

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.  
and BIOCON BIOLOGICS INC.,

Defendants.

Civil Action No. 1:22-cv-00061-TSK

**DEFENDANTS' OPENING POST TRIAL BRIEF – ISSUES  
WHERE DEFENDANTS BEAR THE BURDEN OF PROOF**

## **TABLE OF CONTENTS**

I.	INTRODUCTION .....	1
II.	GENERAL BACKGROUND.....	2
III.	CLAIM CONSTRUCTION.....	2
IV.	THE SCOPE, CONTENT, AND STATE OF THE ART.....	2
A.	Anti-VEGF targets, and the anti-VEGF afibbercept molecule.....	3
B.	Formulating anti-VEGF compounds.....	3
C.	The utility of anti-VEGF compounds. ....	4
1.	Genentech—preclinical Lucentis (ranibizumab). ....	4
2.	Regeneron—preclinical afibbercept. ....	4
3.	Avastin (bevacizumab)—approved anti-VEGF cancer drug; used by physicians intravitreally to target wet AMD and DME. ....	5
4.	Lucentis (ranibizumab) human clinical trials. ....	6
5.	Afibbercept human clinical trials.....	6
V.	LEGAL STANDARDS .....	7
VI.	THE ASSERTED DOSING CLAIMS ARE INVALID.....	8
A.	Claim 6 of the ‘572 patent is both anticipated and obvious.....	9
1.	The level of ordinary skill; the scope and content of the prior art.....	9
2.	The differences, if any, between the claims and the prior art. ....	9
a.	Claim 6 is anticipated by Dixon (DTX 204).....	10
b.	Claim 6 was obvious over Dixon (DTX 204) alone or combined with Hecht (DTX 3588). ....	11
c.	Secondary considerations do not save claim 6. ....	12
B.	Claim 25 of the ‘572 patent and claims 11 and 19 of the ‘601 patent are anticipated and obvious.....	12
1.	The level of ordinary skill; the scope and content of the prior art.....	12

2.	The differences (if any) between the claims and the prior art .....	13
a.	The Regeneron Press Release (DTX 3198) anticipates claim 25 of the ‘572 patent and claims 11 and 19 of the ‘601 patent. ....	14
b.	Any differences between claim 25 of the ‘572 patent and claims 11 and 19 of the ‘601 patent would have been obvious.....	15
3.	Secondary considerations do not save the claims here.....	17
C.	The Asserted Dosing Claims fail to comply with Section 112 requirements.....	18
1.	Claim 6 of the ‘572 patent fails to comply with Section 112. ....	18
2.	The 5 starting dose elements lack written description and enablement. ....	19
a.	There are no blaze marks as written description requires.....	19
b.	Regeneron’s obviousness arguments undermine both the “blaze marks” and enablement.....	19
3.	The “approximately” term is indefinite. ....	20
VII.	THE ASSERTED FORMULATION CLAIMS ARE INVALID; THEY COVER KNOWN AND OBVIOUS FORMULATIONS, AND CLAIMED TOO BROADLY. ....	21
A.	The Asserted Formulation Claims Are Anticipated.....	22
1.	Dix ‘226 (or iterations thereof) anticipates.....	22
B.	The claims cover formulations that follow the Genentech Lucentis and/or Liu’s established pathways, which would have been obvious to a POSA.....	23
1.	Level of ordinary skill; scope and content of the prior art.....	23
2.	The differences, if any, between the claims and the prior art. ....	24
a.	Aflibercept (Fraser) + Lucentis formulation.....	24
b.	Aflibercept (Fraser) + Liu to optimize the formulation. ....	24
c.	Dix ‘226, alone or in view of the knowledge of a POSA. ....	25
3.	Secondary considerations.....	26

C. The Asserted Formulation Claims Are Invalid Under Section 112.....	28
1. “Suitable for intravitreal administration” is indefinite.....	28
2. The written description fails to show possession of the full claim scope. ....	29
3. Practicing the full claim scope imposes undue burdens on the POSA. ....	30
VIII. CONCLUSION.....	30

**TABLE OF AUTHORITIES****Cases**

<i>Abbott Lab'ys v. Andrx Pharms., Inc.</i> , 452 F.3d 1331 (Fed. Cir. 2006) .....	17
<i>Abbott Lab'ys v. Sandoz, Inc.</i> , 566 F.3d 1282 (Fed. Cir. 2009) .....	10
<i>AK Steel Corp. v. Sollac &amp; Ugine</i> , 344 F.3d 1234 (Fed. Cir. 2003) .....	1
<i>Almirall, LLC v. Amneal Pharms. LLC</i> , 28 F.4th 265 (Fed. Cir. 2022) .....	26
<i>Amgen Inc. v. Sanofi</i> , 143 S. Ct. 1243 (2023).....	1, 8, 18
<i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) .....	8, 29
<i>Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.</i> , 501 F.3d 1274 (Fed. Cir. 2007) .....	30
<i>Bayer Pharma AG v. Watson Lab'ys, Inc.</i> , 874 F.3d 1316 (Fed. Cir. 2017) .....	12
<i>Blue Calypso, LLC v. Groupon, Inc.</i> , 815 F.3d 1331 (Fed. Cir. 2016) .....	15
<i>Brenner v. Manson</i> , 383 U.S. 519 (1966).....	8
<i>Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.</i> , 752 F.3d 967 (Fed. Cir. 2014) .....	8
<i>Connell v. Sears, Roebuck &amp; Co.</i> , 722 F.2d 1542 (Fed. Cir. 1983) .....	11, 25
<i>Datamize, LLC v. Plumtree Software, Inc.</i> , 417 F.3d 1342 (Fed. Cir. 2005) .....	28, 29
<i>E.I. DuPont de Nemours &amp; Co. v. Synvina C.V.</i> , 904 F.3d 996 (Fed. Cir. 2018) .....	25, 26
<i>Eli Lilly &amp; Co. v. Barr Lab'ys, Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001) .....	15

# 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.