**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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

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

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Teva submits this response to Plaintiffs' opening claim construction brief. Plaintiffs' arguments largely are built on mischaracterizations of Teva's positions and use of extrinsic evidence that is contrary to the disclosures in the '321 claim language, specification and prosecution history.

As explained in Teva's opening brief, the key difference in the parties' constructions concerns their respective positions on the admixture of the benzimidazole compound and the basic inorganic salt required by the '321 patent claims. (D.I. 131, Teva's Opening Br., pp. 1-2.) Teva's constructions are grounded in intrinsic evidence which makes clear that, regardless of the method used to prepare the lansoprazole formulation, the final product must be a homogenous admixture of the benzimidazole compound and the basic inorganic salt to fall within the scope of the patent. That homogenous admixture is the product that Takeda chose to claim in the '321 patent, and Plaintiffs cannot now expand the claims to encompass Teva's ANDA product in which there is no mixture of the benzimidazole and the basic inorganic salt.

Plaintiffs retreat from the intrinsic evidence and, instead, broadly define the '321 claim terms using extrinsic evidence such as dictionary definitions, an unsupported expert declaration, and a construction from an unrelated litigation.[1] For instance, Plaintiffs rely on dictionary definitions and a declaration from their expert Stephen Byrn to construe the "in contact ... evenly" limitation such that two things can be considered in even contact without physically

[1] Plaintiffs use half of their Preliminary Statement posturing about the effort spent developing the lansoprazole compound claimed in claim 10 of U.S. Patent No. 4,628,098. The structure of the lansoprazole compound is not the subject of the '321 patent. Moreover, while Teva disputes Plaintiffs' statements regarding the lansoprazole compound, any discussion of the '098 patent is irrelevant to the claim construction process because, as explained on p.1 of Teva's opening brief, the parties agree that no terms in claim 10 of the '098 patent require construction by the Court. Teva thus does not address Plaintiffs' statements about the lansoprazole compound or the '098 patent here.

touching. Such a construction reads the limitation out of the claim. Moreover, it ignores language to the contrary in both the '321 specification and prosecution history.

The Federal Circuit has emphasized that claim construction must focus upon how a person of skill in the art, upon reading the patent documents, would understand the claim language. Phillips v. AWH Corp., 415 F. 3d 1303 (Fed. Cir. 2005). This paradigm is in place to ensure that claim terms are construed in the context of the patent and not how a patentee later wishes it had drafted the claims. Teva invites the Court to review the '321 patent documents and see for itself that those documents firmly support the constructions proposed by Teva.

## I. TEVA'S CONSTRUCTION OF THE "IN CONTACT ... EVENLY" LIMITATION IS GROUNDED IN THE INTRINSIC EVIDENCE OF THE '321 PATENT

As explained in Teva's opening brief, the "in contact ... evenly" claim limitation is properly construed to mean that the benzimidazole compound and the basic inorganic salt are present in a homogenous admixture. (Teva's Opening Br., pp. 8-12.) Teva's construction is supported by the '321 claim language, specification, and prosecution history, which demonstrate that the method of mixing the benzimidazole and the basic inorganic salt in the formulation is irrelevant so long as the final product contains a homogenous admixture of these ingredients. This final product is not a preferred embodiment; it is "the invention." (See Ex. 1, col. 9, ll. 45-49.)

Plaintiffs cite selectively to column 9 of the '321 patent in support of their argument that Teva is reading process limitations from the specification into a product claim. (See D.I. 133, Pls.' Opening Br., p. 15.) That argument is incorrect. Col. 9, ll. 56-65, when viewed in full, makes clear that the method (i.e. order) in which the ingredients are mixed is optional so long as the final composition results in the benzimidazole being in contact with the basic inorganic salt evenly (*i.e.*, a homogenous admixture):

> 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.

(See Teva's Opening Br., pp. 10-11 (emphasis added).)

