

# Morgan Lewis



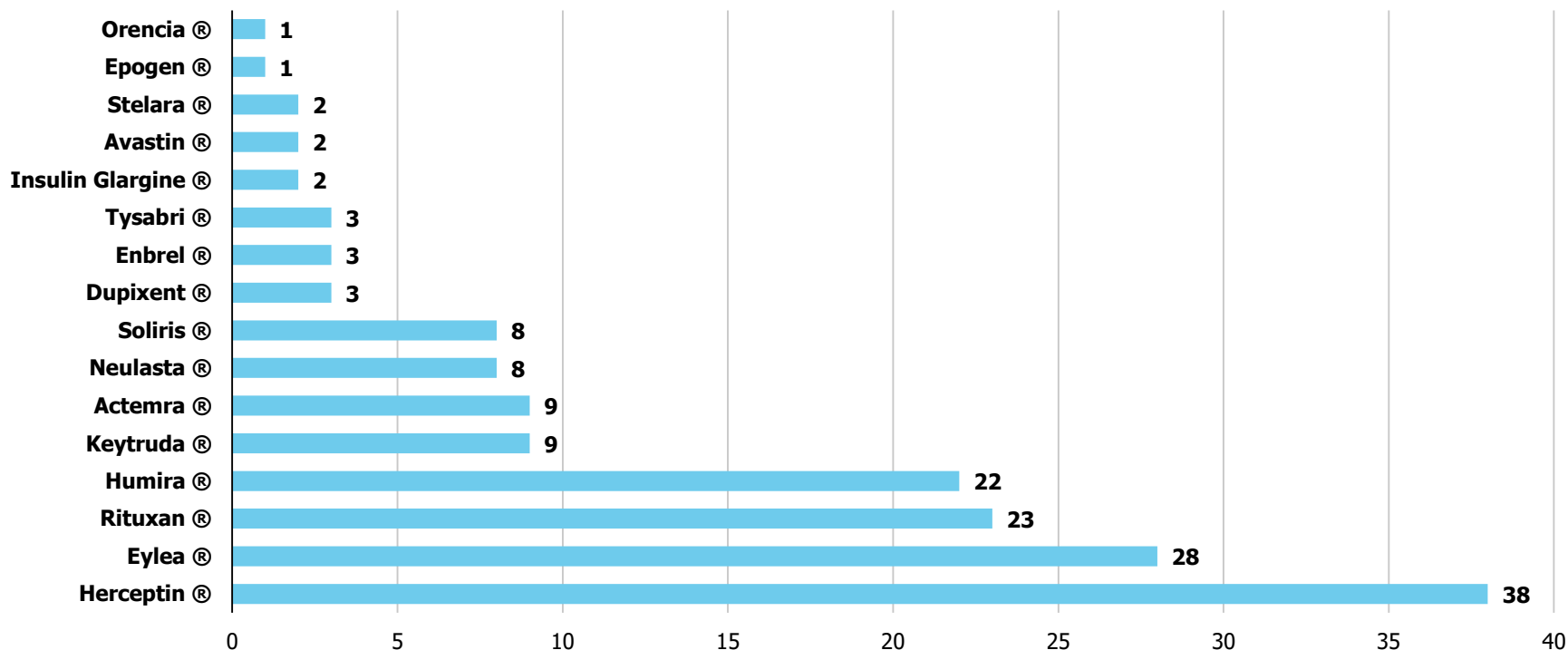
**BLOCKBUSTER BIOLOGICS REVIEW** ISSUE 28

## ***Inter Partes* Reviews (IPRs) and Litigations**

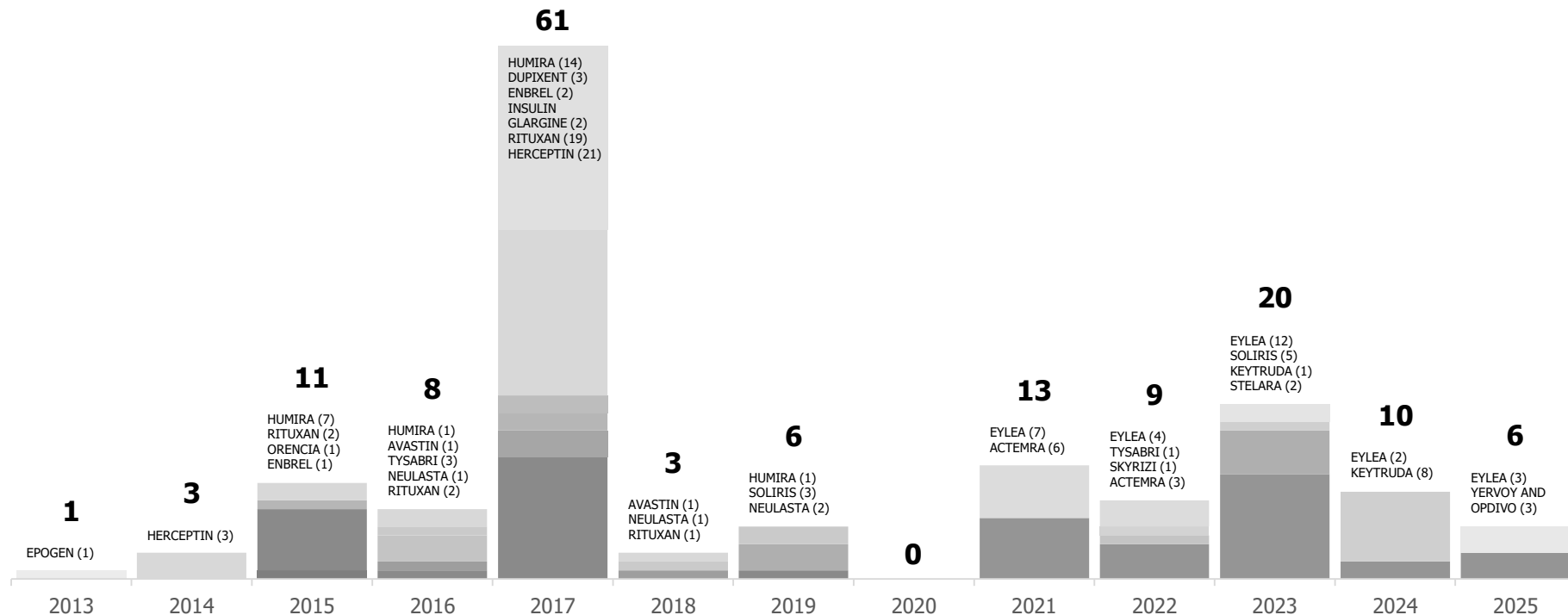
## > **Quick statistics:**

- > The current institution rate for IPR challenges to patents that claim biologics is 58% (excludes IPRs that have settled or otherwise been terminated).
- > Of those IPRs that have been instituted and gone to final written decision (FWD), 60% have resulted in the challenged claims being held unpatentable, with 15% having mixed results.

# IPRs by Reference Product

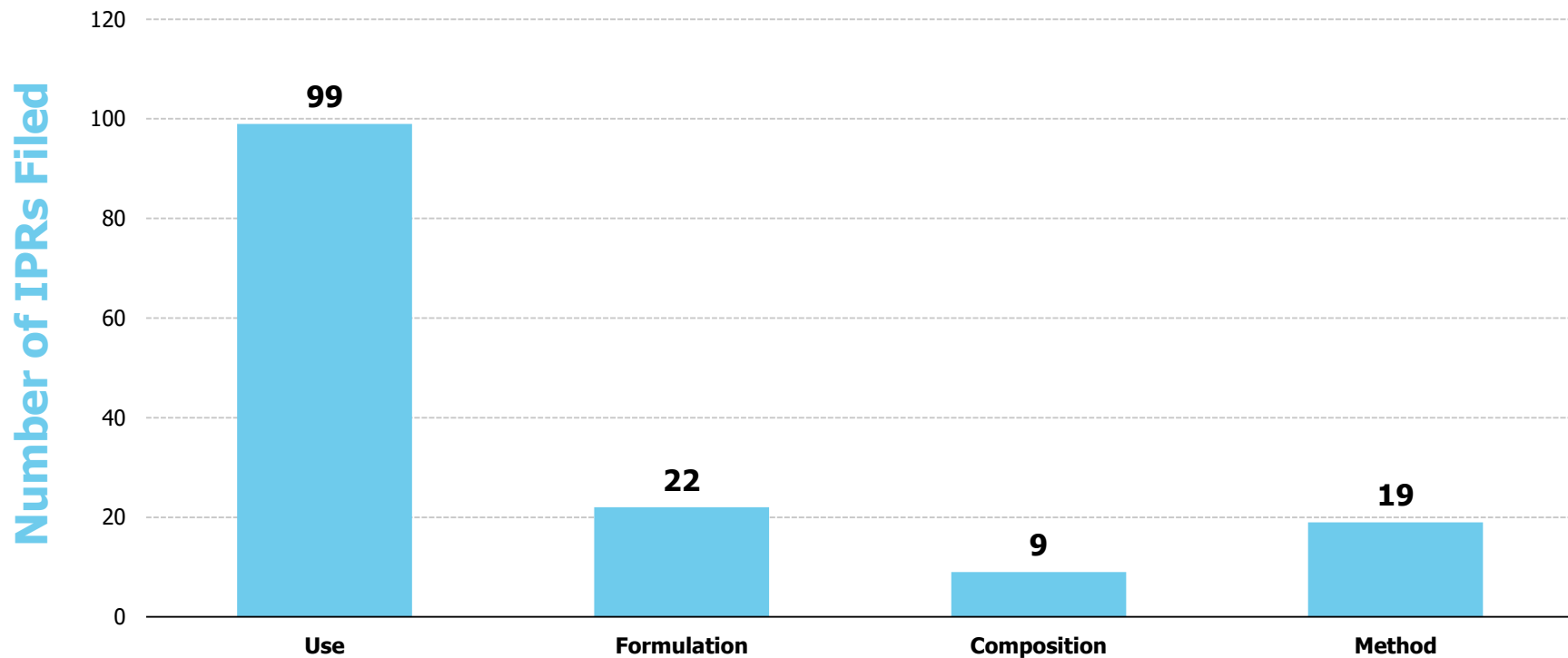


# IPR Timeline



**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	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		8	49	42	70

***Institution rate = 70/119 = 58%***

***\* 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
<b>Tysabri</b> (3)	Swiss Pharma	-	-	-	-
<b>Avastin</b> (2)	Hospira	1	1	-	-
<b>Orencia</b> (1)	Momenta	1	-	1	-
<b>Neulasta</b> (5)	Apotex	1	-	1	-
	Fresenius Kabi	1	-	-	-
	Kashiv Biosciences	2	-	-	-
<b>Enbrel</b> (3)	Coalition for Affordable Drugs	-	-	-	-
	Coherus	-	-	-	-
<b>Epogen</b> (1)	Hospira	-	-	-	-
<b>Keytruda</b> (9)	Merck	9	-	-	-
<b>Dupixent</b> (3)	Sanofi-Aventis	2	-	-	2
<b>Soliris</b> (8)	Amgen	-	-	-	-
	Samsung Bioepis	-	-	-	-
<b>Insulin Glargine</b> (2)	Mylan	2	2	-	-

# IPR Scorecard – FWDs (cont.)

Product (# of IPRs)	Challenger	Inst.*	FWD (invalid)	FWD (upheld)	Mixed
Eylea (26)	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		64	33	13	6

# 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	<ul style="list-style-type: none"> <li>All of these appeals have been consolidated</li> <li>Federal Circuit affirmed five FWDs, finding claims unpatentable as obvious</li> </ul>
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	<ul style="list-style-type: none"> <li>• Appeal No. 2016-01614 voluntarily dismissed</li> <li>• Appeal No. 2018-1885 dismissed with prejudice as part of Settlement and License Agreement</li> <li>• Appeal No. 2018-1924 dismissed as part of litigation settlement (Case No. 18-574-RMB-KMW (D.N.J.))</li> </ul>
Biogen	Pfizer	8,821,873	2017-01168 (2019-1364)	Claims Invalid	<ul style="list-style-type: none"> <li>• Biogen challenging constitutionality of IPRs</li> <li>• Pfizer not participating in appeal</li> <li>• USPTO intervened in appeal</li> <li>• Parties voluntarily dismissed appeal</li> <li>• Issues fully briefed</li> <li>• Affirmed Board's decision</li> </ul>

# 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	<ul style="list-style-type: none"> <li>USPTO intervened</li> <li>Affirmed Board's decision that challenged claims as unpatentable on anticipation and obviousness grounds</li> </ul>
Genentech	Hospira	7,846,441	2017-00731 (2019-1263)	Claims Invalid	<ul style="list-style-type: none"> <li>Hospira withdrew as a party due to settlement, and USPTO intervened</li> <li>Lead case – consolidated with 2019-1267</li> <li>Appeal submitted on briefs</li> <li>Affirmed Board's decision that challenged claims as unpatentable on obviousness grounds</li> </ul>
Genentech	Celltrion	7,846,441	2017-01121 (2019-1267)	Claims Invalid	<ul style="list-style-type: none"> <li>USPTO intervened</li> <li>Consolidated with 2019-1263</li> <li>Affirmed Board's decision</li> </ul>
Genentech	Hospira	6,627,196	2017-00804/ 2017-01958 joined (2019-1173)	Claims Valid	<ul style="list-style-type: none"> <li>Lead case – consolidated with 2019-1174</li> <li>Appeal voluntarily dismissed</li> </ul>

## 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	<ul style="list-style-type: none"> <li>Consolidated with 2019-1173</li> <li>Appeal voluntarily dismissed</li> </ul>
Genentech	Celltrion	6,627,196	2017-01139 (2019-1258)	Claims Valid	<ul style="list-style-type: none"> <li>Consolidated with 2019-1259</li> <li>Parties dismissed the appeal</li> </ul>
Genentech	Celltrion	7,371,379	2017-01140 (2019-1259)	Claims Valid	<ul style="list-style-type: none"> <li>Consolidated with 2019-1258</li> <li>Parties dismissed the appeal</li> </ul>
Genentech	Hospira	7,892,549	2017-00737/ 2017-01960 joined (2019-1265)	Claims Invalid	<ul style="list-style-type: none"> <li>Hospira withdrew as a party due to settlement</li> <li>Samsung Bioepis withdrew as a party</li> <li>Lead – consolidated with 2019-1270</li> <li>Affirmed Board's decision that challenged claims as unpatentable on obviousness grounds</li> </ul>
Genentech	Celltrion	7,892,549	2017-01122 (2019-1270)	Claims Invalid	<ul style="list-style-type: none"> <li>USPTO allowed to intervene</li> <li>Affirmed Board's decision</li> </ul>

