UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. ACTAVIS LABORATORIES FL, INC. et al., Defendants.	Civil Action No. 15-6934 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Impax Laboratories, Inc. ("Impax") and Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (collectively, "Actavis"). In this patent infringement suit involving pharmaceutical patents, the parties seek construction of claims in U.S. Patent No. 8,377,474 ("the '474 patent"). The Court heard oral argument on April 26, 2017.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

This claim construction dispute arises in the context of a Hatch-Waxman case: in short, the Complaint alleges that Actavis seeks to make and sell a generic version of Plaintiff's Rytary® (levodopa/carbidopa) capsules prior to the expiration of the relevant patents. The parties initially briefed the claim construction issues in five related patents at once, and this Court instructed them to start by rebriefing the claim construction issues in only the parent patent, the '474 patent. The parties simultaneously submitted revised briefs limited to the claim construction issues for this patent.

The parties have divided the claim construction issues into four groups.

A. Claim construction issues for Group I

In brief, as to Group I, the parties dispute the meaning of the phrase "distinct component" in three independent claims:

> 1. A controlled release oral solid formulation of levodopa comprising: a. a controlled release component comprising levodopa, a decarboxylase inhibitor and one or more rate controlling excipients, b. a carboxylic acid component comprising a carboxylic acid that is not levodopa or the decarboxylase inhibitor and one or more rate controlling excipients, and c. an immediate release component comprising levodopa and a decarboxylase inhibitor, wherein the carboxylic acid component of (b) is a distinct component and is coated with an enteric polymer; and wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules.
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> 7. A multiparticulate, controlled release oral solid formulation of levodopa comprising: a. a controlled release component comprising levodopa, carbidopa and one or more rate controlling excipients; b. an immediate release component comprising levodopa and carbidopa, and c. a carboxylic acid component comprising a carboxylic acid that is not levodopa or carbidopa and one or more rate controlling excipients, wherein the carboxylic acid component of (c) is a distinct component and is coated with an enteric polymer and wherein the controlled release component (a), the immediate release component (b) and the carboxylic acid component (c) comprise beads or granules.

> 59. A controlled release oral solid formulation of levodopa comprising: a. a controlled release component comprising levodopa and a decarboxylase inhibitor, wherein the component is coated with a rate controlling excipient, b. a carboxylic acid component coated with a rate controlling excipient, and c. an immediate release component comprising levodopa and a decarboxylase inhibitor, wherein the carboxylic acid component of (b) is a distinct component and wherein the carboxylic acid component (b) comprises a carboxylic acid that is not in (a) and (c).

The crux of the dispute is the question of what these claims mean in requiring the carboxylic acid component to be a "distinct component." Impax contends that "distinct component" means "sub-unit of the formulation," adding that "distinct" here means "separated in some way from the other components." (Impax Br. 6.) Actavis contends that this means: "wherein the carboxylic acid component is a bead that contains a carboxylic acid and is coated with an enteric polymer and is physically separate from the controlled and immediate release components." (Actavis Br. 25.)

The dispute turns on the meaning of the word, "distinct." "Distinct" has multiple ordinary meanings. The layers in a layer cake may be described as "distinct" from each other, but one cake that is completely physically unconnected to another cake might be described as "distinct" as well. In order to reduce ambiguity in this discussion, this Court will employ the phrase "freely separable" to express the latter idea, that the two units of interest may be moved independently, separated in space without affecting the integrity or structure of either unit.[1] The

[1] It is difficult to find the perfect phrase to express this concept. Actavis frequently uses the phrase, "physically separate." Neither "physically separate" nor "freely separable" perfectly captures the concept, since particles that are freely separable or physically separate at one point in the manufacturing process might get attached later in the process. The Court notes that, at various points, the '474 patent discloses that the components may be "pressed into a tablet" or "compressed into a tablet." See, e.g., col.5 ll.55-56; col.12 ll.27-28. This Court can see the potential for a quibble that the components of such a tablet are not freely separable after compression, and so qualifies the requirement of being freely separable by recognizing that later

layers in a layer cake, on the other hand, cannot be freely separated without changing the integrity of the cake; the Court will refer to this kind of distinctness as "not intermixed" or "layer cake distinctness."

Actavis contends that, during prosecution, to overcome a rejection, the applicants disclaimed coverage of formulations in which the carboxylic acid component is not freely separable from the controlled release and immediate release components. Impax disagrees, contending that the prosecution history statements identified do not meet the test for finding prosecution history disclaimer.

The Federal Circuit law of prosecution disclaimer is well-settled and straightforward:

> where 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. . .
>
> To balance the importance of public notice and the right of patentees to seek broad patent coverage, we have thus consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope. Rather, we have required the alleged disavowing statements to be both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer. Consequently, for prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324-1326 (Fed. Cir. 2003) (citations omitted).

Actavis points to the following events in the history of the prosecution of the '474 patent. On March 27, 2012, the PTO rejected pending claims 1 and 27 (which ultimately became claims 1 and 7 when the patent issued) as anticipated by US2007/0148238 (the "Nangia" reference).

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manufacturing processes, such as compression into tablet form, might change the free separability of the components.

(IMPAX00265852.) The applicants submitted three rounds of amendments in response to the March 27 office action: on June 11, 2012 (IMPAX00265824-48), a supplemental amendment on Auguist 2, 2012 (IMPAX00312279-97), and a supplemental amendment on September 25, 2012 (IMPAX00312304-33). On December 6, 2012, the PTO issued a notice of allowance. (IMPAX00265788-94.)

Actavis argues that, in order to distinguish Nangia and overcome the rejection, the applicants made unmistakable disclaimers of claim scope. Actavis first points to these statements in the June 11, 2012 amendment:

> Nangia describes a pharmaceutical composition comprising a therapeutically effective amount of levodopa (LD) and carbidopa (CD), dispersed in a hydrophilic matrix, the composition further comprising an organic acid. In Nangia, the organic acid is mixed together with the LD and CD in a single pellet or bead.

(IMPAX00265839.) The last sentence has some ambiguity, as "mixed together" may be understood to mean that: 1) the organic acid, LD, and CD are intermixed with no separation throughout a single bead; or 2) the organic acid, LD, and CD are all present in a single bead, but not necessarily intermixed; they are "mixed together" only in the sense that single beads contain all three components.[2] The remarks continue as follows:

> For example, in Nangia, the CD and LD may be in beads which are fully or partially coated by a bioadhesive polymeric material which may comprise an acidic component (Nangia at paragraph 109). In another embodiment, Nangia describes LD containing controlled release (CR) beads coated with a bioadhesive polymer (Nangia at paragraphs 132 and 136.) In a further embodiment, Nangia describes granulating the CD and LD formulation using a mineral or organic acid (Nangia at paragraph 153.)

[2] This is not an exhaustive exploration of all the possible ways that the three components might be mixed together in a single bead. As will be seen, Nangia Tables 16 and 18 present another variant.

(IMPAX00265839-40.) The applicants thus point to three examples in Nangia: 1) in the first, the acid is in a coating on the bead which contains the CD and LD; 2) the second mentions a coating on a bead without specifying where the acid is; and 3) the third speaks of granulating the CD and LD, possibly by using an organic acid.

In terms of the present inquiry, the first example is significant. In this example, the applicants distinguish Nangia by pointing to a Nangia embodiment with a coating which includes an acidic component. The applicants then state:

> However, Nangia does not describe formulations comprising (1) a controlled release component comprising a mixture of levodopa, a decarboxylase inhibitor (e.g., carbidopa) and a rate controlling excipient, (2) a carboxylic acid component, and (3) an immediate release component comprising a mixture of levodopa and a decarboxylase inhibitor (e.g., carbidopa), wherein the carboxylic acid component (b) is a distinct component as required by the claims. Accordingly, Nangia cannot anticipate the claimed invention.

(IMPAX00265840.) Thus, the applicants distinguished Nangia on the ground that one Nangia example, an embodiment with an acidic coating, differs from what the applicants invented, a formulation in which the carboxylic acid component is a "distinct" component. For this to make sense, the applicants must mean "distinct" to mean "freely separable." They cannot here have meant "distinct" to mean "layer cake distinctness," since that would not distinguish the first Nangia example, which has the acid in a separate layer. In the first Nangia example, as the applicants described it, the acid was in a coating of beads containing the LD and CD. Thus, if the applicants have represented Nangia accurately, and if, as Impax argues, the claimed invention requires only that the carboxylic acid component be a separated subunit (such as a layer), Nangia might well anticipate the claimed invention. "Distinct" must therefore mean "freely separable," and cannot mean "layer cake distinctness."

This conclusion gains support from examination of the applicants' statements distinguishing Nangia in the obviousness section of the remarks.[3] In that section, the applicants stated:

> A. <u>In contrast to the claimed invention, Nangia discloses the use of an acid together with CD and LD not separated therefrom</u>
>
> Nangia describes a pharmaceutical composition comprising a therapeutically effective amount of levodopa (LD) and carbidopa (CD), dispersed in a hydrophilic matrix, the composition further comprising an organic acid. In Nangia, the organic acid is mixed together with the LD and CD in a single pellet or bead. For example, in Nangia, the CD and LD may be in beads which are fully or partially coated by a bioadhesive polymeric material which may comprise an acidic component (Nangia at paragraph 109).

(IMPAX00265844-45.) In this paragraph, the applicants assert that Nangia discloses compositions in which "the organic acid is mixed together with the LD and CD in a single pellet or bead." The applicants then give the example already discussed, the embodiment in Nangia paragraph 109, which discloses a CD/LD bead with an acidic coating. Again, this demonstrates that the applicants understood "mixed together," in the sentence quoted above, to mean only "present within a single pellet or bead," and repeats the disclaimer of embodiments in which the acid component is not freely separable from the CD/LD components. The subheading appearing above this paragraph also clearly makes this point: "separated" here means freely separable, not layer cake distinctness.

