NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, and WARNER CHILCOTT (US), LLC, *Plaintiffs,* v. AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC *Defendants.*	Civil Action No. 11-5989 (FSH)(JBC)
WARNER CHILCOTT COMPANY, LLC, and WARNER CHILCOTT (US), LLC, *Plaintiffs,* v. TEVA PHARMACEUTICALS USA, INC., *Defendant.*	Civil Action No. 11-6936 (FSH)(JBC)
WARNER CHILCOTT COMPANY, LLC, and WARNER CHILCOTT (US), LLC, *Plaintiffs,* v. RANBAXY, INC., and RANBAXY LABORATORIES LIMITED, *Defendants.*	Civil Action No. 12-2474 (FSH)(JBC)
WARNER CHILCOTT COMPANY, LLC, and WARNER CHILCOTT (US), LLC, *Plaintiffs,* v. IMPAX LABORATORIES, INC., *Defendant.*	Civil Action No. 13-6403 (FSH)(JBC) **OPINION** Date: April 9, 2014

HOCHBERG, District Judge:

This matter comes before the Court on requests for claim construction by Amneal Pharmaceuticals, LLC, and Amneal Pharmaceuticals of New York, LLC,[1] ("Amneal"), Teva Pharmaceuticals USA, Inc., ("Teva"), Ranbaxy Inc., ("Ranbaxy"), and Impax Laboratories, Inc., ("Impax"), (collectively "Defendants"), and Warner Chilcott Co., LLC, and Warner Chilcott Co. US, LLC, (collectively "Plaintiffs" or "Warner Chilcott"). The parties have amended their Joint Claim Construction and Prehearing Statement pursuant to this Court's Order requiring a chart reflecting the importance of each disputed term and the impact on the case. Using that process, the parties reached agreement on all but four claim terms. After the parties stipulated to infringement and the relevance of the claim term "pharmaceutically effective absorption," the number of disputed claim terms was further voluntarily reduced to two terms. On January 15, 2014, the Court held a *Markman* hearing on claim construction.

