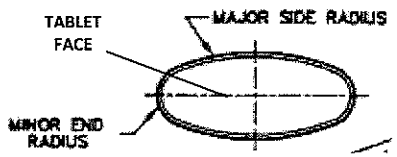
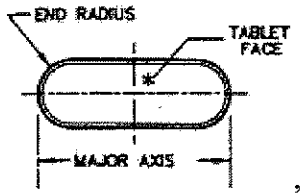
Exhibit B

JOINT CLAIM CONSTRUCTION CHART FOR U.S. PATENT NO. 6,165,513[1]

Warner Chilcott Co., LLC v. Teva Pharm. USA, Inc., (D. Del. 08-CV-627-LPS) (CONSOLIDATED)
April 19, 2011

Claims	Term	Plaintiffs' Proposed Construction and Intrinsic Evidence	Teva's Proposed Construction and Intrinsic Evidence
Asserted claim 1 (from which all other asserted claims depend)	Oval shaped, about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.075 to about 0.3 inches in thickness	**Plaintiffs' Proposed Construction** A form including but not limited to oval, modified oval, or caplet shaped forms, with a length (at its longest point) of approximately 0.23 to approximately 0.85 inches, a width (at its widest point) of approximately 0.11 to approximately 0.4 inches, and a thickness (at its thickest point) of approximately 0.075 to approximately 0.3 inches. **Specification** "The present invention is directed to a pharmaceutical formulation in an oral generally ***oval shaped***, including but not limited to ***oval, modified oval and caplet shaped form***." '513 Patent, col. 2, ll. 3-5 (emphasis added). "Particularly preferred are ***modified oval***	**Teva's Proposed Construction** "oval shaped" means an oral dosage form whose outline in its plan view is constructed from two pairs of different radii as in  and does not include dosage forms which are capsule shaped (as depicted below) in a plan view.  the dimensional limitation should be construed according to its plain meaning.

[1]Apotex Inc. and Apotex Corp. (collectively "Apotex") were not sued on the '513 patent, but brought declaratory judgment actions of non-infringement and invalidity of the '513 patent (C. A. No. 09-143, D.I. 11). Apotex believes that the noninfringement issues in its declaratory judgment action can most likely be resolved after a finding of the Court that the term "oval shaped" used in the '513 patent claims does not include round tablet shapes. Apotex believes, after conferring with Plaintiffs' counsel, that Plaintiffs do not dispute that the "oval shaped" does not mean round. Accordingly, Apotex does not believe there are any issues of claim construction in need of briefing at this time as between Plaintiffs and Apotex. Apotex takes no further position on the issues raised in Teva's brief.

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		shaped, film coated oral dosage forms." '513 Patent, col. 2, ll. 43-44 (emphasis added). "The ***generally oval tablets*** have the following preferred dimensions: length from about 0.23 to about 0.85 inches preferably from about 0.25 to about 0.75 inches, width from about 0.11 to about 0.4 inches preferably from about 0.15 to about 0.35 inches, and a thickness of from about 0.075 to about 0.3 inches, preferably from about 0.10 to about 0.25 inches. The ***modified oval tablet*** as shown in FIGS. 1-3 may have the following dimensions: a length of about 0.455 inches, width of about 0.225 and a thickness of approximately 0.157 inches." '513 Patent col. 6, ll. 13-22 (emphasis added). Example 1 discloses ***modified oval***, film-coated risedronate tablets. '513 Patent col. 8, ll. 61-67; col. 9, ll. 1-33. Example 2 discloses ***caplet shaped***, film-coated alendronate tablets. '513 Patent col. 9, ll. 34-67; col. 10, l. 1. Example 3 discloses ***oval*** risedronate tablets. '513 Patent col. 10, ll. 3-67; col. 11, ll. 1-31.	**INTRINSIC EVIDENCE** ***Prosecution History.*** **U.S. Patent Application 09/095,322 (filed Jun. 10, 1998) (Ex. B at PGOAM 0174567-8):** What is claimed is: 1. A novel oral dosage form to be delivered to the stomach said dsoage[sic] form comprising a safe and effective amount of an active ingredient selected from the group consisting tetracycline antibiotics, iron preparations, quinidine, nonsteroidal anti-inflammatory drugs, alprenolol, ascorbic acid, captopril, theophylline, zidovoudine, bisphosphonates or mixtures thereof and pharmaceutically-acceptable excipients, wherein said oral dosage form is a generally oval form and film coated to facilitate rapid esophageal transit and avoid irritation in the mouth, buccal cavity, pharynx, and esophagus. 11. A dosage form according to Claim 10 wherein said dosage form is a modified oval. 13. A novel oral dosage form according to Claim 12 wherein said dosage form is a modified oval.

