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Paper 45
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKER BIOMARINE AS
Petitioner

v.

NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC.
Patent Owner

Case IPR2014-00003
Patent 8,278,351 B2

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

DECISION
Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Aker Biomarine AS ("Aker") filed a Petition to institute an *inter partes* review of claims 1-94 of U.S. Patent No. 8,278,351 B2 (Ex. 1001; "the '351 patent"). Paper 6 ("Pet."). Neptune Technologies and Bioressources, Inc. ("Neptune") filed a Patent Owner Preliminary Response. Paper 16. Thereafter, the Parties filed a Joint Motion to Limit Petition, requesting that the Board limit the Petition to claims 1-6, 9, 12-13, 19-29, 32, 35-36, and 42-46 of the '351 patent. Paper 18. We granted the Joint Motion, thereby limiting this proceeding to the aforementioned claims. Paper 21.

On March 23, 2014, we instituted a trial based on Petitioner's challenges to: (1) claims 1, 3-6, 9, 12, 13, 19-24, 26-29, 32, 35, 36, and 42-46, but not claims 2 and 25, as anticipated by WO 00/23546 (Ex. 1002, "Beaudoin I"), and (2) all challenged claims as obvious over the combination of Fricke (Ex. 1006), Bergelson (Ex. 1017), Yasawa (Ex. 1015), Itano (Ex. 1009), and the WHO Bulletin (Ex. 1018). Paper 22 ("Decision"). We denied all remaining grounds of unpatentability as redundant to the above grounds, except that we denied all anticipation grounds asserted in the Petition regarding claims 2 and 25. *Id*. at 27-28, 16-20. In its Request for Rehearing, Aker asks that the Board reconsider its denial to institute a review of claims 2 and 25 as anticipated by Beaudoin I. Paper 26 ("Rehearing Req.") 1-3.

II. ANALYSIS

When rehearing a decision on petition, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be determined if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an

unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000). The party requesting rehearing has the burden of showing the decision should be modified, and "[t]he 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." 37 C.F.R. § 42.71(d).

Claims 2 and 25

Dependent claims 2 and 25 each recite the krill extract of claim 1 or 24, respectively, having "a total phospholipid concentration in an amount of about 40% w/w, wherein about represents ±10%." Ex. 1001, 28:65-67, 31:36-38. We denied Aker's ground that Beaudoin I anticipates claims 2 and 25. Decision 17.

In its Request for Rehearing, Aker contends two points. Rehearing Req. 2. First, Aker asserts that the Board incorrectly applied the standard of inherent anticipation, and overlooked that "Beaudoin I *explicitly discloses* a phospholipid concentration within the claimed range." *Id*. at 2, 5-6. We note that we addressed both express and inherent anticipation in our Decision when stating that "Aker fails to explain adequately how the range disclosed by Beaudoin I fell within a range defined as about 40% w/w, wherein about represents ±10%, i.e., from 30% to 50%." Decision 17. That said, we grant the Request for Rehearing to explain more fully why we denied Aker's ground of anticipation of claims 2 and 25 by Beaudoin I, whether it be express or inherent anticipation.

As Aker correctly notes in its Petition, "Beaudoin I discloses 54.1+/-6.1% *phospholipids and polar material* w/w in Fraction I extracts." Pet. 20 (citing Ex. 1002, 23, Table 14) (emphasis added). Thus, Beaudoin I's description of

concentration percentages of "[p]hospholipids or other polar material" in Table 14 does not disclose explicitly a total phospholipid concentration as recited in challenged claims 2 and 25. Ex. 1002, Table 14. Rather, Table 14 in Beaudoin I describes percentages, in krill oil Fractions I and II, of material having phospholipids (at some undisclosed concentration) plus "other polar material" (at some undisclosed concentration). Thus, Aker does not explain sufficiently in its Petition, or in its Request for Rehearing, how one can ascertain the total phospholipid concentration of Fraction I by looking at Table 14 or elsewhere in Beaudoin I.

It is *possible* that Fraction I contains the recited total phospholipid concentration (*see* Decision 17), but Table I does not describe expressly that it does. Table 14 of Beaudoin I indicates that the total phospholipid concentration in Fraction I depends on the amount of "other polar material," as well as the final concentration of "[p]hospholipids or other polar material," existing in that fraction. Ex. 1002, Table 14. Aker fails to establish adequately, with argument or evidence, that "Beaudoin I expressly discloses phospholipid concentrations within the ranges claimed by claims 2 and 25." Rehearing Req. 6-7. Thus, Aker does not establish a reasonable likelihood that it would prevail on the ground that Beaudoin I expressly anticipates challenged claims 2 and 25.[1]

[1] In its Request for Rehearing, Aker also contends that Beaudoin I alone renders claims 2 and 25 *prima facie* obvious. *See*, *e.g.*, Rehearing Req. 9-10, 14. A rehearing 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 . . . ." 37 C.F.R. § 42.71(d). Aker fails to show where it asserted this obviousness ground in its Petition. *See*, *e.g.*, Pet. i-ii, Table of Contents. Consistently, the "error" asserted by Aker in its Request for Rehearing relates to the ground of anticipation by Beaudoin I.

