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[AstraZeneca Pharms. LP v. Anchen Pharms., Inc.](#)

United States District Court for the District of New Jersey

March 28, 2012, Decided; March 29, 2012, Filed

Civil Action No. 10-cv-1835 (JAP)(TJB); Civil Action No. 10-cv-4203 (JAP)(TJB); Civil Action No. 11-cv-2484 (JAP)(TJB); Civil Action No. 10-cv-4205 (JAP)(TJB); Civil Action No. 10-cv-4971 (JAP)(TJB); Civil Action No. 10-cv-5519 (JAP)(TJB); Civil Action No. 11-cv-2483 (JAP)(TJB)

Reporter

2012 U.S. Dist. LEXIS 43989 *; 2012 WL 1065458

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC. OSMOTICA PHARMACEUTICAL CORPORATION, TORRENT PHARMACEUTICALS LIMITED and TORRENT PHARMA INC., MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.

Notice: NOT FOR PUBLICATION

Subsequent History: Affirmed without opinion by [Astrazeneca Pharms. Lp v. Anchen Pharms., Inc., 2013 U.S. App. LEXIS 3070 \(Fed. Cir., Feb. 14, 2013\)](#)

Prior History: [Astrazeneca Pharms. LP v. Handa Pharms., LLC, 2010 U.S. Dist. LEXIS 126078 \(D.N.J., Nov. 30, 2010\)](#)

Core Terms

quetiapine, patent, Seroquel, patients, dose, antipsychotic, formulations, pharmaceutical, drugs, side effect, prior art, occupancy, gel, infringement, receptor, schizophrenia, references, combine, depression, effective, invention, teachings, release form, bipolar, discloses, products, dosage, psychotic, efficacy, reasonable expectation

Counsel: [*1] For TORRENT PHARMACEUTICALS LIMITED, TORRENT PHARMA INC. (3:10-cv-01835), Movants: THOMAS R. CURTIN, LEAD ATTORNEY, GRAHAM CURTIN, PA, MORRISTOWN, NJ.

For ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs: CARISSA L. RODRIGUE, ELINA SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For ANCHEN PHARMACEUTICALS, INC. (3:10-cv-01835), Defendant: JAMES S. RICHTER, JEFFREY P. CATENACCI, MELISSA STEEDLE BOGAD, WINSTON & STRAWN, LLP, NEWARK, NJ.

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For ANCHEN PHARMACEUTICALS, INC. (3:10-cv-01835), Counter Claimant: JAMES S. RICHTER, JEFFREY P. CATENACCI, WINSTON & STRAWN, LLP, NEWARK, NJ.

For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:10-cv-01835), Counter Defendants: JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For TORRENT PHARMACEUTICALS LIMITED, TORRENT PHARMA INC. (3:10-cv-04203), Movants: THOMAS [*2] R. CURTIN, LEAD ATTORNEY, GRAHAM CURTIN, PA, MORRISTOWN, NJ.

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JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MCCARTER & ENGLISH LLP, NEWARK, NJ; HENRY J. RENK; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For OSMOTICA PHARMACEUTICAL CORPORATION (3:10-cv-04203), Defendant: KEITH J. MILLER, LEAD ATTORNEY, DONALD A. ROBINSON, MICHAEL JAMES GESUALDO, LEDA DUNN WETTRE, ROBINSON, WETTRE & MILLER LLC, NEWARK, NJ.

For OSMOTICA PHARMACEUTICAL CORPORATION (3:10-cv-04203), Counter Claimant: LEDA DUNN WETTRE, ROBINSON, WETTRE & MILLER LLC, NEWARK, NJ.

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For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:11-cv-02484), Plaintiffs, Counter Defendants: CARISSA L. RODRIGUE, ELINA SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT [*3] JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For OSMOTICA PHARMACEUTICAL CORPORATION (3:11-cv-02484), Defendant: KEITH J. MILLER, LEDA DUNN WETTRE, LEAD ATTORNEYS, MICHAEL JAMES GESUALDO, ROBINSON, WETTRE & MILLER LLC, NEWARK, NJ.

For OSMOTICA PHARMACEUTICAL CORPORATION (3:11-cv-02484), Counter Claimant: LEDA DUNN WETTRE, LEAD ATTORNEY, MICHAEL JAMES GESUALDO, ROBINSON, WETTRE & MILLER LLC, NEWARK, NJ.

For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:10-cv-04205),

SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

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For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:10-cv-04205), Counter Defendants: JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For ASTRAZENECA PHARMACEUTICALS [*4] LP, ASTRAZENECA UK LIMITED (3:10-cv-04971), Plaintiffs: CARISSA L. RODRIGUE, ELINA SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

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For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:10-cv-04971), Counter Defendants: JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:10-cv-05519), Plaintiffs: CARISSA L. RODRIGUE, ELINA SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK

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For MYLAN PHARMACEUTICALS INC., MYLAN INC. (3:10-cv-05519), Defendants, Counter Claimants: ARNOLD B. CALMANN, GERI L. ALBIN, SAIBER LLC, NEWARK, NJ.

