Biosimilar	Reference Product	Marketing Status	Litigation (Active or Pending)
<i>Name:</i> Zarxio (filgrastim-sndz)	<i>Name:</i> Neupogen® (filgrastim)	Approved by FDA on March 6, 2015.	U.S. Supreme Court opinion issued on June 12, 2017.
Manufacturer: Sandoz BLA: 125553	Manufacturer: Amgen BLA: 103353 Indications/Uses: Treats neutropenia by increasing production of white	Commercial launch by Sandoz/Novartis in September 2015.	U.S. Court of Appeals for the Federal Circuit <u>en banc opinion</u> <u>issued</u> on December 14, 2017.
	blood cells. Often used for patients taking chemotherapy treatments or after bone marrow transplantation.		Litigation in the U.S. District Court for the Northern District of California.
<i>Name:</i> Inflectra (infliximab-dyyb)	<i>Name:</i> Remicade® (infliximab)	Approved by FDA on April 5, 2016.	Litigation in the U.S. District Court for the District of
Manufacturer: Celltrion, Inc. BLA: 125544	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.	2016. Commercial (at- risk) launch by Pfizer/Celltrion in November 2016.	District of Massachusetts. Appealed to the U.S. Court of Appeals for the Federal Circuit; oral arguments held in October 2017.



Name: Erelzi	Name: Enbrel®	Approved by	Litigation in the U.S.
(etanercept-szzs)	(etanercept)	FDA on	District Court for the
	(countercept)	August 30,	District of New
Manufacturer: Sandoz	Manufacturer: Amgen	<u>2016.</u>	Jersey.
		2010.	versey.
BLA: 761042	BLA: 103795	Received	
		unanimous	
	Indications/Uses: Inhibits	support (20-0) of	
	tumor necrosis factor-	approval by	
	alpha to reduce	FDA's Arthritis	
	inflammation in patients	Advisory	
	with the following	Committee on	
	autoimmune diseases:	July 13, 2016.	
	rheumatoid arthritis,		
	ankylosing spondylitis,	Sandoz has	
	psoriatic arthritis, and	agreed not to	
	plaque psoriasis.	launch its	
		biosimilar	
		product Erelzi	
		until an	
		undisclosed date	
		or event occurs.	
Norman Amionita	Name: Humira®	A manager of here	Litization actilement
<i>Name:</i> Amjevita	(adalimumab)	<u>Approved by</u> FDA on	Litigation settlement reached between the
(adalimumab-atto)	(adaminumad)	<u>September 23,</u>	parties in September
Manufacturer: Amgen	Manufacturer: AbbVie	<u>2016.</u>	2017.
Manajaciarer. Aingen		<u>2010.</u>	2017.
BLA: 761024	BLA: 125057	Received	Amgen's press release
		unanimous	reported that AbbVie
	Indications/Uses: Inhibits	support (26-0) of	will grant patent
	tumor necrosis factor-	approval by	licenses for the use
	alpha to reduce inflamm-	FDA's Arthritis	and sale of the
	ation in patients with the	Advisory	product worldwide, on
	following autoimmune	Committee on	a country-by-country
	diseases: rheumatoid	July 12, 2016.	basis.
	arthritis, psoriatic		
	arthritis, ankylosing	Amgen expects	
	spondylitis, Crohn's	to launch its	
	disease, ulcerative colitis,	biosimilar	
	moderate to severe	product in	
	chronic psoriasis,	Europe on	
	moderate to severe	Oct. 16, 2018,	
	hidradenitis suppurativa,	and in the	
	uveitis, and juvenile	United States on	
	idiopathic arthritis.	Jan. 31, 2023.	



