

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

IN RE: AFLIBERCEPT PATENT
LITIGATION

MDL No. 1:24-MD-3103

This Document Relates to:
No. 1:25-cv-74

MEMORANDUM OPINION AND ORDER GRANTING IN PART REGENERON'S MOTION
TO STRIKE CERTAIN AFFIRMATIVE DEFENSES AND DISMISS CERTAIN
COUNTERCLAIMS [ECF NO. 680]

Pending before the Court is Plaintiff Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion to Strike Certain Affirmative Defenses and Dismiss Certain Counterclaims ("Regeneron's Motion") [ECF No. 680]. The Court convened for oral argument on April 7, 2026. ECF No. 802. The motion is fully briefed and ripe for decision. For the reasons set forth herein, the motion is **GRANTED IN PART** and **DENIED IN PART**.

I. PROCEDURAL BACKGROUND

In January 2024, Regeneron filed suit against Defendant Amgen, Inc. ("Amgen") in the Central District of California alleging infringement of 32 patents relating to its biologic Eylea in response to Amgen's submission of an abbreviated Biologics Drug Application for ABP 938, a proposed biosimilar of Eylea. *Regeneron Pharm., Inc. v. Amgen Inc.*, Case No. 2:24-cv-264 (C.D. Cal.). That case was then consolidated with other Eylea biosimilar cases then-pending before this Court. *In re Aflibercept Pat. Litig.*, 2024 WL

1597512, at *1 (J.P.M.L. Apr. 11, 2024). As part of those proceedings, this Court denied Regeneron's motion for preliminary injunction against Amgen, ECF No. 343 ("PI Order"), and the Federal Circuit affirmed, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, 130 F.4th 1372, 1379-80 (Fed. Cir. 2025) ("CAFC Opinion"). Both opinions relied on the accused formulation lacking a separate buffer required by the asserted claims. PI Order at 24-28; CAFC Opinion at 1383-84.

In June 2025, Regeneron brought the present action asserting U.S. Patent No. 12,331,099 (the "'099 patent"), which was also consolidated with the ongoing multidistrict litigation. Judicial Panel on Multidistrict Litigation Conditional Transfer Order (ECF No. 577). In its answer to the 2025 complaint, Amgen alleges inequitable conduct in the procurement of the '099 patent. Amgen's Corrected Answer at ¶¶ 52-98, 229-278 (ECF No. 666). Amgen also alleges antitrust violations based on the assertion of the '099 patent and twelve other patents previously but no longer asserted against Amgen (the "2024 Litigation Patents") (*id.* at ¶¶ 294-324) and asserts additional defenses and counterclaims based in laches (*id.* at ¶¶ 48-50, 217-228), patent misuse (*id.* at ¶¶ 99-111, 279-293), and unclean hands (*id.* at ¶ 41), in addition to others not challenged in Regeneron's Motion.

II. MOTIONS TO STRIKE AND DISMISS STANDARDS

Federal Rule of Civil Procedure ("FRCP") 12(b)(6) allows a plaintiff to move for dismissal of a counterclaim upon the ground that the answer does not "state a claim upon which relief can be granted." In ruling on a 12(b)(6) motion to dismiss, a court must accept as true all of the factual allegations contained in the pleading. *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 188 (4th Cir. 2007) (quoting *Erickson v. Pardus*, 551 U.S. 89, 94 (2007)). However, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

FRCP 12(f) allows the Court to "strike from a pleading an insufficient defense." Any defense that "would not, under the facts alleged, constitute a valid defense to the action can and should be deleted." *Waste Mgmt. Holdings, Inc. v. Gilmore*, 252 F.3d 316, 347 (4th Cir. 2001). "If a movant can show that a defense is clearly insufficient, the court should grant the motion to strike." *EEOC v. Route 22 Sports Bar, Inc.*, 2021 WL 2557087, at *2 (N.D.W. Va. June 22, 2021).

