IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LTD., and TAP PHARMACEUTICAL PRODUCTS INC.,	)	
Plaintiffs and Counterclaim-Defendants,	)	**REDACTED PUBLIC VERSION**
v.	)	C.A. No. 06-033-SLR
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
Defendants and Counterclaim-Plaintiffs.	)	

DEFENDANTS TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S OPENING CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's March 21, 2006 and September 10, 2007 Orders, Defendants and Counterclaim-Plaintiffs Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva") submit this opening brief in support of their constructions of the terms of U.S. Patent No. 5,045,321 ("the '321 patent"). (See Ex. 1.)[1]

I. SUMMARY OF ARGUMENT

The alleged invention of the '321 patent relates to pharmaceutical products known as proton pump inhibitors ("PPIs") which are commonly used to treat ulcers. PPIs contain an active ingredient chosen from a group referred to as benzimidazole compounds which are understood to treat ulcers by reducing the amount of gastric acid in the stomach. Plaintiffs in this action developed and commercialized a PPI product (sold under the name Prevacid) in which the benzimidazole compound lansoprazole is mixed homogenously together in a specific ratio with the basic inorganic salt magnesium carbonate. The homogenous admixture in Prevacid is one of the "pharmaceutical composition[s]" claimed in claims 1 and 2 of the '321 patent.

The admixture of the benzimidazole compound and the basic inorganic salt required by the '321 patent claims is a key issue in this action and the fundamental difference underlying the parties' respective claim constructions. Teva's constructions reflect the ordinary and customary *meaning* of the terms as understood by one of skill in the art because they are premised on the benzimidazole compound and the basic inorganic salt being "mixed homogenously together." The ordinary and customary meaning is determined by reviewing the intrinsic evidence of the patent (*i.e.*, the language of the claims, the specification, and the prosecution history).

In the context of the '321 patent, the benzimidazole and the basic inorganic salt must be "mixed homogenously together." First, the language of claim 1 recites "the benzimidazole

[1] U.S. Patent No. 4,628,098 is also at issue in this action. Plaintiffs assert claim 10 of the '098 patent. The parties have agreed that no terms in claim 10 require construction by the Court.

compound being ***in contact*** with the basic inorganic salt ***evenly***." (Ex. 1, col. 18, ll. 30-31 (emphasis added).) By itself, this claim language tells one of ordinary skill that the benzimidazole and the basic inorganic salt must be "in contact" and the contact must be "even[]." The '321 patent specification and prosecution history go on to explain how the benzimidazole and basic inorganic salt may be mixed in different ways, but at the end of the day this must result in a homogenous mixture where the particles are in "even" contact.

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Plaintiffs, in contrast, ignore the "in contact ... evenly" language and advocate a construction that would cover products where there is minimal touching or "mixing" of the benzimidazole and basic inorganic salt. This attempt to stretch the '321 patent claims to cover Teva's ANDA product is not supported by the claim language, specification or prosecution history, and must be rejected.

Similarly, the other disputed terms relate to impermissible attempts by Plaintiffs to stretch the claims beyond their legitimate scope.

Attached as Exhibit 2 for the Court's convenience is a chart reflecting the parties' proposed constructions.

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II. BACKGROUND

To fully understand the parties' respective constructions, it is useful first to review the background to this action:

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B. The '321 Patent

Takeda's development of its lansoprazole product led to the filing of the application that resulted in the '321 patent, which issued on September 3, 1991 under the name "Stabilized Pharmaceutical Composition and its Production." (See Ex. 1.) Claim 1 of the '321 patent claims the homogenous admixture of the lansoprazole compound and various basic inorganic salts:

> A pharmaceutical composition, wherein the composition is made up into tablets or granules and then coated by a coating agent, which comprises an effective amount of the anti-ulcer compound 2-[[3-methyl-4-(2,2,2-trifluoroethoxy-2-pyridyl]methylsulfinyl] benzimidazole, and at least one of the basic inorganic salts of magnesium and calcium selected from heavy magnesium carbonate, magnesium carbonate, magnesium oxide, magnesium hydroxide, magnesium metasilicate aluminate, magnesium silicate aluminate, magnesium silicate, magnesium aluminate, synthetic hydrotalcite, aluminum magnesium hydroxide, precipitated calcium carbonate and calcium hydroxide; the amount of the basic inorganic salt relative to parts by weight of the benzimidazole compound being about 0.3-20 parts by weight; ***the benzimidazole compound being in contact with the basic inorganic salt evenly.***

