

For the Petitioner

Paper No. ___

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Neifeld IP Law, PC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition For Affordable Drugs V LLC

Petitioner

v.

Biogen MA Inc.

Patent Owner

Case IPR2015-01993

Patent 8,399,514

Title: TREATMENT FOR MULTIPLE SCLEROSIS

DECLARATION OF ROBERT MIHAIL

Coalition Exhibit 1024A

Coalition v. Biogen

IPR2015-01993

1. I am an attorney employed by Neifeld IP Law, PC.
2. On 9/19/2015 I accessed the URL <https://clinicaltrials.gov/show/NCT00168701> and saw that the top-level domain is a “dot-gov” domain.
3. On 4/29/2015 I read that 41 CFR §102-173.30 states “Who may register in the dot-gov domain? Registration in the dot-gov domain is available to official governmental organizations in the United States including Federal, State, and local governments, and Native Sovereign Nations.”
4. Based on the above findings, I concluded that the domain name clinicaltrials.gov of the URL <https://clinicaltrials.gov/show/NCT00168701> is registered by an official governmental organization in the United States.
5. On 9/19/2015 I downloaded the document contained at URL <https://clinicaltrials.gov/show/NCT00168701>, now marked as **Ex. 1040**.
6. On 9/19/2015 I clicked the hyperlinked text “History of Changes” located on the first page of **Ex. 1040**. Upon clicking said hyperlink I was taken to URL <https://clinicaltrials.gov/ct2/archive/NCT00168701>. A copy of the webpage located at said URL is now marked as **Ex. 1041**.
7. On 9/19/2015 I clicked the hyperlinked text “ClinicalTrials.gov Archive Site” located on the first page of **Ex. 1041**. Upon clicking said hyperlink I was taken to

URL <https://clinicaltrials.gov/archive/NCT00168701>. A copy of the webpage located at said URL is now marked as **Ex. 1042**.

8. On 9/19/2015 I clicked the hyperlinked text “Study” located immediately to the right of “2005-09-14” under the Column titled “Updated”. Upon clicking said hyperlink I was taken to URL

https://clinicaltrials.gov/archive/NCT00168701/2005_09_14. A copy of the webpage located at said URL is now marked as **Ex. 1022**.

9. On 9/19/2015 I accessed the URL <https://www.clinicaltrials.gov/ct2/about-site/background> and downloaded the webpage, now marked as **Ex. 1043**.

10. On 9/19/2015 I read from the first page of **Ex. 1043** that “The results database was made available to the public in September 2008. FDAAA 801 also established penalties for failing to register or submit the results of trials. See the History, Policies, and Laws page for more information about the development of ClinicalTrials.gov. Because ClinicalTrials.gov is a government Web site, it does not host or receive funding from advertising or the display of commercial content.”

11. On 9/19/2015 I also read from the second page of **Ex. 1043** that “[t]he full history of changes made to a record can be accessed by viewing the archival version of the record on the ClinicalTrials.gov archive. Once a study is registered on the site, the information about it is not removed.”

Based on my observations of the information and documents contained in paragraphs 1-11 above, I concluded that (1) the webpage now marked as **Ex. 1022** is an archival page of the study marked as “NCT00168701,” that (2) the information on webpage now marked as **Ex. 1022** was publicly available on 09/14/2005 and (3) that information contained on the webpage now marked as **Ex. 1022** was not removed since 09/14/2005.

In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

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

Respectfully submitted

By: /RobertMihail/

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