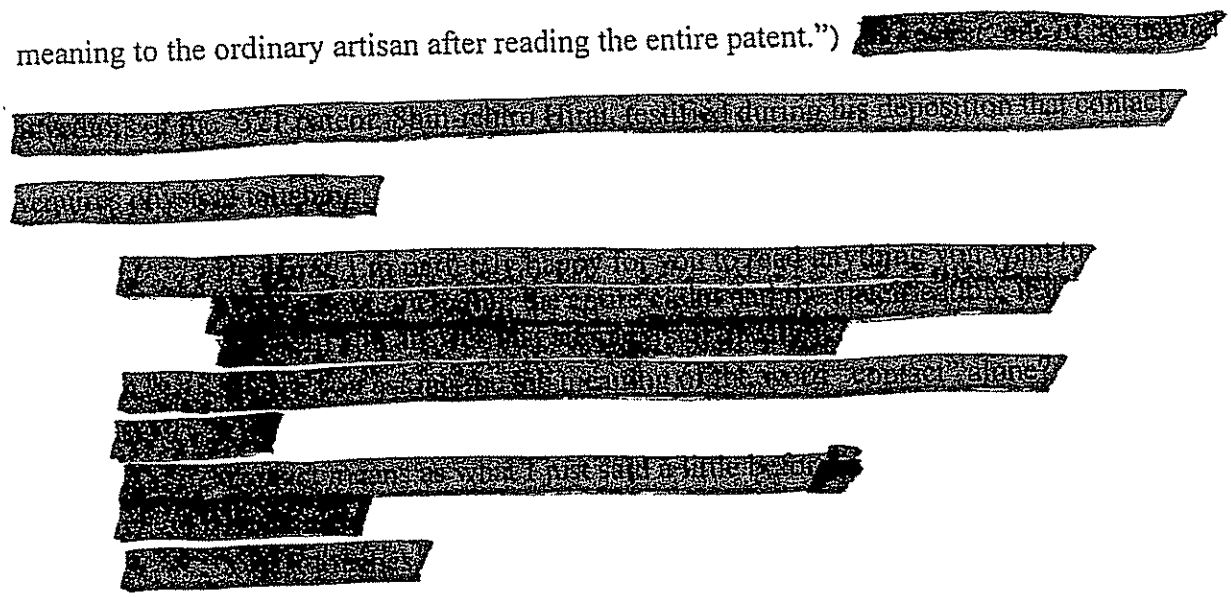
The '321 specification also belies Plaintiffs' assertions that a homogenous mixture of the benzimidazole compound and the basic inorganic salt is not possible in the presence of other components. (See Pls.' Opening Br., p. 18.) Each of the Examples in the '321 patent includes a mixture involving ingredients in addition to the benzimidazole and the basic inorganic salt. Thus, the claimed homogenous mixture plainly is not limited to the benzimidazole and the basic inorganic salt. The fact that the claim was drafted in the "comprising" form supports this conclusion. Claims drafted in the "comprising" form must have the limitations recited but are not limited to them. See Manual of Patent Examining Procedure § 2111.03.

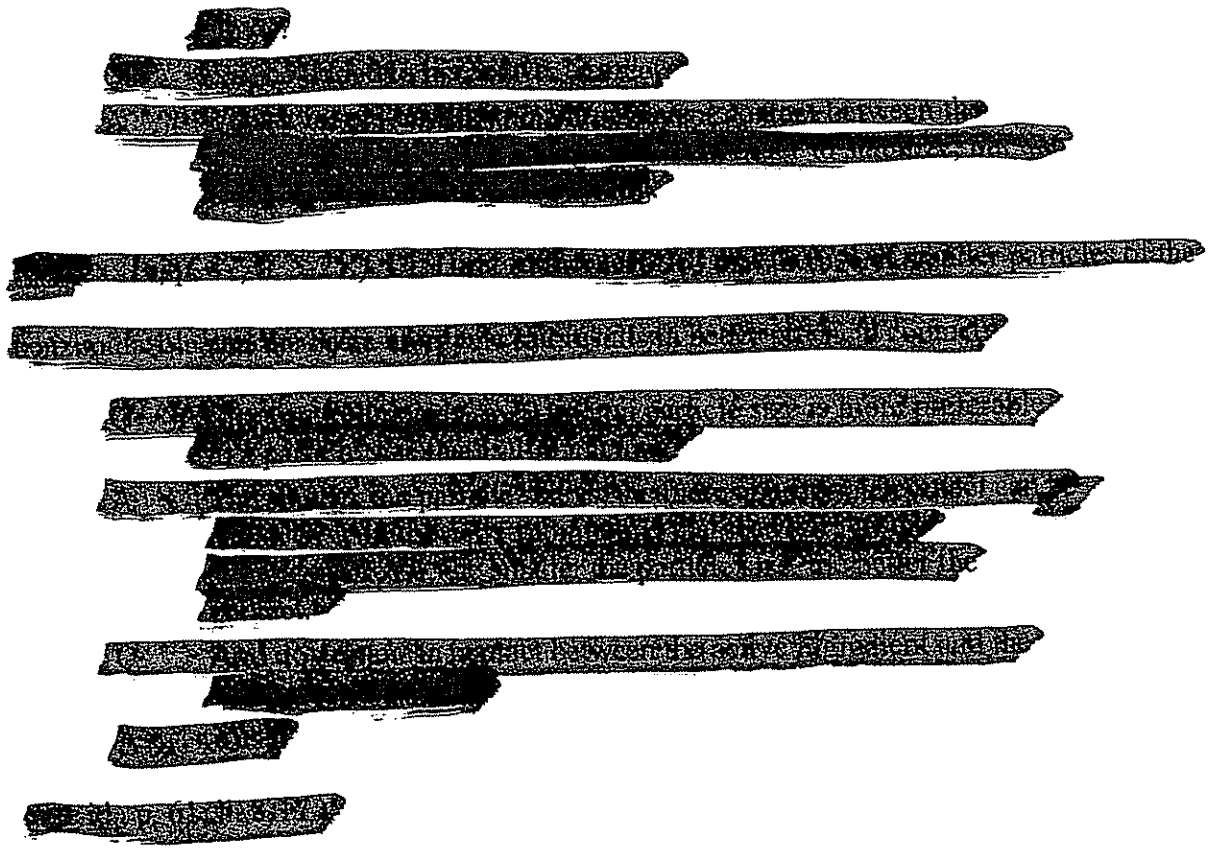
Further, although Plaintiffs suggest that one should look to the prosecution history to construe the "in contact … evenly" limitation (see Pls.' Opening Br., p. 14), Plaintiffs in fact ignore the prosecution history. They fail to cite any of their representations during prosecution that even contact could be achieved only when the claimed product contains a homogenous admixture of the benzimidazole and the inorganic salt. (See Teva's Opening Br., pp. 10-12.)

Plaintiffs' selective citation from the '321 specification and refusal to address the prosecution history is a telling sign that Plaintiffs themselves are aware that their constructions are not supported by the patent documents. Instead, Plaintiffs must rely on the Byrn declaration and dictionary definitions to support a construction that would allow the benzimidazole and the basic inorganic salt to be "in contact … evenly" without physically touching.

Plaintiffs explain that even contact between the benzimidazole and the basic inorganic salt can be achieved if the two components are in "close enough proximity to influence each other" to create "an alkaline environment" or a "microenvironment" that is "uniformly basic." (See Pls.' Opening Br., pp. 16-18; Byrn Decl. ¶¶ 48-51.) None of these phrases appear anywhere in the '321 patent claims, specification, or prosecution history. Furthermore, none of these arguments demonstrate how ***even contact*** would be achieved. A construction that would require only that the benzimidazole and the basic inorganic salt be in close enough proximity to create a "basic environment" effectively reads the words "contact" and "evenly - and thus the entire "in contact … evenly" limitation - out of the '321 claims.

Plaintiffs also rely on the dictionary definitions of "contact" and "even" in support of their argument that the "in contact …evenly" limitation does not require physical touching. (See, e.g., Pls.' Opening Br., pp.16 and 18.) The Federal Circuit has rejected such an approach in favor of a claim construction process that focuses on the intrinsic evidence. See Phillips, 415 F.3d at 1321 ("The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent.")





Plaintiffs mischaracterize the holding in Dow Chemical Co. v. Sumitomo Chemical Co. as establishing that the phrases "homogenous admixing" and "in contact with the basic inorganic salt evenly" must be understood to mean different things because they are both used in the '321 specification. (See Pls.' Opening Br., p. 19 (citing Dow, 257 F.3d 1364, 1377 (Fed. Cir. 2001)).) The Dow court defined two phrases found in a patent specification to have different meanings because to do otherwise "would exclude many of the preferred embodiment experiments." Dow, 257 F.3d at 1377. There is no such issue regarding the '321 patent before this Court. In the '321 patent, *every* embodiment discloses a homogenous admixture of the benzimidazole compound and the basic inorganic salt.

The '321 claims should be construed in light of the intrinsic evidence which discloses a homogenous admixture of the benzimidazole and the basic inorganic salt.[2]

## II. THE INTRINSIC EVIDENCE OF THE '321 PATENT SUPPORTS TEVA'S CONSTRUCTION OF THE TERM "PHARMACEUTICAL COMPOSITION"

Plaintiffs likewise mischaracterize Teva's construction of the term "pharmaceutical composition" as reading process limitations into a product claim. Teva's construction reflects the clear language of claim 1 which states that the "pharmaceutical composition" includes a mixture of the benzimidazole lansoprazole, the basic inorganic salt magnesium carbonate, and any necessary additives that is "made up into tablets or granules and ***then*** coated by a coating agent." (See Ex. 1, col. 17, l. 63 – col. 18, l. 31 (emphasis added).) The claim language thus expressly excludes coating layers from the "pharmaceutical composition."

