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Internet Archive  
300 Funston Avenue  
San Francisco, CA 94118

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## AFFIDAVIT OF DUNCAN HALL

1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.
4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.
5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an "extended URL". Thus, the extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

Mylan Exhibit 1070

Mylan, Defendant, IPD0001-00000



6. Attached hereto as Exhibit A are true and accurate copies of printouts of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.
7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 01/20/2021

*Duncan D Hall*

Duncan Hall

Mylan Exhibit 1070

Mylan Reference ID: 00001-00000

# EXHIBIT A

Mylan Exhibit 1070

Mylan v. Regeneron, IPD2021-00880

<https://web.archive.org/web/20110408231012/http://clinicaltrials.gov/ct2/show/NCT0101297>

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Mylan v. Regeneron, IPR2021-00880



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Joining Petitioner: Apotex

## Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO) (GALILEO)

**This study is ongoing, but not recruiting participants.**

First Received on October 30, 2009. Last Updated on January 25, 2011 [History of Changes](#)

<b>Sponsor:</b>	Bayer
<b>Collaborator:</b>	Regeneron Pharmaceuticals
<b>Information provided by:</b>	Bayer
<b>ClinicalTrials.gov Identifier:</b>	NCT01012973

### Purpose

To determine the efficacy of vascular endothelial growth factor (VEGF) Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion

Condition	Intervention	Phase
Retinal Vein Occlusion	Drug: VEGF Trap-Eye (BAY86-5321) Other: Sham treatment	Phase III

Study Type: Interventional  
Study Design: Allocation: Randomized  
Endpoint Classification: Safety/Efficacy Study  
Intervention Model: Parallel Assignment  
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)  
Primary Purpose: Treatment

Official Title: A Randomized, Double-masked, Sham-controlled Phase 3 Study of the Efficacy, Safety and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)

### Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [Stargardt macular degeneration](#) [X-linked juvenile retinoschisis](#)  
[MedlinePlus](#) related topics: [Edema](#)  
[Drug Information](#) available for: [Aflibercept](#)  
[U.S. FDA Resources](#)

### Further study details as provided by Bayer:

#### Primary Outcome Measures:

- The proportion of subjects who gain at least 15 letters in BCVA on the EDTRS chart compared with baseline at the Week 24 endpoint [ Time Frame: Week 24 ] [ Designated as safety issue: No ]

#### Secondary Outcome Measures:

- Change from baseline in BCVA score [ Time Frame: week 24 ] [ Designated as safety issue: No ]
- Absolute change from baseline in central retinal thickness, assessed by OCT [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Proportion of subjects progressing to anterior segment neovascularization, neovascularization of the optic disc (NVD), or neovascularization of the retina elsewhere (NVE) requiring pan-retinal photocoagulation [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Change in the NEI-VFQ-25 total score from baseline [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Change in the EQ-5D score from baseline [ Time Frame: Week 24 ] [ Designated as safety issue: No ]

Estimated Enrollment: 165  
Study Start Date: October 2009  
Estimated Study Completion Date: March 2012  
Estimated Primary Completion Date: February 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Arm 1: Experimental Intervention: Drug: VEGF Trap-Eye (BAY86-5321)	Drug: VEGF Trap-Eye (BAY86-5321) Intravitreal injection. Weeks 0 to 20 injection of VEGF Trap-Eye every 4 weeks; weeks 24 to 52 every 4 weeks plus additional on week 60 and 68 re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; last visit (no treatment) at week 76.
Arm 2: Sham Comparator Intervention: Other: Sham treatment	Other: Sham treatment Sham treatment. Weeks 0 to 20 sham treatment every 4 weeks; weeks 24 to 48 every 4 weeks re-assessment and sham injection; week 52 VEGF Trap-Eye injection (unless investigator declines for medical reasons), weeks 60 and 68 re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; last visit (no treatment) at week 76.

Mylan Exhibit 1070

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