IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 08-627-LPS (CONSOLIDATED)

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF ON U.S. PATENT 6,165,513

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May 16, 2011

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INTRODUCTION

Teva Pharmaceuticals USA, Inc. submits this brief in response to plaintiffs' opening claim construction brief on U.S. Patent 6,165,513 ("the '513 patent"). (D.I. 153.)

The principal claim construction issue is the meaning of "oval shaped" in the claims of the '513 patent. In its opening brief (D.I. 150), Teva showed that "oval shaped" has a specific meaning both in the art and as P&G defined the term during prosecution. In particular, "oval shaped" does not mean "capsule shaped." The claim itself, the specification, and the prosecution history all support this construction. By contrast, plaintiffs' proposed construction reads the "oval shaped" limitation out of the claims. Plaintiffs would rewrite the claim to recapture other shapes that are not "oval shaped" as P&G itself defined that term during prosecution.

Plaintiffs cannot dispute that the specification identifies several shapes for oral solid dosage forms and that "oval shaped" is only one of those shapes. Nor can plaintiffs dispute that all of the originally-filed independent claims were not limited to an "oval shaped" dosage form, and that P&G limited the claims to only one shape—the oval shape—in response to an examiner's rejection. Plaintiffs cannot recapture through claim construction what it forfeited to obtain the claims.

Another limitation at issue is the term "safe and effective amount." In its opening brief, Teva showed that "safe and effective amount" means "between 1 and 40 mg of bisphosphonate." Plaintiffs' argument that certain language, read in isolation, makes the definition open-ended, is contrary to the principle that the specification must be considered as a whole. Accordingly, the Court should reject plaintiffs' proposal, which obscures the term's meaning and yields a construction that eviscerates any limitation, making the term meaningless.

ARGUMENT

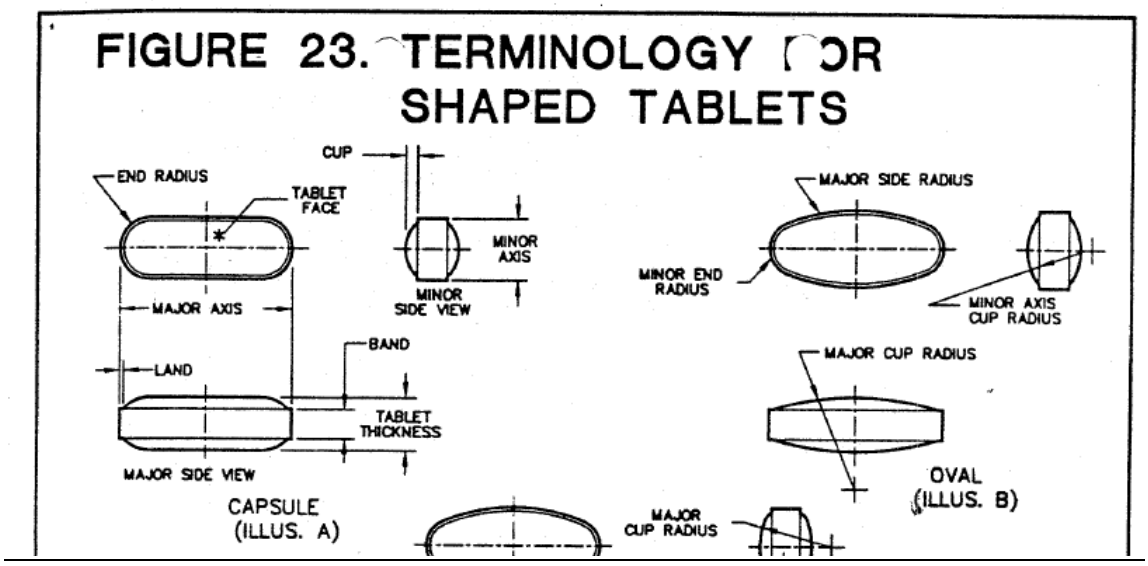
I. PLAINTIFFS' CONSTRUCTION OF "OVAL SHAPED" IS FLAWED BECAUSE IT CONTRADICTS THE DEFINITION SET FORTH IN THE INTRINSIC RECORD AND READS OUT A LIMITATION THAT WAS ADDED DURING PROSECUTION

In their construction of "oval shaped," Plaintiffs ignore both the plain meaning of the claim terms and the intrinsic record, which clearly show the definition of "oval shaped" is different than, and does not include "capsule shaped." Instead, Plaintiffs seek to expand the scope of the claims to recapture shapes that P&G surrendered during prosecution, particularly capsule shaped dosage forms.

