UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

PAR PHARMACEUTICAL, INC., and HANDA PHARMACEUTICALS, LLC, Plaintiffs-Counterdefendants, v. TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTCALS AMERICA, INC., and TAKEDA PHARMACEUTICALS U.S.A. INC., Defendants-Counterclaimants.	Case No.: 13-CV-01927-LHK Consolidated and Related Cases: 13-CV-02416-LHK 13-CV-02420-LHK ORDER CONSTRUING DISPUTED CLAIM TERMS OF U.S. PATENT NOS. 8,461,187 AND 8,173,158

These related cases involve patent infringement claims by the Takeda parties against several pharmaceutical companies who filed Abbreviated New Drug Applications under the Hatch-Waxman Act for generic forms of the branded drug Dexilant®. The parties now seek construction of six disputed terms in the claims of the two asserted patents: U.S. Patent Nos. 8,461,187 (the "'187 Patent") and 8,173,158 (the "'158 Patent"). The Court held a technology tutorial and claim construction hearing on June 5, 2014. The Court has reviewed the claims, specifications, and other relevant evidence, and has considered the briefing and arguments of the parties. The Court now construes the terms at issue.

I. BACKGROUND

A. The Drug and Asserted Patents

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceuticals U.S.A. Inc. (collectively, "Takeda") manufacture and sell Dexilant®, a drug for treatment of gastroesophageal reflux disease ("GERD") or acid reflux disease. *See* First Am. Answer and Counterclaims (ECF No. 32[1]) at 15 ¶¶ 18-19. The active ingredient in Dexilant® is dexlansoprazole, which belongs to the class of compounds known as protein pump inhibitors, or "PPIs." Dexilant® is designed to release dexlansoprazole in two stages, based on different acidity levels in the human intestine, to provide overnight relief from acid reflux. *See id.* Takeda owns patents relating to Dexilant® that are listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). *Id.* at 14-15. Takeda asserts two Orange Book patents in these lawsuits.

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

The '158 Patent is entitled "Methods of Treating Gastrointestinal Disorders Independent of the Intake of Food" and is directed to methods of "treating heartburn, acid reflux or gastroesophageal reflux disease in a patient" by administering a "pharmaceutical composition" with two types of solid particles. '158 Patent cl.1. The '158 Patent notes the preexisting problem that giving patients PPIs (such as dexlansoprazole) together with food can reduce the drugs'

[1] All ECF entries correspond to Case No. 13-CV-1927 unless otherwise stated.

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

B. Procedural History

This litigation involves four separate cases filed by Takeda and several generic pharmaceutical companies. Par Pharmaceutical, Inc. ("Par"), Handa Pharmaceuticals, LLC ("Handa"), Impax Laboratories, Inc. ("Impax"), Sandoz Inc., ("Sandoz"), and TWi Pharmaceuticals, Inc. ("TWi") (collectively, "Defendants") have pursued Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA"), seeking to market generic forms of Dexilant®. *See generally Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1282-86 (Fed. Cir. 2008) (explaining ANDA procedures and patent infringement claims under the Hatch-Waxman Act). Certain Defendants submitted certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), alleging that the '158 Patent is invalid, unenforceable, and/or not infringed. *See, e.g.*, Compl. (ECF No. 1) ¶ 28. Takeda subsequently listed the '187 Patent in the Orange Book for Dexilant® and asserted it in these cases against Defendants. *See, e.g.*, First Am. Answer and Counterclaims at 15 ¶ 21.

On April 26, 2013, Par and Handa sued Takeda (Case No. 13-CV-1927) seeking declaratory judgments under 21 U.S.C. § 355(j)(5)(C) that certain claims of the '158 Patent are invalid and not infringed.[2] *See* Compl. In response, Takeda asserted counterclaims against Par and Handa for infringement of the '158 and '187 Patents. *See* First Am. Answer and Counterclaims. On May 29, 2013, Takeda filed three suits against Impax, Sandoz, and TWi (Case Nos. 13-CV-02416, -02418, and -02420), requesting judgment that each Defendant infringes both asserted

[2] Par and Handa also sought declaratory judgment that claims of U.S. Patent No. 8,105,626 are invalid, but all claims involving that patent have been dismissed. *See* ECF No. 46.

patents. On July 9, 2013, the Court related these four cases. *See* ECF Nos. 29, 56.[3] Takeda and Sandoz have since settled their respective claims. *See* Order, *Takeda Pharms. Co. v. Sandoz, Inc.*, No. 5:13-CV-02418 (N.D. Cal. Oct. 22, 2013).

On February 6, 2014, the parties filed a Joint Claim Construction and Prehearing Statement, identifying disputed claim terms, proposed constructions, and citations to supporting evidence. ECF No. 77 ("Joint Statement"). On March 27, 2014, Takeda filed its opening claim construction brief and supporting expert declarations. *See* ECF No. 79 ("Takeda Br."). On April 24, 2014, the Defendants filed their responsive claim construction brief and expert evidence. *See* ECF No. 88 ("Defs. Br."). On May 25, 2014, Takeda filed its reply brief. *See* ECF No. 90 ("Takeda Reply"). The Court held a technology tutorial and claim construction hearing on June 5, 2014.

II. LEGAL STANDARDS

The Court construes patent claims as a matter of law based on the relevant intrinsic and extrinsic evidence. *See Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (en banc); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Phillips*, 415 F.3d at 1316 (internal quotation marks and citation omitted). Accordingly, a claim should be construed in a manner that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id.*

In construing disputed terms, a court looks first to the claims themselves, for "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id*. at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Generally, the words of a claim should be given their "ordinary and customary meaning," which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13. In some instances, the ordinary meaning to a person of skill in the art is clear, and claim

[3] The parties have also been involved in separate litigation in this District regarding other Orange Book patents listed for Dexilant®. *See Takeda Pharm. Co. v. Handa Pharms., LLC*, No. 11-CV-01609-JCS, 2013 U.S. Dist. LEXIS 187604 (N.D. Cal. Oct. 17, 2013).

construction may involve "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

In many cases, however, the meaning of a term to a person skilled in the art will not be readily apparent, and a court must look to other sources to determine the term's meaning. *See id.* Under these circumstances, a court should consider the context in which the term is used in an asserted claim or in related claims, bearing in mind that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Indeed, the specification "'is always highly relevant'" and "'[u]sually . . . dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Where the specification reveals that the patentee has given a special definition to a claim term that differs from the meaning it would ordinarily possess, "the inventor's lexicography governs." *Id.* at 1316. Likewise, where the specification reveals an intentional disclaimer or disavowal of claim scope by the inventor, the inventor's intention as revealed through the specification is dispositive. *Id.* A court may also consider the patent's prosecution history, which consists of the complete record of proceedings before the United States Patent and Trademark Office ("PTO") and includes the cited prior art references. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* at 1317.

A court is also authorized to consider extrinsic evidence in construing claims, such as "expert and inventor testimony, dictionaries, and learned treatises." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Expert testimony may be particularly useful in "[providing] background on the technology at issue, . . . explain[ing] how an invention works, . . . ensur[ing] that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or . . . establish[ing] that a particular term in the patent or the prior art has a particular meaning in the pertinent field."

Phillips, 415 F.3d at 1318. Although a court may consider evidence extrinsic to the patent and prosecution history, such evidence is considered "less significant than the intrinsic record" and "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1317-18 (internal quotation marks and citations omitted). Thus, while extrinsic evidence may be useful in claim construction, ultimately "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319. Any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" will be significantly discounted. *Id.* at 1318 (internal quotation marks and citation omitted). Finally, while the specification may describe a preferred embodiment, the claims are not necessarily limited only to that embodiment. *Id.* at 1323; *see also Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1151 (Fed. Cir. 2003) ("The general rule, of course, is that claims of a patent are not limited to the preferred embodiment, unless by their own language.").

III. DISCUSSION

The parties request construction of two terms of the '187 Patent and four terms of the '158 Patent. Additionally, the parties stipulate to the following constructions of two terms in the '187 Patent (Joint Statement at 2):

Patent	Term	Agreed Construction
8,461,187	"wherein the PPI is released from the dosage form as a first and a second dose"	"wherein the PPI is released from the dosage form as a first and second amount of PPI" The term "PPI" means "proton pump inhibitor" in each of the claims.
	"wherein each pulse of the PPI is sufficient to maintain plasma concentrations above the threshold concentration for at least 30 minutes"	"wherein each pulse of the PPI is sufficient independently to maintain plasma concentrations above 100 ng/ml for at least 30 minutes"

A. Level of Ordinary Skill in the Art

The Court first addresses the level of ordinary skill in the relevant art of the asserted patents. *See Phillips*, 415 F.3d at 1312-13. Here, the parties have submitted expert declarations with opinions regarding the level of ordinary skill. Takeda relies on opinions from Dr. Robert Bellantone for the '187 Patent (*see* ECF No. 80 ("Bellantone Decl.")) and from Dr. Patrick Sinko

for the '158 Patent (*see* ECF No. 81 ("Sinko Decl.")). The Defendants cite the opinions of Dr. Michael Mayersohn for the '158 Patent (*see* ECF No. 88-1 ("Mayersohn Decl.")).

