IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

QUEST DIAGNOSTICS INVESTMENTS LLC,	)	
Plaintiff,	)	
v.	)	C.A. No. 18-1436 (MN)
LABORATORY CORPORATION OF AMERICA HOLDINGS, ESOTERIX, INC. and ENDOCRINE SCIENCES, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 14th day of January 2020:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 7,972,867 ("the '867 Patent"), 7,972,868 ("the '868 Patent"), 8,101,427 ("the '427 Patent") and 8,409,862 ("the '862 Patent") with agreed-upon constructions are construed as follows (*see* D.I. 81 at 5-6):

1. "generating a protonated and dehydrated precursor ion of said 25-hydroxyvitamin D_2 [said vitamin D metabolite]" means "adding a proton and removing a water molecule from said 25-hydroxyvitamin D_2 [said vitamin D metabolite] to generate a precursor ion" ('867 Patent)

2. "derivatizing" means "reacting two molecules to form a new molecule" ('868 Patent)

3. "derivatizing the dihydroxyvitamin D m metabolites from said sample with 4'-carboxyphenyl-TAD" means "reacting the dihydroxyvitamin D metabolites from said sample with 4'-carboxyphenyl-TAD to form a new molecule" ('868 Patent)

4. no construction necessary for "detecting the amount" ('427 and '862 Patents)

5. no construction necessary for "detecting the presence or amount" ('867 Patent)

6. no construction necessary for "determining the presence or amount" ('867 Patent)

Further, as announced at the hearing on January 7, 2020, IT IS HEREBY ORDERED that the disputed claim terms of the '862, '867 and '427 Patents are construed as follows:

1. "capable of detecting testosterone at concentrations of less than 10 ng/dL [or 5 ng/dL or 1 ng/dL] in the sample" shall be given its plain and ordinary meaning, which is "the method is able to detect testosterone at concentrations below 10 ng/dL [or 5 ng/dL or 1 ng/dL] in the sample" ('862 Patent, claims 1, 8, 9, 15, 23 & 24)

2. "ionizing" shall be given its plain and ordinary meaning, which is "altering a molecule such that it has a net electric charge" ('862 Patent, claims 1, 10-12, 15 & 18-20)

3. "testosterone ions" shall be given its plain and ordinary meaning, which is "one or more testosterone molecules that have been altered to have a net electric charge or one or more fragments thereof with a net electric charge" ('862 Patent, claims 1, 12, 15 & 20)

4. "purifying testosterone" shall be given its plain and ordinary meaning, which is "enriching the amount of testosterone relative to one or more other components of the sample" ('862 Patent, claims 1 & 15)

5. no construction is necessary for "relating the detected ions to the presence or amount of said 25-hydroxyvitamin D_2 in said sample" ('867 Patent, claim 21)[1]

6. no construction is necessary for "relating the detected ions to the amount of said vitamin D metabolite in said sample" ('427 Patent, claim 1)[2]

The parties briefed the issues (*see* D.I. 81) and submitted an appendix containing both intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 87, 88 & 89; *see also* D.I. 72, 73 & 75). Both sides also provided a tutorial describing the relevant technology. (*See* D.I. 80 & 83). The Court carefully reviewed all submissions in connection with the parties' contentions

[1] The Court thus rejects Defendants' attempt to read in a requirement that the amount of 25-hydroxyvitamin D_2 be quantified.

[2] The Court thus rejects Defendants' attempt to read in a requirement that the concentration of vitamin D metabolite be quantified.

regarding the disputed claim terms, heard oral argument (*see* D.I. 96) and applied the following legal standards in reaching its decision:

I. LEGAL STANDARD

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).

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.*, 134 S. Ct. 2120, 2129 (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 '862, '867 and '427 Patents were announced from the bench at the conclusion of the hearing as follows:

> . . . At issue we have three patents in two families,[3] and six disputed claim terms.
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> I am prepared to rule on each of those disputes. I will not be issuing a written opinion, but I will issue an order stating my ruling. I want to emphasize before I announce my decisions that while I'm not issuing a written decision, we have followed a full and thorough process for making the decisions I'm about to state.
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> I have reviewed each of the patents in dispute. I have also reviewed the portions of the prosecution histories submitted. There was full briefing on each of the disputed terms. There was an appendix, which included declarations of experts. There were tutorials on the technology submitted by each side and there has been argument here today. All of that has been carefully considered.

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3 The patents-in-suit with claim construction disputes are U.S. Patent Nos. 7,972,867, 8,101,427 and 8,409,862, the latter being referred to as "the Testosterone patent." The '867 and '427 Patents are related and, together, they are referred to as "the Vitamin D patents." A third Vitamin D patent, U.S. Patent No. 7,972,868, is also asserted in the case but does not contain any disputed terms that require construction.

Now as to my rulings, as an initial matter, I am not going to read into the record my understanding of claim construction law generally and indefiniteness. I have a legal standard section that I have included in earlier opinions, including recently in *Waters Corporation v. Agilent Technologies, Inc.*, C.A. No. 18-1450. I incorporate that law and adopt it into my rulings today and will also set it out in the order that I issue.

As to the person of skill in the art, the parties' definitions are substantially similar and the parties have agreed that the analysis is the same under both parties' definitions of the level of ordinary skill in the art.

Now, the disputed terms.

The first term is "capable of detecting testosterone at concentrations of less than 10 ng/dL [or 5 ng/dL or 1 ng/dL] in the sample," which is found in claims 1, 8, 9, 15, 23 and 24 of the '862 patent. Plaintiff asserts that the term has its plain and ordinary meaning, which is "the method is able to detect testosterone at concentrations below 10 ng/dL [or 5 ng/dL or 1 ng/dL] in the female human sample." Defendants argue that the term is indefinite.

I will give this term its plain and ordinary meaning, i.e., the method is able to detect testosterone at concentrations below 10 ng/dL [or 5 ng/dL or 1 ng/dL] in the sample. This is consistent with the words used in the claim. And this construction is also supported by the intrinsic record. For example, the '862 patent discusses detecting low levels of testosterone, notes the lower level in females and refers to detection at the levels recited in the claims and even below 1 ng/dL.[4]

Defendants, citing the declaration of their expert, Dr. French, argue that there are four different "meanings" for the term, and that because each of these meanings is equally plausible, the term is indefinite. I disagree.

The four meanings asserted by Defendants are: [o]ne, the limit of detection ("LOD"); two, the lower limit of quantitation ("LOQ"); three, the specificity of testosterone determination; and, four, the use of a sample taken from a female human that actually has testosterone at a concentration of less than 10 (or 5 or 1) ng/dL.

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4 (*See, e.g.*, '862 Patent at 1:49-50, 5:62-65 & 18:24-33; *see also id.* at Claims 9 & 24).

Defendants note that when Quest added the disputed language to the claims, it pointed to the text that became the first paragraph of the detailed description of the invention.[5] That paragraph refers to "accurately detecting" and "unambiguously detecting." Defendants say that "accurately detecting" refers to the LOQ, or the lower limit of quantitation, and "unambiguously detecting" refers to specificity and thus the "capable of detecting" language refers to multiple things. Defendants though don't clearly explain how those words or the terms are linked.

I am not persuaded that statements made during the prosecution history or in the specification change the analysis. None of that is inconsistent with the ordinary meaning of the words used in the claims. Indeed, the claims did not use the words "accurately" or "unambiguously" – only "detecting." I find that only one of the four proposed "meanings" offered by Defendants – the limit of detection – corresponds to the language of the claim, i.e., "detecting" testosterone.

The language of the claim itself provides persons of ordinary skill with "reasonable certainty . . . about the scope of the invention" and "clear notice of what is claimed."[6] And Defendants have not met their burden to show indefiniteness by clear and convincing evidence.

The next terms are "ionizing" and "testosterone ions." "Ionizing" is found in claims 1 through 12, 15 and 18 through 20 of the '862 patent. "Testosterone ions" is found in a subset of those, i.e., claims 1, 12, 15 and 20 of the '862 patent. The parties have briefed and argued these terms together.

As with the prior term, Plaintiff argues that these terms should be given their plain and ordinary meaning. For "ionizing," Plaintiff states that that is "altering a molecule such that it has a net electric charge." For "testosterone ions," Plaintiff states that the plain and ordinary meaning is "one or more testosterone molecules that have been altered to have a net electric charge or one or more fragments thereof with a net electric charge." Defendants again assert that those terms are indefinite.

Ionizing and ions are common words with common meaning. The intrinsic evidence uses those terms consistent with their ordinary meanings. The '862 patent defines ionizing at column

5 ('862 Patent at 5:50-6:3).

6 *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909 & 910 (2014).

8, lines 45 to 47, stating that "[t]he term 'ionization' and 'ionizing' as used as herein refers to the process of generating an analyte ion having a net electrical charge equal to one or more electron units." The patent in the lines following that definition explains that the net charge of these ions may be positive or negative.[7] The claims likewise use "ionizing" in its plain and ordinary sense. Independent claims 1 and 15 recite "ionizing said purified testosterone to produce one or more testosterone ions detectable by a mass spectrometer," and dependent claims 10 through 12 and 18 through 20 require the produced ions to have certain mass/charge ratios.

I also credit the opinions of Dr. Chyall, Plaintiff's expert, that the nature of the invention – methods of mass spectrometry – further supports a plain and ordinary meaning of "ionizing" [(*i.e.*, altering a molecule such that it has a net electric charge)] because such methods require electrically charged molecules.[8]

Similarly, as to testosterone ions, in the "summary of the invention," the '862 patent explains that "testosterone ions" are created by "ionizing" testosterone.[9] There is no dispute as to what "testosterone" means, and as I've already noted, "ionizing" is defined in the specification.

I understand Defendants' argument that the specification doesn't clearly refer to ionizing to produce fragments. But as Defendants' counsel acknowledged today, the specification does not preclude that either.

The specification does, however, explain that "testosterone ions" include not only testosterone molecules that have been altered to have a net electric charge, but also testosterone fragments with a net electric charge.[10] And there are also dependent claims – such as claims 11 and 19 that claim that the ionizing of step (b) comprises producing one or more testosterone fragment ions having a mass/charge ratio selected from the group consisting of 109.2 ± 0.05 and 96.9 ± 0.5.

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7 ('862 Patent at 8:47-50).

8 (*See, e.g.*, D.I. 89, Ex. O ¶¶ 24-26).

9 (*See* '862 Patent at 2:17-19).

10 (*See* '862 Patent at 2:8-12; *see also id.* at 2:36-39).

I also here credit Dr. Chyall's unrebutted opinion that ionization techniques disclosed in the specification can generate fragment ions as well as precursor ions.[11]

In sum, Defendants have not met their burden of showing by clear and convincing evidence that these terms are indefinite, and I will construe them to have their plain and ordinary meanings as articulated by Plaintiff.

The fourth term is "purifying testosterone," which is found in claims 1 and 15 of the '862 patent. Plaintiff again offers the plain and ordinary meaning, which it states is "enriching the amount of testosterone relative to one or more other components of the sample." Defendants counter with "enriching the amount of testosterone relative to one or more other components of the sample by removing materials other than the analyte of interest." The crux of dispute is whether the additional language proposed by Defendants, i.e., "by removing materials other than the analyte of interest" belongs in the construction. I conclude that it does not.

In column 3, lines 50 to 54, the '862 patent states that "purification refers to a procedure that enriches the amount of one or more analytes of interest relative to one or more other components of the sample." That is a definition and the parties do not dispute that.

Defendants' proposed additional language comes from the sentences preceding and following the definition that I just read. The preceding sentence states that "[p]urification in this context does not refer to removing all materials from the sample other than the analyte(s) of interest."[12] That refers to what purification is not in the context of the '862 patent rather than what it is, and I find that it is not part of the express definition of the term. Moreover, that sentence seems to suggest that purification does not require removing all other materials from the sample other than the analyte of interest. It does not suggest that purification requires removal of non-analyte materials from the sample as opposed to vice versa.

Defendants also rely on the sentence following the definition, which states: "In preferred embodiments, purification can be used to remove one or more interfering substances, e.g., one or more substances that would interfere with detection of an analyte

11 (*See* D.I. 89, Ex. O ¶¶ 26-30).

12 ('862 Patent at 3:50-51).

ion by mass spectrometry."[13] That language is clearly referring to embodiments of the invention and is not definitional.

Finally, Defendants' construction improperly excludes "extraction" of testosterone without removing other non-analyte materials, which both the claims and the specification describe as purifying. For example, claim 1 of the '862 patent recites: "purifying testosterone from a sample from a female human, wherein said purifying comprises extracting testosterone from said sample." Other sections of the specification cited here today, for example, column 9, lines 54 through 60, similarly refer to "purifying" the analyte of interest without reference to removal of non-analyte material from the sample. I will thus not include the additional language proposed by Defendants in the construction.

The fifth term is "relating the detected ions to the presence or amount of said 25-hydroxyvitamin D2 in said sample." It is found in claim 21 of the '867 patent. Plaintiff asserts that no construction is necessary and simply refers to the words themselves. Defendants argue that the term means "quantifying the presence or concentration of said 25-hydroxyvitamin D2 in said sample based on the detected ions."

Defendants' construction substitutes the word "quantifying" for the language "relating the detected ions to" and substitutes the word "concentration" for amount.

Here, I agree with Plaintiff that the words "relating the detected ions to the presence or amount" encompasses two concepts. The first concept is "relating the detected ions to the presence" and it is qualitative, i.e., 25-hydroxyvitamin D2 is either present or it is not. The second concept is "relating the detected ions to the . . . amount" and it is quantitative, i.e., describing measuring the amount of 25-hydroxyvitamin D2.

The specification of the '867 patent similarly describes how "detected ions" may be related to the presence, which is non-quantitative, or amount, which is quantitative, of 25-hydroxyvitamin D2 in a sample.[14] These passages distinguish between the "presence" and the "amount."

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13 ('862 Patent at 3:54-58).

14 ('867 Patent at 2:43-45 ("In one aspect, the invention provides a method for determining the presence or amount of a vitamin D metabolite in a sample."); *see also id.* at 3:1-28 & 5:51-60).

Although Defendants cite to a number of places in the patent where the amount of analyte is measured, those appear to be embodiments. The Federal Circuit has cautioned against reading embodiments into the claims in *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366, (Fed. Cir. 2002), and *Superguide Corp. v. DirectTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). I will heed that caution and refrain from reading the limitations from embodiments in the specification that Defendants propose I add.

The sixth and final term is "relating the detected ions to the amount of said vitamin D metabolite in said sample," which is found in claim 1 of the '427 patent. The dispute regarding this term is similar to the "relating" term that I just construed. Plaintiff again argues that no construction is necessary and refers to the words themselves. Defendants argue that the term means "quantifying the concentration of said vitamin D metabolite in said sample based on the detected ions."

For the reasons previously stated with respect to the fifth term, I agree that no construction is necessary.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge