IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERVET INC., d/b/a MERCK ANIMAL HEALTH and THE ARIZONA BOARD OF REGENTS, on behalf of The University of Arizona,	:	
Plaintiffs and Counterclaim Defendants,	:	
v.	:	C.A. No. 11-595-LPS
BOEHRINGER INGELHEIM VETMEDICA, INC.,	:	
Defendant and Counterclaim Plaintiff.	:	

Mary B. Graham, Stephen J. Kraftschik, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE
Raymond N. Nimrod, Gregory D. Bonifield, Aaron S. Kaufman, QUINN EMANUEL URQUHART & SULLIVAN LLP, New York, NY

Attorneys for Plaintiffs.

Richard L. Horwitz, David E. Moore, POTTER ANDERSON & CORROON LLP, Wilmington, DE
Mark A. Pals, P.C., Amanda Hollis, Hari Santhanam, KIRKLAND & ELLIS LLP, Chicago, IL

Attorneys for Defendant.

MEMORANDUM OPINION

December 7, 2012
Wilmington, Delaware.

STARK, U.S. District Judge:

Pending before the Court is the issue of claim construction of various disputed terms found in U.S. Patent No. 5,610,059 (the "'059 patent").[1]

I. BACKGROUND

Intervet Inc., d/b/a Merck Animal Health, and the Arizona Board of Regents (collectively "Plaintiffs"), filed this patent infringement action against Defendant Boehringer Ingelheim Vetmedica, Inc. ("Vetmedica" or "Defendant") on July 6, 2011. The '059 patent relates to a newly isolated bacterial agent that causes Porcine Proliferative Enteritis ("PPE"). (*See* '059 patent col. 1 ll.6-8)

The parties completed briefing on claim construction on May 9, 2012. (D.I. 57, 58) The Court held a *Markman* hearing on May 30, 2012. *See Markman* Hr'g Tr., May 30, 2012 (D.I. 67) (hereinafter "Tr.").

II. LEGAL STANDARDS

"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). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d 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.*

[1]The '059 patent is found in the record at D.I. 40 Ex. A.

"[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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. 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.*

A court also may rely on "extrinsic evidence," which "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 ordinary 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.* 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.

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).

III. CONSTRUCTION OF DISPUTED TERMS

Claim 1 of the '059 patent is as follows:

> A biologically pure culture of a mammalian host cell infected by an obligate intracellular bacterium that causes porcine proliferative enteritis after inoculation into pigs having all of the identifying characteristics of ATCC Accession No. 55370.

A. "A biologically pure culture of a mammalian host cell" [infected by an obligate intracellular bacterium][2]

Plaintiffs' Proposed Construction: "a culture of a mammalian host cell infected by an isolated bacterium"

Defendant's Proposed Construction: "a proliferating population of cells of one mammalian host cell line that are infected by an obligate intracellular bacterium of one strain without any other cells, microorganisms, or viruses"

Court's Construction: "a culture of a mammalian host cell infected by an isolated bacterium, without any other cells, microorganisms, or viruses"

The parties disagree on two aspects of the disputed term. First, whether the culture must be proliferating, and second, whether the culture may contain more than a single type of host cell and a single strain of bacteria. On both disputes, the Court agrees with Plaintiff's that Defendant's proposed construction improperly imports limitations into the claim.

The patent does not require any level of active growth in the culture. The specification refers to "organism[s] ***capable*** of repeated passage in vitro . . ." and to "frozen cultures." ('059 patent col. 2 l.45; *id.* col. 3 ll.13-15) (emphasis added) Frozen cultures are not growing and are not a proliferation population of cells. (*See* D.I. 47 at 25) Nor do the dictionary definitions of "culture" cited by the parties strongly support Defendant's construction; instead, while the definitions suggest that a culture is or at one time was capable of growth, they do not necessarily require a culture to have current, active growth. (D.I. 51 at 15) (citing to various medical and biology dictionaries defining culture as "[a] population of . . . cells . . . that grow," "[a] medium on which or within which has grown a population," "[t]he product of the growth of . . . cells")

[2]Defendant adds the bracketed portion for construction. As the parties do not dispute that the host cell is infected by a bacterium (Tr. at 59), the Court will construe the disputed portions of "infected by an obligate intracellular bacterium" in connection with the next term.

The patent also fails to support Defendant's limitation that the culture have only a single type of host cell. The claim calls for "***a*** mammalian host cell." ('059 patent col. 8 l.23) (emphasis added) In patent claims, "the word 'a' is generally understood to mean 'one or more.'" *Xerox Corp. v. Google Inc.*, 801 F. Supp. 2d 293, 300 (D. Del. 2011) (citing *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). Indeed, "that 'a' or 'an' can mean 'one or more' is best described as a rule, rather than merely as a presumption or even a convention." *Baldwin Graphics Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008).