# 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	<ul style="list-style-type: none"><li>• Amgen filed Notice of Appeal</li><li>• USPTO allowed to intervene</li><li>• Board found claims 1-24 of the '138 Patent unpatentable as obvious, and Federal Circuit reversed</li></ul>

# 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	<ul style="list-style-type: none"><li>• Includes constitutional challenge regarding retroactive application of IPR to pre-AIA patent</li><li>• United States intervened</li><li>• Oral argument held July 11, 2019</li><li>• Judgment affirmed</li></ul>

# 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	<ul style="list-style-type: none"><li>Federal Circuit dismissed appeal for lack of standing/jurisdiction and for mootness</li></ul>

# Post-Grant Reviews (PGRs)

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

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

# US BIOSIMILAR-RELATED PATENT LITIGATIONS

# US Biosimilar Litigations: Developments

## > **Eylea Litigation:**

- > Regeneron filed a complaint against Amgen alleging infringement of its patent to a stable liquid formulation of Eylea® that does not require a buffer.

## > **Prolia and Xgeva Litigation:**

- > Amgen filed a complaint against Hikma Pharmaceuticals USA Inc., Gedeon Richter Plc., and Gedeon Richter USA, Inc. alleging that their denosumab biosimilars, RGB-14-P and RGB-14-X, will infringe 32 patents to compositions and methods of using Prolia® and Xgeva®.
- > Amgen and Accord BioPharma ("Accord") reached a settlement agreement enjoining Accord from making, using, selling, or importing its biosimilar into the U.S. until October 1, 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
<b>Humira (7)</b>	<i>AbbVie v. Amgen</i>	No. 16-666-MSG (D. Del.)	10	M, F, U, C	• Settled – US launch of Amjevita on January 31, 2023
	<i>AbbVie v. Boehringer Ingelheim</i>	No. 17-1065-SLR (D. Del.)	8	M, F, U, C	• Parties stipulated to dismissal
	<i>AbbVie v. Sandoz</i>	No. 18-12668 (D.N.J.)	2	U, F	• Settled – US launch of Hyrimoz on July 1, 2023
	<i>Coherus v. Amgen</i>	No. 19-00139 (D. Del.)	3	C	• Parties stipulated to dismissal • Amgen filed motion for determination of exceptional case and award of fees denied

# US Litigation Scorecard – Humira (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Humira (7)	<i>AbbVie v. Alvotech</i>	No. 21-2258 (N.D. Ill.)	4	F, M, U	<ul style="list-style-type: none"> <li>• Court denied motion to dismiss on August 23, 2021 and entered a scheduling order on September 20, 2021</li> <li>• Trial set for August 2022, and court planned to issue trial decision by end of October 2022</li> <li>• Defendant agreed not to launch in United States until after court's trial decision</li> <li>• Settled on March 8, 2022</li> </ul>
	<i>Alvotech v. AbbVie</i>	No. 21-00265 (E.D. Va.)	4	F, M, U	<ul style="list-style-type: none"> <li>• On October 22, 2021, E.D. Va. court transferred case to the N.D. Ill.</li> <li>• Dismissed AbbVie's pending motion to dismiss as moot</li> <li>• Settled on March 8, 2022</li> </ul>
	<i>AbbVie v. Alvotech</i>	No. 21-02899 (N.D. Ill.)	58	F, M, U	<ul style="list-style-type: none"> <li>• Complaint filed May 28, 2021</li> <li>• Settled on March 8, 2022</li> </ul>

# US Litigation Scorecard – Rituxan

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Rituxan (4)	<i>Genentech v. Sandoz</i>	No. 17-13507-RMB-KMW (D.N.J.)	24	M, U, C	<ul style="list-style-type: none"> <li>Stipulated dismissal without prejudice</li> <li>Sandoz decided not to pursue its FDA submission for its biosimilar</li> </ul>
	<i>Celltrion v. Genentech</i>	No. 18-276-JSW (N.D. Cal.) No. 18-2161 (Fed. Cir.) (consolidated with No. 18-2160)	37	M, U	<ul style="list-style-type: none"> <li>Genentech's motion to dismiss granted</li> <li>Final judgment appealed to Federal Circuit</li> <li>Appeal voluntarily dismissed</li> </ul>
	<i>Genentech v. Celltrion</i>	No. 18-574-RMB-KMW (D.N.J.)	40	M, U, C	<ul style="list-style-type: none"> <li>Settled</li> </ul>
	<i>Genentech v. Celltrion</i>	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	<ul style="list-style-type: none"> <li>Settled</li> </ul>

