

IPR2020-00324  
Patent 8,114,833 B2

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN INSTITUTIONAL LLC and PFIZER INC.,  
Petitioners,

v.

NOVO NORDISK A/S,  
Patent Owner.

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Case IPR2020-00324<sup>1</sup>  
Patent 8,114,833

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**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE  
UNDER 37 C.F.R. § 42.64(c)**

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<sup>1</sup> IPR2020-01252 has been joined with this proceeding.

## I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner Novo Nordisk A/S (“Novo Nordisk”) moves to exclude from evidence, in their entirety, Exhibits 1091-1098, 1103, 1106, and 1114-1115, which were submitted by Petitioner Mylan Institutional LLC (“Petitioner”) with its Reply (Paper 35). This Motion is timely pursuant to the Scheduling Order entered in this proceeding on June 23, 2020. Paper 15 at 10.

Petitioner’s expert’s Reply Declaration (Exhibit 1106) offers new scientific theories that could, and should, have been included in the Petition and advances an entirely new basis for the prior art status of Betz (Exhibit 1005), a foundational reference of Petitioner’s Ground 3. Petitioner’s belated disclosure of these arguments contravenes the Board’s rules and prejudices Novo Nordisk, denying its expert an opportunity to respond. It is not the Board’s duty to sift through Petitioner’s 114-page Reply Declaration, separating improper from proper content, and the Board should exclude it in its entirety. At a minimum, the Board should exclude the paragraphs of the Reply Declaration that most clearly espouse new theories, as well as the numerous new Exhibits offered to support them.

The Board should exclude 8 pages of the Reply Declaration which advance Petitioner’s new basis for the prior art status of Betz for the additional and independent reason that Petitioner attempts to improperly incorporate this argument by reference into its Reply, again flouting the Board’s rules.

## II. STATEMENT OF MATERIAL FACTS

On December 14, 2020, Petitioner filed with its Reply 53 Exhibits, including a 114-page Reply Declaration of Dr. Laird Forrest (Ex1106). The twelve Exhibits that are the subject of this Motion were introduced for the first time with Petitioner's Reply, not to counter arguments in the Patent Owner Response, but rather to address deficiencies in Petitioner's *prima facie* case presented in its Petition.

All references that are the subject of this Motion were publicly available at the time of the Petition and would have been revealed by a diligent search. There is no reason that Petitioner could not have filed them with its Petition, nor any reason its expert could not have opined on them in his first declaration. Because Petitioner's untimely evidence and arguments were first submitted on Reply, Novo Nordisk and its expert were denied the opportunity to respond to them in the Patent Owner Response. The technical nature of the arguments, coupled with a lack of expert testimony at the sur-reply stage, denied Novo Nordisk a meaningful opportunity to respond to the arguments there, as well.

Following service of the Reply, Novo Nordisk timely objected to the Exhibits that are the subject of this Motion by filing Patent Owner's Notice of Objections Under 37 C.F.R. § 42.64 on December 21, 2020. Paper 38.

### III. LEGAL STANDARDS

The Federal Rules of Evidence govern the admissibility of evidence and expert testimony in an *inter partes* review. 37 C.F.R. § 42.62(a). Irrelevant evidence is not admissible, and relevant evidence may be excluded “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, [or] confusing the issues.” FED. R. EVID. 402, 403.

A Petitioner’s Reply may only respond to arguments raised in the Patent Owner Response and may not raise new issues. 37 C.F.R. § 42.23(b). The Patent Trial and Appeal Board Consolidated Trial Practice Guide elaborates on this rule:

[A] reply . . . that raises a new issue or belatedly presents evidence may not be considered. The Board is not required to attempt to sort proper from improper portions of the reply. . . . Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the . . . unpatentability of an original . . . claim . . . [and] new evidence . . . that could have been presented in a prior filing.

Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Trial Practice Guide”) at 74 (Nov. 2019), *available at* <https://go.usa.gov/xpvPF>.

Improper new evidence introduced on Reply is inadmissible under 37 C.F.R. § 42.61(a) and thus subject to exclusion. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081 (Fed. Cir. 2015) (“[A] party may move to exclude evidence, whether as improper under the response-only regulation, under the Trial Practice Guide’s advice, or on other grounds.”). The Reply is not an opportunity for Petitioner to resolve deficiencies with the arguments and evidence presented in its Petition. *See Toyota Motor Corp. v. Am. Vehicular Sci. LLC*, IPR2013-00424, Paper 50 at 21 (P.T.A.B. Jan. 12, 2015) (“[Petitioner] cannot rely belatedly on this evidence in its Reply and Reply Declaration . . . to make up for the deficiencies in its Petition.”).

#### **IV. EXHIBITS OUTSIDE THE PROPER SCOPE OF PETITIONER’S REPLY SHOULD BE EXCLUDED UNDER THE PTAB RULES, THE TRIAL PRACTICE GUIDE, AND THE FEDERAL RULES OF EVIDENCE**

Petitioner’s Reply improperly introduced new evidence and arguments intended to address deficiencies in its Petition. The new evidence is inadmissible under 37 C.F.R. § 42.61(a) and should be excluded. *See* 37 C.F.R. § 42.23(b); Trial Practice Guide, 74; *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, IPR2013-00517, Paper 87 at 14-16 (P.T.A.B. Feb. 11, 2015) (rather than rebutting the Patent Owner Response, Petitioner improperly presented new evidence and rationale on Reply); *Lupin Ltd. v. Senju Pharm. Co., Ltd.*, IPR2015-01099, Paper 69 at 27-28, 44-45 (P.T.A.B. Sept. 12, 2016) (according no weight to Petitioner’s

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