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Paper 37
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ HEALTHCARE NUTRITION, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Case IPR2015-00249
Patent 6,481,468 B1

Before PHILLIP J. KAUFFMAN, RAMA G. ELLURU, and BEVERLY M. BUNTING, *Administrative Patent Judges.*

KAUFFMAN, *Administrative Patent Judge*.

DECISION
Denying Request for Rehearing
37 C.F.R. § 42.71

I. OVERVIEW

Petitioner, Nestlé Healthcare Nutrition, Inc., filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1-3, 7, 9, and 20-23 of U.S. Patent No. 6,481,468 B1 (Ex. 1001, "the '468 patent"). Patent Owner, Steuben Foods, Inc., filed a timely Preliminary Response (Paper 9, "Prelim. Resp."). In our Decision to Institute (Paper 25, "Dec."), we determined that Petitioner had demonstrated a reasonable likelihood of prevailing with respect to claims 1-3, 7, and 9 of the '468 patent, but not with regard to claims 20–23.

Petitioner filed a Request for Rehearing (Paper 29, "Req. Reh'g") asking that the Board reconsider its decision not to institute with regard to claims 20–23 on the following two grounds:

References	§	Claims challenged
Biewendt[1], Takei, Bev Tech[2], David,[3] ZFL[4], Chambers[5], Campden[6], and Rose[7]	103(a)	20–23

[1] Ex. 1006, H.-G. Biewendt et al., *Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk* (1996).

[2] Ex. 1007, Luigi Baiocchi, *Latest Innovations In Aseptic Filling*, Int'l Soc. of Beverage Technologists, Prcdgs. of 44th Ann. Conf. "Bev Tech 97," Ft. Lauderdale, FL, Apr. 28-30, 1997, 123-130..

[3] Ex. 1008, J.R.D. David et al., *Aseptic Processing and Packaging of Food: A Food Industry Perspective*, chs. 6, 8 (1996).

[4] Ex. 1012, N. Buchner, *Aseptic Filling of Glass and Plastic Containers*, ZFL Magazine, Vol. 41, No. 5, 295-300 (with translation).

[5] Ex. 1009, Chambers, J. et al. eds., *Principles of Aseptic Processing and Packaging* (2d ed. 1993).

[6] Ex. 1010, Campden Food Preservation Research Association, *Aseptic Packaging: Proceedings of Seminar held on 20th April 1983* (Apr. 1983).

References	§	Claims challenged
ZFL, Takei, Bev Tech, Chambers, and Campden	103(a)	20–23

According to Petitioner, the Board's decision not to institute was based upon a legally erroneous construction of the term "aseptic." Req. Reh'g at 1. In addition, Petitioner asserts that even using the Board's construction of "aseptic," the Board's decision also is based on erroneous factual findings. *Id.* For the reasons that follow, Petitioner's request is denied.

II. STANDARD

When rehearing a decision, the Board will review the decision for an abuse of discretion. *See* 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. *See Arnold Partnership v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004). The party challenging the decision has the burden of showing a decision should be modified, and the request for rehearing must specifically identify all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d).

[7] Ex. 1011, D. Rose, *Pt. 1: Principles of Design, Installation and Commissioning*, Good Manufacturing Practice – Guidelines for the Processing and Aseptic Packaging of Low-Acid Foods (1st ed. 1986).

III. ANALYSIS

As stated above, Petitioner contends that the Board abused its discretion by misconstruing "aseptic," and by incorrectly applying the facts to this claim construction. Req. Reh'g at 1.

A. Claim Construction of "Aseptic"

Petitioner contends that the Decision incorrectly concluded that "[i]f hydrogen peroxide is used as the sterilant, claim 20 requires compliance with the Food and Drug Administration [FDA][8] standard level of residual hydrogen peroxide." Req. Reh'g 3 (quoting Dec. 29). Petitioner asserts that there are three reasons this claim construction is in error: one, there is no "FDA standard" for "aseptic;" two, the FDA requirement of 0.5 ppm H_2O_2 (hydrogen peroxide) is not an "aseptic" standard; and three, the Board's construction renders the claims indefinite. We analyze these arguments in turn.

1. FDA Standard

Petitioner contends that although the '468 patent states that "aseptic" refers to the "FDA level of aseptic," no such level exists, and to the extent that the FDA has defined aseptic, it simply means "free or freed of microorganisms." Req. Reh'g. 3–5. According to Petitioner these and other FDA requirements are FDA standards, but are not a level of "aseptic." *Id.* In sum, Petitioner contends that "there is no measure in the FDA regulations or the patent for defining an 'FDA standard' of aseptic beyond the ordinary meaning of 'free or freed of pathogenic microorganisms.'" *Id.* at 5.

[8] Throughout, we use "FDA" to refer to the United States Federal Drug Administration. *See* Ex. 1001, 2:30–32.

Petitioner contends there is no FDA standard for "aseptic," yet, Petitioner acknowledges that the FDA has standards for "aseptic processing and packaging." *See* Req. Reh'g 3–4 (quoting 21 C.F.R. § 113.3(a) and adding emphases). At the same time, Petitioner contends that "aspetic" as claimed carries its ordinary meaning, yet, Petitioner acknowledges that the '468 patent states that the "the term 'aseptic' denotes the United States FDA level of aseptic." *See* Req. Reh'g 3. Therefore, although we agree with Petitioner that an ordinary meaning of "aseptic" is "free or free of microorganisms," we disagree that this ordinary meaning is applicable to the '468 patent. *See* Dec. 6 (citing Ex. 3001).

Our review of the '468 patent Specification reveals that the '468 patent adopted a special meaning for the term "aseptic," namely, to the FDA level of aseptic. *See Hormone Research, Inc. v. Genentch, Inc.*, 904 F.2d 1558, 1563(Fed. Cir. 1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her lexicographer").

The '468 patent states that it is drawn to a method and apparatus for filling aseptic containers with an aseptic food product. *See* Dec. 5; Ex. 1001 at 2:39-52; Figs. 3, 22. In order to meet FDA "aseptic" standards for packaging of food products, an aseptic filler must, for example: use approved sterilant, meet FDA quality control standards, use a sterile tunnel or clean room, aseptically treat all packaging material, be processed using "Ultra High Temperature" pasteurization, and the packing material must remain in a sterile environment during filling, closure, and sealing operations. Ex. 1001 at 2:13–21.

These requirements are explicitly described in the Specification of the '468 patent as required to meet "FDA *aseptic* standards." *Id.* (emphasis added); *see also Id.* at 2:29–33 (referring to FDA standards for labeling a packaged product as "aseptic"). As such, these requirements go beyond the ordinary meaning of aseptic

proffered by Petitioner. For example, the sterilant itself must be an approved sterilant which is a requirement beyond the absence of microorganisms. Therefore, Petitioner's contention that "aseptic" is strictly limited to the absence of microorganisms is inconsistent with the Specification of the '468 patent. A person of ordinary skill in the art would understand that in the '468 patent, "aseptic" does not carry its ordinary meaning; rather, "aseptic" means to the FDA level of aseptic.

Petitioner asserts that the '468 patent suggests that the 12-log reduction in *Clostridium botulinum* and the 6-log reduction in spores (the "reductions") are FDA requirements when, as acknowledged by Patent Owner, these are guidelines. *Id.* at 4. This disclosure of the '468 patent is consistent with our interpretation. The Specification describes that the aseptic processing apparatus produces such reductions. Ex. 1001 at 5:46–57. The Specification does not state these reductions are FDA requirements. *Id.* Nor does Petitioner explain persuasively why the language of the '468 patent suggests these reductions are FDA requirements. To the contrary, claim 9, for example, states that the bottles are aseptically disinfected to a level producing a 6-log reduction in spore organisms. Ex. 1001, 26:19–22. The '468 patent defines aseptic as to the FDA level of aseptic, so that if the 6-log reduction were an FDA requirement it would be redundant to list the reduction in a claim that already applies FDA requirements. That is, the fact that claim 9 recites "aseptically disinfecting" (disinfecting to the FDA level), and separately states this disinfection produces a 6-log reduction, suggests that the claim drafter believed the 6-log reduction was not an FDA requirement.

Consequently, Petitioner's argument does not persuade us that the Decision made an erroneous interpretation of law in construing claim 20.

2. Aseptic Standard

Petitioner contends that the residual hydrogen peroxide requirement is not an "aseptic" standard. Req. Reh'g 5–7. In making this argument, Petitioner acknowledges that the residual hydrogen peroxide level at issue is an FDA standard. Req. Reh'g 5–7. In particular, we note that Petitioner states that "*all* FDA aseptic processes must comply with all prescribed food product standards." *Id.* at 7; *see also Id.* at 10 (stating the hydrogen peroxide was the only approved FDA container sterilant as of the critical date). This argument is premised on the interpretation that "aseptic" is limited to its ordinary meaning of "free or freed from pathogenic microorganisms." *Id.* 5–7. However, such contention is unpersuasive because, as explained above, "aseptic" does not carry its ordinary meaning in the '468 patent.

Consequently, Petitioner's argument does not persuade us that the Decision made an erroneous interpretation of law in construing claim 20.

3. Indefiniteness

Petitioner contends that the Board's interpretation that "aseptic" as claimed incorporates any applicable United States FDA standard creates an ambiguity that renders the claims indefinite. Req. Reh'g 7–9. In support of this contention, Petitioner contends that claim 9 is similar in scope to claim 20 with regard to the residual sterilant requirement at issue, yet our analysis of the two claims was different. *Id.* at 8–9. Further, Petitioner notes that Patent Owner asserted in the related District Court case that "aseptic," as claimed, covers sterilants not approved by the FDA at the time the application that matured to the '468 patent was filed. *Id.* 9–10.

Patent Owner's assertion in the District Court case is not relevant to our inquiry here.

Petitioner's contention regarding claim 9 is unpersuasive because claim 9 differs in scope from claim 20. Claim 9 depends from independent claim 1, and recites "aseptically disinfecting a plurality of bottles to a level producing at least about a 6 log reduction in spore organisms." The method of claim 9 does not require that the flow of aseptic product is placed into the plurality of aseptically disinfected bottles. In contrast, the method of claim 20 requires the flow of aseptic product to go into the aseptically disinfected containers. The FDA regulation regarding residual hydrogen peroxide applies to food packing material, and because claim 9 does not require that the flow of aseptic product is placed into the plurality of disinfected bottles, this FDA requirement does not apply.[9] *See* Ex. 2048, p. 1. Consequently, our analysis of claim 9 differs from that of claim 20 because the claims differ in scope.

Petitioner has not persuaded us that our claim construction renders the claims indefinite.[10] Our claim construction is not ambiguous; rather, it is stated so that the concept may be applied to the various claims of the '468 patent. As explained in the Decision, "aseptic" as claimed means to any applicable FDA standard[11] in the context of the claimed subject matter. *Id.* at 7. FDA standards may differ depending on, for example, the type of foodstuff processed. *Id.* The analysis of claim 1 illustrates this concept. Patent Owner contended that the FDA standard for processing of Low Acid Canned Food (LACF) applies to claim 1. *Id.*

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[9] Patent Owner did not contend in the Preliminary Response that the FDA requirement for residual hydrogen peroxide applies to claim 9. Paper 9, *passim*.

[10] A ground of unpatentability in an *inter partes* review may not be based upon indefiniteness, and such is not the case here. Rather, Petitioner raises the issue of indefiniteness to allege that our claim construction was incorrect in the Decision.

[11] It has long been accepted that a standard may be included in a claim. *See e.g., In re Saether*, 492 F.2d 849 (CCPA 1974).

at 19. However, because claim 1 recites the step of controlling the flow of an "aseptic product" and is not limited to LACF food products, the FDA standard for LACF does not apply. *Id.* at 20.

Consequently, Petitioner's argument does not persuade us that we made an erroneous interpretation of law in construing claim 20.

B. Application of the Facts

Petitioner acknowledges that the Petition did not specifically call out the teaching regarding residual hydrogen peroxide. Req. Reh'g 12; *see also* Dec. 28–29, 31. Despite this, Petitioner contends that we should institute on claims 20–23 because: the prior art taught this limitation, other Board proceedings have determined this limitation was taught, and Patent Owner's evidence shows the limitation was taught. *Id.* at 11–14. Although the Board seeks consistency, the facts of each case are different, and Board decisions from other proceedings are not binding. More importantly, the relevant inquiry is not whether the limitation was known in the art, determined to be known in another proceeding, or shown by Patent Owner. The relevant inquiry is whether the Petition explained adequately how the construed claim is unpatentable, to include specifying where each element of the claim is found in the prior art and the relevance of evidence relied upon. 37 C.F.R. §§ 42.104(b)(4)–(b)(5). Petitioner acknowledges that the Petition did not meet these requirements.

Consequently, Petitioner's argument does not persuade us that our factual findings are not supported by substantial evidence.

IV. CONCLUSION

Petitioner has not persuaded us that the Decision contains an abuse of discretion. We have considered the Request for Rehearing, but decline to modify the Decision.

V. ORDER

For the foregoing reasons, it is

ORDERED that Petitioner's Request for Rehearing is *denied*.

IPR2015-00249
Patent 6,481,468 B1

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