Biosimilar Litigations

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
AbbVie v. Amgen 1:16-cv-00666 (D. Del.)	Humira® (adalimumab)	Amjevita™ (adalimumab-atto) Approved 9/23/2016 Launched 1/31/2023	8/4/2016	Infringement	Settled 9/28/2017
AbbVie v. Boehringer Ingelheim 1:17-cv-01065 (D. Del.)	Humira® (adalimumab)	Cyltezo® (adalimumab-adbm) Approved 8/25/2017, Interchangeable 10/15/2021 Launched 7/1/2023	8/2/2017	Infringement	Settled 5/15/2019
AbbVie v. Sandoz 3:18-cv-12668 (D.N.J.)	Humira® (adalimumab)	Hyrimoz® (adalimumab-adaz) Approved 10/30/2018 Launched 7/1/2023	8/10/2018	Infringement	Settled 10/16/2018
Coherus v. Amgen 1:19-cv-00139 (D. Del.)	Biosimilar-Biosimilar	Yusimry® (adalimumab-aqvh) Approved 12/17/2021 Launched 7/3/2023 Amjevita™ (adalimumab-atto) Approved 9/23/2016 Launched 1/31/2023	1/24/2019	Infringement	Settled 11/26/2019
AbbVie v. Alvotech 1:21-cv-02258 (N.D. Ill.)	Humira® (adalimumab)	Simlandi® (adalimumab-ryvk) Approved (Interchangeable) 2/23/2024 Launched 5/21/2024	4/27/2021	Infringement	Settled 3/9/2022
Alvotech v. AbbVie 1:21-cv-05645 (N.D. Ill.)	Humira® (adalimumab)	Simlandi® (adalimumab-ryvk) Approved (Interchangeable) 2/23/2024 Launched 5/21/2024	5/11/2021	Declaratory Judgment	Voluntarily dismissed 11/5/2021

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
AbbVie v. Alvotech 1:21-cv-02899 (N.D. Ill.)	Humira® (adalimumab)	Simlandi® (adalimumab-ryvk) Approved (Interchangeable) 2/23/2024 Launched 5/21/2024	5/28/2021	Infringement	Settled 3/9/2022
Regeneron v. Mylan 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-1402, 24-1405; 24-2002	Eylea® (aflibercept)	Yesafili® (aflibercept-jbvf) Approved (Interchangeable) 5/20/2024 Launched 8/3/2026	8/2/2022	Infringement	Judgment 12/27/2023- Claims 4, 7, 9, 11, and 14-17 of U.S. Patent No. 11,084,865 valid and infringed, and claims 6 and 25 of U.S. Patent No. 11,253,572 patent and claims 11 and 19 of U.S. Patent No. 10,888,601 infringed, but invalid as obvious. 3/8/2024- Summary judgment of noninfringement due to disclaimer of U.S. Patent Nos. 10,406,226, 10,464,992, and 10,857,205 4/15/2025- Remaining claims dismissed due to settlement Appeal 24-1402 and Cross Appeal 24-1405- Dismissed for lack of jurisdiction (all claims have not yet been decided by District Court) 6/11/2024- Permanent injunction granted Appeal 24-2002 (permanent injunction)- Settled 4/15/2025
Regeneron v. Celltrion 1:23-cv-00089 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-2058, 24-2147	Eylea® (aflibercept)	Eydenzelt® (aflibercept-boav) Approved 10/2/2025	11/8/2023	Infringement	6/28/2024- Preliminary injunction granted Appeals (preliminary injunction)- Affirmed grant of preliminary injunction 3/5/2025 Settled 10/21/2025, preliminary injunction vacated
Regeneron v. Samsung Bioepis 1:23-cv-00094 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-1966, 24-2083	Eylea® (aflibercept)	Opuviz® (aflibercept-yszy) Approved (Interchangeable) 5/20/2024	11/21/2023	Infringement	6/14/2024- Preliminary injunction granted Appeals (preliminary injunction)- Affirmed grant of preliminary injunction 1/29/2025 Settled 2/11/2026