The applicants then made their clearest statement indicating that "distinct" means "freely separable:"

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[3] The PTO rejected claims 99-108 in the application (as of the supplemental amendment of November 16, 2011) as unpatentable for obviousness over Nangia in view of Fincher. (IMPAX00265853.) The parties have raised no claim construction issues about these claims.

> Applicants discovered the importance of bead-bead interactions between a bead containing levodopa/decarboxylase inhibitor (e.g., carbidopa) and a separate bead containing a carboxylic acid on dissolution and plasma uptake that resulted in a favorable plasma profile for those suffering from Parkinson's disease.

(IMPAX00265845.) Although this statement does not use the word "distinct," it is unmistakable in this statement that the applicants assert that they discovered a composition containing both a CD/LD bead and "a separate bead containing a carboxylic acid." This constitutes a clear and unmistakable disclaimer of embodiments lacking the specified characteristics. The applicants unmistakably disclaimed compositions which lack a carboxylic acid bead freely separable from the CD/LD bead.

Similarly, the applicants stated:

> Contrary to the Office's position, Nangia does not provide an indication of the need to create a separate carboxylic acid bead in the multiparticulate formulation. The particles created by Nangia in the Table and cited paragraphs by the Office were created in such a manner that the carboxylic acid as well as levodopa and a decarboxylase inhibitor (e.g., carbidopa) were all present in a single particle or bead.
> . . .
> Nangia does not describe or suggest having a separate carboxylic acid bead in their formulation. According to Nangia, the carboxylic acid function is primarily in stabilization and bioadhesion, and when such formulation includes an acid, all embodiments provide that such acid should be combined with the CD/LD. There was simply no suggestion to separate the CD/LD from the carboxylic acid.

(IMPAX00265846). This expresses very clearly that the applicants distinguished Nangia as teaching formulations with the carbidopa, levodopa, and acid in the same bead, whereas they invented a formulation in which the carboxylic acid component is on a separate bead.

The applicants submitted a supplemental amendment on August 2, 2012; the remarks point to support for new and amended claims but do not otherwise address the prior rejections. The applicants submitted a further supplemental amendment on September 25, 2012, which

included a remarks section with new argument about the obviousness rejection. The applicants stated:

> Applicants' claimed invention concerns formulations which include a distinct carboxylic acid component (bead or granule) that is coated with an enteric polymer, as recited in the claims. . . .
>
> In Tables 16 and 18, Nangia's formulations comprise IR and CR layers having combination of CD, LD and carboxylic acids together with two bioadhesive layers that also contain a carboxylic acid as part of a orally adhesive or gastroretentive technology to try to keep the active ingredients in a region of absorption for a longer period of time.
>
> One would have no reasonable expectation of success that modifying the formulations of Nangia to include a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules as recited in the claims, would result in a steady and prolonged absorption of the claimed invention . . .

(IMPAX00312330.) The first sentence in this section makes clear that the "distinct" carboxylic acid component that the applicants had in mind was a bead or granule (and therefore freely separable.)[4] The second paragraph cites Nangia tables 16 and 18. Table 16 in Nangia lists the components of Example 38, described as "quadrilayer tablets," and lists citric acid both in the immediate release layer and the two bioadhesive layers, and succinic acid in the controlled release layer.[5] (Margolis Decl. Ex. 21 at 80.) Table 18 in Nangia lists the components of Example 40, described as "quadrilayer tablets," and lists citric acid both in the immediate release layer and the two bioadhesive layers, and succinic acid in the controlled release layer. (Margolis

[4] Defendants' brief highlights this opening sentence as a statement, applicable to all patent claims, which could not be clearer in equating a "distinct" component with a bead or granule. This Court agrees. This easily meets the Federal Circuit criterion of being unmistakable.

[5] The '474 patent specification teaches that citric acid and succinic acid are members of the group of carboxylic acids. '474 patent col.5 ll.38-40.

Decl. Ex. 21 at 81-82.) The applicants distinguish Nangia as teaching the use of carboxylic acid as both: 1) part of the IR and CR layers; and 2) part of two bioadhesive layers. In both of these examples, then, Nangia teaches the use of a carboxylic acid in every layer of a tablet with four layers. In the following paragraph, the applicants argue that a skilled artisan would not have expected success in modifying Nangia by using a "distinct carboxylic acid bead" which is "separately coated" and is "together with the IR and CR beads or granules." The applicants thus unmistakably distinguished Nangia by asserting that it does not teach or suggest the freely separable carboxylic acid bead of their claimed invention.

Furthermore, in the section of the Supplemental Amendment of September 25, 2012 just quoted, the applicants also state twice that they invented formulations in which the carboxylic acid component is coated with an enteric polymer. In this quoted section, the applicants state in the first paragraph, and then again in the third paragraph, that their invention comprises a distinct carboxylic acid bead with an enteric coating. (IMPAX00312330.) The third paragraph contains the clearest statement on this point:

> One would have no reasonable expectation of success that modifying the formulations of Nangia to include a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules as recited in the claims, would result in a steady and prolonged absorption of the claimed invention . . .

(IMPAX00312330.) This statement clearly and unmistakably distinguishes Nangia as *not* having "a distinct carboxylic acid bead separately coated with an enteric polymer," while the present invention *does* have those characteristics. This constitutes a clear and unmistakable disclaimer of formulations which lack "a distinct carboxylic acid bead separately coated with an enteric polymer." The applicants here made clear statements to distinguish the claimed

invention over the prior art, and to overcome a rejection. "[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim." Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998). Thus, as Actavis contends, during prosecution, in order to overcome a rejection based on the prior art Nangia reference, the applicants narrowed the scope of all claims to formulations which include both of these characteristics: 1) a freely separable carboxylic acid bead or granule; and 2) the carboxylic acid component is coated with an enteric polymer.

Impax argues that, to whatever extent the applicants may have appeared to have disclaimed any claim scope in the earlier amendments, the later amendments broadened the scope again. (Impax Br. 17.) This is not supported by the prosecution history.[6] The applicants' remarks that accompanied the amendments of June 11, 2012 as well as the remarks that accompanied the final amendments of September 25, 2012 are consistent in manifesting an understanding of "distinct" as "freely separable," and in distinguishing Nangia as using

[6] Consider, for example, the history of the terminal phrase of claim 1. As of the November 16, 2011 supplemental amendment, it read: "wherein the carboxylic acid of (c) is in a distinct particle bead from (a) or (b)." (IMPAX00265895.) The examiner rejected the claim in March of 2012. As of the June 11, 2012 amendment, it read: "wherein the carboxylic acid component of (b) is a distinct component." (IMPAX00265825.) As of the August 2, 2012 supplemental amendment, it did not change. (IMPAX00312280.) As of the September 25, 2012 supplemental amendment, it read: "wherein the carboxylic acid component (b) is a distinct component and is coated with an enteric polymer; and wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules." (IMPAX00312305.)

This does not support the argument that whatever might look like narrowing of claim scope was undone by later broadening. As to the history of the amendments to claim 1, we see an initial broadening of scope from "distinct particle bead" to "distinct component." From that point forward, however, the only subsequent amendment narrowed the scope of the terminal phrase. Except for the broadening effect of changing "distinct particle bead" to "distinct component," the amendment history does not show a narrowing that was undone by later broadening, as Impax contends.

carboxylic acids in distinct layers but not distinct beads, as in the claimed invention.

Impax argues that Actavis has failed to demonstrate that the prosecution history shows a clear and unmistakable surrender of subject matter, but its arguments are unpersuasive. The applicants clearly and unmistakably surrendered embodiments in which the carboxylic acid component is not freely separable from the controlled release and immediate release components.

Impax argues that the Court should give no weight to the testimony of Dr. Moreton, Actavis' expert. The Court finds that the intrinsic evidence available in this case is rich, meaningful, and sufficient to answer the questions presently at issue. The Court has no need to consider any extrinsic evidence to decide the issues of claim construction before it. See Phillips, 415 F.3d at 1318 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms.")

Impax contends that, although the applicants submitted an amendment to claim 1 which required a carboxylic acid in a distinct particle bead, a later amendment removed that limitation, requiring only a "distinct component." This is correct but irrelevant to the present analysis, which is based on statements made by the applicants during prosecution to overcome a rejection. Actavis does not contend here that the applicants narrowed the scope of the claim based on the history of the proposed claim language, but that they unmistakably disclaimed scope during prosecution to overcome a rejection. The fact that the proposed claim language changed from "bead" to "component" has no impact on the analysis of disclaiming statements in the prosecution history. Actavis has shown that, during prosecution, the applicants unmistakably disclaimed embodiments without a freely separable carboxylic acid component, regardless of the

language used to amend the claims.[7]

Impax next argues that "the invention contemplates multiple embodiments," including both embodiments having a separable carboxylic acid bead and embodiments in which all three components are "coformulated" together. (Impax Br. 16.) Although Impax quotes from a 2009 document, the same language is in the specification of the issued patent. See '474 patent col.6 ll.36-53. There is no reason to believe that "coformulated" here means what Impax suggests it means (i.e., that the carboxylic acid component is not freely separable prior to any tablet compression.) Rather, the specification states that the "coformulated" embodiment is "multiparticulate," which suggests that it is composed of particles which are not homogenous. '474 patent col.6 l.51. Impax has pointed to no evidence which indicates that, in a multiparticulate embodiment, the carboxylic acid component is not freely separable from the IR and CR components prior to any tablet compression. In any case, as already stated, the prosecution history disclaimer is what matters most for the claim construction issue under consideration.

Impax also tries to make headway by refuting the proposition that the carboxylic acid bead cannot contain any component but carboxylic acid. This appears to be setting up a straw man argument and knocking it down, as it is unconnected to any argument Actavis relies on here.

