IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENERON PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	C. A. No.: 22-00697-RGA-JLH
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF
DEFENDANT AMGEN INC.'S MOTION TO STAY

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

GIBSON, DUNN & CRUTCHER LLP
Eric J. Stock
Ben A. Sherwood
200 Park Avenue
New York, NY 10166-0193
(212) 351-4000

Stephen Weissman
Richard G. Parker
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306
(202) 955-8500

Ashley E. Johnson
2001 Ross Avenue, Suite 2100
Dallas, TX 75201
(214) 698-3100

Attorneys for Amgen Inc.

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NATURE AND STAGE OF PROCEEDING

This is a newly-filed antitrust action brought by pharmaceutical company Regeneron Pharmaceuticals, Inc. ("Regeneron") against Amgen Inc. ("Amgen"). There has been no discovery and Amgen's motion to dismiss (D.I. 17) is not yet fully briefed.

Amgen moves to stay this case until the resolution of a patent case between Amgen and Regeneron, which involves the same medicines at issue here. In the patent case, Amgen seeks to enjoin Regeneron from selling its medicine Praluent® based on Regeneron's concession that Praluent® infringes Amgen's patents. *Amgen Inc. v. Sanofi, Aventisub LLC* (*Amgen II*), 987 F.3d 1080, 1083 (Fed. Cir. 2021), *petition for cert. filed*, (U.S. Nov. 18, 2021) (No. 21-757). The patent case, which will address whether Praluent® is lawfully on the market, is currently before the Supreme Court on Amgen's petition for a writ of certiorari. *Id.* In this case, Regeneron alleges that Amgen engaged in anticompetitive conduct by selling its medicine, Repatha®, in a manner that foreclosed Praluent® from the market. Many of Regeneron's allegations refer to the patent litigation. As Regeneron's claims will be mooted if Amgen prevails in the patent case, Amgen makes this motion in order to avoid duplication of work, conserve judicial resources, and save costs and expenses of the parties and non-parties that may turn out to be unnecessary.

SUMMARY OF ARGUMENT

Courts typically decline to allow antitrust claims to proceed while related patent litigation is ongoing, unless there is little to no possibility that the resolution of the patent litigation will simplify the antitrust claims. The rationale for doing so in this case is clear: if Amgen's patents are ultimately found to be valid, Regeneron will have no right to bring Praluent® to market in the first place. Under well-established authority in this Circuit, the exclusion of an unlawful, infringing product from the market does not give rise to antitrust injury or a cognizable antitrust claim. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir.

2017). Accordingly, the patent case may well entirely moot Regeneron's antitrust claims. As a result, staying the antitrust claims in the instant action until the patent case is resolved will spare this Court, as well as the parties and third parties, from the expenditure of significant time and resources that may well have been unnecessary. It would also serve the Court by allowing this case to proceed (if at all) based on the ultimate judicial determination of the lawfulness of Regeneron's launch of Praluent®, rather than Regeneron's speculation that its presence in the market will ultimately be approved.

Granting the requested stay will not prejudice either party. Amgen's petition for Supreme Court review is currently pending, and will likely be resolved before the end of the year, once the U.S. Solicitor General responds to the Supreme Court's invitation to express its views regarding whether the Court should grant review. Staying this recently filed antitrust case until the Supreme Court resolves the patent case (either by denying review or by entering a judgment on the merits) will cause only limited delay and will not impair any rights that Regeneron would have to remedy its claimed harms at the conclusion of the case. To the extent the Supreme Court grants review and issues a decision that would require further proceedings on remand, this Court can then evaluate the propriety of a stay on the facts then existing. Yet a stay will protect Amgen from the prejudice of expensive discovery in defending an antitrust suit by a plaintiff that was never lawfully in the market.

