FISH.

Biosimilars 2023 Year in Review

Tuesday, January 30

Meet the Speakers

Martina Hufnal
Principal

hufnal@fr.com
302-778-8471

Rae Crisler
Principal

crisler@fr.com
214-760-6138

Philip Chen
Associate

pchen@fr.com
617-521-7812

Agenda

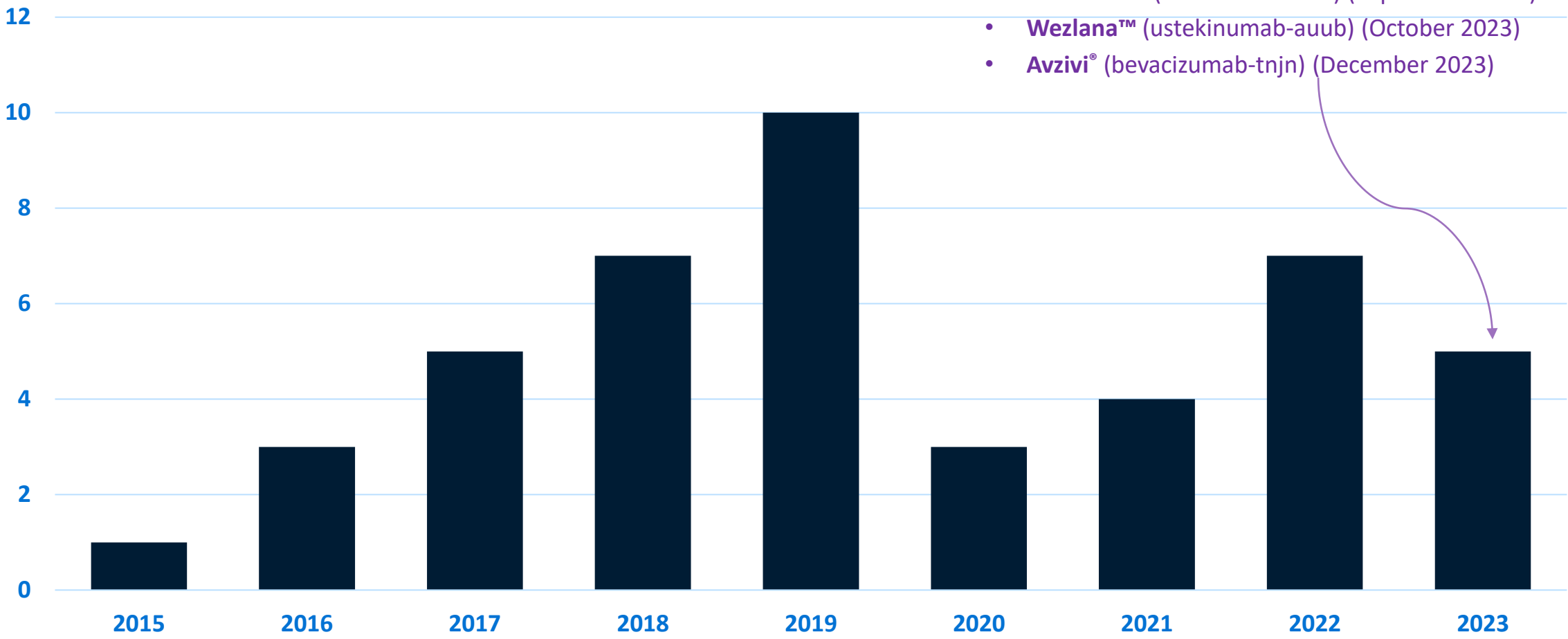
1. Market Update
2. BPCIA Litigation Update
3. Post-Grant Update
4. Antitrust Update
5. Regulatory and Legislative Update
6. Looking Forward to 2024

U.S. Biosimilars Market

FISH.

Biosimilar Approvals: 2015-2023

- **Yuflyma®** (adalimumab-aaty) (May 2023)
- **Tyruko®** (natalizumab-sztn) (August 2023)
- **Tofidence™** (tocilizumab-bavi) (September 2023)
- **Wezlana™** (ustekinumab-auub) (October 2023)
- **Avzivi®** (bevacizumab-tnjn) (December 2023)

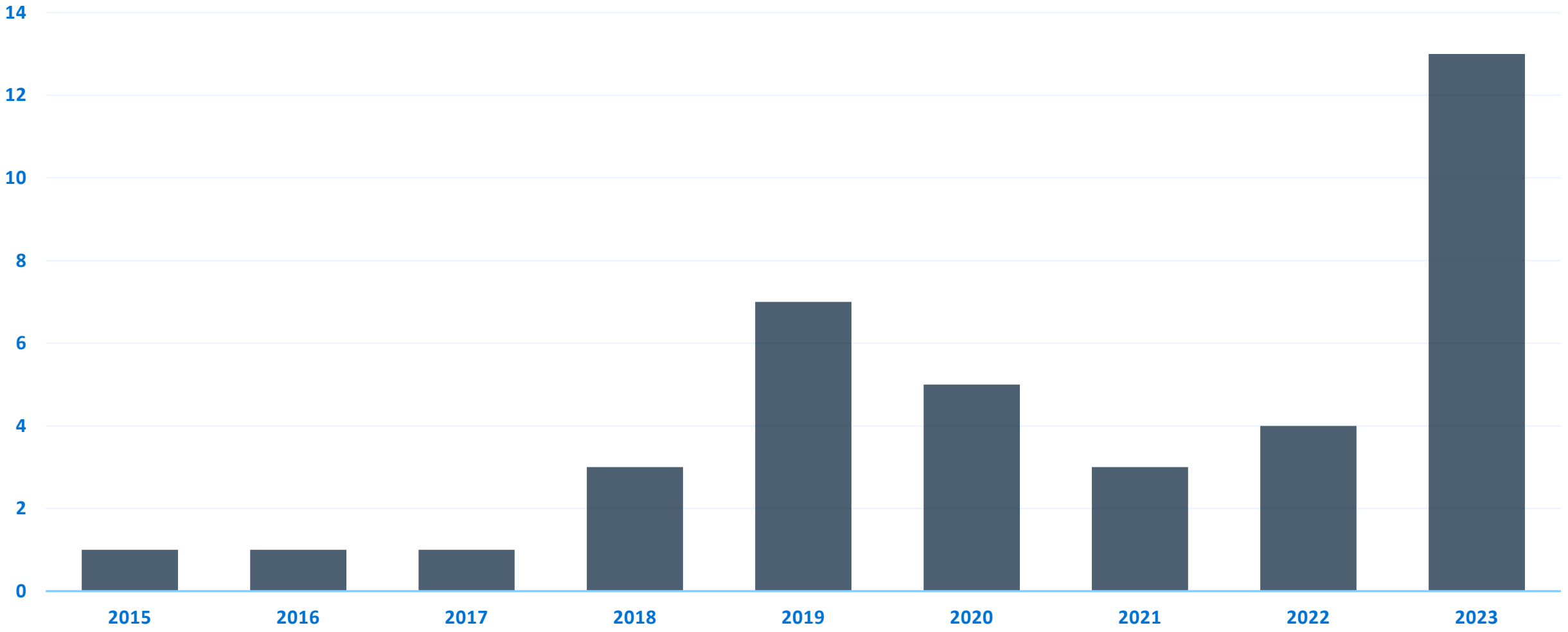


FISH.

Interchangeable Designations Granted in 2023

Biosimilar	Reference Product	Interchangeable Approval Date
Wezlana™ (Amgen)	**Stelara® (ustekinumab) (Johnson & Johnson)**	**October 31, 2023**
Abrilada™ (Pfizer)	**Humira® (adalimumab) (AbbVie)**	**October 5, 2023**
Byooviz™ (Samsung Bioepis)	**Lucentis® (ranibizumab) (Roche / Genentech)**	**October 3, 2023**
Rezvoglar™ (Eli Lilly)	Humira® (adalimumab) (AbbVie)	November 16, 2022
Cimerli™ (Coherus)	Lucentis® (ranibizumab) (Roche / Genentech)	August 2, 2022
Cyltezo® (Boehringer Ingelheim)	Humira® (adalimumab) (AbbVie)	October 15, 2021
Semglee® (Mylan (Viatris) / Biocon)	Lantus® (insulin glargine) (Sanofi)	July 28, 2021

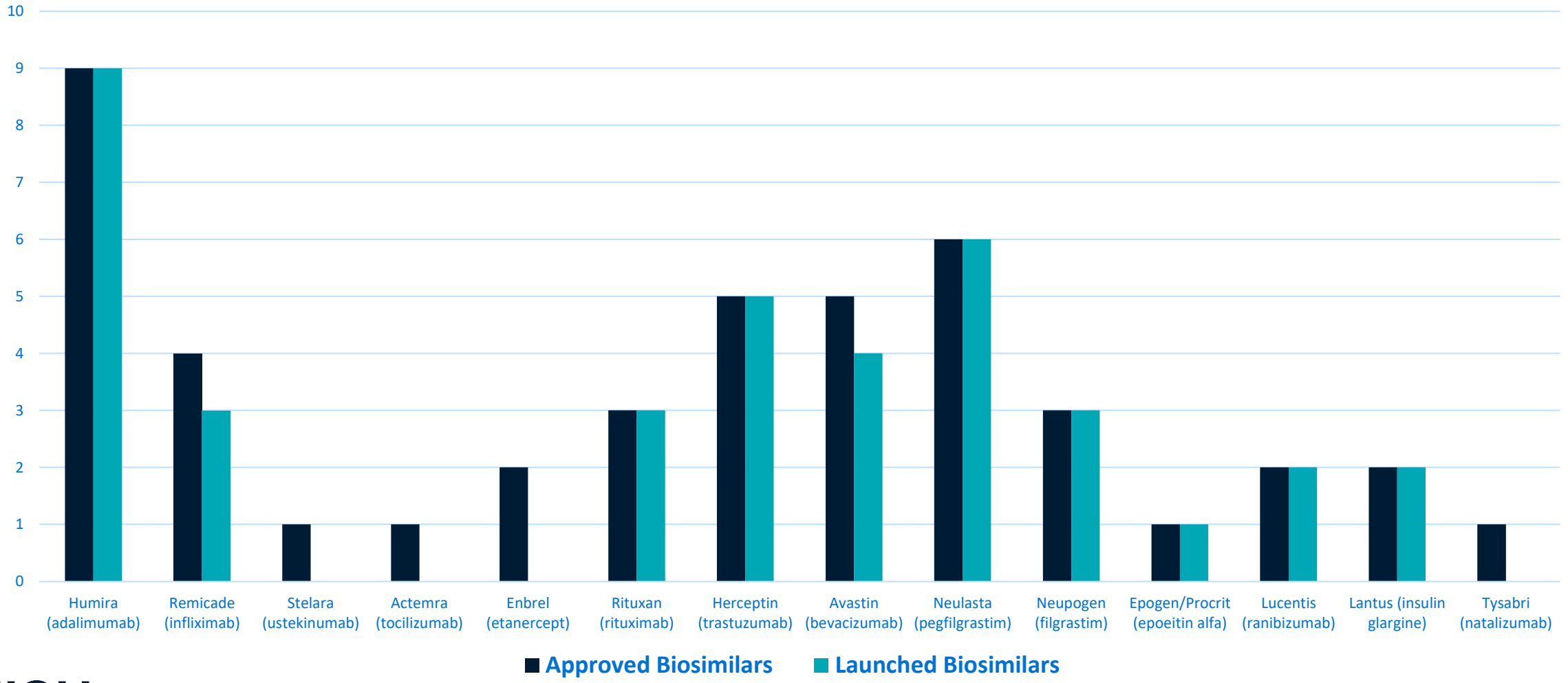
Biosimilar Launches: 2015–2023



Biosimilar Launches in 2023

Biosimilar	Reference Product	Non-Proprietary Name	Launch
Amjevita (Amgen)	Humira (AbbVie)	adalimumab	January 2023
Stimufend (Fresenius Kabi)	Neulasta (Amgen)	pegfilgrastim	February 2023
Rezvoglar (Eli Lilly)	Lantus (Sanofi)	insulin glargine	April 2023
Vegzelma (Celltrion)	Avastin (Roche/Genentech)	bevacizumab	April 2023
Fylnetra (Amneal/Kashiv)	Neulasta (Amgen)	pegfilgrastim	May 2023
Idacio (Fresenius Kabi)	Humira (AbbVie)	adalimumab	July 2023
Yuflyma (Celltrion)	Humira (AbbVie)	adalimumab	July 2023
Yusimry (Coherus)	Humira (AbbVie)	adalimumab	July 2023
Hulio (Mylan)	Humira (AbbVie)	adalimumab	July 2023
Cyltezo (Boehringer Ingelheim)	Humira (AbbVie)	adalimumab	July 2023
Hadlima (Samsung Bioepis/Organon)	Humira (AbbVie)	adalimumab	July 2023
Hyrimoz (Sandoz)	Humira (AbbVie)	adalimumab	July 2023
Abrilada (Pfizer)	Humira (AbbVie)	adalimumab	November 2023

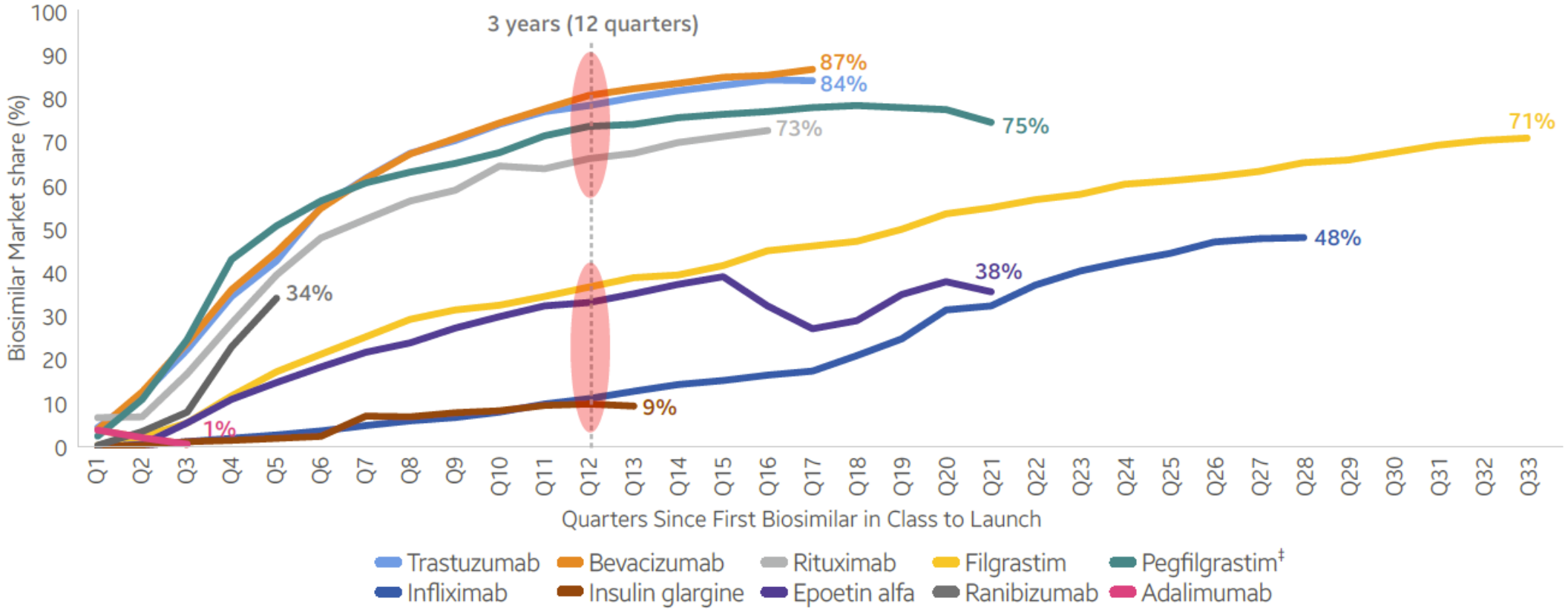
Approvals Versus Launches: 2015–2023



FISH.

Biosimilar Uptake Trends

Figure 7. Biosimilar Market Share Post-Launch[5]

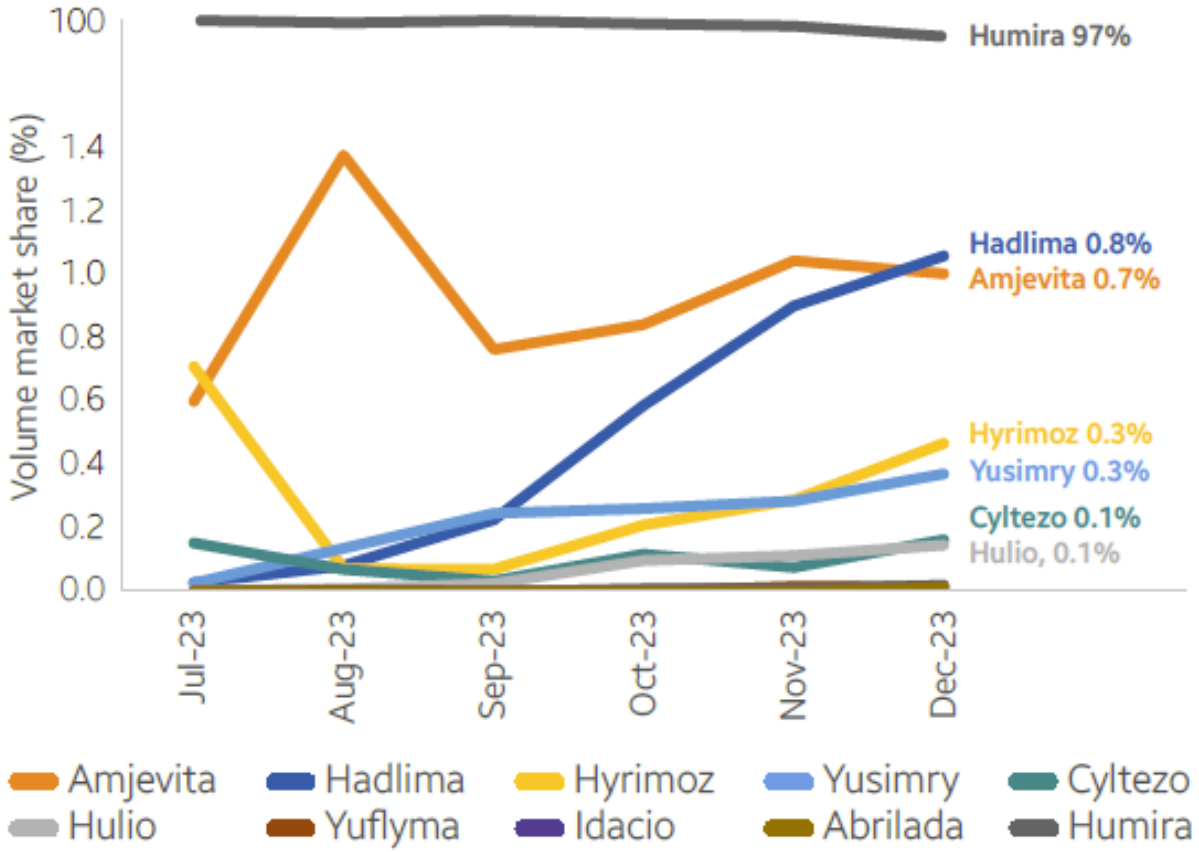


TA: Therapeutic area
*Trastuzumab, bevacizumab, and rituximab are included
†Adalimumab and infliximab are included
‡Onpro is not included

Source: Samsung Bioepis Biosimilar Market Report, Q1 2024, available at https://www.samsungbioepis.com/en/etc/gadown.do?filename=SB+Biosimilar+Market+Report+Q1+2024.pdf

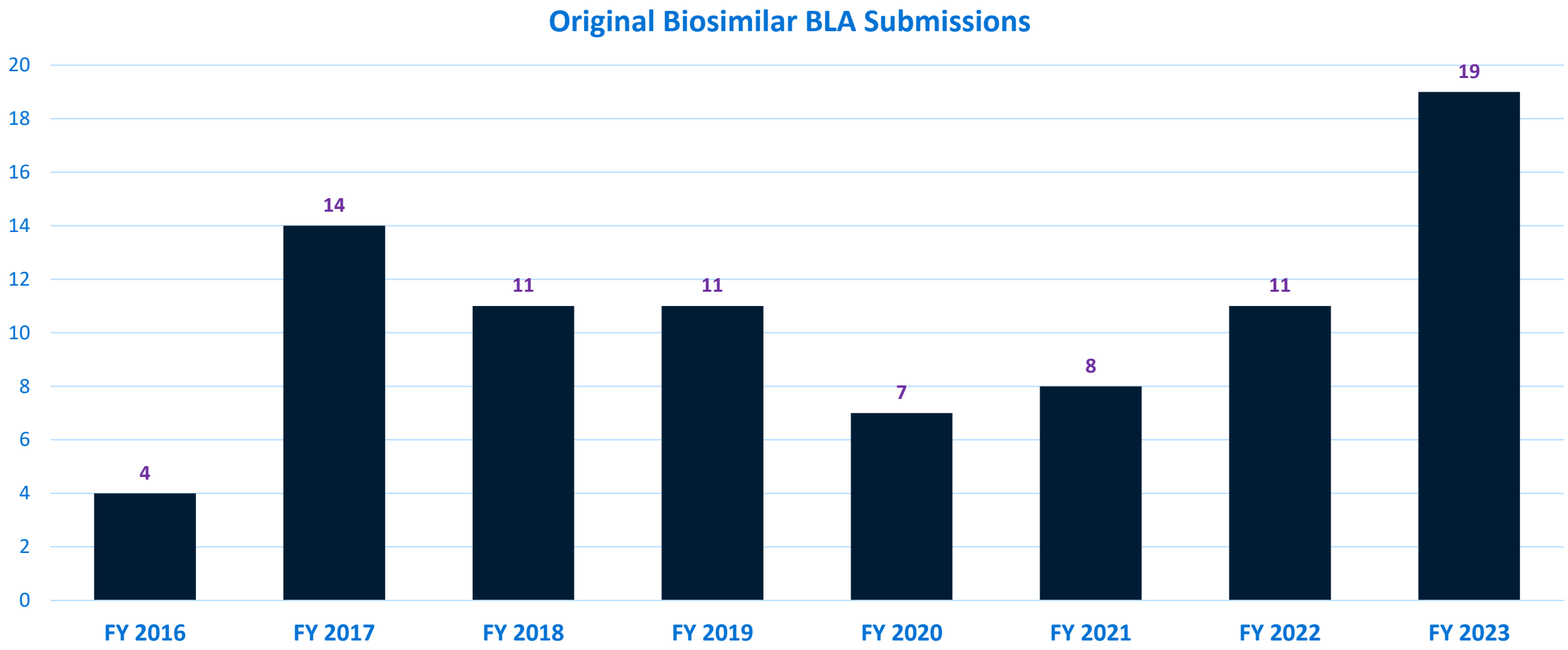
Adalimumab Market After Biosimilar Launches in 2023

Figure 23. Adalimumab Volume Market Share[6]



Source: Samsung Bioepis Biosimilar Market Report, Q1 2024, available at https://www.samsungbioepis.com/en/etc/gadown.do?filename=SB+Biosimilar+Market+Report+Q1+2024.pdf

Biosimilars in the Pipeline



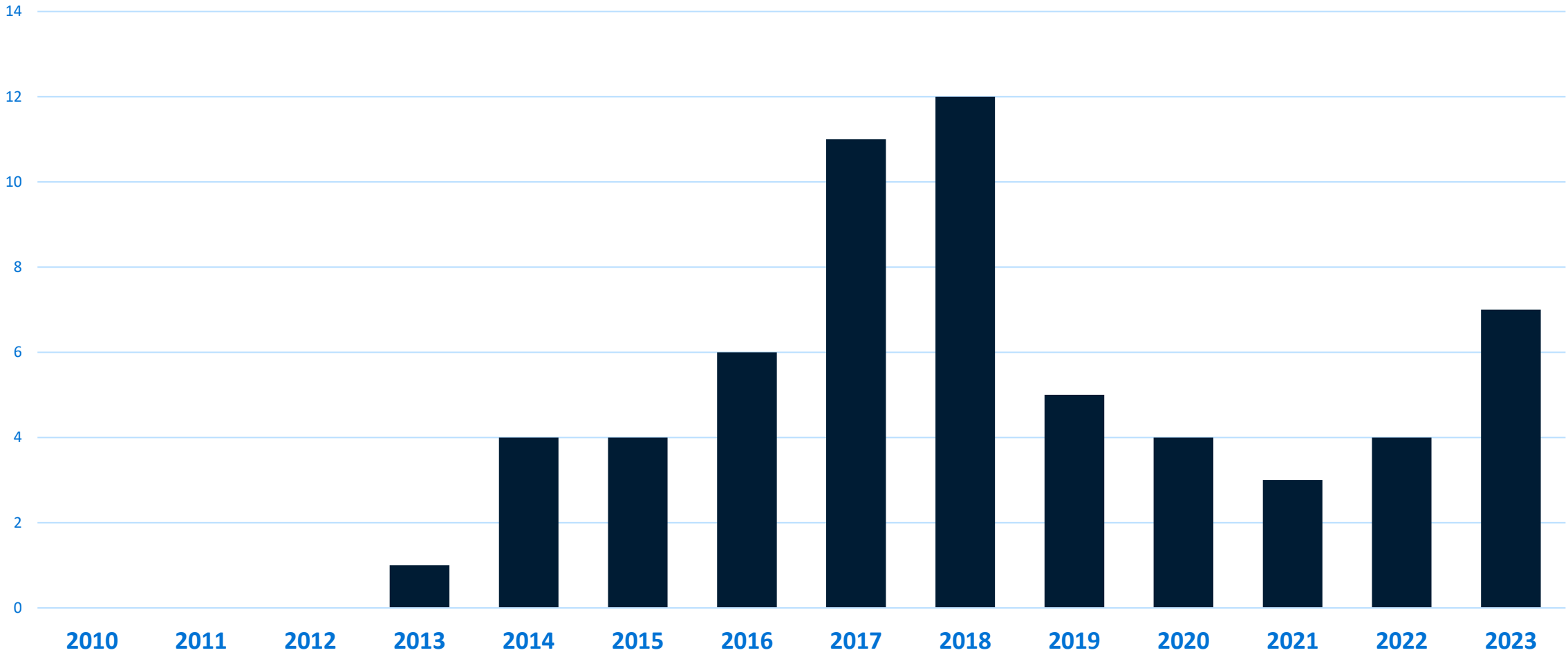
New Wave of Biosimilars After Loss of Exclusivity

Biologic	Estimated Loss of Exclusivity
Simponi (golimumab)	2024
Benlysta (belimumab)	2025
Prolia (denosumab)	2025
Soliris (eculizumab)	2025
Yervoy (ipilimumab)	2025
Kadcyla (ado-trastuzumab emtansine)	2026
Perjeta (pertuzumab)	2026
Trulicity (dulaglutide)	2027
Tysabri (natalizumab)	2027
Eloctate [antihemophilic factor (recombinant), Fc fusion protein]	2028
Keytruda (pembrolizumab)	2028
Opdivo (nivolumab)	2028

BPCIA Litigation

FISH.

BPCIA Cases Filed by Year since BPCIA Enactment



New BPCIA Litigation in 2023

Case Name	Court	Reference Product at Issue
Amgen v. Sandoz **(1:23-cv-02406)**	D.N.J.	Prolia®/Xgeva® (denosumab)
Genentech et al. v. Biogen MA, Bio-Thera **(1:23-cv-11573)**	D. Mass.	Actemra® (tocilizumab)
Regeneron v. Celltrion **(1:23-cv-00089)**	N.D. W. Va.	Eylea® (aflibercept)
Genentech et al. v. Dr. Reddy's Laboratories, Fresenius Kabi **(1:23-cv-22485)**	D.N.J.	Rituxan® (rituximab)
Regeneron v. Samsung Bioepis **(1:23-cv-00094)**	N.D. W. Va.	Eylea® (aflibercept)
Regeneron v. Formycon **(1:23-cv-00097)**	N.D. W. Va.	Eylea® (aflibercept)
Regeneron v. Samsung Bioepis **(1:23-cv-00106)**	N.D. W. Va.	Eylea® (aflibercept)

Regeneron v. Mylan and Biocon

ELECTRONICALLY FILED
Aug 02 2022
U.S. DISTRICT COURT
Northern District of WV

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

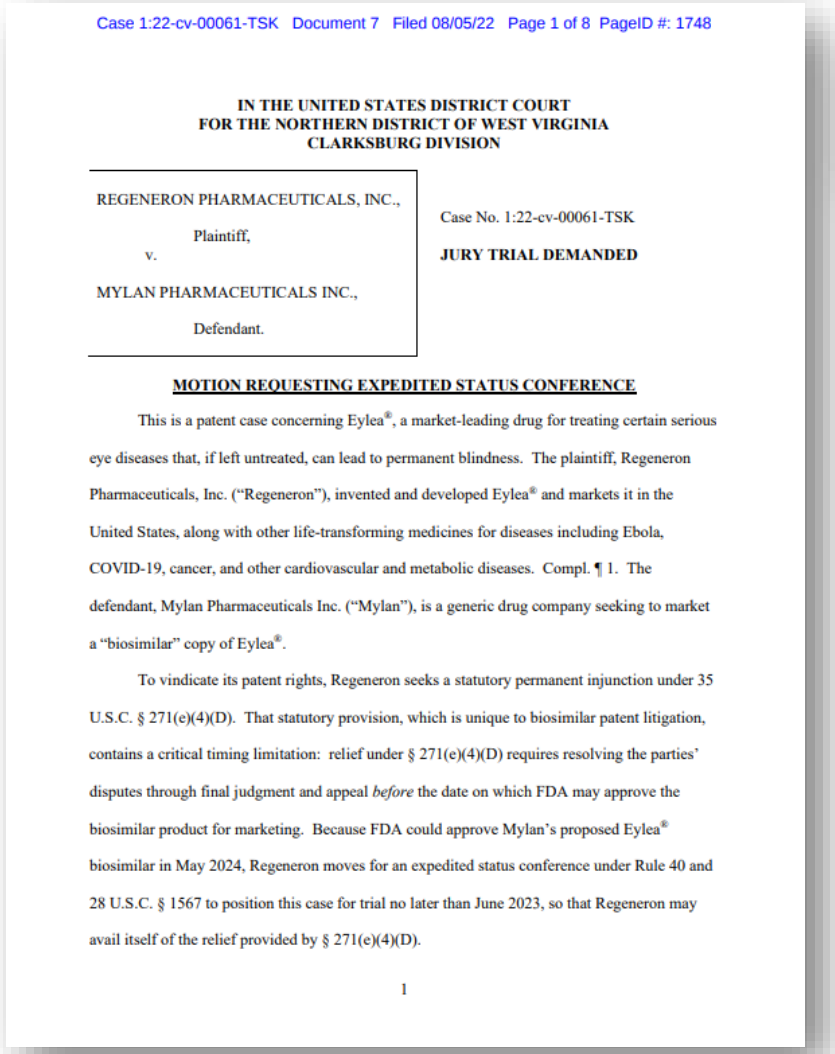
Case No.: **1:22-CV-61 (Kleeh)**

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

- **Filed:** August 2, 2022 in N.D. W. Va.
- **Accused Product:** Eylea® (aflibercept) biosimilar Yesafili™ (formerly called M710)
- **Asserted Patents:** 24
- **Patent Dance:** Full dance

Regeneron: Fast Trial Needed for § 271(e)(4)(D) Injunction



Case 1:22-cv-00061-TSK Document 7 Filed 08/05/22 Page 1 of 8 PageID #: 1748

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

REGENERON PHARMACEUTICALS, INC.,
Plaintiff,
v.
MYLAN PHARMACEUTICALS INC.,
Defendant.

Case No. 1:22-cv-00061-TSK
JURY TRIAL DEMANDED

MOTION REQUESTING EXPEDITED STATUS CONFERENCE

This is a patent case concerning Eylea®, a market-leading drug for treating certain serious eye diseases that, if left untreated, can lead to permanent blindness. The plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), invented and developed Eylea® and markets it in the United States, along with other life-transforming medicines for diseases including Ebola, COVID-19, cancer, and other cardiovascular and metabolic diseases. Compl. ¶ 1. The defendant, Mylan Pharmaceuticals Inc. ("Mylan"), is a generic drug company seeking to market a "biosimilar" copy of Eylea®.

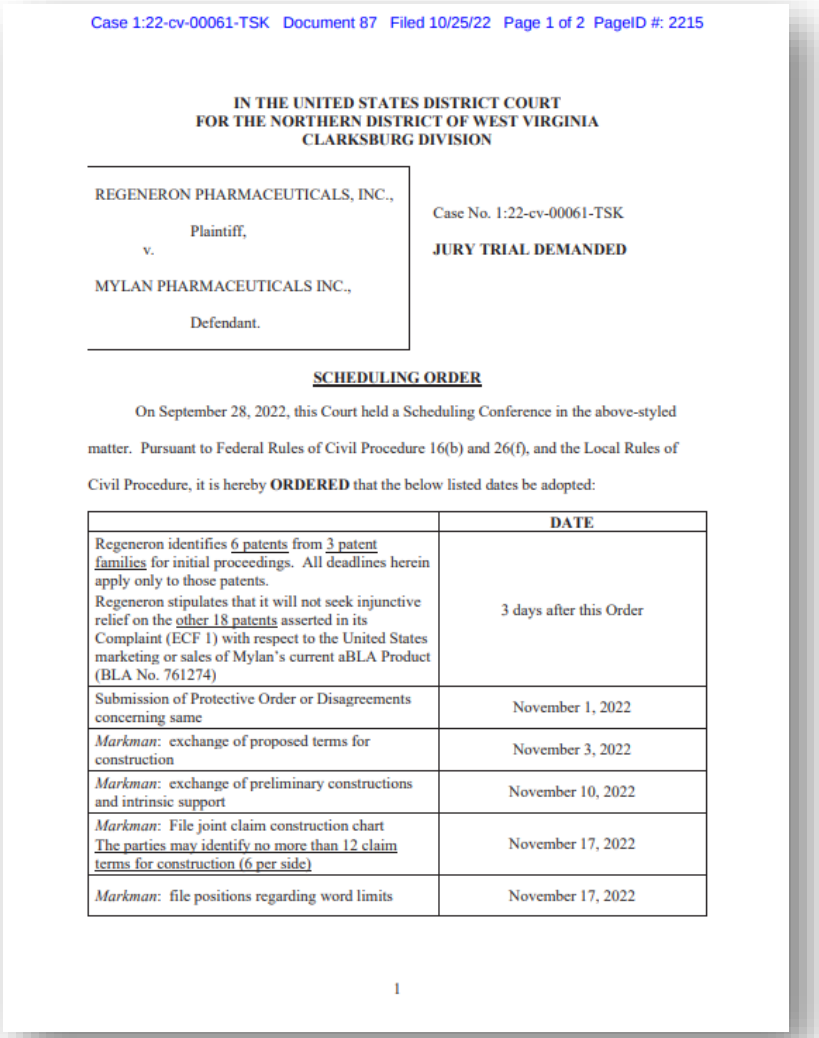
To vindicate its patent rights, Regeneron seeks a statutory permanent injunction under 35 U.S.C. § 271(e)(4)(D). That statutory provision, which is unique to biosimilar patent litigation, contains a critical timing limitation: relief under § 271(e)(4)(D) requires resolving the parties' disputes through final judgment and appeal *before* the date on which FDA may approve the biosimilar product for marketing. Because FDA could approve Mylan's proposed Eylea® biosimilar in May 2024, Regeneron moves for an expedited status conference under Rule 40 and 28 U.S.C. § 1567 to position this case for trial no later than June 2023, so that Regeneron may avail itself of the relief provided by § 271(e)(4)(D).

1

MOTION REQUESTING EXPEDITED STATUS CONFERENCE

To vindicate its patent rights, Regeneron seeks a statutory permanent injunction under 35 U.S.C. § 271(e)(4)(D). That statutory provision, which is unique to biosimilar patent litigation, contains a critical timing limitation: relief under § 271(e)(4)(D) requires resolving the parties' disputes through final judgment and appeal *before* the date on which FDA may approve the biosimilar product for marketing. Because FDA could approve Mylan's proposed Eylea® biosimilar in May 2024, Regeneron moves for an expedited status conference under Rule 40 and 28 U.S.C. § 1567 to position this case for trial no later than June 2023, so that Regeneron may avail itself of the relief provided by § 271(e)(4)(D).

Regeneron v. Mylan and Biocon: Bench Trial



Case 1:22-cv-00061-TSK Document 87 Filed 10/25/22 Page 1 of 2 PageID #: 2215

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

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

JURY TRIAL DEMANDED

SCHEDULING ORDER

On September 28, 2022, this Court held a Scheduling Conference in the above-styled matter. Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f), and the Local Rules of Civil Procedure, it is hereby **ORDERED** that the below listed dates be adopted:

	DATE
Regeneron identifies 6 patents from 3 patent families for initial proceedings. All deadlines herein apply only to those patents. Regeneron stipulates that it will not seek injunctive relief on the other 18 patents asserted in its Complaint (ECF 1) with respect to the United States marketing or sales of Mylan's current aBLA Product (BLA No. 761274)	3 days after this Order
Submission of Protective Order or Disagreements concerning same	November 1, 2022
Markman: exchange of proposed terms for construction	November 3, 2022
Markman: exchange of preliminary constructions and intrinsic support	November 10, 2022
Markman: File joint claim construction chart The parties may identify no more than 12 claim terms for construction (6 per side)	November 17, 2022
Markman: file positions regarding word limits	November 17, 2022

1

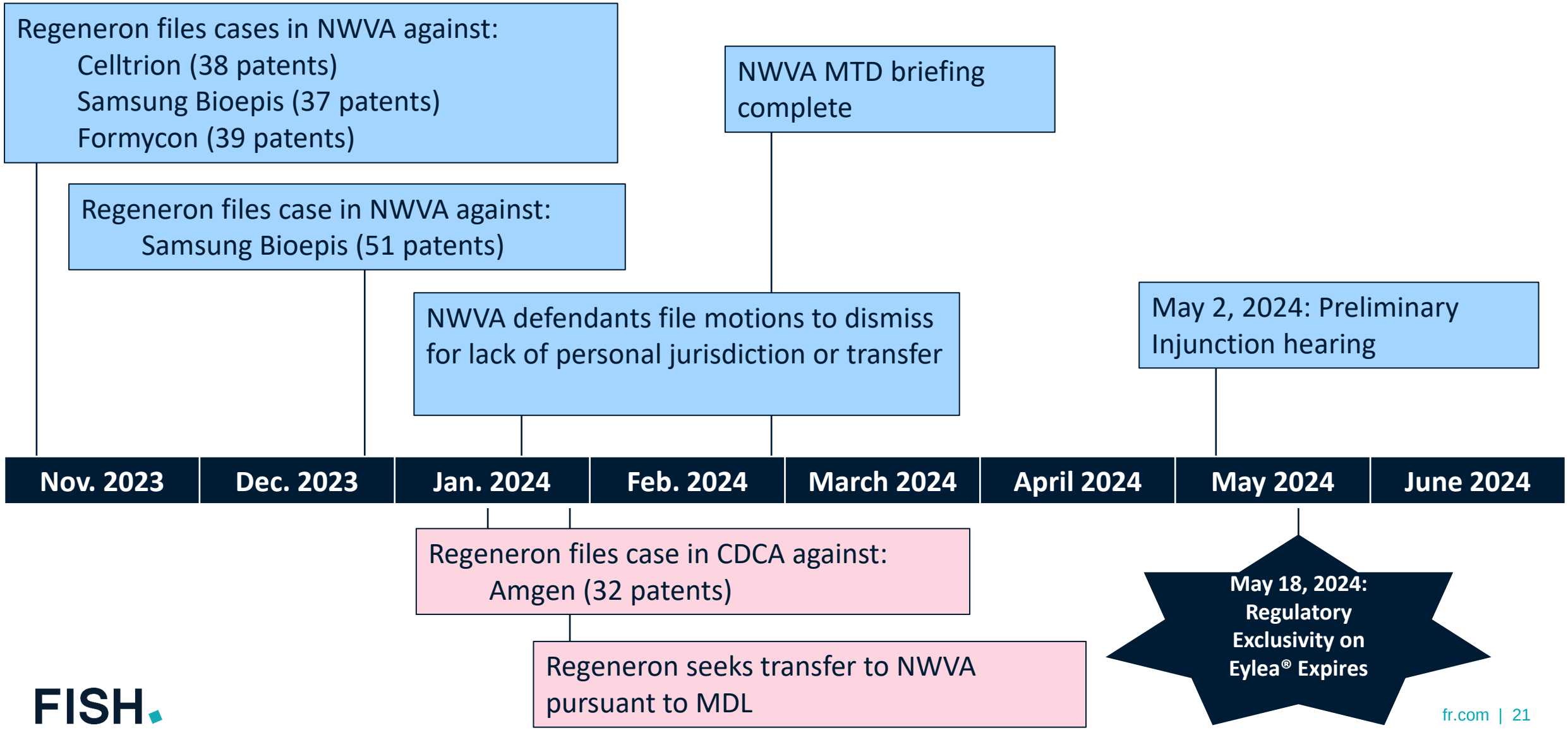
SCHEDULING ORDER

	DATE
Regeneron identifies 6 patents from 3 patent families for initial proceedings. All deadlines herein apply only to those patents. Regeneron stipulates that it will not seek injunctive relief on the other 18 patents asserted in its Complaint (ECF 1) with respect to the United States marketing or sales of Mylan's current aBLA Product (BLA No. 761274)	3 days after this Order
Regeneron narrows initial proceedings to 3 patents and 25 claims	7 days after *Markman* order or 7 days after close of fact discovery, whichever is later
Trial	June 12-23, 2023

Regeneron v. Mylan and Biocon: Bench Trial

Patent No.	Claims	Claim Nos.	Anticipated	Obvious	§ 112	Infringed
11,084,865	Biological products	4, 7, 9, 11, 14, 15, 16, 17	**No**	**No**	**No**	**Yes**
11,253,572	Method of treatment	6, 25	No	Yes		Yes (induced)
10,888,601	Method of treatment	11	No	Yes		Yes (induced)
		19		Yes		Yes (induced)

Other Eylea® (aflibercept) Cases



Biogen v. Sandoz and Polpharma

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC. and BIOGEN MA INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH and POLPHARMA BIOLOGICS S.A.,	)	**REDACTED - PUBLIC VERSION**
	)	**Original Filing Date: September 9, 2022**
	)	**Redacted Filing Date: September 19, 2022**
Defendants.	)	

- **Filing:** September 9, 2022 in D. Del.
- **Accused Product:** Tysabri® (natalizumab) biosimilar Tyruko® (formerly called PB006)
- **Asserted Patents**: 28 (17 in first and second amended complaints)
- **Patent Dance:** Partial dance

Biogen v. Sandoz and Polpharma: PI Proceeding

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC. and BIOGEN MA INC.

Plaintiffs,

v.

SANDOZ INC. and POLPHARMA BIOLOGICS S.A.,

Defendants.

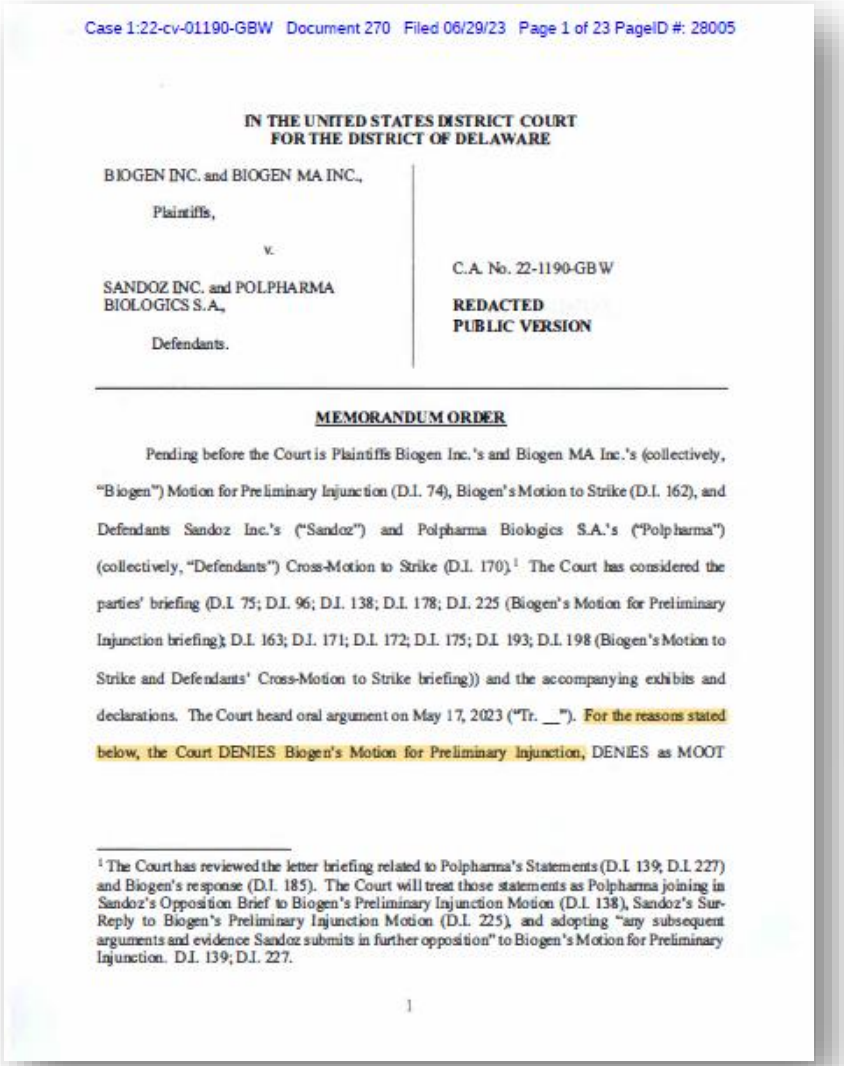
REDACTED - PUBLIC VERSION
(Filed October 19, 2022)
C.A. No. 22-1190-GBW

[redacted]

JOINT STIPULATION AND SCHEDULING ORDER FOR EXPEDITED PRELIMINARY INJUNCTION PROCEEDINGS

Friday, November 18, 2022	Biogen 1) elects up to 5 patents and up to 10 claims to be asserted in preliminary injunction motion, subject to the right to seek leave of court to add or substitute patents or claims for good cause; and 2) serves infringement contentions for elected patent claims.

Biogen v. Sandoz and Polpharma: PI Motion Denied



Case 1:22-cv-01190-GBW Document 270 Filed 06/29/23 Page 1 of 23 PageID #: 28005

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC. and BIOGEN MA INC.,

Plaintiffs,

v.

SANDOZ INC. and POLPHARMA BIOLOGICS S.A.,

Defendants.

C.A. No. 22-1190-GBW

REDACTED
PUBLIC VERSION

MEMORANDUM ORDER

Pending before the Court is Plaintiffs Biogen Inc.'s and Biogen MA Inc.'s (collectively, "Biogen") Motion for Preliminary Injunction (D.I. 74), Biogen's Motion to Strike (D.I. 162), and Defendants Sandoz Inc.'s ("Sandoz") and Polpharma Biologics S.A.'s ("Polpharma") (collectively, "Defendants") Cross-Motion to Strike (D.I. 170).[1] The Court has considered the parties' briefing (D.I. 75; D.I. 96; D.I. 138; D.I. 178; D.I. 225 (Biogen's Motion for Preliminary Injunction briefing); D.I. 163; D.I. 171; D.I. 172; D.I. 175; D.I. 193; D.I. 198 (Biogen's Motion to Strike and Defendants' Cross-Motion to Strike briefing)) and the accompanying exhibits and declarations. The Court heard oral argument on May 17, 2023 ("Tr. __"). For the reasons stated below, the Court DENIES Biogen's Motion for Preliminary Injunction, DENIES as MOOT

[1] The Court has reviewed the letter briefing related to Polpharma's Statements (D.I. 139; D.I. 227) and Biogen's response (D.I. 185). The Court will treat those statements as Polpharma joining in Sandoz's Opposition Brief to Biogen's Preliminary Injunction Motion (D.I. 138), Sandoz's Sur-Reply to Biogen's Preliminary Injunction Motion (D.I. 225), and adopting "any subsequent arguments and evidence Sandoz submits in further opposition" to Biogen's Motion for Preliminary Injunction. D.I. 139; D.I. 227.

1

III. DISCUSSION

a. Biogen's Motion for Preliminary Injunction

For the reasons set forth below, the Court concludes that Biogen has not met its burden of proving that it will suffer irreparable harm if an injunction is not granted and that it will likely succeed on the merits. Thus, Biogen's Motion for Preliminary Injunction is denied.

Amgen v. Sandoz

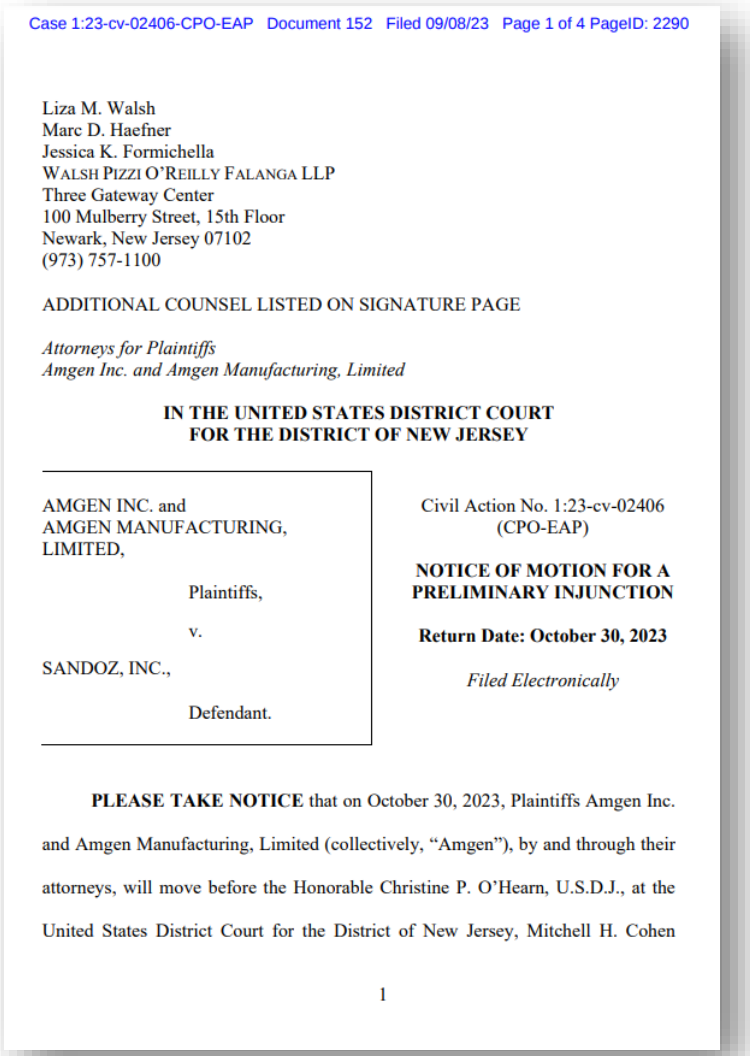
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING, LIMITED Plaintiffs, v. SANDOZ INC., SANDOZ GMBH, LEK PHARMACEUTICALS D.D., NOVARTIS PHARMACEUTICALS PRODUCTION D.O.O., and NOVARTIS AG Defendants.	Civil Action No. **COMPLAINT & DEMAND FOR A JURY TRIAL** **Redacted Version**

COMPLAINT FOR PATENT INFRINGEMENT

- **Filing:** May 1, 2023 in D.N.J.
- **Accused Product:** Prolia®/Xgeva® (denosumab) biosimilar GP2411
- **Asserted Patents**: 21
- **Patent Dance:** Partial dance

Amgen v. Sandoz: Preliminary Injunction Hearing



Case 1:23-cv-02406-CPO-EAP Document 152 Filed 09/08/23 Page 1 of 4 PageID: 2290

Liza M. Walsh
Marc D. Haefner
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

ADDITIONAL COUNSEL LISTED ON SIGNATURE PAGE

Attorneys for Plaintiffs
Amgen Inc. and Amgen Manufacturing, Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and
AMGEN MANUFACTURING,
LIMITED,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 1:23-cv-02406
(CPO-EAP)

NOTICE OF MOTION FOR A PRELIMINARY INJUNCTION

Return Date: October 30, 2023

Filed Electronically

PLEASE TAKE NOTICE that on October 30, 2023, Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen"), by and through their attorneys, will move before the Honorable Christine P. O'Hearn, U.S.D.J., at the United States District Court for the District of New Jersey, Mitchell H. Cohen

1

- **September 8, 2023**
  - Amgen filed a motion for preliminary injunction
- **October 30-November 1, November 3, 2023**
  - Four-day preliminary injunction hearing
- **November 14, 2023**
  - The court ordered that Sandoz must notify the court 30 days prior to making any announcement concerning the launch of any denosumab biosimilar product
- **November 30, 2023**
  - Additional expert testimony from Sandoz's damages expert
- **November and December 2023**
  - Parties filed proposed findings of fact and conclusion of law under seal
- **No ruling yet**

Janssen v. Amgen

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC.,

Plaintiff,

v.

AMGEN INC.,

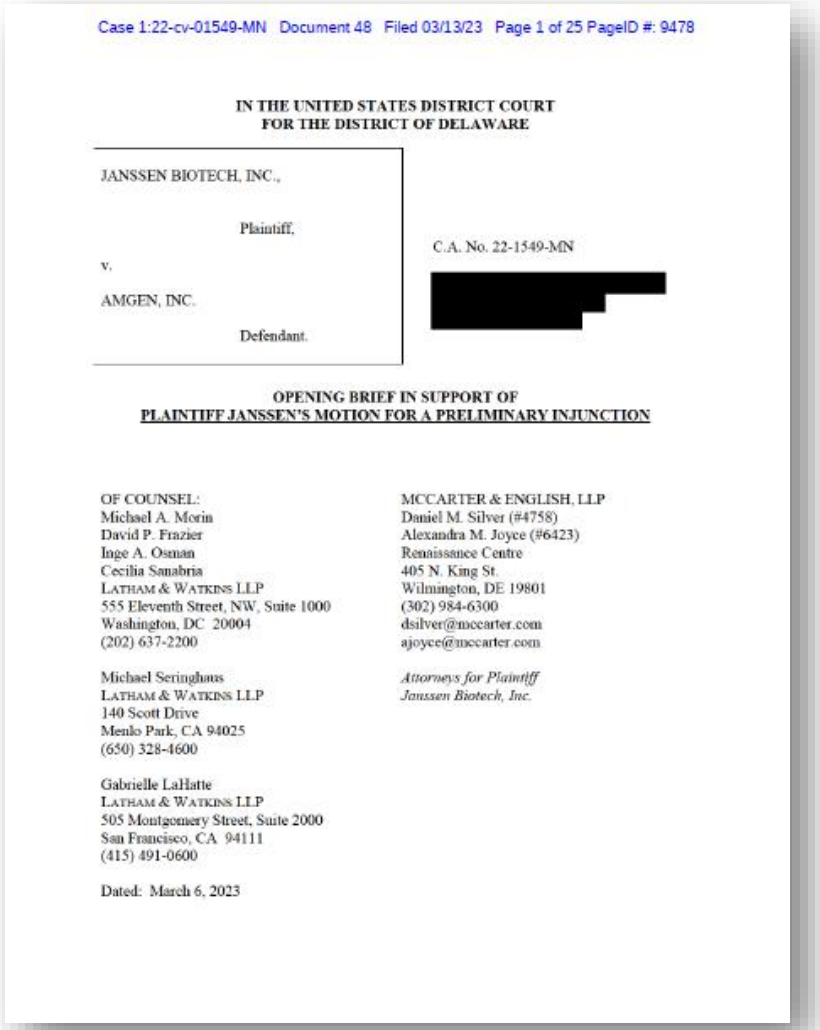
Defendant.

C.A. No. _____

COMPLAINT

- **Filing:** November 29, 2022 in D. Del.
- **Accused Product:** Stelara® (ustekinumab) biosimilar Wezlana™ (formerly called ABP 654)
- **Asserted Patents**: 2 (6 in first amended complaint)
- **Patent Dance:** No dance

Janssen v. Amgen: Motion for Preliminary Injunction



Case 1:22-cv-01549-MN Document 48 Filed 03/13/23 Page 1 of 25 PageID #: 9478

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC.,

Plaintiff,

v.

AMGEN, INC.

Defendant.

C.A. No. 22-1549-MN

[redacted]

OPENING BRIEF IN SUPPORT OF
PLAINTIFF JANSSEN'S MOTION FOR A PRELIMINARY INJUNCTION

OF COUNSEL:
Michael A. Morin
David P. Frazier
Inge A. Osman
Cecilia Sanabria
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
(202) 637-2200

Michael Seringhaus
LATHAM & WATKINS LLP
140 Scott Drive
Menlo Park, CA 94025
(650) 328-4600

Gabrielle LaHatte
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
(415) 491-0600

Dated: March 6, 2023

MCCARTER & ENGLISH, LLP
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King St.
Wilmington, DE 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Janssen Biotech, Inc.

Second, Amgen's proposed launch will cause Janssen irreparable harm that cannot be fully remedied with money damages. Access to STELARA® is determined largely by Pharmacy Benefit Managers (PBMs) engaged by insurance companies to administer coverage for prescription drugs. PBMs demand price concessions from manufacturers based upon the sales volumes of individual drugs and portfolios. Amgen's infringing launch of ABP 654 will compromise Janssen's ability to maintain patient access to STELARA® and its broader portfolio, and result in irretrievable loss of STELARA® market share, as well as price erosion, loss of goodwill, and harm to Janssen's relationships with payors and customers. By the time Janssen ultimately prevails at trial, it will be extraordinarily difficult—if not impossible—to fully quantify how STELARA® and other drugs would have fared absent Amgen's untimely launch. And it will be virtually impossible to revert to the contractual status quo preceding that launch.

Genentech v. Dr. Reddy's Labs., Fresenius Kabi

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC., HOFFMANN-LA ROCHE INC., and BIOGEN INC.

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES SA, DR. REDDY'S LABORATORIES LTD., FRESENIUS KABI USA, LLC, FRESENIUS KABI SWISSBIOSIM GmbH, and FRESENIUS KABI DEUTSCHLAND GmbH,

Defendants.

C.A. No. _____

JURY TRIAL REQUESTED

COMPLAINT FOR PATENT INFRINGEMENT

- **Filing:** November 13, 2023 in D.N.J.
- **Accused Product:** Rituxan® (rituximab) biosimilar DRL_RI
- **Asserted Patents**: 15
- **Patent Dance:** Partial dance

FISH.

Genentech v. Biogen MA, Bio-Thera

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GENENTECH, INC., HOFFMANN-LA ROCHE, INC., and CHUGAI PHARMACEUTICAL CO., LTD,

Plaintiffs,

v.

BIOGEN MA INC and BIO-THERA SOLUTIONS, LTD.,

Defendants.

Case No.: _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

- **Filing:** July 13, 2023 in D. Mass.
- **Accused Product:** Actemra® (tocilizumab) biosimilar Tofidence
- **Asserted Patents**: 20
- **Patent Dance:** Full dance

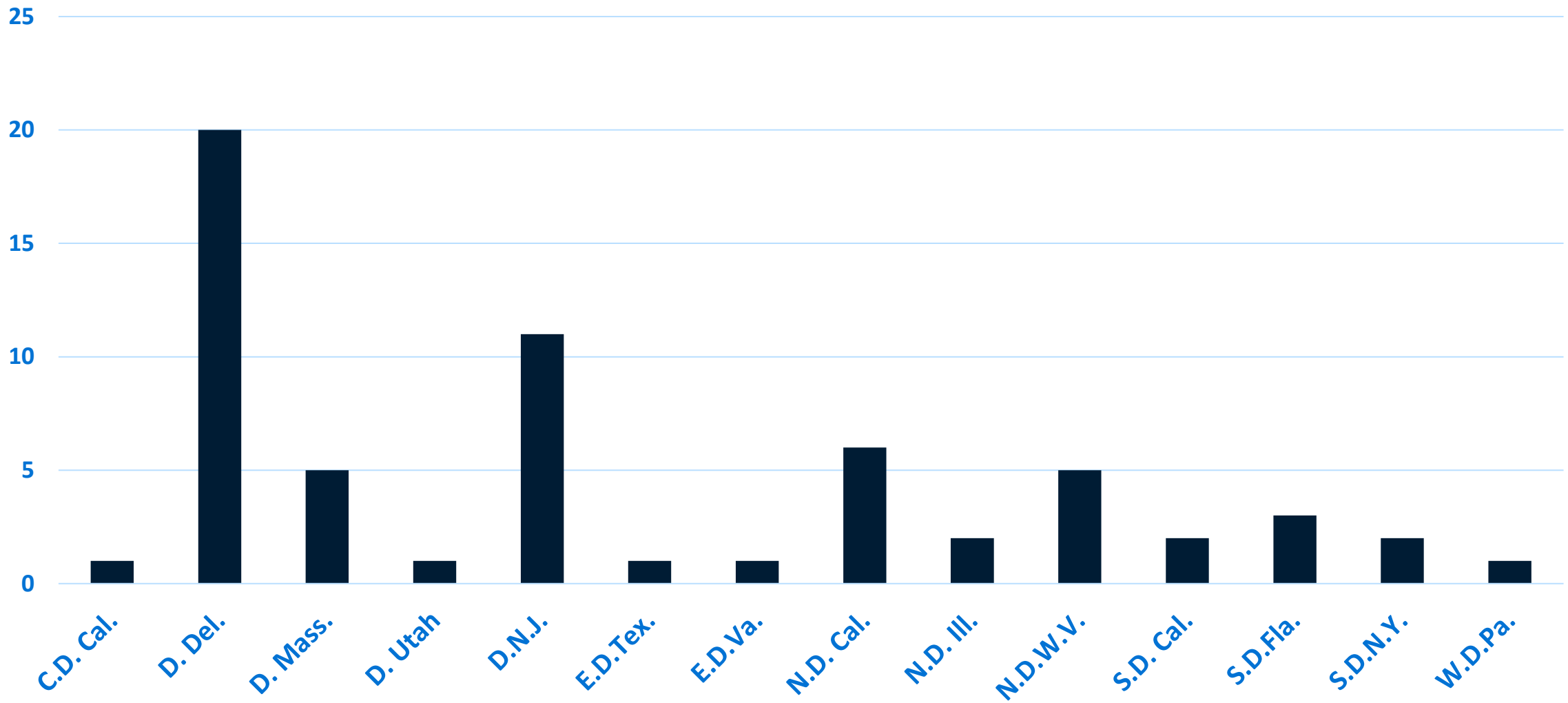
New BPCIA Litigation in Early 2024

Case Name	Court	Reference Product at Issue
Alexion v. Samsung Bioepis **(1:24-cv-00005)**	D. Del.	Soliris® (eculizumab)
Regeneron v. Amgen **(2:24-cv-00264)**	C.D. Cal.	Eylea® (aflibercept)

BPCIA Litigation Resolved in 2023

Case Name	Court	Reference Product at Issue
Genentech v. Tanvex **(3:22-cv-00809)**	S.D. Cal.	Herceptin® (trastuzumab)
Janssen v. Amgen **(1:22-cv-01549)**	D. Del.	Stelara® (ustekinumab)
Genentech et al. v. Biogen MA, Bio-Thera **(1:23-cv-11573)**	D. Mass.	Actemra® (tocilizumab)

Where BPCIA Cases Are Filed



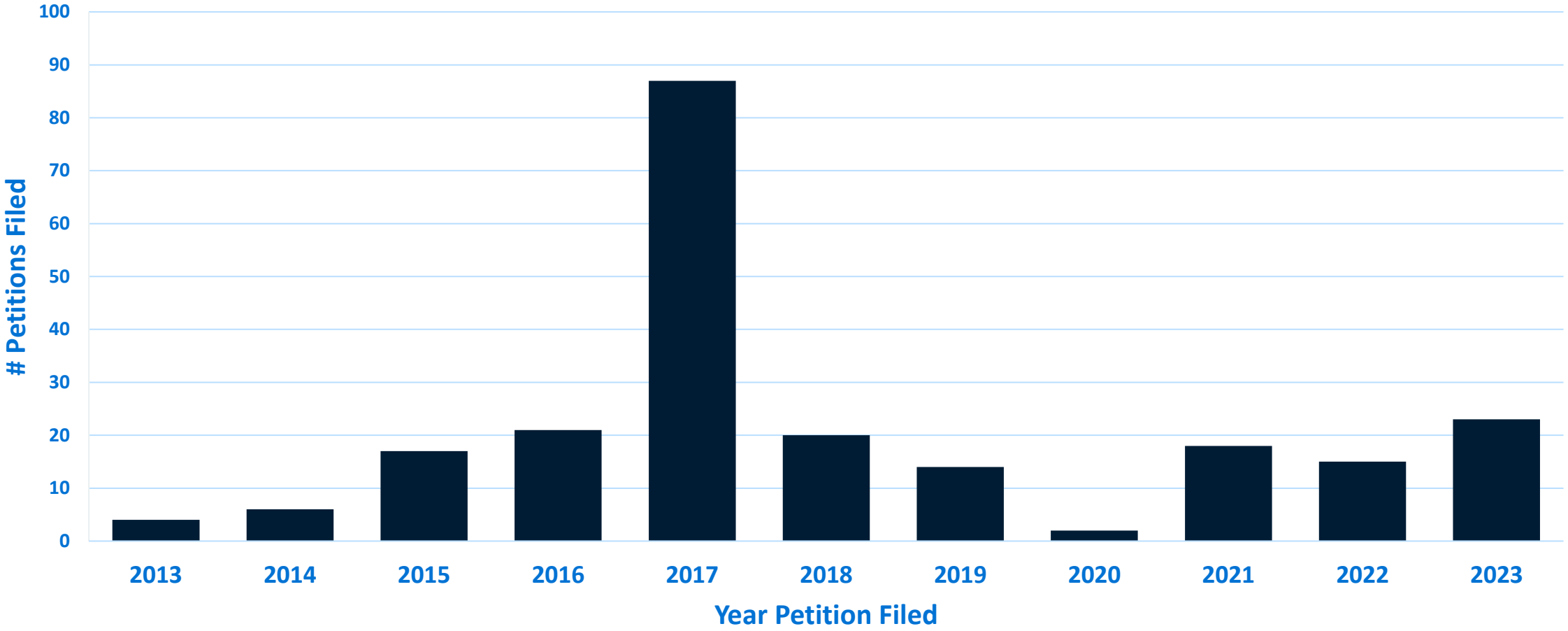
To Dance or Not to Dance?

Case Name	Court	Reference Product at Issue	
Amgen v. Sandoz **(1:23-cv-02406)**	D.N.J.	Prolia®/Xgeva®	**Some Dance**
Genentech et al. v. Biogen MA and Bio-Thera **(1:23-cv-11573)**	D. Mass.	Actemra®	**Full Dance**
Regeneron v. Celltrion **(1:23-cv-00089)**	N.D. W. Va.	Eylea®	**Some Dance**
Genentech et al. v. Dr. Reddy's Laboratories and Fresenius Kabi **(1:23-cv-22485)**	D.N.J.	Rituxan®	**Some Dance**
Regeneron v. Samsung Bioepis **(1:23-cv-00094)**	N.D. W. Va.	Eylea®	**Some Dance**
Regeneron v. Formycon **(1:23-cv-00097)**	N.D. W. Va.	Eylea®	**Some Dance**
Regeneron v. Samsung Bioepis **(1:23-cv-00106)**	N.D. W. Va.	Eylea®	**Unknown**

Post-Grant Update

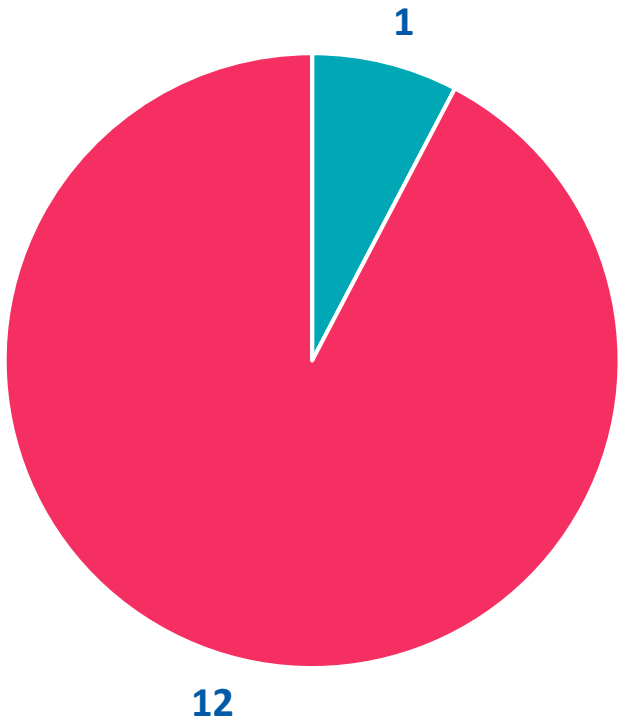
FISH.

Biologic-Related IPRs in 2023

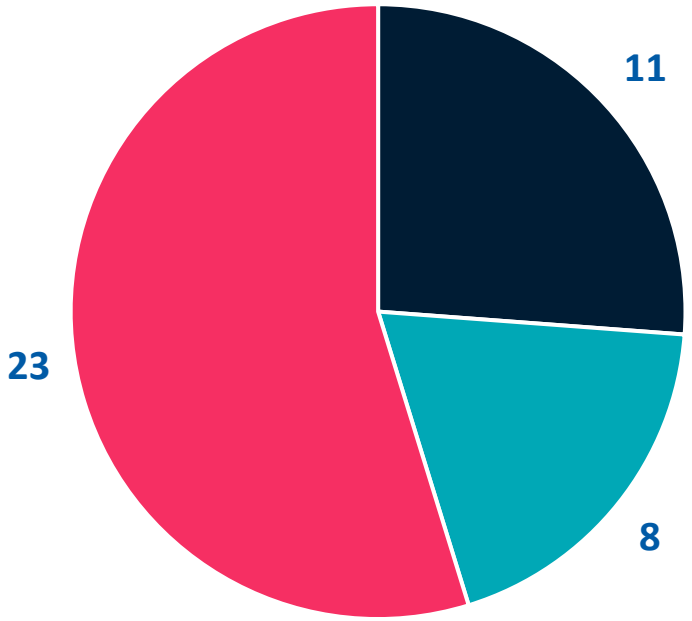


Final Written Decisions in Biologic-Related IPRs

FWD - Patentable (2017-2023)



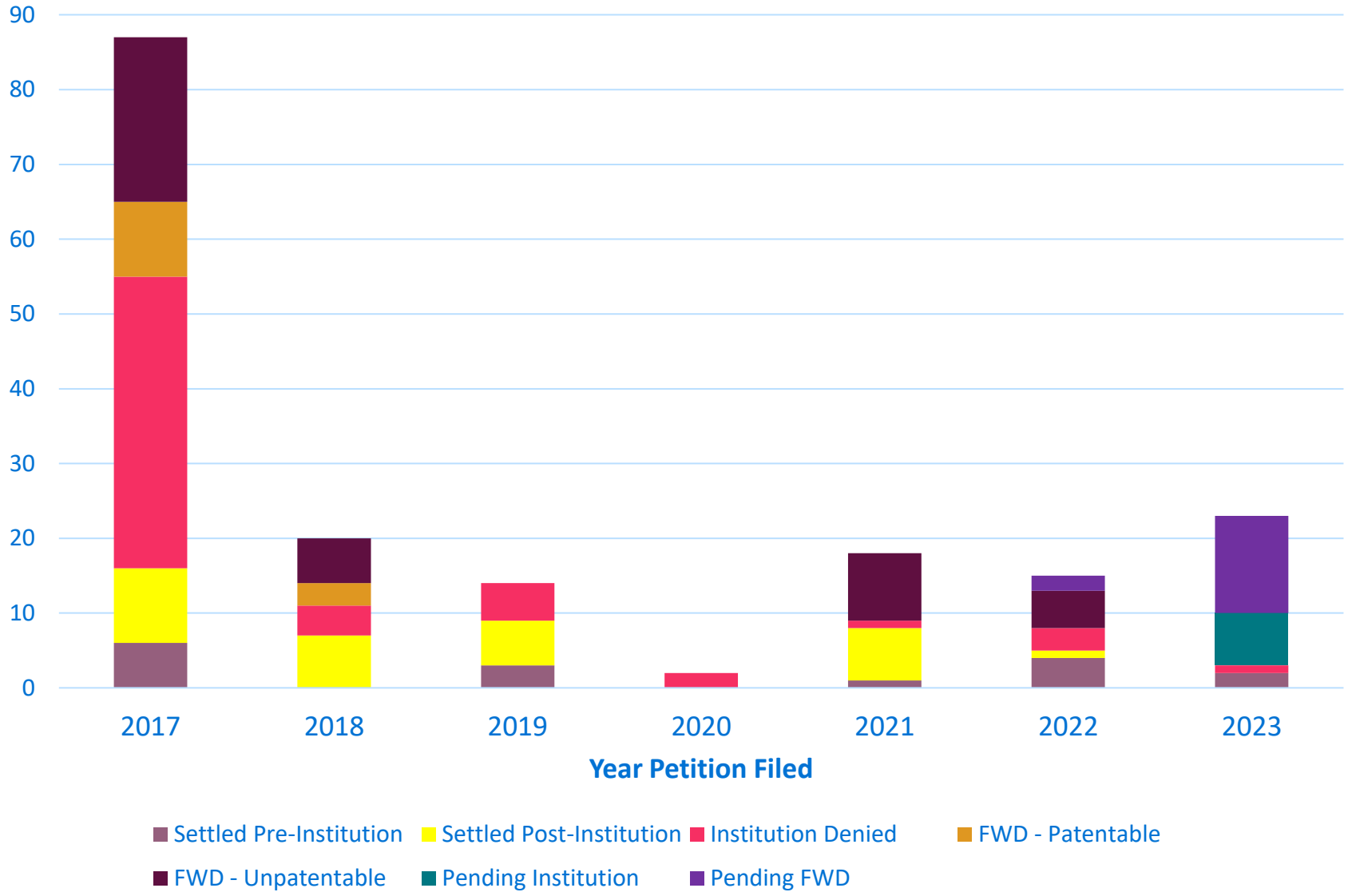
FWD - Unpatentable (2017-2023)



■ Formulation ■ Composition ■ Method of Treatment

FISH.

Outcome of Biologic-Related IPRs: 2017-2023



Select Post-Grant Disputes Before the PTO

Eylea® (aflibercept) / Zaltrap® (ziv-aflibercept)

- Chengdu, Mylan/Biocon, Apotex, Celltrion, and Samsung Bioepis filed or joined IPRs challenging Regeneron's U.S. Pat. Nos. 9,254,338; 9,669,069; 10,130,681; 10,406,226; 10,464,992; 10,857,205; 10,888,601; 11,253,572.
- Related BPCIA litigation involving Mylan/Biocon, Celltrion, and Samsung Bioepis in W.D. Va. concerns the same patents.

Keytruda® (pembrolizumab)

- In November 2023, Merck filed IPR challenging Johns Hopkins University's U.S. Pat. No. 11,591,393 (IPR2024-00240).
- Merck previously filed a declaratory judgment action in November 2022 in the District of Maryland, asserting claims of non-infringement as well as breach of contract (1:22-cv-03059 D. Md.).

Select Post-Grant Disputes Before the PTO

Stelara® (ustekinumab)

- In June 2023, Samsung Bioepis filed an IPR challenging Janssen's U.S. Pat. No. 10,961,307 (IPR2023-01103). Parties settled and terminated the IPR in November 2023.
- In November 2023, Biocon filed a follow-on IPR challenging the Janssen's '307 patent (IPR2023-01444).

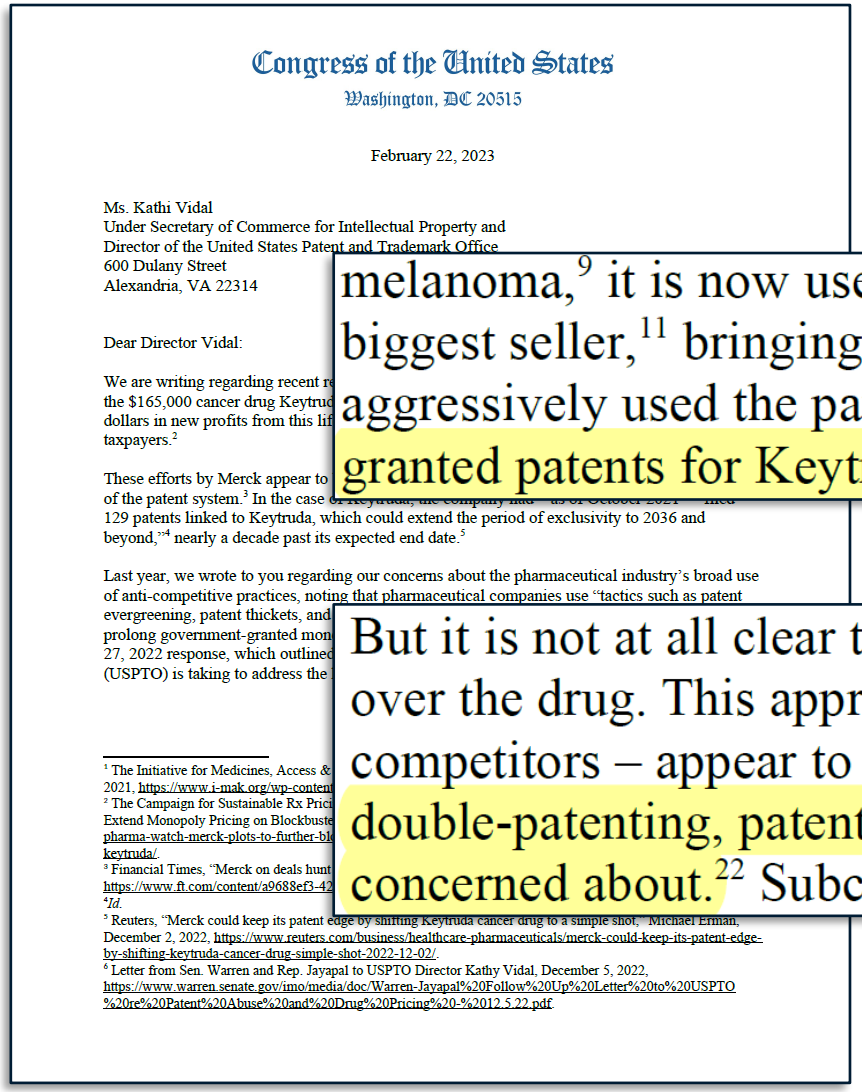
Tysabri® (natalizumab)

- In July 2022, Sandoz filed a PGR petition challenging Biogen's U.S. Patent No. 11,292,845 (PGR2022-00054). In February 2023, the PTAB denied institution.
- Related litigation in Delaware between Sandoz and Biogen concerns the same patent.

