BIOLOGICS HQ

Spotlight On: Rituximab

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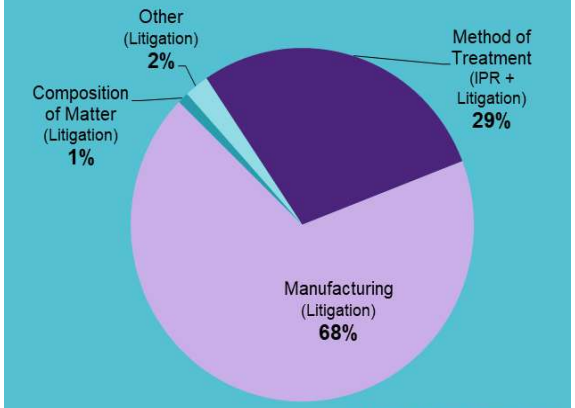
October 31, 2026

Rituximab Timeline

- **Nov. 1997** Rituxan® FDA Approval (BL 103705) (Genentech)
- **Apr. 2017** IPR2017-01166, 01167 Petitions Filed [Institution Denied]; IPR2017-01168 Petition Filed [FWD- All Claims Unpatentable; Appeal 19-1364 Affirmed]
- **Jun. 2017** Truxima® aBLA Accepted by FDA (Celltrion / Teva)
- **Sep. 2017** Rixathon® aBLA Accepted by FDA (Sandoz)
- **May 2018** Rixathon® Complete Response Letter (Sandoz)
- **May 2018** IPR2018-01019 Petition Filed [Settled]
- **Oct. 2017** IPR2017-02126, 02127 Petitions Filed [Institution Denied]
- **Nov. 2017** IPR2018-00086 Petition Filed [Institution Denied]
- **Jul. 2018** *Celltrion v. Genentech* (1:18-cv-11553 (D.N.J.)) Complaint Filed [Settled]; Appeal 18-2161 from 4:18-cv-00276 (N.D. Cal.) Filed [Dismissed]
- **Sep. 2018** Ruxience® aBLA Accepted by FDA (Pfizer)
- **Jan. 2020** Biosimilar Ruxience® Launch
- **Apr. 2024** Biosimilar DRL_RI CRL (Dr. Reddy's)
- **Nov. 2018** Biosimilar Truxima® FDA Approval (aBLA 761088) (Celltrion / Teva)
- **Dec. 2020** Biosimilar Riabni™ FDA Approval (aBLA 761140) (Amgen / Allergan)
- **Dec. 2014** IPR2015-00415, 00417, Petitions Filed [Terminated]; IPR2015-00418 Petition Filed [Institution Denied]
- **Aug. 2015** IPR2015-01733, 01744 Petitions Filed [Terminated]
- **Aug. 2016** IPR2016-01614 Petition Filed [FWD – No Claims Unpatentable; Appeal 18-1924 Dismissed]; IPR2016-01667 Petition Filed [Institution Denied]
- **Mar. 2017** IPR2017-01093, 01094, 01227, 01229, 01230 Petitions Filed [Institution Denied]; IPR2017-01095 Petition Filed [FWD- All Claims Unpatentable; Appeal 19-1253 Dismissed]; IPR2017-01115 Petition Filed [FWD – No Claims Unpatentable; Appeal 18-1885 Settled]
- **Jul. 2018** *Celltrion v. Genentech* (1:18-cv-11553 (D.N.J.)) Complaint Filed [Settled]; Appeal 18-2161 from 4:18-cv-00276 (N.D. Cal.) Filed [Dismissed]
- **Aug. 2017** IPR2017-01923 Petition Filed [Settled]; IPR2017-02036, 02042 Petitions Filed [Institution Denied]
- **Dec. 2017** IPR2018-00285 Petition Filed [Settled]; IPR2018-00186, 00231 Petitions Filed [Terminated]
- **Dec. 2017** *Genentech v. Sandoz* (1:17-cv-13507 (D.N.J.)) Complaint Filed [Dismissed]
- **Jan. 2018** *Celltrion v. Genentech* (4:18-cv-00276 (N.D. Cal.)) Complaint Filed [Dismissed]; *Genentech v. Celltrion* (1:18-cv-00574 (D.N.J.)) Complaint Filed [Settled]
- **Jul. 2019** Biosimilar Ruxience® FDA Approval (aBLA 761103) (Pfizer)
- **Nov. 2019** Biosimilar Truxima® Launch
- **Dec. 2019** Riabni™ aBLA Submitted to FDA (Amgen / Allergan)
- **Jul. 2023** Biosimilar DRL_RI aBLA Accepted by FDA (Dr. Reddy's)
- **Nov. 2023** *Genentech v. Dr. Reddy's* (1:23-cv-22485 (D.N.J.)) Complaint Filed [Settled]
- **Jul. 2026** Truxima® Interchangeable Approved (Celltrion / Teva)
- **Aug. 2026** Biosimilar Zimrixby™ FDA Approval (aBLA 761376) (Dr. Reddy's)

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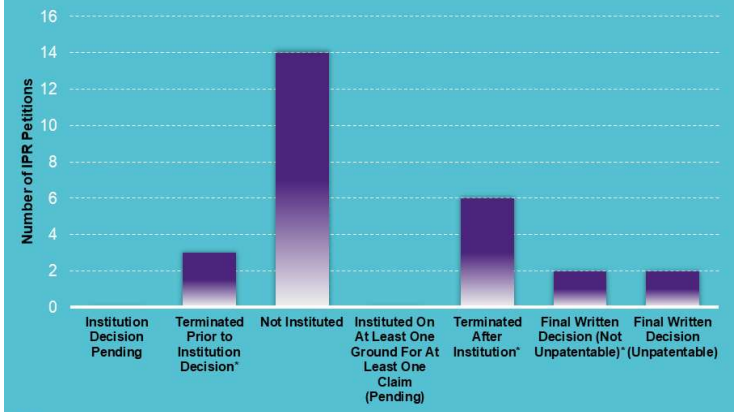
Rituximab Challenged Claim Types in IPR and Litigation*



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

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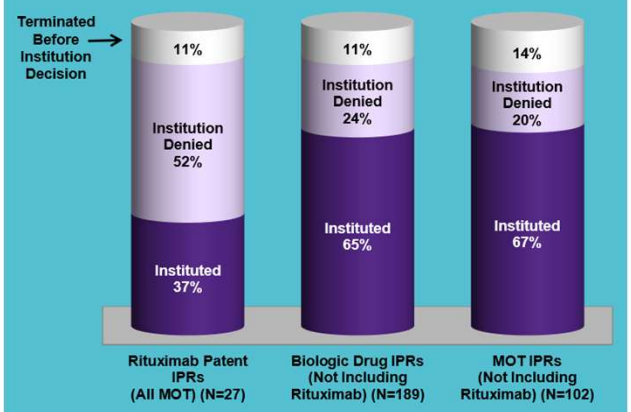
Rituximab IPR Status (All Method of Treatment Claims)



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*Joinder counted as separate decisions

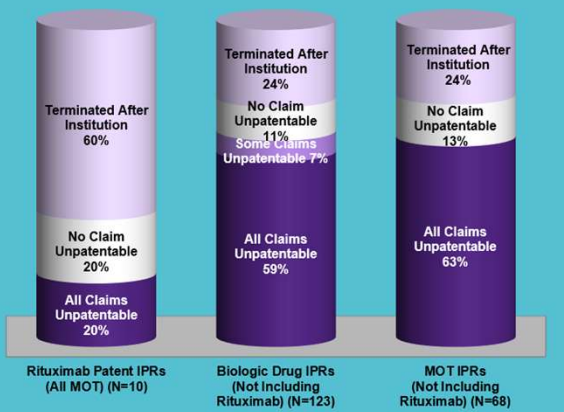
IPR Institution Rates*



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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

	Genentech v. Celltrion 1:18-cv-11553 (D.N.J.) Settled Cont'd below	*Genentech v. Celltrion* 1:18-cv-00574 (D.N.J.) Settled Cont'd below	*Celltrion v. Genentech* 4:18-cv-00276 (N.D. Cal.) Dismissed; Appeal No. 18-2161 Dismissed Cont'd below	*Genentech v. Sandoz* 1:17-cv-13507 (D.N.J.) Dismissed Cont'd below	*Genentech v. Dr. Reddy's* 1:23-cv-22485 (D.N.J.) Settled Cont'd below	*Celltrion v. Genentech* IPR2017-01227 Institution denied	*Celltrion v. Genentech* IPR2017-01230 Institution denied	*Pfizer v. Genentech* IPR2017-02126 Institution denied	*Boehringer Ingelheim v. Genentech* IPR2015-00415 Petitioner request for adverse judgment after institution	*Celltrion v. Genentech* IPR2015-01744 Petitioner dismissed prior to institution decision	*Celltrion v. Genentech* IPR2016-01614 FWD (no instituted claim unpatentable); Appeal 18-1924 dismissed	*Pfizer v. Genentech* IPR2017-01115 (Joined with IPR2016-01614) FWD (no instituted claim unpatentable); Appeal 18-1885 dismissed (settled)
6,121,428		x		x								
6,242,177		x										
6,331,415	x	x	x	x								
6,417,335		x	x									
6,455,043		x	x									
6,489,447	x	x	x	x								
6,586,206		x	x									
6,610,516	x	x	x	x								
6,620,918	x	x	x	x								
6,716,602		x	x									
6,870,034				x								
7,381,560	x	x		x								
7,390,660		x	x									
7,485,704	x	x	x	x	x							
7,682,612		x	x			x	x	x				
7,807,799	x	x	x	x								
7,820,161	x	x	x	x					x	x	x	x
7,923,221	x	x	x	x		*Boehringer Ingelheim v. Genentech* IPR2015-00417 Petitioner request for adverse judgment after institution	*Celltrion v. Genentech* IPR2015-01733 Petitioner dismissed prior to institution decision	*Celltrion v. Genentech* IPR2016-01667 Institution denied	*Pfizer v. Genentech* IPR2017-01923 Settled after institution	*Sandoz v. Genentech* IPR2017-02036 Institution denied	*Sandoz v. Genentech* IPR2017-02042 Institution denied	*Celltrion v. Genentech* IPR2018-01019 Joined with IPR2017-01923; Settled after institution
7,976,838	x	x	x	x	x	x	x	x	x	x	x	x

FWD = Final Written Decision

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	Genentech v. Celltrion 1:18-cv-11553 (D.N.J.) Settled (Cont'd)	*Genentech v. Celltrion* 1:18-cv-00574 (D.N.J.) Settled (Cont'd)	*Celltrion v. Genentech* 4:18-cv-00276 (N.D. Cal.) Dismissed; Appeal No. 18-2161 Dismissed (Cont'd)	*Genentech v. Sandoz* 2:17-cv-13507 (D.N.J.) Dismissed (Cont'd)	*Genentech v. Dr. Reddy's* 1:23-cv-22485 (D.N.J.) Settled (Cont'd)	*Celltrion v. Genentech* IPR2017-01229 Institution denied	*Pfizer v. Biogen* IPR2017-02127 Institution denied	*Boehringer Ingelheim v. Biogen* IPR2015-00418 Institution denied	*Celltrion v. Biogen* IPR2017-01093 Institution denied	*Pfizer v. Biogen* IPR2017-01166 Institution denied; Request for rehearing withdrawn	*Pfizer v. Biogen* IPR2018-00285 Settled after institution	
8,044,017		x	x									
8,206,711	x	x	x	x		x	x					
8,314,225				x								
8,329,172	x	x	x	x				x	x	x	x	
8,357,301		x	x			*Pfizer v. Genentech* IPR2018-00086 Institution denied	*Celltrion v. Biogen* IPR2017-01094 Institution denied	*Pfizer v. Biogen* IPR2017-01167 Institution denied	*Pfizer v. Biogen* IPR2017-01168 FWD (All instituted claims unpatentable); Appeal 19-1364 affirmed with US, settled with Pfizer	*Celltrion v. Biogen* IPR2017-01095 FWD (All instituted claims unpatentable); Appeal 19-1253 dismissed as to US, settled with Celltrion	*Pfizer v. Biogen* IPR2018-00186 Terminated after institution	*Pfizer v. Biogen* IPR2018-00231 Petitioner dismissed prior to institution decision
8,460,895		x	x		x							
8,512,983		x	x	x	x							
8,545,843	x	x	x	x		x						
8,557,244	x	x	x	x			x	x				
8,574,869	x	x	x	x	x							
8,633,302		x	x									
8,710,196		x	x	x								
8,771,988		x	x									
8,821,873	x	x	x	x					x			
8,822,655		x	x									
9,047,438		x	x									
9,080,183		x	x									
9,296,821	x	x	x	x						x	x	
9,428,548		x	x									
9,428,766		x	x									
9,487,809		x	x									
9,504,744	x	x	x	x								x
9,714,293		x	x	x	x							

Chart continued on next page

	Genentech v. Dr. Reddy's 1:23-cv-22485 (D.N.J.) Settled (Cont'd)
10,017,732	x
10,336,983	x
10,450,379	x
10,654,940	x
10,662,237	x
10,676,710	x
10,759,866	x
10,829,732	x
10,982,003	x

Technology: Rituximab is a chimeric murine/human monoclonal antibody that is directed against the CD20 antigen. CD20 is a protein that is primarily found on the surface of immune system B cells. CD20 is involved in cell growth and differentiation.