IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING INTERNATIONAL CENTER S.A., FERRING B.V., and POLYPEPTIDE LABORATORIES A/S	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-431 (MN)
FRESENIUS KABI USA, LLC,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 14th day of June 2021:

IT IS HEREBY ORDERED that the claim terms of U.S. Patents Nos. 9,579,359 ("the '359 Patent"), 10,729,739 ("the '739 Patent"), 9,415,085 ("the '085 Patent"), 10,695,398 ("the '398 Patent"), 8,841,081 ("the '081 Patent"), and 9,877,999 ("the '999 Patent") with agreed-upon constructions (*see* D.I. 69 at 2), are construed as follows:

1. "prostate cancer" means "any cancer of the prostate gland in which cells of the prostate mutate and begin to multiply out of control" ('359 Patent cl. 1; '739 Patent cl. 1, 14, 27; '085 Patent cl. 1; '398 Patent cl. 1, 8);

2. "monthly" means "about once every 28 days" ('359 Patent cl. 2; '739 Patent cl. 2, 15, 28; '085 Patent cl. 3, 5, 9; '398 Patent cl. 3, 5);

3. "IUIL" means "IU/L" ('081 Patent cl. 16–18); and

4. "having a serum alkaline phosphatase (S-ALP) level above a normal range for S-ALP" means "having a S-ALP level above 147 IU/L" ('999 Patent cl. 1, 12–15, 17, 24).

Further, as announced at the hearing on May 5, 2021, IT IS HEREBY ORDERED that the following disputed claim terms of the '359 Patent, the '739 Patent, the '085 Patent, the '398 Patent,

the ’081 Patent, the ’999 Patent, U.S. Patent No. 8,828,938 (“the ’938 Patent”), and U.S. Patent No. 10,973,870 (“the ’870 Patent”) (collectively, “the Patents-in-Suit”) are construed as follows:

1. “in a subject with a reduced likelihood of causing a testosterone spike or other gonadotrophin releasing hormone (GnRH) agonist side-effect” shall have its plain and ordinary meaning (’359 Patent cl. 1; ’739 Patent cl. 1, 14, 27);

2. “the [treated] subject has a decreased likelihood of developing or experiencing an undesirable side effect during treatment compared to treatment with [the] gonadotrophin releasing hormone (GnRH) agonist leuprolide” shall have its plain and ordinary meaning (’359 Patent cl. 3; ’739 Patent cl. 3, 16);

3. “wherein administration of degarelix to the subject decreases the frequency of an additional cardiovascular event in the subject as compared to the frequency of an additional cardiovascular event upon treatment with a gonadotrophin releasing hormone (GnRH) agonist in a subject with a history of at least one cardiovascular event” shall have its plain and ordinary meaning (’085 Patent cl. 1);

4. “wherein a risk of developing or experiencing an additional cardiovascular event upon treatment with degarelix is diminished compared to a risk of developing or experiencing an additional cardiovascular event upon treatment with a GnRH agonist” shall have its plain and ordinary meaning (’398 Patent cl. 1);

5. “metastatic stage prostate cancer” and “metastatic prostate cancer” mean “a cancer that has spread to distant organs from the original tumour site, e.g., the prostate gland” (’081 Patent cl. 1, 15; ’999 Patent cl. 1, 15, 17, 18, 19, 24)

6. “[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine” means “[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of [-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine using the claimed method and prior to purification steps directed at removing other impurities” (’938 Patent cl. 1);

7. “[a] method of manufacture of degarelix . . . comprising step-wise providing a solution of an amino acid or peptide in which an α-amino group is protected by Fmoc” shall have its plain and ordinary meaning, with the

caveat that the ordinary meaning does not exclude further modifications[1] ('938 Patent cl. 1); and

8. "to decrease the likelihood of developing a musculoskeletal disorder or a connective tissue disorder compared to GnRH agonist treatment when treating prostate cancer in the subject" and "to decrease the likelihood of developing a musculoskeletal disorder or a connective tissue disorder compared to leuprolide treatment when treating prostate cancer in the subject" shall have their plain and ordinary meaning ('870 Patent cl. 1, 15).

The parties briefed the issues, (*see* D.I. 77, 94), and submitted a Joint Claim Construction Chart containing intrinsic evidence, (*see* D.I. 69). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument, (*see* D.I. 127), and applied the following legal standards in reaching its decision.

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

[1] At the hearing, the parties agreed upon the construction of this term. (*See* D.I. 127 at 7:8–21). The Court adopts this agreed-upon construction.

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. Indefiniteness

Section 112 of the Patent Act requires a patent applicant to "particularly point out and distinctly claim the subject matter" regarded as the applicant's invention. 35 U.S.C. § 112 ¶ 2. "The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.* competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g.*, *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

II. THE COURT'S RULING

The Court's rulings regarding the disputed claim terms of the Patents-in-Suit were announced from the bench at the conclusion of the hearing as follows:

> . . . Thank you for the arguments today. At issue we have eight patents, in four families,[2] and nine disputed claim terms.
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> I am prepared to rule on eight of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want

[2] The '359 Patent, '739 Patent, and '870 Patent share a first specification, the '085 Patent and '398 Patent share a second specification, the '081 Patent and '999 Patent share a third specification, and the '938 Patent has a fourth specification.

to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents in dispute. I have also reviewed the portions of the prosecution history, the European proceedings, the invalidity contentions, and the responses to interrogatories, all of which were included in the joint appendix, as well as the declarations of Dr. Neal Shore and Dr. J. Bruce Robertson. There was briefing on each of the disputed terms. There were tutorials submitted by the parties. And there has been argument here today. All of that has been carefully considered.

I am not going to read into the record my understanding of claim construction law and indefiniteness generally. I have a legal standard section that I have included in earlier opinions, including recently in *Gentex Corp. v. Galvion Ltd.,* C.A. No. 19-921. I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

As to the person of ordinary skill in the art, the parties have suggested differing definitions. But no party suggests that the differences are relevant to the issues currently before me.

Now the disputed terms. I am going to refer to the terms using the numbering in the Joint Brief, but will give my rulings based on the order of the presentation today.

The eighth term is "[a] method of manufacture of degarelix . . . comprising step-wise providing a solution of an amino acid or peptide in which an [α]-amino group is protected by Fmoc" in claim 1 of the '938 Patent. During the argument today the parties agreed that this term should be given its plain and ordinary meaning with the caveat that everyone also agrees that the ordinary meaning does not exclude further modifications. I will adopt that construction.

The seventh term is "[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of [Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine]" in claim 1 of the '938 Patent. Plaintiffs argue that this term should be given its plain and ordinary meaning. Defendant contends that the term should be construed as "[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of [Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine] using the claimed method and prior to any purification."

The crux of the dispute is whether the requisite level of purity must be achieved solely using the claimed method without additional purification. Here, I agree with Defendant and will construe the term as "[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of [Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine] using the claimed method and prior to purification steps directed at removing other impurities."

First, the patent states that "[t]he invention claimed is . . . a method of manufacture of degarelix . . . containing 0.3% by weight or less of Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine."[3] This language suggests that the claimed method discloses steps for obtaining the stated level of purity.

The specification confirms that interpretation. The specification explains that it was known in the art that "under basic conditions, compounds comprising a dihydrouracil moiety undergo rearrangement to compounds comprising a hydantoin moiety."[4] It then states that the inventors found that degarelix containing less than 0.3% of the hydantoin moiety can be manufactured by solid-phase synthesis because, "[u]nexpectedly, the Aph(L-Hor) moiety ***does not undergo rearrangement*** during solid-phase synthesis in spite of . . . basic conditions."[5] This means that the claimed method itself does not produce the impurity, and therefore will result in pharmaceutically pure degarelix without additional purification steps. And the patentee itself clearly had this understanding of the claims – during prosecution of the corresponding European patent, the patentee explained that "[t]he hydantoin impurity is simply not formed during the process according to the invention and no removal of it is necessary."[6]

Nothing in the specification contradicts this construction. Plaintiffs claim that Defendant's proposed construction would exclude the embodiment described in Example 3. I don't agree. As Plaintiffs argued during prosecution of the European patent, the purification

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3 ('938 Patent col. 10 ll. 4–12).

4 ('938 Patent col. 2 ll. 5–7).