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

As demonstrated in Teva's opening brief, oval shaped has a plain meaning in the tableting field that is separate and distinct from capsule shaped. In their opening brief, plaintiffs point to the TABLETING SPECIFICATION MANUAL, (4th ed. 1995) ("TSM") to show the definiteness of the term "oval shaped," but they refuse to adopt the TSM definition. Plaintiffs cannot have it both ways.

The TSM describes both "oval shaped" and "capsule shaped." Plaintiffs acknowledge the former and ignore the latter. In the context of the tableting art, the plain language of the term could not be clearer: it is "oval shaped" not "capsule shaped." (Ex. B at PGOAM0174614, (Fig. 23).) Specifically, "Illustration B" defines an "oval," while "Illustration A" defines a "capsule."



Plaintiffs ignore the characteristic differences between the "oval" and "capsule" shapes, particularly that an oval "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 defined 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).)

Oval shaped is a term that the tableting world distinguishes from capsule shaped. The Court should decline plaintiffs' construction because it blurs the distinction that the art has established and that P&G adopted during prosecution.

B. Plaintiffs Ignore the Narrowing Amendments Which Surrendered "Modified Oval" Shapes

Plaintiffs are estopped from arguing that "oval shaped" can be defined as "modified oval" because P&G limited the term to its plain meaning during prosecution of its patent. P&G provided a precise definition for oval shaped, then proceeded to narrow its claims to disclaim any other shaped dosage forms.

As Teva showed in its opening brief, during prosecution of the '513 patent, P&G explicitly 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."

(Ex. B at PGOAM0174600 (Response to Office Action and Amendment, March 20, 2000, at 4).) In doing so, P&G forfeited the additional scope the terms "generally oval" and "modified oval or caplet shape" would encompass.

P&G narrowed the claims and adopted the TSM definition to overcome two examiner rejections to the claims, one for indefiniteness and the other for obviousness. To overcome the indefiniteness rejection, P&G expressly adopted the TSM definition of the term "oval," amended the claims to change the broad term "generally oval" to the narrower term "oval shaped," and cancelled claims containing the term "modified oval or caplet shape." (Ex. B at PGOAM0174597–605 (Response to Office Action and Amendment, March 20, 2000 at 1–9).)

In addition, P&G narrowed the claims to "oval shaped" to overcome the examiner's rejection for obviousness 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).) Relying on its narrow definition of the term "oval shaped," P&G told the examiner 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).)

Plaintiffs cannot support their position that P&G's amendments were not narrowing amendments. Amendments to overcome indefiniteness rejections and amendments to overcome prior art are narrowing amendments unless the patentee specifically provides evidence to the contrary. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737 (2002) ("A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to

comply with § 112"). P&G did not merely amend the claims for consistency, it amended them to provide a specific narrowing definition. The case law plaintiffs cite is inapposite. In *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576 (Fed. Cir. 1996), the court rejected the proposed construction because it relied on extrinsic evidence. Moreover, *Vitronics* stands for the proposition that intrinsic evidence such as narrowing amendments made during prosecution control claim construction. 90 F.3d at 1583. Teva relies on such intrinsic evidence here. In that regard, plaintiffs' argument that Teva's construction of oval shape excludes a "preferred embodiment" is irrelevant. First, the argument does not exclude any such embodiment. Second, even if Teva's construction excludes a preferred embodiment, that exclusion derived from P&G's forfeiture during prosecution of any shapes other than "oval shaped."

C. Plaintiffs' Arguments About Dimensional Limitations are Irrelevant

Plaintiffs incorrectly rely on the dimensional limitations of the claims of the '513 patent in support of their erroneous construction of the term "oval shaped." The dimensional limitations claim a length, width, and thickness for the dosage form, but those limitations are separate from the "oval" shape limitation. Indeed, even a rectangular dosage form can have the dimensional limitations, and even plaintiffs would not argue that rectangles are "oval shaped."

