IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This is an action for infringement of two patents owned by plaintiff Heron Therapeutics, Inc. ("Heron"), a pharmaceutical manufacturer. Heron accuses three related defendants, Azurity Pharmaceuticals, Inc.; Azurity Pharmaceuticals India LLP; and Slayback Pharma LLC (collectively, "Azurity") of infringing claims 5 and 23 of Heron's U.S. Patent No. 12,115,255 ("the '255 patent") and claim 8 of Heron's U.S. Patent No. 12,290,520 ("the '520 patent"). Heron's cause of action arises under the infringement provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). In its defense, Azurity argues that the asserted claims from the two patents are invalid.[1]

[1] In a related case, Heron has asserted that Azurity has infringed ten other patents from the same family of patents. *See Heron Therapeutics, Inc. v. Azurity Pharms., Inc.*, No. 24-830 (D. Del.). That case was consolidated with this one for purposes of discovery. The cases have remained separate in other respects, however, and the patents asserted in that case are not at issue in this one. Pursuant to a stipulation entered by the parties and approved by the court, the disposition of Case No. 24-830 will be governed by the outcome of this case. *See* Case No. 24-830, D.I. 194; Case No. 24-1363, D.I. 119.

Before trial, Azurity stipulated to literal infringement of the claims asserted by Heron. D.I. 112 ¶ 1. In that stipulation, the parties agreed that the only remaining issues in this case are whether the asserted claims of the '520 and '255 patents are invalid for lack of written description and lack of enablement under 35 U.S.C. § 112. D.I. 119 ¶ 6.

On November 17 and 18, 2025, I held a two-day bench trial on the issue of invalidity. After the bench trial, the parties filed post-trial briefs and responses. D.I. 187, 189, 194, 195. I heard oral argument on the issues addressed in the briefing on March 24, 2026. D.I. 213.

FINDINGS OF FACT

I. Background

Heron markets Cinvanti, an injectable emulsion formulation containing the active pharmaceutical ingredient aprepitant.[2] Cinvanti is used to treat severe nausea and vomiting that patients frequently experience as a side effect of cancer chemotherapy treatment. D.I. 82 ¶ 39. The U.S. Food and Drug Administration ("FDA") approved Cinvanti for marketing in November 2017. *Id.* ¶ 38.

A key ingredient in the Cinvanti formulation is an emulsifier known as egg lecithin (or "egg yolk lecithin"), which is also referred to as Lipoid E 80.[3] The concentration of egg lecithin in the Cinvanti formulation is 14.3 percent by weight. PTX 51 at SLAY-APREP0000093.

Defendants Azurity Pharmaceuticals India LLP and Slayback Pharma LLC are wholly owned subsidiaries of defendant Azurity Pharmaceuticals, Inc. D.I. 82 ¶ 43; D.I. 85 at 14. On

[2] An emulsion is a heterogeneous system in which one immiscible liquid is dispersed as droplets in another liquid. DTX 61 at 1069. Emulsions are thermodynamically unstable and slowly begin to degrade once they are manufactured. DTX 116 at 28. Emulsions can be in the form of oil-in-water emulsions or water-in-oil emulsions. The emulsions at issue in this case are oil-in-water emulsions in which oil droplets are suspended in water.

[3] Emulsifiers are substances that are used to stabilize mixtures and prevent the separation of liquids that would otherwise not normally mix well, such as oil and water.

September 28, 2023, Azurity submitted New Drug Application ("NDA") No. 218754 to the FDA, seeking to market an injectable emulsion containing the same aprepitant active ingredient as Cinvanti. Azurity's proposed product contains approximately 17.8 percent egg lecithin by weight, and it differs from Cinvanti with respect to certain other components of the emulsion formulation. Tr. 416:3–22. Azurity represented, however, that its product is bioequivalent to Cinvanti.[4] D.I. 82 ¶¶ 15, 20. The FDA subsequently approved Azurity's NDA, but Heron filed this action in December 2024. Azurity's launch of its product has been stayed pending the resolution of this case.

II. The Relevant Statutory Provisions

The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) and 35 U.S.C. §§ 156, 271, 282), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Hatch-Waxman Act was designed to strike a balance between two competing policy interests: (1) to induce pioneering research and development of new drugs; and (2) to enable competitors to bring low-cost generic copies of those drugs to market rapidly if those drugs are not entitled to patent protection or if the generic drug would not infringe the issued patent. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

[4] Because the components of Azurity's product differ somewhat from those of Cinvanti, the reference listed drug, Azurity filed its application as an NDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), and not as an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Act, 21 U.S.C. § 355(j). An NDA filed under section 505(b) is commonly referred to as a "paper NDA." *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1078 (Fed. Cir. 2025).

To promote those objectives, the Hatch-Waxman Act provides for a prompt determination of whether drugs made and sold by brand-name pharmaceutical companies are protected by valid patents. If it is determined that the proposed generic products infringe the patents at issue and that the patents are not invalid, the generic products cannot be made or sold until the patents expire. If the patents are held to be invalid or not infringed, the Act provides a mechanism for prompt FDA approval of the generic versions of the drugs.

To obtain the necessary FDA approval to market a new drug, a pharmaceutical company must file an NDA. That application is designed to show the FDA, through rigorous testing procedures, that the drug is safe and effective for its proposed uses. After considering the application, and often after extended negotiations with the pharmaceutical company, the FDA may grant the application and authorize the company to market the drug for particular indications. The company is restricted to marketing the drug for those indications, as dictated by FDA regulations that govern both labeling and advertising for all prescription drugs. *See* 21 C.F.R. §§ 201.1–201.327 (labeling), *id.* § 202.1 (advertising).

To speed up the approval process for generic drugs, the Hatch-Waxman Act provides that a generic drug manufacturer may submit an ANDA under 21 U.S.C. § 355(j) for approval of a drug that is identical to the reference drug, or an NDA under 21 U.S.C. § 355(b)(2), referred to as a "paper NDA," for approval of a drug that is bioequivalent to the reference drug. If, as in this case, the generic company intends to market a drug that is bioequivalent to the first pharmaceutical company's approved drug, the generic company's paper NDA may rely on the FDA's existing findings of safety and effectiveness or studies not performed by the NDA applicant. *See Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015).

Under the Hatch-Waxman Act, NDA holders are required to notify the FDA of all patents that "claim [] the drug for which the [NDA] applicant submitted the application . . . and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

The Hatch-Waxman Act creates what is referred to as an "artificial" type of infringement that allows for the adjudication of the parties' rights regarding patents that would be infringed if the generic company's ANDA or paper NDA were issued and the generic product made, used, or sold in this country. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). In particular, 35 U.S.C. § 271(e)(2)(A) provides that it shall be an act of patent infringement to submit an ANDA or a paper NDA for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of the submission of the ANDA or the paper NDA is to obtain approval to engage in the commercial manufacture, use, or sale of the drug claimed in the patent, or the use of which is claimed in the patent, before the patent's expiration.

III. The Patents in Suit

Heron began seeking patent protection for its aprepitant emulsion with the filing of Provisional Application No. 62/052,948 in 2014. The specification filed at that time has remained largely unchanged and has served as the basis for a large family of patents that Heron has obtained, beginning in 2018. The patents that Heron has asserted against Azurity in this case were filed and issued more recently. The application for the '255 patent was filed on January 19, 2024, and that

patent issued on October 15, 2024. The application for the '520 patent was filed on January 9, 2024, and that patent issued on May 6, 2025.

Azurity contends that the asserted claims of both patents are invalid under 35 U.S.C. § 112, both for lack of an adequate written description of the claimed inventions and for lack of enablement of those inventions. Heron responds that the specifications of the two patents adequately describe the claimed inventions and enable the claimed inventions to be made and used.

1. The claims

In this case, Heron has asserted claim 8 of the '520 patent and claims 5 and 23 of the '255 patent against Azurity. The asserted claim of the '520 patent, along with the claims from which it depends, is reproduced below:

> 1. An injectable emulsion, comprising:
> aprepitant.
> 13 wt/wt % to 20 wt/wt % of an egg lecithin;
> 9 wt/wt % to 10 wt/wt % of soybean oil;
> a co-emulsifier which is an alcohol, wherein the alcohol is present in the emulsion at less than 10 wt/wt %;
> a tonicity modifier;
> a pH modifier, wherein the pH modifier is sodium oleate; and
> water;
> wherein the ratio of egg lecithin to aprepitant is between about 20:1 to 25:1;
> wherein the pH of the emulsion ranges from about 7.5 to 9.0; and,
> wherein the emulsion is physically stable.
>
> 7. The emulsion of claim 1, wherein the alcohol in the emulsion is ethanol.
>
> **8.** The emulsion of claim 7, wherein the ethanol is present in the emulsion at a concentration of about 2 wt/wt % to 3 wt/wt %.

The asserted claims of the '255 patent, along with the claims from which they depend, are reproduced below:

> 1. An injectable emulsion, comprising:
> 0.7-0.8 wt % aprepitant;
> 13 wt/wt % to 20 wt/wt % of an emulsifier;

an oil;
a co-emulsifier which is an alcohol;
a tonicity modifier;
a pH modifier; and
water;
wherein the pH of the emulsion ranges from about 7.5 to 9.0.

5. The emulsion of claim 1, wherein the emulsifier is an egg lecithin.

14. The emulsion of claim 1, wherein the alcohol in the emulsion is ethanol.

16. The emulsion of claim 14, wherein the ethanol is present in the emulsion at a concentration of about 2 wt/wt % to 3 wt/wt %.

19. The emulsion of claim 16, wherein the sucrose is present at a concentration of about 5 wt/wt %.

21. The emulsion of claim 19, wherein the sodium oleate is present at a concentration of about 0.4 wt/wt % to 0.5 wt/wt %.

23. The emulsion of claim 21, wherein the phospholipid is an egg lecithin.

2. The specifications

The specifications of the two patents in suit are quite similar in most respects, although the specification of the '520 patent is specifically directed to emulsion formulations of aprepitant, while the specification of the '255 patent is addressed to emulsion formulations of "an NK-1 receptor antagonist," which includes aprepitant. However, the claims of the '255 patent that are asserted in this case are both limited to aprepitant. All the patents in the family of patents stemming from the 2014 provisional application, including the two patents at issue in this case, are based on the specification that was filed at that time. For purposes of this case, the specifications of the two patents in suit can be regarded as identical.[5]

[5] For convenience, citations to the two specifications will refer solely to the specification of the '520 patent unless otherwise noted.

The specifications explain that aprepitant can be effective in preventing "acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy." '520 patent, col. 21, ll. 50–52. Because of the nausea and vomiting experienced by chemotherapy patients, the specification explains that oral administration of the drug is impractical, and "it is desirable to formulate aprepitant as a liquid suitable for parenteral or intravenous administration." *Id.* at col. 1, ll. 54–57. As the specifications note, however, aprepitant is poorly soluble, so it is challenging to deliver it to patients intravenously or parenterally in liquid form. *Id.* at col. 1, ll. 53–60; *see also* Tr. 146:15–19, 305:20–306:3. By preparing an emulsion containing aprepitant, the specifications explain, the drug can be delivered as an injectable formulation with enhanced bioavailability of the aprepitant once it is administered. *Id.* at col. 1, ll. 60–64.

The main challenge for making such an emulsion is that the emulsion formulation must contain very small droplet sizes in order for the emulsion to circulate in the bloodstream without causing capillary blockage or embolization. *See* DTX 61 at 1070. In addition, the emulsion formulation must be physically and chemically stable for long enough to be serviceable as a pharmaceutical injection. *Id.* at col. 1, line 65, through col. 2, line 41.

In the Brief Summary sections of the two patents, the specifications list a large number of what the specifications refer to as "embodiments," including broad ranges in the concentration of various components of proposed emulsion formulations. As relevant here, the specifications list ranges between 10 and 20 percent emulsifier, such as egg yolk lecithin, *id.* at col. 2, line 66, though col. 3, line 7; col. 9, ll. 58–67, and ratios of emulsifier to aprepitant between 10:1 and 30:1, *id.* at col. 3, ll. 43–47.

At three places in each specification, the patents set forth lists of possible weight percentages of the emulsifier. The first states:

> the composition comprises about 10 wt/wt % to 20 wt/wt %, 12 wt/wt % to 17 wt/wt %, 13 wt/wt % to 16 wt/wt%, 13 wt/wt % to 15 wt/wt%, or 13 wt/wt% to 14 wt/wt % emulsifier. In another embodiment, the composition comprises about 13 wt/wt %, 13.5 wt/wt %, 14 wt/wt %, 14.5 wt/wt %, 15 wt/wt %, 16 wt/wt %, 17 wt/wt %, 18 wt/wt %, 19 wt/wt % or 20 wt/wt % emulsifier.

'520 patent, col. 2, line 66, through col. 3, line 5; '255 patent, col. 3, ll. 49–58.

The second states:

> The amount of phospholipids, by weight, in the emulsions of the present disclosure may be within a range of about 10 wt/wt % to about 20 wt/wt %, 11 wt/wt % to 19 wt/wt %, 11 wt/wt % to 15 wt/wt %, 12 wt/wt % to 13 wt/wt %, 13 wt/wt % to 14 wt/wt %, 13 wt/wt % to 20 wt/wt %, or 12 wt/wt % to 18 wt/wt %. In certain embodiments, the phospholipids in the emulsions are at a concentration, by weight, about 11 wt/wt %, 12 wt/wt %, 12.5 wt/wt %, 13 wt/wt %, 13.5 wt/wt %, 14 wt/wt %, 14.5 wt/wt %, or 15 wt/wt %.

'520 patent, col. 9, ll. 58-67; '255 patent, col. 11, ll. 51-60.[6]

The third states:

> phospholipid emulsifier is added to a concentration of greater than 10 wt/wt %, 11 wt/wt %, 12 wt/wt % or 13 wt/wt % of the emulsion but less than 15 wt/wt %, 17 wt/wt % or 20 wt/wt % of the emulsion.

'520 patent, col. 11, ll. 10–14; '255 patent, col. 14, ll. 1–4.

Both specifications also contain lists of the ratios of emulsifier to aprepitant that the patents characterize as embodiments of the inventions.

The relevant portion of the '520 specification reads as follows:

> In one embodiment, the ratio of emulsifier to aprepitant (wt %:wt %) in the composition ranges from about 15:1 to 30:1, 20:1 to 25:1, 18:1 to 22:1 or 10:1 to 30:1. In another embodiment, the ratio of emulsifier:aprepitant (wt %:wt %) in the composition is about 15:1, 18:1, 19:1, 20:1, 21:1, 22;1, 23:1, 24.1, or 25:1.

[6] Elsewhere, the specifications note that egg lecithin is an example of a phospholipid that can serve as an emulsifier. *See* '520 patent, col. 9, ll. 35–57; '255 patent, col. 11, ll. 28–50.

’520 patent, col. 3, ll. 43–48.

Elsewhere, the ’520 specification states as follows:

> The ratio of emulsifier to aprepitant may also vary. For example, the ratio of emulsifier:aprepitant (wt %:wt %) within the oil portion ranges from about 15:1 to 30:1, 20:1 to 25:1, 18:1 to 22:1 or 10:1 to 30:1. In one embodiment the emulsifier:aprepitant (wt %:wt %) is about 15:1, 18:1, 19:1, 20:1, 21:1, 22:1 or 23:1.

’520 patent, col. 14, ll. 23–28.

The relevant portion of the ’255 specification reads as follows:

> In some embodiments, the ratio of emulsifier to NK-1 receptor antagonist [which includes aprepitant] (wt %:wt %) in the composition ranges from about 10:1 to 30:1, 10:1 to 20:1, 15:1 to 30:1, 20:1 to 25:1, 18:1 to 22:1, 19:1 to 20:1, or 10:1 to 30:1. In other embodiments, the ratio of emulsifier:NK-1 receptor antagonist (wt % :wt %) in the composition is about 10:1, 11:1, 13:1, 14:1, 15:1, 18:1, 19:1, 20:1, 21:1, 22:1, 23:1, 24:1, 25:1, or 30:1).

’255 patent, col. 4, line 63, through col. 5, line 3.

Elsewhere, the specification of the ’255 patent reads as follows:

> The ratio of emulsifier to NK-1 receptor antagonist [which includes aprepitant] in the final emulsion can be about 20:1 but may also vary. For example, the ratio of emulsifier:NK-1 receptor antagonist (wt %:wt %) within the oil portion ranges from about 15:1 to 30:1 20:1 to 25:1, 18.1 to 22.1, 19:1 to 20:1, or 10:1 to 30:1. In one embodiment, the emulsifier:NK-1 receptor antagonist (wt %:wt %) is about 15:1, 18:1, 19:1, 20:1, 21.1, 22.1 or 23:1.

’255 patent, col. 17, ll. 38–45.

Following the listing of those broad ranges of component concentrations and ratios, the specifications set forth six examples in which the inventors tested six formulations and determined that four of them resulted in stable injectable emulsions. Two of the examples (examples 4 and 5) were based on formulations taken from prior art references. Those examples were found not to be stable for a sufficiently long period to be usable as a pharmaceutical injection. Those two examples had egg lecithin concentrations of 2.50 percent and 9.95 percent, respectively. *See* ’520 patent, col. 18, line 23, through col. 19, line 35. The other four examples were successful formulations

prepared by the inventors, each of which was determined to be physically stable for an extended period of time and thus to be suitable for use as a commercial product. *See id.* at col. 16, line 59, through col. 18, line 66, and col. 19, line 36, through col. 20, line 34.

The four successful examples (examples 1, 2, 3, and 6) each had a ratio of emulsifier to aprepitant of 20:1 and egg lecithin concentrations between 11.7 percent and 14.3 percent. Specifically, the four successful examples had egg lecithin concentrations of 13.6 percent, 14.3 percent, 11.7 percent, and 13.8 percent, respectively. *See* '520 patent, col. 16, line 1, through col. 20, line 34. The specification reported that three of the four successful examples—the ones with egg lecithin concentrations of 13.6 percent, 11.7 percent, and 13.8 percent—proved stable for two months when stored at 25 degrees centigrade, and the one with an egg lecithin concentration of 14.3 percent proved stable for three months under the same conditions. *Id.* at col. 20, line 36, through col. 21, line 10.

IV. The *Heron v. Fresenius* Case

In 2022, prior to the institution of the action in this case, Heron sued Fresenius Kabi USA, LLC, another generic drug manufacturer, for infringing two other Heron patents from the same patent family, U.S. Patent Nos. 9,561,229 ("the '229 patent"), and 9,974,794 ("the '794 patent"). *See Heron Therapeutics, Inc. v. Fresenius Kabi USA, Inc.*, No. 22-985 (D. Del.). Although those patents shared essentially the same specification as the patents at issue in this case, the claims in those patents differed significantly from the claims in the present suit. The asserted claims in the *Fresenius* litigation were substantially narrower than the claims at issue in this case, in two main respects. First, the claimed aprepitant emulsion formulations at issue in the *Fresenius* case recited egg lecithin as an emulsifier in a concentration range of 13 to 15 percent (a concentration of 14 percent in some claims), as opposed to a range of 13 percent to 20 percent in the claims in this

case. Second, the ratio of egg lecithin recited in the claims at issue in the *Fresenius* patents was 20:1, as opposed to a range from "about 20:1 to about 25:1" recited in the '520 patent and a range from approximately 16.3:1 to approximately 28.6:1 in the '255 patent.[7]

The *Fresenius* case went to trial before me in 2024. Fresenius argued that the claims of the two patents at issue in that case would have been obvious in light of two prior art references that contained lesser concentrations of egg lecithin and taught aprepitant emulsions having concentrations of egg lecithin of less than 10 percent. The two prior art references that were the main focus of the defendant's argument in the *Fresenius* case were a Chinese patent to Zhou and others, known as CN845 (reproduced in this case as JTX 27), and an article from a Chinese journal written by Zhou and others (reproduced in this case as JTX 28). The Zhou references described an aprepitant emulsion that used egg lecithin as an emulsifier, with emulsifier concentrations of up to 9.95 percent egg lecithin.

Following the trial in *Fresenius*, I found that Fresenius had failed to prove that the '229 and '794 patent claims would have been obvious in light of the cited prior art. On the one hand, I found that a person of ordinary skill in the art would have recognized that the Chinese formulators had successfully solubilized aprepitant in an emulsion by using up to eight times as much emulsifier as had been used in conventional emulsions. In addition, I found that the Zhou article showed that the Chinese formulators were able to achieve a degree of stability with at least one of their formulations. I also found that a person of ordinary skill in the art would have recognized

[7] Because the '520 specification defines the term "about" to include a range of up to 20 percent below the recited 20:1 ratio and 20 percent above the recited 25:1 ratio, *see* '520 patent, col. 8, ll. 3–4, the full claimed range of ratios for the asserted claims of the '520 patent is 16:1 to 30:1. The cited ratios of egg lecithin to aprepitant in the '255 patent are based on calculations derived from the limitations of asserted claims 5 and 23 of the '255 patent, which recite (by way of independent claim 1) a range of 0.7% to 0.8% aprepitant and a range of 13% to 20% egg lecithin.

that the Chinese patent recommended the use of an emulsifier at the top of the 0.5% to 10% concentration range used by the Chinese inventors, and that nothing in the Chinese references indicated that a concentration any higher than 10% would cause the emulsion to fail.

On the other hand, Heron responded in the *Fresenius* case by pointing to evidence that a person of skill in the art would have been discouraged from making an aprepitant emulsion with an emulsifier concentration as high as 14%. In his testimony, Heron's expert Dr. Steven Little focused on the Zhou article, which was published in 2012, shortly after the Chinese patent. Dr. Little explained that a person of ordinary skill in the art confronted with the broad range of emulsifier concentrations in the Chinese patent would look to the Chinese inventors' other work—namely, the results reported in the Zhou article—for further guidance when picking the concentration within CN845's range to focus on. Dr. Little noted that the Zhou article disclosed that the "optimal formulation" of an aprepitant emulsion would contain only 2.5% egg lecithin, in contrast to the 8 percent to 10 percent concentration level suggested in the Chinese patent.

Dr. Little, who also served as Heron's expert witness in this case, testified in the *Fresenius* case that as of the priority date of the '229 and '974 patents, other products using egg lecithin as an emulsifier employed concentrations of egg lecithin in the low single digits,[8] and he stated that in his opinion, "going up to 14 percent is not what a person of ordinary skill in the art would even be thinking about doing" prior to Heron's invention. DTX 37 at Tr. 1282:13–19 (in the *Fresenius* case). That opinion, Heron argued, was consistent with the Zhou article's characterization of the

[8] For example, the aprepitant emulsion disclosed in the Hingorani patent application publication relied on by Fresenius (*see* JTX 21 in the *Fresenius* case), contained only 1.2% egg lecithin. *See* Tr. 262:131–21, 327:25–328:8, 1284:17–1286:7 (portions of which are reproduced in DTX 037 in this case). Similarly, the emulsions described in the Washington reference (JTX 113 in the *Fresenius* case), also relied on by Fresenius, contained only 1.2% lecithin. *See* Tr. 364:8–365:24 and JTX 113 at 2 (in the *Fresenius* case).

optimal emulsifier concentration level as being 2.5%. Accordingly, I found that Fresenius had not shown by clear and convincing evidence that a person of ordinary skill in the art would have had a motivation to modify Zhou's formulation by increasing the amount of egg lecithin to concentration levels above the range disclosed in CN845. *See* Tr. 227:18–228:14, 224:8–20 (in the *Fresenius* case). Nor did I find that Fresenius had adduced clear and convincing evidence that a person of ordinary skill in the art would have had a reasonable expectation of success with such a formulation.

V. The Events Leading to This Case

The FDA approved Cinvanti for marketing on November 9, 2017. Thereafter, Slayback, Azurity's predecessor-in-interest, filed its NDA with the FDA, seeking permission to market a product similar to Cinvanti. On December 12, 2023, Slayback submitted the statutorily required "notice letter" to Heron, notifying Heron of Slayback's NDA. Slayback's product contained approximately 18 percent aprepitant by weight and a ratio of egg lecithin to aprepitant of about 25:1, both of which fell outside the ranges in the patents that were at issue in the *Fresenius* case. Shortly thereafter, on January 9, 2024, and January 19, 2024, Heron filed the patent applications that ultimately became the '255 patent and the '254 patent. Also on January 9, 2024, Heron filed a patent application that ultimate became the '520 patent. Each of those patents contained claims broad enough to cover Slayback's NDA product.