The '321 specification explains that the coating layers are used to coat the "pharmaceutical composition" and are not part of the composition. (See Ex. 1, col. 10, ll. 6-7; see also Teva's Opening Br., p. 13.) The specification also states that the pharmaceutical composition can be admixed with other excipients (i.e. coating agents), a statement that does not make sense if the pharmaceutical composition already contains the coating layers. (See Ex. 1, col. 10, ll. 43-48; see also Teva's Opening Br., p. 14.)

The prosecution history further demonstrates that the coating layers are not part of the "pharmaceutical composition." As discussed in Teva's opening brief, the term "pharmaceutical composition" was included in the patent claims as filed but the language "wherein the composition is made up into tablets or granules and then coated by a coating agent" was later

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[2] Plaintiffs insert a discussion of Teva's proposed lansoprazole product in support of their construction of "in contact ... evenly." (See Pls.' Opening Br., p. 17.) Teva disputes Plaintiffs' characterizations of Teva's proposed products, but this brief is not the proper time to address those arguments. Teva will demonstrate at trial that its proposed lansoprazole products do not infringe the '321 patent.

added to the claims. (See Teva's Opening Br., p. 14.) Through the addition of this language, the applicants make clear that the composition (in tablet or granule form) is coated by separate coating layers.[3]

Plaintiffs argue that the term "pharmaceutical composition" has a "long-known and well-understood ordinary meaning" that includes coating layers in the composition. (See Pls.' Opening Br., p.4.) In support of their construction, Plaintiffs cite to an unrelated litigation, the Byrn declaration, and dictionary definitions of the word "composition." A construction based on such extrinsic evidence should not be adopted because it is inconsistent with the '321 claim language, specification and prosecution history. See Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (stating that claims should not be construed in a "manner inconsistent with the specification").

Indeed, Plaintiffs' claim that the term "pharmaceutical composition" has been used in more than 40,000 different patents serves to demonstrate that the term should be construed in the context of the '321 patent and not through extrinsic evidence. It would defy common sense that a term is used in the same way in 40,000 patents. For instance, in the unrelated litigation Abbott Laboratories v. Sandoz, Inc., cited by Plaintiffs, the court adopted a construction of "pharmaceutical composition" that is different than the "ordinary meaning" espoused by Plaintiffs in this action. (See Pls.' Opening Br., p. 4 (citing Abbott, __ F. Supp. 2d __, 2007 WL 1141635, at *17) (N.D. Ill. Apr. 16, 2007).) The construction adopted by the Abbott court is consistent with Teva's construction. The Abbott court does not construe "pharmaceutical composition" to include a final dosage form, but only "an aggregated product formed from two or more substances ***for [later] use as a drug in medical treatment.***" (See id. (emphasis added).)

[3] Plaintiffs' citation to previous cases relating to "wherein clauses" are inapplicable in this situation where the clause specifically excludes the coating layers from the "pharmaceutical composition."

## III. THE INTRINSIC EVIDENCE OF THE '321 PATENT SUPPORTS TEVA'S CONSTRUCTION OF THE REMAINING DISPUTED TERMS

### A. "coated by a coating agent"

Plaintiffs' construction of the phrase "coated by a coating agent" effectively reads out the requirement that the "pharmaceutical composition" must be made into tablets or granules that are *then* coated by a coating agent. As discussed previously, such a construction is inconsistent with the claim language, specification, and prosecution history and should not be adopted. (See Section II., supra; see also Teva's Opening Br., pp. 15-16.)

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

Plaintiffs attempt to broaden the claim limitation "the amount of the basic inorganic salt relative to parts by weight of the benzimidazole compound being about 0.3-20 parts by weight" so that any amount of benzimidazole and basic inorganic salt in the final dosage form can be counted towards the claimed ratio. (See Pls.' Opening Br., pp. 13-14.) As discussed in Teva's opening brief, the specification supports Teva's construction that this ratio does not apply to the amount of basic inorganic salt contained *anywhere* in the final dosage form but to the amount that is homogenously mixed with the benzimidazole. (See Teva's Opening Br., p. 17; see also Ex. 1, col. 9, ll. 45-48 & col. 12, l. 55 – col. 16, l. 15.)

### C. "granule"

Teva maintains that the term "granule" in claim 1 does not need to be construed by the Court.[4] (Teva's Opening Br., p. 17.) The interpretation of "granule" does not affect any of the infringement or invalidity issues involved in this action.

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[4] Teva likewise maintains that the term "basic inorganic salt" does not require construction. (See Teva's Opening Br., p. 18.) Plaintiffs now appear to agree, as their opening brief provides no construction despite originally proffering a construction to Teva.

## IV. CONCLUSION

For the foregoing reasons, and those set forth in Teva's opening brief, Teva submits that its proposed constructions are supported by the intrinsic evidence of the '321 patent and should be adopted by the Court.

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