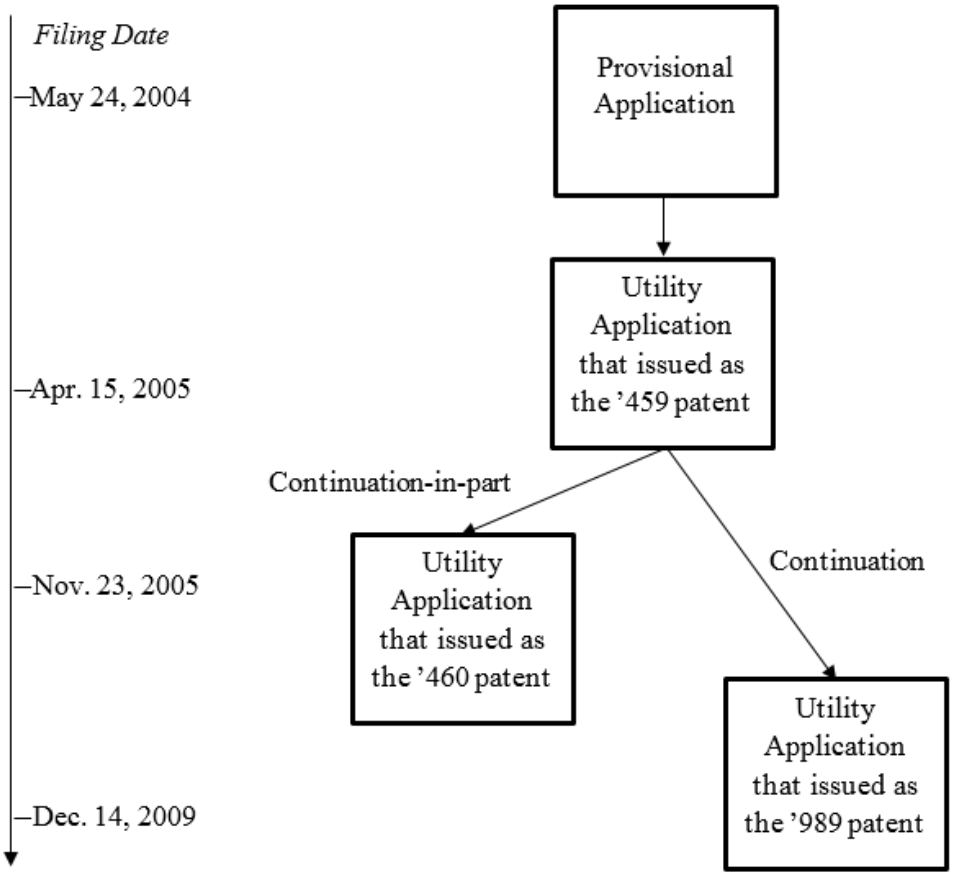
I. BACKGROUND

These cases allege patent infringement under the Federal Food, Drug, and Cosmetics Act ("FFDCA"), and, more specifically, the Hatch-Waxman Amendments to that law. Warner Chilcott is the owner, by assignment from The Proctor & Gamble Co., of U.S. Patent No. 7,645,459 (the "'459 patent"), U.S. Patent No. 7,645,460 (the "'460 patent"), and U.S. Patent No. 8,246,989 (the "'989 patent").[2] All three patents share a provisional application filed on May 24,

[1] Watson Laboratories Inc. – Florida ("Watson") was originally a Defendant in this action. After Amneal purchased its ANDA from Watson, the Court ordered a substitution of parties on November 6, 2013. In this opinion, "Amneal" will be used to refer to both the current Defendant and its predecessor-in-interest.

[2] The '459 patent, entitled "Dosage Forms of Bisphosphonates," and the '460 patent, entitled "Dosage Forms of Risedronate," issued on January 12, 2010. The '989 patent, also entitled

2004. The utility application that issued as the '459 patent was filed on April 15, 2005. The utility application that issued as the '460 patent was filed on November 23, 2005 and is a continuation-in-part of the application that issued as the '459 patent. The application that issued as the '989 patent was filed on December 14, 2009 and is a continuation of the application that issued as the '459 patent. Each of the patents relates to a delayed release formulation of an osteoporosis medication. Plaintiffs hold an approved New Drug Application ("NDA"), No. 22-560, under § 505(a) of the FFDCA, 21 U.S.C. § 355(a), for a 35 mg delayed release risedronate tablet formulation marketed as ATELVIA®. These tablets were approved by the FDA on October 8, 2010, and are marketed for the treatment of osteoporosis and Paget's disease.



"Dosage Forms of Bisphosphonates," issued on August 21, 2012. The patentee disclaimed the terminal part of the '460 and '989 patents beyond the expiration of the '459 patent.

As required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), each Defendant provided Plaintiff Warner Chilcott with a "paragraph IV certification," notifying Plaintiffs that they had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture and market generic delayed release formulations of ATELVIA® before the expiration of the '460 and '459 patents.[3]

Warner Chilcott (and before it Proctor & Gamble) had been developing the use of bisphosphonates, a class of compounds used to combat osteoporosis. Bisphosphonates tend to inhibit bone resorption, thus promoting bone growth. Plaintiffs filed a patent, which is not at issue in this case, covering a species of bisphosphonate, called risedronate. It marketed risedronate as ACTONEL®, which is the predecessor drug to the delayed release formulation at issue here, ATELVIA®. One drawback of bisphosphonate formulations, including the predecessor drug ACTONEL®, is that the active ingredient binds to charged ions commonly found in food, forming insoluble complexes. These complexes render the active ingredient ineffective because it is unable to interact with the site of the drug's action. This phenomenon, called the "food effect," causes the amount of risedronate active ingredient available for absorption to be negligible in the presence of food. Consequently, patients using the predecessor drug ACTONEL® must take the medication without food, waiting at least thirty minutes after administration before eating.

[3] Amneal gave Plaintiffs notice of its ANDA, No 20-3090, on August 29, 2011; Teva gave Plaintiffs notice of its ANDA, No. 20-3217, on October 13, 2011; Ranbaxy gave Plaintiffs notice of its ANDA, No. 203925, on March 22, 2012; and Impax gave Plaintiffs notice of its ANDA, No. 205066, on September 10, 2013. Warner Chilcott brought these patent infringement actions against each Defendant within the forty-five day statutory period, filing a Complaint against Amneal on October 12, 2011, against Teva on November 22, 2011, against Ranbaxy on April 26, 2012, and against Impax on October 23, 2013. The actions against Teva, Ranbaxy and Amneal have been consolidated for pretrial purposes. (Docket No. 32). The action against Impax has not been consolidated, however, Impax participated in claim construction.