The parties generally agree that the relevant art for both patents would be the related fields of pharmacy or pharmaceutical drug development, pharmacokinetics, and pharmacodynamics. *See* Bellantone Decl. ¶ 32; Sinko Decl. ¶ 89; Mayersohn Decl. ¶ 36. While the '187 and '158 Patents have different priority dates (June 16, 2004 and October 12, 2007, respectively), both sides also generally agree that the person of ordinary skill in the art would have had a doctorate degree (Ph.D. or Pharm.D.) in pharmaceutical sciences or a related field and one year of relevant experience, or a Master's Degree with many years of experience.[4] *See id.* Accordingly, the Court adopts the parties' agreed positions regarding the level of ordinary skill for claim construction purposes. There is no dispute that each expert here meets or exceeds the requisite qualifications.

B. The '187 Patent

As noted above, the '187 Patent is generally directed to formulations that contain a first and second dose of a PPI. Claims 1-5 and 10-19 recite a "dosage form," while claims 6-9 cover methods of "treating a gastrointestinal disorder" that involve administering the claimed dosage forms. Takeda asserts combinations of claims 1-2, 5-8, and 10-17 against the individual Defendants. *See* Joint Statement at 2; Defs. Br. at 4 n.3. The parties dispute two terms—one in independent claim 1, and one in dependent claim 2.

1. "wherein the first and second doses are released from the dosage form as discreet pulses of the PPI separated by a period of time" (claim 1)

Defendants' Proposed Construction	Takeda's Proposed Construction
"wherein the first and second amounts of PPI are released from the dosage form as discontinuous pulses of the PPI separated by the time between completing the release of the first amount and starting the release of the second amount"	"wherein release of the second dose of PPI from the dosage form begins a period of time after release of the first dose begins"

The first disputed phrase appears in claim 1 of the '187 Patent. Independent claim 1 recites:

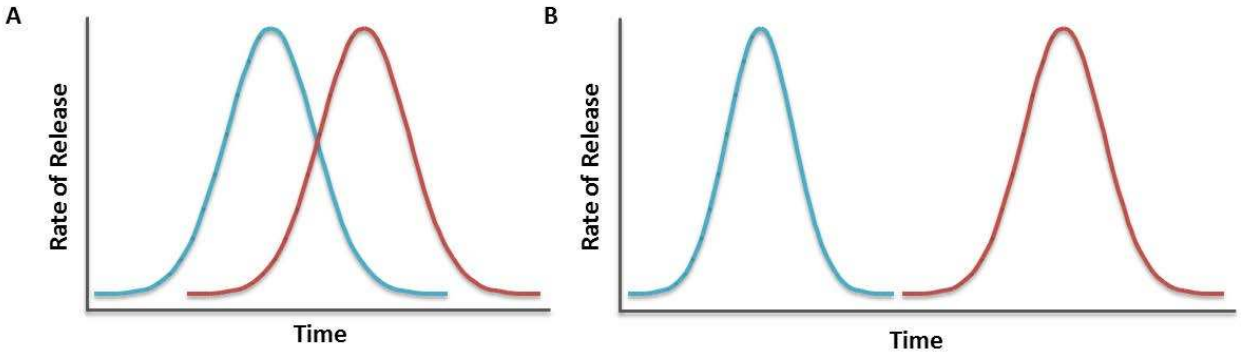
> 1. A dosage form comprising a PPI wherein the PPI is released from the dosage form as a first and a second dose, **wherein the first and second doses are released**

[4] As to the '158 Patent, Dr. Mayersohn states that "a Bachelor's or Master's Degree and a commensurately greater number of years of experience in the appropriate field" would suffice. Mayersohn Decl. ¶ 36.

from the dosage form as discreet pulses of the PPI separated by a period of time, wherein the second dose contains at least 10% more of the PPI than the first dose, and wherein each of the first and second doses comprise a sufficient amount of the PPI to raise plasma levels of the PPI to a threshold concentration of at least 100 ng/ml.

'187 Patent cl.1 (emphasis added).

Claim 1 requires release of a first and second dose of PPI "as discreet pulses" that are "separated by a period of time." The primary dispute is how the "period of time" must be measured. Takeda argues that the time period refers to the delay between the times when the two doses (or pulses) *begin* to be released. *See* Takeda Br. at 7-8. Defendants contend that the pulses must be "discontinuous," in that the time period refers to the time between when the first dose is *completely* released and when the second dose begins to be released. *See* Defs. Br. at 5-6. Therefore, under Defendants' construction, claim 1 requires that the second dose not begin releasing until 100% of the first dose is released, while Takeda's construction permits overlap between the release periods. A diagram from Dr. Bellantone's declaration (which both sides cite) illustrates the difference between the constructions:



Bellantone Decl. at 12; *see also* Defs. Br. at 6. Takeda's construction would encompass the release profiles shown in both Figures A and B above, while Defendants' construction would exclude the release profile in Figure A.

For the reasons below, the Court determines that Takeda's construction is the most consistent with the relevant intrinsic and extrinsic evidence.

a. Claim Language

Both sides argue that the plain meaning of the claims supports their constructions. As an initial matter, the parties concur that "discreet" is a typo, and that claim 1 should read "discrete."

See Bellantone Decl. ¶ 39 ("the word "discreet" (meaning 'careful and circumspect') is misspelled and should be 'discrete' (meaning 'separate')"); Defs. Br. at 5 ("Claim 1 requires 'discre[te] pulses . . . ."). Defendants argue that the plain meaning of the claim phrase requires that "the *entire pulses*, and not just their starts, must be discontinuous and separated by a period of time—that is, they must not overlap" because "[p]ulses that overlap are by definition not 'separated by a period of time.'" Defs. Br. at 6-7. However, the claim language is not so limited. Even if "discrete" means "separate" (as the parties agree), claim 1 requires only separate pulses that are "separated by a period of time." Claim 1 does *not* state that the pulses must be "discontinuous" with absolutely no overlap. For example, under the release profile shown in Figure A above, the two pulses are distinguishable and occur over different periods—and are thus "separate"—even though they partially overlap in time. Accordingly, the plain claim language does not support importing Defendants' limitation into claim 1. *See, e.g., Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1322 (Fed. Cir. 2003) ("This additional negative limitation finds no anchor in the explicit claim language.").

In addition to plain meaning, the parties raise several arguments regarding claim differentiation and the language of other claims in the '187 Patent. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987). "[T]he doctrine of claim differentiation is at its strongest" when comparing independent and dependent claims. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). First, Takeda argues that dependent claims 2-4 and 7 support its interpretation because those claims refer to specific times "wherein the second dose *begins to be released* . . . after the first dose *begins to be released*," indicating that the relevant point for measuring the "period of time" separating doses in claim 1 is the beginning of each release period. *See* Takeda Br. at 8. However, Defendants respond correctly that this language in the dependent claims is also consistent with Defendants' interpretation. *See* Defs. Br. at 7-8. While the dependent claims specify a delay between the start times of the two doses, that does not mean the release times necessarily overlap. For example, claim 2 recites a dosage form where release of the second dose begins "between 2 and 20 hours" after release of the

first dose begins, but does not specify how long the first dose lasts. If the first dose finishes releasing in one hour, it will not overlap with the second dose. Furthermore, claim 7 refers to a treatment method where the two doses are released "as discreet pulses of the PPI *and* the second dose begins to be released between 2 and 20 hours after the first dose begins to be released," strongly suggesting that the requirements for (1) "discre[te] pulses" and (2) a time gap between release start times are independent. Therefore, Takeda's argument is unconvincing.

Next, Takeda relies on dependent claim 9, which recites a method where the two doses "are released *continuously* such that there is a[n] *extended release* of the PPI." According to Takeda, "continuous" and "extended" release requires "no period of time separating the end of release of the first dose from the beginning of release of the second dose." Takeda Br. at 10. Claim 9 supports Takeda's position because "continuous" release implies at least some drug being released throughout the entire dosage period. This would be possible under Defendants' construction only if the second dose begins releasing at the *precise instant* that the first dose finishes releasing, with no overlap or delay, rendering claim 9 nearly impossible to satisfy. "[A] construction that renders the claimed invention inoperable should be viewed with extreme skepticism." *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir. 2002), *vacated and remanded on other grounds*, 537 U.S. 802 (2002); *see also Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir. 2010) (rejecting construction that excluded "essentially all guaifenesin formulations").[5]

Defendants raise another claim differentiation argument. Dependent claims 17-19 refer to the dosage form of claim 1 "wherein the period of time" is a specific range. Defendants point out that, under Takeda's construction, claims 2-4 and claims 17-19, which recite the same delay between releases, would be identical, and thus violate the presumption that different claims mean different things. For example, the comparison below shows that, under Takeda's position,

[5] Defendants argue that, during prosecution, the '187 Patent applicants disclaimed "continuous" release and that claim 9 is also invalid under 35 U.S.C. § 112 ¶ 4. *See* Defs. Br. at 10-11 & n.8. However, the Court addresses—and rejects—that argument below in analyzing the prosecution history.

dependent claims 2 and 17 would both recite a delay of 2-20 hours that is measured by when each release period begins:

Claim 2	Claim 17 Under Takeda's Construction
"The dosage form of claim 1 wherein the second dose begins to be released between 2 and 20 hours after the first dose begins to be released."	"The dosage form of claim 1, wherein the [release of the second dose of PPI from the dosage form begins] between 2 hours and 20 hours [after release of the first dose begins]."

See Defs. Br. at 8-9. This analysis also applies to claims 3 and 18, and claims 4 and 19. Takeda and Dr. Bellantone concede that these claims would be redundant under their construction, but argue that this is legally permissible. *See* Takeda Reply at 2-3; ECF No. 88-9 (Bellantone Depo.) at 20:7-13 ("They're saying the same thing.").

