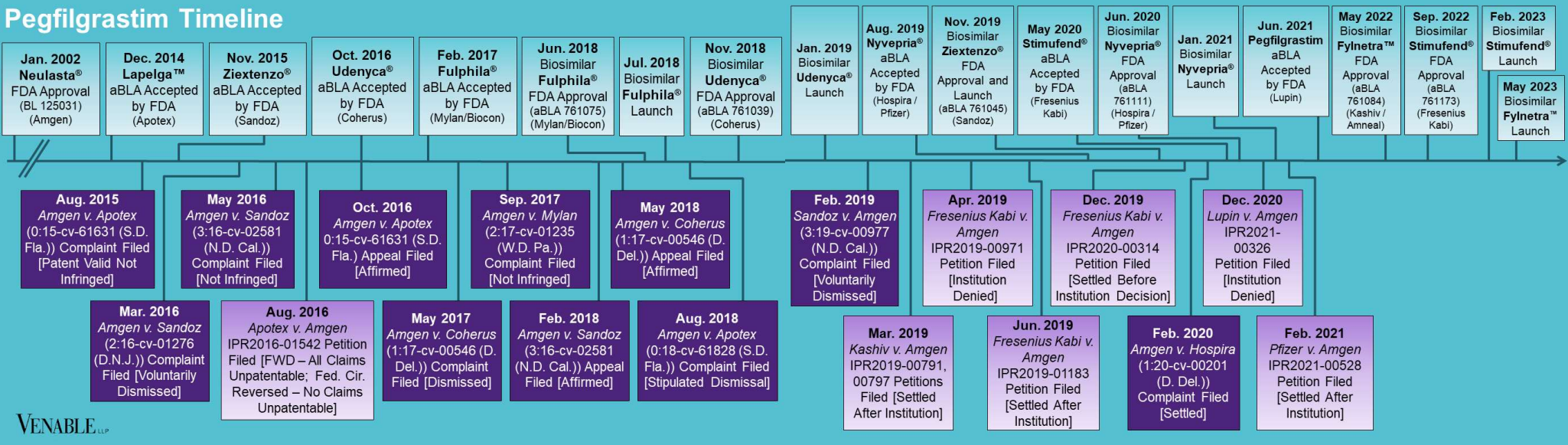


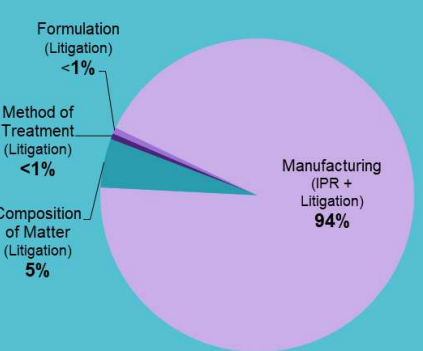
Spotlight On: Pegfilgrastim

April 30, 2025

Pegfilgrastim Timeline

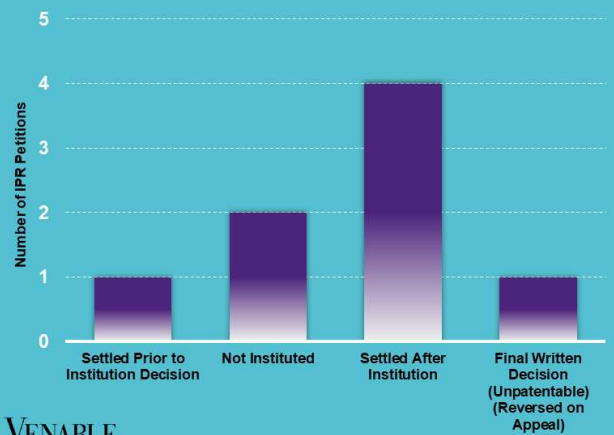


Pegfilgrastim Challenged Claim Types in IPR and Litigation*

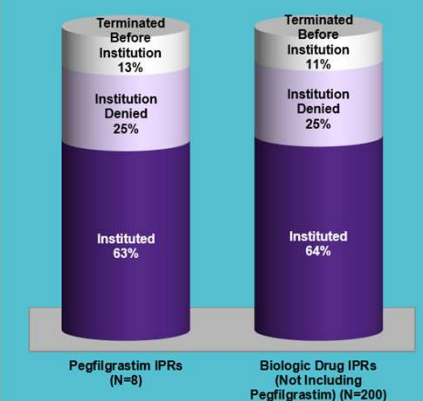


*In litigations, it has been alleged that at least these claims will be infringed or are invalid.

