UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

U.S. Patent No. 9,795,604 to Byrd *et al.*
Issue Date: October 24, 2017
Title: Methods of Treating and Preventing Graft Versus Host Disease

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Inter Partes Review No. IPR2019-00865

PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO STRIKE

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Striking a portion of a brief is "an exceptional remedy that the Board expects will be granted rarely." Trial Practice Guide at 80. The Board should deny Patent Owner's belated (*see id*. at 81) Motion to Strike §§ III.B and III.C.1 of Petitioner's Reply (Paper 17) because those sections permissibly respond to arguments raised in the Patent Owner Response ("POR," Paper 13). Moreover, unlike in *In re NuVasive, Inc.*, 841 F.3d 966, 971 (Fed. Cir. 2016), cited by Patent Owner, here there is no prejudice because Patent Owner has already addressed the sections in its Surreply (Paper 24, at 7–9 and 9–10, respectively) and may do so again at oral argument.

I. The Board Should Not Strike Section III.B of the Reply.

In the Petition, Petitioner argued that the '085 Publication anticipated dependent claims 4, 13, and 15. Pet., Paper 2, at 38–39. In the Institution Decision, the Board preliminarily found these claims not anticipated. Dec., Paper 8, at 20. During trial, Patent Owner cross-examined Petitioner's expert (Dr. Ferrara), and he provided testimony supporting anticipation of these claims. *See* Reply, § III.B. Despite that testimony, and without even addressing it, Patent Owner argued in the POR that "[i]t is undisputed that the steroid-resistant/refractory limitations are not disclosed in the '085 Publication." POR at 20. In Section III.B of the Reply, Petitioner explained that Patent Owner is wrong—the '085 Publication anticipates because, among other reasons, and consistent with Dr. Ferrara's testimony, the '085 Publication explicitly discloses the limitations of dependent claims 4, 13, and 15.

Petitioner's Reply permissibly responded to the POR arguments. "Replies are a vehicle for responding to arguments raised in a corresponding patent owner response." *Unified Patents v. Intellectual Ventures*, IPR2016-01643, Paper 51 at 50 (PTAB Mar. 26, 2018). The Board has permitted, and relied on, Reply arguments that respond to a POR argument, even if the Petition had not addressed them. *See, e.g.*, *Juniper Networks v. Chrimar Sys.*, IPR2016-01391, Paper 66 at 77 (PTAB Dec. 20, 2017) (denying motion to strike where Reply arguments, while not raised in the Petition, responded to POR arguments); *Idemitsu Kosan Co. v. SFC Co.*, 870 F.3d 1376 (Fed. Cir. 2017) ("To the extent [Patent Owner] suggests that the Board could not reach a counterargument because it was not preemptively addressed by the petition or institution decision, [Patent Owner] is plainly mistaken.").

Patent Owner's cases are inapposite. In *Arista Networks, Inc. v. Cisco Systems, Inc.*, the Board found that the "explanations in the Reply . . . [were] not responsive to Patent Owner's arguments." IPR2016-00308, Paper 42 at 14 (PTAB May 25, 2017). In *Henny Penny Corp. v. Frymaster LLC*, there was no suggestion or argument that Petitioner's "new theory first raised in reply" was responsive to Patent Owner's arguments. 938 F.3d 1324, 1331 (Fed. Cir. 2019). Finally, in *Ariosa Diagnostics v. Verinata Health, Inc.*, the court stated that the applicable regulation "limit[s] Reply submissions to matter responsive to the Patent Owner's Response," invoking "efficiency and fairness interests." 805 F.3d 1359, 1368 (Fed. Cir. 2015).

Here, the Reply section sought to be struck directly responds to the POR. Moreover, Patent Owner itself elicited the testimony cited in the Reply (*see* EX2056, 207:11–213:22) and has already addressed the testimony in its Surreply (at 7–9). *See SK Hynix v. Netlist*, IPR2017-00577, Paper 26 at 30 (PTAB July 5, 2018) ("[T]he alleged new theory relies on the same references detailed in the Petition and the Institution Decision and, because the alleged new theory occurred in a deposition held prior to filing the Patent Owner Response, Patent Owner had an opportunity to address the alleged new theory before the hearing and Final Written Decision.").

II. The Board Should Not Strike Section III.C.1 of the Reply.

In the Petition, Petitioner argued that the '085 Publication anticipated certain dependent claims. Pet. at 39–41. Addressing the base claims, Petitioner argued that "the '085 Publication discloses ***administering ibrutinib to treat*** GVHD." *Id*. at 39 (emphasis added). The POR argued that the '085 Publication is "completely silent as to partial or complete response rates for any drug." POR at 17. The Reply then repeated what Petitioner earlier said in the Petition—the Reply argued that "[t]he '085 Publication discloses a 'method of treating' certain diseases by 'administering' ibrutinib, including treating '[GVHD].'" Reply at 10–11 (citation omitted). In response to the POR, the Reply emphasized that "treating" encompasses the claimed patient outcomes. *Id*. at 11. The argument was not new, responded to the POR, has been addressed by Patent Owner in the Surreply (at 9–10), and should not be struck.

Date: June 9, 2020

RESPECTFULLY SUBMITTED,

ALSTON & BIRD LLP

/Kirk T. Bradley/
Kirk T. Bradley
Registration No. 46,571

Counsel for Petitioner
Sandoz Inc.

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