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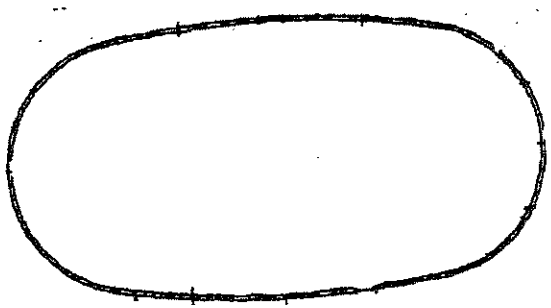
		Prosecution History During prosecution, the Examiner rejected then-pending claims as indefinite because, among other reasons, the terms "generally" and "modified" are relative. Ex. B, Prosecution History of U.S. Application No. 09/095,322, Office Action (Sept. 13, 1999) at PGOAM174588. In response to those indefiniteness rejections, Applicants deleted the recitation of the relative term "generally" from claim 1 and cancelled dependent claims 5, 11, and 13, which recited the relative term "modified." *See* Ex. B, Prosecution History of U.S. Application No. 09/095,322, Response (Mar. 20, 2000) at PGOAM017459-600. Applicants amended claim 1 from "generally oval form" to "oval shaped." *See* Ex. B, Prosecution History of U.S. Application No. 09/095,322, Response (Mar. 20, 2000) at PGOAM017459 (citing the use of "oval shaped" in the specification).	***Id.* at PGOAM 0174570:**  Fig. 1 **Office Action (Sep. 13, 1999) (Ex. B at PGOAM 0174587 to PGOAM 0174592):** ***Claim Rejections — 35 USC § 112*** The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. Claims 1–15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

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			failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. . . . D. In claim 1, the term "generally oval form" is indefinite. The term "generally oval" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. . . . F. In claims 5, 11, and 13, the terms "modified oval or caplet shape" and "modified oval" are indefinite. These terms are relative terms which render the claims indefinite. These terms are not defined by the claims, and the specification does not provide a standard for ascertaining the requisite degree and/or type of modification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. . . . ***Claim Rejections — 35 USC § 103*** 9. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dansereau et al., US. Pat. No. 5,622,721 (4/97: filed 11/91) and/or Bechard, US.

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			Pat. No. 5,431,920 (7/95) in view of Sadek, U.S. Pat. No. 5,146,730 (9/92) and Parekh et al., U.S. Pat. No. 5,658,589 (8/97). Dansereau et al. disclose oral dosage delivery formulations of "polyphosponic acid" compounds (e.g. see col. 1, lines 25-30), such as risedronate (e.g. see abstract), in amounts within the scope of the present invention (e.g. 0.25%-40%: see col. 5, lines 60-70); to which the oral dosage delivery forms comprise tablets/capsules (coated Of uncoated) comprising active ingredients (coated/uncoated), the delivery forms being "generally oval" within the scope of the presently claimed invention. The cellulose polymer coat or film "inherently" is soluble at pH 1.2-5. E.g. see bottom of col. 11-top of col. 12; col. 13, Examples II-IV (col. 15-17) and patent claims 1-2, and 12-22. Similarly, Bechard disclose an enteric-coated oral dosage delivery form comprising an bisphosphonic acid compound (e.g. alendronate, pamindroate, risedronate) which comprises a "generally oval" tablet or coated/uncoated granules containing the active ingredient in which the subcoat and/or the outer coating comprises a cellulose compound which inherently is soluble at pH 1.2-5. E.g. See Abstract; col. I, col. 5-6; Examples 1-6; patent claims 1-7. The Dansereau or Bechard references, taken separately or in combination, differ from the presently claimed invention only with regard to their failure to explicitly disclose dosage form (e.g. tablet/caplet)

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			dimensions e.g. .23 - .85 inches/.11-.4inches/.075-.3 inches as claimed in claim 4 for length width and height. However, the use of oval tablets and caplets with modifiable dimensions, within the scope of the presently claimed invention, for delivery of pharmaceutically active ingredients is conventionally known within the art. See e.g. Sadek et al. caplet type tablets (e.g. Abstract; col. 8, ; col 15, lines 20-40); and Parekh et al. capsules (e.g. Abstract; Figures 1-5; col. 2; col. 5-6; Examples and patent claims. Additionally, as disclosed by Sadek and Parekh references, the dimensions can be modified in order to further optimize delivery. Accordingly, the use of conventional "oval" oral delivery formulations with dimensions as disclosed in the prior art (e.g. Sadek and/or Parekh) for use in the Dansereau and/or Bechard reference oral delivery compositions would have been obvious to one of ordinary skill in the art who wishes to optimize oral delivery as disclosed in the Sadek and/or Parekh references. **Remarks to Amendment (Mar. 20, 2000) (Ex. B at PGOAM 0174597- PGOAM 0174605).** ***Amendment to the claims*** Kindly cancel Claims 4-6, 11, and 13-15 without prejudice. Kindly amend the following claims:

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			1. (Once amended) 1. [A novel] oral dosage form [to be delivered to the stomach said dsoage form] comprising a safe and effective amount of a bisphosphonate [an active ingredient selected from the group consisting tetracycline antibiotics, iron preparations, quinidine, nonsteroidal anti-inflammatory drugs, alprenolol, ascorbic acid, captopril, theophylline, zidovoudine, bisphosphonates or mixtures thereof and pharmaceutically-acceptable excipients,] wherein said oral dosage form is [a generally] oval [form] shaped, about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.075 to about 0.3 inches in thickness and said oral dosage form is film coated to facilitate rapid esophageal transit and avoid irritation in the mouth, buccal cavity, pharynx, and esophagus wherein said film coating allows for delivery of said bisphosphonate to the stomach. . . . ***I. Claim Rejections — 35 USC § 112, second paragraph*** . . . The definiteness of a claim must be evaluated in light of the teachings of the prior art. MPEP § 2173.02. By this amendment, the term generally," which rendered the term "generally oval form"

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			relative, has been removed from Claim 1. Claim 1 is now directed to oral dosage forms that are "oval shaped." Support for this amendment to Claim 1 is found in the specification at page 7, lines 10-11. Applicants respectfully assert that this claim language, when read in light of the teachings of the prior art, is clear to one of ordinary skill in the art of tablet design and manufacture. Turning to the teachings of the prior art, Applicants have included herewith a copy of Sections 1 and 3 from The Tableting Specification Manual, 4th Ed. (1995) for the Examiner's review. The Tableting Specification Manual is published by the American Pharmaceutical Association and contains the "only established standards in the world for tablet design and tablet tooling manufacturing." Tableting Specification Manual at ix. Generally, tablets fall into one of two categories: round or shaped. Tableting Specification Manual at 4 and 45. Both round and shaped tablets are described in detail in Section 3. Applicants direct the Examiner's attention to Section 3 at page 48 wherein the term "oval" is defined under the heading "Shaped Tablet Terminology." Oval is defined as follows: "Although an oval may resemble an elliptical shape, it is formed using only two radii: the major side radius and the minor end radius." The "major side radius" and the "minor end radius" are illustrated in Figure 23 on the previous page (Illustration B). These two radii are further illustrated on page 583 of Pharmaceutical Dosage forms, 2nd Ed. (2 Herbert

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			Lieberman et al., Pharmaceutical Dosage Forms (2nd Ed. 1990). Applicants have included herewith a copy of Chapter 7, the chapter containing page 583, for the Examiner's convenience. In that illustration, "R" represents the Radius of the Long Side or the "major side radius," and "r" represents the Radius of the Small end or the "minor side radius." From these two illustrations one can see which two radii to measure to determine whether or not a given tablet is "oval shaped." These two radii are easily measured using methods known to one of ordinary skill in the art. In light of these prior art teachings, Applicants respectfully assert that the claim term "oval shaped" has an art-recognized meaning and is clear to one of ordinary skill in the art. In addition, Applicants have amended Claim I such that specific length, width, and thickness dimensions have been included. Thus, Claim I is further limited to oral dosage forms that are "oval shaped, about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.075 to about 0.3 inches in thickness." Like radii, length, width, and thickness are easily measured using methods known to one of ordinary skill in the art. In light of the prior art teachings and Applicants' specification, Applicants respectfully assert that one of ordinary skill in the art can determine whether or not an oral dosage form is oval shaped, and if so, whether or not it is within Applicants' claimed dimensions. Thus, the boundaries of the invention are clear to one

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			of ordinary skill in the art. Accordingly, Applicants respectfully assert that the rejection has been overcome by the instant amendment. . . . ***IV. Claims Rejection under 35 U.S.C. § 103*** Claims 1-15 are stand "rejected under 35 U.S.C. 103(a) as being unpatentable over Dansereau et al., U.S. Patent No. 5,622,721 (4/97: filed 11/91) and/or Bechard, U.S. Patent No. 5,431,920 (7/95) in view of Sadek, U.S. Patent No.5, 146,730 (9/92) and Parekh et al., U.S. Patent No. 5,658,589 (8/97). Applicants respectfully traverse the rejection. A *prima facie* case of obviousness requires that the prior art references teach or suggests all claim limitations and that there be "some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings." MPEP § 2143. The present invention is directed to film-coated, oval-shaped tablets comprising a bisphosphonate active ingredient that are about 0.23 to about 0.85 inches in length, about 0.11 to about 0.4 inches in width, and about 0.075 to about 0.3 inches in thickness, and that achieve delivery of the bisphosphonate active to the stomach. Applicants respectfully assert that the Examiner's obviousness rejection fails to meet these

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			requirements for a proper rejection because none of the cited references teach or suggest Applicants' film-coated, oval-shaped tablets having the dimensions required by the amended claims. As stated above, the '721 patent teaches enteric coated dosage forms of risedronate that are specifically designed to deliver the risedronate active to the small intestine and the large intestine (the lower gastrointestinal tract), not the stomach. This is achieved by selecting appropriate coating materials, selecting an appropriate method of coating, using other pharmaceutically acceptable excipients, and/or adjusting the coating thickness. Column 7, lines 29-39 and lines 50-56. Thus, even though some dosage forms taught therein contain a coating that is soluble at pH 1.2-5, all dosage forms taught therein achieve delivery of the risedronate active in the small or large intestine, not the stomach. An oval shaped tablet is disclosed; however, no dimensions are disclosed. See Example III in Column 16. Similarly, the '920 teaches enteric coated dosage forms of bisphosphonates that are specifically designed to deliver the active to the lower gastrointestinal tract, not the stomach. These dosage forms comprise "a stability enhancing subcoat which minimizes migration of active from core tablet to the surface of the enteric coating." Column 2, lines 24-41. Thus, even though some dosage forms taught therein contain a subcoating that maybe soluble at pH 1.2-5, all dosage forms taught III the '920 patent are

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			specifically formulated to achieve delivery of the active in the lower gastrointestinal tract, not the stomach. The '730 patent (Sadek) teaches gelatin-enrobed tablets and a process for making same. The dosage forms taught therein contain gelatin layers which can produce tablets that have more than one color and that may be tamper-evident. See Abstract. While oval-shaped tablets are disclosed generally, the '730 patent neither teaches nor suggests oval· shaped tablets comprising a bisphosphonate active ingredient within Applicants' claimed dimensions. Rather, the '730 patent teaches that the gelatin layers can be applied to tablets "of various sizes and shapes." See Column 3, line 56-58. Thus, the '730 patent leads the skilled artisan to conclude that there is nothing special in selecting the specific shape and size dimensions. Furthermore, the '730 patent teaches that the gelatin-enrobed tablets may be further processed to contain an enteric coating to achieve delivery of the active past the stomach. This is in direct contrast to the dosage forms of present invention that achieve delivery of the active to the stomach. The '589 patent (Parekh) teaches gelatin-coated caplets which contain a subcoating that promotes a "smooth uniform and substantially bubble-free outer coating." See Abstract. The '589 patent neither teaches nor suggests oval-shaped tablets comprising a bisphosphonate active ingredient. Additionally, the '589 patent neither teaches nor suggests oval-shaped

