UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., Petitioner v. REGENERON PHARMACEUTICALS, INC., Patent Owner

Inter Partes Review No.: Unassigned

U.S. Patent No. 11,253,572 Filed: June 21, 2021 Issued: February 22, 2022 Inventor: George D. Yancopoulos Title: USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

**DECLARATION OF ANGELO P. TANNA, M.D.** 

DOCKET

Δ

## TABLE OF CONTENTS

I.	INTRODUCTION1				
II.	QUALIFICATIONS				
III.	MATERIALS CONSIDERED				
IV.	LEGAL STANDARDS4				
V.	BACKGROUND OF THE TECHNOLOGY				
	А.	Angiogenic Eye Disorders			
		1.	Age-Related Macular Degeneration (AMD)	14	
		2.	Diabetic Retinopathy (DR)	15	
		3.	Diabetic Macular Edema (DME)	16	
		4.	Retinal Vein Occlusion (RVO)	16	
	B. VEGF Antagonists		17		
	C.	Aflit	percept	18	
VI.	DETAILED OPINIONS			24	
	А.	Leve	el of Skill in the Art	24	
	B.	Clair	n Construction	24	
		1.	"initial dose," "secondary dose," and "tertiary dose."	24	
		2.	"4 weeks" and "8 weeks," after the immediately preceding dose	25	
		3.	"wherein the patient achieves/gains"	26	
		4.	"wherein exclusion criteria for the patient include both of"	26	
	C.	Scon	be and Content of the Prior Art References		
	C.	1.			
		1. 2.	Regeneron Press Releases and Clinical Trials		
		2. 3.	SEC Filings		
	D	-			
	D.	Grounds for Unpatentability—Detailed Analysis			
		1.	Ground 1: Dixon anticipates Claims 1-5, 8-11, 14, and 26-30	62	

Declaration of Angelo Tanna, Ph.D. U.S. Patent No 11,253,572

2.	Ground 2: Regeneron (8-May-2008) anticipates Claims 1-5, 8-11, 14, and 26-30	76
3.	Grounds 3 and 4: NCT-795 and NCT-377 each anticipates Claims 1-5, 8-11, 14, and 26-30	88
4.	Ground 5: Claims 6, 7, 12, and 13 are obvious over Dixon, or Regeneron (8-May-2008), or NCT-795, or NCT-377 in combination with Hecht.	100

I, Angelo Tanna, M.D., declare and state as follows:

#### I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Apotex, Inc. for the above captioned *inter partes* review ("IPR") regarding U.S. Patent No. 11,253,572 ("the '572 patent"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$750 per hour. My compensation is not contingent on the conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

#### **II. QUALIFICATIONS**

3. I received an M.D. from Columbia University College of Physicians and Surgeons in 1994 and served as an intern in internal medicine at Graduate Hospital in Philadelphia, Pennsylvania from 1994-1995. From 1995-1998, I completed my ophthalmology residency at The Wilmer Ophthalmological Institute at Johns Hopkins University School of Medicine. From 1998 to 1999, I completed my glaucoma fellowship at The Wilmer Ophthalmological Institute. During my fellowship, I was also an ophthalmology attending at the Johns Hopkins Bayview Medical Center, primarily managing patients with glaucoma. 4. I joined the faculty of the Northwestern University School of Medicine as an Instructor in the Department of Ophthalmology and served in that position from 1999 to 2002. When I joined the Northwestern faculty, I became Director of the Glaucoma Service and continue to hold that position. I was promoted to Assistant Professor of Ophthalmology at Northwestern University Feinberg School of Medicine in 2002, Associate Professor in 2012 and Professor in 2019. In 2010, I became the Vice Chairman of the Department of Ophthalmology at Northwestern University Feinberg School of Medicine, a position I currently maintain.

5. From 1999 to 2014, I served as an attending ophthalmologist in charge of the Glaucoma Service at the Veterans Administration Hospital in Chicago. In that role (which ranged from 0.125 to 0.25 "full time equivalent"), I supervised the education of ophthalmology residents in the surgical and medical management of patients with glaucoma.

6. I was inducted as a member of Alpha Omega Alpha Medical Honor Society in my senior year as a medical student at Columbia University College of Physicians and Surgeons. Since 2005, I have been continuously listed in Best Doctors in America. I was recipient of the American Academy of Ophthalmology's Achievement Award in 2009, its Senior Achievement Award in 2017 and its Secretariat Award in 2019. I was recipient of the Teacher of the Year

# 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.