IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB MANUFACTURING IRELAND LIMITED, UCM PHARMA GMBH and LTS LOHMANN THERAPIE-STSTEME AG,	:	
Plaintiffs,	:	
v.	:	C.A. No. 16-1023-LPS
ZYDUS WORLDWIDE DMCC and CADILA HEALTHCARE LTD, d/b/a/ ZYDUS CADILA,	:	
Defendants.	:	

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MEMORANDUM OPINION

June 1, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs UCB, Inc., UCB Manufacturing Ireland, Limited, UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs" or "UCB") filed suit against Defendants Zydus Worldwide DMCC and Cadila Healthcare Ltd., d/b/a Zydus Cadila (collectively, "Defendants" or "Zydus"), alleging infringement of U.S. Patent Nos. 6,884,434, 8,617,591, and 8,246,979.

Presently before the Court is the issue of claim construction. The parties dispute only one term appearing in the '434 patent. The '434 patent describes and claims transdermal therapeutic systems to treat symptoms of Parkinson's disease. *See* '434 Patent at 1:9-27.

The parties submitted briefs (*see* D.I. 96, 99, 105, 107) and the Court held a claim construction hearing on April 5, 2018. (*See* D.I. 127 ("Tr."))[1]

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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).

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[1]At the hearing on April 5, 2018, the Court granted Zydus's request to submit a second supplemental declaration from its expert, Dr. David W. Osborne, to respond to certain opinions of UCB's expert, Dr. Alexander M. Klibanov, which were untimely disclosed. (Tr. at 62; *see* D.I. 115) On May 3, 2018, in response to the submission of Dr. Osborne's supplemental declaration, UCB sought leave to submit an additional declaration from Dr. Klibanov, which the Court denied. (*See* D.I. 129, 130, 131) While the Court considered the extrinsic evidence raised by the parties' experts, the extrinsic evidence did not impact the Court's decision, which is based solely on the intrinsic evidence.

"[T]here is no magic formula or catechism for conducting claim construction." *Id.* 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 must also 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." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). 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.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "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 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. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERM[2]

"all of said free base being present in the matrix in the absence of water"[3]

UCB No construction necessary. Plain and ordinary meaning as would be understood by a person of ordinary skill in the art in view of the intrinsic evidence, which is "the free base is present in the matrix, which does not contain an aqueous phase or any water other than as the result of impurities."
Zydus "all of said free base being present in the matrix that is free of water"
Court "the free base is present in the matrix, which does not contain an aqueous phase or any water other than as the result of impurities."

UCB contends this term needs no construction, but to the extent the Court finds one necessary, proposes a construction that acknowledges the presence of water in the matrix only as a result of impurities. (D.I. 99 at 7) Zydus contends the patentee disclaimed the presence of water in the claimed matrix system, even as an impurity. (D.I. 105 at 2) Zydus has failed to meet its burden to show a clear and unmistakable disclaimer. *See 3M Innovative Prop. Co. v.*

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[2]The Court will adopt the parties' agreed-upon construction of the term "microreservoir," appearing in claims 1, 8, 11, 12, and 13 of the '979 patent and claims 1, 2, 3, 10, and 11 of the '591 patent, as "particulate, spatially and functionally separate compartments consisting of pure drug or a mixture of drug and crystallization inhibitor, which are dispersed in the self-adhesive (polymer) matrix." (*See* D.I. 91 at 7)

In addition, prior to oral argument, the parties disputed construction of the term "wherein the matrix is based on a [sic] an acrylate-based or silicone-based polymer adhesive system having a solubility of ≥5% (w/w) for the free base (-)- 5, 6, 7,8-tetrahydro-6-[propyl-[2-(2-thienyl) ethyl]-amino]-1-naphthalenol [rotigotine]," appearing in claim 1 of the '434 patent. At the hearing, the parties agreed they no longer have a dispute. (*See* Tr. at 59)

[3]This term appears in claim 1 of the '434 patent.

Tredegar Corp., 725 F.3d 1315, 1325 (Fed. Cir. 2013) ("[I]n order for prosecution disclaimer to attach, the disavowal must be both clear and unmistakable.").

During prosecution, the applicants explained that "the property 'non-aqueous' which is coterminous with 'free of water', is a [guarantee] for firstly the presence of the free base form of [rotigotine] in the adhesive layer and secondly the absence of an additional hydrophilic phase." (D.I. 105 at 3) (quoting D.I. 91 Ex. 8 at 13) In contending the applicants disclaimed the presence of water impurities, Zydus points primarily to the applicants' proposed amendment of current claim 1 (then, claim 18) in which the applicants proposed including the term "substantially" in two places. (Tr. at 33) Claim 18, as proposed, recites in relevant part:

> 18. (Currently amended) A transdermal therapeutic system comprising a self-adhesive matrix layer containing the free base . . . wherein the matrix is based on a ~~non-aqueous~~ ***substantially*** water-free, acrylate-based or silicone-based polymer adhesive system . . . , all of said free base being present in the matrix ***substantially*** in the absence of water, ...

(D.I. 91 Ex. 11 at NEU_483) (emphasis added) In proposing to amend this claim, the applicants explained they were responding to a telephone interview with the Examiner, during which the Examiner agreed that the claim would probably be allowable if it were amended to "recite that the adhesive system is water-free and all of the free base is present in the matrix substantially in the absence of water." (*Id.* at NEU_481) The applicant reiterated in its remarks submitted with the amendment that "the underlying point which the amendments to claim 18 address is that the present invention does not rely on an aqueous phase for the drug. Apart from that, some water may be present; for that reason, the qualification 'substantially' has been inserted." (*Id.* at

NEU_481-82) The applicants then provided examples of other "[s]ources of water" that may be present, including "atmospheric humidity from which water diffuses into the matrix" and "residual water in the free base." (*Id.*)

The Examiner rejected this amended claim as failing to comply with the written description requirement, finding that "[t]he specification lacks support to the matrix that is ***substantially*** water-free. The entire specification and the examples describe a matrix based on non-aqueous polymers, which means water-free polymers in order to have the single-phase matrix. The expression 'substantially' permits the presence for small amount of water that is not disclosed in the specification or the examples." (D.I. 91 Ex. 13 at NEU_506) The applicant thus struck from the claim the word "substantially" in both instances, leading to claim 18's allowance. (*Id.* Ex. 14 at NEU-512; *Id.* Ex. 15 at NEU_565)

Considering the prosecution history in context, the Court finds no clear and unmistakable disclaimer of the presence of water ***as an impurity***. The Examiner's objection to "substantially water-free" was based on an understanding that the phrase would encompass matrices that use a separate aqueous phase for the drug – which are not described by the '434 invention, which solely relates to non-aqueous polymers. (*See* D.I. 91 Ex. 13 at NEU_506) ("The entire specification and the examples describe a matrix based on non-aqueous polymers, which means water-free polymers in order to have the single-phase matrix.") While the applicants identified "sources of water" that could be present in the matrix, that use of "substantially" was not the basis of the Examiner's concern or rejection. In its objections, the Examiner did not reference the second "substantially" – the requirement that the free base be present in the matrix "substantially in the absence of water." There is no evidence the Examiner objected to the

presence of water in the matrix due to impurities. There is also no evidence that the applicants' deletion of "substantially" – specifically, the second "substantially" – correlated to any intention of the applicants to exclude the presence of water due to impurities. In fact, both parties acknowledge that it is ***unclear*** why the applicants deleted the second "substantially." (*See* Tr. at 46, 52) The Court agrees and also finds no unambiguous disclaimer of the presence of water impurities. *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2016 WL 7210837, at *22 (E.D. Tex. Dec. 13, 2016) ("[A]ny characterization of a pharmaceutical product in a patent claim must be assumed to include impurities, unless the claim very clearly prohibits the presence of all such impurities.").

Further, the specification recites the presence of additives in the polymer adhesive system that contain water as an impurity. *See, e.g.*, '434 patent at 3:66-4:5, 4:57-63. A construction allowing water impurities to be present is also consistent with the Court's prior finding in *UCB v. Watson* that the fact that Neupro patches "may contain a small amount of water is not dispositive." (*UCB v. Watson*, C.A. No. 14-1083 D.I. 270 at 70-71) Finally, Zydus's proposal would read out all preferred embodiments of the claims. *See Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("[I]t is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.").

III. CONCLUSION

The Court will construe the disputed term as explained above. An appropriate Order follows.

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Plaintiffs,	:	
v.	:	C.A. No. 16-1023-LPS
ZYDUS WORLDWIDE DMCC and CADILA HEALTHCARE LTD, d/b/a/ ZYDUS CADILA,	:	
Defendants.	:	

ORDER

At Wilmington, this **1st** day of **June, 2018**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 6,884,434, 8,617,591, and 8,246,979 are construed as follows:

Claim Term	**Court's Construction**
all of said free base being present in the matrix in the absence of water [claim 1 of the '434 patent]	the free base is present in the matrix, which does not contain an aqueous phase or any water other than as the result of impurities
microreservoir [claims 1, 8, 11, 12, and 13 of the '979 patent and claims 1, 2, 3, 10, and 11 of the '591 patent]	particulate, spatially and functionally separate compartments consisting of pure drug or a mixture of drug and crystallization inhibitor, which are dispersed in the self-adhesive (polymer) matrix

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE