Trials@uspto.gov
571-272-7822

Paper 13
Entered: January 22, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERIAL LIMITED,
Petitioner,

v.

VIRBAC,
Patent Owner.

Case IPR2014-01279
Patent 8,501,799 B2

Before FRED E. McKELVEY, JAMES T. MOORE, and LINDA M. GAUDETTE, *Administrative Patent Judges*.

McKELVEY, *Administrative Patent Judges*.

DECISION
Denying Institution of Inter Partes Review
37 C.F.R. § 42.108

I. INTRODUCTION

Merial Limited ("Merial") filed an original Petition (Paper 1) to institute an *inter partes* review trial of claims 1–15 (all the claims) of U.S. Patent No. 8,501,799 B2 ("the '799 patent"; Ex. 1001). 35 U.S.C. §§ 311–319; 37 C.F.R. § 42.104.

Thereafter, with permission of the Board (Paper 6), Merial timely filed a revised Petition ("Pet."; Paper 8) replacing the original Petition.

We consider the revised Petition.

Virbac ("Patent Owner") timely filed a Preliminary Response. (Paper 10). 35 U.S.C. § 313; 37 C.F.R. §42.107(a).

Thereafter, with the permission of the Board, Virbac timely filed a Supplemental Preliminary Response (Paper 12).

We have considered the Preliminary Response and the Supplemental Preliminary Response.

We have been delegated authority by the Director to determine whether to institute an *inter partes* review trial. 37 C.F.R. § 42.4.

For the reasons to be discussed, Petitioner has not established a reasonable likelihood of prevailing on its challenge of claims 1–15 of the '799 patent. Accordingly, we do not institute *inter partes* review of any claim.

II. BACKGROUND

A. The '799 patent

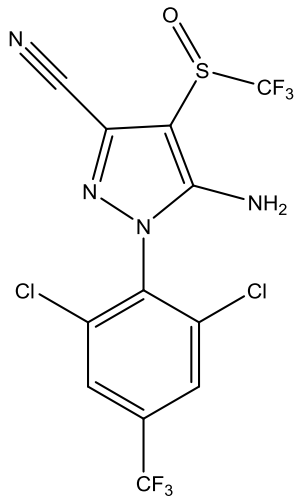
The '799 patent relates to antiparasitic pharmaceutical compositions said to be useful for treating flea infestation on pets, particularly dogs and cats. Ex. 1001, 3:36–37, 3:55.

Independent claim 1 reads:

> A liquid pharmaceutical composition, comprising:
>
> [1] as active principle, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(trifluoromethylsulfinyl)-1H-pyrazole-3 carbonitrile (fipronil),
>
> [2] at least 5% (weight/volume) of benzyl alcohol and
>
> [3] at least 50% (weight/volume) of an organic solvent chosen from
>
> [a] propylene glycol monomethyl ether,
> [b] dipropylene glycol n-butyl ether,
> [c] ethylene glycol monomethyl ether,
> [d] ethylene glycol monoethyl ether,
> [e] diethylene glycol monomethyl ether and
> [f] propylene glycol, and
> [g] mixtures thereof,
>
> [4] it being understood that said composition is free of C_1-C_4 alcohol.

Ex. 1001, 11:16–27 (lettering and numbering in brackets and indentation added).

The compound 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(trifluoromethylsulfinyl)-1H-pyrazole-3 carbonitrile, also known as fipronil, has the following structure:



Paper 7, 2.

B. Prior Art and Asserted Grounds

Merial relies on the following evidence (listed in order by Exhibit Number):

Reference Name	Exhibit Number	Reference Citation	Date
Huet et al. "Huet '333"	Ex. 1005A	US 6,426,333 B1	July 30, 2002
Bonneau et al. "Bonneau"	Ex. 1014A	*Comparative Efficacy of Two Fipronil Spot-on Formulations Against Experimental Flea Infestations (Ctenocephalides felis) in Dogs*, 8(1) INTERN. J. APPL. RES. VET. MED. 16-20	2010
Saito et al. "Saito '125"	Ex. 1015A	US 2004/0254125 A1	Dec. 16, 2004
Sirinyan et al. "Sirinyan WO '541"	Ex. 1017A	WO 2008/080541 A1	July 10, 2008
Sirinyan et al. "Sirinyan '387"	Ex. 1018A	US 2009/031287 A1	Dec. 17, 2009
Etchegaray "Etchegaray '765"	Ex. 1019A	US 6,395,765 B1	May 28, 2002

Reference Name	Exhibit Number	Reference Citation	Date
Etchegaray et al. "Etchegaray '724"	Ex. 1020A	US 6,797,724 B2	Sept. 28, 2004

Huet '333, Saito '125, Etchegaray '765, and Etchegaray '724 are prior art under 35 U.S.C. § 102(b).

Sirinyan WO '541 is prior art under 35 U.S.C. § 102(a).

Bonneau is not prior art having been published after the filing date of the application which matured into the involved '799 patent.

