

A u g u s t 1 0 , 2 0 2 2

IPR2021-00880, -00881

U.S. Patent Nos. 9,669,069 & 9,254,338

**REGENERON<sup>®</sup>**

---

## Overview

- VEGF Trap-Eye: All Grounds, All Claims
- IPR2021-00880—U.S. Patent No. 9,669,069
  - Ground 4 – All Claims: No Anticipation or Obviousness Based on Dixon Disclosure of VIEW Dosing Regimen
  - Ground 5 – Claim 8: No Anticipation or Obviousness Based on Heier- of Mitchell or Dixon
- IPR2021-00881—U.S. Patent No. 9,234,338
  - Claim Construction
  - Grounds 1-5 – All Claims: No Anticipation Based on Lack of “Treatment
  - Ground 6 – All Claims: No Obviousness Based on Prospective VIEW Regimen



# VEGF Trap-Eye

3

# Petitioner's Grounds Do Not Disclose the Recited Acid or Nucleic Acid Sequences

Drug Evaluation

**Expert Opinion**

## VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration

James A Dixon, Scott CN Oliver<sup>1</sup>, Jeffrey L Olson & Narsis Mandava  
*University of Colorado Denver, Health Sciences Center, Department of Ophthalmology, 1675 North Aurora Avenue, PO Box 6516, Mail Stop F-751, Aurora, CO 80045-2929*

**Background:** Age-related macular degeneration (AMD) is a leading cause of blindness in developed countries. Although 90% of patients with AMD have the non-neovascular form, neovascular AMD accounts for the vast majority of cases leading to significant vision loss. Until recently, the treatment of neovascular AMD. The use of anti-VEGF agents, such as ranibizumab, bevacizumab, and aflibercept, has significantly improved the safety and efficacy of treatment. In addition to anti-VEGF agents, anti-angiogenic agents such as aflibercept and bevacizumab, a number of other agents are currently under investigation. Trap-Eye, a fusion protein consisting of VEGF Trap and a placental growth factor (PGF) receptor, is a novel approach to the treatment of neovascular AMD. Two Phase II clinical trials of VEGF Trap-Eye for neovascular AMD are currently underway, providing a vital insight into the clinical applicability of this novel approach.

**Introduction**

1. Introduction

2. Background

3. Conclusion

4. Expert opinion

**informa healthcare**

1573

Mylan Exhibit 1006  
Mylan v. Regeneron, IPR2021-00880  
Page 1

Dixon Ex.1006

COVER STORY

## Intravitreal VEGF Trap for AMD: An Update

The CLEAR-IT 2 Extension Study was presented at the Association for Research in Vision and Ophthalmology (ARVO) earlier this year. The results of the initial CLEAR-IT 2 as well as the extension study.

**Figure 1:** VEGF Trap-Eye is a fusion protein designed to bind all forms of the proteins VEGF-A and PlGF, which both play a part in abnormal growth of new blood vessels.

**Mylan Exhibit 1020**  
Mylan v. Regeneron, IPR2021-00880  
Page 1

Heier-2009 Ex.1020

## REGENERON

**Bayer and Regeneron Extend Development Program for CRVO**

April 30, 2009

Bayer and Regeneron Extend Development Program for CRVO to start in the second half of this year.

BERLIN and TARRYTOWN, N.Y., April 30 (PRNewswire) - Bayer and Regeneron today announced that the companies are extending their global development program for the safety of VEGF Trap-Eye in the treatment of CRVO in the second half of this year. The Phase 3 program in CRVO will consist of two, multicenter studies that will evaluate the safety and efficacy of VEGF Trap-Eye in the treatment of CRVO in the second half of this year. The Phase 3 program in CRVO will consist of two, multicenter studies that will evaluate the safety and efficacy of VEGF Trap-Eye in the treatment of CRVO in the second half of this year.

**Regeneron**

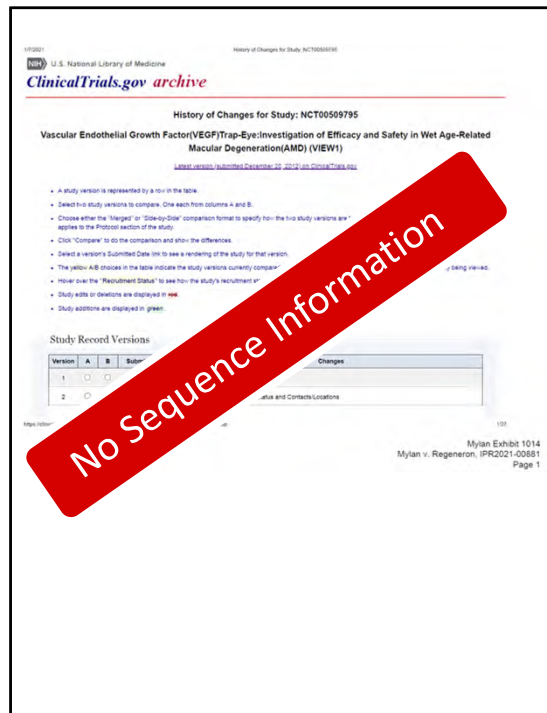
**Mylan Exhibit 1020**  
Mylan v. Regeneron, IPR2021-00880  
Page 1

Regeneron Ex.1020

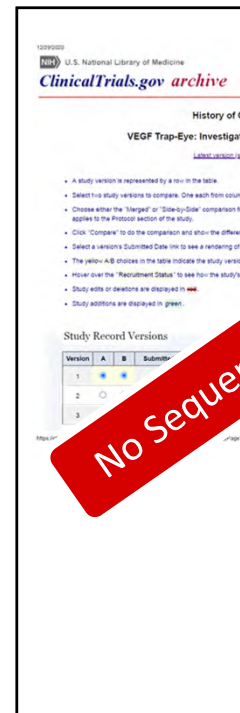
# Petitioner's Grounds Do Not Disclose the Recited Acid or Nucleic Acid Sequences



Regeneron (8-May-2008)  
Ex.1013



NCT-795 Ex.1014



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.