Similarly, Impax argues that none of the prosecution history statements addresses the location of the immediate release component. This seems to be heading off on a tangent. Claim 1 requires that the carboxylic acid component be distinct from the controlled release and

[7] As the analysis in the preceding footnote shows, the history of the amendments to the terminal phrase of claim 1 shows a narrowing of scope that is consistent with this, not contrary.

immediate release components. Under the interpretation arrived at in today's decision, claim 1 requires that the carboxylic acid component be freely separable from the controlled release and immediate release components prior to any final embedding or compression process. The location of the immediate release component is not presently at issue.

At oral argument, counsel for Impax offered the following approach to understanding the prosecution history. Nangia, he contended, disclosed a formulation in which the immediate release, controlled release, and carboxylic acid components were not separated in any way, not by separate beads or separate layers on one bead. The '474 applicants distinguished Nangia by saying that the present invention required that the carboxylic acid component be separated in some way. According to this view, during prosecution, the applicants overcame Nangia by showing that the invention required only some separation of the carboxylic acid component, whereas Nangia required none. In other words, the '474 patent requires at least layer cake separateness of the carboxylic acid component, and Nangia did not teach the benefits of putting the carboxylic acid component in a separate layer.

This Court finds that this approach does not accurately reflect the record, not in its characterization of Nangia, nor in its characterization of the prosecution history. As already discussed, in the further supplemental amendment of September 25, 2012, the applicants pointed to the formulations in Nangia Tables 16 and 18, which both disclose the structure of a quadrilayer tablet. (IMPAX00312330.) Every layer in both examples appears to contain a carboxylic acid, either citric acid or succinic acid. Nangia thus here clearly discloses a layer cake structure: the CR and IR components are distinct layers and are separated by bioadhesive layers. It is thus incorrect to say that Nangia did not separate the IR and CR components in any

way.[8] Nangia, in Tables 16 and 18, disclosed a layered structure with distinct IR and CR layers.

Furthermore, as already discussed, the '474 prosecution history shows the applicants distinguishing Nangia on the basis of the distinct carboxylic acid bead:

> One would have no reasonable expectation of success that modifying the formulations of Nangia to include a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules as recited in the claims, would result in a steady and prolonged absorption of the claimed invention . . .

(IMPAX00312330.) It is not possible to read this statement as supporting the view Impax advanced at oral argument. This statement unmistakably distinguishes Nangia from the invention on the basis of "a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules."

Impax next points to dependent claims 96, 112, and 116 that were pending at the time the applicants made the alleged disclaimers. Impax argues that these indicate that the independent claims are broader, quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend.") Impax does not develop this point, but there appears to something to it. Claims 96, 112, and 116 in the amendments of

[8] Based on only the formulations disclosed in Nangia Tables 16 and 18, one could conceivably argue that Nangia did not teach putting the carboxylic acid component in its own distinct layer, unmixed with either the IR or CR layers. And then, as a hypothetical, the applicants might argue that they discovered the benefits of putting the carboxylic acid component in its own distinct layer. This is not, however, what the prosecution record shows. The applicants unmistakably distinguished Nangia by touting the discovery of putting the carboxylic acid component in its own separate bead, not its own distinct layer, and that, in a nutshell, is the obstacle that Impax has failed to overcome here. See Tech. Props. Ltd. LLC v. Huawei Techs. Co., 849 F.3d 1349, 1359 (Fed. Cir. Mar. 3, 2017) ("we hold patentees to the actual arguments made, not the arguments that could have been made.")

September 25, 2012 became claims 30, 44, and 48 in the issued patent:

> 30. The controlled release oral solid formulation of claim 1, wherein the component of (a), (b), or (c) is a bead or granule.
>
> 44. The controlled release oral solid formulation of levodopa of claim 1, wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component are distinct, separable beads or granules; and wherein the carboxylic acid component (b) comprises a carboxylic acid that is not in (a) and (c).
>
> 48. The controlled release oral solid formulation of claim 1, wherein the carboxylic acid is physically separated from levodopa and the decarboxylase inhibitor.

Impax is correct in arguing that these claims, when considered under the doctrine of claim differentiation, raise the possibility that independent claim 1 should be construed more broadly. This Court is not, however, persuaded that this issue carries enough weight to determine the outcome of the claim construction. As the Federal Circuit has colorfully explained:

> [C]laim differentiation is a rebuttable presumption that may be overcome by a contrary construction dictated by the written description or prosecution history. . . Claim differentiation is not conclusive; it is a guide, not a rigid rule. Although it is a useful tool, claim differentiation does not require that the "dependent claim tail . . . wag the independent claim dog" in this case.

Howmedica Osteonics Corp. v. Zimmer, Inc., 822 F.3d 1312, 1323 (Fed. Cir. 2016) (citations omitted). Such is exactly the case here: the rebuttable presumption of claim differentiation has been overcome by a contrary construction dictated by the prosecution history. The dependent claim tail will not wag the independent claim dog here. The surrender of claim scope during prosecution is unmistakable, and Impax has not presented a developed claim differentiation argument that poses any challenge to that conclusion.