III. DISCUSSION

A. Inequitable Conduct

Regeneron challenges Amgen's Thirteenth Additional Defense and Fourth Counterclaim, which allege inequitable conduct in the

fraudulent procurement of the 2024 Litigation Patents and '099 patent. Amgen's Corrected Answer at ¶¶ 52-98, 229-278.

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). "To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id.* at 1287.

In response to several noted problems with the high volume and low quality of inequitable conduct assertions, the Federal Circuit raised the bar for the defense in, among other opinions, *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009); and *Therasense*, 649 F.3d 1276. As announced in *Therasense*, "the materiality required to establish inequitable conduct is but-for materiality." 640 F.3d at 1291-92. In other words, the party alleging inequitable conduct must show that the patent in question would not have issued but for the alleged conduct.

Though the question of "[w]hether inequitable conduct has been adequately pled is a procedural matter," "it bears on an issue that 'pertains to or is unique to patent law'" and thus Federal Circuit law applies. *Central Admixture Pharmacy Services, Inc. v.*

Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1356-57 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 648 (2007) (quoting *Intel Corp. v. Commonwealth Sci. & Indus. Research Org.*, 455 F.3d 1364, 1369 (Fed. Cir. 2006)).

As a form of fraud (formerly known as “fraud on the Patent Office,” see 6 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 39:13 (2026)), inequitable conduct pleading must meet the particularity requirement of FRCP 9(b). *Exergen*, 575 F.3d at 1326-27. That particularity requirement applies whether inequitable conduct is raised as a counterclaim or an additional defense. *Id.* at 1317, 1325-31 (applying FRCP 9(b) to counterclaim and affirmative defense without distinction); FRCP 9(b) (“[I]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”) (emphasis added); See also *Int’l Bus. Machines Corp. v. Priceline Grp. Inc.*, No. CV 15-137-LPS-CJB, 2017 WL 1349175, at *4 (D. Del. Apr. 10, 2017); *Chiron Corp. v. Abbott Lab’ys*, 156 F.R.D. 219, 221 (N.D. Cal. 1994).

Specifically, under FRCP 9(b), proper inequitable conduct pleading “requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO” and “must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2)

withheld or misrepresented this information with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1327-29.

While Amgen’s answer “describe[s] how Regeneron’s representatives withheld material references from the PTO, only to disclose them late in the examination process, in a manner designed to obscure their materiality,” “those allegations go to Regeneron’s intent” and are not themselves alleged as instances of inequitable conduct. Amgen’s Opposition at 12 (ECF No. 703). Rather, Amgen alleges inequitable conduct in two allegedly false representations made to the PTO by Regeneron. *Id.*

First, Amgen alleges that Regeneron submitted false inventorship declarations when obtaining the ’099 patent. Amgen’s Corrected Answer at ¶¶ 56-81. Specifically, Amgen disputes inventorship with respect to the lack of a buffer in the aflibercept formulation claimed by the ’099 patent. During prosecution, Regeneron resubmitted inventorship declarations used in a parent application¹ that *did* require a buffer, in compliance with § 602.05 of the Manual of Patent Examining Procedure. Amgen alleges that those declarations are false because of the allegedly new subject matter of the ’099 patent.

In evaluating Amgen’s pleading under FRCP 9(b), this Court is not required to accept unsupported conclusions or those based

¹ U.S. Patent App. No. 13/914,996; issued as U.S. Patent No. 8,481,046.

merely on "information and belief" without further factual support. *Exergen*, 575 F.3d at 1330 (affirming denial of leave to amend answer to add inequitable conduct counterclaim against specific entities where allegation was based only on "information and belief"). While it is true that pleading based on "'information and belief' is permitted under Rule 9(b) when essential information lies uniquely within another party's control," such pleading must still "set[] forth the specific facts upon which the belief is reasonably based." *Id.*

Such specific facts are important "lest inequitable conduct devolve into 'a magic incantation to be asserted against every patentee.'" *Exergen*, 575 F.3d at 1331 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)). Indeed, Federal Circuit case law requires "specific and demanding showings of evidence before a party may assert the defense of inequitable conduct." *Pressure Products Medical Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1320 (Fed. Cir. 2010) (affirming denial of leave to amend answer to add inequitable conduct defense based on undue delay and noting likely insufficiency of pleading). Amgen pleads little in the way of specific facts that distinguish its pleading from that which could be made in every case of patent infringement.

