IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, SHIONOGI SEIYAKU KAUBSHIKI KAISHA, and THE BRIGHAM AND WOMEN'S HOSPITAL, INC.,	:	Civil Action No. 10-915-LPS
Plaintiffs,	:	
v.	:	UNSEALED ON FEBRUARY 9, 2012
WATSON LABORATORIES, INC. (NV) and EGIS PHARMACEUTICALS PLC,	:	
Defendant.	:	

Ford F. Farabow, Esquire of FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP, Washington, DC. Charles E. Lipsey, Esquire; Kenneth M. Frankel, Esquire; and York M. Faulkner, Esquire of FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP, Reston, VA. John D. Livingstone, Esquire of FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP, Atlanta, GA. Mary K. Ferguson, Esquire of FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP, Cambridge, MA. Mary W. Bourke, Esquire of CONNOLLY, BOVE, LODGE, & HUTZ LLP, Wilmington, DE.

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MEMORANDUM OPINION

February 2, 2012
Wilmington, Delaware.

STARK, U.S. District Judge:

I. INTRODUCTION

Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., AstraZeneca AB, Shionogi Seiyaku Kabushiki Kaisha, and the Brigham and Women's Hospital, Inc. (collectively, "AstraZeneca") filed a complaint against Defendant Watson Laboratories, Inc. ("Watson") on October 26, 2010. (D.I. 1) AstraZeneca alleges that Watson's application for FDA approval to sell rosuvastatin tablets constitutes infringement of U.S. Patent No. RE37,314 ("the '314 patent"). (*Id.*) Presently before the Court is the matter of claim construction. Briefing on claim construction was completed on December 9, 2011. (D.I. 123; D.I. 127; D.I. 144; D.I. 147) The Court held a claim construction hearing on January 13, 2012. (D.I. 204) (hereinafter "Tr.")

II. BACKGROUND

The '314 patent is directed to novel compounds that inhibit the biosynthesis of cholesterol and therefore are useful in the treatment of cardiovascular diseases. Among the disclosed compounds is rosuvastatin, the active ingredient in CRESTOR®, a prescription drug manufactured and marketed by AstraZeneca. The original U.S. patent application was filed on June 12, 1992 and issued as U.S. Patent No. 5,260,440 on November 9, 1993. Reissue proceedings were subsequently initiated on August 27, 1998, resulting in the grant of the '314 patent on August 7, 2001.

Independent claim 6 was added during the reissue proceedings, and is specifically directed to rosuvastatin in the form of a non-toxic pharmaceutically acceptable salt:

> The compound7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R,5S)-dihydroxy-(E)-6-heptenoic acid in the form of a non-toxic pharmaceutically acceptable salt thereof.

During related litigation brought by AstraZeneca against different generic drug manufacturers, the Court previously construed the term "non-toxic pharmaceutically acceptable salt" of claim 6 to mean rosuvastatin salts formed with "a cation capable of forming a non-toxic pharmaceutically acceptable salt." *See In re Rosuvastatin Calcium Patent Litigation*, C.A. No. 08-md-1949, 2009 WL 3378602, at *1 (D. Del. Oct. 20, 2009); *In re Rosuvastatin Calcium Patent Litigation*, C.A. No. 08-md-1949, 2009 WL 1220542, at *8 n.6 (D. Del. May 4, 2009).

III. 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 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., Ltd. 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). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

IV. DISCUSSION

"a cation capable of forming a non-toxic pharmaceutically acceptable salt"[1]

1. AstraZeneca's Construction: a cation that is related to or classified under a subsuming principle with, i.e. works like, an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein ammonium ion includes both substituted and unsubstituted ammonium ions

2. Watson's Construction: an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein the ammonium ion is unsubstituted

3. Court's Construction: an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein the ammonium ion is unsubstituted

The parties disagree on two related points regarding whether and to what extent the language "a cation capable of forming a non-toxic pharmaceutically acceptable salt" restricts the scope of claim 6 to the alkali metal, alkaline earth metal, and ammonium ions explicitly identified in the specification.[2] Watson contends that the specification expressly defines the "cation" term to include only (1) an alkali metal ion, alkaline earth metal ion, or ammonium ion,

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[1]The parties have asked the Court to clarify its previous construction based on language appearing in the specification, which the Court may do in order to resolve actual disputes over claim scope. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009); *O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

[2]The precise boundaries of the Court's prior construction of claim 6 was not at issue in the prior litigation because the proposed products in that case all contained rosuvastatin calcium salts, and calcium is described in the specification as a preferred cation. ('314 patent, col. 2 l. 21) Here, by contrast, Watson's proposed product contains a rosuvastatin zinc salt, and zinc is not described anywhere in the '314 patent specification.

wherein (2) the ammonium ion includes only unsubstituted ammonium.[3] AstraZeneca's proposed construction, by contrast, would more broadly encompass additional cations with similar chemical properties, including both substituted and unsubstituted ammonium ions.

