On Behalf Of:

DOCKET

Novartis AG and LTS Lohmann Therapie-Systeme AG, Patent Owners

By: Raymond R. Mandra ExelonPatchIPR@fchs.com (212) 218-2100

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC., and MYLAN PHARMACEUTICALS INC. Petitioner,

v.

NOVARTIS AG and LTS LOHMANN THERAPIE-SYSTEME AG, Patent Owner.

> Case No. IPR2014-00549¹ U.S. Patent 6,316,023 B1

NOVARTIS AG and LTS LOHMANN THERAPIE SYSTEME AG's NOTICE OF APPEAL UNDER 37 C.F.R. § 90.2(a)

¹ Case IPR2015-00265 has been joined with this proceeding.

Case No. IPR2014-00549 U.S. Patent 6,316,023 B1

Notice is hereby given, pursuant to 37 C.F.R. § 90.2(a) and 35 U.S.C. § 142, that Patent Owners Novartis AG and LTS Lohmann Therapie Systeme AG appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("Board") in Case IPR2014-00549 entered on September 28, 2015 (Paper 69) ("Final Written Decision") and from the Decision Denying Patent Owner's Request for Rehearing entered on November 30, 2015 (Paper 77) ("Rehearing Request Denial"), and from all underlying orders, decisions, rulings and opinions, including without limitation the Decision Instituting Inter Partes Review entered on October 14, 2014 (Paper 10) ("Institution Decision").

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owners indicate that the issues on appeal include, but are not limited to: the Board's failure to observe procedure required by law, including, but not limited to, 5 U.S.C. §§ 554 and 556, 35 U.S.C. §§ 2, 311, 314 and 316, and 37 C.F.R. §§ 42.1, 42.20, and 42.104; the Board's failure to abide by its burden under *In re Baxter International, Inc.*, 678 F.3d 1357, 1365 (Fed. Cir. 2012) to "ideally . . . not arrive at a different conclusion" from the Federal Circuit's decision in *Novartis Pharmaceuticals Corp. v. Watson Laboratories, Inc.*, 611 F. App'x 988 (Fed. Cir. 2015) affirming the nonobviousness of the U.S. Patent No. 6,316,023 ("'023 patent"); the Board's impermissible shifting of the burden to Patent Owners to show patentability in

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violation of 35 U.S.C. § 316(e), 5 U.S.C. § 556(d), and 37 C.F.R. § 42.20(c); the Board's failure to consider only prior art consisting of patents or printed publications in contravention of 35 U.S.C. § 311; the Board's determination that the challenged claims of the '023 patent are unpatentable under 35 U.S.C. § 103, which is factually incorrect, not supported by law or substantial evidence, is not based on consideration of the complete record, was not the result of a logical and rational process, and is incorrect as a matter of law; and any finding or determination supporting or related to these issues, as well as all other issues decided adversely to Patent Owners in any orders, decisions, rulings and opinions, all of which, taken together or independently, caused prejudicial harm to Patent Owners.

Simultaneous with this submission to the Director of the United States Patent and Trademark Office, a copy of this Notice of Appeal is being filed electronically with the Patent Trial and Appeal Board. In addition, a copy of this Notice of Appeal is being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit, along with the required docketing fee.

Respectfully submitted,

Patent Owners: Novartis AG and Lohmann Therapie-Systeme AG

Dated: January 29, 2016

/Raymond R. Mandra/

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Case No. IPR2014-00549 U.S. Patent 6,316,023 B1

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Case No. IPR2014-00549 U.S. Patent 6,316,023 B1

CERTIFICATE OF FILING

I certify that the foregoing NOVARTIS AG and LTS LOHMANN

THERAPIE SYSTEME AG's NOTICE OF APPEAL UNDER 37 C.F.R. § 90.2(a)

was filed electronically through the Board's PRPS System, and the original version

was served by priority mail express (Mail Label: EK 476560805 US) on this 29th

day of January, 2016, with the Director of the United States Patent and Trademark

Office, at the following address:

United States Patent and Trademark Office c/o Office of the General Counsel P.O. Box 1450 Alexandria, Virginia 22313-1450

CERTIFICATE OF FILING

I certify that a true and correct copy of the foregoing NOVARTIS AG and

LTS LOHMANN THERAPIE SYSTEME AG'S NOTICE OF APPEAL UNDER

37 C.F.R. § 90.2(a) was filed electronically through the CM/ECF System on this

29th day of January, 2016, with the Clerk's Office of the United States Court of

Appeals for the Federal Circuit, at the following address:

United States Court of Appeals for the Federal Circuit 717 Madison Place NW, Suite 401 Washington, DC 20005

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