Two different claim terms cannot define the same element in contradictory ways. Here, plaintiffs attempt to rely on the dimensional limitations (length, width, and thickness) to support their position on the shape limitation ("oval" as distinguished from "capsule" or "rectangle"). Such a construction is unsupported by the evidence, legally improper, and contradicts P&G's binding statements made and actions taken before the PTO.

D. Plaintiffs Cannot Rely on Figure 1 is Because Figure 1 is New Matter that Cannot be Employed to Construe the Claims

In their arguments concerning the term "oval shaped," Plaintiffs only point to Figure 1 of the '513 from the issued patent:

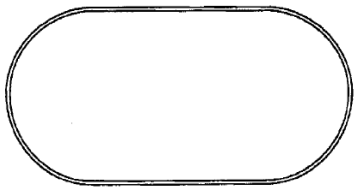


FIG.1

(Ex. A at p.2.) In its opening brief, Teva explained that plaintiffs 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 not part of the application that the PTO examined. It was "new matter," added in violation of 35 U.S.C. § 132(a), which prohibits the addition of new matter after the application has been filed. The original Fig. 1 that was filed with the application is different:

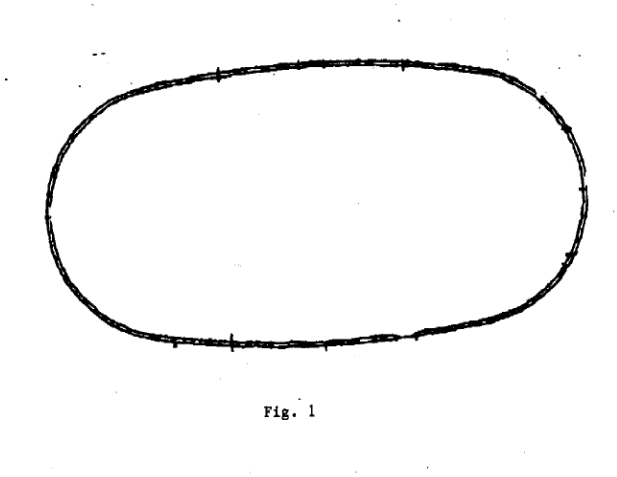


Fig. 1

(Ex. B at PGOAM0174570 (Originally filed Fig. 1).) This drawing, which shows a shape with four curved sides, was in the application at all times during the examiner's consideration of it.

Plaintiffs offer no explanation for the newly substituted figure, but they cannot dispute that it was new matter added after the claims had been allowed. Plaintiffs therefore cannot rely on Figure 1 of the issued patent to support their argument that "oval shaped" includes "capsule shaped."

II. PLAINTIFFS' PROPOSED CONSTRUCTION OF "SAFE AND EFFECTIVE AMOUNT" IS FLAWED BECAUSE IT IGNORES THE DEFINITE BOUNDARIES SET FORTH IN THE SPECIFICATION

Although a patentee may act as his or her own lexicographer, statements in the specification should not be read in isolation. The specification does state that "[s]afe and effective amount of bisphosphonate" means an amount "within the scope of sound medical judgment," (Ex. A at col. 4, ll. 14–23; col. 6, ll. 37–42), but that definition cannot be divorced from the limits set forth in the patent. Instead, it should be read together with them in the context of the specification as a whole. The specification does not mention an oral dosage form containing more than 40 mg of a bisphosphonate. Moreover, plaintiffs have asserted claims 1, 2, 8, 9, and 10, and claims 8, 9, and 10 specify risedronate. The patent contains a detailed discussion of an oral dosage form containing risedronate, and provides as the broadest limits between 1 and 40 mg of that bisphosphonate. (Ex. A at col. 4, ll. 14–23.)

When read in isolation, plaintiffs' proposed definition is not clear. Plaintiffs do not provide any limitation for the amount of bisphosphonate that a tablet can contain, and do not state that 150 mg of bisphosphonate would be a safe and effective amount within the scope of sound medical judgment. Since plaintiffs do not provide any way to determine an amount of bisphosphonate that the claimed dosage form can contain, 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 May 16, 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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