BIOLOGICS HQ

Spotlight On:

Trastuzumab

VENABLE LLP

October 31, 2026

Trastuzumab Timeline

Sep. 1998 **Herceptin®** FDA Approval (BL 103792) (Genentech)

Jan. 2017 **Ogivri®** aBLA Accepted by FDA (Mylan/Biocon)

Jul. 2017 **Kanjinti®** (Amgen/Allergan) **Herzuma®** (Teva/Celltrion) aBLAs Accepted by FDA

Aug. 2017 **Trazimera®** aBLA Accepted by FDA (Pfizer)

Dec. 2017 Biosimilar **Ogivri®** FDA Approval (aBLA 761074) (Mylan/Biocon)

Ontruzant® aBLA Accepted by FDA (Samsung Bioepis)

Dec. 2018 Biosimilar **Herzuma®** FDA Approval (aBLA 761091) (Celltrion/Teva)

Jan. 2019 Biosimilar **Ontruzant®** FDA Approval (aBLA 761100) (Samsung Bioepis)

Mar. 2019 Biosimilar **Trazimera®** FDA Approval (aBLA 761081) (Pfizer)

Jun. 2019 Biosimilar **Kanjinti®** FDA Approval (aBLA 761073) (Amgen / Allergan)

Jul. 2019 Biosimilar **Kanjinti®** Launch

Dec. 2019 Biosimilar **Ogivri®** Launch

Feb. 2020 Biosimilar **Trazimera®** Launch

Apr. 2020 Biosimilar **Ontruzant®** Launch

Oct. 2021 **TX-05** aBLA Submitted to FDA (Tanvex)

Dec. 2021 **EG12014** aBLA Submitted to FDA (Sandoz / EirGenix)

Feb. 2023 **HLX02** aBLA Accepted by FDA (Accord / Shanghai Henlius Biotech)

Apr. 2024 Biosimilar **Hercessi™** FDA Approval (aBLA 761346) (Accord / Shanghai Henlius)

Aug. 2016 IPR2016-01693, 01694 Petitions Filed [Settled]

Sep. 2016 IPR2016-01837 Petition Filed [FWD]

Jan. 2017 IPR2017-00731, 00737, 00804, 00805 Petitions Filed [FWD]

IPR2017-00739 Petition Filed [Institution Denied]

Feb. 2017 IPR2017-00959 Petition Filed [Claims Cancelled]

Mar. 2017 IPR2017-01121, 01122, 01139, 01140 Petitions Filed [FWD]

May 2017 IPR2017-01373, 01374, 01488, 01489 Petitions Filed [FWD]

Jul. 2017 IPR2017-01726, 01727 Petitions Filed [Institution Denied]

Aug. 2017 IPR2017-02019, 02020 Petitions Filed [Settled]

IPR2017-01958, 01959, 01960 Petitions Filed [Joined IPR2017-00804, 00805, 00737]

Sep. 2017 IPR2017-02063, 02139, 02140 Petitions Filed [Joined IPR2017-01121, 01488, 01489]

Oct. 2017 IPR2018-00016 Petition Filed [Institution Denied]

Nov. 2017 IPR2018-00192 Petition Filed [Institution Denied]

Nov. 2017 *Genentech v. Pfizer* (1:17-cv-01672 (D.N.J.)) Complaint Filed [Settled]

Dec. 2017 IPR2018-00330, 00331 Petitions Filed [Institution and Joinder Denied]

Jan. 2018 *Genentech & Celltrion* (1:18-cv-00095 (D.N.J.), 4:18-cv-00274 (N.D. Cal.)) Complaints Filed [Settled]

Mar. 2018 IPR2016-01837 FWD [All Claims Unpatentable]

May 2018 IPR2016-01837 Fed. Cir. Appeal Filed [Affirmed]

Jun. 2018 *Genentech v. Amgen* (1:18-cv-00924 (D. Del.)) Complaint Filed [Settled]

Jul. 2018 *Genentech v. Celltrion* (1:18-cv-01025 (D. Del.)) Complaint Filed [Settled]

Oct. 2018 IPR2017-00731, 00737/01960, 01121/02063, 01122 FWDs [All Claims Unpatentable]

IPR2017-00804/01958, 00805/01959, 01139, 01140 FWDs [No Claims Unpatentable]

Sep. 2018 *Genentech v. Samsung Bioepis* (1:18-cv-01363 (D. Del.)) Complaint Filed [Settled]

Nov. 2018 IPR2017-01373, 01374, 01488/02139, 01489/02140 FWDs [Some Claims Unpatentable]

IPR2017-00804/01958, 00805/01959 Fed. Cir. Appeals Filed [Dismissed]

Dec. 2018 IPR2017-00731, 00737/01960, 01121, 01122 Fed. Cir. Appeals Filed [Affirmed]

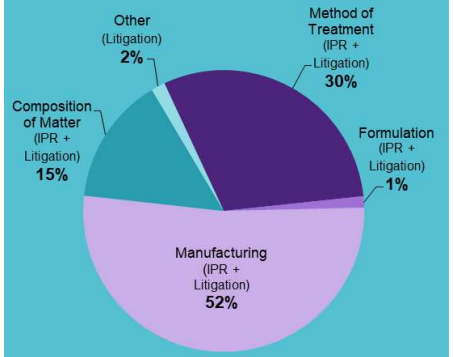
IPR2017-01139, 01140 Fed. Cir Appeals Filed [Dismissed]

Jun. 2022 *Genentech v. Tanvex* (3:22-cv-00809 (S.D. Cal.)) Complaint Filed [Settled]

Nov. 2024 Biosimilar **Hercessi™** Launch

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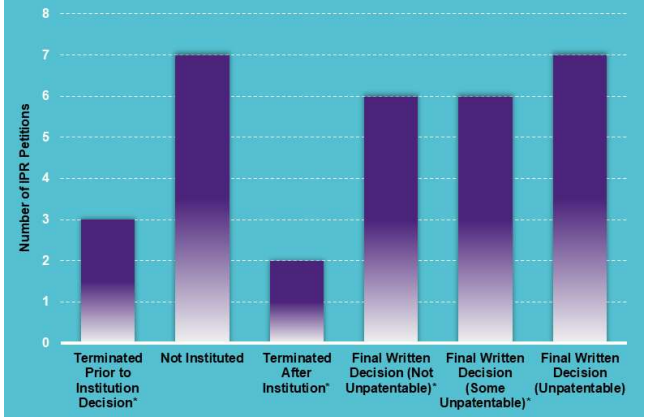
Trastuzumab Challenged Claim Types in IPR and Litigation*



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*In litigations, it has been alleged that at least these claims will be infringed or are invalid.

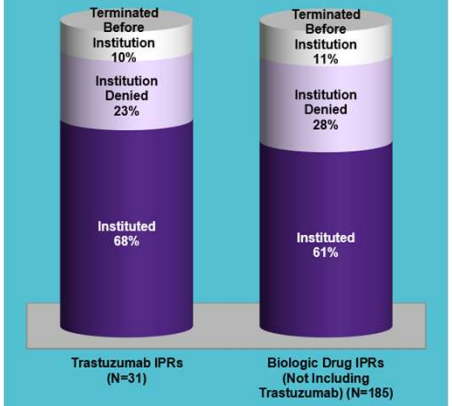
Trastuzumab IPR Status



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*Joinder counted as separate decisions

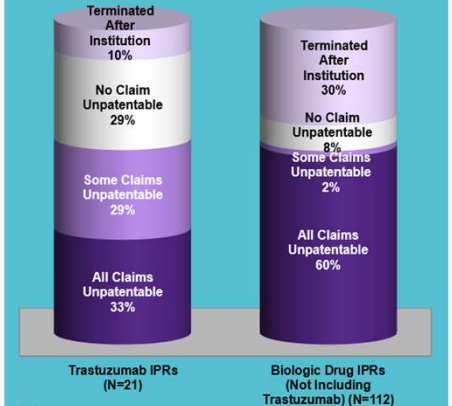
IPR Institution Rates*



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*Joinder counted as separate decisions

Outcomes After Institution*



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*Joinder counted as separate decisions

FWD = Final Written Decision

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Technology: Trastuzumab is a humanized monoclonal antibody that targets the HER2/neu receptor, which is overexpressed in some types of cancer. The HER2 pathway is involved in cell growth and division.

