UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

TAKEDA PHARMACEUTICAL CO., LTD., et al.,

Plaintiffs,

v.

TWI PHARMACEUTICALS, INC.,

Defendant.

Case No.: 5:13-CV-02420-LHK

ORDER GRANTING IN PART AND DENYING IN PART MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 143, 144

Before the Court are the parties' summary judgment motions. Defendant TWi Pharmaceuticals, Inc. ("TWi") moves for summary judgment on all four counts of the complaint filed by Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"). ECF No. 143 ("TWi MSJ"). Takeda moves for summary judgment on TWi's affirmative defenses of inequitable conduct. ECF No. 144 ("Takeda MSJ"). Having considered the parties' written submissions and their oral arguments at the April 9, 2015 hearing, the relevant law, and the record in this case, the Court hereby GRANTS in part and DENIES in part the parties' summary judgment motions.

I. BACKGROUND

A. The Drug and Asserted Patents

Takeda manufactures and sells Dexilant®, a drug for treatment of gastroesophageal reflux disease ("GERD"), commonly known as acid reflux disease. See ECF No. 104 (First Am. Answer and Counterclaims) at 14-15. The active ingredient in Dexilant® is dexlansoprazole, which belongs to a class of compounds known as proton pump inhibitors ("PPI"). Dexilant® is designed to release dexlansoprazole in two stages, based on different acidity levels in the human intestine, to provide overnight relief from acid reflux. See id. Takeda owns patents relating to Dexilant® that are listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Id. at 4. Takeda asserts two Orange Book patents in this lawsuit: U.S. Patent Nos. 8,461,187 (the "'187 Patent") and 8,173,158 (the "'158 Patent") (collectively, the "Asserted Patents").

The '187 Patent is entitled "Multiple PPI Dosage Form" and is directed to pharmaceutical dosage forms containing a first and second dose of a PPI, as well as methods of administering those dosage forms. According to the '187 Patent, "PPIs rapidly degrade in acidic environments and therefore, dosage forms containing PPIs generally are designed to protect the PPI from the acidic environment of the stomach." '187 Patent at col.1 ll.21-24. The inventors claim to have discovered that combining two doses in a single dosage form taken in the morning can prevent symptoms at night: "Moreover, the first and the second dose can be administered in a single oral dosage form that can be taken once a day to alleviate nocturnal breakthrough events." Id. at col.2 ll.19-21. The '187 Patent issued on June 11, 2013, and claims priority to a provisional application filed on June 16, 2004.

The '158 Patent is entitled "Methods of Treating Gastrointestinal Disorders Independent of the Intake of Food" and is directed to methods of "treating heartburn, acid reflux or gastroesophageal reflux disease in a patient" by administering a "pharmaceutical composition" with two types of solid particles. '158 Patent cl. 1. The '158 Patent notes the preexisting problem

that giving patients PPIs (such as dexlansoprazole) together with food can reduce the drugs' effectiveness: "the administration of such PPIs in conjunction with the intake of food decreases the systemic exposure of the PPI." Id. at col.10 ll.7-9. To address this problem, the inventors discuss use of a pharmaceutical composition that "comprises at least two solid particles each of which contain at least one proton pump inhibitor," permitting administration "independent of the intake of food." Id. at col.1 ll.15-20. The '158 Patent issued on May 8, 2012, and claims priority to a provisional application filed on October 12, 2007.

B. TAP Pharmaceuticals and TAK-390MR

In the 1970s, Takeda Chemical Industries, Ltd. ("Takeda Japan") and Abbott Laboratories, Inc. ("Abbott") formed a joint venture called TAP Pharmaceuticals, Inc. ("TAP"). See ECF No. 144-36 ("Stipulation of Interests") ¶ 3; see also ECF No. 143-18 ("Watkins Dep.") at 16:23-18:21.[1] TAP developed Prevacid®, a PPI that is generally administered once a day before breakfast. Some patients who took Prevacid®, or other conventional PPIs, would nevertheless experience nighttime heartburn. See generally '187 Patent at col.1 ll.28-48.

In early 2003, TAP scientists Drs. Majid Vakily[2] and Rajneesh Taneja began working on a new PPI dosage form that could be taken once a day but still prevent nighttime heartburn. Their work led to the Asserted Patents.

Meanwhile, Takeda Japan, separately from the TAP joint venture, was developing a new PPI containing dexlansoprazole. The new PPI dosage form was called TAK-390MR, the development code name for Dexilant®. See ECF No. 144-8 (Kurasawa Dep.) at 9:21-11:3. One of the scientists working on TAK-390MR was Dr. Akiyama. Id. Dr. Akiyama's work led to Takeda Japan's international patent application disclosing TAK-390MR. PCT Publication No. WO 2004/035020 ("Akiyama I"). The international application entered the U.S. phase and in

[1] Takeda Japan later acquired Abbott's share in TAP, and TAP was renamed Takeda Pharmaceuticals U.S.A., Inc., a plaintiff in this case. See Stipulation of Interests ¶¶ 7-9.

[2] Dr. Vakily's full last name is "Vakilynejad," although he usually uses the last name "Vakily." See ECF No. 147-4 ("Vakily Dep.") at 7:13-21. Both parties refer to Dr. Vakilynejad as "Dr. Vakily," and the Court does so too.

September 2010 was issued as U.S. Patent No. 7,790,755 ("Akiyama II").

In 2003, Takeda Japan began sharing data about TAK-390MR with TAP. See ECF No. 143-28 ("Taneja Dep.") at 42:4-44:20. Soon thereafter, Dr. Vakily recognized that TAK-390MR could be useful in his own research into a new PPI. Vakily Dep. at 182:1-185:6. Accordingly, TAP agreed to work with Takeda Japan to develop TAK-390MR. In February 2004, TAP and Takeda Japan signed an agreement whereby Takeda Japan licensed TAP to, inter alia, develop, use, and sell TAK-390MR. See ECF No. 144-35 (License Agreement). From that point forward, TAP led the clinical development of TAK-390MR in the United States. The work eventually culminated in Takeda obtaining approval from the Food and Drug Administration ("FDA") to sell Dexilant® in the United States on January 30, 2009. ECF No. 144-37 (NDA Approval) at DEX0091470.

C. Procedural History

On May 29, 2013, Takeda filed the instant lawsuit against TWi, alleging infringement of the '158 Patent. ECF No. 1 (Compl.) ¶¶ 26-35. On July 9, 2013, Takeda filed its First Amended Complaint, this time alleging infringement of both Asserted Patents. ECF No. 17 (First Am. Compl.) ¶¶ 29-48. On October 29, 2013, Takeda filed its four-count Second Amended Complaint ("SAC"), which is the operative complaint in this action. ECF No. 36. TWi answered the SAC on November 18, 2013. ECF No. 41.

On February 6, 2014, the parties filed a Joint Claim Construction and Prehearing Statement, identifying disputed claim terms, proposed constructions, and citations to supporting evidence. ECF No. 60. After receiving claim construction briefing, the Court held a technology tutorial and claim construction hearing on June 5, 2014. The following day, the Court issued its Order Construing Claims, which construed two terms from the '187 Patent and four terms from the '158 Patent. ECF No. 78 at 38.

At a case management conference held on December 10, 2014, it was brought to the Court's attention for the first time that Takeda had failed to produce various documents, including

TAP inventor e-mails and licensing documents. ECF No. 129. As the fact discovery cutoff date had elapsed two months prior, see ECF No. 87, the Court amended the case schedule to allow Takeda sufficient time to produce the missing documents and TWi sufficient time to review them prior to the filing of dispositive motions, ECF No. 129. At the Court's request, Takeda filed a case narrowing statement on February 2, 2015, indicating that Takeda was asserting seven claims: claim 1 of the '158 Patent and claims 1, 2, 5, 6, 7, and 16 of the '187 Patent. ECF No. 138. Takeda will file a further statement narrowing its case to at most five asserted claims by April 16, 2015. ECF No. 167.

