

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUGEL, INC.,
Petitioner,

v.

MEDYTOX INC.,
Patent Owner.

IPR2023-00604
Patent 11,331,598 B2

Before JO-ANNE M. KOKOSKI, KRISTINA M. KALAN, and
JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

KOKOSKI, *Administrative Patent Judge*.

ORDER
Denying Petitioner's Motion for
Leave to File a Reply to the Preliminary Response
37 C.F.R. §§ 42.5, 42.108(c)

On February 21, 2023, Hugel Inc. (“Petitioner”) filed a Petition for *inter partes* review of claims 1–9 (“the challenged claims”) of U.S. Patent No. 11,331,598 (“the ’598 patent”). Paper 2 (“Pet.”). In the Petition, Petitioner contends that the challenged claims would have been obvious over two combinations of prior art references, each of which includes Jung.¹ *Id.* at 3–4. Medytox Inc. (“Patent Owner”) filed a Preliminary Response on May 30, 2023. Paper 6 (“POPR” or “Prelim. Resp.”). On June 15, 2023, Petitioner sent an email to the Board seeking authorization to file a reply to Patent Owner’s Preliminary Response to address Patent Owner’s arguments with respect to Jung, and to submit “a small number of exhibits.” Ex. 1032, 4. With our authorization (*id.* at 1), Petitioner filed a Motion for Leave to File s Reply to Patent Owner’s Preliminary Response (Paper 7, “Motion” or “Mot.”), and Patent Owner filed an Opposition (Paper 8, “Opposition” or “Opp.”).

In the Motion, Petitioner argues that Patent Owner “has taken unforeseeable positions in its POPR regarding its own Jung reference, and the Board will benefit from further briefing on the limited issues discussed below.” Mot. 1. Specifically, Petitioner argues that Patent Owner “expressly and repeatedly argues throughout its POPR concerning Jung’s substance, i.e, that it purportedly fails to disclose isolating botulinum toxin type A (‘BoNTA’) macro complex.” *Id.* (citing Prelim. Resp. 1, 22, 29) (emphasis omitted). Petitioner contends that this argument was unforeseeable at the time it filed the Petition, because “it contradicts public evidence, including statements made by [Patent Owner’s] former licensee, Allergan, as well as [Patent Owner’s] own statement to the Office during

¹ Jung, US 8,993,268 B2, issues Mar. 31, 2015 (Ex. 1002).

prosecution of” the ’598 patent. *Id.*; *see id.* at 2–3. Petitioner contends that the evidence it seeks to file with its requested reply is “relevant information that is inconsistent with a position advanced by [PO] during the proceeding.” *Id.* at 1 (citing 37 C.F.R. § 42.51(b)(1)(iii)). Petitioner also argues that Patent Owner unforeseeably “attempt[ed] to mislead the Board on basic case law.” *Id.* at 3–4.

Patent Owner responds that its argument in the Preliminary Response “was that the Petition was fatally flawed because its ‘cited evidence does not support’ Petitioner’s assertion that Jung discloses isolating the botulinum toxin A (‘BoNTA’) macro complex” and that “the Petition ‘offered no evidence or argument explaining how or why’ Jung discloses isolating BoNTA macro complex.” Opp. 1 (citing Prelim. Resp. 32, 33). In particular, Patent Owner asserts that it argued that Jung is silent with respect to whether the isolated toxin was one in which BoNTA naturally occurs and what form of BoNTA is isolated, and, therefore, “Petitioner accordingly failed to establish that Jung discloses isolating the BoNTA macro complex.” *Id.* at 1–2 (citing Prelim. Resp. 22, 32–35). Patent Owner further argues that the Motion “erroneously focuses on what is *presently known* rather than what the prior art disclosed at the time of the invention,” whereas “the POPR focused on the Petition’s deficient showing about what was known at the legally relevant time, i.e., the time of the invention.” *Id.* at 3. Patent Owner also disagrees with Petitioner’s characterization of the evidence Petitioner wishes to provide with the reply. *Id.* at 2–3.

Our rules provide that a petitioner may seek leave to file a reply to the preliminary response, but is required to “make a showing of good cause.” 37 C.F.R. § 42.108(c). After considering the parties’ respective positions,

we are not persuaded that Petitioner has shown that good cause exists for a reply under these circumstances.

An *inter partes* review may not be authorized unless the information in the *Petition* shows a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. See 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(c). The information in the *Petition* must include “a statement of the precise relief requested for each claim challenged” including “where each element of the claim is found in the prior art patents or printed publications relied upon.” 37 C.F.R. § 42.104(b)(4). It is reasonably foreseeable, then, that Patent Owner would respond to the *Petition* by arguing that Jung either fails to disclose the elements of the claim, or that Petitioner fails to meet its burden of showing where the elements of the claim can be found in Jung. Thus, the particular arguments in the Preliminary Response on which Petitioner bases its request for leave appear to raise issues that Petitioner could have anticipated in advance of filing the *Petition*. Moreover, Petitioner does not allege that it was unaware, before the *Petition* was filed, of the publicly-available evidence that allegedly contradicts Patent Owner’s arguments² in the Preliminary Response. See Mot. 1–2.

We are also not persuaded by Petitioner’s argument that Patent Owner’s alleged misstatement of law constitutes good cause to file a reply. The Board is capable determining whether cited caselaw supports the proposition for which it is offered.

² We note that the discovery obligations under 37 C.F.R. § 42.51 apply after institution of trial.

For these reasons, Petitioner has not shown good cause for filing a reply to the Preliminary Response. Should the Board institute trial in this proceeding, the parties will have the opportunity to investigate and address the issues addressed herein to the extent permitted under our rules.

Accordingly, it is hereby:

ORDERED that Petitioner's request for leave to file a reply to Patent Owner's Preliminary Response is *denied*.

FOR PETITIONER:

Dion M. Bregman
Guylaine Haché
Charles H. Rexer Jr.
MORGAN LEWIS & BOCKIUS LLP
dion.bregman@morganlewis.com
guylaine.hache@morganlewis.com
charles.rexer@morganlewis.com
MLB-Hugel-IPR-Team@morganlewis.com

FOR PATENT OWNER:

Jonathan B. Roses
Stephen Rabinowitz
Blaine Hackman
WOLF GREENFIELD & SACKS, P.C.
JRoses-PTAB@wolfgreenfield.com
SRabinowitz-PTAB@wolfgreenfield.com
BHackman-PTAB@wolfgreenfield.com