



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. Alnylam 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 one hundred occasions, Mr. Malackowski has served as an expert in U.S. Federal Court, U.S. Bankruptcy Court, State Court, Court of Chancery, the Ontario Superior Court of Justice, the U.S. Patent and Trademark Office Patent Trial and Appeal Board, and global arbitrations on questions relating to intellectual property economics including the subject of valuation, reasonable royalty, lost profits, price erosion, commercial success, corrective advertising, creditor allocations, Hatch Waxman Act market exclusivity, business significance of licensing terms including RAND obligations, venture financing including expected risk/return, and 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, a part of J.S. Held. Mr. Hess' consulting efforts at Ocean Tomo are concentrated in the areas of damages expert witness testimony in intellectual property infringement lawsuits 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 McSorley** is a Managing Director with in the Intellectual Property Disputes Financial Expert Testimony practice, working out of the Chicago office of Ocean Tomo, a part of J.S. Held. 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 Managing Director in the Intellectual Property Disputes Financial 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, a part of J.S. Held'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

Ocean Tomo LLC provides Expert Opinion, Management Consulting, and Advisory services focused on matters involving intellectual property (IP) and other intangible assets. Practice offerings address economic damage calculations and testimony; business licensing strategy and contract interpretation; trade secret reasonable measures; asset and business valuation; strategy and risk management consulting; merger and acquisition advisory; debt and equity private placement; and IP brokerage.

Ocean Tomo experts are routinely qualified in U.S. District Courts, U.S. Bankruptcy Courts, U.S. Tax Court, U.S. Court of Federal Claims, state courts, the U.S. Patent and Trademark Office Patent Trial and Appeal Board, international courts, and arbitration tribunals on questions relating to intellectual property economics. The firm's professionals have provided expert opinions on IP valuation, reasonable royalty, lost profits, price erosion, commercial success, corrective advertising, creditor allocations, Hatch-Waxman Act market exclusivity, business licensing terms including RAND obligations, venture financing, and equities of a potential injunction. The firm's experience extends to general business valuation and commercial disputes, domestic and foreign, as well as policy issues affecting international technology transfer and economic matters before the International Trade Commission.

Intangible assets comprise 90 percent of business value but are also subject to significant impairment due to enterprise and regulatory compliance risk. Our services are built upon more than three decades of experience assessing intellectual property in the most rigorous of venues. Our financial, market, scientific, and technical experts have deep experience with tangible and intangible assets protected by intellectual property. We bring a unique understanding of the contributory value of proprietary innovation to every engagement. This is the cornerstone of our business.

Subsidiaries of the firm include Ocean Tomo Investments Group, LLC, a registered broker-dealer. As a part of J.S. Held, Ocean Tomo works alongside more than 1500 professionals globally and assists clients – corporations, insurers, law firms, governments, and institutional investors – on complex technical, scientific, and financial matters across all assets and value at risk.

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## About J.S. Held

J.S. Held is a global consultancy providing technical, scientific, and financial expertise across all assets and value at risk. Our professionals serve as trusted advisors to organizations facing high-stakes events demanding urgent attention, staunch integrity, clear-cut analysis, and an understanding of both tangible and intangible assets. The firm provides a comprehensive suite of products, data, and services that enable clients across industries to navigate complex, contentious, and often catastrophic situations.

In 2022, Ocean Tomo joined J.S. Held, continuing the strategic growth of the firm. Leveraging the J.S. Held team of more than 1,500 professionals around the world, our clients will now have access to J.S. Held's suite of specialized services, including:

- Construction Advisory Services
- Corporate Finance
- Economic Damages and Valuation Services
- Environmental, Health, and Safety Services
- Equipment Consulting
- Forensic Accounting
- Forensic Architecture and Engineering
- Global Investigations
- Property and Infrastructure Damage Consulting
- Surety Services

Headquartered in New York, J.S. Held has offices across the United States, Canada, Latin America, Europe, Asia Pacific, and the Middle East.

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