The FDA gave tentative approval for Slayback's NDA product on July 25, 2024. Subsequently, on October 15, 2024, the PTO issued the '254 and '255 patents. On December 12, 2024, Heron filed this action (No. 24-1363) against the Slayback and Azurity entities, alleging infringement of the newly issued '254 and '255 patents. On May 6, 2025, the PTO issued the '520

patent to Heron. Shortly thereafter, on May 23, 2025, Heron filed a first amended complaint in this case, in which it added allegations of infringement of the '520 patent.[9]

VI. The Trial in This Case

At trial, each side presented three witnesses. Each side presented two witnesses by deposition and one witness—the expert on each side—through live testimony. Somewhat unusually, the two non-expert witnesses called by each party were witnesses who were, or had been, affiliated with the opposing party. Azurity presented deposition testimony from the two inventors, Dr. Hannah Han[10] and Dr. Thomas Ottoboni, and live testimony from Azurity's expert, Dr. Mansoor Amiji. Heron presented deposition testimony from Srinivasan Rao Kodela, the director of regulatory affairs for Azurity Pharmaceuticals, and Dr. Ashish Dubewar, the associate vice president of Azurity Pharmaceuticals. Heron also presented live testimony from its expert, Dr. Little.

1. Dr. Han

Dr. Han, one of the inventors of both patents in suit, worked under Dr. Ottoboni. She prepared the emulsions that led to the patents in suit. Tr. 110:2–6, 113:5–10, 184:15–25, 205:22–206:4. Azurity offered her testimony via deposition.

Dr. Han testified that in the course of her work she prepared aprepitant emulsions in accordance with two of the formulations set forth in the Zhou references having concentrations of 2.5 percent egg lecithin and 9.95 percent egg lecithin, respectively. She determined that neither

[9] On July 18, 2024, prior to the issuance of the '254, '255, and '520 patents, Heron filed suit in the companion case to this one, No. 24-830, alleging that Azurity's product would infringe ten other patents previously issued to Heron. As noted, that case has been stayed pending the outcome of this one.

[10] Dr. Han is identified as "Han Han" in the Heron patents, but she identified herself as "Hannah Han" at trial and was referred to in that way throughout the trial.

of those formulations was physically stable under the standards required for approval by the FDA for injectable pharmaceuticals in the United States. Tr. 122:11–14. She also prepared four other formulations, containing higher egg lecithin concentrations of 13.6 percent, 14.3 percent, 11.7 percent, and 13.8 percent, all of which she determined satisfied the FDA standards and were stable for between two and three months when stored at room temperature.

Dr. Han testified that aprepitant is highly insoluble in water, and even when it is prepared for injection in an emulsion, "aprepitant crashes out of solution quickly" if the emulsion is unstable. Tr. 123:21–124:2. Preparing an aprepitant emulsion that will remain stable, she explained, is difficult, as "the aprepitant emulsion is very complex, has many components, needs specific ratios." Tr. 128: 8–9. She added: "You have to test the different emulsifiers, oils, and other excipients to determine if it will make a stable emulsion." Tr. 138:1–3.

In addition to the amount of the emulsifier in the formulation, Dr. Han explained, the "amount of co-emulsifier and pH modifier can impact emulsion stability." Tr. 137:8–9. Asked whether one could know in advance which combinations of ingredients would result in a stable emulsion and which would not, she responded, "You have to make a range of emulsions to determine which one is physically stable." Tr. 139:15–16. "We do not know which ones would result in [a] stable emulsion. . . . You have to test the different emulsifiers, oils, and other excipients to determine if it will make a stable emulsion." Tr. 137:10–17, 138:1–3.

Dr. Han explained the chemistry applicable to aprepitant emulsions, noting that given the difficulty of solubilizing aprepitant, she used not only egg lecithin as a solubilizer, but also soybean oil and ethanol to help solubilize the aprepitant and the egg lecithin in the formulations she made. Tr. 150:7–151:11. Ethanol, she explained, was a necessary co-solvent in the preparation of the aprepitant emulsion. *Id.*

Asked about increasing the concentration of aprepitant, she responded that to do so would mean that other concentrations in the formulation would have to change. Tr. 156:21–157:3. She noted: "Because everything affects each other. You cannot just increase one concentration and expect to have the same result." Tr. 157:23–25.

I found Dr. Han to be a careful witness whose testimony was highly credible.

2. Dr. Ottoboni

Dr. Ottoboni, the other named inventor on the patents in suit, supervised Dr. Han and collaborated with her in the work Heron did on the aprepitant emulsion project. He acknowledged that aprepitant has "a very challenging solubility profile," Tr. 165:25–166:6, and that "the emulsion formulation of aprepitant was a very complex formulation. And all the components working together are critical for the ultimate stability of the formulation." Tr. 237:6–10; *see also* Tr. 170:7–9 (emulsion formulations "are quite complex."). Dr. Ottoboni testified that he and Dr. Han studied a number of combinations of components and discovered what he referred to as a "small range" or a "little island of stability" among the many combinations that they explored. Tr. 171:11–15, 195:17–196:7. In response to a question whether Dr. Han would have been able to obtain a stable emulsion if she had changed some or all of the amounts of the components she was experimenting with, he said: "We formulated many, many combinations of these components and, again, over time, through extensive experimentation, found a small range—a range of these components that together provided a stable formulation. That's as much as I can really state." Tr. 171:4–16. He added that "given the many, many experiments we did throughout the development, we never had success with formulations that were outside the range of stability we identified for Cinvanti." Tr. 171:23–172:1.

Dr. Ottoboni acknowledged that the specifications of the patents in suit did not include any references to experiments that he or Dr. Han had conducted with egg lecithin concentrations higher than 14.3 percent. Tr. 222:4–10. However, he stated that he believed they had tested "at least one" formulation having a concentration in the range of 17 to 18 percent egg lecithin that he recalled was stable for a period of more than seven days. Tr. 223:15–224:14, 233:33–234:4. Based on notations in Dr. Han's laboratory notebook regarding an emulsion prepared on June 10, 2014, Dr. Ottoboni agreed that the formulation prepared at that time appeared to have "creamed" in less than six days. DTX 104 at HER_THER_0031975. He added, however, that he did not regard "creaming" as necessarily indicative of failure. Tr. 232:3–6. But upon being shown further notations in Dr. Han's laboratory notebook stating that the emulsion in question had "very slight crystals" after 30 minutes, Dr. Ottoboni acknowledged that since Dr. Han detected the formation of crystals, the formulation could not be considered stable. Tr. 233:2–22.

Dr. Han testified otherwise with regard to creaming. She explained that "creaming" is "the separation that occurs in emulsion [between] the top layer and the bottom layer" such that "the top layer contains more oil droplets than the bottom layer." Tr. 119:19–23. She added that in the case of the aprepitant emulsions that she tested, "if we observed creaming, then we determined [the emulsion] to be unstable." Tr. 119:24–120:3.

Apart from the emulsion prepared on June 14, 2014, Dr. Ottoboni was asked if he had reviewed Dr. Han's laboratory notebooks to determine if she had conducted any experiments with emulsifiers in excess of 15 percent by weight that proved to be stable. He responded that there was "at least one, that I recall right now, that was stable for a period of more than -- more than seven days." Tr. 233:23–234:4. But he was unable to recall any of the details regarding that

formulation, and he admitted that he had "looked at a lot -- many, many examples. They're all -- kind of all muddled." Tr. 234:8–12.[11]

I found Dr. Ottoboni's testimony to be generally credible, although I found his testimony about whether Dr. Han had conducted at least one successful experiment with a concentration of egg lecithin greater than 15 percent to be uncertain and shaded somewhat in Heron's favor. In particular, I credit Dr. Han's testimony regarding "creaming" over Dr. Ottoboni's testimony on that subject.

3. Dr. Amiji

Azurity's expert, Dr. Amiji, testified about emulsion science, emphasizing that to create a stable emulsion containing oil and water , it is necessary to have enough of the emulsifier to ensure that the emulsifier covers the oil droplets in the mixture. Tr. 252:6–13. If the formulation contains too much of the emulsifier, however, he testified that the emulsifier molecules "are aggregated by themselves and create micelles," which can destabilize the emulsion. Tr. 252:19–23.

Dr. Amiji stated that in his opinion the asserted claims of the '520 and '255 patents do not satisfy the written description and enablement requirements of section 112 of the Patent Act. While noting that the specifications of the two patents disclose examples of stable injectable emulsions having concentrations of egg lecithin between 11.7 percent and 14.3 percent, Dr. Amiji stated that in his opinion the specifications do not provide written description or enablement

[11] On cross-examination, Heron's expert Dr. Little was asked if he had identified any experiment that the inventors conducted that produced a stable formulation with an emulsifier content above 15 percent. Tr. 651:3–6. He was unable to point to anything in his report to that effect, but he testified that from reviewing Dr. Han's laboratory notebooks he remembered "there being a discussion of, I think, like 18-something percent that was stable." Tr. 653:11–13. Heron did not point to anything in the laboratory notebooks to back up Dr. Little's testimony, and given Dr. Little's somewhat equivocal testimony on that point, I do not find that Dr. Little's testimony establishes that such a test was performed and proved successful.

support for the full range of egg lecithin concentrations of between 13 and 20 percent, and did not support the claims of ratios of egg lecithin to aprepitant of about 20:1 to about 25:1 (in the '520 patent) or between approximately 16.3:1 and 28.6:1 (in the '255 patent). Tr. 276:14–278:2, 288:25–289:20. He added that the amounts of the oil, the tonicity modifier, and the co-emulsifier (alcohol) to be used in the emulsion are all unspecified in the patent specifications. Tr. 276:19–277:5. While Dr. Amiji noted that the specifications contain some references to concentrations of emulsifier of up to 20 percent, he referred to that range as "generic" and regarded it as unsupported by evidence in the specifications that the inventors had actually invented stable or injectable emulsions with egg lecithin concentrations throughout the range between 13 and 20 percent. Tr. 278:8–20.

4. Mr. Kodela

Called as a witness (by deposition) for Heron, Mr. Kodela explained that following the release of Cinvanti, Azurity (through its predecessor Slayback) decided to develop an aprepitant emulsion product similar to Heron's Cinvanti. As noted, because Slayback's product was similar to Cinvanti but not identical to it, Slayback filed a "paper NDA" pursuant to section 505(b)(2) of the Hatch-Waxman Act, 21 U.S.C. § 355(a)(2), rather than an ANDA. Tr. 376:21–377:6. Slayback identified Heron's Cinvanti as the reference listed drug for purposes of its aprepitant emulsion product.

[redacted]

Slayback ultimately settled on a product having an egg lecithin concentration of 18 percent.

[redacted]

There were some additional differences between Slayback's product and Cinvanti. For example, the ratio of emulsifier to aprepitant in Slayback's product was 25:1, not 20:1, as in Cinvanti. PTX 51 at SLAY-APREP0000093. However, most of the ingredients were similar between the two formulations, with only slight variations. Tr. 388:6–19; PTX 51 at SLAY-APREP0000093.

[redacted]

5. Dr. Dubewar

Heron introduced testimony from Dr. Dubewar, who was familiar with Slayback's competing product as well as other products manufactured by Slayback and its successor, Azurity. He testified that Slayback's aprepitant product was equivalent to Cinvanti, even though there were slight differences in the composition of Slayback's product and Cinvanti. Tr. 415:21–416:22, 438:12–439:5.

Heron questioned Dr. Dubewar about an emulsion preparation made by Slayback that contained meloxicam, an anti-inflammatory drug. [redacted] Tr. 416:14–22, 426:22–429:12. Dr. Dubewar further acknowledged that Slayback's patent on its meloxicam product, U.S. Patent No. 11,040,008 ("the '008 patent"), covered formulations that included emulsifier concentrations of between 5 and 25 percent and taught how to make and use stable emulsions with between 5 and 25 percent emulsifier for meloxicam. Tr. 421:16–423:4.

