



Warner Chilcott Company LLC v. Zydus Pharmaceuticals (USA) Inc. et al

2013 | Cited 0 times | D. Delaware | April 22, 2013

STATES COURT FOR OF

COMPANY,

V. ZYDUS PHARMACEUTICALS (USA)

ZYDUS

05-RGA

CONSTRUCTION

Steven Sipes,

P.

Zydus (USA)

2013

I i

t: r I I ' f I i ' l ' ! ([IN THE UNITED DISTRICT

THE DISTRICT DELAWARE

WARNER CHILCOTT LLC,

Plaintiff,

INC., and CADILA HEALTHCARE LIMITED (d/b/a CADILA),

Defendants.

C.A. No. 11-11



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CLAIM

J. Balick, Esq., Wilmington, Delaware; Christopher N. Esq. (argued) Washington, D.C.; Megan Keane, Esq. (argued), Washington D.C.; Attorneys for Plaintiff Warner Chilcott Company, LLC. John C. Phillips, Jr., Esq., Wilmington, Delaware; Michael J. Gaertner, Esq. (argued), Chicago, Illinois; James T. Peterka, Esq. (argued), Chicago, Illinois; Attorneys for Defendants Pharmaceuticals Inc. and Cadila Healthcare Limited.

, Wilmington, Delaware

l "Zydus") ("ANDA") 800-mg

Plaintiff

Patent ("662 Patent"). Patent

Patent.

DISCUSSION

370,388-90

Of "always

term." 1303, 2005) 90 This is a claim construction opinion. Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively filed an Abbreviated New Drug Application

seeking approval to market a generic equivalent of Asacol® HD, an delayed- release mesalamine tablet. Warner Chilcott Company LLC sells Asacol® HD in the United States. Warner Chilcott filed a patent infringement suit against Zydus, alleging that the ANDA infringes Warner Chilcott's U.S. No. 6,893,662 The '662 relates to formulations and methods of delivering mesalamine to the lower part of the gastrointestinal tract, especially the colon. The patent teaches that the mesalamine dosage form should be lined with an inner coating layer and an outer coating layer of enteric polymers. The coating layers are intended to delay the release of the mesalamine until it reaches its intended target area. They help reduce the possibility of coating fractures that may occur during production of the dosage form, thus preventing premature dissolution of the drug in the gastrointestinal tract.

This opinion construes the disputed claim terms for the '662

Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967,977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. (1996). When construing the claims of a patent, a court considers the



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literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 979. these sources, the specification is highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed Phillips v. AWH Corporation, 415 F.3d 1312- 17 (Fed. Cir. (en bane) (citing Vitronics Corp. v. Conceptronic, Inc., F.3d 1576, 1582

However,"[

restriction.'" 2004)

2002)).

"flaws" "is

evidence").

AI 730

I 980

740 (Fed. Cir. 1996)). e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or

Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898,906 (Fed. Cir. (quoting Teleflex, Inc. v. FicosaN. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir.

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 1318-19; Markman, 52 F.3d at 979-80. However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 1318-19 (discussing inherent in extrinsic evidence and noting that extrinsic evidence unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. George, Inc., F.2d 753, 759 (Fed. Cir. 1984). Ifthe patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in the patent). If possible, claims should be construed to uphold validity. In re Yamamoto, F.2d 1569,



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1571 (Fed. Cir. 1984).

2 of "coating layer,"

31} "A

layer."

of "inner layer" "outer layer."

Plain "inner

layer" "the

layer." "A

layer." Plain Plain "inner

layer" "the

layer." "A

coat." Plain 1. "Coating layer"

The parties briefed the construction but later came to agreement (D.I. 88) as to the following construction:

Term: "coating layer" (claims 1, 2, 5, 7, 11, 14, 16, 26, Agreed upon thickness of a coating material completely encasing or coating all of the construction: solid unit dosage form or the inner coating

2. "Inner coating layer" and "outer coating layer"

The parties dispute the construction coating and coating The proposed constructions and the construction of the Court follow:

Term: "inner coating layer" (claims 1, 2, 5, 7, 11, 14, 16) Warner Chilcott's and ordinary meaning. In the alternative, the proposed construction: coating is coating layer which is closer to the core

relative to the outer coating Zydus' proposed coating layer covering the solid unit dosage form with construction: boundaries defined by the outer surface of the solid unit dosage



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form and the inner boundary of the outer coating Construction of the Court: and ordinary meaning. Term: "outer coating layer" (claims 1, 2, 5, 7, 11, 14, 16) _ Warner Chilcott's and ordinary meaning. In the alternative, the proposed construction: coating is coating layer which is farther from the core

relative to the inner coating Zydus' proposed distinct coating layer covering the inner coating layer with construction: boundaries defined by the outer surface of the inner coating layer

and (i) the surface of the finished dosage form or, (ii) optionally, the inner boundary of a shiny finish Construction of the Court: and ordinary meaning.

3 "inner layer" "outer layer"

"an

" Zydus "outer layer" "applied layer"

"boundary" "boundaries" "boundary" Patent. of "an layer"

"boundary." "inner layer" "outer layer,"

"continuous methods"

See Patent "boundaries"

of "inner layer" "outer layer."

"An "an

"an layer" "an layer"

"an "an The dispute of scope in regard to coating and coating is whether the two coating layers must be separated by defined boundaries. Both phrases are used as follows in claim 1: outer coating layer, applied to the inner coating layer, said outer coating layer comprising ... argues that the fact the is to the inner

necessarily implies the existence of defined boundaries between the two layers. Warner Chilcott disagrees, arguing that there is no justification in the patent for the boundary limitation.

The Court finds no reason to read a limitation into the claims. Neither

nor are words found within the '662 Further, the plain meaning outer coating layer, applied to the



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inner coating does not necessarily imply the existence of a It is true that the coating must be distinguishable from the coating but the requirement that the layers be separated by a boundary would suggest some sort of definitive dividing line that is not envisioned anywhere within the patent. This understanding is bolstered by the possibility that the transition between layers is gradual, as could be the result of spray used to apply the coating layers, or the result of applying the outer coating layer before the inner coating layer is dried or cured. '662

at 8:59-9:01. For these reasons, the Court rejects the limitation and adopts the plain and ordinary meaning coating and coating

3. inner coating layer" and outer coating layer"

At oral argument (D.I. 87, p. 45), the parties agreed to the construction of inner coating and outer coating as follows:

Terms: inner coating layer" and outer coating layer" (claims

1, 2, 5, 7, 11, 14, 16

4 "One "an of." layer:"

"One "an of." layer:"

"the layer."

Plain "the

properties." "The material." "The

properties."

"wherein layer[.]"

J I Agreed upon construction inner coating layer, no matter how many sub-layers it is for inner coating comprised

Agreed upon construction outer coating layer, no matter how many sub-layers it is for outer coating comprised

4. "The inner coating layer is not the same as the outer coating layer"



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The next term is inner coating layer is not the same as the outer coating The proposed constructions and the construction of the Court follow:

Term: "The inner coating layer is not the same as the outer coating

layer" (claims 1, 11) Warner Chilcott's and ordinary meaning. In the alternative, inner proposed construction: coating layer is different from the outer coating layer because the

coating layers comprise different materials or exhibit different characteristics or Zydus' proposed inner coating layer and the outer coating layer are not construction: composed of the same pharmaceutically acceptable coating

Construction of the Court: inner coating layer is different from the outer coating layer

because the coating layers comprise different materials or the coating layers have different structural

The phrase appears in claim 1 as follows: the inner coating layer is not the same as the outer coating The parties agree that there must be some difference between the inner and outer coating layers. They disagree as to what may constitute this difference. Zydus argues that this difference refers to the use of distinct pharmaceutical materials in each layer. Warner Chilcott disagrees, instead arguing that it is possible for the layers to be formed from the same pharmaceutical material, so long as they have different compositional characteristics or

5 "not same,"

"not same"

[PMM [PMM [PMM [PMM

Patent "any fractures[.]" "any

material"

See properties. Warner Chilcott argues this would be the case if the outer layer was made more plastic or spongier than the inner layer, thus giving the layers different structural properties and making them the even if formed by the same material.

There is no evidence requiring the layers to be formed from distinct material. The patentee made no statements restricting the categories of differences distinguishing the inner and outer coating layers, and certainly did not restrict those differences to types of pharmaceutical materials. The Court is convinced that the plain and ordinary meaning of the in regard to pharmaceutical coating layers



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includes both difference of material and difference of structure. The following quotation from the specification supports this construction:

Generally, if the inner coating layer is 1: 1] (Eudragit® L) then the outer coating layer is not 1 :2] (Eudragit® S) or is not a mixture of 1:1] and 1 :2]. The outer coating layer can be any coating material that protects the inner coating layer from fractures during handling and that dissolves or is removed in the gastrointestinal tract prior to the inner coating layer. '622 at 4:33-43. This description shows that the outer coating layer may be formed by

coating material that protects the inner coating layer from The fact that coating may be used to form the outer coating layer is inconsistent with strictly requiring it to be a different material from the inner coating layer.

Zydus argues that a change in process parameters is not sufficient to make two layers different, citing examples from the specification where different process parameters formed just a single layer. This supposedly undermines the argument that different process parameters invariably produce distinguishable layers. id at 9:7-12:8. It is not necessary, however, for every change in process parameters to invariably result in distinguishable layers. So long as certain variations in process parameters can form distinguishable layers using a single pharmaceutical material, the fact that the patent describes other changes in process parameters

6 "the layer"

of"selected of."

Plain "identified

being." Zydus' "An

others." "the PMM PMM

excluded."

"an that do not have this effect is inconsequential. For these reasons, the Court will not require each layer be formed of different pharmaceutical materials.

That is not to say any imaginable difference between layers is sufficient to satisfy the claims. For example, trivial differences in taste or color should not be understood to make the layers distinct, as those types of differences would not accomplish the goal of reducing coating fractures. The layers at minimum must have distinct structural properties. For this reason, the Court construes inner coating layer is not the same as the outer coating to require the layers to either (1) be made from distinct



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pharmaceutical materials or (2) have distinct structural properties.

5. "Selected from the group consisting of"

The parties dispute the construction from the group consisting The proposed constructions follow, as does the construction of the Court:

Term: "Selected from the group consisting of" (claims 1, 8, 11, 17) Warner Chilcott's and ordinary meaning. In the alternative, from proposed construction: a number of options, those options

proposed exclusionary term that allows for the inclusion of only the construction: listed substances and excludes all Construction of the Court: In the context of claim 1, inner coating layer must be either

1 :2, 1 : 1, or a mixture of the two. The presence of any other polymer is excluded. The presence of non-polymer substances such as excipients, solvents or carriers is not

The phrase is used in claim 1 as follows: inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1 :2, poly(methacrylic acid, methyl

7 thereof[.] "The

else."

2000). "Markush group."

2003).

"an " "Markush group."

"inner layer" "inner

layer"

"inner layers"

See, Patent methacrylate) 1 : 1, and mixtures phrase 'consisting of is a term of art in patent law signifying restriction and exclusion [i]n simple terms, a drafter uses the phrase 'consisting of to mean 'I claim what follows and nothing Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1383 (Fed. Cir. Such language is said to create a



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See *Abbott Laboratories v. Baxter Pharm. Products, Inc.*, 334 F.3d 1274, 1281 (Fed. Cir.

Both parties acknowledge that inner coating layer selected from a group consisting of ... creates a The parties disagree, however, as to the exact claim component that the phrase restricts. Zydus argues that the Markush Group limits the entirety of the coating to the specifically listed polymers. 1

This would mean that the coating must be purely formed from the listed polymers and cannot include additional substances, such as excipients, solvents, or carriers. Warner Chilcott urges the contrary position, arguing that a person of ordinary skill in the art would interpret the Markush Group as only providing the universe of polymers within the layer, but placing no restrictions on the presence of additional substances within the layer. In support of this argument, Warner Chilcott cites portions of the specification that clearly show coating formed by a polymer with additional excipients, solvents, or plasticizers. 2

According to Warner Chilcott, this makes clear that the patentee never intended to exclude those substances, and nor should the scope of the Markush group.

1 Although the briefmg refers to claims 1, 8, 11, and 17, the dispute is focused on claim 1. The Markush groups in claims 8, 11, and 17 do not present the same dispute. 2

e.g. '662 at 6:64-67, 7:45-47, 9:21, 9:22, 9:30, 9:47-58.

8 "selected of"

"Consisting of," L.C., 460 2006).

"unrelated invention,"

2004).

