



OCEAN TOMO

# HATCH-WAXMAN LITIGATION



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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** has testified by deposition in more than 100 matters, the large majority of which are intellectual property disputes. On more than 50 occasions, Mr. Malackowski has served as an expert in federal court or the International Trade Commission on questions relating to intellectual property economics, including the subject of business valuation, reasonable royalty, lost profits, price erosion, commercial success, corrective advertising, Hatch Waxman Act market exclusivity and the equities of a potential injunction.

Mr. Malackowski brings a truly unique experience base to his work as an expert drawing upon his role as a Certified Public Accountant, Certified Licensing Professional, adjunct MBA instructor, inventor of numerous issued U.S. patents and investor in IP assets. Issued U.S. patents and investor in IP assets.



**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.

For a quarter century 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. Mr. Hess has testified in both federal and state courts.



**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 Intellectual Property Disputes 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.

Unique among Ocean Tomo's other testifying experts, Mr. Clemons holds both a JD and MBA. This background best positions him to understand, anticipate, and adapt to the ever changing legal landscape surrounding damages proof requirements, while developing creative solutions to the most challenging damages issues. He has extensive experience across numerous industries related to the assessment of economic damages in litigation matters involving intellectual property, breach of contract, and other claims. In addition, Mr. Clemons consults with clients on strategic IP management issues, licensing assistance, and IP transaction support.



## CONTACT

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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 (DC Metro), 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.