UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INTERVET, INC., **Plaintiff,** **v.** **MERIAL LIMITED, et al.,** **Defendants.**	**Civil Action 06-00658 (HHK)**

MEMORANDUM OPINION

By this action, plaintiff Intervet, Inc. ("Intervet") seeks a declaratory judgment that its vaccine does not infringe on 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"). Before the Court is Intervet's motion for summary judgment of noninfringement [#197]. Upon consideration of the motion, the opposition thereto, and the record of this case, the Court concludes that the motion should be granted.

I. BACKGROUND

A. The Patent Process

An inventor seeking to obtain a patent must file a specification of the purported invention with the United States Patent and Trademark Office ("PTO"). 37 C.F.R. § 1.51(b)(1). A specification must include both a written description of the invention and an enablement for a claimed invention that explains the "manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112 para. 1; *see also* 37 C.F.R. § 1.71(a). At the end of the written description and enablement, a proper specification should conclude with

a list of "claims," which identify the specific innovations, components or subparts of the invention, the applicant regards as hers. 35 U.S.C. § 112 para. 2. A claim is a single sentence description of what the applicant believes to be her invention, setting the boundaries of the invention the applicant wishes the PTO to examine. A single claim can be composed of multiple elements and/or limitations. Elements are the previously known physical components that make up the claimed invention. Limitations, on the other hand, usually describe the claim's restrictions. An application may contain several claims, and each claim usually contains several restrictions. It is these claims that define the scope of patent protection. *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002).

After an inventor files her application, the PTO submits the application to an examiner with the necessary technical competence. *In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003). Before issuing a patent, the PTO must find that the claimed invention is sufficiently different from "prior art" that it would not have been obvious at the time of its making to a person having ordinary skill in the relevant art. *See* 35 U.S.C. § 103(a). The patent also must particularly point out and distinctly claim the subject matter which the applicant regards as the invention. 35 U.S.C. § 112. After examining the application, the examiner sends the applicant an "Office action," which may grant or reject the listed claims. 37 C.F.R. § 1.104(a)(2). The applicant may respond by submitting, in writing, a reply that "distinctly and specifically points out the supposed errors in the examiner's action and [replies] to every ground of objection and rejection in the prior Office action." *Id*. § 1.111(b). An applicant may also respond by amending her claims to address the reasons for the examiner's rejections. If and when the examiner and applicant finally cannot agree on the disposition of certain claims, the applicant may appeal the examiner's

decision to a panel of administrative patent judges, and if the panel sustains the rejections, to the Federal Circuit or this Court. 35 U.S.C. §§ 134(a), 141, 145.

B. Factual and Procedural Background

The '601 Patent, held by Merial and at issue in this case, claims certain porcine circoviruses (or PCVs). 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 stated that these five newly discovered porcine circoviruses exhibited extremely strong homology vis-a-vis each other and were responsible for Postweaning Syndrome.[1] In the '601 Patent, the inventors named these five porcine circoviruses "porcine circoviruses of type II" (or "PCV-2") to distinguish them from the previously known porcine circoviruses, which the inventors named "porcine circoviruses of type I" (or "PCV-1"). These new porcine circoviruses can be used to make vaccines to protect against Postweaning Syndrome.

After the '601 Patent application was filed, Intervet began producing a pig vaccine named "Porcine Circovirus Vaccine Type 2" using a porcine circovirus isolate that it named PCV

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

WT2/1.[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.

The '601 Patent contains thirty-five specific claims. Merial alleges that Intervet's vaccine infringes on six of these claims - claims 9, 15, 16, 32, 33 and 35. In 2007, the Court conducted a *Markman* hearing and later construed six terms found in the '601 patent. One of the central issues in that proceeding was how broadly the Court should construe the range of viruses covered by the term "PCV-2." Merial argued that the term "PCV-2" encompassed a broad range of viruses that were homologous to the five strains listed in their patent; Intervet argued that the term "PCV-2" must be construed to include only the five specific strains listed in the '601 Patent. The Court agreed with Intervet. The Court construed the term "PCV-2" to mean "[t]he five viral strains identified in the '601 patent." *Intervet v. Merial*, 2007 WL 5685349, at *12 (D.D.C. November 28, 2007). Of relevance to this motion, the Court also construed the term "ORFs 1-13"[3] to mean "[t]he specific DNA sequences defined as ORFs 1-13 in Example 13 [of the '601 Patent]," and the term "[a]n isolated DNA molecule comprising a nucleotide sequence encoding

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[2] Merial's expert explains that, "[a]lthough the terms 'isolate' and 'strain' are sometimes used interchangeably in the scientific community, the term isolate refers to the result of a particular virus isolation, whereas the term strain is broader. Once a particular viral isolate is characterized and determined to be unique it may be considered representative of a particular strain." Opp'n to Mot. Summ. J. of Noninfringement Dec. Ex. 23 at 11, n. 5.

[3] ORF stands for "open reading frame." An open reading frame is the portion of an organism's genome that contains a sequence of nucleotides that could potentially encode a protein. Nucleotides are the molecules that make up the structural units of DNA.

an epitope which is specific to PCV-2 and not specific to PCV-1"[4] to include "[a]n 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." *Id*. All of these terms will be discussed in greater detail later in this memorandum opinion.

In resolving Intervet's motion for summary judgment of noninfringement, in which Intervet argues that its vaccine does not infringe on the '601 Patent, there are two primary claims at issue – claim 9 and claim 32 of the '601 Patent. Claim 9 claims "A vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13 of porcine circovirus type II." Mot. Summ. J. Infringement Ex. B at INT 0028426.[5] Claim 32 claims "An isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1." *Id*.

II. ANALYSIS

"To support a summary judgment of noninfringement it must be shown that, on the correct claim construction, no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee." *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002). A patent may be infringed both literally and by a substantial equivalent. *See id.* Intervet argues that its vaccine does not literally infringe the '601 Patent and that Merial cannot resort to an argument that Intervet's vaccine

[4] An epitope is an immunodominant region of a protein (i.e., it is the part of the protein that is recognized by the immune system).

[5] All subsequent citations to the exhibits to Intervet's motion for summary judgment on infringement and Merial's response shall be cited to only according to their INT number.

infringes the '601 Patent through substantial equivalence. The Court will address each argument in turn.

A. Intervet's Vaccine Does Not Literally Infringe Claim 9 of the '601 Patent.

"To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused [product]." *Id*. Claim 9 of the '601 patent claims: "A vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13 of porcine circovirus type II." INT 0028426. In its claim construction, the Court defined "PCV-2" (or "porcine circovirus type II") to be "the five viral strains identified in the '601 patent." *Intervet*, 2007 WL 5685349, at *12. The Court defined "ORFs 1-13" to be the "specific DNA sequences defined as ORFs 1-13 in Example 13." *Id*. Therefore, putting together the claim and the Court's prior construction, Intervet's vaccine only literally infringes upon claim 9 of the '601 patent if it:

> contains a vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of the specific DNA sequences defined as ORFs 1-13 in Example 13 of the five viral strains identified in the '601 patent.

See id. Intervet argues that there is no issue of material fact that its vaccine is made using a strain that is different than any of the five strains claimed by the '601 Patent and that it employs a DNA sequence that is different from each of ORFs 1-13.

Merial responds that evidence shows that Intervet's PCV WT2/1 isolate is the same strain as one of the viral strains identified in the '601 patent because the term "strain" includes more than the term "isolate" and because viral isolates do not need to have 100 percent nucleotide sequence identity to be considered the same strain, but need only be highly similar or homologous. Merial states that Intervet's isolate is 99.7 percent identical to the sequence of Imp.

1010, one of the five strains included in its patent. A person of skill in the art would understand that a viral isolate whose sequence is so similar to one or more listed "PCV-2" strains would necessarily be classified as a "PCV-2" strain, according to Merial. Intervet replies that Merial is essentially asking the Court to reinterpret its claim construction and that the Court has already rejected Merial's argument for a broader definition of "PCV-2." Intervet is correct.

The Court has already rejected the argument Merial makes. During the claim construction phase of this litigation, Merial argued that the term PCV-2 refers to a broad group of porcine circoviruses including those with "significant serological similarity," "equivalent sequences" or a "high homology" with the five strains listed. *Id*. at *4. The Court concluded that this argument could not withstand analysis because it was overbroad and failed to provide any guidance as to how to determine whether a porcine circovirus is properly classified as a PCV-2. *Id*. at *5 Instead, the Court limited the definition of PCV-2 to the five viral strains listed in the invention. *Id*. at *6. Merial may not now re-argue that Intervet's vaccine is made with a PCV-2 strain and thus literally infringes on the '601 Patent because Intervet's isolate has equivalent sequences to or is highly homologous with or has significant serological similarity to one of the five PCV-2 strains.

Merial further argues that Intervet's vaccine contains ORF 13 and therefore literally infringes on the '601 Patent. Merial states that Example 13 of the patent defines the sequences encoding ORFs 1-13 not by including any particular DNA sequence, but based on the start and stop nucleotides, the strand ID, the size in nucleotides, and the resulting predicted protein size. The patent examiner, according to Merial, could not have understood the term ORFs 1-13 to require an infringing patent to have 100 percent sequence identity because, if so, the limitation

"of porcine circovirus type II," which the patent examiner insisted that Merial add to claim 9 so that it would not be anticipated by prior art, would not be necessary. Merial contends that a complete ORF analysis demonstrates that the ORF used in Intervet's vaccine has the exact start position, end position and nucleotide length as ORF 13 of Imp. 1010. Intervet replies that the Court defined the term "ORFs 1-13" to mean the specific DNA sequences defined as ORFs 1-13 in the '601 Patent, and that Merial's argument reads the specific sequences portion out of the Court's construction. Intervet is correct.

The Court's claim construction defines "ORFs 1-13" as "[t]he *specific DNA sequences* defined as ORFs 1-13 in Example 13." *Id*. at *12 (emphasis added). Merial is correct that Example 13 only describes ORFs 1-13 according to their start and end positions, strand ID, size in nucleotides, and anticipated protein size. Example 13, however, also states that the positions of the start and end of each ORF refer to the sequence presented in figure 4. Figure 4 contains the precise DNA sequence of one of the five listed strains and thus Example 13, while it does not include the specific DNA sequence of each ORF, refers to a figure from which those specific DNA sequences can be determined. Given this, the Court declines to read the language "specific DNA sequence" out of its claim construction, and therefore concludes that Intervet's vaccine does not contain one of ORFs 1-13.

Accordingly, the Court concludes that Intervet's vaccine does not literally infringe claim 9 of the '601 patent. Because claims 15 and 16 are dependent on claim 9, the Court concludes that Intervet's vaccine also does not literally infringe on these claims.

B. Intervet's Vaccine Does Not Literally Infringe Claim 32 of the '601 Patent.

Claim 32 of the '601 patent claims "[a]n isolated DNA molecule comprising a nucleotide

sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1." INT 0028426. The Court construed this claim to mean "[a]n 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 [the five viral strains identified in the '601 patent] and not from the genome of a [non-pathogenic porcine circovirus that can be derived from PK/15 cells]." *Intervet*, 2007 WL 5685349, at *12. In coming to this construction, the Court explained that "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." *Id*. at *10. The Court agreed with Merial, writing that "the DNA molecule must include at least one nucleotide sequence that encodes for epitopes 'specific' to PCV-2, [but that] the DNA molecule only need *comprise* such a sequence," i.e. the DNA molecule "must include at least one sequence that codes for epitopes that are 'specific' to PCV-2, but [it] can also include sequences that code for epitopes common to PCV-1 and PCV-2." *Id*. at *11.

Intervet argues that the Court's construction made clear that the DNA molecule must include a nucleotide sequence that codes for an epitope *found only* on a "PCV-2" and that because Intervet's DNA is not one of the five strains defined as "PCV-2," any epitope that Intervet's PCV WT2/1 isolate may encode cannot possibly be an epitope *found only* on a "PCV-2" virus. Intervet further argues that its DNA is not "from the genome of a PCV-2 circovirus" in that it is not derived from a "PCV-2" circovirus. Merial responds that the Court's construction did not require that an infringing sequence be derived from (i.e., created from) a "PCV-2" circovirus and that it is clear from the Court's memorandum that it only meant that the infringing

DNA sequence had to be *present in* one of the PCV-2 strains. Merial asserts that there are several DNA sequences within the DNA molecule used to make Intervet's vaccine that encode an epitope that are identical to those of the PCV-2 strains detailed in the '601 patent, but are not identical to any sequences in a PCV-1.