(Ex. 1, col. 17, l. 63 - col. 18, l. 31 (emphasis added).) Claim 2 of the '321 patent depends from claim 1 and adds the further limitation that "the basic inorganic salt of magnesium is magnesium carbonate." (Ex. 1, col. 18, ll. 32-34.) The parties agree that the claim 2 terms do not require construction beyond the construction issues in claim 1. (See Ex. 2.)[3]

The '321 patent specification provides context for claims 1 and 2 in explaining that "***[t]he composition of the invention*** is prepared by ***homogenously admixing*** the above benzimidazole compound, the basic inorganic salt of magnesium and/or basic inorganic salt of calcium, and the above additives." (Ex. 1, col. 9, ll. 45-49 (emphasis added).) Further, in prosecuting the application that led to the '321 patent, the applicants explained on multiple occasions that there should be "mixing sufficient to establish even contact" between the benzimidazole and the basic inorganic salt. (Ex. 4, Takeda-739814.)

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[3] During the course of this action, Teva has understood Plaintiffs to assert claims 1 and 2 against its proposed lansoprazole products. On September 10, 2007, Teva received Plaintiffs first draft of the Final Pre-Trial Order in which Plaintiffs narrowed their assertions to only claim 2.

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D. Plaintiffs' Attempts to Broaden the Claims of the '321 Patent to Cover Teva's ANDA Product

Plaintiffs ignore their own admissions and representations in the '321 patent and its prosecution history in their attempt to broaden the scope of claims 1 and 2 to cover Teva's product. Plaintiffs no longer agree that the lansoprazole and the magnesium carbonate need to be "in contact ... evenly." Instead, Plaintiffs contend that any contact between the lansoprazole and magnesium carbonate, even if the mixing is only a couple of molecules, is sufficient to fall

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within the patent's scope and constitute infringement as long as there is a "uniformly basic environment" - a concept nowhere found in the patent. (See Ex. 2.) Their construction totally ignores the "evenly" portion of the plain claim language.

III. THE LAW OF CLAIM CONSTRUCTION

"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.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citations omitted). The first step in the claim construction process is to examine the "language of the claim itself." CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1316 (Fed. Cir. 2000). In construing the claims, the Federal Circuit Court of Appeals has "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." Phillips, 415 F.3d at 1312-13 (internal citations omitted).

"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.'" Id. at 1314 (citations omitted). Claim construction thus "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., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004) (citations omitted).

"The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument,' consisting principally of a specification that concludes with the claims. For that reason, claims 'must be read in view of the specification, of which they are a part.'" Phillips, 415 F.3d at 1315 (citations omitted). As the Federal Circuit stated in Vitronics Corp. v. Conceptronic, Inc., the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The Phillips court also held that a court "should also consider the patent's prosecution history, if it is in evidence." 415 F.3d at 1317 (citations omitted). "The prosecution history, which we have designated as part of the 'intrinsic evidence,' consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." Id. (citations omitted). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. (citations omitted). "Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent." Id.

Finally, while the Federal Circuit has emphasized the importance of intrinsic evidence in claim construction, courts also may rely on extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Phillips, 415 F.3d at 1317 (citations omitted). Such extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language,'" Id. at 1317 (internal citations omitted), and may only be used "to help the court come to a proper understanding of the claims." Vitronics, 90 F.3d at 1584. Extrinsic evidence "may not be used to vary, contradict, expand, or limit the claim language."

Novartis Pharms. Corp. v. Abbott Labs., 375 F.3d 1328, 1335 (Fed. Cir. 2004) (citations omitted).

IV. TEVA'S PROPOSED CONSTRUCTIONS FOR CLAIM 1 OF THE '321 PATENT

Claim 1 of the '321 patent contains four terms which the parties agree require construction by the Court, and two additional terms ("granule" and "basic inorganic salt") which Plaintiffs seek to construe but Teva maintains require no construction. To the extent that the Court decides to construe the term "granule," Teva has provided proposed construction for that term. With respect to "basic inorganic salt," Teva maintains that such term does not require construction and has provided no alternative construction. Because the proper construction of the phrase "in contact ... evenly" is at the crux of the parties' disagreement, that construction is addressed first. This limitation, of course, must be viewed in the context of the language of the claims as a whole.

