

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS	)	
IRELAND CO., LTD. and ASTELLAS	)	
PHARMA GLOBAL DEVELOPMENT,	)	
INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 23-486-JFB-EGT (Consolidated)
	)	
ASCENT PHARMACEUTICALS, INC.,	)	
MSN PHARMACEUTICALS INC. and	)	
MSN LABORATORIES PRIVATE	)	
LIMITED	)	
	)	
Defendants.	)	

**REPORT AND RECOMMENDATION**

Presently before the Court is the motion of Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, “Plaintiffs” or “Astellas”) to dismiss Ascent Pharmaceutical, Inc.’s (“Defendant” or “Ascent”) counterclaims of inequitable conduct and to strike the related affirmative defenses. (D.I. 227). For the reasons set forth below, the Court recommends that Plaintiffs’ motion be GRANTED-IN-PART and DENIED-IN-PART.

**I. BACKGROUND**

Plaintiffs hold approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets, which contain mirabegron as the active ingredient and are used in the treatment of overactive bladder. (*See* D.I. 1 ¶¶ 15-17; D.I. 210 ¶ 5). The present case is one of many in the long-running patent dispute between Plaintiffs and various generic manufacturers seeking to market a generic version of Myrbetriq®.

Plaintiffs originally sued Ascent in May 2023 for infringement of U.S. Patent No. 10,842,780 (“the ’780 Patent”) in response to Ascent filing an Abbreviated New Drug Application

seeking to market generic versions of 25 mg and 50 mg strength Myrbetriq® tablets. (D.I. 1 ¶ 39 in C.A. No. 24-1084; D.I. 210 ¶¶ 6 & 8). Plaintiffs filed another suit against Ascent in September 2024, alleging infringement of three newly issued patents directed to modified-release formulations of mirabegron: U.S. Patent Nos. 12,059,409 (“the ’409 Patent”), 11,707,451 (“the ’451 Patent”) and 12,097,189 (“the ’189 Patent”). (See D.I. 1, *Astellas Pharma Inc. et al. v. Ascent Pharmaceuticals, Inc. et al.*, C.A. No. 24-1084-JFB-EGT (D. Del. Sep. 27, 2024)). The two cases were later consolidated into the present action. (D.I. 151).

The ’780, ’409, ’451 and ’189 Patents (“the Asserted Patents”) are all listed in the Orange Book as part of the Myrbetriq® NDA. Conduct that occurred during prosecution of some of these patents – or other applications in the patent families – underlie Ascent’s broad allegations of inequitable at issue here.

On April 15, 2025, Ascent filed a first motion to amend its answer, seeking to add, *inter alia*, counterclaims and related affirmative defenses of inequitable conduct for the ’780, ’409, ’451 and ’189 Patents based on Plaintiffs’ allegedly withholding information from the United States Patent and Trademark Office (“the Patent Office”) or taking inconsistent positions before the Patent Office and the FDA. (D.I. 180 & 185).<sup>1</sup> On May 2, 2025, this Court allowed the proposed amendments as to the ’409, ’451 and ’189 Patents, but not the ’780 Patent. (D.I. 222 at 53:22-56:14). Ascent then docketed its Amended Answer and Counterclaims consistent with the Court’s ruling. (D.I. 210). Ascent also objected to the Court’s ruling as to the ’780 Patent (D.I. 219), and those objections were ultimately overruled (D.I. 280).

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<sup>1</sup> The deadline to amend pleadings in the initial case was August 1, 2024. (D.I. 19 ¶ 2). The deadline to amend pleadings in the consolidated case was May 23, 2025. (D.I. 151 ¶ 2).

Barely three weeks after this Court ruled on Ascent’s first motion to amend, Ascent filed a second motion to amend on May 23, 2025, again seeking to add counterclaims and affirmative defenses relating inequitable conduct for ’780 Patent, this time based on newly obtained deposition testimony. (D.I. 221 & 241). Specifically, Ascent attempted to plead that those involved in prosecuting the families of the four Asserted Patents had a duty to investigate whether any prior art patents were listed in the Orange Book as covering Myrbetriq®. (D.I. 225 & 241). On June 9, 2025, this Court denied Ascent’s second motion to amend on procedural and substantive grounds. (D.I. 265 at 31:6-36:12). Ascent again objected to the Court’s ruling (D.I. 266), and those objections were similarly overruled (D.I. 280).

On May 28, 2025, Plaintiffs filed the present motion to dismiss (D.I. 227), which is directed to the first proposed amended answer that the Court allowed (D.I. 210). Plaintiffs’ motion seeks dismissal of all counterclaims of inequitable conduct under Federal Rule of Civil Procedure 12(b)(6) as insufficiently pleaded. (D.I. 228 at 6-13). Plaintiffs also seek to strike the related affirmative defenses. (*Id.* at 13). The motion is fully briefed. (D.I. 263 & 271).

## **II. LEGAL STANDARDS**

### **A. Motion to Dismiss for Failure to State a Claim**

In ruling on a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept all well-pleaded factual allegations in the complaint as true and view them in the light most favorable to the plaintiff. *See Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010); *see also Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232-33 (3d Cir. 2008). “[A] court need not ‘accept as true allegations that contradict matters properly subject to judicial notice or by exhibit,’ such as the claims and the patent specification.” *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017) (quoting *Anderson v. Kimberly-Clark Corp.*, 570 F. App’x 927, 931 (Fed. Cir. 2014)). Dismissal under Rule 12(b)(6) is only appropriate if a complaint does not

contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

### **B. Motion to Strike**

Although Rule 12(b)(6) does not allow the Court to “dismiss” an affirmative defense, the Court may strike any insufficient defense pursuant to Rule 12(f). *Zadro Prods., Inc. v. SDI Techs., Inc.*, No. 17-1406 (WCB), 2019 WL 1100470, at \*2 (D. Del. Mar. 8, 2019) (Bryson, J., sitting by designation); FED. R. CIV. P. 12(f). Motions to strike are generally disfavored and a court should not grant such motions “unless the insufficiency is ‘clearly apparent.’” *Fesnak & Assocs., LLP v. U.S. Bank Nat’l Ass’n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010) (quoting *Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986)). That being said, a court need not “accept affirmative defenses that are mere bare bones conclusory allegations” and “may strike such inadequately pleaded defenses.” *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-452-WCB, 2019 WL 2121395, at \*2 (D. Del. May 15, 2019) (Bryson, J., sitting by designation).

### **C. Inequitable Conduct**

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.” *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense I)*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc). Inequitable conduct requires that “the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [Patent Office].” *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007).

The materiality requirement for an inequitable conduct claim is usually but-for materiality, *Therasense I*, 649 F.3d at 1291, meaning that the patent challenger must show that the Patent Office “would not have allowed the claim but for the nondisclosure or misrepresentation,” *In re*

*Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012). Undisclosed prior art is considered but-for material if the Patent Office would have rejected a claim had it been aware of the prior art reference. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1186 (Fed. Cir. 2014). An exception to the but-for materiality requirement exists when the patentee has engaged in “affirmative acts of egregious misconduct” before the Patent Office, “such as the filing of an unmistakably false affidavit.” *Therasense I*, 649, F.3d at 1292. In those cases, the misconduct is considered material without any but-for showing. *Id.* (“[A] patentee is unlikely to go to great lengths to deceive the [Patent Office] with a falsehood unless it believes that the falsehood will affect issuance of the patent.”).

As to the intent requirement of an inequitable conduct claim, the accused infringer must allege “that the applicant knew of the reference or prior commercial sale, knew that it was material, and made a deliberate decision to withhold it.” *Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1299 (Fed. Cir. 2018).

Although “a broader concept than fraud,” inequitable conduct “must be pled with particularity” under Federal Rule of Civil Procedure 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *see also* FED. R. CIV. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”). A patent challenger must identify “the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [Patent Office].” *Exergen*, 575 F.3d at 1327. “Moreover, although ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of

the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [Patent Office].” *Id.* at 1328-29.

### **III. DISCUSSION**

Ascent alleges that Astellas committed inequitable conduct by (1) failing to inform the Patent Office that certain prior art was listed in the Orange Book as covering Myrbetriq®, (2) failing to disclose relevant litigation documents to the Patent Office and (3) failing to disclose to the Patent Office that examples in ’451 and ’189 Patents use a dihydrochloride salt instead of mirabegron. (*See* D.I. 210 ¶¶ 51-76 (Counterclaim II directed to inequitable conduct for ’409 Patent) & ¶¶ 99-137 (Counterclaim V directed to inequitable conduct for ’451 and ’189 Patents)). The Court addresses each purported ground for inequitable conduct in turn.

#### **A. Prior Art Listed in the Orange Book**

In Ascent’s view, Astellas’s failure to disclose to the Patent Office that certain prior art was listed in the Orange Book as covering Myrbetriq® constitutes inequitable conduct. (D.I. 210 ¶¶ 31-37, 60-76 & 110-137). As alleged, this purported inequitable conduct renders unenforceable three of the Asserted Patents – *i.e.*, the ’409, ’451 and ’189 Patents.

Starting first with the ’409 Patent, Ascent alleges that Astellas committed inequitable conduct during prosecution of the parent, U.S. Patent Application No. 12/568,313 (“the ’313 Application”). There, the Examiner rejected claims as obvious over Astellas’s U.S. Patent No. 6,699,503 (“the ’503 Patent”) and, in response, Astellas argued that the ’503 Patent did not teach the mirabegron release profile claimed in the ’313 Application. (D.I. 210 ¶¶ 56-57). At the time Astellas made this argument, the ’503 Patent was already listed in the Orange Book for Myrbetriq®. (*Id.* ¶ 61). Ascent contends that Astellas’s failure to disclose to the Patent Office that the ’503 Patent was listed in the Orange Book is inequitable conduct that renders the ’313 Application’s children unenforceable – *i.e.*, the 409 Patent. (*Id.* ¶¶ 65-68; *see also* D.I. 263 at 7-

8). Ascent advances a similar (but more attenuated) theory for the '451 and '189 Patents. These patents are in the same family and have the same parent application, U.S. Patent Application No. 14/584,933 (“the '933 Application”). During prosecution of the '933 Application, Astellas argued that prior art U.S. Patent No. 6,436,441 (“the '441 Patent”) did not teach mirabegron as a potential active ingredient because it was not known to be suitable for a sustained-release formulation. (D.I. 210 ¶ 105). While arguing to the Patent Office that the '441 Patent did not teach mirabegron in a sustained-release formulation (*see id.*), Astellas had already listed its sibling patent (the '503 Patent) in the Orange Book for Myrbetriq®. (*Id.* ¶¶ 114-15).<sup>2</sup> Ascent contends that Astellas’s failure to disclose that the '441 Patent is a sibling to an Orange Book-listed patent while prosecuting the '933 Application is inequitable conduct that renders unenforceable that application’s children – *i.e.*, the '451 and '189 Patents. (*Id.* ¶¶ 118-120; *see also* D.I. 263 at 7-8).

As an initial matter, the Court notes that the Federal Circuit has held that “[a]n applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.” *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000). Ascent attempts to push back on this case law, arguing that citing references to an examiner does not absolve a patentee of inequitable conduct.<sup>3</sup> But the complained-of references here (the '503 and '441 Patents) were more than just cited. The Patent Office expressly considered

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<sup>2</sup> The '503 and '441 Patents contain substantially identical written descriptions.

<sup>3</sup> Ascent cites to *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995), for the proposition that burying a piece of prior art in a long list of references disclosed to the examiner may constitute inequitable conduct. (D.I. 263 at 17). Although some courts have found *Molins* to mean that “burying” a highly pertinent piece of prior art among numerous references in an information disclosure statement (“IDS”) may constitute inequitable conduct, other courts disagree. *Compare Coolsystems, Inc. v. Nice Recovery Sys. LLC*, No. 16-02958-PJH, 2016 WL 6091577, at \*4 (N.D. Cal. Oct. 19, 2016), with *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353 (D. Del. 2009). The Court need not decide the issue, however, because Ascent does not accuse Astellas of burying the '503 and '441 Patents in a lengthy IDS. *Molin* is therefore inapplicable here.

both references and rejected the pending claims over them. (D.I. 210 ¶¶ 55 & 104). Seemingly recognizing this hurdle, Ascent tries to craft a different kind of inequitable conduct theory.

Ascent contends that Astellas was under a duty to provide the Patent Office with specific information about the prior art already under consideration – namely, that it was listed in the Orange Book as covering Myrbetriq® (or related to a patent that was). In arguing that withholding this information constitutes inequitable misconduct, Ascent relies on a mishmash of authorities. First, Ascent claims that in order to list a patent in the Orange Book as claiming a drug, the patent must claim the active ingredient, relying on *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, 124 F. 4th 898 (Fed. Cir. 2024), and the relevant authority cited therein. (D.I. 263 at 11). Next, Ascent points to the Patent Office’s *Manual of Patent Examining Procedure* (“MPEP”) §§ 2001.06(e) and 2015, as well as *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, 11 F.4th 1345 (Fed. Cir. 2021), and *Therasense, Inc. v. Becton, Dickinson & Co. (Therasense II)*, 864 F. Supp. 2d 856 (N.D. Cal. 2012), for the proposition that Astellas had a duty to disclose to the Patent Office any inconsistent positions it took between regulatory bodies (such as the Patent Office and the FDA). (D.I. 263 at 12 & 17-19). The problem with Ascent’s theory, however, is that there is no plausible allegation of but-for materiality here.<sup>4</sup>

“To establish materiality, it must be shown that the [Patent Office] would not have allowed the claim but for the nondisclosure or misrepresentation.” *In re Rosuvastatin*, 703 F.3d at 519. Despite arguing that the ’503 Patent must cover mirabegron given its listing in the Orange Book

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<sup>4</sup> Ascent does not appear to allege that omitting disclosure of the Orange Book listing qualifies as affirmative egregious misconduct. (See D.I. 210, 263). In any event, such omissions would not rise to the level of affirmative egregious misconduct and would be analyzed under the but-for standard. *Therasense I*, 649 F.3d at 1292-93 (“Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality.”).



for Myrbetriq® (D.I. 263 at 11), Ascent never alleges in its counterclaims that the '503 Patent discloses or teaches mirabegron as the active ingredient (D.I. 210 ¶¶ 54-76 & 99-137). Or that Astellas made a false statement to the Patent Office regarding the '503 Patent's disclosure. (D.I. 210 ¶¶ 54-76 & 99-137). It is unclear how the complained-of conduct resulted in the Patent Office allowing any claim over the '503 Patent when it would not have otherwise.

Ascent nevertheless maintains that inequitable conduct exists here because Astellas made inconsistent statements to the FDA and the Patent Office about the '503 Patent. (D.I. 263 at 2-3 & 11-12; D.I. 210 ¶¶ 65-68). In particular, Ascent contends that listing the '503 Patent in the Orange Book is an affirmative representation (to the FDA) that the patent must cover “the Myrbetriq final dosage form containing the active ingredient, mirabegron.” (D.I. 263 at 12; D.I. 210 ¶¶ 56-68). Ascent further contends that this listing is irreconcilably inconsistent with Astellas arguing to the Patent Office that the '503 Patent did not disclose or teach the claimed mirabegron release profile in the '409 Patent's parent application. (*Id.*). And that this listing is inconsistent with Astellas arguing to the Patent Office that the sibling '441 Patent is irrelevant to the '451 and '189 Patents' parent application. (D.I. 263 at 9). Ascent argues, without support, that this is enough to establish the but-for materiality required for inequitable conduct. (*Id.* at 17). But inconsistent statements do not on their own establish but-for materiality because mere inconsistency does not demonstrate that the Patent Office would have rejected a claim. Or that the patent applicant made a false statement or material omission.

Ultimately, Ascent's entire theory is that “Astellas had a duty to disclose to the Patent Office any statements or arguments to the FDA that are inconsistent with the positions Astellas took during prosecution” and that failure to do so is inequitable conduct. (D.I. 263 at 12). Ascent relies on MPEP § 2001.06(e) for this proposition and also *Belcher Pharmaceuticals, LLC v.*

*Hospira, Inc.*, 11 F. 4th 1345 (Fed. Cir. 2021). (D.I. 263 at 17-18). But Ascent’s reliance is misplaced. MPEP § 2001.06(e) and 2015 were added in 2022 – years after the complained-of conduct. See U.S. PAT. & TRADEMARK OFFICE, CHANGE SUMMARY FOR THE NINTH EDITION, REVISION 07.2022, at 42-43 (2023). And in *Belcher*, the Federal Circuit affirmed a finding of inequitable conduct when the patentee’s chief science officer **withheld** prior art that disclosed the claimed pH range he described as “inventive” to the examiner. *Id.* at 1353-54.<sup>5</sup> The prior art here was not withheld; it was provided to and expressly considered by the examiner. (D.I. 210 ¶¶ 55 & 104). Moreover, in *Belcher*, the Federal Circuit found materiality based on the patentee not challenging the district court’s finding that the claims were invalid as obvious based on testing of the withheld prior art system, which ultimately had a pH within the claimed range. *Belcher*, 11 F.4th at 1352. Materiality was thus established by an unchallenged invalidity finding – not the mere existence of inconsistent arguments, as Ascent seems to suggest. *Id.* at 1352-53.

The only other case that Ascent cites in support of its “inconsistent statement” theory, *Therasense II*, is likewise unpersuasive. (D.I. 263 at 18). On remand from the Federal Circuit, the court in *Therasense II* found that the patentee had engaged in inequitable conduct by taking different positions on the meaning of the phrase “optionally, but preferably” in a prior art patent describing the use of a protective membrane. *Id.* at 860-63. In a brief to the European Patent Office, the patentee argued that “optionally, but preferably” in the prior art meant **both** the use of

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<sup>5</sup> Ascent also quotes *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000), for the proposition that not disclosing a reference with “a more complete combination of relevant features” may rise to the level of inequitable conduct even where the features are present in other references before the examiner. (D.I. 263 at 17). But that case addressed withheld references, not references properly before the examiner. See *Semiconductor Energy Lab ’ys Co.*, 204 F.3d at 1374 (“A **withheld** reference may be highly material when it discloses a more complete combination of relevant features . . . .” (emphasis added)).

a protective membrane and the absence of a protective membrane. *Id.* at 862. Years later, the patentee argued before the U.S. Patent Office that the phrase meant a protective membrane was **required** and that the apparent equivocation would have been understood by a skilled artisan as mere “patent phraseology.” *Id.* at 861. Although *Therasense II* found inequitable conduct where a prior art reference was disclosed and considered by the examiner, it differs from this case in one important way: the argument presented to the U.S. Patent Office there was false. *See id.* at 864 (“The plain language of the [prior art] disclosure was clear that the disclosure taught that a protective membrane was preferable for use with live blood and optional in all other cases including whole blood; [the protective membrane] was never required in any case.”). Contrary to Ascent’s suggestion here, the inequitable conduct found in *Therasense II* was not based on the mere existence of inconsistent statements, but rather that the statements made to the U.S. Patent Office were false. *Id.* The patentee knew as much. *Id.* And the material falsehood was specifically pleaded in the *Therasense II* patent challenger’s counterclaims. *See* Defendant Becton, Dickinson & Co.’s Amended Answer and Counterclaims at Counterclaims ¶ 27, *Therasense II*, 864 F. Supp. 2d 856 (N.D. Cal. 2012) (No. 3:04-cv-02123), ECF No. 311 (“People of skill in the art in the relevant time period would have understood the word ‘optional’ in the [prior art] patent to have the normal meaning of the word, i.e. not required. [The patentee’s] own research . . . back to 1983 demonstrated it understood no membrane was required.”). No such allegation is present here.

Distilled down, Ascent’s theory is that the mere existence of inconsistent statements provided to different governmental agencies is enough to find inequitable conduct. The Court disagrees. Where, as here, the references are before the Patent Office, Ascent was required to plead that Astellas made false statements to the Patent Office or committed some other egregious misconduct. *See Therasense I*, 649 F.3d at 1292-93. Having failed to do so, Ascent has not

sufficiently alleged the requisite but-for materiality. And because but-for materiality is lacking, the Court need not reach the issue of specific intent. The inequitable conduct counterclaims for the '409, '451 and '189 Patents based on Astellas's failure to disclose that the '503 Patent was listed in the Orange Book should be dismissed.<sup>6</sup>

## **B. Litigation Documents**

Ascent next alleges that, during prosecution of the '409, '451 and '189 Patents, Astellas improperly withheld “material information from litigation relating to the '780 [P]atent.” (D.I. 210 ¶¶ 69, 126-27). Ascent also claims that Astellas improperly withheld materials from litigation involving the '451 Patent during prosecution of the newer '409 and '189 Patents. (*Id.* ¶¶ 69, 127).

As to the theory of inequitable conduct based on withheld litigation material, Astellas argues that Ascent's pleading lacks the specificity required by Rule 9(b). (D.I. 228 at 11). Astellas points out that, although Ascent alleges that broad categories of litigation materials were withheld from the Patent Office, only Judge Bataillon's June 9, 2023 order invalidating the '780 Patent (“the '780 Order”) was specifically identified. (*Id.*). Moreover, because the '780 Order was disclosed to the Patent Office, in Astellas's view, it cannot be the basis of an inequitable conduct claim. (*Id.*). Ascent responds that it has pled these inequitable conduct allegations with sufficient particularity. (D.I. 263 at 14). Ascent claims, without support, that the identification of litigation documents as “including ‘pleadings, briefs, court rulings, expert reports, contentions, trial testimony and[] deposition testimony” is sufficient to satisfy the “what” prong of the inequitable conduct pleading standard. (*Id.* (quoting D.I. 210 ¶¶ 69-70 & 128)). The Court disagrees.

Alleging generally that the '451, '409 and '189 Patents would not have issued if broad swathes of litigation documents had been disclosed to the Patent Office is insufficient to meet the

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<sup>6</sup> To be clear, this analysis applies to Ascent's theory regarding the sibling '441 Patent.

pleading standard of Rule 9(b). (D.I. 210 ¶¶ 70, 126-29). Ascent does not “identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found – *i.e.*, the ‘what’ and ‘where’ of the material omissions.” *Exergen*, 575 F.3d at 1329. Instead, Ascent asserts – broadly and generically – that the omitted documents were material and omitted with deceptive intent. (D.I. 210 ¶¶ 71 & 131). Yet Ascent fails to identify which documents were not disclosed to the Patent Office or which claims those documents were material to. (*See id.* ¶¶ 69-76, 126-34). Ascent does not even identify what information allegedly appears in the withheld documents. (*See id.*). In fact, Ascent identifies only a single case, *Astellas Pharma Inc v. Lupin Ltd.*, C.A. No. 23-819-JFB-EGT (D. Del. filed July 28, 2023), but fails to point to any particular documents associated with this case, any particular information contained in those documents or any particular claims allegedly invalid over that information. (*See* D.I. 210 ¶¶ 69 & 127). This is insufficient to meet the pleading standard of *Exergen*.

As to the one document specifically identified in the Amended Answer – the ’780 Order – that document was before the Patent Office. (D.I. 210 ¶¶ 70 & 128). Ascent describes this as “a single-line entry in an Information Disclosure Statement.” (*Id.*). But Ascent’s characterization does nothing more than describe the proper format for submitting information to the Patent Office.<sup>7</sup> *See* 37 C.F.R. § 1.98. An explanation of relevance is not required unless the disclosed document “is not in the English language.” 37 C.F.R. § 1.98(a)(3)(i); *see also TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, C.A. No. 21-1126-GBW-SRF, 2023 WL 1860186, at \*6 (D. Del. Feb. 9, 2023) (“[A]n IDS does not require an explanation of a reference’s relevance.”). Moreover, the face of the ’409 and ’189 Patents indicate that the examiner did, in fact, consider this reference.

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<sup>7</sup> Ascent does not appear to accuse Astellas of “burying” the ’780 Order.

(*See, e.g.*, '189 Patent at Page 4 (“References Cited” including “Memorandum and Order in *Astellas Pharma Inc. v. Sandoz Inc., et al.*; 1:20CV1589; Case 1:21-cv-00664-JFB-CJB (Jun. 2023))). Given that Astellas did disclose the reference (and Ascent seemingly acknowledges this), Ascent fails to adequately allege but-for materiality of the '780 Order as related to the '409 and '189 Patents. And although the '780 Order was not cited to the Patent Office during prosecution of the '451 Patent, Ascent fails to identify which claims of the '451 Patent are affected by this omission or how the '780 Order would cause the Patent Office to reject the claims of the '451 Patent – *i.e.*, the “what” and “how” of *Exergen*. 575 F.3d at 1329-30. But-for materiality of the '780 Order is therefore also lacking as to the '451 Patent. The Court need not reach the issue of specific intent for the '780 Order as applied to any of the '409, '451 and '189 Patents.

Because the claims based on withheld litigation documents fail to allege but-for materiality (for the '780 Order) or are not pleaded with particularity (for the remaining documents), the Court recommends that Ascent’s inequitable conduct claims based on litigation documents be dismissed.

### **C. Dihydrochloride Salt**

Ascent’s final inequitable conduct theory is based on Astellas’s purported failure to disclose during prosecution of the '451 and '189 Patents that the examples therein were carried out with a dihydrochloride salt, not mirabegron.<sup>8</sup> (D.I. 210 ¶ 121). According to Ascent’s brief, these counterclaims allege that Astellas and its prosecuting attorneys argued that the examples employed mirabegron and “that this was not true.” (D.I. 263 at 5). In Astellas’s view, these

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<sup>8</sup> Astellas’s opening brief only addressed this ground in a footnote. (*See* D.I. 228 at 8 n.2). Ordinarily, arguments presented in footnotes are waived. *See John Wyeth & Bro. Ltd. v. Cigna Int’l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997). Albeit short, the opening brief footnote substantively presents the entirety of Astellas’s argument, and Ascent responded at length to the argument without ever suggesting that Astellas waived this argument. (*See* D.I. 263 at 5-6, 15-16 & 19). As such, and out of an abundance of caution, the Court will address Ascent’s inequitable conduct arguments based on the dihydrochloride salt.

allegations are self-defeating because Ascent simultaneously claims that Astellas withheld information (what was used in the patent examples) from what Ascent necessarily concedes was before the Patent Office (the patents). (D.I. 228 at 8 n.2). The Court agrees with Astellas.

Although Ascent contends that its counterclaims allege that Astellas and its prosecuting attorneys “argued that the examples were performed with mirabegron,” a careful reading of the counterclaims shows otherwise. Ascent alleges that the examples were not carried out with mirabegron. (D.I. 210 ¶ 121). And Ascent alleges that Astellas’s prosecuting attorney failed to disclose that fact when arguing for patentability. (*Id.* ¶¶ 121-22). But Ascent does not allege that Astellas affirmatively stated that the examples were carried out with mirabegron. Indeed, Ascent frames the alleged misconduct as an “omission” or “misrepresentation.” (*Id.* ¶ 123).

The Court struggles to understand how this qualifies as inequitable conduct. This is not a case of a prior art reference being withheld or mischaracterized. The allegedly “omitted” or “misrepresented” material is the examples set forth in the very applications under review by the examiner. (D.I. 210 ¶ 121). The examiner is presumed to do his or her job. And that presumption should include being able to consider and understand the scope of the pending application. *Cf. Molins*, 48 F.3d at 1184 (“Absent proof to the contrary, [courts] assume that the examiner did consider the references.”). That seems especially true where, as here, Ascent does not allege false statements by Astellas. Because Ascent’s entire theory is based on an alleged omission, but-for materiality is required. Yet Ascent has failed to plead any facts to support the inference (plausible or otherwise) that failing to explain (rather than falsely explaining) an example in the patent application under review resulted in any claim being allowed when it should not have been.<sup>9</sup>

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<sup>9</sup> The parties dispute – vigorously – whether the compound disclosed in the patent examples is mirabegron or the dihydrochloride salt. (*Compare* D.I. 263 at 6, *with* D.I. 271 at 9 n.4)

Moreover, Ascent fails to identify which specific claims (or claim limitations) are impacted by this conduct, thereby failing to adequately allege the “what” and “how” of *Exergen*. See 575 F.3d at 1327. Astellas’s characterizations of the examples of the ‘189 and ‘451 Patents is not but-for material, and the Court recommends dismissal without reaching the issuing of specific intent.

#### **D. Affirmative Defenses**

Astellas requests that the Court strike Ascent’s sixth, eighth and tenth affirmative defenses as directed to the same inequitable conduct alleged in the counterclaims. (D.I. 228 at 13). Ascent responds that the defenses “are not duplicative of the inequitable conduct counterclaim[s]” but are instead “different from and broader than inequitable conduct.” (D.I. 263 at 20).

Turning first to the sixth and tenth affirmative defenses, Ascent alleges the following in its Amended Answer:

#### **SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs’ claims as to the ‘409, ‘451, and ‘189 patents are barred by the doctrines of estoppel and unclean hands. . . .

#### **TENTH AFFIRMATIVE DEFENSE**

Plaintiffs come before the Court as to the ‘409, ‘451, and ‘189 patents with unclean hands as a result of their improper and unjust conduct, which includes but is not limited to Plaintiffs having engaged in equitable [sic] conduct to procure these patents in suit and improperly extending their patent monopoly to exclude competition.

(D.I. 210 at 3-4).

Ascent argues that these defenses are broader and not duplicative of the inequitable conduct counterclaims. (D.I. 263 at 20). Yet Ascent offers no explanation for how the defenses differ,

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(Astellas asserting “that the structure of Example 41 is mirabegron.”)). The Court need not resolve this because Ascent fails to adequately allege but-for materiality either way.



providing the Court with no reason to conclude that they are, in fact, different. The Court therefore recommends striking Ascent's sixth and tenth affirmative defenses from its Amended Answer.

As to Ascent's eighth affirmative defense, the Court reaches a different result. Ascent's eighth affirmative defense recites:

Because Plaintiffs are estopped as to the '409, '451, and '189 patents from challenging their prior representations, which are inconsistent with the arguments Plaintiffs made in the Patent Office to distinguish the prior art and obtain these patents in suit, each of these patents in suit is invalid and/or unenforceable.

(D.I. 210 at 3). Astellas seeks to strike this defense as premised on the (now rejected) inequitable conduct allegations or, alternatively, because it is a barebones conclusory allegation. (D.I. 228 at 13; D.I. 271 at 10). The Court disagrees as to both. First, this defense does not require fraudulent conduct (or any misconduct) on the part of Astellas. Ascent merely alleges that, because Astellas is precluded from challenging its prior statements, the patents are invalid. And as to Astellas's complaint about this affirmative defense being "conclusory," the Court notes that motions to strike are generally disfavored. *See IOENGINE*, 2019 WL 2121395, at \*2. The Court recommends that Astellas's motion to strike Ascent's eighth affirmative defense be denied.<sup>10</sup>

#### **E. Leave to Amend**

Ascent requests leave to further amend "to cure any deficiencies found by the Court." (D.I. 263 at 20). As to the Orange Book listing allegations, the Court recommends dismissal of Ascent's counterclaims because they were either legally deficient or the complained-of actions would not qualify as inequitable conduct – not because the allegations were inartfully pled. Amendment would be futile and, as such, the Court recommends leave to amend be denied as to the Orange Book defenses. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434

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<sup>10</sup> The Court expresses no opinion as to the merits of this defense.

(3d Cir. 1997) (“Among the grounds that could justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice and futility.”).

As to the counterclaims of inequitable conduct premised on withheld litigation documents and the dihydrochloride salt (and related affirmative defenses), the Court recommends leave to amend be denied on the basis of prejudice. Ascent’s thirty-month stay expires on September 22, 2025. (D.I. 3 at 1). Trial is scheduled to begin on October 27, 2025. (D.I. 151 ¶ 18). And Ascent has already attempted twice to amend its pleading and was unable to adequately plead claims of inequitable conduct with the requisite particularity. (*See* D.I. 204 & 253). To allow Ascent yet another attempt to allege greater factual detail now – after the close of both fact and expert discovery, less than two months from trial and when the previous allegations were so lacking as to provide any kind of notice – would cause great prejudice to Astellas.<sup>11</sup> The Court therefore recommends that leave to amend also be denied as to the counterclaims and defenses based on the litigation documents and the examples in the ’451 and ’189 Patents.

#### **IV. CONCLUSION**

For the foregoing reasons, the Court recommends that Astellas’s motion to dismiss Ascent’s counterclaims of inequitable conduct and to strike the related affirmative defenses (D.I. 227) be GRANTED-IN-PART and DENIED-IN-PART.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Federal Rule of Civil Procedure 72(b)(1) and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be limited to ten (10) pages and filed within fourteen (14) days after being served with a copy of this Report and Recommendation. *See* FED. R. CIV. P. 72(b)(2).

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<sup>11</sup> Although the Third Circuit has suggested that leave to amend should be granted when dismissal is predicated on failure to comply with Rule 9(b)’s particularity requirement, *Burlington Coat Factory*, 114 F.3d at 1435, because of the prejudice facing Astellas if amendment is allowed, denial of Ascent’s request for leave to amend is appropriate.

Any responses to the objections shall limited to ten (10) pages and filed within fourteen days (14) after the objections. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the District Court. See *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which is available on the court's website, <https://www.ded.uscourts.gov>.

Dated: September 22, 2025

  
UNITED STATES MAGISTRATE JUDGE