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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

ABAXIS, INC.,)	Case No.: 10-CV-02840-LHK
)	
Plaintiff and Counter-Defendant,)	ORDER GRANTING MOTION TO
v.)	DISMISS INEQUITABLE CONDUCT
)	COUNTERCLAIM
CEPHEID,)	
)	
Defendant and Counter-Claimant.)	
)	
)	

Currently before this Court is Plaintiff Abaxis, Inc.’s motion to dismiss Defendant Cepheid’s eighth and ninth defenses and ninth counterclaim. Dkt. No. 74 (“Mot.”); *see also* Dkt. No. 82 (“Reply”). Cepheid opposes this motion. Dkt. No. 78 (“Opp’n”). After reviewing the parties’ submissions, considering the relevant legal authorities, and hearing oral argument, the Court hereby GRANTS Abaxis’s motion to dismiss.

I. BACKGROUND

In its first amended complaint (“FAC”), Abaxis alleges that Cepheid is infringing four of its patents and is in breach of a license agreement. Dkt. No. 24. Cepheid has denied liability. Cepheid’s initial answer alleged inequitable conduct during the prosecution of United States Patent Nos. 5,413,732 (“the ’732 patent”), 5,624,597 (“the ’597 patent”), 5,776,563 (“the ’563 patent”),

1 and 6,251,684 B1 (“the ’684 patent”) (collectively “the patents-in-suit”)¹. Dkt. No. 32. On March
2 22, 2011, this Court dismissed Cepheid’s eighth defense and ninth counterclaim with leave to
3 amend. Dkt. No. 45. Cepheid filed an amended answer and counterclaims on April 12, 2011. Dkt.
4 No. 50. Abaxis filed a motion to dismiss on April 26, 2011. Dkt. No. 51. On June 15, 2011, this
5 Court granted Cepheid leave to further amend its answer and counterclaims in light of the recent
6 Federal Circuit decision, *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-
7 1512, 2008-1513, 2008-1514 & 2008-1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011). *See* Dkt.
8 No. 67. Abaxis withdrew its motion to dismiss in anticipation of Cepheid’s forthcoming
9 amendments on June 16, 2011. Dkt. No. 68. In its subsequent amended answer and third amended
10 counterclaims (“amended answer”), filed June 17, 2011, Cepheid raises ten defenses and asserts
11 eleven counterclaims. Dkt. No. 72 (“Ans.”). Abaxis filed the instant motion to dismiss on June 29,
12 2011. Dkt. No. 74.

13 Cepheid’s eighth and ninth defenses and ninth counterclaim are at issue here. They allege
14 that Abaxis engaged in inequitable conduct during the prosecution of the ’732, ’597 and ’563
15 patents. Ans. 6-25. They also allege that the ’684 patent is infected by the inequitable conduct
16 during the prosecution of the ’732, ’597 and ’563 patents. Ans. 25-28. As a result, Cepheid seeks
17 judgment that the patents-in-suit are unenforceable. Ans. 33. Alternatively, Cepheid alleges that
18 Abaxis’s claims are barred by the doctrine of unclean hands because of Abaxis’s inequitable
19 conduct and are therefore unenforceable. Ans. 28, 33.

20 **A. Abaxis’s Alleged Failure to Disclose Material Prior Art**

21 Cepheid’s eighth defense contains allegations that Kevin L. Bastian, the attorney who
22 prosecuted the ’732, ’597 and ’563 patents for Abaxis, knowingly and intentionally failed to
23 disclose to the United States Patent & Trademark Office (“PTO”) material prior art while
24 prosecuting these three patents.² Ans. ¶¶ 17, 39.³ According to the amended answer, this material

25 ¹ These patents were pending before the PTO for the following periods, at the close of which the
26 patents issued: (1) the ’732 patent was pending from August 19, 1991, until May 9, 1995; (2) the
27 ’597 patent from May 8, 1995, until April 29, 1997; (3) the ’563 patent from June 6, 1995, until
28 July 7, 1998; and (4) the ’684 patent from April 24, 1998, until June 26, 2001. Dkt. No. 72
29 (“Ans.”) ¶¶ 18-21.

