

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

OUTSIDE COUNSEL EYES ONLY

FILED UNDER SEAL

**DEFENDANT MYLAN PHARMACEUTICALS INC.'S L.R. CIV. P. 7.02 STATEMENT
OF UNCONTROVERTED FACTS FOR PURPOSES OF MYLAN'S MOTION FOR
SUMMARY JUDGMENT OR PARTIAL SUMMARY JUDGMENT ON U.S. PATENT
NOS. 11,104,715 (PROCESS PATENT); 11,084,865 (FORMULATION PATENT); AND
10,888,601 & 11,253,572 (DOSING PATENTS)**

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A. The ‘715 manufacturing patent 1

1. The ‘715 patent and claims. 1

2. Regeneron has not contested that Mylan’s accused process does not infringe the ‘715 patent’s independent claims under Mylan’s claim construction, which the Court has now adopted (Dkt. 427, Markman Order at 53-54, 75). 2

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'865 patent or the Formulation Patent	U.S. Patent No. 11,084,865
'601 patent	U.S. Patent No. 10,888,601
'601 Contentions	Final Infringement Contentions of Plaintiff Regeneron Pharmaceuticals, Inc. for U.S. Patent No. 10,888,601
'572 patent	U.S. Patent No. 11,253,572
'572 Contentions	Final Infringement Contentions of Plaintiff Regeneron Pharmaceuticals, Inc. for U.S. Patent No. 11,253,572
'572 Institution Decision	<i>Apotex Inc. v. Regeneron Pharms., Inc.</i> , IPR2022-01524, Paper 9 (P.T.A.B. Mar. 10, 2023)
'715 patent or the Manufacturing Patent	U.S. Patent No. 11,104,715
'715 Contentions	Final Infringement Contentions of Plaintiff Regeneron Pharmaceuticals, Inc. for U.S. Patent No. 11,104,715
Albini Opn.	February 2, 2023 Opening Expert Report of Dr. Thomas A. Albini
BCVA	Best Corrected Visual Acuity
CDM	Chemically Defined Media or Chemically Defined Medium
Dixon	James A Dixon et al., <i>VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration</i> , 18 EXPERT OPINION ON INVESTIGATIONAL DRUGS 1573 (2009)
Dosing Patents	U.S. Patent Nos. 10,888,601 and 11,253,572
ETDRS	Early Treatment Diabetic Retinopathy Study or Early Treatment Diabetic Retinopathy Study Letter Score
Csaky Opn.	February 2, 2023 Opening Expert Report of Dr. Karl Csaky
Csaky Resp.	March 2, 2023 Responsive Expert Report of Dr. Karl Csaky
Csaky Reply	March 30, 2023 Reply Expert Report of Dr. Karl Csaky
Csaky Tr.	Transcript of April 14, 2023 Deposition of Karl Csaky
Chu Tr.	Transcript of December 16, 2022 Deposition of Karen Chu
MacMichael Supp.	March 30, 2023 Supplemental Responsive Expert Report of Gregory MacMichael, Ph.D. Regarding the Non-Infringement of Claim 18 of U.S. Patent No. 11,084,865
Manning Rep.	March 2, 2023 Report of Richard Manning, Ph.D.
POSA	Person of ordinary skill in the art
PTAB	Patent Trial and Appeal Board
Retina Society Meeting Presentation 2008	Retina Society, <i>VEGF Trap-Eye in Wet AMD CLEAR-IT 2: Summary of One-Year Key Results, A Phase 2, Randomized, Controlled Dose- and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients With Neovascular, Age-Related Macular Degeneration</i> (Sept. 28, 2008)
Swartzwelder Opn.	February 2, 2023 Opening Expert Report and Declaration of Dr. Franklin Swartzwelder Regarding Mylan's Infringement of U.S. Patent No. 11,104,715
Trout Opn.	February 2, 2023 Opening Expert Report of Bernhardt L. Trout, Ph.D.

Trout Reply	March 30, 2023 Reply Expert Report of Bernhardt L. Trout, Ph.D.
Swartzwelder Tr.	Transcript of April 12, 2023 Deposition of Franklin Swartzwelder
Yancopoulos Tr.	Transcript of January 18, 2023 Deposition of George D. Yancopoulos
YESAFILI™	YESAFILI™, the accused product, which is the aflibercept-containing product that is the subject of Biologics License Application No. _____.
YESAFILI™ label	Proposed Prescribing Information for YESAFILI™, last revised August 2022

TABLE OF RECORD CITATIONS

Abbreviation	Description
Dkt. 427, Markman Order	Order on Claim Construction, dated April 19, 2023

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