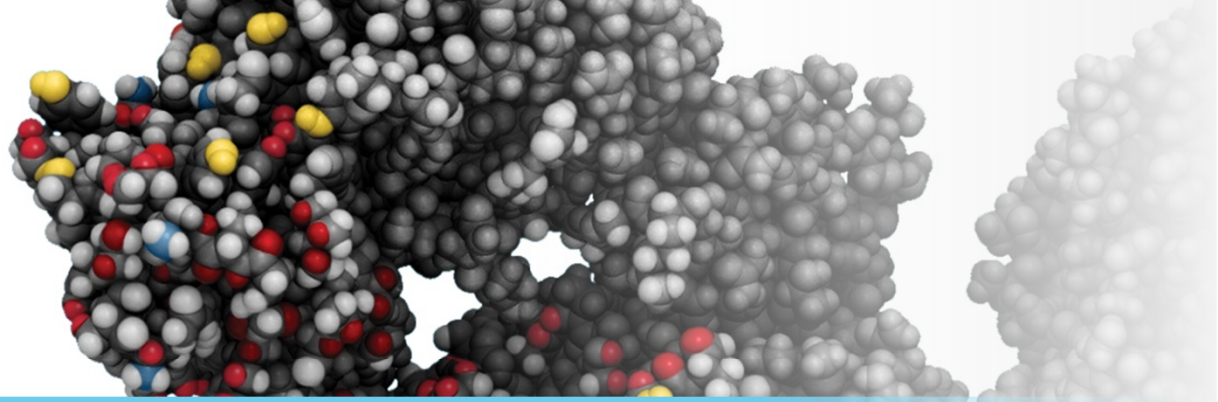
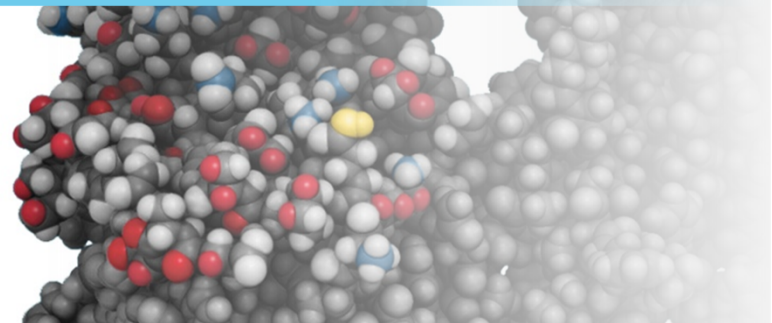
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 29

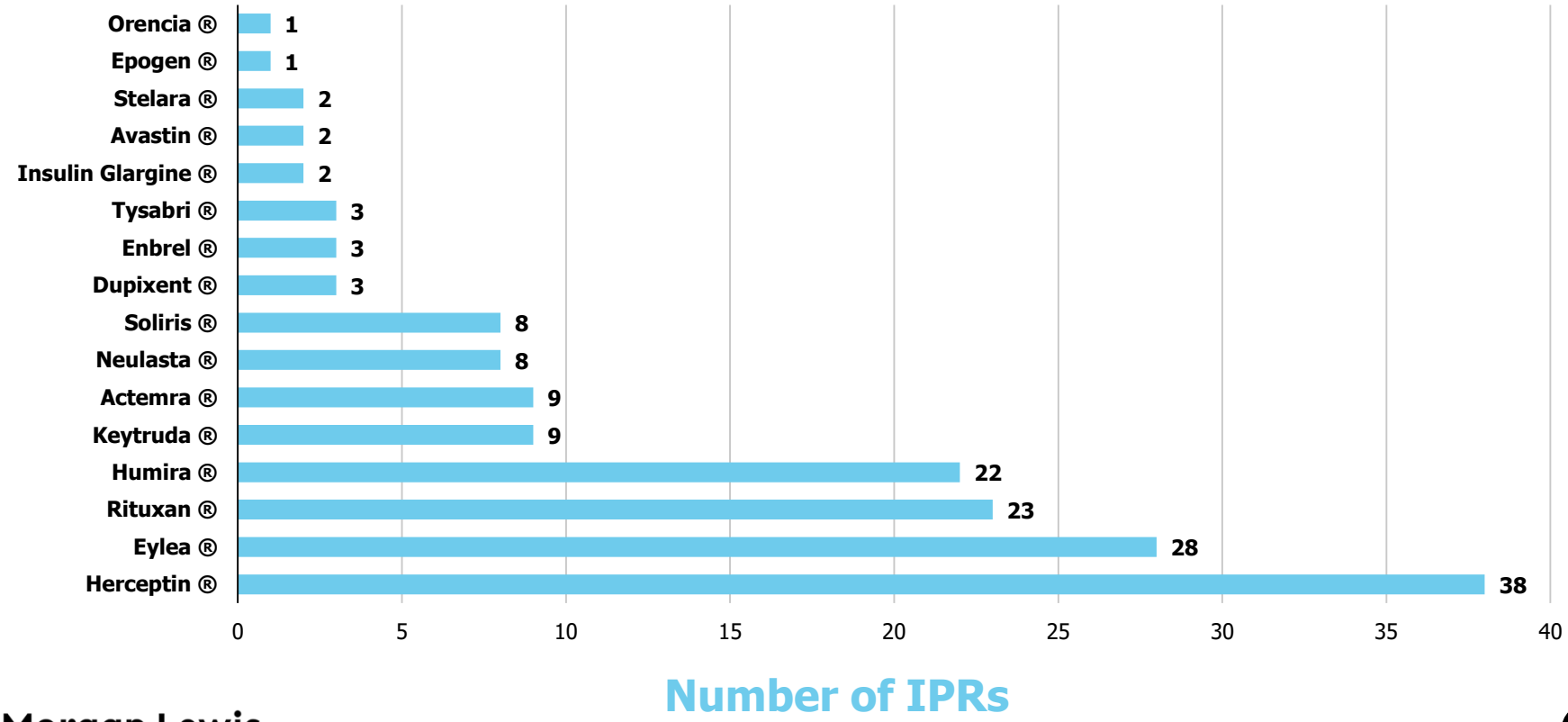
Inter Partes Reviews (IPRs) and Litigations



