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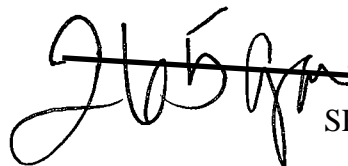
UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

**RICHARD W. WIEKING**  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

Case No. C-11-00840 JCS

TAKEDA PHARMACEUTICAL CO., LTD,
et al.,
Plaintiffs,
v.
HANDA PHARMACEUTICALS, LLC, et al.,
Defendant.

**ORDER RE SUMMARY JUDGMENT  
MOTIONS [Docket Nos. 188, 192 (redacted  
publicly filed versions); 215, 230 (sealed  
versions)]  
PUBLIC VERSION  
~~FILED UNDER SEAL~~  
[REDACTED VERSION]**



SEALED DKT NO.

**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 Abbreviated New Drug Application ("ANDA") No. 202-294, filed with the Food and Drug Administration ("FDA") by Defendant Handa Pharmaceuticals, Inc. ("Handa"), seeking approval to market dexlansoprazole delayed release capsules as a generic version of Takeda's drug DEXILANT (dexlansoprazole). Handa and Par Pharmaceutical, Inc. ("Par") entered into an exclusive acquisition and license agreement concerning ANDA No. 202-294, and Par is now the owner of that ANDA.<sup>1</sup> Joint Statement of Undisputed Facts for Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("JSUF (Takeda Motion)") ¶¶ 5-6.

Takeda asserts that the ANDA products infringe the following patents (hereinafter, "Asserted Patents"): 1) U.S. Patent No. 6,462,058 ("the '058 Patent"); 2) U.S. Patent No.

<sup>1</sup> The Court refers to Handa and Par collectively as "Handa."

United States District Court  
Northern District of California

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1 6,664,276 (“the ‘276 Patent”); 3) U.S. Patent No. 6,939,971 (“the ‘971 Patent”); 4) U.S. Patent  
2 No. 7,737,282 (“the ‘282 Patent”); 5) U.S. Patent No. 7,285,668 (“the ‘668 Patent”) and 6) U.S.  
3 Patent No. 7,790,755 (“the ‘755 Patent”). Handa, in turn, asserts counterclaims seeking  
4 declaratory judgment of non-infringement and invalidity as to all of the Asserted Patents.

5 Presently before the Court are the parties’ cross-motions for summary judgment. Takeda  
6 has filed a motion seeking summary judgment of infringement of the ‘282 Patent based on what it  
7 contends is undisputed evidence that the dexlansoprazole drug product in Handa’s ANDA  
8 contains every element of claims 1 and 2 of the ‘282 Patent. *See* Docket No. 230 (Motion for  
9 Summary Judgment of Infringement of the ‘282 Patent (“Takeda SJ Motion (Handa)”). Handa  
10 brings a motion for partial summary judgment that: 1) its ANDA product does not infringe the  
11 ‘755 Patent because both Takeda’s

12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED] 2) its ANDA product does not  
15 infringe the ‘276 Patent because Takeda has not produced any evidence [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]

19 [REDACTED]; and 3) claims 1  
20 and 2 of the ‘282 Patent are invalid because they are anticipated by the Larsson<sup>2</sup> and Barberich<sup>3</sup>  
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22  
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24 <sup>2</sup> “Larsson” refers to WO 96/02535 (“Larsson I”) and U.S. Patent No. 5,948,789 (“Larsson II”).  
25 The parties agree that there is no material difference between the disclosures of Larsson I and  
26 Larsson II. Joint Statement of Undisputed Facts in Support of Defendants Handa  
27 Pharmaceuticals, LLC and Par Pharmaceutical, Inc.’s Motion for Partial Summary Judgment  
28 (“JSUF (Handa Motion)”) ¶ 23.

<sup>3</sup> “Barberich” refers to WO 99/38513 (“Barberich I”) and U.S. Patent App. No. 2003/0008903  
28 (“Barberich II”). The parties agree that there is no material difference between the disclosures of  
Barberich I and Barberich II. JSUF (Handa Motion) ¶ 24.

1 prior art references. See Docket No. 215 (Defendants Handa Pharmaceuticals, LLC's and Par  
2 Pharmaceutical, Inc.'s Motion for Partial Summary Judgment ("Handa SJ Motion")).<sup>4</sup>

3 Hearings on the motions were held on February 8, 2013 and February 22, 2013. For the  
4 reasons set forth below, Takeda's summary judgment motion is GRANTED. Handa's summary  
5 judgment motion is GRANTED in part and DENIED in part.<sup>5</sup>

6 **II. BACKGROUND**

7 **A. The Accused Product**

8 In its ANDA, Handa seeks FDA approval to market dexlansoprazole delayed-release  
9 capsules [REDACTED]

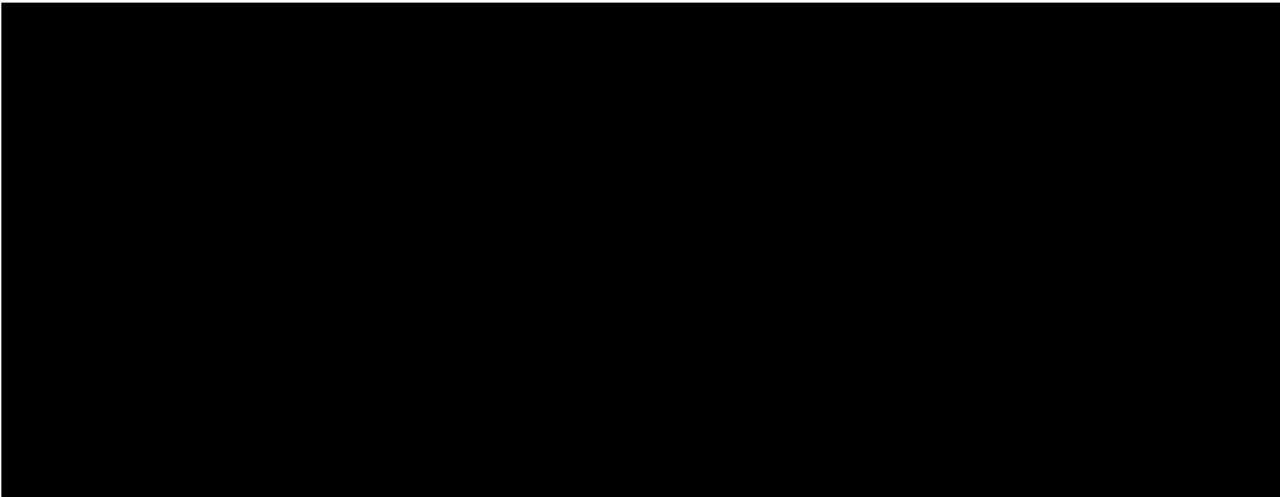
10 [REDACTED]  
11 It is also undisputed that: 1) the ANDA  
12 product is a pharmaceutical composition that contains at least one pharmaceutically acceptable  
13 excipient; [REDACTED]

14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 According to Handa,  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]

24 <sup>4</sup> Handa also joins in TWi Pharmaceuticals, Inc.'s Motion for Summary Judgment in related Case  
25 No. C-11-1609 JCS as to TWi's request for summary judgment on the grounds that: 1) the '755  
26 Patent is invalid as indefinite under *Honeywell* if the Court adopts Takeda's test for "begins to  
27 release"; and 2) claims 1 and 2 of the '282 Patent are invalid for lack of the required written  
description. See Docket No. 248. The Court's rulings on those issues are set forth in a separate  
order, filed in the related case, and are adopted in this case.

28 <sup>5</sup> The parties have consented to the jurisdiction of a United States Magistrate Judge pursuant to 28  
U.S.C. § 636(c).

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**B. Asserted Claims of the '282 Patent**

Takeda alleges that Handa's ANDA product infringes 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." 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. Asserted Claims of the '755 Patent**

Takeda alleges that Handa's ANDA product infringes claims 2, 4 and 6 of the '755 Patent, each of which depends from claim 1. JSUF (Handa Motion) ¶ 2. 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 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,

1 represents the *only* pH values at which release or dissolution occurs. The Court adopted Takeda’s  
2 proposed construction, construing the claim term “released in the pH range of no less than 5.0 to  
3 no more than 6.0” to mean that the dexlansoprazole “begins to be released from the tablet, granule  
4 or fine granule at pH values within the range from 5.0 to 6.0.” Claim Construction Order at 70.  
5 In response to the argument that the claim term is indefinite because a person skilled in the art  
6 would not know what percentage of the drug needs to be released to satisfy the “begins to be  
7 released” requirement, the Court noted that “the phrase ‘begins to release’ is not a claim term but  
8 merely a proposed construction intended to convey the idea that the pH values in the term  
9 represent a threshold.” *Id.* at 67. The Court went on to find that the question of what amount of  
10 drug release satisfies this requirement does not render the claim term insolubly ambiguous to a  
11 person of ordinary skill in the art. *Id.*

12 **D. Asserted Claims of the ‘276 Patent**

13 Takeda alleges that the ANDA Product infringes claims 2 and 3 of the ‘276 Patent. JSUF  
14 (Handa Motion) ¶ 8. Claims 2 and 3 recite:

- 15 2. A crystalline compound of (R)-2-[[[3-methyl-4-(2,2,2-  
16 trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1 H-benzimidazole.
- 17 3. A pharmaceutical composition comprising:  
18 a crystalline compound of (R)-2-[[[3-methyl-4-(2,2,2-  
19 trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole or  
20 a salt thereof; and  
21 a pharmaceutically acceptable excipient, carrier or diluent.

22 The Court construed the term “crystalline compound” to mean “regularly repeating pattern of  
23 molecules with long range order extending in three dimensions.” Claim Construction Order at 70.

24 **E. The Parties’ Contentions**

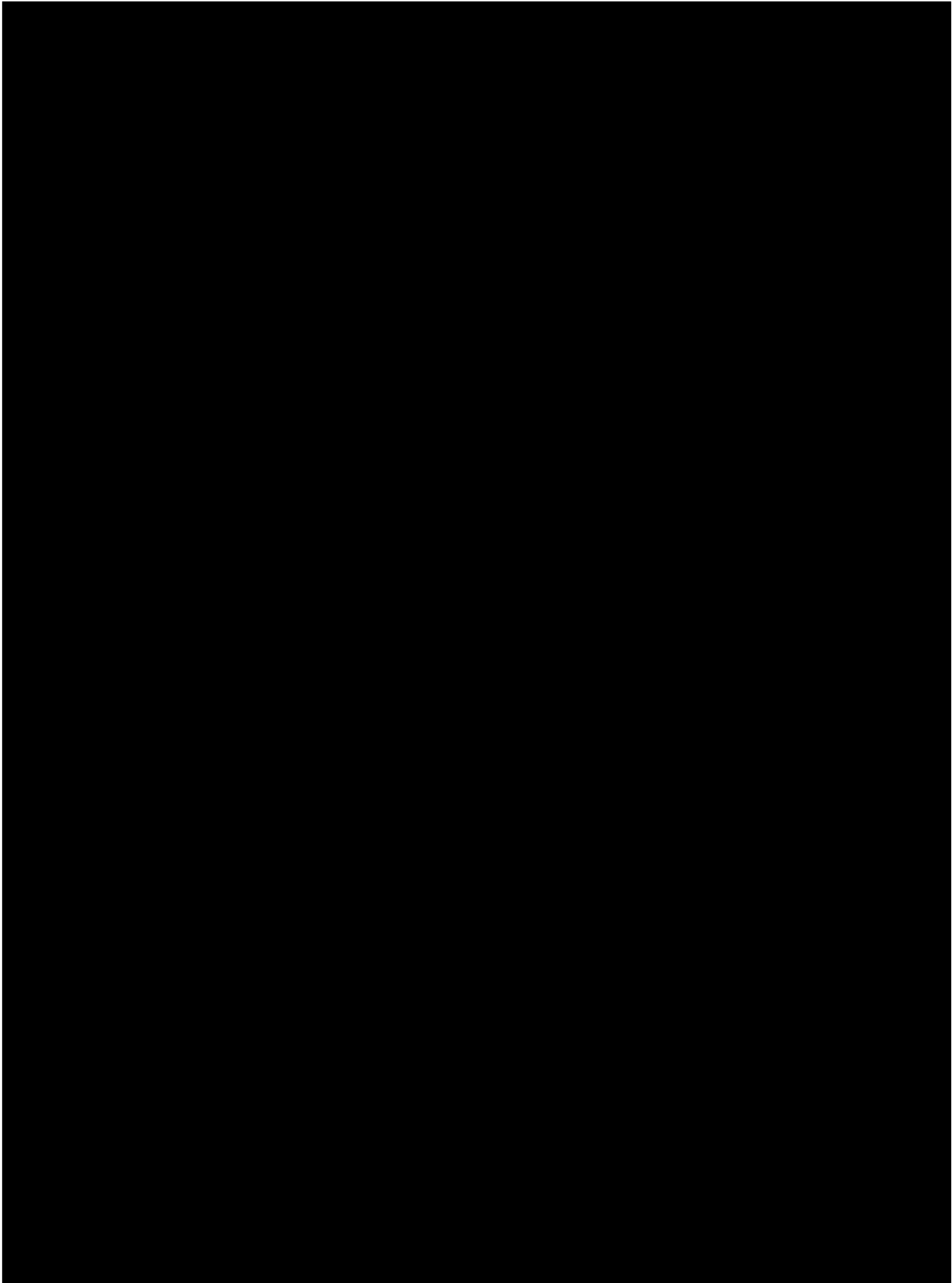
25 **1. Infringement of the ‘282 Patent**

26 **a. Takeda’s Motion**

27 Takeda contends that it is entitled to summary judgment of infringement of claims 1 and 2  
28 the ‘282 Patent, both of which require an amorphous compound of dexlansoprazole, on the basis

