UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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

Plaintiffs,

v.

TWI PHARMACEUTICALS, INC., et al.,

Defendant.

Case No. C-11-01609 JCS

Related Cases: C-11-0840 JCS, C-11-01610 JCS

ORDER RE SUMMARY JUDGMENT MOTIONS [Docket Nos. 160, 175 (redacted publicly filed versions); 166, 204 (sealed versions)]

[REDACTED VERSION]

~~FILED UNDER SEAL~~

United States District Court
Northern District of California

I. INTRODUCTION

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (hereinafter, referred to collectively as "Takeda") initiated this action under 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, in response to Defendants' Abbreviated New Drug Applications ("ANDA") No. 202-666, seeking approval from the Food and Drug Administration ("FDA") to manufacture and sell generic versions of Takeda's drug DEXILANT (dexlansoprazole).[1] Takeda alleges that TWi's ANDA products infringe two of its patents, U.S.

[1] Takeda alleged in its First Amended Complaint ("FAC") that the ANDA was submitted to the FDA by Defendant Anchen Pharmaceuticals, Inc. ("Anchen") and that ownership of the ANDA was transferred to TWi Pharmaceuticals, Inc. ("TWi") on May 10, 2011. FAC ¶¶ 33, 38. Anchen has been dismissed from this action, *see* Docket No. 103, but the parties agree that any references to Anchen's ANDA products apply with equal force to TWi because they refer to the same products. Hereinafter, the Court refers to the products in ANDA No. 202-666 as "TWi's ANDA products."

Patent No. 7,737,282 ("the '282 Patent") and U.S. Patent No. 7,790,755 ("the '755 Patent").[2] TWi, in turn, asserts counterclaims seeking declaratory judgment that no valid claims of the '755 or '282 Patents are infringed.

Presently before the Court are the parties' cross-motions for summary judgment. Takeda has filed a motion seeking summary judgment of infringement of the '282 Patent based on what it contends is undisputed evidence that the 30-mg and 60-mg dexlansoprazole drug products in TWi's ANDA contain the amorphous form of dexlansoprazole and therefore contain every element of claims 1 and 2 of the '282 patent. *See* Motion for Summary Judgment of Infringement of the '282 Patent ("Takeda SJ Motion (TWi)"). TWi brings a motion seeking summary judgment that: 1) its ANDA products do not infringe the '755 Patent because Takeda cannot establish that the composition of those products "begins to release" the active ingredient at a pH level of no less than 5.0 and no more than 6.0, as is required under the asserted claims; 2) there is no subject matter jurisdiction over claims IV and VII of Takeda's complaint to the extent they are based on alleged infringement of the '282 Patent because the '282 Patent is not listed in the FDA Orange Book and TWi has not filed a Paragraph IV certification with respect to it; 3) claims 1 and 2 of the '282 Patent are invalid because they are anticipated by the Larsson[3] and Barberich[4] references; and 4) claims 1 and 2 of the '282 Patent are invalid as lacking the required written description of the claimed dexlansoprazole salts and compositions containing them.[5] *See* Defendant TWi Pharmaceuticals, Inc.'s Motion for Summary Judgment ("TWi SJ Motion").

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[2] Originally, Takeda alleged that TWi's ANDA products infringed six of its patents. Judgment of non-infringement was entered as to four of these patents, *see* Docket No. 146, leaving only the '282 and '755 Patents at issue.

[3] Larsson" refers to WO 96/02535 ("Larsson I") and U.S. Patent No. 5,948,789 ("Larsson II"). Local Rule 56-2 Stipulation of Undisputed Facts ("JSUF (TWi Motion)") ¶¶ 90-91. The parties agree that there is no material difference between the disclosures of Larsson I and Larsson II. JSUF (TWi Motion) ¶ 92.

[4] "Barberich" refers to WO 99/38513 ("Barberich I") and U.S. Patent App. No. 2003/0008903 ("Barberich II"). The parties agree that there is no material difference between the disclosures of Barberich I and Barberich II. JSUF ¶¶ 93-94 (TWi Motion).

[5] TWi also incorporates and joins in "any invalidity summary judgment motion offered by any defendant in any related case with respect to claims 1 and 2 of the '282 patent." TWi SJ Motion at 15 n. 9.

Hearings on the motions were held on February 8, 2013 and February 22, 2013. For the reasons set forth below, Takeda's summary judgment motion is GRANTED. TWi's summary judgment motion is GRANTED in part and DENIED in part.[6]

II. BACKGROUND

A. The Accused Products

In its ANDA, TWi seeks approval from the FDA to market dexlansoprazole delayed-release capsules in 30-mg and 60-mg dosage forms. JSUF (Takeda Motion) ¶¶ 5,16. TWi manufactures its ANDA products in Taiwan. *Id.* ¶ 13.

B. The Asserted Claims of the '282 Patent

Takeda alleges that TWi's ANDA products infringe claims 1 and 2 of the '282 Patent. Claim 1 of the '282 Patent claims an "amorphous compound of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole or a salt thereof." Joint Statement of Undisputed Facts for Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("JSUF (Takeda Motion)"), ¶ 1. The parties agree that the term "(R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1 H-benzimidazole" in the '282 Patent refers to dexlansoprazole. *Id.* ¶ 4. Claim 2 of the '282 patent, which depends from claim 1, requires a "pharmaceutical composition comprising the amorphous compound according to claim 1 and a pharmaceutically acceptable excipient, carrier or diluent." *Id.* ¶ 2. The Court has construed the term "amorphous compound" in claims 1 and 2 of the '282 Patent to mean "a non-crystalline solid that lacks the long-range order characteristic of a crystal." *Id.* ¶ 3; Claim Construction Order at 71.

C. The Asserted Claims of the '755 Patent

Takeda alleges that TWi's ANDA products infringe claims 2 and 4 of the '755 Patent, each of which depends from claim 1. JSUF (TWi Motion) ¶ 1. Claim 1 describes a capsule comprising two compositions, one of which is "soluble in the pH range of 6.0 to 7.5" ("composition (i)") and another in which the drug is "released in the pH range of no less than 5.0

[6] The parties have consented to the jurisdiction of a United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

to no more than 6.0" ("composition (ii)"). At the claim construction stage of the case, the Court was asked to construe the claim term specifying the range for composition (ii) (hereinafter, the "release term"). The primary dispute focused on whether the specified pH range refers to the threshold level at which release of the active ingredient begins, as Takeda asserted, or rather, represents the *only* pH values at which release or dissolution occurs. The Court adopted Takeda's proposed construction, construing the claim term "released in the pH range of no less than 5.0 to no more than 6.0" to mean that the dexlansoprazole "begins to be released from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0." Claim Construction Order at 70. In response to the argument that the claim term is indefinite because a person skilled in the art would not know what percentage of the drug needs to be released to satisfy the "begins to be released" requirement, the Court noted that "the phrase 'begins to release' is not a claim term but merely a proposed construction intended to convey the idea that the pH values in the term represent a threshold." *Id.* at 67. The Court went on to find that the question of what amount of drug release satisfies this requirement does not render the claim term insolubly ambiguous to a person of ordinary skill in the art. *Id.*

D. The Parties' Contentions

1. Subject Matter Jurisdiction Over '282 Infringement Claim

a. TWi's Motion

TWi asserts there is no subject matter jurisdiction over Takeda's '282 Patent infringement claim under 35 U.S.C. § 271(e)(2) because Takeda has not listed the '282 Patent in the "Orange Book" and TWi's ANDA does not include a Paragraph IV certification. TWi SJ Motion at 14-15 (citing *Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958, at *6 (D.N.J. Dec. 20, 2007); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925, 936 (N.D.Ill.,1995)). According to TWi, a Paragraph IV certification is a jurisdictional requirement under the Hatch-Waxman Act.[7]

[7] In the Motion, TWi requests dismissal of both Count IV (asserted under the Hatch-Waxman Act) and Count VII of Takeda's First Amended Complaint on this basis. Count VII, however, is asserted under § 271(a) and the Declaratory Judgment Act rather than the Hatch-Waxman Act. Therefore, this argument does not apply to Count VII.

b. Takeda's Opposition

Takeda rejects TWi's assertion that the Court lacks subject matter jurisdiction under § 271(e)(2) because the '282 Patent is not listed in the Orange Book. Takeda Opposition at 19-21. According to Takeda, Supreme Court and Federal Circuit authority establish that it is the submission of an ANDA, not a paragraph IV certification, that establishes jurisdiction in the district courts for an act of infringement under § 271(e)(2). *Id.* at 19-20 (citing *Caraco Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1680 n. 5 (2012); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1376-77 (Fed. Cir. 2012); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1343-44 (Fed. Cir. 2004); *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1372-73 (Fed. Cir. 2006)). Takeda cites district court decisions that it contends have reached the same conclusion. *Id.* at 12 (citing *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009); *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009)).

c. TWi's Reply

In its Reply brief, TWi asserts that Takeda has not cited any case in which a patentee was able to maintain "an ANDA patent infringement action with respect to a patent that was never listed in the Orange Book." TWi Reply at 12. According to TWi, *Eisai* is closely on point and in that case, the court found that a Paragraph IV certification was required for subject matter jurisdiction. *Id.* (citing 2007 WL 4556958, at *14 (D.N.J. Dec, 20, 2007). TWi argues that the cases cited by Takeda are "easily distinguished" on the grounds that in those cases: "(1) the asserted patent was shortly thereafter listed in the Orange Book," *id.* at 12 n. 6 (citing *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *4 (D. Del. Mar. 1. 2012)); "(2) changes in patent certification from 'paragraph IV' to other certifications did not destroy already existing jurisdiction over listed Orange Book patents," *id.* (*citing Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1680 (2012); *Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No. 08-cv-00953, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009)); and "(3) 'old-antibiotic' cases

that are expressly excluded from Orange Book listing requirements altogether provided jurisdiction," *id.* (citing *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004)).[8]

2. Infringement of the '282 Patent

a. Takeda's Motion

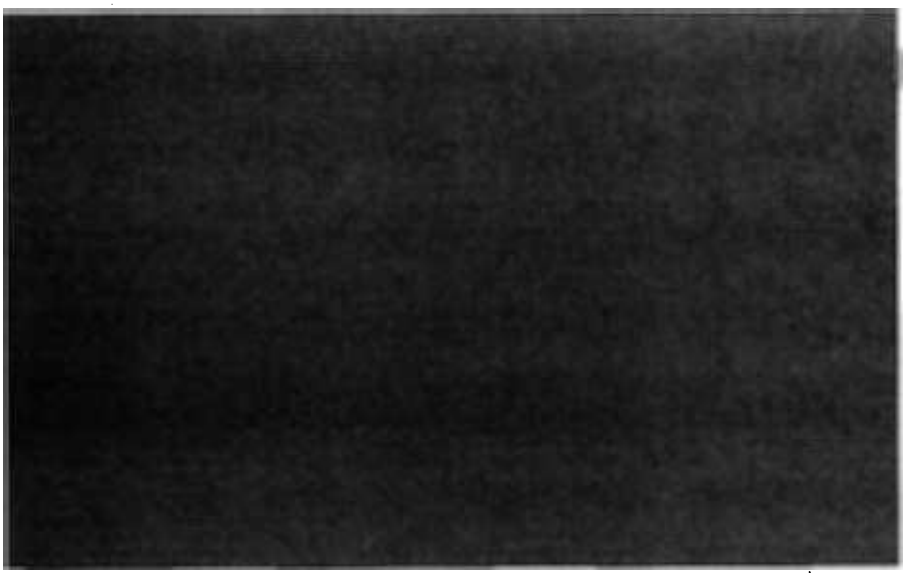
Takeda asserts in its summary judgment motion that TWi's ANDA products should be found to infringe the '282 claims because TWi's representations to the FDA and its admissions in discovery establish that those products contain the claimed amorphous compound of dexlansoprazole. Takeda SJ Motion (TWi) at 1. Takeda acknowledges that because the drug products are manufactured in Taiwan, the fact that the dexlansoprazole used to manufacture them is the solid amorphous form of dexlansoprazole does not establish infringement; rather, Takeda must establish that the *finished* product that will be imported and sold into the United States will contain amorphous dexlansoprazole in order to establish infringement. *Id.* at 6 (citing JSUF (Takeda Motion) ¶ 6).

