



Joseph O'Malley

Partner, Litigation Department

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Joseph M. O'Malley, Jr. is a partner in the Intellectual Property practice at Paul Hastings. He has extensive patent litigation experience across a broad range of technologies, including chemicals and pharmaceuticals. Mr. O'Malley has served as lead trial counsel for many branded pharmaceutical clients including Pfizer, Merck, Abbott, Eisai, Sunovion (formerly Sepracor), and Takeda (formerly Nycomed), and has prevailed at trial and appeal in billion-dollar-a-year Hatch-Waxman Act pharmaceutical patent litigations.

Accolades and Recognitions

- Recognized in Best Lawyers in America, 25th Edition
- Recognized by the National Law Journal in 2017 as an IP Trailblazer
- Winner of Law360 MVP award for Life Sciences
- Recognized by respected publications, including Chambers, The Legal 500, Intellectual Property Magazine, Benchmark Litigation, IAM Patent 1000, LMG Life Sciences and by Managing Intellectual Property IP Stars
- Finalist, Lawyer of the Year Award, Intellectual Property Magazine
- Ranked, Chambers Global 2015 and 2016, USA, Intellectually Property: Patent
- Chambers USA (2015) says Mr. O'Malley "takes the helm on pharmaceutical cases on behalf of the leading names in the field." The publication has referred to him as "the complete package" and cites his "winning combination" of a "tremendous work ethic, personable demeanor and litigation skills." Chambers USA (2016) recognizes him as a "good strategist," "charismatic" and a "subject matter expert." Sources also reserve praise for his "calm and unflappable demeanor" and business-focused approach. Chambers USA (2017) says the "excellent" Joseph O'Malley is highly rated for his work on complex IP issues in the life sciences space, where interviewees describe him as "a good strategic thinker." Sources say: "He is good at getting the big picture of litigations, including the business and political aspects."
- IAM Patent 1000 ranks Mr. O'Malley in the Gold band noting him as a "true leader" in the space, and recognizing his work on the most high-profile, big-

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Practice Areas

Litigation
Life Sciences and Healthcare
Patent Litigation
Patent Office
Intellectual Property

Admissions

New York Bar

Education

Rutgers School of Law -
Camden, J.D. 1992
Rutgers, The State University
of New Jersey, B.S. 1982

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ticket work from the most demanding of clients. According to the publication, Mr. O'Malley "has driven the firm to huge success and is everything customers seek in a pharmaceutical patent litigator." The publication cites his "immense courtroom experience" that "shows each time he steps up to the plate" and has noted the "complex scenarios" he has handled "requiring creative strategies." According to IAM Patent 1000 (2015): such is his standing among peers, he is hailed as "a great credit to the legal profession." In IAM Patent 1000 (2016): "O'Malley is a challenging guy to litigate against – he is very comfortable in court and in command of all the issues at all times. He has amazing attention to detail and comes prepared with very effective game plans." One highly ranked peer reported: "I have never seen anybody better than Joe in settling difficult conflicts on a win-win basis."

- LMG Life Sciences has recognized Mr. O'Malley among its "US Life Sciences Stars" and notes he is a "preeminent litigator in the industry."
- National Litigation Star, Benchmark Litigation
- Recipient, Burton Award for Legal Achievement
- *Altana Pharma, AG, et. al. v. Teva Pharmaceuticals USA, Inc. et. al., D.N.J.* — Mr. O'Malley was co-lead trial counsel in this Hatch-Waxman Act litigation representing Pfizer (Wyeth) and Takeda in connection with the patent protecting the companies' \$2 billion-dollar-per-year Protonix® (pantoprazole) acid reflux medication. In April 2010, Mr. O'Malley, along with co-counsel, won the jury trial in favor of Wyeth and Altana, finding the patent covering Protonix® to be valid and rejecting generic drug manufacturers' obviousness and obviousness-type double patenting defenses.
- *Dey, L.P., et al v. Sunovion Inc., S.D.N.Y (2009-2012)* — In March of 2012, Paul Hastings secured a summary judgment ruling, on behalf of defendant Sunovion, that five of the seven patents asserted against Sunovion's Brovana® product were invalid under 35 U.S.C. 102(b) due to Sunovion's public use of the claimed subject matter during a clinical trial. The Court also held on summary judgment that plaintiffs were precluded from obtaining any damages for infringement of the two remaining patents which may have occurred during the four and a half years prior to the issuance of reexamination certificates for those patents. Following that summary judgment decision, and a later pre-trial claim construction decision in which the Court adopted every one of our client's proposed definitions, the case settled on confidential terms. Portions of the case are being appealed by plaintiffs Dey and Mylan.
- *Sunovion Inc. v. Teva Pharmaceuticals USA Inc. et. al., D.N.J. (2009 to present)* — Mr. O'Malley was lead trial counsel on Sunovion's behalf in one of the largest Hatch-Waxman Act cases ever filed, with 22 generic defendants. At issue were the patents protecting Sunovion's Lunesta® (eszopiclone) sleeping

