

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

THE PROCTER & GAMBLE COMPANY and)	
HOFFMANN-LA ROCHE INC.,)	
)	
Plaintiffs,)	
v.)	C.A. No. 08-627-LPS
)	
TEVA PHARMACEUTICALS USA, INC.,)	(CONSOLIDATED)
)	
Defendant.)	

**DEFENDANT TEVA PHARMACEUTICALS USA, INC.’S
OPENING CLAIM CONSTRUCTION BRIEF
ON U.S. PATENT 6,165,513**

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April 18, 2011

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INTRODUCTION

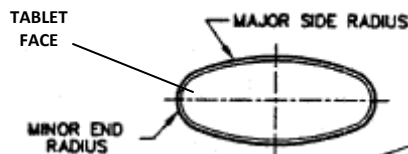
Teva Pharmaceuticals USA, Inc. submits this claim construction brief on U.S. Patent 6,165,513 (“the ’513 patent”) separately because Teva is the only party against which plaintiffs have asserted that patent.¹ The ’513 patent claims a drug tablet that contains a “safe and effective amount” of a bisphosphonate. The claims are directed to particular shape for that tablet. Essentially, the patent claims a tablet that is “oval shaped,” as distinguished from some other shape, such as round or capsule-shaped. The text of asserted claim 1 of the ’513 patent, from which all of the other claims depend, is set forth below with the two disputed claim terms underlined:

1. An oral dosage form comprising a safe and effective amount of a bisphosphonate wherein said oral dosage form is 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 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.

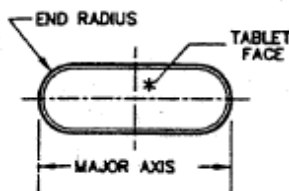
(Ex. A, ’513 patent at col. 11–12) (emphasis added).

With respect to the term “oval shaped,” the intrinsic record boxes in the meaning of this term to make clear that it cannot be expanded beyond its ordinary meaning. In particular, “oval shaped” must be construed to mean an oral dosage form whose outline in its plan view is constructed from two pairs of different radii as in

¹ Teva has been informed of the following: 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.



In the drawing above, all four sides are curved, and each curve is defined by a radius. By contrast, the term “oval shaped” does not encompass a dosage form which are capsule shaped (as depicted below) in a plan view.



Unlike the oval tablet, the capsule shaped tablet has two straight sides, i.e., sides not defined by a radius, and two curved sides. The claim language and prosecution history require that “oval shaped” be construed according to its ordinary meaning in the tableting field, and that ordinary meaning does not encompass “capsule shaped” tablets.

The second claim term to be construed is “safe and effective amount of bisphosphonate.” “Safe and effective amount of bisphosphonate” should be construed to mean between 1 and 40 mg of bisphosphonate, because that is the only dosing range set forth by the patent as safe and effective. (Ex. A at col. 6, ll. 37-42.) The patent specification does not describe any other range, and does not suggest that the claimed tablet could include any amount outside that range.

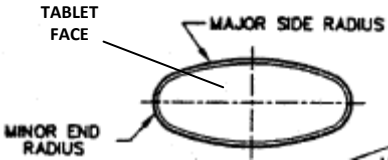
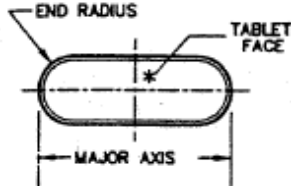
ARGUMENT

Claim construction is an issue of law. *See Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996). Particularly applicable here is the principle that the prosecution history forms an important part of the intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). Thus, a patentee is not entitled to construe its claims narrowly in order to obtain them

from the PTO, and then expand their scope during litigation. *See Springs Window Fashions LP v. Novo Indus., LP*, 323 F.3d 989, 994 (Fed. Cir. 2003) (prosecution history limits the interpretation of claim terms to exclude any interpretation disclaimed during prosecution) (citations omitted). Such an unjustified reversal in position, if permitted, would violate the public notice function of the claims. *See id.* at 995 (“The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.”).

I. THE TERM “OVAL SHAPED” IN CLAIMS 1, 2, 8, 9, AND 10 DOES NOT INCLUDE “CAPSULE SHAPED”

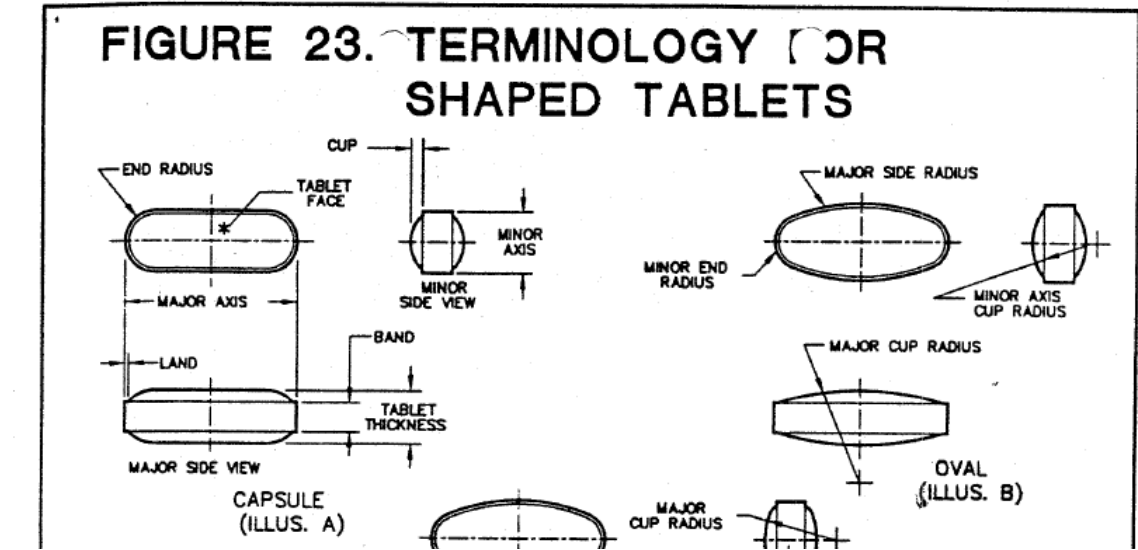
The parties have proposed the following constructions of the term “oval shaped.”

Disputed Term/Phrase	Teva’s Proposed Construction	Plaintiffs’ Proposed Construction
<p>“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”</p>	<p>“oval shaped” means an oral dosage form whose outline in its plan view is constructed from two pairs of different radii as in</p>  <p>and does not include dosage forms which are capsule shaped (as depicted below) in a plan view.</p>  <p>the dimensional limitation should be construed according to its plain meaning.</p>	<p>An oblong form having rounded ends, including but not limited to oval, modified oval, or caplet shaped forms,</p> <p>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.</p>

Teva's proposed construction is supported by (i) the term's ordinary meaning as reflected in the '513 patent specification and prosecution history, (ii) the patent applicants' express limitation of the term to that ordinary meaning to overcome rejections during prosecution, and (iii) the applicants' disclaimer of caplet shaped tablets to distinguish the claims from the prior art. Plaintiffs' proposed construction, on the other hand, which would encompass capsule shaped tablets, is contrary to the ordinary meaning of oval shaped and seeks to recapture precisely what the applicants gave up to get their claims in the first place.

A. The Plain Meaning of "Oval Shaped" Does Not Include "Capsule Shaped"

Oval shaped has a plain meaning in the tableting field that is separate and distinct from capsule shaped. The term oval shaped means that the shape is defined by two pairs of different radii, a major side radius and minor end radius. P&G, the assignee of the application for the '513 patent, expressly adopted this definition during prosecution of the '513 patent. (*See* Ex. B, File History for U.S. Patent 6,165,513 at PGOAM0174597-4605 (Response to Office Action and Amendment, March 20, 2000 at 3-4).) Additionally, this definition comports with the plain meaning of the term as defined in the bible for this art, the TABLETING SPECIFICATION MANUAL, (4th ed. 1995) ("TSM"). P&G itself relied on the TSM during the prosecution of its application. The TSM is part of the intrinsic record because P&G cited it during prosecution and adopted it to define the term "oval shaped" in overcoming rejections to their proposed claims. (*See* Ex. B, at PGOAM0174607-617 (TSM).) As P&G represented, the TSM reflects the state of the tableting field as of the filing date of the '513 patent. The TSM describes an "oval shaped" tablet and a "capsule shaped" tablet as separate and distinct shapes defined by two different sets of parameters. (Ex. B at PGOAM0174614, (Fig. 23).) Specifically, "Illustration B" defines an "oval," while "Illustration A" defines a "capsule."