Here, Defendant does not offer any persuasive reason to read "a" as limited to a single type of host cell. Defendant contends the phrase "biologically pure" modifies the entire culture, including the host cell and bacterium, so the culture must be limited to a single host type. The Court, however, agrees with Plaintiffs that "biologically pure" refers to the isolated bacterium. The specification states that "[t]he infected host Henle 407 cells were used . . . as a source for obtaining a supply of ***biologically pure PPE-causing agent*** . . . ." ('059 patent col. 3 ll.29-31) (emphasis added) This would appear to distinguish between the host cells – which may or may not be "biologically pure" – and the bacterium, which is "biologically pure." Throughout the specification, the bacterium is referred to as either an "isolated" or "purified" agent. (*Id.* col. 2 ll.58-59; *id.* col. 4 ll.28, 57-58) (referring to "purified agent" and stating "[t]he present invention is directed to the purification of an intracellular bacterial organism") Also, the specification refers to possible hosts other than Henle 407, again suggesting the culture might contain more than one host cell. (*See id.* at col. 4 ll.32-46) The prosecution history is not inconsistent with this conclusion. (*See, e.g.*, D.I. 40 Ex. B at IVET-00177 (distinguishing prior art by stating that '059 patent "isolated and cultured a ***bacterium***") (emphasis added); *id.* at IVET-00219 ("[T]he

host cell is merely a carrier that maintains the genetic element . . . . There is nothing special about the particular host cell used by applicants to deposit the organism with ATCC."))

Defendant's argument that the culture may only contain a single strain of bacterium is likewise unavailing. The specification states, "The PPE-causing agent was isolated from infected enterocystes in the intestinal tissue of ***pigs*** having PPE lesions." ('059 patent col. 3 ll.4-5) (emphasis added) Similarly, the method of isolation of the PPE-causing agent also refers to "[i]ntestinal tissue from ***pigs***." (*Id.* col. 6 l.37) (emphasis added) If the isolated bacteria may come from multiple pigs, it is possible that the isolation process will result in multiple strains.

Finally, the Court notes that while the parties disagree on the number of host cells and strains, the parties agree that the culture is not contaminated with other cells, bacteria, or viruses. (Tr. at 9, 18, 120; D.I. 51 at 13; *see also* '059 patent col. 6 ll. 47-48 (stating intestinal tissue from pigs was washed and exposed to antibiotics to kill "contaminating gut flora")) For purposes of clarity, the Court will add to its construction Defendant's proposed phrase "without any other cells, microorganisms, or viruses."

B. "An obligate intracellular bacterium that causes porcine proliferative enteritis after inoculation into pigs"

Plaintiffs' Proposed Constructions: "a bacterium that is *Lawsonia intracellularis* and that causes porcine proliferative enteritis after inoculation into pigs in its virulent form"

or, alternatively,

"an obligate intracellular bacterium that causes porcine proliferative enteritis after inoculation into pigs in its virulent form that is of the species that has all of the identifying characteristics of the bacterium isolated from infected enterocytes in the intestinal tissue of pigs having PPE lesions"

Defendant's Proposed Construction: "causes . . . when inoculated into pigs" should be given its plain and ordinary meaning

Court's Construction: "a bacterium that is *Lawsonia intracellularis* and that causes porcine proliferative enteritis after inoculation into pigs in its virulent form"

As Plaintiffs observe, there are two issues in dispute: "(1) whether Claim 1 claims species of newly isolated bacterium or whether the claim is limited to something less than the species (to just virulent strains of the species); and (2) whether the claimed species is the same bacterium now named *Lawsonia intracellularis*." (D.I. 47 at 13) Defendant argues that the plain and ordinary meaning of the claim covers only virulent strains of the species, rather than the species itself. The Court agrees with Plaintiffs on both issues.

The claim language, "causes porcine proliferative enteritis," is of a type commonly used in the art to identify a species, because a species is referred to as the causative agent of a disease, encompassing all strains. For example, Vetmedica's U.S. Patent No. 5,714,375 (the '375 patent) uses the species name *IS intracellularis*, referring to it as the "causative agent of PPE," as well as the "causative bacteria which can be obtained from PPE infected swine or other animals . . . and

any variants or mutants of any of the above bacteria, whether spontaneously or artificially obtained." ('375 patent col. 1 l.17; *id.* col. 3 ll.2-6)[3] The '375 patent's reference to *IS intracellularis* as the causative agent, in any variant form, suggests that both virulent and avirulent strains are within the species as referred to in the art as the causative agent.[4]

The specification also supports Plaintiffs' proposed construction. It states that "because the PPE-causing agent may be cultured and purified, it is now possible to develop a bacterin, or inactivated preparation of the PPE-causing agent, using techniques known to the art." ('059 patent col. 4 ll.5-13) This suggests that the PPE-causing agent contains the avirulent strain and, thus, the avirulent strain may be referred to as the PPE-causing agent. (*See* Tr. at 10-11)

The Court's conclusion that the species claimed is *Lawsonia intracellularis* is supported by the prosecution history (and not inconsistent with anything in the claims or specification). During prosecution, the Examiner rejected the claims for lack of written description. (D.I. 40 Ex. B at IVET-00000211-13) The applicants overcame this rejection by explaining that, at the time of their invention, the newly discovered bacteria did not have a scientific name. The applicants cited a later published article identifying the bacterium as "Ileal Symbiont intracellularis," now

---

[3]The '375 patent is found in the record at D.I. 48 Ex. 6.

[4] Plaintiffs cite patents that also support the conclusion that a causative agent is understood to include both virulent and avirulent strains. (*See* D.I. 47 at 8-10) Defendant notes that the cited examples – unlike the '059 patent's claims – involve a causative agent in an independent claim and a separate dependent claim to an avirulent strain. (D.I. 51 at 12) However, as Plaintiffs respond, an independent claim covering a causative agent must include both virulent and avirulent strains if a dependent claim is to properly encompass the avirulent strain. (Tr. at 13-14; *see also* 35 U.S.C. 112; *AT&T Corp. v. Excel Commc'ns*, 1999 WL 1050064, at *13 (D. Del. Oct. 25, 1999) (citing *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1277 (Fed. Cir. 1995), for proposition that scope of independent claims incorporates scope of claims which depend from them))

known as *Lawsonia intracellularis*; they further stated that the named organism in the article was the same as claimed in the patent. (*Id.* at IVET-00000219) The prosecution history reveals that the applicant would have added the name *Ileal Symbiont intracellularis* but did not "out of fear that this would be considered new matter." Instead, the claim was amended to include "having all of the identifying characteristics of ATCC Accession No. 55370" and then the claim was allowed. (*Id.* at IVET-00000216-17, 36-37)

Finally, Plaintiffs cite to WIPO Patent Application WO 2009/049306 A1, which refers to the '059 patent as "describ[ing] and claim[ing] . . . *Lawsonia intracellularis*."[5] This unrelated, 2009 patent application is further evidence that one of ordinary skill in the art reads (at least in 2009) the '059 patent as claiming *Lawsonia intracellularis*, of which ATCC Accession No. 55370 is the "prototype organism."

C. "Porcine Proliferative Enteritis"

Plaintiffs' Proposed Construction: The term does not need to be construed and should be given its plain and ordinary meaning

Defendant's Proposed Construction: "an intestinal disease of pigs characterized by crypt hyperplasia, the presence of intracellular campylobacter-like organisms, thickening of intestinal walls, and clinical symptoms including intermittent diarrhea, anorexia, marked dullness and apathy, and a wasting syndrome"

Court's Construction: "an intestinal disease of pigs characterized by crypt hyperplasia, the presence of intracellular campylobacter-like organisms, and the thickening of intestinal walls, and may also include clinical symptoms such as intermittent diarrhea, anorexia, marked dullness and apathy, or a wasting syndrome"

The parties disagree on whether PPE must include crypt hyperplasia, the presence of

[5]WIPO Patent Application WO 2009/049306 A1 is found in the record at D.I. 48 Ex. 9.

intracellular campylobacter-like organisms, thickening of intestinal walls, and clinical symptoms including intermittent diarrhea, anorexia, marked dullness and apathy, and a wasting syndrome. Defendant's construction requires all of these characteristics and symptoms. Plaintiffs assert that one of the ordinary skill in the art is familiar with PPE and no construction is necessary.[6] The Court concludes that the parties' dispute should be resolved by construing the claim term and adopts much, but not all, of Defendant's proposed construction.

The specification indicates that PPE is characterized by crypt hyperplasia, the presence of intracellular campyiobacter-like organisms, and thickening of intestinal walls. (*See* '059 patent col. 1 ll.15-16, 34, 51) However, the patent also makes clear that not every pig with PPE exhibits every potential symptom. The specification describes different phases of the disease which are associated with different symptoms. For example, in the acute phase, the villi become swollen, and the submucosa usually contain lymphatic tissue nodules. (*See* '059 patent col. 1 ll.45-48) In the chronic stage, PPE may be associated with thickening of parts of the intestine or inflammation, or the mucosa may show hyperemia and hemorrhaging. (*See id.* col. 1 ll.50-54) Furthermore, the specification uses language like "may," "usually," and "frequently" to describe the presence of potential symptoms. It is clear from the specification that all pigs do not display every one of Defendant's listed symptoms. For instance, Example 2 in the specification reports infected pigs with severe diarrhea, but makes no mention of other clinical symptoms. (*See id.* col. 7 ll.22-23)

---

[6]*See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute.").

The prosecution history is consistent with the Court's construction. Literature contained in the prosecution history observes that "affected animals vary from clinically unremarkable to marked dullness and apathy" and "[d]iarrhea is not always a feature." (D.I. 40 Ex. C at VM-INT0002265) Defendant points out that the applicants distinguished the '059 patent from prior art by stating that the organism could induce all of the symptoms of PPE – but the applicants did not state that the organism must always induce all of the symptoms in all affected pigs.

D. "Having all of the identifying characteristics of ATCC Accession No. 55370"

Plaintiffs' Proposed Construction: This language is definite and complies with 35 U.S.C. § 112. Plaintiffs propose that the language be construed as part of the larger phrase which encompasses it.

Defendant's Proposed Construction: This limitation is indefinite under 35 U.S.C. § 112. The '059 patent does not identify what "all of the identifying characteristics" are and the ATCC deposit having Accession No. 55370 is not available. The identifying characteristics include, but are not limited to: (1) the mammalian host cells are of the Henle 407 cell line; (2) the bacterium is 0.24-0.27μm in width and 1.4-2.4 μm in length; (3) the bacterium has a curved shape; and (4) cytopathic effect (CPE) occurs in the recited cells 2-4 days after inoculation and is characterized by the elongation and subsequent rounding and sloughing of cells by day 7-10.

Court's Construction: This language is definite. Based on the other claim terms that have been construed, no additional construction is necessary for this disputed term.

Defendant contends that this term is invalid due to indefiniteness. The Court is not persuaded. *See generally Personalized User Model LLP v. Google, Inc.*, 2012 WL 295048, at *22 (D. Del. Jan. 25, 2012) (stating Court "does not permit summary judgment arguments, including indefiniteness arguments, during the claim construction phase of the litigation"). A claim is "sufficiently definite to survive claim construction" unless the term is "insolubly ambiguous." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir.

2008); *see also Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 2003 WL 124149, at *1 n.1 (D. Del. Jan. 13, 2003). Defendant has failed to establish "by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton*, 514 F.3d at 1249.

Real-world evidence supports the Court's conclusion. Dr. Gebhart – whom the parties agree is, at minimum, a person of ordinary skill in the art (Tr. at 51, 103) – is a coauthor on WIPO Patent Application WO 2009/049306 A1, which states:

> Joens and Glock (U.S. Patent No. 5,610,059) describe and claim the isolation and characterization of a PPE organism and reproduction of the disease using the organism, . . . now known as *Lawsonia intracellularis*. . . . Since this initial report, at least four additional isolates have been obtained and shown to demonstrate the same growth characteristics as ATCC 55370, confirming that ATCC 55370 is the prototype organism.

A claim is indefinite "if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). As evidenced by Dr. Gebhart's patent application, one of ordinary skill in the art would be able to determine the claimed subject matter of the '059 patent: *Lawsonia intracellularis*.

Plaintiffs assert that the identifying characteristics of the claimed bacterium are that it is (1) an obligate intracellular microorganism, and (2) causes PPE. The prosecution history supports this assertion. Plaintiffs overcame a rejection based on inadequate written description when the Examiner added "having all of the identifying characteristics of ATCC Accession No.

55370" instead of a species name; at the time the application was filed, the species name was unknown. The Court's construction of the various claim terms in dispute includes the species name as well as Plaintiffs' asserted identifying characteristics.[7] Thus, no additional construction is necessary for the term "having all of the identifying characteristics of ATCC Accession No. 55370."

Finally, to the extent Defendant would have the Court construe this term as limited just to the identifying characteristics described in Defendant's proposed construction (i.e., a specific host cell, size, shape, and cytopathic effect), the Court disagrees, as this would improperly narrow the scope of the claim to that of a preferred embodiment disclosed in the specification. *See generally Kara Tech. Inc. v. Stamps.com*, 582 F.3d 1341, 1348 (Fed. Cir. 2009).

IV. CONCLUSION

For the foregoing reasons, the Court will construe the disputed claim terms in the '059 patent consistent with this Memorandum Opinion. An appropriate Order follows.

[7]These are the same identifying characteristics noted by the Examiner in the statement of reasons for allowance of the '059 patent. (D.I. 40 Ex. B at IVET-00236-37) ("The microorganism taught by the closest prior art causes only symptoms of PPE and is not an intracellular organism")