

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Case IPR2015-00195
Patent 6,475,435 B1

Before MICHAEL P. TIERNEY, BEVERLY M. BUNTING, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

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

Patent Owner, Steuben Foods, Inc. requests rehearing of the Board's Final Written Decision dated June 2, 2016 (Paper 97) (the "FWD" or "Decision") with respect to our conclusion that Petitioner Nestlé USA, Inc. has shown by a preponderance of the evidence that the challenged claims are unpatentable over the combination of Biewendt in view of Chambers, the FDA Regulations, Buchner, ZFL, Scholle, Kelbrick, Akai, Koder, and Elliott. Paper 98 ("Req. Reh'g").

The requirements for rehearing are set forth in 37 C.F.R. § 42.71(d), which provides, in relevant part, that "[t]he burden of showing a decision should be modified lies with the party challenging the decision," and that "[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." We determine that we did not misapprehend the evidence and arguments of record supporting our conclusion of obviousness based on Biewendt, and for the reasons that follow, Patent Owner's request for rehearing is denied. .

**THAT THE BOARD MISAPPREHENDED THE OPERATION OF
BIEWENDT**

Patent Owner argues that the Board misapprehended the manner in which the Biewendt system operates and incorrectly concluded that the sterilization machine is "pressurized" as required by the challenged claims. Req. Reh'g 1–5. We are unpersuaded by this line of argument.

First, Patent Owner points to no persuasive evidentiary basis for its contention that only the specific air flow rates disclosed in the '435 patent, as opposed to Biewendt's more general disclosure that hot sterile air is blown into the sterilizing machine, could result in a "pressurized"

environment. *Id.* at 1–2. Indeed, the challenged independent claims of the ’435 patent do not require any particular air flow rates. As such, we considered the parties arguments and evidence in view of the claims. Nor was any claim construction previously proposed by Patent Owner that required specific air flow rates to satisfy the “pressurized” requirement.

Second, Patent Owner has failed to demonstrate error in our consideration of Dr. Heldman’s unequivocal testimony—based on his studying of clean room technology for 40 years—that he expected that Biewendt’s sterilization machine would be kept above atmospheric pressure based on its description as a “clean room.” FWD, 29; *see generally* Ex. 2055, 146:3–157:19. Indeed we accorded the testimony of both Dr. Heldman and Dr. Sharon the weight that was appropriate in view of the arguments and evidence of record in the trial.¹ As to Patent Owner’s argument that this was a “new position” not presented in the Petition or the accompanying declaration, we note that Dr. Heldman was merely responding to questions posed by Patent Owner’s counsel during his deposition, rather than injecting a new theory of his own accord. *See, e.g.*, Ex. 2055, 147:13–14 (“Q. Are all clean rooms overpressured? A. That’s the only design that I know.”). Dr. Heldman’s testimony is consistent with the statement in the Petition “that the entire sterilization machine of *Biewendt* is maintained under positive pressure to prevent contamination from the

¹ It is within our discretion to assign the appropriate weight to the testimony of both Dr. Heldman and Dr. Sharon. *See, e.g., Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding the Board has discretion to give more weight to one item of evidence over another “unless no reasonable trier of fact could have done so”); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004).

ambient environment.” Pet. 16. Moreover, Patent Owner had a sufficient opportunity to respond to Dr. Heldman’s testimony, and did so in its Patent Owner Response. See PO Resp., 32–33. As such, given that Dr. Heldman’s testimony regarding clean rooms was properly part of the record evidence, we find nothing improper in our reliance on such testimony as part of the Final Written Decision. See *Genzyme Therapeutic Products Ltd. P’ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) (“[T]he introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA.”).

Furthermore, we considered fully the testimony of Dr. Sharon and other evidence relied upon by Patent Owner, but do not find that it discredited Dr. Heldman’s opinion that the clean room of Biewendt’s sterilization machine would have been kept above atmospheric pressure. Req. Reh’g 3–4. There is no credible basis for Patent Owner’s contention that the phrase “clean room” in the certified English translation of Biewendt would have a different meaning from Dr. Heldman’s understanding that it referred to a pressurized chamber. *Id.* at 3. The fact that Patent Owner points to a single, unrelated reference referring to a negative pressure clean room does not undermine our conclusion. *Id.* (citing Ex. 2052).

Third, the evidence of record does not support Patent Owner’s argument that we “overlooked the fact that the cited passage in ZFL says that the “fully enclosed system, which is ventilated by sterile air at a slight overpressure, is *free of unsterile transport media* that may get into the system and works with packages and lids which are sterile on all sides.”

Req. Reh’g 4 (citing Ex. 1010, 298). Specifically, that “ZFL and Buchner are consistent with Biewendt in explaining that that those portions of the machine *downstream of the sterilization chamber* are kept at a pressure above atmospheric in order to ensure sterility during the filling and sealing process.” *Id.* at 5. Patent Owner, however, did not previously present this interpretation of ZFL and Buchner, and a request for rehearing is not an opportunity to present such new arguments. Moreover, contrary to Patent Owner’s new argument, these references plainly indicate that the “fully enclosed system” and the “entire plant” of the Bosch system is subject to a “slight overpressure.” Ex. 1010, 298; Ex. 1011, 27. As such, we find no basis in the record to conclude that we overlooked any persuasive evidence suggesting that only those portions of the Bosch system downstream of the sterilization machine are subject to overpressure.

THAT THE BOARD MISAPPREHENDED THAT BIEWENDT’S
BOTTLES ARE NOT FOGGED WITH HYDROGEN PEROXIDE

Patent Owner further argues that “the Board misapprehended the manner in which Biewendt operates” because “both portions of Biewendt cited by the Board discuss the same hydrogen peroxide application step in the sterilization machine” and “[t]here are not two separate hydrogen peroxide steps such that the bottles are sterilized once in the sterilization machine and then fogged with hydrogen peroxide in the bottle filling machine.” Req. Reh’g 6. We recognize that the cited portions of Biewendt do not suggest a separate hydrogen peroxide application step in the aseptic filling machine. To the extent our Decision indicated otherwise when generally summarizing the prior art reference (FWD, 16), we clarify that we rely only upon Biewendt’s teaching of the hydrogen peroxide application

step in the sterilization machine. Nonetheless, even with this clarification, Patent Owner has not persuaded us that “[t]he Board’s misapprehension undermines the Board’s ultimate conclusion that Petitioner met its burden with respect to the Biewendt-based combination because . . . the sterilization machine cannot be included in the sterilization tunnel of Biewendt.” Req. Reh’g 7. As set forth fully in our Decision and further addressed above, we find that a preponderance of the evidence supports our conclusion that Biewendt’s sterilization machine is “pressurized,” and thus considered properly part of the claimed “sterilization tunnel” when determining whether the sterilant concentration ratio is satisfied. FWD, 28–29.

**THAT THE BOARD MISAPPREHENDED THAT EACH ZONE
MUST BE PRESSURIZED**

Finally, we are unpersuaded by Patent Owner’s contention that we misapprehended that each zone of the sterilization tunnel must be pressurized. Req. Reh’g 7–8. Patent Owner argues that the Board “has apparently construed the claims as not requiring that each zone be pressurized.” *Id.* at 7. Although we observed that “the claims, on their face, do not require the entirety of the sterilization tunnel be kept above atmospheric pressure,” we specifically indicated that “even if the claims were interpreted to require all ‘zones’ in the sterilization tunnel be kept above atmospheric pressure, Biewendt’s apparatus still satisfies that requirement” FWD, 29. Thus, our conclusion of obviousness was not dependent upon a new claim construction that Patent Owner did not have a prior opportunity to address. Instead, we considered fully Patent Owner’s arguments and evidence, but found them insufficient.

CONCLUSION

Having not been shown where we misapprehended or overlooked a matter, Patent Owner's Request does not persuade us that our Decision should be modified. *See* 37 C.F.R. § 42.71(d).

ORDER

In consideration of the foregoing, it hereby:

ORDERED that Patent Owner's Request for Rehearing is *denied*.

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