NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUNOVIAN PHARMACEUTICALS INC.,	**Hon. Dennis M. Cavanaugh**
Plaintiff,	**OPINION**
v.	(Markman Hearing)
TEVA PHARMACEUTICALS USA, INC., *et al*	Civil Action No. 09-cv-1302
Defendants.	

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court by request of Sunovian Pharmaceuticals Inc. ("Sunovian" or "Plaintiff"); Teva Pharmaceuticals USA, Inc.; Sun Pharma Global Inc.; Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries, LTD; Alphapharm Pty, LTD; Mylan, Inc.; Mylan Pharmaceuticals Inc.(collectively the "10% Defendants"); Dr. Reddy's Laboratories, LTD; and Dr. Reddy's Laboratories Inc. (collectively "DRL") for a claim construction hearing, pursuant to Local Patent Rule 4.5. The parties sought the Court's interpretation of one disputed term in U.S. Patent Nos. 6,864,257 (the "'257 patent"), 6,319,926 (the "'926 patent"), and 6,444,673 (the "'673 patent") (collectively the "patents-in-suit").[1] A Markman hearing was held on February 22, 2012 at which all parties ably presented sophisticated and intelligent arguments. Having considered the parties'

[1] U.S. Patent 7,381,724 (the "'724 patent") is also included in the patents-in-suit. The disputed claim term is not found in the '724 patent.

written and oral arguments, the Court has set forth its construction of the disputed term.

I. BACKGROUND

A Markman hearing was held to aid the Court in construction of one disputed term in the patents-in-suit. These patents are used by Sunovian to produce and market a sleep medication, Lunesta®.[2] Defendants each filed Abbreviated New Drug Application forms ("ANDA") with the U.S. Food and Drug Administration which contained certifications alleging that Sunovian's patents covering its Lunesta® product, directed to eszopiclone and methods of using that compound, are not infringed, invalid, and/or unenforceable. Sunovian contends that the products described in the ANDAs would infringe the patents-in-suit and filed suit alleging the same on March 20, 2009. The only term that remains in dispute is the term "essentially free."

II. LEGAL STANDARD

Claim construction is a matter of law to be determined solely by the court. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006). Analysis of a patent infringement claim is a two-step process. Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002). A court must first construe the meaning and scope of the patent claims, Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), and then compare the claims as construed to the alleged infringing product. Tate, 279 F.3d at 1365. At this stage, the Court will only engage in the first step.

To construe the terms of a patent, a court should look first to the language of the claim itself.

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[2]The instant suit was originally filed by Sepracor, Inc. on March 20, 2009. On October 12, 2010, Sepracor Inc. changed its name to Sunovian Pharmaceuticals Inc. The caption has been revised to reflect this change. All references made to Plaintiff herein will be made to Sunovian.

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Terms within a claim "are generally given their ordinary and customary meaning." Id. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

To determine how a person of skill in the art would understand a patent's claim language, a court must first examine the intrinsic record–the patent itself, including the claims, the specification and the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit has explained that the specification is "usually . . . dispositive . . .[and is the] best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582)(internal quotations omitted). It is proper for a court to "rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

A patent's prosecution history is also a critical source of guidance, as it "provides evidence of how the [Patent Trademark Office] and the inventor understood the patent." Id. The prosecution history is the complete record of the proceedings before the PTO, and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. The Federal Circuit has repeatedly emphasized the need to consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." See Rhodia Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005) (recognizing that, in exchanges

with the PTO, a patent applicant may disavow or disclaim certain claim coverage, thereby precluding any claim interpretation that would encompass the disavowed or disclaimed subject matter).

After consulting intrinsic evidence, a district court may also examine extrinsic evidence—i.e., "all evidence external to the patent and prosecution history." Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. Markman, 52 F.3d at 980. However, extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of claim language." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). Extrinsic evidence, when relied upon, must be considered in view of the specification and prosecution history. Phillips, 415 F.3d at 1320. ("[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence.").

III. DISCUSSION

A. "ESSENTIALLY FREE"

The parties dispute the construction of the phrase "essentially free." Specifically, the parties disagree on the amount of the levorotatory isomer that can be present and yet satisfy the "essentially free" limitation in the claims.[3] Sunovian, as well as the 10% Defendants (collectively the "10% Proponents"), maintain that "essentially free" is defined as "[l]argely but not wholly free of the

[3]Isomers are molecules having the same chemical formula, but with their atoms arranged in space as nonsuperimposable "mirror images" of one another. Isomer pairs are distinguished by the direction that they rotate polarized light: "(+)" or "d-" for destrorotatory isomers and "(-)" or "l-" for levorotatory isomers. The dispute regarding the term "essentially free" concerns the relative proportions of these isomer pairs that are allowable under the claims asserted in the patents-in-dispute.

levoratatory isomer, which encompasses greater than approximately 90% dextrorotatory isomer by weight of the total weight of zopiclone" (the "10% Construction"). DRL suggest a more narrow definition, and maintains that "essentially free" should be defined as "less than 0.25% of [its/the] levorotatory isomer" (the "0.25% Construction").

1. Plain Meaning

The 10% Proponents first propose that the term "essentially free" has a plain meaning, and that this Court's analysis should be guided accordingly. Such a construction is proposed in an effort to require a clear prosecution disclaimer to alter the scope of the term. See Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1377 (Fed. Cir. 2009)(holding that to the extent a plain meaning is found, a court will not narrow a claim under prosecution disclaimer unless the statements clearly and unambiguously manifest patentee's intent). To the extent that a plain meaning is found, the party challenging that plain meaning must demonstrate a clear and unambiguous disavowal of the term's meaning by the patentees to arrive at a different definition. Id.

This Court finds that there is no plain meaning for the term "essentially free." The Federal Circuit has held that terms of approximation such as "essentially," "substantially,"and "largely" are terms of approximation that are capable of multiple meanings. Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1322-23 (Fed. Cir. 2003)(concluding that the term "substantially" is capable of multiple interpretations, and turning to the intrinsic evidence to determine what definition should be adopted.); Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1369 (Fed. Cir. 2001)(resolving the definition of "substantially uniform" upon consultation with the procedural history of the patent); see also Glaxo Group Ltd. v. Ranbaxy Pharm., Inc., 262 F.3d 1333, 1336 (Fed. Cir. 2001). Under such circumstances, the Federal Circuit has turned to the intrinsic

record of the patent for clarification of the scope of the claim term. Id. Accordingly, this Court will turn to the intrinsic evidence of the patents-in-suit to determine the appropriate definition for "essentially free."

2. Prosecution History

It is undisputed that neither the claims nor the specifications of the patents define what degree of enantiomeric purity of the d-isomer of zopiclone composition is "essentially free" of the levorotatory isomer. Therefore, this Court must turn to the prosecution history of the patents-in-suit to properly construe the disputed term. See Phillips., 415 F.3d at 1317 (noting that the prosecution history was created by the patentee in an attempt to explain and obtain the patent and reflects how the PTO and the inventor understood the patent).

The parties highlight different elements of the patents' history in support of their respective definitions. The 10% Proponents direct this Court to rely on statements made in the file history of the'673 patent in which the patents-in-suit were compared to an unrelated patent with a similar 10% limitation. DRL rather relies on statements and submissions made by the Patentees to overcome an enablement objection to the patents-in-suit, as well as the circumstances under which the claim language was amended to include the "essentially free" language. Based upon this evidence, DRL concludes that the Patentees represented that their invention was a purified eszopiclone having less than 0.25% the l- or r- isomer.

DRL highlights, inter alia, the following record evidence from the prosecution history of the patents-in-suit to support their conclusion that both the Examiner and the Patentees understood the claimed invention to contain less than 0.25% of the l-isomer:

(1) Statements made to overcome a Section 112 rejection (hereinafter the

"enablement rejection"), in which the applicants relied on Example 1 and concluded that the description in Example 1 "provides evidence of the fact that the material of the instant invention consists essentially of the d-isomer of zopiclone."(the "October 21 Response") (Radin Decl. Ex. 16, Oct. 21, 1994 Response U.S. Patent 08/232,313 , p. 5, ECF No. 243-5);

(2) Applicant's submission of the Roussel Declaration which stated that the final product of Example 1 had less than 0.25% of the l-isomer of the invention and "demonstrate the purity of the d-isomer of the invention and shows that the instant invention consists essentially of the d-isomer of zopiclone."(the "Roussel Declaration") (Radin Decl. Ex. 18, Roussel Declaration, ¶¶ 4, 7, 9, ECF No. 243-6); and

(3) Applicants arguments advanced to overcome an obviousness rejection in view of racemic zopiclone, in which applicants argued that "[i]n determining whether the prior art suggests the claimed invention, it is useful to determine whether the skilled artisan would seek the result achieved," and pointed to the d-isomer of Example 1 as the result. (Radin Decl. Ex. 21, Apr. 18, 1996 Response U.S. Patent 08/493,946, ECF No. 243-6).[4]

The aforementioned references occurred prior to the amendment to the claim language to include the disputed claim term "essentially free" (the "Amendment"). The Parties dispute the import of the record evidence as well as the meaning of the subsequent Amendment to the claim language. Based upon the following, this Court resolves that the record evidence supports a claim construction consistent with the 0.25% Construction.

a. The Enablement Rejection

The parties first dispute the relevance of the statements made and the evidence provided by the Patentees to overcome the Examiner's enablement rejection. The Examiner's stated

[4]Specifically, the Patentees provided the following: "There is no motivation, hence no suggestion in the prior art which would lead one of ordinary skill achieve the claimed result; namely, the resolution of the racemate to yield the d-isomer. The Examiner provides no reason why the skilled artisan would be motivated to undertake the complex resolution process disclosed in the specification which yields only about 23% of the d-isomer. See Example 1."(emphasis added).

reason for the objection concerned the claimed purity of the invention. Specifically, the Examiner stated "[t]he claim requires that the zopidone be "essentially" (i.e. entirely, except for irrelevant materials) D-isomer. However, no such assertion is made in the specification, that the product obtained does not have some L-isomer contaminant. Since there was no attempt made to determine the purity of the product, no such statement could have been made anyhow." (Radin Decl. Ex. 12, Advisory Action U.S. Patent Application No. 07/821,662, Jan. 24, 1992, ECF No. 243-5).[5] In response to the Examiner's objection, the Patentees directed the Examiner's attention to Example 1 in the patent and stated "Applicants believe that [Example 1] provides evidence of the fact that the material of the instant invention consists essentially of the d-isomer of zopiclone." (Radin Decl. Ex. 13, Jan. 11, 1993 Response, p. 2, ECF No. 243-5). Upon further rejection by the Examiner,[6] the Patentees came forth with the Roussel Declaration, and concluded "[i]t can be seen from the declaration that the content of the l-isomer in the d-isomer is lower than 0.25% and there is no enantioconversion of the l- to d-isomer." (Radin Decl. Ex. 19, Apr. 13, 1995 Response U.S. Patent Application No. 08/342,794, pp. 3-4, ECF No. 243-6).

The 10% Proponents challenge the use of this exchange to define the scope of the claim language for two reasons. First, the 10% Proponents challenge the relevance of the statements as

[5] See also Radin Decl. Ex. 15, Advisory Action U.S. Patent Application No. 08/034,199, Jul. 23, 1993, p. 4, ECF No. 243-5 ("there is no way the specification could have said its material was "essentially" free of any l-isomer because there was never any attempt to determine the optical purity in the first place. The material could have a non-trivial amount of the other isomer present and the applicant would never know it.")

[6] Specifically, the Examiner stated, "the traverse of the 35 USC 112 rejection is unpersuasive. Applicant is reading into the specification that which simply isn't there. It does not state that it is a "pure" product - nor could it, since no attempt was made to determine its purity." (Radin Decl. Ex. 14, Advisory Action U.S. Patent Application No. 07/821, 662, Jan. 26, 1993, p. 2, ECF No. 243-5).

they were made in response to an enablement rejection and are therefore not definitional. Defendants rely on the case of Aventis Pharma Deutschland GmbH v. Lupin Ltd., for the conclusion that evidence submitted to overcome an enablement rejection cannot be used to limit claim terms. No. 05-0421, 2006 WL 1314413, at *12 (E.D.Va. May 12, 2006). However, the case at hand is clearly distinguishable from Aventis Pharma Deutschland. There, the Court found that examples provided in response to an enablement rejection were not relevant to construing the disputed claim term and were insufficient to provide the unambiguous disavowal of the term's plain and ordinary meaning. Id. Here, this Court has found that there is no plain meaning for "essentially free" and that the evidence submitted is directly relevant to the scope of the term in dispute. Therefore, Aventis Pharma Deutschland does not preclude the consideration of evidence submitted to overcome the enablement rejection.

Alternately, the 10% Proponents argue that to the extent such statements are found to be definitional, they are definitional for the wrong term as they were made at a time when "essentially free" had not yet been included in the patent. Novo Nordisk, A/S v. Sanofi Aventis U.S., LLC, No. 07-32906, 2009 WL 2185905, at *8 (D.N.J. July 22, 2009). Regardless of the fact that the exchange occurred prior to the inclusion of the disputed claim term, this Court finds that pursuant to the exchange, the Patentees effectively defined their invention as containing content of l-isomer that was lower less than 0.25% of the l-isomer. Moreover, such statements reflect the Patentee's own characterization and understanding of the claimed invention. See Rhodia Chimie v. PPG Indus., 402 F.3d at 1384 (precluding any claim interpretation that would encompass a coverage that was disavowed or disclaimed during prosecution). Accordingly, the Patentees are bound by their own limitations of the claimed invention.

This Court therefore concludes that the evidence submitted and statements made in response to the enablement rejection are relevant to the construction of "essentially free" and lend support to the 0.25% Construction.

b. The Amendment

The evidence concerning the Amendment to the claim language is not to the contrary. As previously stated, the 10% Proponents maintain that the statements made by Patentees to overcome the enablement rejection were made at a time prior to the inclusion of the "essentially free" language. This Court finds, however, that the statements remain relevant to the claim language as amended as Patentees relied upon the same evidence and explicitly stated that the amendment to the claim language did not alter the scope of the claimed invention.

Patentees sought the Amendment on November 17, 1997 to "more particularly point out and distinctly claim that which Applicants consider to be their invention." (Radin Decl. Ex. 24, Amendment After Final Under 27 C.F.R. § 1.116, '946 Patent, Nov. 17, 1997, p. 2, ECF No. 243-8). At that time, the Amendment sought to include the language "essentially free" without removing the "consisting essentially of" language that was already present in the patent's preamble. Id. The Examiner rejected this proposed amendment and concluded that the new limitation didn't make sense because the "preamble already requires that it be "essentially . . . d-isomer, meaning that everything, including l-isomer, is already excluded." Id. Upon rejection of the first request for Amendment, the Patentees filed a Second Preliminary Amendment and Request that an Interference be Declared on February 12, 1999. (Radin Decl. Ex. 25, Second Preliminary Amendment and Request that an Interference be Declared Under 37 C.F.R. § 1.607,

Feb. 12, 1999, ECF No. 243-9). Pursuant to the Second Amendment Patentees eliminated the "consisting essentially of" language, and left the "essentially free" term intact. Id. Within the request, Patentees specifically referred to the Roussel Declaration, stating "Roussel establishes the d-isomer obtained as described in Example 1 of the RPR-US 1-7 contains less than 0.25% l-isomer. The d-isomer, as recited in claim 6, is therefore essentially free of the l-isomer." Id. at 10-11. Importantly, applicants stated that "[n]o new matter ha[d] been added by this proposed amendment," nor did it "raise new issues or necessitate the undertaking or any additional search of the art by the Examiner." Id.

While the Parties dispute the import of the Examiner's indefiniteness rejection,[7] what is clear is that the Patentees did not seek to alter the scope of the claimed invention through the Amendment. In light of Patentee's continued reliance on the Roussel Declaration and statements that the new claim language did not change the claimed invention, this Court finds that such record evidence supports the 0.25% Construction of "essentially free."

c. Example 1

The parties next dispute the import of Example 1 itself. As per the statements made by the Patentees regarding Example 1, DRL interprets the Example as exhibiting purity levels of less than 0.25%. The 10% Proponents rather conclude that the Example is not itself definitional, and rather demonstrates an imprecise purity level that covers a range of roughly 90 to 95 percent

[7]DRL reads the Examiner's indefiniteness rejection as interpreting the terms "essentially free" with "consisting essentially of" to mean the same term, and was therefore redundant. The 10% Proponents rather argue that redundancy in claims does not render them indefinite, see In re Robins, 429 F.2d 452, 458 (C.C.P.A. 1970), and rather suggest that the language was rejected as inconsistent because "essentially free" had a broader scope than "consisting essentially of."

or greater. To support this conclusion, the 10% Proponents point to the Declaration of Professor Samuel J. Danishefsky, Ph.D., wherein he opined that the Example conveys a range of roughly 90 to 95 percent or greater. (Danishefsky Decl., pp. 16 - 18, ECF No. 245-7). Further, the 10% Proponents cite to statements made by the Examiner in the course of the rejection in which he said the Example could convey the same optical purity regardless of whether "one batch is 90 % d, 10 % l, and the other is 10 % d, 90 % l." (Dittmann Decl., Ex. 14, Nov. 4, 1994 Advisory Action, p. 4, ECF No. 245-3). Finally, the 10% Proponents characterize Example 1 as demonstrating a "complex resolution process" that "describes" but does not "define" the claimed invention. The 10% Proponents conclude based upon the foregoing that such evidence precludes the 0.25% Construction.

This Court finds the arguments advanced by the 10% Proponents are not persuasive. First, the conclusions drawn by Professor Danishefsky are an extrinsic interpretation of the Example and are limited by the fact that he did not read the entire file history of the patent. Moreover, such a construction is clearly overcome by the Patentees' own repeated characterization of the Example as demonstrating less than 0.25% of the l-isomer. Accordingly, this Court finds that the 10% Proponents have failed to set forth sufficient evidence to overcome the express representations made by the Patentees regarding Example 1. Example 1 supports the 0.25% Construction.

d. The Interference

Finally, this Court rejects the conclusions drawn by the 10% Proponents from the Interference declared on June 30, 1999 as insufficient to define the disputed claim language. The

interference was requested in the course of a continuation application (the "'651 application") which eventually resulted in the '926 patent. The Examiner specifically addressed the scope of the '651 application claims vis-a-vis the claims of an unrelated patent (the "'357 Patent"). Based upon said comparisons, the Examiner concluded that the invention claimed by the '651 patent was "patently indistinguishable from the '357 claims to products that are "substantially free of its (-) isomer." The '357 patent defined "substantially free" in a preferred embodiment in its specification which provided that "the amount of (+) zopiclone or a pharmaceutically acceptable salt thereof is greater than approximately 90% by weight of the total weight of zopiclone." The 10% Proponents therefore conclude that based upon this comparison, the claims in the patents-in-suit to "essentially free of the levorotatory isomer" of zopiclone should be given the same 10% construction. The 10% Proponents again point to the interpretation of Example 1 provided by Professor Danishefsky as further confirmation of the 10% Construction.

This Court finds the evidence in support of the 10% Construction to be insufficient in light of the record evidence. The 10% limitation was found in the claims of an unrelated patent, and the Examiner's conclusions that the unrelated patent would amount to largely the same thing as the claims in suit cannot be sufficient to overcome the express representations made by the Patentees themselves. Accordingly, this Court rejects the 10% Construction and finds that the term "essentially free" is properly defined as "less than 0.25% of [its/the] levorotatory isomer."

IV. CONCLUSION

The Court, in accordance with the discussion above, has construed the terms of the '257, '926, and '673 Patents.

S Dennis M. Cavanaugh
DENNIS M. CAVANAUGH, U.S.D..J.

Date: April 10, 2012
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Mark Falk, U.S.M.J.