Name: Renflexis	Name: Remicade®	Approved by	N/A
(infliximab-abda)	(infliximab)	FDA on	IN/A
(IIIIIXIIIIad-adda)	(IIIIIIXIIIIau)		
		<u>April 21, 2017.</u>	
Manufacturer:	Manufacturer: Janssen	a	
Samsung Bioepis/Merck	Biotech, Inc.	Commercial	
		launch by Merck	
BLA: 761054	BLA: 103772	in late July	
		2017.	
	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.		
	1 5		
Name: Cyltezo	Name: Humira®	Approved by	Litigation in the U.S.
	(adalimumab)	FDA on	District Court for the
Manufacturer:	(August 25,	District of Delaware.
Boehringer Ingelheim	Manufacturer: AbbVie	2017.	
200000000000000000000000000000000000000			Expert discovery not
BLA: Unknown	BLA: 125057		scheduled to close
			until May 2020.
	Indications/Uses: Inhibits		<i>union 1.109 20201</i>
	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.		



Name: Mvasi	Name: Avastin®	Approved by	Litigation in the U.S.
(bevacizumab-awwb)	(bevacizumab)	FDA on	District Court for the
(,	(September 14,	Central District of
Manufacturer:	Manufacturer:	2017.	California and in the
Amgen/Allergan	Genentech		District of Delaware.
88		Received	
BLA: 761028	BLA: 125085	unanimous	
		support (17-0) of	
	Indications/Uses:	approval by	
	Vascular endothelial	FDA's	
	growth factor-specific	Oncologic	
	angiogenesis inhibitor	Drugs Advisory	
	indicated for the treat-	Committee on	
	ment, either alone or as	July 13, 2017.	
	part of combination	<i>vary</i> 10, 2017.	
	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.		
	peritonear earleer.		
Name: Ogivri	Name: Herceptin®	Approved by	None.
(trastuzumab-dkst)	(trastuzumab)	FDA on	
		December 1,	Mylan announced
Manufacturer:	Manufacturer:	2017.	global license
Mylan/Biocon	Genentech		agreement for
5		Received	trastuzumab with
BLA: 761074	BLA: 103792	unanimous	Genentech on
		support (16-0) of	March 13, 2017.
	Indications/Uses:	approval by	
	HER2/neu receptor	FDA's	
	antagonist indicated for	Oncologic	
	(1) the treatment of	Drugs Advisory	
	· /	Committee on	
	HER2 overexpressing	July 13, 2017.	
	breast cancer; and (2) the	-	
	treatment of HER2-		
	overexpressing metastatic		
	gastric or		
	gastroesophageal		
	junction adenocarcinoma.		



Name: Ixifi (infliximab-	Name: Remicade®	Approved by	None under the
	(infliximab)	<u>Approved by</u> FDA on	BPCIA.
qbtx)	(IIIIIIXIIIIa0)		BFCIA.
Manufacturer Dfigor	Manufacturen Ionsoon	<u>December 13,</u>	Antitrust lawsuit
Manufacturer: Pfizer	Manufacturer: Janssen	<u>2017.</u>	
DIA 7(1072	Biotech, Inc.		against Janssen/J&J
BLA: 761072	DLA 102772		pending in the U.S.
	BLA: 103772		District Court for the
	T 1. (* /TT		Eastern District of
	Indications/Uses:		Pennsylvania.
	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.		
			.
Name: Retacrit	Name: Epogen® or	Pending FDA	Litigation in the U.S.
	Procrit® (epoetin alfa)	approval;	District Court for the
Manufacturer: Hospira		delayed after	District of Delaware.
	Manufacturer: Amgen	being issued a	
BLA: 125545	(Epogen); Janssen	second	
	Biotech (Procrit)	Complete	
		Response Letter	
	<i>BLA:</i> 103234	("CRL") by	
		FDA in June	
	Indications/Uses:	2017, related to	
	Stimulates red blood cells	manufacturing	
	to treat anemia. Often	problems.	
	used for patients taking		
	chemotherapy treatment	Received	
	or who have chronic	support (14-1)	
	renal failure.	for approval by	
		FDA's	
		Oncologic	
		Drugs Advisory	
		Committee on	
		May 25, 2017.	
		-	



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 <i>Amgen v. Apotex</i> pegfilgrastim litigation, above).



