

Case No. IPR2016-01332

Patent No. 8,822,438

Filed: April 19, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC., ACTAVIS  
LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC,  
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S  
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, INC.,  
TEVA PHARMACEUTICALS USA, INC., WEST-WARD  
PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,  
Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

---

Case IPR2016-01332<sup>1</sup>

Patent 8,822,438 B2

---

**PETITIONERS' REPLY TO JANSSEN'S PATENT OWNER RESPONSE**

---

<sup>1</sup> Case IPR2017-00853 has been joined with this proceeding.

**TABLE OF CONTENTS**

	<b>Page</b>
I. INTRODUCTION .....	1
II. ARGUMENT .....	3
A. Skilled Artisans Would Have Been Motivated To Administer Abiraterone Acetate With Prednisone To A Prostate Cancer Patient, With A Reasonable Expectation Of Success. ....	4
1. Steroid synthesis inhibitors were accepted treatments for advanced prostate cancer, and they required concomitant glucocorticoid therapy. ....	4
2. Abiraterone acetate was a known next-generation steroid synthesis inhibitor. ....	5
3. Prednisone was a preferred choice in administration of glucocorticoid replacement therapy. ....	8
B. Abiraterone Acetate’s Selective Mechanism of Action Would Have Further Motivated Skilled Artisans to Administer It With Prednisone .....	8
1. A skilled artisan would have administered glucocorticoid replacement therapy with abiraterone acetate to prevent adrenal insufficiency and low adrenal reserve.....	9
2. A skilled artisan would have administered glucocorticoid replacement therapy with abiraterone acetate to prevent mineralocorticoid excess.....	14
C. The Claims Do Not Require Prednisone To Have an Anti-Cancer Effect.....	17
D. Nothing About Prednisone’s Side Effects Would Have Dissuaded Skilled Artisans From Administering It To Advanced Prostate Cancer Patients With Abiraterone Acetate .....	19
1. Prednisone’s side effects were minimal and greatly outweighed by the dangerous side effects it resolved. ....	19
2. The prior art did not teach that prednisone fueled prostate cancer. ....	20

**TABLE OF CONTENTS**  
**continued**

	<b>Page</b>
E. Janssen’s Suggestion That Ketoconazole Was Not Safe And Effective Is Meritless.....	20
F. No Secondary Considerations Overcome Obviousness.....	22
1. There are no unexpected results.....	22
2. There was no industry skepticism or failure of others.....	24
3. The alleged invention did not satisfy a long-felt but unmet need. ....	25
4. Janssen has not established commercial success. ....	25
III. CONCLUSION.....	27

**TABLE OF AUTHORITIES**

**Page**

**CASES**

*Ethicon Endo-Surgery, Inc. v. Covidien LP*,  
812 F.3d 1023 (Fed. Cir. 2016) .....26

*Galderma Labs., L.P. v. Tolmar, Inc.*,  
737 F.3d 731 (Fed. Cir. 2013) .....26

*Hoffman-La Roche Inc. v. Apotex Inc.*,  
748 F.3d 1326 (Fed. Cir. 2014) .....4

*In re Copaxone Consol. Cases*,  
No. 14-1171-GMS, 2017 WL 401943 (D. Del. Jan. 30, 2017) .....25

*In re Grasselli*,  
713 F.2d 731 (Fed. Cir. 1983) .....24

*KSR Int’l Co. v. Teleflex Inc.*,  
550 U.S. 398 (2007).....3

*Novartis AG v. Torrent Pharm. Ltd.*,  
No. 2016-1352, 2017 WL 1337268 (Fed. Cir. Apr. 12, 2017).....26

*Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*,  
719 F.3d 1346 (Fed. Cir. 2013) .....7

*Pfizer, Inc. v. Apotex, Inc.*,  
480 F.3d 1348 (Fed. Cir. 2007) .....4

*PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*,  
491 F.3d 1342 (Fed. Cir. 2007) .....12

*Symbol Techs., Inc. v. Opticon, Inc.*,  
935 F.2d 1569 (Fed. Cir. 1991) .....25

**TABLE OF ABBREVIATIONS**

<b>Abbreviation</b>	<b>Definition</b>
'438 Patent	U.S. Patent No. 8,822,438
ACTH	Adrenocorticotropic hormone
AR	Androgen receptor
CRPC	Castration-resistant prostate cancer
mCRPC	Metastatic castration-resistant prostate cancer
CYP17	17 $\alpha$ -hydroxylase/C17,20-lyase
DHT	Dihydrotestosterone
IDS	Information Disclosure Statement
LH	Luteinizing hormone
NDA	New Drug Application
POSA	Person of Ordinary Skill in the Art
PSA	Prostate-specific antigen
RCE	Request for Continued Examination
TTPP	Time to PSA progression
Resp. Br.	Janssen's Patent Owner's Response (Paper No. 35)
Rettig Decl.	Declaration of Matthew B. Rettig, M.D. in Support of Janssen Oncology, Inc.'s Patent Owner Response
Auchus Decl.	Declaration of Richard Auchus, M.D., Ph.D. in Support of Janssen Oncology, Inc.'s Patent Owner Response
Rettig Dep.	Transcript of the March 31, 2017 Deposition of Matthew B. Rettig, M.D.
Auchus Dep.	Transcript of the April 10, 2017 Deposition of Richard Auchus, M.D., Ph.D.
Vellturo Dep.	Transcript of the April 5, 2017 Deposition of Christopher A. Vellturo, Ph.D.
Vellturo Decl.	Declaration of Christopher A. Vellturo, Ph.D. in Support of Patent Owner Response

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.