In support of its contention that TWi's prior statements establish infringement of the '282 Patent, Takeda points first to the undisputed fact that TWi has informed the FDA that the active pharmaceutical ingredient used in the manufacture of its ANDA products is the amorphous form of dexlansoprazole. *Id.* at 2 (citing JSUF (Takeda Motion) ¶ 6). Takeda next cites the following statement made by TWi to the FDA in the ANDA relating to its layering process[9]:

[redacted]

[8] In its reply brief, TWi also cites *Eisai*'s holding that the plaintiff's claim seeking a declaratory judgment based on future infringement failed because the alleged future infringement depended on two contingent future events, namely, FDA approval of the ANDA and the manufacturer's decision to market the generic drug pursuant to the ANDA. *Id.* at 12 (citing 2007 WL 4556958, at *18). This argument goes to the question of whether Takeda can establish standing under the Declaratory Judgment Act, an argument that should have been raised in TWi's opening brief. As TWi raised this issue for the first time in its reply brief, the Court declines to rule on it, as discussed further below.

[9] In its brief, Takeda explains that TWi's drug products, as described in the ANDA, are capsules that contain multilayered "pellets," which control the release of the active ingredient. *Id.* at 3 (citing Declaration of Allan S. Myerson, PhD, in Support of Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("Myerson Decl."), Ex. 3 (Chen Dep. Ex. 40) at ANC-DEXL 0000437 & fig.)



Id. at 4 (citing Myerson Decl., Ex. 8 (Chen Dep. Ex. 51) at ANC-DEXL0000779; JSUF (Takeda Motion) ¶ 11). Takeda contends that this statement to the FDA indicates that TWi's ANDA products do not crystallize during the manufacturing process and therefore this statement is tantamount to an admission that the finished product contains the amorphous form of dexlansoprazole. *Id.*

This conclusion finds further support, Takeda argues, in the deposition testimony of TWi's 30(b)(6) witness, Dr. Shou-Chiung Chen, who is TWi's Vice President for Research and Development, that [redacted] *Id.* at 4 (citing Myerson Decl., Ex. 7 (Jun. 20, 2012 Chen Dep. Tr. 118:1-10, 123:24-124:6-8); JSUF (Takeda Motion) ¶ 10). Takeda also cites other statements made in this litigation that it contends are admissions that TWi's ANDA products contain amorphous dexlansoprazole. First, Takeda points to TWi's interrogatory responses stating that its "ANDA drug products do not contain a crystal or crystalline compound of dexlansoprazole . . . ." *Id.* at 4 (citing Myerson Decl., Ex. 9 (TWi's Responses and Objections to Plaintiffs First Set of Joint Interrogatories, July 28, 2011) at 17; JSUF (Takeda Motion) ¶ 14). Takeda also relies on TWi's paragraph IV letter to Takeda, which states that "the ANDA drug products do not include a crystal or crystalline compound of dexlansoprazole." *Id.* (citing

[redacted]

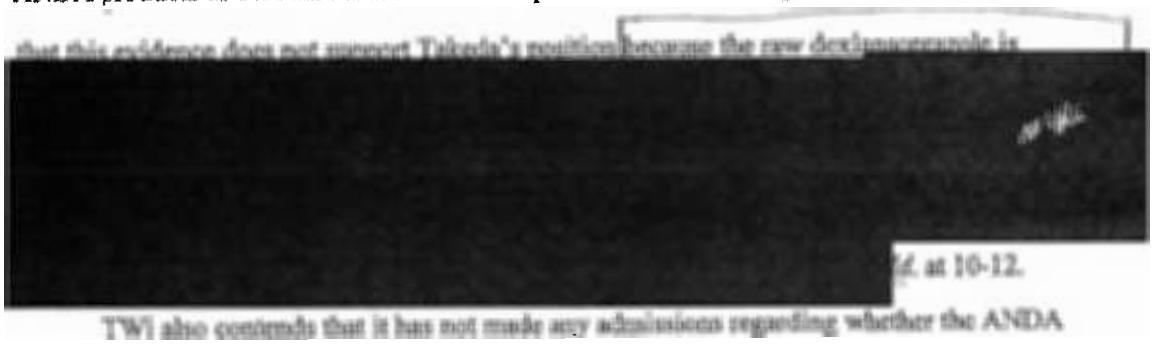
Myerson Decl., Ex. 10 at ANC-DEXL0000258; JSUF (Takeda Motion) ¶ 15). Based on this evidence, Takeda's expert, Dr. Myerson, concluded that TWi's ANDA products contain amorphous dexlansoprazole. *Id.* at 5, 7 (citing Expert Report of Allan S. Myerson, PhD, Regarding Infringement by TWi ("Myerson Report (TWi)" ¶¶ 22, 58-61). Dr. Myerson opines, *inter alia*, that if TWi's drug product is not crystalline, as TWi has admitted in its interrogatory responses and in its ANDA, "it must be the amorphous form of dexlansoprazole." Myerson Report ¶ 60. According to Takeda, because TWi has not offered any expert testimony to rebut the opinion of Dr. Myerson, there is no genuine dispute of material fact and it is entitled to summary judgment of infringement of the '282 Patent. *Id.* at 8.

b. TWi's Opposition

TWi argues that Takeda is not entitled to summary judgment of non-infringement because it has not pointed to any final product testing that shows that the form of the dexlansoprazole in the ANDA products is amorphous. TWi Opposition at 1. TWi points out that at claim construction, Takeda asked the Court to exclude dexlansoprazole molecules such as those mixed with solvents or air, from its construction of "an amorphous compound" and the Court agreed. *Id.* at 3 (citing Claim Construction Order at 37, 39-40, 47). Thus, TWi contends, for the purposes of this case, dexlansoprazole exists in three forms: 1) a crystalline solid, characterized by a molecular pattern over a long range; 2) an amorphous solid, which has no pattern over a long range; and 3) "where the dexlansoprazole molecules constitute neither a crystalline or an amorphous solid, *i.e.*, other." *Id.* at 3-4. According to TWi, in order to prevail on its summary judgment motion Takeda must offer evidence that establishes, as a matter of law, that the finished product is the amorphous form and not one of the other two forms of dexlansoprazole. *Id.* at 4. TWi contends that Takeda has failed to meet this burden. *Id.*

TWi notes that Takeda has acknowledged that it is required to establish that the finished product contains amorphous dexlansoprazole and further points to testimony by Takeda's expert conceding that he has not conducted any testing of TWi's ANDA products. *Id.* at 5-6. TWi further cites statements made by Takeda in this litigation that dexlansoprazole naturally tends to convert to crystalline form. *Id.* at 7-9. In light of these statements and admissions by Takeda,

TWi asserts, summary judgment of infringement of the '282 Patent is not warranted. *Id.* at 9. TWi further argues that Takeda relies on the use of amorphous dexlansoprazole to manufacture its ANDA products as evidence that the finished product contains amorphous dexlansoprazole, but



at 10-12.

TWi also contends that it has not made any admissions regarding whether the ANDA products contain amorphous dexlansoprazole, arguing that in its notice letter to Takeda it only stated that Takeda would be "unable to carry its burden of proof to show that the proposed ANDA products contain the claimed 'crystalline compound' or a 'crystal' of dexlansoprazole." *Id.* at 12. TWi also notes that its statements were made prior to the Court's claim construction and therefore do not constitute admissions that its ANDA products contain amorphous dexlansoprazole as that term has been construed by the Court in this action. *Id.* at 12-13.

c. Takeda's Reply

In its Reply brief, Takeda reiterates its position that it has offered significant evidence of infringement, including TWi's statements to the FDA and in this litigation and expert testimony, even if it has not conducted its own testing. Takeda Reply at 3. Takeda rejects TWi's suggestion that the dexlansoprazole in its ANDA products might take the form of "molecules in gases, solutions, and oils," asserting that there is no factual support for that position. *Id.* Takeda points out that in its Claim Construction order, the Court acknowledged that "typically amorphous materials used in oral pharmaceuticals are solids." *Id.* (citing Claim Construction Order at 48). Takeda further notes that at his deposition, TWi's expert was not able to name any orally-ingested non-solid amorphous materials used in pharmaceuticals. *Id.* (citing Takahashi Reply Decl., Ex. 2 (Dec. 9, 2011 Rogers Dep. Tr.) at 58:3 - 59:3, 72:6-20). Further, Takeda contends, TWi's statements to the FDA acknowledge that the dexlansoprazole in its ANDA products is in a solid form. *Id.* (citing Myerson Decl., Ex. 3 at ANC-DEXL0000438 (indicating that excipients used in

ANDA product fell below "limits for solid, oral dosage forms"); Myerson Decl., Ex. 8 at ANC-DEXL0000769 (same); Takahashi Reply Decl., Ex. 3 (ANC-DEL0000796) (statement in ANDA that a particular test was not performed on the ANDA product because it is "[n]ot applicable for solid oral dosage forms").

Takeda also cites the testimony of its own expert, Dr. Myerson, that [redacted] *Id.* at 4 (citing Mizerk Decl., Ex. A (Oct. 25, 2012 Myerson Dep. Tr.) at 116:16- 123:16 ("[W]e're forming a, basically, a solid . . . ."); *id.* ("[E]verything in there when this is done is a solid."). Dr. Myerson also testified that solids must be either crystalline or amorphous, and Takeda contends that the binary nature of solids is well-supported in the scientific literature. *Id.* (citing Decl. of Allan S. Myerson, Ph.D., in Support of Takeda's Opening Claim Construction Brief ("Myerson Claim Construction Decl.") ¶ 81 ("Solids can be crystalline or amorphous."), ¶ 23 ("Solids that are not crystalline and have no long range order . . . are said to be amorphous."); Myerson Rep. ¶ 22 (same); Myerson Claim Construction Decl., Ex. 11 at DEX0014516 ("The terms amorphous and non-crystalline are synonymous . . . and can be used interchangeably."); *id.*, Ex. 12 at DEX0014612 ("[N]ot all solids are crystals. Materials that have short-range rather than long range ordering . . . are non-crystalline solids. A noncrystalline solid is often referred to as an amorphous solid."); *id.*, Ex. 13 at DEX0014769 ("A liquid may solidify in two ways: . . . to a crystalline solid or . . . to an amorphous solid."); *id.*, Ex. 27 at DEX0014491 (defining "[a]morphous [s]olid" as "[a] noncrystalline solid"); Expert Decl. of Robin D. Rogers in Support of Handa Pharmaceuticals, LLC's Opening Markman Brief ("Rogers Claim Construction Decl."), Ex. 3 at DEX0003649 ("Some authors [] sub-divide solids into crystalline and amorphous."); *id.*, Ex. 4 at IPXL-0009902 (defining "amorphous" as "[n]oncrystalline . . ."); *id.*, Ex. 5 at IPXL-0010285 (same); Takahashi Reply Decl., Ex. 2 (Dec. 9, 2011 Rogers Dep. Tr.) at 19:5-13; Rogers Claim Construction Decl. ¶ 30 ("[T]he term 'amorphous' is an adjective that is synonymous with 'noncrystalline.'"); *id.* ¶¶ 28-29).

Barberich references. *Id.* at 15. TWi points to the following undisputed facts to show that the claimed "amorphous compound" of dexlansoprazole or salt thereof described in claim 1 of the '282 Patent is disclosed in Larsson: 1) Larsson discloses dexlansoprazole, *id.* at 16 (citing JSUF (Twi Motion) ¶ 95); 2) Larsson discloses making salts with dexlansoprazole, *id.* (citing JSUF (TWi Motion) ¶ 96; and 3) pharmaceutical salts of dexlansoprazole prepared by "conventional processes" are claimed in claim 1 of Larsson II, U.S. Patent No. 5, 948,789, *id.* (citing JSUF (TWi Motion) ¶ 82). Further, these disclosures are presumed to be enabled, TWi asserts, because they are disclosed in a U.S. patent. *Id.* at 16 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012) ("both claimed and unclaimed materials disclosed in a patent are presumptively enabling."). With respect to the "pharmaceutical composition" limitation of claim 2, TWi points to the disclosure in Larsson of the use of dexlansoprazole "in medicine." *Id.* (citing Mizerk Decl., Ex. 4 and 5).

