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Biosimilar Product	Reference Biological Product	Marketing Status	Litigation (Active or Pending)
Name: Zarxio® (filgrastim-sndz) *Manufacturer:* Sandoz *BLA:* 125553	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.	Approved by FDA on March 6, 2015. Commercial (at-risk) launch by Sandoz/ Novartis in September 2015.	U.S. Supreme Court opinion issued on June 12, 2017. U.S. Court of Appeals for the Federal Circuit *en banc* opinion issued on December 14, 2017. Summary judgment of non-infringement by Sandoz entered in the U.S. District Court for the Northern District of California on January 1, 2018 and then appealed to the U.S. Court of Appeals for the Federal Circuit on claim construction grounds. The Court of Appeals affirmed the district court's claim construction and summary judgment order in a precedential opinion issued on May 8, 2019.
Name: Inflectra® (infliximab-dyyb) *Manufacturer:* Celltrion, Inc. *BLA:* 125544	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis.	Approved by FDA on April 5, 2016. Commercial (at-risk) launch by Pfizer/Celltrion in November 2016.	Summary judgment of non-infringement by Celltrion entered in the U.S. District Court for the District of Massachusetts in July 2017. Grant of Celltrion's summary judgment motion was appealed to the U.S. Court of Appeals for the Federal Circuit and remains pending.

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Name: Erelzi® (etanercept-szzs) *Manufacturer:* Sandoz *BLA:* 761042	*Name:* Enbrel® (etanercept) Manufacturer: Immunex Corporation (Amgen subsidiary) *BLA:* 103795 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.	Approved by FDA on August 30, 2016. Received unanimous support (20-0) of approval by FDA's Arthritis Advisory Committee on July 13, 2016. Sandoz has agreed not to launch its biosimilar product Erelzi in the U.S. until an undisclosed date or event occurs.	Litigation in the U.S. District Court for the District of New Jersey; bench trial took place in September 2018. District court ruling entered in favor of Immunex on August 9, 2019, finding no patent invalidity and infringement by defendant Sandoz. Sandoz has appealed the ruling to the U.S. Court of Appeals for the Federal Circuit (pending).
Name: Amjevita™ (adalimumab-atto) *Manufacturer:* Amgen *BLA:* 761024	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflammation in patients with the following autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis.	Approved by FDA on September 23, 2016. Received unanimous support (26-0) of approval by FDA's Arthritis Advisory Committee on July 12, 2016.	Global settlement between AbbVie and Amgen for Amjevita announced in April 2018 and provides for a U.S. market entry date of January 31, 2023.
Name: Renflexis® (infliximab-abda) *Manufacturer:* Samsung Bioepis/ Merck	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc.	Approved by FDA on April 21, 2017. Commercial (at-risk) launch by Merck in late July 2017.	Litigation under the BPCIA settled in November 2017.

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BLA: 761054	*BLA:* 103772		
Name: Cyltezo® (adalimumab-adbm) *Manufacturer:* Boehringer Ingelheim *BLA:* 761058	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Approved by FDA on August 25, 2017.	Global settlement between AbbVie and Boehringer Ingelheim for Cyltezo announced in May 2019 and provides for a U.S. market entry date of July 1, 2023.
Name: Mvasi™ (bevacizumab-awwb) *Manufacturer:* Amgen/Allergan *BLA:* 761028	*Name:* Avastin® (bevacizumab) *Manufacturer:* Genentech *BLA:* 125085 *Indications/Uses:* Vascular endothelial growth factor-specific angiogenesis inhibitor indicated for the treatment, either alone or as part of combination regimens, of: metastatic colorectal cancer; non-squamous non-small cell lung cancer; glioblastoma; metastatic renal cell carcinoma; cervical cancer; and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.	Approved by FDA on September 14, 2017. Received unanimous support (17-0) of approval by FDA's Oncologic Drugs Advisory Committee on July 13, 2017. Commercial (at-risk) launch by Amgen/ Allergan in July 2019.	Litigation in the U.S. District Court for the District of Delaware, with trial scheduled to begin in July 2020. An interlocutory appeal to the U.S. Court of Appeals for the Federal Circuit based on the denial of Genentech's request for preliminary injunction to stop commercial sales of Mvasi is currently pending.
Name: Ogivri™ (trastuzumab-dkst) *Manufacturer:* Mylan/Biocon *BLA:* 761074	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for the treatment of (1) HER2 overexpressing breast cancer; and (2) HER2-overexpressing metastatic gastric or gastro-	Approved by FDA on December 1, 2017. Received unanimous support (16-0) of approval by FDA's Oncologic Drugs Advisory Committee on July 13, 2017. Commercial launch of Ogivri by Mylan/Biocon on December 2, 2019.	Global licensing agreement between Mylan and Genentech for trastuzumab announced in March 2017.

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	esophageal junction adenocarcinoma.		
Name: Ixifi™ (infliximab-qbtx) *Manufacturer:* Pfizer *BLA:* 761072	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772	Approved by FDA on December 13, 2017. No current plans by Pfizer for commercial launch of Ixifi.	None under the BPCIA.
Name: Retacrit® (epoetin alfa-epbx) *Manufacturer:* Hospira/Pfizer *BLA:* 125545	*Name:* Epogen® (epoetin alfa) *Manufacturer:* Amgen *BLA:* 103234 *Indications/Uses:* Stimulates red blood cells to treat anemia. Often used for patients taking chemotherapy treatment or who have chronic renal failure.	Approved by FDA on May 15, 2018. Received support (14-1) for approval by FDA's Oncologic Drugs Advisory Committee on May 25, 2017. Commercial (at-risk) launch of Retacrit by Hospira/Pfizer in November 2018.	Litigation initiated in the U.S. District Court for the District of Delaware; jury found infringement and entered a judgment in favor of Amgen with a $70 million damages award, plus interest. Judgment affirmed by the U.S. Court of Appeals for the Federal Circuit on December 16, 2019; petition for rehearing *en banc* is currently pending.
Name: Fulphila® (pegfilgrastim-jmdb) *Manufacturer:* Mylan/Biocon *BLA:* 761075	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients in chemotherapy or after a bone marrow transplant. Neulasta is the long-acting formulation of Neupogen.	Approved by FDA on June 4, 2018. Commercial (at-risk) launch by Mylan in or around July 2018.	Litigation under the BPCIA settled in September 2019.
Name: Nivestym® (filgrastim-aafi) *Manufacturer:* Hospira/Pfizer	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen	Approved by FDA on July 20, 2018. Commercial (at-risk) launch by Pfizer on	Litigation in the U.S. District Court for the District of Delaware; trial scheduled to begin on June 15, 2020.

BLA: 761080	*BLA:* 103353	or around October 1, 2018.	
Name: Hyrimoz™ (adalimumab-adaz) *Manufacturer:* Sandoz *BLA:* 761071	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Approved by FDA on October 30, 2018.	Global settlement between AbbVie and Sandoz for Hyrimoz announced in October 2018 and provides for a U.S. market entry date of September 30, 2023.
Name: Udenyca® (pegfilgrastim-cbqv) *Manufacturer:* Coherus BioSciences *BLA:* 761039	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031	Approved by FDA on November 2, 2018. Commercial launch of Udenyca by Coherus on January 3, 2019.	Complaint filed in the U.S. District Court for the District of Delaware dismissed on February 2, 2018. Dismissal affirmed by the U.S. Court of Appeals for the Federal Circuit on July 29, 2019 in a precedential opinion.
Name: Truxima® (rituximab-abbs) *Manufacturer:* Celltrion, Inc. *BLA:* 761088	*Name:* Rituxan® (rituximab) *Manufacturer:* Genentech *BLA:* 103705 *Indications/Uses:* Targets CD-20 antigen on the surface of B-cells to treat (1) Non-Hodgkin's Lymphoma; (2) Chronic Lymphocytic Leukemia; (3) Rheumatoid Arthritis in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies; (4) Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis in adult patients in	Approved by FDA on November 28, 2018. Received unanimous support for approval from FDA's Oncologic Drugs Advisory Committee on October 10, 2018. Commercial launch of Truxima by Celltrion/Teva Pharmaceuticals on November 11, 2019.	Litigation under the BPCIA settled in November 2018.

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	combination with glucocorticoids.		
Name: Herzuma® (trastuzumab-pkrb) *Manufacturer:* Celltrion, Inc. *BLA:* 761091	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792	Approved by FDA on December 14, 2018. Celltrion/Teva have indicated that the U.S. commercial launch of Herzuma is being planned for the first quarter of 2020.	Litigation under the BPCIA settled in December 2018.
Name: Ontruzant® (trastuzumab-dttb) *Manufacturer:* Samsung Bioepis/ Merck *BLA:* 761100	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792	Approved by FDA on January 18, 2019.	Litigation under the BPCIA settled in June 2019.
Name: Trazimera™ (trastuzumab-qyyp) *Manufacturer:* Hospira/Pfizer *BLA:* 761081	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792	Approved by FDA on March 11, 2019. Pfizer has announced that commercial launch of Trazimera will be on February 15, 2020.	Litigation under the BPCIA settled in December 2018.
Name: Eticovo™ (etanercept-szzs) *Manufacturer:* Samsung Bioepis *BLA:* 761066	*Name:* Enbrel® (etanercept) Manufacturer: Immunex Corporation (Amgen subsidiary) *BLA:* 103795	Approved by FDA on April 25, 2019.	Litigation in the U.S. District Court for the District of New Jersey; consent injunction order entered by the court on January 8, 2020 against Samsung Bioepis from using, importing, offering to sell, or selling etanercept in the U.S. Subsequently, the parties jointly requested an administrative stay of the litigation, which the district court granted on January 15, 2020.