# US Litigation Scorecard – Herceptin

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Herceptin (7)	<i>Celltrion v. Genentech</i>	No. 18-274-JSW (N.D. Cal.) No. 18-2160 (Fed. Cir.)	38	M, U, C	<ul style="list-style-type: none"> <li>• Genentech's motion to dismiss granted</li> <li>• Final judgment appealed to Federal Circuit</li> <li>• Appeal voluntarily dismissed</li> </ul>
	<i>Genentech v. Celltrion</i>	No. 18-095-CFC (D. Del.)	40	M, U, C	<ul style="list-style-type: none"> <li>• All Delaware cases were before Judge Colm F. Connolly and coordinated</li> <li>• <i>Markman</i> hearing in April 2019</li> <li>• Trial in December 2019</li> <li>• Lead case</li> <li>• Settled</li> </ul>
	<i>Genentech v. Pfizer</i>	No. 17-1672-CFC (D. Del.)	40	M, U, C	<ul style="list-style-type: none"> <li>• Settled</li> </ul>

# US Litigation Scorecard – Herceptin (cont.)

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

# US Litigation Scorecard – Neupogen

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	<i>Amgen v. Sandoz</i>	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	<ul style="list-style-type: none"> <li>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</li> <li>District court ruled in favor of Sandoz; on appeal, Federal Circuit and Supreme Court did the same</li> <li>District court subsequently granted Sandoz's motion for summary judgment of noninfringement; affirmed on appeal</li> <li>Petition for rehearing en banc denied</li> </ul>
	<i>Amgen v. Apotex</i>	No. 15-62081-JIC (S.D. Fla.)	2	M, C	<ul style="list-style-type: none"> <li>Consolidated with <i>Amgen v. Apotex</i> pegfilgrastim (Neulasta) litigation, No. 15-61631-JIC, where district court entered judgment of noninfringement for Sandoz</li> <li>Affirmed</li> </ul>

# US Litigation Scorecard – Neupogen (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	<i>Amgen v. Kashiv</i>	No. 18-3347-JMV-SCM (D.N.J.)	17	M	<ul style="list-style-type: none"> <li>Amended Complaint filed, reducing number of patents to four and naming Amneal Pharmaceuticals as co-defendant</li> <li>Amneal moved to dismiss Amended Complaint for failure to state a claim and lack of subject-matter jurisdiction</li> <li>Claim construction briefed</li> <li>On June 10, 2019, Kashiv substituted in place of Adello</li> <li>On November 25, 2019, parties stipulated to dismissal without prejudice</li> </ul>
	<i>Amgen v. Hospira</i>	No. 18-1064 (D. Del.)	1	M	<ul style="list-style-type: none"> <li>Parties stipulated to dismiss all claims and counterclaims with prejudice</li> </ul>
	<i>Sandoz v. Amgen</i>	No. 19-00977 (N.D. Cal.)	1	M	<ul style="list-style-type: none"> <li>Sandoz voluntarily dismissed action without prejudice</li> </ul>

# US Litigation Scorecard – Neupogen (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neupogen (7)	<i>Amgen v. Tanvex</i>	No. 19-1374-AJB-MSB (S.D. Cal.)	1	M	<ul style="list-style-type: none"> <li>Complaint and Answer to Complaint filed</li> <li>On December 19, 2019, parties entered into stipulation of dismissal without prejudice</li> </ul>
	<i>Amgen v. Hospira</i>	No. 20-561 (D. Del.)	1	M	<ul style="list-style-type: none"> <li>Parties filed stipulation of dismissal with prejudice</li> </ul>

# US Litigation Scorecard – Neulasta

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	<i>Amgen v. Apotex</i>	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	<ul style="list-style-type: none"> <li>Amgen found not to have infringed</li> <li>Supreme Court denied Apotex's petition for certiorari</li> <li>Federal Circuit affirmed district court ruling</li> <li>District court:               <ol style="list-style-type: none"> <li>granted Amgen's motion for summary judgment re invalidity defenses except nonenablement</li> <li>awarded judgment of noninfringement for Apotex</li> <li>dismissed Apotex's nonenablement defense without prejudice</li> </ol> </li> </ul>
	<i>Amgen v. Sandoz</i>	No. 16-1276-SRC-CLW (D.N.J.)	Litigation over whether Sandoz violated BPCIA	NA	<ul style="list-style-type: none"> <li>Dismissed after Sandoz restarted patent-dance negotiations</li> </ul>

# US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	<i>Amgen v. Sandoz</i>	No. 16-02581-RS (N.D. Cal.) No. 18-1552 (Fed. Cir.) (consolidated with No. 18-1551)	2	M, F	<ul style="list-style-type: none"> <li>On appeal, fully briefed, pending scheduling of oral argument</li> <li>Summary judgment of noninfringement granted for Sandoz</li> <li>Affirmed</li> </ul>
	<i>Amgen v. Coherus</i>	No. 17-546-LPS (D. Del.) No. 18-1993 (Fed. Cir.)	1	M	<ul style="list-style-type: none"> <li>Court granted Coherus's motion to dismiss for failure to state a claim</li> <li>Judgment entered against Amgen; case dismissed</li> <li>Affirmed</li> </ul>

# US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	<i>Amgen v. Mylan</i>	No. 17-1235-MRH (W.D. Pa.)	2	M	<ul style="list-style-type: none"> <li>Claim Construction Order issued</li> <li>Amgen ordered to file, with infringement contentions, a statement identifying facts relied on outside of Mylan's FDA filings</li> <li>Motion for summary judgment of noninfringement of US Patent No. 9,643,997 filed – ruling deferred</li> <li>Abeyance in place, pending further order to be issued in August 2019</li> <li>Parties stipulated to noninfringement of US Patent No. 9,643,997</li> </ul>
	<i>Amgen v. Apotex</i>	No. 18-61828 (S.D. Fla.)	1	M	<ul style="list-style-type: none"> <li>District court denied Apotex's motion to dismiss Amgen's complaint for failure to state a claim</li> <li>Joint Claim Construction Statement filed</li> <li>Accord BioPharma substituted in place of Apotex as defendant in August 2019</li> <li>On November 14, 2019, parties entered into stipulation of dismissal without prejudice</li> </ul>

# US Litigation Scorecard – Neulasta (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Neulasta (7)	<i>Amgen v. Hospira</i>	No. 20-201 (D. Del.)	1	M	<ul style="list-style-type: none"> <li>• Complaint filed February 11, 2020</li> <li>• Hospira and Pfizer filed a motion to dismiss for failure to state a claim, arguing that Amgen surrendered subject-matter jurisdiction during prosecution</li> <li>• Motion to dismiss denied</li> <li>• Case stayed following Claim Construction Order until decision made as to whether early summary judgment practice as to noninfringement should be entertained</li> <li>• Settled and jointly dismissed by the parties on March 18, 2022</li> </ul>

# US Litigation Scorecard – Enbrel

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Enbrel (2)	<i>Immunex v. Sandoz</i>	No. 16-01118-CCC-JBC (D.N.J.) No. 20-1037 (Fed. Cir.)	5	C, F, U	<ul style="list-style-type: none"> <li>Before trial, Sandoz stipulated to infringement to certain asserted claims of two of the five patents-in-suit</li> <li>Bench trial held in September 2018 and district court judge ruled in favor of Immunex, holding that patents-in-suit were valid</li> <li>Sandoz appealed to Federal Circuit</li> <li>Federal Circuit affirmed on July 1, 2020</li> <li>Petition for rehearing en banc denied</li> </ul>
	<i>Immunex v. Samsung Bioepis</i>	No. 19-11755-CCC (D.N.J.)	5	C, U, M, F	<ul style="list-style-type: none"> <li>Court entered final judgment and permanent injunction against Samsung Bioepis on November 3, 2021</li> <li>Permanent injunction in effect until April 24, 2029, when patents expire</li> </ul>

# US Litigation Scorecard – Epogen

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
<b>Epogen (1)</b>	<i>Amgen v. Hospira</i>	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	<ul style="list-style-type: none"> <li>• Jury found infringement and awarded \$70M in damages</li> <li>• Final judgment entered with pre- and post-judgment interest</li> <li>• Hospira appealed, arguing that all of its batches of product should be subject to safe-harbor provision about which jury was given erroneous instructions</li> <li>• Amgen responded that there was sufficient evidence supporting jury's finding that only seven of 21 drug batches qualified for safe-harbor provision</li> <li>• Oral argument held September 30, 2019</li> <li>• Judgment affirmed December 16, 2019</li> <li>• Petition for rehearing and petition for rehearing en banc denied</li> </ul>

# US Litigation Scorecard – Avastin

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Avastin (8)	<i>Genentech v. Amgen</i>	No. 17-165-GMS (D. Del.)	Litigation over violations of BPCIA	NA	<ul style="list-style-type: none"> <li>Dismissed complaint without prejudice</li> </ul>
	<i>Amgen v. Genentech</i>	No. 17-7349-GW-AGR (C.D. Cal.)	27	M, C, F, U	<ul style="list-style-type: none"> <li>Genentech's motion to dismiss for lack of subject-matter jurisdiction granted</li> </ul>
	<i>Genentech v. Amgen</i>	No. 17-1407-CFC (D. Del.)	24	M, C, F, U	<ul style="list-style-type: none"> <li>Consolidated with No. 17-1471</li> <li>Lead case</li> <li>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</li> <li>Joint stipulation of dismissal filed on July 7, 2020</li> </ul>
	<i>Genentech v. Amgen</i>	No. 17-1471-CFC (D. Del.)	25	M, C, F, U	<ul style="list-style-type: none"> <li>Consolidated with No. 17-1407</li> </ul>
	<i>Genentech v. Pfizer</i>	No. 19-00638-CFC (D. Del.)	22	M, C, F, U	<ul style="list-style-type: none"> <li>Settled</li> </ul>