In its second point, Aker further contends that the "Board adopted Aker's argument that because 'the processes described in the '351 patent and . . . the prior art [Beaudoin I] are virtually indistinguishable,' as a result so, too, 'would be the resulting extracts.'" Rehearing Req. 2-3, 11 (citing Pet. 12;[2] Decision 13). Thus, according to Aker, it established a *prima facie* case of anticipation, and under *In re Best* and "its progeny," the burden shifted to Neptune to produce evidence as to why the resulting compositions would be different, which Aker contends Neptune failed to do. *Id*. at 3, 10-13 (citing *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977); *In re Spada*, 911 F.3d 705, 708 (Fed. Cir. 1990)).

Contrary to Aker's assertion, we did not "adopt" Aker's contention that the processes of the '351 patent and Beaudoin I are virtually indistinguishable. Rehearing Req. 2-3, 11. Aker cites our Decision at page 13, which discusses the asserted ground of anticipation of claims 1 and 24 by Beaudoin I. While we discuss some of Aker's contentions, the Decision concludes that "evidence presented by Aker tends to demonstrate that the *E. pacifica* krill extract disclosed in Beaudoin I comprised at least one phospholipid" recited in claim 1 "under the principles of inherency as explained by Aker," citing page 12 of Aker's Petition. Decision 13 (citing Pet. 12). On page 12 of its Petition, Aker asserts that Neptune "identif[ies] phospholipid molecules that naturally occur in krill and all prior krill extracts," i.e., an inherency position. Pet. 12.

In support of its inherency position regarding claims 1 and 24, Aker cited declaration evidence, including the van Breeman Declaration (Ex. 1040). Pet. 14. Specifically, as noted in our Decision, the "van Breemen Declaration, in particular,

[2] The Request for Rehearing cites Paper 4 at 12. *See* Rehearing Req. 2-3. Paper 4 is a Certificate of Service. We assume that Aker intends to refer to its Petition (Paper 6) at 12.

provides mass spectrometry evidence that the *E. pacifica* acetone extracts contained PC-EPA/EPA, PC-DHA/DHA, and PC-EPA-DHA." Decision 11 (citing Ex. 1040, ¶¶ 73-85, 93-98). That declaration evidence, not Aker's contention that the processes of Beaudoin I and the '351 patent are virtually indistinguishable, persuaded us that Aker established a reasonable likelihood that it would prevail on the ground that Beaudoin I anticipates claims 1 and 24.

Moreover, in relation to claims 2 and 25, Aker argued in its Petition that "Beaudoin I discloses 54.1+/-6.1% phospholipids and polar material w/w in Fraction I extracts (Ex. 1002, Table 14, p. 23[])[,] which falls within or touches the claimed ranges." Pet. 20. Thus, Aker did not assert the "virtually indistinguishable" process argument in relation to claims 2 and 25 in its Petition, nor did it explain how *In re Best* applies in the context of the additional limitations added by these two dependent claims. Rather, Aker only made that argument in relation to independent claims 1 and 24. *Id*.; *see also id*. at 12-19.

Even if we assume that Aker's contentions regarding claims 1 and 24 apply equally to claims 2 and 25, however, Aker still fails to establish a reasonable likelihood of prevailing. In its Request for Rehearing, Aker contends that it explained previously that the extraction processes in Beaudoin I and the '351 patent are "virtually indistinguishable." Rehearing Req. 10-11 (citing Pet. 12). In its Petition, Aker relies on declarations by Drs. Storrø and Brenna, "which present a line-by-line comparison of the '351 and the Beaudoin I and II methods," and points to certain processes described in Beaudoin I and the '351 patent. Pet. 12, 17 (citing Ex. 1046, ¶ 7; Ex. 1042, ¶ 63; Ex. 1002, 5:21-6:20; Ex. 1001, 18:53-19:9).

Notably, the "line-by-line" comparisons presented in the declarations by Drs. Storrø and Brenna, as well as cited disclosures in Beaudoin I and the

'351 patent themselves, describe that multiple steps in the referenced processes include different options. *See, e.g.*, Ex. 1046, ¶ 7 (using terms such as "preferable," "preferred," "preferably," and "optionally"); Ex. 1042, ¶ 63 (using terms such as "best," "preferred," "preferably," and "optionally"). Aker does not establish sufficiently what specific processes (i.e., which exact options) Beaudoin I used when making extracts, such as the fractions described in Table 14.

Moreover, evidence cited by Aker in relation to its "virtually indistinguishable" contention, including the "line-by-line comparison," all indicate that the relevant processes in Beaudoin I and the '351 patent include two separate extraction steps, e.g., "a 2 hour extraction with 6:1 volume ratio of acetone," and extraction "with alcohol, such as ethanol, isopropanol, t-butanol or alternatively with ethyl acetate, preferably two volumes (original volume of material)." Ex. 1002, 5:30-6:17; Ex. 1001, 18:32-45 (stating that the "most preferred extraction solvent system is 100% acetone in the first extraction followed with a 95%/5% ethyl acetate/ethanol mixture" extraction). Table 14 of Beaudoin I, however, describes "[p]hospholipids or other polar material" in Fractions I and II. Ex. 1002, 23, Table 14. Beaudoin I describes that Fraction I (subjected to the first extraction step only) contains 54.1 ±6.1 percent of "[p]hospholipids or other polar material," while Fraction II (subjected to both extraction steps) contains only 8.5 ±1.6 % of the same material. *Id.* at Table 14, notes a) and b).

Thus, Beaudoin I describes that its processes involving two extraction steps, which Aker contends are "virtually indistinguishable" to processes described in the '351 patent, produce an extract (Fraction II) that does not have the total phospholipid concentration recited in claims 2 and 25. Instead, Beaudoin I's Fraction II has a lower total phospholipid concentration (i.e., a portion of 8.5 ±1.6 % of "[p]hospholipids or other polar material," as compared to 30-50%

phospholipids), indicating that processes of Beaudoin I and the '351 patent are not, in fact, "virtually indistinguishable." Aker has not established sufficiently, therefore, that Beaudoin I, when preparing extracts, such as those analyzed in Table 14, used a process that was "virtually indistinguishable" from that used by the '351 patentee when preparing the extracts recited in claims 2 and 25 (*see, e.g.*, Ex. 1001, 17:49-18:6, Table 5).

Thus, on the record before us, Aker does not establish that the Board abused its discretion when concluding that Aker failed to establish a reasonable likelihood that it would prevail on the ground that Beaudoin I anticipates challenged claims 2 and 25, expressly or inherently.

Claims 3 and 26

Having granted Aker's Request for Rehearing with regard to claims 2 and 25, we also address a matter misapprehended in our Decision regarding dependent claims 3 and 26. Claims 3 and 26 are similar to claims 2 and 25, except that each of claims 3 and 26 recite the krill extract of claim 1 or 24, respectively, having "a total phospholipid concentration in an amount of about 45% w/w, wherein about represents ±20%," i.e., a total phospholipid concentration in the range of 25-65% w/w. Ex. 1001, 29:1-3, 31:39-41. We previously concluded that "there is a reasonable likelihood that Aker will prevail in demonstrating unpatentability of claims 3 and 26 as anticipated by Beaudoin I." Decision 14.

Upon reconsideration of our Decision regarding these claims, we conclude that Aker has not established a reasonable likelihood that it would prevail on the ground that Beaudoin I anticipates challenged claims 3 and 26, expressly or inherently, for all of the same reasons discussed above, and in our previous Decision (Decision 17), in relation to claims 2 and 25. For example, Beaudoin I's Fraction II has a lower total phospholipid concentration (i.e., a portion of

8.5 ±1.6 % of "[p]hospholipids or other polar material," as compared to 25-65% phospholipids as required by claims 3 and 26), indicating that processes of Beaudoin I and the '351 patent are not, in fact, "virtually indistinguishable." Similarly, we conclude that Aker has not established a reasonable likelihood that it would prevail on the ground that Beaudoin II (Ex. 1003), Maruyama (Ex. 1004), Fujita (Ex. 1005), or Fricke (Ex. 1006) anticipates challenged claims 3 and 26, for the same reasons discussed above and previously (Decision 18-20), in relation to claims 2 and 25.

Thus, we modify our previous Decision to deny Aker's grounds that Beaudoin I, Beaudoin II, Maruyama, Fujita, or Fricke anticipates claims 3 and 26.

III. CONCLUSION

We grant Aker's Request for Rehearing to explain in more detail our reasoning for denying institution of a trial based on the ground of anticipation of claims 2 and 25 by Beaudoin I. For the reasons discussed above, Aker has not carried its burden of demonstrating an abuse of discretion in our Decision in relation to anticipation of claims 2 and 25. 37 C.F.R. § 42.71(c). We modify our previous Decision, however, to deny Aker's ground that Beaudoin I anticipates claims 3 and 26, and to clarify that we deny Aker's grounds that Beaudoin II, Maruyama, Fujita, and Fricke each anticipate claims 3 and 26, for the same reasons discussed above in relation to claims 2 and 25.

IV. ORDER

For the reasons given, it is

ORDERED that our previous Order in our Decision instituting *inter partes* review (Paper 22, 28-29) is modified to the extent that we deny the Petition with respect to the grounds that claims 3 and 26 of the '351 patent, under 35 U.S.C. § 102, are anticipated by each of Beaudoin I, Beaudoin II, Maruyama, Fujita, and Fricke.

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