

**Filed On Behalf Of:**

Novartis AG and LTS Lohmann Therapie-Systeme AG

**By:**

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**NOVEN PHARMACEUTICALS INC.  
AND MYLAN PHARMACEUTICALS INC.,**  
Petitioners

v.

**NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,**  
Patent Owners

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*Inter Partes* Review No. 2014-00550<sup>1</sup>

U.S. Patent 6,335,031

CERTIFICATION PURSUANT TO FED. R. EVID. 902(11)

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<sup>1</sup> Case IPR2015-00268 has been joined with this proceeding.

I, Peter McArdle, declare pursuant to 28 U.S.C. § 1746:

1. I am an Executive Director of Drug Regulatory Affairs at Novartis Pharmaceuticals Corporation (“Novartis”). I make this certification to establish that the record referenced herein and attached hereto is a record of a regularly conducted activity or business record within the meaning of Federal Rule of Evidence 803(6) and so that it may be offered as evidence of the truth of the matters stated in the record at the trial of this matter.

2. I certify that it is part of my duty as an Executive Director of Drug Regulatory Affairs to maintain the following record pursuant to law and for the purpose of documenting the pharmaceutical regulatory approval process:

<b>Bates Range</b>	<b>Description</b>
N0002374-N0002403	Excerpt from NDA 22-038, Rivastigmine (ENA713-NXA Base) Drug substance (Ex. 2059 in the above captioned proceeding is Bates page N0002403 of the attached record)

3. I am familiar with the manner and process in which this record is maintained by virtue of my duties and responsibilities.

4. Documents maintained in the Novartis archives (hard copy and/or electronic), are true and correct copies of records made by Novartis as a regular business practice and as part of the regularly conducted business of Novartis.

5. In accordance with the regular practice at Novartis, this record would have been generated at or near the time of the activity described therein by a person with knowledge of those matters.

6. This document was collected from the regulatory records archives at Novartis. Novartis kept the record in the regulatory records archives as part of its regularly conducted business activity.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: April 28, 2015

Mc Ardle Peter

Digitally signed by Mc Ardle Peter  
DN: SERIALNUMBER=590103 + CN=Mc Ardle Peter,  
OU=PH, OU=people, DC=novartis, DC=com  
Reason: I attest to the accuracy and integrity of this  
document.  
Date: 2015.04.28 05:37:53 +03:00

I certify that a copy of the foregoing CERTIFICATION PURSUANT TO FED. R. EVID. 902(11) was served on April 28, 2015 by causing them to be sent by email to counsel for Petitioners at the following email addresses:

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Dated: April 28, 2015

/s/ Raymond R. Mandra  
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