United States District Court  
Northern District of California

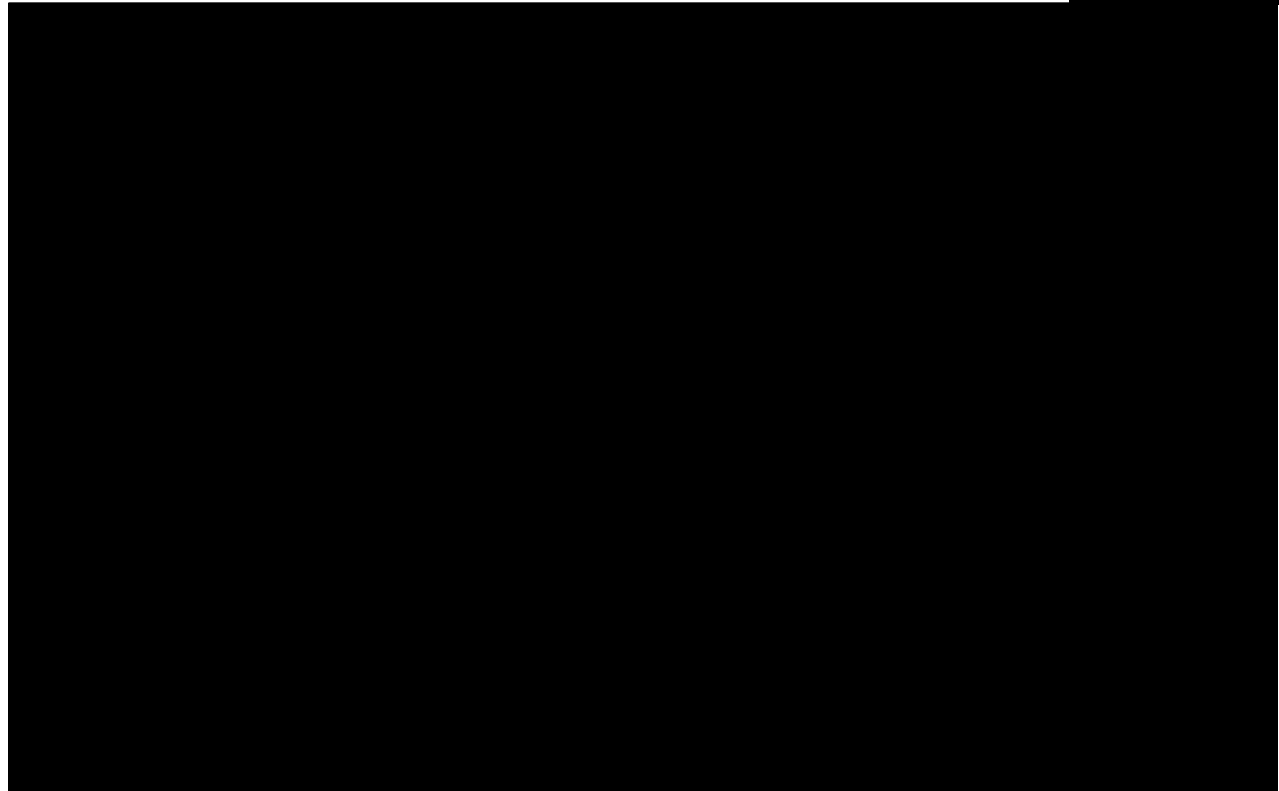
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Takeda also cites the following statements made by Handa in this litigation:



**b. Handa's Opposition**

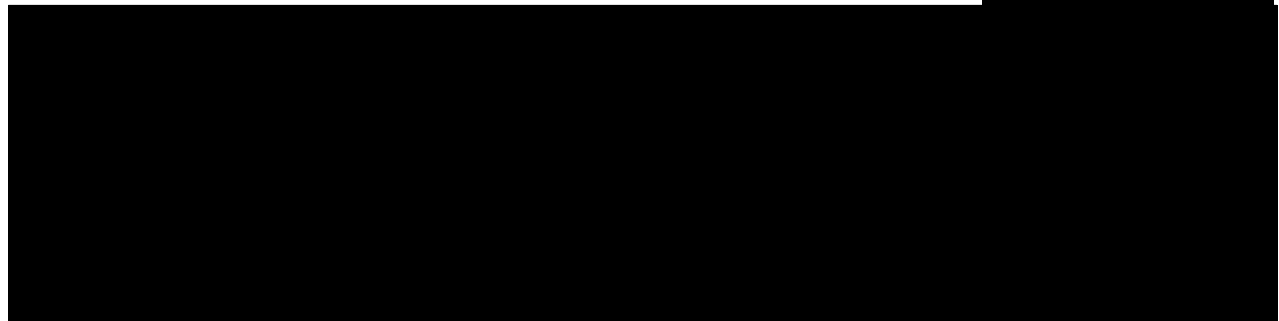
In its Opposition, Handa argues that Takeda is not entitled to summary judgment of infringement of the '282 Patent because: 1) it is Takeda's burden to establish infringement and

Takeda



Defendants Handa

Pharmaceuticals, LLC's and Par Pharmaceutical, Inc.'s Opposition to Motion for Summary Judgment of Infringement of the '282 Patent ("Handa Opposition") at 4; 2)



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[REDACTED]

4) there is no subject matter jurisdiction over Takeda’s ‘282 Patent infringement claims under 35 U.S.C. § 271(e)(2) because Takeda has not listed the ‘282 Patent in the “Orange Book.” *Id.* at 9-12 (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)).

**c. Takeda’s Reply**

In its Reply brief, Takeda again points to statements by Handa [REDACTED] Reply in Support of Takeda’s Motion for Summary Judgment of Infringement of the ‘282 Patent (“Takeda Reply”) at 1-3. In addition to the statements cited in Takeda’s opening brief, Takeda cites statements by Handa in its own motion for summary judgment in which it states that its ANDA product [REDACTED] Reply at 1 (quoting Handa SJ Motion at p. v). Takeda also cites the Handa SJ Motion at 1 (“[T]he ANDA Product lacks a limitation common to each of the asserted claims of the ‘276 Patent, that is, a

[REDACTED]

Takeda argues that if Handa’s ANDA

[REDACTED]

Reply at 5. Takeda points to the Court’s claim construction, which construes “amorphous compound” as solid and non-crystalline. *Id.* As it is undisputed that the [REDACTED]

[REDACTED]

Takeda asserts. *Id.* at 5-6. Further, Takeda argues, because a solid must be either



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crystalline or amorphous, Handa's assertions that [REDACTED]

[REDACTED] *Id.* at 6.

Takeda rejects Handa's argument that it is required to provide test results showing that the

[REDACTED]

[REDACTED] *Id.* at 7 (citing *Martek*

*Biosciences Corp. v. Nutrovina, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009)). Takeda notes that it

[REDACTED] addressed in the briefing on

Handa's request for summary judgment of noninfringement of the '276 Patent, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at 8.

Takeda further contends that having made a showing that Handa's ANDA product

[REDACTED] the burden shifted to Handa to produce specific evidence to

show that a genuine dispute exists and that Handa, [REDACTED]

[REDACTED] has not met

that burden. *Id.* at 9. Takeda rejects Handa's reliance on the deposition testimony of Dr.

Myerson that [REDACTED] arguing that

this testimony was taken out of context. *Id.* Takeda argues that Dr. Myerson merely testified

that he cannot say [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 11.

Takeda rejects Handa's assertion that the Court lacks subject matter jurisdiction under §

271(e)(2) because the '282 Patent is not listed in the Orange Book and Handa has not included a

Paragraph IV certification as to the '282 Patent in its ANDA. *Id.* According to Takeda, Supreme

Court and Federal Circuit authority establish that it is the submission of an ANDA, not a

Paragraph IV certification, that gives rise to jurisdiction in the district courts for an act of

infringement under § 271(e)(2). *Id.* at 11-12 (citing *Curaco Pharmaceutical Labs., Ltd. v. Novo*

1 *Nordisk A/S*, 132 S. Ct. 1670, 1680 n. 5 (2012); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669  
2 F.3d 1370, 1376-77 (Fed. Cir. 2012); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1343-44  
3 (Fed. Cir. 2004); *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1372-73 (Fed. Cir.  
4 2006)). Takeda cites district court decisions that it contends have reached the same conclusion.  
5 *Id.* at 20-21 (citing *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 363  
6 n.49 (D. Del. 2009); *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at \*5 (D. Del. Mar. 1,  
7 2012); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004); *Bayer*  
8 *Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at \*9 (E.D. Wis. Sept. 24, 2009).  
9 Further, Takeda asserts, the decision cited by Handa, *Eisai Co. v. Mutual Pharmaceutical Co.*,  
10 *Inc.*, 2007 WL 4556958, at \*6 (D.N.J. Dec. 20, 2007), “stands alone against the great weigh of  
11 authority . . . in holding that a suit pursuant to § 271(e)(2) may not be brought if the asserted  
12 patent is not listed in the Orange Book.” *Id.* at 13.

13 Finally, Takeda argues that Handa has misconstrued its complaint and ignored the plain  
14 language of Count VII in arguing that in its Second Amended Complaint Takeda did not assert  
15 infringement under § 271(a) based on Handa’s use of amorphous dexlansoprazole in the  
16 manufacture of its ANDA product. Reply at 13-14. In particular, it points to the complaint’s  
17 allegations that:

18 61. Defendants’ commercial **manufacture**, use, sale, or offer for  
19 sale within the United States or importation into the United States  
20 **of the Proposed Capsules** will constitute infringement of the ‘058,  
21 ‘276, ‘971, ‘282, ‘668, and ‘755 Patents

22 62. Defendants’ infringing commercial **manufacture**, use, sale, or  
23 offer for sale within the United States or importation into the United  
24 States **of the Proposed Capsules** complained of herein will begin  
25 following FDA approval of ANDA No. 202-294.

26 63. . . .Plaintiffs thus are entitled to a declaration that the **making**,  
27 using, sale, offer for sale, and importation into the United States **of**  
28 **the Proposed Capsules** according to ANDA No. 202-294 infringe  
one or more claims of the Asserted Patents.

29 *Id.* (quoting Second Amended Complaint, ¶¶ 61-63 (emphasis added in Reply brief)). This  
30 language, Takeda contends, makes clear that its claim encompasses not only infringement based

1 on the finished ANDA product but also infringement arising from the use of a patented invention  
2 in the manufacture of Handa's ANDA product. *Id.*

3 **2. Validity of the '282 Patent**

4 **a. Handa's Motion**

5 Handa contends that claims 1 and 2 of the '282 Patent are anticipated by both Larsson and  
6 Barberich and therefore, are invalid. Handa SJ Motion at 19-24. With respect to Larsson, Handa  
7 argues that there is no genuine dispute of material fact that this prior art discloses an "amorphous  
8 compound" of dexlansoprazole or a "salt thereof," which is the only requirement of claim 1 of the  
9 '282 Patent. *Id.* at 19. Handa notes that the Court has construed the term "amorphous  
10 compound" as "a non-crystalline solid that lacks the long-range order characteristic of a crystal."  
11 *Id.* It further points out that the parties are in agreement that Example 22 of Larsson discusses a  
12 process involving placing lansoprazole in a solvent, precipitating the lansoprazole, and  
13 evaporating off the solvent, and that Larsson reported obtaining an oil of dexlansoprazole after  
14 this process was performed "a couple of times." *Id.* (citing Rogers Decl., Ex. 6 (Expert Report of  
15 Robin D. Rogers, Ph.D. Regarding Invalidity of U.S. Patent No. 7,737,282 ("Rogers Report") at  
16 ¶¶ 68, 73; Jansen Decl., Ex. 11 (Expert Report of Jerry L. Atwood, Ph.D., in Response to the  
17 Expert Reports of Robin D. Rogers, Ph.D., and Edmund J. Elder, Jr., Ph.D., R.Ph., Regarding the  
18 Validity of the '282 Patent ("Atwood Report")) at ¶¶ 66, 67; *id.*, Ex. 6 (Oct. 16, 2012, Atwood  
19 Dep. Tr.) at 21:1-22:23). Thus, the only remaining question is whether the undisputed facts show  
20 that Larsson discloses a solid, as is required under the Court's claim construction. *Id.* Handa  
21 contends that it does because Larsson *inherently* discloses a solid amorphous compound of  
22 dexlansoprazole. *Id.*

23 To establish inherent disclosure of an amorphous compound of dexlansoprazole, Handa  
24 cites deposition testimony of Takeda's experts, Drs. Myerson and Atwood, as well as testimony  
25 by its own experts, Drs. Rogers and Elders, that it contends supports the conclusion that if one  
26 were to repeat the process described in Example 22 more than a couple of times, one would  
27 eventually obtain a solid. *Id.* at 19-20 (citing Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.)  
28 at 32:11-33:20; 35:3-21; 37:21-38:3; 42:17-43:12; *id.*, Ex. 14 (Oct. 25, 2012 Myerson Dep. Tr.) at

1 134:21-135:19; *id.*, Ex. 7 (Oct. 17, 2012 Atwood Dep. Tr.) at 233:14-234:12; *id.*, Ex. 3 (Oct. 12,  
2 2012 Elder Dep. Tr.) at 58:1-6; 69:3-22). Handa also cites the results obtained by researchers at  
3 the University of Wisconsin (“UW”) who, working under the direction of Dr. Elder (one of  
4 Handa’s experts), allegedly obtained a solid by replicating the synthesis described in Example 22  
5 of Larsson. *Id.* at 20 (quoting Declaration of Edmund J. Elder, Jr., Ph.D., R.Ph., In Support of  
6 Defendants’ Motion for Partial Summary Judgment (“Elder Decl.”), Ex. 4 (Final Report for  
7 Custom Synthesis (hereinafter, “UW Report”)) at 3, 10 (“[t]he final enriched product of R-(+)-  
8 lansoprazole was isolated as a brown dry foam, which could be transferred to a vial via spatula.  
9 The dry foam crumbled into a powder when transferred.”). According to Handa, Takeda’s expert,  
10 Dr. Atwood, did not dispute that the UW researchers obtained an amorphous compound of  
11 dexlansoprazole, nor did he question the XRPD analysis conducted by them. *Id.* (citing Jansen  
12 Decl., Ex. 6 (Oct. 16, 2012 Atwood Dep. Tr.) at 215:19-216:2). Handa further notes that Dr.  
13 Atwood did not attempt to perform the process disclosed in Example 22 himself. *Id.* (citing  
14 Jansen Decl., Ex. 6 (Oct. 16, 2012 Atwood Dep. Tr.) at 204:15-205:4; 211:23-212:6). Therefore,  
15 Handa contends, Dr. Atwood’s opinion that “Larsson was unable to obtain (R+)-lansoprazole as  
16 an amorphous solid” according to Example 22 and that it would be “unlikely that the ordinarily  
17 skilled person performing those steps in 1999 could have” done so is unfounded. *Id.* at 20-21  
18 (citing Jansen Decl., Ex. 11 (Atwood Report) at ¶ 81).