Sirinyan '387 is not prior art because (1) a PCT application on which it is based was not published in English and (2) the § 371 filing date is after the filing date of the application which matured into the '799 patent.

Merial seeks cancellation of claims 1–15 on the following grounds.

Ground (1): unpatentability under 35 U.S.C. § 103 over Huet '333 in view of Saito '125 alone, or further in view of Bonneau. Pet. 20.

Ground (2): unpatentability under 35 U.S.C. § 103 over Huet '333 alone, or in view of Sirinyan WO '541 alone or further in view of Bonneau. Pet. 35.

Ground (3): unpatentability under 35 U.S.C. § 103 over Etchegaray '765 in view of Etchegaray '724 and Bonneau alone or further in view Saito '125. Pet. 48.

III. ANALYSIS

A. Preliminary Matters

1. Bonneau

As noted above, Bonneau is not prior art.

Bonneau is relied upon by Merial in support of all three grounds in an attempt to establish facts associated with results of experimental testing said to be reported by Bonneau.

Experimental work described by Bonneau is not admissible at this stage to prove the truth of the experimental work. 37 C.F.R. § 42.62(a); Fed. R. Evid. 802.

To get around any hearsay consideration, Merial relies on Bonneau as evidence of an *admission* on the part of Virbac that there is no practical difference between two spot-on formulations: (1) Effipro® Spot-on (said to be a Virbac product) and (2) Frontline® Top spot (said to be a Merial product). Pet. 48 (next to last line); Fed. R. Evid. 801(d)(2).

Even assuming that one of the authors of Bonneau (Stéphane Bonneau) is an employee of Virbac authorized to make admissions on behalf of Virbac, we nevertheless decline to give any weight to Bonneau.

According to Bonneau, "[b]oth Effipro® Spot-on and Frontline® Top spot are 10% w/v fipronil-based spot-on solutions but some of their vehicles are different." Ex. 1014, 20 (col. 1, first full paragraph).

We have not been directed to or found in Bonneau any description of the precise ingredient make-up of the two spot-on solutions said to have been tested.

Therefore, we are unable to determine the precise differences between the solutions tested and we are in no position to know on this record exactly what has been admitted by Virbac.

Accordingly, we decline to give Bonneau any weight.

2. Translation Issue

When Merial filed its original Petition, it did not include a certified translation of Sirinyan WO ’541 (Ex. 1017A).

Instead Merial relied on an “equivalent” patent document, *viz.*, Sirinyan ’387 (Ex. 1018A).

Virbac called attention to the fact that the “equivalent” does not comply with the requirement for a translation. 37 C.F.R. § 42.63(b).

During a conference call, Merial maintained that because Sirinyan WO ’541 is based on a PCT application, a translation was not required, and that Sirinyan ’387 should suffice.

The Board disagreed and called attention to *Stevens v. Tamai*, 366 F.3d 1325 (Fed. Cir. 2004), involving a similar situation under similar translation requirements of the interference rules (37 C.F.R. § 41.154(b)).

As a result, Merial agreed to submit a certified translation and that translation was timely filed as Ex. 1021A.

Lack of a certified translation is no longer an issue.

Sirinyan ’387 and the certified translation appear to the same.

Sirinyan ’387 has paragraph numbers and the certified translation lacks paragraph numbers; to the extent necessary we will refer to Sirinyan ’387.

3. Multiple Grounds

Virbac accurately points out that with respect to each of Grounds (1) through (3), Merial has included more than one basis in support of the ground.

For example, in presenting Ground (1) Merial argues that Claim 1 is unpatentable under 35 U.S.C. § 103 over Huet ’333 in view of Saito ’125 alone, or further in view of Bonneau. Pet. 20.

At least two rationales are cited: (1) a combination of Huet '333 and Saito '125 and (2) a combination of Huet '333, Saito '125, and Bonneau.

Alternative phraseology such as that set out in Grounds (1) through (3), has been discouraged. *See In re Herrick*, 344 F.2d 713, 716 (CCPA 1965) (combining multiple references using "and/or" create geometrically expanding number of rejections that are difficult to address individually).

Accordingly, we will consider each of Grounds (1) through (3) solely on the basis of *all* evidence cited and decline to consider "grounds" involving less than all the evidence cited.

If a case of obviousness cannot be made out on the basis of all the evidence, it follows that the case cannot be made out on less than all the evidence.

4. Unexpected Results

In its Preliminary Response, Virbac relies on data set out in the '799 patent as evidence of unexpected results.

However, to the extent that Virbac relies on the data to establish facts to prove unexpected results, the data at this stage is hearsay. Fed. R. Evid. 802.

The content of the '799 patent may be relied upon to establish what is described in the patent, but it may not in this *inter partes* proceeding be relied upon to establish the truth of what is described.

5. Virbac's Argument that Merial's Arguments are Similar to Examiner's Rationale Initially Rejecting Claims

Virbac maintains that a trial should not be instituted because Merial's arguments in support of unpatentability are essentially the same as the Examiner's rationale in rejecting, and subsequently allowing, claims.

Accordingly, Virbac maintains that Merial should not be allowed to reargue matters previously considered by the Examiner. 35 U.S.C. § 325(d).

The statute gives the Director discretion to take into account whether, and reject a petition because, the same or substantially the same prior art or arguments previously were presented to the Office. *Id*.

Examination of an application takes place in an ex parte environment. *Glaxo Wellcome Inc. v. Cabilly*, 56 USPQ2d 1983, 1984 (BPAI 2000) (the Board is not bound in an *inter partes* case by an ex parte decision of a patent examiner); *Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. 274, 279 (1877) (patents are procured ex parte and the public is not bound by decision of the Patent Office to issue the patent); *see also Sze v. Bloch*, 458 F.2d 137, 140 (CCPA 1972) (holding during ex parte examination cannot be binding in a subsequent *inter partes* case involving application in which holding was made); *Swengel v. Burkig*, 455 F.2d 577, 579 (CCPA 1972) (same); *Switzer v. Sockman*, 333 F.2d 935, 940–41 (CCPA 1964) (same)); *Turchan v. Bailey Meter Co.*, 167 F. Supp. 58, 63–64 (D. Del. 1958) (same).

There are different burdens in an *inter partes* review proceedings vis-à-vis ex parte examination.

For example, an examiner is free to accept showings described in a specification as sufficient to establish an unexpected result even if Rule 132 testimony is not presented.

In an *inter partes* review, the Federal Rules of Evidence apply and unexpected results must be proved via testimony subject to cross-examination.

If an *inter partes* review trial is instituted, a patent owner would have an opportunity to present testimony establishing any unexpected result said to be shown by experiments described in the specification.

In this case, we believe the better course is to evaluate Merial's Petition on the merits as to Grounds (1) and (2).

However, as to Ground (3), and for reasons hereinafter given, we take into account, and deny the Petition, because we find that the same or substantially the same prior art was previously presented to, and considered by, the Office during ex parte examination of the application which matured into the '799 patent.

B. Claim Construction

The Petition proposes interpretation of numerous claimed limitations. Pet. 4–20.

However, there is only one claim phrase which we believe requires consideration for purposes of this decision, *viz.*: "it being understood that said composition is free of C_1-C_4 alcohol."

According to Merial, the phrase is "Nonsense and Does NOT Limit the '799 Patent Claims." Pet. 12.

We disagree.

Limitations in claims should be interpreted in light of the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (the meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art at the time of the invention after read in light of the entire patent).

We have to determine how one skilled in the art would have interpreted the limitation in question as of the applicable filing date, *viz.*, December 16, 2008.

The invention involves pharmaceutical fipronil-containing compositions said to be useful in treatment of and prevention from flea infestations on pets. Ex. 1001A, 3:15–20.

The inventor (Guy Derrieu) was not the first to invent the use of fipronil for treatment of pets. The '799 patent explains:

> fipronil is often difficult to formulate and may lead to crystallization. In order to overcome this problem, it has already been proposed, especially in patent application EP 0 881 881, to formulate N-phenylpyrazole derivatives [fipronil being an N-phenylpyrazole derivative] in solvent medium in the presence of a crystallization inhibitor and a C_1-C_4 alcohol. The product Frontline® Spot-On Chat et Chien, sold in France by the company Merial SAS is [said to be] based on this technology.

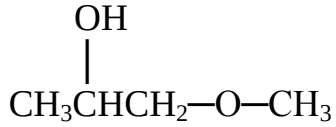
Id. at 2:60–67.

In the *broadest* sense a "C_1-C_4 alcohol" could be any alcohol having 1 to 4 carbon atoms and at least one hydroxyl group, i.e., a ─OH group. Ex. 1013A, 30 (*see* Alcohol, I. Monohydric, 1. Aliphatic, (a) paraffinic (ethanol)).

However, Merial suggests that the "C_1-C_4 alcohol" limitation in claim 1 is meaningless. Why? Some of the glycols set out in part [3] of claim 1, as reproduced above, have 3 or 4 carbon atoms and at least 1 ─OH group.

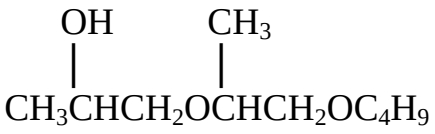
The structural formulas of the glycols set out in part [3][a-f] of claim 1 are set out below.

The major isomer of propylene glycol monomethyl ether has 4 carbon atoms, 1 ─OH group, and the formula:



Ex. 1003A (Pate Declaration) ¶ 7.1; Ex. 1007, 1.

Dipropylene glycol n-butyl ether has 10 carbon atoms, 1 ─OH group and the formula:



Ex. 1003A (Pate Declaration), ¶ 7.2; Ex. 1008A, 1.