The essential difference between Intervet's and Merial's arguments is that Intervet argues that the infringing DNA sequence must encode an epitope *found only* on one of the five strains listed in the '601 patent, while Merial argues that the infringing DNA sequence must encode an epitope *found* on one of the five strains and not on a PCV-1 circovirus. The Court concludes that Intervet has the better argument. It is clear from the Court's claim construction that the infringing sequence must be "unique to" or "specific to" or "found only on" a "PCV-2" circovirus (i.e., one of the five strains listed in the '601 patent). *Id*. at *10-11. Merial's only citation supporting an interpretation that the infringing sequence must simply be located or found on a "PCV-2" strain is a cite to the portion of the Court's memorandum in which the Court explains that someone skilled in the art can determine which epitopes are located on a "PCV-2" circovirus. *See id*. at *11. The Court concludes that in order to infringe claim 32 of the '601 patent, the infringing product must include at least one DNA sequence encoding an epitope that is *found only* on one of the five "PCV-2" strains. Because Intervet's vaccine contains an isolate from a non-"PCV-2" circovirus, any DNA sequence encoding an epitope that it contains cannot be *found only* on one of the "PCV-2" strains.

Accordingly, the Court concludes that Intervet's vaccine does not literally infringe claim 32 of the '601 patent. Because claims 33 and 35 are dependent on claim 32, the Court concludes that Intervet's vaccine also does not literally infringe these claims.

C. Merial May Not Invoke the Doctrine of Equivalents.

"The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002) ("*Festo VIII*"). This doctrine is termed the doctrine of equivalents. It is limited by prosecution history estoppel, which is the rule that "[w]hen the patentee responds to the rejection [of a claim] by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent" under the doctrine of equivalents. *Id*. at 727.

Intervet argues that Merial cannot rely on the doctrine of equivalents because Merial is estopped from doing so based on the narrowing amendments it made while prosecuting the '601 Patent and because Merial cannot rebut the presumption that through its narrowing amendment Merial abandoned any argument that Intervet's vaccine is equivalent. Merial rejoins that in narrowing its claims it did not surrender the territory encompassing equivalents like Intervet's vaccine and that, even if it did, Merial can rebut the presumption of surrender. The Court concludes that Merial did surrender the territory encompassing Intervet's vaccine and that it cannot rebut the presumption of surrender.

The Court of Appeals for the Federal Circuit explained the steps a court should follow in determining whether a patent holder is estopped from employing the doctrine of equivalents because of a narrowing amendment it made during the prosecution of its patent. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) ("*Festo IX*"). The court must ask three questions to determine whether the patentee surrendered the territory encompassing the alleged equivalent. If so, there is a presumption of estoppel. The

court must then determine whether the patent holder may rebut this presumption. If so, she may employ the doctrine of equivalents; if not, she may not.

The first of the three questions the court must ask to determine if there is a presumption of estoppel is "whether an amendment filed in the Patent and Trademark Office . . . has narrowed the literal scope of the claim." *Id*. at 1366. If so, the second question is "whether the reason for the amendment was a substantial one relating to patentability." *Id*. If so, the third question is whether "the scope of the subject matter surrendered by the narrowing amendment" encompasses the alleged equivalent. *Id*. at 1367. The presumption is "that the patentee has surrendered all territory between the original claim and the amended claim limitation." *Id*.

In order to answer the first three questions with respect to each claim, it is necessary to understand the narrowing amendments made during the patent prosecution proceedings. With respect to claim 9, Merial originally claimed "[a] vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13." INT0021544. The patent examiner rejected this claim as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention" and as obvious in view of prior art. INT0021962-64. In response, Merial amended its claim to claim "[a] vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13 *of porcine circovirus type II*." INT 0021967 (emphasis added). The Court has construed the term porcine circovirus type II to mean "[t]he five viral strains identified in the '601 patent." *Intervet*, 2007 WL 5685349, at *12.