# US Litigation Scorecard – Avastin (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Avastin (8)	<i>Genentech v. Immunex and Amgen</i>	No. 19-00602-CFC (D. Del.) No. 19-2155 (Fed. Cir.)	14	M, C, F, U	<ul style="list-style-type: none"> <li>Genentech's motion to enforce statutory prohibition on commercial marketing and TRO denied</li> <li>Federal Circuit denied Genentech's motion for an injunction pending appeal</li> <li>Genentech appealed regarding commercial marketing</li> <li>Federal Circuit affirmed</li> </ul>
	<i>Genentech v. Samsung Bioepis</i>	No. 20-cv-00859 (D. Del.)	14	M, C, F, U	<ul style="list-style-type: none"> <li>Complaint filed June 28, 2020</li> <li>Joint stipulation to dismiss filed September 7, 2022</li> </ul>
	<i>Genentech v. Centus</i>	No. 20-cv-00361 (E.D. Tex.)	10	M, U	<ul style="list-style-type: none"> <li>Complaint filed November 12, 2020</li> <li>Parties filed joint motion to stay all deadlines and notice of settlement</li> <li>Motion to dismiss with prejudice granted due to parties' settlement</li> </ul>

# US Litigation Scorecard – Remicade

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
<b>Remicade (5)</b>	<i>Janssen v. Celltrion</i>	No. 15-10698-MLW (D. Mass.) No. 17-1120 (Fed. Cir.)	2	C, U	<ul style="list-style-type: none"> <li>Partial summary judgment of invalidity granted with respect to one patent ('471 patent)</li> <li>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</li> <li>Dismissed without prejudice in favor of No. 17-11008</li> </ul>
	<i>Janssen v. Celltrion</i>	No. 16-11117-MLW (D. Mass.)	1	M (cell culture media)	<ul style="list-style-type: none"> <li>Dismissed without prejudice in favor of No. 17-11008</li> </ul>
	<i>Janssen v. HyClone</i>	No. 16-00071-BCW (D. Utah)	1	M (cell culture media)	<ul style="list-style-type: none"> <li>Case administratively closed on November 26, 2019, per related litigation in District of Massachusetts</li> </ul>

# US Litigation Scorecard – Remicade (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
<b>Remicade (5)</b>	<i>Janssen v. Celltrion</i>	No. 17-11008 (D. Mass.) No. 18-2350 (Fed. Cir.)  Lead appeal (No. 18-2321)	1	M (cell culture media)	<ul style="list-style-type: none"> <li>Judgment entered for defendants after court allowed motion for summary judgment of noninfringement based on ensnarement</li> <li>Affirmed on appeal</li> </ul>
	<i>Janssen v. Samsung Bioepis</i>	No. 17-3524-MCA-SCM (D.N.J.)	3	M	<ul style="list-style-type: none"> <li>Janssen voluntarily dismissed its patent-infringement claims</li> <li>Suit dismissed with prejudice</li> </ul>

# US Litigation Scorecard – Eylea

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Eylea (8)	<i>Regeneron Pharm., Inc. v. Mylan Pharm. Inc.</i>	No. 1-22-cv-61 (N.D. W. Va.)	24	M, U, F, C	<ul style="list-style-type: none"> <li>Court granted permanent injunction against Mylan on June 11, 2024</li> <li>Permanent injunction and final judgment vacated after parties reached a settlement agreement.</li> </ul>
	<i>Regeneron Pharm., Inc. v. Celltrion, Inc.</i>	No. 1-23-cv-89 (N.D. W. Va.)	38	M, F	<ul style="list-style-type: none"> <li>Court granted preliminary injunction against Celltrion on June 24, 2024</li> <li>Federal Circuit affirmed preliminary injunction on March 5, 2025 preventing Celltrion from launching its biosimilar</li> </ul>
	<i>Regeneron Pharm., Inc. v. Samsung Bioepis, Co.</i>	No. 1-23-cv-94 (N.D. W. Va.)	37	M, F	<ul style="list-style-type: none"> <li>Court granted preliminary injunction against Samsung Bioepis on June 14, 2024</li> <li>Federal Circuit affirmed preliminary injunction preventing Samsung Bioepis from marketing its biosimilar of Eylea on January 29, 2025</li> </ul>

