

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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INTAS PHARMACEUTICALS LTD.  
Petitioner,

v.

ATOSSA THERAPEUTICS, INC.  
Patent Owner.

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CASE: PGR2023-00043

Patent No. 11,572,334

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**PATENT OWNER'S MOTION FOR *PRO HAC VICE* ADMISSION OF  
SUSAN M. KRUMPLITSCH**

EXHIBIT	DESCRIPTION
2001	Expert Declaration of Stephen Graham Davies, D. Phil. (“Davies Decl.”)
2002	Elkins et al., “Characterization of the isomeric configuration and impurities of (Z)-endoxifen by 2D NMR, high resolution LCMS, and quantitative HPLC analysis,” J. Pharmaceutical and Biomedical Analysis, 88:174-179 (2014) (“Elkins”)
2003	U.S. Patent No. 11,261,151 (“’151 patent”)
2004	Excerpt of ’151 Patent File History - IDS Filings, Receipts, List Considered (“’985 File History 1”)
2005	Excerpt of ’151 Patent File History - Liu (“’985 File History 2”)
2006	Excerpt of ’151 Patent File History - FOA and NOA (“’985 File History 3”)
2007	Intl. Pub. No. WO 2010/135703A2 by Ahmad et al.
2008	Intl. Pub. No. WO 2009/032699A1 by Bortz et al.
2009	Intl. Pub. No. WO 2009/120999A2 by Kushner et al.
2010	Excerpt of File History for U.S. Patent 9,333,190 - Office Actions, Responses, Declarations, and Allowance (“Ahmad File History”)
2011	Ali et al., “Endoxifen is a new potent inhibitor of PKC: A potential therapeutic agent for bipolar disorder,” Bioorganic & Medicinal Chem. Letters, 20:2665-2667 (2010) (“Ali”)
2012	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, “Impurities: Guideline for Residual Solvents,” Step 4 Version (2021) (“ICH Guidelines”)
2013	Stephen Graham Davies, D. Phil. <i>Curriculum Vitae</i>
2014	Center for Drug Evaluation and Research, FDA Guidance Document, “Development of New Stereoisomeric Drugs,” (1992) (“FDA Guidance”)

EXHIBIT	DESCRIPTION
2015	Lv et al., “Synthesis of mixed (E,Z)-, (E)-, and (Z)-norendoxifen with dual aromatase inhibitory and estrogen receptor modulatory activities,” J. Med. Chem., 56: 4611-4618 (2013) (“Lv”)
2016	Buchanan et al., “Solubilization and Dissolution of Tamoxifen-Hydroxybutenyl Cyclodextrin Complexes,” J. Pharm. Sciences, 95(10):2246-2255 (2006) (“Buchanan”)
2017	Gupta et al., “Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations,” Molecules, 23:1719 (2018) (“Gupta”)
2018	Jacques et al., <i>Enantiomers, Racemates, and Resolutions</i> (1981) (“Jacques”)
2019	Declaration of Susan M. Krumplitsch in Support of Motion to Appear <i>Pro Hac Vice</i>

Pursuant to 37 C.F.R. § 42.10(c), Patent Owner Atossa Therapeutics, Inc. (“Patent Owner”) respectfully requests the *pro hac vice* admission of attorney Susan M. Krumplitsch for purposes of the above-captioned post-grant review proceeding. Patent Owner has conferred with counsel for Intas Pharmaceuticals, Ltd., (“Petitioner”), and Petitioner does not oppose this motion.

**I. STATEMENT OF FACTS SHOWING GOOD CAUSE FOR THE BOARD TO RECOGNIZE SUSAN M. KRUMPLITSCH *PRO HAC VICE* IN THIS PROCEEDING**

The Board may recognize counsel *pro hac vice* during a post-grant review proceeding upon a showing of good cause, “subject to the condition that lead counsel be a registered practitioner and to any other conditions as the Board may impose.” 37 C.F.R. § 42.10(c). *See also* Paper 3 at 2. “For example, where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.” 37 C.F.R. § 42.10(c).

This Motion for *Pro Hac Vice* Admission is accompanied by a Declaration of Ms. Susan M. Krumplitsch (Exhibit 2019, “Krumplitsch Decl.”) as required by Order -- Authorizing Motion for *Pro Hac Vice*, Paper 7, in Case IPR2013-00639. As set forth below and in the accompanying Krumplitsch Decl. (Exhibit 2019), the

following statement of facts shows that there is good cause for the Board to recognize Ms. Krumplitsch *pro hac vice*.

Ms. Krumplitsch is a member in good standing of the State Bar of California (Bar No. 241016). *See* Exhibit 2019, ¶2.

Ms. Krumplitsch has never been suspended or disbarred from practice before any court or administrative body. *Id.* at ¶3.

None of Ms. Krumplitsch's applications for admission to practice before any court or administrative body have ever been denied. *Id.* at ¶4.

Ms. Krumplitsch has never been sanctioned nor has she had a contempt citation imposed on her by any court or administrative body. *Id.* at ¶5.

Ms. Krumplitsch has read and agrees to comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trial set forth in part 42 of 37 C.F.R. *Id.* at ¶6.

Ms. Krumplitsch has acknowledged and agrees that she will be subject to the USPTO Rules of Professional Conduct set forth in 37 C.F.R. § 11.101 et. seq. and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). *Id.* at ¶7.

Ms. Krumplitsch is Partner in the Life Sciences Patent Litigation practice of DLA Piper LLP (US), based in Palo Alto, California. She is an experienced patent litigation attorney focusing on pharmaceuticals, biologics, and related life science

technologies. She has been practicing for over 18 years, representing pharmaceutical and life science clients in patent infringement suits in federal district courts across the country as well as proceedings before the Patent Trial and Appeal Board. *Id.* at ¶8.

Ms. Krumplitsch was most recently admitted *pro hac vice* in a proceeding before the Board in *Mylan Pharmaceuticals Inc. v. Horizon Pharma USA, Inc.*, IPR2018-00272, Paper 67 (PTAB Jun. 10, 2019). Exhibit 2019 at ¶9.

Ms. Krumplitsch possesses a technical background relevant to the issues in this proceeding, including a M.S. in immunology and infectious diseases from Harvard University School of Public Health. She is very familiar with the subject matter of this proceeding as she has studied and analyzed the field of technology relevant to the challenged '334 patent; the claims, specification and prosecution history of the '334 patent; and the alleged prior art references asserted by Petitioner in this proceeding. Exhibit 2019 at ¶9.

In view of Ms. Krumplitsch's knowledge of the subject matter at issue in this proceeding, Patent Owner has a substantial need for Ms. Krumplitsch's *pro hac vice* admission and her involvement in this proceeding.

## II. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board recognize Ms. Susan M. Krumplitsch as counsel *pro hac vice* during this proceeding.

Respectfully submitted,

Dated: November 30, 2023

/Melissa M. Harwood/  
Melissa M. Harwood, Reg. No. 60,229  
Susan M. Krumplitsch, *pro hac vice* to be  
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PO Motion for *Pro Hac Vice* Admission of Susan M. Krumplitsch  
PGR2023-00043  
U.S. Patent No. 11,572,334

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 30th day of November 2023, a true copy of the foregoing Patent Owner's Motion for *Pro Hac Vice* Admission of Susan M. Krumplitsch and Declaration were served on Petitioner INTAS PHARMACEUTICALS LTD. by emailing a copy to counsel of record for Petitioner at the email addresses listed below:

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Dated: November 30, 2023

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