The first question, whether the amendment has narrowed the literal scope of the claim, is easily answered in the affirmative. The initial version of the claim claimed vectors comprising

isolated DNA molecules comprising sequences selected from ORFs 1-13 of *any organism*, while the amended version covered vectors comprising isolated DNA molecules comprising sequences selected from ORFs 1-13 of *the five viral strains identified in the '601 patent.* Therefore, the amendment narrowed the literal scope of the claim. The second question, whether the amendment was for a substantial reason related to patentability, is also easily answered in the affirmative. The Supreme Court has held that where an amendment was made in response to an objection of indefiniteness or prior art, that amendment was made for a substantial reason related to patentability. *See Festo VIII*, 535 U.S. at 736-37.

With respect to the third question, whether the scope of the subject matter surrendered by the narrowing amendment encompasses the alleged equivalent, Merial argues that it does not. Merial contends that its narrowing amendment merely clarified that its invention did not encompass vectors made from PCV-1 and can only amount to a surrender of the territory encompassing PCV-1. A person of skill in art, according to Merial, would understand that the patentees, by adding the words "porcine circovirus type II" did not surrender territory encompassing those porcine circoviruses that are greater than 96 percent homologous to the five listed "PCV-2" strains. To hold otherwise would mean that the doctrine of equivalents could not extend beyond the exact sequences of the representative isolates, a conclusion Merial argues the Supreme Court rejected in *Festo VIII*. Intervet replies that Merial again improperly attempts to reargue the Court's construction of "PCV-2," and that its argument is premised on a construction of the term that is at odds with the Court's construction. Intervet is correct.

"A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo*

VIII, 535 U.S. at 740. Here, the territory between vectors comprising isolated DNA molecules comprising sequences selected from ORFs 1-13 of *any organism* and vectors comprising isolated DNA molecules comprising sequences selected from ORFs 1-13 of *the five viral strains identified in the '601 patent* includes Intervet's PCV WT2/1 isolate. As described in Part A, Intervet's vaccine is not a vector that comprises a sequence selected from ORFs 1-13 of the five viral strains identified in the '601 patent. Therefore, the Court determines that Merial surrendered the territory encompassing Intervet's isolate and that the presumption of prosecution history estoppel applies

The analysis of the first three questions with respect to claim 32 is virtually identical to that for claim 9. Claim 32 as originally filed claimed "[a]n isolated DNA molecule comprising a nucleotide sequence encoding a PCV-2 epitope." INT0021967. The patent examiner rejected this claim as anticipated by prior art. INT0021977. Merial responded by amending claim 32 to claim "[a]n isolated DNA molecule comprising a nucleotide sequence encoding an epitope *which is specific to PCV-2*." INT0021987 (emphasis added). The examiner again rejected the claim as anticipated by prior art. INT0021994-95. Merial further amended claim 32 to claim "[a]n isolated DNA molecule comprising a nucleotide sequence encoding an epitope *which is specific to PCV-2 and not specific to PCV-1*." INT0022027 (emphasis added).

The Court concludes that Merial narrowed the literal scope of claim 32 for a reason substantially related to patentability. Further, the Court concludes that Intervet's product falls within the surrendered territory because it falls between comprising an isolated DNA molecule comprising a nucleotide sequence encoding an epitope *found on* one of the five viral strains listed in the '601 patent and comprising an isolated DNA molecule comprising a nucleotide sequence

encoding an epitope that is *specific to* or *found only on* one of the five viral strains listed in the '601 patent as discussed in Part B. Therefore, the Court determines that the presumption of prosecution history estoppel also applies with respect to claim 32.

The Court now turns to the question of whether Merial has rebutted the presumption of estoppel with respect to claims 9 and 32. The *Festo* presumption that equivalents are surrendered "may be rebutted if a patentee shows that 'one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalents.'" *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1312 (Fed. Cir. 2006) (citing *Festo VIII*, 535 U.S. at 741). "The burden of rebutting the *Festo* presumption lies with the patentee." *Id*. There are three ways in which a patentee may overcome the presumption. Specifically, the patentee must demonstrate (1) "that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment," (2) "that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question," or (3) "that there was 'some other reason' suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent." *Festo IX*, 344 F.3d at 1368 (quoting *Festo VIII*, 535 U.S. at 740-41).

The first criterion, unforeseeability, presents an objective inquiry, asking "whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment," and by its very nature "depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment." *Id*. at 1369. The second criterion, tangential relation, "focuses on the patentee's objectively apparent reason for the narrowing amendment," which

reason "should be discernible from the prosecution history record." *Id*. Finally, the third criterion, "while vague, must be a narrow one" and "may be satisfied where there was some reason, such as the shortcomings of language, why the patentee was prevented from describing the alleged equivalent when it narrowed the claim." *Id*. at 1370. The determination of this criterion, like the second, "should also be limited to the prosecution history record" when possible. *Id*. Merial argues that all three of these criteria apply. The Court will address each of the three criterion in turn.

Merial argues that the first criterion, unforeseeability, applies, because although it was certainly foreseeable at the time of the amendments at issue that the strains set forth were representative of a new type of PCV, the particular DNA sequence of the genome of each member of the new type of PCV, including the one used by Intervet, was not foreseeable to a person of skill in the art at the time of the amendment. Merial argues that it is permissible to claim a group of biological specimens by setting forth a representative number of members of the claimed group. Further, Merial contends that the PCV WT2/1 isolate used by Intervet was not known in the prior art at the time of the amendment. Intervet responds that the accused equivalent does not have to have been known in the prior art in order for it not to be foreseeable. Moreover, Intervet argues, porcine circoviruses similar to the five "PCV-2s" claimed by Merial were known at the time of the narrowing amendments and even recognized in the '601 patent. Because Merial discussed other porcine circoviruses similar to the five "PCV-2s" but did not claim them, Merial cannot now argue that such other porcine circoviruses were unforeseeable, according to Intervet. The Court agrees with Intervet.

The '601 patent refers to "any porcine circovirus capable of being isolated . . . from a

diseased pig having the PMWS syndrome." INT0028413. Therefore, Merial "admittedly knew" that there were other porcine circoviruses of the same type as the five strains listed in the '601 patent at the time of the narrowing amendment. *See Amgen*, 457 F.3d at 1313. Merial appears to argue that it was not objectively foreseeable that the Court's construction of the term "PCV-2" would not include Intervet's PCV WT2/1 isolate, but this is not the relevant inquiry. *See id.* at 1313. The question is whether Intervet's PCV WT2/1 isolate was a foreseeable equivalent, not whether the particular DNA sequence of the PCV WT2/1 isolate was known at the time of the narrowing amendment. Where the alleged equivalent is foreseeable, the burden falls to the patentee to literally claim it. *See Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) ("[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] foreseeable alteration of its claimed structure."); *see also Johnson & Johnston Assoc. Inc.*, 285 F.3d at 1057 (Rader, J., concurring) ("A foreseeability bar thus places a premium on claim drafting and enhances the notice function of claims. . . . In other words, the patentee has an obligation to draft claims that capture all reasonably foreseeable ways to practice the invention.").

Here, Merial clearly foresaw other PCV isolates that were highly homologous to or with great serological similarity to the five listed strains, and so it cannot now argue that such isolates were unforeseeable. *See* INT 0028413. Moreover, Merial cites to no evidence that Intervet's PCV WT2/1 isolate was unforeseeable at the time of the narrowing amendment. *See* Opp'n to Mot. Summ. J. Infringement at 37; *see also Amgen*, 457 F.3d at 1312 (holding that the burden is on the patentee to demonstrate that the alleged equivalent was unforeseeable); *Festo IX*, 344 F.3d

at 1369 (holding that resolution of the foreseeability criterion depends on the underlying facts). Accordingly, the Court concludes that Merial cannot rebut the *Festo* presumption under the foreseeability criterion.

Merial argues that the second criterion, tangential relation, applies because the amendments at issue were not made to avoid prior art that contains the alleged equivalent, but were rather made to clarify that the scope of the invention did not encompass the previously known PCV-1. Intervet replies that when a claim is amended to overcome prior art rejection, the equivalent in question need not fall within the distinguished prior art to be directly relevant, and that in this case the narrowing amendments were directly relevant to the alleged equivalent because the alleged equivalent relates to the same parameter as the amendment. Intervet is correct.

