

PHARMACEUTICAL ANTITRUST CONSULTING



In the case of *FTC v. Actavis, Inc.*, 133 S.Ct. 2223 (2013), the U.S. Supreme Court held that reverse payment settlements may violate U.S. antitrust laws even if the agreement’s anticompetitive effects fell within the scope of the exclusionary potential of the patent-in-suit. Subsequent Federal court opinions have indicated that such potential violations are not limited to monetary reverse payments.¹

The *Actavis* Court adopted a “rule of reason” approach to evaluate settlement agreements, and set forth five factors to examine in determining whether such agreements bring about anticompetitive consequences. These factors include financial and economic evidence concerning, among other things, the fair value of the consideration offered to generic firms that challenge the validity of their patents.

In the case of *In re Nexium Antitrust Litigation* (2014 WL 4370333) the Massachusetts District Court applied the *Actavis* factors in its evaluation of three settlement agreements. In each agreement, the generic challenger agreed to delay market entry of their product. In its summary judgment opinion, the *Nexium* Court addressed the fair value and potential anticompetitive impact of the non-monetary consideration extended to these generic firms. The consideration included:

- A refrain from producing an Authorized Generic (AG)
- Distribution rights for other drugs
- Supply agreements
- Favorable settlement terms in a different Hatch-Waxman dispute
- A refrain from appealing a different Hatch-Waxman dispute

Our Capabilities and Professional Services

Ocean Tomo’s extensive Hatch-Waxman litigation experience as well as our experience valuing intangible assets and intellectual property make us uniquely qualified to assist pharmaceutical firms seeking to comply with FTC regulations and U.S. antitrust laws as they negotiate Hatch-Waxman-related agreements.

The financial and economic consulting services we offer both branded and generic firms depend, in part, on the procedural posture of either the Hatch-Waxman litigation or the ensuing antitrust action(s). Figure 1 below illustrates our economic and financial services at different stages of these proceedings.

FIGURE 1

Hatch-Waxman to Settlement	Antitrust Litigation
<p>CRAFTING THE DEAL</p> <ul style="list-style-type: none"> • Advice on deal terms that will meet scrutiny and satisfy fair value assessment • Support the final settlement with a fair value assessment 	<p>DEFENDING THE DEAL</p> <ul style="list-style-type: none"> • Opine on fair market value of various elements of deal consideration • Opine on the economic feasibility of an at-risk-launch

¹See, *In re Lipitor Antitrust Litigation*, 2013 WL 4780496 (“[N]othing in *Actavis* strictly requires that the payment be in the form of money.”); *In re Nexium (Esomeprazole) Antitrust Litigation*, 2014 WL 4370333 (“[U]nlawful reverse payments are not limited to monetary payments.”); but see, *In re Lamictal Direct Purchaser Antitrust Litigation*, 2014 WL 282755 (“*Actavis* requires scrutiny only of patent settlements that contain reverse payments.”); and *In re Loestrin 24 Fe Antitrust Litigation*, 2014 WL 4368924 (“Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements.”).

HATCH-WAXMAN SETTLEMENTS

Ocean Tomo can quantify the fair value of the consideration to be exchanged in connection with a settlement agreement. Our Valuation practice has extensive experience providing fair value assessments relating to the value of intangible assets, intellectual property, and other contractual rights and obligations.

Should the settlement agreement encompass other litigation, our Expert Testimony Business Unit has the experience to quantify the reasonable royalty or other measure of damages. Ocean Tomo professionals have quantified the measure and amount of damages in hundreds of patent infringement cases, including several significant pharmaceutical matters.

Our fair value assessments may be presented to Federal courts in support of the parties' request to approve settlement agreements, and may also be presented to the FTC.

ANTITRUST LITIGATION

After an antitrust action has been initiated by the FTC or a private plaintiff, Ocean Tomo can assist both branded and generic pharmaceutical firms in addressing certain economic and financial issues of the alleged antitrust violations, such as the following:

- Evaluating the relevant market and assessing the brand/patentee's ability, if any, to impose or maintain "higher-than-competitive" pricing and profits through the settlement agreement at issue.
- Analyzing the economic feasibility of an at-risk launch by the generic firm(s) challenging the patent-in-suit through an evaluation of the firm's projected drug substitution rates, market shares, annual prescriptions, annual unit sales, and anticipated pricing and cost structure, as well as its potential damages exposure.
- Determining the fair value of the consideration extended to the generic firm(s), which may take the form of, for example, a brand agreeing to refrain from launching an authorized generic, a brand reducing or waiving the damages it may recover in connection with a different matter, a brand granting a generic exclusive or non-exclusive rights to market other branded drug products, and/or the generic firm agreeing to help market and sell the brand's drug products in the U.S. or abroad.
- Research and quantify the legal fees and related expenses the patentee incurred to date as well as the anticipated fees to be incurred through appeal in connection with the dispute to be settled.

Where the antitrust issues involve analyses better suited for traditional economists, Ocean Tomo has partnered with independent professionals to address those issues. Where the relevant issues are within our areas of expertise, our Expert Testimony professionals call upon our education, training and substantial experience providing expert testimony in depositions and at trial.

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

*FTC v. Actavis, Inc., 133 S.Ct. 2223, 2231 (2013).

*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.



Nikki Tavasoli-Hozouri, Ph.D., is an economist specializing in the application of econometric modeling, machine learning, and causal inference to high-stakes regulatory matters. She is a Manager in the Intellectual Property Disputes and Financial Expert Testimony practice of Ocean Tomo, a part of J.S. Held. The practice area quantifies economic damages arising from intellectual property disputes and provides general litigation support. With experience at the U.S. Food and Drug Administration (FDA), Dr. Tavasoli has led data-driven investigations into drug pricing, market competition, and healthcare policy, developing predictive models and frameworks to assess market behavior, damages, and regulatory impacts. Her work includes analyzing generic drug lifecycles, designing opioid pricing models to inform federal policy, and evaluating the economic effects of substance bans—expertise directly applicable to antitrust, intellectual property disputes, and damages quantification in healthcare, pharmaceuticals, and biotechnology.



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James E. Malackowski is the Chief Intellectual Property Officer (CIPO) of J.S. Held and the firm's Intellectual Property (IP) Practice Leader with shared responsibility for the firm's artificial intelligence strategy.

He is a Co-founder and Senior Managing Director of Ocean Tomo, a part of J.S. Held.



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About Ocean Tomo

Ocean Tomo, a part of J.S. Held, provides Expert Opinion, Management Consulting, Advisory, and Patent Analysis and Reverse Engineering 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; patent-focused business intelligence; portfolio development strategy; litigation support; 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.

Our 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. Our 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, a registered broker-dealer. As a part of J.S. Held, Ocean Tomo works alongside more than 1,500 professionals globally and assists clients – corporations, insurers, law firms, governments, and institutional investors – on complex technical, scientific, financial, and strategic matters across all assets and value at risk.

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About J.S. Held

J.S. Held is a global consulting firm that combines technical, scientific, financial, and strategic expertise to advise clients seeking to realize value and mitigate risk. Our professionals serve as trusted advisors to organizations facing high stakes matters demanding urgent attention, staunch integrity, proven experience, clear-cut analysis, and an understanding of both tangible and intangible assets. The firm provides a comprehensive suite of services, products, and data that enable clients to navigate complex, contentious, and often catastrophic situations.

More than 1,500 professionals serve organizations across six continents, including 81% of the Global 200 Law Firms, 70% of the Forbes Top 20 Insurance Companies (85% of the NAIC Top 50 Property & Casualty Insurers), and 65% of the Fortune 100 Companies.

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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