

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: CERTAIN CONSOLIDATED : Civil Action No. 15-3375 (FLW)  
ROFLUMILAST CASES :  
: MEMORANDUM OPINION  
: AND ORDER

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Currently before this Court are two related applications: 1) the request of certain defendants for leave to serve second amended invalidity contentions, and 2) the request of certain defendants for leave to file amended pleadings to allege unenforceability of three of the asserted patents for inequitable conduct. Plaintiffs have filed a separate motion to dismiss certain of Defendant Mylan’s counterclaims [dkt. no. 167] which is pending before U.S. District Judge Freda L. Wolfson.

I. Certain defendants’ application for leave to serve second amended invalidity contentions.

Defendants Apotex, Torrent, Hetero, Strides, Breckenridge, Princeton and MSN (collectively, “the Movants”) seek permission to serve second amended invalidity contentions with respect to U.S. Patent Nos. 8, 536, 206 (“the ‘206 patent”), 8, 504, 064 (“the ‘064 patent”) and 8, 618, 142 (“the ‘142 patent”) (collectively, “the Patents”) in order to assert invalidity under 35 U.S.C. §102(f) for derivation and improper inventorship. *See* the Movants’ letter to the Court dated January 11, 2017 (“Ltr. d. 1/11/17”) [dkt no. 152]. In short, the Movants contend that the named inventors of the Patents derived their invention from the work of Dr. Herman Amschler, the named inventor of another asserted patent (U.S. Patent No. 5,712,298), and that none of the named inventors contributed to the conception of the subject matter of the Patents. The Movants argue that their application is timely, supported by good cause, and will not prejudice Plaintiffs. *Id.*

Plaintiffs have opposed the Movants' application arguing that the Movants were not diligent in moving to amend their contentions and that Plaintiffs will be prejudiced if the application is granted. *See* Plaintiffs' letter to the Court dated January 27, 2017 ("Ltr. d. 1/27/17"). The Movants replied to Plaintiffs' opposition in a letter to the Court dated January 31, 2017 ("Ltr. d. 1/31/17") [dkt. no. 160].

A. Legal Standard

The instant application is governed by Local Patent Rule 3.7 pursuant to which leave to amend a party's contentions may be granted "by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. A party seeking to amend its contentions bears the burden of demonstrating diligence in discovering the basis for the proposed amendment as well as moving promptly to amend when new evidence is discovered. *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, C.A. No. 12-3289 (PGS), 2014 WL 997532, at \*3 (D.N.J. Jan. 6, 2014). The moving party must also establish that the amendments will not unduly prejudice the non-moving party. *Astrazeneca AB v. Dr. Reddy's Labs, Inc.*, C.A. No. 11-2317 (JAP), 2013 WL 1145359, at \*5 (D.N.J. Mar. 18, 2013).

B. Analysis

1. The Movant's application is supported by good cause and is not untimely.

The Movants contend that through the depositions of Drs. Zingel and Mueller and Mr. Palosch in late 2016 they learned "critical facts" that support the derivation and improper inventorship defenses contained in their proposed amended contentions. Further, the Movants argue that these facts were "non-public" and unavailable prior to those depositions. Ltr. d. 1/11/17 at pp. 5-7. As to derivation, the Movants state, they "needed to confirm that none of the named inventors actually contributed to the conception of [the Patents'] claims." *Id.* at p. 6. As to improper

inventorship, the Movants state, the depositions revealed additional information concerning the respective roles of Dr. Amschler and the named inventors in the conception and reduction to practice of the subject matter of the Patents. *Id.*

To the contrary, Plaintiffs maintain that “as of Plaintiffs’ production on April 20, 2016, [the Movants] had all the information they rely on in their proposed amendment.” *See* Ltr. d. 1/27/17 at p. 4. Further, Plaintiffs argue, “nothing that came out of this fall’s inventor depositions added new information to what was in the documents.” *Id.* Consequently, Plaintiffs argue, the Movants’ “diligence should be measured from receipt of the documents in April 2016” and not the date of the inventors’ depositions. *Id.* On this basis alone, Plaintiffs argue, the Movants’ application should be denied. *Id.* at p. 5.

