

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS HOLDINGS
INC., AND APOTEX HOLDINGS, INC.,

Petitioners,

v.

OSI PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2016-01284

U.S. Patent No. 6,900,221

DECLARATION OF KRISTOPHER A. BOUSHIE

| | | |
|-------|---|----|
| I. | QUALIFICATIONS | 2 |
| II. | PURPOSE OF THIS DECLARATION..... | 4 |
| III. | FACTS AND DATA CONSIDERED IN FORMING MY OPINIONS | 4 |
| IV. | SUMMARY OF CONCLUSIONS..... | 5 |
| V. | COMMERCIAL SUCCESS AS A SECONDARY CONSIDERATION OF NONOBVIOUSNESS..... | 6 |
| VI. | TARCEVA [®] | 7 |
| A. | PATENTS COVERING TARCEVA [®] | 7 |
| B. | INDICATED USES OF TARCEVA [®] | 8 |
| C. | USES OF TARCEVA [®] COVERED BY THE '221 PATENT..... | 11 |
| VII. | COMMERCIAL SUCCESS OF TARCEVA [®] | 11 |
| A. | COMMERCIAL SUCCESS OF TARCEVA [®] RELATED TO THE RE '065 PATENT | 11 |
| B. | MR. REISENAUER DOES NOT ANALYZE COMMERCIAL SUCCESS ATTRIBUTABLE TO THE CHALLENGED CLAIMS OF THE '221 PATENT | 12 |
| VIII. | CONCLUSIONS..... | 14 |
| IX. | POSSIBLE SUPPLEMENTATION OF THIS REPORT | 15 |
| X. | AVAILABILITY TO TESTIFY..... | 15 |

I. Qualifications

1. I am an Associate Director in the Washington, DC office of NERA Economic Consulting (“NERA”), where I am a member of the firm’s Intellectual Property Practice. I have over 30 years of experience in financial and litigation consulting, with an emphasis on forensic valuation issues, and over 25 years of experience focused on intellectual property matters. My expertise includes the analysis of historical and projected financial-related business records and preparation of economic damage estimates in the areas of intellectual property infringement, antitrust, distributorship terminations, contract disputes, and tort claims.

2. Throughout my professional career, I have frequently analyzed business sales and profitability data in the context of valuing intellectual property. Most of my work involving patents has been in connection with patent infringement lawsuits. This work often resulted in expert opinions regarding damages related to a party’s alleged patent infringement. I have also researched, written, and presented on intellectual property valuation and damages-related topics.

3. I am an editor and contributing author of *Calculating and Proving Damages* published by Law Journal Press. I am also a regular contributor to the

Financial Valuation and Litigation Expert journal and am on its Panel of Experts.

I have prepared and presented a number of Continuing Legal Education and Continuing Professional Education seminars on a variety of topics related to the estimation of damages and valuation issues.

4. I am a member of the American Institute of Certified Public Accountants; the Virginia Society of Certified Public Accountants (where I am a past chairman of the Litigation Services Committee); the National Association of Certified Valuators and Analysts (“NACVA,” where I am a member of the Chapter Foundation Committee and immediate past Chair of the Executive Advisory Board); and the Association of Certified Fraud Examiners (“ACFE”). I am a member of the Intellectual Property Owners Association, where I am a member of the Trade Secret Committee. I am also an affiliate member of the American Intellectual Property Law Association and an associate member of the American Bar Association, Intellectual Property Law Practice Section.

5. I am a Certified Public Accountant, licensed in Virginia, Accredited in Business Valuation (through the American Institute of Certified Public Accountants, “AICPA”), and Certified in Financial Forensics (through the AICPA). I am also a Certified Valuation Analyst (through NACVA) and a Certified Fraud Examiner (through ACFE).

6. NERA is being compensated for my services in this matter at a rate of \$605 per hour and for the services of consultants and researchers at their customary rates. Neither my nor NERA's compensation in this matter is dependent on the outcome of this case or the substance of my opinions. A copy of my curriculum vitae is attached as Appendix A.

II. Purpose of this Declaration

7. I have been asked by counsel for Petitioners Apotex Inc., Apotex Corp., Apotex Pharmaceuticals Holdings Inc., and Apotex Holdings, Inc. to review the declaration of Mark L. Reisenauer and other materials, and to present my opinion on whether the sales of Tarceva[®] are related to claims 44-46 and 53 of U.S. Patent No. 6,900,221 B1 (the '221 patent) and whether there is any evidence of commercial success attached to these challenged claims.

III. Facts and Data Considered in Forming my Opinions

8. My opinions expressed in this declaration are based on my professional training and experience, my review and analysis of information produced by the parties, and certain third-party information. This information includes, but is not limited to, the Declaration of Mr. Mark L. Reisenauer and accompanying exhibits, the July 13, 2017 deposition of Mr. Reisenauer and related exhibits, the decision regarding the institution of *inter partes* review in this matter,

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.