IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-830 (WCB)
	)	
AZURITY PHARMACEUTICALS, INC., AZURITY PHARMACEUTICALS INDIA LLP f/k/a SLAYBACK PHARMA INDIA LLP, and SLAYBACK PHARMA LLC,	)	C.A. No. 24-1363 (WCB)
	)	
Defendants.	)	

MEMORANDUM OPNION AND ORDER

The defendants in this consolidated case—Azurity Pharmaceuticals, Inc.; Azurity Pharmaceuticals India LLP f/k/a Slayback Pharma India LLP; and Slayback Pharma LLC (collectively, "Azurity")—have lodged an objection to what they refer to as a "new theory" raised by plaintiff Heron Therapeutics shortly before the trial in this case, which is scheduled to begin on November 17, 2025. Heron responds that the issue is not new and has not been concealed from Azurity.

1. This dispute relates to Heron's position, as articulated by its expert witness, Dr. Steven Little, that the asserted claims of two of the patents at issue in this case, U.S. Patent Nos. 12,115,254 ("the '254 patent") and 12,115,255 ("the '255 patent"), do not require proof that the emulsions at issue be shown to be physically stable. The preamble of claims 1-29 of the '255 patent refer to "an injectable emulsion," and the preamble of claim 30 of the '255 patent and all claims of the '254 patent refer to "an injectable pharmaceutical emulsion." None of the claims of either of those asserted patents expressly requires that the claimed emulsion be physically stable.

Azurity contends that Heron did not timely disclose its theory that physical stability is not a required limitation of the asserted claims, and therefore Heron should be prohibited from presenting that theory at trial. In the alternative, Azurity argues that it should be allowed to present evidence and argument at trial that the claims of the '254 and '255 patents, although not explicitly requiring that the claimed emulsions be physically stable, should nonetheless be construed to require proof of physical stability.

I am not persuaded by Azurity's argument that it was unfairly surprised by Dr. Little's position that the asserted claims of the '254 and '255 patents do not require proof of physical stability. As Heron notes, there are a number of reasons that Azurity should have been aware that Heron did not regard physical stability to be a limitation of the asserted claims of either of those patents.

First, none of the asserted claims contains an express limitation referring to physical stability, even though similar claims in other asserted patents do contain such a limitation, *see* U.S. Patent Nos. 12,290,520; 9,974,793; and 9,974,794, all of which are related to the '254 and '255 patents, contain express limitations regarding physical stability. The presence of an express reference to physical stability in some of the patents and the absence of such a reference in others gives rise to an inference that the claims lacking a reference to physical stability do not require it.[1]

[1] Courts have noted that in appropriate circumstances the doctrine of claim differentiation can be applied not only within a single patent, but also across related patents, while recognizing that the doctrine is not as strong when it is applied across related patents as it is when the differing claim limitations appear in different claims of the same patent. *See, e.g., Clare v. Chrysler Grp. LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016); *In re Rambus*, 694 F.3d 42, 48 (Fed. Cir. 2012); *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369–70 (Fed. Cir. 2007); *Vifor (Int'l) AG v. Mylan Lab'ys Ltd.*, No. 19-13955, 2021 WL 2652123, at *13 (D.N.J. June 28, 2021); *Acceleration Bay LLC v. Activision Blizzard, Inc.*, No 16-453, 2017 WL 6508715, at *5 n.2 (D. Del. Dec. 20, 2017); *Alstom Grid LLC v. Certified Measurement, LLC*, No. 15-72, 2016 WL 4151394, at *7 (D. Del. Aug. 3, 2016) (the doctrine of claim differentiation "may be applied between related patents").

