

Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW

Quarterly Update – April 2020

Christopher J. Betti, Ph.D.
Robin M. Silva
Maria E. Doukas

Blockbuster Biologics Newsletter 1Q Update

Welcome to our 1Q 2020 update relating to biologics and biosimilars, including post-grant and patent litigation challenges to blockbuster biologics.

Notably, the BPCIA celebrated its 10-year anniversary on March 23, 2020. During the time it has been in force, 26 biosimilars have been approved 16, of which have launched despite the call for legislative/regulatory fixes to increase competition. Strikingly, the number of post-grant challenges against biologics patents has precipitously dropped since reaching a peak in 2017, marking a shift to challenges in district court.

Additionally, on this anniversary of the BPCIA, applications for insulins are now deemed to be a license for the product under the Public Health Service (PHS) Act. This will, for the first time, enable submission of applications for products that are proposed as biosimilar to these insulins.

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

— Chris, Robin, and Maria

Table of Contents

1. Quarterly Post-Grant Update	2
A. <i>Inter Partes</i> Reviews (IPRs)	5
i. Developments	6
ii. IPRs by Reference Product	7
iii. IPR Timeline	8
iv. Types of Claims Being Challenged	9
v. IPR Scorecard – Institution	10
vi. IPR Scorecard – Final Written Decisions (FWDs)	12
vii. IPR Appeals	14
B. Post-Grant Reviews (PGRs)	21

Table of Contents (cont.)

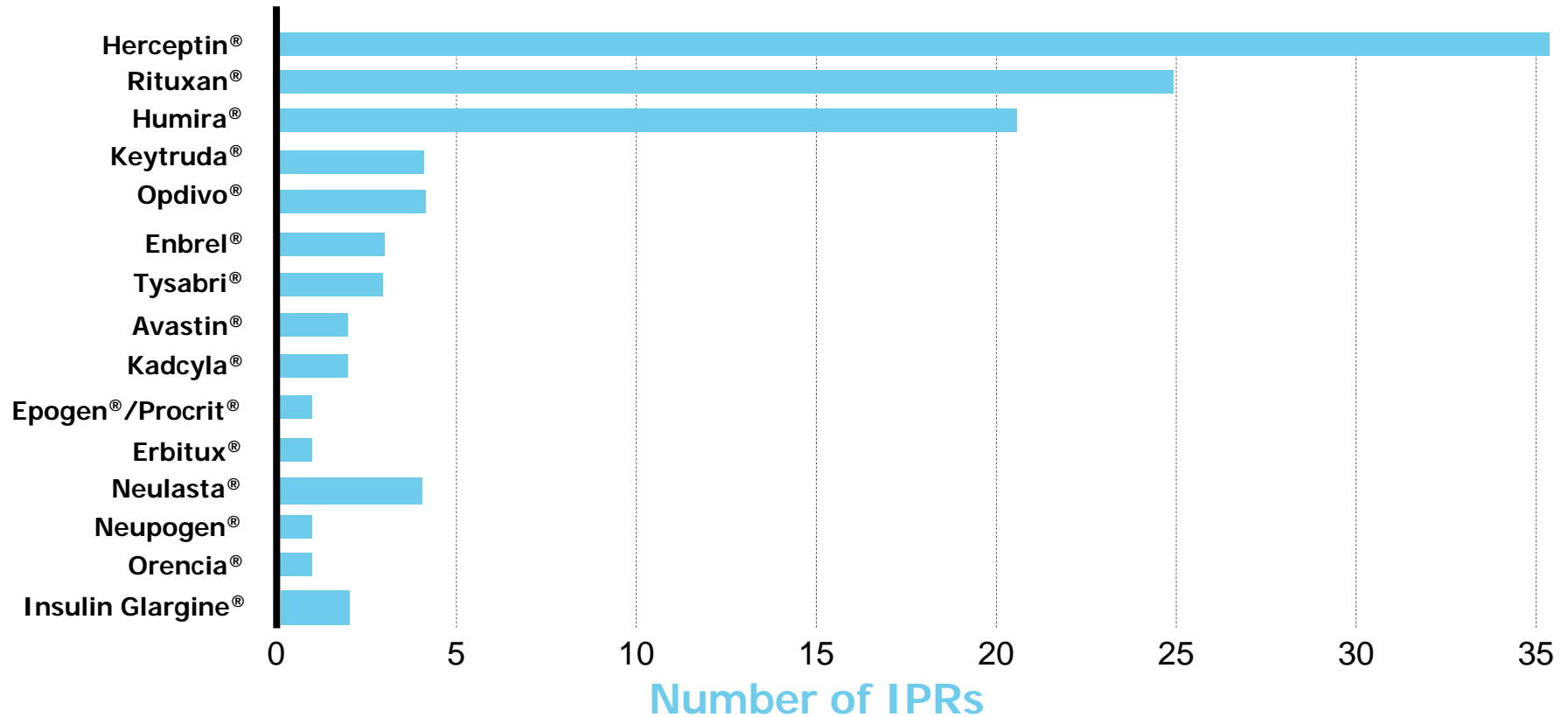
2. US Biosimilar-Related Patent Litigations	22
i. Developments	23
ii. Scorecard	28
3. Legislative Updates	45
4. Biosimilar Approvals and Launches	48
5. Contacts	51
6. Appendix – IPR Detailed Analysis	53

INTER PARTES REVIEWS (IPRS)