As to Barberich, TWi cites to the following undisputed facts: 1) Barberich discloses dexlansoprazole; 2) Barberich discloses making pharmaceutical salts with dexlansoprazole; 3) Barberich discloses dexlansoprazole as a "flowable powder"; 4) Barberich discloses specific examples of tablets and capsules, both of which are solid dosage forms, containing dexlansoprazole. *Id.* (citing JSUF (TWi Motion) ¶¶ 97-99, 101). TWi further cites testimony by Takeda's experts, Drs. Myerson and Atwood, in which they "specifically admit that even the oil from Larsson could be used to prepare a salt of dexlansoprazole." *Id.* at 16-17 (citing JSUF (TWi Motion) ¶ 83 (citing Mizerk Decl., Ex. 10 (Oct. 16, 2012 Atwood Dep. Tr.) at 255-56); Mizerk Decl., Ex. 12 (Oct. 25, 2012 Myerson Dep. Tr.) at 131). In fact, TWi asserts, there is no dispute that preparation of the salts described in claim 1 of the '282 Patent is not difficult using methods known in 1999, as inventor Keiji Kamiyama conceded. *Id.* at 17 (citing Mizerk Decl., Ex. 11 (July 11, 2012 Kamiyama Dep. Tr.) at 153). Based on these undisputed facts, TWi contends that both Larsson and Barberich anticipate the asserted claims of the '282 Patent.

ii. Written Description

If Takeda takes the position that Larsson and Barberich do not disclose the salts claimed in claim 1 of the '282 Patent and their use with pharmaceutical excipients (described in claim 2),

Takeda rejects TWi's contention that the fact that the dexlansoprazole used to manufacture its ANDA products is amorphous has no bearing on the form of the dexlansoprazole in the finished product. *Id.* at 6. Rather, Takeda cites testimony by Dr. Myerson that [redacted] *Id.* (citing Myerson Decl., Ex. 3 at ANC-DEXL0000458; Myerson Report ¶ 58; JSUF (Takeda Motion) ¶ 12) [redacted] *Id.* (citing Myerson Decl., Ex. 7 (Jun. 20, 2012 Chen Dep. Tr.) at 94:19-95:3; 118:1-10, 123:24-124:8).

Takeda argues that testing is not required to show infringement, contrary to TWi's assertions, and that in the face of the evidence offered by Takeda, TWi has failed to produce specific evidence demonstrating the existence of a genuine dispute of fact. *Id.* at 7-8 (citing *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009)).

3. Validity of the '282 Patent

a. TWi Motion

TWi contends in its summary judgment motion that claims 1 and 2 of the '282 patent are anticipated by Larsson[10] and Barberich.[11] TWi SJ Motion at 15-17. In the alternative, TWi argues, the asserted claims of the '282 Patent are invalid because they are not supported by sufficient written description in the specification. *Id.* at 17-19.

i. Anticipation

According to TWi, even if there is a factual dispute about whether Larsson discloses pure dexlansoprazole as an amorphous solid, the undisputed facts establish that the dexlansoprazole "salts" and "compositions" claimed in the '282 patent are anticipated by both the Larsson and

[10] "Larsson" refers to WO 96/02535 ("Larsson I") and U.S. Patent No. 5,948,789 ("Larsson II"). Larsson I and II are attached as Exhibits 4 and 5, respectively, of the Mizerk Declaration. The parties agree that there is no material difference between the disclosures of Larsson I and II. JSUF (TWi Motion) ¶ 92.

[11] Barberich" refers to WO 99/38513 ("Barberich I") and U.S. Patent App. No. 2003/0008903 ("Barberich II"). Barberich I and II are attached as Exhibits 6 and 7, respectively, of the Mizerk Declaration. The parties agree that there is no material difference between the disclosures of Barberich I and II. JSUF (TWi Motion) ¶ 94.

TWi contends, it must implicitly concede that the '282 Patent does not contain adequate written description of these claimed features. *Id.* at 17-19. According to TWi, Takeda admits that there is no explicit description in the '282 Patent of the salts claimed in claim 1 or their use with any pharmaceutical excipients and that there is no way to know whether such salts, if made, would be amorphous or crystalline. *Id.* at 18 (citing JSUF (TWi Motion) ¶ 84 (citing Mizerk Decl., Ex. 10 (Oct. 16, 2012 Atwood Dep. Tr.) at 347-349)). TWi also cites deposition testimony by the inventor, Keiji Kamiyama, that as far as he knew, no one at Takeda had actually made any salts of dexlansoprazole before 1999 and that "no one at Takeda, including the inventors, even attempted to incorporate amorphous dexlansoprazole in a pharmaceutical formulation." *Id.* (citing JSUF (TWi Motion) ¶87 (citing Mizerk Decl., Ex. 11 (July 11, 2012 Kamiyama Dep. Tr.) at 153-156)). *Id.* According to TWi, this evidence is sufficient to establish, as a matter of law, that the specification of the '282 Patent does not have sufficient written description to show that the inventors were in possession of the claimed invention. *Id.* at 18-19 (citing 35 U.S.C. § 112; *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344, 1351-1352 (Fed. Cir. 2010) (en banc); *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1362-1364 (Fed. Cir. 2011)).

b. Takeda's Opposition

i. Anticipation

Takeda rejects TWi's anticipation theory, arguing that neither Larsson nor Barberich discloses dexlansoprazole as an amorphous solid in salt form.[12] According to Takeda, TWi's position as to Larsson is based on the proposition that Larsson inherently discloses an amorphous salt of dexlansoprazole because it expressly discloses the synthesis of an oil of dexlansoprazole and "[t]he obtained products may thereafter be converted to pharmaceutically acceptable salts thereof by conventional processes." Takeda Opposition at 22 (citing JSUF (TWi Motion) ¶¶ 95-96; Mizerk Decl., Ex. 5 (Larsson II) at col.1, ll.14-17). Takeda does not dispute that at the

[12] Takeda does not challenge TWi's assertions that Larsson or Barberich disclose the "pharmaceutical composition" element of claim 2 of the '282 Patent.

priority date, a person of ordinary skill in the art would have been aware of conventional methods for making salts. *Id.* Takeda argues that such a person would not, however, have known how to make an amorphous salt of dexlansoprazole that was a solid, as is required under the Court's claim construction. *Id.* (citing Claim Construction Order at 71).

First, Takeda points out that TWi does not cite any expert testimony from Dr. Rogers, TWi's expert on invalidity, that the salt made from the dexlansoprazole oil disclosed in Larsson would be a solid. *Id.* at 23. Takeda also cites the testimony of its own expert, Dr. Atwood, that "[i]f one started with dexlansoprazole as a solid and carried out the reaction, then one should end up with a solid salt [but that] [i]f one started . . . with an oil, one might well end up with an ionic liquid, an oil." *Id.* at 23 (quoting Purles Opposition Decl., Ex. 16 (Oct. 16, 2012 Atwood Dep. Tr.) at 201:4-13). The testimony of Dr. Kamiyama that TWi cites -- that it was easy to prepare an amorphous salt of dexlansoprazole that is solid -- is not relevant, Takeda contends, because Dr. Kamiyama was testifying about the synthesis of amorphous salts conducted in 2000, after the priority date of the '282 Patent; moreover, Takeda argues, the only evidence in the record is that in the experiments Dr. Kamiyama was describing, he used solid forms of dexlansoprazole as starting materials rather than an oil. *Id.* (citing Purles Opposition Decl., Ex. 17 (July 11, 2012 Kamiyama Dep. Tr.) at 151:11-152:14; *id.*, Ex. 18 (Dep. Ex. 700 (U.S. Patent No. 7,271,182, assigned to Drs. Kamiyama and Hashimoto), at Reference Example 1 and Examples 4 and 5 (describing synthesis of amorphous salts from crystalline dexlansoprazole)). Because TWi has not produced any evidence that shows that the salt made from the oil disclosed in Larsson would necessarily be a solid, Takeda argues, TWi has not established by clear and convincing evidence that Larsson inherently anticipates claim 1 of the '282 Patent. *Id.* at 24.

Second, Takeda argues that Barberich also does not anticipate the asserted claims because it does not disclose the synthesis of any solid form of dexlansoprazole, but merely incorporates by reference the synthesis methods disclosed in prior art such as Larsson. Because Larsson also does not disclose the synthesis of a solid form of dexlansoprazole as a salt, Barberich is not enabled, Takeda contends. *Id.* at 23-24 (citing Atwood Report ¶ 70-71, 100-106; *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003)).

Finally, Takeda argues that TWi's "dexlansoprazole salt" theory should not be considered because it was not raised during discovery and therefore is in violation of Patent Local Rule 3-3. *Id.* at 22-23 (citing Patent L.R. 3-3(a), (c); Purles Opposition Decl., Ex. 15 (Invalidity Contentions) at 66; *02 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355 (Fed. Cir. 2006)).

ii. Written Description

Takeda argues that claims 1 and 2 of the '282 patent are not invalid for lack of adequate written description. *Id.* at 24. Takeda does not dispute that there is no explicit description in the '282 Patent of the amorphous salt of claim 1 or its use in a pharmaceutical composition but contends that the written description requirement is satisfied because the '282 Patent discloses the synthesis of an amorphous solid of dexlansoprazole and describes specific examples of salts of dexlansoprazole. *Id.* According to Takeda, this disclosure "in combination with conventional processes that TWi admits were in the prior art," would be sufficient to describe an amorphous solid salt of dexlansoprazole to a person of ordinary skill in the art. *Id.* (citing '282 Patent, col.1, l. 65 - col. 2, l. 2; col. 2, ll. 3-10; Atwood Report ¶ 121)).

Takeda argues that actual reduction to practice is not required to satisfy the written description requirement, so long as one of skill in the art can "visualize or recognize" the claimed invention based on the disclosure in the specification. *Id.* (citing *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011); *Volterra Semiconductor Corp. v. Primarion, Inc.*, 796 F. Supp. 2d 1025, 1064 (N.D. Cal. 2011)). Takeda points to the testimony of Drs. Atwood and Kamiyama, which Takeda contends supports the conclusion that the '282 Patent contains adequate written description of a solid salt of dexlansoprazole. *Id.* at 25 (citing Purles Opposition Decl., Ex. 16 (Oct. 16, 2012 Atwood Dep. Tr.) at 201:4-13 (testifying that "[i]f one started with dexlansoprazole as a solid and carried out the reaction, then one should end up with a solid salt."); *id.*, Ex. 17 (July 11, 2012 Kamiyama Dep. Tr.) at 153:5-22 (testifying that it was "not that difficult" to prepare an amorphous solid salt of dexlansoprazole from an amorphous solid compound of dexlansoprazole). Moreover, Takeda asserts, the person of ordinary skill in the art in 1999 would have understood the inventors of the '282 Patent had possession of a

pharmaceutical composition of an amorphous solid salt of dexlansoprazole in light of the fact that such a person would have understood from prior art such as Barberich how to make a solid dosage form of dexlansoprazole. *Id.* (citing Mizerk Decl., Ex. 7 (Barberich II) at 4 (Example 2); Atwood Report ¶ 122; Purles Opposition Decl., Ex. 19 (Nov. 9, 2012 Rogers Dep. Tr.) at 65:9-16 (admitting that the teachings of Larsson could be used to make a pharmaceutical composition)). Thus, Takeda asserts, the evidence at a minimum creates a factual dispute as to whether one skilled in the art would have understood Takeda's invention to encompass salts of the amorphous solid of dexlansoprazole, precluding summary judgment of invalidity for lack of adequate written description.

c. TWi Reply

i. Anticipation

TWi asserts that Takeda has conceded that both Larsson and Barberich disclose amorphous and crystalline salts of dexlansoprazole, thus supporting entry of summary judgment of anticipation. TWi Reply at 14. TWi rejects Takeda's reliance on the testimony of its expert, Dr. Atwood, that a salt of dexlansoprazole made using conventional processes "might or might not" be a solid, pointing to testimony by Dr. Atwood in which he stated that "typically one would expect the salt to be a solid." *Id.* (citing JSUF (TWi Motion) ¶ 82). TWi further contends that whether one starts with a solid or an oil is irrelevant as Takeda admits that the first step of preparing a salt is dissolving the dexlansoprazole in a solvent. *Id.* (citing JSUF (TWi Motion) ¶¶ 87-89). According to TWi, "[g]iven that Dr. Atwood testified that [the] expectation is that the salt would be a solid, Takeda has not rebutted the presumption that the Larsson and Barberich references disclose the claimed solid dexlansoprazole salts." *Id.* (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012)). Because Takeda has failed to come forward with evidence that the disclosures of Larsson and Barberich are not enabled, TWi argues, this prior art anticipates claim 1. *Id.* Further, TWi asserts, Takeda did not address in its Opposition brief TWi's argument that Larsson and Barberich disclose the "pharmaceutical composition" required under claim 2 of the '282 Patent. *Id.*

ii. Written Description

TWi argues that Takeda's assertion that dexlansoprazole subjected to conventional processes is sufficient disclosure to meet the written description argument is inconsistent with its position as to anticipation. *Id.* According to TWi, "Takeda cannot have it both ways." *Id.* To the extent Takeda argues that Larsson and Barberich do not disclose the claimed salts, the written description in the '282 Patent is insufficient, TWi asserts. *Id.*

