

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.  
Petitioner

v.

3M COMPANY et al.  
Patent Owner

---

Case IPR2015-02002  
Patent 6,743,413

---

**PATENT OWNER 3M COMPANY'S  
PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

I.	INTRODUCTION .....	1
II.	BACKGROUND .....	4
	A. Solution Aerosol Formulations for Metered Dose Inhalers are Different from Suspension Aerosol Formulations.....	4
	B. Replacing CFC Propellants in Aerosol Formulations Was Challenging .....	6
	C. Researchers Believed that Stable Suspensions with Propellant 134a Required Surfactant.....	8
III.	THE ‘413 PATENT.....	10
IV.	CLAIM CONSTRUCTION .....	11
	A. “Formulation consisting essentially of particulate drug” .....	11
	B. “Stabilizing amount of surfactant” (claims 17-19 and 22-24). 12	
	C. “Substantially free of surfactant” (claims 14-16) .....	14
V.	CLAIMS 14-19 AND 22-24 ARE PATENTABLE OVER THE ‘011 PCT APPLICATION.....	14
	A. The ‘011 PCT Application Does Not Anticipate Claims 14-19 and 22-24.....	15
	1. The ‘011 PCT application does not disclose treating a mammal with the surfactant-free control formulations .....	16
	2. The ‘011 PCT application does not disclose formulations that are “substantially free” of surfactant.....	18
	B. The ‘011 PCT Application, Alone or in Combination with the ‘051 Patent or Weir, Does Not Render Claims 14-19 and 22-24 Obvious .....	21

1. The ‘011 PCT application teaches that surfactants are required in 134a-containing suspension formulations for treating patients .....	22
2. The ‘011 PCT application’s teaching that surfactants are required in 134a-containing suspension formulations for treating patients is consistent with the state of the art prior to the ‘413 patent’s filing date.....	26
3. Mylan’s proposed combination of the ‘011 PCT application with either the ‘051 patent or Weir fails to render claims 15-16, 17-18, or 23-24 unpatentable .....	29
4. Mylan’s obviousness arguments are hindsight-based reconstructions supported only by a declarant who was not working in the field during the relevant timeframe .....	30
VI. CLAIMS 14-19 AND 22-24 ARE PATENTABLE OVER THE ‘333 PCT APPLICATION.....	32
A. The ‘333 PCT Application Does Not Anticipate Claims 14 and 22 .....	34
1. The ‘333 PCT application describes only surfactant-containing formulations .....	37
2. The Purewal ‘183 patent demonstrates that a person of ordinary skill in the art would not have read the ‘333 PCT application as describing surfactant-free, 134a-based suspension formulations .....	38
3. <i>Upsher-Smith</i> does not apply because the statement in the ‘333 PCT application is “sparse and ambiguous”.....	40
B. The ‘333 PCT Application, Alone or in Combination with the ‘051 Patent or Weir, Does Not Render Claims 14-19 and 22-24 Obvious .....	42
1. A person of ordinary skill would read the ‘333 PCT application as teaching that surfactants are required in 134a-containing suspension formulations for treating patients .....	43

2. Mylan provides no evidence demonstrating why a person of ordinary skill would have been motivated to modify the '333 PCT application formulations to treat asthma or COPD ..... 46

VII. CONCLUSION ..... 48

**TABLE OF AUTHORITIES**

<b>Cases</b>	<b>Pages</b>
<i>Allergan v. Apotex</i> , 754 F.3d 952 (Fed. Cir. 2014) .....	33, 41
<i>Cheese Sys., Inc. v. Tetra Pak Cheese and Powder Sys., Inc.</i> , 725 F.3d 1341 (Fed. Cir. 2013) .....	30
<i>Crocs, Inc. v. International Trade Com'n</i> , 598 F.3d 1294 (Fed. Cir. 2010) .....	24
<i>Dayco Products, Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed. Cir. 2003) .....	36, 37
<i>In re Arkley</i> , 455 F.2d 586 (CCPA 1972).....	17
<i>In re Cuozzo Speed Techs., LLC</i> , No. 2014-1301 (Fed. Cir. 2015) .....	11
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012) .....	3
<i>In re Gurley</i> , 27 F.3d 551 (Fed. Cir. 1994) .....	23, 24
<i>In re Hughes</i> , 345 F.2d 184 (CCPA 1965).....	37
<i>In re Translogic Tech., Inc.</i> , 504 F.3d 1249 (Fed. Cir. 2007) .....	11
<i>InTouch Techs., Inc. v. VGO Commc'ns, Inc.</i> , 751 F.3d 1327 (Fed. Cir. 2014) .....	30, 31
<i>Net MoneyIN, Inc. v. Verisign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008) .....	17

# 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.