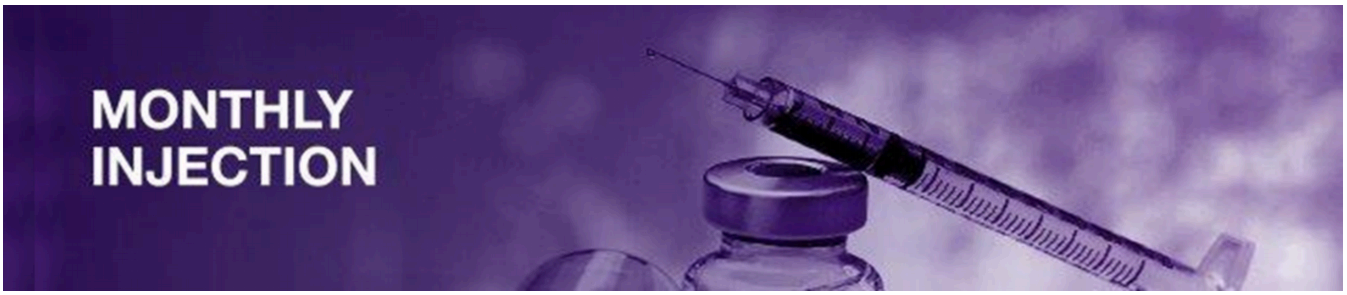
BIOLOGICS HQ

VENABLE LLP



August 11, 2026

Latest News

Impact of USPTO Directors Stewart and Squires on Pharmaceutical Patent Challenges at the PTAB

Congressional Committees Advance Biosimilar Bills Addressing Clinical Study Requirements and Interchangeability

Celltrion's Truxima® Approved as First Interchangeable Rituxan® Biosimilar

Accord Announces FDA Approval of Neulasta® Biosimilar Ennumo™

DOJ Files Amicus Brief in Moderna COVID-19 Vaccine Patent Appeal

PTAB Denies Institution of Additional Elevidys® Gene Therapy IPR

Accord Announces Commercial Launch of Prolia® / Xgeva® Interchangeable Biosimilars Osvyrti® / Jubereq® (denosumab-desu)

Genentech Files BPCIA Litigation Against Biocon's Proposed Perjeta® Biosimilar Bmab 1500

Fresenius Kabi and Polpharma Submit aBLA for Proposed Entyvio® (vedolizumab) Biosimilar PB016

Read More News

Spotlight On

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings and FDA-approvals for biologic drugs and related biosimilars, and an overview of the status of U.S. biosimilar patent litigations through July 31, 2026.

Actemra® (tocilizumab)

Enbrel® (etanercept)

Herceptin® (trastuzumab)

Humira® (adalimumab)

Lantus® / Lantus® SoloSTAR® (insulin glargine)

Neulasta® (pegfilgrastim)

Prolia® / Xgeva® (denosumab)

Rituxan® (rituximab)

Biosimilar Litigation Dashboard

IPRs and PGRs

- Keytruda Qlex™ (pembrolizumab; berahyaluronidase alfa-pmph):
  - On July 8, 2026, Halozyme filed a request for Director Review of the Final Written Decision in Merck's PGR2025-00004 finding all challenged claims of Halozyme's U.S. Patent No. 12,018,298 unpatentable.
  - On July 10, 2026, Halozyme filed a request for Director Review of the Final Written Decision in Merck's PGR2025-00009 finding all challenged claims of Halozyme's U.S. Patent No. 12,123,035 unpatentable.
  - On July 22, 2026, the PTO Director denied Halozyme's requests for Director Review of the Final Written Decisions finding all claims unpatentable in Merck's PGR2025-00003 (U.S. Patent No. 11,952,600), PGR2025-00004 (U.S. Patent No. 12,018,298), PGR2025-00006 (U.S. Patent No. 12,152,262), and PGR2025-00009 (U.S. Patent No. 12,123,035).

- Elevidys® (delandistrogene moxeparvovec-rokl): On July 21, 2026, the PTO Director denied institution of Sarepta's IPR2026-00270, challenging Genzyme's U.S. Patent No. 12, 298,313, in a bulk opinion.

Litigations

- Bizengri® (zenocutuzumab-zbco): On July 7, 2026, Merus and Xencor voluntarily dismissed Case No. 1:24-cv-00913 (D. Del.).
- Simponi® / Simponi Aria® (golimumab): On July 29, 2026, Janssen filed a motion for preliminary injunction against the commercial launch of Alvotech's AVT05 (golimumab) in Case No. 1:26-cv-01754 (E.D. Va.).
- Perjeta® (pertuzumab): On July 29, 2026, Genentech filed BPCIA Case No. 2:26-cv-09585 (D.N.J.) against Biocon alleging infringement of 28 patents by Biocon's proposed Perjeta® (pertuzumab) biosimilar Bmab 1500 (pertuzumab).

aBLA Applications and FDA Activity

- Truxima® (rituximab-abbs): On July 1, 2026, the FDA approved Celltrion / Teva's Truxima® (rituximab-abbs) as the first interchangeable biosimilar of Genentech's Rituxan® (rituximab).

Truxima® was first approved as a biosimilar of Rituxan® in November 2018.

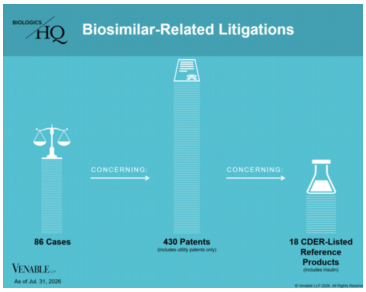
- Ennumo™ (pegfilgrastim-pccg): On July 9, 2026, Accord announced the May 2026 FDA approval of Ennumo™ (pegfilgrastim-pccg), a biosimilar of Amgen's Neulasta® (pegfilgrastim).
- Osvyrti® / Jubereq® (denosumab-desu): On July 23, 2026, Accord announced the launch of Osvyrti® / Jubereq® (denosumab-desu), interchangeable biosimilars of Amgen's Prolia® / Xgeva® (denosumab), in the U.S.
- Bmab 1500 (pertuzumab): On July 29, 2026, in a BPCIA Complaint, it was disclosed that the FDA had accepted for review Biocon's aBLA for Bmab 1500 (pertuzumab), a proposed biosimilar of Genentech's Perjeta® (pertuzumab), on an undisclosed date prior to January 2026.
- PB016 (vedolizumab): On July 31, 2026, Fresenius Kabi and Polpharma announced the FDA acceptance of their aBLA for PB016 (vedolizumab), a proposed biosimilar of Takeda's Entyvio® (vedolizumab).

CDER Purple Book Updates

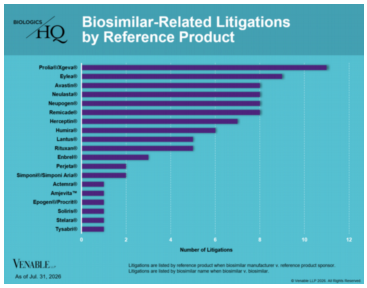
- Trutakna™ (ataciept-vymj): On July 7, 2026, the FDA approved Vera Therapeutics' Trutakna™ (ataciept-vymj).
- Sarclisa Escena™ (isatuximab-irfc): On July 9, 2026, the FDA approved Sanofi's Sarclisa Escena™ (isatuximab-irfc).

Statistics

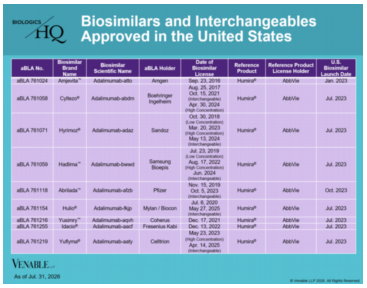
Biosimilar-Related Litigations



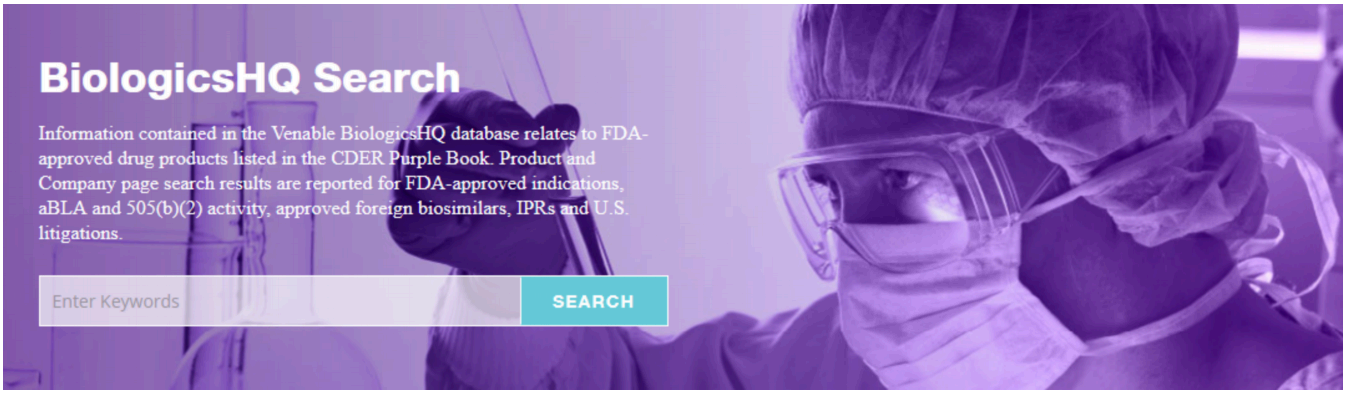
Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States



View More Statistics



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