United States District Court,
District of Columbia.

INTERVET, INC,
Plaintiff.
v.
MERIAL LIMITED, et al,
Defendants.

Civil Action No. 06-00658 (HHK)

Nov. 28, 2007.

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MEMORANDUM OPINION AND ORDER

HENRY H. KENNEDY, JR., **District Judge.**

By this action, plaintiff Intervet, Inc. ("Intervet") seeks a declaratory judgment that its vaccine does not infringe any valid and enforceable claim of U.S. Patent No. 6,368,601 (" '601 Patent"), a patent that is exclusively licensed to defendant Merial Limited ("Merial"). This matter is before the court now on the issue of claim construction. Intervet and Merial dispute the meaning of six terms included in the claims section of the ' 601 Patent.

Upon consideration of the parties' submissions and the record of this case, including the parties' presentations at a *Markman* hearing, the court construes the six terms as set forth and explained below.

I. BACKGROUND

Prior to the '601 Patent application, the scientific community was aware of the existence of porcine circoviruses, which are small viruses with circular, single-stranded DNA. These circoviruses were known to be nonpathogenic and not associated with Postweaning Multisystemic Wasting Syndrome ("Postweaning Syndrome"), a slow and progressive disease that causes gradual weight loss, lesions, and jaundice in young pigs. The '601 Patent, which is entitled "Porcine Circovirus Vaccine and Diagnostics Reagents," identified five new porcine circoviruses that were unlike the previously known porcine circoviruses. The inventors

claimed that these five newly discovered porcine circoviruses exhibited extremely strong homology FN1 vis-a-vis each other and were responsible for Postweaning Syndrome. In the ' 601 Patent, the inventors named these five porcine circoviruses "porcine circoviruses of type II" ("PCV-2") to distinguish them from the previously known porcine circoviruses, which the inventors named "porcine circoviruses of type I" ("PCV-1").

FN1. Homology refers to the degree to which genetic materials are related, and it is measured by comparing protein or DNA sequences.

After the '601 Patent application was filed, Intervet began producing a pig vaccine named "Porcine Circovirus Vaccine Type 2." Intervet filed the present action seeking a declaratory judgment that its vaccine does not infringe the claims of the '601 Patent and that the claims of the '601 Patent are invalid and unenforceable.

II. ANALYSIS

This court must construe the following six terms in the claims section of the '601 Patent: (1) PCV-2; (2) PCV-1; (3) ORFs 1-13; (4) vector; (5) epitope; and (6) an isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1. There are well defined principles that govern the court's claim construction analysis.

Claim construction is a question of law that begins "with the words of the claim[s] [themselves]." Mars, Inc. v. H.J. Heinz Co. ., 377 F.3d 1369, 1373 (Fed.Cir.2004); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim construction is "the judicial statement of what is and what is not covered by the technical terms and other words of the claims." Netword LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001). Thus, when construing claims, the "analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point out [ ] and distinctly claim [ ] the subject matter which the patentee regards as his invention.' " Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. s. 112); *see also* Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) ("It is a 'bedrock principle' of patent law that 'the elements of a patent define the invention to which the patentee is entitled the right to exclude.' ") (quotation source omitted). "Because the patentee is required to 'define precisely what his invention is,' it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.' " Phillips, 415 F.3d at 1312 (quotation source omitted).

To determine the meaning of the claims, the court must first look to the intrinsic evidence of record. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Intrinsic evidence is comprised of the patent itself, including the claims, the specification, and, if in evidence, the prosecution history. *Id.* If there is still doubt regarding the meaning of the claims after review of the intrinsic evidence, then "consideration of extrinsic evidence may be necessary to determine the proper construction." *Id.* at 1583. Extrinsic evidence is evidence that is external to the patent and prosecution history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles. *Id.*

When analyzing the relevant evidence, the court must always be mindful that the words of the claims are presumed to take on the ordinary and customary meaning attributed to them by those of ordinary skill in the

art. BrookhillWilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed.Cir.2003). However, "a patentee may act as ... her own lexicographer." That is, a patentee may attribute an unique meaning to a word. But to do so, a patentee "must [clearly] express intent to impart a novel meaning." Unitronics Ltd. v. Gharb, 511 F.Supp.2d. 123, 2007 WL 2781921,(D.D.C. Sept.25, 2007).

The court now applies these principles of claim construction to the six disputed terms.

