

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

QUALICAPS CO., LTD,  
Patent Owner

---

IPR2017-00203  
Patent 6,649,180 B1

---

**PATENT OWNER RESPONSE**

**TABLE OF CONTENTS**

I. INTRODUCTION ..... 1

II. LEVEL OF SKILL AND CLAIM CONSTRUCTION ..... 1

    A. Claim Construction..... 1

    B. Person of Ordinary Skill in the Art ..... 1

        1. Petitioner’s definition of the level of skill ..... 1

        2. The person of ordinary skill, by the Petitioner’s definition, would have lacked the skill to make the claimed invention..... 2

III. PETITIONER HAS NOT PROVED THAT CLAIMS 1 AND 4 ARE OBVIOUS OVER THE COMBINATION OF YAMAMOTO AND JP..... 7

    A. Petitioner failed to show that one of ordinary skill would have had reason to modify the prior art and thereby reach the claimed invention ..... 7

        1. Petitioner infected its argument with hindsight by using outdated and incomplete prior art ..... 8

        2. One of ordinary skill would have understood Yamamoto as disclosing only one HPMC type..... 12

        3. One of ordinary skill in the art would have regarded HPMC types 2208 and 2906 as unsuitable for making capsules ..... 17

    B. Petitioner failed to show that one of ordinary skill would have had a reasonable expectation of success..... 24

        1. HPMC 2910 was assigned that number to indicate about 29% MO and about 10% HPO, leading one of ordinary skill to expect about 39% ..... 25

2.	Petitioner cites no evidence that HPMC 2910 within the claimed range ever existed.....	26
3.	Petitioner cites no evidence that the invention resulted from routine testing.....	27
C.	Petitioner failed to rebut Patent Owner’s evidence of unexpected results .....	28
1.	The person of ordinary skill would have expected HPMC capsules to have similar properties throughout the pharmacopeia substitution percentage range .....	29
2.	The inventors discovered a surprising problem and invented an unexpected solution.....	31
3.	The evidence has nexus with the claims.....	37
4.	Petitioner failed to address this evidence in its case-in-chief and may not do so in its Reply.....	37
D.	Dr. Kibbe’s testimony has been repeatedly discredited in multiple IPR proceedings.....	40
IV.	THE CONSTITUTIONALITY OF THE IPR PROCESS HAS BEEN CHALLENGED.....	43
V.	CONCLUSION.....	44

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Allergan, Inc. v. Sandoz, Inc.</i> , 796 F.3d 1293 (Fed. Cir. 2015) .....	37
<i>Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.</i> , 807 F.2d 955 (Fed. Cir. 1986) .....	10
<i>Dastar Corp. v. Twentieth Century Fox Film Corp.</i> , 539 U.S. 23 (2003).....	41
<i>Dr. Reddy’s Labs., Inc. v. Pozen, Inc.</i> , IPR2015-00802.....	42
<i>Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc.</i> , 825 F.3d 1360 (Fed. Cir. 2016) .....	40
<i>Gray Square Pharm., LLC v. Pozen, Inc.</i> , IPR2016-00191.....	42
<i>IBS, Inc. v. Illumina Cambridge Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016) .....	38
<i>In re Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011) .....	29, 36
<i>Leo Pharm. Prods, Ltd. v. Rea</i> , 726 F.3d 1346 .....	33
<i>In re NuVasive, Inc.</i> , 841 F.3d 966 (Fed. Cir. 2016) .....	40
<i>Oil States Energy Services, LLC v. Greene’s Energy Group, LLC</i> , No. 16-712 (U.S. cert. granted June 12, 2017).....	43
<i>Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.</i> , 678 F.3d 1280 (Fed. Cir. 2012) .....	11

*Parker v. Frilette*,  
462 F.2d 544 (C.C.P.A. 1972)..... 28

*Rowe v. Dror*,  
112 F.3d 473 (Fed. Cir. 1997) ..... 15

*Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*,  
661 F.3d 1378 (Fed. Cir. 2011) ..... 28

*Torrent Pharm. Ltd. v. Novartis AG*,  
IPR2014-00784..... 41

*WBIP, LLC v. Kohler Co.*,  
829 F.3d 1317 (Fed. Cir. 2016) ..... 29, 37, 39

**Other Authorities**

37 C.F.R. § 42.23(b) ..... 37

37 C.F.R. § 42.65(a) ..... 10

77 Fed. Reg. 48,756 (Aug. 14, 2012) ..... 37

# 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.