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 is the Chairman and Chief Executive Officer 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. He is a Director of the Ann & Robert H. Lurie Children's Hospital of Chicago Research Center and has served since 2002 as a Trustee or Director of Invent Now, Inc., an organization providing summer enrichment programs for more than 80,000 students annually.

Robert Hess is Chief Financial Officer, 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 Director with Ocean Tomo, LLC. Mr. McSorley has more than 25 years of experience addressing the economic, financial, and accounting issues surrounding commercial litigation. Recently, Mr. McSorley's practice has focused on Hatch-Waxman disputes concerning U.S. patents covering pharmaceutical drug products.

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 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.

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Mr. McSorley has more than 25 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, the Intellectual Capital Merchant Banc™ firm, provides companies with financial services related to intellectual property and intangible assets including financial expert testimony, valuation, strategy consulting, patent analytics, investment advisory, innovation management consulting and transaction brokerage.

Our Opinion, Management, and Advisory Services are built upon more than three decades of experience valuating intellectual property in the most rigorous of 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 involving IP worth in excess of $10 billion including over 300 valuation and 500 financial damages expert testimony engagements;
- Successfully closed hundreds of IP sale transactions with a cumulative transaction value well in excess of $750 million;
- Served as a trusted advisor involving the biggest IP transactions in history;
- 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 100 different industry segments. Because our past success provides the best indication of our capabilities, we are proud to feature a few representative engagements and encourage potential clients to seek references from past clients.

Headquartered in Chicago, Ocean Tomo has offices in Greenwich, Houston and San Francisco.

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.

Ocean Tomo assists clients – corporations, law firms, governments and institutional investors – in realizing Intellectual Capital Equity® value broadly defined.