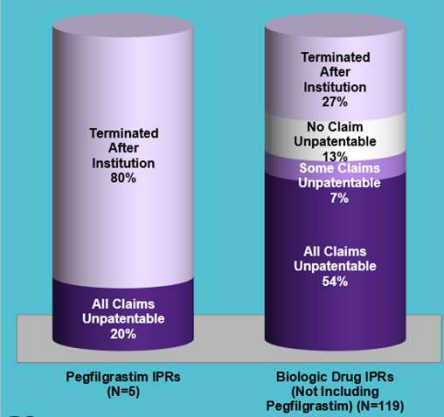
Pegfilgrastim IPR Status



IPR Institution Rates*



Outcomes After Institution*



FWD = Final Written Decision

Spotlight On: Pegfilgrastim

April 30, 2025

Technology: Pegfilgrastim is a PEGylated form of the recombinant human granulocyte colony-stimulating factor (GCSF) analog filgrastim. It stimulates bone marrow to produce neutrophils (a type of white blood cell) to fight infection.

	<i>Amgen v. Apotex</i> 0:15-cv-61631 (S.D. Fla.) '784 Patent settled, '138 Patent not infringed, not unenforceable, invalidity dismissed Fed. Cir. 17-1010 Affirmed	<i>Amgen v. Sandoz</i> 2:16-cv-01276 (D.N.J.) (BPCIA declaratory judgment suit, infringement / invalidity not alleged) Voluntarily dismissed	<i>Amgen v. Sandoz</i> 3:16-cv-02581 (N.D. Cal.) Summary judgment of non- infringement; Fed. Cir. 18-1552 Affirmed, Petition for <i>en banc</i> rehearing granted- in-part, denied-in- part	<i>Amgen v. Apotex</i> 0:18-cv- 61828 (S.D. Fla.) Stipulated dismissal	<i>Apotex v. Amgen</i> IPR2016-01542 FWD (All claims unpatentable on request for rehearing); Request for Director Review denied; Fed. Cir. 19-2171 Reversed (No claims unpatentable)	<i>Kashiv BioSciences v. Amgen</i> IPR2019- 00791 Settled after institution	<i>Fresenius Kabi v. Amgen</i> IPR2019- 00971 Institution denied	<i>Fresenius Kabi v. Amgen</i> IPR2020- 00314 Settled prior to institution decision	<i>Lupin v. Amgen</i> IPR2021- 00326 Institution denied
5,824,784	X	X	X						
8,940,878		X	X			X			
8,952,138	X				X				
9,856,287				X			X	X	X

	<i>Amgen v. Coherus</i> 1:17-cv-00546 (D. Del.) Dismissed for failure to state a claim; Fed. Cir. 18-1993 Affirmed	<i>Amgen v. Mylan</i> 2:17-cv-01235 (W.D. Pa.) '997 Patent stipulation of non-infringement, '707 Patent judgment of non-infringement	<i>Sandoz v. Amgen</i> 3:19-cv-00977 (N.D. Cal.) Voluntarily dismissed	<i>Amgen v. Hospira</i> 1:20-cv-00201 (D. Del.) Settled	<i>Kashiv BioSciences v. Amgen</i> IPR2019-00797 Settled after institution	<i>Fresenius Kabi v. Amgen</i> IPR2019-01183 Settled after institution	<i>Pfizer v. Amgen</i> IPR2021-00528 Settled after institution
8,273,707	X	X		X			X
9,643,997		X	X		X	X	