For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA [*5] UK LIMITED (3:10-cv-05519), Counter Defendants: CARISSA L. RODRIGUE, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED (3:11-cv-02483), Plaintiffs, Counter Defendants: CARISSA L. RODRIGUE, ELINA SLAVIN, JOHN EDMUND FLAHERTY, JONATHAN M.H. SHORT, MARK H. ANANIA, MCCARTER & ENGLISH LLP, NEWARK, NJ; ROBERT JOHN CZARNECKI, JR., FITZPATRICK CELLA HARPER & SCINTO, NEW YORK, NY.

For MYLAN PHARMACEUTICALS INC., MYLAN INC. (3:11-cv-02483), Defendants, Counter Claimants: ARNOLD B. CALMANN, SAIBER LLC, NEWARK, NJ.

Judges: Joel A. Pisano, United States District Judge.

Opinion by: Joel A. Pisano

Opinion

PISANO, District Judge.

I. INTRODUCTION

These are several Hatch-Waxman Act patent infringement actions brought by plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited against Anchen Pharmaceuticals, Inc. ("Anchen"); Osmotica Pharmaceutical Corporation ("Osmotica"); Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

Inc. ("Mylan Pharms") and Mylan Inc. (together, "Mylan"). The patent-in- [*6] suit claims sustained release formulations of the antipsychotic compound quetiapine and a method for treating psychotic states by administering an effective amount of the claimed formulations.

A 12-day bench trial was held in October 2011. Upon hearing the testimony on behalf of the parties and reviewing documentary evidence presented at trial, the Court herein sets forth its findings of fact and conclusions of law, and finds in favor of Plaintiffs.

II. BACKGROUND

A. Procedural Background

Plaintiffs in all actions are AstraZeneca Pharmaceuticals LP ("AZLP") and AstraZeneca UK Limited ("AZUK") (collectively, "AstraZeneca" or "Plaintiffs"). Below is a summary of the instant civil actions:¹

Anchen

- On April 10, 2010, AstraZeneca filed a complaint against Anchen (Civil Action No. 10-1835) alleging that Anchen's filing of its Abbreviated New Drug Application ("ANDA") No. 90-757 infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).

Osmotica

- On August 16, 2010, AstraZeneca filed a complaint against Osmotica (Civil Action No. 10-4203) alleging that Osmotica's filing of its ANDA No. 201424 infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).
- On July 11, 2011, AstraZeneca filed a second [*7] complaint against Osmotica (Civil Action No. 11-2484) alleging that Osmotica's filing of

¹ Plaintiffs settled with certain defendants prior to the conclusion of trial. Those civil actions that were concluded

its AND A No. 202587 infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).

Torrent

- On August 16, 2010, AstraZeneca filed a complaint against Torrent (Civil Action No. 10-4205) alleging that Torrent's filing of its ANDA No. 201996 infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).
- On September 28, 2010, AstraZeneca filed a second complaint against Torrent (Civil Action No. 10-4971) alleging that Torrent's filing of its ANDA No. 202000 infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).

Mylan

- On October 22, 2010, AstraZeneca filed a complaint against Mylan (Civil Action 10-5519) alleging infringement of the '437 patent under 35 U.S.C. § 271(e)(2)(A) based on Mylan Pharms's submission of an ANDA No. 202228.
- On April 29, 2011, AstraZeneca filed a second complaint against Mylan (Civil Action No. 11-2483) alleging infringement of the '437 patent under 35 U.S.C. § 271(e)(2)(A) based on Mylan Pharms's submission of an amendment to its ANDA No. 202228.

Claims 1-13 of the '437 patent are asserted against defendants Anchen and Mylan. Claims 1, 2, 10-13 are asserted against defendants Osmotica and Torrent. Anchen, Osmotica, and Mylan have conceded infringement but assert, along with Torrent, that the '437 patent is invalid for obviousness. The trial of this matter proceeded in essentially two parts. The first part of the trial was directed to Plaintiffs' infringement claims against Torrent. The second part of the trial was directed to Defendants' defense of invalidity based upon obviousness.

B. Witnesses at Trial

During the 12-day bench trial, all parties were provided the opportunity to present evidence. On the claim of infringement against Torrent, AstraZeneca called two witnesses, both expert

witnesses: Dr. Martyn Davies (Bench Trial Transcript ("Tr.") at 24-41), an expert in pharmaceutical delivery systems including sustained release formulations; and Dr. Robert Prud'homme (Tr. at 42-125), an expert in gels, pharmaceutical formulation and drug delivery. AstraZeneca also presented the video deposition testimony of William Blakemore, the 30(b)(6) witness for FMC Corporation, the manufacturer of the sustained [*9] release ingredient in Torrent's ANDA product.

In response, Torrent proffered two fact witnesses on the issue of infringement: Kamesh Venugopal (Tr. at 176-198), president of Torrent's U.S. subsidiary, and Rajiv Shah (Tr. at 199-275), director of the patent department at Torrent. Torrent also presented testimony by video deposition of Mr. Blakemore.

On the issue of obviousness, Defendants called two witnesses for their case-in-chief, Dr. Niham Park (Tr. at 375-570), an expert in the area of pharmaceutical formulation and drug delivery and, particularly, in formulating sustained release solid oral dosage form using hydroxypropyl methylcellulose; and Dr. Lee Kirsch (Tr. at 572-706), an expert in the field of formulation development and pharmaceutical delivery system including sustained release formulations.

AstraZeneca responded to Defendants' obviousness case with the following seven witnesses, five of whom were expert witnesses and two of whom are fact witnesses: David DiCicco (Tr. at 746-787), President of Acumen Research and a specialist in marketing research for pharmaceuticals; Dr. Stuart Montgomery (Tr. at 787-898), an expert and practicing psychiatrist and a researcher in psychiatric [*10] illnesses; Dr. Philip Seeman (Tr. at 947-1044), an expert in neuropsychopharmacology with particular emphasis in antipsychotic drugs and how they affect the dopamine d2 receptor; Henry Grabowski (Tr. at 1045-1199), an expert in the economics of pharmaceutical industry; Dr. Joseph Calabrese (Tr. at 1201-1390), an expert in the clinical development of treatment options for psychotic diseases and in the use of quetiapine containing

Dr. Prud'homme (Tr. at 1391-1500); and Sandford Sommer (Tr. at 1537-1610), Executive Director of Commercial Operations for AstraZeneca's Seroquel IR and XR business.

In rebuttal, Defendants called three expert witnesses: Dr. Robert Mark Hamer (Tr. at 1614-1666), an expert in biostatistics, clinical trial methodology and research methodology; Dr. Christopher Reist (Tr. at 1697-1819), an expert in the area of the treatment of psychiatric patients, including patients that need antipsychotic medication; and Harry Boghigian (Tr. at 1848-1952), an expert in the areas of commercialization,² marketing and lifecycle management of pharmaceutical drug products.

The testimony of a number of witnesses was also submitted by both Plaintiffs and Defendants on the question of obviousness through deposition testimony. Defendants submitted deposition testimony of the following witnesses:

Dr. William Addicks, a former AstraZeneca employee, is one of the inventors of the '437 patent. Dr. Addicks testified about AstraZeneca's development of a sustained release quetiapine formulation.

Dr. Glenn Meyer is the Chief Scientific Officer of Osmotica. Dr. Meyer testified about Osmotica's work in developing a sustained release form of quetiapine.

Dr. Jamie Mullen, a psychiatrist, is an AstraZeneca employee. Dr. Mullen testified about AstraZeneca's clinical trials relating to its sustained release quetiapine formulations.

Dr. Svante Nyberg, a psychiatrist and AstraZeneca employee, has conducted extensive research on the effect of Seroquel IR and Seroquel XR at various receptors in the brain. Defendants rely on Dr. Nyberg's testimony about dosing regimens.

Dr. Bhavnish Parikh, a former AstraZeneca employee, is one of the inventors of the '437

patent. Dr. Parikh testified about work at AstraZeneca on sustained release quetiapine formulations.

Dr. Steven Potkin [*12] is a physician who participated in clinical trials of Seroquel IR and Seroquel XR.

Dr. Robert Sepelyak is an AstraZeneca employee who testified as a Rule 30(b)(6) witness about AstraZeneca's research work on sustained release quetiapine formulations.

Dr. Robert Timko, an AstraZeneca employee, is one of the inventors of the '437 patent. Dr. Timko testified regarding AstraZeneca's work on sustained release quetiapine formulations.

Dr. Martin Deberardinis is an AstraZeneca employee who testified about AstraZeneca's work on sustained release quetiapine.

Mr. Marcelo Ricci is Vice President of Product Development of Osmotica Pharmaceutical Argentina. Mr. Ricci testified about Osmotica's work on sustained release quetiapine formulations.

Plaintiffs presented deposition testimony of the following witnesses:

Mr. Daragh Bradley was an employee of Biovail Technologies (Ireland) Ltd., an affiliate of former defendants Biovail Laboratories International SRL, Biovail Corporation, and BTA Pharmaceuticals, Inc. ("Biovail").³ Mr. Bradley worked on Biovail's quetiapine fumarate sustained release formulation project. Mr. Bradley testified that quetiapine has pH-dependent solubility, and that this characteristic [*13] is a complicating factor in formulating a drug for sustained release.

Mr. James Dunne was also an employee of Biovail. He worked on Biovail's quetiapine fumarate sustained release formulation project and testified that "dose dumping" is a concern when formulating a sustained release dosage form.

Mr. Graham Jackson is an employee of Biovail. Mr.

²In this context, "commercialization" is limited to marketing

³Biovail is a defendant in a related civil action brought by

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