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Regeneron v. Formycon 1:23-cv-00097 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-2009, 24-2156	Eylea® (aflibercept)	Ahzantive® (aflibercept-mrbb) Approved 6/28/2024	11/29/2023	Infringement	6/21/2024- Preliminary injunction granted Appeals (preliminary injunction)- Affirmed grant of preliminary injunction 1/29/2025 Settled 9/29/2025, preliminary injunction vacated
Regeneron v. Samsung Bioepis 1:23-cv-00106 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-1965, 24-2082	Eylea® (aflibercept)	Opuviz® (aflibercept-yszy) Approved (Interchangeable) 5/20/2024	12/27/2023	Infringement	6/14/2024- Preliminary injunction granted Appeals (preliminary injunction)- Affirmed grant of preliminary injunction 1/29/2025 Settled 2/11/2026
Regeneron v. Amgen 1:24-cv-00039 (N.D.W. Va.) (Transferred from 1:24-cv-00264 (C.D. Cal.)) / MDL 1:24-md-03103 (N.D.W. Va.) Fed. Cir. 24-2351	Eylea® (aflibercept)	Pavblu™ (aflibercept-ayyh) Approved 8/23/2024 Launched 10/2024	1/10/2024	Infringement	Ongoing; 9/23/2024- Preliminary injunction denied Appeal (preliminary injunction)- 9/25/2024- Temporary injunction granted; 10/22/2024- Preliminary injunction pending appeal denied, temporary injunction lifted; 3/14/2025- Affirmed denial of preliminary injunction
Regeneron v. Celltrion 1:24-cv-00053 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.)	Eylea® (aflibercept)	Eydenzelt® (aflibercept-boav) Approved 10/2/2025	5/17/2024	Infringement	Settled 10/21/2025
Regeneron v. Sandoz 1:24-cv-00085 (N.D.W. Va.) (Transferred from 2:24-cv-08760 (D.N.J.)) / MDL 1:24-md-03103 (N.D.W. Va.)	Eylea® (aflibercept)	Enzeevu™ (aflibercept-abzv) Approved 8/9/2024 (Provisionally Interchangeable)	8/26/2024	Infringement	Settled 9/9/2025
Regeneron v. Amgen 1:25-cv-00074 (N.D.W. Va.) (Transferred from 2:25-cv-05499 (C.D. Cal.)) / MDL 1:24-md-03103 (N.D.W. Va.)	Eylea® (aflibercept)	Pavblu™ (aflibercept-ayyh) Approved 8/23/2024 Launched 10/2024	6/17/2025	Infringement	Ongoing

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Genentech v. Amgen 1:17-cv-00165 (D. Del.)	Avastin® (bevacizumab)	Mvasi® (bevacizumab-awwb) Approved 9/14/2017 Launched 7/2019	2/15/2017	Declaratory judgment (failure to comply with BPCIA)	Dismissed 3/1/2017- Patent dance not mandatory
Amgen v. Genentech 2:17-cv-07349 (C.D. Cal.)	Avastin® (bevacizumab)	Mvasi® (bevacizumab-awwb) Approved 9/14/2017 Launched 7/2019	10/6/2017	Declaratory judgment	Dismissed 2/2/2018- Declaratory judgment not available to biosimilar
Genentech v. Amgen 1:17-cv-01407 (D. Del.)	Avastin® (bevacizumab)	Mvasi® (bevacizumab-awwb) Approved 9/14/2017 Launched 7/2019	10/6/2017	Infringement	Settled 7/7/2020
Genentech v. Amgen 1:17-cv-01471 (D. Del.)	Avastin® (bevacizumab)	Mvasi® (bevacizumab-awwb) Approved 9/14/2017 Launched 7/2019	10/18/2017	Infringement	Consolidated with 1:17-cv-01407 (D. Del.); Settled 7/7/2020
Genentech v. Immunex 1:19-cv-00602 (D. Del.) Fed. Cir. 19-2155	Avastin® (bevacizumab)	Mvasi® (bevacizumab-awwb) Approved 9/14/2017 Launched 7/2019	3/29/2019	Infringement	District Court- Temporary Restraining Order and Motion to Enforce Statutory Prohibition on Commercial Marketing denied 7/18/2019; Settled 7/7/2020 Appeal (TRO and Commercial Marketing)- Affirmed 7/6/2020
Genentech v. Pfizer 1:19-cv-00638 (D. Del.)	Avastin® (bevacizumab)	Zirabev® (bevacizumab-bvzr) Approved 6/27/2019 Launched 12/2019	4/5/2019	Infringement	Settled 9/20/2019
Genentech v. Samsung Bioepis 1:20-cv-00859 (D. Del.)	Avastin® (bevacizumab)	SB8 (bevacizumab) aBLA Pending	6/28/2020	Infringement	Settled 9/8/2022

