UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKER BIOMARINE AS and ENZYMOTEC LTD.
Petitioners

v.

NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC.
Patent Owner

CASE IPR2014-00003[1]
U.S. Patent No. 8,278,351 B2

PATENT OWNER'S MOTION TO EXCLUDE PURSUANT TO 37 C.F.R. § 42.64

[1] Case IPR2014-00556 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64 and the parties' stipulation regarding Due Dates 1-5 (Paper 63),[2] Patent Owner Neptune Technologies & Bioressources Inc. ("Neptune") moves to exclude AKBM Ex. 1107. Neptune timely served notice of its objections pursuant to 37 C.F.R. § 42.64(b)(1).[3]

I. Legal Standards

With limited exceptions, the Federal Rules of Evidence apply in IPR proceedings. *See* 37 C.F.R. § 42.62. Accordingly, irrelevant evidence is not admissible. Fed. R. Evid. 402. To be relevant, evidence must make a fact, which is "of consequence in determining" the issues in dispute, "more or less probable than it would be without the evidence." Fed. R. Evid. 401. Even if evidence is relevant, it may still be excluded if its probative value is outweighed by a danger of unfair prejudice or wasting time. Fed. R. Evid. 403.

II. The Board Should Exclude AKBM Ex. 1107

AKBM Ex. 1107 includes selected correspondence between Neptune and the FDA in 2002 regarding planned Neptune products, including Neptune Krill Oil, Aquateine, LyO-Krill, and Krill Euphasia. *See* AKBM Ex. 1107 at 2. The correspondence resulted from a

[2] The Board accepted the parties' stipulation regarding Due Dates 1-5. *See* IPR2014-00556, Paper 19.

[3] Petitioners served AKBM Ex. 1107 with Petitioners' Reply on September 18, 2014 (*see* Paper 85 at 17), and Neptune served its objections on September 23, 2014. *See* Exhibit 2065.

submission Neptune made to the FDA on February 28, 2002 (which itself is not included in Ex. 1107). *See id.* at 2. In response to Neptune's submission, the FDA requested further information, including information regarding the "extraction procedure" used to make the Neptune products at issue. *See id.* at 2, 94-147. To provide information regarding its extraction procedure, Neptune submitted the issued Beaudoin I patent in lieu of disclosing the trade secret details of its proprietary manufacturing process at the time.

Petitioners rely on AKBM Ex. 1107 to assert that Neptune "told the FDA it used Beaudoin to make its claimed invention."[4] *See* Petitioners' Reply, Paper 84, at 5 (Sept. 18, 2014).

AKBM Ex. 1107 is irrelevant to the alleged express or inherent anticipation by Beaudoin and so should be excluded under Federal Rule of Evidence 402. "[I]nvalidity by anticipation requires that the four corners of a single [ ] prior art document describe every element of the claimed invention." *TriMed, Inc. v. Stryker Corp.*, 608 F. 3d 1333, 1343 (Fed. Cir. 2010) (internal citation omitted). Aker does not and cannot contend that Neptune's correspondence with the FDA sheds any light on what the Beaudoin reference itself discloses or how the reference relates to the patent claims at issue in this proceeding. *See* MPEP 2131.01 (only one reference should be used to make an anticipation rejection unless the additional documents cited prove enablement or inherency, or explain the meaning of terms

[4] This contention is not only irrelevant, it is also not responsive to any argument raised in Neptune's Patent Owner Response. *See* 37 C.F.R. 42.23(b).

used in the primary reference). Thus, Neptune's correspondence with the FDA is irrelevant.

Even if Ex. 1107 has some marginal relevance, it should nevertheless be excluded under Federal Rule of Evidence 403 because the risk of unfair prejudice and waste of time outweighs any probative value of the documents. Aker is offering these documents in an attempt to mislead the Board into believing that Neptune "t[old] the FDA it used Beaudoin to make its claimed invention." But as discussed above, Neptune merely provided the Beaudoin patent as an expedient way to satisfy the FDA's inquiry regarding ***extraction*** method, and did not indicate that Beaudoin relates to Neptune's post-extraction refinement steps or any other aspect of Neptune's manufacturing process.[5] Moreover, the anticipation analysis requires a comparison of the prior art to the limitations of the patented claims, not commercial embodiments. *See Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 667 (D. Del. 2004), *vacated in part on other grounds*, 406 F.3d 1365 (Fed. Cir. 2005) ("Anticipation is determined by comparing the limitations of the asserted claims, not of commercial embodiments as described in [FDA] 510(k) submissions, to the disclosure found in a single piece of prior art."). It would unfairly prejudice Neptune to have this FDA correspondence considered as evidence of alleged anticipation.

It is also a waste of the Board's time to delve into the hundred of pages of correspondence contained in Ex. 1107 in attempt to understand a Neptune FDA submission

[5] Such post-extraction refinement steps may include, for example, solvent removal. *See* Patent Owner Response, Paper 66, at 19 (July 1, 2014).

that is only partially included in the exhibit and that, in any event, has no bearing on what Beaudoin does or does not disclose.

III. Conclusion

For these reasons, the Board should exclude AKBM Ex. 1107 pursuant to Federal Rules of Evidence 402 and/or 403.

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Respectfully submitted,
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