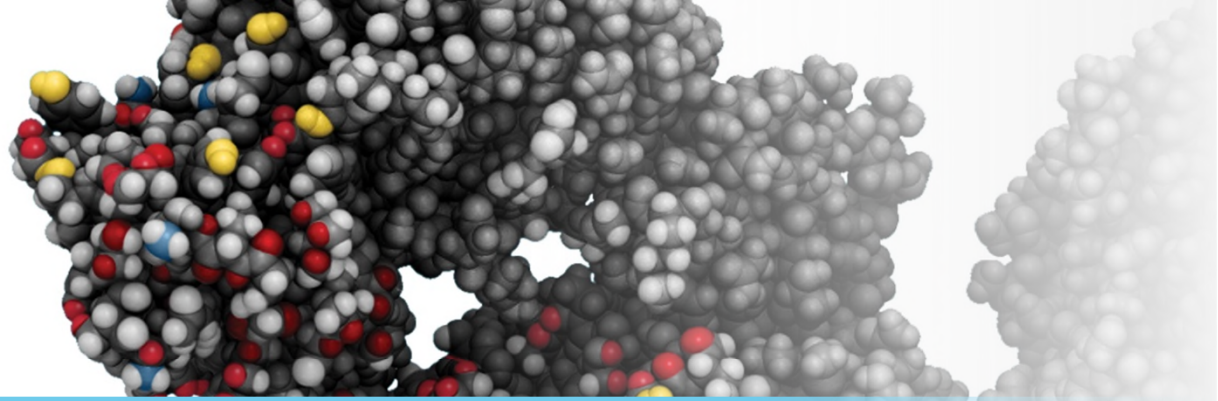
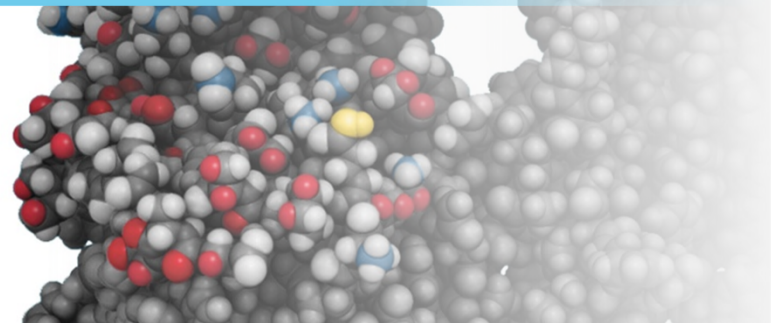
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW

Quarterly Update – March 2026

Christopher J. Betti, Ph.D.
Kelly A. Plummer, Ph.D.
Maarika L. Kimbrell
Maria E. Doukas
Margaret C. Harney



Blockbuster Biologics Newsletter 1Q 2026 Update

Welcome to our quarterly update relating to biologics and biosimilars, including post-grant and patent litigation challenges to blockbuster biologics.

Since the enactment of the Biologics Price Competition and Innovation Act (BPCIA), 82 biosimilars have been approved, 63 of which have launched. Notably, since our last update, Genentech filed a complaint against Biocon in the International Trade Commission alleging infringement of several patents relating to PERJETA. In addition, Genentech settled a dispute with Shanghai Henlius and Organon over a biosimilar to PERJETA, Regeneron settled disputes with Biocon and Samsung Bioepis over biosimilars to EYLEA, and Amgen, Hikma, and Gedeon settled their dispute over biosimilars to PROLIA and XGEVA.

In legislative and regulatory developments, in February 2026, Senator Bill Cassidy (R-LA), as chair of the Senate Health, Education, Labor and Pensions (HELP) Committee, released a report containing proposed legislative and regulatory reforms to modernize the Food and Drug Administration (FDA). The proposed reforms include (1) reducing certain data requirements for biosimilar approval and (2) creating a new biologic approval pathway that is a hybrid between a full 351(a) biologic application and a 351(k) biosimilar application.

We hope you find this update informative. As always, please feel free to reach out to us with any questions.

— Chris, Kelly, Maarika, Maria, and Meg

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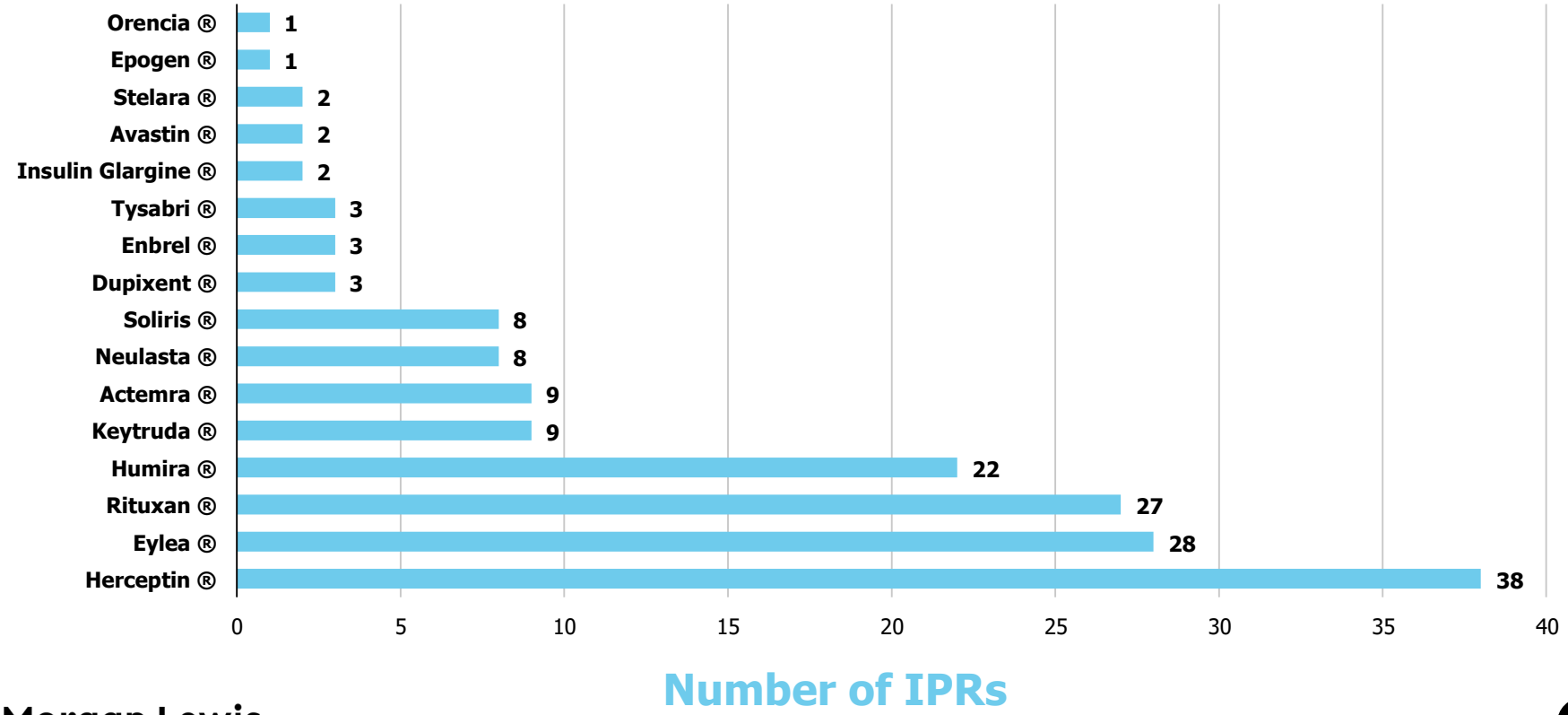
INTER PARTES REVIEWS (IPRs)

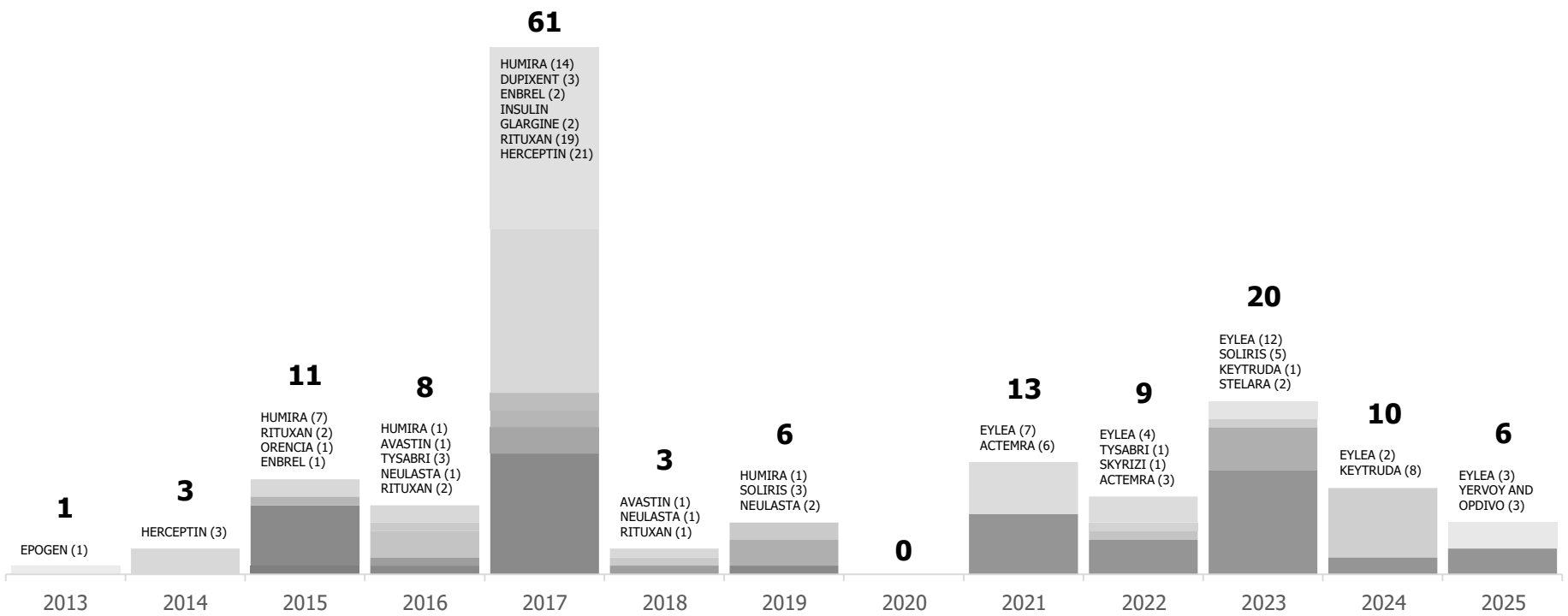
IPRs: Developments

- **Quick statistics:**
  - The current institution rate for IPR challenges to patents that claim biologics is 57% (excludes IPRs that have settled or otherwise been terminated).
  - Of those IPRs that have been instituted and gone to final written decision (FWD), 68% have resulted in the challenged claims being held unpatentable, with 10% having mixed results.

IPRs by Reference Product

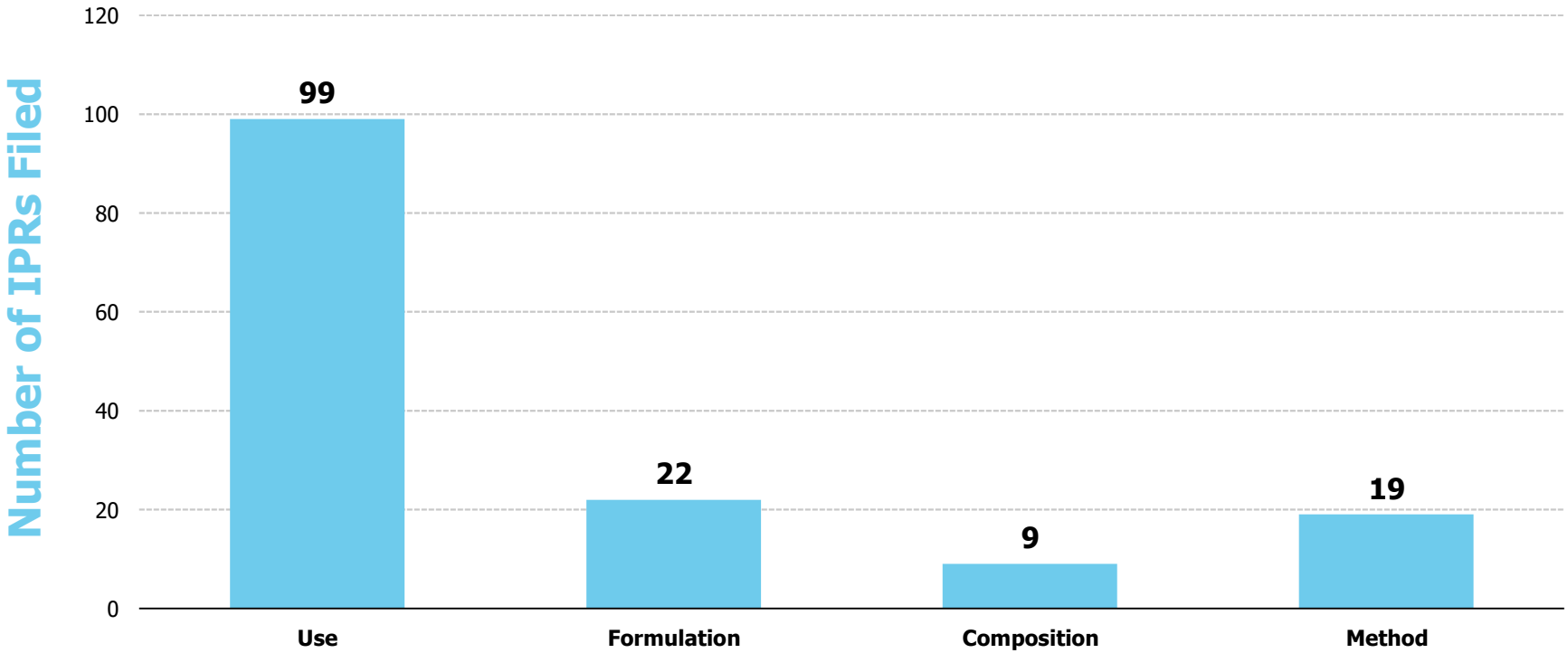


IPR Timeline



US Patent and Trademark Office (USPTO)
(Fiscal Year: October–September)

Types of Claims Being Challenged



IPR Scorecard – Institution

Product (# of IPRs)	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.*
Humira (22)	Amgen	0	2	-	-
	Boehringer Ingelheim	0	-	-	2
	Coherus	0	5	2	3
	Sandoz	0	6	2	-
Rituxan (27)	Boehringer Ingelheim	0	1	0	2
	Celltrion	0	6	3	2
	Pfizer	0	5	4	2
	Sandoz	0	2	0	0
Herceptin (38)	Phigenix	0	1	-	1
	Mylan	0	-	2	-
	Hospira	0	1	-	5
	Celltrion	0	-	1	6
	Pfizer	0	6	2	5
	Samsung	0	1	-	5
	Boehringer Ingelheim	0	-	2	-
Tysabri (3)	Swiss Pharma	0	3	-	-
Keytruda (9)	Merck	0	0	0	9
Avastin (2)	Hospira	0	0	-	1
	Pfizer	0	1	0	0
Orencia (1)	Momenta	0	-	-	1

IPR Scorecard – Institution (cont.)

Product (# of IPRs)	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.*
Neulasta (8)	Apotex	0	-	-	1
	Fresenius Kabi	0	1	2	-
	Kashiv Biosciences	0	-	2	-
	Lupin	0	1	-	-
	Hospira	0	-	1	0
Enbrel (3)	Coalition for Affordable Drugs	0	1	-	0
	Coherus	0	2	-	-
Epogen (1)	Hospira	0	-	1	0
Dupixent (3)	Sanofi-Aventis	0	1	-	2
Soliris (8)	Amgen	0	0	3	0
	Samsung Bioepis	0	-	5	0
Insulin Glargine (2)	Mylan	0	0	-	2
Eylea (28)	Mylan	0	1	-	4
	Apotex	0	1	-	2
	Celltrion	0	2	-	6
	Samsung Bioepis	0	1	-	5
	Biocon Biologics	0	0	0	2
	Chengdu	0	0	1	0
	Formycon AG	0	1	0	0
	Fresenius	0	2	0	0

IPR Scorecard – Institution (cont.)

Product (# of IPRs)	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.*
Stelara (2)	Samsung Bioepis	**0**	**-**	**1**	**-**
	Biocon Biologics	**0**	**-**	**1**	**-**
Actemra (9)	Fresenius Kabi USA	**0**	**-**	**7**	**-**
	Celltrion	**0**	**-**	**0**	**2**
Yervoy and Opdivo (3)	Amgen	**3**	**-**	**-**	**-**
TOTALS		**5**	**52**	**42**	**70**

Institution rate = 70/122 = 57%

**** IPRs instituted but later settled or otherwise terminated are not included***

IPR Scorecard – Final Written Decisions (FWDs)

Product (# of IPRs)	**Challenger**	**Inst.***	**FWD** (invalid)	**FWD** (upheld)	**Mixed**
Humira (22)	Amgen	-	-	-	-
	Boehringer Ingelheim	**2**	**2**	-	-
	Coherus	**3**	**3**	-	-
	Sandoz	-	-	-	-
Rituxan (27)	Boehringer Ingelheim	-	-	-	-
	Celltrion	**2**	**1**	**1**	-
	Pfizer	**2**	**1**	**1**	-
	Sandoz	-	-	-	-
Herceptin (38)	Phigenix	**1**	-	**1**	-
	Mylan	-	-	-	-
	Hospira	**5**	**3**	**2**	-
	Celltrion	**6**	**2**	**2**	**2**
	Pfizer	**5**	**3**	**2**	**0**
	Samsung	**5**	**1**	**2**	**2**
	Boehringer Ingelheim	-	-	-	-

IPR Scorecard – FWDs (cont.)

Product (# of IPRs)	**Challenger**	**Inst.***	**FWD** (invalid)	**FWD** (upheld)	**Mixed**
Tysabri (3)	Swiss Pharma	-	-	-	-
Avastin (2)	Hospira	**1**	**1**	-	-
Orencia (1)	Momenta	**1**	-	**1**	-
Neulasta (8)	Apotex	**1**	-	**1**	-
	Fresenius Kabi	**1**	-	-	-
	Kashiv Biosciences	**2**	-	-	-
Enbrel (3)	Coalition for Affordable Drugs	-	-	-	-
	Coherus	-	-	-	-
Epogen (1)	Hospira	-	-	-	-
Keytruda (9)	Merck	**0**	**9**	-	-
Dupixent (3)	Sanofi-Aventis	**2**	-	-	**2**
Soliris (8)	Amgen	-	-	-	-
	Samsung Bioepis	-	-	-	-
Insulin Glargine (2)	Mylan	**2**	**2**	-	-

Invalidation rate = 39/61 = 68%, with mixed results for 10%

**** IPRs instituted but later settled or otherwise terminated are not included***

IPR Scorecard – FWDs (cont.)

Product (# of IPRs)	Challenger	Inst.*	FWD (invalid)	FWD (upheld)	Mixed
Eylea (28)	Mylan	4	4	-	-
	Apotex	2	2	-	-
	Celltrion	4	4	-	-
	Samsung Bioepis	2	2	-	-
	Biocon Biologics	-	-	-	-
	Chengdu	-	-	-	-
	Formycon AG	-	-	-	-
Stelara (2)	Samsung Bioepis	-	-	-	-
	Biocon Biologics	-	-	-	-
Actemra (9)	Celltrion	2	2	0	0
TOTALS		55	42	13	6

Invalidation rate = 39/61 = 68%, with mixed results for 10%

**** IPRs instituted but later settled or otherwise terminated are not included***

Blockbuster Biologics: IPR Appeals (Humira)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
AbbVie	Coherus	8,889,135	2016-00172 (2017-2304)	Claims Invalid	• All of these appeals have been consolidated • Federal Circuit affirmed five FWDs, finding claims unpatentable as obvious
AbbVie	Boehringer Ingelheim	8,889,135	2016-00408 (2017-2362)	Claims Invalid	
AbbVie	Boehringer Ingelheim	8,889,135	2016-00409 (2017-2363)	Claims Invalid	
AbbVie	Coherus	9,017,680	2016-00188 (2017-2305)	Claims Invalid	
AbbVie	Coherus	9,073,987	2016-00189 (2017-2306)	Claims Invalid	

Blockbuster Biologics: IPR Appeals (Rituxan)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Genentech	Celltrion	7,820,161	2016-01614 (2018-1885) 2017-01115 joined (2018-1924)	Claims Valid	• Appeal No. 2016-01614 voluntarily dismissed • Appeal No. 2018-1885 dismissed with prejudice as part of settlement and license agreement • Appeal No. 2018-1924 dismissed as part of litigation settlement (Case No. 18-574-RMB-KMW (D.N.J.))
Biogen	Pfizer	8,821,873	2017-01168 (2019-1364)	Claims Invalid	• Biogen challenging constitutionality of IPRs • Pfizer not participating in appeal • USPTO intervened in appeal • Parties voluntarily dismissed appeal • Issues fully briefed • Affirmed Board's decision

Blockbuster Biologics: IPR Appeals (Herceptin)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Genentech	Hospira	7,807,799	2016-01837 (2018-1933)	Claims Invalid	• USPTO intervened • Affirmed Board's decision that challenged claims as unpatentable on anticipation and obviousness grounds
Genentech	Hospira	7,846,441	2017-00731 (2019-1263)	Claims Invalid	• Hospira withdrew as a party due to settlement, and USPTO intervened • Lead case – consolidated with 2019-1267 • Appeal submitted on briefs • Affirmed Board's decision that challenged claims as unpatentable on obviousness grounds
Genentech	Celltrion	7,846,441	2017-01121 (2019-1267)	Claims Invalid	• USPTO intervened • Consolidated with 2019-1263 • Affirmed Board's decision
Genentech	Hospira	6,627,196	2017-00804/ 2017-01958 joined (2019-1173)	Claims Valid	• Lead case – consolidated with 2019-1174 • Appeal voluntarily dismissed

Blockbuster Biologics: IPR Appeals (Herceptin) (cont.)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Genentech	Hospira	7,371,379	2017-00805/ 2017-01959 joined (2019-1174)	Claims Valid	• Consolidated with 2019-1173 • Appeal voluntarily dismissed
Genentech	Celltrion	6,627,196	2017-01139 (2019-1258)	Claims Valid	• Consolidated with 2019-1259 • Parties dismissed the appeal
Genentech	Celltrion	7,371,379	2017-01140 (2019-1259)	Claims Valid	• Consolidated with 2019-1258 • Parties dismissed the appeal
Genentech	Hospira	7,892,549	2017-00737/ 2017-01960 joined (2019-1265)	Claims Invalid	• Hospira withdrew as a party due to settlement • Samsung Bioepis withdrew as a party • Lead – consolidated with 2019-1270 • Affirmed Board's decision that challenged claims as unpatentable on obviousness grounds
Genentech	Celltrion	7,892,549	2017-01122 (2019-1270)	Claims Invalid	• USPTO allowed to intervene • Affirmed Board's decision

Blockbuster Biologics: IPR Appeals (Neulasta)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Amgen	Apotex	8,952,138	2016-01542 (2019-2171)	Claims Invalid	• Amgen filed Notice of Appeal • USPTO allowed to intervene • Board found claims 1-24 of the '138 Patent unpatentable as obvious, and Federal Circuit reversed

Blockbuster Biologics: IPR Appeals (Avastin)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Genentech	Hospira	7,622,115	2016-01771 (2018-1959)	Claims Invalid	• Includes constitutional challenge regarding retroactive application of IPR to pre-AIA patent • United States intervened • Oral argument held July 11, 2019 • Judgment affirmed

Blockbuster Biologics: IPR Appeals (Orencia)

Patent Owner	Challenger	Patent No.	IPR No. (Appeal No.)	Decision Appealed	Status of Appeal
Bristol-Myers Squibb	Momenta	8,476,239	2015-01537 (2017-1694)	Claims Valid	• Federal Circuit dismissed appeal for lack of standing/jurisdiction and for mootness

Post-Grant Reviews (PGRs)

> Six PGRs have been filed to date in connection with a blockbuster biologic.

Product	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.
Neupogen	Adello/Apotex	-	-	1	**1**
Eylea	Celltrion	-	1	-	-
	Alvotech	1	-	-	-
Skyrizi	Sandoz	-	1	-	-
Humira	Fresenius Kabi USA	-	1	-	-
Tysabri	Sandoz	-	1	-	-

US BIOSIMILAR–RELATED PATENT LITIGATIONS

US Biosimilar Litigations: Developments

- **Eylea® Litigation:**
  - Following earlier settlements in the United States and Canada, Regeneron and Biocon entered a global settlement and license agreement.
    - The agreement allows for worldwide commercialization of Biocon's biosimilar, Yesafili®.
  - Regeneron also settled its dispute with Samsung Bioepis on February 11, 2026.
    - Per the agreement, Samsung Bioepis can launch its biosimilar, Opuviz®, in January 2027.

US Biosimilar Litigations: Developments (cont.)

- **Prolia® and Xgeva® Litigation:**
  - Amgen, Hikma, and Gedeon settled their dispute on November 24, 2025.
    - Under the agreement, Hikma and Gedeon were enjoined from selling their biosimilar products until January 1, 2026.

US Biosimilar Litigations: Developments (cont.)

- **Perjeta® Litigation:**
  - Genentech filed a complaint against Biocon in the International Trade Commission on February 27, 2026.
    - The complaint alleges Biocon infringes several Perjeta® patents by importing its biosimilar, BMAB 1500/PERT-IJS, into the United States.
  - Genentech also settled a District of New Jersey dispute with Shanghai Henlius and Organon on January 30, 2026.
    - Shanghai's drug, Poherdy®, is currently the only FDA-approved biosimilar of Perjeta®.

US Biosimilar Litigations: Developments (cont.)

> Summary of 11 Humira Biosimilar Settlements

Party	US Market Entry
Amgen	January 31, 2023
Biogen and Samsung Bioepis	June 30, 2023
Boehringer Ingelheim	July 1, 2023
Alvotech	July 1, 2023
Fresenius Kabi	July 1, 2023
Mylan	July 31, 2023
Sandoz	September 30, 2023
Fresenius Kabi	September 30, 2023
Momenta	November 20, 2023
Pfizer	November 20, 2023
Coherus	December 15, 2023

US Biosimilar Litigations: Developments (cont.)

- Products in patent litigation that we are monitoring include:
  - Avastin
  - Eylea
  - Neulasta
  - Rituxan
  - Imfinizi
  - Enbrel
  - Herceptin
  - Neupogen
  - Stelara
  - Xgeva and Prolia
  - Epogen
  - Humira
  - Remicade
  - Actemara
  - Soliris
  - Perjeta
- These litigations are summarized on the following slides.

US Litigation Scorecard – Humira

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Humira (7)	*AbbVie v. Amgen*	No. 16-666-MSG (D. Del.)	10	M, F, U, C	• Settled – US launch of Amjevita on January 31, 2023
	AbbVie v. Boehringer Ingelheim	No. 17-1065-SLR (D. Del.)	8	M, F, U, C	• Parties stipulated to dismissal
	AbbVie v. Sandoz	No. 18-12668 (D.N.J.)	2	U, F	• Settled – US launch of Hyrimoz on July 1, 2023
	Coherus v. Amgen	No. 19-00139 (D. Del.)	3	C	• Parties stipulated to dismissal • Amgen filed motion for determination of exceptional case and award of fees denied

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Humira (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Humira (7)	*AbbVie v. Alvotech*	No. 21-2258 (N.D. Ill.)	4	F, M, U	• Court denied motion to dismiss on August 23, 2021 and entered a scheduling order on September 20, 2021 • Trial set for August 2022, and court planned to issue trial decision by end of October 2022 • Defendant agreed not to launch in United States until after court's trial decision • Settled on March 8, 2022
	Alvotech v. AbbVie	No. 21-00265 (E.D. Va.)	4	F, M, U	• On October 22, 2021, E.D. Va. court transferred case to the N.D. Ill. • Dismissed AbbVie's pending motion to dismiss as moot • Settled on March 8, 2022
	AbbVie v. Alvotech	No. 21-02899 (N.D. Ill.)	58	F, M, U	• Complaint filed May 28, 2021 • Settled on March 8, 2022

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Rituxan

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Rituxan (4)	*Genentech v. Sandoz*	No. 17-13507-RMB-KMW (D.N.J.)	24	M, U, C	• Stipulated dismissal without prejudice • Sandoz decided not to pursue its FDA submission for its biosimilar
	Celltrion v. Genentech	No. 18-276-JSW (N.D. Cal.) No. 18-2161 (Fed. Cir.) (consolidated with No. 18-2160)	37	M, U	• Genentech's motion to dismiss granted • Final judgment appealed to Federal Circuit • Appeal voluntarily dismissed
	Genentech v. Celltrion	No. 18-574-RMB-KMW (D.N.J.)	40	M, U, C	• Settled
	Genentech v. Celltrion	No. 18-11553 (D.N.J.) (consolidated with No. 18-574-RMB-KMW)	18 (Claims mirror those of No. 18-574-RMB-KMW filed to ensure compliance with BPCIA)	M, U, C	• Settled

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Herceptin

Product (# of litigations)	**Case Name**	**Case No. (Jurisdiction)**	**# of Asserted Patents**	**Types of Claims***	**Status**
Herceptin (7)	*Celltrion v. Genentech*	No. 18-274-JSW (N.D. Cal.) No. 18-2160 (Fed. Cir.)	38	M, U, C	• Genentech's motion to dismiss granted • Final judgment appealed to Federal Circuit • Appeal voluntarily dismissed
	Genentech v. Celltrion	No. 18-095-CFC (D. Del.)	40	M, U, C	• All Delaware cases were before Judge Colm F. Connolly and coordinated • *Markman* hearing in April 2019 • Trial in December 2019 • Lead case • Settled
	Genentech v. Pfizer	No. 17-1672-CFC (D. Del.)	40	M, U, C	• Settled

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Herceptin (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Herceptin (7)	*Genentech v. Amgen*	No. 18-924-CFC (D. Del.)	37	M, U, C	• Parties stipulated to dismissal on July 7, 2020
	Genentech v. Celltrion	No. 18-1025-CFC (D. Del.)	40	M, U, C	• Settled
	Genentech v. Samsung Bioepis	No. 18-01363-CFC (D. Del.)	21	M, U, C	• Dismissed due to settlement
	Genentech v. Tanvex	No. 22-0809 (S.D. Cal.)	3	M	• Parties filed notice of agreement in principle on January 6, 2023

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neupogen

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	*Amgen v. Sandoz*	No. 14-04741-RS (N.D. Cal.) No. 15-1499 (Fed. Cir.) Nos. 15-1039, 15-1195 (Supreme Court) No. 18-1551 (Fed. Cir.)	1	M	• Complaint alleged that Sandoz violated BPCIA by (1) failing to provide its aBLA and manufacturing information within 20 days of FDA acceptance and (2) providing notice of commercial marketing before FDA approval of its aBLA • District court ruled in favor of Sandoz; on appeal, Federal Circuit and Supreme Court did the same • District court subsequently granted Sandoz's motion for summary judgment of noninfringement; affirmed on appeal • Petition for rehearing en banc denied
	Amgen v. Apotex	No. 15-62081-JIC (S.D. Fla.)	2	M, C	• Consolidated with *Amgen v. Apotex* pegfilgrastim (Neulasta) litigation, No. 15-61631-JIC, where district court entered judgment of noninfringement for Sandoz • Affirmed

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neupogen (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	*Amgen v. Kashiv*	No. 18-3347-JMV-SCM (D.N.J.)	17	M	• Amended Complaint filed, reducing number of patents to four and naming Amneal Pharmaceuticals as co-defendant • Amneal moved to dismiss Amended Complaint for failure to state a claim and lack of subject-matter jurisdiction • Claim construction briefed • On June 10, 2019, Kashiv substituted in place of Adello • On November 25, 2019, parties stipulated to dismissal without prejudice
	Amgen v. Hospira	No. 18-1064 (D. Del.)	1	M	• Parties stipulated to dismiss all claims and counterclaims with prejudice
	Sandoz v. Amgen	No. 19-00977 (N.D. Cal.)	1	M	• Sandoz voluntarily dismissed action without prejudice

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neupogen (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	*Amgen v. Tanvex*	No. 19-1374-AJB-MSB (S.D. Cal.)	1	M	• Complaint and Answer to Complaint filed • On December 19, 2019, parties entered into stipulation of dismissal without prejudice
	Amgen v. Hospira	No. 20-561 (D. Del.)	1	M	• Parties filed stipulation of dismissal with prejudice

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neulasta

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	*Amgen v. Apotex*	No. 15-61631-JIC (S.D. Fla.) No. 16-1308 (Fed. Cir.) No. 17-1010 (Fed. Cir.) No. 16-332 (Supreme Court)	2	M, F	• Amgen found not to have infringed • Supreme Court denied Apotex's petition for certiorari • Federal Circuit affirmed district court ruling • District court: 1) granted Amgen's motion for summary judgment re invalidity defenses except nonenablement 2) awarded judgment of noninfringement for Apotex 3) dismissed Apotex's nonenablement defense without prejudice
	Amgen v. Sandoz	No. 16-1276-SRC-CLW (D.N.J.)	Litigation over whether Sandoz violated BPCIA	NA	• Dismissed after Sandoz restarted patent-dance negotiations

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	*Amgen v. Sandoz*	No. 16-02581-RS (N.D. Cal.) No. 18-1552 (Fed. Cir.) (consolidated with No. 18-1551)	2	M, F	• On appeal, fully briefed, pending scheduling of oral argument • Summary judgment of noninfringement granted for Sandoz • Affirmed
	Amgen v. Coherus	No. 17-546-LPS (D. Del.) No. 18-1993 (Fed. Cir.)	1	M	• Court granted Coherus's motion to dismiss for failure to state a claim • Judgment entered against Amgen; case dismissed • Affirmed

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	*Amgen v. Mylan*	No. 17-1235-MRH (W.D. Pa.)	2	M	• Claim Construction Order issued • Amgen ordered to file, with infringement contentions, a statement identifying facts relied on outside of Mylan's FDA filings • Motion for summary judgment of noninfringement of US Patent No. 9,643,997 filed – ruling deferred • Abeyance in place, pending further order to be issued in August 2019 • Parties stipulated to noninfringement of US Patent No. 9,643,997
	Amgen v. Apotex	No. 18-61828 (S.D. Fla.)	1	M	• District court denied Apotex's motion to dismiss Amgen's complaint for failure to state a claim • Joint Claim Construction Statement filed • Accord BioPharma substituted in place of Apotex as defendant in August 2019 • On November 14, 2019, parties entered into stipulation of dismissal without prejudice

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	*Amgen v. Hospira*	No. 20-201 (D. Del.)	1	M	• Complaint filed February 11, 2020 • Hospira and Pfizer filed a motion to dismiss for failure to state a claim, arguing that Amgen surrendered subject-matter jurisdiction during prosecution • Motion to dismiss denied • Case stayed following Claim Construction Order until decision made as to whether early summary judgment practice as to noninfringement should be entertained • Settled and jointly dismissed by the parties on March 18, 2022

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Enbrel

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Enbrel (2)	*Immunex v. Sandoz*	No. 16-01118-CCC-JBC (D.N.J.) No. 20-1037 (Fed. Cir.)	5	C, F, U	• Before trial, Sandoz stipulated to infringement to certain asserted claims of two of the five patents-in-suit • Bench trial held in September 2018 and district court judge ruled in favor of Immunex, holding that patents-in-suit were valid • Sandoz appealed to Federal Circuit • Federal Circuit affirmed on July 1, 2020 • Petition for rehearing en banc denied
	Immunex v. Samsung Bioepis	No. 19-11755-CCC (D.N.J.)	5	C, U, M, F	• Court entered final judgment and permanent injunction against Samsung Bioepis on November 3, 2021 • Permanent injunction in effect until April 24, 2029, when patents expire

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Epogen

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Epogen (1)	*Amgen v. Hospira*	No. 15-839-RGA (D. Del.) No. 16-2179 (Fed. Cir.) (appeal dismissed) No. 19-1067 and No. 19-1102 (Fed. Cir.)	2	C, M	• Jury found infringement and awarded $70M in damages • Final judgment entered with pre- and post-judgment interest • Hospira appealed, arguing that all of its batches of product should be subject to safe-harbor provision about which jury was given erroneous instructions • Amgen responded that there was sufficient evidence supporting jury's finding that only seven of 21 drug batches qualified for safe-harbor provision • Oral argument held September 30, 2019 • Judgment affirmed December 16, 2019 • Petition for rehearing and petition for rehearing en banc denied

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Avastin

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Avastin (8)	*Genentech v. Amgen*	No. 17-165-GMS (D. Del.)	Litigation over violations of BPCIA	NA	• Dismissed complaint without prejudice
	Amgen v. Genentech	No. 17-7349-GW-AGR (C.D. Cal.)	27	M, C, F, U	• Genentech's motion to dismiss for lack of subject-matter jurisdiction granted
	Genentech v. Amgen	No. 17-1407-CFC (D. Del.)	24	M, C, F, U	• Consolidated with No. 17-1471 • Lead case • Granted Genentech's motion to dismiss Amgen's counterclaims and seek declaratory judgment that two patents are invalid, unenforceable, and not infringed for lack of subject-matter jurisdiction • Joint stipulation of dismissal filed on July 7, 2020
	Genentech v. Amgen	No. 17-1471-CFC (D. Del.)	25	M, C, F, U	• Consolidated with No. 17-1407
	Genentech v. Pfizer	No. 19-00638-CFC (D. Del.)	22	M, C, F, U	• Settled

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Avastin (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Avastin (8)	*Genentech v. Immunex and Amgen*	No. 19-00602-CFC (D. Del.) No. 19-2155 (Fed. Cir.)	14	M, C, F, U	• Genentech's motion to enforce statutory prohibition on commercial marketing and TRO denied • Federal Circuit denied Genentech's motion for an injunction pending appeal • Genentech appealed regarding commercial marketing • Federal Circuit affirmed
	Genentech v. Samsung Bioepis	No. 20-cv-00859 (D. Del.)	14	M, C, F, U	• Complaint filed June 28, 2020 • Joint stipulation to dismiss filed September 7, 2022
	Genentech v. Centus	No. 20-cv-00361 (E.D. Tex.)	10	M, U	• Complaint filed November 12, 2020 • Parties filed joint motion to stay all deadlines and notice of settlement • Motion to dismiss with prejudice granted due to parties' settlement

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Remicade

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Remicade (5)	*Janssen v. Celltrion*	No. 15-10698-MLW (D. Mass.) No. 17-1120 (Fed. Cir.)	2	C, U	• Partial summary judgment of invalidity granted with respect to one patent ('471 patent) • Federal Circuit dismissed appeal as moot upon affirming decision in appeal (No. 17-1257) from ex parte reexamination ruling by USPTO that same patent's claims are unpatentable for double patenting • Dismissed without prejudice in favor of No. 17-11008
	Janssen v. Celltrion	No. 16-11117-MLW (D. Mass.)	1	M (cell culture media)	• Dismissed without prejudice in favor of No. 17-11008
	Janssen v. HyClone	No. 16-00071-BCW (D. Utah)	1	M (cell culture media)	• Case administratively closed on November 26, 2019, per related litigation in District of Massachusetts

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Remicade (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Remicade (5)	*Janssen v. Celltrion*	No. 17-11008 (D. Mass.) No. 18-2350 (Fed. Cir.) Lead appeal (No. 18-2321)	1	M (cell culture media)	• Judgment entered for defendants after court allowed motion for summary judgment of noninfringement based on ensnarement • Affirmed on appeal
	Janssen v. Samsung Bioepis	No. 17-3524-MCA-SCM (D.N.J.)	3	M	• Janssen voluntarily dismissed its patent-infringement claims • Suit dismissed with prejudice

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Eylea

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Eylea (8)	*Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*	No. 1-22-cv-61 (N.D. W. Va.)	24	M, U, F, C	• Court granted permanent injunction against Mylan on June 11, 2024 • Permanent injunction and final judgment vacated after parties reached a settlement agreement
	Regeneron Pharm., Inc. v. Celltrion, Inc.	No. 1-23-cv-89 (N.D. W. Va.)	38	M, F	• Court granted preliminary injunction against Celltrion on June 24, 2024 • Federal Circuit affirmed preliminary injunction on March 5, 2025, preventing Celltrion from launching its biosimilar
	Regeneron Pharm., Inc. v. Samsung Bioepis, Co.	No. 1-23-cv-94 (N.D. W. Va.)	37	M, F	• Court granted preliminary injunction against Samsung Bioepis on June 14, 2024 • Federal Circuit affirmed preliminary injunction preventing Samsung Bioepis from marketing its biosimilar of Eylea on January 29, 2025 • Settled on February 11, 2026

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Eylea (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Eylea (8)	*Regeneron Pharm., Inc. v. Formycon AG*	No. 1-23-cv-97 (N.D. W. Va.)	39	M, F	• Court granted preliminary injunction against Formycon on June 21, 2024 • Federal Circuit affirmed preliminary injunction preventing Formycon from marketing its biosimilar of Eylea on January 29, 2025 • Settled on September 29, 2025
	Regeneron Pharm., Inc. v. Samsung Bioepis, Co.	No. 1-23-cv-106 (N.D. W. Va.)	51	M, F	• Court granted preliminary injunction against Samsung Bioepis on June 14, 2024 • Settled on February 11, 2026
	Regeneron Pharm., Inc. v. Amgen, Inc.	No. 1-24-cv-39 (N.D. W. Va.)	32	M, C, F, U	• Court denied Regeneron's motion for preliminary injunction on October 1, 2024 • Federal Circuit affirmed the denial of preliminary injunction on March 14, 2025 • District court entered Stipulation and Order Vacating Permanent Injunction and Dismissing All Claims and Counterclaims with Prejudice on April 22, 2025
	Regeneron Pharm., Inc. v. Sandoz Inc.	No. 1-24-cv-85 (N.D. W. Va.)	46	M, C, F, U	• Case filed in District of New Jersey on August 26, 2024 • Transferred to the Northern District of West Virginia on September 13, 2024 • Settled on September 9, 2025
	Regeneron Pharm., Inc. v. Amgen, Inc.	No. 2:25-cv-5499 (C.D. Cal)	1	F	• Case filed in Central District of California on June 17, 2025 • Amgen filed counterclaims which Regeneron moved to strike and dismiss on November 12, 2025

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Stelara

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Stelara (1)	*Janssen v. Amgen*	No. 22-01549 (D. Del)	6	U, C, M	• Janssen asserted six patents against Amgen • Janssen filed a motion for preliminary injunction in March 2023 • Settled on May 22, 2023 • Settlement allows for Amgen to launch biosimilar no later than January 1, 2025

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Imfinzi

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Imfinzi (1)	*Bristol-Myers Squibb v. AstraZeneca*	(D. Del.)	1	M	• Bristol-Myers Squibb filed a complaint alleging willful infringement of its patent covering methods of treating cancer using an anti-PD-L1 antibody

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Tysabri

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Tysabri (1)	*Biogen v. Sandoz*	22-1190-GBW (D. Del.)	5	M, U	• Complaint alleges that Sandoz infringed 28 Biogen patents based on Sandoz's BLA submission • Biogen filed motion for preliminary injunction • Court required Biogen to elect up to five patents and 10 claims to assert as part of preliminary injunction • Court denied Biogen's motion for preliminary injunction

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Xgeva and Prolia

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Xgeva and Prolia (11)	*Amgen v. Sandoz*	No. 23-cv-02406 (D.N.J.)	21	C, M	• Parties stipulated to dismissal
	Amgen v. Celltrion	No. 24-cv-06497 (D.N.J.)	29	M, C	• Settled on January 23, 2025
	Amgen v. Samsung Bioepis	No. 24-cv-08417 (D.N.J.)	34	M, C	• Complaint filed August 12, 2024 • Settled on September 5, 2025
	Amgen v. Fresenius Kabi	No. 1:25-cv-01080 (D.N.J.)	33	M, C	• Complaint filed October 4, 2024 • Dismissed on March 7, 2025, following settlement agreement by parties
	Amgen v. Accord Biopharma	No. 5-24-cv-00642 (E.D.N.C.)	34	M, C	• Complaint filed November 13, 2024 • Dismissed on July 16, 2025, following settlement agreement by parties
	Amgen v. Hikma Pharma.	No. 1:25-cv-12152 (D.N.J.)	32	M, C	• Complaint filed June 30, 2025 • Settled on November 24, 2025
	Amgen v. Shanghai Henlius	No. 1:25-cv-12160 (D.N.J.)	26	C, M	• Complaint filed June 25, 2025
	Amgen v. Biocon Biologics	No. 1:25-cv-11867 (D.M.A.)	34	C, M	• Complaint filed June 30, 2025 • Settled on September 30, 2025
	Amgen v. Dr. Reddy's	No. 1:25-cv-17277 (D.N.J.)	31	C, M	• Complaint filed November 6, 2025
	Amgen v. Amneal	No. 1:25-cv-17278 (D.N.J.)	31	C, M	• Complaint filed November 6, 2025

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Xgeva and Prolia (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Xgeva and Prolia (11)	*Amgen v. Alkem*	No. 1-25-cv-17596 (D.N.J.)	35	C, M	• Complaint filed on November 14, 2025

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Actemra

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Actemra (1)	*Genentech v. Biogen*	No. 1:23-CV-11573 (D.N.J.)	20	C, M, U	• Parties filed joint stipulation of dismissal

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Soliris

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Soliris (1)	*Alexion v. Samsung*	No. 1:2024cv00005 (D. Del.)	6	M	• Complaint filed January 3, 2024 • Court denied Alexion's motion for preliminary injunction on May 6, 2024 • Parties settled on August 30, 2024

*See slide 98 for legend of abbreviations.

US Litigation Scorecard – Perjeta

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Perjeta (2)	*Genentech v. Shanghai Henlius Biotech*	2-25-cv-14648 (D.N.J)	24	C, M	• Complaint filed August 14, 2025 • Settled on January 30, 2026
	Genentech v. Biocon	ITC-337-3890-20260227 (ITC)	4	C, M	• Complaint filed February 27, 2026

*See slide 98 for legend of abbreviations.

LEGISLATIVE AND REGULATORY UPDATES

Senate Report Highlights Potential Biosimilar Reforms

- On February 17, 2026, Senator Cassidy, chair of the Senate Health, Education, Labor and Pensions (HELP) Committee released a report detailing potential legislative and regulatory reforms to modernize the FDA. The report could indicate potential policy riders that could be considered by Congress in connection with anticipated FDA user-fee reauthorizations in 2027.
- Within the proposed reforms, two focus on biosimilars:
  - *Reducing Evidentiary Burdens.* The report considers whether legislative action should be taken to codify or otherwise address indications from the FDA that certain biosimilar data requirements may in many cases be unnecessary, including (1) comparative clinical studies for biosimilarity determinations and (2) switching studies for interchangeability designations.
  - *Pathway Flexibility.* The report suggests that a new biologic approval pathway should be added to the FDA's authorities. This pathway would be a hybrid pathway between a full 351(a) biologic application and a 351(k) biosimilar and would permit partial reliance on a previous licensure, akin to the 505(b)(2) pathway for small molecules. This pathway could enable an abbreviated path for "biobetters."

BIOSIMILAR APPROVALS AND LAUNCHES

Biosimilar Approvals and Launches – Updates

- **New biosimilars approved in the United States in Q4 2025.**
  - The FDA approved Armlupeg, the seventh Neulasta® biosimilar, in November 2025.
  - The FDA further approved several biosimilars in December 2025:
    1. Nufymco® (Lucentis® biosimilar); and
    2. Boncresa® and Oziltus® (Prolia® and Xgeva® biosimilars).
       - Nufymco® is Formycon AG's second Lucentis® biosimilar, while Boncresa® and Oziltus® are the ninth Prolia® and Xgeva® biosimilars.

Biosimilar Approvals and Launches – Updates (cont.)

- **New biosimilars approved in the United States in Q1 2026.**
  - The FDA approved the Neupogen® biosimilar Filkri® in January 2026.
    - Filkri® is a leukocyte growth factor used to decrease the incidence of infection (febrile neutropenia) in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs.

US Biosimilar Approvals – 82 Total

Drug Name	Approval Date
Filkri (filgrastim-laha)	January 2026
Boncresa and Oziltus (denosumab-mobz)	December 2025
Nufymco (ranibizumab-leyk)	December 2025
Armlupeg (pegfilgrastim-unne)	November 2025
Poherdy (pertuzumab-dpzb)	November 2025
Osvyrti and Jubereq (denosumab-desu)	October 2025
Eydenzelt (aflibercept-boav)	October 2025
Enoby and Xtrenbo (denosumab-qbde)	September 2025
Aukelso and Bosaya (denosumab-kyqq)	September 2025
Bildyos and Bilprevda (denosumab-nxxp)	August 2025
Kirsty (insulin aspart-xjhz)	July 2025
Starjemza (ustekinumab-hmny)	May 2025

Drug Name	Approval Date
Jobevne (bevacizumab-nwgd)	April 2025
Bomyntra and Conexxence (denosumab-bnht)	March 2025
Omlyclo (omalizumab-igec)	March 2025
Stoboclo and Osenvelt (denosumab-bmwo)	February 2025
Merilog (insulin aspart-szjj)	February 2025
Ospomyvtm and Xbryktm (denosumab-dssb)	February 2025
Avtozma (tocilizumab-anoh)	January 2025
Steqeyma (ustekinumab-stba)	December 2024
Yesintek (ustekinumab-kfce)	November 2024
Imuldosa (ustekinumab-srlf)	October 2024
Otulfi (ustekinumab-aauz)	September 2024
Pavblu (aflibercept-ayyh)	August 2024
Enzeevu (aflibercept-abzv)	August 2024
Epysqli (eculizumab-aagh)	July 2024
Ahzantive (aflibercept-mrbb)	June 2024
Nypozi (filgrastim-txid)	June 2024
Pyzchiva (ustekinumab-ttwe)	June 2024

US Biosimilar Approvals – 82 Total (cont.)

Drug Name	Approval Date
Bkemv (eculizumab-aeeb)	May 2024
Yesafili (aflibercept-jbvf)	May 2024
Opuviz (aflibercept-yszy)	May 2024
Hercessi (trastuzumab-strf)	April 2024
Selarsdi (ustekinumab-aekn)	April 2024
Tyenne (tocilizumab-aazg)	March 2024
Jubbonti and Wyost (denosumab-bbdz)	March 2024
Simlandi (adalimumab-ryvk)	February 2024
Avzivi (bevacizumab-tnjn)	December 2023
Wezlana (ustekinumab-auub)	October 2023
Tofidence (tocilizumab-bavi)	September 2023
Tyruko (natalizumab-sztn)	August 2023
Yuflyma (adalimumab-aaty)	May 2023

Drug Name	Approval Date
Idacio (adalimumab-aacf)	December 2022
Vegzelma (bevacizumab-adcd)	September 2022
Stimufend (pegfilgrastim-fpgk)	September 2022
Cimerli (ranibizumab-eqrn)	August 2022
Fylnetra (pegfilgrastim-pbbk)	May 2022
Alymsys (bevacizumab-maly)	April 2022
Releuko (filgrastim-ayow)	February 2022
Yusimry (adalimumab-aqvh)	December 2021
Rezvoglar (insulin glargine-aglr)	December 2021*
Byooviz (ranibizumab-nuna)	September 2021
Semglee (insulin glargine-yfgn)	July 2021
Riabni (rituximab-arrx)	December 2020
Hulio (adalimumab-fkjp)	July 2020

*Subsequently approved as an interchangeable on November 16, 2022.

US Biosimilar Approvals – 82 Total (cont.)

Drug Name	Approval Date
Nyvepria (pegfilgrastim-apgf)	June 2020
Avsola (infliximab-axxq)	December 2019
Abrilada (adalimumab-afzb)	November 2019
Ziextenzo (pegfilgrastim-bmez)	November 2019
Hadlima (adalimumab-bwwd)	July 2019
Ruxience (rituximab-pvvr)	July 2019
Zirabev (bevacizumab-bvzr)	June 2019
Kanjinti (trastuzumab-anns)	June 2019
Eticovo (etanercept-ykro)	April 2019
Trazimera (trastuzumab-qyyp)	March 2019
Ontruzant (trastuzumab-dttb)	January 2019
Herzuma (trastuzumab-pkrb)	December 2018
Truxima (rituximab-abbs)	November 2018

Drug Name	Approval Date
Udenyca (pegfilgrastim-cbqv)	November 2018
Hyrimoz (adalimumab-adaz)	October 2018
Nivestym (filgrastim-aafi)	July 2018
Fulphila (pegfilgrastim-jmdb)	June 2018
Retacrit (epoetin alfa-epbx)	May 2018
Ixifi (infliximab-qbtx)	December 2017
Ogivri (trastuzumab-dkst)	December 2017
Mvasi (bevacizumab-awwb)	September 2017
Cyltezo (adalimumab-adbm)	August 2017
Renflexis (infliximab-abda)	May 2017
Amjevita (adalimumab-atto)	September 2016
Erelzi (etanercept-szzs)	August 2016

US Biosimilar Approvals – 82 Total (cont.)

Drug Name	Approval Date
Inflectra (infliximab-dyyb)	April 2016
Zarxio (filgrastim-sndz)	March 2015

Biosimilars by Reference Product

- **Actemra (tocilizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Avtozma (tocilizumab-anoh)	Biosimilar	Celltrion, Inc.	January 24, 2025
Tyenne (tocilizumab-aazg)	Biosimilar	Fresenius Kabi USA LLC	March 7, 2024
Tofidence (tocilizumab-bavi)	Biosimilar	Biogen Inc.	September 29, 2023

Biosimilars by Reference Product (cont.)

- **Avastin (bevacizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Jobevne (bevacizumab-nwgd)	Biosimilar	Biocon Biologics Inc.	April 9, 2025
Avzivi (bevacizumab-tnjn)	Biosimilar	Bio-Thera Solutions, Ltd.	December 6, 2023
Vegzelma (bevacizumab-adcd)	Biosimilar	Celltrion, Inc.	September 27, 2022
Alymsys (bevacizumab-maly)	Biosimilar	Amneal Pharmaceuticals, Inc.	April 13, 2022
Zirabev (bevacizumab-bvzr)	Biosimilar	Pfizer Inc.	June 27, 2019
Mvasi (bevacizumab-awwb)	Biosimilar	Amgen Inc.	September 14, 2017

Biosimilars by Reference Product (cont.)

- **Enbrel (etanercept) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Eticovo (etanercept-ykro)	Biosimilar	Samsung Bioepis Co., Ltd.	April 25, 2019
Erelzi (etanercept-szzs)	Biosimilar	Sandoz Inc.	August 30, 2016

Biosimilars by Reference Product (cont.)

- **Epogen/Procrit (epoetin alfa) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Retacrit (epoetin alfa-epbx)	Biosimilar	Hospira Inc.	May 15, 2018

Biosimilars by Reference Product (cont.)

- **Herceptin (trastuzumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Hercessi (trastuzumab-strf)	Biosimilar	Accord BioPharma Inc.	April 29, 2024
Kanjinti (trastuzumab-anns)	Biosimilar	Amgen Inc.	June 13, 2019
Trazimera (trastuzumab-qyyp)	Biosimilar	Pfizer Inc.	March 11, 2019
Ontruzant (trastuzumab-dttb)	Biosimilar	Samsung Bioepis Co., Ltd.	January 18, 2019
Herzuma (trastuzumab-pkrb)	Biosimilar	Celltrion, Inc.	December 14, 2018
Ogivri (trastuzumab-dkst)	Biosimilar	Mylan GmbH	December 1, 2017

Biosimilars by Reference Product (cont.)

- **Humira (adalimumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Simlandi (adalimumab-ryvk)	Biosimilar	Alvotech and Teva Pharmaceuticals	February 24, 2024
Yuflyma (adalimumab-aaty)	Biosimilar	Celltrion USA	May 24, 2023
Idacio (adalimumab-aacf)	Biosimilar	Fresenius Kabi	December 13, 2022
Yusimry (adalimumab-aqvh)	Biosimilar	Coherus BioSciences, Inc.	December 17, 2021
Hulio (adalimumab-fkjp)	Biosimilar	Mylan Pharmaceuticals Inc.	July 6, 2020
Abrilada (adalimumab-afzb)	Biosimilar	Pfizer Inc.	November 15, 2019
Hadlima (adalimumab-bwwd)	Biosimilar	Samsung Bioepis Co., Ltd.	July 23, 2019
Hyrimoz (adalimumab-adaz)	Biosimilar	Sandoz Inc.	October 30, 2018
Cyltezo (adalimumab-adbm)	Interchangeable	Boehringer Ingelheim Pharmaceuticals, Inc.	August 25, 2017
Amjevita (adalimumab-atto)	Biosimilar	Amgen Inc.	September 23, 2016

Biosimilars by Reference Product (cont.)

- **Lantus (insulin glargine) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Rezvoglar (insulin glargine-aglr)	Interchangeable	Eli Lilly and Company	November 16, 2022
Semglee (insulin glargine-yfgn)	Interchangeable	Mylan Pharmaceuticals Inc.	July 28, 2021

Biosimilars by Reference Product (cont.)

- **Lucentis (ranibizumab) biosimilar**

Name	Regulatory Designation	Company Name	FDA Approved
Nufymco (ranibizumab-leyk)	Biosimilar	Formycon AG	December 18, 2025
Cimerli (ranibizumab-eqrn)	Interchangeable	Coherus BioSciences, Inc.	August 2, 2022
Byooviz (ranibizumab-nuna)	Biosimilar	Samsung Bioepis Co., Ltd.	September 20, 2021

Biosimilars by Reference Product (cont.)