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			tablets within Applicants' claimed dimensions. Rather, the '589 patent's teaching is limited to tablets that are "capsule-like." In summary then, none of the cited references teach or suggest film-coated, oval-shaped tablets comprising a bisphosphonate active ingredient that are within Applicants' claimed dimensions and that achieve delivery of the active to the stomach. Thus, the cited references do not teach or suggest all of Applicants' claim limitations. Additionally, none of the references motivate the skilled artisan to modify these teachings to arrive at the present invention. For these reasons, Applicants respectfully assert that the Examiner has failed to provide Applicants with a prima facie obviousness rejection. Accordingly, Applicants request withdrawal of the rejection. **Reference accompanying Amendment (Mar 20,**

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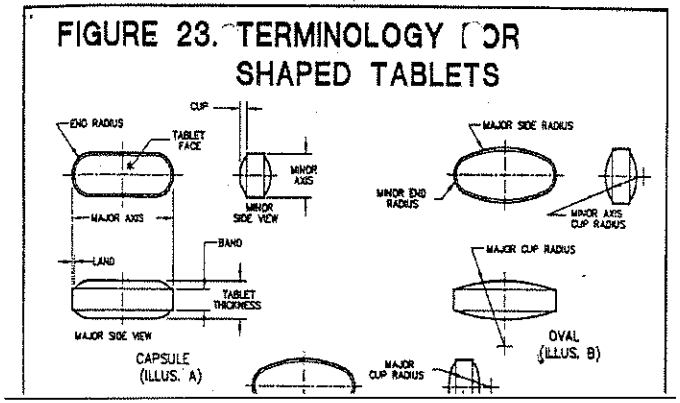
			2000) (Ex. B at PGOAM 0174607 - PGOAM 0174617):  **Notice of Allowance of 1-Oct-2004 in 09/095,322 at PGOAM 0174660** ***Reasons for Allowance*** 1. The following is an examiner's statement of reasons for allowance: the prior art of record neither discloses nor suggests oral dosage formulations for stomach delivery of bisphosphonates using oval dosage formulation possessing the presently claimed parameters.

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Asserted claim 1 (from which all other asserted claims depend)	Safe and effective amount	**Plaintiffs' Proposed Construction** An amount high enough to significantly positively modify the symptoms and/or condition to be treated, but low enough to avoid serious side effects (at a reasonable benefit/risk ratio), within the scope of sound medical judgment. **Specification** "The phrase 'safe and effective amount', as used herein means an amount of a compound or composition high enough to significantly positively modify the symptoms and/or condition to be treated, but low enough to avoid serious side effects (at a reasonable benefit/risk ratio), within the scope of sound medical judgment." '513 Patent, col. 6, ll. 36-42. "The safe and effective amount of active ingredient for use in the method of the invention herein will vary with the particular condition being treated, the age and physical condition of the patient being treated, the severity of the condition, the duration of the treatment, the nature of concurrent therapy, the particular active ingredient being employed, the particular pharmaceutically-acceptable excipients utilized, and like factors within the	**Teva's Proposed Construction** between 1 and 40mg of bisphosphonate **INTRINSIC EVIDENCE** ***U.S. Patent No. 6,165,513 (issued Dec. 26, 2000)*** **The '513 Patent (Ex. A , col. 4 ll. 14-23):** The effective oral dose of the active ingredient depends on the extent of the disease. For examples, for adults the amount of risedronate usually amounts to from about 1 mg to about 40 mg daily, preferably from about 1 mg to about 30 mg daily. When the dose is to be administered cyclically, the dose is preferably from 5-40 mg/day, preferably from 10-30mg/day.

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		knowledge and expertise of the attending physician." '513 Patent, col. 6, ll. 36-42. "***For example***, for adults the amount of risedronate ***usually*** amounts to from about 1 mg to about 40 mg daily." '513 Patent, col. 4, ll. 14-23 (emphasis added).	