UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Inter Partes Review No.: IPR2021-00880[1]

U.S. Patent No. 9,669,069 B2
Filed: December 17, 2015
Issued: June 6, 2017
Inventor: George D. Yancopoulos

Title: USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

PETITIONER'S DEMONSTRATIVES FOR ORAL ARGUMENT

[1] IPR2022-00257 and IPR2022-00301 have been joined with this proceeding.

Mylan Pharmaceuti
Regeneron Pharmace
IPR2021-00880 & IPR

Petitioner, Mylan Pharma

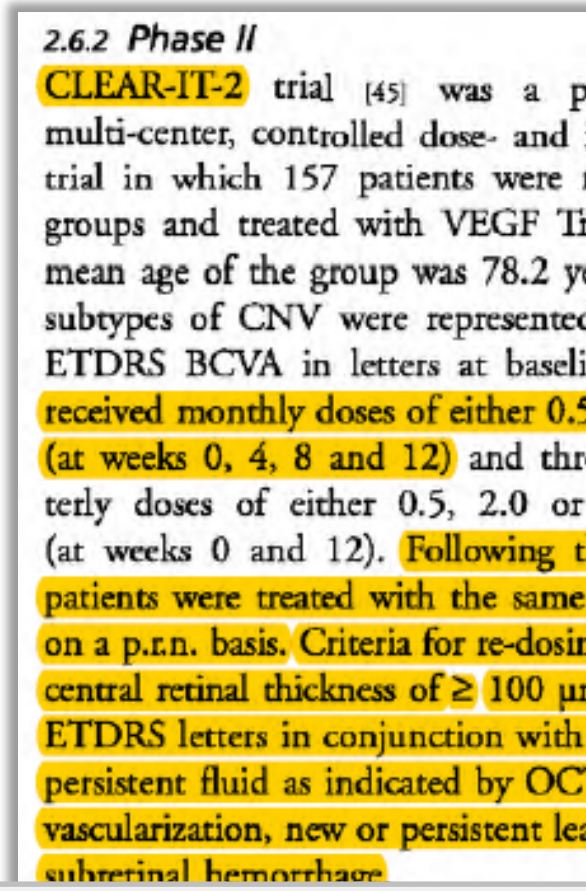
–Oral Argument

August 10, 2022

'069 Patent: Anticipation Gr

- **The dosing regimen disclosures of Dixon, Heie April 2009 Press Release are undisputed.**
  - **E.g., Dixon (Ground 2) discloses the VEGF Trap-Eye CLEAR monthly loading doses (i.e., an initial dose and one or mo**
  - **Heier-2009 (Ground 1) discloses the same trial and regimen (Ex.1020)**

(IPR2021-00880, Paper 1, 32-36, 45-50)