- **Neulasta (pegfilgrastim) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Armlupeg (pegfilgrastim-unne)	Biosimilar	Lupin Pharmaceuticals, Inc.	November 28, 2025
Stimufend (pegfilgrastim-fpgk)	Biosimilar	Fresenius Kabi USA, LLC	September 1, 2022
Fylnetra (pegfilgrastim-pbbk)	Biosimilar	Amneal Pharmaceuticals, Inc.	May 26, 2022
Nyvepria (pegfilgrastim-apgf)	Biosimilar	Pfizer Inc.	June 10, 2020
Ziextenzo (pegfilgrastim-bmez)	Biosimilar	Sandoz Inc.	November 4, 2019
Udenyca (pegfilgrastim-cbqv)	Biosimilar	Coherus BioSciences, Inc.	November 2, 2018
Fulphila (pegfilgrastim-jmdb)	Biosimilar	Mylan N.V.	June 4, 2018

Biosimilars by Reference Product (cont.)

- **Neupogen (filgrastim) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Filkri (filgrastim-laha)	Biosimilar	Accord BioPharma Inc.	January 15, 2026
Nypozi (filgrastim-txid)	Biosimilar	Tanvex BioPharma USA, Inc.	June 28, 2024
Releuko (filgrastim-ayow)	Biosimilar	Kashiv BioSciences, LLC	February 25, 2022
Nivestym (filgrastim-aafi)	Biosimilar	Pfizer Inc.	July 20, 2018
Zarxio (filgrastim-sndz)	Biosimilar	Sandoz Inc.	March 6, 2015

Biosimilars by Reference Product (cont.)

- **Prolia and Xgeva (denosumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Boncresa and Oziltus (denosumab-mobz)	Biosimilar	Amneal Pharmaceuticals	December 22, 2025
Osvyrti and Jubereq (denosumab-desu)	Biosimilar	Accord BioPharma, Inc.	October 29, 2025
Enoby and Xtrenbo (denosumab-qbde)	Biosimilar	Hikma Pharmaceuticals USA Inc.	September 26, 2025
Aukelso and Bosaya (denosumab-kyqq)	Biosimilar	Biocon Biologics, Inc.	September 16, 2025
Bildyos and Bilprevda (denosumab-nxxp)	Biosimilar	Shanghai Henlius Biotech, Inc.	August 29, 2025

Biosimilars by Reference Product (cont.)

- **Prolia and Xgeva (denosumab) biosimilars (cont.)**

Name	Regulatory Designation	Company Name	FDA Approved
Bomyntra and Conexxence (denosumab-bnht)	Biosimilar	Fresenius Kabi USA, LLC	March 25, 2025
Osenvelt and Stoboclo (denosumab-bmwo)	Biosimilar	Celltrion, Inc.	February 28, 2025
Ospomyv (denosumab-dssb)	Biosimilar	Samsung Bioepis Co. LTD.	February 13, 2025
Xbryk (denosumab-dssb)	Biosimilar	Samsung Bioepis Co. LTD.	February 13, 2025
Jubbonti (denosumab-bbdz)	Biosimilar	Sandoz Inc.	March 5, 2024
Wyost (denosumab-bbdz)	Biosimilar	Sandoz Inc.	March 5, 2024

Biosimilars by Reference Product (cont.)

- **Remicade (infliximab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Avsola (infliximab-axxq)	Biosimilar	Amgen Inc.	December 6, 2019
Ixifi (infliximab-qbtx)	Biosimilar	Pfizer Inc.	December 13, 2017
Renflexis (infliximab-abda)	Biosimilar	Samsung Bioepis Co., Ltd.	April 21, 2017
Inflectra (infliximab-dyyb)	Biosimilar	Celltrion, Inc.	April 5, 2016

Biosimilars by Reference Product (cont.)

- **Rituxan (rituximab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Riabni (rituximab-arrx)	Biosimilar	Amgen Inc.	December 17, 2020
Ruxience (rituximab-pvvr)	Biosimilar	Pfizer Inc.	July 23, 2019
Truxima (rituximab-abbs)	Biosimilar	Celltrion, Inc.	November 28, 2018

Biosimilars by Reference Product (cont.)

- **Stelara (ustekinumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Starjemza (ustekinumab-hmny)	Biosimilar	Bio-Thera Solutions, Ltd.	May 22, 2025
Steqeyma (ustekinumab-stba)	Biosimilar	Celltrion, Inc.	December 17, 2025
Yesintek (ustekinumab-kfce)	Biosimilar	Biocon Biologics Ltd.	November 29, 2024
Imuldosa (ustekinumab-srlf)	Biosimilar	Accord BioPharma, Inc.	October 10, 2024
Otulfi (ustekinumab-aauz)	Biosimilar	Fresenius Kabi USA, LLC	September 27, 2024
Pyzchiva (ustekinumab-ttwe)	Biosimilar	Samsung Bioepis Co., Ltd.	June 28, 2024
Selarsdi (ustekinumab-aekn)	Biosimilar	Alvotech and Teva Pharmaceuticals	April 16, 2024
Wezlana (ustekinumab-auub)	Biosimilar	Amgen Inc.	October 31, 2023

Biosimilars by Reference Product (cont.)

- **Tysabri (natalizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Tyruko (natalizumab-sztn)	Biosimilar	Sandoz Group AG	August 25, 2023

Biosimilars by Reference Product (cont.)

- **Eylea (aflibercept) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Eydenzelt (aflibercept-boav)	Biosimilar	Celltrion, Inc.	October 2, 2025
Pavblu (aflibercept-ayyh)	Biosimilar	Amgen, Inc.	August 23, 2024
Enzeevu (aflibercept-abzv)	Biosimilar	Sandoz Inc.	August 9, 2024
Ahzantive (aflibercept-mrbb)	Biosimilar	Formycon AG	June 28, 2024
Yesafili (aflibercept-jbvf)	Biosimilar	Biocon Biologics Inc.	May 20, 2024
Opuviz (aflibercept-yszy)	Biosimilar	Samsung Bioepis Co., Ltd.	May 20, 2024

Biosimilars by Reference Product (cont.)

- **Soliris (eculizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Epysqli (eculizumab-aagh)	Biosimilar	Samsung Bioepis Co., Ltd.	July 19, 2024
Bkemv (eculizumab-aeeb)	Biosimilar	Amgen Inc.	May 28, 2024

Biosimilars by Reference Product (cont.)

- **Novolog (insulin aspart) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Merilog (insulin aspart-szjj)	Biosimilar	Sanofi-Aventis U.S. LLC	February 14, 2025

Biosimilars by Reference Product (cont.)

- **Xolair (omalizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Omlyclo (omalizumab-igec)	Biosimilar	Celltrion, Inc.	March 7, 2025

Biosimilars by Reference Product (cont.)

- **Perjeta (pertuzumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Poherdy (pertuzumab-dpzb)	Biosimilar	Shanghai Henlius Biotech, Inc.	November 13, 2025

Biosimilars by Reference Product (cont.)

- **Novolog (insulin aspart) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Kirsty (insulin aspart-xjhz)	Biosimilar	Biocon Biologics Inc.	July 15, 2025

US Biosimilar Approval Statistics

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen	Nov. 25, 2015	Sep. 23, 2016	Jan. 31, 2023	303 days	2,624 days	2,321 days
aBLA 761058	Cyltezo®	Adalimumab-abdm	Boehringer Ingelheim	Oct. 27, 2016	Aug. 25, 2017	Jul. 1, 2023	302 days	2,438 days	2,136 days
aBLA 761071	Hyrimoz™	Adalimumab-adaz	Sandoz	Oct. 30, 2017	Oct. 30, 2018	Jul. 1, 2023	365 days	2,070 days	1,705 days
aBLA 761059	Hadlima™	Adalimumab-bwwd	Samsung Bioepis	Jul. 23, 2018	Jul. 23, 2019	Jul. 1, 2023	365 days	1,804 days	1,439 days
aBLA 761118	Abrilada™	Adalimumab-afzb	Pfizer	Nov. 16, 2018	Nov. 18, 2019	Nov. 1, 2023	367 days	1,811 days	1,444 days
aBLA 761154	Hulio®	Adalimumab-fkjp	Mylan / Biocon	Jul. 12, 2019	Jul. 6, 2020	Jul. 3, 2023	360 days	1,452 days	1,092 days
aBLA 761216	Yusimry™	Adalimumab-aqvh	Coherus	Dec. 18, 2020	Dec. 17, 2021	Jul. 3, 2023	364 days	927 days	563 days
aBLA 761255	Idacio®	Adalimumab-aacf	Fresenius Kabi	Dec. 13, 2021	Dec. 13, 2022	Jul. 3, 2023	365 days	567 days	202 days
aBLA 761219	Yuflyma®	Adalimumab-aaty	Celltrion	Nov. 24, 2020	May 23, 2023	Jul. 2, 2023	910 days	950 days	40 days
aBLA 761299	Simlandi®	Adalimumab-ryvk	Alvotech / Teva	Dec. 20, 2021	Feb. 23, 2024	May 20, 2024	795 days	882 days	87 days
aBLA 761028	Mvasi™	Bevacizumab-awwb	Amgen	Nov. 14, 2016	Sep. 14, 2017	Jul. 19, 2019	304 days	977 days	673 days
aBLA 761099	Zirabev™	Bevacizumab-bvzr	Pfizer	Jun. 29, 2018	Jun. 27, 2019	Dec. 31, 2019	363 days	550 days	187 days
aBLA 761231	Alymsys®	Bevacizumab-maly	Amneal / mAbxience	Apr. 13, 2021	Apr. 13, 2022	Oct. 3, 2022	365 days	538 days	173 days

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761268	Vegzelma®	Bevacizumab-adcd	Celltrion	Sep. 30, 2021	Sep. 27, 2022	Apr. 17, 2023	362 days	564 days	202 days
aBLA 761198	Avzivi®	Bevacizumab-tnjn	Bio-Thera / Sandoz	Nov. 27, 2020	Dec. 6, 2023	N/A	1,104 days	N/A	N/A
aBLA 761362	Jubbonti®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 days
aBLA 761362	Wyost®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 days
aBLA 125545	Retacrit®	Epoetin Alfa-epbx	Hospira / Pfizer	Dec. 16, 2014	May 15, 2018	Nov. 12, 2018	1,246 days	1,427 days	181 days
aBLA 761042	Erelzi®	Etanercept-szzs	Sandoz	Jul. 30, 2015	Aug. 30, 2016	N/A	397 days	N/A	N/A
aBLA 761066	Eticovo™	Etanercept-ykro	Samsung Bioepis	May 25, 2017	Apr. 25, 2019	N/A	700 days	N/A	N/A
aBLA 125553	Zarxio®	Filgrastim-sndz	Sandoz	May 8, 2014	Mar. 6, 2015	Sep. 3, 2015	302 days	483 days	181 days
aBLA 761080	Nivestym™	Filgrastim-aafi	Pfizer	Sep. 21, 2017	Jul. 20, 2018	Oct. 1, 2018	272 days	375 days	103 days
aBLA 761082	Releuko™	Filgrastim-ayow	Kashiv	Jul. 8, 2017	Feb. 25, 2022	Nov. 29, 2022	1,693 days	1,970 days	277 days
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion / Pfizer	Aug. 8, 2014	Apr. 5, 2016	Nov. 28, 2016	606 days	843 days	237 days
aBLA 761054	Renflexis®	Infliximab-abda	Samsung Bioepis / Merck	Mar. 21, 2016	Apr. 21, 2017	Jul. 24, 2017	396 days	490 days	94 days
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer	Feb. 13, 2017	Dec. 13, 2017	N/A	303 days	N/A	N/A

*Estimated

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761086	Avsola®	Infliximab-axxq	Amgen	Dec. 14, 2018	Dec. 6, 2019	Jul. 6, 2020	357 days	570 days	213 days
aBLA 761201	Semglee® (interchangeable)	Insulin Glargine-yfgn	Mylan / Biocon	Jul. 29, 2020	Jul. 28, 2021	Nov. 16, 2021	365 days	476 days	112 days
aBLA 761215	Rezvoglar®	Insulin Glargine-aglr	Eli Lilly	Dec. 17, 2020	Dec. 17, 2021	Apr. 1, 2023	365 days	835 days	470 days
aBLA 761322	Tyruko®	Natalizumab-sztn	Sandoz / Polpharma	May 24, 2022	Aug. 24, 2023	Nov. 17, 2025	457 days	1273 days	816 days
aBLA 761075	Fulphila®	Pegfilgrastim-jmdb	Mylan / Biocon	Dec. 9, 2016	Jun. 4, 2018	Jul. 30, 2018	542 days	598 days	56 days
aBLA 761039	Udenyca™	Pegfilgrastim-cbqv	Coherus	Aug. 9, 2016	Nov. 2, 2018	Jan. 3, 2019	569 days	877 days	308 days
aBLA 761045	Ziextenzo®	Pegfilgrastim-bmez	Sandoz	Aug. 27, 2015	Nov. 5, 2019	Nov. 15, 2019	1,531 days	1,541 days	10 days
aBLA 761111	Nyvepria™	Pegfilgrastim-apgf	Pfizer / Hospira	Jun. 10, 2019	Jun. 11, 2020	Jan. 1, 2021*	367 days	571 days	204 days
aBLA 761084	Fylnetra®	Pegfilgrastim-pbbk	Kashiv / Amneal	Aug. 11, 2020	May 26, 2022	May 16, 2023	653 days	1,008 days	355 days
aBLA 761173	Stimufend®	Pegfilgrastim-fpgk	Fresenius Kabi	Mar. 27, 2020	Sep. 1, 2022	Feb. 16, 2023	888 days	1,056 days	168 days
aBLA 761202	Byooviz™	Ranibizumab-nuna	Samsung Bioepis	Sep. 17, 2020	Sep. 20, 2021	Jul. 1, 2022	368 days	652 days	284 days
aBLA 761165	Cimerli™	Ranibizumab-eqrn	Coherus / Bioeq / Formycon	Aug. 2, 2021	Aug. 2, 2022	Oct. 3, 2022	365 days	427 days	62 days

*Estimated

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761088	Truxima®	Rituximab-abbs	Celltrion / Teva	Apr. 28, 2017	Nov. 28, 2018	Nov. 11, 2019	579 days	927 days	348 days
aBLA 761103	Ruxience®	Rituximab-pvvr	Pfizer	Jul. 25, 2018	Jul. 23, 2019	Jan. 23, 2020	363 days	547 days	184 days
aBLA 761140	Riabni™	Rituximab-arrx	Amgen / Allergan	Dec. 19, 2019	Dec. 17, 2020	Jan. 12, 2021	364 days	390 days	26 days
aBLA 761354	Tofidence™	Tocilizumab-bavi	Biogen / Bio-Thera	Sep. 29, 2022	Sep. 29, 2023	May 6, 2024	365 days	585 days	220 days
aBLA 761275	Tyenne®	Tocilizumab-aazg	Fresenius Kabi	May 30, 2022	Mar. 5, 2024	Apr. 15, 2024	645 days	686 days	41 days
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan / Biocon	Nov. 3, 2016	Dec. 1, 2017	Dec. 2, 2019	393 days	1,124 days	731 days
aBLA 761091	Herzuma®	Trastuzumab-pkrb	Celltrion / Teva	May 30, 2017	Dec. 14, 2018	Mar. 16, 2020	563 days	1,021 days	458 days
aBLA 761100	Ontruzant®	Trastuzumab-dttb	Samsung Bioepis / Merck	Oct. 20, 2017	Jan. 18, 2019	Apr. 15, 2020	455 days	908 days	453 days
aBLA 761081	Trazimera™	Trastuzumab-qyyp	Pfizer	Jun. 22, 2017	Mar. 11, 2019	Feb. 15, 2020	627 days	968 days	341 days
aBLA 761073	Kanjinti™	Trastuzumab-anns	Amgen / Allergan	Jul. 28, 2017	Jun. 13, 2019	Jul. 19, 2019	685 days	721 days	36 days
aBLA 761346	Hercessi™	Trastuzumab-strf	Accord BioPharma / Henlius	Dec. 13, 2022	Apr. 25, 2024	Nov. 29, 2024	499 days	717 days	218 days
aBLA 761285 / 76133	Wezlana®	Ustekinumab-auub	Amgen	Oct. 31, 2022	Oct. 31, 2023	Jan. 1, 2025	365 days	793 days	428 days

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761343	Selarsdi™	Ustekinumab-aekn	Alvotech / Teva	Oct. 11, 2022	Apr. 16, 2024	Feb. 21, 2025	553 days	864 days	311 days
aBLA 761350	Opuviz®	Aflibercept-yszy	Samsung Bioepis Co., Ltd.	Feb. 17, 2023	May 20, 2024	N/A	458 days	N/A	N/A
aBLA 761274	Yesafili®	Aflibercept-jbvf	Biocon Biologics Inc.	Oct. 29, 2021	May 20, 2024	N/A	934 days	N/A	N/A
aBLA 761333	Bkemv®	Eculizumab-aeeb	Amgen Inc.	Feb. 28, 2023	May 28, 2024	Mar. 5, 2025	455 days	736 days	281 days
aBLA 761373	Pyzchiva®	Ustekinumab-ttwe	Samsung Bioepis Co., Ltd.	Mar. 30, 2023	Jun. 28, 2024	Feb. 24, 2025	456 days	698 days	242 days
aBLA 761126	Nypozi®	Filgrastim-txid	Tanvex BioPharma USA, Inc.	Sep. 28, 2018	Jun. 28, 2024	N/A	2,100 days	N/A	N/A
aBLA 761378	Ahzantive®	Aflibercept-mrbb	Formycon AG	Jun. 28, 2023	Jun. 28, 2024	N/A	364 days	N/A	N/A
aBLA 761340	Epysqli®	Eculizumab-aagh	Samsung Bioepis Co., Ltd.	Apr. 21, 2023	Jul. 19, 2024	Apr. 7, 2025	455 days	718 days	263 days
aBLA 761382	Enzeevu®	Aflibercept-abzv	Sandoz Inc.	Aug. 10, 2023	Aug. 9, 2024	Nov. 24, 2025	365 days	N/A	N/A
BLA 761298	Pavblu®	Aflibercept-ayyh	Amgen, Inc	Aug. 23, 2023	Aug. 23, 2024	Oct. 30, 2024	365 days	434 days	68 days

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
BLA 761379	Otulfi®	Ustekinumab-aauz	Fresenius Kabi USA, LLC	Sep. 28, 2023	Sep. 27, 2024	Mar. 3, 2025	365 days	523 days	158 days
BLA 761364	Imuldosa®	Ustekinumab-srlf	Accord BioPharma, Inc.	Oct. 9, 2023	Oct. 10, 2024	Aug. 18, 2025	366 days	679 days	312 days
BLA 761406	Yesintek®	Ustekinumab-kfce	Biocon Biologics Inc.	Nov. 29, 2023	Nov. 29, 2024	Feb. 24, 2025	366 days	453 days	87 days
BLA 761338	Steqeyma®	Ustekinumab-stba	Celltrion, Inc.	Jun. 30, 2023	Dec. 17, 2024	Mar. 12, 2025	536 days	621 days	85 days
BLA 761420	Avtozma®	Tocilizumab-anoh	Celltrion, Inc.	Jan. 26, 2024	Jan. 24, 2025	Oct. 13, 2025	364 days	626 days	262 days
BLA 761392	Ospomyvtm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 11, 2024	Feb. 13, 2025	Jun. 2, 2025	368 days	477 days	109 days
BLA 761392	Xbryktm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 12, 2024	Feb. 13, 2025	N/A	367 days	N/A	N/A
BLA 761325	Merilog®	Insulin aspart-szjj	Sanofi-Aventis U.S. LLC	Sep. 8, 2022	Feb. 14, 2025	N/A	890 days	N/A	N/A
BLA 761404	Stoboclo®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
BLA 761404	Osenvelt®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
BLA 761399	Omlyclo®	Omalizumab-igec	Celltrion, Inc.	Mar. 8, 2024	Mar. 7, 2025	Sep. 19, 2025	364 days	560 days	196 days
BLA 761398	Bomyntra®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	Jul. 1, 2025	365 days	463 days	98 days