The Court also allowed Takeda to file a Motion to Strike portions of TWi's expert reports, which Takeda did on February 9, 2015. ECF No. 139. Specifically, Takeda moved to strike expert opinion testimony regarding two invalidity theories TWi had allegedly failed to disclosed in its Invalidity Contentions: (1) anticipation of the asserted claims of the '187 Patent by the Dietrich reference, and (2) nonenablement of the formulation of the asserted claim of the '158 Patent. Id. at 1. Finding that TWi had not adequately disclosed either theory in violation of the Patent Local Rules, the Court granted Takeda's motion on March 17, 2015. ECF No. 156.

The motions at hand—TWi's Motion for Summary Judgment on all four counts of Takeda's SAC and Takeda's Motion for Summary Judgment on TWi's affirmative defenses of inequitable conduct[3]—were filed on February 19, 2015. The parties opposed each other's motions on March 5, 2015. ECF No. 147 ("TWi Opp."); ECF No. 149 ("Takeda Opp."). The parties replied on March 12, 2015. ECF No. 152 ("Takeda Reply"); ECF No. 155 ("TWi Reply"). The Court held a hearing on the summary judgment motions on April 9, 2015.

II. LEGAL STANDARD

Summary judgment is appropriate if, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party, there are no genuine disputes of

[3] Takeda does not move for summary judgment on any of the counts in its SAC. The Court notes, however, that TWi confirmed at the April 9, 2015 hearing that it has stipulated to infringement of the asserted claims of the '187 patent. See Takeda Opp. at 1 n.2.

material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 321 (1986). At the summary judgment stage, the Court "does not assess credibility or weigh the evidence, but simply determines whether there is a genuine factual issue for trial." House v. Bell, 547 U.S. 518, 559-60 (2006). A fact is "material" if it "might affect the outcome of the suit under the governing law," and a dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The moving party bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. Id. at 322-23. But on an issue for which the opposing party will have the burden of proof at trial, the party moving for summary judgment need only point out that "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." Id. at 323. Once the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, "specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 250.

If evidence produced by the moving party conflicts with evidence produced by the nonmoving party, a court must assume the truth of the evidence set forth by the nonmoving party with respect to that fact. See Leslie v. Grupo ICA, 198 F.3d 1152, 1158 (9th Cir. 1999). "Bald assertions that genuine issues of material fact exist," however, "are insufficient." Galen v. Cnty. of L.A., 477 F.3d 652, 658 (9th Cir. 2007); see also United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc., 637 F.3d 1047, 1061 (9th Cir. 2011) ("To survive summary judgment, a plaintiff must set forth non-speculative evidence of specific facts, not sweeping conclusory allegations."). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (citations omitted).

III. DISCUSSION

Each side has filed a motion for summary judgment. TWi moves for summary judgment on all four counts of Takeda's SAC, arguing that the Asserted Patents are invalid as a matter of law and, in the alternative, that Takeda cannot show infringement of the '158 Patent as a matter of law. See generally TWi MSJ. Takeda moves for summary judgment on TWi's ninth and tenth affirmative defenses—i.e., that the Asserted Patents are unenforceable due to inequitable conduct. See generally Takeda MSJ. For the reasons stated below, the Court GRANTS in part and DENIES in part the parties' summary judgment motions.

A. Invalidity

An invention is not patentable if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States" or if "the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." 35 U.S.C. § 102(b), (e) (2006).[4] In its summary judgment motion, TWi argues that the asserted claims of the '187 Patent are anticipated by Takeda Japan's alleged offer to sell TAK-390MR to TAP. TWi MSJ at 5-9. TWi argues further that the asserted claims of both the '187 and '158 Patents are anticipated by Akiyama II. Id. at 9-11, 14-19.[5] The Court addresses each argument in turn.

1. Offer for Sale

a. Legal Standard

[4] As the applications leading to the Asserted Patents were filed before the America Invents Act's ("AIA") effective date of March 18, 2013, the pre-AIA version of § 102 applies. See Medisim Ltd. v. BestMed, LLC, 758 F.3d 1352, 1354 n.1 (Fed. Cir. 2014).

[5] TWi also argues that the asserted claims in the '187 patent are anticipated by the Dietrich reference, and that claim 1 of the '158 patent is not enabled. TWi MSJ at 11-14, 19-20. These arguments, however, were the subject of Takeda' motion to strike, which the Court has granted. ECF No. 156. Consequently, the Court does not consider either argument.

The Supreme Court has held that § 102(b)'s "on-sale bar applies when two conditions are satisfied before the critical date": (1) "the product must be the subject of a commercial offer for sale"; and (2) "the invention must be ready for patenting." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67 (1998). Application of the "on-sale bar" to patentability is a question of law "based upon underlying factual considerations." Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1257 (Fed. Cir. 2001) (internal quotation marks omitted). "In order to overcome the presumption of validity, such underlying facts supporting a determination of invalidity must be proven by clear and convincing evidence." Id.

b. Analysis

TWi argues that a May 5, 2003 letter sent from Takeda Japan's managing director to Tom Watkins ("Watkins"), then-president of TAP, amounts to an offer for sale under § 102(b) that renders the '187 Patent invalid. TWi MSJ at 6-9. In that letter, titled "Re: TAK390MR licensing terms," Takeda Japan's managing director wrote: "I understand that our R&D experts will explain Takeda [Japan]'s sustained release form of TAK 390 ('TAK390MR') at the upcoming [management committee meeting]. In this connection, we would like to propose the following terms and conditions." ECF No. 143-17 ("Offer Letter") at DEX1169490. Those terms included an initial payment of 3 billion Yen "upon signing TAK390MR license agreement"; a royalty payment of 6% of net sales; a transfer price per 60 mg capsule; and a supply term stating that "TAP shall purchase TAK390MR preparations from [Takeda Japan] until the last TAK390MR patent is expired." Id.

Takeda disagrees. The Offer Letter, according to Takeda, "was a licensing offer and not an offer for sale." Takeda Opp. at 4. Takeda says it "was not seeking to sell TAK-390MR tablets; rather, Takeda [Japan] was seeking a licensing partner to perform the work necessary to commercialize an eventual product"—conduct that does not come under § 102(b)'s ambit. Id. "At a minimum," Takeda concludes, "a significant factual dispute exists regarding the nature of the [Offer Letter]." Id. at 5. In addition, Takeda argues that the Offer Letter was not sufficiently

"definite" to constitute an offer for sale under § 102(b). Id. at 5-6. Because the Offer Letter "specifically reference[d] a future 'TAK390MR license agreement'" and "omitted numerous material terms," Takeda says "it could not have been accepted by TAP" in its existing form. Id. at 5.

Viewing the evidence, as the Court must, in the light most favorable to Takeda, the Court finds a genuine dispute as to whether the Offer Letter constituted an offer for sale under § 102(b). It is well established that "a sale of rights in a patent, as distinct from a sale of the invention itself, is not within the scope of the statute, and thus does not implicate the on-sale bar." Elan Corp., PLC v. Andrx Pharm., Inc., 366 F.3d 1336, 1341 (Fed. Cir. 2004) (quoting Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1049 (Fed. Cir. 2001)). "In certain situations," however, "a 'license' . . . may be tantamount to a sale (e.g., a standard computer software license), whereupon the bar of § 102(b) would be triggered because the product is just as immediately transferred to the 'buyer' as if it were sold." In re Kollar, 286 F.3d 1326, 1331 n.3 (Fed. Cir. 2002) (alterations and internal quotation marks omitted).

Whether this case presents such a situation is a question for the trier of fact. Indeed, the Offer Letter's title refers to "TAK390MR licensing terms," and the letter itself speaks of a "license agreement." Offer Letter at DEX1169490 (emphases added). Watkins, to whom the Offer Letter was addressed, testified in his deposition that the letter was "a proposal to license to TAP . . . whatever existed at the time on a compound that was referred to as 390 or 390MR." Watkins Dep. at 33:18-22; see also id. at 35:13-15 ("[T]his memo apparently is proposing licensing terms should we agree that we want to license this thing."). According to Watkins, "this is not an uncommon way for a holder of a chemical entity to talk to a potential developer of that chemical entity about licensing what they have." Id. at 34:3-7.