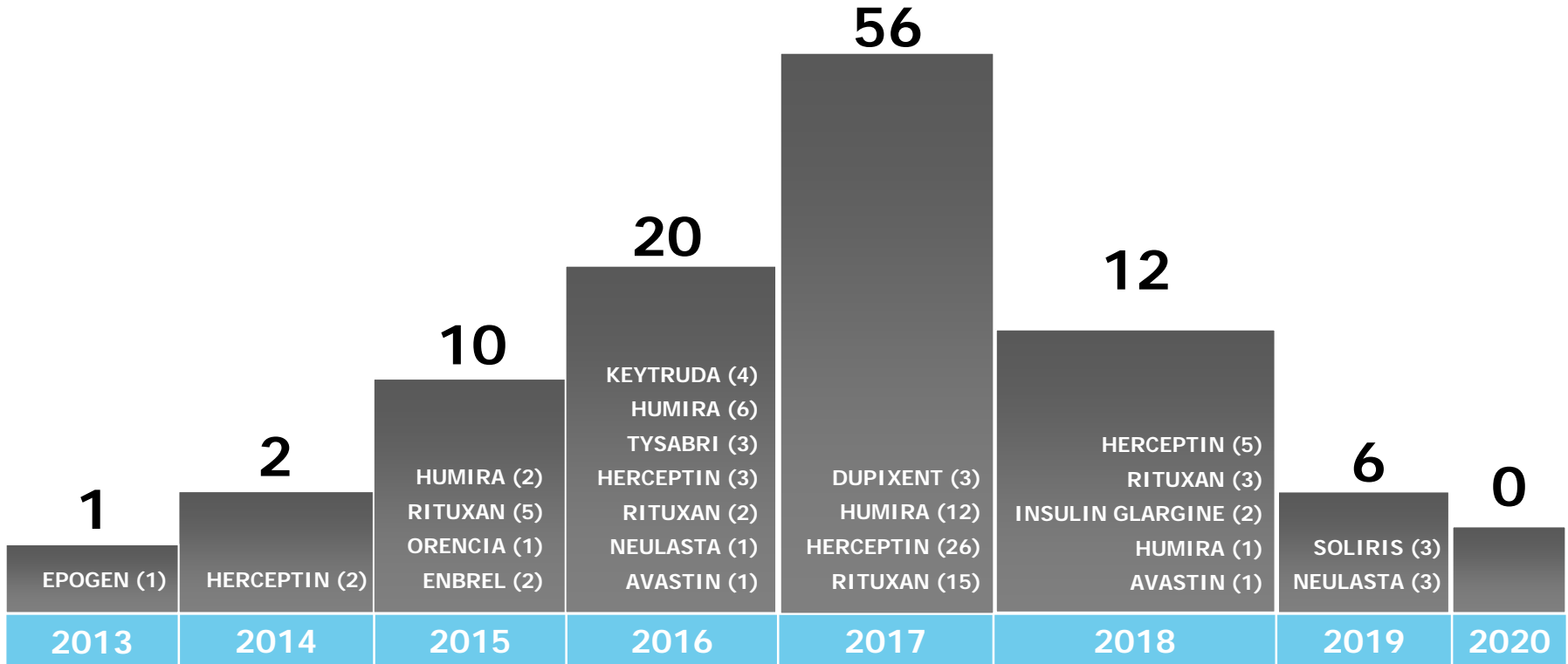
> **Quick statistics:**

- > The current institution rate for IPR challenges to patents that claim biologics is 50% (excludes IPRs that have settled or otherwise been terminated)
- > Of those IPRs instituted and that have gone to final written decision (FWD), 46% have resulted in the challenged claims being held unpatentable, with 18% having mixed results

IPRs by Reference Product

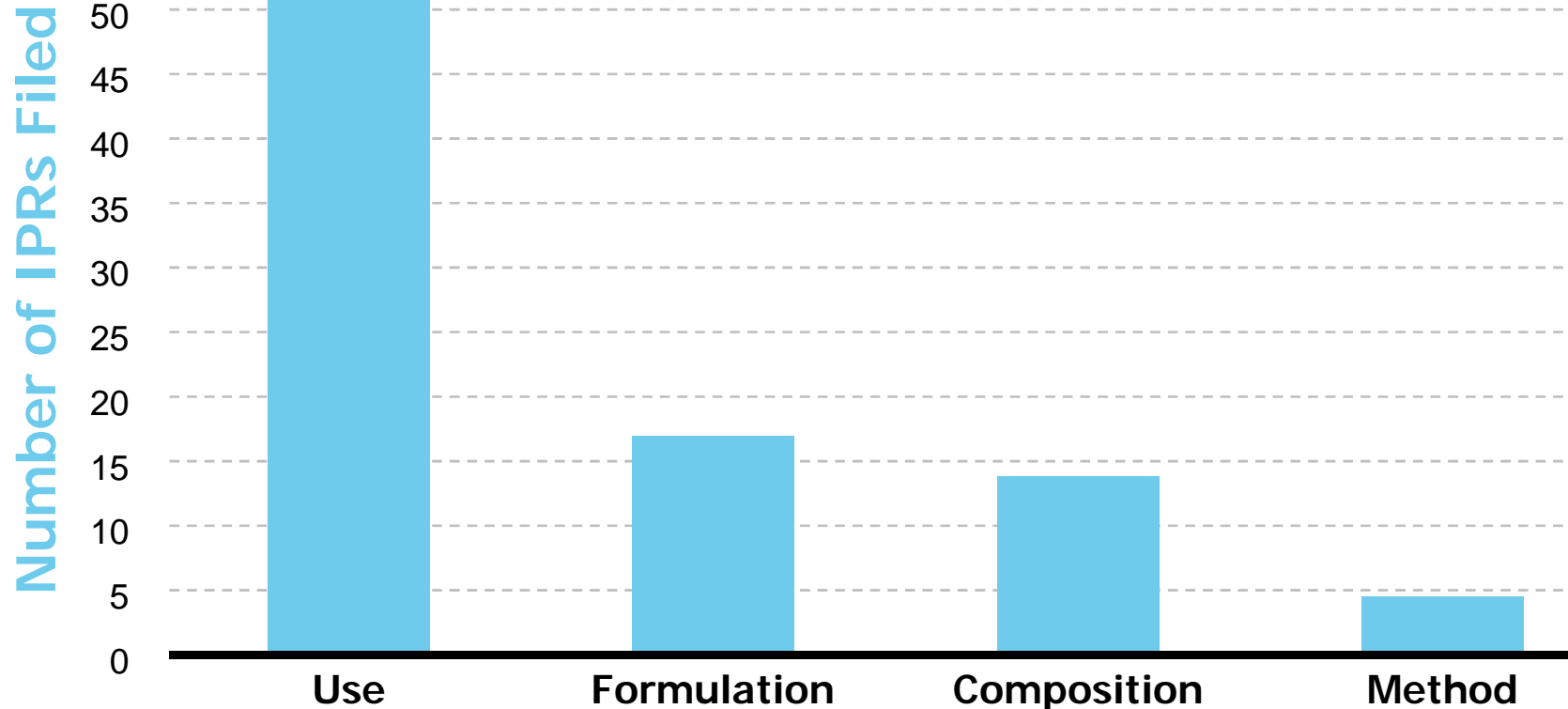


IPR Timeline



Patent and Trademark Office (PTO) Fiscal Year
(September–October)

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	-	-

Institution rate = 35/78 = 48%

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

IPR Scorecard – Institution (cont.)

Product (# of IPRs)	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.*
Avastin (2)	Hospira	0	1	-	1
Orencia (1)	Momenta	0	-	-	1
Neulasta (4)	Apotex	0	-	-	1
	Fresenius Kabi	0	1	-	-
	Kashiv Biosciences	0	-	-	2
Enbrel (3)	Kyle Bass	0	1	-	-
	Coherus	0	2	-	-
Epogen (1)	Hospira	0	-	1	-
Keytruda (4)	Merck	0	0	4	-
Dupixent (3)	Sanofi-Aventis	0	1	-	2
Soliris (3)	Amgen	0	0	-	3
Insulin Glargine (2)	Mylan	0	0	-	2
TOTALS		2	43	23	44

Institution rate = 44/88 = 50%

** 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	-	-	-	-

Invalidation rate = 16/37 = 43%, w/ mixed results 19%

** 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
Tysabri (3)	Swiss Pharma	-	-	-	-
Avastin (2)	Hospira	1	1	-	-
Orencia (1)	Momenta	1	-	1	-
Neulasta (4)	Apotex	1	-	-	1
Enbrel (3)	Kyle Bass	-	-	-	-
	Coherus	-	-	-	-
Epogen (1)	Hospira	-	-	-	-
Keytruda (4)	Merck	-	-	-	-
Dupixent (3)	Sanofi-Aventis	2	1	1	-
Insulin Glargine (2)	Mylan	2	2	-	-
TOTALS		39	18	11	7

Invalidation rate = 18/39 = 46%, w/ mixed results 18%

**** 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	<ul style="list-style-type: none">• 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	9,017,987	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	2016-1614 (2018-1885) 2017-01115 joined (2018-1924)	Claims Valid	<ul style="list-style-type: none"> • Appeal No. 2016-1614 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	<ul style="list-style-type: none"> • Biogen challenging constitutionality of IPRs • Pfizer not participating in appeal • PTO intervened in appeal • Parties voluntarily dismissed appeal • Issues fully briefed • Oral argument held on December 6, 2019

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"> • PTO intervened • Affirmed Board's decision challenged claims unpatentable on anticipation and obviousness grounds
Genentech	Hospira	7,846,441	2017-00731 (2019-1263)	Claims Invalid	<ul style="list-style-type: none"> • Hospira withdrew as party due to settlement and PTO intervened • Lead case – consolidated with 2019-1267 • Appeal submitted on briefs • Affirmed Board's decision challenged claims unpatentable on obviousness grounds
Genentech	Celltrion	7,846,441	2017-01121 (2019-1267)	Claims Invalid	<ul style="list-style-type: none"> • PTO intervened • Consolidated with 2019-1263 • Affirmed Board's decision
Genentech	Hospira	6,627,196	2017-00804/ 2017-01958 joined (2019-1173)	Claims Valid	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> Consolidated with 2019-1173 Appeal voluntarily dismissed
Genentech	Celltrion	6,627,196	2017-01139 (2019-1258)	Claims Valid	<ul style="list-style-type: none"> Consolidated with 2019-1259 Parties dismissed appeal
Genentech	Celltrion	7,371,379	2017-01140 (2019-1259)	Claims Valid	<ul style="list-style-type: none"> Consolidated with 2019-1258 Parties dismissed appeal
Genentech	Hospira	7,892,549	2017-00737/ 2017-01960 joined (2019-1265)	Claims Invalid	<ul style="list-style-type: none"> Hospira withdrew as party due to settlement Samsung Bioepis withdrew as party Lead-consolidated with 2019-1270 Affirmed Board's decision challenged claims unpatentable on obviousness grounds
Genentech	Celltrion	7,892,549	2017-01122 (2019-1270)	Claims Invalid	<ul style="list-style-type: none"> PTO 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	<ul style="list-style-type: none">• Amgen filed Notice of Appeal• PTO allowed to intervene• Amgen raised an Appointments Clause challenge• Board's decision vacated and case remanded to Board for proceedings consistent with court's decision in <i>Arthrex</i>

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

Post-Grant Reviews (PGRs)

- > Only one PGR has been filed to date in connection with a blockbuster biologic (US 9,856,287)

Product (# IPRs)	Challenger	Pend. Inst.	Pet. Not Inst.	Sett. Term.	Inst.
Neupogen (1)	Adello/Apotex	-	-	-	1

US BIOSIMILAR-RELATED PATENT LITIGATIONS

US Biosimilar Litigations: Developments

> **NEULASTA Litigation:**

- > On February 11, 2020, Amgen filed a complaint in the District of Delaware accusing Pfizer and Hospira of infringing U.S. Patent No. 8,273,707 with their proposed Neulasta biosimilar (No. 1-20-cv-00201)
- > On March 4, 2020, Pfizer and Hospira filed a motion to dismiss for failure to state a claim, arguing Amgen surrendered subject matter during prosecution

> **NEUPOGEN Litigation:**

- > On April 24, 2020, Amgen filed a complaint in the District of Delaware accusing Pfizer and Hospira of infringing U.S. Patent No. 10,577,392 with their proposed Neupogen biosimilar (No. 1-20-cv-00561)

> **REMICADE Litigation:**

- > On March 5, 2020, the Federal Circuit affirmed the district court's judgment of non-infringement regarding Celltrion's Remicade biosimilar

US Biosimilar Litigations: Developments (cont.)

> Summary of Nine Humira Biosimilar Settlements

Party	US Market Entry	EP Market Entry
Amgen	January 31, 2023	October 16, 2018
Biogen and Samsung Bioepis	June 30, 2023	October 16, 2018
Mylan	July 31, 2023	---
Sandoz	September 30, 2023	October 16, 2018
Fresenius Kabi	September 30, 2023	Upon approval
Momenta	November 20, 2023	---
Pfizer	November 20, 2023	---
Coherus	December 15, 2023	---
Boehringer Ingelheim	July 1, 2023	---

US Biosimilar Litigations: Developments (cont.)