19 Handa further asserts that claim 2 of the ‘282 Patent is anticipated by Larsson. *Id.* at 21.  
20 As noted above, claim 2 depends from claim 1 and recites the additional limitation that the  
21 amorphous compound must be part of a “pharmaceutical composition” comprising “a  
22 pharmaceutically acceptable excipient, carrier or diluent.” According to Handa, “[a]lthough Dr.  
23 Atwood disputes Dr. Rogers’ assertion that water, which is disclosed in Larsson, is a  
24 pharmaceutically acceptable diluent . . . , he does not challenge any other assertions regarding  
25 Larsson with respect to the ‘pharmaceutical composition’ limitation of claim 2 of the ‘282  
26 Patent.” *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 161; Jansen Decl., Ex. 11 (Atwood  
27 Report) at ¶ 93). Therefore, Handa contends, it is undisputed that Larsson discloses the use of an  
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1 amorphous compound of dexlansoprazole in a pharmaceutical composition. *Id.* (citing Rogers  
2 Decl., Ex. 6 (Rogers Report) at ¶¶ 158-160, 162-63).

3 According to Handa, the asserted claims of the '282 Patent are also anticipated by the  
4 Barberich prior art. First, Handa contends, it is undisputed that Barberich incorporates by  
5 reference the synthesis of dexlansoprazole disclosed in Larsson and therefore, that Barberich, like  
6 Larsson, inherently discloses an "amorphous compound" of dexlansoprazole. *Id.* at 22 (citing  
7 Rogers Decl., Ex. 6 (Rogers Report) at ¶ 200; Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep.  
8 Tr.) at 79:12-25; 80:1-6; *id.*, Ex. 11 (Atwood Reports) at ¶ 70; *id.*, Ex. 7 (Oct. 17, 2012 Atwood  
9 Dep. Tr.) at 317:21-318:10). Second, Handa argues that Barberich *literally* discloses an  
10 "amorphous compound" of dexlansoprazole as it discloses "[c]ompressed tablets [that] may be  
11 prepared by compressing in a suitable machine the active ingredient in a freeflowing form such as  
12 a powder or granules." *Id.* (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 200 (quoting  
13 Barberich I)). In addition, Handa's expert points to Examples 1 and 2 of Barberich, which he  
14 contends disclose solid oral dosage forms using dexlansoprazole. *Id.* (citing Rogers Decl., Ex. 6  
15 (Rogers Report) at ¶ 201; Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 86:16-88:7).

16 Handa rejects the opinion of Dr. Atwood that the disclosure in Barberich is merely  
17 "prophetic" and that the Barberich inventors did not actually create an amorphous compound of  
18 dexlansoprazole. *Id.* at 22-23 (citing Jansen Decl., Ex. 7 (Atwood Dep.) at 318:11- 319:14;  
19 321:4-21; *id.*, Ex. 11 (Atwood Report) at ¶¶ 71, 102). Arguing that Dr. Atwood's opinion was  
20 unfounded, Handa points to his testimony that he did not "know Barberich." *Id.* (citing Jansen  
21 Decl., Ex. 7 (Oct. 17, 2012 Atwood Dep. Tr.) at 319:15-16). As further evidence that Dr.  
22 Atwood's opinion is "baseless," Handa points to a statement in Takeda's interrogatory responses  
23 that it is "possible" that Barberich Examples 1 and 2 were only "paper experiments." *Id.* (citing  
24 Jansen Decl., Ex. 12 (Plaintiffs' Responses To Handa Pharmaceuticals LLC's First Set Of  
25 Interrogatories) at 6) ("as Examples 1 and 2 of Barberich are written in the present tense, it is  
26 possible that these Examples were paper examples and not actually performed"). Further,  
27 according to Handa, Dr. Atwood's position is based on an incorrect understanding of the law  
28 because even a "prophetic" disclosure is sufficient to establish anticipation. *Id.* at 23. In

1 particular, Handa contends that the law does not require actual creation or reduction to practice of  
2 prior art subject matter but only that an anticipatory reference “enable subject matter that falls  
3 within the scope of the claims at issue.” *Id.* at 23 (citing *Schering Corp. v. Geneva Pharms., Inc.*,  
4 339 F.3d 1373, 1380-81 (Fed. Cir. 2003); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)).

5 Handa argues that Barberich also anticipates claim 2 of the ‘282 Patent because it  
6 discloses using dexlansoprazole to treat patients and teaches pharmaceutical compositions  
7 containing dexlansoprazole. *Id.* at 23-24 (citing Rogers Decl., Ex. 6 (Rogers Report) at ¶ 208;  
8 Jansen Decl., Ex. 13 (Nov. 9, 2012 Rogers Dep. Tr.) at 82:7-14).

9 **b. Takeda’s Opposition**

10 Takeda argues that the asserted claims of the ‘282 Patent are not anticipated by either  
11 Larsson or Barberich. Takeda’s Opposition to Handa and Par’s Motion for Partial Summary  
12 Judgment (“Takeda Opposition”) at 15-19. With respect to Larsson, Takeda rejects Handa’s  
13 contention that Larsson inherently discloses the synthesis of an “amorphous compound” of  
14 dexlansoprazole, arguing that the evidence does not show that Example 22 *necessarily* results in  
15 the synthesis of such a compound. *Id.* at 16. First, it argues that the testimony of the Handa  
16 experts – that had the inventors repeated the process in Example 22 they would have obtained an  
17 amorphous solid – is not sufficient because Larsson does not disclose that the oily form described  
18 in Example 22 may be evaporated to obtain a solid. *Id.* According to Takeda, even assuming  
19 these experts were correct, this testimony would represent only the common knowledge of the  
20 skilled artisan, which cannot be used to establish inherency. *Id.* (citing *Rockwell Int’l Corp. v.*  
21 *SDL, Inc.*, 103 F. Supp. 2d 1202, 1207 (N.D. Cal. 2000) (citing *Structural Rubber Prods. Co. v.*  
22 *Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984))). Further, Takeda contends, this would not  
23 have been common knowledge as Example 22 suggests the opposite, namely, that repeating the  
24 procedure would result in an oil. *Id.* at 16-17.

25 Takeda also challenges Handa’s reliance on the testimony of its experts, Drs. Myerson and  
26 Atwood. *Id.* at 17. With respect to Dr. Myerson, Takeda argues that his deposition testimony on  
27 anticipation is inadmissible hearsay and should be excluded because he is Takeda’s expert on  
28 infringement, not validity, and therefore, Handa may use his deposition testimony only to

1 impeach his opinions on infringement. *Id.* (citing Fed. R. Civ. Proc. 32(a); 8A Fed. Prac. & Proc.  
2 Civ. § 2145 (3d Ed. 2012); *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 2005 WL 2296613, at \*2 (D. Del.  
3 Sept. 20, 2005)). Further, it argues, Dr. Myerson’s opinion does not establish anticipation as he  
4 merely testified that “[i]f you dried the oil, which is very hard to do, you should be able to  
5 eventually make it what you would consider an amorphous solid. But it might take a really long  
6 time.” *Id.* (quoting Jansen Decl., Ex. 14 (Oct. 25, 2012 Myerson Dep. Tr.) at 134:21 - 135:19).  
7 This testimony, Takeda argues, is insufficient to establish anticipation and relates only to  
8 obviousness. *Id.* (citing *Structural Rubber Prods.*, 749 F.2d at 716; *Impax Labs., Inc. v. Aventis*  
9 *Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008)). Dr. Atwood’s testimony also does not  
10 establish anticipation, Takeda argues. *Id.* Dr. Atwood only testified that “it is possible that the oil  
11 is going to set into a solid.” *Id.* (citing Purles Opposition Decl., Ex. 11 (Oct. 17, 2012 Atwood  
12 Dep. Tr.) at 233:14-238:14). According to Takeda, this testimony does not meet the requirement  
13 for inherency that such a result is inevitable. *Id.* at 17-18.

14 Takeda also rejects Handa’s reliance on the experiments by Dr. Elder and the UW  
15 researchers in which the process in Example 22 was repeated and allegedly resulted in the  
16 synthesis of a solid. *Id.* at 18. First, Takeda argues that the UW lab “did not obtain an amorphous  
17 solid of dexlansoprazole by evaporating an oil to dryness; rather, the UW lab obtained a solid  
18 immediately *before* the final evaporation step in Example 22, and never actually obtained an oil.  
19 *Id.* (citing Elder Decl., Ex. 4 (UW Report) at 8 (emphasis in Takeda brief)).<sup>6</sup> Second, Takeda

20  
21 <sup>6</sup> At the February 22, 2013 hearing, Takeda conceded that this opinion was not stated by any of its  
22 experts. Takeda pointed to the following passage in the UW Report in support of its assertion:

23 After stirring for 16 h at room temperature, to the solution was  
24 added toluene (50 ml) and the resultant solution was extracted three  
25 times with aqueous ammonia (12%, 3x100 ml). The combined  
26 aqueous layers were neutralized by the addition of concentrated  
27 acetic acid (30 ml). Thereafter, the workup procedure employed  
28 extraction by ethyl acetate (3x100 ml), evaporation and by silica gel  
flash column chromatography . . . yielding 1.4 g of light brown  
solid (yield: 65%) title compound with enantiomeric excess (e.e.) of  
56 % (chiral analysis). After treating the residue with acetonitrile  
there was obtained a precipitate that was removed by filtration.  
Evaporation of the filtrate afforded a foam product with enhanced  
optical purity. Performing this procedure 5 total times . . . afforded

1 argues that the UW research does not establish inherency because the only way the researchers  
 2 could obtain a solid amorphous compound of dexlansoprazole was by departing from the plain  
 3 language of the experimental protocol described in Example 22. *Id.* (citing Jansen Decl., Ex. 11  
 4 (Atwood Report) at ¶¶ 89-90). In particular, when the UW researchers applied “as strict of [an]  
 5 interpretation of the Larsson procedure as possible,” their first attempt resulted in a solid of  
 6 racemic lansoprazole rather than dexlansoprazole. *Id.* (citing Elder Decl., Ex. 4 (UW Report) at  
 7 3-4).<sup>7</sup> Thus, in order to obtain the solid amorphous compound, Takeda contends, the UW  
 8 researchers had to adjust the procedure by adding the oxidant (cumene hydroperoxide) drop-by-  
 9 drop over a period of 30 minutes via syringe pump – which is a procedure that is not described  
 10 anywhere in Example 22. *Id.* (citing Elder Decl., Ex. 4 (UW Report) at 4, 8; Jansen Decl., Ex. 11  
 11 (Atwood Report) at ¶¶ 83-84; Purles Opposition Decl., Ex. 12 (Oct. 12, 2012 Elder Dep. Tr.) at  
 12 42:6-43:22) (testifying that Example 22 does not describe adding cumene hydroperoxide).  
 13 Because the researchers obtained the amorphous compound of dexlansoprazole in only one of two  
 14 experiments and had to adjust the protocol in the second one to include steps that were not  
 15 described in Example 22, Takeda asserts, this evidence does not establish inherency. *Id.* (citing  
 16 *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-1269 (Fed. Cir. 1991)).<sup>8</sup>

17 Takeda argues that Barberich “adds nothing to the analysis.” *Id.* Takeda does not dispute  
 18 that Barberich refers to solid pharmaceutical compositions of dexlansoprazole but contends that it  
 19 does not disclose the synthesis of any solid form of dexlansoprazole; instead, it merely  
 20 incorporates by reference prior art such as Larsson. *Id.* at 18-19 (citing Jansen Decl., Ex. 11

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21 0.53 g (24.5 % yield) of the desired compound as a brown foam  
 22 with an optical purity of 97.8 % ee.

23 Elder Decl., Ex. 4 (UW Report) at 8.

24 <sup>7</sup> At the February 22, 2013 hearing, Handa conceded that on their first attempt, the UW  
 25 researchers obtained a racemate rather than dexlansoprazole.

26 <sup>8</sup> At the February 22, 2012 hearing, Takeda cited a case that was not included in its brief, *Scripps*  
 27 *Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) in support of  
 28 their argument that the UW research cannot be used to “fill in the gaps” for Larsson’s inadequate  
 disclosure. The Federal Circuit stated in *Scripps* that “a finding of anticipation requires that all  
 aspects of the claimed invention were already described in a single reference: a finding that is not  
 supportable if it is necessary to prove facts beyond those disclosed in the reference in order to  
 meet the claim limitations.” 927 F.2d at 1576.