² Cepheid’s ninth defense and ninth counterclaim are both based on the allegations made in its
eighth defense, which they incorporate by reference. Both parties focused their briefing on the

1 prior art was United States Patent No. 4,470,202 (“the Buxton Patent”).⁴ *Id.* ¶ 17. As described in
2 Cepheid’s amended answer, the patents-in-suit “relate to the production of freeze-dried reagent
3 beads for pharmaceutical and diagnostic applications. The beads are formed by dispensing drops
4 of reagent solutions into a cryogenic liquid. The frozen drops are then lyophilized (*i.e.*, freeze-
5 dried), which is a process that drives off water molecules, leaving a dried, allegedly rapidly-
6 dissolving bead.” *Id.* ¶ 26. Cepheid claims that “Abaxis’ purported advance over the prior art is
7 uniformity in bead production.” *Id.*

8 Cepheid alleges that the Buxton Patent discloses “reagent spheres and a process of making
9 reagent spheres that have both short dissolution times and uniformity.” *Id.* ¶ 28. Specifically,
10 Cepheid alleges that the Buxton Patent’s disclosures include: (1) “drop-wise dispensing of reagents
11 for freezing;” (2) “use of [a] pump to dispense drops;” (3) “uniform size of spheres;” (4) “unit
12 dosages;” (5) “fast dissolution;” and (6) a “chemical lattice.” *Id.* ¶ 30. Cepheid’s amended answer
13 provides four tables setting forth what Cepheid considers to be the “close overlap between the
14 Buxton teachings and the Patents-in-Suit” that would make the patents-in-suit “unpatentable due to
15 anticipation and/or obviousness in view of the Buxton patent.” *Id.* ¶ 31, 33. In particular, Cepheid
16 considers the Buxton Patent’s disclosure of “drop-wise dispensing of reagents into liquid for
17 freezing” to be but-for material⁵ to the patents-in-suit and non-cumulative of other prior art
18 submitted to the PTO. *Id.* ¶ 32-33.

19 Cepheid claims that at least Kevin L. Bastian was aware of the but-for materiality of the
20 Buxton Patent and failed to disclose the patent to the PTO during the prosecution of the patents-in-
21 suit with the intent to deceive the PTO. *Id.* ¶ 39. Kevin L. Bastian, the same attorney who
22 prosecuted the ’732, ’597, and ’563 patents, also prosecuted United States Patent No. 5,275,016

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24 sufficiency of the eighth defense. This Court will likewise focus on the eighth defense, as its
viability determines the viability of the ninth defense and ninth counterclaim.

25 ³ Paragraph numbers refer to the paragraph numbers beginning on page 4 of Cepheid’s amended
answer under the heading, “Affirmative and Other Defenses.”

26 ⁴ The Buxton Patent is entitled “Process and Apparatus for Freezing a Liquid Medium” and issued
on September 11, 1984, more than a year before the earliest claimed priority date for the patents-in-
27 suit. *Id.* ¶ 27.

28 ⁵ A withheld reference is but-for material “if the PTO would not have allowed a claim had it been
aware of the undisclosed prior art.” *Therasense*, 2011 WL 2028255, at *11. At oral argument, the
parties agreed that *Therasense* established a new standard for materiality.

1 (“the ’016 patent”). *Id.* ¶ 35. The ’016 patent and the patents-in-suit share the same three
2 inventors: Steven N. Buhl, Bhaskar Bhayani, and Thuy N. Tang. *Id.* ¶ 34. Cepheid alleges that the
3 ’016 patent “performs the methods claimed in the Patents-in-Suit and produces the reagent spheres
4 claimed in the Patents-in-Suit.” *Id.* ¶ 37. According to the amended answer, on July 16, 1993, Mr.
5 Bastian received the International Search Report for the Patent Cooperation Treaty (“PCT”)
6 counterpart of the ’016 patent, which cited the Buxton Patent as a “document of particular
7 relevance” to some of the claims of the PCT application. *Id.* ¶ 43. Cepheid alleges that these
8 claims in the PCT counterpart of the ’016 patent “closely parallel claims of the Patents-in-Suit.”
9 *Id.* ¶ 44. On August 6, 1993, while prosecuting the ’016 patent, Mr. Bastian submitted a
10 supplemental disclosure statement to the PTO. *Id.* ¶ 51. Cepheid alleges that this statement was
11 accompanied by a copy of the Buxton Patent. *Id.* According to Cepheid’s amended answer, “[t]he
12 identical features of the Buxton patent which made it material to the ’016 patent . . . also made the
13 Buxton patent but-for material to the ’732, ’597, and ’563 patents.” *Id.* ¶ 53.⁶

14 Cepheid further alleges that Mr. Bastian made several statements to the PTO while
15 prosecuting the patents-in-suit. According to Cepheid, these statements were made in order to
16 distinguish the patents-in-suit from prior art cited by the PTO. *Id.* ¶ 54, 58-64. Cepheid’s amended
17 answer alleges that in making these statements, Mr. Bastian claimed that the patents-in-suit taught
18 features that were actually disclosed in the Buxton Patent. *Id.* Cepheid specifically claims that Mr.
19 Bastian knew these statements “were false in light of information contained in the Buxton patent,
20 which was not before the Examiners, and Mr. Bastian knowingly withheld this information.” *Id.* ¶
21 64. Cepheid argues that had the Buxton Patent been disclosed, “neither the ’732, ’597, nor ’563
22 patents would have issued . . . because the claimed features allegedly missing from the prior art of
23 record were disclosed in the Buxton Patent.” *Id.* ¶ 65.