US Biosimilar Approval Statistics (cont.)

aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
BLA 761398	Conexxence®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	Jul. 1, 2025	365 days	463 days	98 days
BLA 761175	Jobevne®	Bevacizumab-nwgd	Biocon Biologics Inc.	Dec. 27, 2019	Apr. 9, 2025	N/A	1930 days	N/A	N/A
BLA 761419	Starjemza®	Ustekinumab-hmny	Bio-Thera Solutions, Ltd.	May 22, 2024	May 22, 2025	Nov. 6, 2025	365 days	533 days	168 days
BLA 761188	Kirsty™	Insulin aspart-xjhz	Biocon Biologics Inc.	Jul. 16, 2020	Jul. 15, 2025	N/A	1825 days	N/A	N/A
BLA 761444	Bildyos® and Bilprevda®	Denosumab-nxxp	Shanghai Henlius Biotech, Inc.	Aug. 30, 2024	Aug. 29, 2025	N/A	364 days	N/A	N/A
BLA 761436	Aukelso® and Bosaya®	Denosumab-kyqq	Biocon Biologics Inc.	Sep. 16, 2024	Sep. 16, 2025	Oct. 1, 2025	365 days	380 days	15 days
BLA 761439	Enoby® and Xtrenbo®	Denosumab-qbde	Hikma Pharmaceuticals USA Inc.	Sep. 27, 2024	Sep. 26, 2025	Jan. 19, 2026	364 days	479 days	115 days
BLA 761377	Eydenzelt®	Aflibercept-boav	Celltrion, Inc.	Jun. 29, 2023	Oct. 2, 2025	N/A	826 days	N/A	N/A
BLA 761450	Poherdy®	Pertuzumab-dpzb	Shanghai Henlius Biotech, Inc.	Nov. 29, 2024	Nov. 13, 2025	N/A	349 days	N/A	N/A
BLA 761212	Armlupeg®	Pegfilgrastim-unne	Lupin Pharmaceuticals, Inc.	Apr. 2, 2021	Nov. 28, 2025	N/A	1701 days	N/A	N/A
BLA 761473	Nufymco®	Ranibizumab-leyk	Formycon AG	Dec. 27, 2024	Dec. 18, 2025	N/A	356 days	N/A	N/A
BLA 761456/ 716457	Boncresa® and Oziltus®	Denosumab-mobz	Amneal Pharmaceuticals	Sep. 27, 2024	Dec. 22, 2025	N/A	451 days	N/A	N/A
BLA 761027	Filkri®	Filgrastim-laha	Accord BioPharma Inc.	Dec. 13, 2014	Jan. 15, 2026	N/A	4042 days	N/A	N/A
						Average:	**609 days**	**857 days**	**368 days**

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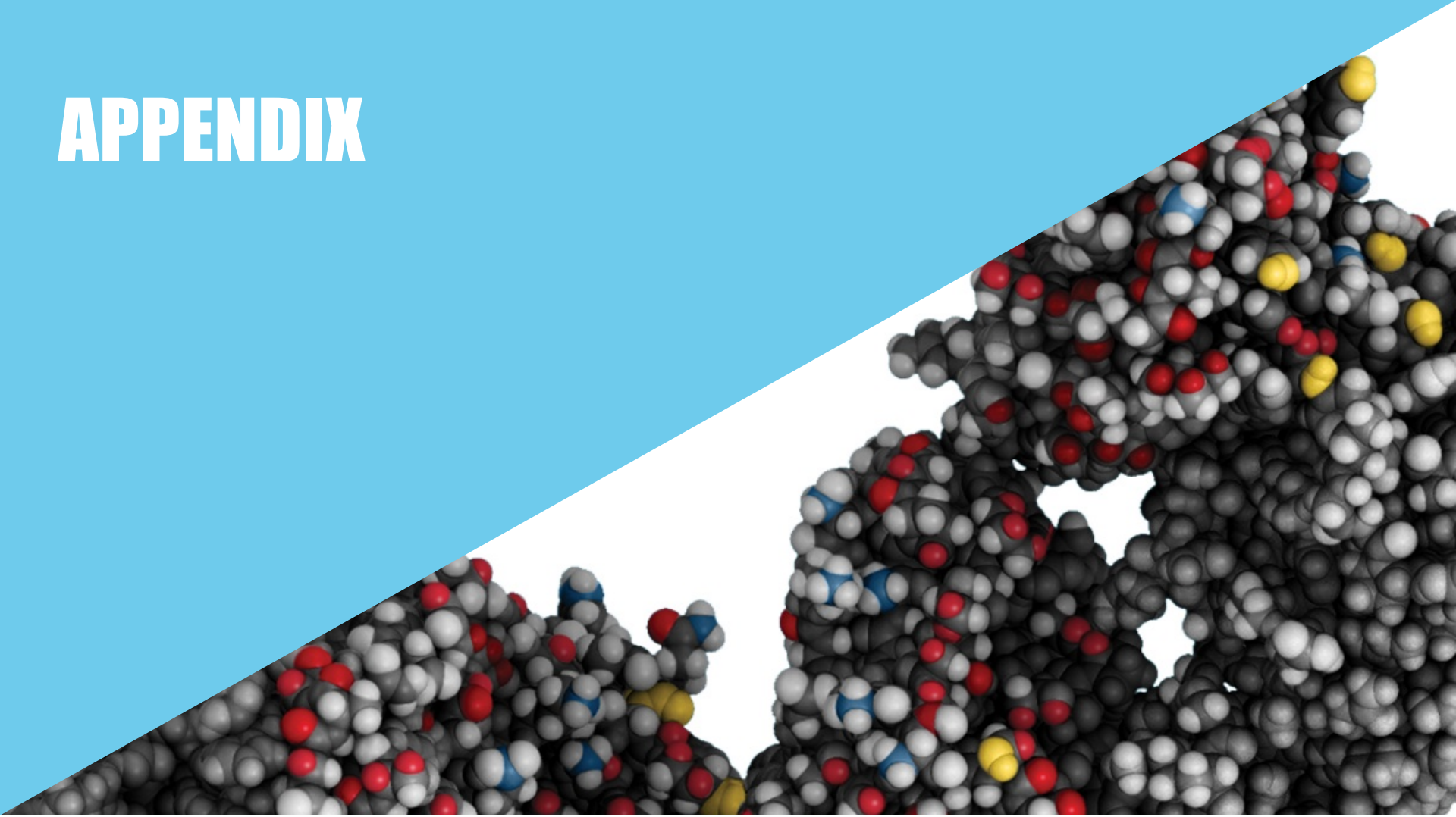
APPENDIX



Legend

P	Petitioner
PO	Patent Owner
2-Consid.	Secondary Considerations raised by PO to support nonobviousness
U	Use
F	Formulation
C	Composition
M	Method
FWD	Final Written Decision
Pending	IPR has been instituted and is pending an FWD
Institution Denied	PTAB has denied institution of IPR
J/W	Joined with
N/A	Not Applicable
Y/N	Yes/No

HUMIRA

Humira-Related IPRs

> 22 IPRs filed challenging 14 different patents

AbbVie Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,916,157	Amgen	2015-01514	1/0	Y	F (20-150 mg)	Institution Denied
8,916,158	Amgen	2015-01517	1/0	Y	F (20-150 mg)	Institution Denied
8,889,135	1) Coherus	1) 2016-00172	1) 2/5	1) Y	1) U (RA)	1) FWD – Claims Invalid (Appealed)
	2) Boehringer Ingelheim	2) 2016-00408	2) 2/5	2) Y	2) U	2) FWD – Claims Invalid (Appealed)
	3) Boehringer Ingelheim	3) 2016-00409	3) 2/5	3) Y	3) U	3) FWD – Claims Invalid (Appealed)
9,017,680	Coherus	2016-00188	3/5	Y	U (RA)	FWD – Claims Invalid (Appealed)
9,073,987	Coherus	2016-00189	3/5	Y	U (RA)	FWD – Claims Invalid (Appealed)

Humira-Related IPRs (cont.)

> 22 IPRs filed challenging 14 different patents

AbbVie Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,114,166	Coherus	2016-01018	2/0	Y	F (50 mg)	Institution Denied
9,085,619	Coherus	1) 2017-00822 2) 2017-00823 3) 2017-00826 4) 2017-00827 5) 2017-01008 6) 2017-01009	1) 1/0 2) 1/0 3) 2/NA 4) 2/NA 5) 2/0 6) 2/0	1) Y 2) N 3) Y 4) Y 5) Y 6) Y	F (Bufferless)	1-2) Institution Denied 3-4) IPRs Dismissed April 11, 2017* 5-6) Institution Denied
9,067,992	Sandoz	2017-02106	1/1	Y	U (Psoriatic arthritis)	Terminated Due to Settlement
8,911,737	Sandoz	2017-01987	6/0	Y	U (Crohn's)	Institution Denied
8,974,790	Sandoz	2017-01988	6/0	Y	U (Ulcerative colitis)	Institution Denied
9,090,689	Sandoz	2017-02105	3/2	Y	U (Plaque psoriasis)	Terminated Due to Settlement

*** IPRs 2017-01008 & 2017-01009 replaced IPRs 2017-00826 & 2017-00827**

Humira-Related IPRs (cont.)

> 22 IPRs filed challenging 14 different patents

AbbVie Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,802,100	Sandoz	2017-01823	1/0	N	F (45-150 mg)	Institution Denied
9,512,216	Sandoz	1) 2017-01824 2) 2018-00002	1) 2/0 2) 2/0	1) Y 2) Y	U (Plaque psoriasis)	1) Institution Denied 2) Institution Denied
9,187,559	Sandoz	2018-00156	2/0	Y	U (IBD)	Institution Denied

8,916,157 Patent IPR

Representative Claim

1. A stable liquid aqueous pharmaceutical formulation comprising:
   a) a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody, or an antigen-binding portion thereof, at a concentration of 20 mg/ml to 150 mg/ml;
   b) a tonicity agent;
   c) a surfactant; and
   d) a buffer system having a pH of 4.0 to 8.0, wherein the antibody comprises the light chain variable region (LCVR) and the heavy chain variable region (HCVR) of D2E7.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2015-01514	1-8, 10-13, 15-30	None	1/0	Y	F	Institution Denied

8,916,158 Patent IPR

Representative Claim

1. A stable liquid aqueous pharmaceutical formulation comprising:
   a) a human IgG1 anti-human TNFα antibody, or an antigen-binding portion thereof, at a concentration of 20 mg/ml to 150 mg/ml;
   b) a tonicity agent;
   c) a surfactant; and
   d) a buffer system having a pH of 4.0 to 8.0, wherein the antibody comprises the LCVR and HCVR of D2E7.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2015-01517	1-4, 9-18, 20-30	None	1/0	Y	F	Institution Denied

8,889,135 Patent IPRs

Representative Claim

1. A method for treating rheumatoid arthritis in a human subject by administering subcutaneously a total body dose of 40 mg of a human anti-TNFα antibody once every 13–15 days for a period sufficient to treat the rheumatoid arthritis, wherein the anti-TNFα antibody comprises an IgG1 heavy chain constant region; a variable light (V_L) chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a variable heavy (V_H) chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2016-00172	1-5	§ 103 for all claims	2/5	Y	U	FWD – Claims Invalid (Appealed)
Boehringer Ingelheim	2016-00408	1-5	§ 103 for all claims	2/5	Y	U	FWD – Claims Invalid (Appealed)
Boehringer Ingelheim	2016-00409	1-5	§ 103 for all claims	2/5	Y	U	FWD – Claims Invalid (Appealed)

9,017,680 Patent IPR

Representative Claim

1. A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, comprising:

   a) administering to said patient, in combination with methotrexate, a human anti-TNFα antibody;

   b) wherein the human anti-TNFα antibody is administered subcutaneously in a total body dose of 40 mg once every 13–15 days; and

   c) wherein the anti-TNFα antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2016-00188	1-4	§ 103 for all claims	3/5	Y	U	FWD – Claims Invalid (Appealed)

9,073,987 Patent IPR

Representative Claim

1. A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, comprising:

   a) administering to said patient a total body dose of 40 mg of a human anti-TNFα antibody;

   b) wherein the dose is administered subcutaneously in a 40 mg dosage unit form once every 13–15 days; and

   c) wherein the anti-TNFα antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2016-00189	1-2	§ 103 for all claims	3/5	Y	U	FWD – Claims Invalid (Appealed)

9,114,166 Patent IPR

Representative Claim

1. A stable liquid aqueous pharmaceutical formulation comprising a human anti-human TNFα IgG1 antibody at a concentration of 50 mg/ml, wherein the antibody comprises the LCVR and HCVR of D2E7, and a buffer system; wherein the formulation is isotonic, suitable for single-use subcutaneous injection, and has a pH of 4.0 to 8.0.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2016-01018	1-4, 6-10, 13-16, 23-26, 28	None	2/0	Y	F	Institution Denied

9,085,619 Patent IPRs

Representative Claim

16. An aqueous pharmaceutical formulation comprising:

a) an anti-TNFα antibody comprising an LCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:7; and an HCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:8, wherein the concentration of the antibody is 50 mg/ml to 200 mg/ml; and

b) water; wherein the formulation does not comprise a buffering system.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2017-00822	16-19, 24-30	NA	1/0	Y	F	Institution Denied
Coherus	2017-00823	16-19, 24-30	NA	1/0	N	F	Institution Denied

9,085,619 Patent IPRs (cont.)

Representative Claim

16. An aqueous pharmaceutical formulation comprising:

a) an anti-TNFα antibody comprising an LCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:7; and an HCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:8, wherein the concentration of the antibody is 50 mg/ml to 200 mg/ml; and

b) water; wherein the formulation does not comprise a buffering system.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2017-00826	16-19, 24-30	NA	2/NA	Y	F	Dismissed
Coherus	2017-00827	16-19, 24-30	NA	2/NA	Y	F	Dismissed
Coherus	2017-01008	16-19, 24-30	NA	2/0	Y	F	Institution Denied
Coherus	2017-01009	16-19, 24-30	NA	2/0	Y	F	Institution Denied

9,067,992 Patent IPR

Representative Claim

1. A method of treatment of moderate to severe active psoriatic arthritis in adult patients, wherein each said patient has ≧3 swollen and ≧3 tender joints prior to the treatment and has failed NSAID therapy, comprising administering subcutaneously to each said patient 40 mg of adalimumab every other week, wherein 23% of said patients achieve 70% reduction in American College of Rheumatology (ACR) score at week 24 of the treatment.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-02106	1, 2, 5-7	§ 102 for claims 1, 5, 6; § 103 for all claims	1/1	Y	U	Terminated

8,911,737 Patent IPR

Representative Claim

1. A method for treating Crohn's disease in a human subject by administering subcutaneously a total body dose of 40 mg of a human anti-TNFα antibody once every 13–15 days for a period sufficient to treat Crohn's disease, wherein the anti-TNFα antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-01987	1-6	NA	6/0	Y	U	Institution Denied

8,974,790 Patent IPR

Representative Claim

1. A method for treating ulcerative colitis in a human subject by administering subcutaneously a total body dose of 40 mg of a human anti-TNFα antibody once every 13–15 days for a period sufficient to treat the ulcerative colitis, wherein the anti-TNFα antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-01988	1-6	NA	6/0	Y	U	Institution Denied

9,090,689 Patent IPR

Representative Claim

1. A method of administering adalimumab for treatment of moderate to severe chronic plaque psoriasis by filling adalimumab into vessels and administering subcutaneously 40 mg of said adalimumab every other week.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-02105	1, 4, 7, 10, 13, 16, 19	§ 103 for all claims	3/2	Y	U	Terminated

8,802,100 Patent IPR

Representative Claim

1. A stable liquid aqueous pharmaceutical formulation comprising:
   a) a human IgG1 anti-human TNFα antibody, or an antigen-binding portion thereof, at a concentration of 45 mg/ml to 150 mg/ml;
   b) a polyol;
   c) a polysorbate at a concentration of 0.1 mg/ml to 10 mg/ml; and
   d) a buffer system having a pH of 4.5 to 7.0, wherein the antibody comprises the LCVR and HCVR of D2E7.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-01823	1-29	NA	1/0	N	F	Institution Denied

9,512,216 Patent IPRs

Representative Claim

1. A method for treating moderate to severe chronic plaque psoriasis by administering subcutaneously to an adult patient an initial dose of 80 mg of adalimumab, followed by 40 mg of adalimumab every other week, starting one week after said first dosing, wherein the patient achieves at least Psoriasis Area and Severity Index (PASI) 75 response at week 12 of the treatment.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-01824	1-16	NA	2/0	Y	U	Institution Denied
Sandoz	2018-00002	1-16	NA	2/0	Y	U	Institution Denied

9,187,559 Patent IPR

Representative Claim

1. A multiple-variable dose method for treating idiopathic inflammatory bowel disease in a human subject in need thereof, comprising administering subcutaneously to the human subject:
    a) a first dose of 160 mg of adalimumab administered to the human subject within a day; and
    b) a second dose of 80 mg of adalimumab administered to the human subject within a day, wherein the second dose is administered two weeks following administration of the first dose.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2018-00156	1-30	NA	2/0	Y	U	Institution Denied

RITUXAN

Rituxan-Related IPRs

> 27 IPRs filed challenging 10 different patents

Genentech/ Biogen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,820,161	1) BI	1) 2015-00415	1) 1/0	1) Y	1) U (RA)	1) Petitioner's adverse judgment
	2) Celltrion	2) 2015-01744	2) 1/0	2) Y	2) U	2) Dismissed
	3) Celltrion	3) 2016-01614	3) 2/1	3) Y	3) U	3) FWD – Claims Valid
	4) Pfizer	4) 2017-01115	4) 3/NA	4) Y	4) U	4) FWD – Claims Valid (J/W '614)
7,976,838	1) BI	1) 2015-00417	1) 1/0	1) Y	1) U (RA)	1) Petitioner's adverse judgment
	2) Celltrion	2) 2015-01733	2) 1/0	2) Y	2) U	2) Dismissed
	3) Celltrion	3) 2016-01667	3) 2/0	3) Y	3) U	3) Institution Denied
	4) Pfizer	4) 2017-01923	4) 3/1	4) Y	4) U	4) Terminated – Settled
	5) Sandoz	5) 2017-02042	5) 2/0	5) Y	5) U	5) Institution Denied
	6) Sandoz	6) 2017-02036	6) 2/0	6) Y	6) U	6) Institution Denied
	7) Celltrion	7) 2018-01019	7) 3/0	7) Y	7) U	7) Terminated – Settled (J/W 2017-01923)

Rituxan-Related IPRs (cont.)

