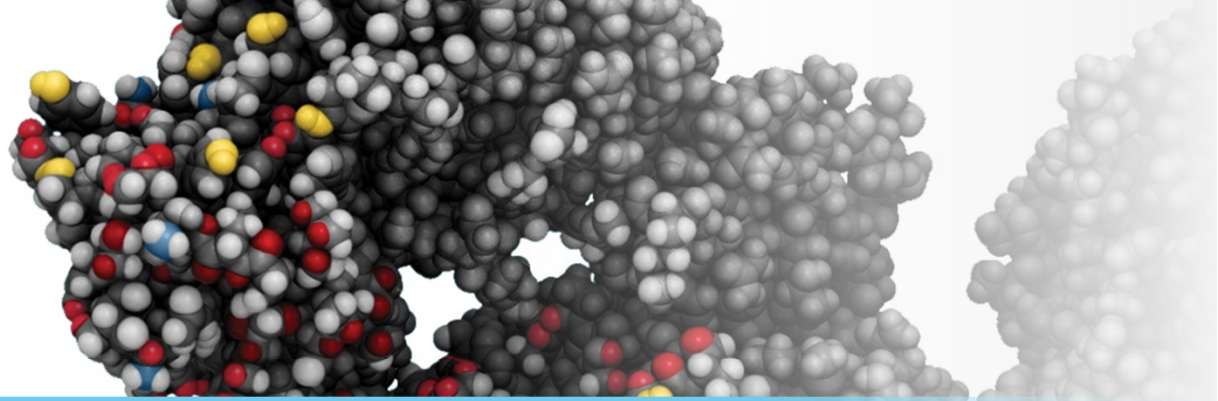
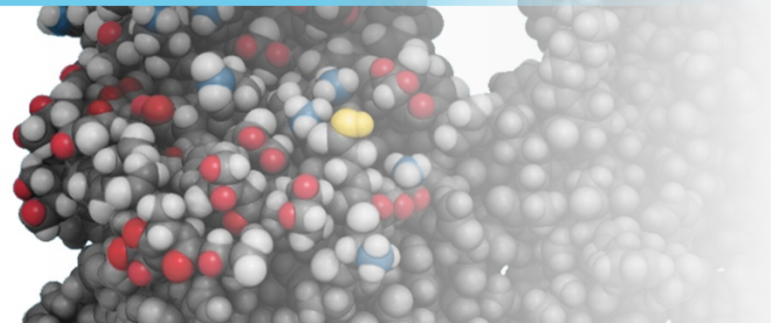
Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 18