24 **B. Infectious Unenforceability of the ’684 Patent**

25 Cepheid also alleges that the Buxton Patent is material to the claims of the ’684 patent and
26 non-cumulative of the prior art submitted to the PTO during the prosecution of the ’684 patent. *Id.*

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28 ⁶ Cepheid does not allege, nor could it, that the Buxton Patent was “but-for material” to the ’016
patent, for the ’016 patent issued despite the disclosure of the Buxton Patent.

1 ¶¶ 74-75. According to the amended answer, “[t]he Examiner found that the claims of the ’684
2 patent were not patentably distinct from the claims of the [other patents-in-suit] and would be
3 invalid for obviousness-type double patenting, absent a terminal disclaimer over these patents.” *Id.*

4 ¶ 78. Cepheid argues that absent the alleged inequitable conduct by Mr. Bastian, the ’563, ’732,
5 and ’597 patents would have been rejected. *Id.* ¶ 79. Thus, the ’684 patent would not have issued
6 either. *Id.* Cepheid also claims that if the Buxton Patent had been disclosed to the PTO during the
7 prosecution of the other patents-in-suit, the Buxton Patent would have been included in the
8 prosecution record of the ’684 patent, and thus, the ’684 patent would not have issued. *Id.* ¶ 85.

9 II. LEGAL STANDARD

10 “To survive a motion to dismiss, a complaint must contain sufficient factual matter,
11 accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 129 S.
12 Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim
13 has facial plausibility when the plaintiff pleads factual content that allows the court to draw the
14 reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*,
15 550 U.S. at 556). These requirements apply with equal rigor to pleadings made under Rules 8 and
16 9 of the Federal Rules of Civil Procedure. *Id.* at 1954.

17 Under Rule 9(b), “[i]n alleging fraud or mistake, a party must state with particularity the
18 circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). “Malice, intent, knowledge,
19 and other conditions of a person’s mind may be alleged generally.” *Id.* “Inequitable conduct,
20 while a broader concept than fraud, must be pled with particularity under Rule 9(b).” *Exergen*
21 *Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (quoting *Ferguson*
22 *Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed.
23 Cir. 2003)) (quotations and alterations omitted). The law of the Federal Circuit, not the law of the
24 regional circuit, applies to the question of whether inequitable conduct has been pled in accordance
25 with Rule 9(b). *See Exergen*, 575 F.3d at 1326 (citation omitted).

26 Although *Exergen* was decided in the context of a motion for leave to amend to add an
27 inequitable conduct claim, its pleading standard is also used to evaluate the sufficiency of
28 pleadings under Rule 9(b) on motions to dismiss. *See In re BP Lubricants USA, Inc.*, 637 F.3d

1 1307, at 1311 (Fed. Cir. 2011) (holding, in the context of a motion to dismiss, that “*Exergen*’s
2 pleading requirements apply to all claims under Rule 9(b)”). As outlined in *Exergen*, the
3 substantive elements of inequitable conduct are as follows: “(1) an individual associated with the
4 filing and prosecution of a patent application made an affirmative misrepresentation of a material
5 fact, failed to disclose material information, or submitted false material information; and (2) the
6 individual did so with a specific intent to deceive the PTO.” *Id.* at 1327 n.3 (citing *Star Scientific,*
7 *Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); *Molins PLC v. Textron,*
8 *Inc.*, 48 F.3d 1172, 1178, 1181 (Fed. Cir. 1995); 37 C.F.R. § 1.56 (2008)). As the parties agreed at
9 the hearing on the motion, *Therasense* further heightened the standard for the materiality element
10 of inequitable conduct, holding that “the materiality required to establish inequitable conduct is
11 but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for
12 material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.”
13 2011 WL 2028255, at *11.

14 “[I]n pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the
15 specific who, what, when, where, and how of the material misrepresentation or omission
16 committed before the PTO.” *Exergen*, 575 F.3d at 1327.⁷ Furthermore, in pleading “knowledge”
17 and “intent,” which may be averred generally under Rule 9(b), a pleading of inequitable conduct
18 “must include sufficient allegations of underlying facts from which a court may reasonably infer
19 that a specific individual (1) knew of the withheld material information or of the falsity of the
20 material misrepresentation, and (2) withheld or misrepresented this information with a specific
21 intent to deceive the PTO.” *Id.* at 1328-29.