As Takeda observes, claim differentiation is not a rigid rule. While there is a "presumption that the difference between claims is significant," "two claims which read differently can cover the same subject matter." *Tandon*, 831 F.2d at 1023. "Different terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper." *Nystrom v. Trex Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005).[6] Here, the redundancy exists only between dependent claims, not between dependent and independent claims where claim differentiation "is at its strongest." *Liebel-Flarsheim*, 358 F.3d at 910. While Defendants' construction would avoid this redundancy, it would also render dependent claim 9 essentially inoperable, as explained above. Moreover, "the doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence," and "claims that are written in different words may ultimately cover substantially the same subject matter." *Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). Accordingly, claim differentiation does not mandate Defendants' construction.

b. Specification

The parties focus on the following portion of the '187 Patent's specification:

[6] Defendants' suggestion that redundant dependent claims would be invalid for statutory double patenting (Defs. Br. at 9, 12) is misplaced, as that doctrine prohibits only "obtaining more than one valid patent" on the same invention. *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

> In cases where the PPI is delivered in pulses, the period between when the first dose ***begins to be release[d]*** and when the second dose ***begins to be released can be separated by varying amounts of time.*** Preferably, the ***onset of release*** of the doses are separated by between 2 hours and 20 hours, more preferably between 3 hours and 16 hours and most preferably between 4 hours and 12 hours. Of course, any of the pulses released from such a dosage form should achieve the threshold concentration and maintain plasma concentrations above such threshold for at least 30 minutes, preferably one hour to 2 hours, and more preferably between 2 hours to 8 hours.

'187 Patent col.9 ll.23-29 (emphases added). Takeda argues that the bolded portions above show that the relevant times for measuring the separation between doses are the start times for release. *See* Takeda Br. at 8. However, this argument repeats Takeda's theory above regarding claims 2-4. For the same reasons, this argument alone is unpersuasive—while the period between release start times can vary as recited in dependent claims 2-4, this does not necessarily demonstrate that the release periods overlap in time.

Other portions of the specification provide some support for Takeda's position. The Summary of the Invention states that "the first and second doses may be separated by *little or no time* delay" ('187 Patent col.1 ll.58-60 (emphasis added)), while another portion refers to "cases where there is no time separating the pulses" (*id.* col.9 ll.33-35). Thus, the inventors recognized that there could be "little" delay between the pulses, which suggests (but does not require) that the pulses may overlap in time. The specification's discussion of drug delivery in spaced pulses also refers generally to "the period between when the first dose begins to be release[d] and when the second dose begins to be released." *Id.* col. 9 ll.23-26. Otherwise, the specification provides little guidance as to whether the two PPI pulses in claim 1 may partially coincide.

Takeda argues that the specification's reference to "combined release of the first and second dose of PPI" (col.8 ll.40-46) also supports its reading. Takeda Br. at 11. This argument is misleading. The quoted sentence refers to "when a[n] *extended release* formulation is employed" (emphasis added). Elsewhere, the specification expressly distinguishes between (1) controlled or extended release and (2) pulse-based formulations: "there are two types of modified drug release. Specifically, there is controlled or extended release, and pulsed release." '187 Patent col.2 ll.57-59. Thus, the excerpt that Takeda quotes does not discuss the two-pulse system of claim 1.

The Court is also unpersuaded by Defendants' arguments regarding the specification's incorporation by reference of two separate patents, Nos. 5,017,381 and 6,228,398. *See id.* col.7 ll.51-60. Defendants argue that the '187 Patent must be limited to discontinuous pulses because the referenced patents disclose pulsed-release systems with discontinuous doses. *See* Defs. Br. at 11; Joint Statement Ex. 1 at 1. Even assuming that the patents are properly incorporated by reference, *see Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006), they provide only non-limiting examples of alternative dosage forms. *Cf.* U.S. Patent No. 5,017,381 col.2 ll.27-32 (describing "pulsed delivery of two drugs or drug formulations simultaneously"); U.S. Patent No. 6,228,398 col.4 ll.56-59 (describing release "in a bimodal or pulsed manner").

c. Prosecution History

Defendants argue that "Applicants expressly disclaimed continuous release from the scope of 'discrete pulses' during the prosecution of the '187 patent." Defs. Br. at 10. During prosecution, the '187 Patent Examiner rejected several pending claims—including the claim that issued as claim 1—as obvious in light of a prior art reference, U.S. Patent Application Publication No. 2003/0091630 to Louie-Helm. That reference is directed to "Formulation of an Erodible, Gastric Retentive Oral Dosage Form." ECF No. 91-1 ("Louie-Helm"). In a July 27, 2012 Reply and Amendment, the '187 Patent applicants argued to the PTO that "Louie-Helm does not teach or suggest a dosage form wherein first and second doses are released from the dosage form as discreet [sic] pulses of PPI separated by a period of time." ECF No. 88-14 at 5. Defendants contend that Louie-Helm teaches "continuous release," and that by distinguishing Louie-Helm, the applicants necessarily disavowed overlapping (or "continuous") release periods under the doctrine of prosecution disclaimer.

"[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega*, 334 F.3d at 1324. Such disclaimer requires "clear and unmistakable" disavowal. *Id.* at 1325-26. Here, Defendants' theory of prosecution disclaimer does not demonstrate an unequivocal disavowal of overlapping doses.

Louie-Helm discusses formulation of "a controlled release dosage form, particularly of the swellable, erodible type," based on certain disintegration test results. Louie-Helm ¶ 0006. As examples of such dosage forms, Louie-Helm discloses "a bilayer tablet" with a first and second layer (*id.* ¶ 0013) and claims a formulation where "a first fraction . . . is released . . . by diffusing" and "a second fraction . . . is released . . . by erosion" (*id.* cl.2). The '187 Patent Examiner initially found that Louie-Helm "addresses first and second dose administration." ECF No. 88-14 at 6. In response, the applicants argued that Louie-Helm "describes continuous release" and teaches away from "discrete pulses," and that "Claim 2 of Louie-Helm does not describe release in discreet pulses." *Id.* at 6-7.

However, the applicants did not clearly and unmistakably disclaim all forms of "continuous release." In their remarks, the applicants argued that Louie-Helm "does not describe a dosage form that is administered once *and releases multiple doses*." *Id.* at 6 (emphasis added). They also cited Louie-Helm ¶ 0112, which states that "the dosage forms of the present invention provide the drug by means of a continuous delivery *instead of the pulse-entry delivery* associated with conventional dosage forms." *Id.* (emphasis added). Therefore, the applicants distinguished Louie-Helm by arguing that it does not teach a single dosage form comprising discrete pulsed doses, but did not disclaim overlapping release periods.

As noted above, Louie-Helm does disclose a "bilayer tablet" and a formulation where two drug fractions begin release at the same time. Louie-Helm ¶ 0013, cl.2; *see also* Takeda Reply at 5 (agreeing that Louie-Helm teaches "two separate releases" that "occurred *at the same time*" (emphasis in original)). The '187 Patent applicants contended that these disclosures do not describe discrete pulses. Accordingly, as Takeda conceded at the June 5, 2014 hearing, the applicants clearly disclaimed a dosage form where two pulses begin release at the same time; *i.e.*, where the "period of time" separating pulses in claim 1 is zero. *Cf.* '187 Patent at col.9 ll.33-35 (referring to "cases where there is no time separating the pulses"). However, there is no indication that the applicants further disclaimed any form of overlapping doses. Accordingly, the Court rejects Defendants' prosecution disclaimer argument.

d. Extrinsic Evidence

Takeda relies on the expert testimony of Dr. Bellantone, who generally repeats and supports Takeda's arguments about the claim language and specification. *See* Bellantone Decl. ¶¶ 42-49. Dr. Bellantone also elaborates on an embodiment in the '187 Patent that describes two pulses that release based on pH: "For example, polymers having different dissolution pHs are commonly used for this purpose. Hence, one population of granules can be coated with a polymer that begins dissolving at a pH of 6 and another population of granules can be coated with a polymer that begins dissolving at a pH of 6.5 to achieve a pulsed release." '187 Patent col.7 l.65-col.8 l.4. Dr. Bellantone opines that this passage indicates overlapping release periods because "The person of ordinary skill also would understand that the first population of granules may not completely finish releasing its drug before the second population of granules begins release, especially because the target pHs of the different enteric coatings in this example are close (pH 6 and pH 6.5)." Bellantone Decl. ¶ 51. Dr. Bellantone provides technical explanations for this conclusion, such as the understanding that some drug granules may pass through the gastrointestinal tract faster or slower, and that the granules' enteric coatings often contain irregularities. *Id.* ¶¶ 51-52. Defendants point out that this pH-based example in the specification does not necessarily disclose overlapping periods, but offer no contrary expert testimony. *See* Defs. Br. at 11. Accordingly, the Court finds that Dr. Bellantone's unrebutted opinions regarding the specification are persuasive and support Takeda's construction.

Both parties also cite several dictionary definitions. *E.g.*, ECF No. 88-12 (Concise Oxford American Dictionary (2006), defining "discrete" as "individually separate and distinct"); ECF No. 80-1, Ex. 6 (Merriam-Webster's Collegiate Dictionary (2000), defining "discrete" as "constituting a separate entity: individually distinct"). However, these extrinsic definitions do not help resolve the question of whether "discrete" encompasses overlapping pulses. As noted earlier, two pulses can be separate and distinguishable even if they partially overlap, as shown in Figure A in the Bellantone Declaration. Indeed, the parties generally agree that "discrete" means "separate" or "distinct," but still strongly disagree about how to construe claim 1.