4. Infringement of the '755 Patent

a. TWi Motion

TWi contends that it is entitled to summary judgment of non-infringement of the '755 Patent because Takeda has not demonstrated a genuine issue of material fact regarding whether "composition (ii)" of TWi's ANDA products "beings to release" the active ingredient at a pH level of 5.0. TWi SJ Motion at 2. In support of this position, TWi makes the following arguments: 1) Takeda has offered evidence based on tests of expired product and therefore, this evidence is inadmissible under *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir. 1995); 2) Takeda's expert testimony based on these tests is inadmissible under *Daubert* because the tests were "created solely for this litigation and ignored other testing showing contrary results;" and 3) even if they are considered, the test results upon which Takeda relies show that TWi's ANDA products begins to release active ingredient at pH less than 5.0 and therefore do not infringe under the Court's claim construction. *Id.*

Regarding the use of expired product, TWi relies on undisputed facts, namely, that: 1) the drug samples used in the Advantar tests that were the basis for Dr. Charman's expert report were manufactured on May 21, 2010; 2) the tests were conducted after Advantar received the samples of TWi's ANDA products, on June 29, 2012; and 3) [redacted] *Id.* at 4 (citing JSUF (TWi), ¶¶ 28-31; Mizerk Decl., Ex. 1 at ¶ 46). TWi contends that under these circumstances, Dr. Charman's conclusions are not sufficiently tied to the facts of the case to satisfy *Daubert* because FDA regulations do not permit the sale of expired product and therefore, the expired product is not the one that will infringe if the ANDA is approved. *Id.* at 5 (citing *Pooshs v. Philip Morris USA, Inc.*, 2012 WL 5199450, at *2 (N.D. Cal. Oct. 22, 2012); *In*

re Brimonidine Patent Litig., 643 F.3d 1366, 1377 (Fed. Cir. 2011)). According to TWi, under similar circumstances, courts have found that opinions based on results obtained from testing expired product are not admissible. *Id.* (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 2002 WL 1613724, at *2 (N.D. Ill. 2002); *Apotex, Inc. v. Cephalon, Inc.*, 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012)).

TWi also argues that Dr. Charman's opinions should be found unreliable under *Daubert* because they were based solely on tests conducted for this litigation and ignored results obtained by Advantar in tests that were conducted for Takeda's counsel before Dr. Charman was retained. *Id.* at 5-10.[13] According to TWi, at the claim construction stage of the case, Dr. Charman could not state what testing methodology should be used to determine whether his definition of the release claim term was met and could not say how much release would be required to find that a drug product begins to be released at the 5.0 pH threshold. *Id.* (citing Docket No. 59, Ex. 2 (Charman Dep.) at 112:8-113:1, 122:21-123:5). It was only after Dr. Charman reviewed the test results in Advantar's June 29, 2012 report, which were obtained using a testing protocol developed by Advantar based on its prior testing and recommended to Dr. Charman by Advantar, that Dr. Charman concluded that the "begins to release" requirement means release of more than 10% of the total drug in the product after two hours. *Id.* at 7. According to TWi, Dr. Charman's reliance on Advantar's testing protocol indicates that the methodology is not scientifically acceptable. *Id.* at 9.

TWi further contends that Dr. Charman's methodology is inconsistent with Takeda's position at the claim construction stage of the case, when Takeda argued that a person of ordinary skill in the art would know how to test to assess whether the release term is met based on the prosecution history. *Id.* at 9-10. According to TWi, the test referenced by Takeda was not used by Dr. Charman. *Id.* at 10. TWi further asserts that in Takeda's '755 Patent contentions, Takeda referenced in vitro release profiles to show that its Dexilant product was covered by the '755

[13] The undisputed facts relating to the earlier Advantar testing, including the results of that testing, are set forth in JSUF (TWi Motion) ¶¶ 33-62.

Patent, referencing tests that differed from those conducted by Dr. Charman. *Id.* (citing JSUF (TWi Motion) ¶¶ 79, 81).

TWi also argues that under the "proper claim construction," there is no material dispute that TWi's ANDA products begin to release active ingredient at a pH level below 5.0. *Id.* (citing JUSF (TWi Motion) ¶¶ 43-70). [redacted] *Id.* (citing JSUF (TWi Motion) ¶ 66) [redacted] *Id.* at 10-1 (citing JSUF (TWi Motion) ¶ 66). TWi asserts that these amounts are particularly significant because [redacted] of the total active ingredient in TWi's ANDA products is contained in the granules alleged to constitute the "composition (ii)" granules. *Id.* at 11 (citing JSUF (TWi Motion) ¶ 25).

According to TWi, Dr. Charman's "10%/two-hour time point is completely arbitrary, and in the case of TWi, appears to have been selected because significant release begins at the two-hour time point and even greater release occurs before the 2 1/2 hour time point is reached under Dr. Charman's testing." *Id.* (citing JSUF (TWi Motion) ¶¶ 43-70). TWi further contends that the '755 Patent specification indicates that release should be measured over at least 5 hours. *Id.* (citing '755 Patent, col. 10, ll. 13-17) ("The rate of elution of active ingredient from the active ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8"). In addition, according to TWi, during patent prosecution, the inventor testified that at a pH level of 6.8, the "composition (i)" disclosed in the '755 Patent, which was designed to release at pH 6.75, the granule "begins to release" after about 3.5 hours. *Id.* (citing JSUF (TWi Motion) ¶ 74 (citing testimony of Takashi Kurasawa)). TWi contends that this testimony contradicts Dr. Charman's position that release should be measured at two hours. *Id.* TWi also notes that in its interrogatory responses, Takeda cited testing of its own Dexilant

product to show that it began to release between pH levels 6.5 and 7.0 even though it took more than two hours to release 10 % of the API. *Id.* (citing JSUF (TWi Motion) ¶ 80).

TWi also argues that Takeda's position amounts to a request for a new claim construction which should be rejected as untimely. *Id.* at 12. Further, it asserts, if this new construction of the release term is adopted, the claim is invalid because the question of how much API must be released to meet the "begins to release requirement" is insolubly ambiguous to a person skilled in the art. *Id.* at 12-13.

b. Takeda Opposition

Takeda does not dispute that the Advantar test results show some measurable release of dexlansoprazole at pH levels below 5.0. It contends, however, that the small amount of dexlansoprazole that is released at pH levels below 5.0 is not sufficient to place the ANDA products outside the scope of the claim and further, that this is a factual issues that can only be resolved at trial. Takeda Opposition at 2. Takeda notes that the Court explicitly declined to specify at the claim construction stage of the case what type of testing would be required to determine whether the release term was satisfied, leaving this question to be addressed at trial through expert testimony. *Id.* at 3-4. This approach is consistent with Federal Circuit precedent, Takeda asserts, pointing to cases holding that courts need not eliminate all ambiguity in construing claim terms but rather, should only define terms to the level of specificity that is warranted by the language of the claim and the evidence. *Id.* at 4 (citing *Acumed LLC v. Strkyer Corp.*, 483 F.3d 800 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351 (Fed. Cir. 1998); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341 (Fed. Cir. 2001); *Modine Mfg. Co. v. Int'l Trade Comm'n*, 75 F.3d 1545 (Fed. Cir. 1996)). According to Takeda, "where 'the claim language does not require a particular form of testing, this inquiry is not a claim construction question' but is 'review[ed] . . . as a question of fact.'" *Id.* at 5 (quoting *Union Carbide Chems. and Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366, 1377 (Fed. Cir. 2005), overruled on other grounds by *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009)).

Takeda argues further that there is a genuine dispute of material fact as to the testing criteria that should be used to decide whether TWi's ANDA products meet the release limitation and that substantial evidence supports Dr. Charman's approach. *Id.* Takeda points to the following evidence in support of Dr. Charman's approach:

- the monograph on dissolution testing in the United States Pharmacopeia ("USP"), which recognizes that for delayed-release dosage forms, a product passes a dissolution test if no individual dosage unit shows more than 10% dissolution in acid medium. *Id.* at 6 (citing Charman Decl., Ex. B.21 (2012 USP section on dissolution) at 301, Acceptance Table 3; Takahashi Decl., Ex. F (1995 USP section on dissolution) at 1796, Acceptance Table 2 (same)).
- the USP section on delayed release lansoprazole (which is an enantiomer of dexlansoprazole), which "permits dissolution of less than 10% in the acid stage in a two-stage experiment designed to simulate passage through an acidic stomach (in the first stage) followed by simulated intestinal dissolution (in the second stage)." *Id.* (citing Takahashi Decl., Ex. G (2009 USP section on lansoprazole delayed-release capsules) at 2753 (stating as to acid stage "[t]olerances" that "[n]ot more than 10% of the labeled amount of [lansoprazole] is dissolved in 60 minutes")).
- the FDA's Dissolution Methods Database entry for dexlansoprazole, recommending that in testing dexlansoprazole dissolution, sampling for the acid stage should be conducted at 120 minutes. *Id.* at 7 (citing Takahashi Decl., Ex. P (Dissolution Methods)).
- testimony by Impax's expert, Dr. Augsburger, that once the delayed release product reaches its target pH, the release should be "relatively rapid." *Id.* (citing Purles Decl., Ex. 6 (Nov. 6, 2012 Augsburger Dep. Tr.) at 116:6-18).
- the statement in the '755 Patent specification noting that "the usual enteric coat" dissolves "rapidly." *Id.* (citing '755 Patent, col. 6, l. 66 - col. 7, l. 12).
- Dr. Charman's deposition testimony that "any meaningful test for infringement must have an amount limitation to account for small amounts of dissolution that inevitably occur in any in vitro dissolution test of any significant duration," especially in light of

manufacturing defects that commonly result in inappropriately coated or uncoated drug in the formulation. *Id.* (citing Purles Decl., Ex. 7 (Nov. 1, 2012 Charman Dep. Tr.) at 58:16-59:8).

Takeda argues that TWi's reliance on the '755 Patent specification and prosecution history is misplaced. *Id.* at 8. As to TWi's reliance on col. 10, ll. 13-17 of the '755 Patent, stating that "[t]he rate of elution of active ingredient from the active ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8," Takeda contends that the specification makes clear that the threshold pH for this formulation was "6.75 or above." *Id.* (citing '755 Patent, col. 10, l.2). In other words, according to Takeda, "'rapid and significant' release for this particular embodiment would only be expected at a pH of 6.75 or higher." *Id.* Takeda reasons, "[t]hat release was relatively slow and minimal at pH 6.0, a pH level significantly below the target pH of this particular embodiment, is in no way inconsistent with Dr. Charman's opinion that the claimed formulation should show rapid and significant dissolution above its target pH." *Id.* Takeda asserts that it has shown as to TWi's formulation significant and rapid release of dexlansoprazole at target pH levels of 5.9 and 7.4, which falls within the scope of the '755 claims. *Id.*

Takeda also rejects TWi's contention that the dissolution testing of Dr. Kurasawa cited by the applicants during patent prosecution contradicts Dr. Charman's position. *Id.* According to Takeda, Dr. Kurasawa's test was conducted at pH 6.8, a pH level "much lower than the pH 7.5 upper end of the pH range for the high-pH granule described in claim 1." *Id.* Thus, it contends, "[t]hat the granule released drug slowly at pH level of 6.8 does not indicate how rapidly the drug would release within two hours at the higher pH of 7.5, and thus in no way undermines Dr. Charman's opinion." *Id.*

Takeda argues that TWi's reliance on its interrogatory responses regarding statements in its New Drug Application ("NDA") addressing whether Dexilant was covered by the '755 patent -- which described testing of its own product -- is also misplaced. *Id.* at 8-9. Takeda does not dispute that different tests were used but argues that the test described in the interrogatory

response was "merely intended to show that the behavior of the Dexilant granules as reflected in the NDA tests was consistent with the limitations of the '755 patent: the low-pH granules in Dexilant dissolved and completely released drug at pH 6.0 within two hours, and the high-pH granules dissolved and completely released drug within 2 hours at pH levels of 7.0, 7.2, and 7.5." *Id.* at 9 (citing Purles Decl., Ex. 9 (NDA Excerpt) at DEX0011277-82; Charman Decl. ¶ 27). According to Takeda, the NDA experiments were designed to show complete release of drug rather than to test for infringement and therefore were not designed to determine the pH level at which release begins. *Id.* (citing Charman Decl. ¶ 27).

