

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**WATSON LABORATORIES, INC.**

Petitioner

v.

**UNITED THERAPEUTICS, INC.<sup>1</sup>**

Patent Owner

Patent No. 9,339,507

Issue Date: July 13, 2017

Title: TREPROSTINIL ADMINISTRATION BY INHALATION

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*Inter Partes* Review No. 2017-01622

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**REQUEST FOR REHEARING OF DECISION AUTHORIZING  
PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY  
RESPONSE UNDER 37 C.F.R. § 42.71**

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<sup>1</sup> The caption identifies Patent Owner as "United Therapeutics, Inc.," whereas the assignment and the patent identify Patent Owner as "United Therapeutics Corporation." Ex. 1001, 1(73). Accordingly, appropriate correction of this caption is suggested.

## I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.71(d), Patent Owner United Therapeutics Corporation (“Patent Owner”) respectfully requests rehearing of the decision dated November 2, 2017 authorizing Petitioner to file a reply to Patent Owner’s Preliminary Response. In its entirety, the November 2<sup>nd</sup> decision (issued by email from the Board’s Supervisory Paralegal) reads as follows (Ex. 2031):

In IPR2017-01621 and IPR2017-01622, Petitioner is authorized to file a Reply to Patent Owner’s Preliminary Response to address Patent Owner’s argument relating to 35 U.S.C. § 315(b) and its assertion that Ghofrani is not prior art by another. The Reply is limited to 5 pages and shall be filed no later than November 9, 2017. A conference call is not necessary at this time.

The parties did not brief the issue beyond Petitioner’s email request for permission to file a reply and Patent Owner’s statement of opposition. Ex. 2031.

## II. ARGUMENT

### A. The Board Should Not Permit a Reply Because the Board Cannot Consider a Reply in Its Institution Decision

The Board should not permit Petitioner to file a reply because the Board cannot consider any reply or accompanying evidence in making its institution decision under 35 U.S.C. § 314. Section 314(a) prohibits the Board from instituting trial “unless the Director determines that the *information presented in the petition* filed under section 311 and *any response* filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (emphasis added). Thus, the statute makes clear that the Board may look to only two sources in making its institution decision: (1) the petition under § 311; and (2) patent owner’s preliminary response under § 313. *Id.*; see also *Leatherman v. Tarrant*

*Cty. Narcotics Intelligence and Coordination Unit*, 507 U.S. 163, 168 (1993) (holding that Rule 9(b)'s enumeration of two specific causes of action excludes others); *Cook v. Principi*, 318 F.3d 1334, 1339 (Fed. Cir. 2003) (“[a]pplying the familiar canon of *expressio unius est exclusio alterius*” to conclude that Congress did not intend exceptions beyond those specifically enumerated). Although the statute does not expressly forbid a reply, § 314(a) prohibits the Board from relying on anything in a Petitioner’s reply in making its institution decision. Thus, Petitioner should not be permitted to submit a reply.

**B. Patent Owner’s Preliminary Response Presented No Evidence Relating to the 35 U.S.C. § 315(b) Issue That Would Have Been Unavailable to Petitioner at the Time It Filed Its Petition**

The facts presented by Patent Owner on the § 315(b) issue in its Preliminary Response were available to Petitioner at the time it filed its petition. Indeed, Petitioner specifically addressed timeliness under § 315(b) in its Petition. Pet. at 5. The Board has refused to permit a petitioner’s reply in other cases. For example, in *ARM, Ltd. v. Godo Kaisha IP Bridge 1*, IPR2016-00825, Paper 11 (PTAB Sept. 29, 2016), the petitioner sought authorization to reply to the patent owner’s argument of priority entitlement. The panel denied the petitioner’s request, explaining that “[p]etitioner had notice and opportunity to raise this issue” as demonstrated by the fact that the petition “makes clear that [p]etitioner at least contemplated the possibility” that the patent owner would rely on foreign priority. *Id.* at 3. Here too, Petitioner should not be permitted to present evidence and arguments in a reply that it should have included in its Petition.

**C. The Board’s Decision Provides No Reasoning and Was Made Without Hearing Arguments from Patent Owner**

Patent Owner was denied an opportunity to be heard. Also, other Board decisions have provided reasoning for authorizing a Petitioner’s Reply and analyzed whether Petitioner’s request satisfied the “good cause” standard. For example, in *Xactware Solutions Inc. v. Pictometry Int’l Corp.*, IPR2016-00593 and-00594, Papers 11 and 12 (PTAB July 1, 2016), a panel denied the petitioner’s request for authorization to file a reply, explaining:

Good cause may exist in certain situations such as where new evidence comes to light after the filing of a petition or a legal argument of first impression is made by the Patent Owner, we are not persuaded that sufficient good cause exists in this case. To the extent that Petitioner seeks to identify new citations or bolster arguments in the Petition, we are not required to allow Petitioner to do so. Additionally, identifying and evaluating statements or misstatements of the facts and law are well within the purview of the Panel of Judges assigned to these proceedings. It may always be the case that a Petitioner is unhappy with how Patent Owner characterizes the facts and law presented in the Petition. Our rules, however, provide for a Petitioner Reply only when good cause exists. Petitioner has not established good cause and as such, we do not authorize the filing of any Replies.

Here too, Petitioner has not shown good cause. Also, the Board’s decision suffers from the same problems noted in *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267 (Fed. Cir. 2017). Namely, the Board’s procedure allowed it to render its decision without providing an explanation or reasoned basis, thus impeding “meaningful appellate review of the agency decision-making.” *Id.* at 1274.

**III. CONCLUSION**

Patent Owner respectfully requests rehearing of the decision to authorize a reply by Petitioner to Patent Owner’s Preliminary Response.

Date: November 3, 2017

Respectfully submitted,

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