Having reviewed the parties' arguments and evidence, the Court agrees with Watson that the specification provides an express definition that limits the term "cation capable of forming a non-toxic pharmaceutically acceptable salt" to an alkali metal ion, alkaline earth metal ion, or ammonium ion.[4] In particular, the specification states:

> The term 'a cation capable of forming a non-toxic pharmaceutically acceptable salt' ***refers to alkali metal ion, alkaline earth metal ion, and ammonium ion***. Examples of alkali metal are lithium, sodium, potassium, and cesium, and examples of alkaline earth metal are beryllium, magnesium, and calcium. Especially, sodium and calcium are preferred.

('314 patent, col.2 ll.16-21) (emphasis added). *See also Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (noting that fact that term is "set off by quotation marks" is "often a strong indication that what follows is a definition").

Additionally, the Detailed Description portion of the specification begins by stating that "the present invention" relates to compounds of the particular formula (I), and depicts the general chemical structure of formula (I), followed by a list of functional groups and potential substituents at various positions of formula (I). ('314 patent, col. 1 ll. 35-63) Immediately

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[3]The parties do not appear to dispute the meanings of substituted and unsubstituted ammonium ions. Substituted ammonium ions are those in which one or more of the hydrogen atoms of NH_4^+ have been replaced or "substituted" by an organic group. Substituted ammonium can exist in primary, secondary, tertiary, and quaternary forms, in which one, two, three, or all four hydrogens are replaced by organic groups, respectively. (D.I. 123 at 15)

[4]The parties agree that salts contain both a cation and an anion; because rosuvastatin is an anion, the rosuvastatin salt of claim 6 necessarily contains a "cation capable of forming a non-toxic pharmaceutically acceptable salt." (D.I. 123 at 8-9; Tr. at 9)

afterwards, the specification provides a list of definitions for those functional groups and their potential substituents. (*Id.* col. 1 l. 63 – col. 2 l. 35) Significantly, each of the defined terms is set off by quotation marks, and several, including "cation capable of forming a non-toxic pharmaceutically acceptable salt," are later recited in the claims, indicating, again, that the inventors acted as their own lexicographers by expressly defining claim terms in the specification. *See generally Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.").

The Court is unpersuaded by AstraZeneca's assertion that the use of the phrase "refers to" renders the inventors' definition open-ended and inclusive of additional cations with similar chemical properties. AstraZeneca contrasts the inventors' use of the phrase "refers to" when defining some terms with the inventors' use of the words "means" and "are" when defining other terms. (D.I. 127 at 14) According to AstraZeneca, these different word choices suggest different meanings, such that definitions employing "refers to" are open-ended while definitions employing "means" and "are" are closed. Although the use of different words can imply different meanings, "that implication is overcome where, as here, the evidence indicates that the patentee used the two terms interchangeably." *Baran v. Medical Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, the specification as a whole indicates that "refers to," "means," and "are" were all used interchangeably for the same purpose of expressly defining various terms. This conclusion is bolstered by the inventors' use elsewhere in the specification of the phrase "and the like" in certain definitions, plainly rendering those definitions open-ended – but "and the like" is missing from the "cation" definition at issue here. (*See* '314 patent, col. 1 l. 63 - col. 2 l. 15) (defining "lower alkyl," "aryl," and "aralkyl") The Court agrees with Watson

that if the phrase "refers to" was by itself open-ended in the context of the patent-in-suit, it would have been unnecessary to add "and the like" when defining "lower alkyl," "aryl," and "aralkyl." Hence, the Court's construction is properly supported by the specification, because it adopts the inventors' explicit lexicography and helps "preserve the patent's internal coherence." *Markman*, 517 U.S. at 390.[5]

The Court further concludes that the prosecution history does not meaningfully support either party's position. AstraZeneca points to the Applicants' statement during prosecution that "[t]he specification . . . defines the term 'cation capable of forming a non-toxic pharmaceutically acceptable salt' as ***referring, for example***, to calcium, with sodium and calcium being 'preferred.'" (D.I. 127 at 10) (emphasis added) But the specification does not repeat the phrase "for example," and instead just says "refers to." Moreover, the phrase "for example" would have been unnecessary if the word "referring" was already inherently exemplary and open-ended. Also, the Applicants' statement was directed only to certain species and preferred embodiments such as calcium and sodium, unlike the express definition in the specification, which more broadly refers to the general categories of "alkali metal ion, alkaline earth metal ion, and ammonium ion" in defining the term "cation capable of forming a non-toxic pharmaceutically acceptable salt."[6]

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[5]To the extent that AstraZeneca relies on technical treatises and other evidence of the plain and ordinary meaning of the "cation" language to a person of ordinary skill in the art, such evidence cannot overcome the inventors' lexicography. *See Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term.").

[6]The Court is similarly unpersuaded by Watson's prosecution disclaimer argument. Watson argues that AstraZeneca limited the scope of claim 6 to only sodium and calcium salts by repeatedly assuring the PTO during the reissue proceedings that its reissue application was limited to those two particular salts, in order to avoid rejections for an improper broadening

The Court further concludes, for similar reasons, that the "ammonium ion" of the claim includes only unsubstituted ammonium (NH_4^+). With respect to this term, the parties appear to agree that the plain and ordinary meaning of "ammonium ion" could possibly refer only to unsubstituted ammonium (NH_4^+), or could further encompass substituted (NR_4^+) forms of ammonium. (D.I. 123 at 14-15; D.I. 127 at 18-19) However, the parties dispute which of these plain and ordinary meanings is best supported by the particular context of the '314 patent and its intrinsic record. *See Phillips*, 415 F.3d at 1313.

Watson insists that, within the particular context of the '314 patent, a person of ordinary skill would interpret "ammonium ion" consistent with its narrower ordinary meaning, in view of the contrast between the specification's detailed description of potential substituents for various functional groups, and the specification's absence of any such descriptions for ammonium ions. (D.I. 123 at 16-17; D.I. 147 at 8) Watson notes that the inventors' general description of formula (I) explicitly provides that various functional groups, such as lower alkyl, aryl, and aralkyl, "may have one or more substituents." (*See* '314 patent, col. 1 ll. 50-60) Immediately following that general description, the inventors' express definitions for the terms "lower alkyl," "aryl," and "aralkyl" further specify the number and identity of possible substituents for those groups. (*Id.*,

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reissue application. (D.I. 123 at 4-5, 9-10) The Court concludes that AstraZeneca's statements did not rise to the level of "clear and unmistakable" surrender of claim scope. Watson's own proposed construction appears to be inconsistent with any alleged disclaimer, as it more broadly includes the alkali metal ions, alkaline earth metal ions, and ammonium ions recited in the inventors' express definition. (Tr. at 35-36)

Having agreed with Watson's proposed construction of the "cation" term, it is unnecessary to address Watson's arguments that AstraZeneca's proposed construction is barred by judicial estoppel and indefiniteness.

col. 2 ll.1-15)[7] By contrast, the inventors' definition for "cation capable of forming a non-toxic pharmaceutically acceptable salt" does not similarly identify the number or identity of any possible substituents with respect to the ammonium ion. (*Id.*, col. 2 ll. 16-21) Watson also points out that the inventors' definition of "cation capable of forming a non-toxic pharmaceutically acceptable salt" provides specific examples of alkali metal ions and alkaline earth metal ions, but no specific examples of ammonium ions, even though the possible universe of substituted ammonium ions is far greater than the number of alkali metal and alkaline earth metal ions. (D.I. 123 at 16)

Although a close question, on balance the Court agrees with Watson that within the particular context of the '314 patent, the repeated listing of possible substituents for various functional groups and specific examples of other cations, coupled with the complete absence of any such disclosures for ammonium, indicates that the inventors did not intend to include substituted ammonium ions within the scope of their definition for "cation capable of forming a non-toxic pharmaceutically acceptable salt." The Court therefore will construe "ammonium ion" to include only unsubstituted ammonium ions.[8]

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[7]Additional terms are similarly described and defined to provide for the possibility of substitution. ('314 patent, col. 2 ll. 25-30) (describing substituents for terms "imino which may have a substituent," "substituted amino as substituent," and "substituted sulfonyl as substituent")

[8]To be clear, the Court does not find that the inventors redefined the term "ammonium ion"; nor does the Court find a clear disavowal or disclaimer. Rather, the Court concludes that, within the context of the '314 patent, a person of ordinary skill would understand the term "ammonium ion" consistent with its narrower ordinary meaning rather than its broader ordinary meaning, for the reasons explained above. The Court's construction, therefore, reflects the plain and ordinary meaning of "ammonium ion," as that term is used in the '314 patent. *See Phillips*, 415 F.3d at 1313.

V. CONCLUSION

For the foregoing reasons, the Court will construe "a cation capable of forming a non-toxic pharmaceutically acceptable salt" to mean "an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein the ammonium ion is unsubstituted." An appropriate Order follows.

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Plaintiffs,	:	
v.	:	Civil Action No. 10-915-LPS
WATSON LABORATORIES, INC. (NV), and EGIS PHARMACEUTICALS PLC,	:	
Defendant.	:	

ORDER

At Wilmington, this **2nd** day of **February 2012**,

For the reasons set forth in the Memorandum Opinion issued this same date, the Court construes "a cation capable of forming a non-toxic pharmaceutically acceptable salt" in the '314 patent to mean "an alkali metal ion, alkaline earth metal ion, or ammonium ion, wherein the ammonium ion is unsubstituted."

UNITED STATES DISTRICT JUDGE