Antitrust Update

FISH.

Lawmakers Urge PTO to Scrutinize Keytruda® Patents



Congress of the United States
Washington, DC 20515

February 22, 2023

Ms. Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Vidal:

We are writing regarding recent re
the $165,000 cancer drug Keytrud
dollars in new profits from this lif
taxpayers.[2]

These efforts by Merck appear to
of the patent system.[3] In the case
129 patents linked to Keytruda, which could extend the period of exclusivity to 2036 and
beyond,"[4] nearly a decade past its expected end date.[5]

Last year, we wrote to you regarding our concerns about the pharmaceutical industry's broad use
of anti-competitive practices, noting that pharmaceutical companies use "tactics such as patent
evergreening, patent thickets, and
prolong government-granted mon
27, 2022 response, which outlined
(USPTO) is taking to address the

[1] The Initiative for Medicines, Access &
2021, https://www.i-mak.org/wp-content
[2] The Campaign for Sustainable Rx Prici
Extend Monopoly Pricing on Blockbuste
pharma-watch-merck-plots-to-further-blo
keytruda/.
[3] Financial Times, "Merck on deals hunt
https://www.ft.com/content/a9688ef3-42
[4] *Id.*
[5] Reuters, "Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot," Michael Erman,
December 2, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/merck-could-keep-its-patent-edge-by-shifting-keytruda-cancer-drug-simple-shot-2022-12-02/.
[6] Letter from Sen. Warren and Rep. Jayapal to USPTO Director Kathy Vidal, December 5, 2022,
https://www.warren.senate.gov/imo/media/doc/Warren-Jayapal%20Follow%20Up%20Letter%20to%20USPTO%20re%20Patent%20Abuse%20and%20Drug%20Pricing%20-%2012.5.22.pdf.

melanoma,[9] it is now used to treat eighteen types of advanced cancer.[10] The drug is Merck's biggest seller,[11] bringing in $5.4 billion in sales in the third quarter of 2022, and Merck has aggressively used the patent system to protect its monopoly on this drug.[12] The company has 53 granted patents for Keytruda, with another 129 applications pending as of 2021.[13] Fifty percent

But it is not at all clear that Merck is doing anything other than extending its monopoly power over the drug. This approach – and Merck's use of dozens of patents to fend off Keytruda competitors – appear to be an example of the anti-competitive business practices, including double-patenting, patent thicketing, product hopping, and evergreening, that we have long been concerned about.[22] Subcutaneous injection for delivery of treatments and medications is not

Settlement Approved in Remicade® Antitrust Litigation

Multiple cases filed in 2017-2018 in E.D. Pa

- All alleged that J&J/Janssen maintained market share and pricing for Remicade® (infliximab) through exclusionary contracts, anticompetitive bundling, and coercive rebates

Pfizer case dismissed on July 20, 2021

- Reported settlement
- Pfizer confirmed it will continue to sell its biosimilar, Inflectra®, in the United States

Consumer and third-party payors case reached proposed settlement for $25 million in 2022

- In March 2023, the court issued final order approving proposed settlement and further awarding class counsel $7 million in attorneys' fees and nearly $2.3 million in expenses

Antitrust Complaint Filed Based on J&J's Stelara®

Carefirst of Maryland v. Johnson & Johnson, 2:23-cv-00629, E.D. Va. (Walker, J.)

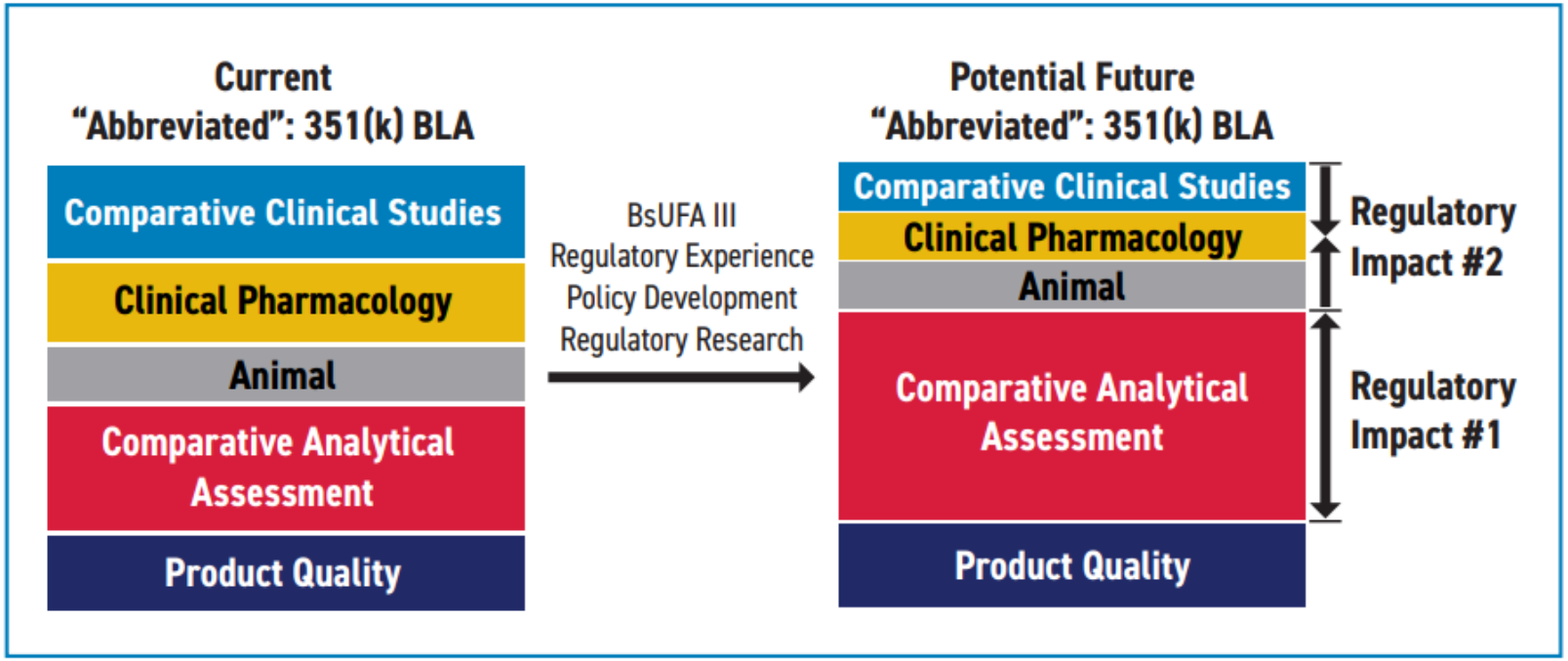
- Class action complaint filed in December 2023 alleging antitrust violations based on "scheme to unlawfully prolong patent protection for Stelara"
  - **Fraud on the PTO to obtain patent covering use of ustekinumab to treat ulcerative colitis**
  - **Anticompetitive acquisition of Momenta and its manufacturing patents**
  - **Leveraging ulcerative colitis patent and Momenta manufacturing patents to obtain settlements from biosimilar developers to delay biosimilar entry**
- J&J's responsive pleading due by February 20, 2024.

Regulatory and Legislative Update

FISH.

FDA Efforts to Promote Biosimilar Development

- FDA BsUFA III Regulatory Research Pilot Program: Research Roadmap



Source: BsUFA III Regulatory Research Pilot Program
https://www.fda.gov/media/164751/download?utm_medium=email&utm_source=govdelivery

FISH.

FDA Efforts to Promote Biosimilar Development

FDA Guidance for Industry

- March 2023: Q13 Continuous Manufacturing of Drug Substances and Drug Products
- September 2023: Draft Guidance, “Labeling for Biosimilar and Interchangeable Biosimilar Products”
- October 2023: Updated FDA Labeling Recommendations for Biosimilar and Interchangeable Biosimilar Products

FDA CDER Paper, “Safety Outcomes When Switching Between Biosimilars and Reference Biologics: A Systematic Review and Meta-Analysis”

- “[N]o difference in the safety profiles or immunogenicity rates in patients who were switched and those who remained on a reference biologic or biosimilar.”

FISH.

Inflation Reduction Act

Drug Name	Active Ingredient Or Active Moiety	Small Molecule Drug or Biological Product	Year of First FDA Approval
Enbrel	Etanercept	Biological Product	1998
NovoLog/Fiasp	Insulin Aspart, Human	Biological Product	2000
Januvia	Sitagliptin	Small Molecule Drug	2006
Stelara	Ustekinumab	Biological Product	2009
Xarelto	Rivaroxaban	Small Molecule Drug	2011
Eliquis	Apixaban	Small Molecule Drug	2012
Imbruvica	Ibrutinib	Small Molecule Drug	2013
Jardiance	Empagliflozin	Small Molecule Drug	2014
Farxiga	Dapagliflozin	Small Molecule Drug	2014
Entresto	Sacubitrilat/Valsartan	Small Molecule Drug	2015

New Proposed Federal Legislation

- **Increasing Access to Biosimilars Act (H.R. 1352)**
  - Requires HHS Secretary to establish project to evaluate shared savings payment for future biosimilars within Medicare
- **Biologics Competition Act (H.R. 1790)**
  - Directs HHS to report to Congress on the process of approving interchangeable products
- **Biosimilar Red Tape Elimination Act (S. 2305)**
  - Deems all biosimilars as interchangeable with their reference product and requires FDA to inform Congress if it intends to require a switching study
- **Preserving Access to Affordable Generics and Biosimilars Act (S. 142)**
  - Bans “reverse payment” settlements between patent owners and new generic or biosimilar entrants
- **Affordable Prescriptions for Patients Act (S. 150)**
  - Prohibits “product hopping,” or making a product switch within prescribed time periods after receiving notice of an ANDA or BLA
- **Interagency Patent and Improvement Act (S. 79)**
  - Establishes task force to share information between the PTO and FDA for technical assistance on patents for drugs and biological products

Looking Forward to 2024

- **Continued BLAs and litigation for next wave of biosimilars**
- **Value of interchangeability**
- **Strategy for BPCIA litigation**
  - Filing of biosimilar BLAs close to reference product loss of exclusivity
  - Partial patent dance by biosimilars
  - Preliminary injunction strategy

Want to Learn More about Biosimilars in 2023?

Check out our Biosimilars 2023 Year in Review Article at fr.com!

Special Thanks

Madelyn McCormick

Kayleigh McGlynn

Casey Kraning

FISH.

fr.com | 51

Martina Hufnal
Principal
hufnal@fr.com

Rae Crisler
Principal
crisler@fr.com

Philip Chen
Associate
pchen@fr.com

Thank You!

Please send your NY/NJ CLE forms to mcleteam@fr.com

Any questions about the webinar, contact the Events team @eventsteam@fr.com

A replay of the webinar will be available for viewing at fr.com/webinars

FISH.