At the same time, however, the Offer Letter contains a "Supply Term" stating that "TAP shall purchase TAK390MR preparations from [Takeda Japan] until the last TAK390MR patent is expired." Offer Letter at DEX1169490 (emphasis added). The Offer Letter also contains other

terms indicative of an offer for sale: an initial payment of 3 billion Yen upon signing the license agreement, a royalty payment of 6% of net sales, and a transfer price per 60 mg capsule. Id. In addition, the letter indicates that the transfer price would be the same for TAK-390MR as for Prevacid®, which Takeda Japan was already selling to TAP. Id.

Viewing this competing evidence in the light most favorable to Takeda, the Court finds a genuine dispute as to whether the Offer Letter amounts to an offer for sale under § 102(b) or an offer to license rights under a patent. See Grp. One, 254 F.3d at 1049 (holding that the documentary evidence was "unclear" as to whether Group One "was offering only to license the patent to Hallmark, and was not offering to license or sell the invention as such," and that, as a result, "[t]he district judge erred in deciding this disputed question of fact on summary judgment"). Because there is a genuine dispute of material fact on this score, the Court DENIES TWi's summary judgment motion as to the on-sale bar.[6]

2. Anticipation by Akiyama II

TWi asserts that Akiyama II, U.S. Patent No. 7,790,755, anticipates the asserted claims of both the '187 and '158 Patents. TWi argues that Akiyama II is prior art to the '187 Patent and anticipates its claims. Takeda disputes that Akiyama II is prior art to the '187 Patent, but admits that Akiyama II would anticipate the '187 Patent if it is prior art. TWi also asserts that Akiyama II anticipates the '158 Patent. The parties do not dispute that Akiyama II is prior art to the '158 Patent, but Takeda disputes that Akiyama II anticipates claim 1 of the '158 Patent, either expressly or inherently.

a. The '187 Patent

Akiyama II was issued to Akiyama et al. on September 7, 2010. ECF No. 143-7 at 1. The international application from which Akiyama II is derived was filed in English on October 15,

[6] As the Court finds a genuine dispute with respect to all the asserted claims in the '187 Patent, and because Takeda does not move for summary judgment on method claims 6 and 7, the Court need not address Takeda's argument in its Opposition that the Offer Letter cannot be an offer for sale of the methods of those two claims. See Takeda Opp. at 6.

2003, and lists the United States as one of the countries in which the inventors sought a patent. Akiyama I at 1. The parties thus agree that, pursuant to 35 U.S.C. § 102(e), the earliest priority date of Akiyama II is October 15, 2003. TWi MSJ at 6 n.2; Takeda Opp. at 7.

The parties also agree that Example 57 of Akiyama II discloses TAK390-MR. See Akiyama II at col.160 ll.18-22; see also TWi MSJ at 9 n.4. Example 57 provides:

> 120 mg of enteric-coated granules obtained in Example 53 and 315 mg of controlled release granules obtained in Example 56 were mixed and the resulting mixture was filled in one capsule #1 to give a capsule (correspond to 90 mg of Compound A).

Id. TWi asserts, and Takeda's expert does not dispute, that Example 57 meets every limitation of the asserted claims of the '187 Patent. TWi MSJ at 9 n.4 (citing expert report of Dr. Robert Bellantone ¶ 15). Accordingly, the sole anticipation issue with regard to the '187 Patent is whether the inventors conceived of the invention of the '187 Patent prior to October 15, 2003. For the reasons explained below, the Court finds that there is a genuine dispute of fact as to whether the inventors conceived of every limitation of the asserted claims of the '187 Patent prior to October 15, 2003.

i. Legal Standard

Conception is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) (internal quotation marks omitted). "It is well established that when a party seeks to prove conception via the oral testimony of a putative inventor, the party must proffer evidence corroborating that testimony." Shu-Hui Chen v. Bouchard, 347 F.3d 1299, 1309 (Fed. Cir. 2003).

The issue of the conception date of an invention is a legal conclusion based on underlying factual findings. Taurus IP, LLC v. DaimlerChrysler Corp., 726 F.3d 1306, 1322 (Fed. Cir. 2013). "While defendants bear the burden of persuasion to show that the [Akiyama II] references are prior art to the [Asserted Patents] by clear and convincing evidence, the patentee nevertheless must meet its burden of production to demonstrate an earlier conception date." Allergan, Inc. v.

Apotex Inc., 754 F.3d 952, 967 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 956 (2015).

ii. Analysis

The conception dispute in this case depends on a single limitation in claim 1 of the '187 Patent. Claim 1 of the '187 Patent reads:

> 1. A dosage form comprising a PPI wherein the PPI is released from the dosage form as a first and a second dose, wherein the first and second doses are released from the dosage form as discre[te][7] pulses of the PPI separated by a period of time, wherein the second dose contains at least 10% more of the PPI than the first dose, and wherein each of the first and second doses comprise a sufficient amount of the PPI to raise plasma levels of the PPI to a threshold concentration of at least 100 ng/ml.

'187 Patent cl. 1 (emphasis added). TWi argues that Dr. Vakily and Dr. Taneja did not conceive of the limitation "wherein the second dose contains at least 10% more of the PPI than the first dose" prior to the October 15, 2003 filing date of Akiyama II. Twi MSJ at 10. The '187 Patent has an earliest filing date of June 16, 2004. See '187 Patent at 1. Thus, whether Akiyama II is prior art under § 102(e) depends on whether the inventors of the '187 Patent conceived of their invention prior to October 15, 2003.[8]

TWi argues that Takeda's Rule 30(b)(6) deponent, Dr. Taneja, admitted that the inventors did not conceive of the '187 Patent claims until December 22, 2003, when the inventors received the results of a site absorption study shown in Example 2 of the '187 Patent. TWi MSJ at 11. Takeda argues that the inventors actually conceived of the invention in March 2003, based on a model developed by Dr. Vakily, which is described in Example 1 of the '187 Patent. Takeda Opp. at 8 (citing ECF No. 144-24) (email from Dr. Vakily to Dr. Taneja sharing the PK-PD Model).

Dr. Taneja testified as follows at the Rule 30(b)(6) deposition, discussing the site absorption study shown in Example 2 of the '187 Patent:

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[7] The parties agree that the term "discreet" is a typographical error and should be "discrete." See TWi MSJ at 5; Takeda Opp. at 10 n.10.

[8] Neither Takeda nor TWi raises any reduction to practice arguments. See, e.g., Spansion, *Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1356-57 (Fed. Cir. 2010) (explaining requirements of conception and reduction to practice).

> Q: And would it be true or fair to say that the site of absorption study allowed you and the other inventor to conceive of the idea that there needed to be a first and second pulse of the active ingredient separated by a period of time?
>
> A: Yes, separated by a period of time to get the maximum beneficial effect.
>
> . . .
>
> Q: The second limitation in claim 1 of the '187 is ["]wherein the second dose contains at least 10 percent more of the PPI than the first dose.["]
>
> Do you believe that your site of absorption study in example 2 of the '187 led to the conception of the second dose containing at least 10 percent more of the PPI than the first dose?
>
> A: It does.

Taneja Dep. at 13:18-25, 14:8-17. TWi takes this exchange as a conclusive admission by Takeda's 30(b)(6) designee that the earliest conception date of the '187 Patent is December 22, 2003, thus making Akiyama II prior art. Twi MSJ at 11.

In response, Takeda submitted a declaration from Dr. Vakily, who avers that, by March 2003, the inventors had hypothesized a dosage form wherein the second dose contains more PPI than the first dose, to account for the decreased absorption of the second dose in the large intestine. ECF No. 149-1 ("Vakily Decl.") ¶ 3. Dr. Vakily disclosed "examples of dosage forms that met these criteria" in his paper "PK-PD Modeling and Simulation for Lansoprazole." Id. ¶ 4; ECF No. 149-2 ("PK-PD Model"). The PK-PD Model proposes various dosage forms wherein the second dose is twice as large as (i.e., 100% more than) the first dose. See PK-PD Model at tbl. 8. The PK-PD Model proposed a 100% higher second dose because Dr. Vakily hypothesized that "the relative oral bioavailability [of the second dose] was assumed to be 50% of the first dose." Id. at tbl. 8 fn. a.

Dr. Vakily also explained at his deposition that the inventors first hypothesized a dosage form with a larger second dose, and then performed the site absorption study to gather data to test their hypotheses. Dr. Vakily testified that he first "determine[d] that in an optimal PPI dosage form there should be more drug in the second dose," and made that determination "originally with the modeling [simulation]," that is, before the site absorption study. Vakily Dep. at 225:19-24.

Dr. Vakily recognized that "at that time we did not have data from our GI absorption studies, so we made several assumptions" in developing the PK-PD Model. Id. at 226:5-11. Then, "when we did the site of absorption study, that confirmed that even we give [sic] the multiunit dosage form, some of them is going to pass the iliosacral junction and they're going to go to the colon and you're going to lose bioavailability, so we need to account for that." Id. at 226:17-23. Takeda thus argues that the inventors conceived of the dosage form in March 2003, in connection with the PK-PD Model, and confirmed their hypotheses about the formulation in December 2003 with the site absorption study. Takeda Opp. At 9; see also Burroughs Wellcome, 40 F.3d at 1228 ("[A]n inventor need not know that his invention will work for conception to be complete.").

TWi, for its part, recognized that Table 8 of Dr. Vakily's PK-PD Model showed a second dose that is 100% more than the first dose, and questioned Dr. Taneja about that disclosure:

> Q: Okay. But in any event, if we look at column 1, the dose 1 and dose 2 –
>
> A. Right.
>
> Q. – in each instance, the second dose is 100 percent more than the first dose, correct?
>
> A. Correct. Based on the data presented here.
>
> Q. And there is no dose 1, dose 2 listed in table 8 in which the second dose is at least 10 percent more than the first dose, correct?
>
> A. Correct.
>
> . . .
>
> Q. Okay. We can agree that there is no dosing regimen in which the second dose is only 10 percent more than the first dose?
>
> A. No, I agree based on the data presented here, but this is just a snapshot in time. There were many, many more modeling for higher doses done with this compound. This is just a piece of it.

Taneja Dep. at 30:21-31:24. According to TWi, this testimony is further proof that Dr. Vakily did not conceive of the "at least 10% more" limitation in the PK-PD Model. TWi Reply at 7-8. What's more, TWi argues that even if the inventors conceived of a second dose that is 100% more

than the first dose in March 2003, that does not equate to conception of the "at least 10% more" limitation in the claims. Id. at 6-7. In fact, as TWi argued at the hearing on the motion for summary judgment, Dr. Vakily's model was based on the assumption that the bioavailability of the second dose would be 50% of the first dose, thus necessitating a 100% larger second dose. PK-PD Model at tbl. 8. fn.a.

Having reviewed the evidence submitted by the parties, the Court finds that there is a genuine issue of fact as to when the inventors conceived of the "at least 10% more" limitation. In In re Jolley, 308 F.3d 1317 (Fed. Cir. 2002), the Federal Circuit affirmed a finding of the Board of Patent Appeals and Interferences that conception of a species within a genus constituted conception of the genus. Jolley involved a claim (or "count," in the language of interferences) to a "'two-component' composition: an HFC refrigerant and an ester lubricant." Id. at 1320. The party asserting an earlier conception date disclosed a "'three-component' system: a refrigerant, an ester, and a polyhydric alcohol (also called a polyol or polyglycol)." Id. at 1321. Within the three-component system, certain esters fell within the claimed two-component composition and some did not. Id. at 1321-22. Thus, the three-component system disclosed some species within the genus of the two-component composition. The Federal Circuit explained that conception of a species may constitute conception of a genus. Id. at 1323; see also Oka v. Youssefyeh, 849 F.2d 581, 584 (Fed. Cir. 1988); In re Taub, 348 F.2d 556, 562 (C.C.P.A. 1965) ("One may establish priority for a generic claim on the basis of a showing that he was prior as to a single species.").

Here, Dr. Vakily's declaration, deposition testimony, and the PK-PD Model show that Dr. Vakily conceived of one species of the "at least 10% more" genus—i.e., a species that is 100% more. See Vakily Decl. ¶ 4; PK-PD Model at tbl. 8; see also 143-21 ¶ 65 (report of TWi's expert, Dr. Edmund Elder, stating that a dosage form where the second dose is "200% more than" the first dose "meets the limitations: 'wherein the second dose contains at least 10% more of the PPI than the first dose.'"). Under Jolley, then, Dr. Vakily's conception of that species may be sufficient for purposes of conceiving the "at least 10% more" genus. At this stage, the Court cannot conclude as

a matter of law that Dr. Vakily's PK-PD Model would not have "fairly suggest[ed] to one of ordinary skill in the art" that Dr. Vakily "held the complete invention in his . . . own mind." Jolley, 308 F.3d at 1323.

In sum, a genuine dispute of material fact exists as to when the inventors conceived of every limitation of claim 1 of the '187 Patent such that the Court cannot determine as a matter of law whether Akiyama II is prior art. Accordingly, the Court DENIES TWi's summary judgment motion as to invalidity of the asserted claims of the '187 Patent based on anticipation by Akiyama II.

b. The '158 Patent

The '158 Patent claims a method of using a composition to treat heartburn, acid reflux, or GERD by administering a formulation "regardless of whether the patient is under fasted or fed conditions." '158 Patent cl. 1. The parties agree that claim 1 covers a method of using TAK-390MR, which is disclosed in Example 57 of Akiyama II. See TWi MSJ at 15-16; Takeda Opp. at 14; see also Akiyama II at col.160 ll.18-22 (Example 57); ECF No. 143-14 ("Charman Rep.") ¶ 26. Akiyama II also discloses orally administering formulations to treat GERD. Id. at col.47 ll.27-52. However, Akiyama II is silent as to the conditions under which the formulation should be administered. Accordingly, the sole issue with regard to anticipation of the '158 Patent is whether Example 57 of Akiyama II anticipates the "regardless of whether the patient is under fasted or fed conditions" limitation in claim 1 of the '158 Patent.[9] The Court construed this limitation to mean "without regard to food." ECF No. 78 at 22.

i. Legal Standard

To prove anticipation, TWi must show that Akiyama II "disclose[s] each and every feature of the ['158 Patent], either explicitly or inherently." Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1375 (Fed. Cir. 2006). A prior art reference is anticipatory regardless of the

[9] The earliest priority date of the '158 Patent is October 12, 2007. Akiyama II is therefore prior art to the '158 Patent under § 102(b).

specific words used, as long as it discloses the substance of each element of the claimed invention. In re Bond, 910 F.2d 831, 832-33 (Fed. Cir. 1990) (the elements need not satisfy "an ipsissimis verbis test" to be expressly anticipating). Further, a prior art reference can inherently anticipate a patent, if a person of skill in the art would understand the limitations are implicitly disclosed. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1347 (Fed. Cir. 2000). Inherency can be established when "prior art necessarily functions in accordance with, or includes, the claimed limitations." In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581 (C.C.P.A. 1981).

ii. Analysis

As TWi explains, "Akiyama [II] does not instruct that the administration of the formulation should be in any particular fed or fasted state." TWi MSJ at 16. With that in mind, TWi makes two arguments: (1) Akiyama II implicitly discloses a method of administering TAK-390MR "without regard to food"; and (2) the '158 Patent only captures the discovery of a previously unknown feature of Akiyama II, which is impermissible as a matter of law. Because the Court finds a genuine dispute of fact as to whether a person of ordinary skill in the art would have read Akiyama II to mean the PPI formulation could be taken "without regard to food," the Court cannot grant TWi's motion.

"For a prior art reference to anticipate a patent claim, the reference, as read by one of ordinary skill in the art, must disclose each claim limitation." Retractable Techs., Inc. v. Becton, Dickinson & Co., 653 F.3d 1296, 1309 (Fed. Cir. 2011). Here, TWi presents no evidence in support of its motion showing how one of ordinary skill would interpret Akiyama II's disclosure. Specifically, TWi has not shown whether one of ordinary skill would understand that Akiyama II disclosed administering the PPI formulation "without regard to food." As such, TWi has not met its burden of showing by clear and convincing evidence that Akiyama II "necessarily functions in accordance with, or includes, the claimed limitations." In re Cruciferous Sprout, 301 F.3d at

1349.