Based on the intrinsic and extrinsic evidence analyzed above, the Court construes the term "wherein the first and second doses are released from the dosage form as discreet pulses of the PPI separated by a period of time" to mean **"wherein release of the second dose of PPI from the dosage form begins a period of time after release of the first dose begins."**

2. "the second dose begins to be released between 2 and 20 hours after the first dose begins to be released" (claims 2 and 7)

Defendants' Proposed Construction	Takeda's Proposed Construction
"none of the second amount of PPI begins to be released until between 2 to 20 hours after any of the first amount of PPI begins to be released"	"release of the second dose begins between 2 hours and 20 hours after release of the first dose begins"

Dependent claims 2 and 7 recite:

> 2. The dosage form of claim 1 wherein ***the second dose begins to be released between 2 and 20 hours after the first dose begins to be released***.
>
> 7. The method of claim 6 wherein the first and second dose are released from the dosage form as discreet pulses of the PPI and ***the second dose begins to be released between 2 and 20 hours after the first dose begins to be released***.

'187 Patent cls. 2, 7 (emphases added). The parties concur that their respective constructions of this term rise and fall with the construction of the previous term in claim 1, and offer no new additional arguments for this term. *See* Takeda Reply at 6; Defs. Br. at 12-13. Accordingly, the Court construes the term "the second dose begins to be released between 2 and 20 hours after the first dose begins to be released" to mean **"release of the second dose begins between 2 hours and 20 hours after release of the first dose begins."**

C. The '158 Patent

The '158 Patent is generally directed to methods of treating stomach problems with "pharmaceutical compositions" of dexlansoprazole. Takeda asserts claims 1-8 against Defendants. *See* Joint Statement at 2. The parties dispute four terms.

1. "regardless of whether the patient is under fasted or fed conditions" (claim 1)

Defendants' Proposed Construction[7]	Takeda's Proposed Construction
"regardless of whether the patient is dosed after an overnight fast, within 5 minutes before a meal, within 30 minutes before a meal, or within 30 minutes after a meal"	"without regard to food"

The first disputed phrase appears in claim 1 of the '158 Patent. Independent claim 1 recites:

> 1. A method of treating heartburn, acid reflux or gastroesophageal reflux disease in a patient in need of treatment thereof, the method comprising the steps of:
>
> a) obtaining a pharmaceutical composition comprising dexlansoprazole from a group of pharmaceutical compositions comprising proton pump inhibitors; and
>
> b) administering to a patient suffering from heartburn, acid reflux or gastroesophageal reflux, ***regardless of whether the patient is under fasted or fed conditions***, a therapeutically effective amount of the pharmaceutical composition obtained in step a), wherein the pharmaceutical composition comprises:
>
> (i) a first solid particle, wherein said first solid particle comprises dexlansoprazole and a first enteric coating, wherein the first enteric coating releases the proton pump inhibitor from the solid particle at a pH of about 5.0 to about 5.5; and
>
> (ii) a second solid particle, wherein said second solid particle comprises dexlansoprazole and a second enteric coating, wherein the second enteric coating releases the proton pump inhibitor from the solid particle at a pH of about 6.2 to about 6.8; wherein the first solid particle comprises from about 15% to about 50% by weight of the pharmaceutical composition and the second solid particle comprises from about 50% to about 85% by weight of the pharmaceutical composition.

'158 Patent cl.1 (emphasis added).

As their respective constructions show, the parties disagree about how the patent defines "fasted" and "fed" conditions. Defendants believe that "fasted or fed" refers to four specific food regimens identified in the specification. *See* Defs. Br. at 15-16. By contrast, Takeda argues that claim 1 encompasses all dosing without regard to food, and that Defendants' construction "would unduly narrow the scope of claim 1 to the administration of the pharmaceutical composition only under the fasted and fed conditions set forth in Table 4 of the '158 patent." *See* Takeda Reply at 7.

[7] In their responsive claim construction brief, Defendants changed their proposed construction from their prior position, which was "wherein the same therapeutic effect is achieved whether the patient has eaten a meal, will eat a meal, or is on an empty stomach." *Compare* Joint Statement Ex. 1 at 6 *with* Defs. Br. at 14-15.

This dispute also overlaps with a contested phrase in claim 4, "wherein the changes in pharmacokinetics . . . under ***fasting or fed conditions*** does not produce statistically significant changes in intragastric pH," which contains similar language and is discussed separately below. Here, the Court agrees with Takeda.

a. Claim Language and Specification

The plain language of claim 1 recites only "regardless of whether the patient is under fasted or fed conditions," and does not define what "fasted" or "fed" means. As a result, both sides focus on Example 2 in the specification, which explains a research study on "The effect and timing of food on the pharmacokinetics and pharmacodynamics of TAK-390MR." '158 Patent col.23 l.35-col.27 l.17. Example 2 discusses a Phase 1 study in which the inventors administered TAK-390MR (another name for Dexilant®) to patients under different food conditions and measured plasma concentrations of dexlansoprazole and intragastric pH levels. *Id.* col.24 ll.11-38; Takeda Br. at 14. The study involved four patient food regimens shown in Table 4:

TABLE 4

Treatment Sequences and Dosing Regimens

Regimen	Timing of Dose of TAK-390MR 90 mg or Placebo
A	Dosed under fasting conditions
B	Fed State: Dosed 30 min after the start of a high-fat breakfast
C	Dosed 5 min before a high-fat breakfast
D	Dosed 30 min before a high-fat breakfast

Id. Tbl.4. Based on the study, the inventors concluded: "The pH results indicate that TAK-390MR can be administered *without regard to food* or the timing of food." *Id.* col.25 ll.49-50 (emphasis added).

Defendants claim that the specification dictates that "fasting or fed conditions" are limited to the four regimens in Table IV. *See* Defs. Br. at 16; Takeda Reply at 7. The Court disagrees. As the Court understands Defendants' position, claim 1 would not literally cover—for example—dosing 35 minutes after the start of a high-fat breakfast. To the extent that Defendants' construction would restrict claim 1 to cover administration only "regardless of whether the patient

is dosed after an overnight fast, within 5 minutes before a meal, within 30 minutes before a meal, or within 30 minutes after a meal," and no other feeding regimens, this would improperly import a limitation from the specification. *See, e.g.*, *In re Huai-Hung Kao*, 639 F.3d 1057, 1073 (Fed. Cir. 2011) (declining invitation "to import from the specification into the claim the limitation that the dosage be adjusted as a result of the informing step").

Here, the inventors claim to have solved the problem where "patients are unable to take PPIs *whenever it is convenient* for them to do so." '158 Patent col.2 ll.10-11 (emphasis added). Indeed, the specification refers repeatedly to dosing without food-based restrictions: enabling dosage "independently of the intake or consumption of food" (*id.* col.2 ll.17-19); administration "without regard to food" (*id.* col.23 ll.53-55); "wherein said pharmaceutical composition can be administered to the patient independent of the intake of food" (*id.* col.1 ll.15-17); and a drug that "can be administered to the patient independently of food or meal intake or consumption" (*id.* col.10 ll.11-13). Thus, the specification supports Takeda's position that "fasting or fed conditions" refers to the purported discovery that patients can take certain forms of dexlansoprazole without regard to food, not just under four specific conditions.

Defendants correctly state that the patent identifies only the four specific fasting or fed conditions listed in Table 4. *See also id.* Figs. 1-2 (listing Regimens A-D). However, the claims do not refer to any of those four regimens, and the inventors concluded from the Example 2 study that "TAK-390MR can be administered without regard to food." Defendants' interpretation would restrict the claims to the precise test conditions disclosed in the specification, and conversely require disclosure of test results for all possible food conditions to support Takeda's interpretation. Accordingly, the specification and claim language support Takeda's position.

b. Prosecution History

Defendants argue that Takeda's construction conflicts with the '158 Patent's prosecution history because the applicants amended the claims to mean something other than "without regard to food." *See* Defs. Br. at 16-17. In an October 12, 2011 Reply during examination, the '158 Patent applicants submitted new claims to the PTO, including pending claim 31, which recited "administering . . . without regard to the patient's intake of food." ECF No. 81-17 at

TAKEDA009396. Afterwards, the Examiner and the applicants held an in-person interview regarding the new claims. According to the Examiner's interview summary, the "Examiner also asked to clarify the 'independent of the intake of food' approach." *Id.* at TAKEDA006967. On December 28, 2011, the applicants filed a Supplemental Reply in which they amended pending claim 31 to recite "administering . . . regardless of whether the patient is under fasted or fed conditions ~~without regard to the patient's intake of food~~." *Id.* at TAKEDA006940. In accompanying remarks, the applicants stated: "Furthermore, the Examiner asked Applicants to clarify the 'independent of the intake of food' approach. Applicants note that in order to address this concern, claim 31 has been amended to recite 'under fasting or fed conditions' instead of 'independent of the intake of food.'" *Id.* at TAKEDA006944. Then, on January 13, 2012, the Examiner allowed the claims, noting that the prior art of record did not teach administration "regardless of fed-or-fasted state of the patient." *Id.* at TAKEDA006876.