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Genentech v. Centus 2:20-cv-00361 (E.D. Tex.)	Avastin® (bevacizumab)	FKB238 (bevacizumab) aBLA Pending	11/12/2020	Infringement	Settled 7/2/2021
Amgen v. Sandoz 1:23-cv-02406 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Jubbonti® / Wyost® (denosumab-bbdz) Approved (Interchangeable) 3/5/2024 Launched 6/2025	5/1/2023	Infringement	Stipulated dismissal and entry of injunction until 2/19/2025, agreement that U.S. Patent No. 7,364,736 is valid and infringed- 4/29/2024
Amgen v. Celltrion 1:24-cv-06497 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Stoboclo® / Osenvelt® (denosumab-bmwo) Approved 2/28/2025, Interchangeable 10/29/2025 Launched 7/2025	5/28/2024	Infringement	Settled 1/23/2025
Amgen v. Samsung Bioepis 1:24-cv-08417 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Ospomyv™ / Xbryk™ (denosumab-dssb) Approved 2/13/2025, Interchangeable 10/29/2025 Launched 12/2025	8/12/2024	Infringement	Settled 9/5/2025
Amgen v. Fresenius Kabi 1:25-cv-01080 (D.N.J.) (transferred from 1:24-cv-09555 (N.D. Ill.)) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Conexxence™ / Bomyntra™ (denosumab-bnht) Approved 3/25/2025, Interchangeable 10/30/2025 Launched 7/2025	10/4/2024	Infringement	Settled 3/7/2025
Amgen v. Accord 1:25-cv-01305 (D.N.J.) (transferred from 5:24-cv-00642 (E.D.N.C.)) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Osvyrti® / Jubereq® (denosumab-desu) Approved 10/29/2025 (Interchangeable) Launched 7/2026	11/13/2024	Infringement	Settled 7/16/2025

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Amgen v. Hikma 1:25-cv-12152 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Enoby™ / Xtrenbo™ (denosumab-qbde) Approved 9/26/2025, Interchangeable 10/29/2025 Launched 1/2026	6/25/2025	Infringement	Settled 11/24/2025
Amgen v. Shanghai Henlius Biotech 1:25-cv-12160 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Bildyos® / Bilprevda® (denosumab-nxxp) Approved 8/29/2025, Interchangeable 10/29/2025 Launched 10/2025	6/25/2025	Infringement	Settled 3/31/2026
Amgen v. Biocon 1:25-cv-13358 (D.N.J.) (transferred from 1:25-cv-11867 (D. Mass.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Bosaya™ / Aukelso™ (denosumab-kyqq) Approved 9/16/2025, Interchangeable 10/29/2025 Launched 4/2026	6/30/2025	Infringement	Settled 9/30/2025
Amgen v. Dr. Reddy's 1:25-cv-17277 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	AVT03 (denosumab) aBLA Pending	11/6/2025	Infringement	Ongoing
Amgen v. Amneal 1:25-cv-17278 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	Boncresa™ / Oziltus™ (denosumab-mobz) Approved (Interchangeable) 12/19/2025	11/6/2025	Infringement	Ongoing
Amgen v. Alkem 1:25-cv-17596 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.)	Prolia® / Xgeva® (denosumab)	ENZ215 (denosumab) aBLA Pending	11/14/2025	Infringement	Ongoing