In response, the Movants argue that it was “impossible for [the Movants] to assert in good faith their derivation and improper inventor defenses before the conclusion of the Mueller and Palosch depositions” because they lacked evidence establishing critical elements of those defenses. *See* Ltr. d. 1/31/17 at pp. 3-8.

The Court finds that once the depositions were complete and the transcripts were obtained, the Movants promptly presented their new defenses and proposed amended invalidity contentions to Plaintiffs on December 15, 2016. Plaintiffs responded on January 6, 2017 and the Movants’ application followed on January 11, 2017. This Court has previously determined that, as in this case, additional discovery, including depositions, may be necessary to reveal, develop or confirm that sufficient evidence exists to support a party’s proposed amendments. *See Helsinn Healthcare S.A. v. Dr. Reddy’s Labs, Ltd.*, CA No. 11-3962 (MLC), 2013 WL 3336859, at \*4 (D.N.J. July 2, 2013); *Warner Chilcott Company, L.L.C. v. Lupin, Ltd.*, CA No. 11-7228 (JAP), 2013 WL 4494949

(D.N.J. Aug. 19, 2013). Here, the Movants may have previously obtained some documentary evidence which would tend to support their amended contentions. However, the inventors' depositions were necessary in order for the Movants to establish critical elements of the "new" defenses. Under the circumstances, the Court concludes that the Movants acted with reasonable diligence and that their application was timely presented to the Court.

2. Granting the application will not prejudice Plaintiffs.

The Movants contend that the proposed amendments will cause no prejudice to Plaintiffs because all facts relevant to these defenses are already in the possession of Plaintiffs, all relevant depositions have been conducted, and no additional fact discovery is required from Plaintiffs. Ltr. d. 1/11/17 at p. 7. Plaintiffs, on the other hand, claim they will be prejudiced in two respects: 1) Plaintiffs will have to seek the testimony of Dr. Mueller and Mr. Patosch at trial to respond to their deposition testimony thereby adding to the expense of presenting their case, and 2) granting the Movants' application will require Plaintiffs to "consider the merits of seeking expert testimony to rebut [the new defenses]." Ltr. d. 1/27/ 17 at p. 6. The Court is not persuaded by Plaintiffs' arguments as to prejudice. The claimed additional expense to Plaintiffs is meager (and perhaps unnecessary) in the context of this litigation as is any additional expert discovery that Plaintiffs may seek. Likewise, the Court is unmoved by Plaintiffs' contention that the Movants will suffer no prejudice by a denial of their application because they will not be able to demonstrate the requisite elements of their defenses by clear and convincing evidence at the time of trial. *Id.* at pp. 6-7. In response to Plaintiffs' argument as to the futility of their defenses, the Movants argue that they will be able to present the necessary proofs at trial and that to deny them that opportunity would be prejudicial. The Court agrees that the Movants would be prejudiced if they were not able to present

their §102(f) defenses.

II. Certain defendants' application for leave to file amended pleadings.

Defendants Apotex, Torrent, Hetero and Strides (collectively, "the Movants II") seek permission to file amended answers, defenses and counterclaims to assert unenforceability of the '206, '064 and '142 patents due to inequitable conduct. *See* Movants II's letter to the Court dated January 18, 2017 ("Ltr. d. 1/18/17"). In short, the Movants II's inequitable conduct claims and defenses are based on their contention that the Patents "were secured through extensive fraud at the U.S. Patent and Trademark Office" including material misrepresentations, submission of false declarations, and material omissions by the named inventors. *Id.* at p. 2.

Plaintiffs opposed the Movants II's application in a letter to the Court dated February 10, 2017 ("Ltr. d. 2/10/17"), arguing: 1) there is not "good cause" under Rule 16(b)(4) to extend the deadline for amending pleadings, and 2) the proposed amendments are futile. The Movants II replied to Plaintiffs' opposition in a letter to the Court dated February 16, 2017 ("Ltr. d. 2/16/17").