# US Litigation Scorecard – Eylea (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Eylea (8)	<i>Regeneron Pharm., Inc. v. Formycon AG</i>	No. 1-23-cv-97 (N.D. W. Va.)	39	M, F	<ul style="list-style-type: none"> <li>Court granted preliminary injunction against Formycon on June 21, 2024</li> <li>Federal Circuit affirmed preliminary injunction preventing Formycon from marketing its biosimilar of Eylea on January 29, 2025</li> </ul>
	<i>Regeneron Pharm., Inc. v. Samsung Bioepis, Co.</i>	No. 1-23-cv-106 (N.D. W. Va.)	51	M, F	<ul style="list-style-type: none"> <li>Court granted preliminary injunction against Samsung Bioepis on June 14, 2024</li> </ul>
	<i>Regeneron Pharm., Inc. v. Amgen, Inc.</i>	No. 1-24-cv-39 (N.D. W. Va.)	32	M, C, F, U	<ul style="list-style-type: none"> <li>Court denied Regeneron's motion for preliminary injunction on October 1, 2024</li> <li>Federal Circuit affirmed the denial of preliminary injunction on March 14, 2025</li> <li>District court entered Stipulation and Order Vacating Permanent Injunction and Dismissing All Claims and Counterclaims with Prejudice on April 22, 2025</li> </ul>
	<i>Regeneron Pharm., Inc. v. Sandoz Inc.</i>	No. 1-24-cv-85 (N.D. W. Va.)	46	M, C, F, U	<ul style="list-style-type: none"> <li>Case filed in District of New Jersey on August 26, 2024</li> <li>Transferred to the Northern District of West Virginia on September 13, 2024</li> </ul>
	<i>Regeneron Pharm., Inc. v. Amgen, Inc.</i>	No. 2:25-cv-5499	1	F	<ul style="list-style-type: none"> <li>Case filed in Central District of California on June 17, 2025</li> </ul>

# US Litigation Scorecard – Stelara

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Stelara (1)	<i>Janssen v. Amgen</i>	No. 22-01549 (D. Del)	6	U, C, M	<ul style="list-style-type: none"> <li>• Janssen asserted six patents against Amgen</li> <li>• Janssen filed a motion for preliminary injunction in March 2023</li> <li>• Settled on May 22, 2023</li> <li>• Settlement allows for Amgen to launch biosimilar no later than January 1, 2025</li> </ul>

# US Litigation Scorecard – Imfinzi

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
<b>Imfinzi (1)</b>	<i>Bristol-Myers Squibb v. AstraZeneca</i>	(D. Del.)	1	M	<ul style="list-style-type: none"> <li>Bristol-Myers Squibb filed a complaint alleging willful infringement of its patent covering methods of treating cancer using an anti-PD-L1 antibody</li> </ul>

# US Litigation Scorecard – Tysabri

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Tysabri (1)	<i>Biogen v. Sandoz</i>	22-1190-GBW (D. Del.)	5	M, U	<ul style="list-style-type: none"> <li>Complaint alleges that Sandoz infringed 28 Biogen patents based on Sandoz's BLA submission</li> <li>Biogen filed motion for preliminary injunction</li> <li>Court required Biogen to elect up to five patents and 10 claims to assert as part of preliminary injunction</li> <li>Court denied Biogen's motion for preliminary injunction</li> </ul>

# US Litigation Scorecard – Xgeva and Prolia

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
<b>Xgeva and Prolia (6)</b>	<i>Amgen v. Sandoz</i>	No. 23-cv-02406 (D.N.J.)	21	C, M	• Parties stipulated to dismissal
	<i>Amgen v. Celltrion</i>	No. 24-cv-06497 (D.N.J.)	29	M, C	• Settled on January 23, 2025
	<i>Amgen v. Samsung Bioepis</i>	No. 24-cv-08417 (D.N.J.)	34	M, C	• Complaint filed August 12, 2024
	<i>Amgen v. Fresenius Kabi</i>	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
	<i>Amgen v. Accord Biopharma</i>	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
	<i>Amgen v. Hikma Pharma.</i>	No. 1:25-cv-12152 (D.N.J.)	32	M, C	• Complaint filed June 30, 2025

# US Litigation Scorecard – Actemra

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Actemra (1)	<i>Genentech v. Biogen</i>	No. 1:23-CV-11573 (D.N.J.)	20	C, M, U	<ul style="list-style-type: none"> <li>Parties filed joint stipulation of dismissal</li> </ul>

# US Litigation Scorecard – Soliris

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims*	Status
Soliris (1)	<i>Alexion v. Samsung</i>	No. 1:2024cv00005 (D. Del.)	6	M	<ul style="list-style-type: none"><li>• Complaint filed January 3, 2024</li><li>• Court denied Alexion's motion for preliminary injunction on May 6, 2024</li><li>• Parties settled on August 30, 2024</li></ul>

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# Legend

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