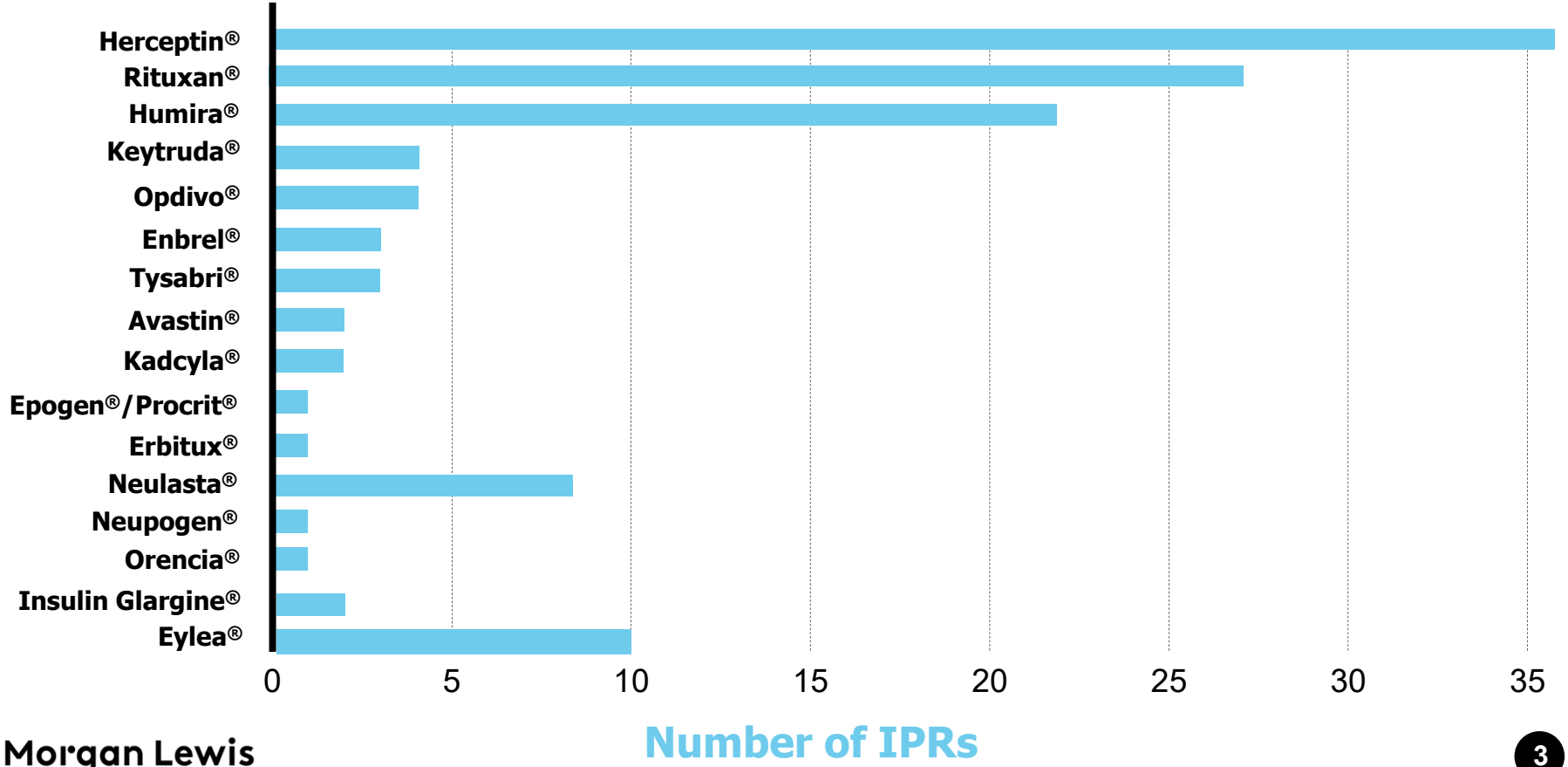
Inter Partes Reviews (IPRs) and Litigations



