

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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IPR2021-00880 (Patent 9,669,069 B2)  
IPR2021-00881 (Patent 9,254,338 B2)<sup>1</sup>

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Before ERICA A. FRANKLIN, JOHN G. NEW, and  
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

ORDER  
*Authorizing Additional Briefing*  
37 C.F.R. § 42.5

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<sup>1</sup> This Order addresses the same issue for the above-identified proceedings. Therefore, we exercise our discretion to issue one order to be filed in each proceeding. The parties are not authorized, however, to use this style heading in any subsequent papers.

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For each of the captioned proceedings, Mylan Pharmaceuticals Inc. (“Petitioner”) has requested, *via* email indicating prior conferral between counsel for Petitioner and Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”), authorization to file a consolidated (dual-captioned) Reply Brief in Response to Patent Owner’s Preliminary Response (Paper 10). A telephone conference was held on September 8, 2021, with counsel for both parties, and the transcript of that conference has been made a part of the record. Ex. 1086.

Specifically, Petitioner seeks authorization to file a Reply Brief for the limited purpose of addressing Patent Owner’s arguments with respect to our discretion to deny institution under 35 U.S.C. § 325(d) and the factors set forth with respect to that discretion in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017)).

Petitioner argues that good cause exists for authorization to file a Reply Brief because it is necessary to illustrate how Patent Owner’s preliminary responses allegedly do not present a fair interpretation of either the Petitions or the relevant facts and law here. Ex. 1086, 8. It is Petitioner’s position that under the facts of the challenged patents, and their respective file histories, that the cited prior art, and Petitioner’s arguments are not cumulative of anything the Examiner asserted or evaluated during prosecution. *Id.* For that reason, argues Petitioner, it could not have anticipated Patent Owner’s argument with respect to the *Becton, Dickinson* factors involving the same or substantially the same art or arguments as a basis for denying institution. *Id.*

Patent Owner opposes Petitioner’s request. According to Patent Owner, there is no good cause for granting Petitioner’s request for additional briefing because *Advanced Bionics, LLC v. MED-EL Elektromedizinische*

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*Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) makes clear that the previously-presented art includes art that was made of record by the Examiner, including in an IDS. Ex. 1086, 12. Patent Owner asserts that Petitioner did nothing to address this issue in either of its petitions in the above-referenced cases, failing to anticipate this position in its Petition. *Id.*

Having considered the circumstances involved and the reasoning presented by both parties, we determine that further briefing would be useful for our determination whether to institute trial. Accordingly, we authorize Petitioner to file a consolidated Reply with respect to both cases, and we similarly authorize Patent Owner to file a consolidated Sur-Reply to address the issue in both cases. The Reply and Sur-Reply briefings are each limited to ten pages, and are subject to the requirements of 37 C.F.R. § 42.6(a). Petitioner's Reply shall be submitted no later than one week following the issuance of this order, and if Patent Owner elects to file a Sur-Reply, it shall be filed no later than one week subsequent to the filing of Petitioner's Reply. No additional briefing is authorized.

## ORDER

It is therefore,

ORDERED that Petitioner is authorized to file in each of the captioned proceedings a consolidated Reply Brief on issue set forth in the preceding discussion, said Reply Brief not to exceed ten pages, and to be filed no later than September 29, 2021, and

FURTHER ORDERED that Patent Owner is authorized in each of the captioned proceedings to file a consolidated Sur-Reply in response to Petitioner's Reply, said Sur-Reply not to exceed ten pages, and to be filed no later than one week after Petitioner's Reply is filed.

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For PETITIONER:

Paul Molino  
Neil McLaughlin  
RAKOCZY MOLINO MAZZOCHI SIWIK LLP  
paul@rmmslegal.com  
nmclaughlin@rmmslegal.com

For PATENT OWNER:

Deborah Fishman  
Amanda Antons  
Alice Sin Yu Ho  
ARNOLD & PORTER KAYE SCHOLER LLP  
Amanda.antons@arnoldporter.com  
Alice.ho@arnoldporter.com  
Deborah.fishman@arnoldporter.com