To combat this "food effect," Proctor & Gamble began using a chelating agent, ethylene diamine tetraacetic acid ("EDTA"), which binds to the ions in food and prevents those ions from complexing with risedronate. This enables the active ingredient to be absorbed into the bloodstream. Depending on the formulation, the combination of EDTA and active ingredient risedronate is released, using a delayed release mechanism, in the lower gastrointestinal tract or specifically the small intestine. Plaintiffs state that this composition addresses the "food effect" and permits the absorption of active ingredient to be roughly similar regardless of whether the patient has fasted or eaten before taking the drug.

II. STANDARD OF REVIEW

In a patent infringement analysis, the first step is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The construction of patent claims is a matter of law reserved exclusively for the court. *Markman*, 52 F.3d at 977-79. There are two categories of evidence available to the Court when construing patent claims: (i) intrinsic evidence; and (ii) extrinsic evidence, such as expert testimony.[4] "When construing a claim, a court principally consults the evidence intrinsic to the patent, including the claims, the written description, and any relevant prosecution history." *Mantech Envtl. Corp. v. Hudson Envtl. Servs.*, 152 F.3d 1368, 1371 (Fed. Cir. 1998); *see also Markman*, 52 F.3d at 979 ("To ascertain the meaning of claims, we consider three sources: The claims, the specifications, and the prosecution history.").

[4] The use of extrinsic evidence is limited in purpose and scope.

The court's analysis must begin with the language of the claims themselves, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2). Claims are "examined through the viewing glass of a person skilled in the art" as of the effective date of the patent, and claim terms are deemed to be read "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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*). When a patentee specifically defines a claim term in the specification, it is that definition that controls. *Id.* at 1316. When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

To determine how a person of skill in the art would understand a patent's claim language, a court must first examine the intrinsic record, *i.e.*, the patent itself, including the claims, the specification and the prosecution history. *Id*. (citing *Markman*, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics*, 90 F.3d at 1582. The Federal Circuit has explained that the specification is "usually . . . dispositive . . . [and is the] best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582) (internal quotations omitted). Therefore, a court should "rely heavily on the written description for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317.

A patent's prosecution history is another useful source of guidance, as it "provides evidence of how the PTO and the inventor understood the patent." *Id.* The prosecution history is

the complete record of the proceedings before the USPTO, and "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.* Courts consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was either disclaimed or disavowed during prosecution).

If the ambiguities of a disputed claim term have not been resolved after analysis of the intrinsic evidence, a court may also consider extrinsic evidence. *Vitronics*, 90 F.3d at 1582-83. While a court may rely on extrinsic evidence to construe a claim, "what matters is for the court to attach the appropriate weight to be assigned to those sources." *Phillips*, 415 F.3d at 1324. Extrinsic evidence ordinarily should not contradict intrinsic evidence. *Id.* at 1322-23.

III. DISCUSSION

a. Claim Construction Regarding U.S. Patent No. 8,246,989

Claim 1 states:

An **oral dosage form** comprising:
(a) about 35 mg of a risedronate salt;
(b) about 100 mg of EDTA or a pharmaceutically acceptable salt thereof; and
(c) a delayed release mechanism to deliver the risedronate salt and EDTA or pharmaceutically acceptable salt thereof to the lower GI tract.

"oral dosage form"[5]

Defendants argue that the term "oral dosage form" should include the limitation "pharmaceutically effective absorption."[6] They contend that an "essential element" of the invention disclosed in the related '459, '460, and '989 patents is that absorption of the active ingredient risedronate is about the same whether the patient has eaten or fasted, thus having "pharmaceutically effective absorption." Both the '459 and the '460 patents reference the fed:fasted ratio in the claim terms, whereas the '989 patent, construed herein, does not. Defendants argue that the fed:fasted ratio should be included as a limitation in the '989 patent: (1) based on an alleged prosecution disclaimer made during prosecution of the related '459 patent;[7] and (2) because the claim language should be construed to impose "an essential element of an invention [that] is literally missing from a patent claim" if it "can reasonably be construed to impose that limitation." (Defs.' Opening Br. in Supp. of Proposed Claim Constructions 22, Docket No. 106-2 (internal quotation marks omitted)).

[5] This disputed term in claim 1 of the '989 patent also appears in asserted dependent claims 8, 9, 12, and 14 of the '989 patent.

[6] In their revised claim construction chart, Defendants proposed the following definition of "oral dosage form:" "a pharmaceutical composition containing a safe and effective amount of a chelating agent that exhibits fed exposure of risedronate within about 50% of fasting exposure." At the claim construction hearing, however, the parties agreed that Defendants' construction of "oral dosage form" would in effect read in the term "pharmaceutically effective absorption" from the '459 patent into the '989 patent. "[T]he only issue before your Honor would be, whatever 'pharmaceutically effective absorption' means, is it in or out of the '989 patent? Because 'pharmaceutically effective absorption' itself, the term language we would agree." (*Markman* Tr. 40:8-12).

[7] There appear to be two steps of alleged disclaimers. Defendants first assert that the fed:fasted ratio is a disclaimer that attached to "pharmaceutically effective absorption." Next, Defendants contend that "pharmaceutically effective absorption" attaches to "oral dosage form" in the '989 patent. Thus, they argue that "oral dosage form" contains the fed:fasted limitation.

(1) Prosecution Disclaimer in Related Patent

The general rule of claim construction is that the "ordinary meaning" of a claim term controls, with two relevant exceptions: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Uship Intellectual Props. v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013).

The term "oral dosage form" in the '989 patent would ordinarily mean exactly what it says – a dose of medication taken by mouth. No party contests this ordinary meaning. (*Markman* Tr. 61:9-24). But here, both sides argue that the term falls under one of the exceptions requiring departure from the ordinary meaning. Defendants argue that the Court should apply the second exception, prosecution disclaimer, asserting that an alleged disclaimer in the application that issued as the '459 patent should be carried forward to the '989 patent because the patents are related. Thus, they argue, an amendment to the '459 patent – adding the term "pharmaceutically effective absorption" to overcome the examiner's obviousness objection – should carry forward to the '989 patent as "an essential element of their alleged invention, and not as an optional or preferred feature." (Defs.' Opening Br. 23). On the other hand, Plaintiffs argue that the Court should apply the first exception, where the patentee acted as his own lexicographer, asserting that the Court should construe "oral dosage form" as defined in the specification: "any pharmaceutical composition intended to be administered to the lower gastrointestinal tract of a human or other mammal via the mouth of said human or other mammal." '989 patent, col. 5, ll. 4-7.

The Court recognizes that the doctrine of prosecution disclaimer may, in appropriate

cases, allow a disclaimer attached to an earlier patent to be carried forward and bar the recapture of claim scope in a continuation application. But the doctrine is inapplicable here. The alleged disclaimer in the prosecution history of the '459 patent does not carry forward to the term "oral dosage form" in the '989 patent because the language and scope of the claim terms are different. The '459 patent claims a family of recipes for a dose of medicine with a particular effect – "pharmaceutically effective absorption." In contrast, the '989 patent's relevant claims have more narrow scope, claiming one single recipe with specific quantities of ingredients. Because the claim language in the '459 patent is not the same as the claim language in the '989 patent, the Court declines to carry forward the alleged disclaimer and instead construes "oral dosage form" consistent with the definition contained in the specification.

"[A]n applicant can broaden as well as restrict his claims during the procedures of patent examination, and . . . continuing applications may present broader claims than were allowed in the parent." *Hakim v. Cannon Avent Grp.*, 479 F.3d 1313, 1317 (Fed. Cir. 2007). But "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." *Elkay Mfg. v. Ebco Mfg.*, 192 F.3d 973, 980 (Fed. Cir. 1999). In order to carry forward a disclaimer in an earlier related application to a continuation application, the claim limitation must be the same. *See Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 943 (Fed. Cir. 2013) ("In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor."). The "requirement that the patents share 'limitations in common' is not a mere technicality." *Id*. Instead, a common limitation is "necessary to support the inference that the patentee's earlier arguments are also applicable to the claim limitations of the patent-in-suit." *Id.*

at 944; *see also Augustine Med., Inc. v. Gaymar Indus.*, 181 F.3d 1291, 1300 (Fed. Cir. 1999) ("the prosecution history of a parent application may limit the scope of a later application using the same claim term"); *Ventana Med. Sys. v. Biogenex Labs.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language."); *Saunders Grp. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007) ("When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply."); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322 (Fed. Cir. 1999) ("this court [earlier] construed claim 8 of the '532 [parent] patent, not the claims of the '345 [child] patent. These claims have different language and different meanings."). "The sole exception is when the disclaimer is directed to the scope of the invention as a whole, not a particular claim." *Regents of Univ. of Minn.*, 717 F.3d at 943 n.8. This exception is inapplicable, however, if the purported disclaimer used "particular language from the claims" rather than describing the "present invention" or "overall method." *Id.* (quoting *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314-15 (Fed Cir. 2007)) (internal alterations omitted).

The application that issued as the '989 patent was filed as a continuation of the application that issued as the '459 patent. Thus, at issue here is whether the scope of the limitation in claim 1 of the '989 patent is substantially the same as claim 1 of the '459 patent, to which an alleged disclaimer applies. *Regents of Univ. of Minn.*, 717 F.3d at 944 ("The proper inquiry is whether the scope of the claim limitation is substantially the same in the subsequent application as it was in the earlier application.").

Comparing the claim limitations of the two patents, claim 1 of the parent application ('459 patent) stated:

> An *oral dosage* form of a bisphosphonate comprising a *safe and effective amount of a pharmaceutical composition* comprising: (a) a bisphosphonate; (b) from about 10 mg to about 1000 mg of a chelating agent; and (c) a delayed release mechanism to deliver the bisphosphonate and the chelating agent in the lower gastrointestinal tract.
>
> (Defs.' Opening Br. Ex. D, Docket No. 106-6, at 3 (emphasis added)).[8]

After the examiner rejected this claim as obvious, the patentee added additional language to the claim: "[c]laim 1 has been amended to recite oral dosage forms having pharmaceutically effective absorption. . . oral dosage forms having pharmaceutically effective absorption exhibit fed exposure within about 50% of fasting exposure." (Defs.' Opening Br. Ex. D, Docket No. 106-6, at 184). Amended claim 1 thus read:

> An *oral dosage* form having *pharmaceutically effective absorption* comprising: (a) from about 1 mg to about 500 mg of a bisphosphonate which is selected from the group consisting of risedronate and acids, salts, esters, hydrates, polymorphs, hemihydrates, solvates, and derivatives thereof; (b) from about 10 mg to about 500 mg of a chelating agent; and (c) a delayed release mechanism to deliver the bisphosphonate and the chelating agent in the lower gastrointestinal tract.
>
> (Defs.' Opening Br. Ex. D, Docket No. 106-6, at 178 (emphasis added)).

"Pharmaceutically effective absorption" is defined in the specification as:

> an amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state. That is, absorption is similar with or without food. Given the high variability of bisphosphonate absorption, fed exposure within about 50% of fasting exposure is expected to be pharmaceutically effective absorption.
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> '459 patent, col. 4, ll. 59-67.

In describing this amendment, the patentee explained that earlier references taught that combinations of active ingredient and chelating agent would result in "vastly different"

[8] Unless otherwise noted, all references to docket entries refer to the 11-5989 docket.

absorption based on whether the patient had fasted or fed. By contrast, "[t]he inventors have discovered oral bisphosphonate compositions that have minimized the food effect, while maintaining pharmaceutically acceptable absorption, regardless of whether the patient is in a fasted state, the current per label state, . . . or the fed state." (Defs.' Opening Br. Ex. D, Docket No. 106-6, at 191).

> Turning to the '989 patent, at issue here, claim 1 states:
>
> An *oral dosage form* comprising: (a) about 35 mg of a risedronate salt; (b) about 100 mg of EDTA or a pharmaceutically acceptable salt thereof; and (c) a delayed release mechanism to deliver the risedronate salt and EDTA or pharmaceutically acceptable salt thereof to the lower GI tract.
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> '989 patent, col. 38, ll. 1-8 (emphasis added).

Unlike the '459 patent, the '989 patent omits any mention of either "pharmaceutically effective absorption" or the language of the '459 patent before amendment, "safe and effective amount." Moreover, the '459 patent claimed a wide range of compositions of bisphosphonate and EDTA (in a certain proportionate amount of ingredients necessary to meet the correct fed:fasted ratio), whereas the '989 patent claims only one composition, with a fixed amount of risedronate and a fixed amount of EDTA.