> 27 IPRs filed challenging 10 different patents

Genentech/ Biogen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,329,172	1) BI	1) 2015-00418	1) 1/0	1) Y	1) U (lymphoma)	1) Institution Denied
	2) Celltrion	2) 2017-01093	2) 2/0	2) Y	2) U	2) Institution Denied
	3) Pfizer	3) 2017-01166	3) 2/0	3) Y	3) U	3) Institution Denied
	4) Pfizer	4) 2018-00285	4) 2/1	4) Y	4) U	4) Terminated – Settled
8,557,244	1) Celltrion	1) 2017-01094	1) 2/0	1) Y	1) U (lymphoma)	1) Institution Denied (Request for Rehearing Denied)
	2) Pfizer	2) 2017-01167	2) 2/0	2) Y	2) U	2) Institution Denied
9,296,821	1) Celltrion	1) 2017-01095	1) 2/0	1) Y	1) U (lymphoma)	1) FWD – Claims Invalid
	2) Pfizer	2) 2018-00186	2) 2/1	2) Y	2) U	2) Terminated

Rituxan-Related IPRs (cont.)

> 27 IPRs filed challenging 10 different patents

Genentech/ Biogen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,682,612	1) Celltrion 2) Celltrion 3) Pfizer	1) 2017-01227 2) 2017-01230 3) 2017-02126	1) 1/0 2) 1/0 3) 2/0	1) Y 2) Y 3) Y	1) U (leukemia) 2) U 3) U	1) Institution Denied 2) Institution Denied 3) Institution Denied
8,206,711	1) Celltrion 2) Pfizer	1) 2017-01229 2) 2017-02127	1) 1/0 2) 2/0	1) Y 2) Y	1) U (leukemia) 2) U	1) Institution Denied 2) Institution Denied
8,821,873	Pfizer	2017-01168	2/1	Y	U (lymphoma)	FWD – Claims Invalid
8,545,843	Pfizer	2018-00086	2/0	Y	U (vasculitis)	Institution Denied
9,504,744	Pfizer	2018-00231	2/0	Y	U (lymphoma)	Terminated

7,820,161 Patent IPRs

Representative Claim

1. A method of treating rheumatoid arthritis in a human by administering:
   a) more than one intravenous dose of a therapeutically effective amount of rituximab; and
   b) methotrexate.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Boehringer Ingelheim	2015-00415	1-12	§ 103 for claims 1, 2, 5, 6, 9, 10	1/0	Y	U	Adverse Judgment
Celltrion	2015-01744	1, 2, 5, 6, 9, 10	None	1/0	Y	U	Dismissed

7,820,161 Patent IPRs (cont.)

Representative Claim

1. A method of treating rheumatoid arthritis in a human by administering:
   a) more than one intravenous dose of a therapeutically effective amount of rituximab; and
   b) methotrexate.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2016-01614	1-12	§ 103 for claims 1-3, 5-7, 9-11	2/1	Y	U	FWD – Claims Valid Celltrion's appeal dismissed as part of litigation settlement (Case No. 18-574-RMB-KMW (D.N.J.))
Pfizer	2017-01115	1-12	§ 103	3/NA	Y	U	FWD – Claims Valid (J/W '614)

7,976,838 Patent IPRs

Representative Claim

1. A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor by administering an antibody that binds to CD20, wherein the antibody is administered as two intravenous doses of 1,000 mg.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Boehringer Ingelheim	2015-00417	1-14	§ 103 for all claims	1/0	Y	U	Adverse Judgment
Celltrion	2015-01733	1-14	NA	1/0	Y	U	Dismissed
Celltrion	2016-01667	1-14	NA	2/0	Y	U	Institution Denied
Pfizer	2017-01923	1-14	§ 103 for all claims	3/1	Y	U	Terminated – Settled

7,976,838 Patent IPRs (cont.)

Representative Claim

1. A method of treating rheumatoid arthritis in a human patient who experiences an inadequate response to a TNFα-inhibitor by administering an antibody that binds to CD20, wherein the antibody is administered as two intravenous doses of 1,000 mg.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sandoz	2017-02036	1-14	NA	2/0	Y	U	Institution Denied
Sandoz	2017-02042	1-14	NA	2/0	Y	U	Institution Denied
Celltrion	2018-01019	1-14	§ 103 for all claims	3/0	Y	U	Terminated – Settled (J/W 2017-01923)

8,329,172 Patent IPRs

Representative Claim

1. A method of treating low-grade, B-cell non-Hodgkin's lymphoma (NHL) in a human patient by administering chemotherapy consisting of cyclophosphamide, vincristine, and prednisone (CVP therapy) to which the patient responds, followed by rituximab maintenance therapy, wherein the maintenance therapy comprises four weekly administrations of rituximab at a dose of 375 mg/m^2 every six months, and wherein the maintenance therapy is provided for two years.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Boehringer Ingelheim	2015-00418	1	NA	1/0	Y	U	Institution Denied
Celltrion	2017-01093	1	NA	2/0	Y	U	Institution Denied
Pfizer	2017-01166	1	NA	2/0	Y	U	Institution Denied
Pfizer	2018-00285	1	§ 103	2/1	Y	U	Terminated – Settled

8,557,244 Patent IPRs

Representative Claim

1. A method of treating a patient with diffuse, large-cell lymphoma by administering an unlabeled chimeric anti-CD20 antibody and CHOP (cyclophosphamide, hydroxydaunorubicin/doxorubicin, vincristine, and prednisone/prednisolone) chemotherapy to the patient, wherein the patient is >60 years old and has bulky disease (tumor >10 cm in diameter).

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2017-01094	1-2	NA	2/0	Y	U	Institution Denied (Request for Rehearing Denied)
Pfizer	2017-01167	1-2	NA	2/0	Y	U	Institution Denied

9,296,821 Patent IPRs

Representative Claim

1. A method for treating low-grade or follicular NHL by administering to a patient a therapeutically effective amount of rituximab during a chemotherapeutic regimen, wherein the chemotherapeutic regimen consists of CVP therapy, wherein the method comprises administering 375 mg/m^2 of rituximab, and wherein the method provides a beneficial synergistic effect in the patient.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2017-01095	1-6	§ 102 for all claims; § 103 for all claims	2/0	Y	U	FWD – Claims Invalid
Pfizer	2018-00186	1-6	§ 102 for claims 4-6; § 103 for all claims	2/1	Y	U	Terminated

7,682,612 Patent IPRs

Representative Claim

1. A method of treating chronic lymphocytic leukemia (CLL) in a human patient by administering an anti-CD20 antibody in an amount effective to treat the CLL, wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2017-01227	23-57	NA	1/0	Y	U	Institution Denied
Celltrion	2017-01230	1-22, 58-60	NA	1/0	Y	U	Institution Denied
Pfizer	2017-02126	1-13, 15-35, 37-60	NA	2/0	Y	U	Institution Denied

8,206,711 Patent IPRs

Representative Claim

1. A method of treating CLL in a human patient by administering rituximab in an amount effective to treat the CLL, wherein the rituximab is administered to the patient at a dosage of 500 mg/m^2.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2017-01229	1-9	NA	1/0	Y	U	Institution Denied
Pfizer	2017-02127	1-9	NA	2/0	Y	U	Institution Denied

8,821,873 Patent IPR

Representative Claim

1. A method of treating a patient with diffuse, large-cell lymphoma by administering anti-CD20 antibody and chemotherapy, wherein the patient is >60 years old, wherein the chemotherapy comprises CHOP, and wherein the anti-CD20 antibody is administered in combination with a stem cell transplantation regimen.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-01168	1-5	§ 103	2/1	Y	U	FWD – Claims Invalid

8,545,843 Patent IPR

Representative Claim

1. A method of treating vasculitis in a human who does not have rheumatoid arthritis or cancer comprising administering to the human a therapeutically effective amount of rituximab, wherein the administration of the rituximab consists of intravenous administration.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2018-00086	1-12	NA	2/0	Y	U	Institution Denied

9,504,744 Patent IPR

Representative Claim

1. A method of treating a >60-year-old diffuse, large-cell lymphoma patient comprising administering anti-CD20 antibody and CHOP chemotherapy to the patient, wherein the anti-CD20 antibody is administered to the patient in combination with a transplantation regimen.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2018-00231	1-16	NA	2/0	Y	U	Terminated

HERCEPTIN

Herceptin-Related IPRs

> 36 IPRs filed challenging 12 different patents

Genentech Patent	Challenger(s)	IPR No.	# P/PO Experts	2-Consid.	Claim Type	Status
8,337,856 (Kadcyla)	Phigenix	2014-00676	1/4	Y	C	FWD – Claims Valid
7,575,748	Phigenix	2014-00842	1/0	Y	U	Institution Denied
6,407,213	1) Mylan	1) 2016-01693	1) 2/0	1) Y	1) C	1) Terminated (Settled)
	2) Mylan	2) 2016-01694	2) 2/0	2) Y	2) C	2) Terminated (Settled)
	3) Celltrion	3) 2017-01373	3) 2/4	3) Y	3) C	3) FWD – Claims Invalid (some)
	4) Celltrion	4) 2017-01374	4) 2/4	4) Y	4) C	4) FWD – Claims Invalid (some)
	5) Pfizer	5) 2017-01488	5) 2/1	5) Y	5) C	5) FWD – Claims Invalid (some)
	6) Pfizer	6) 2017-01489	6) 2/1	6) Y	6) C	6) FWD – Claims Invalid (some)
	7) Boehringer Ingelheim	7) 2017-02032	7) 1/0	7) Y	7) C	7) Adverse Judgment
	8) Boehringer Ingelheim	8) 2017-02031	8) 1/0	8) Y	8) C	8) Adverse Judgment
	9) Samsung Bioepis	9) 2017-02139	9) 4/NA	9) Y	9) C	9) FWD – Claims Invalid (some) (J/W '488)
	10) Samsung Bioepis	10) 2017-02140	10) 4/NA	10) Y	10) C	10) FWD – Claims Invalid (some) (J/W '489)

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

Genentech Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,807,799	Hospira	2016-01837	1/2	Y	M	FWD – Claims Invalid (Appealed)
7,846,441	1) Hospira 2) Celltrion 3) Pfizer 4) Pfizer 5) Samsung Bioepis	1) 2017-00731 2) 2017-01121 3) 2017-02063 4) 2018-00016 5) 2018-00192	1) 4/2 2) 3/2 3) 1/NA 4) 1/1 5) 2/0	1) Y 2) Y 3) Y 4) Y 5) Y	1) U 2) U 3) U 4) U 5) U	1) FWD – Claims Invalid (Appealed) 2) FWD – Claims Invalid (Appealed) 3) FWD – Claims Invalid (J/W '121) 4) Institution Denied 5) Institution Denied
6,627,196	1) Hospira 2) Samsung Bioepis 3) Celltrion	1) 2017-00804 2) 2017-01958 3) 2017-01139	1) 2 2) 3/NA 3) 1/2	1) Y 2) Y 3) Y	1) U 2) U 3) U	1) FWD – Claims Valid (Appealed) 2) FWD – Claims Valid (J/W '804) 3) FWD – Claims Valid (Appealed)

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

Genentech Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,371,379	1) Hospira 2) Samsung Bioepis 3) Celltrion	1) 2017-00805 2) 2017-01959 3) 2017-01140	1) 2 2) 2/NA 3) 1/0	1) Y 2) Y 3) Y	1) U 2) U 3) U	1) FWD – Claims Valid (Appealed) 2) FWD – Claims Valid (J/W '805) 3) FWD – Claims Valid (Appealed)
8,591,897	1) Pfizer 2) Pfizer 3) Celltrion	1) 2017-01726 2) 2017-01727 3) 2017-00959	1) 3/NA 2) 3/NA 3) 1/NA	1) Y 2) Y 3) Y	1) U 2) U 3) U	1) Institution Denied 2) Institution Denied 3) Adverse Judgment
6,339,142	1) Pfizer 2) Pfizer	1) 2017-02019 2) 2018-00330	1) 2/3 2) 3/0	1) Y 2) Y	1) C 2) C	1) Terminated 2) Institution Denied
9,249,218	1) Pfizer 2) Pfizer	1) 2017-02020 2) 2018-00331	1) 2/3 2) 1/0	1) Y 2) Y	1) C 2) C	1) Terminated 2) Institution Denied

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

Genentech Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,892,549	1) Hospira 2) Hospira 3) Celltrion 4) Samsung Bioepis	1) 2017-00737 2) 2017-00739 3) 2017-01122 4) 2017-01960	1) 1/2 2) 1/0 3) 1/2 4) 2/NA	1) Y 2) N 3) Y 4) Y	1) U 2) U 3) U 4) U	1) FWD – Claims Invalid (Appealed) 2) Institution Denied 3) FWD – Claims Invalid (Appealed) 4) FWD – Claims Invalid (J/W '737)
8,314,225* *Also being asserted regarding Rituxan and Avastin	Pfizer	2018-01219	1/0	Y	C	Terminated After Institution (Settled)

8,337,856 Patent IPR

Representative Claim

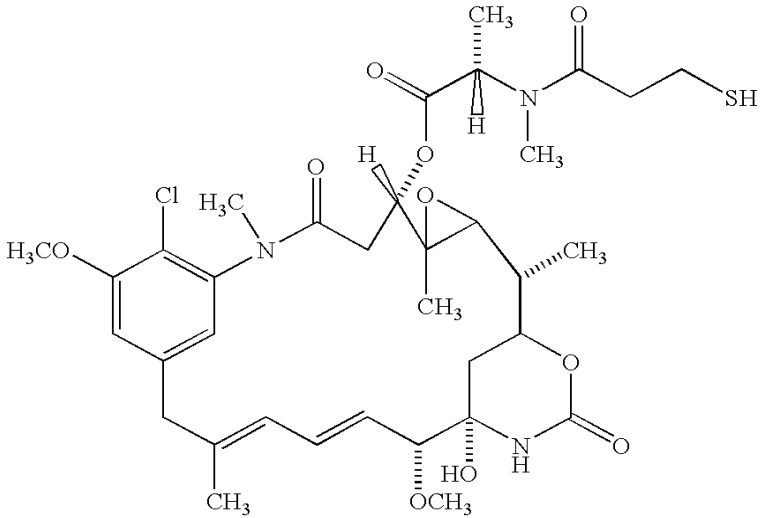
1. An immunoconjugate comprising an anti-ErbB2 antibody conjugated to a maytansinoid, wherein the antibody is huMAb4D5-8.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Phigenix	2014-00676	1-8	§ 103 for all claims	1/4	Y	C	FWD – Claims Valid

7,575,748 Patent IPR

Representative Claim

1. A method for the treatment of a tumor in a mammal, comprising the steps of: (i) identifying said tumor as being characterized by overexpression of an ErbB2 receptor and as being a tumor that does not respond, or responds poorly, to treatment with an anti-ErbB antibody; and (ii) intravenously administering to the mammal a therapeutically effective amount of a conjugate of a humanized antibody huMab 4D5-8 covalently linked via a thioether linking group with a maytansinoid DM1 having the structure at a dose of between about 0.2 mg/kg and about 10 mg/kg (antibody-maytansinoid conjugate weight/body weight) and at a frequency of dosing selected from the group of dosing frequencies consisting of bolus, less than about one time per week, one time per week, two times per week, more than two times per week, and continuous infusion, whereby said tumor, characterized by overexpression of an ErbB2 receptor and that does not respond, or responds poorly, to treatment with an anti-ErbB antibody, is treated.



Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Phigenix	2014-00842	1-20, 25-27	NA	1/0	Y	U	Institution Denied

6,407,213 Patent IPRs

Representative Claim

1. A humanized antibody variable domain comprising non-human Complementarity Determining Region (CDR) amino acid residues that bind an antigen incorporated into a human antibody variable domain, and further comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of 4L, 38L, 43L, 44L, 58L, 62L, 65L, 66L, 67L, 68L, 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, and 92H, utilizing the numbering system set forth in Kabat.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2016-01693	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	NA	2/0	Y	C	Settled
Mylan	2016-01694	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	NA	2/0	Y	C	Settled
Celltrion	2017-01373	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	§ 103 for all claims	2/4	Y	C	FWD – Claims Invalid (1-2, 4, 12, 25, 29-30, 31, 33, 42, 60, 62-64, 66-67, 69, 71, 73-74, 78, 80, 81)
Celltrion	2017-01374	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	§ 102 for claims 1,-2, 4, 25, 29, 62-64, 66, 67, 71-72, 75-76, 80-81; § 103 for claims 1-2, 4, 12, 25, 29-30, 31, 33, 42, 60, 62-67, 69, 71-81	2/4	Y	C	FWD – Claims Invalid (1-2, 4, 25, 29, 30-31, 33, 62-64, 66-67, 69, 72, 78, 80, 81)

6,407,213 Patent IPRs (cont.)

Representative Claim

1. A humanized antibody variable domain comprising non-human CDR amino acid residues that bind an antigen incorporated into a human antibody variable domain, and further comprising an FR amino acid substitution at a site selected from the group consisting of 4L, 38L, 43L, 44L, 58L, 62L, 65L, 66L, 67L, 68L, 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, and 92H, utilizing the numbering system set forth in Kabat.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-01488	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	§ 102 for claims 1-2, 4, 25, 29, 62-64, 66-67, 71-72, 75-76, 80-81; § 103 for claims 1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	2/1	Y	C	FWD – Claims Invalid (1-2, 4, 25, 29-31, 33, 62-64, 66-67, 69, 72, 78, 80-81)
Pfizer	2017-01489	1-2, 4, 12, 25, 29, 62-67, 69, 71-81	§ 103 for all claims	2/1	Y	C	FWD – Claims Invalid (1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-64, 66-67, 69, 71, 73-74, 78, 80-81)
Boehringer Ingelheim	2017-02032	1-2, 4, 25, 29, 62-64, 66-67, 71-73, 75-78, 80-81	§ 102 for claims 1-2, 4, 25, 62-64, 66-67, 69, 71, 73, 75, 78, 80-81; § 103 for claims 1-2, 4, 25, 29, 62-64, 66-67, 69, 71-73, 75-78, 80-81	1/0	Y	C	Adverse Judgment

6,407,213 Patent IPRs (cont.)

Representative Claim

1. A humanized antibody variable domain comprising non-human CDR amino acid residues that bind an antigen incorporated into a human antibody variable domain, and further comprising an FR amino acid substitution at a site selected from the group consisting of 4L, 38L, 43L, 44L, 58L, 62L, 65L, 66L, 67L, 68L, 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, and 92H, utilizing the numbering system set forth in Kabat.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Boehringer Ingelheim	2017-02031	1-2, 4, 25, 29, 62-64, 66-67, 69, 71, 75-76, 78, 80-81	§ 102 for claim 63; § 103 for claims 1-2, 4, 25, 29, 62, 64, 66, 69, 71, 73, 75-78, 80-81	1/0	Y	C	Adverse Judgment
Samsung Bioepis	2017-02139	1-2, 4, 12, 25, 29, 62-64, 66-67, 69, 71-72, 75-76, 80-81	§ 102 for claims 1-2, 4, 25, 29, 62-64, 66-67, 71-72, 75-76, 80-81; § 103 for claims 1-2, 4, 12, 25, 29, 30, 31, 33, 42, 60, 62-67, 69, 71-81	4/NA	Y	C	FWD – Claims Invalid (1-2, 4, 25, 29, 30-31, 33, 62-64, 66-67, 69, 72, 78, 80-81) (J/W '488)
Samsung Bioepis	2017-02140	1-2, 4, 12, 25, 29, 62-67, 69, 71-81	NA	4/NA	Y	C	FWD – Claims Invalid (1-2, 4, 12, 25, 29, 30-31, 33, 42, 60, 62-64, 66-67, 69, 71, 73-74, 78, 80-81) (J/W '489)

7,807,799 Patent IPR

Representative Claim

1. A method of purifying a protein that comprises a CH2/CH3 region by subjecting a composition of said protein to protein A affinity chromatography at a temperature in the range from about 10°C to about 18°C.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2016-01837	1-3, 5-11	§ 102 for claims 1, 2, 5; § 103 for claims 1-3, 5-11	1/2	Y	M	FWD – Claims Invalid Affirmed on Appeal

7,846,441 Patent IPRs

Representative Claim

1. A method for the treatment of a human patient with a malignant progressing tumor or cancer characterized by an overexpression of an ErbB2 receptor by administering a combination of an intact antibody that binds to epitope 4D5 within the ErbB2 extracellular domain sequence and a taxoid, in the absence of anthracycline derivative, to the human patient in an amount effective to extend the time to disease progression in said human patient, without increase in overall severe adverse events.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2017-00731	1-14	§ 103	4/2	Y	U	FWD – Claims Invalid (Appealed)
Celltrion	2017-01121	1-14	§ 103	3/2	Y	U	FWD – Claims Invalid (Appealed)
Pfizer	1) 2017-02063 2) 2018-00016	1) 1-14 2) 1-14	1) § 103 2) NA	1/NA 1/1	1) Y 2) Y	1) U 2) U	1) FWD – Claims Invalid (J/W '121) 2) Institution Denied
Samsung Bioepis	2018-00192	1-14	NA	2/0	Y	U	Institution Denied

7,892,549 Patent IPRs

Representative Claim

1. A method for the treatment of a human patient with breast cancer that overexpresses an ErbB2 receptor, comprising administering a combination of an antibody that binds ErbB2, a taxoid, and a further growth inhibitory agent to the human patient in an amount effective to extend the time to disease progression in the human patient, wherein the antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2017-00737	1-17	§ 103	1/2	Y	U	FWD – Claims Invalid (Appealed) Denied PO's Motion to Amend
Hospira	2017-00739	1-11, 14-17	NA	1/0	N	U	Institution Denied

7,892,549 Patent IPRs (cont.)

Representative Claim

1. A method for the treatment of a human patient with breast cancer that overexpresses an ErbB2 receptor, comprising administering a combination of an antibody that binds ErbB2, a taxoid, and a further growth inhibitory agent to the human patient in an amount effective to extend the time to disease progression in the human patient, wherein the antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2017-01122	1-11, 14-17	§ 103	1/2	Y	U	FWD – Claims Invalid (Appealed)
Samsung Bioepis	2017-01960	1-17	§ 103	2/NA	Y	U	FWD – Claims Invalid (J/W '737)

6,627,196 Patent IPRs

Representative Claim

1. A method for the treatment of a human patient diagnosed with cancer characterized by an expression of an ErbB2 receptor by administering an effective amount of an anti-ErbB2 antibody to the human patient, giving:
   a) an initial dose of at least approximately 5 mg/kg of the anti-ErbB2 antibody; and
   b) a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose, wherein the subsequent doses are separated in time from each other by at least two weeks.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2017-00804	1-3, 5, 7, 9-11, 17-33	§ 103	2	Y	U	FWD – Claims Valid (Appealed)
Samsung Bioepis	2017-01958	1-3, 5, 7, 9-11, 17-33	§ 103	3/NA	Y	U	FWD – Claims Valid (J/W '804)
Celltrion	2017-01139	1-3, 5, 7, 9-11, 17-33	§ 103	1/2	Y	U	FWD – Claims Valid (Appealed)

7,371,379 Patent IPRs

Representative Claim

1. A method for the treatment of a human patient diagnosed with cancer characterized by an overexpression of an ErbB2 receptor by administering an effective amount of an anti-ErbB2 antibody to the human patient, giving:
   a) an initial dose of at least approximately 5 mg/kg of the anti-ErbB2 antibody;
   b) a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose, wherein the subsequent doses are separated in time from each other by at least two weeks; and
   c) an effective amount of a chemotherapeutic agent.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2017-00805	1-3, 5, 7, 9-11, 16-28, 30-40	§ 103	2	Y	U	FWD – Claims Valid (Appealed)
Celltrion	2017-01140	1-3, 5, 7, 9-11, 13-28, 30-40	§ 103	1/0	Y	U	FWD – Claims Valid (Appealed)

7,371,379 Patent IPRs (cont.)

Representative Claim

1. A method for the treatment of a human patient diagnosed with cancer characterized by an overexpression of an ErbB2 receptor by administering an effective amount of an anti-ErbB2 antibody to the human patient, giving:
   a) an initial dose of at least approximately 5 mg/kg of the anti-ErbB2 antibody;
   b) a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose, wherein the subsequent doses are separated in time from each other by at least two weeks; and
   c) an effective amount of a chemotherapeutic agent.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Samsung Bioepis	2017-01959	1-3, 5, 7, 9-11, 16-28, 30-40	NA	2/NA	Y	U	FWD – Claims Valid (J/W '805)

8,591,897 Patent IPRs

Representative Claim

1. A method of adjuvant therapy by administering to a human subject with nonmetastatic HER2 positive breast cancer, following definitive surgery, anthracycline/cyclophosphamide (AC) based chemotherapy, followed by sequential administration of a taxoid and trastuzumab, or an antibody that blocks binding of trastuzumab to HER2.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-01726	1-13	NA	3/NA	Y	U	Institution Denied
Pfizer	2017-01727	1-13	NA	3/NA	Y	U	Institution Denied
Celltrion	2017-00959	1-13	NA	1/NA	Y	U	Terminated – Adverse Judgment

6,339,142 Patent IPRs

Representative Claim

1. A composition of a mixture of anti-HER2 antibody and one or more acidic variants thereof, wherein the amount of the acidic variant(s) is less than about 25%.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-02019	1-3	NA	2/3	Y	C	Terminated
Pfizer	2018-00330	1-3	NA	3/0	Y	C	Institution Denied

9,249,218 Patent IPRs

Representative Claim

1. A therapeutic composition of a mixture of anti-HER2 antibody and one or more acidic variants thereof, wherein:
   a) the amount of the acidic variant(s) is less than about 25%;
   b) the acidic variant(s) are predominantly deamidated variants, wherein one or more asparagine residues of the anti-HER2 antibody have been deamidated;
   c) the anti-HER2 antibody is humMAb4D5-8;
   d) the deamidated variants have Asn30 in CDR1 of either or both VL regions of humMAb4D5-8 converted to aspartate; and
   e) a pharmaceutically acceptable carrier.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-02020	1, 5-7	NA	2/3	Y	C	Terminated
Pfizer	2018-00331	1-20	NA	1/0	Y	C	Institution Denied

8,314,225 Patent IPR*

Representative Claim

1. A nucleic acid encoding the amino acid sequence of the C-terminal part of the CH3-domain of an immunoglobulin of the class IgA or IgG, or the amino acid sequence of the C-terminal part of the CH4-domain of an immunoglobulin of the class IgE or IgM, wherein the glycine-lysine-dipeptide comprised in said amino acid sequence of the C-terminal part of the CH3- or CH4-domain is encoded by one of the following nucleic acid sequences: ggaaca, ggcaac, gggaaa, ggaaag, ggcaag, and gggaag; the nucleic acid ggaaaa; or the nucleic acid ggcaaa.

*Also being asserted regarding Rituxan and Auastin

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2018-01219	1-5, 10-12, 20	§§ 102, 103 for claim 20	1/0	Y	C	Terminated After Institution (Settled)

TYSABRI

Tysabri-Related IPRs

> Three IPRs filed challenging three different patents

Biogen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,815,236	Swiss Pharma	2016-00912	5/0	N	U	Institution Denied
8,349,321	Swiss Pharma	2016-00915	4/0	N	F	Institution Denied
8,900,577	Swiss Pharma	2016-00916	4/0	N	F	Institution Denied

8,815,236 Patent IPR

Representative Claim

1. A method of treatment by administering to a patient with multiple sclerosis a therapeutic amount of a stable, aqueous pharmaceutical formulation of about 20 mg/ml to about 150 mg/ml of natalizumab, about 10 mM phosphate buffer, about 140 mM sodium chloride, and polysorbate 80 present in an amount of about 0.001% to 2% (w/v).

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Swiss Pharma	2016-00912	1-16, 21-22	None	5/0	N	U	Institution Denied

8,349,321 Patent IPR

Representative Claim

1. A stable, aqueous pharmaceutical formulation of 20 mg/ml of natalizumab, about 10 mM sodium phosphate buffer, 8.18 mg/ml of sodium chloride, and 0.2 mg/ml of polysorbate 80, and wherein the formulation has a pH of 6.1.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Swiss Pharma	2016-00915	1-4	None	4/0	N	F	Institution Denied

8,900,577 Patent IPR

Representative Claim

1. A stable, aqueous pharmaceutical formulation of about 20 mg/ml to about 150 mg/ml of natalizumab, polysorbate 80 present in an amount of about 0.001% to 2% (w/v), about 10 mM phosphate buffer, and about 140 mM NaCl.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Swiss Pharma	2016-00916	1, 3-7, 9-12	None	4/0	N	F	Institution Denied

KEYTRUDA

Keytruda-Related IPRs

> Four IPRs filed challenging two patents

Ono Pharm. Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,067,999	1) Merck 2) Merck	1) 2016-01217 2) 2016-01218	1) 1/NA 2) 1/NA	1) NA 2) NA	1) U 2) U	1) Settled 2) Settled
9,073,994	1) Merck 2) Merck	1) 2016-01219 2) 2016-01221	1) 1/NA 2) 1/NA	1) NA 2) NA	1) U 2) U	1) Settled 2) Settled

9,067,999 Patent IPRs

Representative Claim

1. A method of treating a lung cancer comprising administering a composition comprising a human or humanized anti-PD-1 monoclonal antibody to a human with the lung cancer, wherein the administration of the composition treats the lung cancer in the human.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Merck	2016-01217	1, 6-14, 19-20, 24-27, 29-30	§§ 102, 103 for all claims	1/NA	NA	U	Settled
Merck	2016-01218	1, 6-14, 19-20, 24-27, 29-30	§§ 102, 103 for all claims	1/NA	NA	U	Settled

9,073,994 Patent IPRs

Representative Claim

1. A method of treating a metastatic melanoma comprising intravenously administering an effective amount of a composition comprising a human or humanized anti-PD-1 monoclonal antibody and a solubilizer in a solution to a human with the metastatic melanoma, wherein the administration of the composition treats the metastatic melanoma in the human.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Merck	2016-01219	1-3, 8-9, 14-15, 19-22, 25-26	§§ 102, 103 for all claims	1/NA	NA	U	Settled
Merck	2016-01221	1-3, 8-9, 14-15, 19-22, 25-26	§§ 102, 103 for all claims	1/NA	NA	U	Settled

AVASTIN

Avastin-Related IPRs

> Two IPRs filed challenging two patents

Genentech Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,622,115	Hospira	2016-01771	1/2	Y	U	FWD – Claims Invalid; Genentech Appealed
9,795,672	Pfizer	2018-00373	1/0	Y	U	Institution Denied

7,622,115 IPR

Representative Claim

1. A method for treating cancer in a patient by administering an effective amount of bevacizumab and assessing the patient for gastrointestinal perforation.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2016-01771	1-5	§§ 102, 103 for all claims	1/2	Y	U	FWD – Claims Invalid Affirmed on Appeal

9,795,672 IPR

Representative Claim

1. A method for treating cancer in a patient by administering an effective amount of bevacizumab and assessing the patient for gastrointestinal perforation.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2018-00373	1-18	NA	1/0	Y	U	Institution Denied

EPOGEN

6,747,002 IPR

> One IPR filed challenging one patent

Representative Claim

1. A method of administering at least one EPO dose to a patient according to an EPO dosing regimen, wherein said regimen maintains at least a serum EPO concentration above a predose level for about five to about 30 days between doses.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2013-00365	1-7, 12, 14-28	NA	3/0	NA	U	Not Instituted; Janssen Disclaimed All of the Challenged Claims

ORENCIA

8,476,239 IPR

> One IPR filed challenging one patent

Representative Claim

1. A stable formulation suitable for subcutaneous administration of at least 100 mg/ml CTLA4Ig molecule, a sugar selected from the group consisting of sucrose, lactose, maltose, mannitol and trehalose and mixtures thereof, and a pharmaceutically acceptable aqueous carrier, wherein the formulation has a pH range of from 6 to 8, viscosity from 9 to 20 cps, and the weight ratio of sugar:protein of 1.1:1 or higher.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Momenta	2015-01537	1-15	§ 103	1/2	Y	F	FWD – Claims Valid Momenta Appealed (Case No. 17-1694); Momenta ordered to show cause as to why appeal should not be dismissed as moot due to lack of Article III standing

NEULASTA

Neulasta-Related IPRs

> Eight IPRs filed challenging five patents

Amgen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,952,138* *Also asserted against Neupogen	Apotex	2016-01542	1/1	N	M	FWD – Claims 1-24 unpatentable but reversed by Federal Circuit on appeal. Federal Circuit found claims not obvious.
9,856,287	1) Fresenius Kabi 2) Fresenius Kabi 3) Lupin	1) 2019-00971 2) 2020-00314 3) 2021-00326	1) 1/0 2) 1/0 3) 1/1	1) Y 2) N 3) N	1) M 2) M 3) M	1) Institution Denied 2) Terminated Before Institution (Settled) 3) Institution Denied
8,940,878	Kashiv Biosciences	2019-00791	1/0	Y	M	Terminated After Institution (Settled)

Neulasta-Related IPRs (cont.)

> Eight IPRs filed challenging five patents

Amgen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,643,997	1) Kashiv Biosciences 2) Fresenius Kabi	1) 2019-00797 2) 2019-01183	1) 1/0 2) 1/1	1) Y 2) N	1) M 2) M	1) Terminated After Institution (Settled) 2) Terminated After Institution (Settled)
8,273,707	Hospira	2021-00528	1/0	Y	M	Terminated After Institution (Settled)

8,952,138 IPR

Representative Claim

a) A method of refolding a protein expressed in a non-mammalian expression system and present in a volume at a concentration of 2.0 g/L or greater that includes:
   a) contacting the protein with a refold buffer that has a redox component with a final thiol-pair ratio in the range of 0.001 to 100, a redox buffer strength of 2 mM or greater, and one or more of:
      i. a denaturant;
      ii. an aggregation suppressor; and
      iii. a protein stabilizer to form a refold mixture;
   b) incubating the refold mixture; and
   c) isolating the protein from the refold mixture.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Apotex	2016-01542	1-24	§ 103 for all claims	1/1	N	M	FWD – Claims 1-24 unpatentable but reversed by Federal Circuit on appeal. Federal Circuit found claims not obvious.

9,856,287 IPR

Representative Claim

1. A method of refolding proteins expressed in a non-mammalian expression system, the method comprising:
   a) contacting the proteins with a preparation that supports the renaturation of at least one of the proteins to a biologically active form, to form a refold mixture, the preparation comprising:
      i. at least one ingredient selected from the group consisting of a denaturant, an aggregation suppressor, and a protein stabilizer;
      ii. an amount of oxidant; and
      iii. an amount of reductant, wherein the amounts of the oxidant and the reductant are related through a thiol-pair ratio and a thiol-pair buffer strength, wherein the thiol-pair ratio is in the range of 0.001-100; and wherein the thiol-pair buffer strength maintains the solubility of the preparation; and
   b) incubating the refold mixture so that at least about 25% of the proteins are properly refolded.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Fresenius Kabi	2019-00971	1, 4-6, 8-10, 12, 14-16, 19-21, 23-26, 29-30	NA	1/0	Y	M	Institution Denied
Fresenius Kabi	2020-00314	1, 4-6, 8-10, 12, 14-16, 19-21, 23-26, 29-30	NA	1/0	N	M	Terminated Before Institution (Settled)
Lupin	2021-00326	1-30	NA	1/1	N	M	Institution Denied

8,940,878 IPR

Representative Claim

1. A method of purifying a protein expressed in a non-native soluble form in a non-mammalian expression system comprising:
   a) lysing a non-mammalian cell in which the protein is expressed in a non-native soluble form to generate a cell lysate;
   b) contacting the cell lysate with a separation matrix under conditions suitable for the protein to associate with the separation matrix;
   c) washing the separation matrix; and
   d) eluting the protein from the separation matrix, wherein the separation matrix is an affinity resin selected from the group consisting of Protein A, Protein G, and a synthetic, mimetic affinity resin.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Kashiv Biosciences	2019-00791	7-8, 11-13, 15-19, 21	§§ 102, 103	1/0	Y	M	Terminated After Institution (Settled)

9,643,997 IPR

Representative Claim

1. A method of purifying a protein expressed in a non-native soluble form in a non-mammalian expression system comprising:
   a) lysing a non-mammalian cell in which the protein is expressed in a non-native soluble form to generate a cell lysate;
   b) contacting the cell lysate with a separation matrix under conditions suitable for the protein to associate with the separation matrix;
   c) washing the separation matrix; and
   d) eluting the protein from the separation matrix.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Kashiv Biosciences	2019-00797	9-10, 13-15, 17-21, 23, 26-30	§§ 102, 103	1/0	Y	M	Instituted. Terminated After Institution (Settled)
Fresenius Kabi	2019-01183	9-10, 13-21, 23-30	§§ 102, 103	1/1	N	M	Instituted. Terminated After Institution (Settled)

8,273,707 IPR

Representative Claim

1. A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising mixing a preparation containing the protein with a combination of a first salt and a second salt, loading the mixture onto a hydrophobic interaction chromatography column, and eluting the protein, wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1M and about 1.0.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Hospira	2021-00528	1, 2, 4, 8, 10, and 11	NA	1/0	Y	M	Instituted

ENBREL

Enbrel-Related IPRs

> Three IPRs filed challenging two patents

Hoffmann-La Roche Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,163,522	Coalition for Affordable Drugs (Kyle Bass)	2015-01792	1/0	Y	M	Institution Denied
	Coherus	2017-01916	1/2	Y	M	Institution Denied
8,063,182	Coherus	2017-02066	1/2	Y	C	Institution Denied

8,163,522 Patent IPR

Representative Claim

1. A method comprising the steps of:
   a) culturing a host cell with a polynucleotide, wherein the polynucleotide encodes a protein consisting of:
      i. the extracellular region of an insoluble human TNF receptor, wherein the insoluble human TNF receptor has an apparent molecular weight of about 75 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel and the amino acid sequence LPAQVAFXPYAPEPGSTC (SEQ ID NO:10); and
      ii. all of the domains of the constant region of a human IgG immunoglobulin heavy chain other than the first domain of said constant region; and
   b) purifying an expression product of the polynucleotide from the cell mass or the culture medium.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coalition for Affordable Drugs (Kyle Bass)	2015-01792	1-10	NA	1/0	Y	M	Institution Denied
Coherus	2017-01916	1-10	NA	1/2	Y	M	Institution Denied

8,063,182 Patent IPR

Representative Claim

1. An isolated antibody that binds specifically to the polypeptide of SEQ ID NO:548.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2017-02066	2-36	NA	1/2	Y	C	Institution Denied

DUPIXENT

Dupixent-Related IPRs

> Three IPRs filed challenging one patent

Hofmann-LaRoche Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,679,487	Sanofi-Aventis	2017-01879	1/1	N	C	FWD – Claims 1-14, 16-17 Patentable
	Sanofi-Aventis	2017-01129	2/0	N	C	Institution Denied
	Sanofi-Aventis	2017-01884	1/3	N	C	FWD – Claims 1-17 Unpatentable

