

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION
Patent Owners

Case No. IPR2021-00816

U.S. Patent No. 9,220,631

PATENT OWNER'S MOTION TO EXCLUDE

I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.62, 42.64(c), the Board’s Scheduling Order (Paper 14), and the Federal Rules of Evidence (“FRE”), Patent Owner Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, “Patent Owner”), move to exclude from evidence the following:

Exhibit	Description	Petitioner’s Citations
Ex. 1105 ¶¶ 28-29	Koller Reply Declaration	Paper 72 at 6
Ex. 1108	Cohen Declaration	Paper 72 at 5-6

II. FACTUAL BACKGROUND

In order to meet its burden of proving unpatentability of the challenged claims, Petitioner supported its petition with the expert declaration of Horst Koller (Ex. 1003). *See* Pet. (Paper 1). In its Response, Patent Owner demonstrated that there were significant deficiencies in Petitioner’s prima facie case and Mr. Koller’s declaration, and that, accordingly, Petitioner could not meet its burden of proof. Resp. (Paper 40) at 10-13.

In its Reply, Petitioner attempted to fill the deficiencies in its evidence by submitting a reply declaration from Mr. Koller (Ex. 1105), which raised brand new arguments, and the declaration of an entirely new invalidity expert, Dr. Joel Cohen (Ex. 1108). Patent Owner timely filed and served its objections to the new arguments and declaration, identifying them as new evidence that was outside the

scope of proper reply. Objections (Paper 76) at 20-22, 26-28; *see* 37 C.F.R. § 42.23(b). Patent Owner deposed Mr. Koller with respect to his reply declaration on May 16, 2022 (Ex. 2347), and Dr. Cohen on May 19, 2022 (Ex. 2340).

Patent Owner requested leave to file a reply expert declaration to address Petitioner's new evidence. Order (Paper 88) at 2. Petitioner opposed. *Id.* On May 25, 2022, the Board denied Patent Owner's request. *See id.* at 4 (citing Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) ("CTPG") at 73). However, the Order also provided that "[t]o the extent Petitioner presented new evidence in its Reply that may be deemed improper," the Board would "consider such arguments upon a completed record." *Id.* (citing 37 C.F.R. § 42.23(b); CTPG 73-74).

III. LEGAL STANDARD

USPTO regulations and the Federal Rules of Evidence govern the admissibility of evidence and expert testimony in an *inter partes* review ("IPR"). 37 C.F.R. §§ 42.61(a), 42.62(a). "Because of the expedited nature of IPR proceedings," petitioners must "adhere to the requirement that the initial petition identify with particularity the evidence that supports the grounds for the challenge to each claim." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330 (Fed. Cir. 2019) (internal quotation marks and citations omitted). "A reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary

response, patent owner response, or decision on institution.” 37 C.F.R. § 42.23(b). But a petitioner “may not submit new evidence or argument in reply that it could have presented earlier, *e.g.* to make out a prima facie case of unpatentability.” CTPG at 73; *see Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1370 (Fed. Cir. 2016). Such new evidence is inadmissible and subject to exclusion. 37 C.F.R. § 42.61(a); *see Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1081 (Fed. Cir. 2015).

IV. ARGUMENTS

A. Patent Owner’s Motion Satisfies the Procedural Requirements

Patent Owner’s Motion to Exclude satisfies the procedural requirements. Patent Owner timely filed and served its objections to Exhibits 1105 and 1108. 37 C.F.R. § 42.64(b); *see* Objections II at 20-22, 26-28. The chart below, identifies where in the record the evidence sought to be excluded was relied upon by Petitioner. *See* 37 C.F.R. § 42.64(c).

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Patent Owner explains the bases for these objections below. *See* Section IV(B); *see also* 37 C.F.R. § 42.64(c) (requiring that the moving party’s “motion must identify the objections in the record in order and must explain the objections”).

B. Petitioner’s New Evidence Should Be Excluded

Portions of the Koller reply declaration (Ex. 1105 ¶¶ 28-29) and the entirety of the Cohen declaration (Ex. 1108; Regeneron cites specifically to ¶¶ 26, and 29-44) are outside the scope of proper reply. Petitioner “cannot rely belatedly” on Reply Declarations “to make up for the deficiencies in its Petition.” *Toyota Motor Corp. v. Am. Vehicular Sci. LLC*, IPR2013-00424, 2015 WL 183909, at *10 (PTAB Jan. 12, 2015); *see also Laboratoire Francais du Fractionnement et des Biotechnologies SA v. Novo Nordisk Heathcare AG*, No. IPR2017-00028, 2022 WL 1153444, at *7 (PTAB Apr. 13, 2022) (Petitioner cannot offer new arguments and evidence “at the reply stage to bolster the bare bones analysis presented in [its] Petition.”). This evidence is improper on reply, prejudicial to Patent Owner, and, as such, should be excluded. 37 C.F.R. § 42.23(b); *see* CTPG at 73-74; *The Scotts Co. LLC v. Encap, LLC*, IPR2013-00110, 2014 WL 2886290 at *3 (PTAB June 24, 2014).

1. Mr. Koller’s Opinions Regarding Parylene C Not Contacting the VEGF Antagonist Are Untimely

Petitioner’s central reference on unpatentability is WO 2009/030976 (“Boulangé”). *See* Pet. at 21; Ex. 1008 (Boulangé). Boulangé is a patent application directed to the invention of using a chemical called Parylene C to coat syringe stoppers. *See* Ex. 1008.003-004. Petitioner and Patent Owner have offered

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