A. "the benzimidazole compound being in contact with the basic inorganic salt evenly."

Teva's Construction: the benzimidazole compound and the inorganic salt are mixed homogenously together.

The phrase "the benzimidazole compound being in contact with the basic inorganic salt evenly" should be construed to mean "the benzimidazole compound and the inorganic salt are mixed homogenously together." This homogenous admixture must be in the specified weight ratio of 0.3-20 parts by weight of the basic inorganic salt to the benzimidazole compound. As discussed in Section D below, only the particles that are "in contact ... evenly" may be counted when determining whether the weight ratio is met.

One of ordinary skill in the art would understand from the claim language itself that the benzimidazole and the basic inorganic salt are "in contact" and the contact must be "even[]."

The next step in construction of the phrase is to review the '321 patent specification and prosecution history to determine what constitutes "even" contact in the context of the patent.

1. The inventors emphasized homogenous mixing to achieve even contact in the '321 patent specification.

The '321 specification plainly describes the benzimidazole compound and the basic inorganic salt as being mixed homogenously together. (See Ex. 1, col. 9, ll. 45-52, 56-66 and col. 10, ll. 19-24.) Indeed, the applicants for the patent disclosed no way to achieve the claimed even contact *other* than homogenous mixing.

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For instance, the '321 patent states, "***The composition of the invention*** is prepared by ***homogenously admixing*** the above benzimidazole compound, the basic inorganic salt of magnesium and/or basic inorganic salt of calcium, and the above additives." (Ex. 1, col. 9, ll. 45-49 (emphasis added).)[5] In doing so, the specification does not limit its description of the alleged invention to a preferred embodiment; instead, it describes the homogenous admixture as "the invention." As Teva's expert Dr. Chambliss explained, one of ordinary skill in the art would understand from that passage that the benzimidazole and the basic inorganic salt of the invention are mixed homogenously together. (See Ex. 8, p. 24.)[6] Indeed, others of skill in the art have used the term homogenously when discussing the relative location of ingredients in a pharmaceutical product. (See Ex. 9, p. 586) ("A matrix device, as the name implies, consists of drug dispersed homogenously throughout a polymer matrix as represented in Fig. 7.")

[5] The '321 specification's use of homogenously to describe the "even" contact is consistent with the applicable dictionary definition of the term "evenly" as "equally; uniformly; as, *evenly* balanced." (See Ex. 7.)

Plaintiffs' expert Dr. Stephen Byrn admits that the '321 patent describes a "homogenous admixture of a benzimidazole compound and a basic inorganic salt." (See Ex. 14, ¶ 72B.) His attempt to say that non-homogenous mixtures also meet the claim limitation confuses the fact that the patent permits different methods of mixing so long as a homogenous mixture results.

The '321 specification explains that the method of admixing the benzimidazole compound and the basic inorganic salt is optional, but that ***the admixing itself is not optional***:

> The method of admixing is optional if the benzimidazole compound can finally be in contact with the basic inorganic salt of magnesium and/or of calcium evenly. Thus, for example, the additives ***may be admixed*** with a ***mixture*** of the benzimidazole compound and the basic inorganic salt of magnesium and/or calcium as prepared by preliminary ***admixing***, or the basic inorganic salt of magnesium and/or calcium may be added to a ***mixture*** of the benzimidazole compound and the additives as prepared by preliminary ***admixing***.

(Ex. 1, col. 9, ll. 56-66 (emphasis added).) This passage underscores the importance of admixing the ingredients to achieve even contact (*i.e.*, a homogenous admixture) between the lansoprazole and inorganic salt. The only aspect of the admixing that the specification identifies as optional is the order in which the ingredients are added to the mixture.

Even the Examples in the '321 patent make clear that the benzmidazole compound and the basic inorganic salt are required to be homogenously mixed. For instance, Example 5 discloses that the ingredients were "mixed well" (Ex. 1, col. 13, l. 54) and Example 8 describes the ingredients as being "thoroughly mixed together." (Ex. 1, col. 14, l. 46.) (See also Ex. 1, Example 1, col. 12, ll. 57-59; Example 3, col. 13, ll. 25-27; Example 5, col. 13, ll. 54-57; and Example 8, col. 14, ll. 44-47.)

2. Homogenous mixing to achieve even contact was repeatedly emphasized in the prosecution history.

The prosecution history for the '321 patent further supports Teva's construction of the phrase "in contact ... evenly" limitation. That limitation originally was not included in the claims

of the '321 patent; the applicants added the phrase by amendment to overcome an Examiner's rejection. (See Ex. 10, Takeda-739673.) The Amendment underscores the importance of homogenous admixing in the purported invention:

> The importance of the ***even distribution of the basic inorganic salt*** of the present compound is demonstrated by the experimental information presented herewith under 37 C.F.R. 1.132.... In Table 1 of the [D]eclaration [of Shin-ichiro Hirai], it is shown that when the [guidelines for content uniformity set forth in United States Pharmacopeia, 21st revision[7]] are met, each individual unit will have an ***even contact between the benzimidazole compound and the included inorganic salt*** which leads to a stabilization not shown to be expected in the prior art.

(Ex. 10, Takeda-739674-75 (emphasis added).) The applicants defined "an even or homogenous mixture" as being "when each individual unit is within 6 percent of the relative standard deviation.... [When this parameter is met,] each individual unit will have an even contact between the benzimidazole compound and the included inorganic salt which leads to a stabilization not shown to be expected in the prior art." (Id.) Later in prosecution, the applicants again relied upon the statements in the Hirai Declaration in support of patentability, stating that "[i]nadequate mixing, resulting in uneven contact, yielded unstable products." (Ex. 12, Takeda-739757.)

Ultimately, the applicants were forced to appeal the patentability of their purported invention. During the appeals process, the applicants repeatedly emphasized that the claimed ingredients must be mixed sufficiently for the benzimidazole compounds and inorganic salt to be in "even" contact. (See id., Takeda-739755-56 ("No evidence of record suggests why one of ordinary skill would infer that the Rainer et al. antacids should be ***mixed evenly*** with the benzimidazole derivatives.") (emphasis added); Ex. 4, Takeda-739814 ("[T]he Rainer et al.

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[7] The United States Pharmacopeia is a public standards-setting authority for prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. (See Ex. 11.)

reference does not disclose or suggest any mixing of antacids with the picoline derivatives discovered by Rainer et al., ***much less mixing sufficient to establish even contact***.... The present record fails to establish any reason why the antacids would have to be mixed at all..., ***much less any reason for continuing the mixing to the extent that even contact is obtained***.") (emphasis added); Ex. 13, Takeda-739832 ("[T]he question is not whether the salts are known excipients, but rather whether it would have been obvious ***to mix the salt with the active ingredient so as to provide even contact with the active ingredient, as required by the present claims***.") (emphasis added).) While the Board of Appeals and Patent Interferences ultimately did not rely on these representations in its ruling on the application for the '321 patent, these admissions constitute strong evidence undercutting Plaintiffs' arguments before this Court.

Plaintiffs take the position that any amount of contact between the benzimidazole and the basic inorganic salt, no matter how small, satisfies the "in contact ... evenly" limitation. (See Ex. 2; see also Ex. 14, ¶ 72.) This despite the repeated references to homogenous mixing in the '321 specification and prosecution history. Such a construction lacks substantiation and should not be adopted by the Court.

B. "A pharmaceutical composition..."

> *Teva's Construction*: The mixture of lansoprazole with a basic inorganic salt of magnesium and/or calcium, which may contain any necessary additives that are used to make the tablet or granules but does not include any excipients used for coating the pharmaceutical composition.

The debate regarding the construction of the term "A pharmaceutical composition" further reflects Plaintiffs' attempts to broaden the claims beyond their proper scope in hopes of establishing infringement at trial. Like the prior construction regarding "in contact ... evenly,"

the mixing of the benzimidazole and the basic inorganic salt underlies the parties' proposed constructions of "pharmaceutical composition."

This term has no single accepted meaning to those of ordinary skill in the art. A person of ordinary skill in the art thus would look to the context in which "pharmaceutical composition" is used in the '321 patent to determine its proper meaning. Viewed in context, the term should be construed to mean "the mixture of lansoprazole with a basic inorganic salt of magnesium and/or calcium, which may contain any necessary additives that are used to make the tablet or granules but does not include any excipients used for coating the pharmaceutical composition." This is in contrast to Plaintiffs' construction that the "pharmaceutical composition" should be the final dosage form "suitable for administration to a patient." (See Ex. 2.)

The analysis of this term begins with the claim language, which makes clear that the "pharmaceutical composition" includes the admixture of the lansoprazole, basic inorganic salt, and any necessary additives that are ***then*** made into a tablet or granule and coated by a coating agent (*i.e.*, excipient). (See Ex. 1, col. 17, l. 63 - col. 18, l. 31 (emphasis added).)