- > Products in patent litigation that we are monitoring include:
 - > Avastin
 - > Herceptin
 - > Neupogen
 - > Enbrel
 - > Humira
 - > Remicade
 - > Epogen
 - > Neulasta
- > These litigations are summarized on the following slides

Blockbuster Biologics: US Litigation Scorecard – Humira

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Humira (4)	<i>AbbVie v. Amgen</i>	No. 16-666-MSG (D. Del.)	10	M, F, U, C	<ul style="list-style-type: none"> Settled – US launch of Amjevita expected January 31, 2023
	<i>AbbVie v. Boehringer Ingelheim</i>	No. 17-1065-SLR (D. Del.)	8	M, F, U, C	<ul style="list-style-type: none"> Parties stipulated to dismissal
	<i>AbbVie v. Sandoz</i>	No. 18-12668 (D.N.J.)	2	U, F	<ul style="list-style-type: none"> Settled – US launch of Hyrimoz expected September 20, 2023
	<i>Coherus v. Amgen</i>	No. 19-00139 (D. Del.)	3	C	<ul style="list-style-type: none"> Parties stipulated to dismissal Amgen filed motion for determination of exceptional case and an award of fees; parties' briefing filed

Blockbuster Biologics: 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"> Stipulated dismissal without prejudice Sandoz decided not to pursue its FDA submission for its biosimilar
	<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"> Genentech's Motion to Dismiss granted Final judgment appealed to Federal Circuit Appeal voluntarily dismissed
	<i>Genentech v. Celltrion</i>	No. 18-574-RMB-KMW (D.N.J.)	40	M, U, C	<ul style="list-style-type: none"> Settled
	<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"> Settled

Blockbuster Biologics: US Litigation Scorecard – Herceptin

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Herceptin (6)	<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"> • Genentech's Motion to Dismiss granted • Final judgment appealed to Federal Circuit • Appeal voluntarily dismissed
	<i>Genentech v. Celltrion</i>	No. 18-095-CFC (D. Del.)	40	M, U, C	<ul style="list-style-type: none"> • All Delaware cases are before Judge Connolly and being coordinated • <i>Markman</i> hearing April 2019 • Trial set for December 2019 • Lead case • Settled
	<i>Genentech v. Pfizer</i>	No. 17-1672-CFC (D. Del.)	40	M, U, C	<ul style="list-style-type: none"> • Settled

Blockbuster Biologics: US Litigation Scorecard – Herceptin (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Herceptin (6)	<i>Genentech v. Amgen</i>	No. 18-924-CFC (D. Del.)	37	M, U, C	<ul style="list-style-type: none"> • Early discovery • Claims regarding expired patents and Amgen's defense of unclean hands/inequitable conduct voluntarily dismissed • Court denied Genentech's Motion for TRO and lifted standstill order given July 10, 2019 • Trial set for February 2021
	<i>Genentech v. Celltrion</i>	No. 18-1025-CFC (D. Del.)	40	M, U, C	<ul style="list-style-type: none"> • Settled
	<i>Genentech v. Samsung Bioepis</i>	No. 18-01363-CFC (D. Del.)	21	M, U, C	<ul style="list-style-type: none"> • Dismissed due to settlement

Blockbuster Biologics: 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"> Complaint alleged 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 Non-infringement; affirmed on appeal Petition for rehearing en banc denied
	<i>Amgen v. Apotex</i>	No. 15-62081-JIC (S.D. Fla.)	2	M, C	<ul style="list-style-type: none"> Consolidated with <i>Amgen v. Apotex</i> pegfilgrastim (Neulasta) litigation, No. 15-61631, where district court entered judgment of non-infringement for Sandoz Affirmed

Blockbuster Biologics: 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"> 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 June 10, 2019, Kashiv substituted in place of Adello November 25, 2019, parties stipulated to dismissal, without prejudice
	<i>Amgen v. Hospira</i>	No. 18-1064 (D. Del.)	1	M	<ul style="list-style-type: none"> Scheduling Order issued: Close of fact discovery was August 23, 2019 <i>Markman</i> hearing held May 15, 2019 Trial is set for May 2021
	<i>Sandoz v. Amgen</i>	No. 19-00977 (N.D. Cal.)	1	M	<ul style="list-style-type: none"> Sandoz voluntarily dismissed action without prejudice

Blockbuster Biologics: 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"> Complaint and Answer to Complaint filed December 19, 2019, parties entered into stipulation of dismissal, without prejudice
	<i>Amgen v. Hospira</i>	No. 20-561 (D. Del.)	1	M	<ul style="list-style-type: none"> Complaint filed April 24, 2020

Blockbuster Biologics: 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"> • Amgen found not to infringe • Supreme Court denied Apotex's Petition for Certiorari • Federal Circuit affirmed district court ruling • District court: <ol style="list-style-type: none"> 1) granted Amgen's Motion for Summary Judgment re: invalidity defenses except non-enablement 2) awarded judgment of non-infringement for Apotex 3) dismissed Apotex's non-enablement defense without prejudice
	<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"> • Dismissed after Sandoz restarted patent dance negotiations

Blockbuster Biologics: 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"> • On appeal, fully briefed, pending scheduling of oral argument • Summary Judgment of Non-infringement granted for Sandoz • Affirmed
	<i>Amgen v. Coherus</i>	No. 17-546-LPS (D. Del.) No. 18-1993 (Fed. Cir.)	1	M	<ul style="list-style-type: none"> • Court granted Coherus's Motion to Dismiss for Failure to State a Claim • Judgment entered against Amgen and case was dismissed • Affirmed

Blockbuster Biologics: 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"> • 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 Non-infringement of US Patent No. 9,643,997 filed – ruling deferred • Abeyance in place pending further order to be issued around August 14, 2019 • Parties stipulated to non-infringement of U.S. Patent No. 9,643,997
	<i>Amgen v. Apotex</i>	No. 18-61828 (S.D. Fla.)	1	M	<ul style="list-style-type: none"> • 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 • November 14, 2019, parties entered into stipulation of dismissal, without prejudice

Blockbuster Biologics: 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">• Complaint filed February 11, 2020• Hospira and Pfizer filed motion to dismiss for failure to state a claim, arguing Amgen surrendered subject matter during prosecution