Defendants contend that the applicants changed the claim language from "without regard to the patient's intake of food" to "regardless of whether the patient is under fasted or fed conditions" in response to the Examiner's inquiries. Defendants point to statements by Dr. Sinko that "without regard to the patient's intake of food" means the same as "without regard to food." Sinko Decl. at 30 n.5. Thus, Defendants posit, the applicants must have meant something other than "without regard to food" when they amended the claim language, otherwise the amendment would not have addressed the Examiner's concerns. *See* Defs. Br. at 16-17.

Defendants' theory is unavailing. The prosecution history shows that the Examiner did not reject claim 31 based on its recitation of "without regard to the patient's intake of food," but rather requested clarification about the "'independent of the intake of food' approach." The fact that the applicants amended the language to "clarify" this approach does not mean that they disclaimed the construction of "without regard to food." Indeed, the Examiner's Notice of Allowability indicates that the claims were allowed because the prior art did not teach dosing "regardless of fed-or-fasted state." Moreover, Dr. Sinko opined that *both* "without regard to the patient's intake of food" (the original language of claim 31) and "regardless of whether the patient is under fasted or fed conditions" (the issued claim language) mean "without regard to food." Sinko Decl. at 30 n.5. At

minimum, the applicants' statements do not rise to a "clear and unmistakable" disavowal required for prosecution disclaimer. *Omega*, 334 F.3d at 1325-26. Indeed, Defendants do not assert that the applicants expressly disclaimed Takeda's proposed construction as a matter of prosecution disclaimer. Rather, Defendants cite *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 (Fed. Cir. 2004), which addressed a situation where two *separate* sets of claims employed different language, which is not the situation here. *See* Defs. Br. at 17.

In short, the cited prosecution history of the '158 Patent does not demonstrate any disclaimer by the applicants or support Defendants' construction.

c. Extrinsic Evidence

Once again, the parties rely on opposing expert opinions, from Drs. Mayersohn (Defendants) and Sinko (Takeda). Both experts have notable credentials: Dr. Mayersohn has served on committees for the FDA and U.S. Pharmacopeia (which is cited in the '158 Patent), Mayersohn Decl. ¶¶ 20-21, while Dr. Sinko has worked with the National Institutes of Health, Sinko Decl. ¶¶ 11-12. Regarding this claim term, however, the experts largely parrot the parties' arguments regarding the intrinsic evidence without providing independent or detailed analysis. *Compare* Mayersohn Decl. ¶¶ 41-42, *with* Sinko Decl. ¶¶ 97-101. Accordingly, the Court finds the competing expert opinions of little help beyond their summaries of the intrinsic record.

Takeda also relies on extrinsic documentation. First, Takeda submits the FDA's "Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies," dated December 2002 (prior to the '158 Patent's priority date). ECF No. 81-3 ("FDA Guidance"). These guidelines are instructive because they explain how to test the effect of food on drugs, recommending a "single-dose, two-treatment (fed vs. fasting)" test. *Id.* at TAKEDA0014717. The FDA Guidance identifies only one "fed" regimen, where the subject starts a high-fat breakfast 30 minutes before administration, which corresponds to Regimen B in the '158 Patent. *Id.* at TAKEDA0014719; '158 Patent Tbl.4. Furthermore, the Guidance indicates that a comparison between this single "fed" regimen and a fasting regimen can demonstrate a drug's food-independence, stating that a high-fat breakfast provides "conditions that are expected to provide the *greatest effects* on GI physiology so that systemic drug availability is *maximally affected*," and that a successful test

allows a drug maker to state that "[the drug] could be taken *without regards to meals*." FDA Guidance at TAKEDA0014718, 14720 (emphases added). Thus, these guidelines provide persuasive evidence that a person of ordinary skill would have understood that comparing one fed and one fasted condition (Regimens A and B in the '158 Patent) could support the conclusion that a drug could be dosed "without regard to food," as Takeda proposes.

By contrast, Takeda's reliance on the FDA-approved Dexilant® label is misplaced. The label states that "DEXILANT can be taken without regard to food." *See* Takeda Br. at 15-16 (citing ECF No. 81-10 at TAKEDA012767). Defendants correctly point out, however, that this label was not available until 2009—two years after the '158 Patent's asserted priority date—and therefore could not have informed the person of ordinary skill at the relevant time. *See Phillips*, 415 F.3d at 1312-13.

Overall, the Court finds that Takeda's construction aligns most closely with the totality of the intrinsic and extrinsic evidence presented. Accordingly, the Court construes the term "regardless of whether the patient is under fasted or fed conditions" to mean **"without regard to food."**

2. "wherein the changes in pharmacokinetics . . . under fasting or fed conditions does not produce statistically significant changes in intragastric pH" (claim 4)

Defendants' Proposed Construction[8]	Takeda's Proposed Construction
"Wherein the changes in pharmacokinetics . . . when the patient is dosed after an overnight fast, within 5 minutes before a meal, within 30 minutes before a meal, or within 30 minutes after a meal does not produce any statistically significant differences in mean intragastric pH and percentage of time that gastric pH is greater than 4. The term 'statistically significant' means that the P value for the pairwise comparisons of the fed and fasted regimens is less than 0.05."	"Wherein differences in pharmacokinetics . . . between fasting conditions, meaning dosing after an overnight fast, and fed conditions, meaning dosing within 30 minutes before or after a meal, do not produce statistically significant changes in mean intragastric pH over the 24-hour postdose interval. The term 'statistically significant' means that the P value for the pairwise comparison of the fed regimen with the fasted regimen is less than 0.05."

This disputed phrase appears in dependent claim 4, which recites:

[8] Defendants have revised their prior construction, which was "wherein the changes in pharmacokinetics . . . when the patient has eaten a meal, will eat a meal, or is on an empty stomach does not produce any statistically significant differences in mean intragastric pH and % time that gastric pH is greater than 4, as measured by a 0.05 P value for pairwise comparisons." *Compare* Joint Statement Ex. 1 at 15 *with* Defs. Br. at 23.

> 4. The method of claim 1, wherein the changes in pharmacokinetics after administration to the patient of a single dose of a therapeutically effective amount of the pharmaceutical composition comprising dexlansoprazole under fasting or fed conditions does not produce statistically significant changes in intragastric pH.

'158 Patent cl.4. Construction of this term overlaps with the preceding term in claim 1 because claim 4 recites "fasting or fed conditions," while claim 1 contains the similar language of "fasted or fed conditions." Both sides agree that "'statistically significant' means that the P value for the pairwise comparison[s] . . . is less than 0.05." The parties identify two areas of disagreement: (1) the scope of "fasting or fed conditions," and (2) the relevant tests for "intragastric pH." *See* Takeda Reply at 12. The Court considers the intrinsic and extrinsic evidence in addressing each of these disagreements.

a. "under fasting or fed conditions"

Defendants argue that "fasting or fed conditions" refers to the four food regimens in Table 4, and that claim 4 requires pairwise statistical comparisons between all four regimens, including between the three "fed" regimens. *See* Defs. Br. at 23-24. In other words, Defendants claim that claim 4 requires comparing each fed regimen with each other fed regimen (for example, Regimens B and C in Table 4). Defendants also point out that claim 1 uses essentially the same language of "fasted or fed conditions" and argue that this language should have the same meaning in claim 4. *Id.* at 15. On the other hand, Takeda contends that "fasting or fed conditions" encompass an overnight fast and "dosing within 30 minutes before or after a meal," which includes the three "fed" regimens in Table 4. *See* Takeda Reply at 13-14. Takeda further argues that claim 4 assesses statistical significance only between a fed regimen and a fasting regimen, not between fed regimens. *See id.*

The Court agrees with Defendants that "fasting or fed conditions" in claim 4 should have the same meaning as "fasted or fed conditions" in claim 1. Generally, "a claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). "A word or phrase used consistently throughout a claim should be interpreted consistently." *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998); *see also Phillips*, 415

F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Turning to the claim language, there is no dispute that the phrases are essentially identical in claims 1 and 4. As explained above, the specification repeatedly discusses dosing "independent of the intake of food" and "without regard to food"—which is how Takeda asked the Court to construe claim 1. Indeed, the specification shows that the inventors believed that dosing under any food conditions would not significantly affect pharmacodynamic results.

For claim 4, Takeda now argues that "fasted or fed conditions" can have an entirely different meaning. However, Takeda cannot have it both ways: reading "fasted or fed conditions" in claim 1 more broadly to encompass any dosing regimen "without regard to food," but restricting "fasting or fed conditions" in claim 4 to a much narrower range of food regimens—dosing up to 30 minutes before or after eating. Takeda argues that claim 4 provides a different "context" than claim 1 because claim 4 "refers to the test conditions for subjects participating in a food-effect study like the study disclosed in Example 2." Takeda Br. at 24. However, the claim language is not so limited and does not incorporate any studies or tests.[9] Takeda provides no convincing reason why claim 4's reference to "statistically significant changes" shows that "fasting and fed conditions" in that claim (but not claim 1) are "tied to specific clinical data." Takeda Reply at 14.

Takeda cites two cases where the Federal Circuit interpreted the same or similar terms differently in separate claims, but both cases are distinguishable. *See* Takeda Reply at 13-14. In *Aventis Pharmaceuticals, Inc. v. Amino Chemicals Ltd.*, the court construed "substantially pure" in two different ways, but did so because the term as used in the claims and specification modified two different chemicals—an intermediate and an end product. 715 F.3d 1363, 1374-75 (Fed. Cir. 2013). Here, there is no such distinction between claims 1 and 4, and no indication that "fasted and fed conditions" and "fasting and fed conditions" refer to different sets of conditions. In *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, the Federal Circuit held that

[9] Unasserted dependent claims 9 and 12, which the parties did not address in briefing, also refer to a "fed state" and "fasted state." Claim 9 requires bioequivalence between dosings in a fed state and a fasted state, while claim 12 requires a specific mean intragastric pH level "regardless of whether the dexlansoprazole was administered in a fed or fasted state." At oral argument, Takeda suggested that a fed/fasted "state" may differ from a fed/fasted "condition."

"control code" could have different meanings based on the context of the claims at issue, but for purposes of deciding that the challenged claims were not indefinite under the former "insolubly ambiguous" standard.[10] 520 F.3d 1367, 1375-77 (Fed. Cir. 2008). Indefiniteness is not at issue here, and again, the language of claim 4 does not provide a context that warrants an entirely different construction from claim 1.

As to extrinsic evidence, the experts' opinions again offer no definitive guidance. For Defendants, Dr. Mayersohn opines that "fasted or fed conditions" in claim 1 and "fasting or fed conditions" in claim 4 should be "the same." Mayersohn Decl. ¶¶ 40, 54. However, his additional opinions on this issue are limited to whether all fed conditions must be statistically comparable, as Defendants propose. *See id.* ¶ 55. For Takeda, Dr. Sinko declares that, to statistically compare intragastric pH under different food conditions, "it would be necessary to perform a food-effect study like that disclosed in Example 2, in which the dosage form is administered under both fasting and fed conditions." Sinko Decl. ¶ 156. Dr. Sinko also opines that "in the context of claim 4, the known FDA regulations regarding testing for food effect of pharmaceutical products, the term 'under fasting or fed conditions' refers to the test conditions for subjects participating in a food-effect study like the study disclosed in Example 2," citing the FDA Guidance. *Id.* ¶ 160. Here, however, Dr. Sinko does not explain why these factors do not apply equally to claim 1, other than a vague reference to the "context of claim 4." Again, claim 4 does not refer to the FDA Guidance or the additional "fed" regimens in Example 2 that are not required by the FDA Guidance. Dr. Sinko also provides no reason why a person of ordinary skill could not evaluate statistical significance between food regimens other than the four delineated in Table 4 or the two regimens described in the FDA Guidance.

For the foregoing reasons, the Court determines that "fasting or fed conditions" should be construed consistently with "fasted or fed conditions" in claim 1. As a result, the parties' dispute as to whether claim 4 requires comparisons between a fasting condition and each of the three "fed"

[10] *Cf. Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369, 572 U.S. ____, 2014 WL 2440536, slip op. at 1 (June 2, 2014) (replacing "insolubly ambiguous" test with a "reasonable certainty" standard).

conditions in Table 4 is mooted. Rather, claim 4 requires that dosing without regard to food "does not produce statistically significant changes in intragastric pH."

b. "intragastric pH"

For this term, the parties contest how intragastric pH (or stomach acidity, *see* Sinko Decl. ¶ 70) is properly measured. Defendants claim that "intragastric pH" refers to "mean intragastric pH and percentage of time that gastric pH is greater than 4." Takeda interprets this term as "mean intragastric pH over the 24-hour postdose interval." Thus, the parties agree that mean intragastric pH is an appropriate metric for "intragastric pH" as claimed. Defendants also appear to agree with Takeda that a 24-hour postdose interval is the proper measurement period, for they contend that percentage of time that gastric pH is greater than 4 is measured "for a period of 24 hours after the patient is dosed" using the same data. *See* Defs. Br. at 24 & n.12. The parties therefore disagree only about whether claim 4 also requires measurement of the percentage of time that gastric pH is greater 4.

Starting with the claims themselves, the plain language of claim 4 does not resolve this dispute. However, claim 12 (which depends from claim 1) refers to "*mean* intragastric pH." This suggests that "intragastric pH" is not limited to "mean" intragastric pH because the use of "mean" in claim 12 would otherwise be superfluous. Generally, courts construe claims "to avoid rendering any part superfluous." *Frans Nooren Afdichtingssystemen B.V. v. Stopaq Amcorr, Inc.*, 744 F.3d 715, 722 (Fed. Cir. 2014). Although Defendants have not argued that the rule against superfluity applies here, claim 12 demonstrates that the '158 Patent applicants knew how to specify "mean intragastric pH" and did not do so in claim 4.

Turning to the specification, the '158 Patent provides varying statements about "intragastric pH." Example 2 reflects data for both mean intragastric pH and percentage of time with pH greater than 4. As Defendants note, the inventors used "intragastric pH results" to refer to both types of pH results. '158 Patent col.25 ll.15-27. Table 7 also includes both types of data. *Id.* Tbl.7. On the other hand, the inventors also observed a statistically significant difference in percentage of time with pH greater than 4 between fed and fasting regimens, but concluded that "dosing under different fasting/fed conditions did not produce relevant differences in *intragastric pH*," suggesting

that "intragastric pH" refers only to mean intragastric pH. *Id.* col.25 ll.23-27, ll.46-49 (emphasis added). However, taken as a whole, Example 2 shows that the inventors tested and relied on both mean intragastric pH and percentage of time with gastric pH greater than 4 to evaluate the food-dependency of their formulation.

Takeda's primary argument regarding the specification is that Defendants' construction would exclude a preferred embodiment—use of TAK-390MR—because that formulation resulted in a statistically significant difference with respect to time with pH over 4. *See* Takeda Reply at 14-15. If claim 4 requires no statistically significant changes between food regimens, as Defendants propose, than the formulation used in Example 2 would be excluded. Defendants respond that the specification does not refer to Example 2 as a "preferred" embodiment and discloses other sample formulations with varying amounts of dexlansoprazole, such that no one formulation is preferred. *See* Defs. Br. at 25.

The Federal Circuit has warned that "[a] claim construction that excludes the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support," *Adams Respiratory*, 616 F.3d at 1290 (quotation and citation omitted), but "has acknowledged that a claim need not cover all embodiments," *Intamin, Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1237 (Fed. Cir. 2007). More specifically, a preferred embodiment need not be covered by all claims in a given patent. In *Helmsderfer v. Bobrick Washroom Equipment, Inc.*, the patentee objected to a claim construction for excluding the preferred embodiment from certain dependent claims. 527 F.3d 1379, 1383 (Fed. Cir. 2008). The court rejected this argument, stating: "It is true that the plain meaning of 'partially hidden from view' does not include totally hidden from view, and that therefore claims 6-7 do not cover the preferred embodiment or the other illustrated embodiments. However, this does not mean that these embodiments are all excluded from the scope of the invention, but rather that they are excluded from the scope of these particular claims." *Id.; see also August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1285 (Fed. Cir. 2011) (rejecting construction "where, as here, other unasserted claims in the parent patent cover the excluded embodiments").

Here, the Court concludes that TAK-390MR is a preferred embodiment and that Defendants' construction would exclude TAK-390MR from claim 4, but finds this irrelevant because other claims may cover TAK-390MR. The specification recites multiple characteristics that are "preferably" included in a pharmaceutical composition, *see* '158 Patent col.2 ll.56-67, and explains that TAK-390MR has most or all of those qualities, *id.* col.20 ll.47-56. *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1357 (Fed. Cir. 2003) ("[T]he use of the term 'preferably' makes clear that the language describes a preferred embodiment."). It is undisputed that Defendants' construction would exclude TAK-390MR from claim 4 due to the test results in Example 2 regarding percentage of time that gastric pH is greater than 4. However, Takeda conceded at the June 5, 2014 hearing that not all dependent claims must cover TAK-390MR, and has not argued that no other claims of the '158 Patent as properly construed would encompass that embodiment. For example, independent claim 1 lacks claim 4's limitations about the statistical significance of differences between dosing regimens. As *Helmsderfer* explains, a court need not construe dependent claims to include a preferred embodiment when other claims may encompass that embodiment.

The parties' extrinsic evidence is consistent with Defendants' position. Dr. Mayersohn expresses the view that the patent relies on both mean intragastric pH and percentage of time with pH over 4 "to determine the effect of food on intragastric pH," but largely repeats excerpts from the specification. Mayersohn Decl. ¶¶ 56-57. Dr. Sinko opines that "the plain meaning of the term 'intragastric pH' to one skilled in the art is the 'pH of the stomach'" and does not connote percentage of time where pH is above 4. Sinko Decl. ¶ 146. However, Dr. Sinko testified that both parameters are based on the same pH data and are both "measurements of intragastric pH . . . manipulated differently." ECF No. 88-15 (Sinko Depo.) at 162:10-19. This testimony is consistent with the inventors' use of both parameters to assess intragastric pH in Example 2.

Overall, the language of claims 4 and 12 strongly suggests that "intragastric pH" is not the same as "mean intragastric pH." The specification and extrinsic evidence are consistent with Defendants' construction, which does not impermissibly exclude the preferred embodiment of

TAK-390MR from the scope of all claims. Therefore, the Court adopts Defendants' construction as to "intragastric pH."