Plaintiffs contend this case is analogous to *Ventana Med. Sys., Inc. v. Biogenex Labs.*, Inc., 473 F.3d 1173, 1183 (Fed. Cir. 2006), which found that a disclaimer attached to a parent application did not carry forward to a child application because the child omitted the claim term. There, a parent application covered a method of dispensing reagent onto microscope slides and contained the claim language "dispensing a selected reagent *directly* to a sample." *Id.* at 1178 (emphasis added). But in construing the child application, the district court found that the terms "dispensing reagents onto a slide" required *directly* dispensing the reagents – *i.e.* dispensing

without an intermediate device – because the patentee had disclaimed the use of an intermediate device in prosecuting the parent application. *Id.* at 1178. The Federal Circuit reversed, finding that the disclaimer in the parent application did not attach to the child because the child omitted the modifier "directly" from the phrase "dispensing reagents onto a slide." *Ventana*, 473 F.3d at 1180. "Because claims 1 and 5 of the [child] patent use different claim language—that is, they do not require that reagent be 'dispensable directly to a sample'—the alleged disclaimer . . . during the prosecution of the [parent] application does not apply to the asserted claims of the [child] patent." *Id.* at 1182.

Similarly, the Federal Circuit did not carry forward a disclaimer in a related patent where the patentee described the invention in different terms and omitted the term with the disclaimer attached. *Regents of Univ. of Minn. v. AGA Med. Corp*., 717 F.3d 929, 945 (Fed. Cir. 2013). The Circuit held that, "our cases establish that the two patents must have the same or closely related claim limitation language. If the language of the later limitation is significantly different, the disclaimer will not apply." *Id.* at 943. Because the patentee in that case claimed the subject matter using different terms in the later related patent, and omitted the language with the disclaimer attached, the disclaimer did not carry forward to the related patent. Thus, "it is permissible for a patentee to take a different approach to claiming an invention in subsequent patents, either by adding limitations or by altering the claims' format. When the patentee does so, however, we cannot rely on the dubious argument that dissimilar claims present equivalent issues of validity, or that the applicant's disclaimer with respect to one claim would be equally applicable to another claim." *Id.* at 944-45.

Here, in the earlier parent application that issued as the '459 patent, the patentee modified "safe and effective amount of a pharmaceutical composition" to "pharmaceutically effective

absorption" to achieve patentability. The amendment added a term that refers to an ideal proportion of compounds – "an amount . . . high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate" – not a fixed amount. Thus, the scope of the limitation in the parent application is a broad range of a class of bisphosphonates (between 1 mg and 500 mg) and a broad range of EDTA (between 10 and 500 mg). The amendment modified this broad range with the term "pharmaceutically effective absorption" to encompass only combinations of levels of EDTA and bisphosphonate that exhibit fed absorption in about the same amount as fasted absorption.

In the '989 patent, however, the patentee omitted the term "pharmaceutically effective absorption" or any similar term referencing the efficacy of the pharmaceutical composition, such as "safe and effective amount." Instead of broadly claiming a range of compositions of EDTA and risedronate, the scope of the limitation in the '989 patent is a precise amount of EDTA (100 mg) with a precise amount of risedronate (35 mg).

The subject matter of the claims also differ. The '459 patent describes the invention by claiming a discovered beneficial property: oral dosage forms with pharmaceutically effective absorption that address the food effect. The '989 patent describes the invention by claiming the particular amount of each ingredient in a pharmaceutical composition. In claiming particular amounts in the '989 patent, the patentee used different claim terms to capture different, narrower, claim scope.[9] Because the claim scope is not "substantially the same," the alleged disclaimer that attached to the range of ingredients in claim 1 of the '459 patent should not logically carry

[9] Defendants note that these amounts may not always achieve fed absorption within about 50% of fasted absorption depending on the location of release. (Defs.' Responding Br. 10-11, Docket No. 115).

forward to the fixed proportion of ingredients in an "oral dosage form" of claim 1 of the '989 patent. [10]

Defendants rely on *Hakim v. Cannon Avent Grp.*, 479 F.3d 1313, 1317 (Fed. Cir. 2007), and argue that because the same examiner evaluated both the '459 and the '989 patents, the Court should presume that the "examiner regarded the 'oral dosage forms' of the '989 patent claims as also being limited to those that produce 'pharmaceutically effective absorption.'" (Defs.' Responding Br. 15, Docket No. 115). In *Hakim*, the patentee had filed a parent application covering drinking cups that prevent spills by use of a valve, which the patentee described as a "slit" to overcome prior art. The patentee abandoned the parent application and instead filed a continuation application based on the same specification, but described the valve with broader language, claiming an "opening." *Id.* at 1316. The Circuit did not permit the applicant to "recapture claim scope that was surrendered or disclaimed" by abandoning the parent application, filing a continuation, and merely changing the modifier to which the disclaimer had attached. *Id.* at 1317. The scope of the claim limitation in the parent was substantially the same as in the continuation: the description of the gap in the valve. By contrast, here, the patentee changed more than a modifier, omitting a claim limitation entirely – "pharmaceutically effective absorption" – and using different language to claim more precise scope: a single amount of each ingredient in a single identified formula. Absent common claim language and scope, there is