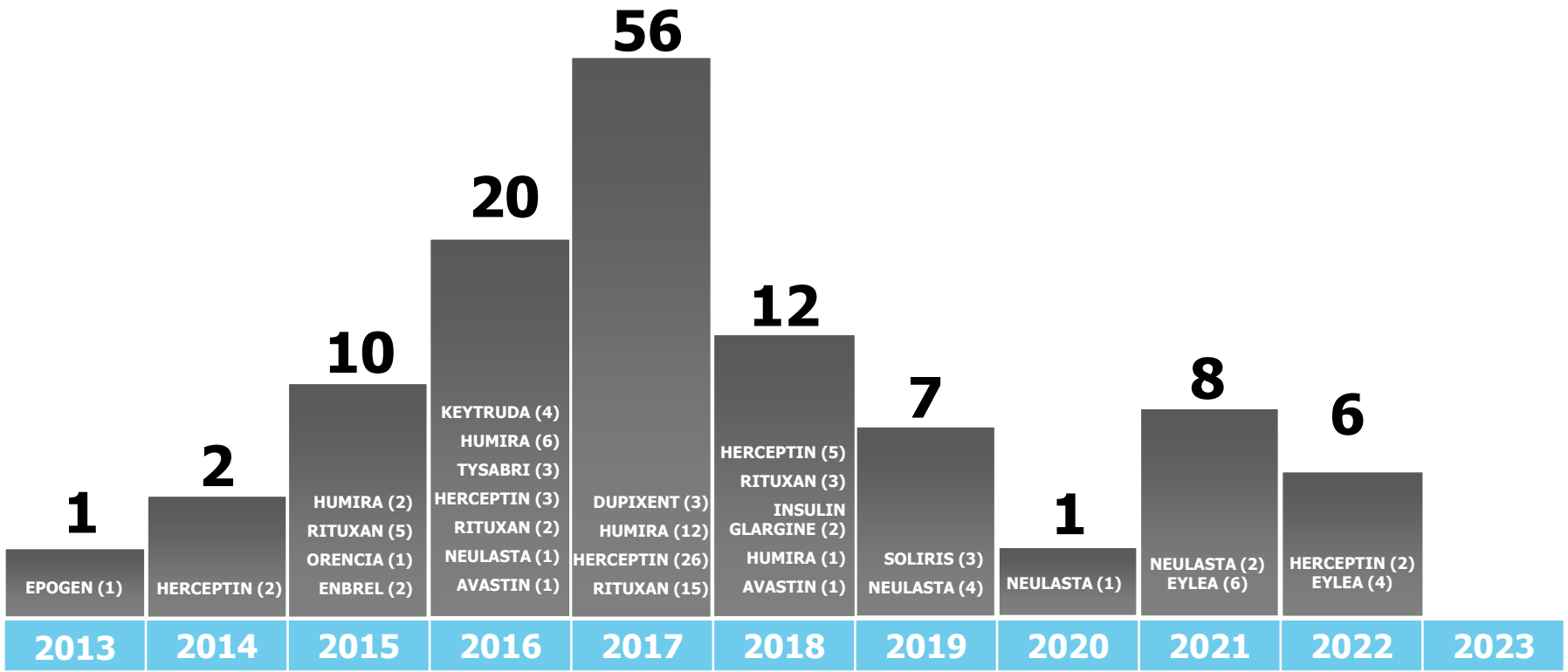
IPRs: Developments

- **Quick statistics:**
  - The current institution rate for IPR challenges to patents that claim biologics is 36% (excludes IPRs that have settled or otherwise been terminated).
  - Of those IPRs that have been instituted and gone to final written decision (FWD), 45% have resulted in the challenged claims being held unpatentable, with 60% having mixed results.

IPRs by Reference Product



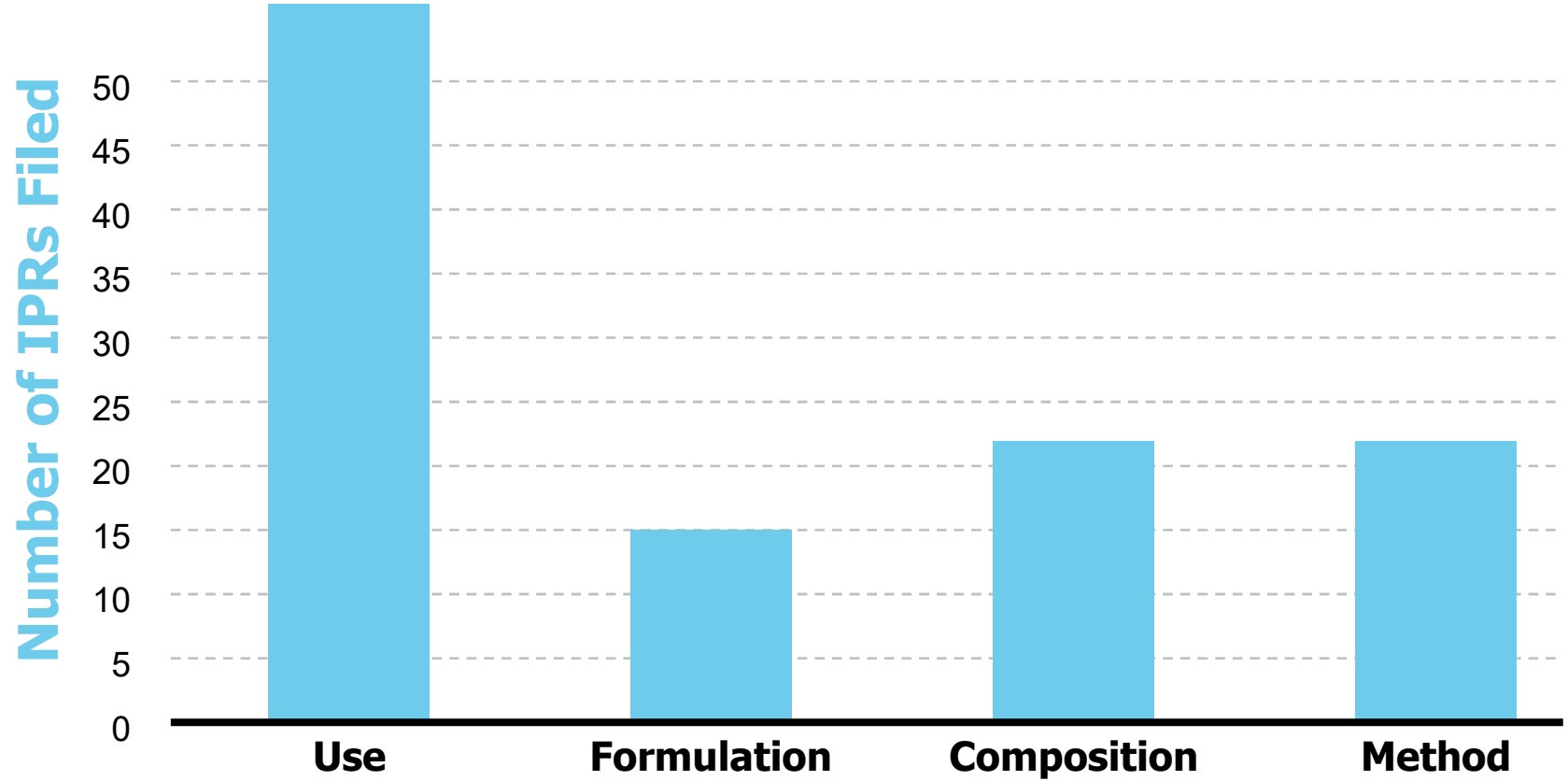
IPR Timeline



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	2	-
	Celltrion	0	6	2	3
	Pfizer	0	5	3	3
	Sandoz	0	2	-	-
Herceptin (36)	Phigenix	0	1	-	1
	Mylan	0	-	2	-
	Hospira	0	1	-	5
	Celltrion	0	-	1	6
	Pfizer	0	5	2	4
	Samsung	0	1	-	5
	Boehringer Ingelheim	0	-	2	-
Tysabri (3)	Swiss Pharma	0	3	-	-
Keytruda (4)	Merck	0	0	4	-
Avastin (2)	Hospira	0	1	-	1
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)	Kyle Bass	0	1	-	-
	Coherus	0	2	-	-
Epogen (1)	Hospira	0	-	1	-
Dupixent (3)	Sanofi-Aventis	0	1	-	2
Soliris (3)	Amgen	0	0	-	3
Insulin Glargine (2)	Mylan	0	0	-	2
Eylea (6)	Mylan	3	-	-	2
	Apotex	1	-	-	-
TOTALS		4	45	28	44

Institution rate = 44/121 = 36%

**** 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	**3**	**1**	**1**	-
	Pfizer	**3**	**1**	**1**	-
	Sandoz	-	-	-	-
Herceptin (36)	Phigenix	**1**	-	**1**	-
	Mylan	-	-	-	-
	Hospira	**5**	**3**	**2**	-
	Celltrion	**6**	**2**	**2**	**2**
	Pfizer	**4**	**1**	-	**2**
	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 (5)	Apotex	1	-	1	-
	Fresenius Kabi	1	-	-	-
	Kashiv Biosciences	2	-	-	-
Enbrel (3)	Kyle Bass	-	-	-	-
	Coherus	-	-	-	-
Epogen (1)	Hospira	-	-	-	-
Keytruda (4)	Merck	-	-	-	-
Dupixent (3)	Sanofi-Aventis	2	1	1	-
Insulin Glargine (2)	Mylan	2	2	-	-
Eyelea (6)	Mylan	2	2	-	-
TOTALS		44	20	12	6

Invalidation rate = 20/44 = 45%, with mixed results for 60%

**** 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 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 appeal
Genentech	Celltrion	7,371,379	2017-01140 (2019-1259)	Claims Valid	• Consolidated with 2019-1258 • Parties dismissed appeal
Genentech	Hospira	7,892,549	2017-00737/ 2017-01960 joined (2019-1265)	Claims Invalid	• Hospira withdrew as party due to settlement • Samsung Bioepis withdrew as 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)

> Two 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	-	**-**

US BIOSIMILAR-RELATED PATENT LITIGATIONS

US Biosimilar Litigations: Developments

- **Eylea Litigation: *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.***
  - On August 2, 2022, Regeneron filed suit in West Virginia asserting that Mylan infringed 24 patents with its proposed biosimilar of Eylea.
  - On October 25, 2022, the Court issued a Scheduling Order requiring Regeneron to identify six patents from three patent families for initial proceedings set for trial in June 2023.
  - On December 9, 2022, Mylan filed a Motion for Leave to amend its Answer.
  - On December 16, 2022, Regeneron filed a Motion for Judgment on Pleadings to dismiss Mylan's inequitable conduct defense/counterclaim.

US Biosimilar Litigations: Developments (cont.)

- **Stelara Litigation: *Janssen Biotech, Inc. v. Amgen Inc.***
  - On November 29, 2022, Janssen filed a complaint against Amgen in the District of Delaware regarding Amgen's biosimilar to Stelara.
  - Janssen asserted two patents against Amgen.
    - US Patent No. 6,902,734 ("the '734 patent") covering ustekinumab (the active compound in Stelara)
    - US Patent No. 10,961,307 ("the '307 patent") covering methods of treating ulcerative colitis with this medicine

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
  - Enbrel
  - Epogen
  - Eylea
  - Herceptin
  - Humira
  - Neulasta
  - Neupogen
  - Remicade
  - Rituxan
  - Stelara
- 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 expected 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 expected September 20, 2023
	Coherus v. Amgen	No. 19-00139 (D. Del.)	3	C	• Parties stipulated to dismissal • Amgen's filed motion for determination of exceptional case and award of fees denied

*See slide 71 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 plans 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 71 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 71 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 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 71 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	• Complaint filed and answered

*See slide 71 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, where district court entered judgment of noninfringement for Sandoz • Affirmed

*See slide 71 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 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 71 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 71 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 71 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 71 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 71 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 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 71 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 71 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 71 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 71 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 71 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 71 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 71 for legend of abbreviations.

US Litigation Scorecard – Eylea

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Eylea (1)	*Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*	No. 1-22-cv-61 (W. Va.)	24	M, U, F	• Regeneron filed Complaint on August 2, 2022 • Court issued Scheduling Order requiring Regeneron to identify six patents from three patent families for expedited schedule with trial set for June 2023 • Mylan filed motion to amend answer to add DJ counterclaim of no lost profits or injunctive relief for remaining patents • Regeneron filed judgment for motion on pleadings as to Mylan's inequitable conduct defense/counterclaims

*See slide 71 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	2	U, C	• Janssen filed Complaint asserting infringement of two patents

*See slide 71 for legend of abbreviations.

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