Takeda also rejects TWi's contention that Dr. Charman's opinions do not satisfy the requirements of Rule 702 of the Federal Rules of Evidence and *Daubert*. *Id.* According to Takeda, there is no "off-the-shelf" dissolution test for determining whether drug release *does not* occur below a given pH; rather, dissolution testing is typically used to establish the amount of dissolution that occurs at a particular pH. *Id.* (citing Charman Decl. ¶ 8). Therefore, it asserts, Advantar was required to design a customized dissolution test. *Id.* The fact that the test was developed for this litigation, however, does not render the test inadmissible, Takeda argues. *Id.* at 10-11. Rather, according to Takeda, expert testimony prepared for litigation is admissible if "the experts . . . explain precisely how they went about reaching their conclusions and point to some objective source -- a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like -- to show that they have followed the scientific evidence method, as it is practiced by (at least) a recognized minority of scientists in their field." *Id.* at 11 (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir. 2003)).

Here, Takeda asserts, Dr. Charman has developed a test that is supported by scientific principles and objective sources. *Id.* at 11-12 (citing Charman Report ¶¶ 58-81; Charman Decl. Exs. B.3, B.4 and B.5 (Advantar reports)). Takeda argues that TWi has not identified any specific ways in which Dr. Charman's testing fails to adhere to scientific method or lacks objective support and its assertion that Takeda manipulated the prior test results by modifying the protocol to omit the use of the surfactant sodium dodecyl sulfate ("SDS") or use a two-stage test are

unfounded. *Id.* at 12. Takeda contends that Dr. Charman's decision not to use SDS in the tests upon which he based his report, even though SDS had been used in the earlier tests conducted by Advantar, was based on Advantar's conclusion that the SDS was causing the enteric coating of the low pH granules to disintegrate below the target pH level. *Id.* at 12-13 (citing Charman Decl. ¶¶ 19-22; Takahashi Decl., Ex. J (May 9 Report) at DEX1672037). Takeda points out that TWi also conducted dissolution testing of dexlansoprazole granules without using SDS. *Id.* at 13 (citing Purles Decl., Ex. 20 (Dep. Ex. 110) at ANC-DEXL0006471 (setting forth a protocol for dissolution testing that does not include SDS); *id.*, Ex. 10 (Nov. 8, 2012 Gray Dep. Tr.) at 31:17-32:3, 57:19-59:20). Furthermore, Takeda asserts, Dr. Charman testified that he never contemplated including the use of SDS in Advantar's testing protocol for dissolution testing of dexlansoprazole. *Id.* (citing Purles Decl. Ex. 7 (Nov. 1, 2012 Charman Dep. Tr.) at 109:22-112:24; *id.* Ex. 1 (Oct. 31, 2012 Charman Dep. Tr.) at 196:2-198:2).

Takeda also argues that a February 7, 2012 email from Takeda's counsel asking Advantar if SDS should be used in the dissolution medium and whether a two-stage test should be used does not support TWi's assertion that Takeda acted improperly. *Id.* at 13 (citing Mizerk Decl., Ex. 1-R at DEX1678010 (Feb. 7, 2012 email). According to Takeda, these questions do not show any improper conduct on its part given that TWi has conducted dissolution tests that do not use SDS and a two-stage approach is provided for in the USP. *Id.* (citing Purles Decl., Ex. 11 (Jun. 20, 2012 Chen Dep. Tr.) at 186:9-19 (testimony from TWi's 30(b)(6) witness that "for the R&D experiment, we don't use any SDS in the medium")). Takeda also notes that Dr. Charman made several changes to the Advantar testing protocols, further undermining TWi's position. *Id.* (citing Charman Report ¶ 60). According to Takeda, the prior testing by Advantar has no bearing on the admissibility of Dr. Charman's tests and at most goes to the weight of the evidence. *Id.* at 14 (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998)). Takeda also cites testimony of the experts of the other Defendants in the related cases that they found Dr. Charman's testing to be "reasonable," even though they believed SDS should be included in the dissolution medium. *Id.* (citing Purles Decl., Ex. 5 (Nov. 14, 2012 Amiji Dep. Tr.) at 110:24-111:19; *id.*, Ex. 6 (Nov. 6, 2012 Augsburger Dep. Tr.) at 49:19-50:19, 51:9-52:4). In addition, to

the extent TWi challenges Dr. Charman's interpretation of the test results, Takeda argues, this is a question that goes to the weight of the evidence, not its admissibility. *Id.* at 15 (*Gutierrez v. Johnson & Johnson*, 2006 WL 3246605, at *8 (D.N.J. Nov. 6, 2006); *Tristrata Tech., Inc. v. Mary Kay, Inc.*, 423 F. Supp. 2d 456, 463–64 (D. Del. 2006); *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 962545, at * 13 (E.D. Pa. June 28, 2000)).

Takeda rejects TWi's assertion that Dr. Charman's results are inadmissible because expired product was used by Advantar. *Id.* at 16. According to Takeda, "there is 'no reason to assume that on the date a product is no longer within the FDA-required shelf life for the purposes of commercialization, it also ceases to be structurally representative of the product.'" *Id.* at 16 (quoting *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 495 (S.D.N.Y. 2007)). Takeda notes that TWi has not provided any evidence showing that the expired samples were not representative of its ANDA products. *Id.* (citing *Roche Palo Alto LLC v. Ranbaxy Labs., Inc.*, 2009 WL 3261252, at *13 n.26 (D.N.J. Sept. 30, 2009)) [redacted] *Id.* (citing Purles Decl., Ex. 11 (Jun. 20, 2012 Chen Dep. Tr.) at 176:6-8). As the Advantar tests were conducted within this [redacted] period, Takeda asserts, TWi cannot now assert that the test results are not relevant to its ANDA products. *Id.* Takeda also notes that TWi's expert, Dr. Gray, had the same batch tested as Dr. Charman. *Id.* (citing Purles Decl., Ex. 10 (Nov. 8, 2012 Gray Dep. Tr.) at 39:17-45:21 (representation from TWi's counsel that the samples tested by Boston Analytical are from the same batch as the samples provided by TWi to Takeda); *id.*, Ex. 13 (Gray Rep. Ex. N) at 1 (Boston Analytical Report, signed Oct. 18, 2012); Charman Rep. ¶ 82).

Finally, Takeda rejects TWi's contention that if Dr. Charman's approach is accepted the claim will be rendered indefinite, an argument that it contends was already rejected by the Court and has no merit. *Id.* at 16-18.

Accordingly, Takeda argues that TWi is not entitled to summary judgment of non-infringement of the '755 Patent because there is a genuine issue of material fact that must be resolved at trial.

c. TWi Reply

In its Reply brief, TWi reiterates its position that Dr. Charman's approach is not supported by any acceptable scientific methodology, arguing that because the test was developed for litigation, it is presumed to be inappropriate and Takeda bears the burden of showing that the results are reliable -- a burden TWi contends has not been met. TWi Reply at 2 (citing *Cooper v. Brown*, 510 F.3d 870, 944 n. 29 (9th Cir. 2007)). TWi rejects Takeda's explanation that in developing the test, "Takeda and Advantar were guided by the fact that Dexilant is a preferred embodiment of the '755 patent, and thus could be expected to meet the claim limitations." *Id.* at 4 (citing Takeda Opposition at 12). This approach is improper, according to TWi, because "[i]t is legally impermissible to determine infringement by comparing an accused device to the patentee's product." *Id.* (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1347 (Fed. Cir. 2003)).

TWi also objects to Takeda's reliance on the declaration offered by Dr. Charman in support of Takeda's opposition brief, in which he explains why he made certain choices in designing the Advantar tests. *Id.* at 4-6. TWi contends Dr. Charman merely combined components from various tests in the field, asserting that "Takeda's 'Frankenstein' dissolution test simply was not the product of any acceptable scientific methodology." *Id.* at 5. TWi further asserts that Takeda should be precluded from relying on the declaration because it is untimely. *Id.* at 5 (citing *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358 (Fed. Cir. 2011); *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001); *Quevedo v. Trans-Pacific Shipping, Inc.*, 143 F.3d 1255, 1258 (9th Cir. 1998)). According to TWi, the declaration also should be disregarded because it contradicts Dr. Charman's earlier testimony. *Id.* In particular, TWi points to Dr. Charman's statement in his declaration that "[p]hotographs of the granules taken at the conclusion of experiments, with and without SDS, demonstrate that SDS is interacting with the enteric polymer in the coat of the low-pH granules...." *Id.* (citing Charman Decl. ¶ 22). TWi asserts that Dr. Charman "expressed no such opinion in his report or at his deposition" and further points to the following statements in the March 12, 2012 and May 9, 2012 Advantar reports that TWi contends conflict with this opinion: 1) "The mechanism whereby SDS reduces lag time for

release is unknown." *Id.* (citing Mizerk Decl., Ex. 17 at DEX1672899 (emphasis added); Mizerk Decl., Ex. 1 at Ex. H at DEX1671969 (same)); 2) "The SDS effect does not appear to relate to elevated solubility limits for DEX. Rather a direct effect on the granule enteric coating or possibly granule contents seems *likely*." *Id.* (citing Mizerk Decl., Ex. 17 at DEX1672901 (emphasis added in TWi brief)); and 3) "Specifically, additional investigations should include the following: . . . Further study of SDS effects on granule dissolution profiles." *Id.* (citing Mizerk Decl., Ex. 17 at DEX1672902). TWi contends that no further investigation was conducted on the effects of SDS and that because Dr. Charman's opinion in his declaration regarding the effects of the SDS is a new opinion that contradicts his earlier report and deposition testimony, it should not be admitted. *Id.* at 6 (citing *Chime v. PPG Indus., Inc.*, 402 F.3d 1371, 1381 (Fed. Cir. 2005); *Delaware Valley Floral Group, Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374, 1382 (Fed. Cir. 2010)).

Regarding the use of expired batches of TWi's ANDA products for testing, [redacted] *Id.* at 7. According to TWi, the cases cited in its motion establish that evidence based on expired drug product is not relevant to infringement. *Id.* at 7 (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 2002 WL 1613724, at *2 (N.D. Ill. 2002); *Apotex, Inc. v. Cephalon, Inc.*, 2012 WL 1080148, *14 (E.D. Pa. Mar. 28, 2012)). Further, Takeda's reliance on *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007) is misplaced, TWi argues, because in that case, the party offering the testing provided additional testing that the expired product continued to meet the approval specifications in the ANDA. *Id.* at 8. In other words, it is Takeda's burden, and not TWi's, to show that the tests were representative of the ANDA products. *Id.*

Finally, TWi reiterates its position that Takeda is improperly seeking a new claim construction and that if the Court adopts Takeda's proposed (new) construction, the asserted claims of the '755 Patent will be rendered indefinite. *Id.* at 8-11.

III. ANALYSIS

A. Legal Standards

1. Legal Standard Governing Summary Judgment

Summary judgment on a claim or defense is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show the absence of a genuine issue of material fact with respect to an essential element of the non-moving party's claim, or to a defense on which the non-moving party will bear the burden of persuasion at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to designate "specific facts showing there is a genuine issue for trial." *Id.* "[T]he inquiry involved in a ruling on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof that would apply at the trial on the merits. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the non-movant. *Id.* at 255.

2. Legal Standard Governing Infringement

A determination of infringement is a two-step process. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The first step is claim construction, which is a question of law to be determined by the court. *Id.* The second step is an analysis of infringement, in which it must be determined whether a particular device infringes a properly construed claim. *Id.* A device literally infringes if each of the limitations of the asserted claim is found in the accused device. *Id.* The patentee always bears the burden of proof on infringement. *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, a patentee is entitled to summary judgment if it can show that it is "more likely than not" that the accused product possesses all of the elements of the asserted claim. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (citing *Anderson v. Liberty Lobby Inc.*, 477 U.S. at 252). Once the patentee has made a prima facie showing that it is more likely than not that all the claim limitations are met, the accused infringer must come forward with more than

a scintilla of evidence to create a genuine issue of material fact as to non-infringement. *Id.* Conversely, an accused infringer is entitled to summary judgment of non-infringement where it shows "that the patentee failed to put forth evidence to support a finding that a limitation of the asserted claim was met by the structure in the accused devices." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1578 (Fed. Cir. 1989).

Takeda asserts its infringement claims under 35 U.S.C. § 271(e)(2); it also seeks a declaratory judgment of infringement and injunctive relief under 35 U.S.C. § 271(a) and the Declaratory Judgment Act. Section 271(e)(2) provides that:

> [i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

3. Legal Standards Governing Invalidity

In a patent infringement action, the accused infringer bears the burden of proving invalidity of the asserted patent by clear and convincing evidence. *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1357-58 (Fed. Cir. 2007).

a. Anticipation

Under 35 U.S.C. § 102(a), a patent may be anticipated if the claimed invention was described in a printed publication "before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). The claim limitations may be disclosed "either expressly or inherently." *EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955,

970 Fed. Cir. 2001); *In re Kratz*, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound's existence was not known)). In *Continental Can Co. v. Monsanto Co.*, the Federal Circuit explained that "inherent" disclosure "may not be established by probabilities or possibilities" but must be "necessarily present in the thing described in the reference" as viewed by persons of ordinary skill in the art. 948 F.2d 1264, 1269 (Fed. Cir. 1991).

"[A]nticipation is a question of fact, including whether or not an element is inherent in the prior art." *Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). The accused infringer bears the burden of proving invalidity of the asserted patent by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 U.S. (2011). In *Microsoft*, the Court explained that this heavy burden is based on § 282(a) of the Patent Act, which provides that an issued patent "shall be presumed valid" and that "[t]he burden of establishing invalidity ... rest[s] on the party asserting such invalidity." Nonetheless, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 2003) (*Amgen II*), the Federal Circuit announced an exception to this rule, holding that a presumption of enablement applies to both the claimed and unclaimed disclosures of prior art patents. *Amgen II*, 314 F.3d at 1355. Thus, the burden is on the *patentee* defending against an invalidity challenge based on a prior art patent to "present persuasive evidence of non-enablement to overcome this presumption." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1307 (2006) (*Amgen III*).

The Federal Circuit in *Amgen II* reasoned as follows:

> In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue. . . . *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (C.C.P.A.1980) ("[W]hen the PTO cited a disclosure which expressly anticipated the present invention ... the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior art patent] by a preponderance of the evidence." (citation omitted)). The applicant, however, can then overcome that rejection by proving that the

> relevant disclosures of the prior art patent are not enabled. *Id.* We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff. Thus, a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled. Like the applicant in ex parte prosecution, however, the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art. If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.

Amgen II, 314 F.3d at 1355.

In a footnote, the Federal Circuit in *Amgen II* noted that "by logical extension, our reasoning here might also apply to prior art printed publications as well," *id.* n. 22, and recently, in *In re Antor Media Corp.*, the Federal Circuit squarely held "that a prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent applicant or patentee." *Id.* at 1288. In *Antor*, the Federal Circuit rejected the patentee's argument, based on § 282, that the presumption should not extend to non-patent prior art, explaining that in *Amgen*, the court did not rely only on § 282 as the source of the presumption but also on that fact that it is "procedurally convenient to place the burden on the applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not enabling or operative." *Id.*

Although the Federal Circuit in *Antor* addressed whether the presumption of enablement applied in the context of patent prosecution, the reasoning of that decision persuades the Court that the presumption also applies in the district court, just as the Federal Circuit found in *Amgen II* with respect to patent prior art cited to establish anticipation. Therefore, the Court finds that where a prior art printed publication is asserted in support of an anticipation defense, the prior art is presumed enabled unless the patentee can present "evidence of nonenablement that a trial court finds persuasive." *See Amgen II*, 314 F.3d at 1355. Further, the Court concludes based on the *Amgen II* court's reliance on *In re Sasse* that the amount of evidence required to rebut the

presumption is a preponderance of the evidence and that if the patentee meets that burden, the court must then exclude the prior art in its anticipation analysis. *See id*; *see also Amgen III*, 457 F.3d at 1307 (noting that on remand, the district court found that the patentee met its "burden of proving by a preponderance of the evidence" that the prior art that was alleged to anticipate was not enabled and affirming the district court's holding).

b. Lack of Written Description

The Patent Act requires that every patent must contain a written description and be enabled, as stated in 35 U.S.C. § 112 ¶ 1, which provides as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

To satisfy the written description requirement, "the description 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

The Federal Circuit in *Ariad* acknowledged that the term "possession" "has never been very enlightening." *Id.* It explained that "the hallmark of written description is disclosure" and that the "test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* "For generic claims, [the Federal Circuit has] set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Id.* Thus, the inquiry is a question of fact and is context-specific. *Id.* (citing *Ralston Purina*, 772 F.2d at 1575; *Capon*

v. *Eshhar*, 418 F.3d 1349, 1357–58 (Fed.Cir.2005)). However, certain "broad principles . . . hold true across all cases." *Id.* at 1352. The Federal Circuit described these principles as follows:

> We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366–67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541 F.3d 1115, 1122 (Fed.Cir.2008), or that the specification recite the claimed invention in haec verba, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571–72 (Fed.Cir.1997).

Id. at 1352.

Finally, to meet the written description requirement, "[a]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)). Thus, "[a] specification may, within the meaning of 35 U.S.C. § 112 para. 1, contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." *Id.* (quoting *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir.1988)). Further, "[a] patent need not teach, and preferably omits, what is well known in the art." *Epistar Corp. v. International Trade Commission*, 566 F.3d 1321, 1336 (Fed. Cir. 2009) (quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 2009)).

In *Ariad*, the Federal Circuit made clear that the written description requirement is distinct from the enablement requirement, although the two "often rise and fall together." 598 F.3d at 1352.

4. Legal Standards Governing Admissibility of Expert Testimony

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

F.R.Evid. 702. In determining whether expert testimony meets the requirements of Rule 702, courts follow the approach set forth in *Daubert v. Merrell Dow Pharms., Inc.*, in which the Supreme Court described the relevant inquiry as follows:

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. 579, 590 (1993). The Court declined to set forth a definitive list of factors, but offered some "general observations" about the types of factors that might be considered. *Id.* at 593. These include: 1) whether the methodology can be or has been tested; 2) whether the theory and technique has been subjected to peer review; 3) if a "particular scientific technique" is involved, the known or potential rate of error; and 4) the degree of acceptance in the relevant scientific community. *Daubert*, 509 U.S. at 592-94.

If the basis for the expert's opinion is clearly unreliable, the district court may disregard that opinion in deciding whether a party has created a genuine issue of material fact. See *id.* at 596 (if "the trial court concludes that the scintilla of [expert] evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to . . . grant summary judgment").

The Ninth Circuit has held that a significant factor to be considered is "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). Thus, "if the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on "scientifically valid principles." *Id.* at 1317-1318; *see also Clausen v. M/V NEW CARISSA*, 339 F.3d 1049 (9th Cir. 2003) (holding that even where scientific evidence is based on research that was conducted for the purpose of testifying and was not subjected to normal scientific scrutiny through peer review and publication, it may still be admissible if the experts have explained "precisely how they went about reaching their conclusions and point[ed] to some objective source -- a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like -- to show that they have followed the scientific evidence method, as it is practiced by (at least) a recognized minority of scientists in their field.").

The determination of reliability is left to the discretion of the district court, consistent with its gatekeeping function under Rule 702. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999).

B. Infringement of the '282 Patent

1. Existence of Subject Matter Jurisdictions

TWi contends that there is no subject matter jurisdiction over Takeda's '282 Patent infringement claim under 35 U.S.C. §271(e)(2) because Takeda did not list that patent in the Orange Book. The Court disagrees.

The Hatch-Waxman Act gives manufacturers of generic drugs a safe harbor in which to develop their products without threat of patent litigation. See 35 U.S.C. § 271(e)(1). In return, Congress gave patentees the right to challenge a generic drug when the generic manufacturer files an ANDA, deeming the filing of the ANDA "a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning

infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir.1997). This compromise is embodied in subsections (1) and (2) of 35 U.S.C. § 271(e), which provides, in relevant part as follows:

> (e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.
>
> (2) It shall be an act of infringement to submit---
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,
> . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e) (1) & (2).

Further, "the Hatch-Waxman Act . . . establishes a procedure called a 'Paragraph IV certification,' 21 U.S.C. § 355(j)(2)(A)(vii)(IV), by which an entity that seeks to market a generic counterpart of a patented drug product or method of use, before the patent has expired, may challenge the patent before actually marketing the drug." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330 (Fed. Cir. 2013). As part of this procedure, most patentees and New Drug Applicant ("NDA") holders are required to list patents related to their approved drugs in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). 21 U.S.C. § 355(b)(1). A company that manufactures generic drugs, in turn, is required to consult the Orange Book before filing an ANDA and certify that either (I) no patent

information is listed in the Orange Book for the proposed generic drug; (II) that the listed patents have expired; (III) that the listed patents will expire before the generic company markets its product; or (IV) that the patents listed are invalid or will not be infringed by the generic drug (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

Here, Takeda has alleged jurisdiction under 28 U.S.C. § 1338, which provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." Thus, the existence of subject matter jurisdiction over Takeda's § 271(e)(2) claim based on the '282 Patent depends on whether that claim "arises under" the Hatch-Waxman Act even though TWi's ANDA did not include a Paragraph IV certification. Some courts have found that a Paragraph IV certification is a jurisdictional requirement for bringing a claim under the Hatch-Waxman Act. *See, e.g., Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007). In *Eisai*, the court recognized that "[t]he plain text of § 271(e)(2) does not require that the alleged infringer file an ANDA with a Paragraph IV certification, or that the drug claims be listed in the Orange Book." *See* 2007 WL 4556958, at *9. Nonetheless, based on extended discussion of the ANDA process in decisions by the Federal Circuit, the *Eisai* court concluded that a Paragraph IV requirement should be "read into" § 271(e)(2). *Id.* at * 12.

The undersigned does not find the reasoning of *Eisai* persuasive given the clear language of the statute and the fact that none of the Federal Circuit cases addressed in *Eisai* directly addressed the question of whether a Paragraph IV certification was required in order for a patentee to bring an infringement claim under the Hatch-Waxman Act. See *id.* at *11 ("The Federal Circuit has never squarely faced the question before this Court"). The Federal Circuit subsequently resolved any doubt on this issue in *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012). In *AstraZeneca*, the Federal Circuit held that under the Hatch-Waxman Act, "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims." 669 F.3d at 1376-77.

Further, in *Caraco Pharm. Labs.., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), the Supreme Court also made clear that a Paragraph IV certification is not a jurisdictional requirement for bringing an action under the Hatch-Waxman Act. In that case, the generic drug manufacturer, *Caraco*, initially included a Paragraph IV certification in its ANDA but later inserted a statement under § 355(j)(2)(A)(viii) ("section viii statement"). 132 S. Ct. at 1679. A section viii statement asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents and is an alternative to a Paragraph IV certification for obtaining FDA approval. *Id.* at 1677-1678. Before the FDA had approved the generic on the basis of the section viii statement, however, the patentee, Novo, amended its use codes to cover the uses for which the generic manufacturer sought approval. *Id.* at 1679. In the ensuing Hatch-Waxman infringement action initiated by Novo, the generic manufacturer asserted a counterclaim seeking to compel Novo to amend its use codes such that *Caraco* would be able to obtain FDA approval under section viii rather than under Paragraph IV. The question before the Supreme Court was whether *Caraco* could assert such a counterclaim. In that context, Novo argued that there was no subject matter jurisdiction over the action. 132 S. Ct. 1670, 1680 n.5 (2012). The Court rejected that argument, reasoning as follows:

> On Novo's theory, [a section viii] statement (unlike a paragraph IV certification) does not count as an act of infringement under the patent statute, see 35 U.S.C. § 271(e)(2)(A), and so cannot provide a jurisdictional basis for the suit. But that argument is wrong even assuming (as Novo contends) that Caraco's section viii filing terminated its paragraph IV certification and that a section viii filing is not an act of infringement. The want of an infringing act is a merits problem, not a jurisdictional one. Nothing in the section of the statute defining certain filings as acts of infringement suggests anything to the contrary. And "we are not inclined to interpret statutes as creating a jurisdictional bar when they are not framed as such." *Stern v. Marshall*, 564 U.S. ——, ——, 131 S. Ct. 2594, 2607, 180 L.Ed.2d 475 (2011). In the absence of such a bar, the federal courts have jurisdiction over this suit for a single, simple reason: It "ar[ose] under a[n] Act of Congress relating to patents." 28 U.S.C. § 1338(a).

Id.

In light of the *Caraco* decision and the Federal Circuit's recent decision in *Astrazeneca*, this Court joins a number of other district courts in concluding that there is no requirement under the Hatch-Waxman Act that a patent must be listed in the Orange Book in order for a drug manufacturer to bring an infringement action based on that patent against an ANDA applicant. See *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 2013 WL 591976 (D.N.J. Feb. 14, 2013) (declining to follow *Eisai* on the basis that "more recent precedent of the Federal Circuit controls" and holding that under *AstraZeneca* it is clear that the requirements for jurisdiction in the district courts are met once a patent owner alleges that the filing of an ANDA infringes its patent under § 271(e)(2), regardless of whether the ANDA includes a Paragraph IV certification); *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012) (rejecting the reasoning and "sweeping conclusion" of *Eisai* that the court lacked jurisdiction under the Hatch-Waxman Act where there was no paragraph IV certification); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009) (holding that "[t]here is no requirement that infringement actions against ANDA filers must be based on patents listed in the Orange Book"); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004) ("The language of § 271(e)(2)(A) does not require that the ANDA contain a [paragraph IV] certification to constitute an act of infringement. It only requires that the [ANDA] application be filed under § 355(j)"); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009) (holding in a case involving an Abbreviated New Animal Drug Application that "a paragraph IV certification is not required to trigger an infringement action under § 271(e)(2)").

Therefore, the Court concludes that it has subject matter jurisdiction over Takeda's infringement claim under § 271(e)(2) even though the '282 Patent was not listed in the Orange Book.

2. Whether Takeda has Established Infringement

Takeda seeks summary judgment of infringement of the '282 Patent based on what it contends is substantial evidence that TWi's ANDA products contain amorphous dexlansoprazole. Takeda relies primarily on TWi's statements, both to the FDA and in this litigation, rather than on its own testing of the ANDA products. For the reasons discussed below, the Court concludes that

this evidence is sufficient to find, as a matter of law, that TWi's ANDA products contain amorphous dexlansoprazole and therefore, that Takeda is entitled to summary judgment of infringement of the '282 Patent under the Hatch-Waxman Act (Count IV). The Court declines to enter summary judgment in Takeda's favor on Count VII, however, because Takeda has not established that it meets the constitutional requirements for bringing claims under the Declaratory Judgment Act.

To establish a case or controversy under Article III of the U.S. Constitution, a claim must be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)(quotations omitted). Some courts have permitted claims seeking declaratory judgment of infringement under § 271(a) based on the filing of an ANDA. *See, e.g., Cephalon v. Sandoz,* Inc., 2012 WL 682045 , at *5 (D. Del. Mar. 1, 2012); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.,* 2009 WL 6337911, at *13-14 (E.D. Wis. Sept. 24, 2009). Other courts, however, have held that such claims are not sufficiently real and immediate to satisfy the requirements of *MedImmune. See, e.g., Eisai,* 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 983 (N.D. Ill. 1995) (questioning whether such a claim is consistent with Congress' intent in providing a safe haven for generic manufacturers under the Hatch-Waxman Act). Although TWi alluded to this issue in its Reply brief, Takeda did not have an opportunity to respond on this question. Therefore, the Court does not reach the question of whether Takeda can establish the existence of a "definite and concrete" controversy on its infringement claims under § 271(a) and the Declaratory Judgment Act. The Court now turns to the substantive question of whether Takeda is entitled to summary judgment that TWi's ANDA products contain amorphous dexlansoprazole.

"A patentee may prove infringement by 'any method of analysis that is probative of the fact of infringement' . . . , and circumstantial evidence may be sufficient." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (citing *Forest Labs. v. Abbott*

Labs., 239 F.3d 1305, 1312 (Fed. Cir. 2001), *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006)). Further, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367. 1373 (Fed. Cir. 2002); see also *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1351 (Fed. Cir. 2007)("[t]here is no prohibition against using the admissions of a party, whether in the form of marketing materials or otherwise, as evidence in an infringement action"). Whether a statement made in a party's legal brief is considered a binding judicial admission is within the discretion of the court. *Gospel Missions of America v. City of Los Angeles*, 328 F.3d 548, 557 (9th Cir. 2003).

In light of the rule stated in *Abbott*, the Court looks first to TWi's statement to the FDA in its ANDA describing its choice of layering process [redacted] *See* Myerson Decl., Ex. 8 (Chen Dep. Ex. 51), at ANC-DEXL0000779; JSUF (Takeda Motion) ¶ 11. Given that it is undisputed that the dexlansoprazole used in the manufacture of the ANDA products is amorphous dexlansoprazole, this statement is sufficient to establish that the finished product also contains amorphous dexlansoprazole.

Further, even if the statement to the FDA in the ANDA did not, by itself, require such a finding, the Court further finds that Takeda is entitled to summary judgment on this question because TWi's statements in this litigation also establish that its ANDA products more likely than not contains amorphous dexlansoprazole. These statements include: 1) deposition testimony by Dr. Shou-Chiung Chen, TWi's 30(b)(6) witness, [redacted] *see* Myerson Decl., Ex. 7 (Jun. 20, 2012 Chen Dep. Tr. 118:1-10, 123:24-124:6-8); 2) TWi's interrogatory responses stating that its "ANDA drug products do not contain a crystal or crystalline compound of dexlansoprazole . . . .," *see* Myerson Decl., Ex. 9 (TWi's Responses and Objections to Plaintiff's First Set of Joint Interrogatories, July 28, 2011) at 17; 3) TWi's paragraph IV letter to Takeda, which stated that "the ANDA drug products do not

include a crystal or crystalline compound of dexlansoprazole." *See* Myerson Decl., Ex. 10 (ANCDEXL0000238-277), at ANC-DEXL0000258.

In reaching this conclusion, the Court rejects TWi's suggestion it should find that there is a material dispute of fact because the dexlansoprazole in the ANDA products *might* be molecular dexlansoprazole rather than an amorphous solid. The only evidence in the record indicates that the dexlansoprazole in the ANDA products is a solid; indeed, TWi characterized it as such in its ANDA. *See* Myerson Decl., Ex. 3, at ANC-DEXL0000438 (indicating that excipients used in ANDA products fell below "limits for solid, oral dosage forms"); Myerson Decl., Ex. 8, at ANC-DEXL0000769 (same); Takahashi Reply Decl., Ex. 3 (ANC-DEL0000796) (statement in ANDA that a particular test was not performed on the ANDA products because it is "[n]ot applicable for solid oral dosage forms"). Further, there is substantial evidence in the record that a solid form of dexlansoprazole must be either amorphous or crystalline. *See* Myerson Claim Construction Decl. ¶ 81 ("Solids can be crystalline or amorphous."), ¶ 23 ("Solids that are not crystalline and have no long range order . . . are said to be amorphous."); Myerson Rep. ¶ 22 (same); Myerson Claim Construction Decl. Ex. 11 at DEX0014516 ("The terms amorphous and non-crystalline are synonymous . . . and can be used interchangeably."); *id.*, Ex. 12, at DEX0014612 ("[N]ot all solids are crystals. Materials that have short-range rather than long range ordering . . . are non-crystalline solids. A noncrystalline solid is often referred to as an amorphous solid."); *id.*, Ex. 13 at DEX0014769 ("A liquid may solidify in two ways: . . . to a crystalline solid or . . . to an amorphous solid."); *id.*, Ex. 27, at DEX0014491 (defining "[a]morphous [s]olid" as "[a] noncrystalline solid"); Rogers Claim Construction Decl., Ex. 3, at DEX0003649 ("Some authors [] sub-divide solids into crystalline and amorphous."); *id.*, Ex. 4 at IPXL-0009902 (defining "amorphous" as "[n]oncrystalline . . ."); *id.*, Ex. 5 at IPXL-0010285 (same); Takahashi Reply Decl., Ex. 2 (Dec. 9, 2011 Rogers Dep.) at 19:5-13; Rogers Claim Construction Decl. ¶ 30 ("[T]he term 'amorphous' is an adjective that is synonymous with 'noncrystalline.'"); *id.*, ¶¶ 28-29).

Because the Court finds that TWi has not identified specific facts establishing the existence of a genuine issue of material fact as to whether its ANDA products contain the claimed

amorphous dexlansoprazole, the Court concludes that Takeda is entitled to summary judgment of infringement of the '282 Patent by TWi's ANDA products under the Hatch-Waxman Act (Count IV). Further, if Takeda can establish at trial that it has standing under the Declaratory Judgment Act, it will be entitled to judgment in its favor on Count VII as well.

C. Validity of the '282 Patent

1. Anticipation

TWi argues that the '282 Patent is anticipated by the Larsson and Barberich references. This dispute turns primarily on two questions: 1) whether Larsson inherently discloses an amorphous salt of dexlansoprazole, as is required under claim 1 of the '282 Patent; and 2) whether the disclosure of such a salt is enabled. The Court finds that this feature is not inherently disclosed in Larsson, which therefore does not anticipate the asserted claims of the '282 Patent. The Court further finds that although a solid salt of dexlansoprazole is disclosed in Barberich, there is a fact question as to whether the disclosure is enabled and therefore, summary judgment on the question of whether Barberich anticipates the asserted claims of the '282 Patent is inappropriate.

In support of its contention that Larsson inherently discloses making a salt of dexlansoprazole consistent with the Court's claim construction, which requires that the salt must be a solid, TWi cites Dr. Atwood's testimony that "typically" one would expect a salt of dexlansoprazole made through conventional processes to be a solid. This evidence is insufficient to establish inherent disclosure. As stated above, inherent disclosure may not be established by "probabilities or possibilities." *Bettcher Industries, Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)). "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* For example, in *GlaxoInc. v. Novapharm Ltd.*, the defendant argued that the asserted patent was anticipated based on inherent disclosure in the prior art, citing evidence that its expert had reproduced the prior art method thirteen times, each time obtaining the claimed crystals. 52 F.3d 1043, 1047 (Fed. Cir. 1995). However, the patentee had presented evidence that two of its own experts had used the same method to produce different crystals. *Id.* Because the method described in the prior art did

not "always yield" the claimed invention but rather, "*could* yield" something different, the Federal Circuit affirmed the district court's holding that there was no inherent disclosure and therefore, that the asserted patent was not anticipated. *Id.*

Dr. Atwood did not testify that conventional processes for making a salt of dexlansoprazole always result in a solid salt of dexlansoprazole, as is claimed in the '282 Patent. To the contrary, he testified that such processes will not always result in a salt that is a solid. Thus, his testimony does not establish inherent disclosure. Nor does Dr. Atwood's testimony that one would "typically" expect a solid give rise to a "presumption that the Larsson and Barberich references disclose the claimed solid dexlansoprazole salts." *See* TWi Reply at 14. TWi's reliance on *In re Antor Media Corp.*, 689 F.3d 1282, 1288 Fed. Cir. 2012) in support of this assertion is misplaced. That case addressed the presumption of *enablement* that the Federal Circuit found applies to a printed prior art publication during patent prosecution. It did not address the question of inherent disclosure of an allegedly anticipating reference. In the absence of disclosure of the claimed *solid* salt of dexlansoprazole, the Court does not reach the question of enablement as to Larsson.

On the other hand, it is undisputed that a solid amorphous compound of dexlansoprazole *is* disclosed in Barberich. Further, Takeda does not dispute that a person skilled in the art at the priority date would have known how to obtain "a salt thereof" and that a salt obtained from a solid amorphous compound would also be a solid. Therefore, the Court finds that the "salt thereof" of claim 1 is disclosed in Barberich. The question of whether Barberich anticipates the '282 Patent, then, turns on enablement, that is, whether a person of ordinary skill in the art could create a salt of an amorphous compound of dexlansoprazole (which must be solid under the Court's claim construction) based on the disclosure in Barberich. As it is undisputed that a person of ordinary skill knew how to obtain a salt and that a salt made from a solid amorphous compound of dexlansoprazole would also be solid, the only remaining question is whether a person of ordinary skill in the art would have been enabled as to creating the claimed amorphous compound of dexlansoprazole, which must be a solid under the Court's claim construction. Barberich does not offer any guidance on how to create such a compound, instead incorporating

Larsson. The only guidance in Larsson, however, is set forth in Example 22. For the reasons set forth in the Court's Order in related case C-11-0840, the Court finds that there is a fact question as to whether the disclosure in Larsson would be sufficient to create the claimed amorphous compound without undue experimentation.[14] Therefore, there is also a fact question as to whether the claimed amorphous solid salt of dexlansoprazole disclosed in Barberich is enabled. Accordingly, summary judgment on this question is not appropriate.

2. Lack of Written Description

TWi contends that Takeda's anticipation argument, if credited, leads to the conclusion that the '282 Patent lacks sufficient written description because it does not describe how the solid salt of dexlansoprazole is created. TWi's position fails because it is undisputed that a person of skill in the art would know how to derive a salt of amorphous dexlansoprazole. Because the '282 Patent also describes the synthesis of an amorphous compound of dexlansoprazole that is solid, this disclosure shows that the inventors were in possession of the claimed salt of dexlansoprazole, which was a solid rather than an oil. Therefore, TWi is not entitled to summary judgment of invalidity on this basis.

D. Infringement of the '755 Patent

1. Whether Dr. Charman's Opinions Should be Excluded Under *Daubert*

TWi argues that Dr. Charman's opinions are not supported by any scientifically acceptable methodology and are based on what it colorfully describes as a "Frankenstein" dissolution test. In support of its position, TWi relies primarily on the fact that the test methodology was developed for litigation. It dismisses the explanation offered by Dr. Charman in his opposition declaration, in which he sets forth his reasons for adopting the protocol that was used by Advantar, as an untimely attempt to survive TWi's *Daubert* motion by articulating new opinions that conflict with Dr. Charman's earlier report. The Court finds TWi's arguments unpersuasive.

As a preliminary matter, the Court addresses whether the declaration of Dr. Charman in supported of Takeda's opposition should be excluded. TWi appears to seek exclusion of this

[14] In its Motion, TWi expressly joined in the invalidity arguments set forth in Handa's summary judgment motion. *See* TWi SJ Motion at 15 n. 9.

declaration as a discovery sanction, pursuant to Rule 37 of the Federal Rules of Civil Procedure.[15] The Federal Circuit has noted that "Rule 37(c)(1) 'gives teeth' to the written report requirement of Rule 26(a)(2)(B) by forbidding a party's use of improperly disclosed information at a trial, at a hearing, or on a motion, unless the party's failure to disclose is substantially justified or harmless." *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1365 (Fed. Cir. 2011) (citing *Yeti By Molly Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001)). TWi contends that Dr. Charman's declaration contains new opinions that conflict with his expert report or at least were not disclosed in them. TWi points to only one concrete example of a new opinion however, namely, Dr. Charman's statement that "[p]hotographs of the granules taken at the conclusion of experiments, with and without SDS, demonstrate that SDS is interacting with the enteric polymer in the coat of the low-pH granules...." *Id.* (citing Charman Decl. ¶ 22). This opinion is new and contradictory, according to TWi, because it was not expressed in Dr. Charman's report, and the Advantar documents upon which Dr. Charman relied stated only that it was "likely" that the effect of the SDS in the earlier tests resulted from its "effect on the granule enteric coating or possibly granule contents." *See* Mizerk Decl., Ex. 17 at DEX1672901. The Court finds that this variation in the degree of certainty as to reason for the SDS effect in the earlier Advantar tests is insignificant and does not represent the sort of new and undisclosed opinion that would warrant exclusion under Rule 37. The Court further notes that TWi's counsel had the opportunity to depose Dr. Charman after Dr. Charman had reviewed the earlier test protocols. Therefore, the Court does not find that the Charman opposition declaration should be excluded.

The Court also rejects TWi's contention that Dr. Charman's tests are not supported by any acceptable scientific methodology. TWi's position is largely based on unsupported accusations and innuendo. It makes much of the fact that at his November 11, 2011 deposition, Dr. Charman testified, when asked what experiments he would conduct to determine whether a product met his proposed claim construction, that he had not "considered the experiments that one may undertake

[15] The Court notes that to the extent TWi seeks exclusion of the Charman opposition declaration as a discovery sanction, it has failed to adhere to the Local Rules of this district, which require that a request for sanctions must be set forth in a separately filed motion. *See* Civ. L. R. 7-2.

in order to meet the proposed claim construction" because this was outside the scope of what he had been asked to address in the context of claim construction. *See* Purles Decl., Ex. 12 at 112. TWi suggests that when Dr. Charman did eventually develop a test protocol, it was created only to ensure that the results would support Takeda's position and not for any scientifically valid reasons; it is for this reason, according to TWi, that Dr. Charman chose to conduct the Advantar tests upon which he relied without SDS.

Dr. Charman's report, however, as well as the Advantar report cited therein, provides scientific reasons for choosing to conduct the Advantar tests without SDS. *See* Charman Decl., Ex. B (Charman Report Regarding Infringement by TWi) ¶ 71 & Ex. 3 (Advantar Aug. 23, 2012 Report) at DEX1668807. In particular, in his report, Dr. Charman states as follows:

> Due to lansoprazole's low solubility in water, compendial (USP) monograph methods for release from lansoprazole capsules include surfactant (sodium dodecyl sulfate or "SDS") in the dissolution medium to enhance dissolution. The quantities of granules used in Advantar's experiments, however, were such that dexlansoprazole's solubility was not exceeded. Therefore, SDS, which is not found in the GI environment into which the drug is ingested, was neither required nor included in the dissolution medium.

Charman Report (TWi) ¶ 71 (citing Advantar Aug. 23, 2012 Report at 2). TWi does not point to any expert testimony that addresses these reasons or explains why they are not scientifically valid. Under these circumstances, the Court concludes that Dr. Charman's opinions based on the Advantar tests are admissible, even though those tests were conducted within the context of litigation and have not been subjected to peer review, because Dr. Charman has provided scientific reasons in support of his protocol and TWi has not cited expert testimony establishing (or even opining) that those reasons are not based on scientifically valid principles. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

The Court rejects TWi's *Daubert* challenges.

2. Whether Test Results Establish Non-Infringement

TWi contends that even if the Court finds that Dr. Charman's opinions based on the Advantar tests are admissible, the results of those tests establish, as a matter of law, that TWi's ANDA products do not infringe the asserted claims of the '755 Patent. Because the Court finds

that Takeda's position on this issue amounts to a request for a revised construction of the release term, the Court first addresses whether such a revision is appropriate.[16] Having carefully considered the supplemental claim construction briefs and supporting materials filed by the parties in this action and the related actions, the Court declines to revise its previous construction. Further, the Court finds that under that construction, the undisputed facts establish, as a matter of law, that TWi's ANDA products do not infringe the asserted claims of the '755 Patent.

As noted above, at the claim construction stage of the case, the Court construed the phrase "released in the pH range of no less than 5.0 to no more than 6.0" to mean "begins to be released from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0." The Court's construction makes clear that the range set forth in the release term is a threshold at which release begins. The Court acknowledged in its claim construction order that the parties disagree about what testing should be conducted to determine infringement but found that this disagreement goes to infringement rather than indefiniteness, rejecting the defendants' argument that a person skilled in the art would not know how to determine when release "begins." Now, however, Takeda argues that there is a fact question on infringement -- even though the undisputed evidence (Takeda's own testing) shows measurable dissolution of the API of TWi's ANDA product at pH levels below 5.0 -- because the release is not significant and rapid; according to Takeda's expert, such release does not occur unless at least 10% of the drug is released in a 2-hour period. Takeda is essentially asking the Court to adopt a broader construction of the release term than it adopted in its claim construction order. In light of the intrinsic evidence, the Court concludes that Takeda's position is incorrect.

First, the Court looks to the claim language. "Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning." *Elekta Instrument S.A. v. O.U.R. Scientific International, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (citation omitted). The plain language of the release term of claim 1 sets forth a specific range of pH values in which release of the API must begin. This range captures the idea set forth in the specification that composition (ii)

[16] The general legal standards governing claim construction are set forth in the Court's claim construction order. *See* Docket No. 81. Therefore, the Court does not repeat them here.

dissolves at a pH of "about 5.5." *See* '755 Patent, col. 2, ll. 48-53 (stating in the "Disclosure of Invention" section that the invention provides a "capsule . . . which comprises a tablet, granule or fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5"). In other words, the claim language *already* allows for some dissolution to occur below the 5.5 target pH level for composition (ii) while remaining within the scope of the claim. Were the Court to insert further qualifying language in its construction that allowed release *below* the lower end of the range claimed by the inventors, it would not only be ignoring the ordinary meaning of the claim term but would also be rendering the lower end of the range in the claim superfluous to the extent that release would be permitted both below 5.0 *and* above 5.0. *See Elekta*, 214 F.3d at 1307 (reversing district court's construction of the term "only within a zone extending between latitudes 30° - 45°" as meaning "beginning at the edge of the helmet (0°) and extending to a point between 30° - 45°" on the basis that it was inconsistent with ordinary meaning of claim language and rendered lower end of the range superfluous); *U.S. Philips Corp. v. Isasaki Elec. Co.*, 505 F.3d 1371, 1376 (Fed. Cir. 2007) (affirming district court's construction of term "between 10^{-6} and 10^{-4} <<mu>>mol/mm ^{3}" as meaning "between 1×10^{-6} and 1×10^{-44} <<mu>>mol/mm ^{3}" and noting that district court was correct that "the overall phrase - 'a quantity between -- and --' - is a construction that 'implies a specific range . . . it does not imply a range between two values which are themselves ranges"). Thus, the unambiguous language of the claim supports a construction that does not permit release of the API outside of the claimed range.

Further, nothing in the prosecution history or the specification of the '755 Patent persuades the Court that it is appropriate to read into the release term a requirement that release must be significant and rapid (or to state it somewhat differently, that the claim covers embodiments in which there is no *significant* release below the lower end of the range, pH 5.0). The parties hotly dispute the significance of: 1) the applicants' reliance on the Kurasawa testing during patent prosecution; and 2) the disclosure in columns 9 and 10 of the '755 Patent. Beyond the fact that both describe testing that was conducted over a longer period of time than Takeda asserts is appropriate for determining whether the release limitation is satisfied, suggesting that the two-hour limitation proposed by Takeda is incorrect, the Court finds that neither the prosecution

history nor the passage in the specification offers significant guidance as to the construction of the release term.

On one hand, the Kurasawa testing revealed a dissolution rate of less than 5% dissolution after 2 hours and thus, the embodiment of the invention tested by Kurasawa would not have satisfied the "significant and rapid" requirement that Takeda asks the Court to read into the release term.[17] On the other hand, the single example describing testing in the specification, found in columns 9 and 10, arguably supports Takeda's position that claim 1 allows some release below the claimed pH ranges. That passage states as follows:

> It is desirable that the coating material is used alone or, if necessary, in combination so that the polymer is dissolved, preferably at a pH of 6.0 or above, more preferably at a pH of 6.5 or above, and further more preferably at a pH of 6.75 or above. . . . The rate of elution of active ingredient from the active-ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8.

'755 Patent, col. 9, l. 65 - col. 10, l. 17. Neither of the examples, however, addresses whether (or when) the release described in them falls within the range set forth in the release term. Moreover, even if Takeda is correct that the passage in the specification describes an embodiment that is excluded under the Court's current construction of the release term, this does not justify modifying the construction because "the unambiguous language of the . . . claim controls over any contradictory language in the written description." *Elekta*, 214 F.3d at 1308. Finally, to the extent that the Court finds that the claims themselves are unambiguous, reliance on extrinsic evidence, such as the USP, is not a proper basis for varying the meaning of the term. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

[17]The Court notes that the Kurasawa testing involved the high pH granule rather than the low pH granule that is the subject of the release term. Nonetheless, at claim construction Takeda argued that the Kurasawa testing would have offered guidance to a person of ordinary skill in the art as to how to measure whether the release term was satisfied.

For these reasons, the Court concludes that it is not appropriate to revise its construction of the release term to insert qualifying language requiring that release must be rapid and significant. Rather, the Court finds that a product falls outside of the ambit of claim 1 if there is any measurable release of the API from the low pH granule below the range specified in the release term. Because Takeda's own testing shows measurable release of the low pH capsule of TWi's ANDA products below a level of pH 5.0, the Court finds as a matter of law that those products do not infringe the asserted claims of the '755 Patent.[18]

IV. CONCLUSION

For the reasons stated above, Takeda's Motion for Summary Judgment is GRANTED. TWi's Motion is GRANTED in part and DENIED in part.

IT IS SO ORDERED.

Dated: April 8, 2013

Joseph C. Spero
United States Magistrate Judge

[18] Because the Court finds that TWi is entitled to summary judgment of non-infringement as to the '755 Patent, it need not reach TWi's argument that the Advantar test results are not relevant because they were run after the ANDA product batch had already expired.