[10] Nor does the exception noted in *Regents of University of Minnesota* apply, where the purported disclaimer is directed to the "present invention" as a whole, rather than the "particular language from the claims." 717 F.3d at 943 n.8. The patentee's statement was directed to "pharmaceutically effective absorption," a particular term in claims 1 and 8 of the '459 patent. Neither the term to which the alleged disclaimer attached, nor any substantially similar language, appears in the '989 patent. Although *Regents of University of Minnesota* was decided after the parties had briefed claim construction, it was decided well before oral argument in this case. Defendants have not asserted that the exception applies.

insufficient similarity "necessary to support the inference that the patentee's earlier arguments are also applicable to the claim limitations of the patent-in-suit." *Regents of Univ. of Minn.* 717 F.3d at 944.

(2) Essential Element of the Invention

Defendants next rely upon *MBO Laboratories, Inc. v. Becton, Dickinson & Co.* to argue that a claim which literally omits an essential element of an invention should be construed as imposing that limitation if the term is reasonably subject to that construction. 474 F.3d 1323, 1330-31 (Fed. Cir. 2007).

In *MBO*, the three claims at issue related to protective syringe covers that shielded the pointed tip of a needle upon removing the syringe from a patient's flesh. *Id.* One of the three claims contained the word "immediately," which the district court construed as "simultaneously with the needle's withdrawal." Two of the claims did not contain the term "immediately." *Id.* at 1328. Based on the patentee's arguments distinguishing the prior art, the district court also imposed the limitation "immediately" upon the two claims where it did not literally appear. The Federal Circuit stated that, although "[w]e sympathize with the district court's choice, since we agree that [immediately] is an essential element of the invention . . . we cannot endorse a construction analysis that does not identify a textual reference in the actual language of the claim with which to associate a proffered claim construction." *Id.* at 1331-32. Thus, the Circuit reversed a claim construction that imposed this additional limitation because "the district court improperly construed the terms in light of the rule against recapture instead of relying on the terms' ordinary meanings . . . ."[11] *MBO Labs., Inc. v. Becton,*

[11] Similarly, Defendants ask this Court to construe "oral dosage form" in a manner that would purportedly "satisfy the requirement of § 112 that the limitation 'pharmaceutically effective absorption' be present within the language of the claim." (Defs.' Opening Br. 23). But the case

Dickinson & Co., 602 F.3d 1306, 1311 (Fed. Cir. 2010).

Here, Defendants must identify a textual reference in the claim terms in order to import a limitation that is allegedly an essential feature of the invention. Defendants argue that a reasonable reading of the claim term "oral dosage form" includes "pharmaceutically effective absorption," a phrase that refers neither to the mouth nor to a form of the drug. In order to achieve this rather unlikely construction of "oral dosage form," Defendants stack five definitions upon one another to conflate "oral dosage form" and "pharmaceutically effective absorption," to wit: "oral dosage form" is defined as "any pharmaceutical composition intended to be administered to the lower gastrointestinal tract of a human or other mammal via the mouth," '989 patent, col. 5, ll. 4-8; "pharmaceutical composition" is defined as "an oral dosage form comprised of a safe and effective amount of bisphosphonate active ingredient and at least one or more pharmaceutically-acceptable excipients including at least one chelating agent," '989 patent, col. 4, ll. 34-38; then combine these two definitions to say that "oral dosage form" requires a "safe and effective amount of a chelating agent." (Defs.' Opening Br. 26).

The Court admires the creative lawyering that went into this claim-language stacking but declines to adopt it. "Oral dosage form" has the meaning of its definition in the patent specification.

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upon which Defendants rely, *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376-79 (Fed. Cir. 2009), does not require that claims be construed in a manner that meets the written description requirement. Instead, the Court in that case construed the claim consistent with its "ordinary and customary meaning," and then found the claim invalid under § 112. *Id.* at 1374. At this stage, the Court declines make any finding as to whether the claims meet the requirements of § 112.

b. Claim Construction Regarding U.S. Patent No. 7,645,460

Claim 1 states:

> An oral dosage form having pharmaceutically effective absorption comprising:
> (a) from about 1 mg to about 250 mg of a bisphosphonate selected from the group consisting of risedronate and acids, salts, and esters thereof;
> (b) from about 10 mg to about 500 mg of EDTA; and
> (c) a **delayed release mechanism** to immediately release the risedronate and the EDTA in the small intestine, wherein said composition weighs no greater than 1 gram.

"**delayed release mechanism**"[12]

Plaintiffs assert that "mechanism" should be construed broadly to include any mechanism designed to effect release in the lower GI tract. They allege that this would include delivery via a mechanical research device, which was described in the provisional application, but not included in the utility application that issued as the '460 patent. Defendants, on the other hand, contend that "mechanism" should be construed to mean: "one or more excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the lower GI tract."

Plaintiffs agree that an excipient is an "inactive ingredient added to a formulation." (*Markman* Tr. 71:10-11). The patent provides several examples of excipients that are included as part of a pharmaceutical composition to delay release, such as a time-release excipient. '460 patent col. 8, ll. 64-67. By definition, a "pharmaceutical composition" contains inactive ingredients as it is "comprised of a safe and effective amount of a bisphosphonate active

[12] This disputed term in claim 1 of the '460 patent also appears in asserted claim 13 of the '460 patent and asserted claims 8, 9, 12, and 14 of the '989 patent. The term is used similarly in the claims of the '989 patent: "a delayed release mechanism to deliver the risedronate salt and EDTA or pharmaceutically acceptable salt thereof to the lower GI tract."

ingredient and one or more pharmaceutically-acceptable excipients including at least one chelating agent." '460 patent, col. 4, ll. 41-44. Thus, Defendants contend that the delayed release "mechanism" is limited to inactive ingredients in a pharmaceutical composition.

The specification contains a definition for "delayed release":

> The term "delayed release or delayed delivery," as used herein, refers to formulating the pharmaceutical composition comprising risedronate and the chelating agent so that their release will be accomplished at some generally predictable location in the small intestine.
>
> '460 patent, col. 4, ll. 30-34.

The definition requires a "mechanism" that achieves delivery by "formulating the pharmaceutical composition" so that release is delayed. This means that a person practicing the patent adds some ingredient to the risedronate-EDTA combination, which has the effect of delaying release – *i.e.*, the pharmaceutical composition *contains* the delayed release mechanism. Pharmaceutical compositions contain inactive ingredients and active ingredients. The active ingredient here is risedronate; everything else in the pharmaceutical composition, including EDTA and the delayed release mechanism, must be an inactive ingredient – an excipient. Thus, a person of ordinary skill in the art would understand that "delayed release mechanism" means combining the active ingredient with excipients to formulate a pharmaceutical composition that delays release. The plain language of the definition does not include a mechanical device that "contains the formulation." (*Markman* Tr. 71:14).

Plaintiffs argue that "mechanism" includes a mechanical Enterion capsule because Example XIX in the patent contains data derived from the Enterion capsule. The provisional application, filed May 24, 2004, contained a reference to the capsule, but this reference was removed from the utility application. The Court rejects the argument that "mechanism" should be construed to include this device merely because an experiment involving the drug was

designed based on data recorded using the device. It does not persuasively support the argument that a person of ordinary skill in the art would interpret the claim to include the use of a scientific study device known as the Enterion capsule.

Plaintiffs next argue that the doctrine of claim differentiation compels a broader interpretation because the term "mechanism" in the independent claim should be construed more broadly than any of the specific mechanisms described in the dependent claims, such as a pH-triggered delivery system, a bacterial-enzyme delivery system or a time delivery system. "The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not in the independent claim." *SanDisk Corp. v. Kingston Tech. Co*., 695 F.3d 1348, 1361 (Fed. Cir. 2012). Although this doctrine could support a broader reading than any particular described excipient, it does not compel a construction broader than the entire class of excipients. Because the above definition requires delayed delivery by "formulating a pharmaceutical composition," the term "mechanism" is limited to ingredients that may be formulated to create a pharmaceutical composition, *i.e.* excipients in a dosage form. Thus, the Court finds that the term "delayed release mechanism" means "one or more excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the lower GI tract."

IV. CONCLUSION

For the reasons set forth in this opinion, the Court construes the disputed claim terms of the '460 and '989 patent in accordance with the discussion above. An appropriate Order will issue.

s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.