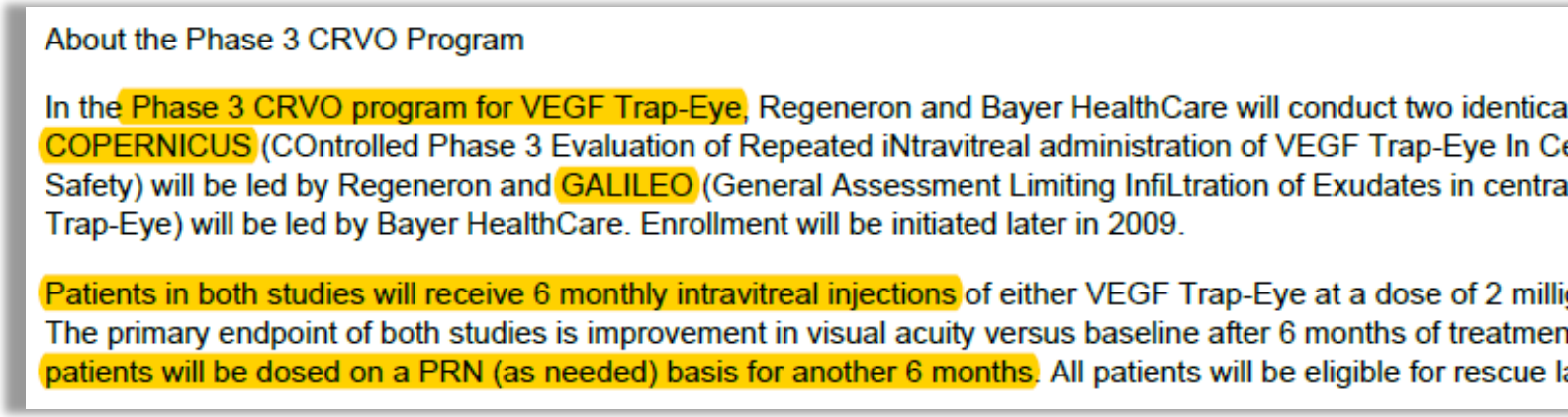
2.6.2 *Phase II*

CLEAR-IT-2 trial [45] was a p
multi-center, controlled dose- and
trial in which 157 patients were
groups and treated with VEGF Ti
mean age of the group was 78.2 y
subtypes of CNV were represented
ETDRS BCVA in letters at baseli
received monthly doses of either 0.5
(at weeks 0, 4, 8 and 12) and thr
terly doses of either 0.5, 2.0 or
(at weeks 0 and 12). Following t
patients were treated with the same
on a p.r.n. basis. Criteria for re-dosi
central retinal thickness of ≥ 100 µ
ETDRS letters in conjunction with
persistent fluid as indicated by OC
vascularization, new or persistent lea
subretinal hemorrhage

'069 Patent: Anticipation Gr

- **The dosing regimen disclosures of Dixon, Heie 2009, and Regeneron April 2009 Press Release are undisputed.**
  - **The Press Release discloses the VEGF Trap-Eye Phase 3 CR trials - PRN dosing after six monthly loading doses (i.e., a initial dose and one or more secondary doses)**

    (IPR2021-00880, Paper 1, 45-53)



About the Phase 3 CRVO Program

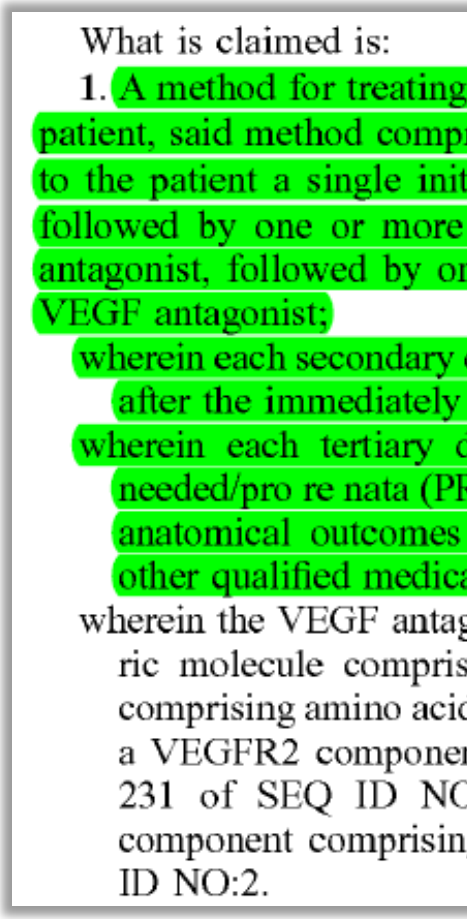
In the Phase 3 CRVO program for VEGF Trap-Eye, Regeneron and Bayer HealthCare will conduct two identica COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Ce Safety) will be led by Regeneron and GALILEO (General Assessment Limiting InfiLtration of Exudates in centra Trap-Eye) will be led by Bayer HealthCare. Enrollment will be initiated later in 2009.

Patients in both studies will receive 6 monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 milli The primary endpoint of both studies is improvement in visual acuity versus baseline after 6 months of treatmen patients will be dosed on a PRN (as needed) basis for another 6 months. All patients will be eligible for rescue la

’069 Patent: Anticipation Gr

- **Thus, Petitioner’s asserted references cover each and every limitation of the claims**
  - **It is undisputed that the references disclose the dosing regimen steps and the molecule, VEGF Trap-Eye, also known as aflibercept**
  - **The sole dispute over Petitioner’s anticipation grounds is over the sequence element**

    (IPR2021-00880, Paper 68, 25-36)



What is claimed is:

1. A method for treating
patient, said method compr
to the patient a single init
followed by one or more
antagonist, followed by or
VEGF antagonist;

wherein each secondary
after the immediately

wherein each tertiary
needed/pro re nata (PR
anatomical outcomes
other qualified medica

wherein the VEGF antag
ric molecule compris
comprising amino acid
a VEGFR2 componer
231 of SEQ ID NO
component comprisin
ID NO:2.

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