	Genentech v. Pfizer 1:17-cv-01672 (D. Del.) Settled Cont'd below	*Celltrion v. Genentech* 4:18-cv-00274 (N.D. Cal.) Dismissed; Fed. Cir. 18-2160 Dismissed Cont'd below	*Genentech v. Celltrion* 1:18-cv-00095 (D. Del.) Settled Cont'd below	*Genentech v. Amgen* 1:18-cv-00924 (D. Del.) Settled; Fed. Cir. 19-2156 TRO/PI Denied Cont'd below	*Genentech v. Celltrion* 1:18-cv-01025 (D. Del.) Settled Cont'd below	*Genentech v. Samsung Bioepis* 1:18-cv-01363 (D. Del.) Settled Cont'd below	*Pfizer v. Genentech* IPR2017-02019 Settled after institution; IPR2018-00330 Institution and joinder denied	*Celltrion v. Genentech* IPR2017-01373 IPR2017-01374 FWD- Some claims unpatentable	*Pfizer & Samsung Bioepis v. Genentech* IPR2017-01488 IPR2017-02139 (joined) FWD- Some claims unpatentable	*Pfizer & Samsung Bioepis v. Genentech* IPR2017-01489 IPR2017-02140 (joined) FWD- Some claims unpatentable	*Pfizer & Samsung Bioepis v. Genentech* IPR2017-00804 IPR2017-01958 (joined) FWD- No claims unpatentable, Fed. Cir. 19-1174 Settled	*Celltrion v. Genentech* IPR2017-01139 FWD- No claims unpatentable, Fed. Cir. 19-1258 Settled	*Hospira v. Genentech* IPR2016-01837 FWD- All claims unpatentable, Fed. Cir. 18-1933 Affirmed (US as Intervenor, Hospira settled)
6,121,428	x		x	x	x								
6,242,177	x		x	x	x								
6,331,415	x	x	x	x	x	x							
6,339,142	x	x	x		x	x	x						
6,407,213	x	x	x	x	x	x		x	x	x			
6,417,335	x	x	x	x	x	x	*Pfizer & Samsung Bioepis v. Genentech* IPR2017-00805 IPR2017-01959 (joined) FWD- No claims unpatentable, Fed. Cir. 19-1173 Settled	*Celltrion v. Genentech* IPR2017-01140 FWD- No claims unpatentable, Fed. Cir. 19-1259 Settled	*Hospira v. Genentech* IPR2017-00731 FWD- All claims unpatentable, Fed. Cir. 19-1263 Affirmed (US as Intervenor, Hospira settled)	*Celltrion & Pfizer v. Genentech* IPR2017-01121 IPR2017-02063 (joined) FWD- All claims unpatentable, Fed. Cir. 19-1267 Affirmed (US as Intervenor, Other parties settled)			
6,489,447	x	x	x	x	x								
6,586,206	x	x	x	x	x								
6,610,516	x	x	x		x	x							
6,620,918	x	x	x	x	x								
6,627,196	x	x	x	x	x	x					x	x	
6,716,602	x	x	x		x								
6,870,034				x							*Pfizer v. Genentech* IPR2018-00016 Institution denied	*Samsung Bioepis v. Genentech* IPR2018-00192 Institution denied	*Trustees of U of Penn. v. Genentech* 1:22-cv-00145 (D. Del.) Summary judgment (some claims invalid), remainder settled
7,371,379	x	x	x	x	x	x	x	x					
7,390,660	x	x	x		x	x							
7,449,184	x	x	x	x	x								
7,485,704	x	x	x		x	x							
7,501,122	x	x	x	x	x								
7,625,558													x
7,807,799	x	x	x		x	x							
7,846,441	x	x	x	x	x	x			x	x	x	x	

FWD = Final Written Decision

Chart continued on next page

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	Genentech v. Pfizer 1:17-cv-01672 (D. Del.) Cont'd from above	*Celltrion v. Genentech* 4:18-cv-00274 (N.D. Cal.) Cont'd from above	*Genentech v. Celltrion* 1:18-cv-00095 (D. Del.) Cont'd from above	*Genentech v. Amgen* 1:18-cv-00924 (D. Del.) Cont'd from above	*Genentech v. Celltrion* 1:18-cv-01025 (D. Del.) Cont'd from above	*Genentech v. Samsung Bioepis* 1:18-cv-01363 (D. Del.) Cont'd from above	*Genentech v. Tanvex* 3:22-cv-00809 (S.D. Cal.) Settled	*Pfizer & Samsung Bioepis v. Genentech* IPR2017-00737 IPR2017-01960 (joined) FWD- All claims unpatentable, Fed. Cir. 19-1265 Affirmed (US as Intervenor, Other parties settled)	*Pfizer v. Genentech* IPR2017-00739 Institution denied	*Celltrion v. Genentech* IPR2017-01122 FWD- All claims unpatentable, Fed. Cir. 19-1270 Affirmed (US as Intervenor, Celltrion settled)
7,892,549	x	x	x	x	x	x		x	x	x
7,923,221	x	x	x	x	x	x				
7,993,834	x	x	x	x	x	x				
8,044,017	x			x						
8,076,066	x	x	x	x	x	x				
8,314,225	x			x						
8,357,301		x	x	x	x			*Pfizer v. Genentech* IPR2017-02020 Settled after institution; IPR2018-00331 Institution and joinder denied	*Celltrion v. Genentech* IPR2017-00959 Terminated before institution (claims cancelled)	*Pfizer v. Genentech* IPR2017-01726 IPR2017-01727 Institution denied (claims previously cancelled)
8,425,908	x	x	x	x	x	x				
8,440,402	x	x	x	x	x	x				
8,460,895	x	x	x	x	x					
8,512,983	x	x	x	x	x	x				
8,574,869	x	x	x	x	x	x	x			
8,591,897									x	x
8,633,302	x	x	x		x					
8,691,232	x	x	x	x	x					
8,710,196	x			x						
8,771,988	x	x	x	x	x					
8,822,655	x	x	x		x					
9,047,438		x	x	x	x					
9,080,183		x	x	x	x					
9,249,218	x	x	x	x	x	x		x		
9,428,548		x	x		x					
9,428,766	x	x	x	x	x					
9,487,809	x	x	x	x	x					
9,493,744	x			x						
9,714,293	x	x	x	x	x	x				
9,868,760				x						
10,160,811				x						
10,662,237							x			
10,808,037							x			