

Spotlight On: Biosimilar Litigations

July 31, 2019

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 Settlement market entry 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 Settlement market entry 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 Settlement market entry 9/30/2023	8/10/2018	Infringement	Settled 10/16/2018
<i>Coherus v. Amgen</i> 1:19-cv-00139 (D. Del.)	Biosimilar- Biosimilar	CHS-1420 (adalimumab) Phase III trials (application not yet filed) Settlement market entry 12/15/2023 Amjevita™ (adalimumab-atto) Approved 9/23/2016 Settlement market entry 9/30/2023	1/24/2019	Infringement	Ongoing
<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

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<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	Ongoing
<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	Ongoing; Consolidated with 1:17-cv-01407 (D. Del.)
<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- Ongoing, Temporary Restraining Order and Motion to Enforce Statutory Prohibition on Commercial Marketing denied 7/18/2019 Appeal (TRO and Commercial Marketing)- Ongoing
<i>Genentech v. Pfizer</i> 1:19-cv-00638 (D. Del.)	Avastin® (bevacizumab)	Zirabev™ (bevacizumab-bvzr) Approved 6/27/2019	4/5/2019	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): Ongoing
<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- 11/19/2013: Dismissed for lack of subject matter jurisdiction Appeal- 12/5/2014: Affirmed

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<i>Amgen v. Sandoz</i> 2:16-cv-01118 (D.N.J.)	Enbrel® (etanercept)	Erelzi® (etanercept-szzs) Approved 8/30/2016	2/26/2016	Infringement	Ongoing
<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	Ongoing
<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; Petition for rehearing <i>en banc</i> pending
<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- 11/13/2017: Affirmed

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<i>Amgen v. Adello</i> 2:18-cv-03347 (D.N.J.)	Neupogen® (filgrastim)	TPI G-CSF (filgrastim) aBLA Pending	3/8/2018	Infringement	Ongoing
<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	Ongoing
<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	Ongoing
<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 LA-EP2006 (pegfilgrastim) aBLA Pending	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. Tanvex</i> 3:19-cv-01374 (S.D. Cal.)	Neulasta® (pegfilgrastim)	TX-01 (pegfilgrastim) aBLA Pending	7/23/2019	Infringement	Ongoing
<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- 7/5/2016: Affirmed S. Ct.- 12/12/2016: Cert denied Infringement/Validity: District Court- 9/6/2016: Not infringed, not unenforceable, invalidity dismissed Appeal 17-1010- 11/13/2017: Affirmed

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<i>Amgen v. Sandoz</i> 2:16-cv-01276 (D.N.J.)	Neulasta® (pegfilgrastim)	LA-EP2006 (pegfilgrastim) aBLA Pending	3/4/2016	Declaratory judgment (BPCIA non-compliance)	Dismissed 3/31/2017
<i>Amgen v. Sandoz</i> 3:16-cv-02581 (N.D. Cal.) Fed. Cir. 18-1552	Neulasta® (pegfilgrastim)	LA-EP2006 (pegfilgrastim) aBLA Pending	5/12/2016	Infringement	District Court- 12/19/2017: Summary judgment of non-infringement Appeal (consolidated with 18-1551)- 5/8/2019: Affirmed
<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- 4/18/2018: Dismissed for failure to state a claim Appeal- 7/29/2019: Affirmed
<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	Ongoing
<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; Remainder of case ongoing 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	5/17/2017	Infringement	Stipulated dismissal 11/30/2017
<i>Janssen v. Celltrion</i> 1:17-cv-11008 (D. Mass.)	Remicade® (infliximab)	Inflectra® (infliximab-dyyb) Approved 4/5/2016 Launched 11/2016	5/31/2017	Infringement	Ongoing
<i>Genentech v. Sandoz</i> 1:17-cv-13507 (D.N.J.)	Rituxan® (rituximab)	Rixathon® (rituximab) aBLA Filed	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	1/1/2018	Declaratory judgment	District Court- 5/10/2018: Dismissed for failure to state a claim 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	1/12/2018	Infringement	Settled 11/1/2018

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<i>Genentech v. Celltrion</i> 1:18-cv-11553 (D.N.J.)	Rituxan® (rituximab)	Truxima® (rituximab-abbs) Approved 11/28/2018	7/11/2018	Infringement	Related to 1:18-cv-00574 (D.N.J.) Settled 11/1/2018
<i>Genentech v. Pfizer</i> 1:17-cv-01672 (D. Del.)	Herceptin® (trastuzumab)	Trazimera™ (trastuzumab-qyyp) Approved 3/11/2019	11/17/2017	Infringement	Settled 12/4/2018
<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	1/11/2018	Declaratory judgment	District Court- 5/10/1028: Dismissed for failure to state a claim 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	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	6/21/2018	Infringement	District Court- Ongoing, Temporary Restraining Order and Preliminary Injunction denied 7/18/2019 Appeal (TRO and PI)- Ongoing
<i>Genentech v. Celltrion</i> 1:18-cv-01025 (D. Del.)	Herceptin® (trastuzumab)	Herzuma® (trastuzumab-pkrb) Approved 12/14/2018	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	9/4/2018	Infringement	Settled 7/1/2019