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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANGELIQUEO E. PADILLA and GEORGE A. BAKLAYAN

Appeal 2019-000150
Application 14/082,662
Technology Center 1600

Before ULRIKE W. JENKS, ELIZABETH A. LAVIER, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellant¹ requests rehearing of the Decision entered March 13, 2020. Appellant raises several points “believed to have been misapprehended or overlooked by the Board.” Req. Reh’g 1. As explained below, Appellant has not persuasively shown that the Board overlooked or misapprehended the matters alleged. Accordingly, we do not modify the Decision.

Appellant contends that the Decision “misapprehends or overlooks the fact” that there is no teaching “of any actual storage stable solution specifically including each of polyquaternium-1, bromfenac, water, and non-ionic surfactants such as poloxamers and polyethoxylated castor oil in

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies Beiersdorf AG as the real party in interest. Appeal Br. 3.

Desai.” *Id.* at 1. This argument is not persuasive. As explained in the Decision, “Desai teaches aqueous pharmaceutical compositions comprising all of the ingredients recited in [Appellant’s] claim 1.” Decision 5 (citing FF1–FF2). The fact that Desai also teaches formulations comprising other acidic drugs, both with and without the recited non-ionic surfactants, “does not render any particular formulation any less obvious.” *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

Appellant urges that “Desai only discloses bromfenac as a possible active agent, and the noted surfactants as optional components that each might or might not be used.” Req. Reh’g 2. We disagree. Desai teaches “storage-stable preserved ophthalmic compositions containing acidic drugs in combination with polymeric quaternary ammonium compounds’ such as polyquaternium-1.” Decision 3 (quoting Desai, Abstr., 2:49–50). Indeed, Desai specifically identifies bromfenac as one of approximately 10 such acidic drugs and teaches that all of them are “suitable” for stabilization by formulation with polyquaternium-1. Desai, 3:7-18. Desai further teaches that certain of the recited non-ionic surfactants (e.g., poloxamers and polyethoxylated castor oil) “may additionally” be included in these formulations. *Id.* Thus, we agree with Examiner that Desai, in fact, teaches compositions comprising all of the ingredients recited in claim 1.

Appellant argues that our reliance on *In re Dillion*, 919 F.2d 688 (Fed. Cir. 1990) is misplaced because “Examiner has not provided any reason or motivation to make any selection of specific surfactants from the mere possibilities of various optional components disclosed in Desai and Sawa.” Req. Reh’g 2. Again, we are not persuaded because Desai teaches formulations comprising all of the claimed ingredients. Moreover, Sawa

additionally teaches bromfenac in combination with various of the non-ionic surfactants recited in Appellant's claims. Decision 4 (FF4). We agree with Examiner that it would have been obvious to use such surfactants in Desai's compositions because Sawa teaches that their "combination with bromfenac is considered to be old and well known." *Id.* at 5 (quoting Final 4); *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). Thus, the record is sufficient to establish a prima facie case of unpatentability based on the structural similarity between the prior art and Appellant's claims. *Id.* at 6.

Appellant further argues that the Decision overlooked or misapprehended various points related to its unexpected results evidence. *See* Req. Reh'g 3–5. First, Appellant contends that it was not required to demonstrate unexpected results as compared to the formulations taught in Desai because "there is no actual composition disclosed in Desai which comprises all of the ingredients of claim 1, and in particular no actual composition comprising bromfenac [sic]." *Id.* at 3. As explained above, we disagree with the premise of Appellant's argument because Desai teaches compositions comprising all of the ingredients of claim 1. Thus, contrary to Appellant's assertion, the Decision does not suggest that Appellant must demonstrate unexpected results as compared to a "non-existing, theoretical composition." *Id.* at 3. Rather, we agreed with Examiner (*see* Ans. 8) that Appellant had not demonstrated unexpected results as compared to those formulations in Desai comprising bromfenac, polyquaternium-1, water, and a non-ionic surfactant such as a poloxamer. Decision 7.

Appellant next asserts that the Board’s determination that Appellant had “not shown that the difference in the percentage of bromfenac remaining after one month is a difference in ‘kind and not merely in degree’ . . . should be designated as a new grounds of rejection first stated in the Decision.”

Req. Reh’g 4, 6. We are not persuaded. As our reviewing court has explained:

When considering whether the PTAB issued a new ground of rejection, the ultimate criterion of whether a rejection is considered new in a decision by the PTAB is whether applicants have had fair opportunity to react to the thrust of the rejection. The PTAB is not limited to reciting and agreeing with the examiner’s rejection *in haec verba*; indeed, it may further explain the examiner’s rejection and thoroughly respond to an applicant’s argument.

Knowles Electronics LLC v. Iancu, 886 F.3d 1369, 1376–77 (Fed. Cir. 2018) (internal quotations omitted).

Appellant, here, had a fair opportunity to respond to the rejection and present unexpected results evidence to attempt to overcome Examiner’s prima facie showing. Moreover, it was Appellant’s burden to establish that any such results “are unexpected and significant.” MPEP § 716.02(b)(I). Appellant, however, did not present “sufficient evidence to show that the differences observed in the data here would have been beyond the capability of a skilled artisan such that they are more than mere differences in degree.” Decision 8. That observation is not a new ground of rejection, but simply a more thorough explanation of Examiner’s determination that Appellant’s unexpected results evidence was unpersuasive.

Appellant additionally contends that “a ‘difference in degree’ of 7%” is “a difference in kind as it represents losing 100% more bromfenac (i.e.,

losing twice the amount of bromfenac).” Reh’g Req. 4. That argument, like those in Appellant’s prior briefing, is “unsupported attorney argument” and not persuasive. *See* Decision 8 (citing *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)).

Finally, Appellant urges that the Board “misapprehends or overlooks that the claims have been limited to specific combinations of preservatives and surfactants, where each specific claimed combination has been shown to enable the specific claimed high level of bromfenac stability, while other possible combinations . . . have been shown to result in significantly lower levels of stability than that required for the present claimed invention.” Reh’g Req. 5. This argument is not persuasive for the reasons noted in the Decision. *See* Decision 7–9 (identifying “shortcomings” in Appellant’s unexpected results evidence and determining such “evidence is insufficient to overcome the strong prima facie showing”).

In conclusion, Appellant has not identified an issue of fact or law that was overlooked or misunderstood. Therefore, the Request is denied.

Outcome of Decision on Rehearing:

Claims	35 U.S.C. §	Reference(s)/Basis	Denied	Granted
1, 3, 6–9, 13, 15, 18, 21–23	103	Desai, Sawa	1, 3, 6–9, 13, 15, 18, 21–23	

Final Outcome of Appeal after Rehearing:

Claims	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3, 6–9, 13, 15, 18, 21–23	103	Desai, Sawa	1, 3, 6–9, 13, 15, 18, 21–23	

REHEARING DENIED