Amgen's Antitrust Claims to proceed in parallel with the core patent-infringement case would cause significant hardship for Regeneron. *See Romeo*, 2021 WL 2933176, at *3. The Supreme Court has explained that antitrust litigation is complex and that discovery in such cases can constitute a "potentially enormous expense"—"a sprawling, costly and hugely time-consuming undertaking" that is not easily constrained. *Twombly*, 550 U.S. at 559-60 & n.6. The Fourth Circuit and other courts likewise have noted "the substantial cost that discovery in an antitrust case can impose[]" and "recognize[d] that the cost largely falls on the [antitrust] defendants." *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 434 (4th Cir. 2015); *see also, e.g.*, *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 995 (N.D. Ill. 2003) (Posner, J., sitting by designation) (warning of the "inevitably costly and protracted discovery phase"

inherent in patent antitrust suits). "When not appropriately managed, that cost can have an extortionate effect, compelling some defendants to enter early settlements even in meritless suits." *SD3*, 801 F.3d at 434. And, "[w]hile there may be considerable overlap between the antitrust and patent issues, there will also likely be substantial and expensive discovery that is related solely to antitrust issues, and which may prove to be largely or entirely unnecessary after resolution of the patent issues." *Orthophoenix, LLC v. Dfine, Inc.*, 2015 WL 1938702, at *1 (D. Del. Apr. 28, 2015).

That is precisely the situation here. To prevail on its monopolization and attempted monopolization Antitrust Claims, for example, Amgen will have to demonstrate, *inter alia*, that Regeneron possessed (i) monopoly power (or a dangerous probability of it) (ii) in a relevant market and that (iii) Regeneron's supposedly anticompetitive conduct caused an "antitrust injury." *See Mahaska Bottling Co. v. PepsiCo Inc.*, 271 F. Supp. 3d 1054, 1067 (S.D. Iowa 2017). None of these are elements of a patent-infringement claim, but all are likely to require substantial discovery work from the parties if the Antitrust Claims proceed at this time, including costly and time-consuming expert analysis as well as an investigation of Amgen's litigation decisions and expenses that is highly likely to ignite privilege disputes. Regeneron should not be forced to shoulder the burden of such discovery now when its infringement claims—and the failure of Amgen's inequitable conduct defenses thereto—may obviate the need for such work. *See Fresenius Kabi USA*, 2017 WL 2213123, at *4 (noting that, if the stay were denied and the patents later were found enforceable, "then all of the discovery and litigation on complex issues peculiar to the antitrust counterclaims, such as market definition, anticompetitive effect, and damages, will have been wasted").

C. Staying the Antitrust Claims Would Not Meaningfully Prejudice Amgen.

Amgen, on the other hand, would suffer no meaningful prejudice from a temporary stay of its Antitrust Claims. This is not a case in which an antitrust claimant is being excluded from the

market by the challenged conduct such that time is of the essence in resolving its antitrust claims. Amgen launched its aflibercept biosimilar more than a year ago and continues to make substantial sales while increasing its market share. Ex. 4 ($130M net sales in Q2 2025); Ex. 5 ($213M net sales in Q3 2025).

Rather, the thrust of Amgen's Antitrust Claims is that it has been forced to incur improper litigation costs in defending against claims that it infringes patents that were fraudulently procured. ECF 666 at 125. That, however, is a type of alleged injury that can be remedied with money damages should Amgen ultimately prevail.[4] While a stay might *delay* Amgen's recovery of such damages, courts in this circuit have noted that "delay alone is insufficient" to tilt this factor as "delay is an inherent part of any stay." *Simpson v. Johns*, 2013 WL 588742, at *2 (E.D.N.C. Feb. 13, 2013); *see also, e.g.*, *Software Rights Archive, LLC v. Facebook, Inc*., 2013 WL 5225522, at *5 (N.D. Cal. Sept. 17, 2013) ("Delay alone, without specific examples of prejudice resulting therefrom, is insufficient to establish *undue* prejudice."). "Moreover, even if the delay could be characterized as one that is prejudicial to [Amgen]" the judicial economy benefits outlined above "outweigh any prejudice that might result." *Simpson*, 2013 WL 588742, at *2; *see also Romeo*, 2021 WL 2933176, at *3 (finding that any potential "slight prejudice" to the claimant "is outweighed by the interests of judicial economy").