8,679,487 Patent IPR

Representative Claim

1. An isolated human antibody that competes with a reference antibody for binding to human IL-4 interleukin-4 (IL-4) receptor, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:10, and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:12.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Sanofi-Aventis	2017-01879	1-14, 16-17	§ 102	1/1	N	C	FWD – Claims 1-14, 16-17 Patentable
Sanofi-Aventis	2017-01129	1-17	NA	2/0	N	C	Institution Denied
Sanofi-Aventis	2017-01884	1-17	§ 103	1/3	N	C	FWD – Claims 1-17 Unpatentable

SOLIRIS

Soliris-Related IPRs

> Eight IPRs filed challenging five patents

Alexion Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,725,504	1. Amgen 2. Samsung Bioepis	1. 2019-00739 2. 2023-00999	1. 1/3 2. 1/-	1. N 2. -	1. M 2. M	1. Terminated After Institution (Settled) 2. Instituted
9,718,880	1. Amgen 2. Samsung Bioepis	1. 2019-00740 2. 2023-00998	1. 1/3 2. 1/-	1. Y 2. Y	1. C 2. C	1. Terminated After Institution (Settled) 2. Instituted
9,732,149	1. Amgen 2. Samsung Bioepis	1. 2019-00741 2. 2023-00933	1. 1/3 2. 1/-	1. Y 2. Y	1. C 2. C	1. Terminated After Institution (Settled) 2. Instituted
10,590,189	Samsung Bioepis	2023-01069	1/-	-	M	Instituted
10,703,809	Samsung Bioepis	2023-01070	1/-	-	M	Instituted

9,725,504 IPR

Representative Claim

1. A method of treating a patient suffering from paroxysmal nocturnal hemoglobinuria (PNH) comprising administering to the patient a pharmaceutical composition comprising an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO:2 and a light chain consisting of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00739	1-10	§§ 102, 103	1/3	N	M	Terminated After Institution (Settled)
Samsung Bioepis	2023-00999	1-10	§§ 102, 103	1/-	-	M	Instituted

9,718,880 IPR

Representative Claim

1. A pharmaceutical composition for use in treating a patient afflicted with PNH, wherein the composition is a sterile, preservative free, 300 mg single-use dosage form comprising 30 ml of a 10 mg/ml antibody solution, wherein the antibody comprises a heavy chain consisting of SEQ ID NO:2 and a light chain consisting of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00740	1-3	§§ 102, 103	1/3	Y	C	Terminated After Institution (Settled)
Samsung Bioepis	2023-00998	1-3	§§ 102, 103	1/-	-	C	Instituted

9,732,149 IPR

Representative Claim

1. An antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO:2 and a light chain consisting of SEQ ID NO:4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00741	1	§§ 102, 103	1/3	Y	C	Terminated After Institution (Settled)
Samsung Bioepis	2023-00933	1	§§ 102, 103	1/-	Y	C	Instituted

10,590,189 IPR

Representative Claim

1. A method of treating a patient suffering from paroxysmal nocturnal hemoglobinuria (PNH) comprising administering to the patient a pharmaceutical composition comprising an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4, and wherein the composition comprises a single-unit dosage form comprising 300 mg of the antibody in 30 mL of a sterile, preservative-free solution.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Samsung Bioepis	2023-01069	1-8	§ 103	1/-	-	M	Instituted

10,703,809 IPR

Representative Claim

1. A method of treating a patient having paroxysmal nocturnal hemoglobinuria (PNH), wherein the method comprises intravenously administering to the patient an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Samsung Bioepis	2023-01070	1-29	§ 103	1/-	-	M	Instituted

INSULIN GLARGINE

Insulin Glargine–Related IPRs

> Two IPRs filed challenging two patents

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
7,476,652	Mylan	2017-01526	3/2	Y	F	FWD – Claims 1-25 Unpatentable
7,713,930	Mylan	2017-01528	3/2	Y	F	FWD – Claims 1-20 Unpatentable

Representative Claim

1. A pharmaceutical formulation comprising Gly(A21), Arg(B31), Arg(B32)-human insulin; at least one chemical entity chosen from polysorbate 20 and polysorbate 80; at least one preservative; and water, wherein the pharmaceutical formulation has a pH in the acidic range from 1 to 6.8.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2017-01526	1-25	§ 103	3/2	Y	F	FWD – Claims 1-25 Unpatentable

7,713,930 IPR

Representative Claim

1. A pharmaceutical formulation comprising Gly(A21), Arg(B31), Arg(B32)-human insulin; at least one chemical entity chosen from esters and ethers of polyhydric alcohols; at least one preservative; and water, wherein the pharmaceutical formulation has a pH in the acidic range from 1 to 6.8.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2017-01528	1-20	§ 103	3/2	Y	F	FWD – Claims 1-20 Unpatentable

PEN-TYPE INJECTOR FOR INSULIN GLARGINE

Pen-Type Injector-Related IPRs

> Thirteen IPRs filed challenging six patents related to pen-type injector for insulin

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,603,044	1) Mylan 2) Mylan	1) 2018-01675 2) 2018-01676	1) 3/3 2) 3/3	Y	Pen-type injector	1) FWD – All Challenged Claims Unpatentable 2) FWD – All Challenged Claims Unpatentable
8,679,069	1) Mylan 2) Pfizer	1) 2018-01670 2) 2019-00979	1) 3/3 2) 3/3	Y	Pen-type injector	1) FWD – Claim 1 Unpatentable as Obvious 2) FWD – All Challenged Claims Unpatentable

Pen-Type Injector-Related IPRs (cont.)

> Thirteen IPRs filed challenging six patents related to pen-type injector for insulin

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,992,486	1) Mylan 2) Mylan, Pfizer 3) Mylan, Pfizer 4) Mylan, Pfizer	1) 2018-01677 2) 2018-01678 (2019-00980 joined) 3) 2018-01679 (2019-00981 joined) 4) 2019-00122 (2019-00982 joined)	1) 1/NA 2) 3/3 3) 3/3 4) 3/3	1) NA 2) Y 3) Y 4) Y	Pen-type injector	1) Petitioner's Unopposed Motion to Dismiss Granted 2) FWD – All Challenged Claims Unpatentable 3) FWD – All Challenged Claims Unpatentable 4) FWD – All Challenged Claims Unpatentable

Pen-Type Injector-Related IPRs (cont.)

> Thirteen IPRs filed challenging six patents related to pen-type injector for insulin

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,526,844	1) Mylan, Pfizer 2) Mylan, Pfizer 3) Mylan	1) 2018-01680 (2019-01022 joined) 2) 2018-01682 (2019-01023 joined) 3) 2018-01696	1) 3/3 2) 3/3 3) 1/0	1) Y 2) Y 3) N	Pen-type injector	1) FWD – All Challenged Claims Unpatentable 2) FWD – All Challenged Claims Unpatentable 3) Not Instituted
9,604,008	Mylan, Pfizer	2018-01684 (2019-00987 joined)	3/3	Y	Pen-type injector	FWD – Claims 1, 7, 8, 17 Unpatentable; Claims 3 and 11 Found Patentable
RE47614	Mylan	2019-01657	2/1	N	Pen-type injector	FWD – All Challenged Claims Unpatentable

8,603,044 IPR

Representative Claim

11. A housing part for a medication dispensing apparatus, said housing part comprising: a main housing, said main housing extending from a distal end to a proximal end; a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve; a dose dial grip disposed near a proximal end of said dose dial sleeve; a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing; a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and, a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2018-01675	11, 14, 15, 18, 19	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable
Mylan	2018-01676	11, 14, 15, 18, 19	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable

8,679,069 IPR

Representative Claim

1. A housing part for a medication dispensing apparatus, said housing part comprising: a main housing, said main housing extending from a distal end to a proximal end; a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve; a dose dial grip disposed near a proximal end of said dose dial sleeve; a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing; a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and, a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2018-01670	1	§ 103	3/3	Y	Pen-type injector	FWD – Claim 1 Unpatentable as Obvious
Pfizer	2019-00979	1-3	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable

8,992,486 IPR

Representative Claim

51. A clutch for use within a pen type drug delivery device, said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end; and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2018-01677	51-57	NA	1/NA	NA	Pen-type injector	Petitioner's Unopposed Motion to Dismiss Granted
Mylan, Pfizer	2018-01679 (2019-00981 joined)	51-57	§§ 102, 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable

8,992,486 IPR

Representative Claim

1. A housing part for a medication dispensing apparatus, said housing part comprising: a main housing, said main housing extending from a distal end to a proximal end; a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing; a dose knob disposed near a proximal end of said dose dial sleeve; a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing; a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and, a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan, Pfizer	2018-01678 (2019-00980 joined)	1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable
Mylan, Pfizer	2019-00122 (2019-00982 joined)	1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable

9,526,844 IPR

Representative Claim

21. A drug delivery device comprising: a housing comprising a dose dispensing end and a first thread; a dose indicator comprising a second thread that engages with the first thread; a driving member comprising a third thread; a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator; a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread; a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing; wherein: the housing is disposed at an outermost position of the drug delivery device; the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing; the driving member is configured to rotate relative to the piston rod; the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and the piston rod and the driving member are configured to rotate relative to one another during dose dispensing; and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan, Pfizer	2018-01680 (2019-01022 joined)	21-30	§§ 102, 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable
Mylan, Pfizer	2018-01682 (2019-01023 joined)	21-30	§ 103	3/3	Y	Pen-type injector	FWD – All Challenged Claims Unpatentable
Mylan	2018-01696	21-30	§ 103	1/0	N	Pen-type injector	Not Instituted

9,604,008 IPR

Representative Claim

1. A drive mechanism for use in a drug delivery device comprising: a housing comprising a helical thread; a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing, an insert provided in the housing, where the insert has a threaded circular opening; a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread; a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan, Pfizer	2018-01684 (2019-00987 joined)	1, 3, 7, 8, 11, 17	§ 103	3/3	Y	Pen-type injector	FWD – Claims 1, 7, 8, 17 Unpatentable; Claims 3 and 11 Found Patentable

RE47,614 IPR

Representative Claim

1. A drug delivery device comprising: a housing with a proximal end and a distal end, a cartridge adapted to accommodate a drug, a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing, and a spring washer arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member, wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2019-01657	1-18	§ 103	2/1	N	Pen-type injector	FWD – Claims 1-18 Unpatentable

EYLEA

Eylea-Related IPRs

> 23 IPRs filed challenging eight different patents

Regeneron Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,669,069	1) Mylan 2) Celltrion 3) Apotex	1) 2021-00880 2) 2022-00257 3) 2022-00301	1) 2/3 2) 2/- 3) 2/-	1) Y 2) - 3) -	1) M 2) M 3) M	1) FWD – Claims Unpatentable 2) Joined with IPR2021-00880 3) Joined with IPR2021-00880
9,254,338	1) Mylan 2) Celltrion 3) Apotex	1) 2021-00881 2) 2021-00258 3) 2022-00298	1) 2/1 2) 2/- 3) 2/-	1) Y 2) - 3) -	1) M 2) M 3) M	1) FWD – Claims Unpatentable 2) Joined with IPR2021-00881 3) Joined with IPR2021-00881
10,406,226	1) Celltrion	1) 2023-00620	1) 1/-	1) -	1) M	1) Terminated due to PO filing terminal disclaimer of claims 1-4

Eylea-Related IPRs (cont.)

> 23 IPRs filed challenging eight different patents

Regeneron Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
10,130,681	1) Mylan 2) Celltrion 3) Samsung Bioepsis	1) 2022-01225 2) 2023-00532 3) 2023-00442	1) 2/- 2) 2/- 3) 2/-	1) - 2) - 3) -	1) M 2) M 3) M	1) FWD claims unpatentable 2) Joined with 2022-01225 3) Instituted
10,888,601	1) Mylan 2) Celltrion 3) Samsung Bioepsis 4) Samsung Bioepsis 5) Biocon Biologics	1) 2022-01226 2) 2023-00533 3) 2023-00566 4) 2023-00739 5) 2024-00201	1) 2/- 2) 2/- 3) 2/- 4) 2/- 5) 2/-	1) - 2) - 3) - 4) - 5) -	1) M 2) M 3) M 4) M 5) M	1) FWD claims unpatentable 2) Joined with 2022-01226 3) Joined with 2022-01226 4) Instituted and then PO disclaimed claims so adverse judgment 5) Joined with 2023-00739
11,253,572	1) Apotex 2) Samsung Bioepsis 3) Celltrion 4) Biocon Biologics	1) 2022-01524 2) 2023-00884 3) 2024-00260 4) 2024-00298	1) 1/- 2) 1/- 3) 1/- 4) 1/-	1) - 2) - 3) - 4) -	1) M 2) M 3) M 4) M	1) Denied Institution 2) Instituted. Adverse Judgment after disclaimed all claims. 3) Joined with 00884 4) Joined with 00884

Eylea-Related IPRs (cont.)

> 23 IPRs filed challenging eight different patents

Regeneron Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
10,857,205	1) Mylan	1) 2023-00099	1) 2/-	1) -	1) M	1) Denied Institution because Regeneron disclaimed all claims
10,464,992	1) Chengdu 2) Celltrion 3) Samsung Bioepsis	1) 2021-00402 2) 2023-00462 3) 2023-01312	1) 1/- 2) 1/- 3) 1/-	1) - 2) - 3) -	1) C 2) C 3) C	1) Voluntary Dismissal 2) Instituted but PO disclaimed claims 3) Joned with 00462

9,669,069 Patent IPRs

Representative Claim

1. A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered on an as-needed/pro re nata (PRN) basis, based on visual and/or anatomical outcomes as assessed by a physician or other qualified medical professional;

wherein the VEGF antagonist is a receptor-based chimeric molecule comprising (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and (3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2021-00880	1, 8-12	§§ 102, 103	2/3	Y	M	FWD – Claims Unpatentable
Celltrion	2022-00257	1, 8-12	§§ 102, 103	2/-	-	M	Joined with IPR2021-00880
Apotex	2022-00301	1, 8-12	§§ 102, 103	2/-	-	M	Joined with IPR2021-00880

9,254,338 Patent IPRs

Representative Claim

1. A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered at least 8 weeks after the immediately preceding dose;

wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and (3) a multimerization component comprising amino acids 232-457of SEQ ID NO:2.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2021-00881	1, 3-11, 13-14, 16-24, 26	§§ 102, 103	2/1	Y	M	FWD – Claims Unpatentable
Celltrion	2022-00258	1, 3-11, 13-14, 16-24, 26	§§ 102, 103	2/-	-	M	Joined with IPR2021-00881
Apotex	2022-00301	1, 3-11, 13-14, 16-24, 26	§§ 102, 103	2/-	-	M	Joined with IPR2021-00881

10,130,681 Patent IPRs

Representative Claim

1. A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered at least 8 weeks after the immediately preceding dose;

wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and (3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2;

wherein exclusion criteria for the patient include all of:

(1) active intraocular inflammation;

(2) active ocular or periocular infection;

(3) any ocular or periocular infection within the last 2 weeks prior to treatment.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2022-01225	1, 3-11, 13-14, 16-24, 26	§§ 102, 103	2/-	-	M	FWD claims unpatentable
Celltrion	2023-00532	1, 3-11, 13-14, 16-24, 26	§ 103	2/-	-	M	Joined with IPR2022-01225
Samsung Bioepsis	2023-00442	1, 3-11, 13-14, 16-24, 26	§§ 102, 103	2/-	-	M	Pending

10,888,601 Patent IPRs

Representative Claim

1. A method for treating age related macular degeneration in a patient in need thereof, comprising intravitreally administering, to said patient, an effective amount of aflibercept which is 2 mg approximately every 4 weeks for the first 3 months, followed by 2 mg approximately once every 8 weeks or once every 2 months.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2022-01226	1-9, 34-39, 41-43, 45	§§ 102, 103	2/-	-	M	FWD claims unpatentable
Celltrion	2023-0533	1-9, 34-39, 41-43, 45	§§ 102, 103	2/-	-	M	Joined with 1226
Samsung Bioepsis	2023-00566 2023-00739	1-9, 34-39, 41-43, 45 10-12, 17-19, 21, 25-28, 33	§§ 102, 103	2/-	-	M	Joined with 1226 Instituted. Adverse Judgment after Disclaimer of claims.
Biocon Biologics	2024-00201	10-12, 17-19, 21, 25-28, 33	§§ 102, 103	2/-	-	M	Joined with 00739

11,253,572 Patent IPRs

Representative Claim

1. A method of treating an angiogenic eye disorder in a patient in need thereof comprising sequentially administering to the patient by intravitreal injection a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept, followed by one or more tertiary doses of 2 mg of aflibercept;

   wherein each secondary dose is administered approximately 4 weeks following the immediately preceding dose; and

   wherein each tertiary dose is administered approximately 8 weeks following the immediately preceding dose;

   wherein the patient achieves a gain in visual acuity within 52 weeks following the initial dose.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Apotex	2022-01524	1-14, 26-30	§§ 102, 103	1/-	-	M	Denied Institution
Samsung Bioepis	2023-00884	1-30	§§ 102, 103	1/-	-	M	Pending Institution
Celltrion	2024-00260	1-30	§§ 102, 103	1/-	-	M	Joined with 00884
Biocon Biologics	2024-00298	1-30	§§ 102, 103	1/-	-	M	Joined with 00884

10,857,205 Patent IPRs

Representative Claim

1. A method for treating macular edema following retinal vein occlusion in a human subject comprising administering 2 mg aflibercept to the subject by intravitreal injection once every 4 weeks.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2023-00099	1-3	§§ 102, 103	2/-	-	M	Denied Institution because Regeneron disclaimed all claims

10,406,226 Patent IPRs

Representative Claim

1. A method of manufacturing a VEGF antagonist fusion protein, said method comprising:

a. expressing said VEGF antagonist fusion protein in a Chinese hamster ovary (CHO) cell comprising a polynucleotide encoding the VEGF antagonist fusion protein which comprises amino acids 27-457 of SEQ ID NO: 2 wherein said fusion protein binds vascular endothelial growth factor (VEGF); and

b. purifying said VEGF antagonist fusion proteins; wherein at least 90% of the weight of the purified fusion protein is not present as an aggregate.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Celltrion	2023-00620	1-4	§ 103	1/-	-	M	Terminated due to terminal disclaimer of claims

10,464,992 Patent IPRs

Representative Claim

1. A vial comprising:

a vascular endothelial growth factor (VEGF) antagonist, an organic co-solvent, a buffer, and a stabilizing agent,

wherein the VEGF antagonist is a fusion protein produced in a Chinese Hamster Ovary (CHO) cell, the fusion protein comprising an immunoglobin-like (Ig) domain 2 of a first VEGF receptor and Ig domain 3 of a second VEGF receptor, and a multimerizing component; and

wherein at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Chengdu	2021-00402	1-18	§§ 102, 103	1/-	-	C	Voluntary Dismissal
Celltrion	2023-00462	1-18	§§ 102, 103	1/-	-	C	Instituted but PO disclaimed claims
Samsung Bioepsis	2023-01312	1-18	§§ 102, 103	1/-	-	C	Joined with 00462

Stelara

Stelara-Related IPRs

> Two IPRs filed challenging one patent

Janssen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
10,961,307	1) Samsung Bioepis 2) Biocon Biologics	1) 2023-01103 2) 2023-01444	1) 1/- 2) 1/-	1) - 2) -	M	1) Terminated due to settlement. 2) Terminated due to settlement.

10,961,307 Patent IPRs

Representative Claim

1. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Samsung Bioepis	2023-01103/2023-01444	1-34	§§ 102, 103	1/-	-	M	Terminated due to settlement

THANK YOU