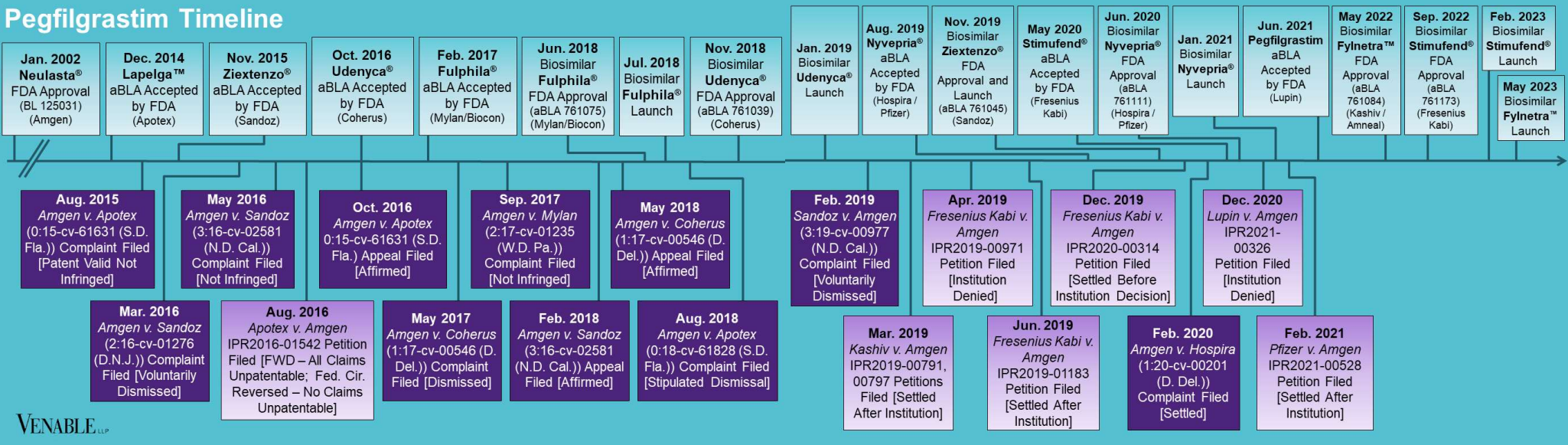


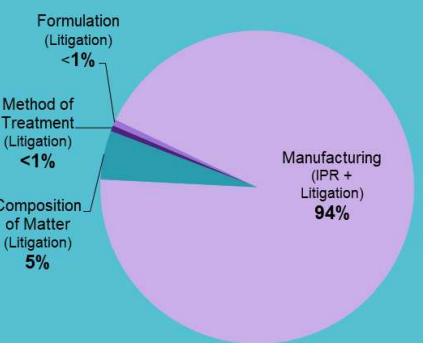
# Spotlight On: Pegfilgrastim

June 30, 2025

## Pegfilgrastim Timeline

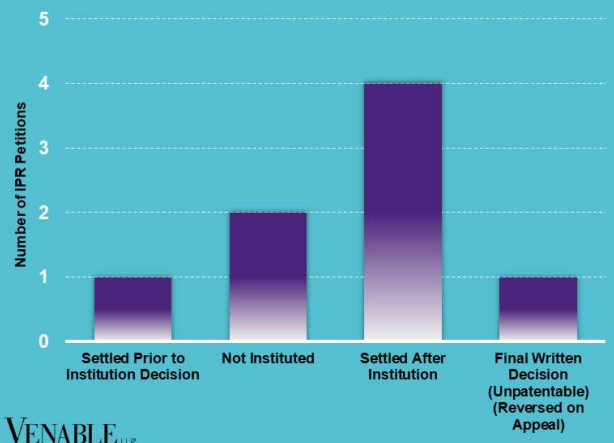


## Pegfilgrastim Challenged Claim Types in IPR and Litigation\*

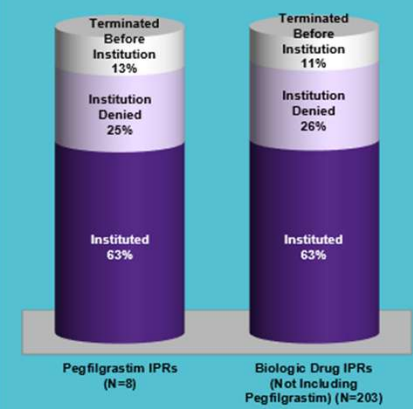


\*In litigations, it has been alleged that at least these claims will be infringed or are invalid.