The characteristic differences between the “oval” and “capsule” shapes are that an oval shape “is formed using only two radii: the major side radius and the minor end radius,” whereas a capsule shape has a straight, uniformly wide body characterized by a minor axis rather than a radius and an “end radius” that defines the curved portions “located at either end.” (Ex B. at PGOAM0174612-14 (Fig. 23).)

The plain meaning of oval shaped, as P&G presented that plain meaning to the PTO, is that set forth in the TSM. Oval shaped is a term that the tableting world carefully distinguishes from capsule shaped. The Court should not blur the distinction that the art has so carefully created and on which P&G so carefully relied.

B. P&G Narrowed the Claims to “Oval Shaped” Defined by Its Plain Meaning to Overcome the Examiner’s Indefiniteness Rejection

Plaintiffs are precluded from arguing that “oval” can be defined more broadly than its plain meaning because P&G limited the term to its plain meaning during prosecution of its patent. P&G not only expressly adopted the TSM definition of the term “oval,” but also amended the claims to change the broad terms “generally oval” to the narrower term “oval shaped,” and cancelled claims containing the term “modified oval or caplet shape,” in order to

overcome the examiner's indefiniteness rejection. (Ex. B at PGOAM0174597-4605 (Response to Office Action and Amendment, March 20, 2000 at 1-9).)

Specifically, the examiner rejected the then pending claims containing the terms "generally oval" and "modified oval or caplet shape" as indefinite since neither the claims nor specification adequately defined either of those terms 35 U.S.C. § 112. (Ex. B at PGOAM0174587-88 (Office Action dated September 13, 1999 at 2-3).) P&G responded to the examiner's rejections by cancelling all claims containing the term "modified oval or caplet shape," and amended the claim term "generally oval" by replacing it with "oval shaped" together with specific length, width, and thickness limitations. (Ex. B at PGOAM0174597-4598 (Response to Office Action and Amendment, March 20, 2000 at 1-2).)

P&G argued that "oval shaped" should be strictly limited to a shape "formed using only two radii: the major side radius and the minor end radius." (Ex. B at PGOAM0174600 (Response to Office Action and Amendment, March 20, 2000, at 4).) P&G pointed out that "oval shaped" has an "art recognized meaning and is clear to one of ordinary skill in the art." (*Id.*) Referring to the TSM, P&G defined the term "oval shaped:"

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."

(*Id.*) P&G's express reference to the plain meaning of "oval shaped" further supports construing the term in accordance with its ordinary meaning. P&G's proposed construction, on the other hand, improperly attempts to expand the term oval shaped beyond that meaning to recapture shapes that it disclaimed during prosecution, and therefore, should be rejected.

C. To Overcome Prior Art Rejections, P&G Argued That Oval Shaped Did Not Include Capsule Shaped

To overcome obviousness rejections over certain prior art references which disclosed capsule shaped tablets, P&G argued that those references did not teach or suggest "oval-shaped

tablets having the dimensions required by the amended claims.” (Ex. B at PGOAM0174604 (Response to Office Action and Amendment, March 20, 2000 at 8).) Specifically, the examiner rejected the claims as unpatentable over several prior art patents, including U.S. Patent 5,658,589 to Parekh *et al.* (Ex. B at PGOAM0174587-92 (Office Action dated September 13, 1999 at 2-7).) According to the examiner, those references disclosed either “generally oval” or “caplet-shaped” tablets. (*Id.*) In responding to the rejections, P&G argued that Parekh “neither teaches nor suggests oval-shaped tablets” because Parekh’s disclosure is “limited to tablets that are ‘capsule-like.’” (Ex. B at PGOAM0174605 (Response to Office Action and Amendment, March 20, 2000 at 9).) The applicants could hardly have made the distinction between what they were claiming and capsule shaped more plain.

Finally, P&G reinforced the distinction it was making by stating that the dimension limitations in the amended claims served to narrow them from the originally filed claims so that they no longer read on “caplet shaped” tablets. (Ex. B at PGOAM0174605 (Response to Office Action and Amendment, March 20, 2000 at 9).) In short, at every turn, P&G made more plain that it intended oval shaped to mean oval shaped and not to mean capsule shaped. Plaintiffs cannot disavow what got P&G the claims in the first place.

D. Figure 1, as New Matter, Cannot be Employed to Construe the Claims

Figure 1 of the '513 patent, as the patent issued, appears to depict a plan view of a capsule shaped tablet.

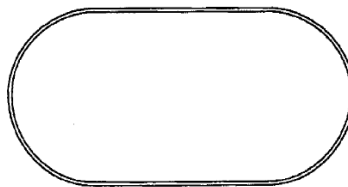


FIG. 1

(Ex. A at p.2.) Plaintiffs, however, cannot rely on that drawing to support the proposition that an “oval shaped” tablet should be construed to include a “capsule shaped” tablet, that is, a tablet with straight, rather than curved, long sides as apparently depicted in Fig. 1 of the issued patent. The reason that Fig. 1 must be disregarded that it was never part of the application on which the examiner acted. The original Fig. 1 that was filed with the application is different:

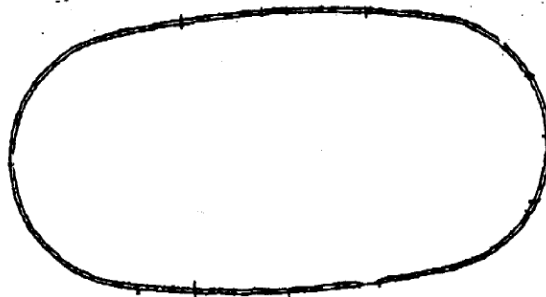


Fig. 1

(Ex. B at PGOAM0174570 (Originally filed Fig. 1).) This drawing, which shows a shape with four curved sides (as distinguished from the two straight sides and two curved sides that characterize the capsule shape of issued Fig. 1 of the patent), depicts an oval. It was this drawing that was in the application at all times during the examiner’s consideration of it. After the examiner allowed the application, and after he had seen it for the last time, P&G replaced Fig. 1 with the version that appears in the patent, i.e., the version with two straight sides. That version is “new matter,” and was added in violation of 35 U.S.C. § 132, which prohibits such changes. Plaintiffs therefore cannot validly argue that Figure 1 of the issued patent supports its argument that “oval shaped” includes “capsule shaped.”

II. “SAFE AND EFFECTIVE AMOUNT” MEANS BETWEEN 1 AND 40MG OF BISPHOSPHONATE

The parties have proposed the following constructions of the term “oval shaped.”

Disputed Term/Phrase	Teva’s Proposed Construction	Plaintiffs’ Proposed Construction
“safe and effective amount”	between 1 and 40mg of bisphosphonate	An amount large enough to significantly positively modify the symptoms and/or condition to be treated, but small enough to avoid serious side effects (at a reasonable benefit/risk ratio), within the scope of sound medical judgment.

The ’513 patent specification exemplifies a safe and effective amount of bisphosphonate as “about 1 mg to about 40 mg” and “when the dose is to be administered cyclically, the dose is preferably from 5-40 mg/day, preferably from 10-30mg/day.” (Ex. A at col. 4, ll. 19-23.) The ’513 patent does not state or otherwise indicate that a dosage outside the range of “about 1 mg to about 40 mg” would be safe and effective, and there is nothing in the prosecution history that would demonstrate that the inventors envisioned their invention to include dosages greater than 40 mg of bisphosphonate. The claim as a whole deals with the design of a tablet to avoid lodging in the esophagus and allow dissolution in the stomach. In this situation, increasing the amount of active drug could have an impact on the design of a tablet meeting the other claim requirements. This is a situation where the size of the dose and corresponding size of the tablet are a very important consideration. Since the patent does not describe how to make or administer a dose greater than 40 mg, it is not clear from the specification or prosecution history that a person of ordinary skill in the art would reasonably expect a dose greater than 40 mg of bisphosphonate per tablet to be “safe and effective.” Thus, the term “safe and effective amount” should be limited to a maximum of 40 mg of bisphosphonate per tablet.

CONCLUSION

For the reasons set forth above, Teva respectfully requests that the Court adopt Teva's proposed constructions of the '513 patent claim terms at issue.

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on April 18, 2011, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered counsel of record.

I further certify that I caused a copy of the foregoing document to be served the following counsel of record in the manner indicated:

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