UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

Case IPR2019-00865
U.S. Patent No. 9,795,604

PATENT OWNER'S MOTION TO STRIKE IMPROPER REPLY ARGUMENTS

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Patent Owner respectfully moves to strike §§ III.B and III.C.1 of Petitioner's Reply (Paper 17) as improper new arguments. Petitioner attempts to fill gaps in its Petition by arguing for the first time in reply that the '085 Publication *explicitly* discloses (1) the patient subpopulations of claims 4, 13, and 15 (Reply at 9-10); and (2) the efficacy limitations of claims 6-8, 29-31, 44-46, and 51-53 (*id.* at 10-11). Petitioner's improper new arguments are not only without merit, they also violate Board rules and Federal Circuit precedent and would be unfairly prejudicial to Patent Owner if considered.

I. ARGUMENT

A. Petitioner Improperly Raises a New Argument and Evidence Regarding Claims 4, 13, and 15 (§ III.B)

Pre-institution, Petitioner's sole anticipation theory for claims 4, 13, and 15 relied on what "a POSA would have known." Pet., 38-39 (repeatedly referring to the knowledge of the POSA). In finding no anticipation, the Board correctly acknowledged in the Institution Decision that this knowledge has no place in an anticipation analysis. Paper 8, 20-21.

In Reply, Petitioner newly argues that the '085 Publication *explicitly* discloses the claimed subpopulations, without once referencing the knowledge of the POSA. Reply, 9-10. Because this argument presents an entirely new rationale, it exceeds the proper scope of reply and should be struck. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1331 (Fed. Cir. 2019) (affirming Board's rejection of a reply

argument presenting an "entirely new rationale" for why a claim was unpatentable).

To support its new argument, Petitioner relies on previously uncited ¶¶ [0121] and [0124] of the '085 Publication and unbidden, non-responsive testimony from its expert, Dr. Ferrara—none of which can properly be considered. *Id.* (citing Ex. 2056, 212:1, 212:6-13). Petitioner did not refer to ¶¶[0121] or [0124] pre-institution. *See* Pet., 38-39. A belated argument that a limitation is disclosed by "previously unidentified" portions of the prior art "crosses the line from the responsive to the new." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015); *see also In re NuVasive, Inc.*, 841 F.3d 966, 971 (Fed. Cir. 2016) (error to rely on different portions of prior art from those presented in petition). Dr. Ferrara likewise did not rely on these paragraphs in his pre-institution declaration. *See* EX1006, ¶¶32, 85-86. Instead, he referenced one of them, ¶[0124], in a non-responsive soliloquy during his post-institution deposition. *See* EX2056, 207:11-213:22. Had Petitioner provided notice of this argument pre-institution, Patent Owner could have cross-examined him on this point. Previous panels have rejected such belated attempts to raise new arguments, especially with post-institution testimony. *Henny Penny Corp*, 938 F.3d at 1331, n.1; *Arista Networks, Inc., v. Cisco Systems, Inc.,* IPR2016-00308, Paper 42 at 13 (PTAB, May 25, 2017). As in *Arista*, the subject matter of Dr. Ferrara's deposition testimony was not relied upon or specifically argued in the Petition or his declaration. As a result, it would be

improper to permit this new argument into the record.

B. Petitioner's Reply Newly Argues Express Anticipation of the Clinical Efficacy Limitations (§ III.C.1)

Initially, Petitioner relied *solely* on a theory of inherency to assert that the '085 Publication allegedly anticipates the efficacy limitations of claims 6-8, 29-31, 44-46, and 51-53. Pet., 39-41 ("the patient outcomes recited in these dependent claims are an *inherent and necessary* effect . . . .") (emphasis added). In Reply, Petitioner adds the new argument, with a dedicated heading, that such claims are "[e]xplicitly" disclosed. Reply, 10-11. Tellingly, nowhere does Petitioner cite to Patent Owner's Response to support the inclusion of this new (and incorrect) argument. *See id*.

Petitioner did not argue express anticipation in the Petition. Petitioner should be held to its strategic choices. *See Arista,* IPR2016-00308, Paper 42 at 14 ("The explanations in the Reply, therefore, are not responsive to Patent Owner's arguments that the limitation is not disclosed. Rather they are a new mapping of the claims to the prior art in light of the gaps that Patent Owner pointed out in its Response.").

II. CONCLUSION

Patent Owner respectfully requests that the Board strike §§ III.B and III.C.1 from Petitioner's Reply and not consider them in the Final Written Decision.

Respectfully submitted,

Date: June 4, 2020

By: / *William B. Raich* /
William B. Raich, Reg. No. 54,386

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Motion to Strike Improper Reply Arguments** was served electronically via email on June 4, 2020 , in its entirety on the following:

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Petitioner has consented to service by email.

Date: June 4, 2020

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