Because a stay may simplify the case, will not prejudice any party, and serves the interests of efficiency, Amgen respectfully requests that this Court follow well-established precedent to stay

this action entirely, or, in the alternative, at least stay discovery, until resolution of related patent litigation.[1]

BACKGROUND

Founded in 1980 with a staff of three, Amgen is now a leading biotechnology company, reaching patients in approximately 100 countries. Amgen focuses on areas of high unmet medical need and strives to develop therapeutics to treat a variety of medical conditions and improve people's lives. At issue in this case is Amgen's prescription medicine Repatha®, a PCSK9-inhibitor. Repatha® reduces low-density lipoprotein (LDL) cholesterol. Amgen owns multiple patents claiming a narrow class of antibodies that bind to a small region of PCSK9 and significantly reduce LDL cholesterol levels in the blood. One of the antibodies disclosed and claimed by Amgen's patents is the active ingredient in Amgen's Repatha®, a PCSK9 inhibitor approved to treat high LDL cholesterol. *Amgen II*, 987 F.3d at 1083. Those include U.S. Patent 8,829,165 and U.S. Patent 8,859,741 (together, the "Infringed Patents"). *Id.*

On October 17, 2014, Amgen sued Regeneron and others in this Court for patent infringement (the "Patent Litigation"). *Amgen Inc. v. Sanofi, Aventisub LLC* (*Amgen I*), 2019 WL 4058927, at *1 (D. Del. Aug. 28, 2019). Amgen contended that Praluent®, a cholesterol treatment product sold by Regeneron, infringed the Infringed Patents as well as other patents Amgen owns, and Amgen thus sought to enjoin Regeneron from selling Praluent®. *Id*. Regeneron ultimately stipulated to infringement and presented to a jury its challenge to the validity of the Infringed Patents. *Amgen II*, 987 F.3d at 1083–84; *see Amgen Inc. v. Sanofi, Aventisub LLC*, No. 1:14-cv-01317-RGA at D.I. 235 (D. Del. Feb. 22, 2016). The jury at the most recent trial found in favor

[1] On August 1, 2022, Amgen moved to dismiss the antitrust complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. (D.I. 17). Should the Court grant Amgen's request for a stay of the proceedings, it need not reach the merits of Amgen's motion to dismiss at this time.

of Amgen, rejecting Regeneron's defenses that the Infringed Patents were invalid for lack of enablement and written description. *Amgen II*, 987 F.3d at 1084.[2]

Regeneron thereafter moved for judgment as a matter of law that the Infringed Patents were invalid for lack of written description and enablement, which this Court denied as to lack of written description but granted as to lack of enablement. *Amgen I*, 2019 WL 4058927, at *5, *13. Amgen appealed this Court's judgment on lack of enablement to the Federal Circuit, which affirmed. *Amgen II*, 987 F.3d at 1082. On November 22, 2021, Amgen petitioned the Supreme Court to grant a writ of certiorari to review the Federal Circuit's decision, which conflicts with longstanding Supreme Court precedent holding that enablement is a question of fact for the jury. *See* Petition for Writ of Certiorari, *Amgen Inc. v. Sanofi, Aventisub LLC*, No. 21-757 (Nov. 18, 2021), 2021 WL 5506421. On April 18, 2022, the Supreme Court "invited [the Solicitor General] to file [a] brief[] in the[] case[] expressing the views of the United States." *Amgen Inc. v. Sanofi, Aventisub LLC*, No. 21-757 (Apr. 18, 2022). The Solicitor General's brief is likely to be filed very soon.

Calling for the views of the Solicitor General means that at least four Justices—the same number of votes required for the Supreme Court to grant a petition for a writ of certiorari—believe the case is sufficiently likely to be worthy of the Court's review to justify holding the case and asking the Solicitor General to weigh in. *See* David C. Thompson and Melanie F. Wachtell, *Empirical Analysis of Supreme Court Certiorari Procedures*, 16 Geo. Mason L. Rev. 237, 273 nn.148, 150 (2009). Indeed, a 2019 analysis concluded that the Supreme Court granted the petition for writ of certiorari in nearly 47% of the cases in which the Supreme Court had sought the views of the Solicitor General in the Obama and Trump administrations, and well over 90% of the cases

[2] This marked the second jury determination in Amgen's favor on these issues; the first was reversed and remanded based on a finding of error in evidentiary rulings and jury instructions. *Amgen II*, 987 F.3d at 1084.

in which the Solicitor General recommended that the Court grant review.[3] Even in circumstances where the Solicitor General recommended *denying* review, the Supreme Court granted review in nearly 25% of cases, much higher than the roughly 1% of cases in which the Supreme Court ordinarily grants review and holds argument.[4]

On May 27, 2022, Regeneron filed the complaint (the "Complaint") in this action (the "Antitrust Litigation"). *See* D.I. 1 (Compl.). The Complaint alleges that Amgen has entered into contracts with certain customers that unlawfully foreclose Praluent®—the same drug at issue in the Patent Litigation—from gaining sales in the relevant market in violation of the antitrust laws. *Id.* ¶ 147. Specifically, Regeneron contends that Amgen "condition[s] rebates for Otezla and Enbrel," drugs sold by Amgen for treating moderate-to-severe psoriasis and rheumatoid arthritis, respectively, on third party payors including Repatha® as the "exclusiv[e] or practical[ly] exclusiv[e]" PCSK9 inhibitor "on [their] formularies." *Id.* ¶ 18. According to Regeneron, because "Third-Party Payors . . . are motivated by securing the lowest net prices—that is, including rebates—across all of the products they cover," certain third-party payors have allegedly made Repatha® the exclusive PCSK9 inhibitor on their formularies, thus allegedly "foreclos[ing] Regeneron's Praluent® from a significant share of the PCSK9i market." *Id.* ¶¶ 18–19.

Regeneron's Complaint seeks to bring Amgen's Patent Litigation into this suit. Although Regeneron does not (and cannot) allege that the Patent Litigation is a sham, it claims that since Praluent® was first approved, Amgen "sought … to exclude Praluent® from the market," and identifies the Patent Litigation as the first of many alleged misdeeds: "Amgen first pursued an

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[3] Adam Feldman, *Empirical SCOTUS: Comparing cert-stage OSG efforts under Obama and Trump*, SCOTUSblog (June 6, 2019, 12:54 PM), *https://www.scotusblog.com/2019/06/empirical-scotus-comparing-cert-stage-osg-efforts-under-obama-and-trump/*.

[4] *Id.*; *Supreme Court Procedure*, SCOTUSblog, *https://www.scotusblog.com/supreme-court-procedure/* (last visited Aug. 10, 2022).

injunction against the sale of Praluent® through a patent litigation campaign in this Court." *Id.* ¶ 8. And the litigation itself was not all. According to Regeneron, Amgen tried through the Patent Litigation to "cover compounds . . . that Amgen had never invented." *Id.* ¶ 2. Regeneron characterizes Amgen's patents as "excessively broad" and repeatedly accuses Amgen of conducting a "patent litigation campaign" or "scheme." *See, e.g.*, *id.* ¶¶ 2, 8–12, 17, 19, 28, 60, 68. Indeed, Regeneron bases its allegation of anticompetitive intent largely on Amgen's filing and pursuit of the Patent Litigation. *Id.* ¶¶ 9–10, 59–65; *see also id.* ¶ 19 ("As Amgen's failed patent-litigation campaign to take Praluent® off the market illustrates, Amgen's purpose and intent . . . has been to foreclose Regeneron's Praluent® from a significant share of the PCSK9i market. . ."); ¶ 68 ("Amgen's patent-litigation scheme and misinformation blitz made transparent Amgen's attempt to insulate Repatha® from competition.").

On August 1, 2022, Amgen filed a Motion to Dismiss for Failure to State a Claim. D.I. 17. No scheduling order has been entered, and no discovery has been served by either party. Amgen's petition for a writ of certiorari remains under consideration while the Court awaits the views of the Solicitor General.

ARGUMENT

I. Staying the Antitrust Litigation Pending Resolution of the Related Patent Litigation Serves the Interests of Justice.

"In the exercise of its sound discretion, a court may hold one lawsuit in abeyance to abide the outcome of another which may substantially affect it or be dispositive of the issues." *Bechtel Corp. v. Loc. 215, Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976). In exercising this discretion, the Court considers "(1) whether the granting of a stay would cause the non-moving party to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical advantage over the non-moving party; (2) whether a stay will simplify the issues for trial; and

(3) whether discovery is complete and a trial date set." *Apotex, Inc. v. Senju Pharm. Co., Ltd.*, 921 F. Supp. 2d 308, 313–314 (D. Del. 2013) (quotation marks omitted).

Of these factors, the "most important" is whether the stay will likely simplify the issues. *Brit. Telecomm. PLC v. IAC/InterActiveCorp*, 2019 WL 4740156, at *7 (D. Del. Sept. 27, 2019). In patent-related antitrust cases, there is often at least a "possibility that a trial on [the] patent issues will potentially eliminate or simplify" antitrust claims or counterclaims, causing this factor to be present. *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 2010 WL 925864, at *3 (D. Del. Mar. 11, 2010). As a result, this Court has routinely "stayed antitrust litigation where there was a possibility that the resolution of underlying patent claims could moot, narrow, or otherwise simplify the antitrust claims." *Apotex*, 921 F. Supp. 2d at 314 (collecting cases); *see also, e.g.*, *Eagle Pharms., Inc. v. Eli Lilly & Co.*, 2018 WL 6201704, at *2 n.3 (D. Del. Nov. 27, 2018) ("[I]t is common practice for courts to stay an antitrust case until after resolution of a related patent case" if "the issues in the antitrust case will at least be narrowed, if not disposed of entirely, by the resolution of the patent case.") (collecting cases).

Each of the three factors courts consider in deciding whether to stay a case weighs decidedly in favor of staying the Antitrust Litigation pending resolution of the Patent Litigation.

First, the stay will not "cause [Regeneron] to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical advantage over the non-moving party." *Apotex*, 921 F. Supp. 2d at 313. Instead, the primary effect of a stay would be to protect *all* parties, as well as non-parties, from the "substantial risk that the parties will engage in costly, time-consuming discovery that might ultimately be unnecessary." *SmithKline Beecham Corp. v. Apotex Corp.*, 2004 WL 1615307, at *8 (E.D. Pa. July 16, 2004). Courts have repeatedly recognized that "antitrust specific discovery" can "be voluminous, time-consuming, and expensive." *Eagle*

Pharms., 2018 WL 6201704, at *3 (staying antitrust lawsuit pending resolution of patent lawsuit); *see also, e.g.*, *Apotex*, 921 F. Supp. 2d at 316 n.15 (acknowledging "the potential burdens and expenses of complex antitrust litigation"). Instead of advantaging Amgen, staying the Antitrust Litigation would—for the Court, the parties, and the numerous non-parties from whom discovery could be sought—"avoid potential waste if the claims in the antitrust action are narrowed or mooted by the resolution of the patent infringement action." *Eagle Pharms.*, 2018 WL 6201704, at *3.

Regeneron has no plausible claim to prejudice from a stay. If Regeneron's antitrust claims in this action were to somehow succeed after a stay was lifted, it could remedy any proven harm through monetary damages. Indeed, "all of [Regeneron's] legal and equitable remedies will be available when the stay is lifted." *Oy Ajat, Ltd. v. Vatech Am., Inc.*, 2012 WL 1067900, at *21 (D.N.J. Mar. 29, 2012). And "delay alone is not a sufficient reason to deny a stay." *Id*. Unless the Supreme Court grants review, the stay will be lifted in a matter of months, because the Supreme Court is likely to decide Amgen's petition for writ of certiorari by the end of 2022. And if the Supreme Court *does* grant Amgen's petition, its decision on the merits would in the normal course be expected in the upcoming Court term. A stay pending that merits decision would be both critical and proper, because the Supreme Court's decision may well moot the Antitrust Litigation altogether, as discussed below. After the Supreme Court issues its decision, this Court could revisit its stay to determine whether, based on the outcome in the Supreme Court, the proper course is to extend the stay or to lift it, or Regeneron could elect to dismiss its lawsuit based on the Supreme Court's decision. By avoiding proceedings that may be unnecessary, this course of proceeding would be the most judicially economical and, for both parties, the least prejudicial course at this

early juncture in the Antitrust Litigation. Moreover, non-parties would be saved the disruption and expense that inevitably comes from discovery in antitrust cases.

Staying the Antitrust Litigation also would not confer advantage on Amgen. This Court has rejected any inference of inappropriate tactical advantage where the court would enter the stay "soon after commencement of the litigation," and where the movant "has a legitimate concern to minimize the potential burdens and expenses of complex antitrust litigation." *Apotex*, 921 F. Supp. 2d at 316 n.15. As Amgen "moved for a stay immediately upon commencement of this litigation . . . . there is no inference that [it] seek[s] an inappropriate tactical advantage." *Vehicle IP, LLC v. Wal-Mart Stores, Inc.*, 2010 WL 4823393 (D. Del. Nov. 22, 2010). Indeed, Amgen would be prejudiced in the absence of a stay if the Supreme Court ultimately grants review and renders a decision that moots this litigation. *See Smithkline Beecham*, 2004 WL 1615307, at *9 (granting stay because it was "the best way to minimize potential harm to all the parties"). If that occurs, Amgen will have been put to the burden and expense of defending this lawsuit—which Regeneron has explicitly based in part on its theory that the Patent Litigation was improper—only for this case to be mooted by developments in the Patent Litigation. Accordingly, while Regeneron would not be prejudiced by a stay, proceeding despite the pendency of the patent litigation would risk substantial prejudice to Amgen.

Second, the stay at least "will simplify the issues for trial," if not obviate the need for any discovery or trial. *Apotex*, 921 F. Supp. 2d at 313–14. That is because there is "a possibility that the resolution of [the Patent Litigation] . . . could moot" the Antitrust Litigation. *Id*. at 314. In order "to maintain an antitrust suit, a plaintiff must establish antitrust standing," and "[t]o establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury." *In re Wellbutrin*, 868 F.3d at 163–64 (quotation marks and footnote omitted). Here, a judgment for Amgen in the

Patent Litigation would preclude Regeneron from pleading or proving its claimed antitrust injury in this action—i.e., that any impairment in Regeneron's ability to compete in the alleged PCSK9i market is actionable under the U.S. antitrust laws.

More specifically, if the Infringed Patents are ultimately judged to be valid, then Regeneron was never entitled to sell Praluent® in the first place. In that circumstance, Regeneron's claim that it has lost sales and profits on Praluent® because of Amgen's conduct would not establish "antitrust injury—that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant['s] acts unlawful.'" *Id*. at 164 (citation and footnote omitted). That is because if Amgen succeeds in the Patent Litigation, the judgment that Praluent® infringes Amgen's valid patents would mean that Praluent® is an "illegal" product that Regeneron has no right to sell. *Id.* at 165. Under the applicable law, excluding an unlawful product from the market does not give rise to antitrust injury. *Id.*; *see also In re Seroquel XR Antitrust Litig.*, 2022 WL 2438934, at *13 (D. Del. July 5, 2022) (dismissing portion of claim for lack of antitrust injury where the plaintiffs failed to dispute that the challenged reverse-payment settlement "'did not injure [them] because [the] generic infringed a valid patent, and so its launch was blocked by the patent laws'"). A contention that a defendant is liable under the antitrust laws because it excluded competition from a competing drug company that "launch[ed] at risk" does not state a claim for antitrust injury unless it can be shown that the competitor "would have won its . . . suit against [the patent holder]" and that the "patents were invalid or not infringed by" the competitor's drug. *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 62–63 (1st Cir. 2016) (holding plaintiff could not show antitrust injury from delayed launch of generic when such injury was precluded by finding at trial that antitrust defendants' patents were not invalid).

To put it another way, if the patent laws make it unlawful for Regeneron to sell Praluent®, then Praluent® is not permitted in the market because "federal patent law . . . prevent[s] market entry." *In re Wellbutrin*, 868 F.3d at 165. In that case, its "injury (if it could still be called that) would be caused not by the [alleged Repatha-Otezla-Enbrel bundle] but by the patent laws prohibiting the launch [of Praluent®]." *Id.*; *see also City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (finding no antitrust injury where "any injury suffered . . . flow[ed] . . . from the realities of the regulatory environment" instead of the defendants' alleged misconduct); Phillip E. Areeda & Herbert Hovenkamp, Fundamentals of Antitrust Law § 3.04[B] (rev. 4th ed. Supp. 2015) ("[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").

Accordingly, in the event Amgen prevails in the Patent Litigation, Regeneron's allegations in the Antitrust Litigation would be moot because Regeneron will not be able to "show" in this action, as it must, "that the launch [of Praluent®] [was] legal." *In re Wellbutrin*, 868 F.3d at 165. Regeneron would thus lack antitrust standing to proceed with this antitrust lawsuit, *regardless* of the propriety of Amgen's practices challenged here. The Antitrust Litigation could therefore be "disposed of entirely" by the resolution of the Patent Litigation, and because of that real possibility, staying the Antitrust Litigation at its earliest juncture is warranted to conserve valuable judicial resources, as well as party and third-party resources. *Eagle Pharms.*, 2018 WL 6201704, at *2 n.3.

Courts, including this one, frequently stay antitrust litigation where there is some likelihood it will be simplified by pending patent litigation. *Id.* (collecting cases). Indeed, as noted, the potential for simplification is often the critical factor in the analysis. In *Apotex*, for example, Senju Pharmaceutical Co. ("Senju") defended antitrust claims associated with alleged delays in entry of

a competing generic drug which were grounded in part on a separate patent infringement action it filed against Apotex. 921 F. Supp. 2d at 313. Senju sought to stay the antitrust litigation pending resolution of its appeal of a decision finding that its patent infringement action was barred by res judicata. *Id.* at 312, 314. As discovery in the related patent case was ongoing, there was a risk that the stay of the antitrust case would create "'time-consuming and expensive discovery disputes as to whether particular discovery is directed at the patent or antitrust claims.'" *Id.* at 315 (citation omitted). This Court nonetheless granted the stay because resolution of the appeal was going to simplify the litigation: "an affirmance . . . would shed light on . . . Senju's right to exclude Apotex from the market at any specific time," and "a reversal by the Federal Circuit . . . would render moot any assertion that Senju brought the action knowing it was barred." *Id*. at 315. The determinative factor was that "resolution of the appeal in the [patent] action could eliminate or narrow some of the antitrust claims and prevent unnecessary expenditure of time and resources." *Id*. Notably, this Court *denied* only that portion of the motion to stay directed to a separately filed patent infringement action that had "limited" potential "to simplify the antitrust litigation" because it related to a different product than the antitrust suit. *Id*. at 316.

This Court took a similar approach in *Eagle Pharmaceuticals*. 2018 WL 6201704. There, it found that, because the "issues in the antitrust case will at least be narrowed, if not disposed of entirely, by the resolution of the patent case," a stay was warranted. *Id*. at *2. The Court reasoned that, if the patent litigation were to demonstrate that the antitrust plaintiff's "product infringe[d] a valid claim of" the defendant, the plaintiff "may not have [had] an antitrust claim" since it would have been "lawfully prohibited from going to market" and therefore have "no antitrust injury." *Id*. (citation omitted). Any concern of prejudice was outweighed by the need to "avoid potential waste

if the claims in the antitrust action are narrowed or mooted by the resolution of the patent infringement action," and the procedural posture favored a stay. *Id*. at *3.

Here, the Antitrust Litigation "will at least be narrowed" for much the same reason as in *Eagle Pharmaceuticals*—Regeneron will have no antitrust injury if Amgen's Patent Litigation succeeds, as discussed above. 2018 WL 6201704, at *2. And staying this case would simplify the issues to an even greater degree than in *Apotex* because no discovery is currently ongoing in the patent case, since it is on appeal. That avoids the context of *Apotex*, where the ongoing discovery in the patent case risked creating "'discovery disputes as to whether particular discovery is directed at the patent or antitrust claims.'" *Id*. at 315 (citation omitted).

The fact that the Federal Circuit has already completed its review of the Patent Litigation does not eliminate the chance that the Patent Litigation could obviate Regeneron's suit. Indeed, courts within the Third Circuit have previously stayed litigation in patent-related antitrust claims when the antitrust defendant is seeking certiorari from the Supreme Court, even absent any indication from the Court (such as an order calling for the views of the Solicitor General) of potential interest. *See, e.g.*, *SmithKline Beecham*, 2004 WL 1615307, at *4, *9 (granting stay where patent holder indicated that it "intend[ed] to seek further review . . . by petitioning for a writ of certiorari from the Supreme Court"). In *In re Effexor XR Antitrust Litigation*, the court stayed antitrust litigation "pending the conclusion of . . . proceedings in the United States Supreme Court" with respect to a Third Circuit decision that potentially impacted the antitrust litigation. 2012 WL 12918362, at *2 (D.N.J. Oct. 23, 2012). The court stayed the case because "a Supreme Court decision" could "allow for the potential simplification [of] the issues in this case and promote judicial economy." *Id.*

The rationale supporting a stay is even stronger here because the Supreme Court's call for the views of the Solicitor General significantly heightens the likelihood that it will grant review of the Patent Litigation. As set forth above, the Supreme Court's decision to call for the input of the Solicitor General dramatically increases the chances review will be granted from around 1% to nearly 50%—and the Supreme Court grants review in nearly *all* cases in which the Solicitor General recommends granting the petition. *See* SCOTUSblog, *supra* nn.3–4; *see also* Thompson & Wachtell, *supra*, at 273–77. This dramatic increase is "quite likely" the result of the reality "that cases which the Court thinks worthy of [seeking the Solicitor General's input] are those it thinks possibly worthy of a grant." *Id*. at 273 n.153.

Third and finally, the inquiry into whether "discovery is complete and a trial date set" favors a stay because this Antitrust Litigation is in its infancy. Regeneron has simply filed the Complaint, which merely "commences" the Antitrust Litigation, Fed. R. Civ. P. 3, and Amgen has moved to dismiss. D.I. 1, 17. Incontestably, then, "the procedural posture of the [Antitrust Litigation] favors a stay; there has not yet been any discovery, scheduling conference, or filing of an answer." *Apotex*, 921 F. Supp. 2d at 315 (staying antitrust litigation pending resolution of patent litigation); *see also, e.g.*, *Eagle Pharms.*, 2018 WL 6201704, at *3 (staying antitrust action pending resolution of patent action where "[n]o schedule ha[d] been entered yet in the antitrust action").

Accordingly, all three factors weigh squarely in favor of staying the Antitrust Litigation pending resolution of the Patent Litigation.

II. In the Alternative, this Court Should Stay Discovery in the Antitrust Litigation Pending the Resolution of the Related Patent Litigation.

Regardless of whether this Court is inclined to allow the motion to dismiss to proceed through briefing to decision, it would nonetheless be appropriate to stay discovery in the Antitrust

Litigation pending resolution of the Patent Litigation. This result is warranted because, absent a stay, "there is a substantial risk" that Regeneron will seek to commence discovery and, as a result, "the parties will engage in costly, time-consuming discovery that might ultimately be unnecessary." *SmithKline Beecham*, 2004 WL 1615307, at *8. As this Court recognized in confronting similar allegations, antitrust-specific discovery is "voluminous, time-consuming, and expensive," which counsels in favor of a stay. *Eagle Pharms.*, 2018 WL 6201704, at *3; *see also Apotex*, 921 F. Supp. 2d at 316 n.15 (citing "the potential burdens and expenses of complex antitrust litigation" in deciding to stay antitrust action pending resolution of patent action). Thus, if the Court determines not to stay the Antitrust Litigation in its entirety pending the resolution of the Patent Litigation, but prefers to proceed with resolution of the motion to dismiss, Amgen respectfully requests that it stay discovery in the Antitrust Litigation until the judgment in the Patent Litigation becomes final.

The parties could, in the meantime and if the Court prefers, fully brief Amgen's motion to dismiss the Complaint. *See* D.I. 6. That motion to dismiss provides an independent reason to grant the motion to stay because, if the motion to dismiss is granted, no discovery will be necessary. *See Mann v. Brenner*, 375 Fed. Appx. 232, 239 (3d Cir. 2010) ("In certain circumstances it may be appropriate to stay discovery while evaluating a motion to dismiss where, if the motion is granted, discovery would be futile."). In similar antitrust cases, courts in this Circuit have stayed discovery pending resolution of a motion to dismiss, "without having formed an opinion on its merits," where the motion had "the potential to dispose of the entire case and eliminate the need for discovery," and where, "[a]s with many antitrust cases, the scope of discovery" would be "enormous." *Pfizer Inc. v. Johnson & Johnson*, 2018 WL 1071932, at *1–2 (E.D. Pa. Feb. 27, 2018); *see also*

McLafferty v. Deutsche Lufthansa A.G., 2008 WL 4612856 (E.D. Pa. Oct. 15, 2008) (granting stay of discovery in antitrust case pending resolution of motion to dismiss).

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court stay the Antitrust Litigation pending resolution of the Patent Litigation, or, in the alternative, that the Court stay discovery in the Antitrust Litigation pending resolution of the Patent Litigation.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

GIBSON, DUNN & CRUTCHER LLP
Eric J. Stock
Ben A. Sherwood
200 Park Avenue
New York, NY 10166-0193
(212) 351-4000

Stephen Weissman
Richard G. Parker
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306
(202) 955-8500

Ashley E. Johnson
2001 Ross Avenue, Suite 2100
Dallas, TX 75201
(214) 698-3100

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Attorneys for Amgen Inc.