OCEAN TOMO

PHARMACEUTICAL ANTITRUST CONSULTING

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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
CRAFTING THE DEAL	**DEFENDING THE DEAL**
• Advice on deal terms that will meet scrutiny and satisfy fair value assessment • Support the final settlement with a fair value assessment	• Opine on fair market value of various elements of deal consideration • Opine on the economic feasibility of an at-risk-launch

[1]See, 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.").

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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

[2]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 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 McSorley is a Managing 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 Managing 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

Andrew W. Carter
Senior Managing Director
+1 312.327.4420
acarter@oceantomo.com

For more than 30 years Mr. Carter has focused on intellectual property infringement damages, providing expert witness testimony in excess of 80 times. Mr. Carter has testified in both Federal and State courts, as well as in front of the International Trade Commission. He is frequently called upon to testify in large scale or complex cases, and was the damages expert for the largest patent damages award in history ($2.5 billion). His clients cover a wide variety of industries, from telecommunications to pharmaceuticals.

CONTACT

Robert M. Hess
Co-Founder and
Managing Director
+1 312.327.4433
bhess@oceantomo.com

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About Ocean Tomo

Established in 2003, Ocean Tomo 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.

Subsidiaries of Ocean Tomo include Ocean Tomo Investments Group, LLC, a registered broker dealer. Ocean Tomo is a part of J.S. Held. With more than 100 offices globally, J.S. Held 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 specialized global consulting firm whose professionals serve as trusted, expert advisors to organizations facing high-stakes events that demand urgent attention, exceptional knowledge, staunch integrity, and clear-cut analysis and advice. The firm provides a comprehensive suite of technical, scientific, financial, and technology advisory services that enable clients across the spectrum of industries to navigate complex, contentious, and often catastrophic situations with precise analysis, reliable insights, and confidence.

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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