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Paper 10
Entered: September 27, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00449
Patent 9,763,876 B2

Before ZHENYU YANG, JON B. TORNQUIST, and
JAMIE T. WISZ, *Administrative Patent Judges.*

TORNQUIST, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing of
Decision Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Aquestive Therapeutics, Inc. ("Petitioner") requests rehearing of the Board's Decision (Paper 7, "Dec. on Inst.") denying institution of an *inter partes* review (Paper 8, "Request for Rehearing" or "Req. Reh'g"). For the reasons set forth below, Petitioner's Request for Rehearing is *denied*.

II. STANDARD FOR REHEARING

Pursuant to 37 C.F.R. § 42.71(d):

> A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion exists where a "decision [i]s based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988).

III. ANALYSIS

In our Decision, we found Petitioner did not demonstrate a reasonable likelihood of prevailing with respect to its obviousness ground based on Cartt '865 and Ueda (claims 8–10, 15, and 30–33), because this ground "relies on a perceived lack of criticality in the choice of ranges for ethanol and benzyl alcohol" that is unsupported by the record. Dec. on Inst. 21. In its Request for Rehearing, Petitioner contends we overlooked that the Petition asserts an additional obviousness rationale with respect to at least

claim 8 that does not rely on a perceived lack of criticality in the choice of ranges for ethanol and benzyl alcohol. Req. Reh'g 4–11.

We agree that in addressing Petitioner's arguments related to a lack of criticality in the recited ranges, we did not address Petitioner's specific arguments regarding the combination of Cartt '865 and Ueda for at least claim 8. Thus, we provide an analysis of that proposed combination below.

Alleged Obviousness of Claim 8 over Cartt '865 and Ueda

Petitioner contends the subject matter of claim 8 would have been obvious over the combined disclosures of Cartt '865 and Ueda. Paper 2, 61–63 ("Pet.").

1. Cartt '865

Cartt '865 discloses pharmaceutical compositions for nasal administration comprising a benzodiazepine drug, one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95%, and one or more alcohols or glycols, or any combinations thereof, in an amount from about 5% to about 70%, preferably about 10% to about 70%. Ex. 1010 ¶ 10.

In some embodiments, the one or more alcohols used in Cartt '865 "are selected from the group consisting of: ethanol, propyl alcohol, butyl alcohol, pentanol, benzyl alcohol, and isomers thereof, or any combinations thereof." *Id.* ¶ 13. Cartt '865 does not disclose, however, a specific example or embodiment utilizing ethanol and benzyl alcohol in combination.

2. Ueda

Ueda discloses "a preparation for topical application intended for the treatment of acne." Ex. 1019, 1:4–5. This composition contains (1) "Compound [I]," which possesses inhibitory activity against hormones of

the male type, (2) a keratolytic agent, and (3) a pharmaceutically acceptable carrier. *Id.* at 1:41–56.

Ueda instructs that "a gelling agent and/or alcohol are preferably used as carriers," as "[a] gelling agent and an alcohol improves poor solubility being so far regarded as the defect of the Compound [I] from the standpoint of processing it into preparations." *Id.* at 3:27–32. Acceptable alcohols for use as a carrier include monohydric alcohols and polyhydric alcohols, such as ethanol, benzyl alcohol, and polyethylene glycol. *Id.* at 3:55–4:11. Ueda explains that "[a]mong others, ethanol and benzyl alcohol are frequently used, and these alcohols, making up for low solubility of the Compound [I], function to increase absorption and penetration of the composition of the present invention." *Id.* at 3:65–4:1.

Ueda contains one unnumbered Table, which is reproduced below:

TABLE

Formulation Examples

Unit: g

Ingredient	Formulation 1	2	3	4	5	6	7	8
Oxendolone	0.2	0.5	0.2	2.0	1.5	1.0	0.2	2.0
Benzyl alcohol	5.0	10.0	5.0	10.0	5.0	10.0	5.0	10.0
Ethanol	20.0	25.0	20.0	37.0	35.0	30.0	40.0	37.0
Polyethylene glycol PEG-300				10.0		10.0		10.0
Polyethylene glycol PEG-600	15.0	20.0	15.0					
1,3-Butanediol					20.0	5.0	20.0	
Carboxyvinyl polymer Carbopol 940	0.8	0.6	0.2	1.0	0.8	1.0	0.8	1.0
Hydroxypropylcellulose					0.2		0.2	
Polyvinyl alcohol				0.1				0.1
Hyaluronic acid	0.1	0.1	0.2					
Polyoxyethylene hydrogenated castor oil, Nikkol HCO-60				2.0	2.0	2.0	2.0	2.0
Urea	1.0	1.0	3.0	1.0				1.0
Resorcinol					2.0			1.0
Salicylic acid						0.5		
Benzoyl peroxide							15.0	
Triethanolamine	0.2	0.2	0.1					
Diisopropanolamine				0.2	0.2	0.2	0.2	0.2
Purified water	57.7	42.6	56.3	36.7	33.3	40.3	16.6	35.7

The Table of Ueda shows the composition of eight example formulations, with formulation 1 containing 5% benzyl alcohol and 20% ethanol and

formulation 2 containing 10% benzyl alcohol and 25% ethanol. *Id.* at Table. Formulations 1 and 2 also include, *inter alia*, a polyhydric alcohol in the form of polyethylene glycol (PEG-600) and a carboxyvinyl polymer (Carbopol 940) that acts as a gelling agent. *Id.* at Table, 3:33–45.

3. Analysis

Petitioner contends Ueda's disclosures that benzyl alcohol and ethanol are frequently used together to make up for the low solubility of compound [I], and "to increase absorption and penetration" of compound [I], are "relevant and useful to a [person of ordinary skill in the art] with respect to the use of ethanol/benzyl alcohol to increase intranasal absorption and penetration of a drug." Pet. 61 (citing Ex. 1041 ¶ 322) ("Thus, Ueda teaches the combination of ethanol/benzyl alcohol as useful for solubilizing a low solubility drug and also for increasing its absorption/penetration."). And because Ueda discloses examples containing 20% ethanol and 5% benzyl alcohol (formulation 1) and 25% ethanol and 10% benzyl alcohol (formulation 2) that fall within the ranges recited in claim 8, Petitioner contends the combination of Cartt '865 and Ueda renders obvious the amounts of benzyl alcohol and ethanol recited in claims 8–10 and 30–31. *Id.* at 62.

We are not persuaded by Petitioner's arguments. Ueda's example formulations utilize other compounds that serve to increase the solubility of compound [I], including 0.8% or 0.6% carboxyvinyl polymer (Carbopol 940) and 15% or 20% polyethlyene glycol (PEG-600) (formulations 1 and 2, respectively). *See* Ex. 1019, Table (disclosing the use of both carboxyvinyl polymer and polyethylene glycol in Formulations 1 and 2), 3:29–30 (noting that a gelling agent and an alcohol improve poor

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