

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ROCHE DIAGNOSTICS CORPORATION, :

Plaintiff, :

v. :

MESO SCALE DIAGNOSTICS, LLC, :

Defendant. :

C.A. No. 17-189-LPS

MESO SCALE DIAGNOSTICS, LLC, :

Counterclaim Plaintiff, :

v. :

ROCHE DIAGNOSTICS CORPORATION, and
BIOVERIS CORPORATION, :

Counterclaim Defendants. :

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MEMORANDUM OPINION

October 9, 2018
Wilmington, Delaware



STARK, U.S. District Judge:

Plaintiff Roche Diagnostics Corporation brought a declaratory judgment suit against Defendant Meso Scale Diagnostics, LLC (“Meso” or “Defendant”) seeking confirmation that it does not infringe Meso’s exclusive license rights of patented diagnostics detection technology known as electrochemiluminescence (“ECL”). (See D.I. 1) Meso filed counterclaims against Roche Diagnostics Corporation and Bioveris Corporation (collectively, “Roche”) asserting infringement of ten patents. (See D.I. 42-1) Four patents are at issue for purposes of claim construction: U.S. Patent Nos. 5,846,485 (the “’485 patent”), 6,165,729 (the “’729 patent”), 6,271,041 (the “’041 patent”), and 6,316,607 (the “’607 patent”). The ’485, ’729, and ’041 patents share a common specification and claim compositions and methods for performing ECL measurements, while the ’607 patent claims specific compounds or compositions that are formed as part of the ECL process. (See D.I. 76 at 2, 5)

Presently before the Court is the issue of claim construction. The parties submitted technology tutorials (*see* D.I. 73, 74), objections to such technology tutorials (*see* D.I. 84, 85), and claim construction briefs (*see* D.I. 75, 76, 82, 83). The Court held a claim construction hearing on August 7, 2018, at which both sides presented oral argument. (See Transcript (“Tr.”))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted).

“[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[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.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[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. Usually, it is dispositive; 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).

While “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. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent.” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide. . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent

claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

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. It bears emphasis that “[e]ven when the specification describes only a single embodiment, 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) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

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), *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, “the district court 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. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, 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.” *Id.* 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.* Furthermore, “statements made by a patent owner during an IPR [inter partes review] proceeding . . . can be considered for claim construction.” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017). Overall, while 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).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct

interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS¹

A. ’485 Patent Terms

1. “kit”²

Roche “a set of reagents packaged and sold together”
Meso “a set of materials for use together”
Court “a set of materials packaged to be used together”

The parties’ proposed constructions differ in three respects: (1) whether the set consists of reagents or materials, (2) whether the set of reagents or materials needs to be packaged together, and (3) whether the set of reagents or materials needs to be sold together.

With respect to the first dispute, both parties agree that the claims refer only to reagents and no other materials. However, Roche also conceded that the distinction is immaterial. (*See Tr. at 15, 31-32*) The Court will use materials in its construction.

Turning to the second issue, Roche argues that “the ordinary meaning [of the term ‘kit’] is a set of materials that are packaged together.” (*Id. at 13*) Meso counters that the set of materials need only be used together and that nothing in the claims requires the materials also to be packaged together. (*See id. at 17-18*) For example, Meso contends that “when all of th[e]

¹The Court will adopt the parties’ agreed-upon constructions.

²This term appears in claims 1-3, 7, 10-16, 18-19, 21-22, and 24-30 of the ’485 patent, as well as claim 2 of the ’729 patent and claim 2 of the ’041 patent.

ingredients are assembled [by the end user] per the seller's instructions for the purpose of being used together, then that would be a kit." (*Id.* at 27; *see also id.* at 24) But the Court agrees with Roche that Meso's position renders the word "kit" meaningless, because the claims already specify that the materials must be used together. (*See id.* at 7-8) Meso even concedes that, in its view, if "a kit" were removed from the claim, "the scope would probably be very similar" – an outcome the Court believes would be improper. (*Id.* at 32-33) The Court further agrees with Roche that it is unnecessary to consider extrinsic evidence because the ordinary meaning of "kit" to a person of ordinary skill in the art requires that the set of materials is packaged for use together, and that those materials exist in some known relationship to one another at some moment prior to the time of use. Although it is an odd result that infringement here may turn on how the materials are packaged, that is the consequence of how the patentee drafted the claims.

The specification provides additional support for this conclusion. It provides that "[t]he formation of the composition is suitably accomplished with a kit comprising one or more reagent components necessary for the formulation step" and also identifies the components of "the overall kit." ('485 patent at 14:12-17) The specification explains why "packaging ingredients used to formulate the composition in a kit" (or in "kit form") is advantageous: providing "standardized ingredients" can "improve the reliability and repeatability" of an ECL assay and "[u]se of reagents and other materials in kit form . . . offers a way to minimize the possibility of degradation of the ingredients before use," as "a result of the kit format's being capable of structuring so as to avoid combinations in which such degradation might occur." (*Id.* at 14:17-27) The kit is formatted such that "[t]he component[s] of the kit is or are typically kept separate by enclosing each in its own vial so as to eliminate cross-contamination prior to combination."

(*Id.* at 14:33-36) These advantages of the “kit form” would not make sense if a kit were just a set of materials that an end user can purchase for creation of his own kit at the time of use.

Roche’s construction is further supported by the prosecution history, as the patent examiner allowed the claims after the applicant pointed out that the disclosure of a kit was not obvious when there was no reason to form a kit. (*See* D.I. 75 at 9-10; D.I. 82 at 2; Tr. at 11-13)

Finally, Roche contends that “sold together” was proposed as being inherent in packaging together for delivery to the customer. (*See* Tr. at 11) Since Roche concedes that “sold” is not necessary for the construction, and the Court agrees, the Court will not include “sold” in its construction.

2. “consists essentially of”³

Roche

’485 patent: “the contents of the kit include all of the recited reagents and cannot include any other reagents whose presence would materially affect the basic and novel characteristics of the claimed kit”

’729 and ’041 patents: “the composition includes all of the recited reagents and cannot include any other reagents whose presence would materially affect the basic and novel characteristics of the claimed composition”

Meso

The term “consists essentially of” is a legal term of art. The meaning of the term is properly addressed as part of jury instructions rather than during claim construction.

Alternatively, “including unlisted [[components][method steps]] that do not materially affect the invention.” (*See* American Intellectual Property Law Association’s (AIPLA) 2017 Model Patent Jury Instructions)

Court

“including unlisted [components] that do not materially affect the basic and novel characteristics of the claimed invention”

³This term appears in claims 1, 11, and 26 of the ’485 patent, as well as claims 1, 9, 12, 18, and 24 of the ’729 patent and claim 1 of the ’041 patent.

The Court finds that construing this claim now, when it has been fully briefed and argued, will be helpful to the parties and the Court. There is no need to wait until jury instructions.

At oral argument, Meso stated it could accept “materially affect the basic and novel characteristics of the claimed invention.” (Tr. at 49-50) Thus, the only distinction between the parties’ proposed constructions is whether the construction should be one of inclusion or exclusion. The parties essentially agree as to what the limitation means, but only disagree as to how to express it. (*See id.* at 54) The Court concludes that a more inclusive construction is more appropriate (and helpful) here.

3. “separate component”⁴

Roche “a separate container in the kit enclosing one or more of the specified reagents”
Meso Plain and ordinary meaning Alternatively, “a separate item that is part of the kit”
Court “one or more of the specified reagents enclosed in a separate contained portion of the kit”

The parties agree that the patent teaches that more than one reagent may be combined in a single container. (*See* D.I. 75 at 12; D.I. 83 at 8) Their dispute stems from confusion over the meaning of “component.” Roche argues that “component” refers to a “container,” while Meso contends that “component” refers to the material inside the container itself. (*See* D.I. 75 at 13; D.I. 76 at 13)

The patent refers to the three reagents as “reagent components” and states that the

⁴This term appears in claims 2-3, 7, 10, and 29 of the ’485 patent.

“components” are “typically kept separate by enclosing each in its own vial.” (’485 patent at 14:13-14, 14:33-35) When the phrase “separate component” is used, the patent appears to be referring to a contained space in the kit. (*See, e.g., id.* at 14:28-48) (noting one or two of three types of reagents can be included in one of three “separate components” depending on structural format of kit) Any apparent contradiction in the specification as to whether “component” refers to a reagent itself or the space that contains one or more reagents is resolved by interpreting “component” or “separate component” as being both, i.e., the combination of the reagent(s) and the space in the kit that it occupies.

B. ’607 Patent Terms

1. “analyte of interest”⁵

<p>Roche “a substance whose presence in a sample is the object of detection in a specific assay”⁶</p>
<p>Meso Plain and ordinary meaning Alternatively, “a substance that is being measured or detected”</p>
<p>Court “a substance that is being detected, directly or indirectly, and, optionally, also being measured, directly or indirectly”</p>

After discussing their arguments at the hearing, the parties ultimately agreed to the following construction: “a substance that is being detected, directly or indirectly, and, optionally, also being measured, directly or indirectly.” (*See Tr.* at 75-77) Accordingly, the Court will adopt

⁵This term appears in claims 6 and 10 of the ’607 patent, as well as claims 44 and 56 of the ’729 patent.

⁶In its responsive brief, Roche agreed to change “chemical, biochemical, or biological substance” to just “substance.” (*See D.I.* 82 at 8)

that construction.

2. “linkage $-(CH_2)_m-$ between X and Z”⁷

Roche

“linkage $-(CH_2)_m-$ ” → “the portion of the structure of the compound, which is directly covalently bonded to the X and Z substructural portions and bridges X and Z, is an alkylene group — i.e., of the form $-(CH_2)_m-$ where m is a positive integer”

Meso

“linkage $-(CH_2)_m-$ between X and Z” → “a moiety linking X and Z that contains $(CH_2)_m$ ”

Court

“a moiety linking X and Z that contains $(CH_2)_m$ and, for listed Z choice (1), is formed from the reaction between X and one of the listed A substructures of Z(1)”

The central dispute between the parties was “whether the linkage *must* be of the form $-(CH_2)_m-$ (Roche’s position) or whether it need only *include* $-(CH_2)_m-$ as one of its elements (Meso’s position).” (D.I. 75 at 16; *see also* D.I. 76 at 15) Following the hearing, the parties agreed on the following construction: “a moiety linking X and Z that contains $(CH_2)_m$ and, for listed Z choice (1), is formed from the reaction between X and one of the listed A substructures of Z(1).” (D.I. 97) Accordingly, the Court will adopt that construction.

⁷This term appears in claim 6 of the ’607 patent.

3. “G is a moiety that reacts with a species”⁸
and “G reacts with a species”⁹

Roche

“G is a reactive functional group covalently attached to the compound structure as shown in the claim that reacts to form a covalent linkage between the compound and a species listed in the claim”

Meso

“G is a component of the compound containing at least one reactive functional group attached to the compound structure as shown in the claim that reacts to form a covalent linkage with a species from the groups listed in the claim”

Court

“G is a component of the compound as shown in the claim containing a reactive functional group that reacts to form a covalent linkage with a species from the groups listed in the claim”

Each of claims 14 and 15 of the '607 patent claims a compound that has a substructure that consists of $-(CH_2)_m-G$ “wherein G is a moiety that reacts with a species” from a selected group. Each of claims 42 and 44 depends on claims 41 and 43, respectively, and provide that “G reacts with a species” from a selected group. Claims 41 and 43, like claims 14 and 15, claim a compound that has a substructure that consists of $-(CH_2)_m-G$ wherein G must be one of eight moieties.

The difference between the parties' proposed constructions is that “Roche defines G to be ‘a reactive functional group,’ whereas Meso defines G to be ‘a component of the compound containing at least one reactive functional group.’” (D.I. 75 at 18-19) Roche argues that “the claim requires that G *itself* is the structure that reacts with the species” and, therefore, G is the reactive functional group. (*Id.* at 19) Roche further argues that “there is no support for a

⁸This term appears in claims 14 and 15 of the '607 patent.

⁹“This term appears in claims 42 and 44 of the '607 patent.

construction that permits G to be a component of a compound containing at least one reactive functional group as part of some larger unspecified structure.” (*Id.*)

Meso contends that it “is not arguing that G is a component ‘of some larger unspecified structure.’” (D.I. 83 at 14) Rather, Meso explains that when a compound reacts with another substance, it “does so through its reactive functional groups – components that are a portion of the compound and not necessarily the entire compound itself.” (*Id.* at 15) Similarly, the moiety G may be a larger moiety “with more than just a single reactive functional group.” (D.I. 76 at 19) In other words, Meso contends that “the moiety G contains, *but is not limited to*, a reactive functional group that forms a covalent linkage with the claimed species through G’s reaction with that species.” (D.I. 83 at 15) Meso argues that Roche’s construction narrowly limits G to “only those specific atoms in the claimed compound directly forming a covalent linkage,” whereas claims 41 and 42 expressly permit G to be a larger moiety that “contains not only the atoms that participate in reactions with the ‘species’ of the asserted claims but also atoms that are not required for these reactions.” (D.I. 76 at 18-19)

In the Court’s view, “a reactive functional group” refers to the chemical structure of a moiety that directly reacts with the species. Roche’s construction seems to narrow the claims to instances in which G itself is the only reactive functional group, which is incorrect. However, Meso’s proposed construction is confusing, because it refers to G as both “a component of the compound” and as having a group that is “attached to the compound structure.” G cannot be both part of something and have a portion that is attached to that same thing. Thus, the Court will adopt a modified construction as shown in the table above.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.