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 AND COMPANY,

Patent Owner.

Case IPR2016-00318[1]
U.S. Patent 7,772,209

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] Identical copies of this motion have been filed in Sandoz Inc. v. Eli Lilly & Company, IPR2016-00318, and Neptune Generics, LLC v. Eli Lilly & Company, IPR2016-00237, IPR2016-00240.

Petitioners Sandoz Inc. ("Sandoz") and Neptune Generics, LLC ("Neptune")[3] hereby request the deposition of inventor Dr. Clet Niyikiza pursuant to either routine discovery under 37 C.F.R. § 42.51(b)(1)(ii), or alternatively, additional discovery under 37 C.F.R. § 42.51(b)(2). Should the Patent Trial and Appeal Board (the "Board") not compel Dr. Niyikiza's deposition, then according to prior Board decisions, Exhibit 2116, which is Dr. Niyikiza's direct testimony at a prior district court trial, should be given no weight because Sandoz and Neptune would not have had the opportunity to cross-examine Dr. Niyikiza about that testimony in the present *inter partes* review ("IPR") proceeding.

I. Background

Exhibit 2116 consists of 102 pages from the August 22, 2013 direct trial testimony of Dr. Clet Niyikiza, who is the sole inventor listed on the face of the patent at issue in these IPRs. This testimony was given in the litigation, to which neither Sandoz nor Neptune was a party, Eli Lilly & Co. v. Teva Parenteral Meds., Inc., No. 1:10-CV-1376 (S.D. Ind.) ("Teva Litigation"). Patent Owner Eli Lilly and Company ("Lilly") relies on 37 pages of Exhibit 2116 in its Patent Owner Responses, citing to the exhibit nine times in each response.

[3] The parties joined in IPR2016-00318, IPR2016-00237, and IPR2016-00240 join this motion.

On October 4 and 10, respectively, Neptune and Sandoz each requested the availability of Dr. Niyikiza to sit for his deposition. Lilly responded that it did not intend to make Dr. Niyikiza available. Subsequently, Lilly served supplemental evidence, which included the deposition transcript and the entire direct, cross, redirect, and re-cross trial testimony of Dr. Niyikiza in the Teva Litigation. The parties met and conferred on October 21 and 26, and then participated in a call with the Board on October 31. During that call, the Board authorized the parties to brief the issue of whether Dr. Niyikiza should be deposed. (Ex. 1062, Tr. at 4:18-5:4, 16:12-18.)

II. Dr. Niyikiza Should Be Deposed Because His Deposition Is Routine Discovery Under 37 C.F.R. § 42.51(b)(1)(ii)

In an IPR, "[u]ncompelled direct testimony must be submitted in the form of an affidavit," 37 C.F.R. § 42.53(a), and a declarant or affiant must be made available for cross-examination, as the deposition is routine discovery, 37 C.F.R. § 42.51(b)(1)(ii). A patentee cannot circumvent this requirement by relying on some other form of sworn testimony. For example, the Board has held that, if substantively relied on by the patent owner, a declaration from *another* proceeding, such as prosecution of a patent application, is also considered "affidavit testimony," in which case the declarant's deposition is routine discovery. *See Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, PGR2015-00011, Paper 29 at 1-2 (P.T.A.B. Apr. 1, 2016); *see also Ikaria, Inc. v. Geno LLC*, IPR2013-00253, Paper

20 at 2 (P.T.A.B. Apr. 1, 2014) (noting deposition required notwithstanding the argument that the declaration was submitted during prosecution and thus "was not prepared for the purposes of this proceeding"). There is no reason to treat sworn *trial* testimony, submitted in place of an affidavit, any differently. In both cases, an individual makes arguments regarding validity, and the Board can only properly weigh those arguments after he or she has been cross-examined in the IPR.

Lilly's Patent Owner Responses repeatedly rely on Dr. Niyikiza's trial testimony to support substantive allegations including alleged skepticism about the claimed invention, alleged industry praise, and Lilly's own version of the invention story. (IPR2016-00318, Paper 36 at 10-12, 57, 59; IPR2016-00237, Paper 33 at 11-12, 55-56; IPR2016-00240, Paper 32 at 11-13, 55-56.) Dr. Niyikiza's testimony and Lilly's extensive reliance on this testimony is equivalent to a party relying on "affidavit testimony" in an IPR. Lilly's reliance on this testimony in this IPR mandates the cross-examination of Dr. Niyikiza as routine discovery. *See Altaire*, PGR2015-00011, Paper 29 at 1-2.

Additionally, Lilly's reliance on Dr. Niyikiza's trial testimony, from a matter to which Sandoz and Neptune were not parties, is an improper attempt to circumvent the Board's rules, which make clear that cross-examination of a declarant is an essential component to IPR proceedings. *See* 37 C.F.R. §§ 42.51(b)(1)(ii), (b)(2). Lilly cannot avoid cross-examination by using testimony

from a prior proceeding. Moreover, Lilly's production of Dr. Niyikiza's cross-examination trial testimony does not excuse Lilly's failure to make Dr. Niyikiza available for a deposition in *these* proceedings, particularly here where lead petitioners never had the opportunity to examine Dr. Niyikiza at trial. By heavily relying on Dr. Niyikiza's trial testimony as if it were an affidavit, Lilly injected Dr. Niyikiza into these IPRs and must make him available for deposition under both the letter and spirit of 37 C.F.R. § 42.51(b)(1)(ii), or suffer the consequences for failing to do so. *See* Section IV, *infra*, at 9.

III. Alternatively, Dr. Niyikiza's Deposition Should Be Ordered As Additional Discovery Under 37 C.F.R. § 42.51(b)(2)

If the Board finds that the deposition of Dr. Niyikiza is not routine discovery, then Sandoz and Neptune move for his deposition as additional discovery that is "necessary in the interest of justice" under the *Garmin* factors. *See* 35 U.S.C. § 316(a)(5); *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 at 6-7 (P.T.A.B. Mar. 5, 2013). All five *Garmin* factors support granting petitioners an opportunity to depose Dr. Niyikiza.

A. *Garmin* Factor 1: There is more than a mere possibility that Dr. Niyikiza's deposition will uncover useful information

Sandoz and Neptune are already in possession of a threshold amount of evidence showing that information useful to petitioners will be uncovered by Dr. Niyikiza's deposition. Lilly's Patent Owner Responses rely on Dr. Niyikiza's trial

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