

Hache, Ph.D., Guylaine

From: Trials <Trials@USPTO.GOV>
Sent: Tuesday, June 27, 2023 7:00 AM
To: Bregman, Dion M.; Trials
Cc: Stein, Alexander B.; MLB-Hugel-IPR-Team; Stephen.Rabinowitz@WolfGreenfield.com; Hache, Ph.D., Guylaine; Jonathan.Roses@WolfGreenfield.com; Eric Rutt
Subject: RE: IPR2023-00604: Requesting a Reply to Patent Owner's Preliminary Response

[EXTERNAL EMAIL]
Counsel,

From the Board –

Petitioner is authorized to file a motion for leave to file a reply to the preliminary response, not to exceed four pages, no later than Friday, June 30th. Patent Owner may file an opposition to Petitioner's motion, also not to exceed four pages, no later than Friday, July 7th. Further briefing is not authorized at this time.

Regards,

Esther Goldschlager
Supervisory Paralegal Specialist
Patent Trial & Appeal Board
U.S. Patent & Trademark Office

From: Bregman, Dion M. <dion.bregman@morganlewis.com>
Sent: Wednesday, June 21, 2023 2:10 PM
To: Trials <Trials@USPTO.GOV>
Cc: Stein, Alexander B. <alexander.stein@morganlewis.com>; MLB-Hugel-IPR-Team <MLB-Hugel-IPR-Team@morganlewis.com>; Stephen.Rabinowitz@WolfGreenfield.com; Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>; Jonathan.Roses@WolfGreenfield.com; Eric Rutt <Eric.Rutt@WolfGreenfield.com>
Subject: RE: IPR2023-00604: Requesting a Reply to Patent Owner's Preliminary Response

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Your honors,

Pursuant to 37 C.F.R. 42.71(d), Petitioner respectfully requests reconsideration of the Board's email decision denying a short reply to the Patent Owner's preliminary response. The rules require an opportunity for Petitioner to articulate its position concerning good cause. 37 CFR 42.108(c) ("A petitioner may seek **leave to file a reply to the preliminary response** in accordance with §§ 42.23 and 42.24(c). **Any such request must make a showing of good cause.**") (emphasis added); *see also, e.g.*, 5 U.S.C. 554(c) and 556(d). Complying with the Board's policy prohibiting substantive arguments via email, and now with no ability to provide the good cause on a conference call, Petitioner has been denied its opportunity to show good cause. Petitioner's prejudice is exacerbated by Patent Owner's improper and highly argumentative email brief, which falsely argued that the POPR did not take substantive positions on Jung's disclosures. That is demonstrably false, as are numerous other positions taken by the Patent Owner in its POPR, including its argument regarding footnotes.

Accordingly, the Board misapprehended or overlooked Petitioner's right to an opportunity to at least articulate good cause for a reply brief, and failed to provide the APA-required "brief statement of the grounds for denial" of Petitioner's request for authorization to file a short reply brief (5 USC 555(e)).

Thank you for your reconsideration.

Regards,

-Dion Bregman
Counsel for Petitioner

Dion M. Bregman

Morgan, Lewis & Bockius LLP

1400 Page Mill Road | Palo Alto, CA 94304

Direct: +1.650.843.7519 | Main: +1.650.843.4000 | Fax: +1.650.843.4001

dion.bregman@morganlewis.com | www.morganlewis.com

Assistant: Kari B. Aguiar | +1.650.843.7877 | kari.aguiar@morganlewis.com



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From: Trials <Trials@USPTO.GOV>

Sent: Tuesday, June 20, 2023 12:49 PM

To: Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>; Jonathan.Roses@WolfGreenfield.com; Trials <Trials@USPTO.GOV>

Cc: Bregman, Dion M. <dion.bregman@morganlewis.com>; Stein, Alexander B. <alexander.stein@morganlewis.com>; MLB-Hugel-IPR-Team <MLB-Hugel-IPR-Team@morganlewis.com>; Stephen.Rabinowitz@WolfGreenfield.com; Eric Rutt <Eric.Rutt@WolfGreenfield.com>

Subject: RE: IPR2023-00604: Requesting a Reply to Patent Owner's Preliminary Response

[EXTERNAL EMAIL]

Counsel,

From the Board –

Petitioner's request for authorization to file a reply to the Preliminary Response is denied. A conference call is not necessary at this time.

Regards,

Esther Goldschlager
Supervisory Paralegal Specialist
Patent Trial & Appeal Board
U.S. Patent & Trademark Office

From: Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>
Sent: Friday, June 16, 2023 2:00 PM
To: Jonathan.Roses@WolfGreenfield.com; Trials <Trials@USPTO.GOV>
Cc: Bregman, Dion M. <dion.bregman@morganlewis.com>; Stein, Alexander B. <alexander.stein@morganlewis.com>; MLB-Hugel-IPR-Team <MLB-Hugel-IPR-Team@morganlewis.com>; Stephen.Rabinowitz@WolfGreenfield.com; Eric Rutt <Eric.Rutt@WolfGreenfield.com>
Subject: RE: IPR2023-00604: Requesting a Reply to Patent Owner's Preliminary Response

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Your honors,

Petitioner declines to substantively respond to Patent Owner's highly argumentative email brief, but is available to discuss the request for a short reply brief on a call with the Board next week (should a call be required).