The '321 specification goes on to explain that "the composition of the invention is prepared by homogenously admixing the above benzimidazole compound, the basic inorganic salt of magnesium and/or basic inorganic salt of calcium, and the above additives." (Id., col. 9, ll. 45-48.) The patent identifies additives that can be part of the pharmaceutical composition to be vehicles, binders, disintegrating agents, surfactants, antioxidants, and lubricants. (Id., col. 9, ll. 32-44.) The "pharmaceutical composition" plainly does ***not*** include coating layers, which are described separately in claim 1 and the specification as being used to coat the pharmaceutical composition. (Id., col. 10, ll. 6-7.)

The '321 specification further states that the pharmaceutical composition of the invention can be admixed with other excipients for oral administration. "The pharmaceutical composition of the invention can be orally administered for the treatment of digestive ulcers in mammals in admixture with pharmacologically acceptable carriers, vehicles, diluents, and so forth and in the form of capsules, tablets, granules, and some other dosage forms, as mentioned hereinabove." (Id., col. 10, ll. 43-48.) As Dr. Chambliss explains, "this discussion of the admixture of the pharmaceutical composition and excipients would not make sense if the pharmaceutical composition existed in a final dosage form for administration to patients (as Plaintiffs suggest) because the excipients already would have been admixed in the final form." (Ex. 8, p. 10.)

The prosecution history likewise supports Teva's construction. The phrase "pharmaceutical composition" was included in the patent claims as filed. During prosecution, however, the claim was amended to include the language "wherein the composition is made up into tablets or granules and then coated by a coating agent." (See Ex. 15, Takeda-739684.) This underscores the fact that the "pharmaceutical composition" does not include the coating layers. The coating must be applied after the tablet or granule is formed from the pharmaceutical composition.

In short, each use of the phrase "pharmaceutical composition" in the '321 patent and the prosecution history support the construction of the phrase to cover only the mixture of lansoprazole, basic inorganic salt, and any necessary additives but not any coating layers.

C. "coated by a coating agent"

Teva's Construction: the tablets or granules containing the pharmaceutical composition are coated with a material that masks the taste or provides enteric or sustained release properties.

The differences in the parties' constructions of the phrase "coated by a coating agent" reflects Plaintiffs' attempt to sidestep the "pharmaceutical composition" limitation addressed above. The phrase "coated by a coating agent" should be construed to mean "the tablets or granules containing the pharmaceutical composition are coated with a material that masks the taste or provides enteric or sustained release properties." This construction is supported by the claim language, the '321 specification, and the prosecution history.

Plaintiffs' construction, which only refers to "covering a tablet or granule with a pharmaceutically acceptable coating" effectively reads out the requirement that the "pharmaceutical composition" must be made into tablets or granules that are then coated by the coating agent. (See Ex. 2.)

Claim 1 states that "the ***composition*** (referring to the pharmaceutical composition) ***is made up into tablets or granules and then coated by a coating agent....***" (Ex. 1, col. 17, l. 63 - col. 18, l. 31 (emphasis added).) One of ordinary skill in the art would understand this plain claim language to require that the "pharmaceutical composition" must be made into tablets or granules before any coating occurs. (See Ex. 8, p. 15.) The '321 specification explains that "[t]ablets, granules and fine granules may be coated by a per se known method for the purpose of masking the taste or providing them with enteric or sustained release property." (Ex. 1, col. 10, ll. 3-6.)

The Examples in the '321 patent also describe the process of coating the tablets or granules. Example 7 describes "coating the granules obtained in Example 2 [which contain the

pharmaceutical composition] with an enteric coating composition...." (Id., col. 14, ll. 18-21.) Example 9 likewise describes "coating the granules obtained in Example 8 with an enteric coating composition...." (Id., col. 15, ll. 3-6.) Example 11 also describes "coating the granules obtained in Example 10 with an enteric coating composition...." (Id., col. 15, ll. 63-66.)

Finally, as explained above in defining the term "pharmaceutical composition," the original application for the '321 patent did not contain the claim language "coated by a coating agent." The applicants amended the original claim to include the phrase "wherein ***the composition*** is made up into tablets or granules and then ***coated by a coating agent.***" (Ex. 15, Takeda-739684 (emphasis added).) The applicants went on to distinguish their purported invention on the basis that "none of the references cited against the claims suggest an anti-ulcer compound which can be made into tablet form and then coated by a coating agent." (Id., Takeda-739689.)