"well

manufacture." 7:65-8:03.

"it As stated above, from the group consisting is a term of art that denotes an exhaustive list. The patentee claims what follows and nothing else. Here, the Markush group presents a universe of polymers, which are (i) poly(methacrylic acid, methyl methacrylate) 1 :2; (ii) poly(methacrylic acid, methyl methacrylate) 1:1; or (iii) mixtures of the two. There is no mention of any additional coating materials or excipients, suggesting they may not be included within the layer. however, is not absolutely restrictive. *Conoco, Inc. v. Energy & Env'tl. Int'l*, F.3d 1349, 1361 (Fed. Cir. If the unrecited element is an impurity normally associated with the claimed component, it is implicitly adopted by



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the ordinary meaning of the compound itself and the Markush group will not exclude it. *Id.* Further, if the unrecited element is to the it will likewise not be excluded. *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32 (Fed. Cir.

The second exception applies here. 3

Nowhere does the patentee suggest that the excipients in question are novel or used in an inventive fashion. To the contrary, the patentee suggests that the incorporation of excipients is known to those skilled in the art to achieve the desired release rate, stability, absorption, and facilitate the dosage form '662 Patent at The presence of excipients can thus be understood to be unrelated to the actual invention. A person skilled in the art would not read the patent to exclude the basic excipients disclosed in the patent, as they are naturally associated with pharmaceutical formulations. The Federal Circuit has stated that is unlikely that an inventor would define the invention in a way that excluded the preferred embodiments, or that persons of skill in this field

3 I think that the decision here is a very close call. I am convinced, however, that this construction most accurately describes the patentee's invention and is consistent with his description of the invention. The public notice function of the '662 Patent is not undone by this construction. A competitor is expected to read the entire patent, and the specification clearly shows the patentee envisioned excipients integrated with the pharmaceutical coating layers.

9 way." 1580

See 9:07-12:07

"selected "the

excluded."

"polymethacrylates" "anionic

11}

"synthetic "polymethacrylates:"

L." "Polymethacrylates

11." "polymethacrylates:"

Qo!Ymethacry



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"synthetic " anwmc

10 would read the specification in such a Hoechst v. Celanese Corp. v. BP Chemicals Ltd, 78 F.3d 1575, (Fed. Cir. 1996). Construing the Markush group to exclude excipients would exclude every preferred embodiment of the invention from the claim, as they all incorporate excipients into both coating layers. id at (Examples 1-5). What the Markush group does restrict is the universe of polymers that may be used to form the layer. For these reasons, the Court adopts, for claim 1, a construction of from a group consisting of' as

inner coating layer must be either PMM 1 :2, PMM 1:1, or a mixture of the two. The presence of any other polymer is excluded. The presence of non-polymer substances such as excipients, solvents or carriers is not

6. "Polymethacrylates" and "anionic polymethacrylates"

The next terms are and polymethacrylates." The proposed constructions and the construction of the Court follow:

Terms: "polymethacrylates" and "anionic polymethacrylates"

(claims 1, Warner Chilcott's Plain and ordinary meaning. In the alternative, proposed construction for cationic and anionic polymers of

dimethylaminoethylmethacrylates, methacrylic acid and methacrylic acid esters in varying ratios. The term encompasses coating polymers labeled with the brand names Eudragit®S or Eudagri t® Zydus' proposed other than those specifically listed in claims construction for 1 and

Construction of the Court Plain and ordinary meaning for lates: Warner Chilcott's Plain and ordinary meaning. In the alternative, proposed construction for polymers of dimethylaminoethylmethacrylates, methacrylic acid

and methacrylic acid esters in varying ratios having a negative polymethacrylates:" charge. The term encompasses coating polymers labeled with

thereof." "Anionic "anionic 11." Court's Plain "anionic

"polymethacrylates" "anionic

"outer layer." Chilcott

Zydus



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Claim "outer of"

Zydus

Zydus "other," Court "Markush group"

See Parte the brand names Eudragit®S or Eudragit®L or mixtures Zydus' proposed polymethacrylates other than those specifically listed construction for in claims 1 and polymethacrylates:"

construction for and ordinary meaning polymethacrylates:"

The parties dispute the construction of and polymethacrylates," terms that are members of a Markush group of polymers that form the

coating Warner argues that the plain and ordinary meanings of these terms are appropriate. disagrees, instead arguing that all terms within a claim must be given independent and distinct meanings. 1 and 11 both contain the limitation that the

coating layer ... compris[es] an enteric polymer ... selected from the group consisting inter alia,

1. polymethacrylates; 2. anionic polymethacrylates; 3. poly(methacrylic acid, methyl methacrylate) 1:1; 4. mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1; and 5. poly(methacrylic acid, ethyl methacrylate) 1:1.

argues that each item must have a distinct and independent meaning; they may not overlap. Accordingly, because the plain and ordinary meaning of items 1 and 2 encompass items 3-5, that construction must be incorrect. Thus, proposes that items 1-2 must be construed to have a meaning than those specifically listed in claims 1 and 11 i.e., items 3-5.

The does not agree. There is persuasive authority for the proposition that a

may have members that overlap with one another, so long as a person skilled in the art would be reasonably apprised of the group's scope. Ex Dale E. Hutchens &

11 APPEAL Pat.

"polymethacrylates" "anionic

"poly(methacrylic :2" "poly(methacrylic I" ("PMM :2" "PMM ").

Plain "anionic "Poly(methacrylic



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:2"

Eudragit®S." Zydus' "An "poly(methacrylic

:2" 135,000, S."

Plain Plain "anionic "poly(methacrylic

1"

Eudragit®L." Zydus' "An

"anionic Norman Cohen, 1996-3292, 1996 WL 1749363, *1 (Bd. App. & Interf. 1996). It is clear that the patentee intended to comprehensively claim and polymethacrylates." The fact that the patentee listed duplicative variations of these polymers should not affect the construction when a person skilled in the art would not have difficulty understanding the Markush group's scope. For this reason, the court construes these terms according to their plain and ordinary meaning.

7. "Poly(methacrylic acid, methyl methacrylate) 1:2" and "poly(methacrylic acid,

methyl methacrylate) 1:1" The Court next construes acid, methyl methacrylate) I and

acid, methyl methacrylate) I: 1 and 1:1 The proposed constructions and the constructions of the Court follow:

Terms "poly(methacrylic acid, methyl methacrylate) 1:2" and

"poly(methacrylic acid, methyl methacrylate) 1:1" (claims 1 and 11) Warner Chilcott's and ordinary meaning. In the alternative, proposed construction for copolymer derived from methacrylic acid and methyl

acid, methacrylate, with a ratio of free carboxyl groups to the ester methyl methacrylate) 1 groups of approximately 1:2. The term encompasses those

coating materials labeled under the brand name proposed anionic copolymer derived from methacrylic acid and construction for methyl methacrylate, with a ratio of free carboxyl groups to the

acid, ester groups of approximately 1:2, and a mean molecular weight methyl methacrylate) I of approximately commonly known as Eudragit Construction of the Court and ordinary meaning. for polymethacrylates: Warner Chilcott's and ordinary meaning. In the alternative, proposed construction for copolymer derived from methacrylic acid and methyl



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acid, methacrylate, with a ratio of free carboxyl groups to the ester methyl methacrylate) 1 : groups of approximately 1: 1. The term encompasses those

coating materials labeled under the brand name proposed anionic copolymer derived from methacrylic acid and construction for methyl methacrylate, with a ratio of free carboxyl groups to the _polymethacrylates:"

12 135,000, L."

"anionic polymethacrylates:"

Zydus

135,000[.]

2012 2012). ester groups of approximately 1: 1, and a mean molecular weight of approximately commonly known as Eudragit Court's construction for Plain and ordinary meaning.

PMM 1 :2 and PMM 1: 1 are examples of polymers used to form the coating layers of claims 1 and 11. The dispute in scope is whether they are explicitly defined and thus (1) their constructions should include a specific mean molecular weight and (2) their constructions should include the Eudragit brand names of the drugs. argues that the specification defines both substances as such, citing the following passage from the specification in support:

In one embodiment the inner coating layer comprises [PMM 1 :2] (Eudragit®S), or other enteric polymer material which has the same pH release characteristics in aqueous media as Eudragit®S. Eudragit®S, an anionic copolymer derived from methacrylic acid and methyl methacrylate, with a ratio of free carboxyl groups to the ester groups of approximately 1:2, and a mean molecular weight of approximately '662 Patent at 4:19-27. A patentee acts as his own lexicographer when he clearly states any special definition of the claim terms within the specification or file history.

