

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**MYLAN PHARMACEUTICALS, INC.**

*Petitioner*

v.

**YEDA RESEARCH AND DEVELOPMENT CO. LTD.**

*Patent Owner*

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**Case No. IPR2015-00644**

Patent No. 8,399,413

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**DECLARATION OF TJALF ZIEMSEN, M.D., Ph.D IN SUPPORT OF  
PATENT OWNER YEDA'S RESPONSE TO PETITION FOR *INTER  
PARTES* REVIEW**

# TABLE OF CONTENTS

	Page
Contents	
<b>I. Introduction.....</b>	<b>1</b>
<b>II. Qualifications And Experience.....</b>	<b>2</b>
<b>III. Legal Standard.....</b>	<b>6</b>
<b>IV. Person Of Ordinary Skill In The Art.....</b>	<b>9</b>
<b>V. Summary Of Opinions.....</b>	<b>10</b>
<b>VI. Overview Of Multiple Sclerosis And Glatiramer Acetate .....</b>	<b>13</b>
<b>A. Multiple Sclerosis Is Associated With A Wide Variety Of Different Symptoms That Can Affect The Ability Of Patients To Carry Out Normal Activities Of Daily Living .....</b>	<b>13</b>
<b>B. The Underlying Causes of MS are Complex and Not Fully Established .....</b>	<b>15</b>
<b>C. Glatiramer Acetate Is A Complex Drug That Is Unlike Traditional Drugs .....</b>	<b>17</b>
<b>1. The Active Molecule in Glatiramer Acetate Remains Unknown .....</b>	<b>18</b>
<b>2. While Not Definitively Characterized, Certain Principles Concerning GA’s Mechanism of Action Were Established in the Prior Art as of 2009. ....</b>	<b>19</b>
<b>3. Standard Pharmacokinetics Cannot Predict the Effects of Glatiramer Acetate.....</b>	<b>29</b>
<b>VII. The Cited References.....</b>	<b>32</b>
<b>A. Pinchasi (Ex. 1005).....</b>	<b>32</b>
<b>B. SBOA (Ex. 1007A) .....</b>	<b>35</b>
<b>C. Flechter (Ex. 1008).....</b>	<b>39</b>
<b>VIII. Discussion And Opinions.....</b>	<b>41</b>
<b>A. The ’413 Patent .....</b>	<b>41</b>
<b>B. Ground 3: The Combination Of Pinchasi In View Of SBOA Would Not Have Rendered Obvious The Invention Claimed In The ’413 Patent .....</b>	<b>43</b>
<b>1. A POSA Would Not Have been Motivated to Increase the Dose of Glatiramer Acetate from 20 mg to 40 mg. ....</b>	<b>44</b>
<b>2. A POSA Would Not Have been Motivated to Decrease the Dosing Frequency of Glatiramer Acetate in 2009.....</b>	<b>51</b>
<b>3. Pinchasi In View Of The SBOA Would Not Motivate The POSA To Dose 40 mg Of GA Three Times Weekly With At Least A Day Between Doses With A Reasonable Expectation Of Success. ....</b>	<b>65</b>

<b>C.</b>	<b>Ground 4: The Combination Of Pinchasi In View Of Flechter Would Not Have Rendered Obvious The Invention Claimed In The '413 Patent .....</b>	<b>68</b>
1.	<b>Flechter does not disclose or suggest using 40 mg of GA three times weekly with at least a day between doses.....</b>	<b>68</b>
2.	<b>Pinchasi In View Of Flechter Would Not Motivate The POSA To Dose 40 mg Of GA Three Times Weekly With At Least A Day Between Doses With A Reasonable Expectation Of Success. ....</b>	<b>71</b>
<b>D.</b>	<b>Other Prior Art Does Not Support an Obviousness Finding.....</b>	<b>72</b>
1.	<b>The Khan 2008 Abstract (Ex. 1010) .....</b>	<b>73</b>
2.	<b>The Rasmussen Patent Application (Ex. 1036) .....</b>	<b>74</b>
3.	<b>Interferon Prior Art Would be Considered Irrelevant by the POSA for Purposes of Developing a Dosing Regimen for GA.....</b>	<b>75</b>
<b>IX.</b>	<b>Unexpected Results Confirm The Nonobviousness Of The Invention ....</b>	<b>76</b>
<b>X.</b>	<b>Conclusion.....</b>	<b>76</b>

**TABLE OF ABBREVIATIONS**

<b><u>Abbreviation</u></b>	<b><u>Description</u></b>
'250 patent	U.S. Pat. No. 8,232,250
'413 patent	U.S. Pat. No. 8,399,413
'302 patent	U.S. Pat. No. 8,969,302
Yeda	Patent Owner Yeda Research & Development Co. Ltd.
Mylan	Petitioner Mylan Pharmaceuticals, Inc.
Teva	Teva Pharmaceuticals Industries Ltd. is the exclusive licensee of the '250, '302, and '413 patents. Teva Pharmaceuticals USA, Inc. is the holder of the New Drug Application for Copaxone®, a drug for which the '250, '302, and '413 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book." Teva Neuroscience, Inc. markets and sells Copaxone® in the United States.
Pinchasi	Ex. 1005, Pinchasi, WO 2007/081975 A2, published July 19, 2007.
The SBOA	Ex. 1007, Summary Basis of Approval for the New Drug Application for 20 mg daily Copaxone® (NDA #20-622).
Flechter	Ex. 1008, S. Flechter et al., Copolymer 1 (Glatiramer Actetate) in Relapsing Forms of Multiple Sclerosis: Open Multicenter Study of Alternate-Day Administration, 25(1) CLIN. NEUROPHARMACOLOGY, 11-15 (2002).
GA	Glatiramer acetate
MS	Multiple sclerosis

...

RRMS	Relapsing-remitting multiple sclerosis
Green Decl.	Ex. 1004
Peroutka Decl.	Ex. 1003
Cohen	Ex. 1006
PK	pharmacokinetics
PD	pharmacodynamics
POSA	Person of ordinary skill in the art

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