

Case IPR2017-00047
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 IPR 2017-00047
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 over eight years of experience as a patent litigator and trial lawyer, appearing and acting as counsel in numerous patent litigation matters before 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 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.

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 United States Patent and Trademark Office 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 ("Board") in the last three years. However, as discussed in ¶ 13 below, Merck, Sharp & Dohme Corp. ("Merck") has a motion pending before the Board for my admission *pro hac vice* in connection with *inter partes* review number IPR2016-01373. *See Merck Sharp & Dohme Corp. v. Genentech, Inc. and City of Hope*, Case IPR2016-01373, Paper 4 (Petitioner Merck Sharp & Dohme Corp.'s Motion for *Pro Hac Vice* Admission of Katherine A. Helm) (July 28, 2016) ("the '1373 Petition").
10. I have an established familiarity with the subject matter at issue in this

Case IPR2017-00047

Patent 6,331,415

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.); *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. 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 involved the same recombinant antibody technology claimed by the ’415 patent.

12. I also presently serve as counsel for 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*

Case IPR2017-00047

Patent 6,331,415

District Court Litigation”). The *Merck* District Court Litigation was filed on July 7, 2016.

13. Merck has also moved for my *pro hac vice* admission on its behalf in connection with the ’1373 Petition currently before the Board for an *inter partes* review of the ’415 patent. ’1373 Petition, Paper 4 (Petitioner Merck Sharp & Dohme Corp.’s Motion for *Pro Hac Vice* Admission of Katherine A. Helm) (July 28, 2016).

14. Given my prior experience as counsel for HGS and Eli Lilly, and my current role as counsel for Merck in the *Merck* District Court Litigation and the ’1373 Petition, 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 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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.