UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
APOTEX INC., APOTEX CORP.,
EMCURE PHARMACEUTICALS LTD.,
HERITAGE PHARMA LABS INC.,
HERITAGE PHARMACEUTICALS INC.,
GLENMARK PHARMACEUTICALS, INC., USA,
GLENMARK HOLDING SA,
GLENMARK PHARMACEUTICALS, LTD.,
MYLAN LABORATORIES LIMITED,
TEVA PHARMACEUTICALS USA, INC.,
and FRESENIUS KABI USA, LLC,
Petitioners,
v.
ELI LILLY & COMPANY,
Patent Owner.

Case No: IPR2016-00318[1]
Patent No. 7,772,209

PATENT OWNER ELI LILLY'S OPPOSITION TO PETITIONERS' MOTION TO CROSS-EXAMINE DR. NIYIKIZA BY DEPOSITION[2]

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[1] Cases IPR2016-01340 and IPR2016-01429 have been joined with the instant proceeding.

[2] Except for the cover page, identical copies of this Opposition have been filed in *Sandoz Inc. v. Eli Lilly & Company*, IPR2016-00318, and *Neptune Generics, LLC v. Eli Lilly & Company*, IPR2016-00237, IPR2016-00240.

In their Motion, Petitioners make a request for a deposition that is wholly untethered from the Board's rules regarding limited discovery. Patent Owner Eli Lilly and Company ("Lilly") submitted excerpts of the district court validity trial testimony of inventor Dr. Clet Niyikiza relating principally to skepticism of the invention. At Petitioners' request, Lilly produced the rest of Dr. Niyikiza's trial testimony (including his trial cross-examination), his deposition on the same issues by Joinder-Petitioners Teva and Fresenius (f/k/a APP), and all of the exhibits used at the validity trial and at his deposition. Unsatisfied, Petitioners seek their own additional deposition.

Contrary to Petitioners' arguments, however, the deposition they seek is not "routine" discovery nor proper "additional" discovery. It is not "routine" discovery because Dr. Niyikiza has not submitted an affidavit "prepared for the proceeding." And because Petitioners have failed to articulate what new information a deposition would provide, they also cannot show a need for "additional" discovery under the standards the Board set forth in *Garmin*. Petitioners' position amounts to a *per se* rule that prior sworn testimony—even where the witness was already subject to cross-examination—can only be submitted and given consideration if the witness is deposed. That is not even the law in district courts, never mind in IPR proceedings where discovery is limited.

I. A Deposition of Dr. Niyikiza Is Not Routine Discovery

Petitioners first assert that they are entitled to a deposition of Dr. Niyikiza because "there is no reason to treat sworn trial testimony" from another proceeding "any differently" from the affidavit testimony for which cross-examination is authorized under 37 C.F.R. § 42.51(b)(1)(ii). Mot. at 3. But there is a very good reason: the controlling regulation expressly distinguishes them.

By the plain language of the regulation, "routine discovery" encompasses only "[c]ross examination of affidavit testimony *prepared for the proceeding*." 37 C.F.R. § 42.51(b)(1)(ii) (emphasis added). This language could not be clearer. Dr. Niyikiza's trial testimony constitutes sworn testimony from a different adversarial proceeding—it was not "prepared for" these IPR proceedings. His deposition is therefore not "routine" discovery and is not authorized under § 42.51(b)(1)(ii).[3]

[3] It is also irrelevant, contrary to Petitioners' arguments, how "extensive" Lilly's reliance on Dr. Niyikiza's testimony is. Mot. at 1, 3. The extent to which Lilly has relied on the testimony does not affect whether it is an "affidavit prepared for the proceeding," which plainly it is not. But Petitioners' assertions are also grossly overstated. The relevance of Dr. Niyikiza's testimony is principally in support of Lilly's skepticism arguments, and even as to those arguments the story is well-supported by documentary evidence that Dr. Niyikiza's testimony serves to

That should end the matter as to Petitioners' first argument. But the conclusion is further supported by the history of the regulation. Until 2015, the regulation provided that "[c]ross examination of affidavit testimony" was routine discovery, without a provision specifying the proceeding for which it had to be prepared. 37 C.F.R. § 42.51(b)(1)(ii) (2012). Panels of the Board were split as to whether the regulation encompassed testimony from other proceedings. *Compare, e.g.*, *GEA Process Eng'g, Inc. v. Steuben Foods, Inc.*, IPR2014-00041, Paper 41 at 2–3 (PTAB June 11, 2014) *with, e.g.*, *Ikaria, Inc. v. Geno LLC*, IPR2013-00253, Paper 20 (PTAB Apr. 1, 2014). The amended regulation resolved this disagreement by "clarify[ing] that routine discovery includes only the cross-examination of affidavit testimony prepared for the proceeding." 80 Fed. Reg. 28563. Petitioners' argument thus not only flies in the face of the regulation's plain language, but it ignores the history that gave rise to that language.

The cases Petitioners cite to the contrary are inapposite. Petitioners rely upon *Ikaria, Inc. v. Geno LLC*, IPR2013-00253, Paper 20 (PTAB Apr. 1, 2014),

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authenticate and contextualize. Dr. Niyikiza's additional testimony as to the background of the invention story further explains the context in which the skepticism arose. Lilly does not rely on that invention story for the teachings of the references at issue or the motivations of the person of ordinary skill.

but that case was decided before the PTO amended § 42.51(b)(1)(ii) in 2015 to clarify that cross-examination of testimony from other proceedings as routine discovery is not authorized. *Ikaria* also involved a written declaration rather than oral testimony that was subjected to cross-examination. *Id.* Similarly, although the panel in *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, PGR2015-00011, Paper 29 (PTAB Apr. 1, 2016), indicated that the Patent Owner must make available for deposition a witness who had submitted affidavit testimony during patent prosecution, *id.* at 1–2, the Patent Owner never raised, and the *Altaire* panel did not discuss or analyze, the "prepared for the proceeding" language of § 42.51(b)(1)(ii). Where the PTAB has addressed the relevant question here, as in *Maxliner, Inc. v. Cresta Tech. Corp.*, IPR2015-00594, Paper 32 at 2 (Jan. 15, 2016), it has followed the clear text of § 42.51(b)(1)(ii) and held that cross-examination of testimony prepared for *another* proceeding is not authorized.

For these reasons, Petitioners' assertion that the submission of prior testimony is somehow a way to "avoid cross-examination" or "circumvent the Board's rules," Mot. at 4, is meritless. Under the rules, witnesses who prepare affidavits "for the proceeding" are automatically subject to cross-examination. Witnesses who testified previously—and, as here, were subject to cross-examination previously—are not.

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