IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Pfizer Inc., et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civ. No. 09-943-LPS
	:	
Dr. Reddy's Laboratories Ltd., et al.,	:	
	:	
Defendants.	:	

Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire, Mary W. Bourke, Esquire, Daniel C. Mulveny, Esquire, Dana K. Severance, Esquire, and Daniel M. Attaway, Esquire, of CONNOLLY BOVE LODGE & HUTZ LLP, Wilmington, Delaware.
Of Counsel: William E. McShane, Esquire, of CONNOLLY BOVE LODGE & HUTZ LLP, Washington, DC.

Attorneys for Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC.

John W. Shaw, Esquire, Karen L. Pascale, Esquire, and James L. Higgins, Esquire, of YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware.
Louis H. Weinstein, Esquire, of BUDD LARNER, P.C., Short Hills, New Jersey.

Attorneys for Defendants, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

MEMORANDUM OPINION

February 28, 2011
Wilmington, Delaware

Stark, District Judge:

This action was filed by plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively, "Pfizer"), on December 8, 2009, alleging infringement of U.S. Patent No. 5,969,156 and its Reexamination Certificate (collectively, "the '156 patent," or "patent-in-suit").[1] (D.I. 1) The Court conducted a *Markman* hearing on the disputed claim terms on February 2, 2011. *See* Transcript of February 2, 2011 *Markman* hearing (D.I. 115) (hereinafter "Tr ."). The Court now provides constructions of the disputed claim terms of the '156 patent.

BACKGROUND

On October 19, 1999, the United States Patent and Trademark Office (the "PTO") issued the '156 patent, entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)-β,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-l-Heptanoic Acid Hemicalcium Salt (Atorvastatin)." (D.I. 1 ¶ 2) On September 26, 2006, the PTO issued an Ex Parte Reexamination Certificate for the '156 patent. (*Id.*) Pfizer holds approved New Drug Application ("NDA") No. 02-0702 for atorvastatin calcium ("atorvastatin") formulations, including 10 mg, 20 mg, 40 mg, and 80 mg dosage strengths, which it sells under the brand name Lipitor® – a drug that lowers cholesterol, specifically "bad" or low-density lipoprotein (LDL) cholesterol in the blood of patients. (*Id.* ¶ 10; D.I. 97 at 2) While the expiration date for the '156 patent is July 8, 2016, the pediatric exclusivity period associated with the '156 patent will expire on January 18, 2017. (D.I. 1 ¶¶ 40, 42)

[1]To the extent not otherwise noted, the '156 patent and file history are located in the record at D.I. 91 and D.I. 92.

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") filed with the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") No. 91-650, seeking FDA approval to market generic atorvastatin tablets in 10 mg, 20 mg, and 40 mg dosage strengths, prior to the expiration of the '156 patent. (*Id.* ¶¶ 12, 43) In response, Pfizer sued DRL for infringement of the '156 patent.

For purposes of construction, the parties have now placed the following three categories of disputed[2] claim terms before the Court:

1. the "Form" terms, i.e.,
    a. "Form I atorvastatin," appearing in claims 1-27, 45, 47, 52-55, 61-99, 110-12, and 115;
    b. "Form II atorvastatin," appearing in claims 28-35, 56-57, 100-05, 113, and 116;
    c. "Form IV atorvastatin," appearing in claims 36-44, 46, 48-51, 58-60, 106-09, 114, and 117;
2. "hydrate," appearing in all claims; and
3. the "having" terms, i.e.,
    a. "[h]aving an X-ray powder diffraction containing," appearing in claims 1-5, 28-31, 36-40, 45-69, 100-10, and 113-17;
    b. "[h]aving a chemical shift difference," appearing in claims 6, 32, 41, and

[2]The parties initially also presented a dispute relating to the term "crystalline," which appears in all claims, disagreeing as to the plain and ordinary meaning of the term. (*See* D.I. 89; D.I. 96 at 2, 12-13; D.I. 97 at 18; D.I. 101 at 5; D.I. 103 at 16) At the Markman hearing, Pfizer stated that either party's proposed construction for this term would be acceptable. (*See* Tr. at 2-3) Hence, the Court will adopt DRL's construction and construe the term "crystalline" as used in all of the claims to mean "a solid form having a long range periodic ordered structure extending in three dimensions."

62-63;

c. "having the following chemical shift differences," appearing in claims 7-8, 33-34, 42-43, 61, 64, and 100-02; and

d. "having the following chemical shifts," appearing in claims 9, 35, 44, 65-69, 103-10, and 113-14.

(*See* D.I. 89; Tr. at 3-4)[3]

LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which 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." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a

[3]The Court agrees with the parties that there is no meaningful distinction among the various "Form" terms or among the various "having" terms. Therefore, the Court addresses the "Form" terms as presenting a singular dispute, and the "having" in the same manner – just as the parties structured their presentations at the hearing. (*See* Tr. at 3-4; *see also* D.I. 89; D.I. 96 at 1-2, 4, 14; D.I. 97 at 7, 19-20)

claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v.*

Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history 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.*

A court also may 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." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary 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.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic

evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted). If possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

CONSTRUCTION OF THE DISPUTED TERMS

I. The Form I, II, and IV Terms

While there are three "Form" terms in dispute, i.e., Forms I, II, and IV,[4] they present the

---

[4]Pfizer proposes "Form I atorvastatin," as used in claims 1-27, 45, 47, 52-55, 61-99, 110-12, and 115, should be construed to mean "a term of convenience or reference used to designate any crystalline form of atorvastatin hydrate having the 2θ values and/or solid-state ^{13}C nuclear magnetic resonance chemical shifts and/or solid-state ^{13}C nuclear magnetic resonance chemical shift differences set forth in each respective claim or the claim from which it depends." (D.I. 89) Pfizer proposes the substantially identical construction also for "Form II atorvastatin," as used in claims 28-35, 56-57, 100-105, 113 and 116, and "Form IV atorvastatin," as used in claims 36-44, 46, 48-51, 58-60, 106-09, 114, and 117; the only difference is that the "or the claim from which it depends" language is not proposed for Forms II and IV. (*Id.*)

DRL's proposed construction for "Form I atorvastatin" is "[a] crystalline form of atorvastatin characterized by its X-ray powder diffraction pattern according to Figure 1 or Table 1, or by its solid state nuclear magnetic resonance spectrum according to Figure 4 or Table 4." (*Id.*) DRL's proposed constructions for "Form II atorvastatin" and "Form IV atorvastatin" differ from its proposed construction of "Form I atorvastatin" only in that the particular Figures and Tables to which they refer differ. (*See id.* (DRL proposing that "Form II" construction include reference to "X-ray powder diffraction pattern according to Figure 2 or Table 2" and to "solid state nuclear magnetic resonance spectrum according to Figure 5 or Table 5," and that "Form IV" construction include reference to "X-ray powder diffraction pattern according to Figure 3 or

same dispute, which need only be resolved once, as the parties agreed at the hearing. (*See* Tr. at 2-3) For ease of reference, the Court will refer here primarily to "Form I atorvastatin," but the analysis applies equally to Form II and Form IV.

Two illustrative claims where the Form I term is found are claims 1 and 4, reproduced below:

> 1. A crystalline ***Form I atorvastatin*** hydrate having an X-ray powder diffraction containing the following 2θ value measured using CuK_{α} radiation: *22.0.*[5]
>
> 4. A crystalline ***Form I atorvastatin*** hydrate having an X-ray powder diffraction containing the following 2θ values measured using CuK_{α} radiation: 9.2, 9.5, 10.3, 10.6, 11.9, 12.2, 17.1, 19.5, 21.6, 22.0, 22.7, 23.3, 23.7, 24.4, 28.9 and 29.2.

('156 patent, col. 1 lines 28-31, 37-41) (emphasis added)

Pfizer contends that when the patentees first invented crystalline atorvastatin, they used the terms "Form I," "Form II," "Form III,"[6] and "Form IV" to describe the crystalline forms in the order of their discovery. (*See* D.I. 97 at 1-3, 8; *id.* Ex. 2 at PF0111618; D.I. 103 at 2, 6) Pfizer submits that one of ordinary skill in the art would grasp that each of these Form terms is

---

Table 3" and to "solid state nuclear magnetic resonance spectrum according to Figure 6 or Table 6"))

[5]The specification explains: "Crystalline Form I, Form II, or Form IV atorvastatin may be characterized by their X-ray powder diffraction ['XRPD'] patterns and/or by their solid state nuclear magnetic resonance spectra (NMR)." ('156 patent, col. 5 lines 53-56) Moreover, "[t]he claims characterize these forms with value(s) obtained from techniques well known in the art to define crystalline structures. Each claim recites either: (a) one or more 2-theta ('2θ') values obtained from [XRPD]; (b) one or more solid-state solid-state ^{13}C NMR ('ss^{13}C NMR') chemical shift differences; and/or (c) one or more ss^{13}C NMR chemical shifts." (D.I. 97 at 3; *see id.* Ex. 1 (Myerson Decl.) ¶ 33)

[6]"Form III" is the subject of another patent and not at issue here. (*See* Tr. at 5)

simply a term of convenience or reference. (D.I. 103 at 1, 7) In Pfizer's view, then, the Form terms are not claim limitations, and their construction should not impact the scope of the claims. (Tr. at 46-47)

DRL, on the other hand, faults Pfizer's proposed construction for leaving the Form terms improperly "devoid of meaning." (D.I. 96 at 1-2; D.I. 101 at 2) DRL would, instead, have the Court construe the Form terms by reference to the specific values disclosed in the '156 patent's specification. To DRL, Pfizer's construction would lead to invalid claims. (*Id.* at 11-12)

Having reviewed the intrinsic and extrinsic evidence,[7] and considered the arguments of the parties, the Court concludes that Pfizer's proposed construction of the Form terms should be adopted. The Court agrees with Pfizer's explanation of how the Form terms are used in the patent-in-suit:

> When claim 1, for example, is read as a whole, common sense dictates that the term "Form I atorvastatin" is a term of reference which, when read in context, simply means "a crystalline form of atorvastatin" that has the particular characteristic value specified in the claim. In other words, claim 1 as written only requires the claimed crystalline atorvastatin to have an XRPD 2θ peak at 22.0. [Ex. 7 ('156 reexam) at col. 1, ll. 29-31.]
>
> The term "Form I atorvastatin" can be used by the reader to find in the '156 patent specification a specific example of Form I atorvastatin wherein a unique crystalline atorvastatin form with the claimed 2θ value of 22.0 was first described. "Form I atorvastatin" cannot be divorced from the 2θ value of 22.0 specifically recited in claim 1, nor can it be used to read into the claim as mandatory elements the multiple additional 2θ values that are specifically recited in *other* '156 claims. From the example of claim 1, it can be seen that when read in context with the specified 2θ values and/or the ss^{13}C NMR values in the claims,

[7]DRL's reference at the hearing to deposition testimony (of a prosecuting attorney and a named inventor) (*see* Tr. at 25-26) was in tension with the view it advocated in its briefing, that "[i]n this case, the intrinsic evidence provides a sufficient basis to construe the claims without resort to extrinsic evidence." (D.I. 96 at 4)

> "Form I", "Form II", or "Form IV" are not meaningless; they refer to particular forms of crystalline atorvastatin wherein the unique XRPD and/or ss^{13}C NMR values or a combination of values specified in the particular claim were first identified. [Ex. 7 ('156 patent) at col. 15, l. 42 to col. 18, l. 33 and ('156 reexam) at col. 1, l. 28 to col. 8, l. 27.]

(D.I. 97 at 7-8)

The patentees were the first to discover the crystalline form of atorvastatin hydrate. (D.I. 103 at 5) It is undisputed that at the time the patent application was filed, Forms I, II, and IV (along with Form III) were the only forms of crystalline atorvastatin hydrate that the patentees had discovered. (Tr. at 51) The Court agrees with Pfizer that this reality, in the circumstances presented here, did not limit the patentee to claiming only Forms I, II, and IV. *See, e.g., Innogenetics, N. V v. Abbott Labs.*, 512 F.3d 1363, 1371-72 (Fed. Cir. 2008) ("Abbott argues that a patent can never be literally infringed by embodiments that did not exist at the time of filing. Our case law allows for after-arising technology to be captured within the literal scope of valid claims that are drafted broadly enough.") (citing *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 878-80 (Fed. Cir. 2004)). Nor would the patentees have been motivated to claim narrowly, as there was no prior art they had to avoid.

Moreover, there are "no words of manifest exclusion or restriction" in the claims, specification, or prosecution history, from which one might conclude that the patentees failed to claim anything more broadly than Forms I, II, and IV. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction."). To the

contrary, for instance, the specification describes the examples it discloses as "non-limiting examples which refer to the accompanying FIGS. 1 to 6." ('156 patent, col. 5 lines 22-24; *see also id.* col. 14 lines 29-31 ("The following nonlimiting examples illustrate the inventors' preferred methods for preparing the compounds of the invention."))

Likewise, the Court finds nothing in the prosecution history to suggest that the patentees limited their claims to the "Form I," "Form II," and "Form IV" examples disclosed in the specification. When the patent application was originally filed, the patentees claimed each of the three Forms with the full list of XRPD 2θ peaks found in Tables 1, 2, and 3 of the specification. (*See* D.I. 97 Ex. 4 (U.S. Provisional Application 60/001,452) at 1, 28-36) During prosecution, Pfizer amended the original '156 claims so they did *not* include all of the 2θ values in corresponding Tables 1, 2, or 3; these amendments were approved by the PTO. (*See* D.I. 97 at 12-13; *id.* Ex. 3 at PF0114388-391) Pfizer similarly amended the original '156 claims so they did *not* include all of the ss^{13}C NMR values in Tables 4, 5, and 6; the PTO approved these amendments as well. (*See* D.I. 97 at 13; *id.* Ex. 3 at PF0114391-395) Subsequently, during reexamination, Pfizer again amended the claims, and added new claims, all "to create sets of claims with varying scope which were defined by different numbers of XRPD 2θ values and/or ss^{13}C NMR chemical shift and/or ss^{13}C NMR chemical shift difference values recited in each claim." (D.I. 97 at 13; *see* D.I. 92 Ex. 4 at PF0111510-522)

Accordingly, the Court will construe the Form terms as terms of convenience, adopting the construction proposed by Pfizer.[8]

---

[8]The Court does not reach any conclusion at this time as to the validity of the patent-in-suit under the claim constructions being adopted.

II. "hydrate"

Pfizer proposes that the Court construe "hydrate," as used in all of the claims, to mean "a crystalline compound in which water is contained within the crystalline structure." (D.I. 89) DRL proposes, instead, "[a] crystalline compound in which water is part of the crystalline structure." (*Id.*) The Court will adopt Pfizer's proposed construction.

Pfizer offers that its construction is consistent with "hydrate's" plain and ordinary meaning as understood by one of ordinary skill in the art, which is consistent with how the term is used in the specification of the '156 patent. Pfizer insists its construction is also "supported by the '156 patent specification which specifically identifies crystalline atorvastatin calcium that *contains* about 1 to 8 mol of water." (D.I. 97 at 19; *see id.* Ex. 7 ('156 patent, col. 11 lines 27-34)) DRL, however, contends that its proposed construction is more precise because "it ensures that crystals with random inclusions of water are not considered hydrates;" thus, under DRL's proposal, "the water must be part of the ordered structure of the crystal." (D.I. 96 at 13; *see* D.I. 98 (Genck Decl.) ¶ 33)

The Court agrees with Pfizer that within the '156 patent claims, "hydrate" includes *all* of the water that is contained within the crystalline structure. Nothing in the claim language, nor the specification or prosecution history, suggests a basis to limit the term in the manner proposed by DRL. Accordingly, the Court will construe "hydrate" to mean "a crystalline compound in which water is contained within the crystalline structure."

III. The "having" terms

According to Pfizer, the word "having" as contained in the phrases at issue requires no construction – "having" means "having." (Tr. at 61) The words of the terms are common and

ordinary, are clear on their face, and are easily understood by one of ordinary skill in the art. (*See* D.I. 89; D.I. 97 at 19-20, Ex. 1 (Myerson Decl.) ¶ 50; D.I. 103 at 16)

DRL argues, however, that "having" as used in the claims means "actually demonstrating." (Tr. at 62) Accordingly, DRL proposes that the four "having" terms each mean that the respective peaks or shifts must be actually demonstrated. (*See* D.I. 89; D.I. 96 at 2-3, 14; D.I. 101 at 6) Otherwise, in DRL's view, the terms recited in the claims would be meaningless. (*See* D.I. 96 at 14; D.I. 101 at 6)

Pfizer responds that "DRL's insistence in adding an 'actually demonstrating' requirement conflates claim construction (i.e., *what* the claims mean) with the determination of infringement (i.e., *how* to establish that an accused product meets the properly interpreted words of the claims)." (D.I. 103 at 16) While "Pfizer agrees that for infringement purposes it must prove that the required elements of the claim are present in the accused product . . . this has nothing to do with what the claims mean, the sole purpose of *Markman*." (*Id.* at 16-17)

The Court agrees with Pfizer and will not provide a specific construction of the "having" terms. The Court has found no case, and none has been cited by DRL, construing "having," which is a term readily understandable to a lay judge and jury. (*See* Tr. at 62) As the Federal Circuit has emphasized, the claim construction process should not become "an obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

CONCLUSION

An appropriate Order will be entered.