6. Dr. Little

Heron's expert Dr. Little stated that in his view the specifications provided adequate written description and enablement for all the asserted claims of the '520 and '255 patents. He testified that he did not regard the range of 13 percent to 20 percent concentration of egg lecithin as a broad range, "especially given what is taught in the specification." Tr. 476:9–19. He explained that the specification mentioned that range in several places. Tr. 476:20–477:11. Dr. Little also stated that while practitioners had previously believed that emulsifier concentrations above the low single digits would result in unstable emulsions, the inventors discovered "a region

of stability" above that level. In light of the inventors' discovery of that region of stability, he testified that there was "no reason to believe" that the region of stability would be confined to emulsifier concentrations between 13 and 15 percent. Tr. 503:20–504:10; 506:1–507:2.

In response to a question from the court regarding how high the emulsion concentration could go and still be consistent with a stable emulsion, Dr. Little testified as follows:

> JUDGE BRYSON: . . . The point that I'm having more problem with is the third point, which is they mention, in the course of the patent, 10 to 15 to 20, up to 20. But there's no data to support 20 percent. And, therefore, we have to take their word for it.
>
> If they had written 10 to 40 percent, would we still take their word for it? So that's the point [on] which I'm having some difficulty.
>
> THE WITNESS: This is a good question. So the question is, from the standpoint of a person of ordinary skill in the art, what would be the reasons that you would expect for there to be an instability going up? Now, there are no mechanisms where if you went up to -- Your Honor used 40. I'm trying to decide whether at 40 this would happen. I think it would happen once you get in the 50s.
>
> If you got up to that high, you're going to have, like, phase inversion. So there are ways you can create an instability by really jacking up that concentration.

Tr. 519:24–520:19.

In concluding that the '520 and '255 patents satisfied the written description requirement of section 112, Dr. Little relied heavily on the fact that the egg lecithin concentration range of 13 to 20 percent and the range of lecithin-to-aprepitant ratios of 10:1 to 30:1 were referred to several times in the specifications, even though those references did not represent actual test results. Tr. 497:2–12, 507:4–8, 525:16–526:10, 528:7–17, 535:19–536:15. In addition, Dr. Little pointed out that Table 7 in the specification showed that among the four examples of stable emulsions set forth in the specification, three were reported as being stable for two months and one was reported as being stable for three months. The one found to be stable for three months was the one containing the greatest concentration of egg lecithin, a concentration of 14.3 percent. Based on that report,

Dr. Little inferred that the stability of emulsions was increasing as the concentration of the egg lecithin increased, from which he concluded that the emulsion would remain stable with egg lecithin concentrations well in excess of 15 percent. Tr. 542:8–544:15.

With respect to the enablement requirement of section 112, Dr. Little testified that emulsions with egg lecithin concentrations between 13 and 20 percent would be easy to make and test, Tr. 558:8–23, and that the results would not be unpredictable. Tr. 562:3–15. Therefore, he concluded, the claims of both patents were not shown to be invalid for lack of enablement. *Id.*

VII. The Parties' Positions

Azurity's principal argument is that the asserted claims of both the '520 patent and the '255 patent are invalid for failure to satisfy the written description requirement of section 112 of the Patent Act. Secondarily, Azurity argues that the asserted claims fail to satisfy the enablement requirement of that statute. Briefly summarized, Azurity's argument is that to provide adequate written description for a patent's claims, the specification must contain disclosures that show that the inventors had possession of the claimed invention—that is, the specification must establish that the inventors actually invented the entire scope of the claimed invention, not just a portion of it. While the specification refers at several points to a range of emulsifier concentrations between 13 and 20 percent, Azurity argues that such a showing is not sufficient unless the specification demonstrates that the inventors actually invented a formulation that was either physically stable (as in the case of the '520 patent) or constituted a viable injectable emulsion (as in the case of the '255 patent) across the full claimed ranges.

With respect to enablement, Azurity argues that while the specifications contain lists and quantities of ingredients to be used to make the claimed emulsions, there was insufficient evidence

to show that the results would either be physically stable or constitute an injectable emulsion, across the full scope of the claimed ranges, without undue experimentation.

For its part, Heron relies heavily on the fact that the specifications contain several references to the range of emulsion concentrations between 13 and 20 percent, and the range of ratios of emulsifier to aprepitant of 20:1 to 25:1 (in the case of the '520 patent) or approximately 16.3:1 to 28.6:1 (in the case of the '255 patent). Those references, according to Heron, are sufficient to satisfy the written description requirement. As for enablement, Heron argues that the detailed descriptions in the specifications of the components that could be used to make the aprepitant formulations are sufficient, and to the extent that further experimentation would be necessary to ensure that the products would be physically stable or usable as injectable emulsions, such experimentation would be routine and well within the capacity of a person of ordinary skill in the art.

CONCLUSIONS OF LAW

I. Legal Standard

The Patent Act requires a patentee to include in the specification both "a written description of the invention" and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). That prescription imposes on the patentee a burden of satisfying the statutory written description and enablement requirements; if the patentee fails to do so, the subject matter is not eligible for patenting. *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938); *Seymour v. Osborne*, 78 U.S. 516, 540 (1870). Once the patent is issued, however, the burden shifts to the patent challenger to show, by clear and convincing evidence, that the patentee has failed to satisfy the written

description or enablement requirements. *Microsoft Corp. v. i4i Ltd. P'ship*¸ 564 U.S. 91, 97 (2011); *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1341 (Fed. Cir. 2021). In this case, then, Azurity bears the burden of showing, by clear and convincing evidence, that Heron failed to satisfy either the written description or the enablement requirements of the statute.

II. Claim Construction

For purposes of the dispute in this case, there are two main differences between the single asserted claim of the '520 patent (claim 8) and the two asserted claims of the '255 patent (claims 5 and 23). First, unasserted claim 1 of the '520 patent, from which claim 8 depends, recites that the emulsion "is physically stable," whereas unasserted claim 1 of the '255 patent, from which asserted claims 5 and 23 depend, does not contain a limitation requiring that the emulsion be "physically stable," but simply recites in its preamble that the aprepitant emulsion must be "an injectable emulsion." Second, claim 1 of the '520 patent recites that "the ratio of egg lecithin to aprepitant is between about 20:1 to about 25:1," while claim 1 of the '255 patent recites that the ratio of egg lecithin to aprepitant covered by that claim, and asserted dependent claims 5 and 23, ranges from approximately 16.3:1 to approximately 28.6:1.[12] There is no dispute regarding the proper construction of the term "physically stable," and there is no dispute regarding the range in the lecithin-to-aprepitant ratio in the asserted claims of the two patents. There is, however, a dispute regarding the meaning of the term "injectable emulsion" in the asserted claims of the '255 patent.

[12] As discussed above, the '255 patent does not provide an explicit ratio or range of ratios, but rather provides a range of aprepitant and emulsifier concentrations from which the range of ratios can be calculated.

1. The ’520 Patent: “Physically Stable”

The parties have stipulated that the term “physically stable” should be construed to mean “meets the criteria under USP <729> for mean droplet size not exceeding 500 nm and PFAT5 not exceeding 0.05%, and no visible aprepitant crystals when viewed at magnification of 4x to 10x, after being stored either at 5º Celsius or at room temperature for a period of at least one week.”[13] D.I. 157 ¶ 26. That construction is supported by definitional language in the ’520 specification. ’520 patent, col. 8, ll. 14–20. I accept that agreed-upon construction of the term “physically stable.”

2. The ’255 Patent: “An Injectable Emulsion”

The parties disagree about the proper construction of the term “an injectable emulsion,” which serves as the preamble of the asserted claims of the ’255 patent. At the outset, the parties disagree about whether the preamble of independent claim 1 of the ’255 patent, which applies to the asserted dependent claims, should be treated as limiting. *See* Tr. 699:23–704:21; 710:11–712:13; D.I. 189 at 23–25; D.I. 194 at 18–19. Azurity argues that the preamble is limiting, while Heron argues that it is not. The parties’ second disagreement is over the meaning of the term “injectable emulsion.” Heron argues that even if the preamble is limiting, it should be understood to mean only that the emulsion “could be injected.” Because the preamble does not expressly state that the term “injectable” refers to injections into human patients for therapeutic purposes, Heron argues that it should not be construed to be limited in that fashion. Tr. 97:19–25.

[13] “USP <729>” refers to chapter 729 of the United States Pharmacopeia, which sets forth the standards the FDA applies in approving injectable emulsions. *See* USP33-NF28 General Chapter <729> for Globule Size Distribution in Lipid Injectable Emulsions. “PFAT5,” is defined in chapter 729 of the USP to refer to the percentage of fat in globules larger than five microns in diameter in lipid emulsions that are delivered intravenously.

Azurity argues that the term "injectable emulsion" should be construed to mean "an emulsion for safe administration to a human, that meets the stability criteria set forth in USP <729> and demonstrates enhanced stability over the prior art injectable emulsion disclosed in Zhou by not exhibiting crystal formation for more than four days when stored at room temperature." D.I. 137 at 3–4. Under Azurity's proposed construction, an "injectable emulsion" would have to satisfy all the requirements of the USP <729> standard but would only need to be stable for at least four days, rather than for at least a week, as is required by the agreed-upon definition of "physically stable" in claim 8 of the '520 patent.

In the alternative, Azurity argues that even if the term "injectable emulsion" is not construed to require physical stability, an emulsion must consist of very small droplets in order to be safely injected into a human and thus should be construed to refer to "a colloidal dispersion of two immiscible liquids in the form of droplets, whose diameter, in general, is between 10 nanometers and 100 microns." Dkt No. 189 at 22.

a. The Preamble

The Federal Circuit has stated that the preamble of a patent claim generally does not limit the claim. *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1236 (Fed. Cir. 2017); *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). However, the court has frequently recognized exceptions to that principle. On a number of occasions, the Federal Circuit has quoted the statement from *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002), that "a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." But as the court has noted, "[t]o say that a preamble is a limitation if it gives 'meaning to the claim' may

merely state the problem rather than lead one to the answer." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir 1989).

As a general rule, a preamble is treated as not limiting when a claim employs the preamble "only to state a purpose or intended use for the invention." *Catalina*, 289 F.3d at 808. That is because such statements "usually do no more than define a context in which the invention operates." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). By contrast, the court has held that a preamble is limiting if it sets forth the "essence" or the "fundamental characteristic of the claimed invention," *Vizio, Inc. v. Int'l Trade Comm'n*, 605 F.3d 1330, 1340 (Fed. Cir. 2010), or if it "recites essential elements of the invention," *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1341 (Fed. Cir. 2021); *see also In re Xencor, Inc.,* 130 F.4th 1350, 1358 (Fed. Cir. 2025); *Poly-Amer., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004). Similarly, the preamble is regarded as limiting if the claim drafter "chooses to use *both* the preamble and body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) (quoting *Bell Commc'ns Rsch., Inc. v. Vitalink Commc'ns Corp.*, 55 F.3 615, 620 (Fed. Cir. 1995)).

I find that the preamble of the '255 patent's asserted claims is limiting because the "essence" or the "fundamental characteristic of the claimed invention" is that it is an injectable emulsion. The specification repeatedly characterizes the invention as an emulsion suitable for injection into patients, and the limitations set forth in the claims are specifically directed to that purpose. *E.g.*, '255 patent Abstract ("Disclosed herein are novel pharmaceutical formulations . . . suitable for parenteral administration including intravenous administration"); col. 1, ll. 46–50 ("oral dosage forms can create a problem for patients suffering from emesis . . . . Accordingly, it

is desirable to have injectable formulations to simplify treatment for these patients"); col. 17, ll. 58–61 ("The present formulations take advantage of the ability to solubilize therapeutically effective amounts of a NK-1 receptor antagonist in an oil phase which can then be used to generate an emulsion suitable for injection.").

The focus of the '255 patent's specification is on the injectability of the claimed compound as a core property and the essence of the improvement over the prior art. Injectability is not simply an intended use or a possible application of the invention. Rather, the claimed focus of the formulation as an injectable emulsion is an essential characteristic of the claimed invention, given the poor solubility of aprepitant in water and its instability in traditional aqueous-based liquid formulations. *See, e.g.*, '255 patent, col. 1, ll. 52–55. The entire burden of the '255 patent is that the use of an injectable emulsion is the solution to the problem of non-oral administration of aprepitant to patients. In sum, the claim drafter in this case has chosen to use both the preamble and the body to define the subject matter of the asserted claims.

As the Federal Circuit explained in the *Boehringer* case, "preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise." 320 F.3d at 1345. In that case, as in this one, the language of the preamble provided "the *raison d'être*" of the invention. *Id.*; *see also In re Xencor*, 130 F.4th at 1358.

Preamble language is also frequently treated as limiting when it provides an antecedent basis for a term later used in the body of the claim. *See Pacing Techs., LLC v. Garmin Int'l, Inc*., 778 F.3d 1021, 1024 (Fed. Cir. 2015) (When "limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.") (quoting *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339

(Fed. Cir. 2015)). Thus "dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention." *Catalina*, 289 F.3d at 808.

Claim 1 of the '255 patent provides a limitation that "the pH of the emulsion ranges from about 7.5 to 9.0," yet there is no antecedent basis provided in the claim for "the emulsion" other than the characterization of the claimed invention as "[a]n injectable emulsion" in the preamble. *See, e.g.*, *In re Fought*, 941 F.3d 1175, 1178 (Fed. Cir. 2019) (finding that the term "travel trailer" in the preamble was limiting because it provided an antecedent basis for the same term used in the body of the claims). In the case of the claim 1 of the '255 patent, the preamble both provides an antecedent basis for the term "emulsion" and conveys the essential nature of the formulation recited in asserted claims 5 and 23. I therefore construe the preamble reference to "an injectable emulsion" to serve as a limitation with regard to claims 5 and 23 of the '255 patent.

b. The Meaning of "Injectable Emulsion"

The more difficult question is whether the term "injectable emulsion" carries with it a requirement that the emulsion be stable, at least for some period of time. Azurity's expert witness, Dr. Amiji, testified persuasively that an aprepitant emulsion is not suitable for injection if the aprepitant precipitates out of solution and forms crystals, either before or soon after the emulsion is injected into a patient. For that reason, Dr. Amiji testified, some degree of stability is inherent in the requirement that the emulsion be "injectable." Tr. 17:16–18.

Dr. Amiji's testimony was less persuasive with regard to his contention that "an injectable emulsion" must be construed to mean an emulsion that satisfies a modified version of the FDA's stability standards for approving pharmaceutical emulsions that are designated for injection into patients. Dr. Amiji first contended that in light of the intrinsic evidence regarding the '255 patent,

the term "injectable emulsion" had to be stable. Tr. 9:4–8. He then proposed the following construction for "injectable emulsion," which Azurity has adopted:

> [An] emulsion for safe administration to a human that meets the civility [sic: stability] criteria set forth in United States Pharmacopeia 729 and demonstrates enhanced stability over the prior art injectable aprepitant emulsion disclosed in Zhou by not exhibiting crystal formulation for more than four days when stored at room temperature.

Tr. 9:18–24. Heron takes issue with Dr. Amiji's proposed construction and argues that the requirement that the emulsion be "injectable" is "a bare minimum requirement just that it could be injected. In terms of it doesn't have any specific requirements that are going to be for human administration." Tr. 97:20–23.

I disagree with both parties' proposed constructions.[14] Heron's construction is unreasonably narrow. Given that the specification is directed to a medication for injectable administration to human patients for treating emesis, it would render the invention unusable if the emulsion were so unstable as to render it impractical (or unsafe) to inject the emulsion into a human patient for therapeutic purposes.

On the other hand, Azurity's construction is contrived and unconvincing. In arguing that an injectable emulsion must be stable, Azurity adopts (for the most part) the detailed standard for physical stability that the FDA applies when approving pharmaceutical emulsions that are to be injected into patients in this country. But Azurity distinguishes the "injectable emulsion" limitation in the '255 patent from the "physical stability" limitation in the '520 patent by arguing that while "physical stability" requires that the emulsion remain stable for at least one week, an "injectable emulsion" need only be stable for four days. Azurity draws the latter requirement from

[14] While I rejected Azurity's proposed construction at trial, Tr. 102:14–104:17, my ruling did not foreclose that there may need to be some level of stability inherent in the requirement that an emulsion be injectable, even if the emulsion need not satisfy the USP <729> physical stability requirements.

Heron's characterization of the emulsion formulations in the Zhou prior art patent as unstable because Zhou's emulsions exhibited crystal formation within four days when stored at room temperature. *See* Tr. 9:17–24.

The fact that Heron uses the term "physical stability" in the '520 patent but not in the '255 patent (a difference that runs through a number of the patents in the Cinvanti family of patents) is a strong indication that Heron did not intend to adopt the U.S. Pharmacopeia definition of physical stability for both patents. Azurity seems to accept that proposition, as it does not argue that both patents contain fully congruent requirements of physical stability. But the problem is that there is no persuasive force to Azurity's argument that the only difference between a "physically stable" emulsion and an "injectable" emulsion is that the former must be stable for at least a week and the latter need only be stable for at least four days. There is no indication that Heron intended to convert the observation that the Zhou emulsions proved unstable within four days into a test for the degree of stability required to satisfy the "injectable emulsion" limitation of the '255 patent claims.

Azurity argues that physical stability must be regarded as a limitation of claims 5 and 23 of the '255 patent because the specification repeatedly emphasizes that the invention described in the specification results in a stable emulsion. D.I. 137 at 4–6. But that does not follow. Simply because the specification touts physical stability of the sort required by USP chapter <729> as a feature of the claimed invention does not mean that physical stability must be regarded as a limitation of the asserted claims when that standard is not adopted in the claims.

As I noted in an earlier filing in this case, D.I. 136 at 6, Azurity's argument conflates an advantage of a claimed invention with a limitation of the claim. The fact that a patentee points to an advantage of an invention, either in the course of prosecution or in the specification 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 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).

In this case, the specification clearly contemplates that the invention will be physically stable, unlike the emulsions that were the subjects of the prior art Zhou patent and article. *See, e.g.,* '255 patent, abstract; col. 2, line 8 ("Emulsion formulations must be physically stable."); col. 12, ll.28–29 ("The present disclosure is directed to stable pharmaceutical compositions . . . ."). However, the specification of the original 2014 provisional application, with slight modifications, has been used as the basis for a large number of patents, some of which contain claims reciting physical stability and some of which do not.[15] In that setting, it is reasonable to conclude that the inventors contemplated that their inventions would all be expected to be physically stable, but that

[15] The patents in the related family of Heron patents that contain a requirement of physical stability include the following: U.S. Pat. Nos. 9,808,465; 9,974,793; 9,974,794; 10,500,208; 10,953,018; 11,878,074; and 12,290,520. The patents in that family that do not contain a requirement of physical stability include U.S. Pat. Nos. 9,561,229; 9,974,742; 10,624,850; 11,173,118; 11,744,800; 12,115,254; and 12,115,255.

the claims would not all require physical stability under the USP chapter <729> standard as a limitation. That is the situation with regard to the asserted claims 5 and 23 of the '255 patent.

Accordingly, I adopt the less rigid construction requiring that an "injectable emulsion" must be safe for injection in a human and thus must not be subject to breaking down within a time or in a manner that renders it unusable for that purpose.

III. The Written Description Requirement

1. General Principles

Section 112(a) of the Patent Act requires that a patent specification "shall contain a written description of the invention." The leading Federal Circuit case expounding on that subject is *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), in which the court stated that a patent specification adequately describes an invention when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* at 1351. That is, the specification "must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.* The court added that "actual 'possession' or reduction to practice outside of the specification is not enough" to satisfy the written description requirement. *Id.*; *see also Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1343 (Fed. Cir. 2021); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019); *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1382 (Fed. Cir. 2019); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008).

As the Federal Circuit recognized in *Ariad*, the term "possession" has "never been very enlightening" as a metaphor for the sufficiency of the written description in a patent specification. *Ariad*, 598 F.3d at 1351. A more useful formulation is that the patentee must demonstrate, in the

specification, that he invented the full scope of the claimed subject matter. In a recent decision, the Federal Circuit accurately summarized the case law regarding the written description requirement in just such terms:

> Judicial gloss in the case law reflects the need that the disclosure show that one actually made the invention that one is claiming, *i.e.*, that it possessed the invention as claimed. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not."

Regents of the Univ. of Minn. v. Gilead Scis. Inc., 61 F.4th 1350, 1355 (Fed. Cir. 2023) (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). In a recent opinion, Judge Freeman summarized the purpose of the written description requirement succinctly, writing that the written description requirement

> implies a documentary function: the inventor must not only know how to practice the invention, but must prove that understanding through the disclosure in the specification. . . . Otherwise, if written description was not required, a patentee could claim a "mere wish or plan" without having fully invented anything, and thus improperly exclude others from the field.

Unicorn Energy AG v. Tesla Inc., 740 F. Supp. 3d 930, 950 (N.D. Cal. 2024) (citing *Ariad*, 598 F.3d at 1351.

The need for a proper written description of the invention is especially acute in the case of genus claims that use functional language to define the boundaries of the claimed genus. In such cases, as the Federal Circuit explained in *Ariad*, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." *Ariad*, 598 F.3d at 1351. Importantly, the *Ariad* court noted that in describing a claimed genus, "merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species." *Id.* at 1350.

In cases both before and after *Ariad*, as in *Ariad* itself, the Federal Circuit has repeatedly made clear that merely naming a species or group of species in a patent specification is not necessarily sufficient to satisfy the written description requirement. In 1989, the Federal Circuit set forth the same standard that the en banc court later adopted in *Ariad*, stating that to satisfy the written description requirement, "the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *In re Gosteli,* 872 F.2d 1008, 1012 (Fed. Cir. 1989). And recently, the court reiterated that "[t]he written description test requires 'an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.'" *Regeneron Pharms., Inc. v. Mylan Pharms., Inc.*, 127 F.4th 896, 914 (Fed. Cir. 2025) (quoting *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1063 (Fed. Cir. 2020)).

"Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Immunex*, 964 F.3d at 1063. "The disclosure must be considered as a whole, as the person of ordinary skill in the art would read it, to determine if it reasonably conveys possession." *Allergan USA, Inc. v. MSN Lab'ys Private Ltd*., 111 F.4th 1358, 1375 (Fed. Cir. 2024).

Finally, as the court in *Ariad* explained, "determining whether a patent complies with the written description requirement will necessarily vary depending on the context." *Ariad*, 598 F.3d at 1352. In particular, "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* "When the technology at issue is 'complex' and 'highly unpredictable,' . . . the level of detail required to satisfy the written description requirement may

be greater." *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 136 F.4th 1367, 1383 (Fed. Cir. 2025).

2. Azurity's Evidence Regarding Written Description

Azurity argues that the specifications of the asserted patents fail to show that the patentees invented the full range of the claimed egg lecithin concentrations or the full range of the claimed ratios of egg lecithin to aprepitant, and that the asserted claims therefore lack adequate written description. First, Azurity argues that the specifications do not disclose that the inventors possessed an aprepitant emulsion with an egg lecithin concentration higher than 14.3 wt/wt %, which was the highest egg lecithin concentration level used in the tests conducted by the patentees and described in the patent specifications. D.I. 189 at 15. Azurity contends that the evidence shows that formulating aprepitant emulsions is an unpredictable art, and that the references in the specifications to various possible egg lecithin concentrations are insufficient to demonstrate that the inventors actually had possession of (i.e., invented) stable emulsion formulations with egg lecithin concentrations of up to 20 percent. *Id.* at 10–13. Because the asserted claims of both the '520 patent and the '255 patent recite the same range of 13 wt/wt % to 20 wt/wt % of egg lecithin as an emulsifier, Azurity's arguments on that issue are the same for both patents.

Azurity makes a similar argument regarding the claimed ranges in the ratios of egg lecithin to aprepitant. As calculated, the asserted claims recite ratios of egg lecithin to aprepitant ranging between 16:1 to 30:1 (for the '520 patent) and between approximately 16.3:1 to approximately 28.6:1 (for the '255 patent). *See* note 7, *supra.* The four examples of stable formulations set forth in the specifications all contain the same 20:1 ratio of egg lecithin to aprepitant.

Heron offers several general responses to Azurity's reliance on the *Ariad* line of cases. First, Heron contends that the claims at issue in this case are not claims to a genus, and therefore

cases addressing genus claims are inapposite. I disagree. The pertinent limitations of the claims at issue in this case are directed to emulsions with a range of egg lecithin concentrations between 13 and 20 percent. Those claims are clearly generic in nature, as they cover any and all egg lecithin concentrations within that range. The same applies to the claim limitation reciting ranges in the ratios of egg lecithin to aprepitant falling between 16:1 and 30:1 (as claimed in the '520 patent), and approximately 16.3:1 to 28.6:1 (as claimed in the '255 patent).

Heron also contends that the claims are not functional in nature. Again, I disagree. Claim 8 of the '520 patent is clearly functional, as it requires that the emulsion be "physically stable," which is a functional limitation. And claims 5 and 23 of the '255 patent are likewise properly viewed as functional, because they require that the emulsion be "injectable," which is also a functional characteristic of the emulsion. That is particularly true given this court's construction of the term "injectable emulsion" as requiring a degree of stability necessary to facilitate safe injection of the emulsion into patients.

Heron acknowledges that the working examples of stable aprepitant emulsions set forth in the specifications cover only a limited portion of the claimed range of egg lecithin concentrations between 13 and 20 percent. The four examples contain egg lecithin concentrations of 11.7 percent, 13.6 percent, 13.8 percent, and 14.3 percent. Only three of those examples fall within the claimed range of 13 to 20 percent, and the three of them together embrace only 10 percent of that range. In addition, the ratio of egg lecithin to aprepitant in all four example formulations is 20:1, while the asserted claim of the '520 patent recites a ratio in the range of 16:1 to 30:1, and the asserted claims of the '255 patent recite ratios in the range of approximately 16.3:1 to 28.6:1. The examples are thus not representative of the full scope of the claimed formulations in either patent.

In response to the argument that the specifications do not contain examples providing written description support for the full scope of the claims, Heron contends that it is not necessary for a specification to contain examples in order to satisfy the written description requirement. While it is true that representative examples or actual reductions to practice are not always required to satisfy the written description requirement, the Federal Circuit has made clear that in the absence of representative examples, there must be some other basis for concluding that the patentee has invented the full category of subject matter that is claimed. As Federal Circuit put it in *Ariad,* a sufficient description of a genus

> requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus. . . . An adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials.

598 F.3d at 1350. *See also Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190–91 (Fed. Cir. 2014) (Examples or a reduction to practice are not required, but "the critical inquiry is whether the patentee has provided a description that 'in a definite way identifies the claimed invention' in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing.") (quoting *Ariad*, 598 F.3d at 1350, 1352).

Heron cites the *Alcon* case repeatedly in its briefs for the proposition that examples are not necessarily required to provide written description support for a claim. That is, of course, true, but as the court in *Alcon* itself noted, in the absence of examples written description must be established by other means. 745 F.3d at 1190–91 (quoting *Ariad*, 598 F.3d at 1350). The problem in this case is that written description is not demonstrated in any other way, and thus Heron is left to rely solely on the examples in its specifications.

When the purported showing of the written description of a genus is based on examples within the genus, the examples must be representative of the entire genus. *See Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1125 (Fed. Cir. 2008) (holding that the disclosure of one gene "was not representative and failed to adequately support the entire genus" of recombinant plasmids). That principle is embodied in the Patent and Trademark Office's *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1105–06 (Jan. 5, 2001), which have been incorporated in section 2163 of the PTO's Manual of Patent Examining Procedure § 2163 (9th ed., rev. Jan. 2024). The Guidelines state that the "written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species" among other ways, and note that a "representative number of species means that the species which are adequately described are representative of the entire genus." The Federal Circuit has cited the PTO's written description guidelines with approval on several occasions. *See Ariad*, 598 F.3d at 1353; *Carnegie Mellon*, 541 F.3d at 1125; *Enzo Biochem, Inc. v. Gen-Probe Inc*, 323 F.3d 956, 964 (Fed. Cir. 2002).

Heron argues that there are enough examples in the specifications to provide written description support for the limitation reciting egg lecithin concentrations between 13 and 20 percent. But the three examples in the specification that fall within the 13-to-20 percent range—the examples containing 13.6, 13.8, and 14.3 percent egg lecithin—are all clustered near the bottom end of that range, and thus are not sufficiently representative to serve as adequate written description of the full claimed range. *See AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014) ("[I]f the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession

of the genus."); *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435, 459 (D. Del. 2021) (same); *Eli Lilly & Co. v. Perrigo Co.*, 202 F. Supp. 3d 918, 997 (S.D. Ind. 2016) (finding "insufficient written description support for the entire range disclosed. . . . To satisfy the written description requirement, the specification must do more than merely invite other researchers to discover the upper amount of [the component] that could conceivably work.").

The same is true for the range in the ratios of egg lecithin to aprepitant. While the specifications refer to a broad range of such ratios, from 10:1 up to 30:1, there is nothing in the specifications to indicate that the patentees invented a stable emulsion across that range of ratios of egg lecithin to aprepitant. The only ratio of egg lecithin to aprepitant disclosed in the four examples given in the specifications was 20:1, and nothing in the specifications suggests that the single example of a 20:1 ratio could be generalized to ranges as low as 16:1 or 16.3:1, or as high as 28.6:1 or 30:1, which are the outer bounds of the lecithin-to-aprepitant ratios claimed in the claims of the two asserted patents in this case.

In response, Heron argues that it has satisfied the written description requirement with respect to the egg lecithin concentrations of between 13 and 20 percent because the specifications of the '520 and '255 patents list a number of concentrations of egg lecithin ranging from 10 to 20 percent. *See* '520 patent, col. 2, line 66, through col. 3, line 5; col. 9, ll. 58–67; col. 11, ll. 10–15; '255 patent, col. 3, ll. 49–58; col. 11, ll. 51–60; col. 14, ll. 1–4. Similarly, Heron argues that it has satisfied the written description requirement with respect to the ratio of egg lecithin to aprepitant, because the specifications of the '520 and '255 patents list a number of lecithin-to-aprepitant ratios ranging from 10:1 to 30:1. *See* '520 patent, col. 3, ll. 43–48; col. 14, ll. 23–28; '255 patent, col. 4, line 63, through col. 5, line 3; col. 17, ll. 38–45.

Heron is wrong in asserting that the written description requirement is satisfied merely because Heron's specifications refer to what the specifications call "embodiments" containing egg lecithin concentrations of up to 20 percent. Those "embodiments" are not actual examples of successful (i.e., stable or injectable) emulsions, but are merely assertions in the specifications that "the composition comprises" egg lecithin concentrations higher than those in the actual examples and that those concentrations of egg lecithin fall within the scope of "the present disclosure." *See* '520 patent, col. 2, line 66, through col. 3, line 5; '255 patent, col. 11, ll. 51–60. Likewise, the references in the specifications to "embodiments" of the invention containing ratios of egg lecithin to aprepitant ranging from 10:1 to 30:1 are not actual examples of successful emulsions. *See* '520 patent, col. 3, ll. 43–48; '255 patent, col. 4, line 63, through col. 5, line 3. Heron has pointed to no other support in the specifications for the proposition that the patentees invented formulations with components having those values.

In a number of cases, including *Ariad*, the Federal Circuit has made clear that simply identifying a genus and naming various species within that genus is not enough to satisfy the written description requirement for all asserted members of the genus. The court in *Ariad* expressly rejected the argument that

> as long as the claim language appears *in ipsis verbis* in the specification as filed, the applicant has satisfied the requirement to provide a written description of the invention. . . . [A] generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that *the applicant has invented species sufficient to support a claim to a genus*.

598 F.3d at 1349 (emphasis added); *see also Nuvo Pharms. (Ireland) Designated Activity Co.*, 923 F.3d at 1380 ("We have expressly rejected the argument that the written description requirement . . . is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification."); *Centrak, Inc. v. Sonitor Techs., Inc.,* 915 F.3d 1360, 1367 (Fed. Cir. 2019)

(Generic claim language in the specification "does not satisfy the written description requirement if it fails to support the scope of the genus claimed."); *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011) ("An *ipsis verbis* disclosure of a claimed genus . . . is not *per se* sufficient to meet the written description requirement."); *Enzo Biochem*, 323 F.3d at 968 (Enzo argues "that the written description requirement for the generic claims is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification. We do not agree."). The Federal Circuit has thus made clear that it is not sufficient to satisfy the written description requirement with regard to the boundaries of a claimed genus merely by asserting a particular boundary without providing a reason that a person of skill in the art would understand that boundary to be meaningful in the physical world.

That proposition has particular force in this case in view of the evidence that making aprepitant emulsions is a complex process with many unpredictable factors. For that reason, Azurity contends, a simple recitation of egg lecithin concentrations and ratios of egg lecithin to aprepitant well outside the ranges shown in the actual examples set forth in the specifications is not enough to show that the inventors actually invented operable formulations with those characteristics. I agree.

The evidence at trial established that Heron and its inventors viewed the creation of aprepitant emulsions as a complex and unpredictable venture, notwithstanding their success in creating stable emulsions in the range of the examples that were included in the specifications. Heron admitted as much in its submission to the FDA, where Heron noted that "the solubility of aprepitant is more complex than expected. It is strongly dependent on the concentration of lecithin instead of on the concentration of oil. In addition, increasing the concentration of one component,

which effectively decreases the concentration of other components, can lead to incomplete aprepitant dissolution or aprepitant recrystallization." DTX 116 at HER_THER_0076300.

The inventors also testified that the creation of aprepitant emulsions is a complex and unpredictable process. Dr. Han testified that the "aprepitant emulsion is very complex, has many components, needs specific ratios." Tr. 128:8–9. She explained that "everything affects each other. You cannot just increase one concentration and expect to have the same result." Tr. 157:23–25. Testing the various combinations of components was critical, she said: "You have to make a range of emulsions to determine which one is physically stable." Tr. 139:11–16. Asked about the emulsions components set forth in claim 1 and whether it was possible to know which combinations of components would result in a stable emulsion without testing them, she responded, "We do not know which ones would result in stable emulsion. . . . You have to test the different emulsifiers, oils, and other excipients to determine if it will make a stable emulsion." Tr. 137:10–138:3.

Dr. Ottoboni testified similarly. He agreed that "aprepitant ha[s] a very challenging solubility profile," Tr. 166:7–8, and aprepitant emulsions "are very complex," Tr. 169:25. Dr. Ottoboni summarized the problems with aprepitant emulsions as follows:

> The formulation -- the emulsion formulation of aprepitant was a very complex formulation. And all the components working together are critical for the ultimate stability of the formulation. Finding that we needed more than 10 percent lecithin was one important aspect of that. But everything played together, as it says here. All the components interact with one another, and the concentrations interact with one another to get to a pharmaceutically acceptable formulation.

Tr. 237:7–18.

In direct reference to aprepitant concentrations above 10 percent, Dr. Ottoboni testified that he and Dr. Han "formulated many, many combinations of these components and, again, over time, through extensive experimentation, found a small range—a range of these components that

together provided a stable formulation." Tr. 171:11–15. When asked if changing one of the non-emulsion components would have resulted in a stable emulsion, Dr. Ottoboni testified that "without doing the experiment, it's difficult. But given the many, many experiments we did throughout development, we never had success with formulations that were outside the range of stability we identified for Cinvanti." Tr. 171:4–177:1. When asked directly what he believed to be "the essential part of the Cinvanti formulation," Dr. Ottoboni responded that it was "the specific combination of all the ingredients at their respective levels to provide a pharmaceutical product that could be injected into humans." Tr. 195:17–24.

From their testimony, it is clear that the inventors considered their invention to be an emulsion that could be safely injected into humans, that the stability of their formulation was very sensitive to changes in the ratios of its ingredients, and that the range of stability for aprepitant emulsions was small. Under those circumstances, the absence of a detailed written description for the claimed ranges in egg lecithin concentrations and egg lecithin to aprepitant ratios is glaring.

