NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **ASTRAZENECA PHARMACEUTICALS LP, et al.,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**SANDOZ INC., et al.,**<br><br>**Defendants.** | **Civil Action No. 23-796 (JCG)**<br><br>**MEMORANDUM OPINION FILED UNDER TEMPORARY SEAL** |

BONGIOVANNI, Magistrate Judge

This matter comes before the Court upon Defendants Cipla Limited, Cipla USA, Inc., Natco Pharma Limited, Sandoz Inc., Zydus LifeSciences Ltd., and Zydus Pharmaceuticals (USA) Inc.'s (collectively, "Defendants") motion to amend their affirmative defenses, counterclaims, and invalidity contentions to include allegations of inequitable conduct, unclean hands, and violations of antitrust laws. (Docket Entry No. 256). Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, "Plaintiffs") oppose Defendants' motion. The Court has fully reviewed and considered all arguments raised in favor of and in opposition to Defendants' motion to amend their affirmative defenses, counterclaims, and invalidity contentions. The Court considers Defendants' motion without argument pursuant to L.Civ.R. 78.1(b). For the reasons set forth more fully below, Defendants' motion to amend is GRANTED.

## I. Background and Procedural History

The parties and the Court are familiar with the facts underlying this matter as well as those underlying Defendants' motion to amend their affirmative defenses, counterclaims, and invalidity contentions. The parties and the Court are equally familiar with the issues presented in Defendants' pending motion. As such, the Court neither restates the facts of the case nor repeats the arguments made in support of or in opposition to Defendants' motion at length herein.

This is a patent infringement case related to Plaintiffs' LUNPARZA® product and Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration (the "FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of LYNPARZA® (Olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 7,449,464 (the "'464 patent"); U.S. Patent No. 8,475,842 (the "'842 patent"); and U.S. Patent No. 8,859,562 (the "'562 patent") (collectively, the "patents-in-suit"). Through the instant motion, Defendants seek to amend their affirmative defenses, counterclaims, and invalidity contentions to include allegations of inequitable conduct, unclean hands, and violations of antitrust laws. Defendants' new allegations relate to what they contend is "an unusual scheme to fraudulently maintain the extended life of . . . the '562 patent[] until 2031, when the patent should have expired in 2024." (Def. Br. at 1; Docket Entry No. 258).

The '562 patent expires in 2031. "Dr. Thomas Helleday is the sole named inventor of the single claim of the '562 patent" and it is that single patent claim that prevents generic competition to Plaintiffs' Lynparza® product. (*Id.*) Defendants argue that "any term of the '562 patent after 2024 is invalid because its single claim is obvious over two other patents Dr. Helleday also invented but that undisputedly expired in 2024—U.S. Patent Nos. 7,351,701 (the "'701 patent") and 7,531,530 (the "'530 patent")". (*Id.*) Defendants argue that the fact that Dr. Helleday is an

inventor on all three patents implicates the doctrine of obviousness-type double patenting ("OTDP"), which would prevent the '562 patent from having a longer term than the '701 and '530 patents that expired in 2024.

Defendants seek leave to amend their affirmative defenses, counterclaims, and invalidity contentions to add allegations of inequitable conduct, unclean hands, and violations of antitrust laws based on Dr. Helleday's decision in 2024 to remove himself as an inventor of the '701 and 530 patents; Defendants note that Plaintiffs contend that this change means Defendants cannot pursue an OTDP defense because there no longer is "joint inventorship" between the '562, '701, and '530 patents. Defendants, however, argue that the facts will establish that "Dr. Helleday's inventorship change is a lie whose sole purpose is to fraudulently save the '562 patent term until 2031[.]" (*Id*. at 2). Defendants argue that their motion to amend should be granted under both the standards governing motions to amend the pleadings, Federal Rule of Civil Procedure ("Rule") 15(a) and Local Civil Rule 15.1, and motions to amend contentions, Local Patent Rule 3.7, because Defendants' proposed claims are not futile and Defendants were diligent in seeking leave to amend, filing their motion in a timely manner with no undue delay, and their proposed amendments will not prejudice Plaintiffs. (*See id.* at 21-28).

Plaintiffs oppose Defendants' motion to amend. In this regard, Plaintiffs take issue with Defendants' characterization of the correction of inventorship, outlining why Dr. Helleday filed petitions with the PTO to remove himself as an inventor with respect to the '710 and 530 patents. In addition, Plaintiffs argue that Defendants were not diligent in seeking to amend, arguing that they delayed for more than a year before proposing their amendment. In this regard, Plaintiffs note that all of the filings relevant to inventorship correction are public and "Dr. Helleday could not have been more transparent" regarding same. (Pl. Opp. Br. at 7; Docket Entry No. 265). Plaintiffs

point out that these documents, which "contain the sole allegedly false statements that form the basis for all of Defendants' proposed amendments" were publicly filed on July 23, 2024, yet Defendants inexplicably waited until September 29, 2025 to file their motion to amend. (*Id*.)

Further, Plaintiffs argue that Defendants' proposed claims are futile. With respect to Defendants' proposed inequitable conduct claim, Plaintiffs argue that this claim fails because "the allegedly inequitable conduct undisputedly did not occur during the prosecution of the '562 patent at issue in this case." (*Id*. at 9). Plaintiffs argue that the infectious unenforceability doctrine provides no recourse to save Defendants' proposed inequitable conduct claim because that doctrine would require a showing of inequitable conduct as to the '701 and '530 patents and an infection spreading from there to the prosecution and issuance of the '562 patent. Plaintiffs contend that Defendants are unable to make the requisite showings. In this regard, Plaintiffs claim that Defendants cannot meet "the applicable materiality standard: that the purportedly fraudulent correction of inventorship somehow was the but-for cause of the Curtin patens' issuance" as "[t]hose patents had issued years earlier, applying a list of inventors Defendants argue was ***correct***." (*Id*. at 9-10). Further, Plaintiffs argue that Defendants' reliance on the infectious unenforceability doctrine also fails because "no precedent allows unenforceability to 'infect' patents that issued years before, where misconduct not only undisputedly did not have, but temporally ***could not have***, any effect on proceedings before the PTO in the purportedly infected '562 patent" because "[i]nfection does not travel backwards in time. And the PTO's issuance of the '562 patent while applying the very understanding of inventorship that Defendants claim Dr. Helleday lied to avoid, forecloses any argument that the alleged inequitable conduct as to the Curtin patents bears the required relationship to the prosecution of the '562 patent." (*Id*. at 12).

Plaintiffs argue that Defendants' unclean hands defense, which is based on the same theories as their inequitable conduct claim, fails for the same reasons. Indeed, Plaintiffs state that "[t]he Federal Circuit's precedent is clear: An unclean hands defense cannot somehow 'override[] this court's inequitable-conduct standards governing unenforceability challenges based on prosecution communications with the PTO.'" (*Id*. at 18 (quoting *Gilead Sciences, Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1240 n.3 (Fed. Cir. 2018))). Thus, Plaintiffs argue that "the sole alleged misconduct involves Dr. Helleday's correction of inventorship "communication[] with the PTO," and the inequitable conduct standards thus govern that correction." (*Id*. (citation omitted)).

In addition, Plaintiffs argue that to the extent Defendants base their unclean hands claim on Plaintiffs' counsel's alleged litigation misconduct the proposed claim remains futile because the only misconduct alleged is that counsel refused to produce non-privileged discovery. Plaintiffs argue that the non-produced discovery is "subject to a still-pending motion to compel, which Plaintiffs opposed[.]" (*Id*. at 20). Plaintiffs argue that "[b]ecause Defendants' motion to compel remains pending . . ., Plaintiffs committed no misconduct by refusing to produce the documents." (*Id*.)

Turning to Defendants' proposed antitrust claim, Plaintiffs note that Defendants base this claim on the same allegations of fraud as their inequitable conduct claim and, thus, this claim fails for the same reasons. Specifically, Plaintiffs point out that Defendants' antitrust claim is premised on alleged *Walker Process* fraud, which itself requires a higher threshold showing of both materiality and intent than inequitable conduct. As such, Plaintiffs argue "[b]ecause Defendants fail to state an inequitable-conduct claim . . . , they necessarily fail to state a *Walker Process* claim[.]" (*Id*. at 21).

Moreover, Plaintiffs argue that even if Defendants' inequitable conduct claim was somehow not futile, Defendants' proposed *Walker* Process claim would, nevertheless, fail as a matter of law. In this regard, Plaintiffs argue that "*Walker Process* requires finding what Defendants do not allege: that the '562 patent itself was '***procured by*** 'intentional fraud,'' *i.e.,* 'knowingly and willfully misrepresenting facts to the Patent Office.'" (*Id*. at 22 (quoting *Argus Chem. Corp. v. Fibre Glass-Evercoat Co., Inc.*, 812 F.2d 1381, 1384 (Fed. Cir. 1987) (citations omitted))). Again, Plaintiffs point out that Defendants make "no allegation of any fraud in procuring the '562 patent[.]" (*Id*.) Since "the '562 patent undisputably was not 'procured by' fraud," Plaintiffs argue that Defendants' *Walker Process* claim necessarily fails. (*Id*.) Further, Plaintiffs argue that the infectious unenforceability doctrine cannot save Defendants' proposed *Walker Process* claim, as "[p]recedent has rejected attempts" to do so and noting that "Defendants cite no case where a court has upheld a *Walker Process* claim based on infectious unenforceability. (*Id*. (citing *Guardant Health v. Found. Med., Inc.*, Civil Action No. 17-1616-LPS-CJB, Civil Action No. 17-1623-LPS-CJB, 2020 WL 2461551, at *10 n. 18 (D.Del. May 7, 2020))).

In addition, Plaintiffs argue that Defendants have failed to adequately plead antitrust injury. Plaintiffs note that because Defendants did not mount a challenge to the '464 patent, they are legally precluded from entering the Olaparib market until 2027. As such, Plaintiffs argue that "Defendants cannot state a claim that they have suffered any antitrust harm." (*Id*. at 23). Further, Plaintiffs maintain that any arguments regarding future harm are too speculative and not ripe for consideration. Indeed, Plaintiffs contend that there are "separate bars to commercialization of Defendants' products" in the form of other patents on Olaparib formulation on which Plaintiffs assert infringement which do not expire until 2029, which "likewise foreclose any antitrust injury." (*Id*. at 23-24). Similarly, Plaintiffs claim that Defendants cannot establish harm through having to

pay attorney fees and costs to defend this litigation because such defense costs "cannot constitute antitrust injury absent an allegation that these costs have prevented Defendants from entering the relevant market." (*Id*. at 24).

Plaintiffs also argue that Defendants' motion to amend should be denied because of prejudicial delay. Plaintiffs claim that "[g]enerally, delay is undue when a motion to amend is filed 'three months or more from the time the defendant obtained critical information relating to an inequitable conduct claim.'" (*Id*. at 25 (quoting *Lipocine Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 19-622 (WCB), 2020 WL 4794576, at *4 (D. Del. Aug. 18, 2020))). As indicated above, Plaintiffs argue that Defendants had all critical information related to their proposed inequitable conduct claim by July 23, 2024, and yet they inexplicably took no action for over a year. Indeed, Plaintiffs argue that it was incumbent upon Defendants to immediately seek leave to amend "once a 'red flag' indicating possible inequitable conduct ha[d] been raised." (*Id*. at 26 (quoting *Wag Acquisition, LLC v. Gattyan Group S.a.r.l.*, Civil Action No. 14-2832 (ES)2020 WL 5105194, at * 4 (D.N.J. Aug. 31, 2020)). Instead, Plaintiffs claim Defendants delayed fourteen months before seeking leave to amend. Plaintiffs argue this delay "indicates idleness rather than diligence." (*Id*.)

Further, Plaintiffs argue that while Defendants claim they sought to amend within weeks of conducting Dr. Helleday's deposition and obtaining third-party discovery from Pfizer, Inc. ("Pfizer"), Defendants fail to explain "***why*** this discovery was necessary to assert their new invalidity theories." (*Id*. at 27). Indeed, Plaintiffs contend that Defendants do not tie any facts purportedly learned after Dr. Helleday's public declaration was filed with the PTO in July 2024 to their proposed amended claims. (*See id.* at 28). As such, Plaintiffs argue that there is no justification for Defendants' delay.

Moreover, Plaintiffs argue that they will be prejudiced by Defendants' proposed amendments because Defendants have already admitted that "their amendment requires at least a two-month further delay ***of all of the deadlines in the case, including trial***" and they have also indicated that additional extensions may be sought. (*Id*. at 29). In addition, Plaintiffs maintain that while Defendants have represented that they do not intend to seek additional discovery beyond what is outstanding, Defendants have made later statements suggesting that the contrary is true and that they might seek further discovery depending on the contents of the withheld documents. (*See id*. at 29-30). Plaintiffs argue that reopening discovery at this late stage of the proceedings would be inherently prejudicial and would "undermine the statutory framework (and Plaintiffs' strong interest) to adjudicate the patents' validity and infringement before FDA approval of the generic applications." (*Id*. at 30).

## II. Analysis Regarding Defendants' Motion to Amend

Rule 15(a) governs motions to amend the pleadings. Under Rule 15(a)(2), "[t]he court should freely give leave [to amend] when justice so requires." The Third Circuit has shown a strong liberality in allowing amendment, favoring decisions on the merits rather than on procedural technicalities. *Boileau v. Bethlehem Steel Corp*., 730 F.2d 929, 938 (3rd Cir. 1984); *see Cureton v. National Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3rd Cir 2001) (citing *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984)). Although the decision to grant or deny leave to amend is within the discretion of the Court, that discretion must be exercised consistent with the liberal standard embodied in Rule 15(a)(2). *Berkshire Fashions, Inc. v. M.V. Hakusan II*, 954 F.2d 874, 886 (3d Cir. 1992); *see Rutter v. Rivera*, 74 F. App'x 182, 186 (3d Cir. 2003). Leave to amend under Rule 15(a) should be granted in the absence of undue delay or bad faith by the movant,

prejudice to the movant, or futility of amendment. *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

Local Patent Rule 3.7 governs amendments of invalidity contentions. Pursuant to L.Pat.R. 3.7, "Amendment of any contentions . . . may be made only by order of the Court upon a timely application and showing of good cause." (Emphasis in original). L.Pat.R. 3.7 sets forth a "[n]on-exhaustive" list of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause." While non-exhaustive, the list makes clear that a moving party's diligence is a key component of the good cause inquiry. *See* L.Pat.R. 3.7(c) (indicating that "recent discovery of nonpublic information . . . which was not discovered, despite diligent efforts," is basis that supports finding of good cause to permit amendment of contentions); *see also AstraZeneca AB v. Hanmi USA, Inc.*, Civil Action No. 11-760 (JAP), 2011 WL 5526009, *4 (D.N.J. Nov. 14, 2011) (noting "[w]hile non-exhaustive, the list of circumstances included in L.Pat.R. 3.7 establishes that a dominant consideration in determining whether good cause exists to permit a requested amendment is the diligence of the moving party.") The Federal Circuit has also confirmed the importance of diligence, holding that to establish good cause, the moving party must "proceed with diligence in amending [its] contentions when new information comes to light in the course of discovery." *O2 Mico Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006)

The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007). Indeed, they "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Info. Storage Devices,*

*Inc.*, No. C 95-1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). As such, unlike proposed amendments of the pleadings, which are liberally granted pursuant to Federal Rule of Civil Procedure 15, amendments to contentions are governed by a more conservative standard. *See Id*. (noting that "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction.") Thus, while L.Pat.R. 3.7 certainly "is not a straitjacket into which litigants are locked from the moment their contentions are served," the "modest degree of flexibility" that it provides must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early on. *Comcast Cable Communs. Corp. v. Finisar Corp.*, No. C 06-04206 WHA, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007).

With these standards in mind, the Court examines Defendants' requests to amend their affirmative defenses, counterclaims, and invalidity contentions to add allegations of inequitable conduct, unclean hands, and violations of antitrust laws.

**A. Undue Delay, Undue Prejudice, and Diligence**

Under Rule 15(a), in determining whether there has been undue delay, courts consider both the length of the delay and resulting prejudice to the opposing party. *Long*, 393 F.3d at 399. Although significant lapses of time may weigh against the moving party, delay alone is insufficient to deny amendment absent a showing of prejudice, bad faith, or dilatory motive. *See id* at 399; *Cureton*, 252 F.3d at 273 (3d Cir. 2001); *see also Adams*, 739 F.2d at 868; *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989). Further, the burden of establishing undue prejudice rests with the non-moving party. *Long*, 393 F.3d at 400. This burden may be met by showing that allowing an amendment "would: (i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii)

prevent [the opposing party] from bringing a timely action in another jurisdiction." *Id.* Moreover, as noted above, when considering a motion to amend contentions under Local Patent Rule 3.7, the Court also considers the diligence of the moving party. If the moving party was not diligent, even if the delay was not undue, a motion to amend contentions could fail even where a motion to amend the pleadings would succeed.

Here, despite Plaintiffs' arguments to the contrary, the Court finds that Defendants acted diligently in seeking to amend their affirmative defenses, counterclaims, and invalidity contentions. While Dr. Helleday submitted his declarations to the PTO requesting to correct the inventorship with respect to the '701 and '530 patents on July 23, 2024, the PTO did not formally change the inventorship on these patents until September 10, 2024. Further, Plaintiffs did not produce the SHEFIELD-003 production volume, which included the complete file histories for the '701 and '530 patents, including Dr. Helleday's declaration seeking a correction of inventorship and the certificates of correction issued by the PTO, until December 20, 2024, and Plaintiffs did not serve their validity contentions, which expressly stated that inventorship had been changed, until January 17, 2025.

Shortly after receiving Plaintiffs' production and validity contentions, Defendants, in February 2025, sought both party and third-party discovery regarding the change in inventorship. Notably, Plaintiffs resisted producing discovery, refusing to respond to Defendants' requests for production of documents and an informal motion to compel regarding same remains pending.[1] After a significant back and forth, non-party Pfizer produced discovery, which Defendants received on August 5 and 13, 2025. Moreover, Defendants only deposed Dr. Helleday on August 15, 2025. Defendants also served Dr. Helleday with a document subpoena at his deposition, to

[1] The Court addresses said discovery dispute later herein.

which he has refused to produce any responsive documents. Under these circumstances, the Court does not find that Defendants unduly delayed by filing their motion to amend on September 29, 2025.

While Plaintiffs are correct that courts have found a lack of diligence and delay to be undue when a motion to amend is filed "three months or more from the time the defendant obtained critical information relating to an inequitable conduct claim" (Pl. Opp. Br. at 25 (quoting *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 2020 WL 4794576, at *4)), Plaintiffs ignore the analysis set forth in *Lipocine* regarding what constitutes critical information. After explicitly referencing the "heavy" burden associated with proving inequitable conduct, the *Lipocine* court noted that "it is common for claims of inequitable conduct to arise only after discovery has been conducted[,]" stating that "[i]n light of the high standards of pleading and proof for inequitable conduct claims, courts in this district have regularly held that it is not unreasonable for patent challengers to postpone raising allegations of inequitable conduct until sufficient discovery has been conducted to enable the challenger [to] confirm its suspicions and gather the evidence necessary to sustain its claim." *Lipocine*, 2020 WL 4794576 at *3. Indeed, the *Lipocine* court determined that "[g]iven that a claim of inequitable conduct requires proof of specific intent to deceive on the part of the applicants or their representatives, it is hardly surprising that responsible defense counsel would wish to depose those individuals before charging them with deceptive intent." *Id*. at 4.

Here, as noted above, Defendants diligently began pursuing party and third-party discovery regarding the inventorship change in February 2025 shortly after Plaintiffs produced the inventorship change documentation on January 17, 2025. Moreover, Plaintiffs resisted producing discovery on said change and Pfizer's production was not made until August 2025, which is also when Dr. Helleday's deposition occurred. Less than a month after Dr. Helleday's deposition took

place, *i.e.*, after Defendants had an opportunity to investigate in an effort to obtain critical information related to Dr. Helleday's intent to allegedly knowingly file false declarations with the PTO, Defendants contacted Plaintiffs seeking their consent to amend. After meeting and conferring, the parties were unable to reach an agreement. Defendants then promptly filed the instant motion to amend.

Plaintiffs also rely on *Wag Acquisition, LLC v. Gattyan Group S.a.r.l.*, 2020 WL 5105194, at *4 (D.N.J. Aug. 31, 2020), to suggest that Defendants failed to act expeditiously, arguing that Defendants had a duty to "take immediate action" to amend their pleadings to incorporate inequitable conduct allegations "once a 'red flag' indicating possible inequitable conduct has been raised[,]" claiming that "[h]ere the supposed 'red flag' giving rise to Defendants' claims was hoisted, in the broad daylight of the PTO's files accessible to everyone with an internet connection, as early as July 24, 2024." (Pl. Opp. Br. at 26 (quoting *Wag*, 2020 WL 5105194, at *4)). Plaintiffs therefore claim that "Defendants could have and should have pursued leave to amend as soon as possible after learning about it" and assert that Defendants' failure to do so for fourteen months "indicates idleness rather than diligence." (*Id.*)

Plaintiffs' reliance on *Wag*, however, much like their reliance on *Lipocine*, is misplaced. The court in *Wag* was not focused on the timing of the defendant's motion to amend, but on the defendant's failure to pursue discovery related to its proposed inequitable conduct claim in a more timely fashion:

> WAG's first document production disclosed that Icecast, a publicly available source code, had been used as the "*model*" of the Geode Distribution Server; that should have raised a red flag, motivating Duodecad to immediately pursue discovery regarding a potential claim of inequitable conduct[.] . . . Duodecad has pointed to no affirmative steps that it took—whether before the assigned District Judge or Judge Hammer—to investigate the inequitable conduct prior to the December 5, 2016 deadline to amend pleadings. As that

> deadline approached, Duodecad failed to take even the minimal step of requesting an extension. Duodecad offers no excuse for that lapse. Finally, Duodecad points to no impediment to its pursuit of this supposedly critical discovery sooner than February 2017.

2020 WL 5105194, at *4. Plaintiffs' arguments notwithstanding, *Wag*, in fact, supports Defendants' arguments that they acted diligently in this matter.

Here, when faced with Plaintiffs' red flag, *i.e.*, Plaintiffs' production of documentation regarding the change in inventorship, Defendants immediately pursued discovery from Plaintiffs, just as the *Wag* court said a diligent defendant should proceed. Thus, unlike Duodecad, Defendants did not fail to act; instead, they swiftly took steps to investigate the inventorship change, not only seeking discovery from Plaintiffs, but also issuing a Rule 45 subpoena on Pfizer. That Plaintiffs refused to produce the requested discovery is not Defendants' fault; nor is the fact that it took several months of negotiation before Pfizer made its production in response to Defendants' subpoena. As noted above, shortly after receiving Pfizer's productions on August 5 and 13, 2025, and after taking Dr. Helleday's deposition on August 15, 2025, and having failed to obtain Plaintiffs' consent to amend, Defendants filed the instant motion on September 29, 2025.

Under these circumstances, the Court finds Defendants acted diligently and did not unduly delay in seeking to amend their affirmative defenses, counterclaims, and invalidity defenses. As a result, absent prejudice to Plaintiffs or futility of the proposed amendments, the Court finds there is good cause to grant Defendants' motion.

With respect to prejudice, while the Court appreciates Plaintiffs' concerns, the Court finds that they will not be unduly prejudiced if Defendants are permitted to amend their affirmative defenses, counterclaims, and invalidity contentions to add allegations of inequitable conduct, unclean hands, and violations of antitrust laws now. While fact discovery closed on August 29, 2025, at the time it closed there remained the still pending informal motion to compel related to

Defendants' discovery requests regarding the inventorship change of the '701 and '530 patents. Outside of this discovery, which has been preserved, it is unlikely that significantly more fact discovery will be needed if Defendants' motion is granted. Further, at the time Defendants' motion was filed, expert discovery had just begun, and no trial had been scheduled. Under these circumstances, the Court finds that Plaintiffs will not be unfairly prejudiced if Defendants are permitted to amend their affirmative defenses, counterclaims, and invalidity defenses as requested.

**B. Futility**

A court may deny a motion for leave to amend where the proposed amendment would be futile. *U.S. ex rel. Schumann v. AstraZeneca Pharms. L.P.*, 769 F.3d 837, 849 (3d Cir. 2014). An amendment is considered futile if the amended complaint would fail to state a claim upon which relief could be granted. *Travelers Indem. Co v. Dammann & Co*., 594 F.3d 238, 243 (3d Cir 2010). The futility of an amended complaint is governed by the same standards of legal sufficiency as a motion to dismiss under Rule 12(b)(6). *Id*.

To determine if a complaint would survive a motion to dismiss under Rule 12(b)(6), the Court must accept as true all the facts alleged in the pleading, draw all reasonable inferences in favor of the plaintiff, and determine if "under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). "[D]ismissal is appropriate only if, accepting all of the facts alleged in the [pleading] as true, the p[arty] has failed to plead 'enough facts to state a claim to relief that is plausible on its face.'" *Duran v. Equifirst Corp.*, Civil Action No. 2:09-cv-03856, 2010 WL 918444, *2 (D.N.J. March 12, 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Put simply, the alleged facts must be sufficient to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The focus is not

on "'whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Bell Atl. Corp.*, 550 U.S. at 563 n.8 (quoting *Scheuer v. Rhoades*, 416 U.S. 232, 236 (1974)). Importantly, unless a proposed amendment is "clearly futile . . . denial of leave to amend is improper." *Morton Intern., Inc. v. A. E. Staley Mfg. Co.*, 106 F.Supp.2d 737, 745 (D.N.J. 2000). Further, in assessing a motion to dismiss, while the Court must view the factual allegations contained in the pleading at issue as true, the Court is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007).

The burden of establishing futility is on the party opposing the amendment and, "given the liberal standard applied to the amendment of pleadings," that burden is a "heavy" one. *Pharm. Sales & Consulting Corp. v. J.W.S Delavau Co.*, 106 F. Supp. 2d 761, 764 (D.N.J. 2000). "If a proposed amendment is not clearly futile, the denial of leave to amend is improper." *Harrison Beverage Co. v. Dribeck Imps., Inc*., 133 F.R.D. 463, 468-69 (D.N.J. 1990). "This standard does not necessitate that parties undertake substantive motion practice concerning the proposed claim or defense." *Id*. "Instead, it requires only that the claim or defense have an adequate basis in fact or law, not being frivolous." *Id*.

**1. Inequitable Conduct**

A claim for inequitable conduct requires "a finding of both intent to deceive and materiality." *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). To prevail on the defense, "the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id*. Because a "[a] counterclaim or affirmative defense of inequitable conduct sounds in fraud[,] it "is subject to the heightened pleading standard of Fed.R.Civ.P. 9(b)." *Aurinia Pharms. Inc. v. Sun Pharm. Inds.,*

*Inc.*, Civil Action No. 20-19805 (GC)(DEA), 2022 WL 3040950, at *8 (D.N.J. Aug. 2, 2022). "Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed Cir. 2009). "At the pleading stage the proponent of the inequitable conduct theory need only plead facts supporting a reasonable inference that a specific individual knew of the misrepresentation and had the specific intent to deceive the PTO." *Sanders v. The Mosaic Co.*, 418 Fed.Appx. 914, 919 (Fed. Cir. 2011) (citing *Exergen*, 575 F.3d at 1328-29). "A reasonable inference is one that is plausible and that flows logically from the facts alleged. . . ." *Exergen*, 575 F.3d at 1329 n.5. In addition, "[a]lthough but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct," an exception exists "in cases of affirmative misconduct." *Therasense*, 649 F.3d at 1292. "When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material." *Id*.

Further, "the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family." *Id*. at 1288. This concept has been "referred to as the doctrine of 'infectious unenforceability.'" *Guardant Health, Inc. v. Found. Med., Inc.*, Civil Action No. 17-1616-LPS-CJB, Civil Action No. 17-1623-LPS-CJB, 2020 WL 2477522, at *4 (D. Del. Jan. 7, 2020) (citing cases). "Pursuant to this infectious unenforceability doctrine, inequitable conduct associated with one patent may render a related patent unenforceable—so long as the inequitable conduct at issue bears 'an immediate and necessary relation to the enforcement of the related patent.'" *Id*. at 5 (citing *e.g.*, *Consol. Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990)). "An 'immediate and necessary relation' requires that the 'inequitable conduct that occurred earlier in

the chain [of issued patents] 'must be related to the targeted claims of the ultimately-issued patent or patents to be enforced.'" *Id*. (quoting *eSpeed, Inc. v. Broketec USA, L.L.C.*, 417 F. Supp. 2d 580, 595 (D.Del. 2006), *aff'd*, 480 F.3d 1129 (Fed. Cir. 2007) (citations omitted)). Notably, "the law on infectious unenforceability requires no direct linkage between the inequitable conduct at issue and the prosecution of the patent-in-question." *Id*. at 6. Instead, so long there is "an 'immediate and necessary relation' between the inequitable conduct and the '*equity* [the patentee now] seeks, namely *enforcement* of the [patent(s)-at-issue,]' this would be sufficient to meet the doctrine's requirements." *Id*. (quoting *Consol. Aluminum*, 910 F.2d at 810-811 (citations omitted)). Further, incorrect inventorship can constitute inequitable conduct under Federal Circuit precedent *See Equil IP Holdings LLC v. Akamai Tech., Inc.*, Civil Action No. 22-677-RGA, 2025 WL 507330, at * (D. Del. Feb. 14, 2025) (citing *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376-77 (Fed. Cir. 2020) (footnote omitted)). Indeed, as the Federal Circuit held in *Egenera*, "It is the inequitable-conduct rules that provide a safety valve in the event of deceit." 972 F.3d at 1377.

Here, the Court finds that Defendants set forth sufficient facts to establish a non-futile inequitable conduct claim. In this regard, Defendants have met Rule 9(b)'s heightened pleading standard, identifying the specific who, what, when, where, and how of the material misrepresentation allegedly made before the PTO, and the facts they allege, when taken as true, support a reasonable inference that Dr. Helleday and Plaintiffs knew Dr. Helleday was making a material misrepresentation when he filed the correction of inventorship paperwork with the PTO and did so with the specific intent to deceive to deceive the PTO.

In summary, to support their inequitable conduct claim, Defendants allege:

- Dr. Helleday is, at a minimum, a co-inventor of the subject matter disclosed and claimed in the '701 and '530 patents.

- Dr. Helleday was a named inventor of the '701 and '530 patents during the entire life of each patent.
- Dr. Helleday and Plaintiffs knew Dr. Helleday was a properly named inventor of the '701 and '530 patents and that there was no legitimate basis to remove Dr. Helleday as an inventor from those patents.
- Despite there being no legitimate basis to remove Dr. Helleday as an inventor from the '701 and '530 patents, Plaintiffs and Dr. Helleday devised a plan to fraudulently change the inventorship of the '701 and '530 patents with the intent to deceive the PTO for the purpose of saving the '562 patent from invalidity for OTDP over those patents in this litigation.
- But for Dr. Helleday's fraudulently filed change of inventorship paperwork, the PTO would not have removed Dr. Helleday as an inventor on the '701 and '530 patents.
- But for the change in inventorship, Plaintiffs would have no credible defense to invalidity of the '562 patent for OTDP over the '701 and '530 patents.
- Dr. Helleday's and Plaintiffs' inequitable conduct bears an immediate and necessary relation to the enforcement of the '562 patent in this litigation, rendering the '562 patent unenforceable.

The Court finds that this is sufficient. The materiality of the purported misrepresentation is evident in that it stems from Dr. Helleday's alleged "affirmative misconduct[,]" *i.e.* the filing of the "unmistakably false" correction of inventorship paperwork. *Therasense*, 649 F.3d at 1292. In addition, Defendants' allegations clearly establish specific intent to deceive. Moreover, while Defendants' theory of inequitable conduct is novel – it does not appear that any court has ever

considered whether a change of inventorship under the circumstances presented here supports an inequitable conduct claim – as noted above, the Federal Circuit has determined that incorrect inventorship can constitute inequitable conduct.

Furthermore, the Court finds that the infectious unenforceability doctrine could plausibly apply under the facts presented here. Defendants do not attempt to rely on said doctrine to suggest that the misconduct they allege occurred, namely Dr. Helleday's fraudulent filing of paperwork with the PTO to change the inventorship of the '701 and '530 patents, in some way "infected" the PTO's issuance of the '562 patent. As Plaintiffs note, the alleged fraudulent correction of inventorship with respect to the '701 and 530 patents temporarily could not have any effect on the PTO's issuance of the '562 patent as the '562 patent issued years before the correction happened and "[i]nfection does not travel backwards in time." (Pl. Opp. Br. at 12). Instead, Defendants argue that Dr. Helleday and Plaintiffs' inequitable conduct with respect to the '701 and '530 patents was done to prospectively extend the life of the '562 patent, in an effort to avoid a finding of invalidity for OTDP of the '562 patent in the instant litigation. While this argument may be novel, it fits within the bounds of the infectious unenforceability doctrine. There is "an 'immediate and necessary relation' between the inequitable conduct and the '*equity* [the patentee now] seeks, namely *enforcement* of the ['562 patent]'." *Guardant Health,* 2020 WL 2477522, at *6 (quoting *Consol. Aluminum*, 910 F.2d at 810-811 (citations omitted)). As a result, the Court finds that Defendants' proposed inequitable conduct claim has an adequate basis in fact and law rendering it not clearly futile.

**2. Unclean Hands**

"A court may find unclean hands when the misconduct of a party seeking relief 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation .

. . for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.'" *Luv n' Care, Ltd. v. Laurain*, 98 4th 1081, (Fed. Cir. 2024) (quoting *Keystone Driller Co. v. Gen. Excavator Co.*. 290 U.S. 240, 245, 54 S.Ct. 146, 78 L.Ed. 293 (1933)). "The 'immediate and necessary relation' standard, in its natural meaning, generally must be met if the conduct normally would enhance the claimant's position regarding legal rights that are important to the litigation if the impropriety is not discovered and corrected" and can even "cover at least some misconduct that ultimately fails to affect the litigation, as when it is discovered before it bears fruit, as long as its objective potential to have done so is sufficient." *Gilead*, 888 F.3d at 1240. Further, in considering unclean hands, courts view "the totality of the evidence-supported misconduct[,]" not simply "individual elements alone[.]" *Id*. Where "the totality of evidence demonstrate[s]" that a party has "engaged in misconduct rising to the level of unconscionable acts, enhancing [its] litigation positions and undermining those of [its adversary], creating immediate and necessary connections between [its] misconduct and the relief it [i]s seeking from the court[,]" a finding of unclean hands is warranted. *Luv n' Care*, 98 F. 4th at 1096.

Importantly, the unclean hands doctrine does not only apply to conduct before a court. Instead, the doctrine also applies "to conduct before the PTO." *Consol. Aluminum*, 910 F.2d at 812. Also, claims of inequitable conduct and unclean hands can both be pursued even when based on the same underlying conduct. *See Equil IP*, 2025 WL 507330, at *2 (holding "[i]n regard to unclean hands, Defendant essentially alleges the same thing that it does in connection with inequitable conduct. I think that, for the same reasons that Defendant has successfully alleged inequitable conduct, it has also alleged unclean hands.")

Here, for similar reasons as explained in the context of Defendants' proposed inequitable conduct claim, the Court finds that their unclean hands claim is not futile. Succinctly put, the following allegations, when taken as true, are sufficient to raise Defendants' unclean hands claim non-speculative and, thus, non-futile:

- Dr. Helleday is, at a minimum, a co-inventor of the subject matter disclosed and claimed in the '701 and '530 patents.
- Dr. Helleday was a named inventor of the '701 and '530 patents during the entire life of each patent.
- Dr. Helleday and Plaintiffs knew Dr. Helleday was a properly named inventor of the '701 and '530 patents and that there was no legitimate basis to remove Dr. Helleday as an inventor from those patents.
- Despite there being no legitimate basis to remove Dr. Helleday as an inventor from the '701 and '530 patents, Plaintiffs and Dr. Helleday devised a plan to fraudulently change the inventorship of the '701 and '530 patents with the intent to deceive the PTO for the purpose of saving the '562 patent from invalidity for OTDP over those patents in this litigation.
- But for Dr. Helleday's fraudulently filed change of inventorship paperwork, the PTO would not have removed Dr. Helleday as an inventor on the '701 and '530 patents.
- But for the change in inventorship, Plaintiffs would have no credible defense to invalidity of the '562 patent for OTDP over the '701 and '530 patents.

- Dr. Helleday's and Plaintiffs' inequitable conduct bears an immediate and necessary relation to the enforcement of the '562 patent in this litigation, rendering the '562 patent unenforceable.

**3. Antitrust Violations**

Defendants seek to assert an antitrust claim based on *Walker Process* fraud. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed. 2d 247 (1965). In *Walker Process*, "Walker's counterclaim alleged that Food Machinery obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office." *Id*. at 177. The Supreme Court stated that "[p]roof of this assertion would be sufficient to strip Food Machinery of its exemption from the antitrust laws." *Id*. Thus, "[i]f a patentee asserts a patent claim and the defendant can demonstrate the required fraud on the PTO, as well as show that 'the other elements necessary to a § 2 case are present,' the defendant counterclaimant is entitled to treble damages under the antitrust laws." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007) (quoting *Walker Process*, 382 U.S. at 175)).

Notably, "[t]o demonstrate *Walker Process* fraud, a claimant must make higher threshold showings of both materiality and intent than are required to show inequitable conduct." *Id*.; *see Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998) (noting "inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim.") Indeed, "[t]he first barrier for a *Walker Process* claimant to clear is the requirement that the patent be obtained through actual fraud upon the PTO." *Id*. Further, "[t]he heightened standard of materiality in a *Walker Process* case requires that the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." *Id*. at 1347.

Plaintiffs argue that Defendants' antitrust claim is clearly futile because *Walker Process* fraud requires that the underlying patent, here the '562 patent, be procured by intentional fraud, and "Defendants' own allegations make clear that the PTO examined the '562 patent ***based on the inventorship Defendants allege to be correct*** for the '701 and '530 patents (that Dr. Helleday was a named inventor of all the patents)." (Pl. Opp. Br. at 22). As such Plaintiffs maintain "the '562 patent undisputably was not 'procured by' fraud, and Defendants' *Walker Process* claim thus fails." (*Id*. (quoting *Agus Chem. Corp. v. Fibre Glass-Evercoat Co., Inc.*, 812 F.2d 1381, 1384 (Fed. Cir. 1987))).

The Court, however, finds that the key components of the antitrust claim discussed in *Walker Process* involved the knowing and willful misrepresentation of facts to the PTO. While *Walker Process* itself dealt with the procurement of a patent, there is no reason to believe that other scenarios involving the knowing and willful misrepresentation of facts to the PTO could not equally support a similar claim. Indeed, given the concerns at issue, rather than limit *Walker Process* fraud solely to the procurement of a patent, given the lack of binding authority to the contrary, the sensible approach is to infer that a *Walker Process* claim is viable if a defendant can show that a patentee procured something of value through actual fraud upon the PTO. This is, in fact, what Defendants allege happened here: Plaintiffs and Dr. Helleday knowingly and willfully mispresented that Dr. Helleday was not an inventor of the '701 and '530 patents with an intent to deceive the PTO so that the PTO would remove Dr. Helleday as an inventor on the '701 and '530 patents for the purpose of saving the '562 patent from invalidity for OTDP over those patents in this litigation.

The Court finds that when taken as true these allegations set forth a knowing and willful material misrepresentation of facts with the intent to deceive the PTO sufficient to support a

*Walker Process* fraud claim, rendering Defendants' proposed antitrust claim non-futile. Further, despite Plaintiffs' arguments to the contrary, the Court finds that Defendants have adequately alleged an antitrust injury. Indeed, in *TransWeb, LLC v. 3M Innovative Props. Co.,* the Federal Circuit held in the context of a *Walker Process* claim that "attorney fees incurred defending the infringement suit are antitrust injury[.]" 812 F.3d 1295, 1312 (Fed. Cir. 2016); *see Guardant Health*, 2020 WL 2461551, at *11 (noting "there is good authority suggesting that such fees and costs amount to actionable injury in this context"). As a result, the Court shall permit Defendants to amend to assert the proposed antitrust violations.

## III. Discovery Dispute

As mentioned above, there is an outstanding discovery dispute regarding Defendants' request for discovery related to their OTDP defense. The parties' letters regarding same can be found at Docket Entry Nos. 209, 214, and 217. The Court heard argument regarding this dispute and on an unrelated issue on October 28, 2025. Only the former is addressed herein.

As the parties are aware, the Court has broad discretion in deciding discovery issues such as those raised by Defendants in their informal motion to compel discovery related to their OTDP defense. *See United States v. Washington*, 869 F.3d 193, 220 (3d Cir. 2017) (noting that "[a]s we have often said, matters of docket control and discovery are committed to [the] broad discretion of the district court"); *Halsey v. Pfeiffer*, Civil Action No. 09-1138, 2010 WL 3735702, at *1 (D.N.J. Sept. 17, 2010) (noting that "[d]istrict courts provide magistrate judges with particularly broad discretion in resolving discovery disputes"); *Gerald Chamles Corp. v. Oki Data Americas, Inc.*, 247 F.R.D. 453, 454 (D.N.J. 2007) (stating that it is "well-settled that Magistrate Judges have broad discretion to manage their docket and to decide discovery issues[.]") Indeed, it is well settled that the appropriate scope of discovery and the management of requests for discovery are left to

the sound discretion of the Court. *See In re Fine Paper Antitrust Litig.*, 685 F.2d 810, 817 (3d Cir. 1982) (finding that conduct of discovery is committed to sound discretion of Court). The Court utilizes said discretion in deciding the instant dispute.

Having granted Defendants' motion to amend and having considered the specific document requests at issue (*see* Docket Entry No. 210-17), the Court rules as follows with request to Defendants' Requests for Production ("RFP"): No later than July 31, 2026, Plaintiffs are directed to produce responsive documents to RFP 117-120, 122-125, and 127-130. With respect to RFP 132, the Court finds that Plaintiffs' production of "the Helleday Research and Development Documents" is sufficient. With respect to RFP 133, Plaintiffs' production of "documents sufficient to show consulting agreements, if any, between Plaintiffs, on the one hand, and Thomas Helleday or Nicola Curtin, on the other, related to this litigation" is sufficient. However, to avoid confusion, "related to this litigation" includes consulting agreements that concern not only the patents-in-suit but also the '701 and '530 patents, even though the '701 and'530 patents aren't explicitly asserted in Plaintiffs' Complaint but only are raised in connection with Defendants' OTDP defense. As a result, all such consulting agreements shall be produced by July 31, 2026. The Court finds that RFP 116, 121, 126, and 131 are overbroad and burdensome. Plaintiffs need not produce information in response to same.

## IV. Conclusion

For the reasons stated above, Defendants' motion to amend is GRANTED. Defendants' informal motion to compel is GRANTED in part and DENIED in part. An appropriate Order follows.

Dated: July 8, 2026

s/Tonianne J. Bongiovanni
**Tonianne J. Bongiovanni**
**United States Magistrate Judge**