

IPR2016-01370  
U.S. Patent No. 8,664,231

Attorney Docket No.  
110670-0009-651

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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KOIOS PHARMACEUTICALS LLC,  
Petitioner

v.

MEDAC GESELLSCHAFT FUER KLINISCHE  
SPEZIALPRÄPARATE MBH,  
Patent Owner

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Case No. IPR2016-01370  
Patent Number 8,664,231

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Before JACQUELINE WRIGHT BONILLA, TONI R. SCHEINER,  
and ERICA A. FRANKLIN, *Administrative Patent Judges*

**PATENT OWNER'S RESPONSE**  
**UNDER 37 C.F.R. § 42.120**

## TABLE OF CONTENTS

	<u>Page</u>
<b>I. Introduction.....</b>	<b>1</b>
<b>II. The Parties and Experts.....</b>	<b>4</b>
<b>A. Patent Owner and Its Experts.....</b>	<b>4</b>
1. Dr. Elena Massarotti.....	5
2. Dr. Sean Nicholson.....	5
3. Dr. Thomas Zizic.....	5
4. Dr. John Clark.....	6
<b>B. Petitioner And Its Experts.....</b>	<b>6</b>
<b>III. The ‘231 Patent and Prosecution History .....</b>	<b>7</b>
<b>A. The ‘231 Patent.....</b>	<b>7</b>
<b>B. Relevant Prosecution History.....</b>	<b>9</b>
<b>IV. MTX and the Treatment of Inflammatory Autoimmune Diseases.....</b>	<b>10</b>
<b>V. Claim Construction .....</b>	<b>14</b>
<b>VI. Anticipation (Grounds 1 and 4): The Cited Art Does Not Anticipate Any Claims .....</b>	<b>15</b>
<b>A. Grint Does Not Disclose The Features Of Claims 1, 2, 4-6, 11-13, 17, And 22 Or Their Arrangement As In Those Claims (Ground 1).....</b>	<b>17</b>
1. Petitioner Failed To Demonstrate That Subcutaneous Administration Of Above 30 mg/ml MTX Was Conventional Or Convenient and Effective .....	22
2. Petitioner Failed To Demonstrate That There Is No Reasonable Difference In How The Claimed Invention Operates Over Grint’s Entire Concentration And Dose Ranges.....	25

<b>B.</b>	<b>Wyeth Does Not Disclose The Features Of Claims 1-6, 11-13, 17-18, And 22 Or Their Arrangement As In Those Claims (Ground 4).....</b>	<b>30</b>
<b>1.</b>	<b>Wyeth’s Focus Is Not On Subcutaneous Administration .....</b>	<b>31</b>
<b>2.</b>	<b>Wyeth Does Not Teach the Claimed Concentrations for Inflammatory Autoimmune Diseases.....</b>	<b>32</b>
<b>VII.</b>	<b>Obviousness (Grounds 2, 3, and 6): The Cited Art Does Not Render Any Claims Obvious .....</b>	<b>42</b>
<b>A.</b>	<b>Grint, Arthur, Moitra, and Insulin Admin Do Not Render Obvious Claims 7-10, 14-16, or 19-21 (Ground 2) .....</b>	<b>45</b>
<b>B.</b>	<b>Grint and Alsufyani Do Not Render Obvious Claim 18 (Ground 3).....</b>	<b>47</b>
<b>C.</b>	<b>Wyeth, Brooks, Arthur, and Moitra Do Not Render Obvious Claims 1-6, 11-13, 17-18, or 22 (Ground 5) .....</b>	<b>47</b>
<b>VIII.</b>	<b>Secondary Considerations Demonstrate Nonobviousness.....</b>	<b>48</b>
<b>A.</b>	<b>Petitioner Ignored Known Evidence of Copying .....</b>	<b>49</b>
<b>B.</b>	<b>The Methods Of The Challenged Claims Have Received Praise .....</b>	<b>50</b>
<b>C.</b>	<b>No One Made The Methods Of The Challenged Claims, Despite Strong Incentives .....</b>	<b>51</b>
<b>IX.</b>	<b>Conclusion .....</b>	<b>52</b>

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>CASES</b>	
<i>Atofina v. Great Lakes Chem. Corp.</i> , 441 F.3d 991 (Fed. Cir. 2006) .....	25, 26, 27, 28
<i>ClearValue, Inc. v. Pearl River Polymers, Inc.</i> , 668 F.3d 1340 (Fed. Cir. 2012) .....	26
<i>Dennison Mfg. Co. v. Panduit Corp.</i> , 475 U.S. 809 (1986).....	3, 42
<i>Graham v. John Deere, Co.</i> 383 U.S. 1 (1966).....	48
<i>In re Arkley</i> , 455 F.2d 586 (C.C.P.A. 1972) .....	16
<i>Ineos USA LLC v. Berry Plastics Corp.</i> , 783 F.3d 865 (Fed. Cir. 2015) .....	26
<i>Net MoneyIN, Inc. v. Verisign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008) .....	17, 22
<i>Synopsis Inc. v. Mentor Graphics Corp.</i> , IPR2012-00041, slip op. (PTAB Feb. 22, 2013) .....	18
<b>OTHER AUTHORITIES</b>	
37 C.F.R. § 42.65(a) .....	2
§ 42.100(b).....	14
§ 42.120.....	1
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### EXHIBIT LIST

Exhibit	Description
2001	Kurnick D. <i>et al.</i> , “Bioavailability of oral vs. subcutaneous low-dose methotrexate in patients with Crohn’s disease,” <i>Aliment. Pharmacol. Ther.</i> , 2003, vol. 18:57-63
2002	Breslin, <i>et al.</i> , “Improving Tolerance and Bioavailability of Methotrexate by Switching from Oral to Subcutaneous Route of Administration,” <i>Rheumatology</i> 388 (2005)
2003	Balis, <i>et al.</i> , “Pharmacokinetics of Subcutaneous Methotrexate,” <i>Journal of Clinical Oncology</i> 6(12):1882-1886 (1988)
2004	Chapter 16: Human: Veterinary Technology Cross Over, Long Acting Animal Health Drug Products: Fundamentals and Applications, Baird et al., Springer (2013)
2005	Chapter 3: Drug Administration, <i>Drug Therapy In Nursing</i> , 3rd Ed., Aschenbrenner DS and Venable SJ, Wolters Kluwer Health (2009)
2006	Antares Pharma Press Release, “Antares Pharma Announces the Publication of a Head-to-Head, Randomized, Crossover Study of Oral versus Subcutaneous Methotrexate in Patients with Rheumatoid Arthritis,” Business Wire (Apr. 17, 2014)
2007	Consulting Agreement between Medac Pharma, Inc. and Dr. Michael Schiff, M.D., executed September 7, 2012
2008	RA Advisory Council: Overview & Meeting Objectives, October 5, 2012
2009	Koios Pharmaceuticals LLC Press Release, “Koios Pharmaceuticals Files Challenge to High-Cost Drug’s Patent,” Business Wire (July 20, 2016)
2010	Declaration of Brian Gummow in Support Of Patent Owner’s Preliminary Response
2011	Declaration of Terri Shoemaker in Support Of Patent Owner’s Preliminary Response
2012	U.S. Patent 8,480,631
2013	Andrea T. Borchers <i>et al.</i> , “The Use of Methotrexate in Rheumatoid Arthritis,” <i>Seminars in Arthritis and Rheumatism</i> , Vol. 34, No. 1 (Aug. 2004)

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