Further, whatever detriment Amgen claims it would experience from a stay would be substantially offset by gains in litigation efficiency. While the high costs of litigating antitrust claims disproportionately fall on antitrust defendants, *see SD3*, 801 F.3d at 434, they are not entirely one sided. If the Antitrust Claims proceed, Amgen will be subjected not only to significant

[4] Indeed, even if Amgen's Antitrust Claims had merit, the modest scope of any such damages relative to the value of Regeneron's infringement claims or even the cost of litigating the Antitrust Claims suggests Amgen's aim may be more to slow and further complicate this litigation than to address any purported antitrust injury.

discovery on classic antitrust issues such as market power and market definition but also intrusive (albeit critical) discovery regarding its litigation conduct and legal fees, given the nature of its purported injury. Any minor "prejudice" Amgen would suffer as a result of delaying resolution of its Antitrust Claims is more than compensated for by the efficiency gains of bifurcation and the potential to spare both Regeneron *and* Amgen needless expense.

II. IN THE ALTERNATIVE, THE COURT SHOULD STAY THE ANTITRUST CLAIMS PENDING RESOLUTION OF REGENERON'S MOTION TO DISMISS.

In the alternative, at a minimum, a limited stay of the Antitrust Claims pending resolution of Regeneron's Motion to Dismiss (ECF 680) is warranted. Any supposed prejudice to Amgen in the event Regeneron's Motion to Dismiss is denied would be de minimis, as its claims would be stayed for only a relatively short time while the Court considers the pending Motion. On the other hand, should the Court grant Regeneron's Motion, a brief delay of Amgen's Antitrust Claims in the near term will spare the Court and Regeneron considerable burden. This is because, consistent with the Court's September Scheduling Order (ECF 663), the parties are about to embark on discovery in this MDL, and Amgen—in what appears to be a bid to dissuade Regeneron from further pursuing its patent claims—has made clear that it intends to employ a scorched-earth approach. Notwithstanding Regeneron's already-enormous production to date, which includes more than 800,000 pages across more than 70,000 documents, Amgen now has served Regeneron with over 300 requests for production. Ex. 6 at 1. Sparing Regeneron from the burden of at least this discovery—and the Court from the burden of the discovery disputes sure to follow—would well serve the interests of judicial economy and efficiency while inflicting no meaningful harm on Amgen. At minimum, the Court should exercise its wide discretion to order a narrow stay of this

sort. *Landis*, 299 U.S. at 254.[5]

CONCLUSION

For the reasons set forth above, Regeneron respectfully requests that the Court enter the attached proposed order bifurcating and staying Counts 5-8 of Amgen's Counterclaims and substantively identical defenses in Case No. 1:25-cv-74-TSK (ECF 666). In the alternative, Regeneron respectfully requests the Court enter the attached proposed order bifurcating and staying the same pending resolution of Regeneron's Motion to Dismiss (ECF 680).

[5] Rule 26 offers an additional basis to stay discovery on Amgen's Antitrust Claims at least pending resolution of Regeneron's Motion to Dismiss. That Rule provides that "[t]he court may, for good cause, issue an order to protect a party . . . from . . . undue burden or expense, including one or more of the following: (A) forbidding the disclosure or discovery; [and] (B) specifying terms, including time and place or the allocation of expenses, for the disclosure or discovery." Fed. R. Civ. P. 26(c)(1)(A-B). The Court likewise has "wide discretion" to control or stay discovery pending a motion to dismiss under this Rule. *Thigpen v. United States*, 800 F.2d 393, 396-97 (4th Cir. 1986).

Date: December 11, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2025, I electronically filed the foregoing using the Court's CM/ECF service. Counsel of record for all parties will be served by the Court's CM/ECF service.

/s/ David R. Pogue
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