1 (Atwood Report) at ¶¶ 70-71, 100-106). Takeda cites the testimony of both Drs. Rogers and Dr.  
2 Genck (the expert of Impax Laboratories, Inc., a defendant in Related Case No. 11-01610 JCS )  
3 that Barberich does not add any teachings regarding the synthesis of dexlansoprazole to the  
4 teachings of Larsson. *Id.* at 19 (citing Purles Opposition Decl., Ex. 13 (Nov. 9, 2012 Rogers  
5 Dep. Tr.) at 78:1-82:20; *id.*, Ex. 14 (Oct. 15, 2012 Genck Dep. Tr.) at 121:16-125:20). Because  
6 Barberich does not “enable one of skill in the art to reduce the disclosed invention to practice,”  
7 Takeda argues, it does not anticipate the asserted claims of the ‘282 Patent. *Id.* (citing *Amgen Inc.*  
8 *v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003)).

9 **c. Handa’s Reply**

10 In its Reply brief, Handa points out that Takeda did not address the question of whether  
11 Larsson or Barberich disclose the “pharmaceutical composition” limitation of claim 2 of the ‘282  
12 Patent, therefore implicitly conceding that this limitation is disclosed in the prior art. Defendants  
13 Handa Pharmaceuticals, L.L.C.’s and Par Pharmaceuticals, Inc.’s Reply in Support of Motion for  
14 Partial Summary Judgment (“Handa Reply”) at 12 n. 7. Thus, the only question as to anticipation  
15 is whether Larsson and Barberich anticipate on the basis of disclosure of a solid amorphous  
16 compound of dexlansoprazole.<sup>9</sup>

17 Handa argues that Takeda has applied the wrong legal standard to the extent it contends  
18 Larsson must expressly recognize that the oil described in Example 22 may be evaporated to  
19 obtain a solid. *Id.* at 13. The correct standard, Handa asserts, requires only that the “feature  
20 necessarily results from what was disclosed.” *Id.* (citing *Schering*, 339 F.3d at 1377;  
21 *Mehl/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999); *Atlas Powder*  
22 *Corp. v. IRECO Inc.*, 190 F.3d 1342, 1348-1349 (Fed. Cir. 1999)). According to Handa, all of  
23 the experts agree that repetition of Example 22 in Larsson would result in the synthesis of such a  
24 compound and this is sufficient to establish anticipation. *Id.* at 12-13. It is not sufficient,  
25 according to Handa, that it might be difficult or take a long time to obtain a solid amorphous

26 \_\_\_\_\_  
27 <sup>9</sup> Handa states in its brief that it does not concede that Larsson does not expressly disclose an  
28 amorphous solid of dexlansoprazole but that this issue is in dispute and therefore “does not form  
the basis for the present motion.” Handa Reply at 12 n. 8. At oral argument, however, Handa  
conceded that Larsson does not expressly disclose an amorphous solid of dexlansoprazole.

1 compound of dextansoprazole, as Dr. Myerson testified, as this is not the test for undue  
2 experimentation, Handa argues. *Id.* at 13-14 (citing *Enzo Biochem., Inc. v. Calgene, Inc.*, 188  
3 F.3d 1362, 1370 (Fed. Cir. 1999); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360  
4 (Fed. Cir. 1998)). Handa also rejects Takeda’s argument that Dr. Myerson’s testimony on  
5 validity is inadmissible, arguing that Rule 56(c)(2) of the Federal Rules of Civil Procedure  
6 permits the citation of deposition testimony and Takeda has not demonstrated that Dr. Myerson’s  
7 testimony could not be presented at trial in “a form that would be admissible.” *Id.* at 14 n. 13.

8 Further, according to Handa, Dr. Atwood did not deny that repeating the process in  
9 Example 22 would result in the synthesis of a solid amorphous compound of dextansoprazole,  
10 admitting that it was “possible” that this would result if the procedure in Example 22 were  
11 performed “two, three, four, five, six times.” *Id.* at 14. Handa points out that Dr. Atwood himself  
12 made no attempt to replicate the process described in Example 22. *Id.* at 14. Because Takeda has  
13 introduced no evidence to contradict the experts’ unanimous opinion that performing Example 22  
14 will result in an amorphous solid, Handa argues, *Glaxo* and *Continental Can*, cited by Takeda, are  
15 not applicable here. *Id.* at 14 n. 13.

16 In a footnote, Handa also cites the conclusion of Dr. Elder and the UW researchers that  
17 repetition of Example 22 yields an amorphous solid of dextansoprazole. Handa states that  
18 “[w]hile Takeda challenges that testing, it fails to raise any genuine dispute of material fact . . .  
19 and summary judgment may in any event be granted on the remaining facts that are not in dispute,  
20 identified herein.” *Id.* Handa does not, however, address Takeda’s specific arguments, based on  
21 the expert opinion of Dr. Atwood, that only one of the two experiments resulted in the creation of  
22 an amorphous compound of dextansoprazole and that the second experiment required a change in  
23 the protocol that was not described in Example 22.

24 Finally, Handa argues that Takeda has not demonstrated a material issue of fact as to  
25 anticipation by Barberich. *Id.* at 15. Handa notes that Takeda does not dispute that Barberich  
26 describes “the active ingredient in a free-flowing form such as a powder or granule,” and  
27 therefore, that Barberich expressly discloses an amorphous solid of dextansoprazole. *Id.* (citing  
28 Takeda Opposition at 18-19). Handa contends that even if this disclosure is “prophetic,” as Dr.

1 Atwood testified, it is sufficient to anticipate and further, that Takeda waived any argument to the  
2 contrary because it did not dispute that a “prophetic” disclosure can anticipate in its Opposition  
3 brief. *Id.* at 15 n. 14.

4 **d. Supplemental Briefing**

5 Following the motion hearings, the parties submitted supplemental briefs at the request of  
6 the Court addressing which party bears the burden of proving enablement when a patentee raises  
7 nonenablement to rebut anticipation based on prior art under 35 U.S.C. § 102. *See* Docket Nos.  
8 256, 258.

9 **3. Infringement of the ‘755 Patent**

10 **a. Handa’s Motion**

11 Handa seeks entry of summary judgment of non-infringement of the ‘755 Patent on the  
12 basis that it is undisputed that the

13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 Handa rejects Dr. Charman’s opinion that these data  
21 do not establish infringement because a person skilled in the art would understand that the “begins  
22 to be released” requirement is not met unless there is “rapid and significant” release of  
23 dexlansoprazole, that is, at least 10% release of the drug in less than two hours. *Id.* (citing Amiji  
24 Decl., Ex. 4, at ¶ 88-89).<sup>10</sup> According to Handa, Takeda’s position amounts to an improper

25 <sup>10</sup> [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 attempt to reargue the Court's construction of the release limitation and is contrary to: 1) the  
2 specification of the '755 Patent; 2) the applicants' arguments during prosecution of the '755  
3 Patent; and 3) Takeda's arguments during claim construction in this action. *Id.* at 6.

4 Handa contends that "nothing in the claims or specification of the '755 Patent support[s]  
5 an argument that the dissolution measurement must be conducted at 120 minutes (two hours), or  
6 that there is no 'release' for the purpose of the pertinent claim term until more than 10% of the  
7 dexlansoprazole in the L-pellets has been released." *Id.* at 6-7. According to Handa, "[t]he only  
8 reference in the '755 Patent to an appropriate dissolution protocol refers to dissolution  
9 measurement after five to eight hours in solution." *Id.* at 7 (citing '755 Patent, col. 10, ll. 13-17  
10 ("The rate of elution of active ingredient from the active ingredient release-controlled tablet,  
11 granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0,  
12 and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8"))).

13 Looking to the prosecution history of the '755 Patent, Handa cites remarks to the PTO by  
14 the applicants in which they relied on the declaration of one of the inventors, Dr. Takashi  
15 Kurasawa, describing the results of dissolution testing that he conducted over a 6-8 hour period.  
16 *Id.* (citing Jansen Decl., Ex. 8, at DEX0007130-31). According to Handa, the applicants  
17 "affirmatively presented the Kurasawa test methodology and results to distinguish the Beckert  
18 prior art reference that had been asserted by the Examiner" by relying on Kurasawa's release  
19 measurements at six hours. *Id.* Handa quotes the following statements of the applicants in  
20 support of this point:

21 As shown in Fig. 1 of the attached Declaration of Mr. Takashi  
22 KURASAWA, who is one of the inventors of the present invention,  
23 Granule H in the Declaration, dissolves at pH 6.8 almost 100% in 6  
24 hours and more than 30% in 4 hours. Further, in Fig. 1 of the  
25 Declaration of Mr. Kurasawa, composition (ii) of claim 41 [now  
26 claim 1], i.e., Granule L-S, dissolves at pH 6.8 almost 100% at 2  
27 hours. . . . further, the composition (i) of claim 41 dissolves at  
28 pH6.0-7.5, and dissolves completely at pH 6.8 at 6 hours . . . . The  
[Beckert] reference, however, discloses that not more than 20% of  
the active ingredient in pellet B is released at pH 6.8 after 6 hours.

1 *Id.* (quoting Jansen Decl., Ex. 8 at DEX0007130-31). Handa further points to Figure 1 in the  
2 Kurasawa affidavit, which it contends shows release of less than 5% of the dexamethasone at  
3 two hours, less than 10% at three hours and 30% at four hours. *Id.* at 8 (citing Jansen Decl., Ex.  
4 8, at DEX0007124). In other words, Handa argues, the applicants relied on test results showing  
5 release of less than 5% of the dexamethasone after two hours; thus, the embodiment offered by  
6 the applicants to distinguish Beckert would not have fallen within the scope of the claims under  
7 Dr. Charman's approach. *Id.* Such a result, according to Handa, is disfavored. *Id.* at 8 (citing  
8 *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008)).

9 Handa also points to Takeda's arguments on claim construction, citing Takeda's reliance  
10 on the same dissolution data in the prosecution history in support of its position that the release  
11 term is not indefinite because a person of ordinary skill in the art could easily replicate the testing  
12 methodology described in the prosecution history. *Id.* (citing JSUF (Handa Motion), at ¶6).

13 Finally, [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 **b. Takeda's Opposition**

20 Takeda does not dispute that the [REDACTED]

21 [REDACTED] It contends, however, [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED] Takeda Opposition at 2-3. Takeda notes that the Court explicitly declined to  
25 specify at the claim construction stage of the case what type of testing would be required to  
26 determine whether the release term was satisfied, leaving this question to be addressed at trial  
27 through expert testimony. *Id.* at 4. This approach is consistent with Federal Circuit precedent,  
28 Takeda asserts, pointing to cases holding that courts need not eliminate all ambiguity in

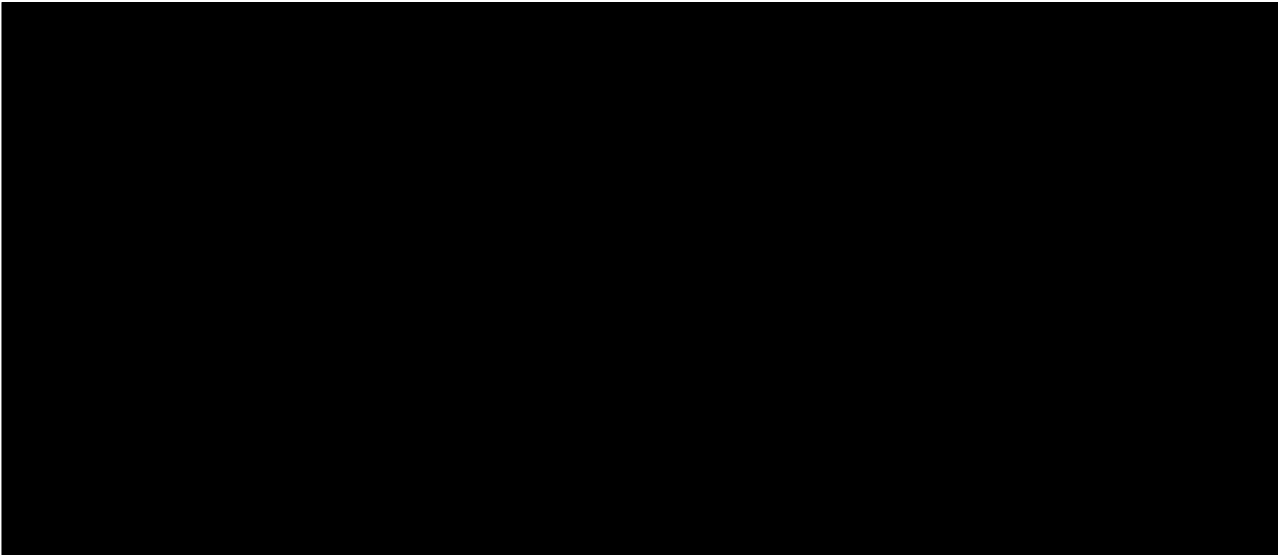
1 construing claim terms but rather, should only define terms to the level of specificity that is  
 2 warranted by the language of the claim and the evidence. *Id.* at 4-5 (citing *Acumed LLC v.*  
 3 *Strkyer Corp.*, 483 F.3d 800 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d  
 4 1351 (Fed. Cir. 1998); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249  
 5 F.3d 1341 (Fed. Cir. 2001); *Modine Mfg. Co. v. Int’l Trade Comm’n*, 75 F.3d 1545 (Fed. Cir.  
 6 1996)). According to Takeda, “where ‘the claim language does not require a particular form of  
 7 testing, this inquiry is not a claim construction question’ but is ‘review[ed] . . . as a question of  
 8 fact.’” *Id.* at 5 (quoting *Union Carbide Chems. and Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d  
 9 1366, 1377 (Fed. Cir. 2005), overruled on other grounds by *Cardiac Pacemakers, Inc. v. St. Jude*  
 10 *Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009)).

11 Takeda argues further that there is a genuine dispute of material fact as to the testing  
 12 criteria that should be used to decide whether Handa’s ANDA product meets the release  
 13 limitation and that substantial evidence supports Dr. Charman’s approach. *Id.* Takeda points to  
 14 the following evidence in support of Dr. Charman’s approach:

- 15 • the monograph on dissolution testing in the United States Pharmacopeia (“USP”), which  
 16 recognizes that for delayed-release dosage forms, a product passes a dissolution test if no  
 17 individual dosage unit shows more than 10% dissolution in acid medium. *Id.* at 6 (citing  
 18 Charman Decl., Ex. A.22<sup>11</sup> (2012 USP section on dissolution ) at 301, Acceptance Table  
 19 3; Takahashi Decl., Ex. F (1995 USP section on dissolution) at 1796, Acceptance Table  
 20 2).
- 21 • the USP section on delayed release lansoprazole (which is an enantiomer of  
 22 dexlansoprazole), which “permits dissolution of less than 10% in the acid stage in a two-  
 23 stage experiment designed to simulate passage through an acidic stomach (in the first  
 24 stage) followed by simulated intestinal dissolution (in the second stage).” *Id.* (citing  
 25 Takahashi Decl., Ex. G (2009 USP section on lansoprazole delayed-release capsules) at

26  
 27 <sup>11</sup> Takeda has submitted separate expert reports by Dr. Charman for each of the three defendants  
 28 in the related cases. Dr. Charman’s report on Handa’s accused product is designated as Exhibit A  
 to his declaration and the exhibits attached to Dr. Charman’s Handa report are designated as A.1  
 to A.23.

1 2753 (stating as to acid stage “[t]olerances” that “[n]ot more than 10% of the labeled  
2 amount of [lansoprazole] is dissolved in 60 minutes”).



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- 12 • testimony of Handa’s expert, Dr. Mansoor Amiji, that the typical transit time through the  
13 small intestine is 3.5 to 4.5 hours, with the pH level rising continuously through the length  
14 of the intestine. *Id.* (citing Purles Decl., Ex. 4 (Nov. 14, 2012 Amiji Dep. Tr.) at 127:7-  
15 129:24 & Ex. 18 (Dep. Ex. 105) at 5). Takeda asserts that in light of the fact that the ‘755  
16 Patent envisions two distinct releases, one at the upper end of the small intestine and  
17 another at the lower end of the small intestine, this testimony offers further support for the  
18 time period suggested by Dr. Charman for measuring dissolution. *Id.* at 7-8 (citing ‘755  
19 Patent, col. 1, ll. 53-57 (“After administered orally, the tablet, granule or fine granule  
20 migrates through gastrointestinal tract with [sic] releasing an active ingredient to stomach,  
21 duodenum, jejunum, ileum and colon sequentially”).
  - 22 • the FDA’s Dissolution Methods Database entry for dexlansoprazole, recommending that  
23 in testing dexlansoprazole dissolution, sampling for the acid stage should be conducted at  
24 120 minutes. *Id.* at 8 (citing Takahashi Decl., Ex. P (Dissolution Methods)).
  - 25 • testimony by Impax’s expert, Dr. Augsburger, that once the delayed release product  
26 reaches its target pH, the release should be “relatively rapid.” *Id.* (citing Purles Decl., Ex.  
27 10 (Nov. 16, 2012 Augsburger Dep. Tr.) at 116:6-18).
- 28

- 1 • the statement in the '755 Patent specification that "the usual enteric coat" dissolves  
2 "rapidly." *Id.* (citing '755 Patent, col. 6, l. 66 - col. 7, l. 12).
- 3 • Dr. Charman's deposition testimony that "any meaningful test for infringement must have  
4 an amount limitation to account for small amounts of dissolution that inevitably occur in  
5 any in vitro dissolution test of any significant duration," especially in light of  
6 manufacturing defects that commonly result in inappropriately coated or uncoated drug in  
7 the formulation. *Id.* (citing Purles Decl., Ex. 1 (Oct. 31, 2012 Charman Dep. Tr.) at 23:18-  
8 30:4, 180:20-181:8, 182:22-183:12, 254:20-260:22); *id.* Ex. 6 (Nov. 1, 2012 Charman  
9 Dep. Tr.) at 58:14-59:8).

10 Takeda argues that Handa's reliance on the '755 Patent specification and prosecution history,  
11 is misplaced. *Id.* at 9. As to Handa's reliance on col. 10, ll. 13-17 of the '755 Patent, stating that  
12 "[t]he rate of elution of active ingredient from the active ingredient release-controlled tablet,  
13 granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0,  
14 and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8," Takeda  
15 contends that the specification makes clear that the threshold pH for this formulation was "6.75 or  
16 above." *Id.* (citing '755 Patent, col. 10, l.2). In other words, according to Takeda, "rapid and  
17 significant' release for this particular embodiment would only be expected at a pH of 6.75 or  
18 higher." *Id.* Takeda reasons, "[t]hat release was relatively slow and minimal at pH 6.0, a pH  
19 level significantly below the target pH of this particular embodiment, is in no way inconsistent  
20 with Dr. Charman's opinion that the claimed formulation should show rapid and significant  
21 dissolution above its target pH." *Id.* at 9. Takeda asserts that it has shown as to Handa's  
22 formulation significant and rapid release of dexlansoprazole at target pH levels of 5.9 and 7.4,  
23 which falls within the scope of the '755 claims. *Id.*

24 Takeda also rejects Handa's contention that the applicants' reliance on the dissolution  
25 testing of Dr. Kurasawa during patent prosecution in the PTO contradicts Dr. Charman's position.  
26 *Id.* According to Takeda, Dr. Kurasawa's test was conducted at pH 6.8, a pH level "much lower  
27 than the pH 7.5 upper end of the pH range for the high-pH granule described in claim 1." *Id.*  
28 Thus, it contends, "[t]hat the granule released drug slowly at pH level of 6.8 does not indicate



1 how rapidly the drug would release within two hours at the higher pH of 7.5, and thus in no way  
2 undermines Dr. Charman's opinion." *Id.* Takeda also argues that the applicant's arguments  
3 distinguishing the Beckert prior art based on the Kurasawa tests are consistent with its position.

4 *Id.* at 10. In particular, it argues:

5 In its response to an Office Action rejecting the claims over a prior  
6 art reference by Beckert, Takeda distinguished the release profile  
7 for its Granule H from Beckert's Pellet B. Specifically, Takeda  
8 showed that Granule H achieved 30% dissolution after four hours,  
9 and nearly 100% after six hours, at pH 6.8, while Pellet B released  
10 not more than 20% after six hours at pH 6.8. See *id.* at  
11 DEX0007130; Charman Decl. ¶ 26. Under Handa's view of  
12 infringement, this minimal and slow release from the Beckert Pellet  
13 B would still have satisfied the claim limitations of the '755 patent;  
14 accordingly, Takeda's comparison would not have shown Beckert  
15 to be patentably distinguishable from the claimed formulations. The  
16 fact that the Examiner understood the different profiles of the two  
17 formulations, as shown by Takeda's comparative data, to be  
18 patentably distinct reflects his understanding that the amount and  
19 rate of release is necessarily critical to determining whether the  
20 limitations of the '755 patent are satisfied.

21 *Id.*

22 With respect to its arguments during claim construction, Takeda contends that it merely  
23 cited to Kurasawa to show that the term "begins to release" is not indefinite because a person  
24 skilled in the art would know how to perform dissolution testing like that performed by  
25 Kurasawa. *Id.* According to Takeda, it was not suggesting that the exact testing that was  
26 performed by Kurasawa should be used to assess infringement; indeed, the Kurasawa test fails to  
27 address "how the high-pH granule would behave at the upper end of the pH range, and thus offers  
28 incomplete information as to the high-pH-releasing granule limitation, and provides no  
information concerning the behavior of the low-pH granule in the claimed 5.0 to 6.0 pH range."

*Id.* at 10-11.

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**c. Handa’s Reply**

In its reply brief, Handa contends that Takeda is improperly attempting to import additional limitations into the asserted claims. Handa Reply at 3. Handa reiterates its position that there is no support in the ‘755 Patent specification for Dr. Charman’s position that release does not begin unless at least 10% of the dexlansoprazole is released over two hours. *Id.* at 5. Handa also rejects Takeda’s reading of the prosecution history, contending that its “effort to distinguish the Kurasawa declaration in the file history is . . . weak and barely intelligible.” *Id.* Handa contends that Takeda merely offers speculation that the release exhibited in the Kurasawa tests would have been more rapid at a higher pH level but that this is “irrelevant.” *Id.* According to Handa, what matters is that both the patent specification and the Kurasawa declaration teach dissolution testing for “far more than the two-hour limit proposed by Takeda.” *Id.* at 6.

Furthermore, Handa asserts, Takeda’s new claim construction position is based almost entirely upon extrinsic evidence, which is disfavored in claim construction. *Id.* (citing *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)). Rather, Handa contends, the Court should look to the ordinary meaning of the claim language as understood by a person of ordinary skill in the art, which in this case is so straightforward that it can be understood by a lay judge. *Id.* (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)). According to Handa, “a person having ordinary skill in the art would understand the term ‘released’ as used in the asserted claims of the ’755 Patent to have its plain meaning in the context of in vitro testing— i.e., any release of drug from the dosage form into the dissolution medium.” *Id.* n. 3 (citing *Amiji Decl.*, Ex. 5, ¶ 41). Finally, Handa rejects Takeda’s reliance on extrinsic evidence such as the USP and the FDA Guidelines on the grounds that these extrinsic documents are not referenced in the ‘755 Patent and there is no justification for turning to this extrinsic evidence to modify the meaning of the claims. *Id.* at 7.

**d. Supplemental Briefs**

Following the February 8 motion hearing, the parties in this case and the related cases submitted supplemental briefing at the request of the Court addressing whether it should engage in additional construction of the release term of the ‘755 Patent. *See* Case No. C-11-0840 JCS,

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Docket Nos. 251 (Takeda), 252 (Handa); Case No. 11-1609, Docket No. 223 (TWi); Case No. C-11-1610, Docket No. 228 (Impax).

**4. Infringement of the '276 Patent**

**a. Handa's Motion**

Handa asserts that it is entitled to summary judgment of non-infringement of the '276 Patent because Takeda has not provided any evidence to show that: 1) the dexlansoprazole API used in the ANDA product [REDACTED] (as required by claims 2 and 3); or 2) the ANDA product is a pharmaceutical composition comprising [REDACTED]

[REDACTED] *Id.* at 10-11. According to Handa, it is undisputed that [REDACTED]

[REDACTED] and that neither Takeda nor its expert, Dr. Myerson, has offered any test results showing that the finished ANDA product contains [REDACTED] *Id.* at 11. This omission is particularly telling, Handa contends, because [REDACTED]

Indeed, Handa points out, [REDACTED]

Handa also points to [REDACTED]

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[REDACTED]

In addition, [REDACTED]

[REDACTED]

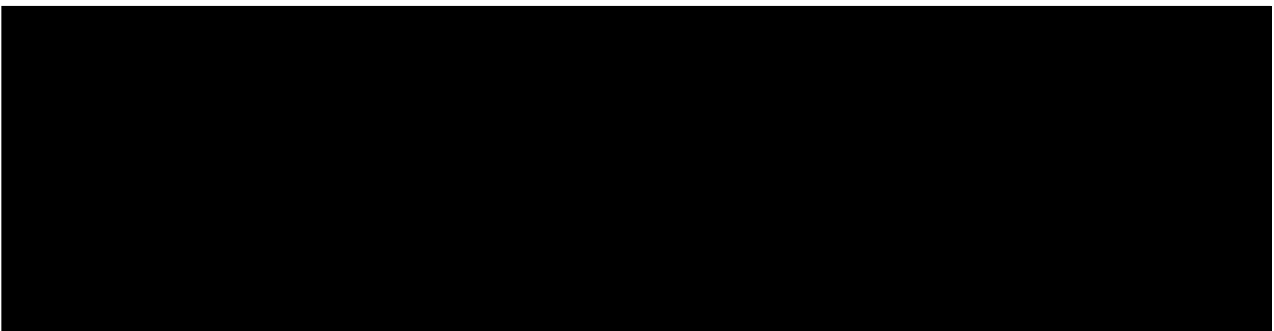
Handa contends that the basis for Takeda's claim that Handa's ANDA product infringes the '276 Patent is simply "[REDACTED]"

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According to Handa, [REDACTED]

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Handa also addresses the specific documents upon which Dr. Myerson relies, arguing that none of them supports Dr. Myerson's position. *Id.* at 15-18. First, Handa rejects Dr. Myerson's reliance on



Similarly, Handa contends that Dr. Myerson's reliance on



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Likewise, Handa rejects Dr. Myerson's reliance

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Handa also rejects Dr. Myerson's reliance on

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Finally, Handa rejects Dr. Myerson's reliance on

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**b. Takeda's Opposition**

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Takeda argues that fact questions preclude entry of summary judgment of non-infringement of the '276 Patent. Opposition at 19. According to Takeda, it is undisputed that Handa's formulated product, which includes the active ingredient dexlansoprazole and the

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[REDACTED]

[REDACTED] *Id.* This question is highly factual, Takeda contends, and will require the Court to evaluate the significance of [REDACTED]

[REDACTED]

According to Takeda, these documents are sufficient to give rise to a fact question as to the existence of crystalline dexlansoprazole in the finished ANDA product.

**c. Handa's Reply**

Handa contends that Takeda has not established a genuine dispute of material fact as to the existence of [REDACTED] but rather relies "solely on uncorroborated speculation." Reply at 7-8.

**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 Patent Infringement

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2 A determination of infringement is a two-step process. *Wright Med. Tech., Inc. v.*  
3 *Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The first step is claim construction,  
4 which is a question of law to be determined by the court. *Id.* The second step is an analysis of  
5 infringement, in which it must be determined whether a particular device infringes a properly  
6 construed claim. *Id.* A device literally infringes if each of the limitations of the asserted claim is  
7 found in the accused device. *Id.* The patentee always bears the burden of proof on infringement.  
8 *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, a  
9 patentee is entitled to summary judgment if it can show that it is “more likely than not” that the  
10 accused product possesses all of the elements of the asserted claim. *Warner-Lambert Co. v. Teva*  
11 *Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (*citing Anderson v. Liberty Lobby Inc.*,  
12 477 U.S. 242, 252 (1986)). Once the patentee has made a prima facie showing that it is more  
13 likely than not that all the claim limitations are met, the accused infringer must come forward  
14 with more than a scintilla of evidence to create a genuine issue of material fact as to non-  
15 infringement to survive a patentee’s summary judgment motion. *Id.* Conversely, an accused  
16 infringer is entitled to summary judgment of non-infringement where it shows “that the patentee  
17 failed to put forth evidence to support a finding that a limitation of the asserted claim was met by  
18 the structure in the accused devices.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1578 (Fed. Cir.  
19 1989).

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

23 [i]t shall be an act of infringement to submit . . . an [ANDA  
24 application to the FDA] . . . if the purpose of such submission is to  
25 obtain approval under such Act to engage in the commercial  
26 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.

27 35 U.S.C. § 271(e)(2). Section 271(a) provides that “whoever without authority makes, uses,  
28 offers to sell, or sells any patented invention, within the United States or imports into the United



1 States any patented invention during the term of the patent therefor, infringes the patent.” 35  
2 U.S.C. § 271(a).

### 3 3. Legal Standard Governing Invalidity Based on Anticipation

4 Under 35 U.S.C. § 102(a), a patent may be anticipated if the claimed invention was  
5 described in a printed publication “before the invention thereof by the applicant for patent.” 35  
6 U.S.C. § 102(a). “To anticipate a patent claim under 35 U.S.C. § 102, ‘a reference must describe .  
7 . . each and every claim limitation and enable one of skill in the art to practice an embodiment of  
8 the claimed invention without undue experimentation.’” *ClearValue, Inc. v. Pearl River*  
9 *Polymers, Inc.*, 668 F.3d 1340, 1344 (Fed. Cir. 2012) (quoting *Am. Calcar, Inc. v. Am. Honda*  
10 *Motor Co.*, 651 F.3d 1318, 1341 (Fed.Cir.2011) (citation omitted)). The claim limitations may be  
11 disclosed “either expressly or inherently.” *EMI Group N. Am., Inc., v. Cypress Semiconductor*  
12 *Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). “In general, a limitation or the entire invention is  
13 inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of  
14 the prior art.” *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)  
15 (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 Fed. Cir. 2001); *In re Kratz*, 592  
16 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the  
17 compound’s existence was not known)). In *Continental Can Co. v. Monsanto Co.*, the Federal  
18 Circuit explained that “inherent” disclosure “may not be established by probabilities or  
19 possibilities” but must be “necessarily present in the thing described in the reference” as viewed  
20 by persons of ordinary skill in the art. 948 F.2d 1264, 1269 (Fed. Cir. 1991).

21 “[A]nticipation is a question of fact, including whether or not an element is inherent in the  
22 prior art.” *Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369, 1375 (Fed.  
23 Cir. 2006). The accused infringer bears the burden of proving invalidity of the asserted patent by  
24 clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 U.S.  
25 (2011). In *Microsoft*, the Court explained that this heavy burden is based on § 282(a) of the  
26 Patent Act, which provides that an issued patent “shall be presumed valid” and that “[t]he burden  
27 of establishing invalidity ... rest[s] on the party asserting such invalidity.” Nonetheless, in *Amgen*  
28 *Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 2003) (*Amgen II*), the

1 Federal Circuit announced an exception to this rule, holding that a presumption of enablement  
2 applies to both the claimed and unclaimed disclosures of prior art patents. *Amgen II*, 314 F.3d at  
3 1355. Thus, the burden is on the *patentee* defending against an invalidity challenge based on a  
4 prior art patent to “present persuasive evidence of non-enablement to overcome this  
5 presumption.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1307 (2006) (*Amgen*  
6 *III*).

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

8 In patent prosecution the examiner is entitled to reject application  
9 claims as anticipated by a prior art patent without conducting an  
10 inquiry into whether or not that patent is enabled or whether or not  
11 it is the claimed material (as opposed to the unclaimed disclosures)  
12 in that patent that are at issue. . . . *In re Sasse*, 629 F.2d 675, 681,  
13 207 USPQ 107, 111 (C.C.P.A.1980) (“[W]hen the PTO cited a  
14 disclosure which expressly anticipated the present invention ... the  
15 burden was shifted to the applicant. He had to rebut the  
16 presumption of the operability of [the prior art patent] by a  
17 preponderance of the evidence.” (citation omitted)). The applicant,  
18 however, can then overcome that rejection by proving that the  
19 relevant disclosures of the prior art patent are not enabled. *Id.* We  
20 hold that an accused infringer should be similarly entitled to have  
21 the district court presume the enablement of unclaimed (and  
22 claimed) material in a prior art patent defendant asserts against a  
23 plaintiff. Thus, a court cannot ignore an asserted prior art patent in  
24 evaluating a defense of invalidity for anticipation, just because the  
25 accused infringer has not proven it enabled. Like the applicant in *ex*  
26 *parte* prosecution, however, the patentee may argue that the relevant  
27 claimed or unclaimed disclosures of a prior art patent are not  
28 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.

24 *Amgen II*, 314 F.3d at 1355.

25 In a footnote, the Federal Circuit in *Amgen II* noted that “by logical extension, our  
26 reasoning here might also apply to prior art printed publications as well,” *id.* n. 22, and recently,  
27 in *In re Antor Media Corp.*, the Federal Circuit squarely held “that a prior art printed publication  
28 cited by an examiner is presumptively enabling barring any showing to the contrary by a patent

1 applicant or patentee.” *Id.* at 1288. In *Antor*, the Federal Circuit rejected the patentee’s  
2 argument, based on § 282, that the presumption should not extend to non-patent prior art,  
3 explaining that in *Amgen*, the court did not rely only on § 282 as the source of the presumption  
4 but also on that fact that it is “procedurally convenient to place the burden on the applicant who is  
5 in a better position to show, by experiment or argument, why the disclosure in question is not  
6 enabling or operative.” *Id.*

7 Although the Federal Circuit in *Antor* addressed whether the presumption of enablement  
8 applied in the context of patent prosecution, the reasoning of that decision persuades the Court  
9 that the presumption also applies in the district court, just as the Federal Circuit found in *Amgen II*  
10 with respect to patent prior art cited to establish anticipation. Therefore, the Court finds that  
11 where a prior art printed publication is asserted in support of an anticipation defense, the prior art  
12 is presumed enabled unless the patentee can present “evidence of nonenablement that a trial court  
13 finds persuasive.” *See Amgen II*, 314 F.3d at 1355. Further, the Court concludes based on the  
14 *Amgen II* court’s reliance on *In re Sasse* that the amount of evidence required to rebut the  
15 presumption is a preponderance of the evidence and that if the patentee meets that burden, the  
16 court must then exclude the prior art in its anticipation analysis. *See id*; *see also Amgen III*, 457  
17 F.3d at 1307 (noting that on remand, the district court found that the patentee met its “burden of  
18 proving by a preponderance of the evidence” that the prior art that was alleged to anticipate was  
19 not enabled and affirming the district court’s holding).

20 **B. Subject Matter Jurisdiction over ‘282 Patent Infringement Claim under Hatch-**  
21 **Waxman Act**

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

25 The Hatch-Waxman Act gives manufacturers of generic drugs a safe harbor in which to  
26 develop their products without threat of patent litigation. *See* 35 U.S.C. § 271(e)(1). In return,  
27 Congress gave patentees the right to challenge a generic drug when the generic manufacturer files  
28 an ANDA, deeming the filing of the ANDA “a defined act of infringement sufficient to create

1 case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning  
2 infringement and validity.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).  
3 This compromise is embodied in subsections (1) and (2) of 35 U.S.C. § 271(e), which provides, in  
4 relevant part as follows:

5 (e)(1) It shall not be an act of infringement to make, use, offer to  
6 sell, or sell within the United States or import into the United States  
7 a patented invention (other than a new animal drug or veterinary  
8 biological product (as those terms are used in the Federal Food,  
9 Drug, and Cosmetic Act and the Act of March 4, 1913) which is  
10 primarily manufactured using recombinant DNA, recombinant  
11 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.

12 (2) It shall be an act of infringement to submit--

13 (A) an application under section 505(j) of the Federal Food, Drug,  
14 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,  
...

15 if the purpose of such submission is to obtain approval under such  
16 Act to engage in the commercial manufacture, use, or sale of a drug,  
17 veterinary biological product, or biological product claimed in a  
18 patent or the use of which is claimed in a patent before the  
expiration of such patent.

19 35 U.S.C. § 271(e) (1) & (2).

20 Further, “the Hatch-Waxman Act . . . establishes a procedure called a ‘Paragraph IV  
21 certification,’ 21 U.S.C. § 355(j)(2)(A)(vii)(IV), by which an entity that seeks to market a generic  
22 counterpart of a patented drug product or method of use, before the patent has expired, may  
23 challenge the patent before actually marketing the drug.” *Cephalon, Inc. v. Watson Pharms., Inc.*,  
24 707 F.3d 1330 (Fed. Cir. 2013). As part of this procedure, most patentees and New Drug  
25 Applicant (“NDA”) holders are required to list patents related to their approved drugs in the  
26 FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” publication (the  
27 “Orange Book”). 21 U.S.C. § 355(b)(1). A company that manufactures generic drugs, in turn, is  
28 required to consult the Orange Book before filing an ANDA and certify that either (I) no patent

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

5 Here, Takeda has alleged jurisdiction under 28 U.S.C. § 1338, which provides that “[t]he  
6 district courts shall have original jurisdiction of any civil action arising under any Act of Congress  
7 relating to patents.” Thus, the existence of subject matter jurisdiction over Takeda’s § 271(e)(2)  
8 claim based on the ‘282 Patent depends on whether that claim “arises under” the Hatch-Waxman  
9 Act even though Handa’s ANDA did not include a Paragraph IV Certification. Some courts have  
10 found that a Paragraph IV Certification is a jurisdictional requirement for bringing a claim under  
11 the Hatch-Waxman Act. *See, e.g., Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL  
12 4556958 (D.N.J. Dec. 20, 2007). In *Eisai*, the court recognized that “[t]he plain text of §  
13 271(e)(2) does not require that the alleged infringer file an ANDA with a Paragraph IV  
14 certification, or that the drug claims be listed in the Orange Book.” *See* 2007 WL 4556958, at \*9.  
15 Nonetheless, based on extended discussion of the ANDA process in decisions by the Federal  
16 Circuit, the *Eisai* court concluded that a Paragraph IV requirement should be “read into” §  
17 271(e)(2). *Id.* at \* 12.

18 The undersigned does not find the reasoning of *Eisai* persuasive given the clear language  
19 of the statute and the fact that none of the Federal Circuit cases addressed in *Eisai* directly  
20 addressed the question of whether a Paragraph IV Certification was required in order for a  
21 patentee to bring an infringement claim under the Hatch-Waxman Act. *See id.* at \*11 (“The  
22 Federal Circuit has never squarely faced the question before this Court”). The Federal Circuit  
23 subsequently resolved any doubt on this issue in *AstraZeneca Pharms. LP v. Apotex Corp.*, 669  
24 F.3d 1370 (Fed. Cir. 2012). In *AstraZeneca*, the Federal Circuit held that under the Hatch-  
25 Waxman Act, “the requirements for jurisdiction in the district courts are met once a patent owner  
26 alleges that another’s filing of an ANDA infringes its patent under § 271(e)(2), and this threshold  
27 jurisdictional determination does not depend on the ultimate merits of the claims.” 669 F.3d at  
28 1376-77.

1 Further, in *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), the  
2 Supreme Court also made clear that a Paragraph IV certification is not a jurisdictional  
3 requirement for bringing an action under the Hatch-Waxman Act. In that case, the generic drug  
4 manufacturer, Caraco, initially included a Paragraph IV certification in its ANDA but later  
5 inserted a statement under § 355(j)(2)(A)(viii) (“section viii statement”). 132 S. Ct. at 1679. A  
6 section viii statement asserts that the generic manufacturer will market the drug for one or more  
7 methods of use not covered by the brand’s patents and is an alternative to a Paragraph IV  
8 certification for obtaining FDA approval. *Id.* at 1677-1678. Before the FDA had approved the  
9 generic on the basis of the section viii statement, however, the patentee, Novo, amended its use  
10 codes to cover the uses for which the generic manufacturer sought approval. *Id.* at 1679. In the  
11 ensuing Hatch-Waxman infringement action initiated by Novo, the generic manufacturer asserted  
12 a counterclaim seeking to compel Novo to amend its use codes such that Caraco would be able to  
13 obtain FDA approval under section viii rather than under Paragraph IV. The question before the  
14 Supreme Court was whether Caraco could assert such a counterclaim. In that context, Novo  
15 argued that there was no subject matter jurisdiction over the action. 132 S. Ct. 1670, 1680 n.5  
16 (2012). The Court rejected that argument, reasoning as follows:

17 On Novo’s theory, [a section viii] statement (unlike a paragraph IV  
18 certification) does not count as an act of infringement under the  
19 patent statute, see 35 U.S.C. § 271(e)(2)(A), and so cannot provide  
20 a jurisdictional basis for the suit. But that argument is wrong even  
21 assuming (as Novo contends) that Caraco’s section viii filing  
22 terminated its paragraph IV certification and that a section viii filing  
23 is not an act of infringement. The want of an infringing act is a  
24 merits problem, not a jurisdictional one. Nothing in the section of  
25 the statute defining certain filings as acts of infringement suggests  
26 anything to the contrary. And “we are not inclined to interpret  
27 statutes as creating a jurisdictional bar when they are not framed as  
28 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).

27 *Id.*

1 In light of the *Caraco* decision and the Federal Circuit’s recent decision in *Astrazeneca*,  
2 this Court joins a number of other district courts in concluding that there is no requirement under  
3 the Hatch-Waxman Act that a patent must be listed in the Orange Book in order for a drug  
4 manufacturer to bring an infringement action based on that patent against an ANDA applicant.  
5 *See Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 2013 WL 591976 (D.N.J. Feb. 14, 2013)  
6 (declining to follow *Eisai* on the basis that “more recent precedent of the Federal Circuit controls”  
7 and holding that under *AstraZeneca* it is clear that the requirements for jurisdiction in the district  
8 courts are met once a patent owner alleges that the filing of an ANDA infringes its patent under §  
9 271(e)(2), regardless of whether the ANDA includes a Paragraph IV certification); *Cephalon,*  
10 *Inc. v. Sandoz, Inc.*, 2012 WL 682045, at \*5 (D. Del. Mar. 1, 2012) (rejecting the reasoning and  
11 “sweeping conclusion” of *Eisai* that the court lacked jurisdiction under the Hatch-Waxman Act  
12 where there was no Paragraph IV certification); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*,  
13 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009) (holding that “[t]here is no requirement that  
14 infringement actions against ANDA filers must be based on patents listed in the Orange Book”);  
15 *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004) (“The  
16 language of § 271(e)(2)(A) does not require that the ANDA contain a [Paragraph IV] certification  
17 to constitute an act of infringement. It only requires that the [ANDA] application be filed under §  
18 355(j)”; *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at \*9 (E.D. Wis.  
19 Sept. 24, 2009) (holding in a case involving an Abbreviated New Animal Drug Application that  
20 “a Paragraph IV certification is not required to trigger an infringement action under § 271(e)(2)”).

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

### 24 C. Infringement of the ‘282 Patent

25 Takeda requests summary judgment of infringement of the ‘282 Patent on two theories.  
26 First, it seeks summary judgment on Count VII of the Second Amended Complaint, for  
27 infringement of claim 1 the ‘282 Patent under § 271(a), based on the undisputed fact that Handa  
28

1 [REDACTED] Second, it  
2 contends that [REDACTED]  
3 [REDACTED] and therefore infringes  
4 claims 1 and 2 of the '282 Patent under § 271(e)(2) and § 271(a) (Counts IV and VII).<sup>12</sup> For the  
5 reasons discussed below, the Court finds, as a matter of law, that the finished product contain the  
6 [REDACTED] and therefore, that Takeda is entitled to summary judgment  
7 of infringement on Count IV of its complaint, asserted under the Hatch-Waxman Act. The Court  
8 also finds, as a matter of law, that the API used in Handa's ANDA product [REDACTED]  
9 [REDACTED] The Court declines to enter summary judgment in Takeda's favor on Count VII,  
10 however, because Takeda has not established that it meets the constitutional requirements for  
11 bringing claims under the Declaratory Judgment Act.

12 To establish a case or controversy under Article III of the U.S. Constitution, a claim must  
13 be “definite and concrete, touching the legal relations of parties having adverse legal interests”;  
14 and that it be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive  
15 character, as distinguished from an opinion advising what the law would be upon a hypothetical  
16 state of facts.’” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)(quotations  
17 omitted). Some courts have permitted claims seeking declaratory judgment of infringement under  
18 § 271(a) based on the filing of an ANDA. *See, e.g., Cephalon v. Sandoz, Inc.*, 2012 WL 682045 ,  
19 at \*5 (D. Del. Mar. 1, 2012); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL  
20 6337911, at \*13-14 (E.D. Wis. Sept. 24, 2009) . Other courts, however, have held that such  
21 claims are not sufficiently real and immediate to satisfy the requirements of *MedImmune*. *See,*  
22 *e.g., Eisai*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Las. v. Zenith Labs., Inc.*,  
23 934 F. Supp. 925, 983 (N.D. Ill. 1995) (questioning whether such a claim is consistent with  
24 Congress’ intent in providing a safe haven for generic manufacturers under the Hatch-Waxman

25 \_\_\_\_\_  
26 <sup>12</sup> As noted above, claim 2 depends from claim 1 and adds a limitation requiring a  
27 “pharmaceutical composition comprising the amorphous compound according to claim 1 and a  
28 [REDACTED] conversely, Takeda does not contend that  
[REDACTED] and therefore  
asserts its claim under § 271(a) only as to claim 1 of the '282 Patent.



1 Act). As the parties have not briefed this issue, the Court does not reach the question of whether  
2 Takeda can establish the existence of a “definite and concrete” controversy on its infringement  
3 claims under § 271(a) and the Declaratory Judgment Act.

4 **1. Use of [REDACTED]**

5 It is undisputed that an [REDACTED] is used in the  
6 manufacture of Handa’s ANDA product. The Court also rejects Handa’s contention that Takeda  
7 has not asserted a claim under § 271(a) on this basis.

8 Count VII seeks declaratory judgment of infringement as to all of the Asserted Patents,  
9 including the ‘282 Patent, under § 271(a). Further, Count VII alleges that: 1) “Defendants’  
10 commercial *manufacture*, use, sale, or offer for sale within the United States or importation into  
11 the United States of the Proposed Capsules will constitute infringement of . . . the ‘282 . .  
12 .Patent[];” 2) “Defendants’ infringing commercial *manufacture*, use, sale, or offer for sale within  
13 the United States or importation into the United States of the Proposed Capsules complained of  
14 herein will begin following FDA approval of ANDA No. 202-24;” and 3) Plaintiffs thus are  
15 entitled to a declaration that the *making*, using, sale, offer for sale, and importation into the United  
16 States of the Proposed Capsules according to ANDA No. 202-294 infringe one or more claims of  
17 the Asserted Patents.” SAC, ¶¶ 61-63 (emphasis added). These allegations are sufficient to  
18 encompass both of Takeda’s theories of infringement, that is, that Handa infringes both on the  
19 basis of [REDACTED] Therefore,  
20 if Takeda can establish at trial that it has standing under the Declaratory Judgment Act, and that  
21 such use is not protected under the safe harbor provisions of the Hatch-Waxman Act, it will be  
22 entitled to judgment in its favor on Count VII to the extent that claim is based on use of the API  
23 used in Handa’s ANDA product.

24 **2. [REDACTED]**

25 Takeda also seeks summary judgment of infringement of claims 1 and 2 of the ‘282 Patent  
26 based on what it contends is substantial evidence that the formulated ANDA product contains an  
27 [REDACTED] As noted above, the Court has construed the term  
28 “amorphous compound” to require a compound that is solid and non-crystalline. The undisputed

1 evidence is that [REDACTED]

2 [REDACTED] See Myerson Decl., Ex. 11 at HANDEX0021652, HANDEX0021657. Thus, aside from  
3 the question of whether Takeda can establish standing with respect to its claim under the  
4 Declaratory Judgment Act, discussed above, the only remaining question is whether the  
5 [REDACTED] If so, Takeda is entitled to  
6 summary judgment of infringement under § 271(e).

7 The primary evidence offered by Takeda to establish that the dexlansoprazole used in  
8 Handa's drug product is [REDACTED]  
9 [REDACTED] Such evidence may be used to establish  
10 infringement. See *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir.  
11 2009) (citing *Forest Labs. v. Abbott Labs.*, 239 F.3d 1305, 1312 (Fed. Cir. 2001), *Liquid*  
12 *Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006))("A patentee may  
13 prove infringement by 'any method of analysis that is probative of the fact of infringement' . . . ,  
14 and circumstantial evidence may be sufficient"). Handa has pointed to no authority (nor has the  
15 Court found any) requiring that infringement must be established on the basis of testing of the  
16 ANDA product. To the contrary, at least with respect to statements made in the ANDA, the  
17 Federal Circuit has held that descriptions of the proposed generic drug "that directly address[ ] the  
18 issue of infringement will control the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.*, 300  
19 F.3d 1367, 1373 (Fed. Cir. 2002). This rule is based on the strict statutory provisions requiring  
20 that generic drug manufactures "sell only those products that comport with the ANDA's  
21 description of the drug." *Id.* Further, "[t]here is no prohibition against using the admissions of a  
22 party, whether in the form of marketing materials or otherwise, as evidence in an infringement  
23 action." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1351 (Fed. Cir. 2007).

24 The Court finds that Handa made [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

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[REDACTED]

Although Handa contends that Takeda “overreaches” in its interpretation of these statements, [REDACTED] the Court finds that no reasonable jury could adopt such an interpretation of Handa’s statements [REDACTED]

[REDACTED] In particular, in discovery and in support of its own request for summary judgment of non-infringement of the ‘276 Patent, Handa has taken the consistent position its ANDA product [REDACTED]

[REDACTED] Handa SJ Motion at p. v; *see also id.* at 1 (“[T]he ANDA Product

[REDACTED]

[REDACTED] Takahashi Decl., Ex. 4 (Handa’s First Supplemental Responses to Plaintiffs’ First Set of Joint Interrogatories, June 15, 2012), at 10 (stating that Handa’s [REDACTED]

[REDACTED]

[REDACTED] Indeed, in its Reply

1 brief, Handa calls the evidence cited by Takeda to establish the existence of [REDACTED]  
2 [REDACTED] “uncorroborated speculation.” Reply at 8. As Handa has  
3 not pointed to any evidence that a [REDACTED]  
4 [REDACTED] Handa’s representations that the [REDACTED]  
5 [REDACTED]  
6 [REDACTED] Further, given that these statements directly address the key  
7 issue upon which infringement of the ‘282 Patent by the ANDA product turns, the Court  
8 considers them to be binding judicial admissions. These admissions, as well as the statements  
9 Handa has made to the FDA, constitute substantial evidence of infringement by Handa’s ANDA  
10 product of the ‘282 Patent.

11 The Court further finds that Handa has not identified specific facts, in the face of Takeda’s  
12 prima facie showing of infringement, to establish the existence of a genuine issue of material fact.  
13 Handa points to Dr. Myerson’s testimony, based on the [REDACTED]  
14 Handa on the ANDA product, that the [REDACTED]  
15 arguing that this creates a factual dispute. *See* Jansen Opposition Decl., Ex. 3 (Oct. 26, 2012  
16 Myerson Dep. Tr.) at 112. Dr. Myerson, however, only testified that [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED] *Id.* This testimony is not sufficient to establish a material issue of fact where Handa  
21 has consistently rejected the possibility that the [REDACTED]  
22 [REDACTED] both in its statements to the FDA and in this litigation.

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24  
25 <sup>13</sup> As Takeda points out in its Reply brief, the evidence presented at claim construction was  
26 consistent in treating solids as being either crystalline or amorphous and the Court treated them as  
27 such in its Claim Construction Order. *See* Takeda Reply at 6 (“it is a binary choice”) (citing Decl.  
28 of Allan S. Myerson, Ph.D., in Support of Takeda’s Opening Claim Construction Br. (“Myerson  
Claim Constr. Decl.”) [D.N. 62] ¶ 81 (“Solids can be crystalline or amorphous.”); *id.*  
¶ 23 (“Solids that are not crystalline and have no long range order . . . are said to be  
amorphous.”); Myerson Rep. ¶ 22 (same); Claim Construction Opinion [D.N. 106] at 36  
(noting references that show that an “amorphous compound’ lacks [] long range order”).

1 Accordingly, the Court finds that Takeda is entitled to summary judgment in its favor on  
2 Count IV, under the Hatch-Waxman Act, to the extent that claim is based on infringement of  
3 claims 1 and 2 the '282 Patent by Handa's ANDA product. To the extent that Takeda also asserts  
4 a claim of infringement under § 271(a) and the Declaratory Judgment Act based on the finished  
5 product, in Count VII, it will be entitled to judgment in its favor if it can establish at trial that it  
6 has standing under the Declaratory Judgment Act and that Handa's use of [REDACTED]  
7 [REDACTED] is not protect by the safe haven provisions of the Hatch-Waxman Act.

8 **D. Validity of the '282 Patent**

9 Handa argues that the asserted claims of the '282 Patent are anticipated by the Larsson and  
10 Barberich references. This dispute turns primarily on two questions: 1) whether Larsson  
11 inherently discloses a solid amorphous compound of dexlansoprazole, as is required under claim  
12 1 of the '282 Patent; and 2) whether the disclosure of amorphous dexlansoprazole in Barberich is  
13 enabled. The Court finds, as a matter of law, that Larsson does not inherently disclose an  
14 amorphous form of dexlansoprazole that meets this claim limitation. The Court further finds  
15 there is a fact question as to whether the disclosure in Barberich is enabled.

16 Inherent disclosure may not be established by "probabilities or possibilities." *Bettcher*  
17 *Industries, Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011) (quoting *In re Oelrich*, 666  
18 F.2d 578, 581 (CCPA 1981)). "The mere fact that a certain thing may result from a given set of  
19 circumstances is not sufficient." *Id.* For example, in *GlaxoInc. v. Novapharm Ltd.*, the defendant  
20 argued that the asserted patent was anticipated based on inherent disclosure in the prior art, citing  
21 evidence that its expert had reproduced the prior art method thirteen times, each time obtaining  
22 the claimed crystals. 52 F.3d 1043, 1047 (Fed. Cir. 1995). However, the patentee had presented  
23 evidence that two of its own experts had used the same method to produce different crystals. *Id.*  
24 Because the method described in the prior art did not "always yield" the claimed invention but  
25 rather, "could yield" something different, the Federal Circuit affirmed the district court's holding  
26 that there was no inherent disclosure and therefore, that the asserted patent was not anticipated.

