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., et al.,	)	
Defendants.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR PROPOSED CLAIM CONSTRUCTIONS OF U.S. PATENT NO. 6,165,513

Of Counsel:
William F. Lee
Vinita Ferrera
Allen C. Nunnally
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

David B. Bassett
Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800
Attorneys for Plaintiffs Warner Chilcott Company, LLC and The Procter & Gamble Co.

Mark E. Waddell
Loeb & Loeb LLP
345 Park Avenue
New York, NY
(212) 230-8800
Attorney for Plaintiff Hoffmann-La Roche Inc.

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Steven J. Fineman (#4025)
fineman@rlf.com
Laura D. Hatcher (#5098)
hatcher@rlf.com
Richards Layton & Finger, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700

Attorneys for Plaintiffs Warner Chilcott Company, LLC, The Procter & Gamble Co., and Hoffmann-La Roche Inc.

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I. INTRODUCTION

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") and Hoffmann-La Roche Inc. ("Roche") (collectively "Plaintiffs") submit this Opening Claim Construction Brief 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").

The '513 patent covers oval, modified oval, and caplet shaped, film-coated oral pharmaceutical formulations for improved upper gastrointestinal tract safety. The primary dispute regarding the construction of the claims of this patent results from Teva's position that the claim term "oval shaped" excludes modified oval and caplet shaped tablets, despite clear evidence to the contrary throughout the specification and prosecution history. Teva also asserts that the claim term "safe and effective amount" should be constrained to a narrower scope than the plain meaning that is supported throughout the specification.

II. BACKGROUND

The '513 patent is directed to addressing the problem of gastrointestinal irritation – particularly in the upper gastrointestinal tract – associated with the oral ingestion of nitrogen-containing bisphosphonates. Doctors believed that such irritation resulted from the active ingredient coming in direct contact with the epithelial and mucosal tissues in that area. Ex. A, '513 patent, col. 1 ll. 35-40. Although possible solutions such as formulations that delayed release of the active ingredient had been proposed, in some cases, delaying release of the active ingredient was undesirable. Ex. A, col. 1 ll. 53-55. Accordingly, there was an unmet need for dosage forms that facilitated rapid transit through the esophageal tract and thereby minimized or avoided release of the active ingredient in the upper GI tract. Ex. A, col. 1 ll. 55-59. The invention of the '513 patent met that need through oval shaped, film-coated tablets.

III. BASIC PRINCIPLES OF CLAIM CONSTRUCTION

Claim construction is a question of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim terms are generally given their ordinary and customary meaning as understood by "a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent . . . the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). "Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" *Id.* (quoting *Innova*, 381 F.3d at 1116).

While "the best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history," *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998), the Federal Circuit has "also authorized district courts to rely on extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (quotation omitted). In particular, expert testimony may be used "to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* "However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any

expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* (quotation omitted).

Looking to the prosecution history may be useful because "[d]uring prosecution, a patent applicant may consistently and clearly use a term in a manner either more or less expansive than it is used in the relevant art, thereby expanding or limiting the scope of the term in the context of the patent claims." *Sorenson v. International Trade Commission*, 427 F. 3d 1375, 1378 (Fed. Cir. 2005). However, "in order to disavow claim scope, a patent applicant must clearly and unambiguously express surrender of subject matter during prosecution." *Id.*; *see also Omega Engineering, 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.").

While the court should construe claim limitations in light of the specification and prosecution history, it is legal error to import into the claim limitations that are not there. The Federal Circuit has repeatedly recognized that there is a difference between construing a term appearing in a claim and adding a limitation that is not there in the first place. The former is permissible; the latter is not. "While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history." *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331-32 (Fed. Cir. 2001) ("in looking to the specification to construe claim terms, care must be taken to avoid reading limitations appearing in the specification ... into [the] claims.") (citations omitted); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999) ("Consistent with the principle that the patented

invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history."); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1348 (Fed. Cir. 1998) ("[I]nterpreting what is meant by a word and a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." (internal quotation omitted)).

IV. ANALYSIS OF CLAIM TERMS

Plaintiffs contend that Defendant Teva literally infringes at least claims 1, 2, 8, 9, and 10 of the '513 patent, which has one independent claim:

> 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, col. 11 ll. 33-37; col. 12 ll. 1-4 (emphasis added). The terms requiring construction by the Court are (a) "safe and effective amount" and (b) "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." Plaintiffs' and Defendants' claim constructions for each of these terms are set forth in Exhibits AA. Each of these terms is discussed separately below.

A. "safe and effective amount" (claims 1, 2, and 8-10)

Claim Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Key Dispute(s)
"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.	Between 1 and 40 mg of bisphosphonate.	Whether the explicit definition provided in the specification is the proper construction.

1. Specification

Plaintiffs' proposed construction mirrors the explicit definition of "safe and effective amount" that the Applicants provided in the '513 patent specification. A patentee may act as his or her own lexicographer, that is, specifically define his or her own claim terms. *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."). If the intrinsic evidence reveals a "special definition," then "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

Here, the specification of the '513 patent does exactly that as to "safe and effective amount":

> 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."

Ex. A, col. 6 ll. 36-42. The specification also explains that the safe and effective amount of active ingredient will vary according to various factors:

> 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 knowledge and expertise of the attending physician.

Ex. A, col. 6 ll. 36-42.

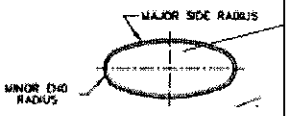
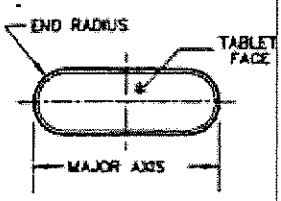
Thus, Plaintiffs' construction, which quotes the specification's definition of "safe and effective amount," is the proper construction.

2. Defendants' Construction is Flawed.

Defendant Teva's proposed construction of "safe and effective amount" as "between 1 and 40 mg of bisphosphonate" unjustifiably narrows the meaning of the term and ignores the express definition supplied by the inventors themselves. Teva appears to be basing its proposed construction of "safe and effective amount" on a statement in the specification that provides an ***example*** of an effective oral dose for adults: "***For example***, for adults the amount of risedronate ***usually*** amounts to from about 1 mg to about 40 mg daily." Ex. A, col. 4, ll. 14-23 (emphases added). It is improper, however, to limit a patent claim to the examples or embodiments described in the specification. *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).

This is particularly true here, where the inventors supplied an explicit definition of the term in dispute that is unambiguously broader that the example. Accordingly, Teva's proposed construction should be rejected.

B. "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" (claims 1, 2, and 8-10)

Claim Term	Plaintiffs' Proposed Construction	Defendants' 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"	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.	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 round or capsule shaped (as depicted below) in a plan view. 	Whether "oval shaped" includes oval, modified oval, or caplet shaped forms.

Defendants included "oral dosage form" in their terms for construction but provided no construction. Plaintiffs agree that "oral dosage form" does not require construction beyond its plain meaning. Thus, the dispute between the parties centers of the meaning of the term "oval shaped."

1. Claim Language

By requiring that oral dosage form be "oval shaped" and meet certain length, width, and

thickness specifications, the claim language itself makes clear that the claims exclude round forms. However, excluding "modified oval" and "caplet" shapes, as proposed by Defendant Teva's construction, improperly reads limitations into the claim term and thus fails to give the claim language its full breadth, and should be rejected. *TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1138 (Fed. Cir. 2004) ("[The patent holder] is entitled to the full breadth of claim scope supported by the words of the claims and the written description."); *Burke*, 183 F.3d at 1340 ("Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history.").

2. Specification

The '513 patent specification discloses "generally oval," "modified oval," and "caplet" shapes. The specification states that 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 shaped***, film coated oral dosage forms." '513 patent, col. 2 ll. 43-44 (emphasis added). Figures 1-3 of the '513 patent, shown below, illustrate (1) a top plan view, (2) a side elevation view, and (3) an end view of a "modified oval" dosage form, respectively.

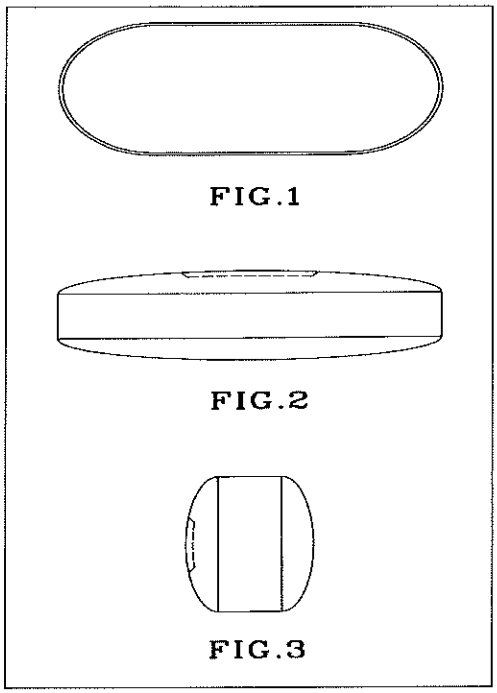


FIG.1

FIG.2

FIG.3

In addition, the specification discloses "generally oval tablets" with broad length, width, and thickness parameters and "modified oval tablets" with parameters that fall within those broad parameters:

> 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.

Ex. A, col. 6 ll. 13-22 (emphasis added).

The specification includes three non-limiting examples to further illustrate the oral dosage forms. 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.

3. Prosecution History

During prosecution, the Examiner rejected then-pending claims as indefinite because, among other reasons, the terms "generally" and "modified" are relative. Ex. BB, Prosecution History of U.S. Application No. 09/095,322, Office Action (Sept. 13, 1999) at PGOAM0174588. 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. BB, Response (Mar. 20, 2000) at PGOAM0174599-600. In addition, claim 1 was amended to add length, width, and thickness parameters, and to recite "oval shaped," rather than "generally oval form."

Applicants amended claim 1 from "generally oval form" to "oval shaped" for consistency with the language of the specification, but in doing so, did not limit the claim scope. *See* Ex. BB, Response (Mar. 20, 2000) at PGOAM0174599 (citing the use of "oval shaped" in the specification). It is evident from original dependent claims 5 and 11, which recited "modified oval or caplet shape" and "modified oval," respectively, that the scope of "oval form" included these dosage forms. Amending "oval form" to "oval shaped" did not narrow the scope to exclude modified oval or caplet shaped dosage forms. Indeed, as discussed above, the specification explicitly states that "oval shaped" includes (but is not limited to) "modified oval and caplet shaped form." Ex. A, col. 2 ll. 3-5.

Applicants cited two references: (a) *Tableting Specification Manual* (4th ed. 1995), and (b) Herbert Lieberman et al., *Pharmaceutical Dosage Forms*, Chapter 7, (2nd ed. 1990) in support of the definiteness of the term "oval shaped," as understood by one of ordinary skill in the art.

Applicants' arguments and claim amendments did not surrender oval tablets that are "modified oval" and "caplet shaped." The addition of length, width, and thickness dimensions

further defined the claimed dosage forms and does not, in any event, exclude modified oval or caplet shaped dosage forms, either of which can have the recited dimensions. Applicants' arguments and claim amendments did not surrender oval tablets that are modified ovals or caplet shaped, and the term "oval shaped" in claim 1 should be construed to include "modified oval" and "caplet shape" dosage forms, which are described and illustrated in the specification, as discussed above.

4. Defendants' Construction is Flawed.

Teva's proposed construction seeks improperly to impose limitations and exclusions on the scope of the claims that are not justified by the plain meaning of the terms, the specification, or a fair reading of the prosecution history. Defendant Teva's proposed construction of "oval" improperly excludes "caplet" forms and "modified oval" forms, which are preferred embodiments illustrated in the specification. Ex. A, col. 6 ll. 5-8 & Figs. 1-3. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (noting that a construction that excludes the preferred embodiment is "rarely, if ever, correct"). Notably, Teva's tablets fall precisely within the dimensional limitations of the claim and appear indistinguishable from the "modified oval" forms illustrated in the specification. Accordingly, Teva's proposed construction – which, not surprisingly, is designed to evade infringement – should be rejected.

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court construe the disputed limitations of the '513 patent as proposed by Plaintiffs herein.

Of Counsel:
William F. Lee
Vinita Ferrera
Allen C. Nunnally
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

David B. Bassett
Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800
Attorneys for Plaintiffs Warner Chilcott Company, LLC and The Procter & Gamble Co.

Mark E. Waddell
Loeb & Loeb LLP
345 Park Avenue
New York, NY
(212) 230-8800
Attorney for Plaintiff Hoffmann-La Roche Inc.

/s/ Laura D. Hatcher
Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Steven J. Fineman (#4025)
fineman@rlf.com
Laura D. Hatcher (#5098)
hatcher@rlf.com
Richards Layton & Finger, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700

Attorneys for Plaintiffs Warner Chilcott Company, LLC, The Procter & Gamble Co., and Hoffmann-La Roche Inc.

Dated: April 18, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2011, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and have sent by Electronic Mail to the following:

Richard K. Herrmann
Mary B. Matterer
Amy A. Quinlan
Morris James LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801

Robert E. Colletti
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Karen L. Pascale, Esquire
Young Conaway Stargatt & Taylor
The Brandywine Building
1000 West Street - 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391

Richard William Riley, Esquire
Duane Morris LLP
1100 North Market Street
Suite 1200
Wilmington, DE 19801

James Galbraith, Esquire
Maria Luisa Palmese, Esquire
Antony Pfeffer, Esquire
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004

Steven E. Feldman, Esquire
Husch Blackwell Sanders Welsh & Katz LLP
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606

/s/ Laura D. Hatcher
Laura D. Hatcher (#5098)
Hatcher@rlf.com