As discussed above, both claims 9 and 32 were subject to narrowing amendments. Claim 9 originally claimed: "A vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13." INT0021544. The patent examiner rejected this claim under 35 U.S.C. § 112 as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *See* INT0021962. She wrote, "[t]he claims are drawn to DNA and vectors that comprise 'ORF's 1-13.' The ORFs are assumed to be derived from porcine circovirus, but as written, could encompass ORFs from any organism." *Id.* The patent examiner also rejected claim 9 under 35 U.S.C. § 103(a) "as being unpatentable over Meehan et al." INT0021963. The patent examiner explained:

The claims are drawn to a vector comprising an isolated DNA comprising ORFs

> 1-13, 4, and 7. Meehan et al. teaches the ORFs limitations in these claims, see above. The reference does not teach these ORFs in a vector. However, one of ordinary skill in the art at the time the invention was made would have been motivated to put these ORFs in an expression vector in order to perform functional recombinant assays.

INT0021963. The patentees subsequently amended claim 9 to read: "A vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1 to 13 *of porcine circovirus type II*." *See* INT0021967 (emphasis added). The examiner withdrew her objection and allowed the claim to go forward. INT0021978.

Claim 32 originally claimed "[a]n isolated DNA molecule comprising a nucleotide sequence encoding a PCV-2 epitope." INT0021967. The patent examiner rejected this claim under 25 U.S.C. § 102(b) as anticipated by prior art. She explained that "[t]he claims are drawn to an isolated nucleic acid encoding a PCV-2 epitope. Tischer et al. isolates PCV DNA expressed from PK-15 cells and characterizes the DNA by isolating and characterizing it by transfection experiments." INT 0021977. The patentees subsequently amended claim 32 to claim "[a]n isolated DNA molecule comprising a nucleotide sequence encoding *an epitope which is specific to PCV-2*." INT0021987 (emphasis added). The patent examiner again rejected this claim, stating that "the isolated PCV nucleic acid sequence of Tischer et al. is anticipatory since 44 and 42 nucleotides, respectively, share 100% sequence identity with that which is instantly taught." INT0021994. The patentees amended the claim again to claim "[a]n isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 *and not specific to PCV-1*." INT 0022027 (emphasis added). The patent examiner allowed this claim. *See* INT0022027.

The Supreme Court explained that the tangential criterion allows "claims of equivalence

for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted" to proceed. *Festo VIII*, 535 U.S. at 738. The "inquiry into whether a patentee can rebut the *Festo* presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment." *Festo IX*, 344 F.3d at 1369. This criterion is "very narrow." *Cross Med. Prods. Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007).

Merial argues that the tangential criterion applies because the amendments at issue were not made to avoid prior art that contains the alleged equivalent, but were rather made to clarify that the scope of the invention did not encompass the previously known PCV-1. Merial "misunderstands the scope of the inquiry into the relationship between the narrowing amendment and the accused equivalent." *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005). An amendment made to avoid prior art that contains the equivalent is certainly not tangential; "[i]t does not follow, however, that equivalents not within the prior art must be tangential to the amendment." *Id*. Instead, the focus of the Court's inquiry is on whether the reason for the narrowing amendment regards a different *aspect* or *characteristic* of the invention. *See Festo VIII*, 535 U.S. at 738 ("Nor is there any call to foreclose claims of equivalence for *aspects* of the invention that have only a peripheral relation to the reason the amendment was submitted.") (emphasis added). *Compare Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005) (explaining that the court found the tangential criterion met in another case because "the reason for the amendment and the alleged equivalent involved different *aspects* of the invention – the location of the vacuum source relative to the resin versus the number of vacuum cups.") (emphasis added) *with id.* at 1306 (explaining that the tangential

relation criterion did not apply in this case despite the fact that the accused equivalent did not fall within prior art because "the reason for the amendment and the accused equivalent in the case before us both relate to the concentration of the fertilizer.").

Here, while Intervet's PCV WT2/1 isolate may not have fallen within the prior art distinguished through Merial's amendments to claims 9 and 32, the reason for the amendment and the alleged equivalent related to the same aspect of the invention. In the case of claim 9, that aspect is the organisms from which ORFs 1-13 could be derived. The original version of claim 9 claimed vectors comprising an isolated DNA molecule comprising a sequence selected from a group consisting of ORFs 1-13, while the amended version limited the claim to ORFs 1-13 "of porcine circovirus type II." *See* INT0021962 (patent examiner statement that "[t]he claims are drawn to DNA and vectors that comprise 'ORF's 1-13.' The ORFs are assume to be derived from porcine circovirus, but as written, the claims could encompass ORFs from any organism."). Thus, both the narrowing amendment and the accused equivalent relate to the organism from which ORFs 1-13 can be derived.

In the case of claim 32, that aspect was the organisms on which the epitope could be found. The original version of claim 32 claimed an isolated molecule comprising a nucleotide sequence encoding a PCV-2 epitope, while the amended version limited the claim to epitopes that are "specific to PCV-2 and not specific to PCV-1." Thus, both the reason for the narrowing amendment and the accused equivalent relate to the range of organisms on which the epitope could be found. Accordingly, the Court concludes that Merial cannot rebut the *Festo* presumption under the tangential relation criterion.

Merial argues that the third criterion, allowing rebuttal where there was some other

reason suggesting that the patentee could not reasonably have been expected to have described the accused equivalent, applies because of shortcomings of language. Merial argues that the new type of PCV claimed in the '601 patent was unknown prior to the patentee's invention and so there was no existing language to describe it; instead, the patentees used the term "representative" to describe the specific strains detailed in the patent. Intervet replies that the vocabulary necessary to claim particular DNA sequences has existed for decades. Further, according to Intervet, Merial's consistent use of terms such as "homologous to" and "cross hybridize with" are contrary to Merial's assertion that there was a shortcoming of language. The Court agrees with Intervet.

The third criterion requires a patentee to establish "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo VIII*, 535 U.S. at 741. The Federal Circuit has held that "[t]his category, while vague, must be a narrow one." *Festo IX*, 344 F.3d at 1370. One of the reasons that a patentee might not reasonably be expected to have described the substitute is because of "shortcomings of language." *Id*. The fact that a person of skill in the art may have thought the patentee's claims encompassed the substitute, however, "does not excuse the patentee's failure to claim the equivalent." *Amgen*, 457 F.3d at 1316.

Here, Merial primarily relies on the Federal Circuit's decision in *Boehringer Ingelheim Vetmedica v. Shering-Plough Corp.*, 320 F.3d 1339 (Fed Cir. 2003) to argue that it did everything that the Federal Circuit has said a patentee should do to claim a type of virus. But *Boehringer* regarded claim construction, not whether there was a shortcoming of language to rebut the *Festo* presumption. *See id*. The Court has already construed Merial's claims and

Boehringer simply does not speak to the issue here. Merial further argues that "it is evident that the language that the inventors used was sufficient to convey to those of skill in the art that the term PCV-2 refers to a new type of virus, and not just certain representative strains." Opp'n to Mot. Summ J. Infringement at 42. This is precisely the argument that was rejected in *Amgen*. *See Amgen*, 457 F.3d at 1316 ("Contrary to Amgen's argument, whether the patentee, the examiner, or a person of skill in the art may have thought the claims encompassed EPO with 165 amino acids does not excuse the patentee's failure to claim the equivalent."). The Court concludes that Merial has failed to carry its burden of demonstrating that shortcomings of language prevented it from describing the substitute in question.

Therefore, the Court concludes that Merial has failed to demonstrate that any of the three criterion for rebutting the *Festo* presumption apply and that Merial cannot argue that the accused vaccine is equivalent to its patented product.[6] Accordingly, the Court grants summary judgment to Intervet that Intervet's vaccine does not infringe on the '601 patent.

III. CONCLUSION

For the foregoing reasons, the Court concludes that Intervet's motion for summary judgment of noninfringement should be granted. An appropriate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge

[6] Because the Court concludes that Merial is estopped from invoking the doctrine of equivalents due to the narrowing amendments it made while prosecuting the patent, it does not reach Intervet's alternative argument that Merial is precluded from invoking the doctrine of equivalents because of the disclosure-disclaimer rule.