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agent. Lunesta® is Sunovion's largest-selling drug product. In June 2010, Paul Hastings secured, on Sunovion's behalf, a dismissal of inequitable conduct claims in a twenty two-defendant Hatch-Waxman litigation relating to Sunovion's popular sleep aid Lunesta®. Judge Cavanaugh of the District of New Jersey issued one of the first post-Exergen Corp. v. Wal-Mart Store decisions dismissing a generic drug manufacturer's inequitable-conduct defenses for failure to satisfy the "stringent pleading standard." In April 2013, all defendants admitted that Sunovion's patent is valid, obviating the need for a validity trial. In a September 2013 ruling in favor of Sunovion, the Federal Circuit reversed the district court's entry of summary judgment in favor of Dr. Reddy's Laboratories, which had been granted in January 2013. This reversal effectively prevented Dr. Reddy's from entering the market with its generic Lunesta® product immediately upon approval, destroying the branded market for Sunovion's largest drug product. The decision also makes new law, namely, that if a generic's application to the FDA permits infringement, then it infringes as a matter of law, notwithstanding other evidence of noninfringement, in this case, a sworn Certification by Dr. Reddy's, filed with the District Court, promising not to infringe.

- Merck & Co., Inc. v. Sandoz Inc., D.N.J. (2009 to present) — Mr. O'Malley is currently co-lead trial counsel with his Partner, Bruce Wexler, in this Hatch-Waxman Act litigation protecting patents covering Merck's Emend® (aprepitant) drug product.
- Eisai Co., Ltd. and Eisai Inc. v. Teva Pharmaceuticals USA Inc., Dr. Reddy's Laboratories and Mylan Laboratories, S.D.N.Y. — Mr. O'Malley was lead trial counsel on behalf of Eisai from 2004 through 2008 during the successful summary judgment proceedings and bench trial involving Eisai's patent covering the company's billion-dollar-a-year acid reflux and ulcer medication, Aciphex® (rabeprazole). As a result of those summary judgment proceedings and trial, Eisai's patent was held valid, enforceable and infringed. The drug product represented 40% of the company's revenues at the time of trial and the patent life extended to 2013, resulting in several billions of dollars to the company being at stake. Mr. O'Malley also successfully argued the appeal to the Court of Appeals for the Federal Circuit resulting in affirmance of those trial court rulings. The Federal Circuit decision from that case has become an important weapon to branded pharmaceutical companies seeking to protect their basic composition-of-matter patents against unenforceability challenges, and against obviousness challenges following the Supreme Court's decision in KSR.
- Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc., D.N.J. — Mr. O'Malley represents Eisai Co., Ltd. regarding the company's two billion-dollar-a-year

