

MONTHLY INJECTION

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](#)

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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 Alvotect'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.

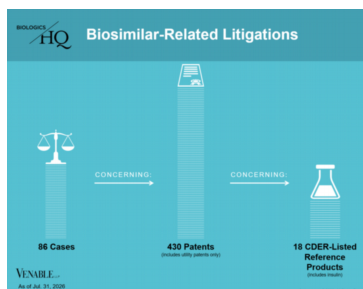
- [Ennumo™ \(pegfilgrastim-pccg\)](#): On July 9, 2026, Accord announced the May 2026 FDA approval of Ennumo™ (pegfilgrastim-pccg), a biosimilar of Amgen's Neulasta® (pegfilgrastim).
- [Osvyrti® / Jubereq® \(denosumab-desu\)](#): On July 23, 2026, Accord announced the launch of Osvyrti® / Jubereq® (denosumab-desu), 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.
- [PBo16 \(vedolizumab\)](#): On July 31, 2026, Fresenius Kabi and Polpharma announced the FDA acceptance of their aBLA for PBo16 (vedolizumab), a proposed biosimilar of Takeda's Entyvio® (vedolizumab).

CDER Purple Book Updates

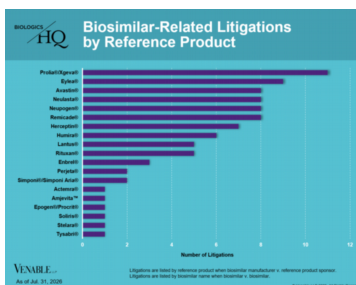
- [Trutakna™ \(ataciept-vymj\)](#): On July 7, 2026, the FDA approved Vera Therapeutics' Trutakna™ (ataciept-vymj).
- [Sarclisa Escena™ \(isatuximab-irfc\)](#): On July 9, 2026, the FDA approved Sanofi's Sarclisa Escena™ (isatuximab-irfc).

Statistics

Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States

Biosimilars and Interchangeables Approved in the United States							
AbA No.	Brand Name	Biologics Sponsor Name	AbA Molecule	Date of Marketing Approval	Reference Product	Reference Product Licensure Holder	AbA Expiration Date
AbA No. 70104	Anapars [®]	Amgen [®]	Adalimumab	Aug. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70108	Cylcho [®]	Amgen [®]	Adalimumab	Oct. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70107	Hyrimo [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70109	Asclera [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70118	Avista [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70114	Hul [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70116	Tysabri [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70119	Yasni [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023
AbA No. 70120	Yasni [®]	Amgen [®]	Adalimumab	Mar. 20, 2013	Humira [®]	AbbVie	Aug. 20, 2023

[View More Statistics](#)

BiologicsHQ Search

Information contained in the Venable BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

SEARCH

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