Blockbuster Biologics: 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"> • Before trial, Sandoz stipulated to infringement to certain asserted claims of two of the five patents-in-suit • Bench trial held September 2018 and district court judge ruled in favor of Immunex, holding patents-in-suit were valid • Sandoz appeal to Federal Circuit pending, with oral argument held March 4, 2020
	<i>Immunex v. Samsung Bioepis</i>	No. 19-11755-CCC (D.N.J.)	5	C, U, M, F	<ul style="list-style-type: none"> • Court entered a Consent Injunction Order on January 8, 2020, prohibiting Samsung Bioepis from using, importing, offering to sell, or selling any entanercept product in the United States, except as allowed by 35 U.S.C. § 271(e)(1) safe harbor • January 15, 2020, court endorsed parties' proposed order to administratively stay the case consistent with the Confidential Stipulation and Consent Injunction

Blockbuster Biologics: US Litigation Scorecard – Epogen

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Epogen (1)	<i>Amgen v. Hospira</i>	No. 15-839-RGA (D. Del.) No. 16-2179 (Fed. Cir.) (appeal was dismissed) No. 19-1067 and No. 19-1102 (Fed. Cir.)	2	C, M	<ul style="list-style-type: none"> • 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 the safe-harbor provision about which the jury was given erroneous instructions • Amgen responded that there was sufficient evidence supporting the jury's finding that only seven of the 21 drug batches qualified for safe harbor • Oral argument held September 30, 2019 • Judgment affirmed December 16, 2019 • Petition for Rehearing and Petition for Rehearing En Banc denied

Blockbuster Biologics: US Litigation Scorecard – Avastin

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Avastin (6)	<i>Genentech v. Amgen</i>	No. 17-165-GMS (D. Del.)	Litigation over violations of BPCIA	NA	<ul style="list-style-type: none"> Dismissed Complaint without prejudice
	<i>Amgen v. Genentech</i>	No. 17-7349-GW-AGR (C.D. Cal.)	27	M, C, F, U	<ul style="list-style-type: none"> Genentech's Motion to Dismiss for Lack of Subject Matter Jurisdiction granted
	<i>Genentech v. Amgen</i>	No. 17-1407-CFC (D. Del.)	24	M, C, F, U	<ul style="list-style-type: none"> Early pleadings and discovery Consolidated with No. 17-1471 Lead case Granted Genentech's motion to dismiss Amgen's counterclaims, seek DJ that two patents invalid, unenforceable, not infringed for lack of subject-matter jurisdiction Trial set for November 2020
	<i>Genentech v. Amgen</i>	No. 17-1471-CFC (D. Del.)	25	M, C, F, U	<ul style="list-style-type: none"> Consolidated with No. 17-1407
	<i>Genentech v. Pfizer</i>	No. 19-00638-CFC (D. Del.)	22	M, C, F, U	<ul style="list-style-type: none"> Settled

Blockbuster Biologics: US Litigation Scorecard – Avastin (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Avastin (6)	<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"> • 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's appeal regarding commercial marketing pending; oral argument set for June 3, 2020

Blockbuster Biologics: US Litigation Scorecard – Remicade

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Remicade (5)	<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"> 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
	<i>Janssen v. Celltrion</i>	No. 16-11117-MLW (D. Mass.)	1	M (cell culture media)	<ul style="list-style-type: none"> Dismissed without prejudice in favor of No. 17-11008
	<i>Janssen v. HyClone</i>	No. 16-00071-BCW (D. Utah)	1	M (cell culture media)	<ul style="list-style-type: none"> Case administratively closed November 26, 2019, per related litigation in D. Mass.

Blockbuster Biologics: US Litigation Scorecard – Remicade (cont.)

Product (# of litigations)	Case Name	Case No. (Jurisdiction)	# of Asserted Patents	Types of Claims	Status
Remicade (5)	<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"> Judgment entered for defendants after court allowed Motion for Summary Judgment of Non-infringement based on ensnarement Affirmed on appeal
	<i>Janssen v. Samsung Bioepis</i>	No. 17-3524-MCA-SCM (D.N.J.)	3	M	<ul style="list-style-type: none"> Janssen voluntarily dismissed its patent infringement claims Suit dismissed with prejudice

LEGISLATIVE UPDATES

- > **FDA issued a final rule amending the definition of “biological product”**
 - > This previous definition included “protein (except any chemically synthesized polypeptide)”
 - > Congress removed the parenthetical in the definition of “protein” in December
 - > FDA now interprets the word “protein” to mean “any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size”

- > **On February 21, 2020, FDA published a final rule transitioning insulin to be regulated as a biologic instead of a small molecule drug**
 - > On March 23, 2020, FDA will begin accepting applications for biosimilars that reference insulin

BIOSIMILAR APPROVALS AND LAUNCHES

US Biosimilar Approvals – 26 total

Drug Name	Approval Date	Drug Name	Approval Date
Avsola (infliximab-axxq)	December 2019	Ontruzant (trastuzumab-dttb)	January 2019
Abrilada (adalimumab-afzb)	November 2019	Herzuma (trastuzumab-pkrb)	December 2018
Ziextenzo (pegfilgrastim-bmez)	November 2019	Truxima (rituximab-abbs)	November 2018
Hadlima (adalimumab-bwwd)	July 2019	Udenyca (pegfilgrastim-cbqv)	November 2018
Ruxience (rituximab-pvvr)	July 2019	Hyrimoz (adalimumab-adaz)	October 2018
Zirabev (bevacizumab-bvzr)	June 2019	Nivestym (filgrastim-aafi)	July 2018
Kanjinti (trastuzumab-anns)	June 2019	Fulphila (pegfilgrastim-jmdb)	June 2018
Eticovo (etanercept-ykro)	April 2019	Retacrit (epoetin alfa-epbx)	May 2018
Trazimera (trastuzumab-qyyp)	March 2019	Ixifi (infliximab-qbtx)	December 2017

US Biosimilar Approvals – 26 total (cont.)

Drug Name	Approval Date
Ogivri (trastuzumab-dkst)	December 2017
Mvasi (bevacizumab-awwb)	September 2017
Cyltezo (adalimumab-adbm)	August 2017
Renflexis (infliximab-abda)	May 2017
Amjevita (adalimumab-atto)	September 2016
Erelzi (etanercept-szsz)	August 2016
Inflectra (infliximab-dyyb)	April 2016
Zarxio (filgrastim-sndz)	March 2015

Contacts



Christopher J. Betti, Ph.D.
Chicago
T: +1.312.324.1449
christopher.betti@morganlewis.com



Robin M. Silva
San Francisco
T: +1.415.442.1379
robin.silva@morganlewis.com



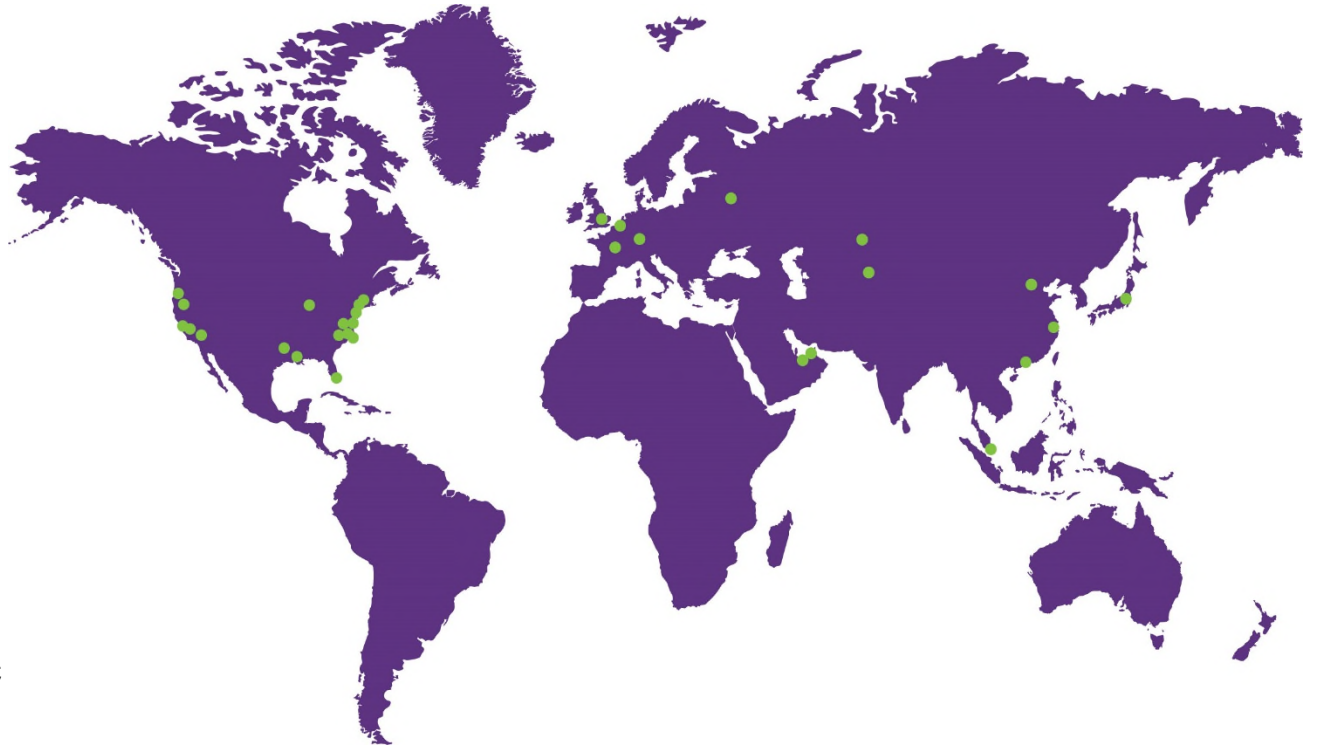
Maria E. Doukas
Chicago
T: +1.312.324.1454
maria.doukas@morganlewis.com

Our Global Reach

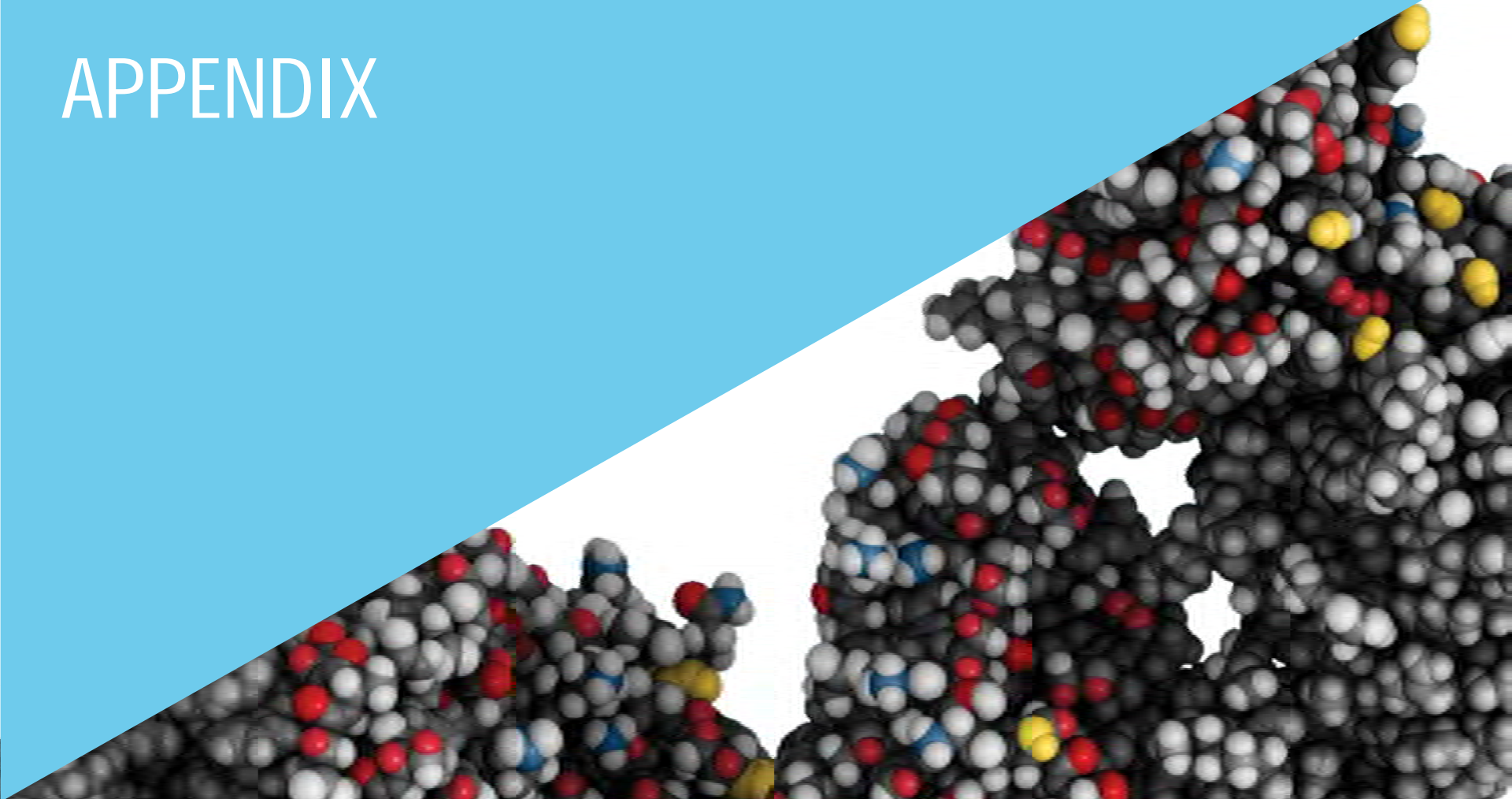
Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
New York
Nur-Sultan
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Shanghai*
Silicon Valley
Singapore*
Tokyo
Washington, DC
Wilmington



