Approved and Pending Biosimilar Applications*

Biosimilar	Reference 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 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. Litigation in the U.S. District Court for the Northern District of California.
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.	Litigation in the U.S. District Court for the District of Massachusetts. Appealed to the U.S. Court of Appeals for the Federal Circuit; oral arguments held in October 2017.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: Erelzi (etanercept-szzs) *Manufacturer:* Sandoz *BLA:* 761042	*Name:* Enbrel® (etanercept) Manufacturer: Amgen *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 until an undisclosed date or event occurs.	Litigation in the U.S. District Court for the District of New Jersey.
Name: Amjevita (adalimumab-atto) *Manufacturer:* Amgen *BLA:* 761024	*Name:* Humira® (adalimumab) *Manufacturer:* AbbVie *BLA:* 125057 *Indications/Uses:* Inhibits tumor necrosis factor-alpha to reduce inflamm-ation 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. Amgen expects to launch its biosimilar product in Europe on Oct. 16, 2018, and in the United States on Jan. 31, 2023.	Litigation settlement reached between the parties in September 2017. Amgen's press release reported that AbbVie will grant patent licenses for the use and sale of the product worldwide, on a country-by-country basis.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: Renflexis (infliximab-abda) *Manufacturer:* Samsung Bioepis/Merck *BLA:* 761054	*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 21, 2017. Commercial launch by Merck in late July 2017.	N/A
Name: Cyltezo *Manufacturer:* Boehringer Ingelheim *BLA:* Unknown	*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 August 25, 2017.	Litigation in the U.S. District Court for the District of Delaware. Expert discovery not scheduled to close until May 2020.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

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 treat-ment, 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.	Litigation in the U.S. District Court for the Central District of California and in the District of Delaware.
Name: Ogivri (trastuzumab-dkst) *Manufacturer:* Mylan/Biocon *BLA:* 761074	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	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.	None. Mylan announced global license agreement for trastuzumab with Genentech on March 13, 2017.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: Ixifi (infliximab-qbtx) *Manufacturer:* Pfizer *BLA:* 761072	*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 December 13, 2017.	None under the BPCIA. Antitrust lawsuit against Janssen/J&J pending in the U.S. District Court for the Eastern District of Pennsylvania.
Name: Retacrit *Manufacturer:* Hospira *BLA:* 125545	*Name:* Epogen® or Procrit® (epoetin alfa) *Manufacturer:* Amgen (Epogen); Janssen Biotech (Procrit) *BLA:* 103234 *Indications/Uses:* Stimulates red blood cells to treat anemia. Often used for patients taking chemotherapy treatment or who have chronic renal failure.	Pending FDA approval; delayed after being issued a second Complete Response Letter ("CRL") by FDA in June 2017, related to manufacturing problems. Received support (14-1) for approval by FDA's Oncologic Drugs Advisory Committee on May 25, 2017.	Litigation in the U.S. District Court for the District of Delaware.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: Lapelga *Manufacturer:* Apotex *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation. Neulasta® is the long-acting formulation of Neupogen®.	Pending FDA approval.	Litigation in the U.S. District Court for the Southern District of Florida.
Name: Grastofil *Manufacturer:* Apotex *BLA:* Unknown	*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.	Pending FDA approval.	Litigation in the U.S. District Court for the Southern District of Florida (consolidated into *Amgen v. Apotex* pegfilgrastim litigation, above).

Approved and Pending Biosimilar Applications*

Name: LA-EP2006 *Manufacturer:* Sandoz *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments. Neulasta® is the long-acting formulation of Neupogen®.	Pending FDA approval; delayed after being issued a CRL by FDA in Q2 2016. Sandoz has stated that it is conducting an additional study per FDA's data request/expected to be completed in early 2019.	Litigation in the U.S. District Court for the Northern District of California (being coordinated for discovery and trial with the *Amgen v. Sandoz* filgrastim matter).
Name: CHS-1701 *Manufacturer:* Coherus BioSciences *BLA:* Unknown	*Name:* Neulasta® (pegfilgrastim) *Manufacturer:* Amgen *BLA:* 125031 *Indications/Uses:* Treats neutropenia by increasing production of white blood cells. Often used for patients taking chemotherapy treatments.	Pending FDA approval; delayed after being issued a CRL by FDA in June 2017.	Litigation in the U.S. District Court for the District of Delaware. Trade secret misappropriation and unfair competition lawsuit also pending in California Superior Court.
Name: MYL-1401H *Manufacturer:* Mylan/Biocon *BLA:* Unknown	*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.	Pending FDA approval; delayed after being issued a CRL by FDA in October 2017.	Litigation in the U.S. District Court for the Western District of Pennsylvania.

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: CT-P6 *Manufacturer:* Celltrion/Teva *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; aBLA accepted for filing in late July 2017.	N/A
Name: ABP 980 *Manufacturer:* Amgen/Allergan *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; aBLA submitted in late July 2017.	N/A

**Based on publicly available information as of the date of this publication.*
Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.

Approved and Pending Biosimilar Applications*

Name: TBD *Manufacturer:* Adello Biologics *BLA:* Unknown	*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.	Pending FDA approval; aBLA accepted for filing in September 2017.	N/A
Name: Rixathon/GP2013 *Manufacturer:* Sandoz *BLA:* Unknown	*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 combination with glucocorticoids.	Pending FDA approval; aBLA accepted for filing in September 2017.	Litigation in the U.S. District Court for the District of New Jersey.

**Based on publicly available information as of the date of this publication. Last revised January 12, 2018 – FOR INFORMATIONAL PURPOSES ONLY.*

Approved and Pending Biosimilar Applications*

Name: SB3 *Manufacturer:* Samsung Bioepis/Merck *BLA:* Unknown	*Name:* Herceptin® (trastuzumab) *Manufacturer:* Genentech *BLA:* 103792 *Indications/Uses:* HER2/neu receptor antagonist indicated for (1) the treatment of HER2 overexpressing breast cancer; and (2) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.	Pending FDA approval; aBLA accepted for filing in late December 2017.	N/A