

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

IN RE: AFLIBERCEPT PATENT LITIGATION

MDL No.: 1:24-md-3103-TSK

THIS DOCUMENT RELATES TO:
Civil Action No. 1:25-cv-74-TSK

**REGENERON'S MEMORANDUM IN SUPPORT OF
MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES
AND DISMISS CERTAIN COUNTERCLAIMS**

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For the past year, Amgen has been selling its copycat aflibercept product, Pavblu, with willful disregard for Regeneron's patents. While those sales have benefited Amgen enormously in the short term, they also have left Amgen in a tenuous position. Though the Court denied Regeneron's request for a preliminary injunction to bar the launch of Pavblu, that motion was based on a single patent—U.S. Patent No. 11,084,865 (the "'865 patent")—and the Court denied that motion only upon determining there were questions as to whether Regeneron ultimately could prove infringement of that patent. But Amgen stands accused of infringing additional patents, and earlier this year, Regeneron filed the present suit against Amgen, asserting the newly issued U.S. Patent No. 12,331,099 (the "'099 patent"). Amgen's sole infringement defense to the '865 claims is unavailable as to the '099 patent—Pavblu plainly infringes. And, given the repeated failed challenges to the validity of the related '865 patent before this Court, the Federal Circuit, and the Patent Trial and Appeal Board, Amgen no doubt has concerns as to its ability to carry its burden of proving invalidity of those infringed claims by clear and convincing evidence. That leaves Amgen with significant risk. Having sold many millions of dollars of infringing Pavblu and caused Regeneron extraordinary harm, Amgen faces the prospect of not only a mammoth lost-profits award but also enhanced, potentially trebled, damages for its willful infringement.

Having backed itself into this corner, Amgen now predictably lashes out. Its Answer and Counterclaims (ECF 666, "Answer") baselessly accuse Regeneron of misconduct and fraud at nearly every turn. Amgen's kitchen-sink approach misstates undisputed facts and overstretches the law in a manner that would convert nearly every patent infringement suit into, at minimum, an inequitable conduct case and, in many instances, an all-consuming antitrust sideshow. The *en banc* Federal Circuit has imposed strict limits to eliminate, at the pleading stage, such careless assertions of inequitable conduct—the "atomic bomb" of patent litigation—and described the

over-deployment of such charges as a “plague” upon the patent system. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288-89 (Fed. Cir. 2011). But Amgen disregards those warnings with Strangelovian nonchalance, and its Answer accordingly presents a bizarre picture of inequitable conduct law. Where Regeneron disclosed hundreds of references to the PTO, Amgen claims it should have told the examiner more, without explaining—as *Therasense* requires—how the purportedly “withheld” information was but-for material to the examiner’s analysis. Where Regeneron *did* disclose challenged material, Amgen claims those references were “buried” (albeit, alongside just a handful of additional, relevant references) and so should not count. Where Amgen has its own invalidity theories regarding “written description” support, it accuses Regeneron of lying to the examiner by not predicting and voicing those (flawed) arguments.

Amgen then doubles down by using its “heads I win, tails you lose” approach—under which Regeneron disclosed either too much or too little to the examiner—as a predicate to introduce antitrust claims into this already-complex litigation. But there too Amgen overreaches, complaining about being forced to incur costs litigating patents not at issue in this action and that Amgen itself, during the parties’ pre-suit “patent dance,” chose to include in the earlier 2024 case.

Amgen’s concerns regarding its potentially enormous infringement liability are understandable; its tactics are not. Whether Amgen’s strategy is to deter Regeneron’s pursuit of its infringement claims by threatening to “paint [Regeneron] as a bad actor” “with ruinous consequences for the reputation of [its] patent attorney[s],” *Therasense*, 649 F.3d at 1288, or simply to inject chaos into this already-complicated MDL on the theory that the best defense is to fabricate an offense, its approach is entirely inconsistent with settled law. The Court should dismiss Amgen’s counterclaims and strike its defenses.

BACKGROUND

Regeneron has been litigating for over three years against entities seeking to market

biosimilar versions of Eylea, including against Amgen since January 2024. Regeneron sued Amgen that month in the Central District of California, alleging that Amgen’s submission of the BLA for its Eylea biosimilar product, Pavblu, infringed a number of patents that Amgen and Regeneron agreed to litigate during the pre-suit BPCIA “patent dance” procedure pursuant to 42 U.S.C. § 262(l)(4)(A). *Regeneron Pharm., Inc. v. Amgen Inc.*, Case No. 2:24-cv-264 (C.D. Cal.), ECF 1. Had the parties not reached agreement on the patents to be included in the complaint, the BPCIA would have left Amgen with “substantial control over the scope of” that case, as Amgen then would have been entitled to dictate the number of patents to be litigated. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 9 (2017); *see also* 42 U.S.C. § 262(l)(5). That initial case then was consolidated with the four Eylea biosimilar actions already pending in this Court. *In re Aflibercept Pat. Litig.*, 2024 WL 1597512, at *1 (J.P.M.L. Apr. 11, 2024).

Regeneron filed a motion for preliminary injunction against Amgen based on only one of the thirty-two patents asserted in the initial complaint, the ’865 patent. ECF 157.¹ The Court denied Regeneron’s motion, solely because it found Amgen’s product likely did not meet the “buffer” limitation of the ’865 patent’s claims. ECF 343. The Court did not address Amgen’s infringement of any of the other thirty-one asserted patents. Soon after the Court’s decision, Amgen launched Pavblu and has generated significant sales, including \$99 million in Q1 of 2025.

In June 2025, Regeneron filed the present suit, alleging infringement of the newly issued ’099 patent. This action was consolidated with the other MDL cases. ECF 577. Even though the second action concerns only the ’099 patent, in its Answer, Amgen hurls a slew of new allegations regarding patents that were asserted in the prior case filed over a year and a half ago. ECF 666.

¹ Unless otherwise noted, docket citations are to Case No. 1:24-md-3103, and emphases are added.

LEGAL STANDARD

Under Rule 12(f), the Court “may 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).

The Court also should dismiss counterclaims that do not “contain enough facts to state a claim to relief that is plausible on its face.” *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 188 n.7 (4th Cir. 2007). Particularly as to antitrust claims, “a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 555 (2007). In evaluating the sufficiency of Amgen’s pleading, the Court may consider documents that are incorporated therein by reference, those subject to judicial notice, and those attached to this Motion if integral to the pleading and authentic. *Penegar v. Liberty Mut. Ins. Co.*, 115 F.4th 294, 300 n.6 (4th Cir. 2024); *Philips v. Pitt Cnty. Mem’l Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009).

Fraud-based claims and defenses are subject to heightened pleading requirements. Fed. R. Civ. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”). This standard applies to both inequitable conduct claims and *Walker Process* claims. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009); *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev’d on other grounds*, 549 U.S. 118 (2007). And, while knowledge and intent “may be averred generally,” the pleadings must “allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Exergen*, 575 F.3d at 1327.

ARGUMENT

I. The Court Should Strike and Dismiss Amgen’s Inequitable Conduct Defense and Counterclaim (Defense 13 and Counterclaim 4).

To adequately plead inequitable conduct, Amgen must identify with Rule 9(b) particularity “the specific who, what, when, where, and how of the material misrepresentation or omission committed.” *Exergen*, 575 F.3d at 1327. In Amgen’s telling, *every* step of the ’099 patent’s prosecution was riddled with inequitable conduct. But bluster cannot substitute for substance—none of Amgen’s three theories approaches the Federal Circuit’s demanding pleading standard or Rule 9(b)’s particularity requirements. *Id.*

A. Amgen Does Not Adequately Allege Any Material Omission.

Amgen’s first inequitable conduct theory is that during prosecution, Regeneron fraudulently omitted “documents material to patentability,” only to later “bury” some of these documents among a list of “over 600 references” after a Notice of Allowance issued, but before the issue fee was paid and before the patent actually issued. ECF 666 at 21-24, 26. The purported omissions were: (i) notice of the ongoing litigation between Regeneron and Amgen; (ii) this Court’s September 2024 order denying a preliminary injunction; (iii) Amgen’s ABP 938 product label; (iv) the identity of the components therein; (v) Amgen’s U.S. Application No. 16/764,463 (the “463 application”), purportedly describing buffer-free aflibercept formulations; and (vi) the Federal Circuit’s March 2025 opinion affirming the preliminary injunction denial. *Id.* at 22.

1. Notice of Litigation and the Preliminary Injunction Decisions.

As to notice of litigation between Regeneron and Amgen and this Court’s and the Federal Circuit’s injunction decisions (items (i), (ii), and (vi)), Amgen’s theory fails for the simple reason that Regeneron *did* disclose that material. The law is clear that an “applicant can[not] be guilty of inequitable conduct if the reference was cited to the examiner.” *Fiskars, Inc. v. Hunt Mfg. Co.*,

221 F.3d 1318, 1327 (Fed. Cir. 2000). Amgen admits Regeneron “did submit the Federal Circuit[’s]” order. ECF 666 at 23-24. Indeed, the public record confirms that Regeneron submitted both the September 2024 Order Denying Regeneron’s Motion for Preliminary Injunction and the March 2025 Opinion affirming that denial. Ex. 1 at 15, 34. When submitting each, Regeneron “invited” “[t]he attention of the Examiner . . . to the documents” and “respectfully requested that the information be expressly considered during the prosecution of this application.” Ex. 1 at 10, 28. The examiner explicitly considered both in his examination, Ex. 1 at 17, 27, 37, 39, and both are listed on the face of the ’099 patent as “References Cited,” Ex. 2 at 12. That is fatal to Amgen’s claim: Because Regeneron disclosed these decisions to the examiner, it “can[not] be guilty of inequitable conduct” by their (purported) omission. *Fiskars*, 221 F.3d at 1327. And to the extent Amgen alleges inequitable conduct by “delay[ing] in disclosing information,” see ECF 666 at 20-21, 23-24, that states no claim for inequitable conduct either. See *Ist Media v. Elec. Arts*, 694 F.3d 1367, 1376-77 (Fed. Cir. 2012) (no inequitable conduct for reference disclosed after notice of allowance); 37 C.F.R. § 1.97(c)-(d) (permitting submission of information disclosure statements after notice of allowance). Amgen alleges nothing to demonstrate why any delay in Regeneron’s disclosures was material to patentability. Nor could it, given that the examiner explicitly noted that he considered those documents. Ex. 1 at 17, 27, 37, 39.

Because disclosure is fatal to a non-disclosure claim, Amgen breezily suggests that Regeneron “buried” the adverse Federal Circuit opinion along with “other voluminous Court decisions” and did not “specifically draw the Examiner’s attention to that Federal Circuit” order. ECF 666 at 23-26. As an initial matter, this dramatically misrepresents the prosecution record, incorporated by reference into Amgen’s Answer. Regeneron provided the examiner with this Court’s September 2024 order in a submission that included only *six* references—two scientific

papers and this Court’s four preliminary injunction decisions. Ex. 1 at 14-15. Regeneron disclosed the Federal Circuit’s 2025 opinion in a separate submission that included only *four* references—the four appellate decisions reviewing this Court’s injunction orders. Ex. 1 at 34. If the submission of purportedly relevant material alongside a few identically situated references were to somehow constitute “burying,” that term would lose all meaning, and it is difficult to imagine a prosecution history that could escape such a charge. Further, though Regeneron had no “obligation to emphasize [the] importance” of a reference it disclosed, *Semiconductor Energy Lab. v. Samsung Elecs.*, 749 F. Supp. 2d 892, 904 (W.D. Wis. 2010); *see Fiskars*, 221 F.3d at 1327, it nevertheless directed the examiner specifically to these ten sources, *including the purportedly “buried” opinions*. Ex. 1 at 10, 28 (“The attention of the Examiner is invited to the documents listed.”).

Further, even were these sources “buried”—and they were not—Amgen’s theory still would fail, because burying is not a legally cognizable theory of inequitable conduct. Consistent with *Fiskars*’ holding that there is no inequitable conduct if a source is disclosed, 221 F.3d at 1327, courts “generally reject[] the claim that a reference, if submitted to the PTO Examiner, can be buried for the purposes of establishing inequitable conduct.” *Radiancy, Inc. v. Viatek Consumer Prods. Grp.*, 138 F. Supp. 3d 303, 317 (S.D.N.Y. 2014), *as amended* (Apr. 1, 2014); *see also, e.g., KFx Med., LLC v. Stryker Corp.*, 2019 WL 2012977, at *5 (S.D. Cal. May 7, 2019) (collecting cases); *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 358 (D. Del. 2009).

Finally, even were “burying” a cognizable theory, Amgen fails to allege with particularity that the allegedly buried references were material, which independently is “fatal under Rule 9(b).” *Exergen*, 575 F.3d at 1330. As in *Exergen*, Amgen alleges in conclusory fashion that “Regeneron’s counsel knew that the [PI denial] was material,” ECF 666 at 26, 88, but nowhere sets forth “‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used

this information in assessing the patentability of the claims,” *Exergen*, 575 F.3d at 1329-30. Amgen thus falls far short of pleading “but-for materiality,” *i.e.*, that “the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Therasense*, 649 F.3d at 1291. Amgen’s failure to plead materiality with the requisite particularity independently dooms its claim.

2. The ABP 938 Label, ABP 938’s Components, and the ’463 Application.

Nor do Amgen’s sparse allegations regarding the remaining materials—the ABP 938 label, ABP 938 components, and Amgen’s ’463 application—state a claim for inequitable conduct. Amgen fails to plead any of these omissions was “but-for material,” *Therasense*, 649 F.3d at 1291, by “identify[ing] which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found,” and “why” the material is “not cumulative,” *Exergen*, 575 F.3d at 1329.

Amgen does not even attempt to satisfy this high bar, much less with the specificity required by Rule 9(b). It nowhere explains their specific teachings, how they were material to specific claims—and “limitations in those claims,” *Exergen*, 575 F.3d at 1329—or why “the PTO would not have allowed” those claims “had it been aware of the undisclosed” documents, *Therasense*, 649 F.3d at 1291. Nor does Amgen attempt to explain how these documents *are even prior art* (they are not, under the pre-2013 priority date the examiner applied during prosecution, Ex. 1 at 17)—much less plead how this allegedly omitted information was “not cumulative to the information already of record.” *Exergen*, 575 F.3d at 1329. Information “is not material to patent prosecution when it is cumulative of information already before the examiner.” *Rothman v. Target Corp.*, 556 F.3d 1310, 1326 (Fed. Cir. 2009). Amgen is foreclosed from even attempting to plead non-cumulativeness: the Court’s PI denial, considered by the examiner, undisputedly identified both the ABP 938 components and Amgen’s “later patent filings” concerning buffer-free formulations, including the publication of the ’463 application. *In re Aflibercept Pat. Litig.*, 2024

WL 4958308, at *3, *20 (N.D.W. Va. Oct. 1, 2024) (citing ECF 206-10). And Amgen alleges no relevance of its label apart from disclosing the ABP 938 components. Moreover, Amgen admits that Regeneron submitted “over 600 references to the USPTO,” ECF 666 at 21, all of which are listed on the patent’s face as “References Cited,” Ex. 2 at 1-13. If Amgen’s chosen three sources disclosed something those 600+ references did not, Amgen needed to plead it. *Exergen*, 575 F.3d at 1329. Having failed to so plead, it cannot proceed with an inequitable conduct claim or defense.

B. Amgen Does Not Adequately Allege Any Material Misrepresentation Made with a Specific Intent to Deceive.

1. Inventorship

Amgen also alleges inequitable conduct on a far-fetched theory that the ’099 patent fraudulently lists the wrong inventors and that unspecified Amgen scientists are its “true inventors.” ECF 666 at 13. But “to survive a motion to dismiss based on the concealment of an inventor, a [party] must . . . plead facts to support that the omitted individual was, indeed, an inventor.” *Beco Dairy Automation v. Global Tech Sys.*, 104 F. Supp. 3d 1023, 1037 (E.D. Cal. 2015). Amgen did not and cannot do so. As detailed below, Amgen’s pleading is deficient because (1) it does not allege inequitable conduct with the requisite particularity by failing to identify the putative Amgen inventors or when their alleged invention occurred, and (2) it fails to adequately allege that Amgen scientists contributed to conception of any limitation of the claimed invention and that the named Regeneron inventors did *not* sufficiently contribute to be named as inventors.

First, Amgen’s bare allegation that “Regeneron fraudulently misrepresented” the ’099 patent’s inventorship, ECF 666 at 124, lacks the particularity that Rule 9(b) requires. Amgen must plead “the specific who, what, when, where, and how of the material misrepresentation.” *Exergen*, 575 F.3d at 1327. But nowhere does Amgen even identify “who” its putative inventors are or “when” their alleged invention occurred. Conception is the touchstone of inventorship, *In re*

VerHoef, 888 F.3d 1362, 1366 (Fed. Cir. 2018), and “must include *every* feature or limitation of the claimed invention,” *Kridl v. McCormick*, 105 F.3d 1446, 1449 (Fed. Cir. 1997). But Amgen alleges *no* such limitation of the claims that any specific Amgen scientist supposedly conceived, much less that such a scientist conceived of all of them. Fatally, Amgen does not point to (1) any claim limitation that Regeneron’s inventors ***did not*** invent; or (2) any limitation that a putative Amgen inventor ***did*** invent. Amgen thus cannot meet the high bar for inequitable conduct.

The reason why Amgen’s pleading lacks the requisite specificity is plain: the Regeneron named inventors and Amgen’s unspecified scientists could not be ***joint*** inventors, because Amgen’s aflibercept work undisputedly occurred ***years after*** Regeneron’s work disclosed in the ’099 patent, which necessarily occurred before the priority application was filed in June 2006. ECF 666 at 27; Ex. 2, 1:39-41. Amgen’s work thus could not be “conjoined with the efforts of the named inventors” arising from “collaboration or concerted effort,” as joint inventorship requires. *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004). Amgen does not plead otherwise. Amgen also cannot plead that Amgen’s scientists were the ***sole*** inventors, because they undisputedly had no role in the work disclosed in the ’099 patent. With no cognizable path to a claim of improper inventorship—much less with the details and particularity required to convert it into a claim of fraud—Amgen instead opts for a fuzzy improper inventorship allegation that comes nowhere close to the strict pleading requirements set forth in *Exergen*.

