

Case IPR2016-01373
Patent 6,331,415

Filed on behalf of: Merck Sharp & Dohme Corp.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners

Case IPR2016-01373
Patent 6,331,415

**DECLARATION OF KATHERINE A. HELM IN SUPPORT OF
MOTION FOR *PRO HAC VICE* ADMISSION ON BEHALF OF
PETITIONER MERCK SHARP & DOHME CORP.**

I, Katherine A. Helm, declare as follows:

1. I am an attorney licensed to practice law in the State of New York, the Commonwealth of Massachusetts, and the District of Columbia. I am also admitted to practice before the United States Court of Appeals for the Federal Circuit, the United States Court of Appeals for the Third Circuit, and the United States District Courts for the Southern and Eastern Districts of New York

2. I am a senior associate in the law firm of Simpson Thacher & Bartlett LLP and a member of the Litigation Department and the Intellectual Property Group in the New York Office. I have approximately eight years of experience as a patent litigator and trial lawyer, appearing and acting as counsel in numerous patent litigation matters in various United States District Courts and the United States Courts of Appeals, including the U.S. Court of Appeals for the Federal Circuit. The majority of these cases have been within the pharmaceutical and biotechnology industries. In addition, I spent five years prior to and during law school working as a technical advisor in the Intellectual Property Group of a large New York law firm, where I focused on pharmaceutical and biotechnology patent prosecution and a variety of contested proceedings in the United States Patent and Trademark Office (“USPTO”) and the European Patent Office.

3. I am a member in good standing in all jurisdictions and courts where I have been admitted to practice.

Case IPR2016-01373

Patent 6,331,415

4. I have never been suspended or disbarred from practice before any court or administrative body.

5. I have never had a court or administrative body deny my application for admission to practice.

6. I have never been sanctioned or cited for contempt by any court or administrative body.

7. I have read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in Part 42 of 37 C.F.R.

8. I agree to 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).

9. I have not appeared *pro hac vice* before the Patent Trial and Appeal Board in the last three years.

10. I have an established familiarity with the subject matter at issue in this proceeding, specifically U.S. Patent No. 6,331,415 ("the '415 patent"). I served as counsel for Human Genome Sciences Inc. ("HGS") and Eli Lilly and Company ("Eli Lilly") in litigations involving the '415 patent in *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, Case No. 2:11-cv-06519 (C.D. Cal.); *Human Genome Sciences Inc. v. Genentech, Inc.*, Case No. 2:11-cv-06546 (C.D. Cal.); *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, Case No. 11-082-LPS (D. Del);

Case IPR2016-01373

Patent 6,331,415

Human Genome Sciences Inc. v. Genentech, Inc., Case No. 11-156-LPS (D. Del.); and *Eli Lilly & Co. et al. v. Genentech, Inc., et al.*, Case No. 13-cv-07248 (C.D. Cal).

11. In addition, I served as counsel for HGS in related district court patent litigation matters, entitled *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, Case No. C.A. No. 11-328-LPS (D. Del); *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, Case No. 2:11-cv-6594 (C.D. Cal.); *Genentech, Inc. et al., v. Glaxo Group Limited et al.*, Case No. 2:11-cv-3065 (C.D. Cal.). These litigations all involved U.S. Patent No. 7,923,221 (“the ’221 patent”), which was filed as a continuation of the application that issued as the challenged ’415 patent and involves the same recombinant antibody technology claimed by the ’415 patent.

12. I also presently serve as counsel for Merck Sharp & Dohme Corp. (“Merck”) in a patent litigation matter also relating to the ’221 patent, entitled *Merck Sharp & Dohme Corp. v. Genentech, Inc. and City of Hope*, Case No. 16-cv-04992-GW (C.D. Cal.) (“*Merck* District Court Litigation”). The *Merck* District Court Litigation was filed on July 7, 2016.

13. Given my prior involvement in *HGS* and *Eli Lilly* cases, and my current involvement with the *Merck* District Court Litigation, I have carefully reviewed, developed an extensive familiarity with, and acquired a substantial understanding of the ’415 patent and file history, the legal subject matter, the

Case IPR2016-01373

Patent 6,331,415

factual and technical subject matter, and the prior art and expert testimony presented in Merck's request for *inter partes* review of the '415 patent, which forms the basis of this proceeding.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the '415 patent.

Dated: July 28, 2016

Respectfully submitted,

By: /s/ Katherine A. Helm

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