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

\_\_\_\_\_

PROLLENIUM US INC., Petitioner,

v.

ALLERGAN INDUSTRIE, SAS, Patent Owner.

\_\_\_\_\_

Case IPR2020-00084 U.S. Patent 9,089,519

\_\_\_\_\_\_

PATENT OWNER RESPONSE



## **TABLE OF CONTENTS**

I.	INT	RODUCTION	1
II.	BACKGROUND		
	A.	The POSA Faced Intricacies And Unpredictability In The Art Of Formulating Dermal Fillers	
		1. Physical And Rheological Properties Must Be Accounted For	5
		2. HA Properties Affect Product Properties	6
		3. Crosslinkers, And The Degree Of Crosslinking, Impact The Physical And Rheological Properties	7
		4. Crosslinking Processes Introduce Additional Variables	9
		5. Gels Differ Between Monophasic And Biphasic	10
		6. Post-Crosslinking Steps Further Complicate The Process	11
		7. Degradation From Heat Sterilization Also Creates Concerns	12
		8. Including Lidocaine Added Complexity And Uncertainty	13
	B.	The '519 Patent	15
III.	PER	SON OF ORDINARY SKILL IN THE ART	17
IV.	CLA	AIM CONSTRUCTION	19
V.	PETITIONER'S ASSERTED REFERENCES		
	A.	P050047/S005	20
	B.	Weinkle	
	C.	U.S. 2010/0028438	21
	D.	Lebreton	22
	E.	Sadozai	
	F.	P050047	
	G.	Kinney	



### **TABLE OF CONTENTS**

VI.	THE PETITION IS PREMISED ON UNSUPPORTED EXPERT OPINION THAT MISCHARACTERIZES THE STATE OF THE ART AND DISPARAGES DR. LEBRETON'S DECLARATION WITHOUT BASIS					
	A.	Dr. DeVore Offers Opinions He Is Unable To Defend Based On Credentials He Does Not Have				
		1.	Dr. DeVore Concedes The Art Is Complex, Contrary To His Declaration's Claims of "Simplicity"	25		
		2.	Dr. DeVore Applied Hindsight	27		
		3.	Dr. DeVore Cannot Or Will Not Explain The Chemistry	28		
		4.	Dr. DeVore Misrepresented His Credentials	29		
	B.	Dr. DeVore's Disparagement Of Dr. Lebreton's Declaration Is Unfounded				
VII.	CLAIMS 1-4 ARE NOT ANTICIPATED (GROUNDS 1-3)					
	A.	Claims 1-4 Pre-Date Petitioner's Asserted Art				
		1.	The Provisional Applications Adequately Describe Claims 1-4	35		
		2.	The Provisional Applications Disclose Sufficient Species To Support The Claims	37		
		3.	The '884 Application Provides Adequate Disclosure	38		
			ns 1-4 Are Not Anticipated By P050047/S005 (Ground 1) Veinkle (Ground 2)	39		
		1.	Petitioner Has Not Proven P050047/S005 Is Prior Art	39		
		2.	P050047/S005 Does Not Anticipate (Ground 1)	40		
		3.	Weinkle Does Not Anticipate (Ground 2)	41		
VIII.	CLAIMS 1-8 WOULD NOT HAVE BEEN OBVIOUS OVER LEBRETON IN VIEW OF SADOZAI (GROUND 4)					
	A.					



## **TABLE OF CONTENTS**

	B.	The POSA Would Have Been Further Discouraged By Lebreton's And Sadozai's Incompatible Processes			
	C.	The POSA Would Have Had No Reasonable Expectation Of Success In Combining Lebreton And Sadozai			
	D.	Lebreton and Sadozai Fail To Teach The Limitations Of Claims 1-8			
		1.	It Would Not Have Been Obvious That A First BDDE-Crosslinked HA Filler Containing Lidocaine Would Have Performed Substantially The Same As An Otherwise Identical Composition Without Lidocaine	51	
		2.	Lidocaine "Freely Released In Vivo" Would Not Have Been Obvious (Claims 2, 4, 8)	53	
		3.	Claims 5-7: The Stability Limitations Would Not Have Been Obvious	57	
IX.	CLAIMS 1-8 WOULD NOT HAVE BEEN OBVIOUS OVER P050047 IN VIEW OF KINNEY (GROUND 5)				
	A.	Petiti	oner Has Not Proven P050047 Is Prior Art	59	
	B.	The POSA Would Not Have Been Motivated To Combine P050047 And Kinney			
	C.	The POSA Would Not Have Had A Reasonable Expectation Of Success For Adding Lidocaine			
	D.		oner's Combination Does Not Teach The Claim rations	65	
		1.	It Would Not Have Been Obvious That A BDDE- Crosslinked HA Dermal Filler Containing Lidocaine Would Have Performed Substantially The Same As An Otherwise Identical Composition Without Lidocaine	65	
		2.	Claims 2, 4, 8: Lidocaine "Freely Released In Vivo" Would Not Have Been Obvious	66	
		3.	Claims 5-7: The Stability Limitations Would Not Have Been Obvious	67	
X.	CON	CLUS	ION	69	



### **EXHIBIT LIST**

Exhibit No.	Exhibit Description
2001	Juvéderm Ultra™ XC Label
2002	Juvéderm Ultra Plus <sup>TM</sup> XC Label
2003	Juvéderm Voluma®XC Label
2004	U.S. Patent Publication No. 2004/0101959 to Marko et al, published May 27, 2004
2005	Excerpts from U.S. 8,822,676 file history
2006	Excerpts from U.S. 9,089,519 file history
2007	About Juvéderm Ultra Plus™ XC
2008	About Juvéderm Volbella® XC
2009	About Juvéderm Voluma® XC
2010	Reserved
2011	Declaration in support of unopposed motion for <i>pro hac vice</i> admission of Elizabeth Flanagan
2012	Updated Declaration in support of unopposed motion for <i>pro hac vice</i> admission of Elizabeth Flanagan
2013	Declaration of Cory J. Berkland, Ph.D
2014	Curriculum Vitae, Cory J. Berkland, Ph.D.
2015	Kuo, Practical Aspects of Hyaluronan Based Medical Products, Chs. 1-6, 2006. ("Kuo")
2016	Hascall and Laurent, <i>Hyaluronan: Structure and Physical Properties</i> , Hyaluronan Today, Vol. 1, 1997, <a href="https://www.glycoforum.gr.jp/article/01A2.html">https://www.glycoforum.gr.jp/article/01A2.html</a> . ("Hascall")
2017	Cleland, et al., <i>Polyelectrolyte Properties of Sodium Hyaluronate</i> . 2. <i>Potentiometric Titration of Hyalyuronic Acid</i> , Macromolecules Vol. 15, 1982; 386-395. ("Cleland")
2018	Knill, et al., Effect of Metal Ions on the Rheological Flow Profiles of Hyaluronate Solutions, Kennedy Ch. 21, Hyaluronan, 2002; 175-180. ("Knill")



# 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.