The only specific facts Amgen pleads to support its inventorship conclusion are its own buffer-free aflibercept

product, ABP 938, and patent filings; the PI Order and CAFC Opinion; and testimony from named inventors of the '099 patent regarding U.S. Patent No. 11,084,865 (the "'865 patent") made during prosecution and subsequent litigation to the effect that the '865 patent's aflibercept formulation requires a buffer. While these facts might support an inference that Regeneron was motivated to seek patent claims not including a buffer, it is unclear how these facts support the conclusion that the '099 patent's inventorship declaration was false. Indeed, Amgen's answer merely recites these facts before drawing its conclusion (see Amgen's Corrected Answer at ¶ 79) and offers no clarification in its Opposition (Amgen's Opposition at 12-15) (ECF No. 703).

Thus, because Amgen's "allegations of underlying facts" do not allow this Court to reasonably infer that inventorship was indeed false, those allegations do not allow this Court to "reasonably infer that a specific individual (1) knew . . . of the falsity of the material misrepresentation, and (2) . . . misrepresented this information with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1328-29.

Amgen's other allegation of inequitable conduct is Regeneron's October 23, 2024, submission of a preliminary amendment and its statement that "[n]o new matter enters by way of the present amendments." Amgen's Corrected Answer at ¶¶ 62, 81, 96. As with its inventorship theory, Amgen does not provide

factual support that elevates its pleading above what any accused infringer could plead where a patentee has amended its claims.

As two other district courts have noted (both before and after the Federal Circuit raised the bar for inequitable conduct in *Star Scientific, Exergen, and Therasense*), an applicant's statement that an amendment contains no new matter is not *itself* material. *Wilson Tool Int'l Inc. v. Mate Precision Tooling Inc.*, No. CV 17-4608, 2018 WL 6706326, at *11 (D. Minn. Apr. 19, 2018) (granting motion to dismiss inequitable conduct counterclaim and citing *Neutrino Dev't Corp. v. Sonosite, Inc.*, 512 F. Supp. 2d 1004, 1009 (S.D. Tex. 2007) *aff'd*, 269 F. App'x 976 (Fed. Cir. 2008)). Without further factual support, "[t]he statement that there is 'no new matter' contained in a patent amendment is no more material than a statement by a patentee that a patent is 'valid.'" *Neutrino*, 512 F. Supp. 2d at 1009 n.14. Such statements "would not bear upon any reasonable patent examiner's evaluation of a patent application" and "are legal conclusions outside of the purview of a patentee." *Id.*

Indeed, the examiner "had before him all material relevant to making an independent determination of new matter as he was required to do" and the applicant's statement "was cumulative to other correct material already of record pertaining to the question of new matter and the statement was not inconsistent with any other position taken by [applicant] during the prosecution." *Wilson*

Tool, 2018 WL 6706326, at *11 (quoting *Neutrino*, 512 F. Supp. 2d at 1009-10).

Thus, because Amgen presents no further factual support for the materiality of the allegedly false statement, this Court cannot “reasonably infer that a specific individual (1) knew . . . of the falsity of the *material* misrepresentation.” *Exergen*, 575 F.3d at 1328-29 (emphasis added).

Regeneron’s motion is therefore **GRANTED** with respect to Amgen’s Thirteenth Additional Defense and Fourth Counterclaim.

B. Antitrust

Regeneron next challenges Amgen’s Sixth through Eighth Counterclaims, which allege antitrust violations based on the alleged fraudulent procurement of the 2024 Litigation Patents and ’099 patent, as well as violation of California’s Unfair Competition Law (“UCL”). Amgen’s Corrected Answer at ¶¶ 294-324.

So-called “*Walker Process* fraud” is an antitrust violation based in the assertion of fraudulently obtained patents. See *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 174 (1965). Because of their basis in fraud, such claims are subject to the heightened pleading standards of FRCP 9(b). *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005).

As one Federal Circuit opinion has noted, it is an open question whether *Walker Process* fraud requires a greater showing

than inequitable conduct. See *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016). However, the standard for the materiality of a misrepresentation underlying a *Walker Process* claim is that "the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007).

Amgen's allegation relating to the '099 patent fails to state sufficient facts for this Court to reasonably infer materiality in the alleged misrepresentations for the reasons discussed above regarding Amgen's inequitable conduct allegations. However, Regeneron's arguments regarding Amgen's allegations based in the 2024 Litigation Patents can result only in a dismissal *without* prejudice.

First, Regeneron argues that Amgen is precluded from asserting its antitrust counterclaims under FRCP 13(a) because it did not assert them in its answer to the suit brought in 2024 (case number 1:24-cv-39). Regeneron's Motion at 18-20.

Amgen does not appear to contest that its counterclaim was compulsory under FRCP 13(a) other than to argue that *Mercoide Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 671 (1944) creates an exception for antitrust counterclaims to patent infringement claims. Amgen's Opposition at 21-22. Regeneron responds that *Mercoide* should be limited to its facts, which are importantly

distinct here. This Court agrees with Regeneron and finds that Amgen's counterclaim was compulsory in case number 1:24-cv-39.

The parties' positions on this issue have been discussed significantly in judicial opinion and scholarly comment. See, e.g., 6 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 39:29 (2026); 6 CHARLES WRIGHT & MILLER'S FEDERAL PRACTICE & PROCEDURE § 1412 (3d ed.) As Regeneron notes, the Fourth Circuit has expressed that *Mercoïd* "has been read narrowly . . . and its continuing validity is open to serious question." *Burlington Indus. v. Milliken & Co.*, 690 F.2d 380, 389 (4th Cir. 1982), cert. denied, 461 U.S. 914 (1983); see also *United States v. Eastport Steamship Corporation*, 255 F.2d 795 (2d Cir. 1958) ("[I]n view of the criticism which the decision has received and the failure of the Court to discuss the principles upon which the decision rests, we think that *Mercoïd* cannot be taken as precedent for other than its own limited facts."). Importantly, *Walker Process* claims like Amgen's would not be recognized by the Supreme Court for over twenty years after *Mercoïd* was decided. See *Walker Process Equip., Inc. v. Food Mach. & Chemical Corp.*, 382 U.S. 172, 177-78 (1965); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 932 (D. Del. 1991). Accordingly, this Court will also read *Mercoïd* narrowly.

Many important distinctions exist between *Mercoïd* and the present case, all of which have been relied on to persuasively distinguish *Mercoïd* by other courts.

First, the antitrust claims at issue in *Mercoïd* were based only on the misuse of a valid and otherwise enforceable patent, rather than the fraudulent procurement of an invalid patent, which is particularly important given the *Mercoïd* Court's reliance on the rationale of preventing schemes to expand a valid patent beyond its legitimate scope. See *Mercoïd*, 320 U.S. at 670; *Critical-Vac Filtration Corp. v. Minuteman Intern., Inc.*, 233 F.3d 697, 702 n. 6 (2d Cir. 2000) (distinguishing *Mercoïd* on this ground), *cert. denied*, 532 U.S. 1019 (2001).

Another important distinction is that the parties to the two actions here are identical, whereas the subsequent defendant in *Mercoïd* had merely paid for the defense of a different party in the prior infringement action. See *Mercoïd*, 320 U.S. at 669; *Lewis Mfg. Co. v. Chisholm-Ryder Co.*, 82 F.R.D. 745, 750 (W.D. Pa. 1979) (distinguishing *Mercoïd* on this ground and citing 3 MOORE'S FEDERAL PRACTICE P 13.13 n.22 at pp. 13-306-07 (2d ed. 1978)).

Finally, in *Mercoïd*, the prior infringement action had resulted in a final judgement before the subsequent action had commenced. *Mercoïd*, 320 U.S. at 669-70; *Ragner Tech. Corp. v. Berardi*, No. CV1157752NLHAMD, 2018 WL 6804486, at *5 (D.N.J. Dec. 27, 2018) (distinguishing *Mercoïd* on these grounds); see also *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 931-32 (D. Del. 1991).

However, while this Court finds Amgen's counterclaim to have been compulsory in the 2024 action, the lack of a final judgment in that action results in a further complication. As noted by the District of New Jersey in *Ragner*, a prior action that has yet to be fully resolved has no preclusive effect. 2018 WL 6804486, at *6; *Fullerton Aircraft Sales and Rentals, Inc. v. Beech Aircraft Corp.*, 842 F.2d 717, 722 (4th Cir. 1988). Instead, "once a court becomes aware that an action on its docket involves a claim that should be a compulsory counterclaim in another pending federal suit, it will stay its own proceedings or will dismiss the claim with leave to plead it in the prior action." 6 CHARLES WRIGHT & MILLER'S FEDERAL PRACTICE & PROCEDURE § 1418 (3d ed.) (collecting cases); see also *Ragner*, 2018 WL 6804486, at *6-8.

Given that the same court is presiding over both actions here, the appropriate route is to dismiss Amgen's counterclaim based on the 2024 Litigation Patents *without* prejudice. Because the parties have not briefed the issue of whether Amgen should be granted leave to amend its Answer to include the antitrust counterclaim regarding the 2024 Litigation Patents, the Court will not here decide that issue.

Regeneron's other argument regarding Amgen's counterclaim is not sufficient to justify dismissal with prejudice. Regeneron argues, without direct precedent, that Amgen cannot claim its legal fees in case number 1:24-cv-39 as injury for Regeneron's alleged

antitrust violations because Amgen did not exclude the 2024 Litigation Patents from its "good faith negotiations to agree on which, if any, patents" would be litigated in that case as required by 42 U.S.C. § 262(1)(4)(A). Regeneron's Motion at 20. In other words, Regeneron argues that *Amgen* is responsible for the assertion of the 2024 Litigation Patents and therefore cannot claim the resulting legal fees as injury. This Court is not persuaded. Regeneron threatened to assert, and ultimately did assert, the patents in question, and Amgen could not have actually defeated either by simply seeking to remove them from a first wave of litigation.

Finally, Regeneron challenges Amgen's Eighth Counterclaim by arguing that Amgen's UCL counterclaim should fall with its Sherman Act counterclaims. Regeneron's Motion at 22. In response, Amgen relies on the proposition, originating in *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999), that "[a] business practice may be unfair, and therefore illegal under the UCL, even if not specifically proscribed by some other law." Amgen's Opposition at 24.

However, "[f]ollowing *Cel-Tech*, courts have found that a UCL claim based on the 'unfair' prong cannot survive when it is premised on the same actions as an alleged statutory antitrust claim." *Distance Learning Co. v. Maynard*, No. 19-CV-03801-KAW, 2020 WL 2995529, at *10 (N.D. Cal. June 4, 2020). Indeed, "where

the same conduct alleged to be unfair under the UCL is also alleged to be a violation of another law, the UCL claim rises or falls with the other claims.” *Id.* quoting *GreenCycle Paint, Inc. v. PaintCare, Inc.*, Case No. 15-cv-4059-MEJ, 2016 U.S. Dist. LEXIS 47960, at *31, 2016 WL 1402845 (N.D. Cal. Apr. 8, 2016).

Amgen’s UCL counterclaim contains no allegation of conduct distinct from that alleged in its Sherman Act counterclaims and therefore falls with those counterclaims. Regeneron’s motion is therefore **GRANTED** with respect to Amgen’s Eighth Counterclaim, though its UCL claim based on its allegations of fraudulent procurement of the 2024 Litigation Patents is only dismissed *without prejudice*.

C. Laches

Regeneron also seeks to strike Amgen’s Eleventh Additional Defense and dismiss Amgen’s Third Counterclaim, which allege unenforceability of the ’099 patent due to prosecution laches. Regeneron’s Motion at 24-25. Specifically, Amgen alleges that Regeneron unreasonably delayed in pursuing the ’099 patent for over eighteen years after its parent provisional was filed, prejudicing Amgen in light of Amgen’s investment in developing a buffer-free aflibercept formulation. Amgen’s Corrected Answer at ¶¶ 48-50.

Prosecution laches is an equitable defense that “may render a patent unenforceable when it has issued only after an

unreasonable and unexplained delay in prosecution.” *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005), *amended on reh'g in part by*, 429 F.3d 1051 (Fed. Cir. 2005). The parties agree that prosecution laches is applicable “only in egregious cases of misuse of the statutory patent system.” Regeneron’s Motion at 24 (quoting *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005)); Amgen’s Opposition at 25.

Regeneron makes a single argument that Amgen’s allegations fail to constitute such an egregious case: that “[p]rosecution laches arose when a patent’s term was defined as 17 years from the date of the issuance, which incentivized certain patentees to delay prosecuting their patents,” and “because the timing of the ‘099 patent’s issuance is irrelevant to the expiry of its term, laches is inapplicable.” Regeneron’s Motion at 24-25 (internal quotations and citations omitted).

Regeneron’s only authority for its position that prosecution laches does not apply to patents applied for after the General Agreement on Tariffs and Trade (“GATT”) changed the expiration of U.S. patents to twenty years after their application date is *Chrimar Sys. v. Alcatel-Lucent Ent.*, 2017 WL 345991, at *4 (E.D. Tex. Jan. 24, 2017), which held that the change in expiry “alleviate[d] the need for the equitable remedy.” However, that same paragraph in *Chrimar* goes on to conclude: “Here, there is no

evidence cited by ALE that there was any unreasonable or unexplained delays in prosecution or any conduct by Chrimar to support such a delay." 2017 WL 345991, at *4. This further reasoning, in combination with that court's usage of the term "alleviate," indicates that there was no announcement of a rule that the date of application alone is dispositive of prosecution laches, and Regeneron provides no such pronouncement from any other court.

Moreover, several courts have held just the opposite. See *GlaxoSmithKline Biologicals SA v. Pfizer Inc.*, No. 24-512-GBW, 2026 WL 1732953, *3-4 (D. Del. Jun. 16, 2026) ("[T]he Court rejects GSK's contention [that prosecution laches does not extend to post-GATT patents.]"); *Mojo Mobility, Inc. v. Samsung Elecs. Co.*, No. 22-398, 2024 WL 3354705, at *1 (E.D. Tex. June 11, 2024), *report and recommendation adopted*, No. 22-398, 2024 WL 3350884 (E.D. Tex. July 9, 2024); *Boston Scientific Corp. v. Cook Med. LLC*, No. 1:17-cv-03448-JRS-MJD, 2023 WL 3691113, *4 (S.D. Ind. May 27, 2023); *Sonos, Inc. v. Google LLC*, No. C 20-06754 WHA, 2023 WL 6542320, at *19 (N.D. Cal. Oct. 6, 2023) (finding prosecution laches for post-GATT patent and rejecting argument based on expiry change alone), *aff'd in part, rev'd in part*, No. 2024-1097, 2025 WL 2473258 (Fed. Cir. Aug. 28, 2025) (reversing finding of prosecution laches on issue of prejudice and not relying on post-GATT expiry of patent at issue).

Regeneron can at most argue that such applications of prosecution laches fall outside of the original purpose of the prosecution laches doctrine.² However, this alone cannot compel the Court to dismiss Amgen's allegations at this stage.

Regeneron's motion is therefore **DENIED** with respect to Amgen's Eleventh Additional Defense and Third Counterclaim.

D. Patent Misuse

Regeneron next seeks to strike Amgen's Fourteenth Additional Defense and dismiss Amgen's Fifth Counterclaim, both of which allege misuse of the '099 patent. Regeneron's Motion at 22-24. Specifically, Amgen alleges that Regeneron impermissibly broadened the scope of the '099 patent when it was amended to not require a buffer and enforced the patent despite knowing that it was invalid and unenforceable. Amgen's Corrected Answer at ¶¶ 99-111, 279-293.