1. PCV-2

Intervet asserts that PCV-2 refers solely to the "five viral strains FN2 identified in the ' 601 Patent" Pl.'s Br. 9, while Merial argues that PCV-2 refers to a broad group of porcine circoviruses that includes, but is not limited to, the five porcine circoviruses identified in the patent. Merial defines this group as consisting of "porcine circovirus[es] of type II that [are] pathogenic to pigs and a causative agent of [Postweaning Syndrome]." Def.'s Br. 23. The court agrees with Intervet's definition because Merial's definition is divorced from the text of the ' 601 Patent, and because Intervet's definition is the only definition that imbues the term PCV-2 with any ascertainable meaning.

FN2. Hereinafter, the phrases "five viral strains" and "five porcine circoviruses" are used interchangeably.

A. Merial's Definition Is Divorced from the Text of the '601 Patent

In support of its position, Merial points out that the '601 Patent describes the five porcine circoviruses identified therein as "representative" of PCV-2. '601 Patent, Col. 1, l. 60. According to Merial, the word "representative" illustrates that PCV-2 refers to a broad group of porcine circoviruses. Similarly, Merial argues the '601 Patent states that "the invention also covers the equivalent sequences in the sense that they are capable of hybridizing with the above sequence ... and belong to group II defined above." Id. at Col. 4, ll. 6-10. Consequently, Merial asserts, group II, i.e. PCV-2, cannot contain "equivalent sequences" *unless* PCV-2 refers to a group of porcine circoviruses that is *broader* than the five porcine circoviruses identified in the '601 Patent.FN3 Merial defines this broad group as a group of "porcine circovirus[es] of type II that [are] pathogenic to pigs and a causative agent of [Postweaning Syndrome]." Def.'s Br. 23.

FN3. At the *Markman* hearing, Intervet argued that the court should ignore this reference to "equivalent sequences" based on the Doctrine of Equivalents. The court declines to do so because, as Intervet concedes, this doctrine is not relevant to claim construction. (*Markman* Hr'g Tr. 131:18-121:25, Aug. 6, 2007).

Intervet argues correctly that Merial's definition of this group has no basis in the text of the '601 Patent. Even though the '601 Patent notes that some porcine circoviruses may be pathogenic, the patent does not specifically identify PCV-2 as pathogenic. As Intervet points out, the '601 Patent merely states that some porcine circoviruses may be pathogenic. '601 Patent, Col. 1, ll. 28-30. The '601 Patent does not specify that these pathogenic porcine circoviruses are PCV-2.

Nor does the patent describe PCV-2 as a group of porcine circoviruses that are causative agents of Postweaning Syndrome. The '601 Patent only states that the five porcine circoviruses identified therein are responsible for Postweaning Syndrome. Id. at Col. 1, l. 5. The '601 Patent does not specify that any porcine circoviruses other than these five porcine circoviruses are responsible for Postweaning Syndrome. Furthermore, the terms "responsible for" and "causative agent" indicate different degrees of causation.

"Responsible for" indicates a direct causative relationship, whereas "causative agent" indicates a more attenuated causative relationship. Accordingly, the two terms are not interchangeable.

Lastly, Merial's definition of PCV-2 as "porcine circovirus of type II" is circular. Interpreting PCV-2 to mean a "porcine circovirus of type II" only begs the question of what type II means in the context of the '601 Patent. Adopting Merial's definition would contradict the purpose of claim construction, which is to clarify the meaning of the claims.FN4

FN4. Intervet also argues that the court must reject Merial's definition because it does not comport with "Koch's Postulates." Because Koch's Postulates are not relevant here, the court will not address this argument.

Merial also argues that the court must accept its definition because it reflects the definition commonly used among persons skilled in the art. Merial notes that Intervet's expert witness, Dr. Raymond Rowland, stated in his deposition that, prior to his work on this patent dispute, he understood PCV-2 as referring to a group of porcine circoviruses. Merial also points out that Intervet itself uses the term PCV-2 to refer to a broad group of porcine circoviruses, as illustrated by the fact that Intervet labels its vaccine that is at issue in this litigation as a vaccine against PCV-2.FN5 The court is not persuaded.

FN5. Merial also argues that the prosecution history supports its definition of PCV-2. The Patent Examiner initially rejected the claim that ultimately issued as Claim 9 because " 'The claims are drawn to DNA and vectors that comprise 'ORFs 1-13.' The ORFs are assumed to be derived from porcine circovirus, but as written, the claims could encompass ORFs from any organism.' " Def.'s Br. 26 (quoting Def.'s Ex. 6). In response, the inventors added the phrase "of porcine circovirus type 2" to the end of Claim 9. Merial argues that because the amendment did not name particular isolates, strains, or sequences, the amendment illustrates that PCV-2 refers to a broad group of porcine circoviruses. This argument is speculative and the court rejects it.

As Intervet points out, all of the above-mentioned facts *postdate* the date of the '601 Patent application. When the '601 Patent application was filed, PCV-2 had no ordinary and customary meaning among persons skilled in the art because the term had not been used prior to the time the '601 Patent was filed.FN6 In construing a claim, the court must determine a disputed claim's meaning as of "*the time of the invention, i.e.,* as of the effective filing date of the patent." Phillips, 415 F.3d at 1313 (emphasis added). Accordingly, because PCV-2 had no ordinary and customary meaning at the time of the ' 601 Patent application, the court must look to the text of the ' 601 Patent to determine the meaning of PCV-2.FN7 *See* id. Because Merial's interpretation is not anchored in the text of the ' 601 Patent, the court rejects it.

FN6. Merial appears to argue that PCV-2 did have an ordinary and customary meaning among persons skilled in the art at the time of the ' 601 Patent application. Merial notes that one month before the '601 Patent application was filed, one of the inventors listed on the '601 Patent contributed to an article that used the term PCV-2. The court is not persuaded. One month simply is not enough time for the term PCV-2 to have acquired an ordinary and customary meaning among persons skilled in the art.

FN7. Intervet also argues that Merial's definition would cause the ' 601 Patent to infringe on prior art.

Intervet is essentially asking the court to construe the claims to avoid ensnaring prior art (i.e. to preserve their validity). *See* Generation II Orthotics, Inc. v. Med. Tech. Inc., 263 F.3d 1356, 1365 (Fed.Cir.2001). The court declines to address this argument because validity analysis is relevant to claim construction only if, "after applying all the available tools of claim construction, ... the claim is still ambiguous." Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed.Cir.2005). Because the plain language of the '601 Patent illustrates that Merial's definition is flawed, the court does not need to engage in validity analysis.

Intervet also argues that the prosecution history shows that PCV-2 should be interpreted narrowly because the Patent Examiner only rejected claims that shared 100% identity with other sequences in GENBANK. Intervet argues that if the Patent Examiner had understood PCV-2 to refer to a broad group of viruses, the Patent Examiner would have rejected more claims as homologous or similar to GENBANK deposits. This argument is too speculative and the court rejects it.

B. Intervet's Definition Is Anchored in the Text of the '601 Patent

In contrast to Merial's definition, Intervet's definition, the "five viral strains identified in the '601 Patent," Pl.'s Br. 9, is firmly anchored in the text of the '601 Patent. The definition of PCV-2 cannot be disconnected from these five porcine circoviruses because the '601 Patent uses these five porcine circoviruses to explain the meaning of the term PCV-2. The first column of the '601 Patent states that "the subject of the present invention is ... [PCV-2] *as defined above*." '601 Patent, Col. 1, ll. 63-65 (emphasis added). The preceding text does not explicitly define PCV-2, however. Rather, the preceding text states that PCV-2 is a new "type" of viral strain that is "represent[ed]" by the five porcine circoviruses identified in the ' 601 Patent. Id. at Col. 1, l. 60. The preceding text explains that the five porcine circoviruses are representative of the PCV-2 viral type because they exhibit a "very strong homology with each other." Id. at Col. 1, ll. 57-61.

This is the only explanatory reference to PCV-2 in the '601 Patent. FN8 As this reference illustrates, the ' 601 Patent bases its explanation of PCV-2 on the five porcine circoviruses and does not describe PCV-2 separate and apart from them. Thus, PCV-2 has no ascertainable meaning unless the definition of PCV-2 refers to these five porcine circoviruses. Accordingly, the court agrees with Intervet that the five porcine circoviruses must be part of the definition of PCV-2.

FN8. There is one other reference in Col. 13, but it is identical.

Intervet asserts that not only must the five porcine circoviruses be part of the definition of PCV-2, the definition must be *limited* to these five porcine circoviruses. Intervet argues that the '601 Patent provides no other guidance as to whether a porcine circovirus is properly classified as PCV-2. Thus, according to Intervet, despite language in the '601 Patent that suggests that PCV-2 refers to a broad group, the only meaningful definition of PCV-2 is one that is limited to the five porcine circoviruses.

Merial disagrees and contends that were the court to limit the definition of PCV-2 to these five porcine circoviruses, it would improperly limit a claim term to its preferred embodiments. *See* Phillips, 415 F.3d at 1323 (warning against limiting claim to preferred embodiments). Merial asserts that the ' 601 Patent includes other descriptions of PCV-2. Specifically, Merial asserts that it is clear that PCV-2 refers to a broad group of porcine circoviruses that encompasses:

(i) porcine circoviruses having a significant serological similarity with the strains listed in the patent; (ii) porcine circoviruses whose DNA cross-hybridizes with the DNA of the strains listed in the patent under

stringency conditions such that there is no hybridization with the PK/15 (i.e.PCV-1) strain; (iii) porcine circoviruses having equivalent sequences, that is to say the sequences which do not change the functionality or the strain-specificity of the sequences described or of the polypeptides encoded by the sequences in the patent; (iv) porcine circoviruses whose sequences differ from the strains listed in the patent by degeneracy of the genetic code; and (v) porcine circoviruses having a high homology with the sequences of the strains listed in the patent.

Def.'s Br. 11 (citing sections of the '601 Patent).

Merial's argument that the above descriptions apply to PCV-2 cannot withstand analysis. Merial assumes that every reference to porcine circoviruses in the ' 601 Patent is also a reference to PCV-2. That is, Merial assumes that the terms "PCV-2" and "porcine circoviruses" are interchangeable. There is no basis for this assumption in the '601 Patent. Indeed, the '601 Patent specifically illustrates that they are *not* interchangeable. The '601 Patent states "the invention relates to any porcine circovirus capable of being isolated ... in particular [PCV-2]." '601 Patent, Col. 1, ll. 66-67-Col. 2, ll. 1-3. This excerpt illustrates that PCV-2 applies to a narrower and more specific group of porcine circoviruses than the general term "porcine circoviruses." Thus, the court rejects Merial's argument that the terms are interchangeable.

Even if Merial is correct that the above descriptions apply to PCV-2, the Federal Circuit's decision in Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed.Cir.1994) demonstrates why the court must decline to incorporate these descriptions into the definition of PCV-2. In *Genentech,* the court had to construe the term "human tissue plasminogen activator." *Id*. at 1563. The patent at issue included four possible definitions, and the court noted that several of them were "hopelessly overbroad." *Id*. at 1564. The court noted that these overbroad definitions covered an "infinite number of permutations," and there was "no basis provided in the specification for determining which of these permutations [were] operative." *Id*. The court concluded that the appropriate way to determine the correct definition was to ignore any definitions on which the Patent Examiner could not have reasonably relied when she approved the patent. *Id*. The court adopted the narrowest definition of the four possible definitions because it was the only definition on which the Patent Examiner could reasonably have relied. *Id*.

The circumstances here are similar to those in *Genentech*. As noted *supra,* Merial asserts that the '601 Patent contains at least five different descriptions of PCV-2. All of these descriptions are extraordinarily broad and fail to provide any guidance as to how to determine whether a porcine circovirus is properly classified as PCV-2. For example, Merial would have the court define PCV-2 as a group that includes porcine circoviruses that are homologous to the five porcine circoviruses identified in the '601 Patent, porcine circoviruses that cross-hybridize with these five porcine circoviruses, and porcine circoviruses that are serologically similar to these five porcine circoviruses. However, the '601 Patent does not identify the degree of homology nor cross-hybridization that qualifies a porcine circovirus as PCV-2. FN9 Nor does the ' 601 Patent provide information as to the degree of serological similarity necessary for a porcine circovirus to be classified as PCV-2.FN10

FN9. Merial's own expert, Dr. Christopher Chase, stated in his deposition that there is no objective standard for determining homology. Nor did Dr. Chase identify the degree of cross-hybridization necessary to identify a porcine circovirus as PCV-2. Thus, any determination of whether a porcine circovirus is homologous or capable of cross-hybridization would necessarily be subjective.

FN10. Merial argues that Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed.Cir.2002) permits it to claim a genus (that is, a broad group of porcine circoviruses), which necessarily incorporates variants that are unknown and unidentified. Id. at 967. However, the patent in *Enzo* defined the claimed genus with more specificity than the '601 Patent describes PCV-2. Id. at 961. In *Enzo,* the patentee claimed a genus consisting of "a composition of matter that is specific for Neisseria gonorrhoea comprising at least one nucleotide sequence *for which the ratio of the amount of said sequence which hybridizes* to chromosomal DNA of Neisseria meningitidis is *greater than about five,* said ratio being obtained by a method comprising the following steps ..." *Id*. at 961(emphasis added). Thus, the patentee in *Enzo* identified a hybridization ratio that enables persons skilled in the art to determine whether the DNA sequence belongs to the relevant group. Here, the '601 Patent provides *no information* about PCV-2 other than the fact that the five porcine circoviruses are properly categorized as PCV-2.

Accordingly, when the Patent Examiner approved the '601 Patent, she could not have reasonably relied on any of these five descriptions of PCV-2. These descriptions are too broad and render the determination as to whether a porcine circovirus is properly classified as PCV-2 too subjective. There is a significant risk that Merial's broad definition would render the '601 Patent invalid for indefiniteness. A claim is invalid for indefiniteness when "one skilled in the art would [not] understand the bounds of the claim when read in light of the specification." Miles Labs., Inc.v. Shandon, Inc., 997 F.2d 870, 875 (Fed.Cir.1993). As discussed above, pursuant to Merial's broad description of PCV-2, a person skilled in the art, such as the Patent Examiner, would have difficulty determining whether a porcine circovirus is properly classified as PCV-2.

In contrast, by limiting the definition of PCV-2 to the five viral strains of the invention, Intervet's proposed definition renders the term PCV-2 definite by providing clear notice as to the "metes and bounds" of the term PCV-2. In re Warmerdan, 33 F.3d 1354, 1360 (Fed.Cir.1994) ("It is the claims which define the metes and bounds of the invention entitled to the protection of the patent system."). Thus, the court concludes that a definition that limits PCV-2 to the five porcine circoviruses identified in the '601 Patent is the only definition on which the Patent Examiner could have relied when she approved the '601 Patent. *Cf*. Wang Labs., Inc. v. AOL, Inc., 197 F.3d 1377, 1383 (Fed.Cir.1999) (stating that where the meaning of a claim term is ambiguous and susceptible to various meanings, a court should construe the claim to preserve, rather than defeat, validity).FN11

FN11. Merial also argues that the doctrine of claim differentiation requires the court to adopt a broad definition of PCV-2. The doctrine of claim differentiation "instructs that different claim terms are presumed to have different meanings." MicroStrategy Inc. v. Business Objects Americas, 238 Fed. Appx. 605, (Fed.Cir.2007). Merial points out that Claims 1 and 9 are identical except for the fact that Claim 1 applies to specific DNA sequences and Claim 9 applies to PCV-2. Merial argues that this distinction illustrates that the claims have different meanings. Merial argues that if the court limits PCV-2 to the five porcine circoviruses, then the claims will effectively have the same meaning and this is impermissible pursuant to the doctrine of claim differentiation. The court disagrees. The doctrine of claim differentiation does not "supplant other canons of construction that compel" a narrow interpretation. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed.Cir.2001). Because PCV-2 has no meaningful definition unless it is limited to the five porcine circoviruses, the court declines to rely on the doctrine of claim differentiation to interpret PCV-2 broadly.

Accordingly, the court adopts Intervet's definition that PCV-2 is "limited to the five viral strains" because the '601 Patent contains no other ascertainable meaning of PCV-2. Pl.'s Br. 9.

2. PCV-1

Intervet and Merial not only dispute the meaning of PCV-2, they also dispute the meaning of "PCV-1." Intervet and Merial's definitions of PCV-1 are parallel to their definitions of PCV2. Intervet argues that PCV-1 refers only to the "nonpathogenic porcine circovirus strains disclosed in the '601 patent." Pl.'s Br. 25. Intervet's definition would limit PCV-1 to two strains identified in Col. 12 of the '601 Patent-strains with accession numbers Y09921 and U49186. In contrast, Merial argues that PCV-1 broadly refers to "a nonpathogenic porcine circovirus that can be derived from PK/15 cells." Def.'s Br. 22.

Although the parties' definitions of PCV-1 parallel their definitions of PCV-2, the court declines to adopt Intervet's narrow definition of PCV-1 even though it adopts Intervet's narrow definition of PCV-2. As discussed *supra,* the definition of PCV-2 must be limited to the five porcine circoviruses identified in the '601 Patent because the '601 Patent contains no other ascertainable meaning of PCV-2. In contrast, the '601 Patent specifies that PCV-1 refers to a broad group of porcine circoviruses that are nonpathogenic and are derived from PK/15 cells.

While the exact term PCV-1 did not exist until around the time of the ' 601 Patent application, the porcine circoviruses that the term defines were well known and were simply referred to as "PCV." The introductory paragraphs of the '601 Patent's specification make clear that the term "PCV-1" was coined by the inventors of the '601 Patent to distinguish the porcine circoviruses that had previously been identified and were known to exist-i.e., the nonpathogenic porcine circoviruses derived from PK/15 cells-from the newly discovered porcine circoviruses, referred to in the '601 Patent as PCV-2. Thus, the court adopts Merial's proposed construction of PCV-1.

3. ORFs 1-13

The court now turns to the term "ORFs 1-13." Open Reading Frames ("ORFs") are the sections of DNA that code for amino acids, which are the building blocks of proteins. In Example 13 of the '601 Patent, the patent identifies thirteen ORFs associated with PCV-2.

Intervet argues that ORFs 1-13 refers to the "specific DNA sequences defined as ORFs 1-13 in Example 13." Pl.'s Br. 20. Merial rejoins that "the specific DNA sequences identified in Example 13 are only representative examples" and that ORFs 1-13 refers, more generically, to "[a] length of DNA sequence (or corresponding RNA sequence) from the genome of a PCV-2 circovirus between an ATG (or AUG) translation start signal (initiation codon) and a termination codon which can be potentially translated into a polypeptide sequence." Def.'s Br. 27. Intervet has the better argument.

Merial's definition is overly broad and disconnected from the language of the claims in the '601 Patent. Merial argues that nothing in the '601 Patent' s written description (that is, the specification and examples) shows an intent to limit the claim scope to the thirteen ORFs identified in Example 13. Merial points out that Example 13 describes the thirteen ORFs as merely "representative" of the various ORFs associated with PCV-2.

What Merial fails to recognize is that the court's analysis "must begin and remain centered on the language of the claims themselves." Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331

(Fed.Cir.2001). The ' 601 Patent's claims specify that the relevant ORFs are ORFs *1-13*. That is, the only relevant ORFs are ORFs 1-13. Example 13 could hardly be clearer when it identifies ORFs 1-13 by stating the "13 ORFs *are* the following." '601 Patent, Col. 13, ll. 33-34 (emphasis added). Example 13 proceeds to detail the ORF sizes, their positions, and their start and end codons.

Merial's definition is nothing more than an attempt to read the reference to "1-13" out of the language of the claims. The court declines to adopt Merial's definition because definitions that render claim language as mere surplusage are highly disfavored. Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1325 (Fed.Cir.2001) (rejecting party's definition because it rendered claim language as surplusage).FN12

FN12. Intervet asserts that the prosecution history of the '601 Patent supports its definition of ORFs 1-13. Intervet argues that because the Patent Examiner only rejected claims having 100% homology with the sequence disclosed in National Center for Biotechnology Information's GENBANK submission AF027217, and allowed claims that were not 100% identical at the nucleotide level, the Patent Examiner understood the claims as having a narrow scope. As with the parties' other arguments based on the prosecution history of the '601 Patent addressed in this memorandum, the court is not persuaded because the argument is too speculative.

4. Vector

A vector is a tool commonly used by scientists to introduce or deliver genetic material into host cells. Intervet argues that vector should be defined as a "a live virus or plasmid DNA." Pl.'s Br. 23. Merial, in turn, argues that vector should be defined as "an agent (virus or plasmid) used to transmit foreign genetic material to a cell or organism; used for the *in vitro* or *in vivo* expression of polypeptides." Def.'s Br. 18. Neither definition is correct, however, and the court, with appropriate caution, adopt its own definition. *See* Yoon Ja Kim v. Conagra Foods, Inc., 465 F.3d 1312, 1319 (Fed.Cir.2006) (stating that courts can reject the parties' proffered definitions and develop their own constructions, but that courts should be hesitant to do so). The court adopts the definition provided by the scientific textbook *Molecular Biology of the Cell,* authored by Bruce Alberts et al. and published in 1994, that a "vector" is "an agent (virus or plasmid) used to transmit genetic material or a cell or organism." *Id*. at G-23.

Merial argues that, at the time of the '601 Patent application, vector had an ordinary and customary meaning attributed to it by those of ordinary skill in the art, and thus the court should adopt this meaning. *See* Brookhill-Wilk 1, LLC, 334 F.3d at 1298. While the court agrees with this argument, Merial's proposed definition is not correct. Merial bases its proposed definition on the definition included in *Molecular Biology of the Cell,* but adds the words "foreign" and "used for the *in vitro or in vivo* expression of polypeptides" to the definition. Merial does not explain why it adds these words to the definition. Neither the textbook nor the '601 Patent cites vector this way.

Nor is Intervet's proposed definition correct. Intervet argues that the inventors acted as their own lexicographers and defined vectors to mean "live virus[es] or plasmid DNA." Intervet relies on an excerpt from the '601 Patent that states: "[a]s appropriate vectors, there *may* be used live viruses ... plasmid DNAs can also be used as vectors." '601 Patent, Col. 4, ll. 44-51 (emphasis added). Intervet argues that this excerpt shows that the inventors acted as their own lexicographers and provided a controlling definition of the claim term.

The law is clear that to act as lexicographers, the inventors must clearly indicate their intent to depart from the term's ordinary and customary meaning. *See* Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1370 (Fed.Cir.2005).FN13 The inventors here did not clearly indicate their intent to deviate from the ordinary and customary meaning of PCV-2. The ' 601 Patent states that live viruses or plasmid DNA *may* be used as vectors. "May" is a *permissive word* that shows the inventors did not intend to limit vectors to live viruses or plasmids. Intervet's proposed construction is an improper attempt to limit the meaning of a term to its preferred embodiments. Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1237 (Fed.Cir.2001) ("it is improper to read limitations from the written description into a claim").

FN13. Intervet also argues that Merial's definition is improper because it includes functional language. The court declines to address this argument because it adopts the ordinary and customary meaning of the term vector, as set forth in *Molecular Biology of the Cell*.

Thus, the court rejects both Merial's and Intervet's definitions and instead adopts the ordinary and customary definition of vector as used at the time of the '601 Patent application. Merial submitted to the court the scientific textbook *Molecular Biology of the Cell's* definition of the term vector. The court has no reason to doubt that the definition in this textbook reflects the ordinary and customary definition of vector at the time of the ' 601 Patent application and the parties do not dispute that such a definition existed. Thus, the court adopts the definition in *Molecular Biology of the Cell,* which is "an agent (virus or plasmid) used to transmit genetic material or a cell or organism."

5. Epitope

Intervet construes the term "epitope" as "an immunodominant region having at least 8-9 amino acids of a protein or peptide." Pl.'s Br. 24. Merial construes the term as "an immunodominant region of a protein." Def.'s Br. 30. Thus, Intervet and Merial agree that the term refers to "an immunodominant region," but disagree as to whether the term is limited to immunodominant regions having at least 8-9 amino acids.

Intervet argues that an epitope must have a minimum size because the '601 Patent specification states "at the very least, ... [an epitope is] a peptide having from 8-9 amino acids." '601 Patent, Col. 6, ll. 51-52. Merial rejoins that this description is simply a preferred embodiment and that it is wrong to read such embodiments into the claim. Merial further argues that epitope had an ordinary and customary meaning at the time of the '601 Patent application, and there is no indication that the inventors intended to act as their own lexicographers and depart from the ordinary meaning of epitope. Merial has the better argument.

There simply is no indication that the inventors intended to act as their own lexicographers. Again, to act as their own lexicographers, the inventors must clearly indicate their intent to depart from the term's ordinary and customary meaning. *See, e.g.,* Merck & Co., 395 F.3d at 1370. They did not do so here. Instead, the '601 Patent is ambiguous as to whether the inventors intended to modify the ordinary meaning of epitope by limiting the definition to peptides having at least 8-9 amino acids. Because of this ambiguity, the court refuses to depart from the ordinary and customary meaning of epitope. Accordingly, the court adopts Merial's definition.

6. An Isolated DNA Molecule Comprising a Nucleotide Sequence Encoding an Epitope Which is Specific to PCV-2 and Not Specific to PCV-1

The parties do not seem to agree on what, precisely, is the last term that the court must construe. Intervet

contends that the court must construe Claim 32 of the '601 Patent in its entirety, which is "an isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1." Intervet asserts that this claim refers to "an isolated DNA molecule which codes for at least one epitope found on PCV-2, but not for an epitope found on PCV-1." Pl.'s Br. 26.

Merial rejoins that the court only need construe the latter portion of Claim 32, which is a "nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV1." Merial contends that this latter portion refers to "a DNA sequence which codes for an immunodominant region of a protein, wherein the sequence is from the genome of a PCV-2 circovirus and not from the genome of a PCV-1 circovirus." Def.'s Br. 31. Merial argues that the first portion of Claim 32 merely stands for the proposition that the DNA molecule must include, but is not necessarily limited to, at least one of the DNA sequences described in the latter portion of Claim 32.

The court agrees with Merial's interpretation of Claim 32. To make sure there is no confusion, the court construes Claim 32 in its entirety, but relies on Merial's interpretation of Claim 32. Accordingly, Claim 32 means: "an isolated DNA molecule that includes, but is not necessarily limited to, a DNA sequence which codes for an immunodominant region of a protein, wherein the sequence is from the genome of a PCV-2 circovirus and not from the genome of a PCV-1 circovirus."

The difference between Merial's and Intervet's interpretations of Claim 32 is as follows: Merial contends that the isolated DNA molecule must have a nucleotide sequence that codes for an epitope wherein the epitope-and hence the sequence that codes for the epitope-is unique to PCV-2, but the isolated DNA molecule can also have sequences that code for epitopes that are common between PCV-1 and PCV-2. Intervet contends that the isolated DNA molecule cannot include *any* common nucleotide sequences, even if the isolated DNA molecule also includes a nucleotide sequence that codes for an epitope that is unique to PCV-2. In other words, Intervet and Merial agree that the DNA molecule must include a nucleotide sequence that codes for an epitope found only on PCV-2, but they disagree as to whether the DNA molecule must *only* include such sequences.

Intervet bases its narrow interpretation on the prosecution history of the ' 601 Patent. In a July 5, 2001 Office Action, the Patent Examiner rejected then-pending Claim 91(which is Claim 32 of the '601 Patent) as anticipated by Tischer et al., *A Very Small Porcine Virus with Circular Single-Stranded DNA,* Nature, 1982, at 66-64 ("Tischer"). Pl.'s Ex. B, INT0021982-84. Claim 91 recited "[a]n isolated DNA molecule comprising a nucleotide sequence encoding a PCV-2 epitope." Id. at 21967. The Patent Examiner explained that Tischer anticipated Claim 91 because Tischer disclosed "PCV DNA expressed from PK-15 cells and characterizes the DNA by isolating and characterizing it by transfection experiments." Id. at 21977. That is, the Patent Examiner concluded that Tischer had already identified the nucleotide sequences referenced in Claim 91, and thus Claim 91 was invalid for infringement on prior art. In response, Merial amended Claim 91 by replacing the words "encoding a PCV-2 epitope" with the words "encoding an epitope which is specific to PCV-2." FN14

FN14. Merial amended the claim a second time to add "and not specific to PCV-1" at the end of the claim. Pl.'s Ex. B, INT0022027.

Intervet argues that Merial's amendment was a surrender of any claim to DNA nucleotide sequences that code for epitopes that are not specific to PCV-2. In other words, Intervet argues that Merial avoided any

infringement on Tischer's prior art by not claiming *any* epitopes that appear on PCV-1, even if they also appear on PCV-2. As Intervet notes, it is well established that patentees cannot recapture specific meanings disclaimed during prosecution. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed.Cir.2003).

Intervet's reading of the prosecution history is incorrect. Merial never surrendered any claim to DNA molecules that include nucleotide sequences that code for epitopes that are common to PCV-2 and PCV-1. Instead, Merial surrendered its claim to DNA molecules that *only* include nucleotide sequences that are common to PCV-2 and PCV-1. That is, while Merial's amendment made clear that the DNA molecule must include at least one nucleotide sequence that codes for epitopes "specific" to PCV-2, Merial specified that the DNA molecule only need *comprise* such a sequence. It is a well established axiom of claim construction that the word "comprise" is non-limiting-it is "inclusive or open-ended and does not exclude additional, unrecited elements or method steps." CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1235 (Fed.Cir.2005). By using the word "comprise," Merial's amendment made clear that Merial claimed a DNA molecule that must include at least one sequence that codes for epitopes that are "specific" to PCV-2, but which can also include sequences that code for epitopes common to PCV-1 and PCV-2.

Intervet further argues that the court should find Claim 32 to be indefinite because the term does not explain how to identify epitopes that are "specific to" PCV-1 and PCV-2. The court disagrees. The '601 Patent provides sufficient information to enable individuals skilled in the art to identify such epitopes. The '601 Patent makes clear that epitopes can be identified using known techniques, such as the use of computer program analyses like PEPSCAN. '601 Patent, Col. 6, ll. 39-43. The patent further explains that by comparing the sequences of PCV-2 and PCV-1 someone skilled in the art can determine which epitopes are located on PCV-2 and not on PCV-1. Id. at Col. 6 ll. 36-43.FN15

FN15. Intervet also argues that the term is void for indefiniteness. The court disagrees. A claim is not indefinite merely because it poses a difficult issue of claim construction. *Banco rp* Servs., L .L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed.Cir.2004).

Intervet also argues that because Claim 32 uses the words "specific to," the term must relate to diagnostics because "specific to" would have been understood at the time of the '601 Patent application as referring to the special affinity of an antigen for a corresponding antibody. The court disagrees. "Specific" is not a technical term and there is no indication in the '601 Patent that it has a specialized meaning. Furthermore, the '601 Patent as a whole illustrates that the claimed invention relates to diagnostics *and* vaccines. The title of the '601 Patent specifies that the '601 Patent relates to a "Porcine Circovirus Vaccine and Diagnostics Reagents." Thus, the court refuses to limit the disputed term to diagnostic applications.

III. CONCLUSION

For the forgoing reasons, it is this 28TH day of November 2007, hereby **ORDERED** that the disputed claim terms are construed as follows:

1. PCV-2: The five viral strains identified in the '601 Patent.

2. PCV-1: A non-pathogenic porcine circovirus that can be derived from PK/15 cells.

3. ORFs 1-13: The specific DNA sequences defined as ORFs 1-13 in Example 13.

4. Vector: An agent (virus or plasmid) used to transmit genetic material or a cell or organism.

5. Epitope: An immunodominant region of a protein.

6. An isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1: An isolated DNA molecule that includes, but is not necessarily limited to, a DNA sequence which codes for an immunodominant region of a protein, wherein the sequence is from the genome of a PCV-2 circovirus and not from the genome of a PCV-1 circovirus.

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