Second, Amgen fails to plead that its unnamed employees contributed to conception of any “feature or limitation of the claimed invention,” as inventorship requires. *Kridl*, 105 F.3d at 1449; *Eli Lilly*, 376 F.3d at 1359 (inventor must “contribute[] to the conception of the claimed invention”); *cf. VerHoef*, 789 F.3d at 1365. The claims of the ’865 patent are similar to those of the ’099 patent; both recite ophthalmic formulations of 40 mg/ml of glycosylated aflibercept,

water, polysorbate, and a stabilizing agent, which achieve 98% native conformation. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652, 693-94 (N.D.W. Va. 2024) ('865 patent claim 4); Ex. 2, claim 11. But the '099 patent's claims have a crucial distinction: unlike the '865 patent's claims, they do not require "a buffer," thereby eliminating Amgen's sole infringement defense. Notably, that distinction does not mean what Amgen says it means—the '099 patent's claims do not *require* a "**buffer-free** aflibercept formulation," ECF 666 at 13, 105, 108, 124, and Amgen identifies nothing in the claims of the '099 suggesting otherwise. Rather, the claims simply do not recite "a buffer" and thus are *agnostic* to the presence of a buffer. The '099 patent claims each use the transition term "comprising," which means that "the claim[s] do[] not exclude additional, unrecited elements." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001); *Stiftung v. Renishaw PLC*, 945 F.3d 1173, 1178 (Fed. Cir. 1991). In other words, the claims encompass formulations both with and without a buffer.

Amgen's inventorship theory proceeds directly from its misreading of the claims. Amgen alleges "on information and belief" that its unnamed employees "were the true inventors of **buffer-free** aflibercept formulations." *E.g.*, ECF 666 at 13. But again, the claims do not recite or require "buffer-free" formulations; they cover a genus or class of formulations that may or may not include a buffer. Stripped of its mischaracterization of the patent's claims, Amgen cannot plead improper inventorship, much less with the specificity required by Rule 9(b). At most, Amgen alleges that its unnamed scientists first conceived of a particular formulation lacking a buffer within the '099 patent's claimed genus of formulations, which encompasses formulations that include a buffer and those that do not include a buffer. ECF 666 at 16, 108. But that is not enough to plead a claim of improper inventorship as a matter of law, given that Amgen does not (and cannot) dispute that Regeneron's named inventors first conceived of and prepared formulations within the scope of the

'099 patent claims. “[O]ne who is prior as to a species within a genus wins a priority award on a count to that genus,” and Regeneron’s inventors indisputably were the first to invent a species (embodiment) of the claims, by the time they filed their 2006 priority application. *Petisi v. Rennhard*, 363 F.2d 903, 905 (C.C.P.A. 1966); see *Plexxikon Inc. v. Novartis Pharm.*, 525 F. Supp. 3d 1104, 1110 (N.D. Cal. 2021) (summarizing precedent). Amgen cannot and does not plead any dispute with the fact that, years before it began its own aflibercept research, ECF 666 at 80-81, the named Regeneron inventors invented the embodiments and disclosures in the '099 patent (sharing a specification with the '865 patent), including the embodiments in Examples 3 and 4 that undisputedly contain every ingredient recited in illustrative claim 11 and achieved the recited 98% native conformation, Ex. 2, 9:20-10:10; *Mylan*, 714 F. Supp. 3d at 752. Thus, Regeneron’s named inventors, not unnamed Amgen scientists, first invented the genus of ophthalmic aflibercept formulations claimed in the '099 patent as a matter of law. *Petisi*, 363 F.2d at 905, 907.

Amgen urges that, years after Regeneron’s work reflected in the '099 patent’s specification, Amgen later reduced to practice a different, “buffer-free” species within the genus described and claimed in the '099 patent. ECF 666 at 85. But as a legal matter, that does not make Amgen an *inventor* on the '099 patent—it makes Amgen an infringer. See *Univ. of Pittsburgh v. Hedrick*, 573 F.3d 1290, 1297-99 (Fed. Cir. 2009) (later contributions did not make scientists inventors where named inventors already had conceived the invention). Rather than somehow giving rise to inequitable conduct in Regeneron’s earlier-priority patent, Amgen’s later-invented embodiment is, if anything, a “selection invention[.]” that is “ubiquitous in patent law,” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003), and “a normal consequence of technological progress” that is “expressly provided for by statute,” *Eli Lilly & Co. v. Zenith Goldline Pharms.*, 364 F. Supp. 2d 820, 897 (S.D. Ind. 2005); 35 U.S.C. § 101 (“Whoever invents

. . . any new and useful . . . composition of matter, or any . . . *improvement thereof* . . . may obtain a patent therefor . . .”). Because an earlier genus and a later “selection” may constitute separate patentable *inventions* entitled to separate patents, they necessarily may have separate *inventors*, as the hornbook rule above reflects, *Petisi*, 363 F.2d at 905. Amgen’s later aflibercept biosimilar work does not retroactively qualify its scientists as inventors on a patent, filed a decade before Amgen began its work, disclosing Regeneron’s prior research in which Amgen undisputedly had no involvement. Amgen’s deficient pleading cannot rewrite history. *See Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, 2022 WL 16921800, at *5-6 (D. Del. Nov. 14, 2022) (rejecting fraud theory that inventor “never invented an eluxadoline composition that did not include colloidal silica” and should have known claims that “eliminated” that requirement were invalid).

Third, Amgen’s other allegations likewise fail to clear the high bar for pleading inequitable conduct based on fraudulent inventorship. Amgen references the opinion construing the term “a buffer” as recited in the ’865 patent claims. ECF 666 at 79; *see id.* at 83-85. But this Court and the Federal Circuit did not address *inventorship* or *the ’099 patent* at all; they simply made a (preliminary) finding that the “buffer” and “VEGF antagonist” limitations in the ’865 patent claims require “distinct components,” and that the specification “reinforces that understanding.” *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 130 F.4th 1372, 1383 (Fed. Cir. 2025). That finding is not remotely relevant to whether the inventors of the ’099 patent, with claims that do not recite “a buffer,” properly were named inventors of the genus of formulations claimed. The Regeneron inventors indisputably conceived every limitation of the ’099 patent claims; Amgen does not allege otherwise, meaning that they cannot be removed as inventors. *See Hedrick*, 573 F.3d at 1298-99.

Amgen also asserts that parent patents to the ’099 patent “exclusively contain claims directed to” both a “VEGF antagonist and an excipient buffer,” which Amgen argues evinces

improper inventorship on the '099 patent. ECF 666 at 79-80. As an initial matter, Amgen's suggestion that different claims of patents in the same family must have different inventors has no legal basis and therefore cannot state a claim for improper inventorship of the '099 patent. In any event, Amgen's assertion that the '099 patent's claims are the only claims in its patent family that do not recite "a buffer" is demonstrably incorrect, as Amgen itself acknowledges in a footnote. ECF 666 at 80 n.16. The claims of related U.S. Patent 11,732,024 (Ex. 3), also in the Furfine family, do not require any excipient buffer but rather require a "salt" (among other limitations), which may be met by either a buffer (sodium phosphate) or a non-buffer (sodium chloride). Ex. 3, claim 41. The '024 patent—issued in 2023 before Regeneron even had sued Amgen²—is thus identically situated to the '099 patent with respect to the absence of "a buffer" requirement. Both patents' claims encompass formulations with and without an excipient buffer. Amgen's allegations are legally baseless and facially unsound.

Amgen also observes that Regeneron "resubmit[ed] the same inventor declarations" from prior applications. ECF 666 at 81-82. But Regeneron did so in accord with the governing PTO procedure: "*A copy of an oath or declaration from a prior application may be submitted with a continuation or divisional application . . . even if the oath or declaration identifies the application number of the prior application.*" Manual of Patent Examining Procedure ("MPEP") § 602.05. Amgen cannot claim fraud by alleging that Regeneron complied with the relevant PTO procedure. *In re Revlimid & Thalomid Purchaser Antitrust Litig.*, 2024 WL 2861865, at *82 (D.N.J. June 6, 2024) (no inequitable conduct where patentee "follow[ed] [PTO's] own procedures" in MPEP).³

² Amgen's patent application on buffer-free aflibercept formulations published in 2019. ECF 666 at 11. That undermines Amgen's calumny that Regeneron somehow "misused Amgen confidential information" from the litigation, as Amgen *published* its buffer-free formulations *years earlier*, ECF 666 at 132.

³ Unsurprisingly, Amgen follows the same PTO procedure: For example, in prosecuting the '137 continuation application subsequent to its '463 Application (ECF 666 at 10-11), Amgen resubmitted the

Finally, Amgen points to testimony from the inventors relating to buffers, none of which plausibly suggests improper inventorship on the '099 patent. ECF 666 at 82-83. Amgen cites Dr. Dix's declaration (relating to validity, not inventorship) *from a different patent family entirely*, ECF 666 at 83, with a different specification and claims, which sheds no light on the inventorship of the '099 patent. Nor can Dr. Furfine's testimony that he "invented the use of a phosphate buffer" with aflibercept (*id.*) support a claim of fraudulent inventorship as to claims that cover, among other things, ophthalmic aflibercept formulations that use a phosphate buffer. There is no dispute that the '099 patent's examples both contain a phosphate buffer and meet the limitations of the '099 patent claims. Thus, Dr. Furfine's trial testimony regarding his invention of ophthalmic formulations of aflibercept containing phosphate buffer is entirely supportive of his being named as an inventor on the '099 patent; as explained, the claims of that patent cover formulations both with and without an excipient buffer—including a phosphate buffer.

2. No New Matter

Amgen's final inequitable conduct theory is an impermissible repackaging of its written-description invalidity position. Specifically, Amgen contends that Regeneron's counsel committed inequitable conduct by "asserting that the claims of the '099 Patent did not present new matter beyond the description in the originally filed application." ECF 666 at 12. Amgen's breathtakingly expansive theory would transform every after-the-fact written-description challenge to a patent that issues from a continuation application into a fraud claim. *See Vas-Cath Inc. v. Mahurkar*, 935 F.3d 1555, 1560 (Fed. Cir. 1991) (explaining that the § 112 written description requirement is also "analyzed in terms of 'new matter'"). That is not the law.⁴

same declaration from its prior '463 Application instead of a newly executed declaration. *Compare* Ex. 4 ('463 application) at 11-15 *with* Ex. 5 ('137 application) at 1-5.

⁴ Were it so, Amgen's patents would be susceptible to near-identical inequitable conduct challenges. For

Amgen's theory fails at several steps. To begin, this "no new matter" statement is protected attorney argument. A "prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman*, 556 F.3d at 1328-29. Statements regarding a patentee's view of the written-description support for proposed claims are paradigmatic examples of protected argument and not "misrepresentations," so long as they are not unreasonable or demonstrably false. *E.g.*, *Wilson Tool Int'l Inc. v. Mate Precision Tooling Inc.*, 2018 WL 6706326, at *11 (D. Minn. Apr. 19, 2018); *Emerson Elec. Co. v. SIPCO LLC*, 2016 WL 11908347, at *14 (N.D. Ga. Dec. 6, 2016), *report and recommendation adopted in part, rejected in part*, 2017 WL 11834356 (N.D. Ga. Feb. 6, 2017); *Schwendimann v. Arkwright Adv. Coating, Inc.*, 2011 WL 4007334, at *6 (D. Minn. Sept. 8, 2011). The examiner had the application language before him—definitionally, argument about its support of the claims cannot be fraud.

Likewise, such a bare "no new matter" argument cannot support a reasonable inference of knowledge of falsity or an intent to deceive. Amgen may *argue* that the '099 patent claims lack adequate written-description support, but such disagreement does not establish or reasonably suggest Regeneron's counsel *knew* the claims lack support or offered its "no new matter" argument with an *intent* to deceive. *See, e.g.*, *Wilson Tool*, 2018 WL 6706326, at *11; *Emerson*, 2016 WL 11908347, at *14; *Softview LLC v. Apple Inc.*, 2011 WL 4571793, at *1 (D. Del. Sept. 30, 2011).

Finally, this "no new matter" prosecution argument could not have been material to the issuance of the '099 patent. Amgen cannot plead facts that plausibly indicate the examiner would not have allowed the claims absent this statement, *Therasense*, 649 F.3d at 1291; *Pfizer Inc. v.*

example, when prosecuting the '463 Application referenced in its Answer, ECF 666 at 11, Amgen similarly argued that "[n]o new matter is added by the amendments" to its claims. Ex. 4 at 16. And in a continuation application claiming priority to the '463 Application, Amgen likewise argued that "[n]o new matter has been added" by its new claims. Ex. 5 at 11. By Amgen's flawed logic, both of those attorney arguments expose Amgen to inequitable conduct charges from any party that argues (as virtually any party accused of infringement does) that Amgen's claims lack written description.

Teva Pharm., 803 F. Supp. 2d 409, 432 (E.D. Va. 2011), *amended*, 803 F. Supp. 2d 464 (E.D. Va. 2011), as the examiner himself necessarily reached the very same conclusion in allowing the claims—that the claims were supported by the written description and thus did not constitute new matter, *Vas-Cath*, 935 F.3d at 1560. Regeneron presented the examiner with, *inter alia*, (i) the description from the originally filed application (with notations to reflect the handful of ministerial changes made in the new application) and (ii) its new, proposed claims. Ex. 1 at 9. The examiner thus reviewed all the information needed to assess whether the original application adequately described the '099 patent claims, and he was charged with answering independently that very question. MPEP §§ 2163, 2163.05 (9th ed. Rev. Jan. 2024). The law presumes he did this job correctly. *Brooktree Corp. v. Adv. Micro Devices, Inc.*, 977 F.2d 1555, 1574-75 (Fed. Cir. 1992). Regeneron's "no new matter" statement thus could not have been material to allowance of the claims. *Wilson Tool*, 2018 WL 6706326, at *11 ("even assuming allegedly new matter was introduced, [patentee's] statement was not material" because the examiner "had before him all material relevant to making an independent determination of new matter as he was required to do"); *Neutrino Dev. Corp. v. Sonosite, Inc.*, 512 F. Supp. 2d 1004, 1009 (S.D. Tex. 2007).

II. The Court Should Dismiss Amgen's Antitrust Counterclaims (Counterclaims 6-7).

Unsatisfied with attacking Regeneron's '099 patent, Amgen seeks to bloat this case by injecting counterclaims for monopolization predicated on alleged fraud in the procurement and assertion of the '099 patent and twelve other patents asserted in the earlier Amgen case—so-called *Walker Process* fraud. See *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 174 (1965). But Amgen's allegations are deficient several times over. Amgen has not alleged actionable fraudulent conduct. As described above, there was no inequitable conduct in the procurement of the '099 patent. And, as to the twelve other patents, while they were not fraudulently procured either, that was a claim that Amgen was required to present, if at all, in the

earlier action in which those patents were asserted. Nor are any of Amgen’s alleged losses relating to those twelve patents “antitrust injuries” attributable to Regeneron—it was Amgen that decided they should be litigated. Amgen’s antitrust counterclaims should be dismissed.

A. Amgen Fails to Allege Fraud in the Procurement of the ’099 Patent.

A *Walker Process* claim, like all fraud claims, must satisfy the heightened standards of Rule 9(b). *MedImmune*, 427 F.3d at 967. Beyond the standard requirements of any antitrust claim, a *Walker Process* claim requires Amgen to demonstrate “that the asserted patent was acquired by means of either a fraudulent misrepresentation or a fraudulent omission and that the party asserting the patent was aware of the fraud when bringing suit.” *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998). If Amgen cannot “establish inequitable conduct” regarding the asserted patent, neither can it bear “its greater burden of establishing the fraud required to support its *Walker Process* claim.” *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987). Amgen’s *Walker Process* claims necessarily fail as to the ’099 patent because they do not sufficiently allege that Regeneron committed inequitable conduct during the prosecution of that patent. *Supra* Section I; *FMC Corp.*, 835 F.2d at 1418.

B. Amgen’s Antitrust Claims Based on the Twelve Other Patents Also Fail.

Amgen’s counterclaims also allege monopolization based on the enforcement of twelve additional patents—separate from the ’099 patent—that Amgen argues Regeneron acquired by fraud. ECF 666 at 123. All twelve patents were asserted in Regeneron’s earlier action (the “2024 Litigation”), following Amgen’s decision (given that Amgen controlled the scope of the litigation, *Sandoz*, 582 U.S. at 9-10) that the parties should litigate, in the first phase of BPCIA litigation, all the patents that were the subject of the patent dance. Amgen answered the complaint in that resulting case almost two years ago, in February 2024, without raising any antitrust counterclaims. No. 24-cv-264 (C.D. Cal.), ECF 90. None of those twelve patents are asserted in this case.

Amgen's antitrust claims based on conduct relating to the patents in the 2024 Litigation were compulsory counterclaims in that action and are foreclosed here. Further, given *Amgen's* decision that those patents should be included in the 2024 Litigation, it cannot demonstrate the necessary causal connection between *Regeneron's* alleged misconduct and its supposed antitrust injury.

1. Amgen's antitrust claims based on the twelve other patents should have been raised long ago in the 2024 Litigation.

A counterclaim is compulsory if it "arises out of the transaction or occurrence that is the subject matter of the opposing party's claim." *Honeywell Int'l Inc. v. OPTO Elec. Co., Ltd.*, 135 F.4th 170, 176 (4th Cir. 2025); Fed. R. Civ. P. 13(a). The "effect of a defendant's failure to assert a counterclaim made compulsory by [Rule 13] is to preclude its assertion in a later action against the former plaintiff." *Mesker Bros. Iron Co. v. Donata Corp.*, 401 F.2d 275, 279 (4th Cir. 1968).

Amgen's counterclaims as to the twelve earlier asserted patents relate entirely to the prior action. *E.g.*, ECF 666 at 34, 36, 45-68. As Amgen repeatedly intones, those patents all were asserted in "the 2024 Litigation." *E.g.*, *id.* at 123-24. It is beyond dispute that its antitrust claims "arise out of" subject matter of the 2024 Litigation: the enforceability of the twelve patents. Indeed, the only concrete harm Amgen pleads in support of its antitrust claims are its supposed "costs defending against Regeneron's assertions of fraudulently-procured patents *in the 2024 Action.*" ECF 666 at 125. Whatever antitrust claims Amgen wished to conjure regarding those twelve patents, it was required to do so in its February 2024 answer.⁵ *See, e.g., Am. Packing Corp. v. Golden Valley Microwave Foods*, 1995 WL 262522, at *4 (E.D. Pa. May 1, 1995); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928 (D. Del. 1991); *USM Corp. v. SPS Technologies*,

⁵ Nor can Amgen invoke *Mercoïd Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 671 (1944), to urge an exception to Rule 13(a) for antitrust counterclaims to patent litigation. As Amgen itself has elsewhere explained, "the Fourth Circuit (like a number of other circuits) has rejected that position and read *Mercoïd* 'narrowly,' even noting that 'its continuing validity is open to serious question.'" Ex. 6 at 28.

Inc., 102 F.R.D. 167 (N.D. Ill. 1984). Where, as here, “the shared subject matter giving rise to the parties’ claims is evident,” that is the end of the inquiry. *Honeywell*, 135 F.4th at 177 n.2.

2. Amgen’s antitrust claims based on the twelve other patents fail to allege an antitrust injury caused by Regeneron.

The antitrust claims based on these twelve patents also fail because Amgen pleads no “antitrust injury,” *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 311 (4th Cir. 2007), meaning a loss that “reflect[s] the anticompetitive effect” of Regeneron’s conduct, *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). For an injury to qualify, it must have a “causal connection” to the alleged antitrust violation. *Novell*, 505 F.3d at 311. The injury must be one “of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant[’s] acts unlawful.” *Panhandle Cleaning & Restoration, Inc. v. Nationwide Mut. Ins. Co.*, 2018 WL 3717108, at *3 (N.D.W. Va. Aug. 3, 2018) (quoting *Brunswick*, 429 U.S. at 489).

The only concrete injury Amgen claims to have suffered are legal fees supposedly spent defending against the patent infringement claims in the 2024 Litigation. ECF 666 at 125. But these purported costs relating to the twelve patents asserted in the 2024 Litigation (itself suspect because those patents were never the subject of any material litigation in that case, which has focused on the ’865 patent to date) do not bear the requisite “causal connection” to Regeneron’s allegedly anticompetitive conduct. *Novell*, 505 F.3d at 311. That is because those patents were included in the 2024 Litigation *at Amgen’s behest*. Before Regeneron filed the 2024 Litigation, the parties participated in the so-called patent dance, a series of information exchanges prescribed by the BPCIA. ECF 666 at 5. After exchanging contentions as to the infringement, validity, and enforceability of Regeneron’s patents, the BPCIA required the parties to “engage in good faith negotiations to agree on which, if any, patents” at issue “shall be the subject of an action for patent infringement.” 42 U.S.C. § 262(l)(4)(A). During that statutorily mandated process, Amgen took

the position that all the patents identified in Regeneron’s contentions, *including the twelve patents at issue here*, should be included in Regeneron’s suit. ECF 666 at 5, 70. At the time Amgen made that decision, it already had raised its dubious inequitable conduct charges as to the twelve patents during the dance, yet it requested to litigate those very patents. *Id.* at 69. Notably, even if the parties had not agreed on the patents to be litigated under § 262(l)(4)(A), whether these twelve patents would be included in the 2024 Litigation would have remained in Amgen’s control. At that point, Amgen would have decided the number of patents to be litigated, and it could have arranged to have the twelve patents included (for example, by deciding to litigate all patents subject to the dance) or not included (for example, by deciding to litigate a smaller number or even just one of the patents subject to the dance). 42 U.S.C. § 262(l)(5). As the Supreme Court has observed, “[t]his process gives [a biosimilar] applicant” like Amgen “substantial control over the scope of the first phase of litigation.” *Sandoz*, 582 U.S. at 9-10.

Having made its choice to litigate these twelve patents, Amgen cannot now pretend as if it were *Regeneron’s* enforcement decision that caused it to incur litigation costs relating to the same. *See, e.g., PNY Techs. v. SanDisk Corp.*, 2012 WL 1380271, at *13 (N.D. Cal. Apr. 20, 2012) (dismissing antitrust claim where plaintiff’s alleged “harm flow[ed] from the terms of the contract into which it voluntarily entered”); *cf. JSW Steel (USA) Inc. v. Nucor Corp.*, 586 F. Supp. 3d 585, 599 (S.D. Tex. 2022).⁶ Regeneron brought its infringement claims on the twelve patents pursuant to the BPCIA’s statutory scheme and Amgen’s own decision—pursuant to the “substantial control” it exercised “over the scope of the first phase of litigation” in 2024, *Sandoz*, 582 U.S. at

⁶ The *JSW* court further noted that “enforcement of the antitrust injury requirement” in that case would “not deprive the [plaintiff] of a remedy” because it could seek to recover its losses through other avenues. 586 F. Supp. 3d at 600. So too here—the Patent Act already provides a mechanism for an aggrieved defendant in an infringement suit to recover its attorney fees. *See* 35 U.S.C. § 285.

9-10—to litigate those patents as called for by that framework. Antitrust law does not “penalize a brand-name manufacturer whose ‘litigiousness was a product of [a statutory scheme],’” as “[d]oing so would punish behavior that Congress sought to encourage.” *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 158 (3d Cir. 2017); *accord Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1058 (Fed. Cir. 2016) (patentees are incentivized to bring suit on patents identified through the above described process—over which biosimilar applicants exercise substantial control—because failure to do so limits the patentee’s remedy to a reasonable royalty). Simply put, the legal fees (if any, as to the 12 patents) that arose from Amgen’s choices under the BPCIA do not constitute an “injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant[’s] acts unlawful.” *Panhandle*, 2018 WL 3717108, at *3 (quoting 429 U.S. at 489).

III. The Court Should Dismiss Amgen’s California UCL Counterclaim (Counterclaim 8).

Amgen’s claims under the California Unfair Competition Law (“UCL”) arise from the same conduct underlying its federal antitrust claims and thus must be dismissed for the same reasons. *See San Jose v. Comm’r of Baseball*, 776 F.3d 686, 691-92 (9th Cir. 2015) (“An independent claim under California’s UCL is therefore barred so long as [defendant]’s activities are lawful under the antitrust laws.”). Amgen does not allege any additional conduct by Regeneron in its UCL claim and instead bases that counterclaim exclusively on the same allegations underpinning its Sherman Act claims. ECF 666 at 129-30. Accordingly, Amgen’s failure to state a claim under the Sherman Act necessarily means Amgen failed to state a claim under the UCL.

IV. The Court Should Strike and Dismiss Amgen’s Patent Misuse Defense and Counterclaim (Defense 14 and Counterclaim 5).

Amgen contends that the allegations giving rise to its defenses and counterclaims of inequitable conduct and laches as to the ’099 patent also support a defense and counterclaim of patent misuse. The Court should strike and dismiss, respectively, the misuse defense and claim.

Even were Amgen’s allegations sufficient to state a claim for inequitable conduct or prosecution laches—and they are far from that, *see* Sections I and V—they fall short of the patent misuse standard. The Federal Circuit has “characterized patent misuse as the patentee’s act of impermissibly broaden[ing] the physical or temporal scope of the patent grant with anticompetitive effect.” *Princo Corp. v. Int’l Trade Comm’n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010). The classic examples of patent misuse are (i) “tying” arrangements, in which a license to a patent is conditioned on purchase of a separate, staple good and (ii) certain arrangements requiring post-expiration royalties. *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997). This case presents neither, and the Federal Circuit has cautioned that “the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce,” *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998). Congress further has expressly excluded from the reach of the doctrine efforts by a patentee “to enforce his patent rights against infringement,” which is all Regeneron seeks to do here. 35 U.S.C § 271(d).

Courts typically allow misuse counterclaims to survive Rule 12 motions only when Defendants plead “facts to support a reasonable inference that” the plaintiff acted with “[1] bad faith and improper purpose in bringing the suit, and . . . [2] impermissibly broadened the scope of the patent grant with anticompetitive effect.” *Nalco Co. v. Turner Designs, Inc.*, 2014 WL 645365, at *10 (N.D. Cal. Feb. 19, 2014) (collecting cases). Amgen’s claim fails at both prongs of this test, but the Court need consider only the second to resolve the present motion. Amgen seeks to satisfy the second requirement by alleging that “Regeneron impermissibly broadened the scope of the application for the ’099 Patent by filing a preliminary amendment . . . that presented claims allegedly encompassing Amgen’s novel buffer-free formulation, which is not described in the patent specification and was not invented by the individuals named as inventors.” ECF 666 at 27.

But here Amgen substitutes the “key inquiry under the patent misuse doctrine [of] whether . . . the patentee has impermissibly broadened the *physical or temporal scope of the patent grant*,” *Princo Corp.*, 616 F.3d at 1328, with an allegation that Regeneron “impermissibly broadened the scope of the *application*.” Amgen does not contend that Regeneron has sought to enforce the ’099 patent past its expiration or beyond the scope of what it claims, but rather, contends that Regeneron was not entitled to claims of the scope the PTO granted. Such allegations are (yet again) no more than a repackaging of Amgen’s argument that the ’099 patent claims lack written description. Amgen has pleaded no facts to support an inference that Regeneron sought to broaden impermissibly the scope of the patent *grant*, such as by claiming infringement of a plainly non-infringing product.

V. The Court Should Strike and Dismiss Amgen’s Laches Defense and Counterclaim (Defense 11 and Counterclaim 3).

Amgen asserts prosecution laches, a defense applicable “only in egregious cases of misuse of the statutory patent system.” *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). Critically, not once has the Federal Circuit upheld a laches defense against a patent like the ’099 patent, the expiration of which is tied to its priority application filing date rather than its issuance date. This Court should reject the defense here.

Prosecution laches arose when a patent’s term was defined as “17 years from the date of issuance,” which “incentivized certain patentees to delay prosecuting their patents by abandoning applications and filing continuing applications in their place,” giving rise to “submarine patents” used to extend the lifetime of a patent family indefinitely. *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1351-52 (Fed. Cir. 2021); *Symbol*, 422 F.3d at 1380, 1386. Laches was applied to curtail this practice of “deliberately and without excuse postpon[ing] beyond the date of the actual invention, the beginning of the term of [the patentee’s] monopoly.” *Hyatt*, 998 F.3d at 1360. In 1995, however, U.S. patent law changed such that a patent’s term was measured as “20 years following the filing

date of the application or an earlier non-provisional application to which the subject application claims priority” *id.* at 1352, thereby abrogating the strategy of extending patent terms with continuation applications. That 20-year term applies to the ’099 patent. And because the timing of the ’099 patent’s issuance is irrelevant to the expiry of its term, laches is inapplicable. *See Chrimar Sys. v. Alcatel-Lucent Ent.*, 2017 WL 345991, at *4 (E.D. Tex. Jan. 24, 2017) (expiry based on filing date “alleviate[d] the need for the equitable remedy” of prosecution laches).

VI. The Court Should Strike Amgen’s Unclean Hands Defense (Defense 4).

Amgen’s “Equitable Doctrines” defense is inadequately pled, without any factual foundation, and should be stricken. Amgen alleges only 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.” ECF 666 at 9. The Fourth Circuit has not addressed whether the *Twombly/Iqbal* pleading standard also applies to affirmative defenses, and district courts are divided on the question. *Bakery & Confectionary Union & Indus. Int’l Pension Fund v. Just Born II, Inc.*, 888 F.3d 696, 700 n.5 (4th Cir. 2018). Even courts that have declined to apply that standard to affirmative defenses, however, have held that “affirmative defenses . . . must include more than bare bones conclusory assertions.” *Tippman Eng’g, LLC v. Innovative Refrigeration Sys., Inc.*, 2020 WL 1644985, at *3 (W.D. Va. Apr. 2, 2020). Amgen’s “threadbare” defense fails to clear even this bar, *id.*, let alone meet the *Twombly/Iqbal* standard, *Titan Sys., LLC v. SRI Int’l*, 787 F. Supp. 3d 72, 80 (D. Md. 2025). And, to the extent this defense is grounded in conduct alleged in Amgen’s inequitable conduct and/or fraud claims, it also fails for the reasons above.

CONCLUSION

For the reasons set forth above, the Court should strike Amgen’s Fourth, Eleventh, Thirteenth, and Fourteenth Additional Defenses and dismiss Amgen’s Third, Fourth, Fifth, Sixth, Seventh, and Eighth Counterclaims.

Date: November 12, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2025, I electronically filed the foregoing using the Court's CM/ECF service. Counsel of record for all parties will be served by the Court's CM/ECF service.

/s/ David R. Pogue _____

David R. Pogue