BIOLOGICS HQ

Spotlight On:

Pegfilgrastim

VENABLE LLP

October 31, 2026

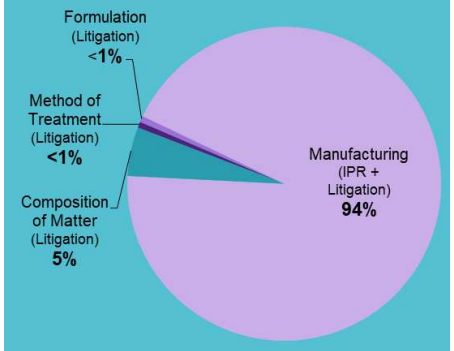
Pegfilgrastim Timeline

- **Jan. 2002** Neulasta® FDA Approval (BL 125031) (Amgen)
- **Dec. 2014** Lapelga™ aBLA Accepted by FDA (Apotex)
- **Nov. 2015** Ziextenzo® aBLA Accepted by FDA (Sandoz)
- **Oct. 2016** Udenyca® aBLA Accepted by FDA (Coherus)
- **Feb. 2017** Fulphila® aBLA Accepted by FDA (Mylan/Biocon)
- **Jun. 2018** Biosimilar Fulphila® FDA Approval (aBLA 761075) (Mylan/Biocon)
- **Jul. 2018** Biosimilar Fulphila® Launch
- **Nov. 2018** Biosimilar Udenyca® FDA Approval (aBLA 761039) (Coherus)
- **Jan. 2019** Biosimilar Udenyca® Launch
- **Aug. 2019** Nyvepria® aBLA Accepted by FDA (Hospira / Pfizer)
- **Nov. 2019** Biosimilar Ziextenzo® FDA Approval and Launch (aBLA 761045) (Sandoz)
- **May 2020** Stimufend® aBLA Accepted by FDA (Fresenius Kabi)
- **Jun. 2020** Biosimilar Nyvepria® FDA Approval (aBLA 761111) (Hospira / Pfizer)
- **Jan. 2021** Biosimilar Nyvepria® Launch
- **Jun. 2021** Pegfilgrastim aBLA Accepted by FDA (Lupin)
- **May 2022** Biosimilar Fylnetra™ FDA Approval (aBLA 761084) (Kashiv / Amneal)
- **Feb. 2023** Biosimilar Stimufend® Launch
- **May 2023** Biosimilar Fylnetra™ Launch

- **Aug. 2015** *Amgen v. Apotex* (0:15-cv-61631 (S.D. Fla.)) Complaint Filed [Patent Valid Not Infringed]
- **May 2016** *Amgen v. Sandoz* (3:16-cv-02581 (N.D. Cal.)) Complaint Filed [Not Infringed]
- **Oct. 2016** *Amgen v. Apotex* 0:15-cv-61631 (S.D. Fla.) Appeal Filed [Affirmed]
- **Sep. 2017** *Amgen v. Mylan* (2:17-cv-01235 (W.D. Pa.)) Complaint Filed [Not Infringed]
- **May 2018** *Amgen v. Coherus* (1:17-cv-00546 (D. Del.)) Appeal Filed [Affirmed]
- **Mar. 2016** *Amgen v. Sandoz* (2:16-cv-01276 (D.N.J.)) Complaint Filed [Voluntarily Dismissed]
- **Aug. 2016** *Apotex v. Amgen* IPR2016-01542 Petition Filed [FWD – All Claims Unpatentable; Fed. Cir. Reversed – No Claims Unpatentable]
- **May 2017** *Amgen v. Coherus* (1:17-cv-00546 (D. Del.)) Complaint Filed [Dismissed]
- **Feb. 2018** *Amgen v. Sandoz* (3:16-cv-02581 (N.D. Cal.)) Appeal Filed [Affirmed]
- **Aug. 2018** *Amgen v. Apotex* (0:18-cv-61828 (S.D. Fla.)) Complaint Filed [Stipulated Dismissal]
- **Feb. 2019** *Sandoz v. Amgen* (3:19-cv-00977 (N.D. Cal.)) Complaint Filed [Voluntarily Dismissed]
- **Apr. 2019** *Fresenius Kabi v. Amgen* IPR2019-00971 Petition Filed [Institution Denied]
- **Dec. 2019** *Fresenius Kabi v. Amgen* IPR2020-00314 Petition Filed [Settled Before Institution Decision]
- **Dec. 2020** *Lupin v. Amgen* IPR2021-00326 Petition Filed [Institution Denied]
- **Sep. 2022** Biosimilar Stimufend® FDA Approval (aBLA 761173) (Fresenius Kabi)
- **Nov. 2025** Biosimilar Armlupeg™ FDA Approval (aBLA 761212) (Lupinl)
- **Mar. 2019** *Kashiv v. Amgen* IPR2019-00791, 00797 Petitions Filed [Settled After Institution]
- **Jun. 2019** *Fresenius Kabi v. Amgen* IPR2019-01183 Petition Filed [Settled After Institution]
- **Feb. 2020** *Amgen v. Hospira* (1:20-cv-00201 (D. Del.)) Complaint Filed [Settled]
- **Feb. 2021** *Pfizer v. Amgen* IPR2021-00528 Petition Filed [Settled After Institution]
- **May 2026** Biosimilar Ennumo™ FDA Approval (aBLA 761147) (Accord)

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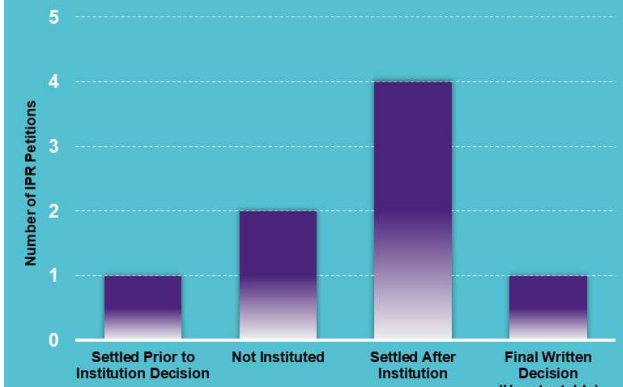
Pegfilgrastim Challenged Claim Types in IPR and Litigation*



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

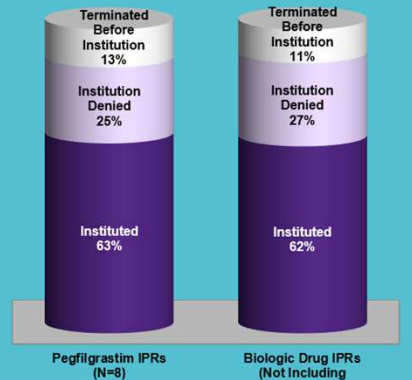
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Pegfilgrastim IPR Status



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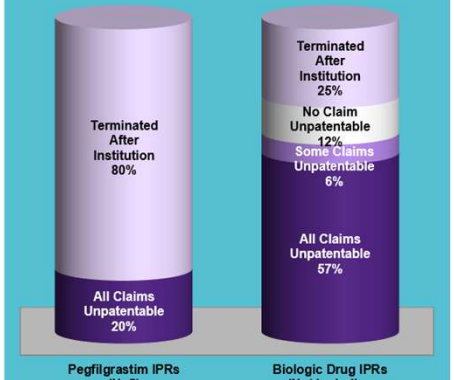
IPR Institution Rates*



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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: 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.

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

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