Name: LA-EP2006	Name: Neulasta®	Pending FDA	Litigation in the U.S.
Traine. En El 2000	(pegfilgrastim)	approval;	District Court for the
Manufacturer: Sandoz	(pegingrasum)	delayed after	Northern District of
Munujuciurer. Sandoz	Manufasturen Amasn		
	Manufacturer: Amgen	being issued a	California (being
BLA: Unknown	DI 4 105001	CRL by FDA in	coordinated for
	BLA: 125031	Q2 2016.	discovery and trial
			with the Amgen v.
	Indications/Uses: Treats	Sandoz has	Sandoz filgrastim
	neutropenia by increasing	stated that it is	matter).
	production of white	conducting an	
	blood cells. Often used	additional study	
	for patients taking	per FDA's data	
	chemotherapy treatments.	request/expected	
	1.2	to be completed	
	Neulasta® is the long-	in early 2019.	
	acting formulation of		
	Neupogen [®] .		
	reapozene.		
Name: CHS-1701	Name: Neulasta®	Pending FDA	Litigation in the U.S.
	(pegfilgrastim)	approval;	District Court for the
Manufacturer: Coherus	(pegingrasum)	delayed after	District of Delaware.
BioSciences	Manufasturen Amasn		District of Delaware.
BioSciences	Manufacturer: Amgen	being issued a	Trade as and
	DLA 105021	CRL by FDA in	Trade secret
BLA: Unknown	BLA: 125031	June 2017.	misappropriation and
			unfair competition
	Indications/Uses: Treats		lawsuit also pending
	neutropenia by increasing		in California Superior
	production of white		Court.
	blood cells. Often used		
	for patients taking		
	chemotherapy treatments.		
Name: MYL-1401H	Name: Neulasta®	Pending FDA	Litigation in the U.S.
	(pegfilgrastim)	approval;	District Court for the
Manufacturer:		delayed after	Western District of
Mylan/Biocon	Manufacturer: Amgen	being issued a	Pennsylvania.
	_	CRL by FDA in	
BLA: Unknown	<i>BLA:</i> 125031	October 2017.	
	Indications/Uses: Treats		
	neutropenia by increasing		
	production of white		
	blood cells. Often used		
	for patients in		
	chemotherapy or after a		
	bone marrow transplant.		
	cono marcow transplant.		



Name: CT-P6	Name: Herceptin®	Pending FDA	N/A
	(trastuzumab)	approval; aBLA	
Manufacturer:		accepted for	
Celltrion/Teva	Manufacturer:	filing in late July	
	Genentech	2017.	
BLA: Unknown		_0177	
	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.		
	junction adenocarcinoma.		
Name: ABP 980	Name: Herceptin®	Pending FDA	N/A
Nume. ABF 980	_		IN/A
Manufacturen	(trastuzumab)	approval; aBLA submitted in late	
Manufacturer:	Managhantan		
Amgen/Allergan	<i>Manufacturer:</i> Genentech	July 2017.	
BLA: Unknown	Genenteen		
BLA: UIIKIIOWII	BLA: 103792		
	<i>BLA</i> : 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.		



Name: TBD	Name: Neupogen®	Pending FDA	N/A
	(filgrastim)	approval; aBLA	
Manufacturer: Adello	(Ingrustini)	accepted for	
Biologics	Manufacturer: Amgen	filing in	
Diologies	Manajaciarer. Milgen	September 2017.	
BLA: Unknown	BLA: 103353	September 2017.	
	<i>DL</i> 1. 105555		
	Indications/Uses: Treats		
	neutropenia by increasing		
	production of white		
	blood cells. Often used		
	for patients taking		
	chemotherapy treatments		
	or after bone marrow		
	transplantation.		
	transplantation.		
Name:	Name: Rituxan®	Pending FDA	Litigation in the U.S.
Rixathon/GP2013	(rituximab)	approval; aBLA	District Court for the
		accepted for	District of New
Manufacturer: Sandoz	Manufacturer:	filing in	Jersey.
	Genentech	September 2017.	
BLA: Unknown		1	
	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.		



Name: SB3	Name: Herceptin®	Pending FDA	N/A
	(trastuzumab)	approval; aBLA	
Manufacturer:		accepted for	
Samsung Bioepis/Merck	Manufacturer:	filing in late	
	Genentech	December 2017.	
BLA: Unknown			
	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.		