A. Legal Standard

Federal Rule 15(a) governs motions to amend pleadings. Once a responsive pleading has been filed, "a party may amend its pleadings only with the opposing party's consent or the court's leave." Fed. R. Civ. P. 15(a)(2). Granting leave to amend is within the Court's discretion and is generally favored unless there is: 1) undue delay or prejudice, 2) bad faith, 3) dilatory motive, 4) failure to cure deficiencies through previous amendment, or 5) futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962).

When considering whether a proposed amendment is futile, the Court applies

essentially the same standard as a Rule 12(b)(6) motion to dismiss; that is, where the complaint, as amended, would fail to state a claim upon which relief could be granted. *See In re NAHC, Inc. Sec. Litig.*, 306 F. 3d 1314, 1332 (3d Cir. 2002). “If a proposed amendment is not clearly futile, then denial of leave to amend is improper.” *Harrison Beverage Co. v. Dribeck, Imp., Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990).

A party seeking to amend its pleadings after the expiration of a Court imposed deadline (*i.e.*: the scheduling order) must show “good cause.” Fed. R. Civ. P. 16(b)(4).

B. Analysis

1. The Movants’ application is supported by good cause and not untimely.

The Movants II maintain that during the depositions of Drs. Zingel and Mueller and Mr. Palosch they obtained the information necessary to support claims of inequitable conduct. After obtaining the deposition transcripts in December 2016, the Movants II provided a draft of their proposed amended pleadings to Plaintiffs on January 5, 2017. On January 11, 2017 Plaintiffs advised the Movants II of their intention to oppose any motion for leave to amend. This application followed one week later, on January 18, 2017.

The Movants II have identified what they allege are “numerous material misrepresentations and omissions that took place during prosecution of [the Patents].” Ltr. d. 1/18/17 at pp. 7-9. In each instance, the Movants II have identified the alleged misrepresentation or omission, the facts they allege and “an explanation as to why they were unable to plead these prior to the depositions of Dr. Zingel, Dr. Mueller, and Mr. Palosch.” *Id.*

Plaintiffs maintain that the Movants II’s “inequitable conduct allegations arise entirely out of three documents” which were produced in April 2016. Ltr. d. 2/10/16 at p. 3. Consequently,

Plaintiffs argue, the instant application could have been made months earlier.

For the same reasons set forth with respect to the Movants' application for leave to serve second amended invalidity contentions, the Court concludes that the Movants II's application is supported by good cause and is not untimely. Further, the Court finds no evidence of undue delay, bad faith or dilatory motive, failure to cure deficiencies through prior amendment on the part of the Movants II, or undue prejudice to Plaintiffs.

2. The proposed amendments to the pleadings are not futile.

Claims of inequitable conduct must be pled with particularity and require that material misrepresentations or omissions of information be committed with intent to deceive the PTO.

*Therasense v. Becton Dickinson and Co.*, 649 F. 3d 1276, 1290 (Fed. Cir. 2011) (*en banc*). “[T]he pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission” and “allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F. 3d 1312, 1326-27 (Fed. Cir. 2009).

The Movants contend that they have complied with the particularly requirements of Fed. R. Civ. P. 9 and the Federal Circuit's *Exergen* decision, and that they properly state a claim of unenforceability of the Patents based on the allegations of inequitable conduct in their proposed amended pleadings. Ltr. d. 1/18/17 at pp. 9-13.

Plaintiffs contend that the Movants II “fail to plead sufficient facts to support a reasonable inference of either materiality or intent to deceive.” Ltr. d. 2/10/17 at p. 9. Consequently, Plaintiffs argue, the Movants II's request for leave to amend is futile.

Upon reviewing the proposed amended pleadings, the Court concludes that the

Movants II have alleged facts, which are assumed to be true for purposes of a futility analysis, which establish that the five instances of misrepresentations or omissions identified by the Movants II are material, and that an intent to deceive may reasonably be inferred from those facts.

ORDER

For the reasons stated above; it is on this 31<sup>st</sup> day of August 2017,

ORDERED THAT:

1. Defendants' application for leave to serve second amended invalidity contentions is GRANTED; and
2. Defendants' application for leave to file amended answers, defenses and counterclaims is GRANTED.

*s/ Douglas E. Arpert* \_\_\_\_\_  
DOUGLAS E. ARPERT  
United States Magistrate Judge