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Alexion v. Samsung Bioepis 1:24-cv-00005 (D. Del.) Fed. Cir. 24-1829	Soliris® (eculizumab)	Epysqli® (eculizumab-aagh) Approved 7/19/2024 Launched 4/2025	1/3/2024	Infringement	District Court- Preliminary injunction denied 5/6/2024; Voluntarily dismissed 8/30/2024 Appeal (preliminary injunction)- Temporary injunction pending appeal denied 7/29/2024; Voluntarily dismissed 8/30/2024
Amgen v. Hospira 1:15-cv-00839 (D. Del.) Fed. Cir. 16-2179 Fed. Cir. 19-1067 Fed. Cir. 19-1102	Epogen® / Procrit® (epoetin alfa)	Retacrit® (epoetin alfa-epbx) Approved 5/15/2018 Launched 11/2018	9/18/2015	Infringement; Declaratory judgment (failure to comply with BPCIA)	District Court- 9/26/2017: Jury Verdict (some claims valid and infringed; some claims invalid) Appeal 16-2179 (motion to compel manufacturing information on patents not asserted)- 8/10/2017: Dismissed for lack of jurisdiction; Petition for writ of mandamus denied Appeal 19-1067 and Cross Appeal 19-1102 (final judgment)- 12/16/2019: Affirmed; 3/16/2020: Petition for en banc rehearing denied
Sandoz v. Amgen 3:13-cv-02904 (N.D. Cal.) Fed. Cir. 14-1693	Enbrel® (etanercept)	Erelzi® (etanercept-szzs) Approved 8/30/2016	6/24/2013	Declaratory Judgment	District Court- Dismissed for lack of subject matter jurisdiction 11/19/2013 Appeal- Affirmed 12/5/2014
Amgen v. Sandoz 2:16-cv-01118 (D.N.J.) Fed. Cir. 20-1037 Sup. Ct. 20-1110	Enbrel® (etanercept)	Erelzi® (etanercept-szzs) Approved 8/30/2016	2/26/2016	Infringement	District Court- 8/9/2019: '182 patent claims 11-23 and 35-36 and '522 patent claims 3, 8, and 10 not invalid. Parties previously stipulated to infringement. Permanent injunction issued. Appeal- Affirmed 7/1/2020; Request for *en banc* rehearing denied 9/29/2020 Supreme Court- Certiorari denied 5/17/2021
Amgen v. Samsung Bioepis 2:19-cv-11755 (D.N.J.)	Enbrel® (etanercept)	Eticovo™ (etanercept-ykro) Approved 4/25/2019	4/30/2019	Infringement	11/3/2021- Final judgment in favor of Amgen, Permanent injunction issued (will terminate when U.S. Patent Nos. 8,063,182 and 8,163,522 expire on April 24, 2029)