Ethylene glycol monomethyl ether has 3 carbon atoms, 1 ─OH group and has the formula:

$HOCH_2CH_2OCH_3$

Ex. 1003A (Pate Declaration), ¶ 7.3; Ex. 1009A, 3 (6038)

Ethylene glycol monoethyl ether has 4 carbon atoms, 1 ─OH group and the formula:

$HOCH_2CH_2OCH_2CH_3$

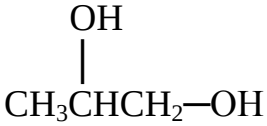
Ex. 1003A (Pate Declaration), ¶ 7.4; Ex. 1010A, 3 (3750).

Diethylene glycol monomethyl ether has 5 carbon atoms, 1 ─OH group and the formula:

$HOCH_2CH_2OCH_2CH_2OCH_3$

Ex. 1003A (Pate Declaration), ¶ 7.5; Ex. 1011A, 3 (1800).

Propylene glycol has 3 carbon atoms, 2 ─OH groups and the formula:



Ex. 1003A (Pate Declaration), ¶ 7.6; Ex. 1012A, 3 (7855).

The phrase "C_1-C_4 alcohol" is not defined *per se* in the written description portion of the specification of the '799 patent.

According to Merial, a "C_1-C_4 alcohol" is a compound having 1 to 4 carbon atoms and at least 1 ─OH group.

Because some of the above-identified "glycols" have 3 or 4 carbon atoms and at least 1 ─OH group, Merial reasons that they fall within the scope of the prohibited "C_1-C_4 alcohol" and therefore the "C_1-C_4 alcohol" limitation cannot have any significant meaning (i.e., is "nonsense" to use Merial's language).

As a result, Merial maintains that "C_1-C_4 alcohol" cannot be a limitation in claim 1 of the '799 patent.

To quote *Reserve Life Ins. Co. v. United States*, 640 F.2d 368, 374 (Ct.Cl. 1981), to the extent that one might initially view the Merial "argument . . . [as] superficially plausible, it does not withstand penetrating analysis."

Binding precedent establishes that all the limitations of a claim must be considered and given weight in evaluation of obviousness under § 103, *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 546 (Fed. Cir. 1994), including claims in proceedings in the USPTO, *In re Gardner*, 449 Fed. Appx. 914, 916 (Fed. Cir. 2011) (nonprecedential).

Hence, we cannot agree with Merial that the limitation is "nonsense," or that it should not be considered.

Rather, the question becomes: What weight should be given to the limitation "C_1-C_4 alcohol" in the context of the '799 patent?

As noted earlier, the specification discusses "C_1-C_4 alcohol" in connection with a discussion of a prior art reference: EP 0 881 881 patent application. Ex. 1001A, 2:60–67.

We find it curious that neither Merial nor Virbac made the EP patent application of record as an exhibit given its mention in the '799 patent in connection with a discussion of the "C1-C4 alcohol".

We elect to take official notice of the patent application because its accuracy is immediately capable of verification given that it is a public record of the European Patent Office. 37 C.F.R. § 42.62(c) ("judicial notice" means "official notice"); Fed. R. Evid. 201(b). *Cf. VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1312–13 (Fed. Cir. 2014) (judicial notice taken of motion to amend filed in a covered business method patent review pending before the Board).

The EP 0 881 881 patent application is made of record as Ex. 3001.

It will be noted that, for the most part, the EP 0 881 881 patent application is written in French.

However, the claims are set out in French, English, and German.

EP 0 811 811 describes a fipronil composition having a co-solvent, the co-solvent being described as including methanol (1 carbon and 1 ─OH), absolute ethanol (2 carbons and 1 ─OH), and isopropanol (3 carbons and 1 ─OH) alcohols. Ex. 3001, 13 (element (d)), 18 (claim 18—"cosolvent d) is selected from among the group consisting of absolute ethanol, isopropanol, methanol.").

Given the reference in the '799 patent to EP 0 881 881, and the representation in the '799 patent that the formulations of EP 0 881 881 have a C_1-C_4 alcohol, one skilled in the art would have a reasonable basis for inferring that the methanol, absolute ethanol, and isopropanol referred to in EP 0 881 881 are the kind of C_1-C_4 alcohols referred to in the '799 patent.

The fact that some of the required glycols mentioned in part [3] of claim 1 also have 3 or 4 carbon atoms as well as at least one ─OH does not mean that those glycols constitute a "C_1-C_4 alcohol" within the meaning of claim 1.

If it were otherwise, one skilled in the art would view claim 1 as not including glycols having 3 or 4 carbon atoms when the claim plainly requires a glycol—some which have 3 to 4 carbon atoms.

Merial's proposed construction of claim 1 is at odds with the plain language of the claim.

In our view, and for the purpose of determining whether to institute a trial, claim 1 has two requirements relating to "alcohols", viz.:

> (1) a glycol within the scope of limitation [3] of claim 1, as reproduced above, must be present in the claimed composition, and
>
> (2) the claimed composition cannot include *at least* methanol, absolute ethanol, or isopropanol.

We need not decide whether any other "C_1-C_4 alcohol" is excluded from the scope of claim 1. As will become apparent, the issue relating to obviousness is whether one skilled in the art would have had a reason to eliminate methanol, ethanol, or isopropanol from compositions described in the prior art references relied upon by Merial.

C. Ground (1)

Merial maintains that claims 1–15 are unpatentable under 35 U.S.C. § 103 over Huet '333 in view of Saito '125 alone, or further in view of Bonneau. Pet. (Paper 8), p. 20.

For reasons already given, we limit our consideration to the rationale based on the combined teachings of (1) Huet '333, (2) Saito '125, and (3) Bonneau (although, as discussed above, we decline to give any weight to Bonneau).

Huet '333 describes a pharmaceutical composition comprising:

> (A) an effective amount of active ingredient which may be fipronil;
>
> (B) an effective amount of a macrocyclic lactone anti-helmintic or antiparasitic agent;
>
> (C) a pharmaceutical or veterinary liquid carrier vehicle; and

(D) optionally a crystallization inhibitor.

Ex. 1005A, 4:4–11.

The liquid carrier vehicle is described as follows:

> (2) the liquid carrier vehicle comprises a solvent and a cosolvent wherein
>
> [1] the solvent is selected from the group consisting of acetone, acetonitrile, *benzyl alcohol*, butyl diglycol, dimethylacetamide, dimethylformamide, *dipropylene glycol n-butyl ether, ethanol, isopropanol, methanol, ethylene glycol monoethyl ether, ethylene glycol monomethyl ether,* monomethylacetamide, dipropylene glycol monomethyl ether, liquid polyoxyethylene glycols, *propylene glycol*, 2 pyrrolidone, in particular N-methylpyrrolidone, *diethylene glycol monomethyl ether*, ethylene glycol, diethyl phthalate fatty acid esters, such as the diethyl ester or diisobutyl adipate, and a mixture of at least two of these solvents and
>
> [2] the cosolvent is selected from the group consisting of *absolute ethanol, isopropanol or methanol*.

Ex. 1005A, 6:5–21 (indentation, spacing, matter in italics, and bracketed material added).

From the above description, one skilled in the art would have recognized that the "solvent" component of the Huet '333 liquid carrier could include one or more of: (1) benzyl alcohol; (2) the glycols in part [3][a-f] of challenged claim 1; (3) methanol, ethanol, and isopropanol; and (4) other listed solvents.

The crystallization inhibitor may be benzyl alcohol. Ex. 1005A, 6:26.

A difference between the subject matter of claim 1 of the '799 patent and Huet '333 is that claim 1 excludes the presence of methanol, ethanol,

and isopropanol, whereas Huet '333 requires a co-solvent selected from the group consisting of methanol, ethanol, or isopropanol.

In order to overcome this difference, Merial turns to Saito '125 (Ex. 1015A).

Saito '125 describes compositions useful for treating fleas. Ex. 1015A ¶ 3.

Fipronil may be included in the composition. Ex. 1015A ¶ 17.

The compositions may be dissolved in a suitable solvent.

> Further, another desirable administration form is a method where preparations are dissolved in a solvent and administered directly to a local site. As for such a solvent, the use of an alcohol such as *ethanol*, *isopropanol*, oleyl alcohol or *benzyl alcohol*; a carboxylic acid such as lauric acid or oleic acid; an ester such as ethyl lactate, isopropyl myristate or propylene carbonate; a sulfoxide such as dimethylsulfoxide; or an amide such as N-methylpyrrolidone, which are known to heighten percutaneous absorptivity, individually or as mixed solvent thereof, is preferable.

Ex. 1015A ¶ 70 (italics added).

The "solvent" discussion of Saito '125 is similar to the "solvent" discussion in Huet '333 (Ex. 1005A 6:5–18).

For example, both Saito '125 and Huet '333 mention as suitable solvents short-chain alcohols (*e.g.*, ethanol), benzyl alcohol, and N-methylpyrrolidone.

The discussions are not similar in that Saito '125 does not mention glycols.

In a light most favorable to Merial, Saito '125 can be said to teach that ethanol and benzyl alcohol may be equivalents "to heighten percutaneous absorptivity." Ex. 1015A ¶ 70.

However, Huet '333 requires both a solvent and a co-solvent.

It is not at all apparent that Saito '125 is discussing co-solvents in the sense that "co-solvents" are discussed by Huet '333.

In this respect, Huet '333 teaches:

> The organic cosolvent for the liquid carrier vehicle will preferably have a boiling point of less than about 100° C., preferably of less than about 80° C., and will have a dielectric constant of between about 10 and about 40, preferably between about 20 and about 30; this cosolvent can advantageously be present in the composition according to a weight/weight (W/W) ratio with respect to the solvent of between about 1/15 and about 1/2; the cosolvent is volatile in order to act in particular as drying promoter and is miscible with water and/or with the solvent. Again, it is well within the skill level of the practitioner to select a suitable solvent on the basis of these parameters.

Ex. 1005A, 10:53–64.

The boiling point of benzyl alcohol is 204.7 ºC at 760 mm Hg (*i.e.*, atmospheric pressure—the pressure at which the Huet '333 and Saito '125 compositions would be used). Ex. 1007A, 186 (1124).

The boiling points of methanol (~ 65ºC) ethanol (~ 78.5 ºC), isopropanol (~ 82.4ºC) are instantly verifiable and are below the <100ºC mentioned by Huet '333. HANDBOOK OF CHEMISTRY AND PHYSICS, CRC Press, 62nd ed., C-290, C-374, C-478 (1981) (Ex. 3002).

Moreover, the Saito '125 solvent is described as being present in the composition "to heighten percutaneous absorptivity" (Ex. 1015A ¶ 70).

whereas the Huet ’333 co-solvent is described as being present “as [a] drying promoter” (Ex. 1005A, 10:61).

Given the different purposes for which the Saito ’125 solvent and the Huet ’333 co-solvent are used, the evidence does not support a finding that benzyl alcohol and ethanol (or methanol or isopropanol) would be “equivalents” insofar as the co-solvent of Huet ’333 is concerned.

The teaching of Saito ’125 does not provide a satisfactory underpinning to support a rationale that one skilled in the art would have considered benzyl alcohol a suitable substitute for methanol, ethanol, or isopropanol as the co-solvent in a Huet ’333 composition. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

We have not overlooked Merial’s reliance of Bonneau.

However, for reasons set out above, we decline to give Bonneau any weight.

For the reasons given, we hold that Merial has not established that there is a reasonable likelihood it would prevail in showing claim 1 of the ’799 patent would have been unpatentable over the combined teachings of Huet ’333, Saito ’125, and Bonneau.

Because dependent claims 2–15 of the ’799 patent are narrower than independent claim 1 of the ’799 patent, it follows that Merial has not established that there is a reasonable likelihood of success in showing unpatentability with respect to any of claims 2–15.

An *inter partes* review trial will not be instituted on the basis of Ground (1).

D. Ground (2)

Merial maintains that claims 1–15 are unpatentable under 35 U.S.C. § 103 over Huet '333 in view of Sirinyan WO '541 alone, or further in view of Bonneau. Pet. 40.

For reasons already given, we limit our consideration to the rationale based on a combination of the teachings of (1) Huet '333 (Ex. 1005A), (2) Sirinyan WO '541 (Ex. 1017A), and (3) Bonneau (Ex. 1014A).

The scope and content of Huet '333 has been described earlier in this opinion.

The difference between '799 patent claim 1 and Huet '333 likewise has been described earlier in this opinion.

With respect to Ground (2), and to overcome the difference between '799 patent claim 1 and Huet '333, Merial turns to Sirinyan WO '541 (Ex. 1017A). Pet. 39.

As explained above, we refer to the corresponding English language U.S. Patent Application Publication (Sirinyan '387; Ex. 1018A) to discuss the scope and content of Sirinyan WO '541.

Sirinyan '387 describes compositions for controlling parasites on animals comprising:

(1) an N-phenylpyrazole;

(2) an aliphatic cyclic carbonate; and

(3) an aliphatic cyclic or acyclic polyether.

Ex. 1018A ¶¶ 5–7.

The N-phenylpyrazole can be fipronil. Ex. 1018A ¶ 59 (7, col. 1, third formula).

The acyclic polyethers include diethylene glycol monoethyl ether—element [3][f] of claim 1 of the '799 patent, as reproduced above.
Ex. 1018A ¶ 71.

Diethylene glycol monoethyl ether is also known as DGME.

From Merial's point of view, the significant teaching of Sirinyan '387 is that a flea-treating composition can be made with fipronil and DGME without any need for a methanol, ethanol, or isopropanol "co-solvent."

Thus, Merial reasons that it would have been obvious to make a Huet '333 composition without a "C_1-C_4 alcohol." Pet. 36–37.

We disagree.

An ingredient required to be present in a Huet '333 composition is an effective amount of a macrocyclic lactone antihelmintic or antiparasitic agent. Ex. 1005A, 4:7-8.

An ingredient required to be present in a Sirinyan '387 composition is an aliphatic cyclic carbonate. Ex. 1018A ¶ 6.

It is true that claim 1 of the '799 patent relates to a composition "comprising" various listed ingredients.

Hence, the scope of the claim is open to the inclusion of other ingredients, *e.g.*, an aliphatic cyclic carbonate.

To meet all the limitations of claim 1 using a combination of Huet '333 and Sirinyan '387, one skilled in the art would have needed a reason to make a composition without a C_1-C_4 alcohol, but including

(1) fipronil,

(2) the macrocyclic lactone antihelmintic or antiparasitic agent of Huet '333,

(3) the aliphatic cyclic carbonate of Sirinyan ’387, as well as

(4) benzyl alcohol in the claimed amounts and

(5) DGME in the claimed amounts.

Merial has not identified persuasive evidence that would have provided a reason for eliminating the “C_1-C_4 alcohol” from Huet ’333.

Moreover, there are unanswered factual matters which make the proposed combination of Sirinyan ’387 and Huet ’333 questionable.

Huet ’333 describes a composition which is said to dry without crystallizing. Ex. 1005A, 4:23. The “C_1-C_4 alcohol” is said to play a significant role in drying without crystallization. Ex. 1005A, 10:61.

We have not been told why one skilled in the art would have expected a combination of ingredients disclosed in Huet ’333 and Sirinyan ’387, absent a C_1-C_4 alcohol, to lead to a composition which would dry without crystallization.

Merial’s witness, Dr. Pate, nowhere explains what one skilled in the art would have expected based on combining the aliphatic cyclic carbonate of Sirinyan ’387 into the Huet ’333 composition, *e.g.*, possible adverse interactions between the macrocyclic lactone antihelmintic or antiparasitic agent of Huet ’333 and the aliphatic cyclic carbonate of Sirinyan ’387.

On the whole, we find that Dr. Pate’s testimony is similar to that of Dr. Anderson in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (expert witness Dr. Anderson simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of the claimed compound would have been obvious).

For the reasons given, we determine that Merial has not shown a reasonable likelihood that it would prevail in showing the unpatentability of claim 1 of '799 patent based on the combined teachings of Huet '333, Sirinyan WO '541, and Bonneau.

Because dependent claims 2–15 of the '799 patent are narrower than independent claim 1 of the '799 patent, it follows that Merial has not established that there is a reasonable likelihood of success with respect to claims 2–15.

An *inter partes* review trial will not be instituted on the basis of Ground (2).

E. Ground (3)

Merial maintains that claims 1–15 are unpatentable under 35 U.S.C. § 103 over (1) Etchegaray '765 in view of (2) Etchegaray '724 and (3) Bonneau alone or further in view (4) Saito '125. Pet. 48.

For reasons already given, we limit our consideration to the rationale based on a combination of the teachings of (1) Etchegaray '765, (2) Etchegaray '724, (3) Bonneau, and (4) Saito '125.

By way of background, during prosecution of the application (US 13/132,996) that matured into the '799 patent, the Examiner entered a rejection of all claims as being unpatentable under 35 U.S.C. § 103 over the combination of (1) Etchegaray '765 and (2) Etchegaray '724. Ex. 1002A, 194.

Merial relies in large measure on the Examiner's rationale in support Ground (3). Pet. 50 ("Petitioner [Merial] adopts the Examiner's logic and . . . [rationale] at pages 5-12 of the September 14, 2012 Office Action in the

prosecution history of the '799 patent (Exhibit 1002A.000188)"). Page 188 of Ex. 1002A is the first page of the Office Action; the Examiner's rationale in support of the rejection appears at Ex. 1002A, pages 194 through 200.

In an AMENDMENT UNDER 37 C.F.R. § 111, Virbac responded to the rejection. Ex. 1002A, 160–169.

In support of its response, Virbac relied on comparative testing set out in the specification. Ex. 1002A, 167 ("[C]omparative Examples 2, 3 and 4 show an . . . unexpected improvement of efficiency on flea infestation prevention of [a] a composition according to the present invention compared to the well known commercial product Frontline®" and "[r]esults presented in Examples 2, 3, and 4 demonstrate that composition A show[s] a substantially longer efficiency against flea infection than Frontline® in dogs and cats.").

Upon consideration of the response, the Examiner held that the "response is found persuasive and the rejection [based on Etchegaray '765 and Etchegaray '724] is hereby withdrawn." Ex. 1002A, 17.

In reaching a decision to allow, the Examiner stated:

> The composition of Etchegaray ['765] is not anticipatory, nor does it render obvious a composition of the instant application for the following reasons:

Instant Composition A (page 10)[1]		Frontline® by Merial
-fipronil	10g	-fipronil 10% (w/v)
-benzyl alcohol	30g	-ethanol
-butylhydroxyanisole	0.02g	-butylhydroxyanisole (BHA)
-butylhydroxytoluene	0.02g	-butylhydroxy[toluene] (BHT)[2]
-diethylene glycol monoethyl ether	100 ml	-ethyl[ene]dig[ly]col
		-polyvidone K17
		-polysorbate 80

> [Virbac] . . . has clearly shown, in a side-by-side comparison, that instant composition A acts more quickly and remains effective for a longer time compared to the commercial product Frontline[®] Spot-on when applied to dogs (0.067 mL per kg body weight, Table I, page 13 [Ex. 1002A, 13-14], Table II, page 17 [Ex. 1002A, 313], and to cats (Table III, page[s] 21-22 [Ex 1002A, 317–318] infested with fleas.
>
> Such an improved and prolonged antiparasitic activity in the treatment and protection of pets is noteworthy and unexpected versus that of the reference commercial product Frontline[®].

Ex. 1002A, 18.

Merial accepts the Examiner's rationale to the extent that the rationale is favorable to Merial, but does not convincingly address that part of the

---

1 Ex. 1002A, 306.

2 While the Examiner refers to butylhydroxyanisole, it is believed that the Examiner meant to refer to butylhydroxytoluene given the Examiner's use of the acronym "BHT".

Examiner's allowance rationale favorable to Virbac found in the prosecution record as part of Ex. 1002A.

Because we do not assume the role of counsel for either party, we decline to undertake an independent analysis of the experimental data found persuasive by the Examiner.

We do not have the benefit of input by Merial in the form of testimony discussing counter-testing of the data set out in the specification.

Had Merial presented an argument and evidence addressing unexpected results (apart from relying on Bonneau) in the Petition, Virbac could have responded and commented on that argument and evidence in its Preliminary Response.

Our procedure and rules are to be interpreted, to secure a just, speedy, and inexpensive resolution of a proceeding. 37 C.F.R. § 42.1(b).

In submitting the Petition, Merial had an opportunity to address the Examiner's rationale in support of allowance of claims in the application maturing into the '799 patent.

Merial elected not to address the Examiner's allowance rationale.

Failure on the part of Merial to address the Examiner's allowance rationale in the Petition leads to the following unacceptable result.

If we were to accept the Examiner's rationale in support of a prima facie case of obviousness without considering unexpected results, then Virbac could present—and probably would have presented—evidence and testimony in support of unexpected results evidence with its Patent Owner's Response. 37 C.F.R. § 42.120(a). At this stage, however, Virbac was not free to do so. 37 C.F.R. § 42.107(c).

Merial then could present, and probably would have presented with its Reply, counter-unexpected results evidence. 37 C.F.R. § 42.23(b).

What becomes apparent is that Virbac would then have no right to file a sur-reply to address Merial's reply evidence.

On the other hand, if in its Petition Merial had submitted testimony and evidence in support of "no unexpected results" including an analysis of the Examiner rationale, and had a trial been instituted, Virbac would have been able to submit with its Patent Owner's Reply both (1) evidence and testimony opposing Merial's "no expected result" rationale as well as (2) evidence supporting unexpected results.

Merial's reply would then have been limited to addressing any evidence of unexpected results submitted by Virbac with its Patent Owner's Response.

In this case, we believe it unfair to impose on Virbac in the first instance the burden of establishing unexpected results in a trial. Merial was aware of the unexpected results showing which the Examiner found persuasive in showing nonobviousness in view of substantially the same prior art combination Merial now relies upon. Merial should have addressed unexpected results in the first instance.

The patentability of claims 1–15 over the combined teachings of Etchegaray '765 and Etchegaray '724 was considered and resolved by the Examiner.

We have not overlooked the fact that in addition to the Etchegaray patents, Merial now additionally relies on Saito '125 and Bonneau.

We decline to give any weight to Bonneau for reasons previously set out in this opinion.

As in the case of Ground (1), we find that Saito '125 adds nothing significant in support of unpatentability under § 103.

The teaching of so-called equivalence of ethanol, isopropanol, and benzyl alcohol (Ex. 1015A ¶ 70) of Saito '125 is nothing more than a confirmation of what is taught by Etchegaray '765 with respect to its "solvent c)." Ex. 1019A, 4:52–62.

As in the case of Huet '333, Saito '125 does not provide a suitable rationale in support of not using the C_1-C_4 alcohols (methanol, ethanol, and isopropanol) described by Etchegaray '765 (Ex. 1019A, 4:56). *KSR*, 550 U.S. at 418.

The combination of teachings of (1) Etchegaray '765 and (2) Etchegaray '724 relied upon by the Examiner is, in the language of 35 U.S.C. § 325(d), "substantially the same prior art" as a combination of teachings of (1) Etchegaray '765, (2) Etchegaray '724, (3) Saito '125, and (4) Bonneau.

For the reasons given, we decline to institute an *inter partes* review trial on the basis of Ground (3).

F. Other Observations

Merial has characterized certain arguments made by Virbac before the Examiner as "clearly false" (Pet. 49) or as "misleading" (*id.* at 50–51).

We have treated the characterizations of those arguments as having been "erroneous" as opposed to "false" or "misleading." 37 C.F.R. § 41.1(c); *Argyropoulos v. Swarup*, 56 USPQ2d 1795, 1812 (BPAI 2000).

IV. DECISION

For the reasons given, we decline to institute an *inter partes* review trial and, therefore, the Revised Petition is *denied*.

For PETITIONER:

Judy Jarecki-Black
John Ezcurra
MERIAL LIMITED
judy.jarecki@merial.com
john.ezcurra@merial.com

Thomas J. Kowalski
Mark W. Russell
VEDDER PRICE PC
tkowalski@vedderprice.com
mrussell@vedderprice.com

For PATENT OWNER:

Nicolas E. Seckel
Scott D. Daniels
Michael J. Caridi
WESTERMAN, HATTORI, DANIELS & ADRIAN LLP
nseckel@whda.com
sdaniels@whda.com
mcaridi@whda.com