

**UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

MARICAL INC., et al.,)	
)	
Plaintiffs,)	
)	
v.)	1:14-cv-00366-JDL
)	
COOKE AQUACULTURE INC., et al.,)	
)	
Defendants.)	

**ORDER ADOPTING IN PART THE RECOMMENDED DECISION ON
CLAIM CONSTRUCTION**

The plaintiffs in this case, Marical Inc., Europharma AS, and Europharma Inc. (Canada) (the “Plaintiffs”), have filed patent infringement claims against the defendants, Cooke Aquaculture Inc., Cooke Aquaculture USA Inc., True North Salmon Co. Ltd., True North Salmon US Inc., True North Sales US, Inc., and Salmones Cupquelan S.A. (the “Defendants”).¹ ECF No. 154 at 1. All parties are engaged in the farming of salmon, which is a type of anadromous fish.² *Id.* at 2.

The Plaintiffs allege that the Defendants produce and import salmon raised by methods that infringe four patents: United States Patent No. 6,463,883 (Patent ‘883); United States Patent No. 6,475,792 (Patent ‘792); United States Patent No. 6,481,379 (Patent ‘379); and United States Patent No. 6,564,747 (Patent ‘747). ECF No. 1 at 1-2.

¹ The Defendants have filed a counterclaim for declaratory judgment of invalidity and non-infringement (ECF No. 16) that is not at issue in this order.

² “Anadromous” means, in its zoological context, “[a]scending to rivers to spawn.” *Oxford English Dictionary*, <http://www.oed.com/view/Entry/6938?redirectedFrom=anadromous#eid>.

The claim construction portion of the case was referred to the United States Magistrate Judge, who filed a Recommended Decision (ECF No. 154) with the court on July 6, 2016, pursuant to 28 U.S.C. § 636(b)(1)(B) and Federal Rule of Civil Procedure 72(b). The Plaintiffs and the Defendants each filed an Objection to the Recommended Decision on July 25, 2016 (ECF Nos. 163 and 164). The Defendants filed their Response to Plaintiffs' Objection (ECF No. 167) and the Plaintiffs filed their Response to the Defendants' Objection (ECF No. 168) on August 9. A hearing on the parties' objections to the Recommended Decision was held on August 11, 2016. ECF No. 169.

I have reviewed and considered the Magistrate Judge's Recommended Decision, together with the entire record, and have made a *de novo* determination of all matters adjudicated by it. I adopt the claim constructions recommended by the Magistrate Judge, with the exception of the constructions discussed below.

I. BACKGROUND

As noted in the Recommended Decision, the grant of a patent is a grant of a monopoly, in exchange for which the inventor is required to teach to others skilled in the art, in clear and precise language, how to make, construct, and use the patented invention. ECF No. 154 at 3 (citing 35 U.S.C. § 112; *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 368-69 (1938)). The requirement that the patentee teach the invention in clear terms is known as the "definiteness requirement," *Nautilus, Inc. v. Biosig Instr., Inc.*, 134 S.Ct. 2120, 2128 (2014), and provides notice of the scope of the patent, *Dow Chem. Co. v. Nova Chem. Corp. (Canada)*, 803 F.3d 620, 630 (Fed. Cir. 2015).

Every patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C.A. § 112(b) (2016). To be definite, terms contained in the patent claim “must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Nautilus*, 134 S.Ct. at 2129 (citation and quotation marks omitted).

II. CLAIM CONSTRUCTION

The initial stage in a patent infringement action—and the current stage of this litigation—involves construction of the patent claim. *Wavetronix LLC v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1354 (Fed. Cir. 2009). “The purpose of claim construction is to determine the meaning and scope of the patent claims asserted to be infringed.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (citation and quotation marks omitted). The construction of patent claims is a matter of law, though the construction of a claim term can have “evidentiary underpinnings” that require subsidiary fact-finding. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 835 (2015).

When construing claim terms, the court looks first to intrinsic evidence, which is “the most significant source of the legally operative meaning of the disputed claim language[.]” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), and which includes the patent claims themselves, the patent specification, and the patent prosecution history, *id.* at 1582-83. The patent specification, in particular, has been described by the Federal Circuit as “the single best guide to the meaning of a

disputed term[.]” “[u]sually . . . dispositive,” and “always highly relevant[.]” *Id.* at 1582.

After considering intrinsic evidence, “a court may also seek guidance from extrinsic evidence such as expert testimony, dictionaries, and treatises.” *Suffolk Techs., LLC v. AOL, Inc.*, 752 F.3d 1358, 1362 (Fed. Cir. 2014). However, extrinsic evidence carries less weight in determining the operative language of claim language. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005).

A. “Freshwater”

The Recommended Decision construes the term “freshwater” in Patents ‘379 and ‘792 to include specified ranges of calcium and magnesium in part 2 of the definition. ECF No. 154 at 46 (“Water described in [part 1] to which has been added calcium and/or magnesium to achieve concentrations in the range of between 2mM and 10 mM calcium and between 0.5 mM and 10.0 mM magnesium.”).

The Defendants object to these ranges of calcium and magnesium, which were not proposed by either party and do not appear in the specifications of Patents ‘379 and ‘792. Instead, the specifications state that freshwater has “less than about 2mM of magnesium, calcium and NaCl[.]” and water “to which magnesium and calcium have been added, as described herein.” ECF No. 1-4 at 4, col. 6, ll. 32-38 (Patent ‘792); ECF No. 1-6 at 2, col. 5, ll. 52-58 (Patent ‘379).

The Recommended Decision’s construction of “freshwater” in Patents ‘883 and ‘747, on the other hand, contains no such specified ranges of calcium and/or magnesium. ECF No. 154 at 46 (“Water described in [part 1] to which has been added a PVCR modulator or more than one PVCR modulator.”). Adopting this construction

for all four patents would more accurately reflect the patent specifications and would resolve the Defendants' objection.

For this reason, the definition of "freshwater" is construed for all four patents as follows:

(1) Water from a freshwater source, such as water sourced from a stream, river, pond, or another non-marine source, having, for example, the following ionic composition: less than about 2 mM of magnesium, calcium, and NaCl; and

(2) Water described in (1) to which has been added a PVCR modulator or more than one PVCR modulator.

B. "At least one PVCR modulator . . . in an amount"

The Recommended Decision construes this term, in pertinent part, to mean "for example, additions of calcium and/or magnesium at the molar concentration described in the specifications[.]" ECF No. 154 at 47.

The Defendants object to the Recommended Decision's construction of this term, arguing that it lacks reasonable certainty because the PVCR modulators listed (i.e., "calcium and/or magnesium") are examples only. ECF No. 164 at 14-15. The Defendants argue that the construction must disclose *all* PVCR modulators. *Id.*

As the Plaintiffs acknowledged at the hearing, the PVCR modulators and their relevant amounts for purposes of the patents are identified in the patent specifications. Therefore, deleting the words "for example" from the Recommended Decision's construction of the claim term provides greater certainty as to what PVCR modulators are within the scope of the claim.

I therefore construe the term "At least one PVCR modulator . . . in an amount" to mean the following:

Additions of “at least one PVCR modulator ... in an amount” means additions of calcium and/or magnesium at the molar concentration described in the specifications, as well as additions of other polycations and amino acids in the concentrations indicated in the specifications.

The Defendants’ objection is denied in all other respects.

C. “Significantly increased level”

The Recommended Decision construes the term “significantly increased level” to be, in pertinent part, “a term of approximation, which term refers to the increase in the PVCR modulator level in serum taught to result from the presence of NaCl in fish feed in the [specified] amount. . . .” ECF No. 154 at 48.

The Defendants object to this construction because they claim that it fails to identify the level of increase necessary to qualify as “significant.” ECF No. 164 at 16. The Defendants made a substantially similar argument in their brief before the Magistrate Judge.³ ECF No. 78 at 28.

The Plaintiffs argued to the Magistrate Judge that the term “significantly” is not indefinite when read in light of the patents’ specifications, and that a person of ordinary skill in the art would understand that “significance” is a statistical term meaning $p < 0.05$. ECF No. 87 at 23-24 (“The disclosures in the patents-in-suit unambiguously show that patentees selected a p-value of less than 0.05 as an indicator of a ‘significant’ change in a measured level, including a significant increase in the level of calcium in the serum of fish.”).

³ The Defendants also argue that the patents, more generally, are indefinite because “they give no insight on what statistical analysis to perform,” ECF No. 78 at 30-31, and that “results can vary with different types of statistical analyses[.]” *id.* at 32. While I acknowledge this argument, I make no ruling on it because this order is limited to the issue of claim construction.

I agree with the Defendants insofar as the term “significantly increased level” should identify a standard by which to measure a “significant” level of increase in PVCR modulator in the serum of fish. I agree with the Plaintiffs that this standard is adequately identified by defining the term “significant” to mean having a p-value of less than 0.05. Both the intrinsic and extrinsic evidence support this construction.

The supporting intrinsic evidence consists of the patent specifications, which indicate that “significant” increases in serum calcium concentrations were those with a p-value of less than 0.05. ECF No. 1-2 at 21, col. 39, ll. 26-28 (Patent ‘883); ECF No. 1-4 at 21, col. 39, ll. 37-39 (Patent ‘792); ECF No. 1-6 at 16, col. 34, ll. 30-32 (Patent ‘379); ECF No. 1-8 at 32, col. 49, ll. 12-14 (Patent ‘747). The specifications for Patent ‘747 also discuss “significant increases in enzyme activity” in the fish, with “significant” defined as “ $p < 0.05$.” ECF No. 1-8 at 45, col. 76, ll. 57-58.

The extrinsic evidence supporting this construction includes the deposition of the Defendants’ expert witness, Dr. Terence M. Bradley, Ph.D., who testified that use of a p-value of less than 0.05 to denote statistical significance is common and that he “typically” uses this standard himself. ECF No. 73-10 at 63. The extrinsic evidence also includes the declaration of the Plaintiffs’ expert witness, Dr. Steven H. Jury, Ph.D., which states that “[i]n the context of the patents, ‘significance’ refers to a statistically significant increase, indicated by a p-value that is generally less than 0.05[.]” ECF No. 72 at 6, ¶ 18.

For the reasons discussed above, I construe the term “significantly increased level” to mean the following:

A statistically significant increase, indicated by a p-value that is less than 0.05, in the concentration of calcium and/or magnesium in the serum of pre-adult anadromous fish.

D. “Person of Ordinary Skill in the Art”

The Recommended Decision construes the term “person of ordinary skill in the art” to be one who, among other things, “has sufficient skill to conduct one or more tests to measure PVCR expression in the tissue of fish and one or more tests to measure PVCR modulator concentrations in fish blood.” ECF No. 154 at 45.

The Defendants object to this construction, arguing that a person of ordinary skill in the art could not have conducted tests to measure PVCR sensitivity at the time of the invention was patented because no such tests were available. ECF No. 164 at 20. The Plaintiffs respond that the “hypothetical ‘person of ordinary skill in the art’ is presumed to be familiar with tests used to measure gene expression and receptor sensitivity, as such tests were known in the relevant art and described in the patents.” ECF No. 168 at 10.

Both parties acknowledged at the August 11 hearing that a person of ordinary skill in the art need not be able to actually conduct the test or tests, but rather, must be able to understand the results of such tests. Given this acknowledgment, I adopt the following construction of the term “person of ordinary skill in the art,” with the italicized language being the only portion that differs from the Recommended Decision’s construction:

The person of ordinary skill in the art is a person with, minimally, a bachelor’s degree in the biological sciences, whose educational background has been developed by managerial responsibility at a fish hatchery that raises anadromous fish for transfer to seawater, who understands the growth cycle of anadromous fish and the biological and

chemical factors that produce osmotic stress in anadromous fish following transfer to seawater, and who *has familiarity with the molecular techniques described in the patents.*

III. CONCLUSION

It is therefore **ORDERED** that the Recommended Decision of the Magistrate Judge (ECF No. 154) is hereby **ADOPTED IN PART**. The recommended constructions that are not adopted are construed in this order, as explained above.

SO ORDERED.

Dated this 2nd day of September 2016.

/s/ Jon D. Levy
U.S. DISTRICT JUDGE