"The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). "Patent misuse relates primarily to a patentee's

² However, this argument has been rejected by at least three district courts. See *Sonos*, 2023 WL 6542320, at *19 (rejecting such an interpretation of Regeneron's primary source for this historical argument, *Hyatt v. Hirshfeld*, 998 F.3d 1347 (Fed. Cir. 2021), and finding post-GATT patents unenforceable due to prosecution laches); *GlaxoSmithKline*, 2026 WL 1732953, at *3-4 (quoting *Mojo Mobility*, 2024 WL 3354705, at *1).

actions that affect competition in unpatented goods or that otherwise extend the economic effect beyond the scope of the patent grant.” *Id.* “The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.” *Id.*

Amgen alleges patent misuse in two instances of Regeneron’s conduct: its amendment of the claims of the ’099 patent to include claims not requiring a buffer, and its enforcement of the ’099 patent. Amgen alleges that the former was an impermissible broadening of the scope of the ’099 patent’s grant and that the latter was a bad-faith assertion of a patent fraudulently obtained and which Regeneron knew was invalid, unenforceable, and not infringed.

Amgen’s allegations regarding Regeneron’s amendment to the ’099 patent’s claims misstate the concept of impermissible broadening. Impermissible broadening of a patent *grant* cannot occur before that patent is granted, and Amgen provides no such case of a court finding patent misuse for amending a patent’s claim.

Amgen’s allegation that the ’099 patent was fraudulently obtained fails to satisfy FRCP 9(b)’s factual basis requirement, as discussed above. Thus, such pleading cannot support a patent misuse claim.

Amgen's allegations of bad-faith litigation, however, present a more difficult question to this Court. As other district courts have noted, courts disagree as to whether bad faith alone, without fraud, can constitute patent misuse. See *Bridgestone Americas Tire Operations, LLC v. Speedways Tyres Ltd.*, No. 4:22-CV-0145-P, 2023 WL 2574576, at *3 (N.D. Tex. Mar. 20, 2023) (collecting cases); see also *Qfix Sys., LLC & Anholt Techs., Inc. v. Klarity Med. Prods., LLC*, No. CV 23-077 (CJB), 2024 WL 5692211 (D. Del. Sept. 25, 2024).

As noted by the District of Delaware in *Qfix*, the root of this disagreement appears to be a contradiction between two Federal Circuit opinions. 2024 WL 5692211. In *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550 (Fed. Cir. 1995), the Federal Circuit upheld a district court finding of no patent misuse where there was not "bad faith and improper purpose in bringing the suit," making no mention of a fraud requirement. 45 F.3d at 1558-59. In stating a requirement of bad faith and improper purpose, the Federal Circuit relied only on cases that did not discuss patent misuse. *Id.* at 1558 (citing *American Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) and *Grip-Pak, Inc. v. Illinois Tool Works, Inc.*, 694 F.2d 466, 472 (7th Cir.1982), *cert. denied*, 461 U.S. 958 (1983)).

Almost four years later, and without discussing *Glaverbel*, the Federal Circuit spoke more clearly and specifically on this

issue in *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998). In that opinion, the Federal Circuit reversed a jury finding of patent misuse because the jury instruction "was focus[ed] primarily on the charge that Bard was attempting to enforce the patents against goods known not to be infringing." *Id.* at 1372-73. The Federal Circuit also specifically noted that "[i]t is not patent misuse to bring suit to enforce patent rights not fraudulently obtained." *Id.* at 1373.

In support of this conclusion, the opinion warns that "the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce." *Id.* The opinion also notes that the "'wrongful' enforcement of patents[] is actively protected under [*Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *California Motor Transp. Co. v. Trucking Unltd.*, 404 U.S. 508 (1972)]". *Id.*

While *Noerr-Pennington* immunity does have a sham litigation exception, patent misuse is a separate doctrine, and a different result obtains when patent misuse is found than when an antitrust violation is found under a sham litigation theory, namely, the patent that has been misused is found unenforceable. As the Northern District of Texas noted in *Bridgestone*, such a result would seem contrary to the text of 35 U.S.C. § 271(d)(3), which provides that "[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be

denied relief or deemed guilty of misuse” when it “[seeks] to enforce [its] patent rights against infringement or contributory infringement.” 2023 WL 2574576, at *4 (quoting § 271(d)(3)). The statute “provides no exception for suits brought in bad faith.” *Id.*

For these reasons, and because *C.R. Bard* is more applicable than *Glaverbel*, this Court is not persuaded that Amgen can sustain a patent misuse defense or counterclaim without fraudulent procurement. Because Amgen’s fraudulent procurement and impermissible broadening theories are not sufficiently pleaded, Regeneron’s motion is **GRANTED** with respect to Amgen’s Fourteenth Additional Defense and Fifth counterclaim.

E. Unclean Hands

Finally, Regeneron seeks to strike Amgen’s Fourth Additional Defense, which states in its entirety that “Regeneron’s claim of patent infringement is barred in whole or in part by the equitable doctrines of waiver, estoppel, and/or unclean hands.” Amgen’s Corrected Answer at ¶ 41.

Such pleading “is ‘threadbare’ and provides insufficient notice of the nature of the defense.” *Tippman Eng'g, LLC v. Innovative Refrigeration Sys., Inc.*, No. 5:19-CV-00087, 2020 WL 1644985, at *3 (W.D. Va. Apr. 2, 2020) (striking affirmative defense that stated only “[t]he claims in the First Amended Complaint are barred by the Plaintiff's unclean hands”) (quoting

Flame S.A. v. Indus. Carriers, Inc., No. 2:13-cv-658, 2014 WL 2871432, at *3 (E.D. Va. June 24, 2014) (striking defendant's defense that "Plaintiff Flame is barred from any equitable remedies due to its unclean hands"))).

Regeneron's motion is therefore **GRANTED** with respect to Amgen's Fourth Additional Defense.

IV. CONCLUSION

For the foregoing reasons, the Court **ORDERS** as follows:

- Regeneron's Motion is **GRANTED IN PART** and **DENIED IN PART** [ECF No. 680];
- Amgen's inequitable conduct defense and counterclaim (Thirteenth Additional Defense and Fourth Counterclaim) are **STRICKEN AND DISMISSED WITH PREJUDICE**;
- Amgen's federal antitrust counterclaims (Sixth and Seventh Counterclaims) are **DISMISSED WITH PREJUDICE** as to the allegations relating to the '099 patent and **DISMISSED WITHOUT PREJUDICE** as to the allegations relating to the 2024 Litigation Patents;
- Amgen's UCL counterclaim (Eighth Counterclaim) is **DISMISSED WITH PREJUDICE** as to the allegations relating to the '099 patent and **DISMISSED WITHOUT PREJUDICE** as to the allegations relating to the 2024 Litigation Patents;

- Amgen's patent misuse defense and counterclaim (Fourteenth Additional Defense and Fifth Counterclaim) are **STRICKEN AND DISMISSED WITH PREJUDICE**;
- Amgen's unclean hands defense (Fourth Additional Defense) is **STRICKEN WITH PREJUDICE**;
- Regeneron's Motion is **DENIED** with respect to Amgen's laches defense and counterclaim (Eleventh Additional Defense and Third Counterclaim); and
- The following motions are **DENIED AS MOOT**: Regeneron's Motion to Bifurcate and Stay Amgen's Antitrust Claims [ECF No. 691], Amgen's Motion for Leave to File a Sur-Reply in Opposition to Regeneron's Motion to Bifurcate and Stay [ECF No. 715], and Regeneron's Conditional Motion to Compel Damages Discovery on Amgen's Antitrust Claims [ECF No. 823].

It is so **ORDERED**.

The Clerk is **DIRECTED** to transmit copies of this Order to counsel of record.

DATED: July 7, 2026



THOMAS S. KLEE, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA