

Pleading Standards for Inequitable Conduct Claims: Motions for Leave to Amend and Motions to Dismiss after *Therasense, Inc. v. Becton, Dickinson & Co.*

Several decisions from judges in the District of Delaware have addressed the pleading standard for inequitable conduct in the years following *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 127 (Fed. Cir. 2011). For example, in a report and recommendation authored by Magistrate Judge Burke and adopted by Judge Stark, the Court held that an assertion of inequitable conduct must be plead with “facts allowing for the reasonable inference of ‘but-for’ materiality.” *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 U.S. Dist. LEXIS 26912, *18-19 n.6 (D. Del. Feb. 3, 2012). Materiality must then be plead with particularity, including “the specific who, what, when, where, and how of the material misrepresentation or omission,” as required by *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). As Magistrate Judge Burke explained, the “single most reasonable inference” language from *Therasense* set forth the “evidentiary standard that must be satisfied at the proof stage, not a pleading standard.” *Wyeth*, 2012 U.S. Dist. LEXIS 26912, *22. At the pleading stage, the requirements of *Exergen* apply, and parties bringing inequitable conduct claims need only set forth sufficient facts to satisfy two prongs: (1) “but-for” materiality and (2) specific intent to deceive. This Trend Watch provides summaries of post-*Therasense* decisions from the District of Delaware that applied the pleading standard in the context of motions for leave to amend and motions to dismiss. Addressing first the cases in which inequitable conduct claims were allowed to proceed, we further address those cases in which inequitable conduct claims were not allowed.

1. Cases in which inequitable conduct claims were allowed:

***Galderma Labs. Inc., et al. v. Amneal Pharma., LLC, et al.*, C.A. No. 11-1106-LPS, Memo. Order (D. Del. Sept. 30, 2013) (Stark, J.).**

In a recent decision, Judge Stark granted a patent infringement defendant’s motion to amend its answer to add claims of inequitable conduct, unclean hands, and breach of contract. Defendant Amneal filed the motion to amend on the last day of fact discovery, well after the deadline to amend pleadings. Accordingly, Amneal had to show good cause to modify the case schedule under Federal Rule of Civil Procedure 16(b)(4). *Galderma Labs. Inc., et al. v. Amneal Pharma., LLC, et al.*, C.A. No. 11-1106-LPS, Memo. Order at 1-2 (D. Del. Sept. 30, 2013). Judge Stark found that Amneal had shown good cause because Amneal did not learn of the facts underlying its new claims until approximately one month before filing its motion. Indeed, it was only shortly before the filing of the motion when Amneal learned of the facts giving rise to its inequitable conduct claim. At the deposition of plaintiff’s prosecution counsel, Amneal learned that plaintiff had only disclosed a portion of the data its prosecution counsel knew about to the PTO and that plaintiff’s litigation counsel had improperly participated in the prosecution of the patent. Accordingly, the proposed amendment was timely. *Id.* at 2. Judge Stark further explained that the amendment would not be futile because the amended pleading raised questions for the Court to consider, and the amendment would not cause undue prejudice because it was filed nearly a year before trial was to begin, leaving sufficient time for whatever limited, additional discovery was required. *Id.* at 2-3.

***Intervet Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, C.A. No. 11-595-LPS, 2012 U.S. Dist. LEXIS 145685 (D. Del. Oct. 9, 2012) (Stark, J.).**

Judge Stark granted a defendant's motion to amend its answer and counterclaims to assert counterclaims of inequitable conduct. *Intervet Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, C.A. No. 11-595-LPS, 2012 U.S. Dist. LEXIS 145685 (D. Del. Oct. 9, 2012). The defendant represented that it could not have known of the facts supporting a claim of inequitable conduct by the deadline for amending the pleadings, and therefore the good cause required by Federal Rule of Civil Procedure 16 to amend the case schedule existed. Specifically, the defendant did not learn until late in the fact discovery phase of the case, after production of one of the inventor's notebooks and the depositions of two of the other inventors, that the inventors knew certain, prior art was material, but did not disclose it to the PTO. Given these circumstances, Judge Stark found that the defendant had "acted diligently in gathering evidence to support its inequitable conduct claim and informed [the plaintiff] of its intention to amend its answer approximately one week after [the relevant] deposition. . . . The Court [did] not find undue delay, bad faith, or dilatory motive in [the defendant's] actions . . . [and the] amended claim [was] not futile." Furthermore, the Court was "not persuaded that [the plaintiff] will be unduly prejudiced if the Court grants [the] motion . . . [as] discovery appears to be ongoing." *Id.* at *3-5. Accordingly, Judge Stark granted the motion to amend the answer and counterclaims.

***Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2012 U.S. Dist. LEXIS 86215 (D. Del. June 21, 2012) (Robinson, J.).**

Judge Robinson granted a counterclaim-defendant's motion to amend the pleadings to add allegations of inequitable conduct. *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2012 U.S. Dist. LEXIS 86215 (D. Del. June 21, 2012). In doing so, the Court rejected the counterclaim-defendant's argument that the amendments were intended "to delay the adjudication of [its] counterclaims" and found that the inequitable conduct pleadings were both sufficiently particular and not futile. Because the "proposed amendment satisfies the . . . pleading standard by identifying the 'who,' the 'what,' the 'when,' the 'where,' and the 'how,'" Judge Robinson allowed the amendment. *Id.* at *6-10.

***Wyeth Holdings Corp., et al. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 U.S. Dist. LEXIS 26912 (D. Del. Feb. 3, 2012) (Burke, M.J.; adopted by Stark, J.).**

Magistrate Judge Burke issued a report and recommendation concluding that plaintiffs' motion to dismiss defendant's inequitable conduct counterclaim and to strike defendant's affirmative defense based on inequitable conduct should be denied. *Id.* at *2, *50-51. Plaintiffs argued that in the wake of *Therasense* defendant's inequitable conduct claim should be dismissed because defendant "did not plead any facts that would allow the Court to conclude that the single most reasonable inference from the applicants' alleged conduct is that the applicants had the specific intent to deceive the PTO." *Id.* at *18 (emphasis in original). Defendant countered that the "single most reasonable inference" language from *Therasense* did not apply because it is not the appropriate pleading standard. *Id.* Instead, defendant argued that the Court should apply the standard articulated by the Federal Circuit in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, *19 (Fed. Cir. 2009) ("whether deceptive intent could be 'reasonably inferred' from the facts as pled."). The Court agreed, holding that "in order to adequately plead the intent prong of

an inequitable conduct defense, the claimant need only allege facts from which the Court could reasonably infer that the patent applicant made a deliberate decision to deceive the PTO.” *Id.* at *22.

Reconciling the Federal Circuit’s language in *Therasense* and *Exergen*, the Court held that the single most reasonable inference requirement of *Therasense* was an “evidentiary standard that must be satisfied at the proof stage, not a pleading standard.” *Id.* The Court found that defendant had pled inequitable conduct with sufficient clarity to survive dismissal, satisfying both the “but-for” materiality and the specific intent to deceive prongs of the standard. Regarding the “but-for” materiality prong, the Court found that defendant had “properly and specifically identified the ‘who, what, where, when and how’ of the alleged material misrepresentations,” *id.* at *28-29, and there was a reasonable inference that one of the patents-in-suit would not have issued “but for the alleged misrepresentations” as pled by defendant. *Id.* at *31. Likewise, regarding the specific intent to deceive prong, the Court found that defendant had “pled sufficient facts, with sufficient particularity, to give a reasonable inference that [plaintiff’s] representatives deliberately acted to deceive the PTO during the prosecution of [one of the patents-in-suit].” *Id.* at *43.

Judge Stark later issued an order adopting Magistrate Judge Burke’s Report and Recommendation. *Wyeth Holdings Corp., et al. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 U.S. Dist. LEXIS 27332 (D. Del. Mar. 1, 2012).

