

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ETON PHARMACEUTICALS, INC.,  
Petitioner,

v.

EXELA PHARMA SCIENCES, LLC,  
Patent Owner.

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PGR2020-00068  
Patent 10,583,155 B1

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Before ULRIKE W. JENKS, SUSAN L.C. MITCHELL, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

ORDER

Conduct of Proceeding

37 C.F.R. §§ 42.5; 42.208(c)

On October 2, 2020, the Board received an email from counsel for Petitioner Eton Pharmaceuticals, Inc. seeking authorization to file a reply brief, no more than 6 pages, to Patent Owner Exela Pharma Science, LLC's Preliminary Response. Ex. 3001. Petitioner asserts that good cause supports a reply to address the following arguments raised by Patent Owner:

[1] Eton's particularity challenge is unexpected and incorrect. Grounds 1-2 of Eton's petition rely on the four corners of the Sandoz Label as invalidating prior art.

[2] Exela's assertions regarding the prior art should be considered in view of the Examiner's July 23, 2020 rejections in related, co-pending application nos. 16/773,641 and 16/746,028 (the rejections occurred after the filing of Eton's petition) and the materials that provide the relevant context for those rejections.

[3] Exela's assertions that the Petition fails to explain "how a POSITA applying 'routine optimization' would have achieved" the claimed invention (POPR at 8) and fails to explain "why a POSITA would have a reasonable expectation of success" solving the aluminum problem (POPR at 9).

*Id.* (bracketed numbers added).

In a related case, PGR2020-00064, we recently authorized Petitioner to file a reply to address the first two issues identified in Petitioner's email above in addition to the issue of whether the "Allergy Process" is a public use. PGR2020-00064, Paper 7. Petitioner, however, did not previously request a reply to address Patent Owner's arguments regarding "routine optimization" and "reasonable expectation of success."

Having considered Petitioner's request, we determine that additional briefing would clarify the record with respect to first two topics identified in Petitioner's email of October 2, 2020. Accordingly, we authorize a reply to allow Petitioner to present arguments in this proceeding similar to those

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presented on the same topics in PGR2020-00064. We determine, however, that Petitioner has not identified any good cause to file a reply on the third topic identified in Petitioner's email. We also determine to grant Patent Owner an opportunity to file a sur-reply in response to Petitioner's reply.

For the reasons given, it is:

ORDERED that Petitioner is authorized to submit a 6-page reply no later than October 19, 2020 to address Patent Owner's particularity challenge and Patent Owner's assertions regarding the Examiner's rejections in related applications;

FURTHER ORDERED that Patent Owner is authorized to submit a 6-page sur-reply no later than October 26, 2020, responsive to Petitioner's reply.

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