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Name: Kanjinti™ (trastuzumab-anns) *Manufacturer:* Amgen/Allergan *BLA:* 761073	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792	Approved by FDA on June 13, 2019. Commercial (at-risk) launch of Kanjinti by Amgen/Allergan on or around July 18, 2019.	Litigation in the U.S. District Court for the District of Delaware. An interlocutory appeal to the U.S. Court of Appeals for the Federal Circuit based on the denial of Genentech's request for preliminary injunction to stop commercial sales of Kanjinti is currently pending.
Name: Zirabev™ (bevacizumab-bvzr) *Manufacturer:* Pfizer *BLA:* 761099	*Name:* Avastin® (bevacizumab) *Manufacturer:* Genentech *BLA:* 125085	Approved by FDA on June 27, 2019. Commercial launch of Zirabev by Pfizer on December 31, 2019.	Litigation under the BPCIA settled in September 2019.
Name: Ruxience™ (rituximab-pvvr) *Manufacturer:* Pfizer *BLA:* 761103	*Name:* Rituxan® (rituximab) *Manufacturer:* Genentech *BLA:* 103705	Approved by FDA on July 23, 2019. Pfizer has announced that commercial launch of Ruxience will be in January 2020.	Patent settlement reached between the parties in March 2019.
Name: Hadlima™ (adalimumab-bwwd) *Manufacturer:* Samsung Bioepis/ Merck *BLA:* 761059	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Approved by FDA on July 23, 2019.	Global settlement between AbbVie and Samsung Bioepis for Hadlima announced in April 2018 and provides for a U.S. market entry date of June 30, 2023.

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Name: Ziextenzo™ (pegfilgrastim-bmez) *Manufacturer:* Sandoz *BLA:* 761045	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031	Approved by FDA on November 4, 2019. Commercial launch of Ziextenzo by Sandoz on or around November 15, 2019.	Summary judgment of non-infringement by Sandoz entered in the U.S. District Court for the Northern District of California in January 2018 and subsequently appealed; the U.S. Court of Appeals for the Federal Circuit affirmed the district court's claim construction and summary judgment order in a precedential opinion issued on May 8, 2019.
Name: Abrilada™ (adalimumab-afzb) *Manufacturer:* Pfizer *BLA:* 761118	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Approved by FDA on November 15, 2019.	Global settlement between AbbVie and Pfizer for Abrilada announced in November 2018 and provides for a U.S. market entry date of November 20, 2023.
Name: Avsola™ (infliximab-axxq) *Manufacturer:* Amgen *BLA:* 761086	*Name:* Remicade® (infliximab) *Manufacturer:* Janssen Biotech, Inc. *BLA:* 103772	Approved by FDA on December 6, 2019.	None under the BPCIA.
Name: Lapelga™ *Manufacturer:* Apotex (Apobiologix) *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031	Pending FDA approval.	Judgment of non-infringement by Apotex entered by the U.S. District Court for the Southern District of Florida in September 2016; affirmed by the U.S. Court of Appeals for the Federal Circuit in November 2017.

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Name: Grastofil® *Manufacturer:* Apotex (Apobiologix) *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353	Pending FDA approval.	Consolidated into *Amgen v. Apotex* pegfilgrastim litigation (see above).
Name: TBD *Manufacturer:* Kashiv Biosciences (formerly Adello Biologics) *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353	Pending FDA approval; aBLA accepted for filing in September 2017. Likely to have received a Complete Response Letter (CRL) from the agency since user fee goal date was in May 2018, although no updates have been provided.	Litigation under the BPCIA settled in November 2019.
Name: TX-01 *Manufacturer:* Tanvex BioPharma *BLA:* Unknown	*Name:* Neupogen® (filgrastim) *Manufacturer:* Amgen *BLA:* 103353	Pending FDA approval; delayed after being issued a CRL by FDA in October 2019.	Litigation under the BPCIA settled in December 2019.
Name: TBD *Manufacturer:* Mylan *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Pending FDA approval.	Global settlement between AbbVie and Mylan for a follow-on adalimumab product announced in July 2018 and provides for a U.S. market entry date of July 31, 2023.
Name: MSB11022 *Manufacturer:* Fresenius Kabi *BLA:* Unknown	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057	Pending FDA approval.	Global settlement between AbbVie and Fresenius Kabi for a follow-on adalimumab product announced in October 2018 and provides for a U.S. market entry date of September 30, 2023.
Name: CHS-1420 *Manufacturer:*	*Name:* Humira® (adalimumab)	aBLA does not appear to have been submitted to FDA	Global settlement between AbbVie and Coherus for a follow-on

Coherus *BLA:* Unknown	*Manufacturer:* AbbVie *BLA:* 125057	but had been targeted for filing in late 2019.	adalimumab product announced in January 2019 and provides for a U.S. market entry date of December 15, 2023.