IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBOR PHARMACEUTICALS, LLC and TAKEDA PHARMACEUTICAL COMPANY LIMITED,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-922 (MN)
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 20th day of July 2021:

As announced at the hearing on July 14, 2021, IT IS HEREBY ORDERED that the disputed claim term of U.S. Patent No. 9,066,936 ("the '936 Patent") is construed as follows:

1. "pH control agent" shall be given its plain and ordinary meaning, which is "a substance or combination of substances that adjusts or maintains pH"

The parties briefed the issues (*see* D.I. 58) and submitted an appendix containing intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 59). Each side provided a tutorial describing the relevant technology. (*See* D.I. 56 & 60). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim term, heard oral argument (*see* D.I. 66) and applied the following legal standards 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.*, 135 S. Ct. 831, 837-38 (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 also must 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*, 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. 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 term of '936 Patent was announced from the bench at the conclusion of the hearing as follows:

> . . . At issue in this case we have three patents but only one term in one of those patents, U.S. Patent No. 9,066,936 ("the '936 Patent"), is disputed.
>
> I am prepared to rule on this dispute. I will not be issuing a written opinion, but I will issue an order stating my ruling. I want

to emphasize before I announce my decision that although I am not issuing a written opinion, we have followed a full and thorough process before making the decision I am about to state.

I have reviewed the '936 Patent and the excerpts of the '936 Patent prosecution history submitted, as well as the expert declarations, articles, and other materials submitted in the joint appendix. The parties each submitted a tutorial on the technology. There was full briefing on the disputed term, and there has been argument here today. All of that has been carefully considered.[1]

As to my ruling, I am not going to read into the record my understanding of claim construction law generally. I have a legal standard section that I've included in earlier opinions. I incorporate that law and adopt it into my ruling today and will set it out in the order I issue.

The disputed term is "pH control agent" in claims 1 and 3 of the '936 Patent. Plaintiffs propose that the term should have its "plain and ordinary meaning, *i.e.*, a substance or combination of substances that adjusts pH when dissolved or suspended in water." Defendants propose that it means "an excipient or combination of excipients that stabilizes the claimed compound during storage of the pharmaceutical composition and improves dissolution of the claimed compound from the pharmaceutical composition."

Although in the initial briefing there was a dispute as to whether the pH control agent must be an "excipient" (or combination of excipients) or a "substance" (or combination of substances), this dispute seems to have been resolved. So the dispute here is whether the pH control agent must stabilize the compound recited in the claim and improve its dissolution from the overall composition. As to this dispute, Defendants argue that Plaintiffs' proposed plain meaning is overly broad and that Plaintiffs disavowed claim scope in the specification.

Here, I mostly agree with Plaintiffs. Starting with the term itself, the plain meaning of the words "pH control agent" is an agent that controls pH – *i.e.*, to a person of skill in the art, this suggests that the agent maintains or changes pH. Plaintiffs argue that the "pH control agent" adjusts the pH, and there is some support in the specification that the "pH control agent" is something that "adjusts" pH.[2] Defendants' construction, however, does not even mention

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1 The parties did not raise any disputes as to the person of ordinary skill in the art ("POSA") that are relevant to the issues raised in connection with claim construction.

2 (*See, e.g.*, '936 Patent at 2:30 & 19:34-37).

the ability of the "pH control agent" to do anything with the pH. This seems contrary to the plain meaning of the words.

Moving to the rest of the claim language, the term "pH control agent" appears in claim 1 as part of a larger phrase: "a solid pH control agent which provides a pH of 3 to 5 when dissolved or suspended in water at a concentration of 1% w/v at 25°C." The term appears in [a similar] phrase in claim 3, which is the only other independent claim.[3] Read in context with the other words in the claim, "pH control agent" is an agent that adjusts the pH to or maintains the pH at between 3 and 5 when dissolved or suspended in water at the specified conditions. This is consistent with Plaintiffs' proposal of the plain meaning, but I think that Plaintiffs are reading redundancy into the meaning of "pH control agent" when the following language already recites dissolution or suspension in water.

Defendants' main argument is that the patentee disclaimed claim scope by limiting the meaning of "pH control agent" in the specification. In Defendants' view, the "pH control agent" recited in the claims must stabilize the claimed compound during storage and also improve the dissolution of the claimed compound from the claimed pharmaceutical composition. Even if disclaimer is not found, Defendants argue that the plain meaning of "pH control agent" nevertheless requires these limitations because a person of skill in the art viewing the specification would understand the plain meaning to include those functional requirements anyway.[4]

Turning to the specification, and starting with the "Technical Field of the Invention," the patent states that the present invention relates to a "pharmaceutical composition comprising . . . compound (I) and a pH control agent, which is superior in both stability and dissolution property of compound (I)."[5] In the "Disclosure of the Invention," the patent explains that the co-presence of a pH control agent that adjusts the pH of the pharmaceutical composition unexpectedly achieved "the stability of compound (I) in a preparation and dissolution property thereof from the

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3 Claim 3 claims a method of stabilizing a compound or improving dissolution of a compound comprising "adding a pH control agent having a pH of 3 to 5 when dissolved or suspended in water at a concentration of 1% w/v at 25°C. to the solid pharmaceutical composition comprising the compound."

4 (D.I. 58 at 23-24).

5 ('936 Patent at 1:16-19).

preparation."[6] And the "Detailed Description of the Invention" provides that "[a]s the pH control agent to be used in the present invention, any pH control agent can be used as long as it can simultaneously achieve the stability of compound (I) in a drug product and dissolution property thereof from the drug product, and is applicable to pharmaceutical products."[7]

I think it's important to view these statements against the problem facing the inventors. As the '936 Patent explains, "the properties of a pharmaceutical preparation need to be adjusted to stabilize compound (I) because compound (I) is unstable in the neutral pH range, at which pharmaceutical preparations are generally produced. Nevertheless, the solubility of compound (I) is low at a pH range where compound (I) is stable."[8] The patent goes on to explain that it is "extremely difficult to simultaneously afford the stability and solubility of compound (I), and simultaneous achievement thereof is desired."[9] And, as set forth in the next section, the inventors found that they could achieve a stable yet soluble compound (I) by using a "pH control agent" and adjusting the pH.[10] In light of this background, I think that a person of skill in the art would understand that the "pH control agent" achieves the desired stability and solubility when the "pH control agent" provides the claimed pH range. I do not think that the parts of the specification identified by Defendants demonstrate a clear and unmistakable disavowal of claim scope such that the meaning of "pH control agent" requires functional limitations.

I also do not agree with the articulation of the functional limitations set forth in Defendants' proposed construction. I do not find in anything cited to me support for reading in the notion that the "pH control agent" must stabilize the claimed compound during a storage period, particularly for an unspecified amount of storage time. Second, Defendants' proposal requires that the "pH control agent" improve dissolution of the claimed compound from the pharmaceutical composition. Although there are some experimental examples in the detailed description that mention improved dissolution, these do not seem to be broad statements applying to the invention as a whole. The only broad mention of improving

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6 (*Id.* at 2:26-31).

7 (*Id.* at 4:63-67).

8 (*Id.* at 2:7-12).

9 (*Id.* at 2:13-15).

10 (*Id.* at 2:25-34).

dissolution is in the "Disclosure of the Invention," where the patent explains that "according to the method of improving dissolution of compound (I), the dissolution property of the compound (I) from a solid pharmaceutical composition can be significantly improved."[11] But this language is related to claim 3, which recites "a method of stabilizing a compound which is [compound (I)] or improving dissolution of a compound which is [compound (I)]" using the claimed "pH control agent."[12] It does not limit the meaning of "pH control agent" generally.

As for the prosecution history, the portions cited to me do not evidence a clear and unmistakable disclaimer of claim scope. In my view, these excerpts just demonstrate that the claimed compound (I) was unexpectedly only stable in mildly acidic conditions – *i.e.*, that extensive degradation occurred under strongly acidic and also basic conditions.

. . . I decline to read in the functional limitations offered by Defendants. Although there are some statements in the specification that do suggest the "pH control agent" stabilizes the claimed compound and achieves the desired solubility, I do not think these statements are clear and unmistakable disavowals of claim scope. I also do not think the specification requires these functional limitations to be part of the plain meaning. It seems like the benefits in stability and dissolution derive from the claimed "pH control agent" being one that provides a pH range of 3 to 5 under the recited conditions. That being said, I think Plaintiffs' proposal is a little redundant in including the water-related language.

Therefore, I will construe "pH control agent" to mean "a substance or combination of substances that adjusts or maintains pH." And I believe that maintaining pH is part of the meaning of the claimed "pH control agent" because the specification explains that buffers may be used as the "pH control agent."[13]

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

11 (*Id.* at 3:26-30).

12 (*Id.* at Claim 3).

13 (*Id.* at 5:36-39).