2. Cases in which inequitable conduct claims were not allowed:

***INVISTA North America S.à.r.l. et al. v. M&G USA Corporation et al.*, C.A. No. 11-1007-SLR-CJB, 2013 U.S. Dist. LEXIS 77685 (D. Del. May 3, 2013) (Burke, M.J.).**

In a report and recommendation, Magistrate Judge Burke recommended that defendants’ motion for leave to amend their pleading to add inequitable conduct claims and defenses be denied. *INVISTA North America S.à.r.l. et al. v. M&G USA Corporation et al.*, C.A. No. 11-1007-SLR-CJB, 2012 U.S. Dist. LEXIS 77685 (D. Del. May 3, 2013). On the date that marked the deadline to amend the pleadings pursuant to the Scheduling Order, defendants moved for leave to amend their answer with inequitable conduct claims and defenses with respect to each of plaintiffs’ asserted patents. *Id.* at *8-9. The Court’s analysis was governed by Federal Rule of Civil Procedure 15(a). *See id.* at *10. Because plaintiffs opposed defendants’ motion “on the sole basis that [their] proposed amendments would be futile,” Magistrate Judge Burke’s consideration of the motion was limited to assessing the alleged futility of the proposed amendments. *Id.* As Magistrate Judge Burke explained, “the standard for assessing futility of amendment is the same standard of legal sufficiency that applies under Fed. R. Civ. P. 12(b)(6).” *Id.* at *11.

With respect to two of the patents-in-suit, the Court found that defendants failed “to sufficiently plead both the ‘who’ of inequitable conduct as well as the scienter requirement.” *Id.* at *42. More specifically, “[n]one of [defendants’] allegations tie specific conduct to any specific individual; instead, as to ‘who’ engaged in misconduct before the PTO, every allegation is pled generally, with reference to ‘Invista,’ ‘Applicant,’ ‘they,’ and ‘their.’” *Id.* at *28. As to knowledge, the “problem with [defendants’] allegations circle[d] back to the Court’s finding

with regard to [defendants'] insufficient pleading as to the 'who' of inequitable conduct." *Id.* at *35. Specifically, Magistrate Judge Burke explained that "[w]ith no real facts pled that are specific to any individual, there is a clearly insufficient basis to reasonably infer that any particular person . . . did in fact know of the materiality of this data, and intentionally failed to disclose the data or disclosed incomplete data." *Id.* at *36-37. Moreover, with respect to an intent to deceive, the defendants failed to satisfy their burden "under *Exergen* by asserting that 'Applicant' or 'INVISTA' as a whole had a 'desire to acquire patent rights in the gas barrier market,' and then suggest[ing] that this general statement should lead to the inference that" a particular individual "knowingly withheld or misrepresented material data because of a specific intent to deceive the PTO." *Id.* at *41-42.

Finally, the Court found that defendants failed to sufficiently plead "but-for" materiality with respect to the third patent. As Magistrate Judge Burke explained, "[m]ere claims that the PTO would not have granted the patent had it known of the omission or misrepresentation are insufficient because they are conclusory legal conclusions under *Iqbal*." *Id.* at *49.

***Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2013 U.S. Dist. LEXIS 19069 (D. Del. Feb. 13, 2013) (Robinson, J.).**

Approximately eight months after the *Butamax* decision granting the plaintiff leave to amend, Judge Robinson denied the defendant's motion "seeking to amend its answer and counterclaims to include an affirmative defense and counterclaim of inequitable conduct." *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2013 U.S. Dist. LEXIS 19069, at *2 (D. Del. Feb. 13, 2013). Even though the Court found defendant met its good cause burden and that there would be no prejudice to plaintiff resulting from a late amendment, the Court denied the motion. *Id.* at *5, *9-10.

Ultimately concluding that defendant failed to plead inequitable conduct with sufficient particularity, the Court determined that defendant's proposed amendment was futile. *Id.* at *10-14. As Judge Robinson explained, when pleading inequitable conduct, the heightened pleading standard of Fed. R. Civ. P. 9(b) applies, which requires a party to identify "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at *6-7 (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009)). This standard requires that the "knowledge" and the "intent to deceive" elements of inequitable conduct be attributed to a specific individual. *See id.* at *12. Judge Robinson found that the "relationship between the general knowledge allegedly depicted on internal presentation slides" upon which defendant intended to rely "and the named individuals is too tenuous to show ownership of the knowledge or attribute a specific intent to deceive." *Id.* at *14. That the named individuals did not withhold this general knowledge was corroborated by "the availability of such general knowledge in other publications, at least one of which was cited in the patent specifications." *Id.* Accordingly, Judge Robinson denied defendant's motion for leave to amend its pleading.

***Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297 (D. Del. Feb. 6, 2013) (Robinson, J.).**

Judge Robinson dismissed a defendant's inequitable conduct counterclaims and related affirmative defenses, with leave to amend, for failing to adequately plead those claims with the particularity required by *Exergen* and *Therasense*. *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 308 (D. Del. 2013). Under *Exergen*, the defendant was required to plead "the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO." *Id.* at 306. Judge Robinson found that the defendant adequately pled the "how" ("misleading the PTO regarding evidence of obviousness, secondary considerations, and the scope of the patent's written description") and the "where" ("materials omitted in submissions to the PTO and teachings of the written description"). *Id.* at 306-07. "[G]iven the volume of materials" submitted during reexamination, the Court concluded that the withheld documents were withheld with knowledge and intent to deceive the PTO, but the defendant did not adequately plead "who" deceived the PTO. *Id.* at 307. Judge Robinson determined that the defendant's allegations of "who" were akin to the language found to be deficient in *Exergen*, *i.e.*, "Exergen, its agents and/or attorneys." *Id.* Essentially, allegations as to "general entities" and "the inventors" generally did not permit the Court "to reasonably infer that any specific individual both knew of the invalidating information and had a specific intent to deceive the PTO." *Id.*

***Inventio AG v. Thyssenkrupp Elevator Ams. Corp.*, C.A. No. 08-874-RGA, Order (D. Del. Jan. 29, 2013) (Andrews, J.).**

Judge Andrews considered a motion for leave to add an inequitable conduct defense that the defendant formulated after obtaining discovery from the plaintiff. *Inventio AG v. Thyssenkrupp Elevator Ams. Corp.*, C.A. No. 08-874-RGA, Order at 1-2 (D. Del. Jan. 29, 2013). With respect to inequitable conduct, Judge Andrews focused on the specificity with which a claim was alleged in the proposed amended and supplemental complaint. In denying the motion, the Court found that inequitable conduct claims related to prior art "are the sort that are easily made, recycling the obviousness defenses as inequitable conduct defenses." *Id.* at 2. Accordingly, the Court held that the defendant had not met its burden simply by making accusations that the inventor "cited prior art to the PTO but did not separately cite the prior art contained within the cited prior art." *Id.*

***Collectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526 (D. Del. Aug. 6, 2012) (Robinson, J.).**

Defendant moved to amend in order to add an inequitable conduct theory. Finding the proposed amendment futile, the Court noted that the alleged inequitable conduct consisted of alleged mischaracterizations of a prior art reference during an in-person interview with the examiner. *Collectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526, 534-35 (D. Del. 2012). Defendant was unable to offer direct evidence of deceptive intent and instead argued that intent should be inferred from the statements made during prosecution and the fact that a certificate of correction was filed. *Id.* In refusing to find intent, Judge Robinson explained that the Court could not "rely solely on a finding of materiality to infer intent; both are separate requirements." Accordingly, Judge Robinson refused to allow the inequitable conduct "'atomic bomb' by mere conjecture As devastating as inequitable conduct can be, pleading the charge should require more." *Id.*

***XpertUniverse, Inc. v. Cisco Systems, Inc.*, 868 F. Supp. 2d 376 (D. Del. June 19, 2012) (Andrews, J.).**

Judge Andrews considered the sufficiency of a defendant’s pleadings and dismissed inequitable conduct counterclaims for failure to sufficiently plead the “who” and “when” of the alleged misconduct. *XpertUniverse, Inc. v. Cisco Systems, Inc.*, 868 F. Supp. 2d 376 (D. Del. 2012). As the Court explained “[i]n order to adequately plead inequitable conduct, the claimant must ‘recite[] facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO.’” *Id.* at 379 (quoting *Delano Farms Co. v. Ca. Table Grape Comm’n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011)). The defendant’s allegations included repeated references to one individual—Zelkin—who the defendant labeled “an officer or employee of [the plaintiff] during prosecution”. *Id.* at 380-81. Each reference to this officer or employee was further qualified by the inclusion of the language “or one or more of the other individuals listed as an inventor.” *Id.* The Court explained that the allegations that Zelkin was an “‘officer or employee’ and that he ‘knew or should have known’ of the prior sales and prior art fall short of concretely alleging that he actually knew of the invalidating information.” *Id.* at 381. The Court went on to note that “[t]hese scant allegations are further diluted by the qualifiers that either Zelkin, or ‘one or more’ of the other inventors, knew about the prior sales and art and their materiality – affording the possibility that Zelkin, the only specific individual named, did not know about them at all.” *Id.* Judge Andrews gave the defendant seven days to amend its pleadings to the extent possible to sufficiently allege inequitable conduct. *Id.* at 386.

***SRI International Inc. v. Internet Security Systems Inc.*, 817 F. Supp. 2d 418 (D. Del. Oct. 4, 2011) (Robinson, J.)**

After the liability phase of the *SRI v. Internet Security Systems* case concluded, a damages trial was scheduled to commence in keeping with Judge Robinson’s standard practice of bifurcating liability and damages in patent infringement cases. During the damages phase of the case, the defendant filed a motion to amend its answer to assert inequitable conduct. *SRI International Inc. v. Internet Security Systems Inc.*, 817 F. Supp. 2d 418, 420 (D. Del. 2011). Judge Robinson noted that the motion presented the question of “whether leave to amend between the liability and damages phases of a bifurcated patent trial is subject to the liberal standard set forth in Federal Rule of Civil Procedure 15(a) or . . . the more conservative standard set forth in Federal Rule of Civil Procedure 15(b).” *Id.* at 421 n.5.

The answer to that question, however, was left for another day because Judge Robinson determined that the motion should be denied under either standard. The Court found the timing of the proposed amendment suspect, indicating that the “chronology of events [makes it appear] that inequitable conduct was an ace in the hole to be used if . . . other attempts to avoid liability in this case failed. Based upon the foregoing, the court would deny the motion at issue on the bases of unexplained delay as well as dilatory motives.” *Id.* at 423. Judge Robinson further found that amendment would be futile, because the defendant could not meet the specific intent to deceive requirement. Given that the prior art at issue was the focus of now-concluded reexamination, Judge Robinson refused to “compare the advocacy of counsel during [the

reexamination] proceedings to that at bar” in order to determine whether “inconsistent statements by counsel” constituted inequitable conduct. *Id.* at 423-24.

***Softview LLC v. Apple Inc., et al.*, C.A. No. 10-389-LPS, 2011 U.S. Dist. LEXIS 112476 (D. Del. Sept. 30, 2011) (Stark, J.).**

Judge Stark granted plaintiff’s motion to dismiss and strike defendants’ inequitable conduct defenses finding that the pleadings “fail[ed] to adequately allege scienter.” *Softview LLC v. Apple Inc., et al.*, C.A. No. 10-389-LPS, 2011 U.S. Dist. LEXIS 112476, at *3 (D. Del. Sept. 30, 2011). In reaching this conclusion, the Court noted that a theory based on a “mere disagreement with . . . prosecution counsel as to whether certain amendments impermissibly added ‘new matter’” along with other related concerns does not “give rise to a reasonable inference that prosecution counsel *knew* he was amending to add new matter and *intended to deceive* the PTO of this fact.” *Id.* at *3-4.

***Asahi Glass Co., Ltd., et al. v. Guardian Indus. Corp.*, 276 F.R.D. 417 (D. Del. Aug. 8, 2011) (Robinson, J.).**

The defendant moved to amend its affirmative defenses and counterclaims to add two new theories of inequitable conduct (both concerning allegations that the applicants concealed or misrepresented the true inventorship of pending claims to the PTO) over six months after the deadline for amendment of the pleadings and after the close of fact discovery. *Ashahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 276 F.R.D. 417, 418 (D. Del. 2011). Defendant’s delay was “largely unexplained” and the Court found that although the delay “is not egregious, allowing defendant’s motion at this late stage would place an unwarranted burden on the court and prejudice plaintiffs in several respects, most notably, opening discovery for the purpose of allowing plaintiffs an opportunity to respond to the new claims cannot be accomplished while maintaining the current trial date.” *Id.* at 420. Judge Robinson, therefore, denied the motion.