

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

MYLAN PHARMACEUTICALS, INC.  
Petitioner

v.

ASTRAZENECA AB  
Patent Owner.

---

Case IPR2016-01316  
U.S. Patent No. 6,774,122

---

**PATENT OWNER'S PRELIMINARY RESPONSE  
TO PETITION FOR *INTER PARTES* REVIEW  
OF U.S. PATENT NO. 6,774,122**

## TABLE OF CONTENTS

	<b>Page</b>
I. INTRODUCTION .....	1
II. THE '122 PATENT .....	5
A. Specification .....	5
B. Claims .....	6
C. Prosecution history .....	8
III. PERSON OF ORDINARY SKILL IN THE ART .....	11
IV. CLAIM CONSTRUCTION .....	12
A. Malignant diseases of the breast.....	12
B. Sufficient amount of castor oil vehicle .....	12
C. Whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml <sup>-1</sup> is attained for at least 2 weeks after injection.....	13
D. Therapeutically significant.....	16
E. Attained .....	16
V. STATE OF THE ART .....	17
A. McLeskey [Ex. 1005] and Howell 1996 [Ex. 1006] .....	17
B. Active: A skilled artisan had no reason to start with fulvestrant .....	20
1. Petitioner ignores the many other treatment options available to the skilled artisan .....	21
2. Fulvestrant had not been established to be an effective treatment.....	23
C. Critical questions remained about the amount of fulvestrant to deliver and how .....	24
1. Amount: Therapeutically effective blood plasma levels .....	24
2. Administration: Route, excipients, and result intertwined .....	25
3. Claimed combination of excipients was unconventional .....	29
VI. THE '122 PATENT IS VALID AND NOT OBVIOUS .....	32
A. Law of Obviousness .....	32

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
B. Ground One: McLeskey .....	34
1. McLeskey describes the fulvestrant formulations as a “treatment failure” .....	39
2. McLeskey utilizes a different route of administration (subcutaneous) with vastly different subjects (genetically engineered mice) .....	42
3. McLeskey provides no pharmacokinetic data nor any suggestion of the specific blood plasma levels and durations claimed .....	46
4. McLeskey does not disclose the “exact” formulation .....	48
C. Ground Two: McLeskey In Combination With Howell 1996 .....	49
1. No reason to combine McLeskey with Howell 1996 .....	50
2. No reasonable expectation of success .....	53
VII. OBJECTIVE INDICIA DEMONSTRATE THE NONOBVIOUS NATURE OF THE CLAIMED METHOD OF TREATMENT .....	58
VIII. CONCLUSION .....	60

## TABLE OF AUTHORITIES

Page(s)

## Cases

<i>Apple, Inc. v. Contentguard Holdings, Inc.</i> , IPR2015-00357, 2015 WL 9899009 (P.T.A.B. June 29, 2015) .....	46
<i>Apple, Inc. v. Contentguard Holdings, Inc.</i> , IPR2015-00449, 2015 WL 4760572 (P.T.A.B. July 15, 2015).....	38
<i>BioDelivery Scis. Int'l, Inc. v. RB Pharms. Ltd.</i> , IPR2014-00325, 2015 WL 4045328 (P.T.A.B. June 30, 2015) .....	15
<i>Boehringer Ingelheim Int'l GmbH v. Biogen Inc.</i> , IPR2015-00418, 2015 WL 4467391 (P.T.A.B. July 13, 2015).....	38, 54
<i>Bumble Bee Foods, LLC v. Kowalski</i> , IPR2014-00224, 2014 WL 2584188 (P.T.A.B. June 5, 2014) .....	53
<i>Daiichi Sankyo Co. v. Matrix Labs., Ltd.</i> , 619 F.3d 1346 (Fed. Cir. 2010) .....	55
<i>Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.</i> , 533 F.3d 1353 (Fed. Cir. 2008) .....	55
<i>General Plastic Indus. Co. v. Canon Inc.</i> , IPR2015-01954, 2016 WL 1084221 (P.T.A.B. Mar. 9, 2016).....	46
<i>Griffin v. Bertina</i> , 285 F.3d 1029 (Fed. Cir. 2002) .....	15
<i>Hoffer v. Microsoft Corp.</i> , 405 F.3d 1326 (Fed. Cir. 2005) .....	13
<i>In re Cyclobenzaprine</i> , 676 F.3d 1063 (Fed. Cir. 2012) .....	33, 34, 54
<i>In re NTP, Inc.</i> , 654 F.3d 1279 (Fed. Cir. 2011) .....	51
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	34, 50

...

**TABLE OF AUTHORITIES**  
**(continued)**

	<b>Page(s)</b>
<i>Lupin Ltd. v. Pozen Inc.</i> , IPR2015–01774, 2016 WL 1081583 (P.T.A.B. Mar. 1, 2016) .....	41, 42, 54
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008) .....	34
<i>Panduit Corp. v. Dennison Mfg. Co.</i> , 810 F.2d 1561 (Fed. Cir. 1987) .....	33
<i>Pfizer, Inc. v. Apotex, Inc.</i> , 480 F.3d 1348 (Fed. Cir. 2007) .....	57
<i>Unigene Labs., Inc. v. Apotex, Inc.</i> , 655 F.3d 1352 (Fed. Cir. 2011) .....	33, 38
<i>Universal Remote Control, Inc. v. Uei Cayman, Inc.</i> , IPR2014-01111, 2014 WL 6737921 (P.T.A.B. Nov. 24, 2014).....	45
 <b>Statutes</b>	
35 U.S.C. § 103(a) .....	32
 <b>Regulations</b>	
37 C.F.R. § 42.104(b)(2).....	37, 48

# 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.