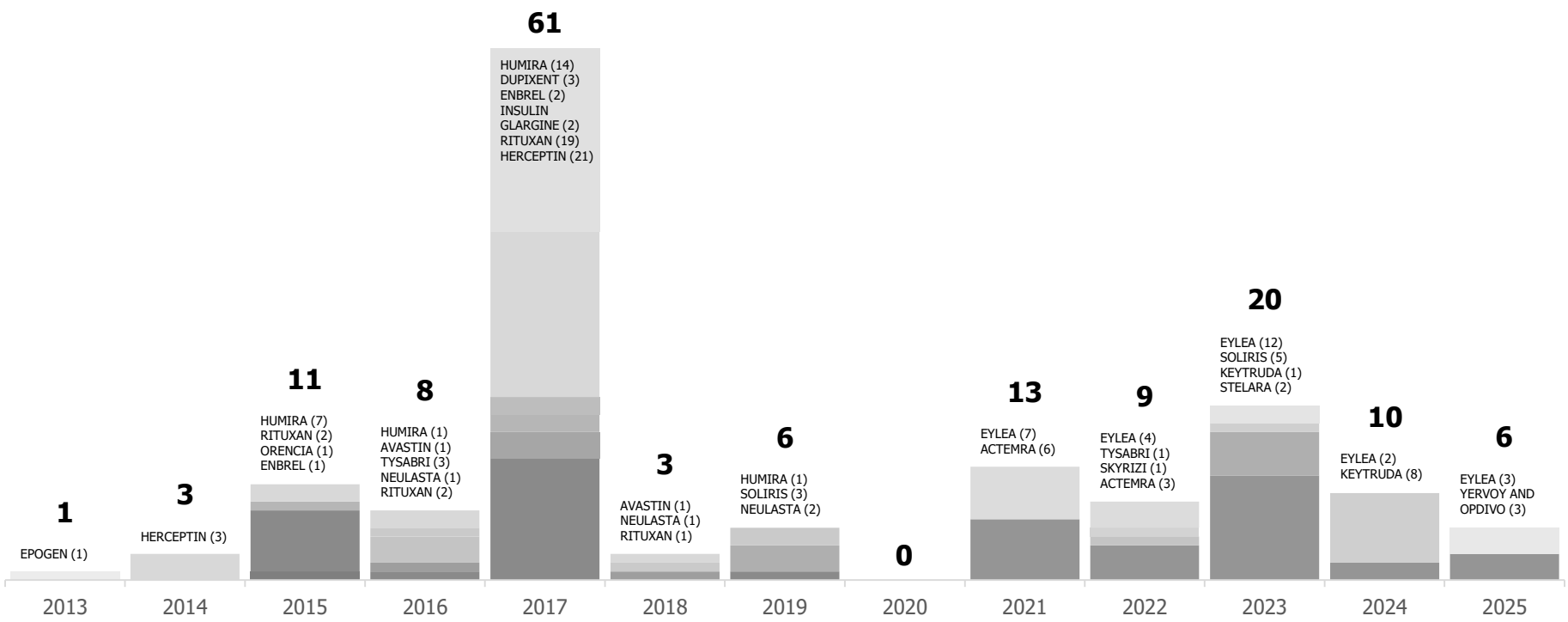
IPRs: Developments

- **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

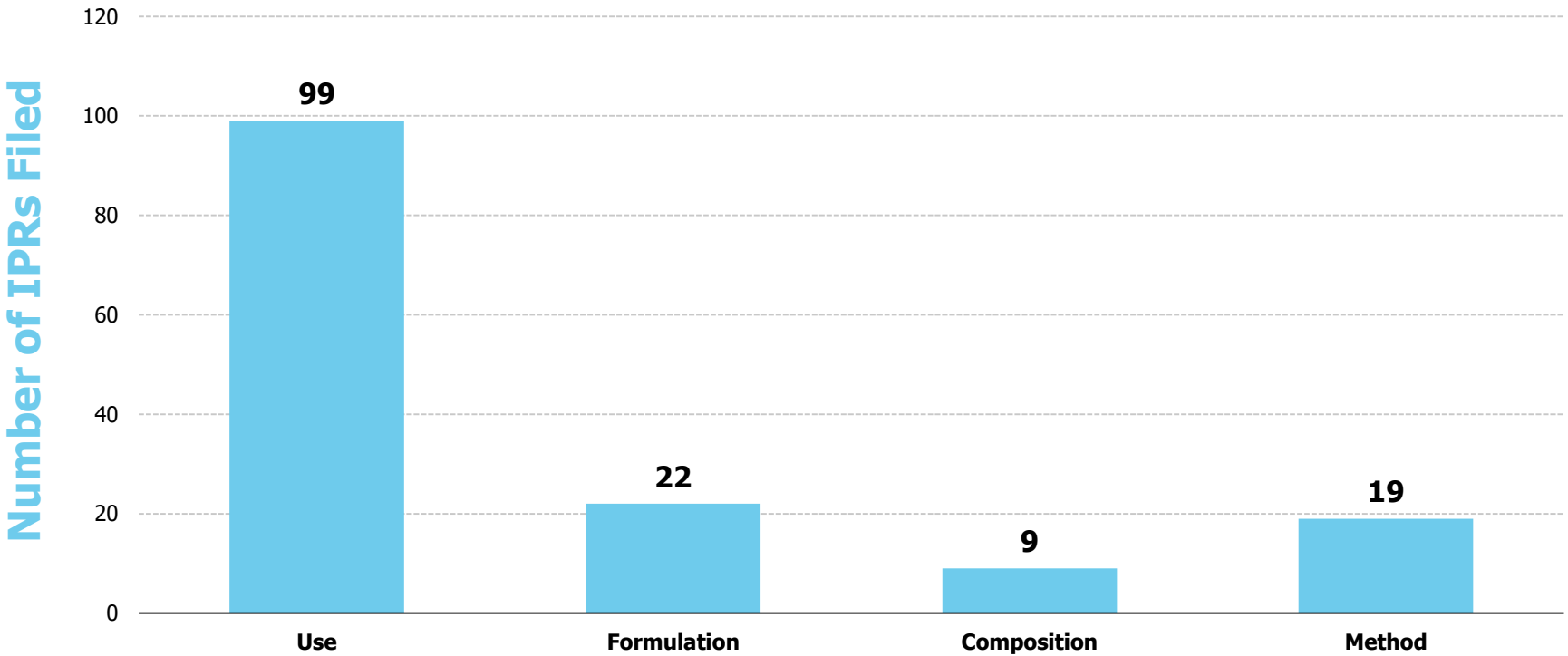


IPR Timeline



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	2	0	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:**
  - Regeneron and Formycon settled their dispute regarding Formycon's biosimilar, Ahzantive® on September 29, 2025.
  - Regeneron and Sandoz also settled their dispute regarding Sandoz's biosimilar, Enzeevu®, on September 9, 2025.
    - The agreement allows Sandoz to launch its biosimilar in the fourth quarter of 2026.

US Biosimilar Litigations: Developments

- **Prolia and Xgeva Litigation:**
  - Amgen filed five suits against several competitors alleging that their denosumab biosimilars will infringe patents to pharmaceutical compositions and methods of manufacturing Prolia® and Xgeva®.
    - The competitors include:
      1. Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd.;
      2. Biocon Biologics, Inc., Biocon Biologics UK Limited, and Biocon Biologics Limited;
      3. Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, GH Genhelix S.A., Universal Farma S.L., and mAbxience Research S.L.;
      4. Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories SA, Dr. Reddy's Laboratories Inc., Alvotech Hf., and Alvotech Swiss AG; and
      5. Alkem Laboratories Ltd., Ascend Laboratories, LLC, and Enzene Biosciences Ltd.
  - Amgen and Biocon later settled on September 30, 2025.
  - Amgen and Samsung Bioepis also settled their dispute regarding Samsung Bioepis's biosimilar, XBRYK™, on September 5, 2025.

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
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
Boehringer Ingelheim	July 1, 2023
Alvotech	July 1, 2023
Fresenius Kabi	July 1, 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
- 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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 53 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

*See slide 53 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
	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 53 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 53 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 53 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 53 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
	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 53 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 53 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 53 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 53 for legend of abbreviations.

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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