BIOLOGICS HQ

Spotlight On:

Insulin Glargine

VENABLE LLP

October 31, 2026

Technology: Insulin glargine is a long-acting recombinant human insulin analog that helps to control blood sugar levels in patients with diabetes.

Insulin Glargine Timeline

Apr. 2000 **Lantus®** FDA Approval (BLA 021081) (Sanofi Aventis US)

Feb. 2015 **Toujeo Solostar®** FDA Approval (BLA 206538) (Sanofi US Services)

Dec. 2015 **Basaglar®** FDA Approval (BLA 205692) [505(b)(2)] (Eli Lilly & Co.)

Jul. 2017 **Lusduna™ Nexvue™** Tentative FDA Approval [505(b)(2)] (Merck)

Jun. 2020 **Semglee®** FDA Approval (BLA 210605) [505(b)(2)] (Mylan / Biocon)

Aug. 2020 Biosimilar **Semglee®** Launch

Jul. 2021 **Semglee®** Interchangeable FDA Approval (BLA 761201) (Viatris (Mylan) / Biocon)

Nov. 2021 Interchangeable **Semglee®** Launch

Dec. 2021 **Rezvoglar™** FDA Approval (aBLA 761215) (Eli Lilly)

Dec. 2022 **Rezvoglar™** Interchangeable FDA Approval (aBLA 761215) (Eli Lilly)

Jan. 2014 *Sanofi v. Eli Lilly* (1:14-cv-00113) Complaint Filed [Settled]

Jul. 2014 *Sanofi v. Eli Lilly* (1:14-cv-00884) Complaint Filed [Settled]

Sep. 2016 *Sanofi v. Merck* (1:16-cv-00812) Complaint Filed [Dismissed]

Jun. 2017 *Mylan v. Sanofi* IPR2017-01526, 01528 Petitions Filed [FWD: All Instituted Claims Unpatentable; Appeals 19-1368 and 19-1369 [Affirmed]

Aug. 2017 *Sanofi v. Merck* (2:17-cv-05914) Complaint Filed [Dismissed]

Oct. 2017 *Sanofi v. Mylan* (2:17-cv-09105) Complaint Filed [Claims Not Infringed, But Invalid]

Sep. 2018 *Mylan v. Sanofi* IPR2018-01670, 01675, 01676, 01678, 01679, 01680, 01682 Petitions Filed [FWD: All Instituted Claims Unpatentable]; IPR2018-01684 Petition Filed [FWD: Some Instituted Claims Unpatentable]; IPR2018-01677 Petition Filed [Terminated Prior to Institution Decision]; IPR2018-01696 Petition Filed [Institution Denied]

Oct. 2018 *Mylan v. Sanofi* IPR2017-01677 Refiled as IPR2019-00122 [FWD: All Instituted Claims Unpatentable]

May 2019 *Pfizer v. Sanofi* IPR2019-00977, 00978, 00980, 00981, 00982, 01022, 01023 Petitions Filed [Joined with Mylan IPRs, FWD: All Instituted Claims Unpatentable]; IPR2019-00987 Petition Filed [Joined with Mylan IPR, FWD: Some Instituted Claims Unpatentable]; IPR2019-00979 Petition Filed [(Joinder Denied); FWD: All Instituted Claims Unpatentable]

Oct. 2019 *Mylan v. Sanofi* IPR2019-01657 Petition Filed [FWD: All Claims Unpatentable, Reversed on Appeal]; IPR2019-01658 Petition Filed [Institution Denied]

Jun. 2020 *Sanofi v. Mylan* Appeal 20-1871 Filed [Affirmed]

Jul. 2020 *Sanofi v. Mylan* Appeals 20-2032, 20-2033, 20-2066, 20-2068, 20-2071 Filed [Affirmed]; 20-2029, 20-2034, 20-2069 Filed [Dismissed as Moot]

Aug. 2020 *Sanofi v. Mylan* Appeals 20-2159 Filed [Affirmed]; 20-2139, 20-2144 Filed [Withdrawn]

Oct. 2020 *Sanofi v. Mylan* Sup. Ct. Appeal 19-1451 Certiorari Denied

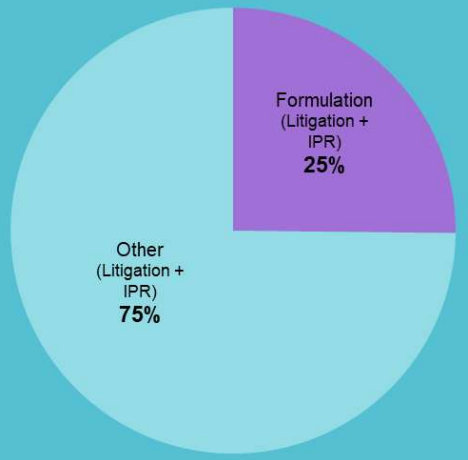
Nov. 2020 *Sanofi v. Mylan* Appeal 21-1262 Filed [Dismissed as Moot]

May 2021 *Sanofi v. Mylan* Appeal 21-1981 Filed [Reversed]

Apr. 2023 **Rezvoglar™** Launch

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Insulin Glargine Challenged Claim Types in IPR and Litigation*



*Litigation Defendants alleged to infringe at least these claims in complaints/amended complaints. Joinder counted separately.

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FWD = Final Written Decision

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	Sanofi v. Eli Lilly 1:14-cv-00113 (D. Del.) Settled	*Sanofi v. Eli Lilly* 1:14-cv-00884 (D. Del.) Settled	*Sanofi v. Merck* 1:16-cv-00812 (D. Del.) Stipulated dismissal	*Sanofi v. Merck* 2:17-cv-05914 (D.N.J.) Stipulated dismissal	*Sanofi v. Mylan* 2:17-cv-09105 (D.N.J.) Claims not infringed, but invalid Appeal 21-1262 Dismissed as Moot	*Mylan v. Sanofi* IPR2017-01526 FWD (All instituted claims unpatentable); Appeal 19-1368 Affirmed, Rehearing denied; Sup. Ct. 19-1451 Cert Denied	*Mylan v. Sanofi* IPR2017-01528 FWD (All instituted claims unpatentable); Appeal 19-1369 Affirmed, Rehearing denied; Sup. Ct. 19-1451 Cert Denied	*Mylan v. Sanofi* IPR2018-01670 FWD (Instituted claim unpatentable) Appeal 20-1871 Pending *Pfizer v. Sanofi* IPR2019-00979 (Joinder denied) FWD (All instituted claims unpatentable); Appeal 20-2159 Affirmed	*Mylan v. Sanofi* IPR2018-01675 IPR2018-01676 *Pfizer v. Sanofi* IPR2019-00977 IPR2019-00978 Joined FWD (All instituted claims unpatentable); Appeals 20-2029 Dismissed as Moot, 20-2032 Affirmed	*Mylan v. Sanofi* IPR2018-01677 Terminated prior to institution decision; Refiled as IPR2019-00122, *Pfizer v. Sanofi* IPR2019-00982 Joined FWD (All instituted claims unpatentable); Appeal 20-2034 Dismissed as Moot	*Mylan v. Sanofi* IPR2018-01678 IPR2018-01679 *Pfizer v. Sanofi* IPR2019-00980 IPR2019-00981 Joined FWD (All instituted claims unpatentable); Appeals 20-2033, 20-2066 Affirmed
7,476,652	x	x	x	x	x	x					
7,713,930	x	x	x	x	x		x				
7,918,833		x	x		x						
8,512,297		x	x		x						
8,556,864	x	x	x		x						
8,603,044	x	x	x		x				x		
8,679,069	x	x	x		x			x			
8,992,486			x		x					x	x
9,011,391			x		x		*Mylan v. Sanofi* IPR2019-01658 Institution denied	*Mylan v. Sanofi* IPR2019-01657 FWD (All instituted claims unpatentable); Appeal 21-1981 Reversed	*Mylan v. Sanofi* IPR2018-01680 IPR2018-01682 *Pfizer v. Sanofi* IPR2019-01022 IPR2019-01023 Joined FWD (All instituted claims unpatentable); Appeals 20-2068 Affirmed, 20-2069 Dismissed as Moot	*Mylan v. Sanofi* IPR2018-01696 Institution denied	*Mylan v. Sanofi* IPR2018-01684 *Pfizer v. Sanofi* IPR2019-00987 Joined FWD (Some instituted claims unpatentable); Appeal 20-2071 Affirmed, 20-2139 & 20-2144 Withdrawn
9,233,211			x		x						
9,408,979					x						
9,457,152			x								
9,486,587			x								
9,526,844			x		x				x	x	
9,533,105			x		x						
9,561,331					x						
9,592,348			x								
9,604,008			x		x						x
9,604,009					x						
9,610,409					x						
9,623,189					x						
RE47,614							x	x			