27 Here, Handa's own evidence establishes that Larsson does not inherently disclose the  
28 "amorphous compound" limitation of the '282 Patent. In particular, when the UW researchers

1 attempted to follow strictly the protocol in Example 22, they first obtained a solid of racemic  
2 lansoprazole rather than an amorphous compound of dexlansoprazole. In other words, the UW  
3 research results show, at best, that following the method described in Example 22 *could* yield an  
4 amorphous compound of dexlansoprazole, not that it always or necessarily yields such a result.  
5 Further, the undisputed evidence shows that the UW researchers had to add a step to the process  
6 described in Example 22 by slowly adding an oxidizing agent to obtain the claimed compound.  
7 This evidence supports the conclusion that merely following the protocol that is actually  
8 described in Example 22 does *not* always yield the claimed compound. Thus, Handa's own  
9 evidence establishes, as a matter of law, that Larsson does not inherently disclose the amorphous  
10 compound of dexlansoprazole claimed in the '282 Patent.

11 Handa attempts to avoid this conclusion by relying on what it contends is evidence of  
12 agreement by all of the experts that repetition of the process in Example 22 will eventually result  
13 in the synthesis of the claimed compound. *See, e.g.*, Handa Reply at 12 n. 9 ("Takeda's reliance  
14 on *Bettcher* and *In re Oelrich* (Opp. at 16) is . . . misplaced, as agreement by experts on both sides  
15 on the result hardly constitutes the mere 'probabilities or possibilities' that were at issue in those  
16 cases"); *id.* at 14 n. 13 ("*Glaxo* and *Continental Can*, on which Takeda relies, are . . . both  
17 inapplicable as Takeda has introduced no evidence to contradict the experts' unanimous opinion  
18 that performing Example 22 will result in an amorphous solid"). Handa's repeated assertions of  
19 unanimity are not supported by the record, however. Dr. Myerson merely states that if you were  
20 to repeat the process in Example 22, "you should be *able*" to make an amorphous compound of  
21 dexlansoprazole but that it would be "very hard to do" and would be likely to take "a really long  
22 time." This testimony does not state that simply by following the procedure in Example 22 one  
23 would *necessarily* obtain the claimed compound. To the contrary, Dr. Myerson's testimony only  
24 supports the conclusion that one *could* obtain such a result – which the Federal Circuit has  
25 repeatedly held is not sufficient to establish inherency. Further, to the extent Dr. Myerson  
26 testifies that it would be "very hard to do," his testimony supports the conclusion that repetition of  
27 the process described in Example 22 would *not* always yield the claimed compound.<sup>14</sup>

28 \_\_\_\_\_  
<sup>14</sup> The Court assumes that Dr. Myerson's testimony is admissible without reaching that question.

1 Nor does Dr. Atwood's testimony support Handa's position. Dr. Atwood, like Dr.  
2 Myerson, merely testified that it was "possible" for the oil described in Larsson to become a solid  
3 through repetition of the Example 22 procedure, not that it necessarily would yield such a  
4 compound. More importantly, Dr. Atwood opined in his report that the Larsson prior art does not  
5 disclose the claimed compound, and addressed in detail the reasons for this opinion. *See* Jansen  
6 Decl., Ex. 11 (Atwood Report) ¶¶ 78-90. Therefore, the Court concludes that the testimony of the  
7 experts cited by Handa does not establish inherent disclosure; nor does the dispute between the  
8 parties' experts give rise to a genuine dispute of material of fact where Handa's own evidence  
9 establishes that the standard for inherent disclosure is not met as to the Larsson prior art.

10 Having found that Larsson does not inherently disclose the "amorphous compound"  
11 limitation of the '282 Patent, the remaining question is whether the Barberich references  
12 anticipate the asserted claims of the '282 Patent. The Barberich references, unlike Larsson,  
13 expressly disclose a solid amorphous compound of dexlansoprazole. *See* Rogers Decl., Ex. 10  
14 (Barberich I) at IPXL-0009198 ("Compressed tablets may be prepared by compressing in a  
15 suitable machine the active ingredient in a free-flowing form such as powder or granules"). Thus,  
16 the question of whether Barberich anticipates turns on enablement. As discussed above, although  
17 it is Handa's burden to establish invalidity by clear and convincing evidence, the Federal Circuit  
18 has created an exception where the patentee seeks to defeat an invalidity defense on the basis that  
19 the prior art reference is not enabled. On that question, Takeda bears the burden of establishing  
20 lack of enablement by the preponderance of the evidence.

21 The test for enablement is whether a person "skilled in the art, after reading the  
22 specification, could practice the claimed invention without undue experimentation." *Sitrick v.*  
23 *Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (citation omitted). In determining whether  
24 a disclosure requires undue experimentation, courts may consider the following factors:

- 25 (1) the quantity of experimentation necessary, (2) the amount of  
26 direction or guidance presented, (3) the presence or absence of  
27 working examples, (4) the nature of the invention, (5) the state of  
28 the prior art, (6) the relative skill of those in the art, (7) the  
predictability or unpredictability of the art, and (8) the breadth of  
the claims.

1 *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *In re*  
2 *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). Although Barberich doesn't offer guidance as to  
3 how to create an amorphous compound of dexlansoprazole, it references Larsson. As discussed  
4 above, the UW Report indicates that at least *some* experimentation was required to obtain the  
5 claimed amorphous compound of dexlansoprazole using the disclosure of Example 22 in Larsson.  
6 On the basis of that evidence, the Court cannot find as a matter of law that Takeda will be unable  
7 to meet its burden at trial of showing that Barberich is not enabled on the basis of its  
8 incorporation of Larsson. Therefore, the Court finds that there is a fact question as to whether the  
9 Barberich disclosure of amorphous dexlansoprazole is enabled. The Court denies Handa's  
10 request for summary judgment of anticipation as to the '282 Patent.

11 **E. Infringement of the '276 Patent**

12 Handa contends that it is entitled to summary judgment of non-infringement of the '276  
13 Patent because Takeda has not shown that there is a genuine dispute of material fact that the  
14 ANDA product [REDACTED]  
15 [REDACTED]  
16 Handa argues that Takeda has not established a  
17 factual dispute because [REDACTED]  
18 Dr. Myerson, however, has opined that [REDACTED]  
19 [REDACTED] Myerson Report ¶ 64. This evidence is sufficient to  
20 establish a factual dispute.

21 Handa's reliance on Dr. Myerson's [REDACTED] in support of his  
22 infringement opinion is misplaced. [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 Nor is the Court persuaded that the [REDACTED] are sufficient to  
27 establish non-infringement of the '276 Patent as a matter of law. While Takeda concedes that the  
28 [REDACTED]



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[REDACTED]

More significantly, the claims cover *any* crystalline form of dexlansoprazole.

[REDACTED]

The Court finds that a genuine issue of material fact exists as to whether Handa’s ANDA product contains [REDACTED]. Accordingly, entry of summary judgment of non-infringement of the ‘276 Patent is not appropriate.

**F. Infringement of the ‘755 Patent**

Handa requests summary judgment of non-infringement of the ‘755 Patent based on the [REDACTED]. 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.<sup>15</sup> 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 Handa’s ANDA product does 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

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<sup>15</sup> The general legal standards governing claim construction are set forth in the Court’s claim construction order. Therefore, the Court does not repeat them here.

1 undisputed evidence (Takeda's own testing) shows [REDACTED]  
2 [REDACTED]

3 according to Takeda's expert, such release does not occur unless at least 10% of the drug is  
4 released in a 2-hour period. Takeda is essentially asking the Court to adopt a broader construction  
5 of the release term than it adopted in its claim construction order. In light of the intrinsic  
6 evidence, the Court concludes that Takeda's position is incorrect.

7 First, the Court looks to the claim language. "Absent an express intent to impart a novel  
8 meaning, claim terms take on their ordinary meaning." *Elekta Instrument S.A. v. O.U.R. Scientific*  
9 *International, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (citation omitted). The plain language  
10 of the release term of claim 1 sets forth a specific range of pH values in which release of the API  
11 must begin. This range captures the idea set forth in the specification that composition (ii)  
12 dissolves at a pH of "about 5.5." *See* '755 Patent, col. 2, ll. 48-53 (stating in the "Disclosure of  
13 Invention" section that the invention provides a "capsule . . . which comprises a tablet, granule or  
14 fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5"). In  
15 other words, the claim language *already* allows for some dissolution to occur below the 5.5 target  
16 pH level for composition (ii) while remaining within the scope of the claim. Were the Court to  
17 insert further qualifying language in its construction that allowed release *below* the lower end of  
18 the range claimed by the inventors, it would not only be ignoring the ordinary meaning of the  
19 claim term but would also be rendering the lower end of the range in the claim superfluous to the  
20 extent that release would be permitted both below 5.0 *and* above 5.0. *See Elekta*, 214 F.3d at  
21 1307 (reversing district court's construction of the term "only within a zone extending between  
22 latitudes 30° - 45°" as meaning "beginning at the edge of the helmet (0°) and extending to a point  
23 between 30° - 45°" on the basis that it was inconsistent with ordinary meaning of claim language  
24 and rendered lower end of the range superfluous); *U.S. Philips Corp. v. Isasaki Elec. Co.*, 505  
25 F.3d 1371, 1376 (Fed. Cir. 2007) (affirming district court's construction of term "between  $10^{-6}$   
26 and  $10^{-4}$  <<mu>>mol/mm<sup>3</sup>" as meaning "between  $1 \times 10^{-6}$  and  $1 \times 10^{-44}$  <<mu>>mol/mm<sup>3</sup>" and  
27 noting that district court was correct that "the overall phrase - 'a quantity between -- and --' - is a  
28 construction that 'implies a specific range . . . it does not imply a range between two values which

1 are themselves ranges”). Thus, the unambiguous language of the claim supports a construction  
2 that does not permit release of the API outside of the claimed range.

3 Further, nothing in prosecution history or the specification of the ‘755 Patent persuades the  
4 Court that it is appropriate to read into the release term a requirement that release must be  
5 significant and rapid (or to state it somewhat differently, that the claim covers embodiments in  
6 which there is no *significant* release below the lower end of the range, pH 5.0). The parties hotly  
7 dispute the significance of: 1) the applicants’ reliance on the Kurasawa testing during patent  
8 prosecution; and 2) the disclosure in columns 9 and 10 of the ‘755 Patent. Beyond the fact that  
9 both describe testing that was conducted over a longer period of time than Takeda asserts is  
10 appropriate for determining whether the release limitation is satisfied, suggesting that the two-  
11 hour limitation proposed by Takeda is incorrect, the Court finds that neither the prosecution  
12 history nor the passage in the specification offers significant guidance as to the construction of the  
13 release term.

14 On one hand, the Kurasawa testing revealed a dissolution rate of less than 5% dissolution  
15 after 2 hours and thus, the embodiment of the invention tested by Kurasawa would not have  
16 satisfied the “significant and rapid” requirement that Takeda asks the Court to read into the  
17 release term.<sup>16</sup> On the other hand, the single example describing testing in the specification,  
18 found in columns 9 and 10, arguably supports Takeda’s position that claim 1 allows some release  
19 below the claimed pH ranges. That passage states as follows:

20 It is desirable that the coating material is used alone or, if necessary,  
21 in combination so that the polymer is dissolved, preferably at a pH  
22 of 6.0 or above, more preferably at a pH of 6.5 or above, and further  
23 more preferably at a pH of 6.75 or above. . . . The rate of elution of  
24 active ingredient from the active-ingredient release-controlled  
25 tablet, granule or fine granule thus obtained is desirably 10% or less  
26 for 5 hours in a solution of pH 6.0, and 5% or less for one hour and  
27 60% or more for 8 hours in a solution of pH 6.8.

28 <sup>16</sup>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.

1 '755 Patent, col. 9, l. 65 - col. 10, l. 17. Neither of the examples, however, addresses whether (or  
2 when) the release described in them falls within the range set forth in the release term. Moreover,  
3 even if Takeda is correct that the passage in the specification describes an embodiment that is  
4 excluded under the Court's current construction of the release term, this does not justify  
5 modifying the construction as "the unambiguous language of the . . . claim controls over any  
6 contradictory language in the written description." *Elekta*, 214 F.3d at 1308. Finally, to the  
7 extent that the Court finds that the claims themselves are unambiguous, reliance on extrinsic  
8 evidence, such as the USP, is not a proper basis for varying the meaning of the term. *See*  
9 *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations,  
10 an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In  
11 such circumstances, it is improper to rely on extrinsic evidence.").

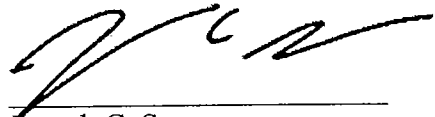
12 For these reasons, the Court concludes that it is not appropriate to revise its construction of  
13 the release term to insert qualifying language requiring that release must be rapid and significant.  
14 Rather, the Court finds that a product falls outside of the ambit of claim 1 if there is any  
15 measurable release of the API from the low pH granule below the range specified in the release  
16 term. [REDACTED]  
17 [REDACTED] the Court finds as a matter of law that that product does  
18 not infringe the asserted claims of the '755 Patent.

19 **IV. CONCLUSION**

20 For the reasons stated above, Takeda's motion is GRANTED. Handa's motion is  
21 GRANTED in part and DENIED in part.

22 IT IS SO ORDERED

24 Dated: April 8, 2013

25   
26 \_\_\_\_\_  
27 Joseph C. Spero  
28 United States Magistrate Judge

UNITED STATES DISTRICT COURT  
FOR THE  
NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD  
ET AL et al,

Plaintiff,

v.

HANDA PHARMACEUTICALS, LLC et al,

Defendant.

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Case Number: CV11-00840 JCS

**SEALED CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that I am an employee in the Office of the Clerk, U.S. District Court, Northern District of California.

That on April 8, 2013, I SERVED a true and correct copy(ies) of the attached, by placing said copy(ies) in a postage paid envelope addressed to the person(s) hereinafter listed, by depositing said envelope in the U.S. Mail, or by placing said copy(ies) into an inter-office delivery receptacle located in the Clerk's office.

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Dated: April 8, 2013

*Karen L. Hom*

Richard W. Wieking, Clerk  
By: Karen Hom, Deputy Clerk