For the reasons above, the Court construes the term "wherein the changes in pharmacokinetics . . . under fasting or fed conditions does not produce statistically significant changes in intragastric pH" to mean **"wherein the changes in pharmacokinetics . . . when the patient is dosed without regard to food does not produce any statistically significant differences in mean intragastric pH and percentage of time that gastric pH is greater than 4. The term 'statistically significant' means that the P value for the pairwise comparisons is less than 0.05."**

3. "enteric coating releases the proton pump inhibitor from the solid particle at a pH of" "about 5.0 to about 5.5" or "about 6.2 to about 6.8" (claim 1)

Defendants' Proposed Construction[11]	Takeda's Proposed Construction
"enteric coating releases all of the proton pump inhibitor from the solid particle at a pH of [no less than 4.95 to a pH of no more than 5.55]/ [no less than 6.15 to a pH of no more than 6.85]"	"the target pH for dissolution of the enteric coating is approximately 5.0 to approximately 5.5 or approximately 6.2 to approximately 6.8"

The disputed phrase appears in claim 1, which recites in relevant part:

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

'158 Patent cl.1 (emphases added).

The parties identify two disagreements. Defendants argue that "about" means ± 0.05 pH units, while Takeda argues that "about" means "approximately." Defendants also argue that "releases the [PPI]" means releasing *all* of the PPI at a pH of no less than the claimed value. Takeda argues that "releases the [PPI]" means that the enteric coating is designed or intended to dissolve at the specified pH. The Court adopts a modified form of Takeda's construction.

[11] Although Defendants' construction appears to require release "at" a particular pH, it "was intended to cover release 'at or above' a particular pH" and "the phrase 'at a pH of' in Defendants' construction should be read to mean 'at or above a pH of.'" *See* Defs. Br. at 18 n.10.

a. "about 5.0 to about 5.5" and "about 6.2 to about 6.8"

i. Claim Language and Specification

Takeda points to the specification to support its construction of "about" as "approximately." The specification uses the terms "about" and approximately" interchangeably when describing a pH level. *Compare* '158 Patent col.20 ll.49-53 ("One type of granule releases drug in the proximal region of the small intestine when the pH reaches *approximately* 5.0-5.5. The second type of granule releases drug more distally in the intestine when the pH reaches *approximately* 6.2-6.8.") (emphases added), *with id.* col.12 ll.6-9, 23-25 ("The first enteric coating surrounds the core and releases the active agent from the solid particle at a pH of *about* 5.0 to *about* 5.5. . . .The second enteric coating surrounds the core and releases the active agent from the solid particle at a pH of *about* 6.2 to *about* 6.8.") (emphases added); *see also id.* col.21 ll.7-8 (Table 1 listing "pH of release (approximate)" of different coatings).

Takeda also argues that in the context of pharmaceutical patents, if the intrinsic evidence does not support a narrower construction, courts have construed the term "about" to mean "approximately," rather than deriving a specific numerical range for the value that it modifies. *See Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005); *see also Biopolymer Eng'g, Inc. v. Immunocorp.*, Nos. 05-536, 05-2972, 2007 WL 4562592, at *10, *12 (D. Minn. Dec. 21, 2007) ("[w]ithout evidence that would provide a basis to specify the permissible deviation from one percent, the Court gives the term 'about' its ordinary meaning of 'approximately'" and "the Court declines to arbitrarily construe 'about' through use of rounding principles. Instead, the Court gives the term 'about' its ordinary meaning of "'approximately.'"); *Unigene Labs., Inc. v. Apotex Inc.*, No. 06cv5571, 2008 WL 3992294, at *4, *9 (S.D.N.Y. Aug. 28, 2008).

Defendants do not point to any intrinsic evidence from the claims or specification, but instead argue that construing "about" as "approximately" "merely replaces one vague term for another." Defs. Br. at 20, citing *Hynix Semiconductor Inc. v. Toshiba Corp.*, No. C-04-04708 VRW, 2006 WL 2547463, at *14 (N.D. Cal. Sept. 1, 2006) (rejecting proposed construction because it would simply "replace the present term with a more ambiguous one"). The Court does not agree that either "about" or "approximately" would be vague to one of ordinary skill in the art.

Defendants did not present any evidence to this effect, and similar terms of degree are frequently used in patent claims, especially in the pharmaceutical arts. *See* Manual of Patent Examining Procedure § 2173.05(b) (9th ed. Mar. 2014) (discussing "Relative Terminology," including "about"). It is for the factfinder to decide whether a specific pH value is "approximately" 5.0 to 5.5 or 6.2 to 6.8. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.").

Accordingly, because the specification does not suggest any specific numerical range and uses "about" and "approximately" interchangeably, the Court determines that Defendants' restrictive numerical range is not supported by the intrinsic evidence.

ii. Extrinsic Evidence

Defendants argue that one of ordinary skill in the art would understand that "about" means ± 0.05 based on the United States Pharmacopeia (the "USP"), which is "a book of public pharmacopeial standards." Mayersohn Decl. ¶ 50. Essentially, the USP is a widely referenced encyclopedia on drug formulation. The USP refers to dissolution pHs and describes pH measures within 0.05 units. Dr. Mayersohn thus concludes that "the USP recognizes that the pH for release of an active agent from a dosage form should be measured to an accuracy of ± 0.05, and persons of ordinary skill in the art would have agreed with this accuracy level as well." *Id.* ¶ 50.

The USP does not link its numerical range of ± 0.05 to "about" or use any words of qualification to describe its range, and therefore sheds little light on how one of ordinary skill in the art would interpret the claims. Instead, the USP teaches one of ordinary skill in the art how to test whether a drug formulation releases an active ingredient at a particular pH: create a solution with a pH within ± 0.05 of the target pH. If one of ordinary skill in the art would consider a pH of ± 0.05 accurate enough to test a drug formulation, the USP would actually seem to support a construction of "*about* 5.0 ± 0.05." Moreover, while the '158 Patent cites the USP, Defendants provide no basis for concluding that the inventors intended to incorporate the USP's pH testing standards into the claims. As a result, the Court finds that this extrinsic evidence is "less significant than the

intrinsic record" and "less reliable than the patent and its prosecution history in determining how to read claim terms." *Phillips*, 415 F.3d at 1317-18 (internal quotation marks and citations omitted). Accordingly, the Court construes "about" to mean "approximately."

b. "enteric coating releases the proton pump inhibitor from the solid particle at a pH of"

Defendants argue that this phrase requires that the "enteric coating releases *all* of the [PPI]" at or above a certain pH. Joint Statement Ex. 1 at 8 (emphasis added). Takeda argues that the phrase merely describes the "target pH for dissolution of the enteric coating." *Id*. While Takeda's construction accurately describes the invention as it would have been understood by one of ordinary skill in the art, the phrase "target pH" is not found in the specification. Defendants' construction, on the other hand, would essentially render the claims inoperable because it requires that all of the drug be released within a very specific pH window, and fails to account for inherent variance in the pharmaceutical arts.

One aspect of the '158 Patent's claimed invention is a method of treating a patient using a dosage form that releases a PPI at two locations: first in the proximal region of the small intestine where the pH is about 5.0 to about 5.5, and later in the distal region of the small intestine where the pH is about 6.2 to about 6.8. *See* '158 Patent col.20 ll.49-56 (Example 1), col.20 ll.1-7, col.11 l.64-col.12 l.10. The enteric coatings are responsible for regulating the release of the PPI and preventing release at undesirable pH levels. *Id.* col.12 ll.22-27.

To accomplish this, the '158 Patent discloses various enteric coatings with known dissolution pHs. *See id.* col.12 ll.9-17 (enteric polymers that dissolve at a pH of about 5.0 to about 5.5), col.12 l.36-col.13 l.2 (enteric polymers that dissolve at a pH of about 6.2 to about 6.8). For example, the specification discloses that Eudragit L 30 D-55, Eudragit L 100-55 (also known as Eudragit 100-55), HP-50, and HP-55 will release drug at a pH of about 5.0 to about 5.5. *See id.* col.12 ll.6-16. Similarly, the specification lists Eudragit L-100 and Eudragit S-100 as polymers that, "in a ratio of 4:1 to 1:4," will dissolve at a pH of about 6.2 to about 6.8. *See id.* col.12 ll.33-41. Takeda presents extensive evidence that the dissolution pH levels of the disclosed enteric polymers were well known and well characterized at the time of the '158 Patent's application, and

Defendants do not argue or present any evidence to the contrary. *See* Sinko Decl. ¶¶ 106-09 (citing industry documents and scientific papers).

Defendants criticize Takeda's construction for several reasons. First, Defendants argue that Takeda's "target pH for dissolution" language is not found in the specification, and therefore cannot be correct. Defendants essentially argue that the construction must include the word "release." Defs. Br. at 18. However, the specification links the concepts of "dissolution" and drug "release." For example, the patent describes pulsed release forms:

> Particle or granule systems have also been proposed for purposes of providing a *pulsed release* of drug. Systems for the pulsed release of a drug typically use distinct populations of drug containing particles to achieve a pulsed release. The populations employ different *coating polymers*, such as those mentioned above, to *release* the drug at different points in time or location. For example, *polymers having different dissolution pHs are commonly used for this purpose*. Hence, one population of granules can be coated with a polymer that begins *dissolving* at a pH of 6 and another population of granules can be coated with a polymer that begins *dissolving* at a pH of 6.5 to achieve a pulsed *release*. In this manner, the first population of granules would *release* the drug in the upper small intestine while the second population of the granules would *release* the drug further down stream and therefore at a later time.

'158 Patent col.19 l.63-col.20 l.12 (emphases added). Reading the claims in light of the specification, one of ordinary skill in the art would recognize that dissolving the enteric coating surrounding the PPI would cause release of the PPI as claimed. Thus, Defendants' argument that "Takeda's proposed construction reads the 'release' requirement entirely out of the claims," Defs. Br. at 18, is without merit. However, the Court agrees with Defendants that "releases" is the language of the claims and therefore uses that term in the Court's construction.