GlaxoSmithKline LLC v. Anchen Pharmaceuticals, Inc., WL 5594540, *2 (D. Del. Nov. 15, The patentee did not do so here. The claims themselves refer to the chemical names of the polymers and do not include a particular molecular weight. Eudragit®S, not PMM 1 :2, is defined according to a molecular weight. The fact that Eudragit®S has a specific mean molecular weight does not necessarily mean that PMM 1 :2 shares that exact characteristic, even if Eudragit®S is the brand name version of the polymer. The same rationale applies to denying the assignment of a particular molecular weight to PMM 1 : 1.

13 Zydus PMM

PMM



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See Patent 6:20-40. "inner layer" "inner layer" "other material" "the PMM PMM

PMM PMM

"enteric polymer."

{claims Plain "a

thereof." Zydus' "A

intestine." "A

fluids."

"Enteric polymer" "an

" argues that because 1 :2 is used interchangeably with Eudragit®S, the molecular weight limitation can be properly attributed to 1:2. The specification suggests, however, that the Eudragit brands are merely used as examples of the polymer and are not intended to constitute the only claimed polymer. '662 at Further, the specification notes that the coating is not limited to Eudragit®S, as the coating may be formed by enteric polymer so long as that material has

same pH release characteristics" as Eudragit®S. Id All of this indicates that 1:2 and 1:1 are not limited to the Eudragit brands. For these reasons, the Court adopts the plain and ordinary meanings of 1 :2 and 1:1.

8. "Enteric polymer"

The next term is The proposed constructions and the construction of the Court follow:

Term: "Enteric _polymer" 1, llj_ Warner Chilcott's and ordinary meaning. In the alternative, substance that, proposed construction: when used to coat a dosage form, is intended to be resistant to

drug release in the stomach or ingress of gastric fluids. The term encompasses coating polymers labeled with the brand names Eudragit®S or Eudragit®L or mixtures proposed polymer which is insoluble in gastric juice but soluble in the construction: less acidic environment of the small or large Construction of the Court: substance that, when used to coat a dosage form, is resistant

to drug release in the stomach or ingress of gastric

is used in claim 1 as follows: outer coating layer, applied to the inner coating layer, said outer coating



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layer comprising an enteric polymer that begins to dissolve in an aqueous medium at a pH of less than about 7 The dispute of scope chiefly

14 "enteric polymer" "insoluble fluids,"

"resistant stomach,"

"enteric polymer" "insoluble" "insolubility"

"enteric polymer" "exhibit fluids." 20

"insoluble." "insoluble" "resistant release"

"enteric polymer" "enteric polymer" "a

fluids."

"mixtures."

I t Plain "a

substances." "A

properties." "A

properties." concerns whether the should be described as in gastric as argued by Zydus, or merely to drug release in the as argued by Warner Chilcott. Zydus also argues that Warner Chilcott's construction inappropriately focuses on intentions of use rather than the claimed pharmaceutical compound itself.

The Court finds there is no requirement for the to be completely insoluble. The words and are nowhere to be found in the patent. Further, Zydus' own extrinsic evidence states that an is expected to lower permeability to gastric (D.I. 71, Exh. at 114). Lower permeability is not equivalent to the zero permeability that is implied by The Court rejects the proposed requirement and adopts the broader to drug limitation. The Court does agree, however, with Zydus' argument that there is no reason to construe

according to subjective intentions. For all these reasons, the Court construes as substance that, when used to coat a dosage form, is resistant to drug release in the stomach or ingress of gastric

9. "Mixtures"



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The next term is The proposed constructions and the construction of the Court follow:

Term: "Mixtures" (claims 1 and 11) Warner Chilcott's and ordinary meaning. In the alternative, system of two proposed construction: or more distinct chemical Zydus' proposed system of two or more distinct chemical substances wherein construction: the components retain their individual chemical Construction of the Court: system of two or more distinct chemical substances wherein

the comp_onents retain their individual chemical

15 1 1 1 t I

j 1

I

"Mixtures" "an

[PMM [PMM thereof1.]"

"mixture" "system substances," Zydus "mixture" "system properties."

Zydus "mixture" "a

properties." "mixtures" "substances combined." Zydus'

Zydus'

Zydus:

"mixture" "substances combined."

Zydus'

l

is used in claim I as follows: inner coating layer selected from the group consisting of 1 :2], 1: I] and mixtures The parties agree that a plain and ordinary meaning is appropriate, but they disagree as to what exactly this meaning is. Warner Chilcott argues that a is a oftwo or more distinct chemical whereas argues that a is a of two or more distinct chemical substances wherein the components



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retain their individual chemical The scope in dispute is thus whether the individual chemical substances used in a mixture must retain their individual chemical properties. Both parties rely on extrinsic evidence.

cites two technical dictionaries. The first dictionary defines as system of two or more distinct chemical substances ... [i]n a mixture there is no redistribution of valence electrons, and the components retain their individual chemical (D .I. 7I, Exh. 2I at The second defines as that are mixed, but not chemically (!d.). These definitions support proposed construction. The first dictionary definition disallows the redistribution of valence electrons between the components of the mixture, which is consistent with the limitation that the mixture must retain individual chemical properties, as a redistribution of valence electrons would result in a new chemical compound. The definition then contains the specific requirement urged by the components of the mixture must retain their individual chemical properties. The second dictionary defines a as that are mixed, but not chemically The Court views this as also consistent with proposal. Warner Chilcott, on the other hand, offers only an expert declaration in support of its construction. (See D.I. 7I, Exh. 22 36-38). Within the hierarchy of extrinsic evidence, technical dictionaries are more persuasive

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See 1303, 2005). of "mixture."

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"the

cured."

fclaims Plain "the

layer." "The

begin." "The

begin."

"The

cured." "separate step" Zydus than the opinions of paid experts. Phillips v. AWH Corp., 415 F.3d 1317-19 (Fed. Cir.



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For this reason, the Court adopts Zydus' construction

"The outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured" The next term phrase is outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or The parties' proposed construction and that of the Court follow:

Term: "The outer coating layer is applied after the inner coating

layer but before the inner coating layer is dried or cured"

7, 16) Warner Chilcott's and ordinary meaning. In the alternative, outer proposed construction: coating layer is applied before the inner coating layer is no

longer tacky, sticky, or damp or has coalesced and reached the state in which is it acceptable for storing and packaging. For example, the outer coating layer may be applied as part of a coating process continuous with the application of the inner coating Zydus' proposed outer coating layer is applied in a separate and distinct step construction: after the inner coating layer is applied but before the inner

coating layer is dried or cured; the application of the inner coating layer must end before the application of the outer coating layer can Construction of the Court: outer coating layer is applied after the inner coating layer

but before the inner coating layer is dried or cured. The application of the inner coating layer must end before the application of the outer coating layer can

This phrase is used in claim 7 as follows: composition of claim 6 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or The dispute concerns whether the application of the outer coating layer must be a and distinct from the application of the inner coating layer. argues that because the claim requires the

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"after"

"the

layer." of "continuous methods" "separate step"

"after."

Otherwise, "after"

"continuous methods"

"separate step" outer coating layer to be applied the inner coating layer, (1) the application of the inner coating layer must end before the application of the outer coating layer begins, and (2) the application of the outer coating layer must constitute a separate and distinct step from the application of the inner coating layer. Warner Chilcott argues that these limitations are not supported by the intrinsic evidence. Specifically, they are said to be inconsistent with claim language as a whole, which requires that solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating. According to Warner Chilcott, the use spray is inconsistent with the and distinct limitation.

The Court finds that the claims do require a temporal distinction between the application of the outer coating layer and the inner coating layer. Indeed, that is the only reasonable understanding of the claims' usage of the word. It is thus appropriate to require the application of the inner coating layer to end before the application of the outer coating layer can begin. the outer coating layer would not be applied the inner coating layer, it would be applied concurrently with the inner coating layer. This is not inconsistent with the

spray limitation of the claim, as the layers may be formed by a continuous spray, so long as the outer coating layer is formed after the inner coating layer. The Court, however, does not agree that it is necessary to include the and distinct limitation. Such a limitation may improperly imply a restriction on the processes of making the layers rather than the timing of their application.

The parties should jointly submit within five days a form of order embodying these constructions.