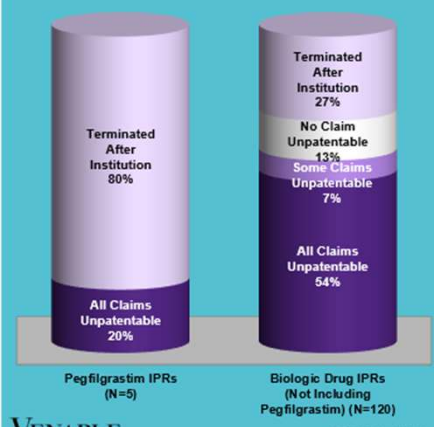
## Pegfilgrastim IPR Status



## IPR Institution Rates\*



## Outcomes After Institution\*



FWD = Final Written Decision

# Spotlight On: Pegfilgrastim

June 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><br>0:15-cv-61631<br>(S.D. Fla.)<br>'784 Patent<br>settled, '138<br>Patent not<br>infringed, not<br>unenforceable,<br>invalidity<br>dismissed<br>Fed. Cir. 17-1010<br>Affirmed | <i>Amgen v. Sandoz</i><br>2:16-cv-01276<br>(D.N.J.)<br>(BPCIA<br>declaratory<br>judgment suit,<br>infringement /<br>invalidity not<br>alleged)<br>Voluntarily<br>dismissed | <i>Amgen v. Sandoz</i><br>3:16-cv-02581<br>(N.D. Cal.)<br>Summary<br>judgment of non-<br>infringement; Fed.<br>Cir. 18-1552<br>Affirmed, Petition<br>for <i>en banc</i><br>rehearing granted-<br>in-part, denied-in-<br>part | <i>Amgen v. Apotex</i><br>0:18-cv-<br>61828 (S.D.<br>Fla.)<br>Stipulated<br>dismissal | <i>Apotex v. Amgen</i><br>IPR2016-01542<br>FWD (All claims<br>unpatentable on<br>request for rehearing);<br>Request for Director<br>Review denied;<br>Fed. Cir. 19-2171<br>Reversed (No claims<br>unpatentable) | <i>Kashiv<br/>BioSciences<br/>v. Amgen</i><br>IPR2019-<br>00791<br>Settled after<br>institution | <i>Fresenius<br/>Kabi v. Amgen</i><br>IPR2019-<br>00971<br>Institution<br>denied | <i>Fresenius<br/>Kabi v. Amgen</i><br>IPR2020-<br>00314<br>Settled<br>prior to<br>institution<br>decision | <i>Lupin v. Amgen</i><br>IPR2021-<br>00326<br>Institution<br>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><br>1:17-cv-00546<br>(D. Del.)<br>Dismissed for<br>failure<br>to state a claim;<br>Fed. Cir. 18-1993<br>Affirmed | <i>Amgen v. Mylan</i><br>2:17-cv-01235<br>(W.D. Pa.)<br>'997 Patent stipulation<br>of non-infringement,<br>'707 Patent judgment of<br>non-infringement | <i>Sandoz v. Amgen</i><br>3:19-cv-00977<br>(N.D. Cal.)<br>Voluntarily<br>dismissed | <i>Amgen v. Hospira</i><br>1:20-cv-00201<br>(D. Del.)<br>Settled | <i>Kashiv<br/>BioSciences<br/>v. Amgen</i><br>IPR2019-00797<br>Settled after<br>institution | <i>Fresenius Kabi v. Amgen</i><br>IPR2019-01183<br>Settled after<br>institution | <i>Pfizer v. Amgen</i><br>IPR2021-00528<br>Settled after<br>institution |
|-----------|---|--|--|--|---|---|---|
| 8,273,707 | X   | X  |  | X  |   |   | X   |
| 9,643,997 |   | X  | X  |  | X   | X   |   |