Defendants next argue that Takeda's construction "only looks to see what the enteric coat is made of." *Id.* This argument misreads Takeda's construction. Takeda's construction does not read "target pH for dissolution of the enteric coating *material*," it reads "target pH for dissolution of the enteric coating." To fit within the scope of the claims, the enteric coating as a whole (not just the material) must have the specified target pH for dissolution. Thus, a dosage form made with a coating of Eudragit L 30 D-55, which material is known to dissolve at about pH 5.5, would not fall within in the claims if the coating was applied in such a manner that it would be expected to dissolve at a pH of about 4.0.

Along a similar line, Defendants argue that Takeda's construction removes limits from the claim because an enteric coating can be manipulated to release outside the target pH of the material. Both experts agree that enteric coats may release at variable pHs due to "thickness and uniformity of the enteric coating, the nature of other excipients in the enteric coat, and the testing conditions." Takeda Br. at 18; Mayersohn Decl. ¶ 45 (explaining that "the release of PPIs is affected by many more factors in addition to the pH, such as thickness and uniformity of the enteric coating, the nature of other excipients in the enteric coat, and the testing conditions."); *see also* Sinko Decl. ¶ 110. As discussed above, because the claim term is construed to require that the enteric coating, not just the material used, is designed to dissolve at a specific pH, Defendants' concern is obviated.

The parties also dispute whether the patent contemplates any release of the PPI outside of the target pH, such as in the stomach, which has a much lower pH than the intestine. *See* '158 Patent col.9 ll.41-52. Defendants' construction requires the release of *all* of the PPI contained within the enteric coating after the claimed threshold pH is reached, as modified by the word "about." Thus, under Defendants' proposed construction, the PPI must not begin to release below the recited threshold pH values. Defendants argue that this is necessary because "[w]ithout such a requirement, the bottom-end pH values recited in the claims become entirely meaningless." Defs. Br. at 19.

Defendants' construction—that *all* of the PPI be released at or above a specific pH—is simply not practicable, and one of ordinary skill would recognize this fact. Mayersohn Decl. at ¶ 45, 47; Sinko Decl. at ¶¶ 111-13 ("the target pH is not an on/off switch . . . It is well known in the field of biopharmaceutics that '[t]here is not in fact a precise pH threshold above which a material is soluble, rather a range of about one pH unit over which a polymer coating varies from being virtually impermeable to being quite readily soluble and quick to rupture.'" (citation omitted)); *id.* at ¶ 121 ("[I]n my opinion, the person of ordinary skill reviewing the specification of the '158 patent, who would be aware of the inherent variability in release of enteric coatings described above, would have understood that the pH ranges disclosed in the specification, as well as claim 1, were intended to relate to the target pHs for the initiation of dissolution of the enteric polymers

described in column 12, and not to the *in vitro* or *in vivo* pH levels at which enteric coatings manufactured from those polymers would begin to show some measurable release of drug."). As Dr. Sinko points out, even using the specific enteric polymers disclosed in the patent as "releasing" at pH 5.0, "an enteric coating made of HP-50 likely will exhibit some dissolution below pH 5.0, its target pH for dissolution." *Id.* at ¶ 113. Defendants' construction would unduly narrow the claims so as to exclude the standard polymeric coatings that the specification expressly states are suitable for making the claimed formulations. As noted above, a construction that excludes the patent's exemplary embodiments is "rarely, if ever, correct." *Adams Respiratory*, 616 F.3d at 1290.

Moreover, adjusting Defendants' construction to account for this reality, by deleting the word "all," would simply copy the claim language into the construction, and would not provide additional clarification. While Takeda's construction does allow for some drug release below the target pH, it does not read limitations out of the claims. If the enteric coating is not designed to dissolve at or about the specific pH levels, then it does not meet the claims. Although the Court agrees with Takeda's position, the Court believes that "designed to release" has more support in the intrinsic evidence and is more precise than "target pH for dissolution." Indeed, Takeda's expert Dr. Sinko uses these phrases interchangeably. *See, e.g.*, Sinko Decl. ¶¶ 50 ("These and other typical enteric coating materials are designed to dissolve (and hence release drug) . . . ."); 75 ("One type of enteric coated granule is designed so as to release drug . . . .").

Accordingly, the Court construes the term "enteric coating releases the proton pump inhibitor from the solid particle at a pH of" "about 5.0 to about 5.5" or "about 6.2 to about 6.8" to mean **"enteric coating is designed to release the proton pump inhibitor from the solid particle at a pH of" "approximately 5.0 to approximately 5.5" or "approximately 6.2 to approximately 6.8."**

4. "enteric coating has a pH of" "about 5.5" or "about 6.75" (claims 2 and 3)

Defendants' Proposed Construction	Takeda's Proposed Construction
"enteric coating has a pH of [no less than 5.45 to no more than 5.55]/[no less than 6.70 to no more than 6.80]"	"the target pH for dissolution of the enteric coating is approximately 5.5 or approximately 6.75"

These disputed terms appear in dependent claims 2 and 3, which recite:

> 2. The method of claim 1, wherein the first enteric coating has a pH of about 5.5.
> 3. The method of claim 1, wherein the first enteric coating has a pH of about 6.75.

'158 Patent cls. 2, 3. The dispute over how to construe "about 5.5" and "about 6.75" is resolved above. The parties also dispute the construction of the phrase "enteric coating has a pH of." Defendants argue that this means the material of the coating has a specific pH, while Takeda argues that claims 2 and 3 simply restate the phrase "enteric coating releases the [PPI]." Defendants rely on claim differentiation and a plain meaning argument in support of their construction. However, when the claims are read in light of the specification, as required by *Phillips*, a modified version of Takeda's construction prevails.

Defendants correctly point out that while claim 1 requires that the enteric coating "releases the [PPI]" at a specific pH, claims 2 and 3 state that the enteric coating "has a pH." Thus, Defendants argue that Takeda's construction violates "the presumption that each claim in a patent has a different scope." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (internal citations omitted). However, this "presumption" does not apply when the specification dictates otherwise. *See CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000); *Kraft Foods v. Int'l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000).

Defendants are also correct that reading the phrase "has a pH of" outside of the context of the '158 Patent would usually be understood as claiming the pH of the material itself. Mayersohn Decl. ¶ 51. However, Defendants recognize that "the requirement that a solid compound, such as an enteric coating, 'have' a pH, is nonsensical." *Id.* Therefore, Defendants propose to measure the pH of the coating by dissolving it in water. *Id.* at ¶¶ 51-52.

Fortunately, the Court does not need to adopt a nonsensical construction of this phrase because the specification shows that the inventors used the phrase "has a pH of" to mean the same thing as "release at a pH of." In the Summary of Invention, the inventors first describe the method of claim 1 (delivering a drug with two release rates), and then refer to the first and second coatings as follows:

> Preferably, the first enteric coating *has* a pH of about 5.5 and comprises a methacrylic acid copolymer dispersion. Preferably, the second enteric coating *has* a pH of about 6.75 and comprises a mixture of a methacrylic copolymer Type B and a methacrylic copolymer Type A in a ratio of 3:1.

'158 Patent col.2 ll.63-67 (emphases added). The only other time the inventors use the phrase "has a pH of" is in claims 2 and 3. Moreover, the inventors never describe an embodiment that defines the pH of the enteric coating; the inventors only disclose coatings that dissolve at specific pH levels. Thus, the specification provides sufficient grounds for construing an otherwise nonsensical term. *See, e.g.*, *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1276-77 (Fed. Cir. 2011) (construing "solid solution" to avoid "a nonsensical result").

Accordingly, because the claims are interpreted in light of the specification, *Phillips*, 415 F.3d at 1313, the Court construes "enteric coating has a pH of" "about 5.5" or "about 6.75" to mean **"enteric coating is designed to release at a pH of" "approximately 5.5" or "approximately 6.75."**

IV. CONCLUSION

In summary, and for the reasons stated herein, the Court construes the parties' disputed terms as follows:

Patent	Disputed Term	Court's Construction
8,461,187	"wherein the first and second doses are released from the dosage form as discreet pulses of the PPI separated by a period of time"	"wherein release of the second dose of PPI from the dosage form begins a period of time after release of the first dose begins"
	"the second dose begins to be released between 2 and 20 hours after the first dose begins to be released"	"release of the second dose begins between 2 hours and 20 hours after release of the first dose begins"
8,173,158	"regardless of whether the patient is under fasted or fed conditions"	"without regard to food"
	"wherein the changes in pharmacokinetics . . . under fasting or fed conditions does not produce statistically significant changes in intragastric pH"	"wherein the changes in pharmacokinetics . . . when the patient is dosed without regard to food does not produce any statistically significant differences in mean intragastric pH and percentage of time that gastric pH is greater than 4. The term 'statistically significant' means that the P value for the pairwise comparisons is less than 0.05."
	"enteric coating releases the proton pump inhibitor from the solid particle at a pH of" "about 5.0 to about 5.5" or "about 6.2 to about 6.8"	"enteric coating is designed to release the proton pump inhibitor from the solid particle at a pH of" "approximately 5.0 to approximately 5.5" or "approximately 6.2 to approximately 6.8."
	"enteric coating has a pH of" "about 5.5" or "about 6.75"	"enteric coating is designed to release at a pH of" "approximately 5.5" or "approximately 6.75."

IT IS SO ORDERED.

Dated: June 6, 2014

Lucy H. Koh

LUCY H. KOH
United States District Judge