Best regards,

Guylaine

Guylaine Haché, Ph.D., J.D.
Morgan, Lewis & Bockius LLP

110 North Wacker Drive, Suite 2800 | Chicago, IL 60606-1511

Direct: +1.312.324.1752 | Main: +1.312.324.1000 | Fax: +1.312.324.1001 | Mobile: +1.312.343.7138

guylaine.hache@morganlewis.com | www.morganlewis.com | **My Morgan Lewis Bio**

Pronouns: she/her/hers

From: Jonathan.Roses@WolfGreenfield.com <Jonathan.Roses@WolfGreenfield.com>
Sent: Friday, June 16, 2023 11:58 AM
To: Trials <Trials@USPTO.GOV>
Cc: Bregman, Dion M. <dion.bregman@morganlewis.com>; Stein, Alexander B. <alexander.stein@morganlewis.com>; MLB-Hugel-IPR-Team <MLB-Hugel-IPR-Team@morganlewis.com>; Stephen.Rabinowitz@WolfGreenfield.com; Eric Rutt <Eric.Rutt@WolfGreenfield.com>; Jonathan.Roses@WolfGreenfield.com; Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>; Jonathan.Roses@WolfGreenfield.com
Subject: RE: IPR2023-00604: Requesting a Reply to Patent Owner's Preliminary Response

[EXTERNAL EMAIL]

Dear Honorable Board,

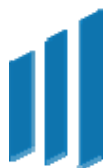
Patent Owner objects to Petitioner's email as improper. Petitioner violated the Board's practice prohibiting argument via email. Worse yet, despite baselessly accusing Patent Owner of a rule violation, Petitioner seeks to silence Patent Owner by suggesting that no Board call is even needed to determine whether Petitioner can establish the required good cause showing for a pre-institution reply.

Petitioner's reckless assertion that Patent Owner violated 37 C.F.R. 42.51(b)(1)(iii) requires a response. It is unsupported and flat wrong. Petitioner identifies no argument in the POPR that is allegedly "inconsistent" with any information Petitioner seeks to submit because there is no such argument. During meet and confer, the alleged "unforeseeable positions" Petitioner articulated related to whether it was known if Jung (EX1002) isolated the macro complex of botulinum toxin. The POPR arguments on this point (Paper 6 at 31-35) were that the Petitioner failed to submit any evidence establishing that limitation.

There is nothing “unforeseeable” about Patent Owner identifying the Petition’s failure to establish a *prima facie* case. Petitioner transparently fabricates an alleged rule violation to justify submission of additional evidence to try to fill a gap in the Petition’s evidentiary showing in violation of the Trial Practice Guide’s prohibition against submitting new evidence in a reply that could have been submitted earlier in an attempt to establish *prima facie* unpatentability. Consolidated Trial Practice Guide at 73-74.

Petitioner’s email does not establish the required good cause showing for a pre-institution reply. See Consolidated Trial Practice Guide at 51-52. The Board should deny Petitioner’s request or hold a call and require Petitioner to make a showing of good cause. If the Board grants Petitioner a reply without a call, Patent Owner respectfully requests a sur-reply of equal length.

With respect,
Jonathan B. Roses
Reg. No. 61,115
Counsel for Patent Owner



Jonathan B. Roses

Pronouns: he/him/his

Shareholder

Admitted to Practice: MA

Jonathan.Roses@WolfGreenfield.com

O: 617.646.8157 | F: 617.646.8646

Wolf, Greenfield & Sacks, P.C.

BOSTON | NEW YORK | WASHINGTON DC

wolfgreenfield.com  

This e-mail message and any attachments may contain confidential or privileged information. If you are not the intended recipient, please notify me immediately by replying to this message. Please destroy all copies of this message and any attachments. Thank you.

From: Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>

Sent: Thursday, June 15, 2023 4:40 PM

To: Trials <Trials@USPTO.GOV>

Cc: Bregman, Dion M. <dion.bregman@morganlewis.com>; Stein, Alexander B. <alexander.stein@morganlewis.com>;

MLB-Hugel-IPR-Team <MLB-Hugel-IPR-Team@morganlewis.com>; Roses, Jonathan B.

<Jonathan.Roses@WolfGreenfield.com>; Rabinowitz, Stephen S. <Stephen.Rabinowitz@WolfGreenfield.com>; Rutt, Eric

<Eric.Rutt@WolfGreenfield.com>

Subject: IPR2023-00604: Requesting a Reply to Patent Owner’s Preliminary Response

Dear Board,

Petitioner respectfully requests authorization to file a 4-page reply to Patent Owner’s Preliminary Response, along with a small number of exhibits. Patent Owner has taken unforeseeable positions in its Preliminary Response concerning its own Jung reference (Ex. 1002), and each of these new exhibits is “relevant information that is inconsistent with a position advanced by [Patent Owner] during the proceeding.” 37 C.F.R. 42.51(b)(1)(iii).

The parties have discussed this request, but were unable to reach agreement. Because Patent Owner was obligated to provide this relevant information with its Preliminary Response, Petitioner does not believe it would be equitable for Patent Owner to receive an extra pre-institution brief.

If the Board requires further details, the parties are available for a conference call on any of the following dates and times: from 4-5 pm ET on Tuesday, June 20, from 1-3 pm ET on Wednesday, June 21, and from 2:30 to 3:30 pm ET on Thursday, June 22.

Best regards,
Guylaine

Counsel for Petitioner, Reg. No. 76,083

Guyline Haché, Ph.D., J.D.

Morgan, Lewis & Bockius LLP

110 North Wacker Drive, Suite 2800 | Chicago, IL 60606-1511

Direct: +1.312.324.1752 | Main: +1.312.324.1000 | Fax: +1.312.324.1001 | Mobile: +1.312.343.7138

guyline.hache@morganlewis.com | www.morganlewis.com | **My Morgan Lewis Bio**

Pronouns: she/her/hers