Paper No. ___
Filed: May 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854[1]
Patent No. 9,187,405

PETITIONERS' OPPOSITION TO NOVARTIS'S SUPPLEMENTAL MOTION TO EXCLUDE 37 C.F.R. §42.64

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[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

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I. INTRODUCTION

Petitioners oppose Novartis's Supplemental Motion to Exclude of April 30, 2018. Novartis fails to establish entitlement to the requested relief. 37 C.F.R. § 42.20(c). A motion to exclude evidence must identify where each objection originally was made, and must explain why the evidence is not admissible, "but may not be used to challenge the sufficiency of the evidence to prove a particular fact." Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48767 (Aug. 14, 2012). Novartis's Motion is also a thinly-veiled merits brief in support of its Motion to Amend. It fails on the merits and should be denied.

II. ARGUMENT

Novartis seeks to exclude Exhibits 1065-1069 "as untimely under the Board's rules, and for lack of any relevance foundation under Fed. R. Evid. 401-403." Mot. at 1. Novartis offers three arguments in support of exclusion. Novartis first argues that Exhibits 1065-1069 were submitted for the first time with Petitioners' Sur-Reply and "without any expert testimony or other evidence to lay any foundation whatsoever," citing 37 C.F.R. 42.23(b). But Rule 42.23(b) does not require expert testimony to accompany the submission of exhibits. Further, Novartis did not object to any of Exhibits 1065-1069 for lack of foundation or authenticity or cite Rule 42.23(b) in its objections. Paper 87. The exhibits are self-authenticating patents or patent publications, and their foundation as such is

established by the documents themselves. F.R.E. 902(1)-(5). Moreover, a motion to exclude is not an appropriate vehicle for raising alleged noncompliance with Rule 42.23(b). *Cisco Sys., Inc. v. TQ Delta, LLC*, IPR2016-01760, Paper 35 at 42-43 ("A motion to exclude is not a vehicle to argue that a reply contains new arguments."); *F5 Networks, Inc. v. Radware, Ltd.*, IPR2017-00124, Paper 48 at 68 ("[T]he Board has repeatedly stated that a motion to exclude is not the proper vehicle to challenge the scope of a reply."); *Blackberry Corp. v. Zipit Wireless, Inc.*, IPR2014-01508, Paper No. 49 at 40 (same); *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM2012-00002, Paper 66 at 62 ("While a motion to exclude may raise issues related to admissibility of evidence, it is not an opportunity to file a sur-reply, and also is not a mechanism to argue that a reply contains new arguments or relies on evidence necessary to make out a prima facie case."); *Kyocera Corp. et al. v. Softview LLC.*, IPR2013-00007, Paper 51 at 34 ("A motion to exclude is neither a substantive sur-reply, nor a proper vehicle for arguing whether a reply or supporting evidence is of appropriate scope.").

Petitioners' Sur-Reply was necessitated when Novartis chose to disregard 37 C.F.R. 42.23(b), which requires that "All arguments for the relief requested in a motion must be made in the motion." Novartis indicated in its Corrected Contingent Motion to Amend (Paper 61 at 2) that it was "instead holding any rebuttal argument until reply." In its Reply in Support of Contingent Motion to

Amend (Paper 64), Novartis made new arguments and cited new testimonial evidence. The Board thus authorized Petitioners to file a sur-reply, including the submission of additional evidence. Paper 66 at 2-3. In Paper 72, the Board limited its authorization "to responding to arguments and citations to expert testimony expressly set forth in Patent Owner's Reply to Petitioner's Opposition to Patent Owner's contingent motion to amend." Paper 72 at 2. Petitioners' April 19, 2018 Sur-Reply (Paper 85) and related submissions (including Exhibits 1065-1069) were timely filed on April 19, 2018 pursuant to the Board's Order. Paper 66 at 3.

Petitioners' April 19, 2018 submissions complied with Rule 42.23(b) and the Board's orders (Papers 66, 72) by responding to arguments raised in Novartis's Reply (Paper 64). Petitioners' Sur-Reply cited Exhibits 1065-1069 to respond to Novartis's reply argument and new expert testimony "that loading dose regimens are species of dosing regimens and that the term dosing regimen means 'a schedule of doses of a therapeutic agent per unit of time." Paper 85 at 10 (citing Reply at 5, EX2096, ¶¶18-20). As Petitioners pointed out, Novartis's argument assumes that "a dosing regimen" in a method for treating must be the only dosing regimen for the same active ingredient, and Novartis argued on that basis that the inclusion of "a dosing regimen" in an open-ended method closes the method off to different dosing regimens for the same active. Paper 85 at 10.

Petitioners cited Exhibits 1065-1069 to demonstrate that methods of

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