D. "the amount of the basic inorganic salt relative to parts by weight of the benzimidazole compound being about 0.3-20 parts by weight"

Teva's Construction: the weight of the basic inorganic salt that is in even contact with the benzimidazole falls between about 0.3 to 20 parts by weight.

In their proposed construction, Plaintiffs attempt to broaden the above limitation so that any amount of the lansoprazole and basic inorganic salt particles can be counted towards the claimed ratio, regardless of whether they are "in contact ... evenly" as required by the language addressed in Subsection A.

The phrase "the amount of the basic inorganic salt relative to parts by weight of the benzimidazole compound being about 0.3-20 parts by weight" should be construed to mean "the weight of the basic inorganic salt that is ***in even contact*** with the benzimidazole falls between about 0.3 to 20 parts by weight." The '321 patent uses this phrase to explain that the weight to

weight ratio of the basic inorganic salt in contact with the benzimidazole compound can range *from* 0.3 parts basic inorganic salt per 1 part benzimidazole compound *to* 20 parts basic inorganic salt per 1 part benzimidazole compound in the pharmaceutical composition. (See Ex. 1, col. 9, ll. 25-31.)

This ratio does not apply to the amount of a basic inorganic salt contained *anywhere* in a final dosage form. Rather, the claimed invention requires that the benzimidazole compound (*i.e.*, lansoprazole) and the basic inorganic salt be homogenously mixed together. (See Ex. 1, col. 9, ll. 45-48.) Each Example in the '321 patent satisfies this ratio, because in each Example the benzimidazole compound and the basic inorganic salt of magnesium or calcium are homogenously mixed together in the pharmaceutical composition. (See id., col. 12, l. 55 - col. 16, l. 15.)

Consequently, Plaintiffs' construction, in which this term means the ratio of all basic inorganic salt present in the final dosage form to all benzimidazole compound present in the final dosage form (see Ex. 2; see also Ex. 14, ¶ 70) plainly is improper.

E. "granule"

> *Teva's Construction*: An irregularly shaped or a spheroid shaped mass of particles made up of a pharmaceutical composition, which also may contain additives.

Teva does not believe the term "granule" needs to be construed by the Court as a person of ordinary skill in the art would understand its meaning. Moreover, interpretation of this term does not affect any of the infringement or invalidity issues involved in this action.[8]

[8] If the Court disagrees and believes a construction is necessary, the term "granule" should be construed to mean "an irregularly shaped or a spheroid shaped mass of particles made up of a pharmaceutical composition, which also may contain additives." Plaintiffs' construction, which construes a granule as referring to a pellet, is imprecise, as "one of ordinary skill in the art ... would not call a granule made by wet or dry granulation a 'pellet.'" (Ex. 8, p. 14.)

F. "basic inorganic salt"

Teva's Construction: the basic inorganic salts listed in claim 1.

Teva does not believe the term "basic inorganic salt" needs to be construed by the Court. A person of ordinary skill in the art would understand the term to be defined by the words of claim 1 which provides the list of basic inorganic salts covered:

> ...and at least one of the basic inorganic salts of magnesium and calcium selected from heavy magnesium carbonate, magnesium carbonate, magnesium oxide, magnesium hydroxide, magnesium metasilicate aluminate, magnesium silicate aluminate, magnesium silicate, magnesium aluminate, synthetic hydrotalcite, aluminum magnesium hydroxide, precipitated calcium carbonate and calcium hydroxide...

(Ex. 1, col. 17, l. 63 – col. 18, l. 31.) Despite this intrinsic evidence, Plaintiffs seek to have the Court construe a basic inorganic salt as "a proton acceptor salt containing an inorganic element." (See Ex. 2.) Such a construction would serve no purpose as none of the issues in this case turn on the definition of a basic inorganic salt. Thus, Teva submits that the Court should not construe the term "basic inorganic salt."

V. CONCLUSION

For the foregoing reasons, Teva requests that the Court adopt its proposed claim constructions for the four terms in claim 1 of the '321 patent that require construction and hold that the terms "granule" and "basic inorganic salt" do not require construction.

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Teva Pharmaceutical Industries Ltd.

CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on September 11, 2007, I caused to be electronically filed a true and correct copy of the foregoing sealed document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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CERTIFICATE OF SERVICE

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