22 “[I]n dismissing for failure to state a claim under Rule 12(b)(6), ‘a district court should
23 grant leave to amend . . . unless it determines that the pleading could not possibly be cured by the
24 allegation of other facts.’” *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (quoting *Doe v.*
25 *United States*, 58 F.3d 494, 497 (9th Cir. 1995)). Whether to grant leave to amend a pleading
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27 ⁷ Even though the *Exergen* court did not list “why” among the questions that a pleading must
28 answer with particularity, it did require, later in the opinion, that the pleading allege why the
withheld information is material and not cumulative. 575 F.3d at 1329.

1 under Rule 15(a) is a procedural matter governed by the law of the regional circuit. *See Exergen*,
2 575 F.3d at 1318.

3 III. ANALYSIS

4 A. The '732, '597, and '563 Patents

5 Abaxis argues that Cepheid's amended allegations of inequitable conduct fail to meet the
6 pleading standard outlined in *Iqbal* and *Exergen*. Abaxis claims that Cepheid has not provided
7 factual allegations from which knowledge and intent to deceive can be reasonably inferred. Mot. at
8 6-7. According to Abaxis, Cepheid's counterclaim also fails to identify with sufficient particularity
9 why the Buxton Patent is but-for material to the patents-in-suit and why it is non-cumulative of the
10 prior art presented to the examiner. Mot. 7-8. This Court agrees with Abaxis that Cepheid has not
11 pled sufficient facts to support a reasonable inference of knowledge and intent. Because failure to
12 plead knowledge and intent is sufficient grounds to dismiss an inequitable conduct claim, the Court
13 need not address whether Cepheid has met the pleading standard for materiality.

14 Specifically, Abaxis argues that Cepheid's amended answer does not properly allege that
15 Mr. Bastian knew of the allegedly but-for material information contained in the Buxton Patent.
16 Mot. 11-14. Abaxis also argues that the amended answer does not properly allege specific intent to
17 deceive the PTO. Reply 5. Cepheid argues that its counterclaim provides ample facts from which
18 it is reasonable to infer that Mr. Bastian knew of the material information contained in the Buxton
19 Patent, that Mr. Bastian knew that information would be but-for material to the patents-in-suit, and
20 that Mr. Bastian withheld the reference with the deliberate intent to deceive the PTO. Opp'n 10-
21 15.

22 1. Knowledge

23 The Court finds the circumstances in this case sufficiently analogous to those in *Exergen*
24 for *Exergen* to be controlling. In *Exergen*, as here, a material reference was disclosed during
25 prosecution of one patent but not disclosed during prosecution of the patents-in-suit. 535 F.3d at
26 1330. As in *Exergen*, this Court finds that Cepheid fails to allege sufficient facts to support a
27 reasonable inference that Mr. Bastian "knew of the specific information in the [Buxton patent] that
28 is alleged to be material to the claims of the [patents-in-suit]." *See id.* at 1330. Thus, although the

1 inequitable conduct claim here does not suffer from the additional defect of failing to identify a
2 specific person alleged to have knowledge of the material reference as in *Exergen*, see 575 F.3d at
3 1329, the claim here still fails for failure to sufficiently allege knowledge.

4 In the order granting Abaxis’s prior motion to dismiss, this Court noted that Cepheid may
5 be able to support a reasonable inference that Mr. Bastian knew that specific information in the
6 Buxton patent was material to the patents-in-suit by alleging facts to show that the Buxton Patent is
7 material to the ’016 patent for the same reasons that the ’732 patent was referenced in the ’016
8 patent. Order at 10. Cepheid’s amended answer does allege additional facts showing that the
9 Buxton Patent is material to the ’016 patent for the same reasons that the ’016 patent is related to
10 the patents-in-suit. Ans. 15-18. Just because the Buxton Patent was of “particular relevance” to
11 some of the claims in the ’016 patent, Ans. ¶ 43, and just because one of the patents-in-suit was
12 referenced in the ’016 patent, it does not necessarily follow that the Buxton Patent was but-for-
13 material to the patents-in-suit. Even more central to the analysis here, the chain of inference is too
14 tenuous to infer that Mr. Bastian *knew* that the information in the Buxton Patent was but-for
15 material to the patents-in-suit.

16 Indeed, the ’016 patent appears to reference the then-pending ’732 patent for the purpose of
17 disclosing “[s]uitable reagent solutions.” ’016 patent, Dkt. No. 75 Ex. 2, col. 4:7-9. This is distinct
18 from the disclosure of the Buxton Patent’s “drop-wise dispensing of reagents into liquid for
19 freezing,” which Cepheid considers but-for material to certain claims of the patents-in-suit. Ans.
20 ¶¶ 32-33. Cepheid alleges only that Mr. Bastian “must have known that the same information
21 made [the Buxton Patent] but-for material to the [patents-in-suit].” *Id.* ¶ 55. If there was any
22 ambiguity after *Exergen*, *Therasense* made clear that such “should have known” inferences are
23 insufficient to meet the knowledge requirement for inequitable conduct. 2011 WL 2028255, at
24 *10; see also *Exergen*, 575 F.3d at 1330 (“[O]ne cannot assume that an individual, who generally
25 knew that a reference existed, also knew of the specific material *information* contained in that
26 reference.”) (emphasis in original). Even if Cepheid’s allegation that “Mr. Bastian must have read
27 the Buxton patent,” Ans. ¶ 52, supports an inference that Mr. Bastian should have been generally
28 aware of the information contained in the Buxton patent, Cepheid’s allegations as a whole fail to

1 support the reasonable inference that he knew that specific information in the Buxton Patent was
2 but-for material to the patents-in-suit. Accordingly, Cepheid’s inequitable conduct counterclaim
3 and defenses fail to adequately plead knowledge.

4 2. Specific Intent

5 “[A] pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of
6 underlying facts from which a court may reasonably infer that a specific individual . . . withheld”
7 material information “with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1328-29
8 (footnote omitted). “[T]he mere fact that an applicant disclosed a reference during prosecution of
9 one application, but did not disclose it during prosecution of a related application, is insufficient to
10 meet the threshold level of deceptive intent required to support an allegation of inequitable
11 conduct.” *Id.* at 1331.

12 Cepheid’s amended answer also fails to allege that Mr. Bastian withheld the Buxton Patent
13 reference with the specific intent to deceive the PTO. Cepheid’s allegations of intent rely on the
14 assumption that Mr. Bastian knew of the information in the Buxton Patent and of its but-for
15 materiality to the patents-in-suit. Ans. ¶ 64. As the Court finds Cepheid’s allegations of
16 knowledge insufficient, its allegations of specific intent must also fail. Furthermore, Cepheid’s
17 argument that specific intent may be inferred from the combination of Mr. Bastian’s knowledge of
18 the Buxton Patent and his “motive to deceive the PTO” based on the alleged but-for materiality of
19 the Buxton Patent, Opp’n 14, would not meet the requirements of *Therasense* to the extent that
20 *Therasense* restricts the Court’s ability to infer intent based on the materiality of a withheld
21 reference. “[A] district court may not infer intent solely from materiality. Proving that the
22 applicant knew of a reference, should have known of its materiality, and decided not to submit it to
23 the PTO does not prove specific intent to deceive.” *Therasense*, 2011 WL 2028255, at *10. Thus,
24 Cepheid’s inequitable conduct counterclaim and defenses also fail to adequately plead specific
25 intent and are therefore dismissed.

26 B. The ’684 Patent

27 Cepheid’s amended answer seeks to invalidate the ’684 patent based on a theory of
28 infectious unenforceability from inequitable conduct during the prosecution of the ’732, ’597, and

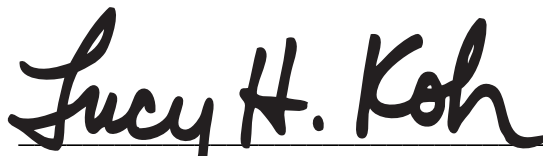
1 '563 patents. Because the Court finds that Cepheid has not met the pleading standard for
2 inequitable conduct as to the '732, '597, and '563 patents, the inequitable conduct counterclaim
3 and defenses against the '684 patent are also dismissed.

4 **IV. CONCLUSION**

5 For the foregoing reasons, the Court GRANTS Abaxis's motion to dismiss Cepheid's
6 amended inequitable conduct defense. The Court also GRANTS Abaxis's motion to dismiss
7 Cepheid's inequitable conduct counterclaim and its unclean hands defense, both of which rely on
8 the allegations of the inequitable conduct defense. As Cepheid has already had the opportunity to
9 amend its inequitable conduct counterclaims and defenses twice, the Court does not give Cepheid
10 leave to amend because the deficiency in the pleading cannot be cured by alleging additional facts.

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12 **IT IS SO ORDERED.**

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14 Dated: August 25, 2011

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16 LUCY H. KOH
17 United States District Judge
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