Impax does, however, argue persuasively that Actavis' proposed construction improperly excludes granules. Actavis proposes a construction which limits a "distinct component" to a

physically separate bead, but the Actavis brief never directly addresses the question of why granules should be excluded. Indeed, in the September 25, 2012 Amendment, the applicants stated: "Applicants' claimed invention concerns formulations which include a distinct carboxylic acid component (bead or granule) that is coated with an enteric polymer, as recited in the claims." (IMPAX00312330.) This is crystal clear: the distinct component may be a bead or a granule. Actavis has not provided any basis for this Court to find otherwise, and the Court agrees with Impax on this point.[9]

Impax next makes an argument based on a statement by the examiner in the "Reasons for Allowance." (IMPAX00265793.) Impax has provided no legal authority for the proposition that this Court may draw inferences from an examiner's statement of a reason for allowance during claim construction, and the parties have not briefed this complicated matter of Federal Circuit law. See, e.g., Alfred E. Mann Found. for Sci. Research v. Cochlear Corp., 841 F.3d 1334, 1341 (Fed. Cir. 2016) (rejecting a claim construction inference from the examiner's reason for allowance). More importantly, however, this line of thinking appears to be chasing down a tangent: in the statement at issue, the examiner commented that the "encapsulation of the carboxylic acid components" was not found in the prior art, and it is not at all clear what he meant by that, or why that should have a limiting effect on the claim construction. (IMPAX00265793.) Impax itself contends that the examiner's statement says nothing about how encapsulation might be accomplished, and so there does not appear to be any value to considering this point.

[9] Impax also notes that the terminal phrase of claims 1 and 7 requires the components to be either a bead or a granule ("and wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules.") Limiting the carboxylic acid component to a bead conflicts with this.

Lastly, Impax contends that claim 59 should not be subject to Actavis' prosecution history disclaimer argument. Impax observes that claim 59 was added in the amendment filed August 2, 2012, and so none of the prior history should apply. While this Court agrees that the statements by the applicants in the amendment filed June 11, 2012 should not be applied to a claim that did not exist at that point, claim 59 (which was claim 127 in the amendment of August 2, 2012) was introduced in the amendment of August 2, 2012, and was before the examiner at the time that the applicants filed the amendment dated September 25, 2012. As already discussed, it was in the September 25, 2012 amendment that the applicants stated: "Applicants' claimed invention concerns formulations which include a distinct carboxylic acid component (bead or granule) that is coated with an enteric polymer, as recited in the claims." (IMPAX00312330.) Claim 59 was before the examiner when the applicants made that statement, which by itself is sufficient to constitute a clear and unmistakable disclaimer of claim scope. Claim 59 is directed to a formulation. Impax has presented no evidence indicating that the applicants intended that claim 59 was excluded from the scope of this general statement about formulations of the invention in the September 25, 2012 amendment.

Impax argues, nevertheless, that the applicants did not expressly include claim 59 as subject to that part of its remarks and, indeed, the statement quoted just above appeared after the subheading, "Rejections under 35 U.S.C. 103." (IMPAX00312329.) The statement about the formulations in the claimed invention, however, was written with the broadest possible phrasing. The applicants did not provide any indication that this statement applied to only a subset of claimed formulations, and this Court does not agree with Impax that, absent an expression applying the statement to every claim, it should be understood more narrowly. Impax has

pointed to nothing in the prosecution history that suggests that the applicants intended that their disclaimers applied to some claims, but not others. This disclaimer clearly and unmistakably applied to every formulation claim.

This concludes the Court's examination of the parties' arguments about the construction of the Group 1 claims. Actavis has demonstrated that, during prosecution, the applicants made a clear and unmistakable disclaimer of claim scope. The Court does not, however, agree fully with either party's proposed construction. The Group 1 claim construction dispute may be boiled down to three questions: 1) in what way must the carboxylic acid component be a distinct component?; 2) must the carboxylic acid component be a bead?; and 3) must the carboxylic acid component be coated with an enteric polymer?

This Court has concluded that, as to claims 1, 7, and 59: 1) the carboxylic acid component must be freely separable from the controlled release and immediate release components prior to any final embedding of all elements in any constraining structure; 2) the carboxylic acid component must be coated with an enteric polymer; and 3) the carboxylic acid component is not limited to a bead. The Court concludes that, during prosecution, in order to avoid the prior art and overcome a rejection, the applicants clearly and unmistakably disclaimed coverage of formulations in which the carboxylic acid component is not freely separable from the controlled release and immediate release components prior to any final embedding of all elements in any constraining structure, as well as formulations in which the carboxylic acid component is not coated with an enteric polymer. If the parties need the Court to reduce this to specific definitions of particular claim phrases, they may ask this Court for further assistance.

B. Claim construction issues for Group II

This dispute concerns claims 1 and 7, which both contain this terminal phrase: "wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules." Actavis contends that this phrase should be given its plain meaning which, Actavis posits, means that each or all of (a), (b), and (c) must comprise beads or granules. Impax also contends that this phrase should be given its plain meaning, but asserts that the plain meaning does not include any "each or all" requirement.

At the outset, this Court disagrees that the phrase at issue has a plain meaning; this Court does not discern a plain meaning to it, and each party contends that its interpretation comes from the plain meaning of the phrase. With that stated, this Court will examine each party's arguments in support of its view of the plain meaning.

Actavis first points to this statement in the prosecution history:

> One would have no reasonable expectation of success that modifying the formulations of Nangia to include a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules as recited in the claims, would result in a steady and prolonged absorption of the claimed invention . . .

(IMPAX00312330.) Actavis argues that this statement confirms its construction, but this is unpersuasive. While this statement does require a separate carboxylic acid bead, nothing in the statement requires that the IR component and the CR component must **each** be on physically separate beads or granules. An embodiment with carboxylic acid beads and combined IR/CR beads would be consistent with this statement.

Actavis next criticizes Impax's proposed construction as resulting in inappropriate ambiguity, with no citation to controlling authority. If the ambiguity is a serious problem, surely

Actavis could have found legal support for its point.

Impax argues that Actavis seeks to add a limitation ("each") to the claim that has no basis in the patent, and that is correct. Actavis' proposed construction is not the plain meaning of the phrase at issue, nor an interpretation based on intrinsic evidence. More importantly, the Actavis construction renders another segment of claim language redundant and superfluous. Consider the terminal language shared by claims 1 and 7:

> wherein the carboxylic acid component of (b) is a distinct component and is coated with an enteric polymer; and wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules.

This can be divided into two parts, split at the semicolon. If Actavis has correctly construed the second part as requiring each of components (a), (b), and (c) to comprise beads or granules, the "distinct component" part of the first phrase is rendered entirely unnecessary. If each of the three components is a bead or granule, there is nothing added by requiring component (b) to be distinct – it is inevitably distinct, as this Court has interpreted that term, if each component is a bead or granule. "[I]nterpretations that render some portion of the claim language superfluous are disfavored." SimpleAir, Inc. v. Sony Ericsson Mobile Communs. AB, 820 F.3d 419, 429 (Fed. Cir. 2016).

If the "distinct component" language were absent, the Actavis interpretation would be conceivable. The challenge is to construe the two phrases together so that everything is meaningful. Considering both the ordinary meaning of the words in the phrase now at issue, in the context of the intrinsic record, the interpretation of the second phrase that fits best is that the claimed formulation must have the three components in the form of beads or granules, as Impax contends. This allows the "distinct component" phrase to meaningfully add the limitation that

the carboxylic acid component must be freely separable from the other two components. The bottom line is that, all together, the two phrases require the formulation to comprise at least two beads or granules. One bead or granule consists of the carboxylic acid component, and the other two components may be together on a second bead or granule, or apart on a second and third bead or granule (or more).

To further clarify this, Figure 1 in the Impax brief is helpful:

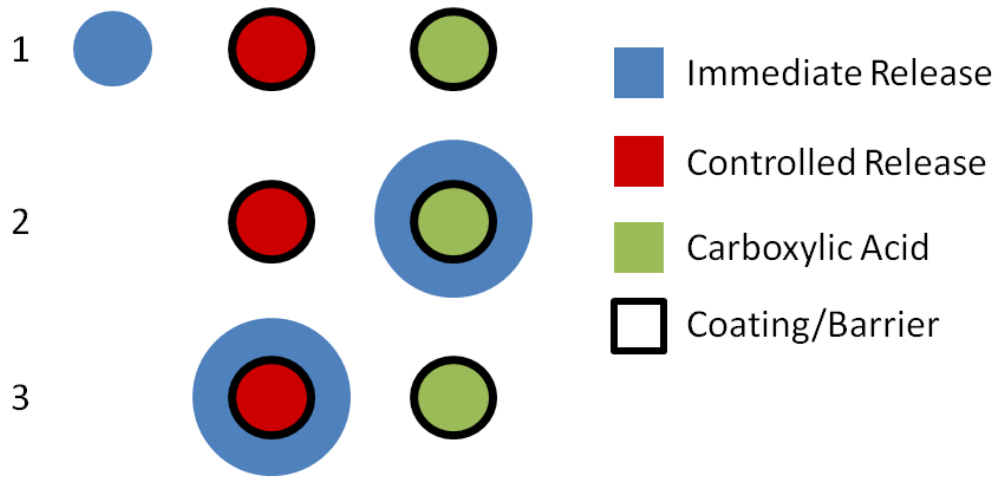

Figure 1 depicts some possible structures for the claimed formulation. Under the construction adopted herein, the claim language at issue requires a formulation such as the structure of the first example (three kinds of beads or granules) or the third example (two kinds of beads or granules, with one being a combined IR/CR bead). The Court need not reach the question of whether the second example (two kinds of beads or granules, with one being a combined carboxylic/IR or CR bead) would be allowable under this construction, because the prosecution history disclaimer surrenders all embodiments without a freely separable carboxylic acid component, which the second example lacks.

