IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

[CORRECTED] PLAINTIFFS' REPLY CLAIM CONSTRUCTION MEMORANDUM FOR U.S. PATENT NO. 6,165,513

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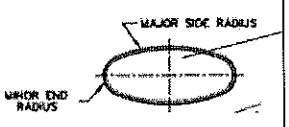
I. INTRODUCTION

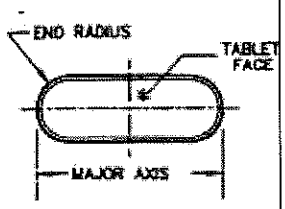
Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") and Hoffman-La Roche Inc. ("Roche") (collectively "Plaintiffs") submit this Reply Claim Construction Memorandum to address disputes with Defendant Teva Pharmaceuticals USA, Inc. ("Teva") over the meaning of two claim terms in U.S. Patent No. 6,165,513 ("'513 patent").

Teva contends that the claim term "oval shaped" excludes modified oval and caplet shaped tablets, despite clear evidence to the contrary in the specification and prosecution history. The '513 patent covers oval, modified oval, and caplet shaped oral dosage forms for improved upper gastrointestinal tract safety. In proposing its claim construction of "oval shaped," Teva fails to cite the specification of the '513 patent and mischaracterizes the prosecution history. Teva also improperly asserts that the claim term "safe and effective amount" should be constrained to a narrower scope than what is explicitly defined in the specification. Accordingly, Teva's proposed constructions should be rejected.

II. ANALYSIS OF CLAIM TERMS

A. "Oval shaped" includes oval, modified oval and caplet shaped forms.

Claim Term	Plaintiff's Proposed Construction	Defendant's Proposed Construction	Key Dispute(s)
"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" '513 Patent, claims 1, 2, and 8-10	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	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	Whether "oval shaped" includes oval, modified oval, or caplet shaped forms.

	thickness (at its thickest point) of approximately 0.075 to approximately 0.3 inches.	are round or capsule shaped (as depicted below) in a plan view. 	

1. Claim Language

Defendant contends that "oval shaped" does not include "capsule shaped." One of ordinary skill in the art understands that caplets are ***cap***sule shaped tab***lets***; thus, regarding shape, the terms "caplet" and "capsule" are interchangeable. For the reasons stated in Plaintiffs' opening brief (P. Br. at 7-8), excluding "modified oval" and "caplet" shapes from the meaning of "oval shaped" fails to give the claim language its full breadth, and should be rejected.

2. Specification

As discussed in Plaintiffs' opening brief (P. Br. at 8-9), the '513 patent specification provides support for oval, modified oval, and caplet shaped forms. Ex. A, '513 Patent, col. 2 ll. 3-5; col. 2 ll. 43-44; col. 6 ll. 13-22; col. 8 ll. 61-67; col. 9 ll. 34-67; col. 10 ll. 3067; col. 11 ll. 1-31. Not surprisingly, Teva therefore does not cite any portion of the specification to support its proposed construction that "oval shaped" excludes modified oval and caplet shaped forms. The specification thus supports Plaintiffs' proposed construction that "oval shaped" includes "modified oval" and "caplet" forms.

3. Prosecution History

a) Applicants did not clearly and unambiguously disclaim "modified oval" and "caplet shape" forms.

Teva contends that amending "generally oval form" to "oval shaped" narrowed the claim scope to exclude modified oval or caplet shaped dosage forms. As discussed in Plaintiffs' opening brief (P. Br. at 10-11), Applicants' amendment from "generally oval form" to "oval shaped" did not limit the claim scope. Instead, the amendment incorporated cancelled claims reciting "modified oval" and "caplet shape" forms into "oval shaped."

Applicants cited to two references to establish that "oval shaped" has an art-recognized meaning and also to distinguish between "round" and "shaped" tablets:

> 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. . . . ***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.
>
> Ex. B, Prosecution History of U.S. Applicant No. 09/095,322, Amendment (Mar. 20, 2000) at PGOAM0174600.

Applicants never state that "oval shaped" excludes "modified oval" and "caplet shape" forms. "[In] order to disavow claim scope, a patent applicant must ***clearly and unambiguously*** express surrender of subject matter during prosecution." *Id.* (emphasis added); *see also Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("We have, however, declined to apply the doctrine of prosecution disclaimer where the alleged disavowal of claim scope is ambiguous."). Applicants did not surrender the subject matter of "modified oval" and "caplet shape" forms at all, and certainly not "clearly and unambiguously."

b) Applicants did not argue that "oval shaped" excluded capsule shaped forms to overcome prior art rejections.

Defendant mischaracterizes Applicants' arguments in contending that Applicants overcame prior art references by arguing that "oval shaped" did not include capsule shaped forms. The Examiner rejected the claims as obvious over references including U.S. Patent No. 5,658,589 to Parekh et al. ("Parekh"). To overcome the rejection, Applicants argued that Parekh "neither teaches nor suggests oval-shaped tablets ***within applicants' claimed dimensions***. Rather, the '589 patent's teaching is limited to tablets that are "capsule-***like***." Ex. B, Amendment (Mar. 20, 2000) at PGOAM0174605 (emphasis added). Thus, Applicants stated that Parekh did not teach the claimed dimensions and did not teach capsule-shaped tablets but only capsule-***like*** tablets. Applicants' statements are consistent with Plaintiffs' construction that "oval-shaped" includes "caplet shape" forms.

Applicants' arguments regarding an anticipation rejection makes clear that "oval-shaped" includes "caplet shape" forms. The Examiner rejected the claims as being anticipated by U.S. Patent No. 5,096,717 to Wirth et al. ("the '717 patent"). Applicants stated that "[t]he ***capsules*** taught in the '717 patent achieve release of the active in the small intestine by 'eliminating' release of the active in the stomach." Ex. B, Amendment (Mar. 20, 2000) at PGOAM0174602-03 (emphasis added). To overcome this anticipation rejection, Applicants did ***not*** argue that the capsules taught by the '717 patent were different from the claimed "oval shaped" forms. Instead, Applicants argued that "the present invention is directed to film coated oral dosage forms comprising a bisphosphonate []wherein said film coating allows for delivery of said bisphosphonate to the stomach." Ex. B, Amendment (Mar. 20, 2000) at PGOAM0174602. Applicants thus made it clear that "oval shaped" encompasses "caplet shape" forms.

c) Figure 1 of the '513 patent illustrates "modified oval" tablets and is not new matter

Defendant mischaracterizes the prosecution history in contending that Figure 1 of the issued patent is "new matter." Figure 1 is not "new matter." Figures 1-3 illustrate a top plan view, side elevation view, and an end view of a "modified oval" tablet. Ex. A, col. 2 ll. 26-30. Applicants submitted formal drawings only in response to the Examiner's request. In the Notice of Allowability, the Examiner stated that Applicants had to submit new formal drawings including the changes required by the Notice of Draftsperson's Patent Drawing Review. Ex. B, Notice of Allowability (May 31, 2000) at PGOAM0174659. The Draftsperson objected that the drawings had poor line quality. Ex. B, Notice of Draftsperson's Patent Drawing Review (May 31, 2000) at PGOAM0174663.

In response to this objection, Applicants submitted formal drawings on July 6, 2000. Contrary to Defendant's assertion, the Examiner had an opportunity to review the new formal drawings and explicitly approved those drawings:

Additionally the Formal Drawings filed on 7/6/00 have been approved.

BENNETT CELSA
PRIMARY EXAMINER
10/16/00

Ex. B, Response to Rule 312 Communication (Oct. 20, 2000) at PGOAM0174672. Clearly, the Examiner approved the formal drawings and did not issue a new matter objection under 35 U.S.C. § 132. As the drawings illustrate "modified oval" tablets, the Examiner's approval supports Plaintiffs' construction that "oval shaped" includes "modified oval" and "caplet shape" forms.

B. "Safe and effective amount" should be construed as explicitly defined in the specification.

Claim Term	Plaintiff's Proposed Construction	Defendant's Proposed Construction	Key Dispute(s)
"safe and effective amount" '513 Patent, claims 1, 2, and 8-10	An amount high enough to significantly and 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.	Between 1 and 40 mg of bisphosphonate.	Whether the explicit definition provided in the specification is the proper construction.

1. Specification

As discussed in Plaintiffs' opening brief (P. Br. at 5), "safe and effective amount" should be construed as explicitly defined in the '513 patent specification, as a patentee may act as his or her own lexicographer. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1344 (Fed. Cir. 2009) ("It is well-settled that an inventor may act as his own lexicographer to define a patent term."). Teva, in contrast, proposes to limit the patent claim only to the embodiments specifically described in the specification, which is improper. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904, 906 (Fed. Cir. 2004); *see also Fuji Photo Film, Co. v. ITC*, 386 F.3d 1095, 1106 (Fed. Cir. 2004) (claim terms are not limited to particular examples provided in the specification unless the specification contains a "clear indication" of such limitation). The specification does not contain a "clear indication" that "safe and effective amount" should be limited to the embodiments disclosed. Instead, the specification provides an explicit definition of "safe and effective amount:"

> An amount high enough to significantly and 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.

Ex. A, col. 6 ll. 36-42. Nothing in the prosecution history is inconsistent with the specification's explicit definition of "safe and effective amount," which should be the construction adopted by the Court.

III. CONCLUSION

For the foregoing reasons and those in Plaintiffs' opening brief, Plaintiffs respectfully request that the Court construe the disputed claims of the '513 patent as proposed by Plaintiffs herein.

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