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- Alzheimer's drug, Aricept® (donepezil hydrochloride). The generic drug maker charged that Eisai's patent should be held unenforceable because Eisai had failed to disclose an allegedly related copending patent application of Eisai's. In 2008, the U.S. District Court for the District of New Jersey granted Eisai's motion for a preliminary injunction, finding that Eisai's patent was valid and infringed and that Teva's remaining defense of patent unenforceability lacked substantial merit. At the time, the preliminary injunction was only the fourth preliminary injunction ever granted by the District of New Jersey on behalf of branded pharmaceutical companies.
- *Biovail Labs. Int'l SRL v. Andrx Pharms., LLC and Andrx Corp., D. Del.* — Mr. O'Malley was lead trial counsel on behalf of Biovail and its marketing partner Abbott Laboratories regarding their successful antihypertensive medication, Cardizem® LA. The case went to trial on November 13, 2007 in the U.S. District Court for the District of Delaware before Chief Judge Gregory M. Sleet. The parties settled the case after presentation of our clients' case-in-chief, which included the testimony of one of our experts who presented the results of elaborate testing, which demonstrated that the generic product fell within the asserted patent claims after it is ingested ("in vivo"). In order to even permit his clients to get past summary judgment, Mr. O'Malley had to convince the Delaware Court to disregard a prior Markman decision and affirmed non-infringement ruling from the District of Florida and the Federal Circuit that rejected an in vivo claim construction of the same patent claims. The Florida case involved the same parties (though different counsel) and a product that was alleged by defendants to be the same as was at issue in the Delaware case.
 - *Warner-Lambert Company v. Teva Pharmaceuticals Inc., D.N.J.* — Mr. O'Malley was lead trial counsel on behalf of Pfizer (Warner-Lambert Company) during a successful bench trial involving Teva's claims that Pfizer's patent was invalid for lack of enablement. In its November 2007 decision, the District Court found that Pfizer's formulation patent covering its cardiovascular drug Accupril® was not invalid for lack of enablement, despite the breadth of the claims. In obtaining this successful trial decision, the Paul Hastings team was able to distinguish a previous decision by the same District Court Judge, which held a pharmaceutical formulation patent of similar breadth to be invalid for lack of enablement. With that trial decision, all issues of infringement, enforceability and validity were decided in Pfizer's favor in the case after eight years of litigation. The case then settled while the appeal of the enablement ruling was pending.
 - *Pfizer, Inc. and Warner-Lambert Company v. Ranbaxy Pharmaceuticals and Teva Pharmaceuticals, D.N.J.* — Mr. O'Malley was lead trial counsel on behalf

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of Pfizer bringing a successful preliminary injunction motion in 2005 against generics Teva and Ranbaxy, halting sales of their generic quinapril product. Mr. O'Malley also successfully argued the affirmance of that preliminary injunction to the Court of Appeals for the Federal Circuit. The case then settled prior to trial. This injunction has been widely hailed as the first preliminary injunction to be obtained against a generic that had already entered the market. In order to obtain the injunction, Mr. O'Malley had to convince the District Court and the Court of Appeals to accept a claim construction that he had expressly advocated against in a prior litigation in front of the same District Court Judge. Mr. O'Malley's rare success in convincing the same Judge to accept the opposite claim construction to that he had previously, successfully advocated was featured in the June 2005 issue of *The American Lawyer*.

- *Warner-Lambert Company v. Teva Pharmaceuticals Inc.*, D.N.J. — Mr. O'Malley was lead trial counsel on behalf of Pfizer (Warner-Lambert) during a successful bench trial in which Senior Judge Debevoise of the District of New Jersey found that Pfizer's patent covering its highly successful Accupril® product was both valid and enforceable. The court had previously granted summary judgment of infringement in Pfizer's favor. Mr. O'Malley also argued the successful appeal to the Federal Circuit that resulted in the affirmance of these trial rulings on behalf of Pfizer.
- *Kos Pharmaceuticals v. Barr Laboratories Inc.*, S.D.N.Y. — Mr. O'Malley was lead trial counsel on behalf of Kos in this Hatch-Waxman Act litigation that covered the company's franchise Niaspan® product. In what was truly a bet-your-company case, the patents at issue in the litigation protected products accounting for 80% of the company's revenues. In the face of a threatened launch by the generic, a preliminary injunction motion was brought to halt the launch. The generic tabled its launch plans in view of the motion, and the case settled on terms favorable to our client Kos on the eve of the Court announcing its preliminary injunction decision.

Speaking Engagements and Publications

- Widely quoted and published on a variety of topics relating to pharmaceutical patent litigation
- Authored articles in both the mainstream media and in trade journals
- Recently appeared on Bloomberg TV to discuss the growing trend of at-risk launches by generic pharmaceutical makers

Professional and Community Involvement

- Prior to law school, Mr. O'Malley worked for seven years as a chemical engineer in DuPont's engineering department, where he supervised the design

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and construction of new chemical and pharmaceutical processing facilities.