Impax observes that the specification contemplates a diverse group of embodiments that is clearly **not** limited to formulations with the controlled release component, the immediate release component, and carboxylic acid component "manufactured as distinct, separable beads." '474 patent, col.6 ll.36-53. This supports Impax's position, but is not conclusive, since every claim need not cover every embodiment.

Impax contends that no construction of the Group II claim phrases is necessary, and that they should have their plain and ordinary meaning. Both parties have argued that the phrase should have its plain and ordinary meaning, with sharply differing ideas of what that meaning is. Although there is no substantial difference between this Court's construction and that proposed by Impax, this Court adopts the proposed construction of neither party. The phrase at issue is construed to mean that the three components must be present in the form of beads or granules. This phrase, alone, does not set any requirement for the number of types of beads or granules. It is, instead, the "distinct component" phrase that sets the requirement for a freely separable carboxylic acid component. As discussed, when all of the parts of today's claim construction are considered together, claims 1 and 7 cover the structures depicted in the first and third examples in Figure 1 in the Impax revised brief: they contain at least two or three kinds of beads or granules, with the carboxylic acid component on a separate bead or granule from the CR and IR components.

Impax also notes that the construction proposed by Actavis creates claim differentiation difficulties with claim 30. If claim 1 requires that each of the three components must be on its own bead or granule, Impax argues, then what sense does dependent claim 30 make, requiring only one of the three to be a bead or granule? While this is worth considering, the relationship

between claims 1 and 30 appears to raise claim differentiation problems under both parties' proposed constructions.[10] The meaning of claim 30 is not, however, presently before this Court.

Actavis next argues that the Group II construction should be applied to claim 59. There is no basis to do so, and there appears to be some confusion about the difference between the Group II construction and the prosecution history disclaimer. Actavis is correct that the prosecution history disclaimer this Court has found applies to all claims. Thus, to be clear, the applicants surrendered any embodiment of claim 59 in which the carboxylic acid component is not a freely separable bead or granule prior to any tablet compression. Claim 59 does not, however, contain the Group II requirement that the three components are present in the form of beads or granules.

C. Groups III and IV: indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014).

Actavis contends that the claims in Group III and Group IV should be held invalid as indefinite. This Court declines to resolve these issues during claim construction. The parties have raised issues of invalidity that rest largely on matters of extrinsic evidence, rather than on the interpretation of claim language. The parties have presented a question of invalidity due to indefiniteness during the claim construction process, but have not asked the Court to construe the meaning of any claim terms. Instead, as Impax expressly stated, the parties have asked for

[10] As noted earlier, while there may be some claim differentiation issues with this patent, the arguments have not been sufficiently developed at this point, nor do the issues appear to be essential to today's decision.

something that requires the Court to find facts, apply the clear-and-convincing evidence standard to those facts, and arrive at a judgment of patent validity or invalidity. This is most appropriately done in the procedural context of a motion for summary judgment or a trial.[11]

The Court concludes that, as to the Group I claims, involving claims 1, 7, and 59, during prosecution, in order to avoid the prior art, the applicants clearly and unmistakably disclaimed coverage of formulations in which the carboxylic acid component is not freely separable from the controlled release and immediate release components prior to any final embedding of all elements in any constraining structure. As to the Group I claims, the Court concludes that: 1) the carboxylic acid component must be freely separable from the controlled release and immediate release components prior to any final embedding of all elements in any constraining structure; 2) the carboxylic acid component is not limited to a bead; and 3) the carboxylic acid component must be coated with an enteric polymer. As to the Group II claims, involving claims 1 and 7, the phrase "wherein the controlled release component (a), the immediate release component (c) and the carboxylic acid component (b) comprise beads or granules" does not require that each component, considered individually, must be a bead or granule. As to the Group III and IV claims, the invalidity for indefiniteness disputes are not amenable to resolution within the present

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[11] Impax points to the trial court decision on indefiniteness in the context of a pharmaceutical plasma profile claim in Endo Pharm. Inc. v. Amneal Pharm., LLC, No. 12 CIV. 8060 (TPG), 2015 WL 9459823, at *53 (S.D.N.Y. Aug. 18, 2015), but the Endo court arrived at that decision after a full trial, with testimony from experts, on, *inter alia*, the question of whether the patent disclosures "would leave a skilled artisan in some doubt as to how those limitations could be satisfied."

Although Impax argues that this Court should now find that these claims are not indefinite, it suggests, in the alternative, that the matter might be deferred until after the close of discovery, citing the non-precedential Federal Circuit decision in ADC Telcoms., Inc. v. Switchcraft, Inc., 281 Fed. Appx. 989, 992 (Fed. Cir. 2008) ("The parties' dispute over the proper testing method is therefore a factual question that the district court properly submitted to the jury.")

claim construction process, and these matters may be raised again at summary judgment or at trial.

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: May 9, 2017