Second, in the preceding case of *Heron Therapeutics, Inc. v. Fresenius Kabi USA, LLC*, No. 22-985, 2024 WL 5317378 (D. Del. Dec. 3, 2024), which involved similar issues and with which the parties are intimately familiar, I pointed out that one of the two patents at issue in that case contained an express limitation requiring physical stability, while the other did not, and I construed the claims of the patent that did not contain such an express limitation as not requiring proof of physical stability. *See* 2024 WL 5317378, at *26 ("Claim 8 of the ['229] patent, from which the asserted claims depend, merely sets forth the components of a composition; it does not contain any requirement of efficacy or stability.").[2]

Third, in his rebuttal expert report, submitted on August 6, 2025, Dr. Little noted that various claims of the related patents, including the asserted claims of the '229 patent, "do not contain the phrase 'physically stable.'" Referring to the report submitted by Azurity's expert, Dr. Mansoor Amiji, Dr. Little added, "To the extent Dr. Amiji suggests that the term 'physically stable' should be read into the '229 patent claims, I disagree." Dkt. No. 122, Exh. 12, at ¶ 368.[3]

Fourth, Dr. Amiji subsequently stated that he agreed with Dr. Little on that point. In his reply report, submitted on August 26, 2025, in response to Dr. Little's rebuttal report, Dr. Amiji stated: "With respect to the '229 Patent, Dr. Little agrees with me that the asserted claims (i.e.,

[2] The relevant claims of the '229 patent (U.S. Patent No. 9,561,229) merely recite "[a]n injectable pharmaceutical emulsion" and set forth the components of that composition. The other patent at issue in the *Fresenius* case, U.S. Patent No. 9,974,794, contains a similar set of components, but the preamble of that patent recites "[a] physically stable pharmaceutical composition."

[3] The preamble of the asserted claims of the '229 patent, which are no longer in dispute, provides for an "injectable pharmaceutical emulsion," just as in the preamble to all claims of the '254 patent and claim 30 of the '255 patent; the preamble to claims 1-29 of the '255 patent simply provides for an "injectable emulsion."

claims 6, 10, and 16) should not be read to include a requirement of 'physical stability.'" Dkt. No. 125, Exh. H, at ¶ 91.

Fifth, in Heron's initial response to Azurity's invalidity contentions, Heron objected to Azurity's argument that the asserted claims were invalid because the term "physically stable" was indefinite. As part of its argument, Heron explained that "the phrase 'physically stable' does not appear in all of the Asserted Claims." Dkt. No. 125, Exh. F, at 62 n.15.

Sixth, it is apparent from the questions Azurity's counsel asked of Dr. Little during his deposition that Azurity was aware that it was Heron's position that the claims that did not expressly require that the claimed emulsion be "physically stable" did not require physical stability at all, either as an implied limitation or as a construction of the terms "injectable emulsion" and "injectable pharmaceutical emulsion." *See* Dkt. No. 122, Exh. 1, at 134:1–135:19, 156:4–157:21, 166:2–167:4,

Seventh, Dr. Little's position on that issue in his September 2025 deposition was not a late-blooming notion on his part; he took the same position on the same issue in his March 13, 2024, deposition in the related *Fresenius* case. *See* Dkt. No. 127, Exh. 13, at 302:22—304:25.

Under these circumstances, Azurity was plainly put on notice that Heron did not agree with Azurity's position that the claims that did not include an express "physical stability" limitation should be construed to include such a limitation anyway. Indeed, it appears that, at least as of the time he submitted his reply report, Dr. Amiji agreed with that position. Therefore, Azurity has not made a persuasive showing that it was misled into believing that Heron would not take the position that those claims that did not include such a limitation.

Although Azurity contends that Heron failed to disclose, in a timely fashion, its position that the claims lacking an express stability limitation do not require proof of stability, it is not clear

when, according to Azurity, Heron should have made such a disclosure. Azurity provides general references to the Federal Rules of Civil Procedure and the Scheduling Order in this case in support of its failure-to-disclose argument. But it is not apparent why it is necessary for a party to disclose its "theory" that a claim that lacks an express requirement of physical stability does not require proof of physical stability.

Azurity has not referenced any point at which Heron took a position with respect to that issue that would have misled Azurity as to Heron's interpretation of that seemingly clear claim language. To the extent that Azurity's position is that the terms "injectable emulsion" and "injectable pharmaceutical emulsion" in the '254 and '255 patents must be construed to include a requirement of stability, that is an issue that Azurity should have raised at an earlier point in the proceedings, particularly in light of the fact that I took a contrary view on that issue in my opinion in the *Fresenius* case.

Azurity's answer to that point is to challenge an aspect of my decision in the *Fresenius* case regarding claim 8 of U.S. Patent No. 9,561,229 ("the '229 patent"). As noted, I ruled in the *Fresenius* case that claim 8 of the '229 patent, like the asserted claims of the '254 and '255 patents in this case, "merely sets forth the components of a composition; it does not contain any requirement of efficacy or stability." *Heron Therapeutics, Inc. v. Fresenius Kabi USA, LLC*, 2024 WL 5317378, at *26. That statement, Azurity argues, was "inconsistent with the Court's determination that the formulations recited in the asserted claims of the '229 patent are not invalid as obvious based on their improved stability over the prior art." Dkt. No. 121 at 2.

I disagree with Azurity that those two conclusions from my opinion in the *Fresenius* case are inconsistent. Stability was a feature of the composition claimed in the '229 patent, but it was not a claimed feature. In concluding that it would not have been obvious to devise a stable

aprepitant formulation suitable for injection that would satisfy the limitations of the asserted claims of the '229 patent, I held that making the composition recited in that claim would not have been obvious to a person of skill in the art seeking to devise a formulation that would achieve the objective of stability. That conclusion is not inconsistent with the conclusion that the composition of claim 1 of the '229 patent, which recites an "injectable pharmaceutical emulsion containing [various components]" does not require proof that the composition would be stable.

A substantial body of case law supports the proposition that even if a patentee points to an advantage of the invention, either in the course of prosecution or in the specification, that does not mean that the claims must be read as if that advantage were incorporated as a limitation of the patent's claims, absent a clear indication, such as a disavowal of claim scope, that indicates that the patentee intended to limit the scope of the claims in that manner. *See, e.g.*, *Purdue Pharma L.P. v. Endo Pharms. Inc.,* 438 F.3d 1123, 1136 (Fed. Cir. 2006) ("Rather than presenting the four-fold dosage range as a necessary feature of the claimed oxycodone formulations, Purdue described it as a property of, or a result of administering, the oxycodone formulations characterized by the in vivo blood plasma concentrations set forth in the claims."); *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001) ("This court's claim construction, however, did not and could not import into the claim a function from the specification, particularly when the claim recites only purely structural limitations."); *Ecolab, Inc. v. Envirochem, Inc.* 264 F.3d 1358, 1367 (Fed. Cir. 2001) ("Where the function is not recited in the claim itself by the patentee, we do not import such a limitation."); *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1278 (Fed. Cir. 1995); *Celgene Corp. v. Hetero Lab'ys Ltd.*, No. 17-3387, 2020 WL 3249117, at *7 (D.N.J. June 16, 2020); *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14-7869, 2016 WL 5898627, at *6 (D.N.J. Oct. 7, 2016); *Pediatric Med. Devices, Inc. v. Indiana Mills & Mfg., Inc.*, No. 1:11-

cv-2613, 2013 WL 2395994, at *15 (N.D. Ga. 2013) ("Here, the universal clamp is a property, not a requirement, of the invention"); *Novartis Corp. v. Lupin Ltd.*, No. 06-5954, 2009 WL 737043, at *7 (Fed. Cir. Mar. 18, 2009); *McNeil-PPC, Inc. v. Perrigo Co.*, 443 F. Supp. 2d 492, 505–06 (S.D.N.Y. 2006); *see also Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (an advantage of a patented invention may be relevant to obviousness, such as by bearing on secondary considerations, even if that feature is not claimed); *Janssen Pharms., Inc. v. Teva Pharms. USA Inc.*, 760 F. Supp. 3d 184, 217 (D.N.J. 2024) ("[A] patent can be shown to solve a long-standing need even if it does not explicitly claim the benefits of its invention.").

Nowhere in my discussion of the purported advantages of the '229 patent in the portion of the *Fresenius* opinion that addressed obviousness did I suggest that physical stability was a limitation of any of the asserted claims of that patent. It was therefore not inconsistent for me to state, in the section of the opinion dealing with the written description requirement, that the asserted claims of the '229 patent did not require a showing that the claimed composition was physically stable.

For the foregoing reasons, I reject Azurity's contention that Heron violated a duty to advise Azurity that Heron was taking the position that the asserted claims of the '254 and '255 patents should be read not to require any particular level of emulsion stability, and that Heron should be barred from taking that position at trial.

2. Azurity makes a fallback argument that if Heron is allowed to argue that the terms "injectable emulsion ('255 patent) and "injectable pharmaceutical emulsion" ('254 and '255 patents) do not require proof of physical stability, Azurity should be allowed to present evidence and argument at trial in support of its theory that those terms should be construed to require proof

of physical stability sufficient to satisfy the requirements of USP33-NF28 General Chapter <729> for Globule Size Distribution in Lipid Injectable Emulsions. Dkt. No. 125, Exh. N, at ¶ 67.

Heron opposes Azurity's request, arguing that Azurity should have raised the claim construction issue much earlier and that Heron would be prejudiced if Azurity were allowed to raise this issue at this late hour. I disagree. Although Azurity should have recognized the issue earlier, it was not so prominent a part of the pretrial proceedings that Azurity should be charged with waiving its right to raise a potentially critical claim construction issue. It is not unusual for a previously unrecognized claim construction issue to arise late in pretrial proceedings or even during trial, and when it does, it is ordinarily the duty of the court to decide the issue. *See O2 Micro Int'l Ltd v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties preset a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it."). If this claim construction issue is not resolved conclusively now, it will continue to hover over the case, perhaps even into any appeal that may be taken from the judgment. Accordingly, I will address the issue, even though it has been raised by Azurity for the first time at a late stage in the proceedings.

* * *

The parties will be allowed to litigate the issue according to the following schedule: Azurity will be given until 5:00 p.m. ET on Monday, November 3, 2025, to file a brief of no more than 10 double-spaced pages, addressing the question whether the asserted claims of the '254 and '255 patents should be construed to require that the claimed emulsion be physically stable, and if so, what meaning should be given to the term "physically stable" in that context. If Azurity intends to rely on a witness or witnesses in support of its position on that claim construction issue, it will

be required to submit a report from any such witness setting forth that witness's testimony, together with any exhibits Azurity wishes the court to consider in connection with that testimony.

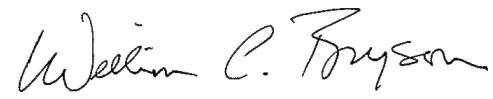
Heron will then be given until 5:00 p.m. ET on Friday, November 7, 2025, to file an answering brief of no more than 10 double-spaced pages addressing the same issue. If Heron elects to rely on a witness or witnesses as to that claim construction issue, it will be required to submit a report from each such witness setting forth that witness's testimony, together with any exhibits Heron wishes the court to consider in connection with that testimony.

Based on the parties' submissions, I may rule on the claim construction issue prior to trial. However, if after the briefs are submitted it appears that live witness testimony would be helpful in resolving the claim construction issue, the parties will be allowed to present such testimony at the outset of the trial, subject to cross-examination and limited to the scope of the witnesses' reports.

For any such witness who submits a report and/or intends to testify on the proffered on the claim construction issue, the party sponsoring that witness will be required to make that witness available for a two-hour deposition prior to trial. Any such depositions may be either virtual or in person.

IT IS SO ORDERED.

SIGNED this 29th day of October, 2025.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE