# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD \_\_\_\_\_\_

### MYLAN PHARMACEUTICALS INC. Petitioner

v.

QUALICAPS CO. LTD.
Patent Owner

U.S. Patent No. 6,649,180

Filing Date: April 13, 2000

Issue Date: November 18, 2003

Title: HARD CAPSULE FORMED OF CELLULOSE ETHER FILM WITH A SPECIFIC CONTENT OF METHOXYL AND HYDROXYPROPOXYL GROUPS

Inter Partes Review No. Unassigned

PETITION FOR INTER PARTES REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 ET SEQ.



#### **TABLE OF CONTENTS**

I.	INTF	RODUCTION 1 -				
II.	MAN	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(B) 1				
	A.	REAL PARTY IN INTEREST 1 -				
	В.	RELATED MATTERS 1 -				
	C.	PAY	MENT OF FEES 2 -			
	D.	DES	IGNATION OF LEAD COUNSEL 3 -			
	<b>E.</b>	SER	VICE INFORMATION 3 -			
	F.	POW	VER OF ATTORNEY			
III.	REQ	REQUIREMENTS FOR INTER PARTES REVIEW 4				
	A.	GROUND FOR STANDING4 -				
	В.	IDENTIFICATION OF CHALLENGE 5				
		1.	Claims Challenged 5			
		2.	Background of the Technology 5			
		3.	Prior Art 12 -			
	C.	STA	TEMENT OF THE PRECISE RELIEF REQUESTED 13 -			
IV.	OVERVIEW OF THE '180 PATENT 13					
	A.	PRIORITY DATE OF THE '180 PATENT 13				
	В.	SUMMARY OF THE '180 PATENT 14 -				
	C.	PERSON OF ORDINARY SKILL IN THE ART 15 -				
	D.	CLAIM CONSTRUCTION 15				
		1.	"gelling agent" 17			
		2.	"gelling aid" 18			



V.	LEGAL STANDARDS 19				
	A.	Obvi	ousness	- 19 -	
VI.	FULL STATEMENT OF THE REASONS FOR THE RELIEF REQUESTED				
	<b>A.</b>	OBV	OUND 1: CLAIMS 1 AND 4 ARE UNPATENTABLE AS TOUS IN VIEW OF YAMAMOTO IN COMBINATION H JAPANESE PHARMACOPEIA	- 21 -	
		1.	Brief Summary of Yamamoto	- 21 -	
		2.	Brief Summary of Japanese Pharmacopeia	- 22 -	
		3.	Claim 1	- 22 -	
		4.	Claim 4	- 33 -	
	В.		OUND 2: CLAIMS 1 AND 4 ARE UNPATENTABLE AS TOUS IN VIEW OF GREMINGER	- 41 -	
		1.	Brief Summary of Greminger	- 41 -	
		2.	Claim 1	- 41 -	
		3.	Claim 4	- 48 -	
	C.	PAT	PROPOSED GROUNDS FOR REJECTION ADDRESS ENTEE'S ASSERTED UNEXPECTED BENEFIT OF LL CLARITY AND STABILITY	- 51 -	
VII.	CONCLUSION 55 ·				



#### **EXHIBIT LIST**

Exhibit No.	Description
1001	United States Patent No. 6,649,180
1002	Complaint, Warner Chilcott (US), LLC et al. v. Mylan Pharmaceuticals, Inc., et al., Case No. 2:15-cv-01740-JRG-RSP (E.D. Texas)
1003	Proof of Service of Complaint, Case No. 2:15-cv-01740-JRG-RSP (E.D. Texas)
1004	United States Patent No. 5,756,123 ("Yamamoto")
1005	The Japanese Pharmacopeia (The Society of Japanese Pharmacopeia, 13th ed. 1996) ("Japanese Pharmacopeia")
1006	United States Patent No. 3,493,407 ("Greminger")
1007	21 C.F.R. § 172.874 (1998)
1008	National Formulary (American Pharmaceutical Association, 12th ed. 1965)
1009	Handbook of Pharmaceutical Excipients (1986)
1010	File History of United States Patent No. 6,649,180
1011	Expert Declaration of Arthur H. Kibbe
1012	Shin-Etsu Chemical Co., Ltd. PHARMACOAT Technical Information
	Shin-Etsu Chemical Co., Ltd. TC-5 Technical Information
1013	Chichester, C.O., E.M. Mrak, and G.F. Stewart, "Utilization of Synthetic Gums in the Food Industry," <u>Advances in Food Research, Volume 12, Technical Center, General Foods Corporation, Tarrytown, N.Y., 1963.</u>
1014	Deposition Transcript of Jason T. McConville, Ph.D., Case No. 2:15-cv-1471-JRG-RSP (E.D. Tex.), July 8, 2016





## DOCKET

## 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.

