

Spotlight On:
Biosimilar Litigations

August 31, 2023

Litigation	Reference Product	Biosimilar	Filing Date	Complaint Type	Status
<i>AbbVie v. Amgen</i> 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
<i>AbbVie v. Boehringer Ingelheim</i> 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
<i>AbbVie v. Sandoz</i> 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
<i>Coherus v. Amgen</i> 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
<i>AbbVie v. Alvotech</i> 1:21-cv-02258 (N.D. Ill.)	Humira® (adalimumab)	AVT02 (adalimumab) aBLA Pending	4/27/2021	Infringement	Settled 3/9/2022
<i>AbbVie v. Alvotech</i> 1:21-cv-05645 (N.D. Ill.)	Humira® (adalimumab)	AVT02 (adalimumab) aBLA Pending	5/11/2021	Declaratory Judgment	Voluntarily dismissed 11/5/2021
<i>AbbVie v. Alvotech</i> 1:21-cv-02899 (N.D. Ill.)	Humira® (adalimumab)	AVT02 (adalimumab) aBLA Pending	5/28/2021	Infringement	Settled 3/9/2022
<i>Regeneron v. Mylan</i> 1:22-cv-00061 (N.D.W.Va.)	Eylea® (aflibercept)	M710 (aflibercept) aBLA Pending	8/2/2022	Infringement	Ongoing

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<i>Genentech v. Amgen</i> 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
<i>Amgen v. Genentech</i> 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
<i>Genentech v. Amgen</i> 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
<i>Genentech v. Amgen</i> 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
<i>Genentech v. Immunex</i> 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
<i>Genentech v. Pfizer</i> 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
<i>Genentech v. Samsung Bioepis</i> 1:20-cv-00859 (D. Del.)	Avastin® (bevacizumab)	SB8 (bevacizumab) aBLA Pending	6/28/2020	Infringement	Settled 9/8/2022

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<i>Genentech v. Centus Biotherapeutics</i> 2:20-cv-00361 (E.D. Tex.)	Avastin® (bevacizumab)	FKB238 (bevacizumab) aBLA Pending	11/12/2020	Infringement	Settled 7/2/2021
<i>Amgen v. Sandoz</i> 1:23-cv-02406 (D.N.J.)	Prolia® / Xgeva® (denosumab)	GP2411 (denosumab) aBLA Pending	5/1/2023	Infringement	Ongoing
<i>Amgen v. Hospira</i> 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
<i>Sandoz v. Amgen</i> 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
<i>Amgen v. Sandoz</i> 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 <i>en banc</i> rehearing denied 9/29/2020 Supreme Court- Certiorari denied 5/17/2021

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<i>Amgen v. Samsung Bioepis</i> 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)
<i>Amgen v. Sandoz</i> 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 <i>en banc</i> granted-in-part
<i>Amgen v. Apotex</i> 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
<i>Amgen v. Adello</i> 2:18-cv-03347 (D.N.J.)	Neupogen® (filgrastim)	Releuko™ (filgrastim) Approved 2/25/2022 Launched 11/2022	3/8/2018	Infringement	Settled 11/25/2019
<i>Amgen v. Pfizer</i> 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

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<i>Amgen v. Tanvex</i> 3:19-cv-01374 (S.D. Cal.)	Neupogen® (filgrastim)	TX-01 (filgrastim) aBLA Pending	7/23/2019	Infringement	Settled 12/20/2019
<i>Amgen v. Pfizer</i> 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
<i>Amgen v. Apotex</i> 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
<i>Sandoz v. Amgen</i> 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
<i>Amgen v. Apotex</i> 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
<i>Amgen v. Sandoz</i> 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

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<i>Amgen v. Sandoz</i> 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
<i>Amgen v. Coherus</i> 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
<i>Amgen v. Mylan</i> 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
<i>Amgen v. Hospira</i> 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
<i>Celltrion v. Janssen</i> 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)
<i>Celltrion v. The Kennedy Trust for Rheumatology Research</i> 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
<i>Hospira v. Janssen</i> 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

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<i>Janssen v. Celltrion</i> 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
<i>Janssen v. Celltrion</i> 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.)
<i>Janssen v. Samsung Bioepis</i> 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
<i>Janssen v. Celltrion</i> 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
<i>Sanofi-Aventis v. Eli Lilly</i> 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
<i>Sanofi-Aventis v. Eli Lilly</i> 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
<i>Sanofi-Aventis v. Merck</i> 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
<i>Sanofi-Aventis v. Merck</i> 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

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<i>Sanofi-Aventis v. Mylan</i> 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
<i>Biogen v. Sandoz</i> 1:22-cv-01190 (D. Del.)	Tysabri® (natalizumab)	Tyruko® (natalizumab-sztn) Approved 8/24/2023	9/9/2022	Infringement	Ongoing, Preliminary injunction denied 6/20/2023
<i>Genentech v. Sandoz</i> 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.
<i>Celltrion v. Genentech</i> 4:18-cv-00276 (N.D. Cal.) Fed. Cir. 18-2161	Rituxan® (rituximab)	Truxima® (rituximab-abbs) Approved 11/28/2018 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
<i>Genentech v. Celltrion</i> 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
<i>Genentech v. Celltrion</i> 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
<i>Genentech v. Biogen</i> 1:23-cv-11573 (D. Del.)	Actemra® (tocilizumab)	BIIB800 (tocilizumab) aBLA Pending	7/13/2023	Infringement	Ongoing
<i>Genentech v. Pfizer</i> 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

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<i>Celltrion v. Genentech</i> 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
<i>Genentech v. Celltrion</i> 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
<i>Genentech v. Amgen</i> 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
<i>Genentech v. Celltrion</i> 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
<i>Genentech v. Samsung Bioepis</i> 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
<i>Genentech v. Tanvex</i> 3:22-cv-00809 (S.D. Cal.)	Herceptin® (trastuzumab)	TX-05 (trastuzumab) aBLA pending	6/2/2022	Infringement	Settled 2/10/2023
<i>Janssen v. Amgen</i> 1:22-cv-01549 (D. Del.)	Stelara® (ustekinumab)	ABP 654 (ustekinumab) aBLA pending	11/29/2022	Infringement	Settled 5/23/2023