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Amgen v. Sandoz 3:14-cv-04741 (N.D. Ca.) Fed. Cir. 15-1499 S. Ct. 15-1039 S. Ct. 15-1195 Fed. Cir. 18-1551	Neupogen® (filgrastim)	Zarxio® (filgrastim-sndz) Approved 3/6/2015 Launched 9/2015	10/24/2014	Infringement; BPCIA Interpretation	**BPCIA Interpretation:** District Court- 3/19/2015: Patent dance not mandatory, 180-day notice can be given before FDA approval Appeal 15-1499- 7/21/2015: Affirmed patent dance not mandatory, but 180-day notice cannot be given before FDA approval. S. Ct. Appeals 15-1039 and 15-1195- 6/12/2017: Agreed with District Court that 180-day notice can be given before FDA approval, no injunction available under federal law to force compliance with patent dance; remanded to determine whether state law provided injunction Appeal 15-1499 (on remand from S. Ct.)- 12/14/2017: State law did not provide injunction for failure to comply with patent dance **Infringement/Validity:** District Court- 1/8/2018: Summary judgment of non-infringement and dismissal of invalidity counterclaims Appeal 18-1551- 5/8/2019: Affirmed summary judgment; 9/3/2019 Petition for rehearing *en banc* granted-in-part
Amgen v. Apotex 0:15-cv-62081 (S.D. Fla.) Fed. Cir. 17-1010	Neupogen® (filgrastim)	Grastofil™ (filgrastim) aBLA Pending	10/2/2015	Infringement	Consolidated with 0:15-cv-61631 (S.D. Fla.) District Court- 9/6/2016: Patent not infringed, not unenforceable, and counterclaims of invalidity dismissed Appeal- Affirmed 11/13/2017
Amgen v. Adello 2:18-cv-03347 (D.N.J.)	Neupogen® (filgrastim)	Releuko™ (filgrastim-ayow) Approved 2/25/2022 Launched 11/2022	3/8/2018	Infringement	Settled 11/25/2019

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Amgen v. Adello 2:18-cv-03347 (D.N.J.)	Neupogen® (filgrastim)	Releuko™ (filgrastim-ayow) Approved 2/25/2022 Launched 11/2022	3/8/2018	Infringement	Settled 11/25/2019
Amgen v. Pfizer 1:18-cv-01064 (D. Del.)	Neupogen® (filgrastim)	Nivestym® (filgrastim-aafi) Approved 7/20/2018 Launched 10/2018	7/18/2018	Infringement	Settled 9/8/2021
Amgen v. Tanvex 3:19-cv-01374 (S.D. Cal.)	Neupogen® (filgrastim)	Nypozi™ (filgrastim-txid) Approved 6/28/2024 Launched 9/2025	7/23/2019	Infringement	Settled 12/20/2019
Amgen v. Pfizer 1:20-cv-00561 (D. Del.)	Neupogen® (filgrastim)	Nivestym® (filgrastim-aafi) Approved 7/20/2018 Launched 10/2018	4/24/2020	Infringement	Settled 9/8/2021
Amgen v. Apotex 0:18-cv-61828 (S.D. Fla.)	Neupogen® (filgrastim) / Neulasta® (pegfilgrastim)	Grastofil™ (filgrastim) aBLA Pending Lapelga™ (pegfilgrastim) aBLA Pending	8/7/2018	Infringement	Settled 11/15/2019
Sandoz v. Amgen 3:19-cv-00977 (N.D. Cal.)	Neupogen® (filgrastim) / Neulasta® (pegfilgrastim)	Zarxio® (filgrastim-sndz) Approved 3/6/2015 Launched 9/2015 Ziextenzo® (pegfilgrastim-bmez) Approved 11/4/2019 Launched 11/2019	2/21/2019	Declaratory judgment	Related to 3:14-cv-04741 (N.D. Cal.) and 3:16-cv-02581 (N.D. Cal.) Voluntarily dismissed 5/13/2019

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Amgen v. Apotex 0:15-cv-61631 (S.D. Fla.) Fed. Cir. 16-1308 S. Ct. 16-332 Fed. Cir. 17-1010	Neulasta® (pegfilgrastim)	Lapelga™ (pegfilgrastim) aBLA Pending	8/6/2015	Infringement	**Preliminary Injunction** District Court- 12/9/2015: Granted preliminary injunction preventing launch until 180 days after post-licensure notice of commercial marketing Appeal 16-1308- Affirmed 7/5/2016 S. Ct.- Cert denied 12/12/2016 **Infringement/Validity:** District Court- 9/6/2016: Not infringed, not unenforceable, invalidity dismissed Appeal 17-1010- Affirmed 11/13/2017
Amgen v. Sandoz 2:16-cv-01276 (D.N.J.)	Neulasta® (pegfilgrastim)	Ziextenzo® (pegfilgrastim-bmez) Approved 11/4/2019 Launched 11/2019	3/4/2016	Declaratory judgment (BPCIA non-compliance)	Dismissed 3/31/2017
Amgen v. Sandoz 3:16-cv-02581 (N.D. Cal.) Fed. Cir. 18-1552	Neulasta® (pegfilgrastim)	Ziextenzo® (pegfilgrastim-bmez) Approved 11/4/2019 Launched 11/2019	5/12/2016	Infringement	District Court- Summary judgment of non-infringement 12/19/2017 Appeal (consolidated with 18-1551)- Affirmed 5/8/2019
Amgen v. Coherus 1:17-cv-00546 (D. Del.) Fed. Cir. 18-1993	Neulasta® (pegfilgrastim)	Udenyca® (pegfilgrastim-cbqv) Approved 11/2/2018 Launched 1/2019	5/10/2017	Infringement	District Court- Dismissed for failure to state a claim 4/18/2018 Appeal- Affirmed 7/29/2019
Amgen v. Mylan 2:17-cv-01235 (W.D. Pa.)	Neulasta® (pegfilgrastim)	Fulphila® (pegfilgrastim-jmdb) Approved 6/4/2018 Launched 7/2018	9/22/2017	Infringement	Terminated 9/16/2019- Stipulation of non-infringement
Amgen v. Hospira 1:20-cv-00201 (D. Del.)	Neulasta® (pegfilgrastim)	Nyvepria® (pegfilgrastim-apgf) Approved 6/10/2020 Launched 1/2021	2/11/2020	Infringement	Settled 3/21/2022

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Janssen v. Accord 1:26-cv-00222 (D. Del.) Fed. Cir. 27-1008	Simponi® / Simponi Aria® (golimumab)	Immgolis™ / Immgolis Intri™ (golimumab-sldi) Approved (Interchangeable) 5/15/2026	3/3/2026	Infringement	Ongoing; Preliminary injunction granted 9/30/2026 Appeal of preliminary injunction pending
Janssen v. Alvotech 1:26-cv-01754 (E.D. Va.)	Simponi® / Simponi Aria® (golimumab)	AVT05 (golimumab) aBLA Pending	6/19/2026	Infringement	Ongoing; Motion for Preliminary Injunction pending
Celltrion v. Janssen 1:14-cv-11613 (D. Mass.)	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	3/31/2014	Declaratory judgment (prior to aBLA filing)	Voluntarily dismissed 10/23/2014 (Biosimilar called Remsima® in complaint, but has since been named Inflectra® in the US)
Celltrion v. The Kennedy Trust for Rheumatology Research 1:14-cv-02256 (S.D.N.Y.)	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	3/31/2014	Declaratory judgment (prior to aBLA filing)	Dismissed for lack of subject matter jurisdiction 12/1/2014
Hospira v. Janssen 1:14-cv-07049 (S.D.N.Y.)	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	8/29/2014	Declaratory judgment (prior to aBLA filing)	Dismissed for lack of subject matter jurisdiction 12/1/2014
Janssen v. Celltrion 1:15-cv-10698 (D. Mass.) Fed. Cir. 17-1120	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	3/6/2015	Infringement	District Court- Partial judgment 9/26/2016 finding '471 patent claims invalid for obviousness-type double patenting; Stipulated dismissals on remaining patents Appeal (double patenting)- 1/23/2018: Dismissed as moot because reexam appeal 17-1257 affirmed claims were unpatentable
Janssen v. Celltrion 1:16-cv-11117 (D. Mass.)	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	6/14/2016	Infringement	Dismissed 8/7/2017. Infringement issues will be litigated in 1:17-cv-11008 (D. Mass.)

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Janssen v. Samsung Bioepis 2:17-cv-03524 (D.N.J.)	Remicade® (infliximab)	Renflexis® (infliximab-abda) Approved 4/21/2017 Launched 7/2017	5/17/2017	Infringement	Stipulated dismissal 11/30/2017
Janssen v. Celltrion 1:17-cv-11008 (D. Mass.) Fed. Cir. 18-2321 Fed. Cir. 18-2350	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	5/31/2017	Infringement	District Court- Summary judgment of non-infringement 7/31/2018 Appeal 18-2321 and Cross-Appeal 18-2350- Affirmed 3/5/2020
Sanofi-Aventis v. Eli Lilly 1:14-cv-00113 (D. Del.)	Lantus® (insulin glargine)	Basaglar® (insulin glargine) Approved 12/16/2015 Launched 12/2016	1/30/2014	Infringement	Settled 9/28/2015
Sanofi-Aventis v. Eli Lilly 1:14-cv-00884 (D. Del.)	Lantus® (insulin glargine)	Basaglar® (insulin glargine) Approved 12/16/2015 Launched 12/2016	7/7/2014	Infringement	Settled 5/8/2015
Sanofi-Aventis v. Merck 1:16-cv-00812 (D. Del.)	Lantus® (insulin glargine)	Lusduna™ Nexvue™ (insulin glargine) Tentative Approval 7/20/2017	9/16/2016	Infringement	Dismissed 10/29/2018 – Merck no longer pursuing product
Sanofi-Aventis v. Merck 2:17-cv-05914 (D.N.J.)	Lantus® (insulin glargine)	Lusduna™ Nexvue™ (insulin glargine) Tentative Approval 7/20/2017	8/8/2017	Infringement	Dismissed 11/13/2018 – Merck no longer pursuing product
Sanofi-Aventis v. Mylan 2:17-cv-09105 (D.N.J.) Fed. Cir. 21-1262	Lantus® (insulin glargine)	Semglee® (insulin glargine-yfgn) Approved 6/11/2020, Launched 8/2020; Interch. Approved 7/28/2021, Launched 11/2021	10/24/2017	Infringement	District Court- 3/9/2020: Claims 21, 22, 25 and 30 of '844 patent not infringed, and invalid for lack of written description Appeal- Dismissed as moot 12/29/2021

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Biogen v. Sandoz 1:22-cv-01190 (D. Del.)	Tysabri® (natalizumab)	Tyruko® (natalizumab-sztn) Approved 8/24/2023 Launched 11/2025	9/9/2022	Infringement	Ongoing, Preliminary injunction denied 6/20/2023
Bristol-Myers Squibb v. Amgen 1:26-cv-01134 (D. Del.)	Opdivo® (nivolumab)	ABP 206 (nivolumab) aBLA Pending	9/8/2026	Infringement	Ongoing
Genentech v. Amneal 1:26-cv-01343 (D. Del.)	Xolair® (omalizumab)	ADL-018 (omalizumab) aBLA Pending	10/16/2026	Infringement	Ongoing
Genentech v. Shanghai Henlius Biotech 2:25-cv-14648 (D.N.J.)	Perjeta® (pertuzumab)	Poherdy® (pertuzumab-dpzb) Approved (Interchangeable) 11/13/2025	8/14/2025	Infringement	Settled 1/30/2026
Genentech v. Biocon 2:26-cv-09585 (D.N.J.)	Perjeta® (pertuzumab)	Bmab 1500 (pertuzumab) aBLA Pending	7/29/2026	Infringement	Settled 10/14/2026
Genentech v. Sandoz 1:17-cv-13507 (D.N.J.)	Rituxan® (rituximab)	Rixathon® (rituximab) aBLA Pending	12/21/2017	Infringement	Stipulated dismissal 12/6/2018. Sandoz no longer pursuing its biosimilar application.
Celltrion v. Genentech 4:18-cv-00276 (N.D. Cal.) Fed. Cir. 18-2161	Rituxan® (rituximab)	Truxima® (rituximab-abbs) Approved 11/28/2018; 7/1/2026 (Interchangeable) Launched 11/2019	1/1/2018	Declaratory judgment	District Court- Dismissed for failure to state a claim 5/10/2018 Appeal voluntarily dismissed 11/30/2018
Genentech v. Celltrion 1:18-cv-00574 (D.N.J.)	Rituxan® (rituximab)	Truxima® (rituximab-abbs) Approved 11/28/2018 Launched 11/2019	1/12/2018	Infringement	Settled 11/1/2018

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Genentech v. Celltrion 1:18-cv-11553 (D.N.J.)	Rituxan® (rituximab)	Truxima® (rituximab-abbs) Approved 11/28/2018 Launched 11/2019	7/11/2018	Infringement	Related to 1:18-cv-00574 (D.N.J.) Settled 11/1/2018
Genentech v. Dr. Reddy's 1:23-cv-22485 (D.N.J.)	Rituxan® (rituximab)	Zimrixby™ (rituximab-cdxx) Approved 8/3/2026	11/17/2023	Infringement	Settled 4/9/2024
Genentech v. Biogen 1:23-cv-11573 (D. Del.)	Actemra® (tocilizumab)	Tofidence™ (tocilizumab-bavi) Approved 9/29/2023	7/13/2023	Infringement	Settled 10/23/2023
Genentech v. Pfizer 1:17-cv-01672 (D. Del.)	Herceptin® (trastuzumab)	Trazimera® (trastuzumab-qyyp) Approved 3/11/2019 Launched 2/2020	11/17/2017	Infringement	Settled 12/4/2018
Celltrion v. Genentech 4:18-cv-00274 (N.D. Cal.) Fed. Cir. 18-2160	Herceptin® (trastuzumab)	Herzuma® (trastuzumab-pkrb) Approved 12/14/2018 Launched 3/2020	1/11/2018	Declaratory judgment	District Court- Dismissed for failure to state a claim 5/10/2018 Appeal- Voluntarily dismissed 11/30/2018
Genentech v. Celltrion 1:18-cv-00095 (D. Del.)	Herceptin® (trastuzumab)	Herzuma® (trastuzumab-pkrb) Approved 12/14/2018 Launched 3/2020	1/12/2018	Infringement	Settled 12/27/2018
Genentech v. Amgen 1:18-cv-00924 (D. Del.) Fed. Cir. 19-2156	Herceptin® (trastuzumab)	Kanjinti® (trastuzumab-anns) Approved 6/13/2019 Launched 7/2019	6/21/2018	Infringement	District Court- Temporary Restraining Order and Preliminary Injunction denied 7/18/2019; Settled 7/7/2020 Appeal (TRO and PI)- Affirmed 3/6/2020
Genentech v. Celltrion 1:18-cv-01025 (D. Del.)	Herceptin® (trastuzumab)	Herzuma® (trastuzumab-pkrb) Approved 12/14/2018 Launched 3/2020	7/11/2018	Infringement	Consolidated with 1:18-cv-00095 (D. Del.), Settled 12/27/2018

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
Genentech v. Samsung Bioepis 1:18-cv-01363 (D. Del.)	Herceptin® (trastuzumab)	Ontruzant® (trastuzumab-dttb) Approved 1/18/2019 Launched 4/2020	9/4/2018	Infringement	Settled 7/1/2019
Genentech v. Tanvex 3:22-cv-00809 (S.D. Cal.)	Herceptin® (trastuzumab)	TX-05 (trastuzumab) aBLA pending	6/2/2022	Infringement	Settled 2/10/2023
Janssen v. Amgen 1:22-cv-01549 (D. Del.)	Stelara® (ustekinumab)	Wezlana™ (ustekinumab-auub) Approved (Interchangeable) 10/31/2023 Launched 1/2025	11/29/2022	Infringement	Settled 5/23/2023
Takeda v. Polpharma 3:26-cv-11002 (D.N.J.)	Entyvio® (vedolizumab)	PB016 (vedolizumab) aBLA Pending	8/26/2026	Infringement	Ongoing
Takeda v. Alvotech 2:26-cv-11301 (D.N.J.)	Entyvio® (vedolizumab)	AVT16 (vedolizumab) aBLA Pending	9/1/2026	Infringement	Ongoing