

OCEAN TOMO

HATCH-WAXMAN LITIGATION



Ocean Tomo's Expert Testimony group is regularly retained on behalf of generic pharmaceutical firms to provide economic and financial analyses and expert opinions relating to Hatch-Waxman disputes. Through our work, Ocean Tomo has developed expertise in evaluating, for example, the economic and business factors as well as the drug product features that influence physician prescription practices.

We are regularly asked to evaluate claims by branded drug companies of irreparable harm (in response to PI Motions) as well as economic damages resulting from the introduction of generic drug products in the United States. In connection with our work, we have analyzed and evaluated the cost structures and profitability of numerous multinational branded drug companies. In addition, we have extensively analyzed market, prescription, sales, and other financial data compiled by third-party research firms such as IMS Health.

Representative Engagements

Our Hatch-Waxman-related assignments generally concern addressing one or more of the following issues:

COMMERCIAL SUCCESS

A secondary consideration of non-obviousness which requires a finding of significant sales in the context of the relevant market with a nexus to the asserted claims of the patent(s)-in-suit. Our evaluation of a relevant market typically considers physician prescribing practices, FDA approved indications for U.S. drug products, and the competitive product landscapes often reflected in the management reports and market studies of the plaintiffs/branded drug companies.

Our work also involves evaluating the economic factors and product features (including APIs disclosed in patents that may be prior art) that influence physician prescribing practices in order to address the nexus issue. In addition, we have researched and identified blocking patents that act as disincentives for third-parties to invest in R&D around the subject matters of the patents-in-suit.

IRREPARABLE HARM

The quantification of damages in pharmaceutical patent infringement cases can be relatively straight forward given the high level of detailed financial data and market research compiled and published by pharmaceutical industry research firms such as IMS Health. This does not however deter branded drug companies from asserting claims of irreparable harm in support of Motions for Preliminary Injunctions.

In response to these Motions, we evaluate the significance of the sales and profits of patented products to the plaintiffs/branded drug company's business, and evaluate the impact of the potential loss of exclusivity. In addition, we are sometimes asked to quantify the bond amount that should be posted by patentees in order to protect in the economic interests of the defendant/generic drug companies.



ECONOMIC DAMAGES

After a drug product has been introduced in the United States, we may be asked to quantify the measure and amount of damages resulting from the alleged patent infringement. Our “but-for” analysis includes a market-expansion evaluation and considers the impact of other generic entrants, as well as any generic product that has been authorized by the branded drug company. When the measure of damages is a reasonable royalty, we consider the significance, if any, of the patented technology on the demand for the patented drug product, and otherwise evaluate the factors set forth in the case of Georgia-Pacific.

OCEAN TOMO FEATURED PHARMACEUTICAL LITIGATION EXPERIENCE*

- Allergan, Inc. v. Sandoz, Inc., et. al.
- Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc.
- Alza Corporation and Janssen Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Mylan Inc.
- AstraZeneca AB et. al., v. Teva Pharmaceutical Industries Ltd., et. al.
- Andrx Pharmaceuticals, LLC v. GlaxoSmithKline, PLC and SmithKline
- Bayer Pharma AG, et. seq. v. Watson Laboratories, Inc.
- Brian D. Zdeb, et. al. v. Baxter International, Inc.
- Bristol-Myers Squibb Company v. Apotex Inc. and Apotex Corp.
- Cephalon, Inc. v. Sun Pharmaceutical Industries, Inc., et. al.
- Hoffman-LaRoche, Inc. v. Cobalt Pharmaceuticals, Inc.
- In Re Gabapentin Patent Litigation
- King Pharmaceuticals v. Lupin Pharmaceuticals
- Leo Pharma A/S v. Tolmar, Inc. et. al.
- Lupin Pharmaceuticals v. Abbott Labs and Astellas Pharma, Inc.
- Pfizer, Inc., et. seq. v. Purepac Pharmaceutical Co., et. al.
- Pharmacia & Upjohn Company, LLC v. Sicor Pharmaceuticals, Inc.
- Putney, Inc. v. Pfizer, Inc.
- Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. v. Genentech, Inc. and City of Hope
- Tekmira Pharmaceuticals Corp. v. Alynlam Pharmaceuticals, Inc.
- ViiV Healthcare UK, Ltd. v. Lupin Limited, et. al.
- ViiV Healthcare UK, Ltd. v. Mylan Inc., et. al.
- Wyeth Pharmaceuticals v. Anchen Pharmaceuticals

*This list includes only those matters in which Ocean Tomo professionals have provided expert testimony.

Ocean Tomo Professionals



James E. Malackowski is the Co-founder & CEO of Ocean Tomo, LLC, an integrated Intellectual Capital Merchant Banc™ firm providing financial products and services related to intellectual property (IP).

Mr. Malackowski is a founding and continuous member of the IP Hall of Fame Academy. He has been recognized annually since 2007 by leading industry publications as one of the fifty most influential people in intellectual property and /or one of the 'World's 300 Leading IP Strategists'. In 2011 Mr. Malackowski was selected by the World Economic Forum as one of less than twenty members of the Network of Global Agenda Councils to focus on questions of IP policy. Mr. Malackowski is Past President for The Licensing Executives Society International, Inc. and LES U.S.A. & Canada, Inc. Mr. Malackowski focuses his non-for-profit efforts with organizations leveraging science and innovation for the benefit of children, including those located in lesser developed countries. He has served since 2002 as a Trustee or Director of the National Inventors Hall of Fame, Inc., an organization providing summer enrichment programs for more than 100,000 students annually. For more than ten years Mr. Malackowski served as a Director of Chicago's Stanley Manne Children's Research Institute, advancing the organization's agenda to measure and report the impact of its pediatric research.



Robert M. Hess is a Managing Director and one of the founding members of Ocean Tomo. Mr. Hess' consulting efforts are concentrated in the areas of damages expert witness testimony in intellectual property matters and general valuation assistance. Mr. Hess' consulting and valuation experience has encompassed a diverse range of industries including pharmaceuticals, financial institutions, healthcare, construction, oil and gas exploration, and government agencies such as the Department of Justice. He has assisted counsel in the litigation process by performing accounting, financial, economic and audit reviews and prepared the corresponding expert reports.

Mr. Hess has consulted in the determination of both liability and damages issues arising from cases of patent infringement, breach of contract, reasonable royalty, misappropriation of trade secrets, price erosion, lost profits, trademark infringement, accountant's liability, and antitrust claims. In addition to his certification in financial forensics, Mr. Hess is a certified public accountant and a licensed public accountant of the state of Illinois.



Robert R. McSorley is a Senior Director with Ocean Tomo, LLC. Mr. McSorley has more than 30 years of experience addressing the economic, financial, and accounting issues surrounding commercial litigation. Mr. McSorley is regularly retained by generic pharmaceutical firms (defendants) involved with Hatch-Waxman litigation.

In connection with Hatch-Waxman disputes, Mr. McSorley has evaluated certain financial and economic factors that shed light on the circumstances surrounding the origin of the subject matter disclosed in the patents-in-suit. In addition, he has considered issues relating to the nature of harms allegedly sustained by patentees from the alleged infringement of their patents. He has also studied certain other aspects of the U.S. pharmaceutical industry, including the profitability of the U.S. Fortune 500 pharmaceutical firms and their ability to finance and recover R&D costs.



Alexander Clemons is a Senior Director in Ocean Tomo's Expert Testimony practice, out of the firm's Chicago headquarters. The practice area quantifies economic damages arising from intellectual property disputes and provides general litigation support.

Prior to joining Ocean Tomo, Mr. Clemons worked as an Attorney, assisting clients in many aspects of both civil litigation and transactional matters. Mr. Clemons graduated with Academic Excellence from the University of Illinois, Urbana-Champaign, with a MBA concentrated in Finance. He graduated Cum Laude from DePaul University, College of Law, with a JD. He also holds a Bachelor of Arts in Rhetoric from the University of Illinois, Urbana-Champaign.



CONTACT

Robert R. McSorley
Senior Director
+1 312.327.4412
rmcsorley@oceantomo.com

Mr. McSorley has more than 30 years of experience addressing the economic, financial, and accounting issues involved in commercial litigation. Mr. McSorley has been retained in connection with Hatch-Waxman Act matters involving patented technologies relating to pharmaceutical products. In connection with these cases, Mr. McSorley has evaluated financial and economic issues that shed light on the circumstances surrounding the origin of subject matters disclosed in U.S. patents.



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About Ocean Tomo

Established in 2003, Ocean Tomo, LLC provides Financial Expert, Management Consulting, and Advisory services related to intellectual property (IP) and other intangible assets; corporate accounting investigations; regulatory and reporting obligations; solvency and restructuring; and contractual or competition disputes.

Practice offerings address economic damage calculations and testimony; accounting investigations and financial forensics; technology and intangible asset valuation; strategy and risk management consulting; mergers and acquisitions; debt and equity private placement; and IP brokerage.

Our services are built upon more than three decades of experience in the most rigorous venues – state, federal, and international courts. Our financial, market, and technical experts provide a unique understanding of the contributory value of proprietary innovation. This is the cornerstone of our business. This insight permeates every practice and client engagement.

Collectively, Ocean Tomo professionals have:

- Completed over 1000 engagements, including over 300 valuation and 500 financial damages expert testimony engagements;
- Consulted and provided expert testimony on some of the highest profile matters over the past decades;
- Successfully closed hundreds of IP sale transactions with a cumulative transaction value well in excess of \$1 billion; and
- Originated more successful IP monetization solutions than any other firm, including creation of the world's oldest and most successful live patent auction.

Our track record of results spans more than 150 different industry segments. Because our past success provides the best indication of our capabilities, we are proud to serve more than 80% of the AM Law 100® and encourage potential clients to seek references from past clients.

Intangible assets comprise 90 percent of business value but are also subject to significant impairment due to enterprise and regulatory compliance risk. Ocean Tomo assists clients – corporations, law firms, governments, and institutional investors – in realizing Intellectual Capital Equity® value broadly defined.

Headquartered in Chicago, Ocean Tomo has offices in Greenwich, Houston, Jacksonville, Reston, San Francisco, and Shanghai. Subsidiaries of Ocean Tomo include Ocean Tomo Investment Group, LLC, a licensed broker-dealer under Federal and State securities law (brokercheck.finra.org Broker Check CRD #: 172912), OTI Data Networks, LLC and Patent Marking, LLC.