3. Heron's Evidence Regarding Written Description

Heron relies heavily on the testimony of its expert, Dr. Little, to support its contention that the specifications provide written description support for stable aprepitant emulsions with egg lecithin concentrations and lecithin-to-aprepitant ratios falling within the ranges recited in the asserted claims. Heron relies in particular on three aspects of Dr. Little's testimony.

First, Heron points to Dr. Little's testimony about what Heron calls a "paradigm shift" in the field resulting from the inventors' work, *see* D.I. 187 at 1, which led to the original provisional application in 2014. Dr. Little testified that prior to the work of Heron's inventors, a person of ordinary skill in the art would not have anticipated that emulsions containing concentrations of egg lecithin above 10 percent would have been stable. But once the inventors' work had been

done, he said, there was no reason to believe that such emulsions would be unstable. At that point, Dr. Little explained, it was understood that stable emulsions could be made with concentrations of egg lecithin of up to 20 percent and ratios of egg lecithin to aprepitant ranging from 15:1 to 30:1. Tr. 494:23–497:12, 506:1–509:8, 522:15–523:5, 582:17–583:8.

The problem with Dr. Little's testimony on that issue is that his conclusion that the patents adequately describe stable emulsions having those limitations was based on the same legal error that Heron made in its briefs: He treated the mere listing of those unsupported ranges at various points in the specifications as providing written description support for the claims. Tr. 476:20–477:11, 507:4–8, 530:16–536:15. That error is based on the fallacy that if you can name a formulation in the specification, you have adequately described it for purposes of the written description requirement. For the reasons set forth in some detail above, Dr. Little's reliance on those unsupported lists of ranges was legally flawed, and thus his testimony based on those passages in the specification is of no probative value.[16]

Second, Heron points to Dr. Little's response to a question from the court as to how much the concentration of egg lecithin could be increased without giving rise to stability concerns. Dr. Little testified that he believed the concentration of egg lecithin could be increased to as much as 50 percent of the emulsion formulation by weight without raising instability concerns. As for the level of egg lecithin concentration that would be required to destabilize the emulsion, he

[16] On this issue, Dr. Little's testimony was entirely the product of his understanding of patent law, and not the product of his scientific expertise. His testimony on that issue of written description law, presumably filtered through Heron's attorneys, is no more persuasive than the arguments made by Heron's attorneys in their briefs as to the sufficiency of the bare recitations in the specifications of egg lecithin concentrations of up to 20 percent and ratios of egg lecithin to aprepitant of between 10:1 and 30:1, which I have rejected on legal grounds.

responded, "I'm trying to decide whether at 40 this would happen. I think it would happen once you get in the 50s." Tr. 520:13–15.

There are several problems with that testimony. First, that opinion was not in Dr. Little's expert report, nor was it supported by anything else in the record. Second, Dr. Little provided only a terse explanation of why he reached that opinion. He stated that there were "no mechanisms" leading to instability until the concentrations of egg lecithin got "into the 50's," i.e., egg lecithin concentrations of as much as 50 percent, at which point "phase inversion" could occur. Tr. 520:11–15. However, Dr. Little did not suggest that his opinion was based on any experimental evidence. Finally, in part no doubt because he was responding to a question from the court and presumably had not been prepared to address the issue, his testimony on that point was not confidently expressed. As a consequence, I treat that testimony as a "spur of the moment" response by an expert who, although knowledgeable in the field, had not explored the issue on which the court questioned him. As such, I do not attach significant weight to that testimony.

Third, Heron points to Dr. Little's testimony about Table 7 in the specifications. Tr. 506:23–509:3, 542:8–544:15. In that table, the inventors reported that the experiments performed with egg lecithin concentrations of 11.7 percent, 13.6 percent, and 13.8 percent remained stable for two months, but the experiment performed with the highest egg lecithin concentration of 14.3 percent remained stable for three months. *See* '520 patent, col. 21, ll. 1–10. Because the experiment with the highest concentration of egg lecithin among those four examples was stable for the longest period of time, Dr. Little testified that a fair inference from that evidence was that the formulation would remain stable at higher concentrations of egg lecithin, at least up to an egg lecithin concentration of 20 percent.

That evidence is entitled to some weight, and it may well have been sufficient to support an inference that the emulsion would remain stable at concentrations of egg lecithin slightly higher than 14.3 percent.[17] But it does not provide a sufficient basis for inferring that the aprepitant emulsion would remain stable with an egg lecithin concentration as high as 20 percent. An increase in egg lecithin concentration from 14.3 percent to 20 percent would be a dramatic increase of almost 50 percent, which would seem to extend the range of stability beyond what Dr. Ottoboni referred to as the "small range" or "little island of stability" that the inventors discovered above the egg lecithin concentration of 10 percent. *See* Tr. 171:10–15, 196:2–7. Without any other supporting evidence, the slight increase in stability noted at the egg lecithin concentration of 14.3 percent is an insufficient basis from which to infer that the "little island" of stability extended as far as a 20 percent concentration of egg lecithin or to lecithin-to-aprepitant ratios across the range from 15:1 to 30:1.[18]

Moreover, as the defendants point out, there are other differences among the four examples in Table 7 that may account for the measured difference in stability between example 2, with an egg lecithin concentration of 14.3 percent, and the other three examples with slightly lower egg lecithin concentrations. In particular, example 2 contained a different amount of soybean oil than

[17] The examples in the specifications showing stability at egg lecithin concentrations between 11.7 percent and 14.3 percent, including increased stability at 14.3 percent concentration would likely be sufficient to support a claim covering an egg lecithin concentration of up to 15 percent, which was the maximum egg lecithin concentration claimed in the Heron patents asserted in the *Fresenius* litigation. *See Heron v. Fresenius*, No. 22-985, 2024 WL 5317378 (D. Del. Dec. 3, 2024). The 15 percent egg lecithin concentration was also the maximum egg lecithin concentration in the eight patents in the Heron family that were filed prior to 2020.

[18] The fact that Table 7 in the specifications reports the stability data to only one significant figure makes it difficult to assess with any precision the degree of the difference in stability between the three examples with the lowest concentrations of egg lecithin (found stable for two months) and the example with the highest egg lecithin concentration (found stable for three months).

the other examples, and example 2 had a significantly higher zeta potential than the other examples.[19] *See* JTX 3 at 18. Given those differences between example 2 and the other tested examples, and the absence of evidence as to the causes or effects of those differences, it is unclear whether the greater stability of example 2 was attributable to the higher egg lecithin concentration in that example or instead was caused by some other characteristic of the emulsion.

Azurity's expert, Dr. Amiji, testified that a person of ordinary skill in the art at the time of the invention would not know what effect a substantial increase in the concentration of egg lecithin would have on the aprepitant emulsion, and that such a person would need to make the emulsion and test it to confirm its properties. Tr. 287:9–288:7. Dr. Amiji further testified that there was no information in the specification that would lead a person of skill in the art to believe that an emulsion with an emulsifier concentration well above the levels disclosed in the specification's examples would be stable. Tr. 288:21–289:6. In addition, the inventors gave similar testimony regarding the unpredictability of aprepitant emulsions notwithstanding their discovery that their aprepitant emulsions were stable in a range of egg lecithin concentration slightly above 10 percent. I find Dr. Amiji's testimony, together with that of the inventors, more persuasive on this point than Dr. Little's testimony.

Heron next points to Azurity's presentation to the FDA, in which Azurity asserted that its competing product, with an egg lecithin concentration of 17.8%, had properties equivalent to those of Cinvanti, including equivalent stability. But that observation provides no support for Heron's

[19] "Zeta potential" or electromagnetic potential in a colloidal dispersion is a measure of the electrostatic repulsive force between similarly charged particles in the dispersion. 3 Van Nostrand's Scientific Encyclopedia 5971 (10th ed. 2008); DTX 115 at 1532; DTX 129 at 261. A higher zeta potential is associated with a more stable formulation, and the zeta potential measured for example 2 was significantly greater than for the other three examples. *See* '520 patent, col. 21, ll. 1–11.

written description argument. It is hardly surprising that Heron's success with formulations having an egg lecithin concentration of up to 14.3 percent, close to the maximum concentration claimed in the patents litigated in the *Fresenius* case, would have motivated a potential competitor to try a formulation with a higher egg lecithin concentration, such as Azurity's 17.8 percent, which fell outside the range of the Heron patents that had issued as of that time. The fact that Azurity experimented with that level of egg lecithin and had success with it is no indication that Heron's unsupported assertions regarding "embodiments" of up to 20 percent egg lecithin were supported by anything in the Heron specifications that would show that Heron had invented formulations with egg lecithin concentrations that high.

Finally, I find that Dr. Little's testimony in this case is in some tension with his testimony in the *Fresenius* case, in which he repeatedly highlighted the unpredictability and difficulty of increasing the emulsifier concentration in aprepitant emulsions. *See, e.g.*, DTX 37 at 1286:11–23 (*Fresenius* trial transcript) ("when you add too much emulsifier, you get -- you get to the point -- where something stable [within a range of concentrations] and then outside of that [range] . . . it's not anymore"); *id.* at Tr. 1287:21–1288:13 ("this really follows a general principle that we have in the formulation sciences, which is that, first of all, you never add something unless you have to. And, second of all, when you add something, you want to add it to the smallest amount that you can. . . . [W]hat you're doing is you're trying to decrease it, to get the lowest amount that you can for it to be stable. Because if you add any more than that, you're going to cause problems with other design parameters that you have and potentially cause instabilities.").

In response to the suggestion that his testimony in this case was inconsistent with the testimony he gave in the *Fresenius* case, Dr. Little explained that the inventors' discoveries that a stable aprepitant emulsion could be made with egg lecithin in a concentration greater than 10

percent dramatically changed the thinking of persons of skill in the field regarding the potential stability of such emulsions. But what Dr. Little's testimony did not provide was a reason that a person of ordinary skill in the art would have assumed that the stability of such emulsions would have extended far beyond the 10 percent (or 14.3 percent) levels.

In light of the evidence regarding the complexity and unpredictability of aprepitant emulsions, I find that a person of ordinary skill in the art would not have concluded, based on the evidence set forth in the specifications in this case, that an increase in the concentration of the emulsifier well above the levels in the specification examples would result in a stable formulation.

4. Heron's Experiments with Lecithin Concentrations Above 15 Percent

Heron offered evidence at trial that it conducted experiments with egg lecithin concentrations above 15 percent, and it contends that those experiments successfully showed that such formulations could be stable. There are several problems with Heron's evidence as it relates to the written description issue. First, as explained above, in order to satisfy the written description requirement, the written description must appear in the specification. It is not enough for the patentees to offer extrinsic evidence that they invented the full scope of the claimed invention; they must instead include information sufficient to make such a showing in the specification. *See Ariad*, 598 F.3d at 1351–52 ("[T]he specification must describe an invention understandable to [the] skilled artisan and show that the inventor actually invented the invention claimed. . . . [W]e have repeatedly stated that actual 'possession' or reduction to practice outside of the specification is not enough. . . . [I]t is the specification itself that must demonstrate possession."); *see also Mondis Tech. Ltd. v. LG Elecs. Inc.*, 149 F.4th 1291, 1300 (Fed. Cir. 2025); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). There is no suggestion from Heron that the evidence of the inventors' work with formulations containing concentrations of egg lecithin greater

than 15 percent were included in the specifications. Thus, for written description purposes, what matters is not what the inventors did in the laboratory, but what they disclosed in the patent specification. And on that score, there is no ambiguity: The specifications do not disclose any examples of a stable emulsion containing a concentration of egg lecithin greater than 14.3 percent.

Second, Heron's evidence regarding its inventors' experiments with formulations containing egg lecithin concentrations of more than 15 percent would not have been helpful to Heron even if that evidence had been reported in the specifications. That is because Heron's evidence regarding those experiments does not show that the inventors were able to develop stable emulsions at egg lecithin concentrations above 15 percent.

In its opening post-trial brief, Heron argues that the inventors were able to make stable formulations with egg lecithin concentrations above 15 wt/wt % and points to Dr. Ottoboni's testimony for support. D.I. 187 at 6. But neither the testimony from Dr. Ottoboni nor the evidence from Dr. Han's laboratory notebooks establishes that the inventors conducted experiments that resulted in stable emulsions with egg lecithin concentrations greater than 15 percent.

Although Dr. Ottoboni testified that he believed he and Dr. Han had tested at least one formulation with an egg lecithin concentration greater than 15 percent that was stable, Dr. Ottoboni's testimony on that subject was equivocal[20] and was not supported by evidence from Dr. Han's laboratory notebooks. The evidence from the notebooks that was adduced at trial showed only three experiments using egg lecithin at concentrations greater than 15 percent, and none of those formulations were shown to be stable. Heron points to two of those formulations, which are

[20] Dr. Ottoboni testified, for example, that in Dr. Han's notebooks, "I believe I recall seeing an emulsion at approximately 18 percent emulsifier." Tr. 223:17–22. When pressed about the formulations recorded in the notebooks, Dr. Ottoboni conceded that "I've looked at a lot – many, many examples. They're all – kind of all muddled." Tr. 234:10–12.

designated as examples 4/17A and 4/17B. Those two formulations had similar compositions, and both contained approximately 18-19 percent egg lecithin.[21] *See* DTX 104 at 24–25. Dr. Han's laboratory notebook describes both examples as creaming after 4 days, with the 4/17A experiment having "particles visible" and turning "viscous" within 15 minutes. *Id.*

In the case of the third example, designated as example 6/10, Dr. Han noted that the formulation "creamed in < 6 days," and that after 30 minutes she observed "very slight crystals." DTX 104 at HER_THER_0031975–76. Dr. Ottoboni testified that in his opinion creaming "is not necessarily a failure." Tr. 232:6. That observation appears to be at least part of the underpinning for Dr. Ottoboni's assertion that "there were formulations that were in the 17 [percent], plus or minus, range that were stable." Tr. 224:12–14, 232:6. However, during his testimony, Dr. Ottoboni conceded that the formulation in example 6/10 was not stable, because it resulted in crystal formation. Tr. 231:12–233:22. In addition, Dr. Ottoboni's testimony that he did not regard emulsion creaming as indicative of instability was contradicted by Dr. Han and Dr. Little, both of whom considered creaming to be an indication of the emulsion's failure to maintain stability. In describing the "common types of instability that a [person of ordinary skill in the art] would expect to encounter when working with emulsions," Dr. Little characterized creaming as one such type of instability. Tr. 462:12-16, 464:2. Likewise, Dr. Han testified that "[i]n the case of the aprepitant emulsion that we developed, if we observed creaming, then we determined it to be unstable." Tr. 120:1–3. I credit the testimony from Dr. Han and Dr. Little on that point. Their testimony was

[21] While the weight of each component is not provided, it can be roughly calculated based on the composition described in the laboratory notebooks. For the calculations provided above, I assumed that the ethanol and water components, which have volumes but not masses provided, have densities of 0.79 g/mL and 1.0 g/mL, respectively. There is some uncertainty to the calculations because of the fact that some of the alcohol may evaporate during preparation and there may be some variation in preparation. Tr. 230:7–23.

supported by several scientific publications in the field, which described creaming as a stage in the process of emulsion degradation that ultimately results in the separation of the oil and water phases of the emulsion. *See* JTX 25 at 4; DTX 62 at 215; DTX 129 at 264. One of Heron's own publications describes the process of emulsion degradation as involving flocculation and coalescence, in which the oil droplets adhere to one another and combine to form larger droplets, resulting in the emulsion separating into two layers by density, which is known as creaming. DTX 116 at 28.

In sum, despite asserting that the inventors tested formulations above 15 wt/wt % and found them to be stable, Dr. Ottoboni failed to point to any supporting evidence that shows that to be the case. Conversely, the examples from Dr. Han's laboratory notebooks to which Heron refers show that those formulations resulted in creaming, and in one case displayed crystal formation. Dr. Ottoboni agreed that crystallization was indicative of an unstable emulsion and would have meant that the 6/10 example was a failure. Likewise, despite not showing crystal formation, the 4/17A and 4/17B examples both creamed by day 4 (with the 4/17A example creaming within 24 hours), and would have been considered failures. DTX 104 at HER_THER_0031857–58.[22]

5. Azurity's Meloxicam Patent

As part of its effort to show that the '520 and '255 patents satisfied the written description requirement, Heron points to U.S. Patent No. 11, 040,008 ("the '008 patent"), a patent obtained by

[22] Heron argues that the creaming of the 4/17A and 4/17B examples "occurred before 4 days but disappeared after 4 days." D.I. 189 at 33 n.20. Dr. Han's laboratory notebooks do not support that assertion, however. While the notebooks contain a note that example 4/17B "creamed b/t [between] day 1 to day 4," there is a second note on the same page that "[a]fter 4 days similar to 4/17A." Example 4/17A creamed within 24 hours, and there is no evidence that the creaming disappeared after 4 days in either example. DTX 104 at HER_THER_0031857–58. Heron's additional argument that creaming "is reversible by shaking and thus does not preclude physical stability within the meaning of the patents" is inconsistent with the testimony of Dr. Han and Dr. Little that creaming is indicative of a lack of stability, as discussed above.

Slayback, Azurity's predecessor. The '008 patent is directed to a formulation consisting of a stable emulsion that delivers meloxicam, an anti-inflammatory drug. Although meloxicam is quite different from aprepitant, the composition of the emulsion in the meloxicam patent is strikingly similar to the composition of the emulsion in Heron's aprepitant patents. Heron argues that Azurity's meloxicam patent "corroborates" the written description of the '520 and '255 patents. Put another way, Heron argues in effect that if the disclosure of the emulsion in the '008 patent provides adequate written description for the claims of that patent, the disclosures in the Heron patents must provide adequate written description for the asserted claims in the '520 and '255 patents.

Azurity responds that the meloxicam patent contains a different active ingredient and that the priority date of the meloxicam patent (2018) is significantly later than the priority dates of the Heron patents (2014 and 2016). Heron replies, first, that Azurity has not pointed to any way in which the nature of the active ingredient affects the stability of the emulsions in the two groups of patents. Second, Heron argues that Azurity has failed to show how any developments in the interim between the priority dates for the Heron and Slayback patents in any way enhanced the adequacy of the written description in the meloxicam patent.

Although the emulsion claimed in the meloxicam patent is very similar to the emulsions in the Heron patents (and may well have been directly or indirectly modeled on the Heron emulsions), that is not evidence that the written description in the Heron patents satisfies the written description requirement. It merely shows that there is another patent containing the same emulsion with a similar specification. The fact that the other patent is owned by Azurity may put Azurity in an awkward position with respect to arguing about the invalidity of Heron's patents, but that does not buttress Heron's claim that its asserted claims are valid. The Heron patents must stand or fall on

their own merits. The fact that there is another patent with a similar disclosure (particularly one that may have been copied from Heron's patents) does not make the case for the validity of Heron's patents any stronger. I therefore consider the meloxicam evidence to be essentially irrelevant to the written description issue in this case.

6. The '255 Patent

As indicated above, much the same written description analysis that applies to the '520 patent applies equally to the '255 patent. I have construed the limitation in the '255 claims requiring that the emulsion composition be "injectable" to mean that the emulsion must be sufficiently stable to enable safe injection into a human patient, even though that degree of stability need not necessarily be the same as the level of "physical stability" that is required by the '520 patent. For the same reasons that the specification of the '520 patent fails to provide a sufficient written description for an emulsion that is "physically stable" across the full scope of claim 8 of the '520 patent, the specification of the '255 patent fails to provide a sufficient written description for an emulsion that is sufficiently stable to be "injectable" across the full range of claims 5 and 23 of the'255 patent. That is, the '255 specification does not contain written description support for the claim limitations requiring that the emulsion be sufficiently stable across the claimed range of egg lecithin concentrations and lecithin-to-aprepitant ratios to serve as an "injectable emulsion" within the meaning of the '255 patent, i.e., an emulsion that would be sufficiently stable to be safe for administration to patients. I therefore conclude that, as in the case of claim 8 of the '520 patent, the record shows that the written description requirement is not satisfied with regard to claims 5 and 23 of the '255 patent.

Heron argues that because the '255 patent does not contain a limitation requiring that the emulsion be physically stable, the written description requirement for the '255 patent is met

without the need to satisfy any functional requirement. According to Heron, all that is necessary to satisfy the written description requirement for the '255 claims is for the '255 specification to recount the components of the claimed emulsions, which it clearly does. The implication of Heron's position is that any emulsion described in the '255 specification having a concentration of egg lecithin up to 20 percent and a ratio of egg lecithin to aprepitant of from approximately 16.3:1 to approximately 28.6:1 has been adequately described for purposes of the written description requirement of section 112(a).

That argument ignores the requirement that the specification satisfy the express requirement in claim 5 of the '255 patent that the emulsion be "injectable." In order for the invention recited in claim 5 to be adequately described in the specification, Heron was required to show that the claimed aprepitant emulsion was injectable over those full ranges. And for reasons that parallel those given in the discussion of the claims of the '520 patent, I find that the specification of the '255 patent, like the specification of the '520 patent, fails to do so.

7. Written Description: Summary

On the first page of its opening post-trial brief, Heron makes a statement that underscores the flaw in Heron's written description argument. Heron states: "Through many experiments and out-of-the box thinking, Heron determined the upper bound of egg lecithin in its inventive emulsion to be 20% and disclosed that finding to the world in exchange for patent protection." D.I. 187 at 1.

The problem is that Heron did not "determine" that 20 percent was the proper upper bound for the egg lecithin concentration in the aprepitant emulsion that it invented. To the contrary, the 20 percent upper bound was unsupported by anything in the specifications other than Heron's say-so. There were no test results or other analysis that would justify extrapolating to the 20 percent

concentration level from the four examples in the specifications. At no point in the trial, in its post-trial briefs, or in the post-trial arguments did Heron explain where the 20 percent number came from. From all that appears, Heron made that selection simply because the 20 percent egg lecithin concentration would be high enough to capture Azurity's competing product.

Heron could just as well have listed egg lecithin concentrations of up to 30 percent, or 40 percent in the specification. If it had, its argument for satisfying the written description requirement would have been identical to the one it is making in this case. And it would be equally flawed under the authorities requiring more than a baseless assertion as to what the inventor has invented. The same is true of the claimed ranges for the ratios of egg lecithin to aprepitant: Those ranges are broad enough to capture Azurity's product, but they are not supported by any scientific evidence set forth in in the specifications. Those, in a nutshell, are the reasons Heron's patents are invalid under well-established written description law.

IV. Enablement

The parties presented evidence at trial regarding whether the asserted claims of the '520 and '255 patents satisfied the enablement requirement of 35 U.S.C. § 112(a). Because I have concluded that the asserted claims of both the '520 and the '255 patents are invalid for lack of an adequate written description, it is not necessary to decide whether those claims are also invalid for lack of enablement.

CONCLUSION

For the reasons stated above, I find that Azurity has proved by clear and convincing evidence that the asserted claims of the '520 and '255 patents are invalid for lack of written description. A judgment to that effect will be entered alongside this order. In addition, pursuant to paragraph 6 of the stipulation of the parties and entered by the court on September 16, 2025,

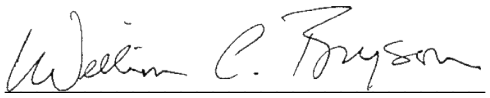
D.I. 119 (in case No. 24-1363) and D.I. 194 (in case No. 24-830), a judgment will be entered in *Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc., Azurity Pharmaceuticals India LLP f/k/a Slayback Pharma India LLP, Azurity Pharmaceuticals India LLP f/k/a Slayback Pharma India LLP, and Slayback Pharma LLC*, No. 24-830 (D. Del.), finding that the claims raised in that action are not infringed.

* * * * *

In an excess of caution, and because some of the materials submitted to the court on the issues addressed in this order were filed under seal, this order is designated as filed under seal. However, the parties are directed to advise the court within five days of the date of this order, whether they regard it as necessary that any portion of this order remain under seal. If so, the party or parties requesting that relief will be required to make a particularized showing of need to maintain the sealed status of the order. The court will promptly rule on any such request to maintain the sealed status of the order.

IT IS SO ORDERED.

SIGNED this 1st day of June, 2026.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE