IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| SUPERNUS PHARMACEUTICALS, INC., | ) | |
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| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. 21-1293 (MN) |
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| LUPIN LIMITED, LUPIN ATLANTIS HOLDINGS S.A., NANOMI B.V., LUPIN INC., and LUPIN PHARMACEUTICALS, INC., | ) | |
| | ) | |
| Defendants. | ) | |

**MEMORANDUM ORDER**

At Wilmington, this 5th day of April 2023:

The Court heard arguments for the disputed claim terms of U.S. Patent No. 8,992,989 ("the '989 Patent"), U.S. Patent No. 9,549,940 ("the '940 Patent"), U.S. Patent No. 9,622,983 ("the '983 Patent") and U.S. Patent No. 10,314,790 ("the '790 Patent") on January 11, 2023.[1] (*See* D.I. 111). As announced at the hearing, IT IS HEREBY ORDERED that the disputed claim terms of the '989, '940, '983 and '790 Patents are construed as follows:

1. "an extended release (XR) topiramate-containing component" means "a component that releases topiramate over a prolonged period of time," with the clarification that "prolonged period of time" means "a continuous period of time of greater than about 1 hour." ('989 Patent, claims 14 & 18; '940 Patent, claims 14 & 18; '983 Patent, claims 13 & 17);

2. "at least two extended release (XR) topiramate-containing components" means "at least two components that release topiramate over a prolonged period of time, each component having a different release rate." ('790 Patent, claims 1 & 12).

[1] The parties presented no agreed-upon constructions. (*See* D.I. 94 at 3).

The parties briefed the issues (D.I. 94) and submitted an appendix containing intrinsic and extrinsic evidence. (D.I. 95). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 111) and applied the legal standards below in reaching its decision.

## I. LEGAL STANDARDS

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). "[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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "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. *Id.* at 1314. "[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 . . . [as] 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). 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. "Even when the specification describes only a single embodiment, [however,] 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) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

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) (en banc), *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, courts "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*, 574 U.S. at 331. 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. 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." *Phillips*, 415 F.3d at 1318. 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, although 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).

## II. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of the '989, '940, '983 and '790 Patents was announced during the Markman hearing on January 11, 2023 as follows:

> At issue there are two disputed claim terms in four patents: U.S. Patent Nos. 8,992,989, 9,549,940, 9,622,983, and 10,314,790. I am prepared to rule on each of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents and all of the evidence submitted by the parties. There was full briefing on each of the disputed terms and we had argument today. All of that has been carefully considered.
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> As to my rulings, I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have included in earlier opinions, including recently in *Rex Computing, Inc. v. Cerebras Systems Inc.*, Civil Action No. 21-525 (MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.
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> Initially, let me note that the briefing in this case was not a model of clarity. I do appreciate the parties' attempts to limit the patents and claims being asserted, but the [joint] brief largely did not cite to the specifications of the patents currently before me and the joint appendix did not even contain most of the patents before me. I understand that the specifications of the patents are largely the same as ones cited, but it seems to be a pretty big failure to not ensure that I have the patents and the claims that you want me to address in the papers submitted.

The first term is "an extended release (XR) topiramate-containing component" in claims 14 and 18 of the '989 Patent, claims 14 and 18 of the '940 Patent, and claims 13 and 17 of the '983 Patent. Plaintiff argues no construction is necessary, but in the alternative proposes the construction "a component that releases topiramate over a prolonged period of time." Defendants propose the construction "at least two populations of extended release topiramate containing beads." I am going to adopt Plaintiff's construction with a slight clarification.

Defendants propose two additional limitations to the claim language: 1) that the XR component must be comprised of beads and 2) that there must be at least two populations of those beads. I'll take these in order.

With respect to beads, nothing in the claim language requires that the claims should be limited to beads. Instead, the claims refer to an XR component that comprises a coating material.[2] Defendants, however, argue that [à] la *Phillips*[3] the intrinsic evidence – in terms of the specification and the prosecution of the parent '576 Patent[4] – only describes release controlling coatings in the context of beads and never discusses coatings in terms of tablets or other dosage forms. For the most part, Defendants cite to what the specification clearly refers to as embodiments that use beads.[5] The specification, however, also discloses an embodiment that is a multilayer tablet rather than beads and there is no suggestion that a multilayer tablet would exclude use of coatings or coating material.[6] With respect to the statements in the prosecution history of the parent application, those statements were simply distinguishing the particular claims at issue – all of which claimed

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2 (*E.g.*, '989 Patent at 21:5-8).

3 *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

4 (U.S. Patent No. 8,298,576 ("the '576 Patent")).

5 (*E.g.*, '790 Patent at 2:66-3:11, 6:55-61 & 11:60-12:10). The parties state that the specifications of the '790, '989, '940 & '983 Patents as well as that of U.S. Patent No. 8,663,683 are substantially identical and cite to them interchangeably. (*See* D.I. 94 at 12 n.6).

6 (*E.g.*, '989 Patent at 11:13-20).

beads.[7] And I do not view those as limiting the claims here which do not specify beads.

With respect to the proposed limitation that the XR component claimed actually means two XR components, Defendants argue that there was a disclaimer of claim scope in the prosecution of the parent '576 Patent application. The standard for finding a disclaimer is a high one.[8] It requires finding that the statements relied on are clear and unmistakable.[9] If the statements are ambiguous or amenable to multiple reasonable interpretations, there is no disclaimer.[10]

There is no question that a patentee generally has the right to file a continuation application and attempt to broaden its claims.[11] Defendants, however, argue that Plaintiff cannot do so here, because of disclaimers during the prosecution of the parent application. First, Defendants argue that in response to a restriction requirement, Plaintiff elected two populations of XR beads and one population of [immediate release] beads to serve as the starting point for the Examiner's search.[12] As Plaintiff points out, however, the claims for the '576 Patent – at the relevant times during prosecution and after patent issuance – expressly claimed a formulation having at least two populations of [XR] beads.[13]

Similarly, Defendants argue that during the prosecution of the '576 Patent, Plaintiff distinguished prior art on the basis that the prior art had a uniform XR component (*e.g.*, a single bead or granule population).[14] Again, however, the claims at issue in that

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7 (*See* D.I. 95, Ex. I at SUPTXR0001288-89 & Ex. K at SUPTXR0002275, SUPTXR0002278).

8 *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016).

9 *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003).

10 *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003).

11 *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1317 (Fed. Cir. 2007).

12 (D.I. 94 at 9-10 (citing D.I. 95, Ex. I at SUPTXR0001288-89)).

13 (D.I. 95, Ex J at SUPTXR0002200; '576 Patent at 19:50-55).

14 (D.I. 94 at 10 (citing D.I 95, Ex. K at SUPTXR0002275, SUPTXR0002278)).

application expressly claimed an extended release component made up of two populations of beads.[15] The claims here do not.

And finally, Defendants argue that each of the asserted patents was initially rejected for obviousness-type double patenting and in each instance the Examiner understood the scope of the claims to be limited to at least two populations of XR topiramate-containing beads. Defendants failed to show why this indicates that the scope of the asserted patents must be the same as that of the parent patent, particularly given that the relevant claim language is different and the Examiner noted that the claim scope was not exactly the same.[16]

I do not find that Plaintiff's statements during the parent prosecution either alone or in combination are clear and unmistakable disavowals of claim scope for claims that included different and broader language that did not require two XR components.

Moreover, I think that it was clear to the Examiner that in the later prosecutions Plaintiff changed the scope of the claims to include only one XR component. Plaintiff, for example, removed the language about two components and also included claims in other continuation applications that referred to having "at least one" XR component.[17] These changes were supported by the specification, which describes, for example in Table 5, formulations having just one XR component.[18] And there is no indication that the Examiner was relying on those earlier statements. Indeed, unlike in *Hakim*, which Defendants rely on here, the Examiner of the patents at issue here did not simply accept the new application and new claims presented, but conducted additional review and prosecution of the applications.[19]

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15 (D.I. 95, Ex J at SUPTXR0002200; '576 Patent at 19:50-55 (claiming "[a] sustained release formulation . . . comprising an immediate release bead population (IR), a first extended release bead population (XR1), and a second extended release bead population (XR2)")).

16 (*See* D.I. 95, Ex. BB at SUPTXR0005541-42).

17 (*E.g.*, '989 Patent at 20:19-20 (claiming an XR component "contained in at least one population of beads")).

18 (*See* '989 Patent at tbl.5).

19 *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1317-18 (Fed. Cir. 2007).

Finally, in the briefing Defendants took issue with Plaintiff's construction, arguing that there is no floor to "prolonged period of time." There was not any argument about that here today. As Plaintiff points out, however, the specification defines "prolonged period of time" as "a continuous period of time of greater than about 1 hour."[20] I understand that that definition appears in the context of differentiating between a "sustained release" formulation and an "immediate release formulation," but I credit the opinion of Plaintiff's expert that a POSA would understand "extended release . . . component" to be consistent with the defined terms.[21] Therefore, I will adopt Plaintiff's construction with the clarification that "prolonged period of time" means "a continuous period of time of greater than about 1 hour."

The second term is "at least two extended release (XR) topiramate-containing components" in claims 1 and 12 of the '790 Patent. Plaintiff argues no construction is necessary, but in the alternative proposes the construction "at least two extended release topiramate-containing components having in vitro release rates for topiramate." Defendants propose the construction "at least two different extended release (XR) topiramate-containing bead populations." I am going to construe this term to mean "[at least] two components that release topiramate over a prolonged period of time, each component having a different release rate."

To the extent that Defendants propose that the claim is limited to bead forms, I reject that for the reasons previously stated.

As for the two XR components having different release profiles, I think that that is supported by the intrinsic evidence. I understand that the claim does not use the word "different," but it does specify that there are two XR components. And the specification describes XR components comprising a population of beads and states that there is a specific release controlling coating for each population.[22] That is, the release for each population would be different because it has a different coating. And that is what is disclosed, for example, in Table 5, which describes XR

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20 ('989 Patent at 3:47-48).

21 (*See* D.I. 95, Ex. B ¶¶ 28-30).

22 ('790 Patent at 2:35-41).

components having different releases when there are multiple XR components. [23]

(D.I. 111 at 51:23-58:11).

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

23 (*See* '790 Patent at tbl. 5).