UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMA AG; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS TECHNOLOGY LLC,

Plaintiffs,

-v-

REGENERON PHARMACEUTICALS, INC.,

Defendant,

1:20-CV-690
'631 Patent case

REGENERON PHARMACEUTICALS, INC.,

Counter Claimant,

-v-

NOVARTIS PHARMA AG; NOVARTIS PHARMACEUTICALS CORPORATION; and NOVARTIS TECHNOLOGY LLC,

Counter Defendants,

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

-v-

1:21-CV-1066
Antitrust case

NOVARTIS PHARMA AG; NOVARTIS TECHNOLOGY LLC; NOVARTIS PHARMACEUTICALS CORPORATION; and VETTER PHARMA INTERNATIONAL GMBH,

Defendants.

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DAVID N. HURD United States District Judge	

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

On June 19, 2020, pharmaceutical companies Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (together "Novartis") filed a complaint (the "'631 Patent case") in this district alleging patent infringement against rival Regeneron Pharmaceuticals, Inc.

("Regeneron"). Essentially, Novartis claims that it has a valid patent for syringes which come pre-filled with a certain medication used to treat degenerative eye disease. By extension, Novartis takes issue with Regeneron's introduction of a competing prefilled syringe—designed to treat the same disease—into the market notwithstanding its patent.

On July 17, 2020, Regeneron fired back with a complaint of its own, alleging four antitrust claims and an additional claim for tortious interference with a contract (the "Antitrust case"). In addition to Novartis, Regeneron also directed some of these claims at Vetter Pharma International GMHB, a pharmaceutical supply chain provider whose niche in the medical marketplace includes filling Novartis's—and formerly Regeneron's—syringes.

According to Regeneron, Vetter and Novartis conspired together to circumvent a binding contract giving Regeneron an ownership interest in any of Vetter's innovations. At the same time, Regeneron claims that Vetter and Novartis defrauded the Patent and Trademark Office ("PTO") to secure for Novartis a stranglehold on the market for prefilled syringes designed to treat degenerative eye disease.

There are three separate pending motions in these two cases. First, in the '631 Patent case, Novartis and Regeneron have submitted their opening claim construction briefs in advance of a potential hearing as contemplated by *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Second, in

the Antitrust case, Novartis and Vetter have both moved to dismiss Regeneron's complaint against them in its entirety under Federal Rule of Civil Procedure ("Rule") 12(b)(6). And third, in both cases, Regeneron has moved for a stay in proceedings while the PTO conducts an *inter partes* review of the validity of Novartis's patent. All three motions, having been fully briefed, will now be decided on the submissions and without oral argument.

II. BACKGROUND

At their core, these two cases are about three different drugs: EYLEA, made by Regeneron, and LUCENTIS and BEOVU, both made by Novartis.[1] *Regeneron Pharms., Inc. v. Novartis Pharma AG*, 1:21-CV-1066, Dkt. 87 ("Antitrust Compl."), ¶ 5. All three drugs are designed to inhibit the body's production of vascular endothelial growth factor ("VEGF"), a naturally occurring protein that erodes vision if overproduced, and in particularly extreme cases can cause blindness. *Id.* ¶¶ 5-6.

EYLEA, LUCENTIS, and BEOVU each need to be injected directly into the eye regularly to do their job as "anti-VEGF" agents. Antitrust Compl. ¶ 6. Traditionally, like most injectable liquids, EYLEA, LUCENTIS,

[1] For the purposes of Novartis and Vetter's motions to dismiss under Rule 12(b)(6), the Court takes the facts in Regeneron's complaint as true. The Court notes that in addition to the redacted First Amended Complaint on the docket, Regeneron has also filed a "clean" version of that document under seal. The Court has consulted the clean version where necessary but will cite to the official version.

and BEOVU were transported in vials. *Id.* The physician would then have to pierce the vial with a syringe, draw some of the drug out, and inject it into the patient's eye. *Id.*

A. Developing the Prefilled Syringe

According to Regeneron, though, it came up with a better idea. Regeneron claims that in 2005, it and Vetter began working together to develop a prefilled syringe ("PFS") that contained EYLEA. Antitrust Compl. ¶¶ 2, 152. The theory went that a prefilled syringe would remove the intermediate step of drawing out the drug, reducing the risk of contamination and making the process safer. *Id.* ¶¶ 76-81. As part of their collaboration, Vetter helped Regeneron by filling its syringes during the testing phase for the EYLEA PFS. *Id.* ¶ 152.

In addition to filling the EYLEA PFS systems, though, Regeneron alleges that it and Vetter also worked together to develop and commercialize the EYLEA PFS. Antitrust Compl. ¶ 152. That collaboration was carried out under an agreement styled the EYLEA PFS Development Agreement (the "Development Agreement"). *Id.*

According to Regeneron, by the terms of the Development Agreement, Regeneron could claim ownership rights to "any inventions, improvements, enhancements, or alike made during the Term [of the agreement] and conceived or reduced to practice or generated by Regeneron and/or Vetter"

relating to an anti-VEGF delivered to Vetter by Regeneron. Antitrust Compl. ¶ 153. The Development Agreement apparently bore fruit, because the Australian government approved EYLEA FPS in 2012. *Id.* ¶ 154.

In the meantime, Regeneron alleges that Novartis and Vetter were also working together to produce a PFS. Antitrust Compl. ¶ 155. That collaboration was similarly successful, and Novartis and Vetter eventually produced LUCENTIS PFS. *Id.* ¶ 141. According to Regeneron, several Vetter employees made "significant contributions" along the way. *Id.* Regeneron further alleges that those significant contributions involved the same anti-VEGF drug from which EYLEA is made. *Id.* ¶ 143.

But Novartis and Vetter's joint efforts did not go off entirely without a hitch. Apparently, on February 27, 2013, Vetter sent Novartis a letter objecting to certain patent applications that Novartis had filed in Germany and Australia. Antitrust Compl. ¶ 142. At bottom, Vetter objected that Novartis claimed credit for inventions and improvements allegedly made by Vetter personnel. *Id.*

Novartis and Vetter met to discuss the matter, and apparently came to a final agreement signed by both parties by October 2, 2013 (the "2013 Amendment"). Antitrust Compl. ¶¶ 145-46. By the terms of that agreement, Novartis agreed that Vetter significantly contributed to developing its PFS patent family. *Id.* ¶ 146. It must be said, though, that the 2013 Amendment

specifically excludes crediting Vetter with contributing to "any [i]nvention." *Id.*

On January 25, 2013, Novartis filed a patent for the LUCENTIS PFS ("the '631 Patent"). Antitrust Compl. ¶ 143. The '631 Patent relates back to Novartis's German patent, and apparently claims the same subject matter. *Id.* ¶ 144. What Regeneron claims the '631 Patent does not do, however, is credit any Vetter employee as an inventor. *Id.* ¶ 147. To the extent any of them qualify, that poses a problem, because 35 U.S.C. § 116 requires that all inventors jointly file for a patent, unless a joint inventor refuses to join in the patent application or cannot be found.

The PTO issued the '631 Patent on December 29, 2015. Antitrust Compl. ¶ 147. Apparently, Novartis only planned on marketing LUCENTIS PFS outside the United States. *See Id.* ¶ 53. For the purposes of serving the United States ("U.S.") market, Novartis licensed the patent for the LUCENTIS PFS to a separate company, Genentech, Inc. ("Genentech"). *Id.* ¶¶ 53-54. Genentech then launched LUCENTIS PFS in the U.S. in early 2017. *Id.* ¶ 84. According to Regeneron, Novartis has a 33.3% ownership stake in Genentech's parent company, Roche. *Id.* And in any case, when BEOVU PFS—another anti-VEGF—is launched, Novartis appears to intend to market it in the U.S. *Id.* ¶ 2.

Summing up, according to Regeneron, Novartis got the jump on its efforts to market an anti-VEGF PFS. But in doing so, Novartis allegedly recruited Vetter's help. Regeneron claims that Novartis's overture towards Vetter violates its rights because any ideas by Vetter relating to EYLEA PSF were contractually Regeneron's property.

And because one of the drugs used in developing the LUCENTA PSF was functionally identical to EYLEA, Regeneron claims that Vetter's contributions to that patent qualified as relating to EYLEA PSF. From Regeneron's perspective, Novartis's exclusion of Vetter's assistance from the patent application was a calculated move to prevent the '631 Patent from becoming Regeneron's property by virtue of the Development Agreement. Antitrust Compl. ¶¶ 147-48.

B. Regeneron's Negotiations with Vetter

In the meantime, Regeneron claims that its experiences with Vetter took a sharp and downward turn once the 2013 Amendment was signed. According to Regeneron, in October 2013, the same month the agreement had taken effect, Vetter sent a sublicense demand to Regeneron. Antitrust Compl. ¶ 166. The letter claimed that the EYLEA PFS would be covered under Novartis's then-pending '631 Patent. *Id.* By extension, if Regeneron wanted to continue to try to market EYLEA PFS, it would have to agree to take out a sublicense from Vetter first. *Id.*

However, Vetter would only agree to offer a sublicense if Regeneron agreed to use Vetter exclusively to fill its EYLEA PFS products for the duration of the '631 Patent, a term of nearly twenty years. Antitrust Compl. ¶ 167. In addition, Vetter's proposed agreement required that Regeneron promise never to challenge the validity of the '631 Patent. *Id.* ¶ 170.

Previously, Vetter had filled EYLEA vials without any exclusivity requirement, so Regeneron claims that it was wary of the sudden pivot. Antitrust Compl. ¶ 167. On top of that, the lengthy duration of the exclusivity clause gave Regeneron pause. *Id.* Finally, Regeneron claims that it felt that Vetter and Novartis's agreement and general relationship with each other raised concerns on Regeneron's part that Vetter would prioritize Novartis's interests over its own. *Id.* ¶ 168.

For these reasons and more, Regeneron refused to sign the agreement. Antitrust Compl. ¶ 174. As a result, Vetter stopped filling EYLEA PFS. *Id.* ¶ 175. Regeneron then found a new supplier but claims that doing so required some alterations to EYLEA PFS's design and took a substantial toll on its time and resources. *Id.*

In 2017, Regeneron claims that it approached Vetter again to discuss working together. Antitrust Compl. ¶ 176. Vetter responded with the same offer it had extended in 2013. *Id.* Regeneron once again refused. *Id.*

C. Novartis's Patent Suit

Despite the '631 Patent, Regeneron released EYLEA PFS sometime around December of 2019. *Novartis Pharma AG v. Regeneron Pharms., Inc.*, 1:20-CV-690, Dkt. 70 ("Patent Compl."), ¶ 29.[2] From Novartis's perspective, that amounts to infringement, because the '631 Patent gives Novartis the exclusive right to market prefilled, sterilized syringes containing an anti-VEGF solution. *Id.* ¶ 15. And according to Novartis, the EYLEA PFS is precisely that. *Id.* ¶¶ 20-28 (describing attributes of EYLEA PFS that allegedly fall under terms of '631 Patent).

But based on Regeneron's version of events, there were some internal hoops Novartis needed to jump through before it could bring the infringement suit. Antitrust Compl. ¶ 186. Apparently, the 2013 Amendment contained a clause which gave Vetter the exclusive right to sublicense the '631 Patent. *Id.* ¶ 156. But on December 18, 2019—around the same time EYLEA PFS was hitting the market—the 2013 Amendment was itself amended (the "2019 Amendment"). *Id.* ¶ 186. By the terms of the new agreement, Novartis was given sole enforcement authority concerning the '631 Patent in exchange for a cut of all license income. *Id.*

[2] The Court refers to the complaint in the '631 Patent case solely to provide context to the parties' disputes. In no way will this complaint be relied upon in reaching a decision on the present motion practice, especially Novartis and Vetter's Rule 12(b)(6) motions.

On June 19, 2020, after the 2019 Amendment took effect, Novartis sued Regeneron for infringing the '631 Patent by marketing EYLEA PFS. *Novartis*, 1:20-CV-690, Dkt. 1. At the same time, Novartis filed a complaint with the United States International Trade Commission ("ITC") claiming infringement of the same patent. *Novartis*, 1:20-CV-690, Dkt. 27, p. 1.[3]

On July 28, 2020, Regeneron moved to stay Novartis's claim before this Court pending resolution of the ITC complaint. *Novartis*, 1:20-CV-690, Dkt. 27, p. 1. Novartis did not oppose, and the stay was granted on July 30, 2020. *Id.*

On April 8, 2021, Novartis voluntarily withdrew its ITC complaint to focus its efforts on this case. *Novartis*, 1:20-CV-690, Dkt. 38-1, pp. 3-6. The stay was then lifted on June 11, 2021. *Novartis*, 1:20-CV-690, Text Minute Entry Dated 6/11/2021.

D. Regeneron's Antitrust Suit

Regeneron was not sitting idle while Novartis's patent claim proceeded. On July 17, 2020, Regeneron filed the antitrust claim against both Novartis and Vetter. *Regeneron*, 1:21-CV-1066, Dkt. 1. Essentially, that complaint alleges that Novartis and Vetter conspired together to freeze Regeneron out of the market for anti-VEGF PFS products by forcing it into a long-term

[3] Pagination corresponds with CM/ECF.

contract with Vetter and requiring it to respect the '631 Patent. *See generally id.*, *passim*. To make matters worse, Regeneron sees itself as the rightful owner of the '631 Patent based on the Development Agreement and accuses Novartis of arranging for Vetter's breach of that contract. In addition, Regeneron accuses Novartis of intentionally omitting information material to the '631 Patent relating to a prior art. Antitrust Compl. ¶¶ 219-22.

More specifically, Regeneron's complaint asserts five causes of action: (I) attempted monopolization through a scheme of patent fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) for omitting prior arts in violation of § 2 of the Sherman Act; (II) attempted monopolization in violation of § 2 of the Sherman Act even without *Walker Process* fraud; (III) unreasonable restraint on trade in violation of § 1 of the Sherman Act; (IV) attempted monopolization through *Walker Process* fraud for omitting the contributions of Vetter inventors in violation of § 2 of the Sherman Act; and (V) tortious interference with a contract under New York state law.[4] Regeneron brings Count III against both Novartis and Vetter. For the remainder, Novartis alone is accused of wrongdoing.

E. <u>The Present Motion Practice</u>

[4] The parties do not dispute that Regeneron's tortious interference claim comes under New York law.

Once the stays were lifted at the conclusion of the ITC proceedings, both cases continued. On October 15, 2021, Novartis and Vetter each moved to dismiss Regeneron's First Amended Complaint—the current operative pleading in the Antitrust case—for failure to state a claim. *Regeneron*, 1:21-CV-1066, Dkts. 184; 186.

But on November 5, 2021, Regeneron moved to stay both the '631 Patent case and the Antitrust case. *Novartis*, 1:20-CV-690, Dkt. 98; *Regeneron*, 1:21-CV-1066, Dkt. 216. Apparently, on April 16, 2021, while the ITC complaint was still pending, Regeneron had asked the PTO for an *inter partes* review to declare the '631 Patent invalid. *Novartis*, 1:20-CV-690, Dkt. 98-4, p. 85; *Regeneron*, 1:21-CV-1066 Dkt. 216-4, p. 85. On October 26, 2021, the PTO agreed. *Novartis*, 1:20-CV-690, Dkt. 98-3, p. 1; *Regeneron*, 1:21-CV-1066 Dkt. 216-3, p. 1. Thus, Regeneron argues that both cases should be stayed until the PTO has an opportunity to determine whether the '631 Patent is valid.

Finally, on December 23, 2021, Novartis and Regeneron both filed their *Markman* briefs in the '631 Patent case. *Novartis*, 1:20-CV-690, Dkts. 103; 104. This decision now follows to resolve all three pending motions.

III. DISCUSSION

The first step in untangling the knot these cases have worked themselves into is deciding which thread to pull on first. To that end, the only dispute

concerning the '631 Patent's claim construction is whether there is actually a dispute in the first place. There is little harm in reaching that simple question first before considering a stay that would leave that dispute unaddressed. After that, should Novartis and Vetter's motions to dismiss have merit, the Antitrust case could be dismissed in its entirety, which would obviously moot the question of staying that case. Accordingly, the Court will turn to the motion to dismiss second, and only reach the motion to stay after considering both other active motions.

A. Claim Construction

"Claim construction is a question of law, the purpose of which is to determine what is covered by the patent's claims." *Verint Sys. Inc. v. Red Box Recorders Ltd.*, 166 F. Supp. 3d 364, 374 (S.D.N.Y. 2016) (citing *Markman*, 517 U.S. at 384. That process is geared toward "elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Verint Sys.*, 166 F. Supp. 3d at 374 (cleaned up) (citing *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000)).

"When faced with 'an actual dispute regarding the proper scope' of a patent claim, the court must construe the allegedly infringed claim to determine its meaning and scope." *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 2014 WL 4199244, at *2 (N.D.N.Y. Aug. 21, 2014). But

the converse is also true: "a trial court need not construe claim terms whose meaning the parties do not dispute." *Holmberg v. United States*, 124 Fed. Cl. 610, 613 (2016).

At any rate, although a court "may have the authority to adopt claim constructions which have not been proposed by either party[, it] should be hesitant to do so." *Holmberg*, 124 Fed. Cl. at 613 (citing *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319 (Fed. Cir. 2006)).

As required under Local Patent Rule for the Northern District of New York ("Local Patent Rule") 4.4, both Regeneron and Novartis submitted a joint claim construction setting out their agreed definitions of the terms of the '631 Patent.[5] *Novartis*, 1:20-CV-690, Dkt. 100. In that document, Novartis agreed with Regeneron's construction of all terms. *See generally id.*, *passim*.

But Novartis's apparent consent does not, it seems, resolve the issue of claim construction on its own. According to Regeneron, Novartis intends to sandbag it and the Court by making arguments at trial contrary to the terms upon which the parties agreed. Specifically, Regeneron claims that Novartis

[5] Both parties would also file short responsive claim construction briefs on January 24, 2022. *Novartis*, 1:20-CV-690, Dkts. 109; 111. In Regeneron's brief, it requested leave to file a reply brief in the event that Novartis filed a responsive brief, because Novartis's initial submission was decidedly barebones. However, because Novartis's responsive brief only dealt with Regeneron's arguments and continues to disavow any true dispute of the claim construction, permitting Regeneron to file a reply brief would be a waste of time and effort that this Court will not indulge.

has not disavowed an intent to argue that a syringe is "terminally sterilized" only if it has been: (1) subjected to stability testing; and (2) protected from further contact after the sterilizing agent has been applied and stability testing conducted.

The problem, it seems, is that the proposed construction of "terminally sterilized" makes no mention of those two additional requirements. In Regeneron's opinion, the only solution is for the Court to take the further step of precluding Novartis from arguing that anything more is required for a syringe to be "terminally sterilized" than what is described in the proposed claim construction.

Regeneron is mistaken. After all, if the proposed construction would foreclose Novartis's argument, then the Court's adoption of that construction would give Regeneron the relief it is requesting without further tampering. On the other hand, the Court can think of only two possible reasons that adopting the proposed claim would *not* foreclose that line of argument.

First, it may be that the construction of the claim has nothing to do with Novartis's argument, in which case it would be an overreach for the Court to hamstring Novartis at the claim construction stage. Or second, it may be that Regeneron could have requested a more favorable construction of the claim and failed to do so. In that case, Regeneron is asking the Court to take the disfavored step of adopting a construction without a proposal simply to

cover for its own tactical misstep. *Holmberg*, 124 Fed. Cl. at 613 (holding that courts should be hesitant to adopt claim constructions not proposed by parties). Under none of those circumstances would the Court be moved to produce its own more restrictive version of the proposed claim construction as Regeneron requests.

Neither is the Court persuaded by Regeneron's argument that the Court is obliged to go looking for disputes that do not appear on the face of the *Markman* briefing. In support of that argument, Regeneron relies on *PPC Broadband*, 2014 WL 4199244 and *Defenshield, Inc. v. First Choice Armor & Equipment, Inc.*, 2013 WL 5323752 (N.D.N.Y. Sept. 20, 2013).

Both of those cases refer to a court's obligation to resolve disputes in claim construction. *See PPC Broadband*, 2014 WL 4199244, at *2 (noting that court is obligated to resolve dispute in claim scope to prevent parties from impermissibly arguing claim construction to jury); *Defenshield*, 2013 WL 5323752, at *8-9 (deciding to construe claim despite potential for common meaning to prevent submitting claim construction question to jury).

But the purpose for that obligation lies in making sure that the jury isn't tasked with trying to sort out the definition of a claim when that should be up to the Court. *See Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1359 (Fed. Cir. 2004) (explaining that it is duty of trial court to inform jurors of claim construction rulings on disputed terms); *see also O2 Micro Int'l Ltd. v.*

Beyond Innovation Tech. Co., Ltd., 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of [ ] claims, the court, not the jury, must resolve that dispute.").

There is no danger of that in this case because the Court *is* construing the claim Regeneron argues to be disputed. In fact, the Court is construing it in precisely the manner that Regeneron requested. The jury will thus be instructed on the '631 Patent's claims in accordance with Regeneron's proposed construction, and the Court need not—and will not—devise its own construction beyond what Regeneron requested. *See, e.g.*, *Holmberg*, 124 Fed. Cl. at 613. The Court thus adopts the proposed claim construction in its entirety and will not require a *Markman* hearing.

B. Novartis's Motion to Dismiss

Having settled the matter of claim construction, the Court turns to Novartis and Vetter's Rule 12(b)(6) motions to dismiss the Antitrust case. To survive a motion to dismiss under that Rule, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). That factual matter may be drawn from "the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010).

Importantly, "the complaint is to be construed liberally, and all reasonable inferences must be drawn in the plaintiff's favor." *Ginsburg v. City of Ithaca*, 839 F. Supp. 2d 537, 540 (N.D.N.Y. 2012) (citing *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002)). If the complaint and its additional materials—when viewed through that pro-plaintiff lens—are not enough to raise the plaintiff's right to relief on a claim above the speculative level, that claim must be dismissed. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

1. Antitrust Claims

"A patentee has the exclusive right to manufacture, use, and sell his invention." *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 690 (2d Cir. 2009) (citing *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 135 (1969)). The purpose behind granting a patent is to incentivize "invention, investment, and disclosure" by granting a "statutory right to exclude" other competitors. *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1355 (Fed. Cir. 1991). By a patent's very nature, then, "[t]he commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist." *Id.* at 1354.

None of that is meant to say that a patent automatically forecloses liability for antitrust violations. Instead, there are at least two ways that a patent holder can run afoul of antitrust law. For the first, "[i]n *Walker*

Process, the Supreme Court held that a plaintiff could bring an action under § 2 of the Sherman Act based on the alleged maintenance and enforcement of a fraudulently[ ] obtained patent." *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016) (citing *Walker Process*, 382 U.S. at 173-74).

The gist of a *Walker Process* claim is that an unlawful patent should be stripped of its usual immunity from antitrust liability. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). Whether a patentholder deserves to lose out on its monopolistic immunity is a question to be answered only under Federal Circuit law. *See id.* However, questions of antitrust law beyond the alleged patent fraud are decided under the law of each regional circuit. *Id.*

There are two global elements to a *Walker Process* claim: (1) "that the antitrust-defendant obtained the patent by knowing and willful fraud on the patent office and maintained and enforced the patent with knowledge of the fraudulent procurement;" and (2) all other elements of a Sherman Act monopolization claim are also met. *TransWeb*, 812 F.3d at 1306.

For an attempted monopolization claim under § 2 of the Sherman Act, like those that Regeneron brings against Novartis, the elements are: (1) predatory or anticompetitive conduct; (2) informed by a specific intent to monopolize;

with (3) "a dangerous probability of achieving monopoly power." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015).

As for the second means of establishing an antitrust violation even with patent protections in play, the Supreme Court held in *Federal Trade Commission v. Actavis, Inc.* that a patentholder may, in certain circumstances, be held liable for using the patent to unreasonably restrain trade. 570 U.S. 136, 147 (2013).

In any case, though, one essential element of all antitrust claims is the existence of a relevant geographic and product market subjected to the defendant's anticompetitive conduct. *Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 383 (S.D.N.Y. 2007). Novartis, Vetter, and Regeneron all agree that the relevant geographic market in this case is the United States, so that first requirement is met.

But the parties are decidedly less in agreement when it comes to defining the relevant product market. To survive a motion to dismiss, a claimed product market must provide "analysis of the interchangeability of use or the cross-elasticity of demand" for products in the market while establishing a product market that strikes the court as plausible. *Chapman v. N.Y. State Div. for Youth*, 546 F.3d 230, 237 (2d Cir. 2008) (citation omitted). Reasonable interchangeability of use or cross-elasticity of demand between

the product itself and its substitutes determine "the outer boundaries of a product market." *Id.* (cleaned up).

Generally, defining a market involves "a deeply fact-intensive inquiry," so courts are wary of granting a motion to dismiss based on a failure to adequately plead the relevant market. *Chapman*, 546 F.3d at 238. Even so, a plaintiff's definition of the product market that fails to reference the rule of reasonable interchangeability and cross-elasticity of demand or else clearly does not encompass all interchangeable substitute products is legally insufficient and may be dismissed even at the pre-answer stage. *Id.*

That marks the second reference to the rule of reasonable interchangeability, so this is a good time to define the term. Effectively, the rule of reasonable interchangeability means that a plaintiff's market definition must include "all products reasonably interchangeable by consumers for the same purposes." *City of N.Y. v. Grp. Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011) (internal citations and quotation marks omitted). The logic behind the rule is that "the ability of consumers to switch to a substitute restrains a firm's ability to raise prices above the competitive level." *Id.*

Although a plaintiff claiming an antitrust violation for medical products need not address every conceivable alternative to the products it claims make up the market, "it must allege sufficient facts about other treatments to make

its proposed product market plausible." *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 578 (S.D.N.Y. 2011) (citing *Rome Ambulatory Surgical Ctr., LLC v. Rome Mem'l Hosp. Inc.*, 349 F. Supp. 2d 389, 419 (N.D.N.Y. 2004) (noting that "a court cannot accept the market boundaries offered by plaintiff without at least a theoretically rational explanation for excluding alternatives" (cleaned up))).

For Regeneron's part, it defines its proposed market as follows: "anti-VEGFs in prefilled syringes that are approved by the FDA for the treatment of certain ophthalmic diseases." Antitrust Compl. ¶ 191. Meanwhile, by the antitrust claim's own terms, the '631 Patent covers a PFS containing any anti-VEGFs. *Id.* ¶ 8.

In other words, the relevant market that Regeneron claims is identical to the protection afforded to Novartis by the '631 Patent. Strange as it may seem that the market should be limited to anti-VEGFs in a PFS when the same drug comes in a vial as well, Regeneron nevertheless tries to justify this more limited scope to the relevant market in three ways.

First, Regeneron argues that PFSs have performance-based advantages over their counterparts in vials because they are quicker, easier, and safer. Antitrust Compl. ¶¶ 196-97. Second, Regeneron also points out that manufacturing anti-VEGF vials requires different equipment than making a PFS. *Id.* ¶ 199. Third, Regeneron states that "a small, but significant, price

increase in the PFS version would not cause physicians to substitute the vial version for PFS . . . ." *Id.* ¶ 200.

None of those three reasons plausibly justifies Regeneron's narrow market. From the outset, that there might be a difference in the equipment required to produce a PFS as opposed to a vial says nothing about whether a consumer would find a vial and PFS interchangeable. Antitrust Compl. ¶ 199; *see Grp. Health Inc.*, 649 F.3d at 155 (explaining that inquiry into product market looks at interchangeability of products to consumer).

Additionally, Regeneron's other two bases for explaining away the interchangeability of vials and PFS packages fail because they would allow any patented product to be a unique market by itself. After all, most any patent will carry with it improvements to a product's efficacy. And that small boost in usefulness will often be valuable enough to merit some heightened costs. The resultant commercial advantage is a sacrifice that the law is willing to make to spur technical and technological advancement. *Abbott Labs.*, 952 F.2d at 1355 (describing patent's right to exclude as incentive for innovation).

That commercial advantage evaporates if Regeneron's theory carries water. After all, if a patent allows its owner to exclude other firms from producing products covered by its terms, and an antitrust plaintiff can define a market so narrowly that the patent itself creates its own market, then

plaintiffs could never fail to plead out an antitrust claim against a patent owner as long as they raised a colorable challenge to the patent's validity. *In re DDAVP Direct*, 585 F.3d at 690. In other words, if the Court accepts Regeneron's proposed market, then all patents would immediately confer complete monopoly power to the inventor.

The problem with that outcome is obvious as soon as *Walker Process* enters the equation. After all, if a plaintiff could simply limit the scope of the relevant product market to the scope of a patent, then each of the three elements of an attempted monopolization claim would be met as a matter of course. *See New York ex rel. Schneiderman*, 787 F.3d at 651. The patent would exclude other firms from participating in the market, which is the definition of anticompetitive conduct. *Id.* Similarly, the mere act of seeking the patent evinces a clear intent to monopolize because a patent is itself a lawful monopoly. *Id.* From there, the patent would not only establish a dangerous probability of monopoly power, but a certainty, because no other firm could compete with the patent holder. *Id.*

In short, defining the relevant product market as narrowly as Regeneron alleges would collapse the second prong of the *Walker Process* inquiry for every patented product. *See TransWeb*, 812 F.3d at 1306 (noting that *Walker Process* requires proof of patent fraud and every element of antitrust claim). By extension, every instance of patent fraud would give rise to an antitrust

claim by definition. If that theory of an antitrust claim were viable, there would have been no need for the Supreme Court to carve out the *Walker Process* framework in the first place. Instead, it could simply have held that patent fraud is itself an antitrust violation.

It did not. On the contrary, the law is clear that "an inventor of new technology [does not] violate the antitrust laws merely because its patented product is favored by consumers." *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1298 (Fed. Cir. 2002). Accordingly, Regeneron has failed to meaningfully explain why anti-VEGF vials are not a reasonable substitute for an anti-VEGF PFS.

Of course, one can imagine a circumstance where the subject of a patent is so novel that there really is no fitting substitute, and the relevant product market would have to be constrained to the patented product. But Regeneron bore the burden of alleging that this case fits that bill. *Chapman*, 546 F.3d at 238 (noting that plaintiff has burden of establishing relevant product market). Instead of explaining why consumers would not be so free to choose between a vial or PFS delivery system for an anti-VEGF as to create a separate market, Regeneron merely explained that the PFS is, like all

valuable patented products, at least marginally superior to the vial. Antitrust Compl. ¶¶ 196-200. That is not enough.[6]

By extension, Regeneron's proposed market fails. As a consequence, all four of Regeneron's antitrust claims must be dismissed. *See, e.g.*, *Chapman*, 546 F.3d at 238-39 (affirming motion to dismiss antitrust claims because plaintiff's definition of relevant market was too narrow); *see also, e.g.*, *Bayer Schering*, 813 F. Supp. 2d at 577-78 (dismissing antitrust claim for failure to plead sufficient facts to demonstrate unavailability of acceptable substitutes when pleadings did not foreclose possibility that two other drugs taken together could achieve same result as single drug plaintiff attempted to use to define market).

2. Tortious Interference with a Contract

However, disposing of Regeneron's antitrust claims says nothing about its state law claim for tortious interference with a contract. To that end, under New York law, a claim for tortious interference charges a plaintiff with proving five elements: (1) a valid contract between the plaintiff and a third party; (2) about which the defendant knew; (3) "defendant's intentional

[6] Although the Court notes that Regeneron alleges that some 80% of anti-VEGF patients switched from vial to PFS once the latter option was introduced, that exodus at current price points does not suggest that if Novartis attempted to raise prices beyond a "small" discrepancy that those patients could not or would not simply switch back to their vials. Thus, Regeneron has still failed to allege that the availability of vials as an alternative would not constrain Novartis's ability to set prices as required to establish a product market. *See Grp. Health*, 649 F.3d at 155.

procurement of the third-party's breach of the contract without justification"; (4) the contract was actually breached; and (5) damages. *Rich v. Fox News Network, LLC*, 939 F.3d 112, 126-27 (2d Cir. 2019) (citing *Lama Holding Co. v. Smith Barney Inc.*, 668 N.E.2d 1370, 1375 (N.Y. 1996)). In establishing that the defendant caused the contract's breach, the plaintiff must prove that but-for the defendant's intervention, the contract would have been performed. *Rich*, 939 F.3d at 127.

Novartis principally argues that Regeneron's tortious interference with a contract claim came only after the statute of limitations had run out. To that end, "the statute of limitations for tortious interference claims is three years." *Enzo Biochem, Inc. v. Amersham PLC*, 981 F. Supp. 2d 217, 225 (S.D.N.Y. 2013) (citing N.Y. C.P.L.R. § 214(4)). The clock begins to tick once the claim becomes enforceable, or "when all elements of the tort can be truthfully alleged in a complaint." *Enzo Biochem*, 981 F. Supp. 2d at 225.

Even if the statute of limitations has long since run, though, a defendant may be equitably estopped from invoking it as a defense if the plaintiff was "induced by fraud, misrepresentations[,] or deception to refrain from filing a timely action."[7] *Weizmann Inst. of Sci. v. Neschis*, 229 F. Supp. 2d 234, 252 (S.D.N.Y. 2002) (citation omitted). But the plaintiff bears the burden of

[7] "Unlike federal law, . . . New York state law does not differentiate between doctrines of fraudulent concealment (equitable tolling) and equitable estoppel." *In re Fischer*, 308 B.R. 631, 656 (E.D.N.Y. 2004).

establishing that it brought the claim within a reasonable time after the deception has come to light. *Id.*

Yet it is worth keeping in mind that equitable estoppel is not a general remedy to punish secretive wrongdoing, but a corrective measure aimed at preventing a defendant from reaping the benefits of deceiving a potential plaintiff to head off a lawsuit. *See Twersky v. Yeshiva Univ.*, 993 F. Supp. 2d 429, 442 (S.D.N.Y. 2014). In other words, equitable estoppel is only "appropriate where the plaintiff is prevented from filing an action within the applicable statute of limitations due to defendants' misconduct toward the potential plaintiff, not a community at large." *Id.* (internal citations and quotation marks omitted) (finding equitable estoppel unsupported where defendant made alleged misrepresentation to public, not specifically to plaintiff for purpose of preventing lawsuit).

In addition, "the equitable estoppel doctrine is not available to a plaintiff who possesses timely knowledge sufficient to place him or her under a duty to make and ascertain all the relevant facts prior to the expiration of the applicable statute of limitations." *Gonzales v. Nat'l Westminster Bank PLC*, 847 F. Supp. 2d 567, 572 (S.D.N.Y. 2012).

In any case, a statute of limitations defense may only be granted on a Rule 12 motion if it "appears beyond doubt that the plaintiff can prove no set of facts in support of [its] claim which would entitle [it] to relief." *Ortiz v.*

Cornetta, 867 F.2d 146, 148 (2d Cir. 1989) (citing *Abdul-Alim Amin v. Universal Life Ins. Co.*, 706 F.2d 638, 640 (5th Cir. 1983)).

Although Regeneron provided a staunch defense for the timeliness of its antitrust claims, it spent not a single word defending its tortious interference claim. That oversight would justify dismissal on its own. S*ee In re Jumei Int'l Holding Ltd. Sec. Litig.*, 2017 WL 95176, at *5 n.4 (S.D.N.Y. Jan. 10, 2017) (noting that arguments not addressed in opposition briefing are conceded). But in the alternative, even if the Court were to read Regeneron's arguments so broadly as to reach its tortious interference claims as well as its antitrust claims, those arguments would still fail.

It is clear that the breach that Regeneron complains of involved Novartis's persuading Vetter to violate the Development Agreement by helping it develop LUCENTIS PFS. Antitrust Compl. ¶¶ 285-91. The culminating act that Regeneron argues amounted to a breach of the Development Agreement was the omission of Vetter employees from the list of inventors for the '631 Patent. *Id.* ¶ 290. But the '631 Patent issued in December of 2015. *Id.* ¶ 147.

In other words, the statute of limitations would have run out on Regeneron's tortious interference claims no later than December of 2018. Even if the Court assumes that Regeneron's tortious interference with a contract claim relates back to its initial complaint, the first antitrust

complaint was not filed until July 17, 2020.[8] *Regeneron*, 1:21-CV-1066, Dkt. 1. That claim appears to be plainly untimely.

But Regeneron would stave off that seeming inevitability. By its logic, Novartis and Vetter embarked on a pattern of fraudulent concealment[9] that kept their wrongdoing hidden until December of 2020, when Regeneron received discovery cluing it in on the terms of the 2013 Amendment. Regeneron's position is that Novartis should be equitably estopped from arguing that the statute of limitations bars Regeneron's tortious interference with a contract claim.

However, several of its allegations make equitable estoppel impossible. Taking its allegations as true, Novartis and Vetter sought to deceive the PTO and the market at large by concealing Vetter's inventorship. Antitrust Compl. ¶ 147. This alleged public deception, even if it was carried out exactly as Regeneron claims, was not tailored to prevent Regeneron from bringing a

[8] Under New York law, a claim asserted for the first time in an amended complaint relates back to the date of the initial complaint for the purposes of calculating the statute of limitations if the facts in the amended and initial complaints cover the same "transaction or occurrence." *Smith v. Bank of N.Y. Mellon Corp.*, 2011 WL 1642318, at *1 (S.D.N.Y. Apr. 25, 2011). Because the initial antitrust complaint also dealt with an alleged breach of the Development Agreement, Regeneron's tortious interference claims likely relate back to the filing of the initial antitrust complaint. However, since both complaints were filed well after 2018, the exercise of relating back is largely academic, so the Court will simply assume relation back for the purposes of the present motion practice.

[9] Because Regeneron exclusively defended the timeliness of its antitrust claims, it frames its arguments that the statute of limitations should be tolled as "fraudulent concealment" by Novartis and Vetter using the language employed in antitrust claims. *See Schenker AG v. Societe Air France*, 102 F. Supp. 3d 418, 424 (E.D.N.Y. 2015) (describing fraudulent concealment defense to statute of limitations in antitrust cases). For the purposes of the present hypothetical exercise the Court will assume that Regeneron also meant to argue for equitable estoppel under a theory of fraudulent concealment under state law.

suit, but instead attempted to secure an advantageous patent for Novartis. In other words, the PTO and every other medical supply company were just as much the targets of Novartis's alleged deception as was Regeneron. *See id.* Because a public deception cannot justify equitable estoppel, Regeneron's claims are not timely and must be dismissed. *See Twersky*, 993 F. Supp. 2d at 442 (explaining that misconduct aimed at community at large cannot satisfy equitable estoppel).

In addition, Regeneron's own allegations establish that it had notice sufficient to call for further investigation into whether it had a tortious interference claim as early as 2013. *See Gonzales*, 847 F. Supp. 2d at 572 (explaining that equitable estoppel is not available when plaintiff had access to information requiring it to investigate further into claim).

Also, Regeneron alleges that in 2013 Vetter suddenly pivoted from a mutually productive relationship to a demand that Regeneron work exclusively with Vetter. Antitrust Compl. ¶¶ 167-68. Vetter's new terms were also so conspicuously protective of Novartis's new patent for an anti-VEGF PFS that Regeneron felt uncomfortable agreeing to them because it believed Vetter would be more interested in protecting Novartis's interests than Regeneron's. *Id.*

But most damning of all, Regeneron alleges that Novartis should have known the rough outline of the Development Agreement between Regeneron

and Vetter because similar agreements are so commonplace among pharmaceutical suppliers and developers when they work together to produce a drug. Antitrust Compl. ¶ 164. By the same logic, Regeneron should by its own allegations have drawn the inverse inference that Vetter and Novartis worked together on the LUCENTIS PFS given the apparent agreement between the two geared towards protecting Novartis's impending patent rights.

In other words, Regeneron cannot justify its own failure to dig into the details concerning Novartis and Vetter's relationship by clinging to common industry knowledge to support Novartis's awareness of the Development Agreement with one hand while pushing that knowledge away with the other once its own expected awareness gets put at issue.

Regeneron claims that one of the things that made it most suspicious of Vetter's renegotiated contract was its insistence on protecting the '631 Patent. Antitrust Compl. ¶ 170. And it also felt from the start that it could not trust that its needs would be prioritized given the apparently—and suddenly so—close relationship between Novartis and Vetter. *Id.* ¶ 168.

Regeneron knew as early as October of 2013 that Vetter had a sudden and powerful interest in protecting Novartis's '631 Patent and claims that similar collaborations on products often involve binding agreements. By extension, Regeneron had ample information to urge it to investigate further into

Novartis and Vetter's relationship as early as 2013. It cannot now claim that Novartis and Vetter wrongfully deceived it when it failed to diligently ascertain whether it was harmed in the first place.

Regeneron's claim for tortious interference with a contract must, as a consequence, be dismissed as time-barred.[10] *See Gonzales*, 847 F. Supp. 2d at 572 (finding equitable estoppel unavailable at Rule 12(b)(6) stage where facts alleged in complaint put plaintiff unquestionably on notice that alleged wrongdoing was possible).

As a result, every claim in Regeneron's antitrust complaint must be dismissed. The only remaining question is whether that complaint's dismissal should be with prejudice or without. Because Regeneron is a counseled litigant that has already amended its complaint once, the Court sees no reason to grant it a third bite at the apple, especially when it has not even asked for one. *See, e.g.*, *Marks v. Energy Materials Corp.*, 2015 WL 3616973, at *10 (S.D.N.Y. June 9, 2015) (noting that dismissal with prejudice is appropriate where counseled plaintiff has already amended complaint once and failed to request leave to amend in response to motion to

[10] To whatever extent Regeneron intended to argue that the continuing violation doctrine would save the timeliness of its tortious interference claims, the Court notes that "[t]ortious interference with contract claims are not continuing torts, instead accruing when the defendant performs an action or inaction that constitutes interference." *Tarazi v. Truehope Inc.*, 2017 WL 5957665, at *19 (S.D.N.Y. July 28, 2017) (citation omitted). That theory thus cannot save Regeneron's tortious interference claims, either.

dismiss). Accordingly, the antitrust complaint must be dismissed with prejudice in its entirety.[11]

C. Regeneron's Motion to Stay

Finally, the Court turns to Regeneron's motion to stay the '631 Patent during the PTO's *inter partes* review of the '631 Patent's validity. On that score, "[t]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the cases on its docket with economy of time and effort for itself, for counsel, and for litigants." *Rensselaer Polytechnic Inst. v. Apple Inc.*, 2014 WL 201965, at *3 (N.D.N.Y. Jan. 15, 2014) (citing *Landis v. N. Am., Co.*, 299 U.S. 248, 254 (1936)). The party seeking the stay bears the burden of demonstrating that it is entitled to one. *Rensselaer Polytechnic Inst.*, 2014 WL 201965, at *3.

When a stay request is instigated by a pending PTO proceeding digging into the validity of patents at issue in the lawsuit, courts generally consider three factors: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Rensselaer Polytechnic*

[11] By extension, Novartis's request for oral argument is denied as moot.

Inst., 2014 WL 201965, at *3 (citation omitted). Those factors are not exclusive, and the inquiry embraces the totality of the circumstances. *Id.*

Of those factors, there is some debate among lower courts as to which is the most important. *Compare, e.g.*, *RetailMeNot, Inc. v. Honey Sci. LLC*, 2020 WL 373341, at *3 (D. Del. Jan. 23, 2020) ("The most important factor bearing on whether to grant a stay is whether the stay is likely to simplify the issues at trial."); *British Telecommunications PLC v. IAC/InterActiveCorp*, 2019 WL 4740156, at *7 (D. Del. Sept. 27, 2019) (same); *Intellectual Ventures II LLC v. BITCO Gen. Ins. Corp.*, 2016 WL 4394485, at *3 (E.D. Tex. May 12, 2016) (same), *with, e.g.*, *InVue Sec. Prods. Inc. v. Vanguard Prods. Grp., Inc.*, 2019 WL 3958272, at *1 (M.D. Fla. Aug. 22, 2019) ("Prejudice against the non-movant is probably the most important factor to consider when determining whether a stay is appropriate."); *Puget BioVentures, LLC v. Med. Device Bus. Servs., Inc.*, 2017 WL 6947786, at *2 (N.D. Ind. Sept. 22, 2017) (same); *ADA Sols., Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d 348, 350 (D. Mass. 2011) (same). In any case, there can be little doubt that simplification of the issues and prejudice to the opposing party are more important than the case's state of completion.

As far as prejudice goes, courts typically consider an additional four sub-factors: (1) the timing of the review request; (2) the timing of the stay

request; (3) the status of the external review; and (4) the relationship of the parties. *Wiesel v. Apple Inc.*, 2021 WL 5038764, at *1 (E.D.N.Y. Oct. 29, 2021). However, when the parties are direct competitors, the stayed party is usually prejudiced. *Boston Sci. Corp. v. Cordis Corp.*, 777 F. Supp. 2d 783, 789 (D. Del. 2011) ("Courts are generally reluctant to stay proceedings where the parties are direct competitors."); *see Nidec Cor. v. LG Innotek Co., Ltd.*, 2009 WL 3673433, at *4 (E.D. Tex. Apr. 3, 2009) (collecting cases for proposition that stay usually incurs prejudice when party opponents are direct competitors).

Regeneron's stay request presents the Court with a close question. The only certainty about where the relevant factors stack up in terms of priority is that the third factor of the extent discovery has been completed and whether trial has been set is of the least importance. And that factor is decidedly mixed. On the one hand, a trial date has yet to be set for the '631 Patent case. But on the other, the parties have agreed that the extensive discovery from the ITC review will carry over for the '631 Patent case before this Court. *Novartis*, 1:20-CV-690, Dkt. 101-9, p. 4.

Ultimately, though, the fact that the Court has just disposed of the issue of claim construction pushes the '631 Patent case forward. Also, the substantial discovery that has been wrapped up through the ITC review similarly suggests that this case is not quite so short in the tooth as

Regeneron would like. Taken together, these facts cut against imposing the stay. *See Sunbeam Prods., Inc. v. Hamilton Beach Brands, Inc.*, 2010 WL 1946262, at *3 (E.D. Va. May 10, 2010) (explaining that case not being ready for trial does not cut in favor of stay so much as suggest that if stay is to be granted it is best to do so in early stages).

Which leaves the Court to consider the two more substantial factors: the extent to which a stay would simplify matters on the one hand and the resulting prejudice to Novartis on the other. On the first point, Regeneron argues that there is a chance that the '631 Patent will be struck down entirely, in which case there is neither need nor benefit to allowing the '631 Patent case to continue towards resolution. But Novartis counters that many of Regeneron's intended arguments in the '631 Patent case will not be available to it during the *inter partes* review. In fact, only its argument for obviousness will. As a result, if the '631 Patent survives the *inter partes* review, this case will not be simplified in any meaningful way.

Many courts in similar positions have held that even if it is possible that the issues will be simplified by a complete dismissal during an *inter partes* review, a stay is typically not warranted if there is a potential that only one issue among many will be resolved. *See Imax Corp. v. In-Three, Inc.*, 385 F. Supp. 2d 1030, 1032 (C.D. Cal. 2005). The Court finds that logic persuasive, given the abundance of arguments Regeneron raises about the

'631 Patent's invalidity, including their fraud challenge that formed the backbone of the Antitrust case. Accordingly, though some simplification may result from the PTO's review, this factor only slightly favors Regeneron.

By contrast, Novartis has amply demonstrated that prejudice to it is likely to result from a stay. For one thing, there can be no doubt that Novartis and Regeneron are direct competitors, which counsels strongly in favor of finding prejudice to Novartis. *Boston Sci. Corp.*, 777 F. Supp. 2d at 789.

To refute that apparent prejudice, Regeneron points out that the board conducting the *inter partes* review owes the parties a final decision no later than October of 2022. 35 U.S.C. § 316(a)(11). But as Novartis correctly counters, the review board may extend the deadline to issue a decision another six months, to April of 2023. *Id.*

On top of that, Regeneron explicitly requests that the Court stay the '631 Patent case until any appeals of the *inter partes* review to the Federal Circuit have concluded. 37 C.F.R. § 90.3 (requiring that any appeals of PTO decision be taken to Federal Circuit). Given that court's heavy caseload, it would not come as a surprise for that process to take more than another year to come to an end. In total, then, a stay while the PTO examines the validity of the '631 Patent could tack on at least another two or three years to this case. Courts routinely find stays of multiple years to be long enough to result in prejudice to the non-moving party. *See, e.g.*, *ADA Sols.*, 826 F. Supp. 2d at

351 (finding prejudice when delay between competitors could stretch on for years).

In other words, upon careful review, though there is at least a chance that the issues in the '631 Patent case could be simplified if the Court sat until the PTO had its say, that possibility is not enough to outweigh the near-certainty of prejudice to Novartis if the stay is granted. All the more so when the bulk of the discovery in this case has already been completed. Regeneron's request for a stay must therefore be denied. *See, e.g.*, *ADA Sols., Inc. v. Engineered Plastics, Inc.*, 826 F. Supp. 2d at 350-52 (declining to grant stay where some issues would be clarified by stay and trial was in early stages but prejudice would result to patent plaintiff).

IV. CONCLUSION

These two cases are not without their complications, to say the least. Between the multiple competing claims, the various avenues of external review, and the three disparate yet roughly contemporaneous motions, the result was something of a quagmire. Nonetheless, at the close of the present motion practice, it is the Court's hope that a clearer path forward has opened. The definitions of all necessary terms for the '631 Patent have been set. The Antitrust case has been dismissed. And the '631 Patent case is proceeding forward towards its resolution. Whether that path will in fact turn out to be

as clear as it seems is a question for another day. For now, there is nothing else to do but to let the parties to begin to walk it.

Therefore, it is

ORDERED that

1. Regeneron Pharmaceuticals, Inc.'s proposed claim construction is adopted in its entirety, and the Court affixes the meanings suggested by Regeneron Pharmaceuticals, Inc. to every disputed claim term;
2. Novartis Pharma AG, Novartis Pharmaceuticals Corporation, Novartis Technology LLC, and Vetter Pharma International GMBH's motion to dismiss Regeneron Pharmaceuticals, Inc.'s complaint in *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, 1:21-CV-1066 is GRANTED;
3. Regeneron Pharmaceuticals, Inc.'s complaint in *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, 1:21-CV-1066 is DISMISSED with prejudice;
4. The clerk of court is directed to enter judgment accordingly and close the case file for *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, 1:21-CV-1066; and
5. Regeneron Pharmaceuticals, Inc.'s motion to stay proceedings in *Novartis Pharma AG v. Regeneron Pharmaceuticals, Inc.*, 1:20-CV-690

pending the Patent and Trademark Office's *inter partes* review of the validity of the '631 Patent is DENIED.

IT IS SO ORDERED.

Dated: January 31, 2022
Utica, New York.

David N. Hurd
U.S. District Judge