BIOLOGICS HQ

Spotlight On: Adalimumab

VENABLE LLP

October 31, 2026

Adalimumab Timeline

Dec. 2002 Humira® FDA Approval (BL 125057) (AbbVie)

Sep. 2016 Biosimilar Amjevita™ FDA Approval (aBLA 761042) (Amgen)

Aug. 2017 Biosimilar Cyltezo® FDA Approval (aBLA 761058) (Boehringer Ingelheim)

Oct. 2018 Biosimilar Hyrimoz® FDA Approval (aBLA 761071) (Sandoz)

Jul. 2019 Biosimilar Hadlima® FDA Approval (aBLA 761059) (Samsung Bioepis)

Nov. 2019 Biosimilar Abrilada™ FDA Approval (aBLA 761118) (Pfizer)

Jul. 2020 Biosimilar Hulio® FDA Approval (aBLA 761154) (Biocon)

Oct. 2021 Cyltezo® Interchang Status Granted (Boehringer Ingelheim)

Dec. 2021 Biosimilar Yusimry® FDA Approval (aBLA 761216) (Coherus)

Aug. 2022 Hadlima® sBLA (high concentr.) FDA Approval (Samsung Bioepis)

Dec. 2022 Idacio® FDA Approval (aBLA 761255) (Fresenius Kabi)

Jan. 2023 Amjevita™ Launch (Amgen)

Mar. 2023 Hyrimoz® sBLA (high concentr.) FDA Approval (Sandoz)

May 2023 Yuflyma® sBLA (high concentr.) FDA Approval (Celltrion)

Apr. 2024 Cyltezo® sBLA (high concentr.) FDA Approval (Boehringer Ingelheim)

Apr. 2025 Yuflyma® Interchang Approval (Celltrion)

May 2025 Hulio® Interchang Approval (Biocon)

Jun. 2015 IPR2015-01514, 01517 Petitions Filed [Institution Denied]

Nov. 2015 IPR2016-00172 Petition Filed [FWD]

Dec. 2015 IPR2016-00188, 00189, 00408, 00409 Petitions Filed [FWD]

May 2016 IPR2016-01018 Petition Filed [Institution Denied]

Aug. 2016 *AbbVie v. Amgen* (1:16-cv-00666) Complaint Filed

Jan. 2017 IPR2017-00822, 00823, 00826, 00827 Petitions Filed [Institution Denied]

Mar. 2017 IPR2017-01008, 01009 Petitions Filed (Replacing IPR2017-00826, 00827) [Institution Denied]

May 2017 IPR2016-00172 FWD [All Claims Unpatentable]

Jun. 2017 IPR2016-00188, 00189 FWDs [All Claims Unpatentable]

Jul. 2017 IPR2016-00408, 00409 FWDs [All Claims Unpatentable]

IPR2016-00172, 00188, 00189, 00408, 00409 Fed. Cir. Appeals Filed [Affirmed]

IPR2017-01823, 01824 Petitions Filed [Institution Denied]

Aug. 2017 *AbbVie v. Boehringer Ingelheim* (1:17-cv-01065) Complaint Filed [Settled]

Aug. 2017 IPR2017-01987, 01988 Petitions Filed [Institution Denied]

Sep. 2017 IPR2017-02105, 02106 Petitions Filed [Settled]

Sep. 2017 *AbbVie v. Amgen* (1:16-cv-00666) Dismissed [Settled]

Nov. 2017 IPR2018-00156 Petition Filed [Institution Denied]

Oct. 2017 IPR2018-00002 Petition Filed [Institution Denied]

Aug. 2018 *AbbVie v. Sandoz* (3:18-cv-12668) Complaint Filed [Settled]

Jul. 2018 IPR2017-01824, IPR2018-00002 Fed. Cir. Appeals Filed [Settled]

Jan. 2019 *Coherus v. Amgen* (1:19-cv-00139) Complaint Filed [Settled]

Apr. 2021 *AbbVie v. Alvotech* (1:21-cv-02258) Complaint Filed [Settled]

May 2021 *Alvotech v. AbbVie* (1:21-cv-05645) Complaint Filed [Voluntarily Dismissed] *AbbVie v. Alvotech* (1:21-cv-02899) Complaint Filed [Settled]

Jul. 2023 Cyltezo® (Boehringer Ingelheim), Hadlima® (Samsung Bioepis), Hulio® (Biocon), Hyrimoz® (Sandoz), Idacio® (Fresenius Kabi), Yuflyma® (Celltrion), Yusimry® (Coherus) Launches

Oct. 2023 Abrilada™ Interchang Approval and Launch (Pfizer)

Feb. 2024 Simlandi® Interchang Approval (aBLA 761299) (Alvotech / Teva)

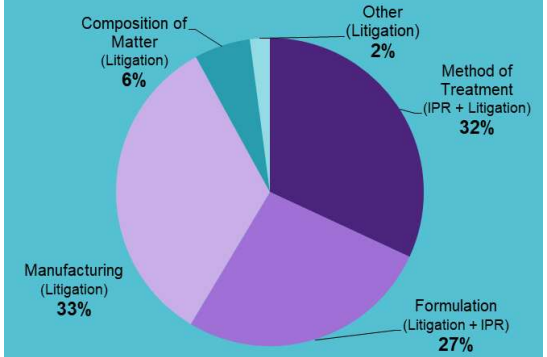
May 2024 Hyrimoz® Interchang Approval (Sandoz) Simlandi® Launch (Alvotech / Teva)

Jun. 2024 Hadlima® Interchang Approval (Samsung Bioepis)

Sep. 2026 Yusimry® High concentr., Interchang Approval (Emerge)

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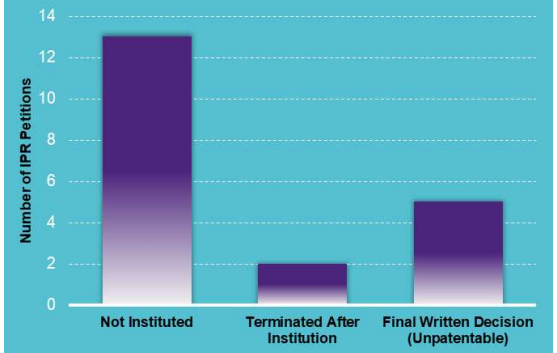
Adalimumab Challenged Claim Types in IPR and Litigation*



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

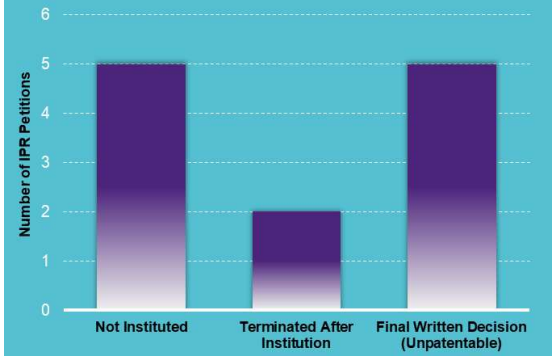
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Adalimumab IPR Status



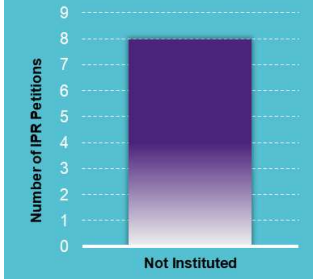
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Adalimumab Method of Treatment Claim IPR Status



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Adalimumab Formulation Claim IPR Status



*Considering IPR2017-00826 and IPR2017-01008 as one IPR, and IPR2017-00827 and IPR2017-01009 as one IPR.

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FWD = Final Written Decision

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Technology: Adalimumab is a human monoclonal antibody that inhibits tumor necrosis factor alpha (TNFα). TNFα is a cytokine cell signaling protein that is involved in the inflammatory response that occurs in autoimmune diseases.

	AbbVie v. Alvotech 1:21-cv-02899 (N.D. Ill.) Settled (cont'd below)	*AbbVie v. Amgen* 1:16-cv-00666 (D. Del.) Settled	*AbbVie v. Boehringer Ingelheim* 1:17-cv-01065 (D. Del.) Settled	*AbbVie v. Alvotech* 1:21-cv-02258 (N.D. Ill.) Settled *Alvotech v. AbbVie* 1:21-cv-05645 (N.D. Ill.) Dismissed	*Amgen v. AbbVie* IPR2015-01514 Institution denied	*Amgen v. AbbVie* IPR2015-01517 Institution denied	*Coherus v. AbbVie* IPR2017-00822, IPR2017-00823 Institution denied	*Coherus v. AbbVie* IPR2017-00826 / IPR2017-01008 Institution denied	*Coherus v. AbbVie* IPR2017-00827 / IPR2017-01009 Institution denied
8,420,081				x					
8,663,945	x	x							
8,911,964	x	x							
8,916,157		x			x				
8,916,158					x	x			
8,926,975			x	x					
8,961,973		x		x					
8,986,693	x	x							
9,018,361			x						
9,090,867	x		x						
9,085,619				x			x	x	x
9,096,666	x	x	x						
9,220,781		x							
9,255,143			x						
9,266,949	x		x						
9,272,041		x	x						
9,359,434	x	x							
9,365,645		x							
9,546,212	x		x						

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	AbbVie v. Alvotech 1:21-cv-02899 (N.D. Ill.) Settled (cont'd)	*Coherus v. AbbVie* IPR2016-00172 FWD: All claims unpatentable; Appeal No. 17-2304 Affirmed (U.S. as Intervenor, Coherus settled)	*Boehringer Ingelheim v. AbbVie* IPR2016-00408, IPR2016-00409 FWD: All claims unpatentable; Appeal Nos. 17-2362 and 17-2363 Affirmed (U.S. as Intervenor, Boehringer Ingelheim settled)	*Coherus v. AbbVie* IPR2016-00188 FWD: All claims unpatentable; Appeal No. 17-2305 Affirmed (U.S. as Intervenor, Coherus settled)	*Coherus v. AbbVie* IPR2016-00189 FWD: All claims unpatentable; Appeal No. 17-2306 Affirmed (U.S. as Intervenor, Coherus settled)	*Sandoz v. AbbVie* IPR2017-01824 Institution denied; Request for rehearing denied; Appeal No. 18-2142 settled	*Sandoz v. AbbVie* IPR2018-00002 Institution denied; Appeal No. 18-2143 settled
8,889,135		x	x				
9,017,680				x			
9,073,987					x		
9,512,216	x					x	x
		Sandoz v. AbbVie IPR2017-01823 Institution denied	*Sandoz v. AbbVie* IPR2017-01987 Institution denied; Settled during request for rehearing	*Sandoz v. AbbVie* IPR2017-01988 Institution denied; Settled during request for rehearing	*Sandoz v. AbbVie* IPR2017-02106 Settled after institution Coherus settled)	*Sandoz v. AbbVie* IPR2017-02105 Settled after institution	*Coherus v. AbbVie* IPR2016-01018 Institution denied
8,802,100		x					
8,911,737	x		x				
8,974,790	x			x			
9,067,992	x				x		
9,090,689	x					x	
9,114,166							x
		Sandoz v. AbbVie IPR2018-00156 Institution denied		*AbbVie v. Sandoz* 3:18-cv-12668 (D.N.J.) Settled		*Coherus v. Amgen* [Related to Amjevita™] 1:19-cv-00139 (D. Del.) Settled	
9,187,559	x	x		x			
9,750,808				x			
10,155,039						x	
10,159,732						x	
10,159,733						x	
10,207,000						x	

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	AbbVie v. Alvotech 1:21-cv-02899 (N.D. Ill.) Settled (cont'd)				
6,805,686	x	9,090,688	x	9,550,826	x
8,231,876	x	9,102,723	x	9,624,295	x
8,708,968	x	9,150,645	x	9,669,093	x
8,715,664	x	9,181,337	x	9,683,033	x
8,808,700	x	9,181,572	x	9,708,400	x
8,883,156	x	9,234,032	x	9,957,318	x
8,889,136	x	9,273,132	x		
8,895,009	x	9,284,370	x		
8,906,372	x	9,284,371	x		
8,906,373	x	9,290,568	x		
8,906,646	x	9,315,574	x		
8,916,153	x	9,328,165	x		
8,961,974	x	9,334,319	x		
8,992,926	x	9,339,610	x		
8,999,337	x	9,346,879	x		
9,061,005	x	9,499,614	x		
9,062,106	x	9,499,616	x		
9,085,618	x	9,505,834	x		
9,085,620	x	9,522,953	x		

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