- Currently on the Industrial Advisory Board of Rutgers College of Engineering

Education

- Rutgers University School of Law Camden, J.D., 1992 (with honors)
- Rutgers University, B.S., 1982 (with highest honors; member, Tau Beta Pi, National Engineering Honor Society)

News

October 10, 2019

Paul Hastings Scores Top Rankings in 2019 LMG Life Sciences

July 26, 2019

Paul Hastings Nominated for Four LMG Life Sciences Awards

June 24, 2019

Paul Hastings Recognized in 2019 Managing Intellectual Property's IP Stars

June 07, 2019

Paul Hastings Recognized in 2019 IAM Patent 1000 as One of the Most Sophisticated Patent Litigation Practices

May 01, 2019

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2019

April 08, 2019

Paul Hastings Wins Top Honors at 2019 Managing IP Americas Awards

October 11, 2018

Paul Hastings Scores Top Rankings in LMG Life Sciences for 2018

September 13, 2018

Paul Hastings Wins Hatch-Waxman Litigation Firm of the Year at LMG Life Sciences Awards

June 18, 2018

Paul Hastings Recognized in 2018 Managing Intellectual Property IP Stars

June 15, 2018

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Paul Hastings Recognized in 2018 IAM Patent 1000 For Superb Track Record in Patent Litigation

May 11, 2018

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2018

February 05, 2018

Paul Hastings Wins Law360 Life Sciences Practice Group of the Year

December 28, 2017

Yar Chaikovsky Named Law360 Technology MVP

August 08, 2017

Paul Hastings Recognized in 2017 IAM Patent 1000 for Pristine Patent Litigation Track Record

June 05, 2017

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2017

February 09, 2017

Paul Hastings Intellectual Property Practice Continues Leadership in PTAB Filings

November 30, 2016

Paul Hastings Scores Top Rankings in LMG Life Sciences for 2016

November 23, 2016

Joseph O'Malley Named Law360 Intellectual Property MVP

October 21, 2016

Paul Hastings' Litigators Score High Rankings in 2017 Benchmark Litigation

July 06, 2016

Paul Hastings' IP Growth Continues with Leading Tech and Life Sciences Partner Additions in Japan and U.S.

June 08, 2016

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2016

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May 20, 2015

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2015

March 30, 2015

Nationally Recognized Technology Patent Trial Team Join Paul Hastings in Palo Alto and Washington, D.C.

May 27, 2014

Paul Hastings Practices and Lawyers Score Top Rankings in Chambers USA 2014

January 15, 2014

Paul Hastings Life Sciences Practice Recognized as a Law360 Practice Group of the Year 2013

June 05, 2013

Paul Hastings Extensive Practice Strength Highlighted in The Legal 500 United States 2013

May 27, 2013

Paul Hastings Employment Practice Honored with Chambers "Award for Excellence" and Firms Leading Practices and Lawyers Ranked in Chambers USA 2013

June 07, 2012

Paul Hastings Excels in Chambers USA 2012 Guide

May 31, 2012

Paul Hastings Prevails on All Arguments in Intellectual Property Defense of Galderma Laboratories

March 12, 2012

Paul Hastings Invalidates Five Patents and Eliminates Alleged Damages for Sunovion

June 10, 2011

Paul Hastings Excels in Chambers USA 2011 Guide

June 01, 2011

Paul Hastings Soars in 2011 Edition of Legal 500 US

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June 14, 2010

Paul Hastings Garners Top Rankings in Chambers USA 2010 Guide

June 07, 2010

Paul Hastings Excels in 2010 Edition of Legal 500 US

September 10, 2009

Paul Hastings Secures Dismissal in Patent Infringement Case on Behalf of Eisai

July 22, 2008

Patent Litigators Secure Final Victory for Eisai Against Generic Drugmakers

March 28, 2008

Paul Hastings Obtains Preliminary Injunction in a Patent Infringement Case on Behalf of Eisai

June 19, 2007

Paul Hastings Earns Top Marks in the Latest Volume of The Legal 500 US

May 20, 2007

Paul Hastings Attorneys Recognized as Super Lawyers in Southern California, Connecticut, Georgia, New York, San Diego and Washington, D.C.

May 14, 2007

Paul Hastings Wins Patent Trial for Eisai Pharmaceuticals

November 06, 2006

Paul Hastings Obtains Summary Judgment for Major Pharmaceutical Company

September 12, 2006

Paul Hastings Bolsters International IP Practice With Addition of Prominent Patent Litigation Lawyers in New York

Insights

February 12, 2019

Federal Circuit Again Affirms Patent-Ineligibility of Diagnostic Method Claims: Key Takeaways from the Athena v. Mayo Decision

November 03, 2017

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Federal Circuit Reverses Judge Sleet's Factual Findings for Failure to Address Unrebutted Evidence

February 21, 2017

Generic Found to Infringe Valid Patent Claims Covering Helsinn's Aloxi® Product

November 06, 2014

District of Delaware Finds Specific Jurisdiction Exists Over an ANDA Filer in the Context of a Hatch-Waxman Case

June 16, 2014

District of New Jersey Prevents Generic Challenger from Using Claim Construction as a Backdoor to Introduce Barred Invalidity Defense

September 26, 2013

In an Issue of First Impression, the Federal Circuit Finds Infringement as a Matter of Law Despite a Sworn Certification Promising No Infringement

August 27, 2012

The Federal Circuit Further Clarifies The Obviousness-Type Double Patenting Doctrine For Composition Claims

March 02, 2012

Defendants Clinical Trial Found to Constitute Invalidating Public Use of Asserted Patents

November 21, 2011

A Sign of Future Biosimilars Litigation?

May 25, 2011

Federal Circuit Significantly Tightens Doctrine of Inequitable Conduct Today in Its *En Banc Therasense* Ruling

April 07, 2011

Failure to Launch

December 29, 2010

Federal Circuit Vacates Injunction Against Generic Drug Manufacturer, Determining That A Settlement Agreement Term Is Ambiguous

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December 20, 2010

District of Delaware Allows Generic Drug Manufacturers to Carve Out Two AstraZeneca Patents Claiming FDA-Approved Uses of Crestor

August 19, 2010

District of New Jersey Resets KUDCos ANDAs Final Approval in Protonix Litigation, Notwithstanding Outstanding Defenses of Teva and Sun

June 08, 2010

Generic Drug Manufacturers Inequitable-Conduct Defenses Dismissed for Failing to Meet Exergens Stringent Pleading Standard

January 27, 2010

Patent Owner Protected by Safe Harbor Provision

January 07, 2009

New District of New Jersey Local Patent Rules Require Early Action in Pharmaceutical Patent Cases

October 28, 2008

Proposed Changes to Federal Rules on Experts

Rankings & Awards

September 30, 2019

Recognized as LMG Life Sciences Stars for 2019

June 07, 2019

Recognized by IAM Patent 1000 for 2019

April 26, 2019

Recognized by Chambers USA 2019

April 05, 2019

Recognized by Managing IP as the Life Sciences IP Litigation Firm of the Year

February 14, 2019

Recognized by Chambers Global 2019

January 30, 2019

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Recognized as the 2019 Post-Grant Firm of the Year by IAM Magazine

October 12, 2018

Recognized as LMG Life Sciences Stars for 2018

September 13, 2018

Recognized as the Hatch-Waxman Litigation Firm of the Year by LMG Life Sciences

June 15, 2018

Recognized by IAM Patent 1000 for 2018

May 15, 2018

Recognized by Chambers USA 2018

February 01, 2018

Recognized as Law360 Practice Group of the Year in Life Sciences

October 06, 2017

Recognized as LMG Life Sciences Stars for 2017

July 05, 2017

2017 National Law Journal Intellectual Property Trailblazers

June 06, 2017

Recognized by IAM Patent 1000 for 2017

June 05, 2017

Recognized by Chambers USA 2017

November 30, 2016

Recognized as LMG Life Sciences Stars for 2016

November 23, 2016

Law360 MVP Awards 2016: Intellectual Property

October 21, 2016

Benchmark Litigation 2017

September 16, 2016

Recognized at the 2016 LMG Life Sciences Awards

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July 27, 2016

Shortlisted for four LMG Life Sciences Awards for 2016

June 08, 2016

Recognized by Chambers USA 2016

May 27, 2016

Recognized by IAM Patent 1000 for 2016

December 09, 2015

Benchmark Litigation 2016

June 17, 2015

Recognized by IAM Patent 1000 for 2015

May 15, 2015

Managing IP's 2015 IP Stars

November 20, 2014

Paul Hastings Lawyers Honored by Law360 with MVP Wins

October 09, 2014

Recognized by LMG Life Sciences for Life Sciences IP Litigation

June 05, 2014

Recognized by IAM Patent 1000 for 2014

April 29, 2014

Managing IP's 2014 Intellectual Property Stars

August 12, 2013

Legal Media Group's 2013 LMG Life Science Awards

June 12, 2012

Recognized by IAM Patent 1000 for 2012

May 01, 2011

Intellectual Asset Management

November 30, 2010

Intellectual Property Magazine

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June 13, 2008

Recognized by Chambers USA 2008