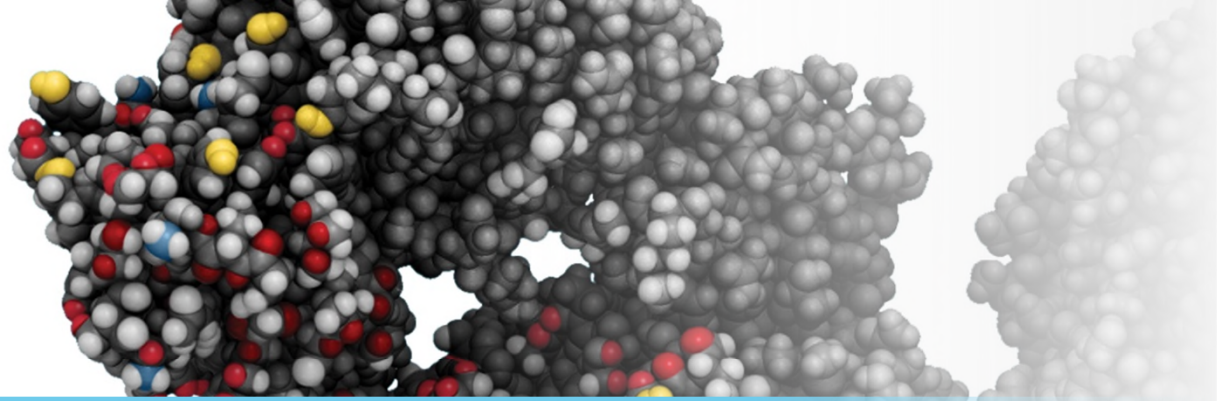
Morgan Lewis



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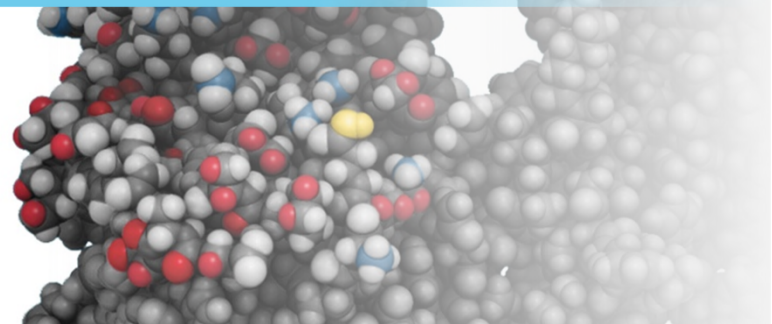
Supporting Documents



Legend

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

HUMIRA

Humira-Related IPRs

> 22 IPRs filed challenging 14 different patents

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

Humira-Related IPRs (cont.)

> 22 IPRs filed challenging 14 different patents

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

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

Humira-Related IPRs (cont.)

> 22 IPRs filed challenging 14 different patents

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

8,916,157 Patent IPR

Representative Claim

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

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

8,916,158 Patent IPR

Representative Claim

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

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

8,889,135 Patent IPRs

Representative Claim

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

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

9,017,680 Patent IPR

Representative Claim

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

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

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

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

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

9,073,987 Patent IPR

Representative Claim

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

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

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

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

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

9,114,166 Patent IPR

Representative Claim

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

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

9,085,619 Patent IPRs

Representative Claim

16. An aqueous pharmaceutical formulation comprising:

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

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

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

9,085,619 Patent IPRs (cont.)

Representative Claim

16. An aqueous pharmaceutical formulation comprising:

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

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

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

9,067,992 Patent IPR

Representative Claim

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

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

8,911,737 Patent IPR

Representative Claim

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

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

8,974,790 Patent IPR

Representative Claim

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

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

9,090,689 Patent IPR

Representative Claim

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

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

8,802,100 Patent IPR

Representative Claim

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

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

9,512,216 Patent IPRs

Representative Claim

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

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

9,187,559 Patent IPR

Representative Claim

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

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

RITUXAN

Rituxan-Related IPRs

> 27 IPRs filed challenging 10 different patents

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

Rituxan-Related IPRs (cont.)

> 27 IPRs filed challenging 10 different patents

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

Rituxan-Related IPRs (cont.)

> 27 IPRs filed challenging 10 different patents

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

7,820,161 Patent IPRs

Representative Claim

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

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

7,820,161 Patent IPRs (cont.)

Representative Claim

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

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

7,976,838 Patent IPRs

Representative Claim

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

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

7,976,838 Patent IPRs (cont.)

Representative Claim

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

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

8,329,172 Patent IPRs

Representative Claim

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

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

8,557,244 Patent IPRs

Representative Claim

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

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

9,296,821 Patent IPRs

Representative Claim

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

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

7,682,612 Patent IPRs

Representative Claim

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

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

8,206,711 Patent IPRs

Representative Claim

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

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

8,821,873 Patent IPR

Representative Claim

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

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

8,545,843 Patent IPR

Representative Claim

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

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

9,504,744 Patent IPR

Representative Claim

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

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

HERCEPTIN

Herceptin-Related IPRs

> 36 IPRs filed challenging 12 different patents

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

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

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

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

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

Herceptin-Related IPRs (cont.)

> 36 IPRs filed challenging 12 different patents

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

8,337,856 Patent IPR

Representative Claim

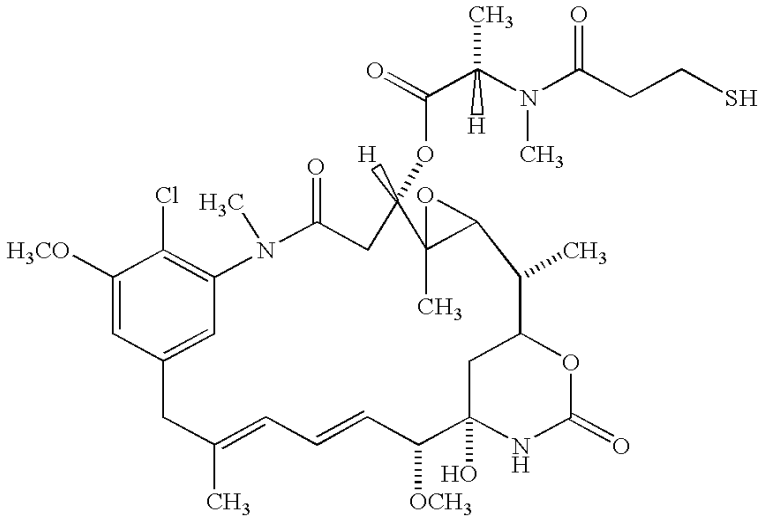
1. An immunoconjugate comprising an anti-ErbB2 antibody conjugated to a maytansinoid, wherein the antibody is huMAb4D5-8.

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

7,575,748 Patent IPR

Representative Claim

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



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

6,407,213 Patent IPRs

Representative Claim

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

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

6,407,213 Patent IPRs (cont.)

Representative Claim

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

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

6,407,213 Patent IPRs (cont.)

Representative Claim

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

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

7,807,799 Patent IPR

Representative Claim

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

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

7,846,441 Patent IPRs

Representative Claim

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

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

7,892,549 Patent IPRs

Representative Claim

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

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

7,892,549 Patent IPRs (cont.)

Representative Claim

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

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

6,627,196 Patent IPRs

Representative Claim

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

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

7,371,379 Patent IPRs

Representative Claim

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

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

7,371,379 Patent IPRs (cont.)

Representative Claim

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

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

8,591,897 Patent IPRs

Representative Claim

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

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

6,339,142 Patent IPRs

Representative Claim

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

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

9,249,218 Patent IPRs

Representative Claim

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

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

8,314,225 Patent IPR*

Representative Claim

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

*Also being asserted regarding Rituxan and Auastin

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

TYSABRI

Tysabri-Related IPRs

- Three IPRs filed challenging three different patents

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

8,815,236 Patent IPR

Representative Claim

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

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

8,349,321 Patent IPR

Representative Claim

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

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

8,900,577 Patent IPR

Representative Claim

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

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

KEYTRUDA

Keytruda-Related IPRs

> Four IPRs filed challenging two patents

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

9,067,999 Patent IPRs

Representative Claim

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

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

9,073,994 Patent IPRs

Representative Claim

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

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

AVASTIN

Avastin-Related IPRs

> Two IPRs filed challenging two patents

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

7,622,115 IPR

Representative Claim

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

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

9,795,672 IPR

Representative Claim

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

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

EPOGEN

6,747,002 IPR

> One IPR filed challenging one patent

Representative Claim

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

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

ORENCIA

8,476,239 IPR

> One IPR filed challenging one patent

Representative Claim

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

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

NEULASTA

Neulasta-Related IPRs

> Eight IPRs filed challenging five patents

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

Neulasta-Related IPRs (cont.)

> Eight IPRs filed challenging five patents

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

8,952,138 IPR

Representative Claim

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

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

9,856,287 IPR

Representative Claim

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

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

8,940,878 IPR

Representative Claim

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

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

9,643,997 IPR

Representative Claim

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

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

8,273,707 IPR

Representative Claim

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

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

ENBREL

Enbrel-Related IPRs

> Three IPRs filed challenging two patents

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

8,163,522 Patent IPR

Representative Claim

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

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

8,063,182 Patent IPR

Representative Claim

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

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

DUPIXENT

Dupixent-Related IPRs

> Three IPRs filed challenging one patent

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

8,679,487 Patent IPR

Representative Claim

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

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

SOLIRIS

Soliris-Related IPRs

> Eight IPRs filed challenging five patents

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

9,725,504 IPR

Representative Claim

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

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

9,718,880 IPR

Representative Claim

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

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

9,732,149 IPR

Representative Claim

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

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

10,590,189 IPR

Representative Claim

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

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

10,703,809 IPR

Representative Claim

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

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

INSULIN GLARGINE

Insulin Glargine–Related IPRs

> Two IPRs filed challenging two patents

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

Representative Claim

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

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

7,713,930 IPR

Representative Claim

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

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

PEN-TYPE INJECTOR FOR INSULIN GLARGINE

Pen-Type Injector-Related IPRs

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

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

Pen-Type Injector-Related IPRs (cont.)

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

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

Pen-Type Injector-Related IPRs (cont.)

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

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

8,603,044 IPR

Representative Claim

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

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

8,679,069 IPR

Representative Claim

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

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

8,992,486 IPR

Representative Claim

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

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

8,992,486 IPR

Representative Claim

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

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

9,526,844 IPR

Representative Claim

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

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

9,604,008 IPR

Representative Claim

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

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

RE47,614 IPR

Representative Claim

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

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

EYLEA

Eylea-Related IPRs

> 23 IPRs filed challenging eight different patents

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

Eylea-Related IPRs (cont.)

> 23 IPRs filed challenging eight different patents

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

Eylea-Related IPRs (cont.)

> 23 IPRs filed challenging eight different patents

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

9,669,069 Patent IPRs

Representative Claim

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

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

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

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

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

9,254,338 Patent IPRs

Representative Claim

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

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

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

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

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

10,130,681 Patent IPRs

Representative Claim

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

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

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

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

wherein exclusion criteria for the patient include all of:

(1) active intraocular inflammation;

(2) active ocular or periocular infection;

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

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

10,888,601 Patent IPRs

Representative Claim

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

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

11,253,572 Patent IPRs

Representative Claim

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

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

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

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

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

10,857,205 Patent IPRs

Representative Claim

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

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

10,406,226 Patent IPRs

Representative Claim

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

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

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

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

10,464,992 Patent IPRs

Representative Claim

1. A vial comprising:

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

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

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

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

Stelara

Stelara-Related IPRs

> Two IPRs filed challenging one patent

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

10,961,307 Patent IPRs

Representative Claim

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

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

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