APPENDIX



Legend

P	Petitioner
PO	Patent Owner
2-Consid.	Secondary Considerations raised by PO to support non-obviousness
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
NA	Not Applicable
Y/N	Yes/No

HUMIRA

> 22 IPRs filed challenging 14 different patents

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

> 22 IPRs filed challenging 14 different patents

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

> 22 IPRs filed challenging 14 different patents

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

Representative Claim

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

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

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2015-01517	1-8, 10-13, 15-30	None	1/0	Y	F	Institution Denied

Representative Claim

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

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

Representative Claim

1. A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, comprising:
 - a) administering to said patient, in combination with methotrexate, a human anti-TNF α antibody;
 - b) wherein the human anti-TNF α antibody is administered subcutaneously in a total body dose of 40 mg once every 13–15 days; and
 - c) wherein the anti-TNF α antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

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

Representative Claim

1. A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, comprising:
 - a) administering to said patient a total body dose of 40 mg of a human anti-TNF α antibody;
 - b) wherein the dose is administered subcutaneously in a 40 mg dosage unit form once every 13–15 days; and
 - c) wherein the anti-TNF α antibody comprises an IgG1 heavy chain constant region; a V_L chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:7, a CDR2 having the amino acid sequence of SEQ ID NO:5, and a CDR3 having the amino acid sequence of SEQ ID NO:3; and a V_H chain region comprising a CDR1 having the amino acid sequence of SEQ ID NO:8, a CDR2 having the amino acid sequence of SEQ ID NO:6, and a CDR3 having the amino acid sequence of SEQ ID NO:4.

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

Representative Claim

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

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

Representative Claim

16. An aqueous pharmaceutical formulation comprising:
- a) an anti-TNF α antibody comprising an LCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:7; and an HCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:8, wherein the concentration of the antibody is 50 mg/ml to 200 mg/ml; and
 - b) water; wherein the formulation does not comprise a buffering system.

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

Representative Claim

16. An aqueous pharmaceutical formulation comprising:
- a) an anti-TNF α antibody comprising an LCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:7; and an HCVR having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:8, wherein the concentration of the antibody is 50 mg/ml to 200 mg/ml; and
 - b) water; wherein the formulation does not comprise a buffering system.

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Coherus	2017-00826	16-19, 24-30	NA	2/NA	Y	F	Dismissed
Coherus	2017-00827	16-19, 24-30	NA	2/NA	Y	F	Dismissed
Coherus	2017-01008	16-19, 24-30	NA	2/1	Y	F	Institution Denied
Coherus	2017-01009	16-19, 24-30	NA	2/1	Y	F	Institution Denied

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

RITUXAN

> 27 IPRs filed challenging 10 different patents

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

> 27 IPRs filed challenging 10 different patents

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

> 27 IPRs filed challenging 10 different patents

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

1. A method of treating low-grade, B-cell non-Hodgkin's lymphoma (NHL) in a human patient by administering chemotherapy consisting of cyclophosphamide, vincristine, and prednisone (CVP therapy) to which the patient responds, followed by rituximab maintenance therapy, wherein the maintenance therapy comprises four weekly administrations of rituximab at a dose of 375 mg/m² every six months, and wherein the maintenance therapy is provided for two years.

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

Representative Claim

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

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

Representative Claim

1. A method for treating low-grade or follicular NHL by administering to a patient a therapeutically effective amount of rituximab during a chemotherapeutic regimen, wherein the chemotherapeutic regimen consists of CVP therapy, wherein the method comprises administering 375 mg/m² of rituximab, and wherein the method provides a beneficial synergistic effect in the patient.

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

Representative Claim

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

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

Representative Claim

1. A method of treating CLL in a human patient by administering rituximab in an amount effective to treat the CLL, wherein the rituximab is administered to the patient at a dosage of 500 mg/m².

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

HERCEPTIN

> 36 IPRs filed challenging 12 different patents

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

> 36 IPRs filed challenging 12 different patents

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

> 36 IPRs filed challenging 12 different patents

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

> 36 IPRs filed challenging 12 different patents

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

*Also being asserted regarding Rituxan and Avastin

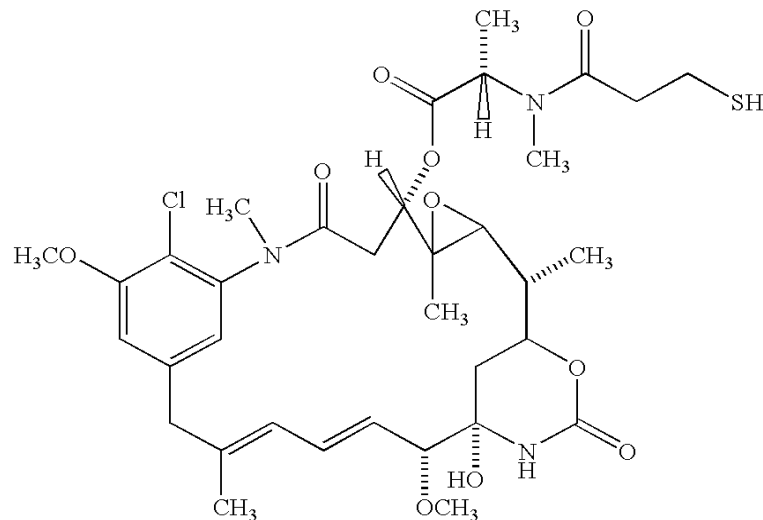
Representative Claim

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

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

Representative Claim

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



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

Representative Claim

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

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

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Pfizer	2017-01488	1-2, 4, 12, 25, 29-31, 33, 42, 60, 62-67, 69, 71-81	§ 102 for claims 1, 2, 4, 25, 29, 62-64, 66, 67, 71, 72, 75, 76, 80, 81; § 103 for claims 1, 2, 4, 12, 25, 29, 30, 31, 33, 42, 60, 62-67, 69, 71-81	2/1	Y	C	FWD – Claims Invalid (1, 2, 4, 25, 29, 30, 31, 33, 62-64, 66, 67, 69, 72, 78, 80, 81)
Pfizer	2017-01489	1-2, 4, 12, 25, 29, 62-67, 69, 71-81	§ 103 for all claims	2/1	Y	C	FWD – Claims Invalid (1, 2, 4, 12, 25, 29, 30, 31, 33, 42, 60, 62-64, 66, 67, 69, 71, 73, 74, 78, 80, 81)
Boehringer Ingelheim	2017-02032	1-2, 4, 25, 29, 62-64, 66-67, 71-73, 75-78, 80-81	§ 102 for claims 1-2, 4, 25, 62-64, 66, 67, 69, 71, 73, 75, 78, 80, 81 § 103 for claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71-73, 75-78, 80-81	1/0	Y	C	Adverse Judgment

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

*Also being asserted regarding Rituxan

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

TYSABRI

> Three IPRs filed challenging three different patents

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

KEYTRUDA

> Four IPRs filed challenging two patents

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

Representative Claim

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

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

Representative Claim

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

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

AVASTIN

> Two IPRs filed challenging two patents

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

Representative Claim

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

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

Representative Claim

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

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

EPOGEN

- > One IPR filed challenging one patent

Representative Claim

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

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

ORENCIA

- > One IPR filed challenging one patent

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Momenta	2015-01537	1-15	§ 103	½	Y	F	FWD – Claims Valid Momenta Appealed (Case No. 17-1694); Momenta ordered to show cause as to why appeal should not be dismissed as moot due to lack of Article III standing

NEULASTA

> Four IPRs filed challenging four patents

Amgen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,952,138* *Also asserted against Neupogen	Apotex	2016-01542	1/1	N	M	FWD – Claims 1-17 and 19-24 unpatentable Claim 18 patentable (non-aerobic) Request for Rehearing denied Appealed
9,856,287	Fresenius Kabi	2019-00971	1/0	Y	M	Institution Denied
8,940,878	Kashiv Biosciences	2019-00791	1/0	Y	M	Terminated after Institution (Settled)
9,643,997	1) Kashiv Biosciences	1) 2019-00797	1) 1/0	1) Y	1) M	1) Terminated after Institution (Settled)
	1) Fresenius Kabi	1) 2019-01183	2) NA	2) Y	2) M	2) Pending

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Apotex	2016-01542	1-24	§ 103 for all claims	1/1	N	M	<p>FWD – Claims 1-17 and 19-24 unpatentable Claim 18 patentable (non-aerobic)</p> <p>Request for Rehearing denied</p> <p>Appealed</p>

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

ENBREL

> Three IPRs filed challenging two patents

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

Representative Claim

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

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

Representative Claim

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

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

DUPIXENT

> Three IPRs filed challenging one patent

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

Representative Claim

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

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

SOLIRIS

> Three IPRs filed challenging three patents

Amgen Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,725,504	Amgen	2019-00739	1/0	N	M	Instituted
9,718,880	Amgen	2019-00740	1/0	Y	C	Instituted
9,732,149	Amgen	2019-00741	1/0	Y	C	Instituted

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00739	1-10	§§ 102, 103	1/0	N	M	Instituted

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00741	1-3	§§ 102, 103	1/0	Y	C	Instituted

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Amgen	2019-00740	1	§§ 102, 103	1/0	Y	C	Instituted

INSULIN GLARGINE

> Two IPRs filed challenging two patents

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

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2017-01526	1-25	§ 103	4/2	Y	F	FWD. Claims 1-25 unpatentable

Representative Claim

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

Challenger(s)	IPR No.	Challenged Claims	Instituted Grounds	# of P/PO Experts	2-Consid.	Claim Type	Status
Mylan	2017-01528	1-20	§ 103	4/2	Y	F	FWD. Claims 1-20 unpatentable

PEN-TYPE INJECTOR FOR INSULIN GLARGINE

> Eighteen IPRs filed challenging five patents related to pen-type injector for insulin

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

> Eighteen IPRs filed challenging five patents related to pen-type injector for insulin

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
8,992,486	1) Mylan 2) Mylan, Pfizer 3) Mylan, Pfizer 4) Mylan, Pfizer	1) 2018-01677 2) 2018-01678 (2019-00980 joined) 3) 2018-01679 (2019-00981 joined) 4) 2019-00122 (2019-00982 joined)	1) 1/NA 2) 3/3 3) 3/3 4) 3/3	1) NA 2) Y 3) Y 4) Y	Pen-type injector	1) Petitioner's motion to dismiss unopposed granted. 2) Instituted 3) Instituted 4) Instituted

> Eighteen IPRs filed challenging five patents related to pen-type injector for insulin

Sanofi Patent	Challenger(s)	IPR No.	# of P/PO Experts	2-Consid.	Claim Type	Status
9,526,844	1) Mylan, Pfizer 2) Mylan, Pfizer	1) 2018-01680 (2019-01022 joined) 2) 2018-01682 (2019-01023) 3) 2018-01696	1) 3/3 2) 3/3 3) 1/0	1) Y 2) Y 3) N	Pen-type injector	1) Instituted 2) Instituted 3) Not Instituted.
9,604,008	Mylan, Pfizer	2018-01684 (2019-00987 joined)	3/3	Y	Pen-type injector	1) Instituted 2) Instituted

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

Representative Claim

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

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

THANK YOU

© 2020 Morgan, Lewis & Bockius LLP

© 2020 Morgan Lewis Stamford LLC

© 2020 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.