That said, the Court notes that nearly all of the evidence cited by Takeda's expert comes from the time of the filing of the '158 Patent (i.e., October 12, 2007) or later, and not the time of the filing of Akiyama II (i.e., October 15, 2003). See Charman Rep. ¶ 29 ("At the filing date of the '158 patent on October 12, 2007, the person of ordinary skill in the art would have understood that Prevacid®, which contains racemic lansoprazole, should be administered before a meal." (emphasis added)). Although the parties should be prepared to clarify the issue at trial, it appears more appropriate to evaluate the understanding of one of ordinary skill in the art at the time of Akiyama II's filing date. See, e.g., In re Baxter Travenol Labs., 952 F.2d 388, 390 (Fed. Cir. 1991) (evaluating teaching of prior art at the time of disclosure).

Nonetheless, and especially as it is TWi's burden to prove invalidity, the Court finds Takeda's evidence sufficient to survive summary judgment. Twice in his report, Dr. Charman cites to one PPI label from 2000, which predates Akiyama II. See Charman Rep. ¶¶ 29-30 (citing a 2000 PDR that states Prilosec "should be taken before eating"). Dr. Charman also states that, in his opinion, "it was not known whether it was possible to administer TAK-390MR, regardless of whether the subject was under fasted or fed conditions" until the inventors conducted their December 2003 site absorption study, suggesting that prior to that study (i.e., at Akiyama II's filing date), one of ordinary skill would have limited administration to a fasted state. Id. ¶ 34.

Because it is not clear that the prior art teaches a method of administering TAK-390MR "without regard to food," TWi's second argument that the '158 Patent impermissibly captures the discovery of a preexisting but unknown feature of TAK-390MR is unavailing. TWi MSJ at 18-19. Significantly, the '158 Patent covers a method of treating and not a "property" or "result" of TAK-390MR. See Atlas Powder v. Ireco, Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (emphasis added)). For example, if claim 1 were a composition claim that read "A formulation

comprising TAK-390MR that is capable of administration regardless of whether the patient is under fasted or fed conditions," rather than a method claim, that claim could potentially be anticipated by Akiyama II. Here, however, the '158 Patent claims a method of administering TAK-390MR in a specific fashion: regardless of whether the patient is under fasted or fed conditions. Thus, like in Perricone v. Medicis Pharmaceutical Corp., the '158 Patent may teach a new method of using a known composition. 432 F.3d 1368, 1378 (Fed. Cir. 2005) ("The issue is not . . . whether [the composition] if applied to skin sunburn would inherently treat that damage, but whether [the prior art] discloses the application of its composition to skin sunburn. It does not.").

As explained above, Takeda's evidence showing that the formulation disclosed in Akiyama II would not necessarily be administered "without regard to food" is sufficient for the Court to find a genuine dispute as to whether Akiyama II anticipates the '158 Patent. Accordingly, the Court DENIES TWi's summary judgment motion as to invalidity of the asserted claim of the '158 Patent based on anticipation by Akiyama II.

B. Infringement

TWi also argues that Takeda cannot show TWi's accused products will infringe claim 1 of the '158 Patent, either literally or under the doctrine of equivalents. TWi MSJ at 20-25. As there is no genuine dispute on this issue, according to TWi, summary judgment is warranted. For the reasons explained below, the Court finds that there is a genuine dispute of fact as to literal infringement, but that Takeda cannot assert infringement under the doctrine of equivalents as a matter of law.

1. Legal Standard

"A determination of patent infringement consists of two steps: (1) the court must first interpret the claim, and (2) it must then compare the properly construed claims to the allegedly infringing device." Playtex Prods, Inc. v. Procter & Gamble Co., 400 F.3d 901, 905-06 (Fed. Cir. 2005). "Direct infringement requires proof by preponderant evidence that the defendant performs

(if a method claim) or uses (if a product claim) each element of a claim, either literally or under the doctrine of equivalents." Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc., 725 F.3d 1341, 1348 (Fed. Cir. 2013).

"To support a summary judgment of noninfringement," which is what TWi seeks, "it must be shown that, on the correct claim construction, no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee." Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1353 (Fed. Cir. 2001). "Summary judgment of noninfringement under the doctrine of equivalents is appropriate if no reasonable jury could determine two elements to be equivalent." Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1164 (Fed. Cir. 2004) (internal quotation marks omitted). Infringement, either literal or under the doctrine of equivalents, is a question of fact. See Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009).

2. Literal Infringement

One aspect of the '158 Patent's claimed invention is a method of treating a patient using a dosage form that releases a PPI at two locations: first in the proximal region of the small intestine where the pH is about 5.0 to about 5.5, and later in the distal region of the small intestine where the pH is about 6.2 to about 6.8. See '158 at Patent col.20 ll.46-56 (Example 1), col.20 ll.1-7, col.11 l.64-col.12 l.10. Enteric coatings surrounding the active ingredient are responsible for regulating the release of the PPI and preventing release at undesirable pH levels. Id. at col.12 ll.22-27. To that end, claim 1 of the '158 patent provides as follows:

> wherein said first solid particle comprises dexlansoprazole and a first enteric coating, wherein the first enteric coating releases the proton pump inhibitor from the solid particle at a pH of about 5.0 to about 5.5; and (ii) a second solid particle, wherein said second solid particle comprises dexlansoprazole and a second enteric coating, wherein the second enteric coating releases the proton pump inhibitor from the solid particle at a pH of about 6.2 to about 6.8;

'158 Patent cl. 1 (emphases added).

As stated in its Order Construing Claims, "the Court construes the term 'enteric coating releases the proton pump inhibitor from the solid particle at a pH of' 'about 5.0 to about 5.5' or

'about 6.2 to about 6.8' to mean 'enteric coating is designed to release the proton pump inhibitor from the solid particle at a pH of' 'approximately 5.0 to approximately 5.5' or 'approximately 6.2 to approximately 6.8.'" ECF No. 78 at 35 (emphasis added). "If the enteric coating is not designed to dissolve at or about the specific pH levels," the Court continued, "then it does not meet the claims." Id.

Based on the Court's construction, TWi offers three independent bases for noninfringement. First, TWi claims there is "no dispute" that its accused products "were designed to release" dexlansoprazole from their first solid particle [redacted] the claimed pH range of 5.0 to 5.5. TWi MSJ at 21. Second, even if the appropriate test focused on the pH at which dexlansoprazole was actually released, rather than the pH at which dexlansoprazole was designed to be released, TWi says there can be no infringement because [redacted] the claimed pH range of 5.0 to 5.5. Id. at 21-23. Lastly, TWi argues that, under the actual release test, there can be no infringement because [redacted] Id. at 23-24. The Court addresses each of TWi's arguments in turn.

a. First Solid Particle

The Court finds a genuine dispute as to whether TWi's first solid particle was "designed to release" dexlansoprazole [redacted] On the one hand, [redacted] In support of this claim, [redacted]

[redacted]

On the other hand, [redacted] see also '158 Patent at col.12 ll.5-17 (identifying Eudragit L30 D-55 as a suitable first enteric coating for release "at a pH of about 5.0 to about 5.5"). Although [redacted] To support his opinion, Takeda's expert cites a patent application assigned to the

[10] [redacted]

manufacturer of [redacted] Other than labeling this evidence "unsubstantiated testimony," TWi offers no counterpoint. TWi Reply at 13.

Though a close call, viewing the above evidence in the light most favorable to Takeda, a reasonable fact finder could conclude that TWi's first solid particle was "designed to release" dexlansoprazole within the claimed pH range of approximately 5.0 to approximately 5.5. [redacted] TWi has not shown the absence of a genuine dispute with respect to its product's objective design—[redacted] On that basis, the Court DENIES TWi's summary judgment motion as to noninfringement with respect to the "designed to release" limitation of the first solid particle.

b. Second Solid Particle

The Court also finds a genuine dispute as to whether TWi's second solid particle was "designed to release" dexlansoprazole at a pH within the claimed pH range of approximately 6.2 to approximately 6.8. On the one hand, TWi argues that its accused products do not infringe because [redacted] Takeda does not dispute these results. See Takeda Opp. at 25. On the other hand, however, TWi does not dispute Takeda's rejoinder that TWi's second solid particle's enteric coating consists of Eudragit L100 and Eudragit S100, which dissolve above pH 6.0 and pH 7.0, respectively. See ECF No. 149-19 (Eudragit L100 product page); ECF No. 149-20 (Eudragit S100 product page). [redacted]

[redacted]

Viewing the competing evidence in the light most favorable to Takeda, a reasonable trier of fact could conclude that TWi's second solid particle was "designed to release" dexlansoprazole within the claimed pH range of approximately 6.2 to approximately 6.8 [redacted] Accordingly, the Court DENIES TWi's summary judgment motion as to noninfringement with respect to the "designed to release" limitation of the second solid particle.

3. Infringement Under the Doctrine of Equivalents

"The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Pozen Inc. v. Par Pharm., Inc., 696 F.3d 1151, 1167 (Fed. Cir. 2012) (internal quotation marks omitted). A plaintiff may prove infringement under the doctrine of equivalents "by showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." Id. (internal quotation marks omitted).

In this case, TWi argues that Takeda cannot, as a matter of law, rely on the doctrine of equivalents to prove that TWi's accused products infringe the "about 5.0 to about 5.5" pH claim limitation. TWi MSJ at 24-25. This is so, says TWi, because the limitation "about 5.0 to about 5.5," which the Court has construed to mean "approximately 5.0 to approximately 5.5," already encompasses equivalents as part of the claim's literal scope. Id. To hold otherwise would permit Takeda to "rely on the doctrine of equivalents to encompass equivalents of equivalents," which, according to TWi, Takeda may not do under Federal Circuit precedent. Id. at 24 (quoting Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1372 (Fed. Cir. 2008)).

The Court agrees. In Cohesive Technologies, the plaintiff sought to apply the doctrine of equivalents to an "about 30 μm" limitation. 543 F.3d at 1371-72. After construing "about 30 μm" to include particles between 23.044 μm and 25.434 μm only if those particles were "of sufficiently large size to assure that a column containing the particles is capable of attaining turbulence," id. at

1370, the Federal Circuit said that "by electing to include the broadening word 'about' in the claim, the patentee has in this case already captured what would otherwise be equivalents within the literal scope of the claim," id. at 1372. Where "a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim," the Federal Circuit held that "the doctrine of equivalents is unavailable to further broaden the scope of the claim." Id. at 1372; see also U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1379 (Fed. Cir. 2007) ("[T]erms like 'approximately' serve only to expand the scope of literal infringement, not to enable application of the doctrine of equivalents.").

The same is true here. In its Order Construing Claims, this Court emphasized that other "courts have construed the term 'about' to mean 'approximately,' rather than deriving a specific numerical range for the value that it modifies." ECF No. 78 at 30; see also id. at 29, 31 (rejecting TWi's proposal to construe "about" as "±0.05" because "the specification does not suggest any specific numerical range"). In other words, 5.0 to 5.5 pH is a specific numerical range that the word "about," a term of approximation, modifies. Having construed "about" to mean "approximately," rather than "a specific numerical range," ECF No. 78 at 30, the Court has already concluded that the claim's literal scope necessarily includes equivalents whose enteric coatings might be designed to release dexlansoprazole just outside the claimed 5.0 to 5.5 pH range. Because certain equivalents are already encompassed by the claim's literal scope, Takeda may not rely on the doctrine of equivalents to prove infringement as a matter of law. See Cohesive Techs., 543 F.3d at 1372 ("Where, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim."). Holding to the contrary would impermissibly allow Takeda to use that doctrine "to encompass equivalents of equivalents." Id.

Additional Federal Circuit precedent fully supports the Court's conclusion. In Pozen Inc. v. Par Pharmaceutical, Inc., 696 F.3d 1151, 1169-70 (Fed. Cir. 2012), the plaintiff sought to apply the doctrine of equivalents to a claim that included the limitation "substantially all," which, the

defendant argued, was "a 'fuzzy' quantitative limitation not entitled to equivalents." The Federal Circuit held that the plaintiff could rely on the doctrine of equivalents, but only because the term "substantially all" was construed to have a specific "quantitative definition"—namely, "at least 90%, and preferably greater than 95%." Id. at 1070. As the claim's literal scope included a precise floor of 90%, rather than an approximate floor of 90%, the court in Pozen held that the doctrine of equivalents could apply and that "a tablet layer with 85% of the agent can be fairly characterized as an insubstantial change from a tablet layer with 90% of the agent." Id. at 1170-71. Here, by contrast, the nonquantitative limitation "about" has been construed to mean "approximately," an equally nonquantitative definition. See ECF No. 78 at 30 (construing "the term 'about' to mean 'approximately,' rather than deriving a specific numerical range for the value that it modifies"). Unlike in Pozen, the term of approximation here was given no specific quantitative meaning such that the doctrine of equivalents could apply. Consequently, the holding of Cohesive Technologies controls.

Neither case cited by Takeda counsels a different result. In Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 32 (1997), the Supreme Court addressed whether prosecution history estoppel precluded application of the doctrine of equivalents where the phrase "at a pH from approximately 6.0 to 9.0" had been added to a claim in order to distinguish the prior art. In holding that the addition of the "lower limit of 6.0 . . . did not necessarily preclude the application of the doctrine of equivalents as to that element," the Supreme Court had no occasion to decide whether use of the term "approximately" foreclosed reliance on the doctrine of equivalents. Id. At most, "there is no indication" in Warner-Jenkinson "that the doctrine of equivalents should be unavailable for expressly fuzzy limitations." Regents of Univ. of Minn. v. AGA Med. Corp., No. 07-CV-4732 PJS/LIB, 2011 WL 13943, at *12 (D. Minn. Jan. 4, 2011) (discussing Warner-Jenkinson). The issue simply was not before the Supreme Court. See Philips, 505 F.3d at 1379 ("Notably, the Supreme Court in Warner-Jenkinson did not even mention the qualifier ['approximately'] in allowing consideration of the doctrine of equivalents.").

Takeda's citation to Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283 (Fed. Cir. 2010), is equally unconvincing. In that case, the Federal Circuit considered whether use of the phrase "at least 3500 hr*ng/mL" precluded application of the doctrine of equivalents. Id. at 1291-93. In holding that the doctrine applied, the Adams court relied on the uncontroversial proposition "that the doctrine of equivalents may apply to claims containing specific numeric ranges." Id. at 1291. The term "at least," the court held, expresses "an open-ended range" not unlike the ranges to which the Federal Circuit had applied the doctrine in the past. Id. at 1292. Unlike here, however, the claim in Adams explicitly did "not contain words of approximation (i.e., 'about at least 3500 hr*ng/mL')." Id. at 1293 (emphasis added). Adams is therefore inapposite and in no way undermines the controlling principle that "a patentee cannot rely on the doctrine of equivalents to encompass equivalents of equivalents." Cohesive Techs., 543 F.3d at 1372.

For these reasons, the Court GRANTS TWi's summary judgment motion as to noninfringement under the doctrine of equivalents. Since the doctrine of equivalents is unavailable as a matter of law, Takeda may only argue literal infringement at trial.

C. Inequitable Conduct

Takeda moves for summary judgment that the Asserted Patents are not unenforceable due to inequitable conduct. See generally Takeda MSJ. TWi asserts that the '187 Patent is unenforceable because Drs. Vakily and Taneja filed a declaration with the Patent Office averring that they were the first to invent the subject matter of the '187 Patent, when they in fact knew that TAK- 390MR, disclosed in Akiyama II, had already been invented. TWi Opp. at 4-11. TWi asserts further that the '158 Patent is unenforceable because the inventors and prosecuting attorney did not disclose to the Patent Examiner (the "Examiner") that the '158 Patent claimed a method of using a known composition. Id. at 11-18. For the reasons explained below, the Court DENIES summary judgment of no inequitable conduct as to the '187 Patent because there are genuine issues of fact as to whether Akiyama II is prior art. The Court GRANTS summary judgment of no inequitable conduct as to the '158 Patent because the inventors disclosed Akiyama II to the Patent

Office during prosecution.

1. Legal Standard

Inequitable conduct is an equitable defense to patent infringement. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011). "To prove inequitable conduct, the challenger must show by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive the PTO." In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 519 (Fed. Cir. 2012) (citing Therasense, 649 F.3d at 1287).

The materiality requirement concerns "but-for" materiality; it "requires proof that the patentee withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing." Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1345 (Fed. Cir. 2013). To assess materiality, the court must look to the standard used by the PTO to allow claims during examination. "The court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." Am. Calcar, Inc. v. Am. Honda Motor Co., Inc., 768 F.3d 1185, 1189 (Fed. Cir. 2014) (citing Therasense, 649 F.3d at 1291-92). "When," however, "the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit," materiality is presumed. Therasense, 649 F.3d at 1292 (citations omitted); see also Outside the Box Innovations, LLC v. Travel Caddy, Inc., 695 F.3d 1285, 1294 (Fed. Cir. 2012) ("[A] false affidavit or declaration is per se material.").

The specific intent to commit inequitable conduct may be inferred from indirect and circumstantial evidence. Therasense, 649 F.3d at 1290. However, deceptive intent must be "the single most reasonable inference able to be drawn from the evidence." Id. at 1290 (quoting Star Scientific Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)). The inference cannot be based on gross negligence, and "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." Therasense, 649 F.3d at 1290-91 (citing

Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

The Court agrees with Takeda that the "single most reasonable interference" standard applies at summary judgment. See, e.g., Mformation Techs., Inc. v. Research in Motion Ltd., 830 F. Supp. 2d 815, 829 (N.D. Cal. 2011) (granting summary judgment of no inequitable conduct where the evidence was "insufficient to require a finding of deceitful intent" because the plaintiff "provide[d] evidence which permits the reasonable inference" that the patent applicant acted in good faith); KFx Med. Corp v. Arthrex, Inc., No. 11CV198 DMS (BLM), 2013 WL 10125673, at *4 n.1 (S.D. Cal. July 10, 2013) ("This Court agrees with Plaintiff's interpretation of Therasense: That summary judgment is appropriate unless the evidence requires a finding of deceptive intent."). The two cases that TWi cites generally deal with motions for summary judgment by the accused infringer, not the patentee. See Interwoven, Inc. v. Vertical Computer Sys., No. CV 10-04645 RS, 2013 WL 75770 (N.D. Cal. Jan. 4, 2013); TV Interactive Data Corp. v. Sony Corp., No. 10-0475, 2012 WL 6020113, at *27 (N.D. Cal. Dec. 3, 2012) (cross-motions for summary judgment). Nonetheless, all facts and inferences are viewed in the light most favorable to TWi. See Celotex, 477 U.S. at 331.

2. The '187 Patent

The '187 Patent includes both composition and method of treatment claims. The composition claims cover a dosage form "comprising a PPI wherein the PPI is released from the dosage form as a first and a second dose." '187 Patent cl. 1. During prosecution of the '187 Patent, Drs. Vakily and Taneja filed a declaration averring: "I believe I am . . . an original, first and joint inventor . . . of the subject matter which is claimed and for which a patent in sought." ECF No. 144-41 41 ("Excerpts of '187 File History") at TAKEDA012476-78 ("Inventorship Declaration").

TWi asserts that Drs. Vakily and Taneja were not the first to invent the two-dose formulation, and that they knew Takeda scientists in Japan had already invented such a formulation. TWi Opp. at 4. Consequently, TWi argues, the Inventorship Declaration filed by

Drs. Vakily and Taneja during prosecution of the '187 Patent "constituted [a] material misstatement[] to the PTO." Id.

a. Materiality

As discussed in Part III.A.2.a, supra, the parties agree that TAK-390MR, which is disclosed in Akiyama II, anticipates the asserted claims of the '187 Patent. However, the parties disagree as to whether Akiyama II is prior art to the '187 Patent under § 102(e). Nonetheless, the inventors disclosed Akiyama II to the Patent Office during prosecution of the '187 Patent. See Excerpts of '187 File History at TAKEDA009526 (showing examiner considered Akiyama I); id. at TAKEDA009580 (showing examiner considered Akiyama II). TWi now goes one step further, arguing that even if Akiyama II is not prior art under § 102(e), Drs. Vakily and Taneja knew that they were not the "first to invent" the subject matter of the '187 Patent, and therefore the Inventorship Declaration is an "unmistakably false affidavit," for which materiality is presumed. Therasense, 649 F.3d at 1292 (citations omitted).

Takeda counters that the "first to invent" requirement is limited by the various subsections of § 102, such that "first to invent" really means "first to invent in this country." Takeda Reply at 6-8. The Court finds that because a foreign invention is not available as prior art until disclosure of the foreign invention triggers some provision of § 102, an inventorship declaration is not necessarily materially false for failing to acknowledge the foreign invention.

As the Supreme Court explained in Alexander Milburn Co. v. Davis-Bournonville Co., "by the words of [a prior version of § 102] a previous foreign invention does not invalidate a patent granted here [i.e., in the United States] if it [the foreign invention] has not been patented or described in a printed publication." 270 U.S. 390, 400 (1926). More recently, the predecessor to the Federal Circuit explained that "the specifying in 102(e) of an application filed 'in the United States' clearly demonstrates a policy in our patent statutes to the effect that knowledge and acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in priority disputes." Application of Hilmer, 359 F.2d 859, 878 (C.C.P.A.

1966).[11]

Thus, the failure to disclose that the inventors knew about TAK-390MR's conception in Japan is only material to patentability if Akiyama II is prior art. In this instance, even if the inventors had told the Patent Office about Takeda Japan's development of TAK-390MR, the Patent Office could not have used that disclosure to reject the patent claims. This is so because § 102 only recognizes a foreign invention once it is disclosed publicly in certain limited contexts. See, e.g., 35 U.S.C. § 102(a) (stating that a foreign invention can anticipate under § 102(a) only if it was "described in a printed publication"). Here, the first time TAK-390MR was disclosed in a fashion recognized by any subsection of § 102 was on October 15, 2003, the earliest filing date of Akiyama II recognized by § 102(e). As discussed in Part III.A.2.a.ii, supra, the Court finds that there is a question of fact as to when the subject matter of the '187 Patent was conceived, and therefore whether Akiyama II is § 102(e) prior art. The Court therefore cannot find one way or the other that the Inventorship Declaration was "unmistakably" false, as required by Therasense to show materiality as a matter of law. 649 F.3d at 1292 (emphasis added). Accordingly, the Court DENIES summary judgment of no inequitable conduct as to the '187 Patent.

b. Intent

Turning now to intent, the Court finds that TWi has presented sufficient evidence to allow a reasonable fact finder to conclude that the '187 Patent inventors intended to deceive the Patent Office, if Akiyama II is prior art. TWi presents evidence that the '187 Patent inventors recognized that Takeda Japan possessed TAK-390MR, and tested it in humans, in early 2003. See TWi Opp. at 5-6. Specifically, Dr. Vakily testified at his deposition that he recognized the two-dosage formulation in a May 6, 2003 presentation given by scientists from Takeda Japan:

> Q: And when they presented this, was it your understanding that it was a two-pulse formulation?

[11] The "except as applicants may become involved in priority disputes" refers to interference proceedings, where two parties seeking claims to the same invention attempt to prove which is entitled to the patent before the Patent Office. See Hilmer, 359 F.2d at 861 (explaining that the case arose from a "priority dispute" in an interference).

> A: Well, when they presented, first I thought that they are presenting my simulations because it was [a] surprise to me.
>
> And then, because I distinctly remember, I asked [Dr. Taneja], what, is this our stuff, and then we notice[d] that they did the clinical study they're presenting.

Vakily Dep. at 150:4-13. TWi also presents evidence showing that the inventors received and reviewed specific information about the TAK-390MR formulation prior to filing their own patent application. TWi Opp. at 5-6. TWi's evidence thus suggests that the inventors knew that they were not the first invent the formulation of the '187 Patent.

Construing the evidence in the light most favorable to TWi, a reasonable fact finder could conclude that the '187 Patent inventors knew that they were not the first to invent, but submitted a declaration to the Patent Office stating otherwise. The knowing submission of a false declaration "raises a strong inference of intent to deceive." Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339, 1345 (Fed. Cir. 2013). Accordingly, the Court DENIES summary judgment of no inequitable conduct as to the '187 Patent.

3. '158 Patent

The '158 Patent claims a method of treating acid reflux disease. '158 Patent cl. 1. TWi argues that the '158 Patent is unenforceable due to inequitable conduct because the inventors did not disclose to the Patent Office that the '158 Patent claims are based on a method of using a known substance, specifically TAK-390MR. TWi Opp. at 11-18. Takeda argues that because the inventors disclosed Akiyama II to the Patent Office, TWi cannot show inequitable conduct. Takeda Reply at 13-14.

a. Materiality

Takeda does not dispute that the '158 Patent claims encompass a method of using TAK-390MR, a known formulation that is one of the examples disclosed in Akiyama II. However, Takeda argues that because the inventors disclosed Akiyama II to the Patent Office during prosecution of the '158 Patent, Akiyama II is per se not material. Takeda MSJ at 18-19.

The Court agrees. It is well established that "[a]n applicant cannot 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). An applicant is also not required to state the "relevance of the references listed" in a disclosure to the Patent Office. Id. In fact, the Patent Office eliminated the requirement "that the applicant explain the relevance of the references listed" in an Information Disclosure Statement in 1992. Id.

Here, there is no dispute that Akiyama II—and thus TAK-390MR—was disclosed to the Examiner. See ECF No. 144-40 (Excerpts of '158 File History) at TAKEDA006887 (showing Examiner considered Akiyama I); id. at TAKEDA006862, -85 (showing Examiner considered Akiyama II). As Takeda disclosed Akiyama II to the Patent Office during prosecution of the '158 Patent, and Takeda was under no obligation to explain Akiyama II's relevance, TWi cannot show materiality as a matter of law. See Ohio Willow Wood, 735 F.3d at 1345; Fiskars, 221 F.3d at 1327.

TWi's arguments to the contrary are unpersuasive. First, TWi argues that the specification of the '158 Patent "obfuscate[s] the facts" because the inventors listed ranges for ingredients in their example formulations, rather than specific amounts. TWi Opp. at 12-13; '158 Patent at tbl. 2. Second, TWi argues that the prosecuting attorney misled the Examiner by arguing that the formulations disclosed in the '158 Patent were novel, when in fact the inventors knew that TAK-390MR already existed. TWi Opp. at 13-15.[12]

To start, TWi points to the formulations disclosed in the '158 Patent as evidence that the inventors misled the Patent Examiner. TWi Opp. at 12. Specifically, the inventors disclosed ranges of ingredients for the formulations, instead of a specific amount. For example, the

[12] Takeda argues that TWi has improperly introduced a new theory of inequitable conduct. See Takeda Reply at 9-10. However, TWi's Answer and Invalidity Contentions both contain the theory TWi now asserts: that TAK-390MR is prior art to the '158 Patent. See ECF No. 104 (First Am. Answer and Counterclaims) at 8-9; ECF No. 153-2 (Invalidity Contentions) at 116-17. Although TWi did not specifically identify Akiyama II in its inequitable conduct allegations, TWi did identify TAK-390MR, which is part of Akiyama II's disclosure. Id. Accordingly, the Court will consider whether the inventors' disclosure of Akiyama II—specifically, the failure to disclose that the '158 Patent claims a method of using a compound disclosed in Akiyama II—constitutes inequitable conduct.

inventors disclosed a formulation containing 21.5-23.5 mg of TAK-390 in the '158 Patent, when in fact they tested a formulation containing 22.5 mg of TAK-390. Id. (citing '158 Patent at tbl. 2 and ECF No. 147-19 ("Description and Composition of TAK-390MR Capsules (90mg)") at DEX136541). TWi calls the disclosure of ranges rather than actual formulations "chicanery" and "obfuscation." Id. at 12-13. However, TWi provides no support for its contention that disclosing a range—which truthfully captures the invention—leads to a finding of inequitable conduct or is improper. Even if TWi had, TWi cannot escape the holding of Fiskars, which says that Takeda's undisputed disclosure of Akiyama II was sufficient as a matter of law to defeat a charge of inequitable conduct. 221 F.3d at 1327.

As to the prosecution history, TWi argues that the inventors and prosecuting attorney "argued to the [Patent Office] that the formulation was a novel aspect of the invention." TWi Opp. at 13. TWi points to a Supplemental Reply to an Office Action that amended the claims and contained an Interview Summary. ECF No. 147-21 ("Supplemental Reply"). Yet nothing in the Supplemental Reply states that the compositions are novel. TWi also points to the Inventorship Declaration, arguing that the inventors, by signing the Declaration, misrepresented themselves as inventors of a novel formulation. This argument is not persuasive, however, because it elides the critical distinction that the claims of the '158 Patent are method claims, and not formulation claims. Unlike with the '187 Patent, there is no evidence that the inventors of the '158 Patent falsely claimed to have invented a method of administering a formulation disclosed in Akiyama II.

Following the Supplemental Reply, the Examiner allowed the amended claims and stated: "The prior art does not teach or suggest the claimed invention as pharmaceutical composition comprising dexlansoprazole with the claimed components in the claimed amount that provide effective treatments of acid reflux, heart burn or gastroesophageal reflux regardless of fed-or-fasted state of the patient optimizing thereby the drug consumption." ECF No. 147-22 (Notice of Allowance) at 3. TWi argues that this statement suggests that the Examiner believed the composition was novel. TWi Opp. at 13-14. However, it is less than clear how a statement that

includes the method of treating "regardless of [the] fed-or-fasted state of the patient" suggests that the Examiner believed that the formulation described within the method claims of the '158 Patent was the point of novelty. More importantly, as Takeda points out, "there is no obligation to respond to an examiner's statement of Reasons for Allowance." ACCO Brands, Inc. v. Micro Sec. Devices, Inc., 346 F.3d 1075, 1079 (Fed. Cir. 2003). So even if the Examiner's Notice of Allowance suggested that the Examiner believed the novel aspect of the '158 Patent claims was the formulation, the applicants had no duty to respond.

At bottom, there is no dispute that Takeda disclosed Akiyama II to the Patent Office during prosecution of the '158 Patent. As Takeda was under no obligation to explain Akiyama II's relevance to the Examiner, TWi cannot show materiality as a matter of law. See Fiskars, 221 F.3d at 1327. Accordingly, the Court GRANTS Takeda's motion for summary judgment of no inequitable conduct as to the '158 Patent.

b. Intent

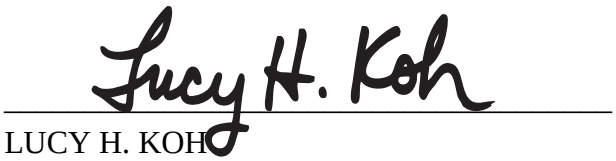
Because TWi cannot show materiality as a matter of law, the Court need not consider whether TWi can show intent to deceive. See In re Rosuvastatin, 703 F.3d at 519 (explaining that a party seeking to prove inequitable conduct must separately establish materiality and intent). For the reasons stated in the previous section, the Court GRANTS Takeda's motion for summary judgment of no inequitable conduct as to the '158 Patent.

IV. CONCLUSION

For the foregoing reasons, the Court hereby GRANTS in part and DENIES in part the parties' summary judgment motions. Specifically, TWi's motion is GRANTED as to noninfringement under the doctrine of equivalents, and otherwise DENIED. Takeda's motion is GRANTED as to the '158 Patent and DENIED as to the '187 Patent.

IT IS SO ORDERED.

Dated: April 10, 2015



LUCY H. KOH
United States District Judge

United States District Court
Northern District of California