### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

\_\_\_\_\_

FRESENIUS KABI USA, LLC and FRESENIUS KABI SWISSBIOSIM GmbH Petitioners,

v.

CHUGAI SEIYAKU KABUSHIKI KAISHA Patent Owner.

IPR 2021-01024 Patent 7,521,052

PATENT OWNER'S RESPONSE



## TABLE OF CONTENTS

I.	INTRODUCTION			1		
II.	BACKGROUND					
	A.	Rheumatoid Arthritis				
	В.	Treatments	3			
		1.	NSAIDs, Steroids, and Traditional DMARDs	4		
		2.	Biologic DMARDs	5		
		3.	Combination Therapies	8		
III.	THE	E '052 PATENT10				
IV.	CLAIM CONSTRUCTION					
	A.	"administering an anti-IL-6 receptor antibody and methotrexate (MTX)"1		12		
	B.	"an effective amount of an anti-IL-6 receptor antibody (anti-IL-6R antibody)"; "an effective amount of methotrexate (MTX)"15				
V.	ARGUMENT					
	A.		and 1: <i>Yoshizaki</i> Does Not Disclose a Combination tment with Effective Amounts of the Two Drugs	18		
		1.	Yoshizaki	19		
		2.	Analysis	20		
	B.		Ground 2: <i>Nishimoto</i> Does Not Disclose a Combination Treatment of Effective Amounts of the Two Drugs3			
		1.	Nishimoto 2002			
		_,		31		
	C.	Grou	Ground 3: <i>Nishimoto 2002</i> and <i>Weinblatt 2003</i> Do Not Render Claim 1 Obvious			
		1.	Both Experts Agree That a "Successful" RA Combination Therapy Requires Improved Efficacy Without Undue Toxicity.	33		
		2.	There Was No Reasonable Expectation that the Claimed Combination Would Demonstrate Increased Efficacy	35		



	3.	There Was No Reasonable Expectation That the Claimed			
		Combination Would Have Been Safe	45		
VI.	CONCLUS	ION	51		



## **TABLE OF AUTHORITIES**

## **CASES**

Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274 (Fed. Cir. 2003)	18
Baran v. Med. Device Tech., Inc., 616 F.3d 1309 (Fed. Cir. 2010)	15
Bettcher Indus., Inc. v. Bunzl USA, Inc., 661 F.3d 629 (Fed. Cir. 2011)	29
CommScope Tech. LLC v. Dali Wireless Inc., 10 F. 4th 1289 (Fed. Cir. 2021)	28
Eli Lilly and Co. v. Teva Pharms. Int'l, GmbH, 8 F.3d 1331 (Fed. Cir. 2021)	32, 33, 51
ERBE Elektromedizin GmbH v. Int'l Trade Comm'n, 566 F.3d 1028 (Fed. Cir. 2009)	15
<i>In re Montgomery,</i> 677 F.3d 1375 (Fed. Cir. 2012)	29
Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007)	28
Novartis Pharms. Corp. v. WWard Pharms. Int'l Ltd., 923 F.3d 1051 (Fed. Cir. 2019)	33
Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)	12
Sanofi v. Lupin Atlantis Holdings S.A., No. 15-415-RGA, 2016 WL 5842327 (D. Del. Oct. 3, 2016)	18
Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283 (Fed. Cir. 2015)	28
Vitronics Corp. v. Conceptronic, Inc., 90 F 3d 1576 (Fed. Cir. 1996)	12



STATUTE	
35 U.S.C. § 103	33



# DOCKET A L A R M

# 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.