5 ('938 Patent col. 3 ll. 50–54 (emphasis added)).

6 (D.I. 78, Ex R at 8).

described in step 15 of Example 3 would not remove the hydantoin impurity[7] and they do not contest now that that step is not directed at reducing the hydantoin moiety.[8] To the extent Plaintiffs argue that Defendant's proposed construction would require measurement of the hydantoin moiety impurity "prior to *any* purification," I do not agree.[9] The patent allows for measurement after purification steps directed to removing other impurities.

Therefore, I will construe this term as "[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of [Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine] using the claimed method and prior to purification steps directed at removing other impurities."

The sixth term is "identifying a subject with metastatic stage prostate cancer having an S-ALP [level/range] above [a/the] normal range for S-ALP" in claims 1, 17, and 24 of the '999 Patent. Plaintiffs contend that the term should be given its plain and ordinary meaning. Defendant asserts that the term should be construed as "identifying by testing the S-ALP level in a subject with metastatic stage prostate cancer to determine a subject having an S-ALP range above the normal range for S-ALP."

In the briefing, Plaintiffs agreed that "baseline S-ALP levels must . . . be obtained by testing."[10] Today, however, they changed their position, arguing that physicians could identify patients with elevated levels without testing.[11] Plaintiffs cited to no intrinsic or extrinsic evidence to support these arguments. That being said, the word *identify* is different than the word *test* as used in other claims.[12] Given that the parties did not really brief the issue now raised, I am not going to construe this term today and may simply

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7 (D.I. 77 at 63; D.I. 78, Ex. R at 8).

8 (*See* D.I. 77 at 64, D.I. 127 at 9:19–25).

9 (*See* D.I. 77 at 64).

10 (D.I. 77 at 51 ("Ferring agrees that baseline S-ALP levels must have been or be obtained by testing.")).

11 (*See* D.I. 127 at 19:11–12, 22:25–23:3).

12 (*Compare, e.g.*, '999 Patent col. 24 ll. 37–39 ("identifying a subject"), *with, e.g.*, '999 Patent col. 25 ll. 32–36, (explicitly requiring testing S-ALP of a potential subject before "selecting the potential subject for treatment")).

refrain from construing it and may require the parties to address it during the bench trial.

The fifth term comprises two related phrases: "metastatic stage prostate cancer," which is in claims 1 and 15 of the '081 Patent and claims 1, 17, 18, 19, and 24 of the '999 Patent, and "metastatic prostate cancer," which is in claim 15 of the '999 Patent. Plaintiffs assert that this term should be construed as "the most advanced stage of prostate cancer where cancer has spread to distant organs from the original tumour site, e.g., the prostate gland." Defendant argues that the term should be construed as "prostate cancer where the cancer has spread to distant organs from the original tumour site, e.g., the prostate gland."

The crux of the dispute is whether I should add to the construction that "metastatic prostate cancer" is the most advanced stage of prostate cancer.

At column 5 starting at line 66, the '081 Patent defines "metastatic stage prostate cancer" as "a cancer that has spread to distant organs from the original tumour site, e.g., the prostate gland." It is well-settled that the specification may define a claim term and that, when it does, "the inventor's lexicography governs." That's *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

"To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning."[13]

Here, Plaintiffs don't dispute that the specification has a definition. Instead they essentially say that the definition does not resolve the infringement issue. Although that may be true, it appears to me that the issue is a factual issue regarding whether the Fresenius label meets the claim term, not an issue of claim construction. So I will adopt the definition used in the specification.

Finally, I am going to address the first four terms and the ninth term together.

[The first term is "in a subject with a reduced likelihood of causing a testosterone spike or other gonadotrophin releasing hormone (GnRH) agonist side-effect" in claim 1 of the '359 Patent and claims 1, 14, and 27 of the '739 Patent.

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13 *Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015).

The second term is "the [treated] subject has a decreased likelihood of developing or experiencing an undesirable side effect during treatment compared to treatment with [the] gonadotrophin releasing hormone (GnRH) agonist leuprolide" in claim 3 of the '359 Patent and claims 3 and 16 of the '739 Patent.

The third term is "wherein administration of degarelix to the subject decreases the frequency of an additional cardiovascular event in the subject as compared to the frequency of an additional cardiovascular event upon treatment with a gonadotrophin releasing hormone (GnRH) agonist in a subject with a history of at least one cardiovascular event" in claim 1 of the '085 Patent.

The fourth term is "wherein a risk of developing or experiencing an additional cardiovascular event upon treatment with degarelix is diminished compared to a risk of developing or experiencing an additional cardiovascular event upon treatment with a GnRH agonist" in claim 1 of the '398 Patent.

And the ninth term comprises two similar phrases: "to decrease the likelihood of developing a musculoskeletal disorder or a connective tissue disorder compared to GnRH agonist treatment when treating prostate cancer in the subject" and "to decrease the likelihood of developing a musculoskeletal disorder or a connective tissue disorder compared to leuprolide treatment when treating prostate cancer in the subject," which are in claims 1 and 15 of the '870 Patent, respectively.]

For each of these terms, Plaintiffs assert that the term should be given its plain and ordinary meaning. Defendant asserts that each term is indefinite and does not propose an alternative construction.

For a claim to be held invalid for indefiniteness, there must be clear and convincing evidence.[14] Although I have some questions regarding some of the terms, on the record before me, Defendant has not met its burden to show that these terms are indefinite. Should there still be a disagreement regarding these claim terms in the future, Defendant may use their time at trial to further pursue this argument.

So for now, I will give the terms their plain and ordinary meanings.

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14 *See Nautilus*, 572 U.S. at 912 n.10 (citing *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011))).

Following the hearing on May 5, the parties submitted a letter to the Court seeking clarification of the Court's construction of the seventh term, "[a] method of manufacture of degarelix . . . containing 0.3% by weight or less of Ac-D-2Nal-D-Phe(4Cl)-D-3Pal-Ser-X-D-4Aph(Cbm)-Leu-ILys-Pro-D-Ala-NH2, wherein X is 4-([2-(5-hydantoyl)]acetylamino)-phenylalanine." (*see* D.I. 134). Defendant suggested that the Court's construction "allows additional purification steps [directed] at removing other non-hydantoin impurities, but does not allow additional steps for removing the hydantoin impurity." (*Id.* at 2). Plaintiff, meanwhile, proposed that the Court's construction was inconsistent with the statement that "[t]he patent allows for measurement after purification steps directed to removing other impurities," (*id.* at 1 (citing D.I. 127 at 67:18–19)), and suggested that the construction "would allow for measurement after a purification step specifically directed to the hydantoin impurity, which contradicts the rationale underlying the Court's construction," (*id.* at 2).

As stated during the hearing, "the claimed method itself does not produce the impurity, and therefore will result in pharmaceutically pure degarelix without additional purification steps." (D.I. 127 at 66:23–67:1). This means that the requisite purity level – 0.3% by weight or less of the hydantoin moiety – must be obtained before any purification steps, regardless of whether those additional purification steps are directed to removing hydantoin or a different impurity. To prove that the requisite purity level was achieved before additional purification steps, however, the parties need not show that the level of hydantoin was *measured* before purification steps. So long as there is some way of showing that there must have been 0.3% by weight or less of the hydantoin moiety after the claimed method steps (e.g., through expert testimony) it is irrelevant when the level of hydantoin was actually measured. Such a scenario was proposed by the Court during the hearing on May 5:

> I want you to assume for right now that . . . an expert would testify [that "]when you use that method, you are always going to have very little hydantoin and when I look at this, I think they're going to have less than 0.3% at that step.["] But your client doesn't measure it then. Instead, it goes on, does other purifications that have nothing to do with hydantoin, but those other purification steps don't change the fact that there was already less than 0.3%.

(D.I. 127 at 14:8–16). As Defendant acknowledged, this scenario would fall within the scope of the patent because "[t]he focus of the dispute . . . is not about the testing, at what point it occurs." (*Id.* at 15:13–14). Accordingly, the Court's construction requires that the claimed method be used to achieve degarelix containing 0.3% by weight or less of the hydantoin moiety prior to any additional purification steps, regardless of whether that purification is directed at hydantoin or other impurities, but the construction imposes no requirements as to when testing must be done.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge