



November 12, 2024



LATEST NEWS



Amgen Files Fourth BPCIA Lawsuit Against Proposed Prolia® / Xgeva® Biosimilar – Fresenius Kabi’s FKS518

By: [Robert S. Schwartz, Ph.D.](#)

On October 4, 2024, Amgen filed Case No. 1:24-cv-09555 (N.D. Ill.) against Fresenius Kabi, alleging FKS518 (denosumab), its proposed Prolia® / Xgeva® (denosumab) biosimilar, would infringe 33 of Amgen’s patents.

The patents asserted include two patents with composition claims, four patents with composition of matter claims, 31 patents with manufacturing claims, one patent with claims directed to host cells, and one patent with claims covering devices.

Biosimilar	aBLA Holder	Date of Biosimilar License	Settlement Mark Entry Date
Wezlana™ (ustekinumab-aaub)	Amgen	10/31/2023 (Interchangeable)	1/1/2025
Selarsdi™ (ustekinumab-atekn)	Alvotect / Teva	4/16/2024	2/21/2025
Pyzchiva™ (ustekinumab-twte)	Samsung Bioepis / Sanofi	6/28/2024 (Interchangeable)	2/22/2025
Outlfi™ (ustekinumab-aaaz)	Fresenius Kabi / Formycon	9/27/2024	2/22/2025
Imuldosa™ (ustekinumab-srlf)	Accord	10/10/2024	5/15/2025
Proposed Biosimilar	aBLA Holder	Date of FDA Acceptance	Settlement Mark Entry Date, Pending FDA Approval
CT-P43	Celltrion	Submitted June 2023	3/7/2025
Bmab 1200	Biocon	Announced January 2024	2/22/2025
BAT2206	Bio-Thera	July 2024 (with request for interchangeability)	N/A

Accord BioPharma’s Stelara® Biosimilar Imuldosa™ Approved by FDA

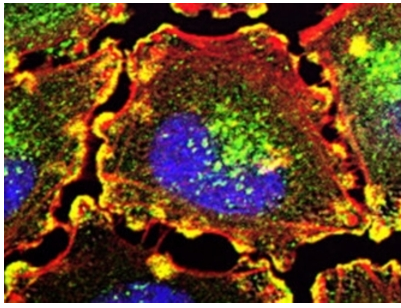
By: [Robert S. Schwartz, Ph.D.](#)

On October 10, 2024, the FDA approved Accord BioPharma’s Imuldosa™ (ustekinumab-srlf), the fifth biosimilar of Janssen / Johnson & Johnson’s Stelara® (ustekinumab). Imuldosa™ was developed by Dong-A ST in

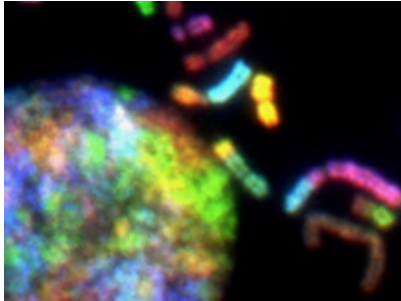
collaboration with Meiji Seika Pharma, and Accord is responsible for commercialization in the U.S. Under an October 2023 settlement agreement, Imuldosa™ can launch in the U.S. beginning no later than May 15, 2025.

Amgen Plans At-Risk Launch of EYLEA® Biosimilar Pavblu™ After Federal Circuit Lifts Temporary Injunction

By: [Robert S. Schwartz, Ph.D.](#)



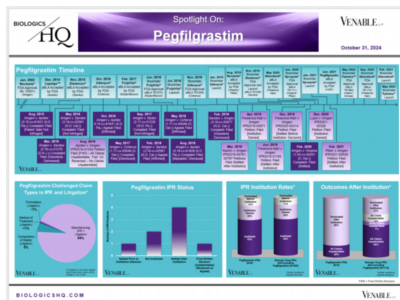
On October 22, 2024, the Federal Circuit (CAFC Case No. 24-2351) denied Regeneron's request for an injunction pending appeal for Amgen's EYLEA[®] (afibercept) biosimilar Pavblu[™] (afibercept-ayyh). The appeal concerns the District Court's (Case No. 1:24-cv-00039 (N.D.W. Va.) / 1-24-md-2103 (N.D.W. Va.)) September 2024 denial of a preliminary injunction against the commercial launch of Pavblu[™]. The CAFC is expediting the appeal, with briefing due in November and an oral argument in January 2025.



FDA Accepts aBLAs for Prolia[®] / Xgeva[®] Biosimilars from Organon and Teva

By: [Robert S. Schwartz, Ph.D.](#)

On October 30, 2024, Organon announced the FDA acceptance of its aBLA for HLX14, a proposed biosimilar of Amgen's Prolia[®] / Xgeva[®] (denosumab). Organon licensed the commercialization rights for HLX14 in the U.S. from Shanghai Henlius Biotech. Earlier in October, Teva announced that the FDA and EMA accepted applications for its proposed Prolia[®] biosimilar TVB-009P.



Spotlight On: Actemra[®] (tocilizumab) / Tofidence[™] (tocilizumab-bavi) / Tyenne[®] (tocilizumab-aazg)

Spotlight On: Neulasta[®] (pegfilgrastim) / Fulphila[®] (pegfilgrastim-jmdb) / Udenyca[®] (pegfilgrastim-cbqv) / Ziextenzo[®] (pegfilgrastim-bmez) / Nyvepria[®] (pegfilgrastim-apgf) / Fylnetra[™] (pegfilgrastim-apgf) / Stimufend[®]

(pegfilgrastim-fpgk)

Spotlight On: Herceptin[®] (trastuzumab) / Ogivri[®] (trastuzumab-dkst) / Herzuma[®] (trastuzumab-pkrb) / Ontruzant[®] (trastuzumab-dttb) / Trazimera[®] (trastuzumab-qyyp) / Kanjinti[®] (trastuzumab-anns) / Hercessi[™] (trastuzumab-strf)

Spotlight On: Biosimilar Litigations

Spotlight On: Rituxan[®] (rituximab) / Truxima[®] (rituximab-abbs) / Ruxience[®] (rituximab-pvvr) / Riabni[™] (rituximab-arrx)

Spotlight On: Humira[®] (adalimumab) / Amjevita[™] (adalimumab-atto) / Cyltezo[®] (adalimumab-adbm) / Hyrimoz[®] (adalimumab-adaz) / Hadlima[™] (adalimumab-bwwd) / Abrilada[™] (adalimumab-afzb) / Hulio[®] (adalimumab-fkjp) / Yusimry[™] (adalimumab-aqvh) / Idacio[®] (adalimumab-aacf) / Yuflyma[®] (adalimumab-aaty) / Simlandi[®] (adalimumab-ryvk)

Spotlight On: Enbrel[®] (etanercept) / Erelzi[®] (etanercept-szszs) / Eticovo[®] (etanercept-ykro)

Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant) / Basaglar[®] (insulin glargine) / Semglee[®] (insulin glargine-yfgn) / Rezvoglar[™] (insulin glargine-aglr)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning tocilizumab (Actemra[®], Tofidence[™], Tyenne[®], and CT-P47), pegfilgrastim (Neulasta[®], Fulphila[®], Udenyca[®], Ziextenzo[®], Nyvepria[®], Fylnetra[™], Stimufend[®], Lapelga[™], and Pegfilgrastim (Lupin)), trastuzumab (Herceptin[®], Ogivri[®], Herzuma[®], Ontruzant[®], Trazimera[®], Kanjinti[®], Hercessi[™], TX-05, and EG12014), rituximab (Rituxan[®], Truxima[®], Ruxience[®], Riabni[™] and DRL RI), adalimumab (Humira[®], Amjevita[™], Cyltezo[®], Hyrimoz[®], Hadlima[™], Abrilada[™], Hulio[®], Yusimry[™], Idacio[®], Yuflyma[®], and Simlandi[®]), etanercept (Enbrel[®], Erelzi[®], and Eticovo[®]), and insulin glargine (Lantus[®] / Lantus[®] SoloSTAR[®], Basaglar[®], Semglee[®], and Rezvoglar[™]) have been updated with activity through October 31, 2024.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through October 31, 2024.

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More
News

UPDATES

IPRs and PGRs

Keytruda[®] (pembrolizumab):

- On October 3, 2024, the PTAB instituted Merck's IPR2024-00648 against The John's Hopkin's University's U.S. Patent No. 11,643,462.

Litigations

Prolia[®] / Xgeva[®] (denosumab):

- On October 4, 2024, Amgen filed Case No. 1:24-cv-09555 (N.D. Ill.) against Fresenius Kabi related to its proposed biosimilar FKS518 (denosumab).

Eylea[®] (aflibercept):

- On October 22, 2024, the CAFC issued an order denying Regeneron's motion for a preliminary injunction pending appeal and lifting its temporary injunction in CAFC Case No. 24-2351. The appeal is related to the District Court's denial of Regeneron's motion for a preliminary injunction against Amgen's Pavblu[™] (aflibercept-ayyh) in Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.).

aBLA Applications and FDA Activity

TVB-009P (denosumab):

- On October 8, 2024, **Teva** announced the FDA acceptance of its aBLA for **TVB-009P (denosumab)**, with a request for interchangeability with **Amgen's Prolia® (denosumab)**.

Imuldosa™ (DMB-3115) (ustekinumab-srlf):

- On October 10, 2024, the FDA approved **Accord BioPharma's Imuldosa™ (ustekinumab-srlf)** as a biosimilar of **Janssen / Johnson & Johnson's Stelara® (ustekinumab)**.

HLX14 (denosumab):

- On October 30, 2024, **Organon** and **Shanghai Henlius Biotech** announced the FDA acceptance of their aBLA for **HLX14 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**.

CDER Purple Book Updates

Hypnavzi™ (marstacimab-hncq):

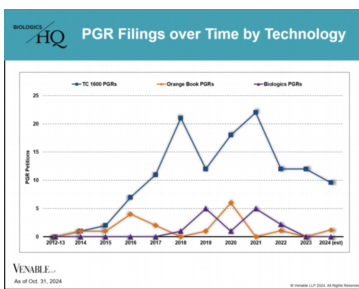
- On October 11, 2024, the FDA approved **Pfizer's Hypnavzi™ (marstacimab-hncq)**.

Vyloy™ (zolbetuximab-clzb):

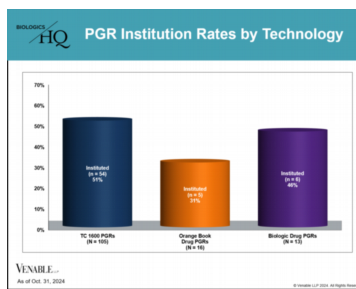
- On October 18, 2024, the FDA approved **Astellas's Vyloy™ (zolbetuximab-clzb)**.

STATISTICS

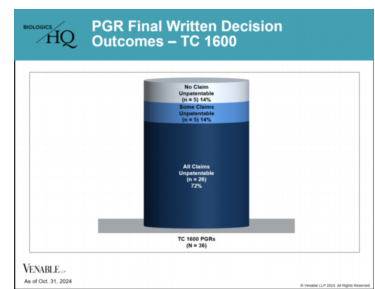
PGR Filings Over Time by Technology



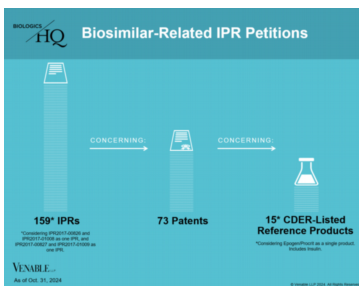
PGR Institution Rates by Technology



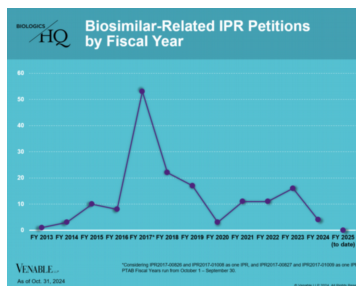
PGR Final Written Decision Outcomes – TC 1600



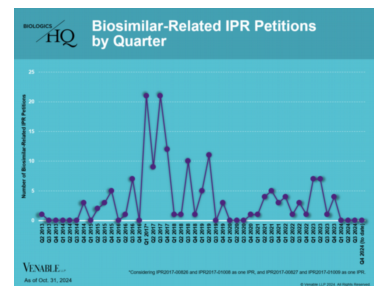
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



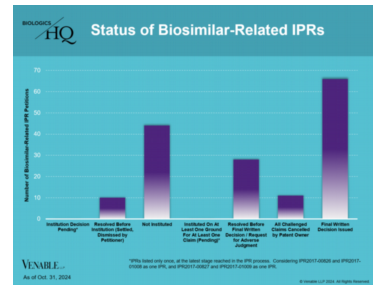
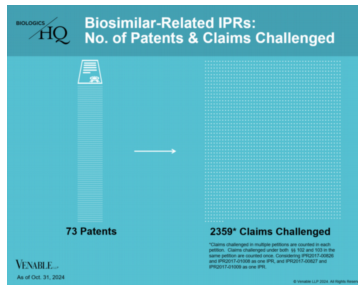
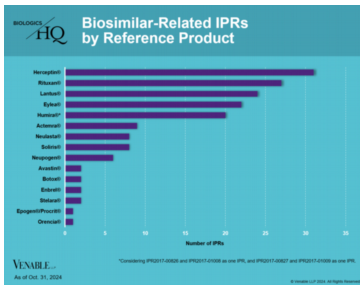
Biosimilar-Related IPR Petitions by Quarter



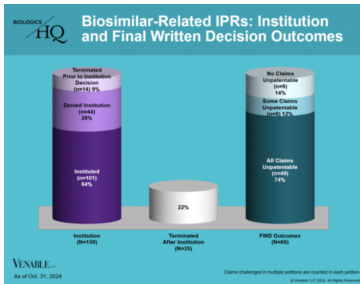
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

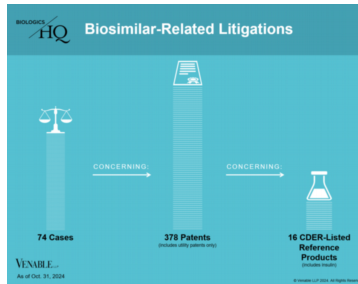
Status of Biosimilar-Related IPRs



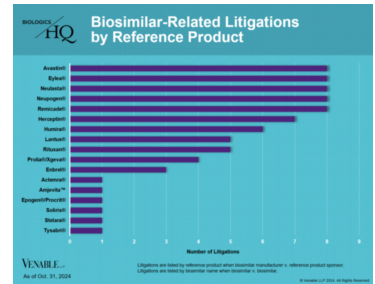
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



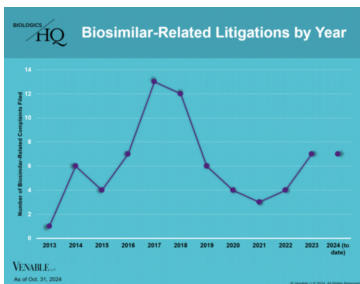
Biosimilar-Related Litigations



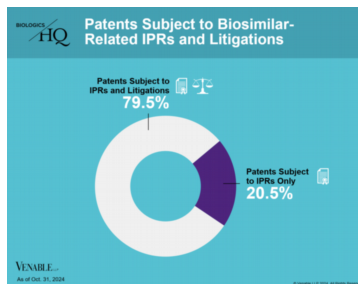
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars and Interchangeables Approved in the United States

Biosimilars and Interchangeables Approved in the United States

USLA No.	Reference Product	Biosimilar Scientific Name	USLA Holder	Date of Approval/USLA Closure	Reference Product Lessor Holder	U.S. Biologics License Date
USLA 701001	Humira®	Adalimumab-actemra	Amgen	Oct 20, 2019 Oct 20, 2021	Amgen	Jan 2023
USLA 701002	Cylteco®	Adalimumab-actemra	Beringer Ingelheim	Apr. 30, 2024 180-day commercial	Amgen	Jan 2023
USLA 701003	Humira®	Adalimumab-actemra	Sandoz	Oct 30, 2019 Oct 20, 2021 May 13, 2024	Amgen	Jan 2023
USLA 701004	Humira®	Adalimumab-actemra	Trinity Biotech	Jul 23, 2019 Jul 23, 2021 High commercial	Amgen	Jan 2023
USLA 701005	Humira®	Adalimumab-actemra	Trinity Biotech	Nov. 10, 2019 Oct 13, 2021	Amgen	Jan 2023
USLA 701006	Humira®	Adalimumab-actemra	Pfizer	Nov. 10, 2019 Oct 13, 2021	Amgen	Jan 2023
USLA 701007	Humira®	Adalimumab-actemra	Novartis	Jul 6, 2020	Amgen	Jan 2023
USLA 701008	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701009	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701010	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701011	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701012	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701013	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701014	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701015	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701016	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701017	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701018	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701019	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023
USLA 701020	Humira®	Adalimumab-actemra	Novartis	Dec 10, 2021	Amgen	Jan 2023

VENABLE LLP
As of Oct. 31, 2024

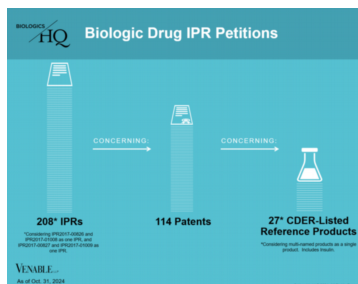
Biosimilar and Interchangeable Applications Pending in the United States

Biosimilar and Interchangeable Applications Pending in the United States*

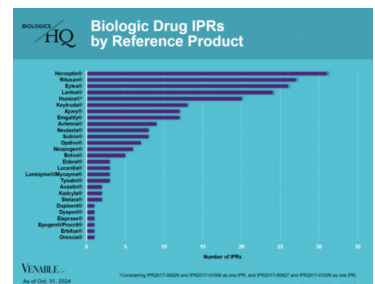
Biosimilar Name	Scientific Name	USLA Number	Reference Product	Reference Product Lessor Holder	FDA Status
CTP142	Actemra®	020101	Actemra®	Regeneron	Submitted Jan. 2023
FXB238	Benralizumab	020102	Benralizumab	Amgen	Accepted Nov. 2019
788	Benralizumab	020103	Benralizumab	Genentech	Accepted Nov. 2019
SMC14022	Benralizumab	020104	Benralizumab	Genentech	Accepted Mar. 2020, CRL Feb. 2023
CTP141	Denosumab	020105	Denosumab	Amgen	Submitted Nov. 2022
FXB218	Denosumab	020106	Denosumab	Amgen	Accepted May 2024
SB16	Denosumab	020107	Denosumab	Amgen	Underwent Drug Data Review in Aug. 2023
YB-00P	Denosumab	020108	Denosumab	Amgen	Accepted Oct. 2023, with request for interchangeability
HL14	Denosumab	020109	Denosumab	Amgen	Accepted Oct. 2024
Grasim®	Fitumumab	020110	Fitumumab	Amgen	Accepted Feb. 2015
Accut®	Fitumumab	020111	Fitumumab	Amgen	Underwent Drug Data Review in Jan. 2024
MPV-18102	Health Affairs	Vianna / Bristol	Neulasta®	Novo Nordisk	Accepted 2012, CRL Jan. 2022, CRL Oct. 2023
Humira®	Health Affairs	Bristol	Humira®	Amgen	Accepted 2012, CRL Oct. 2023
Lantus®	Health Affairs	Bristol	Lantus®	Novartis	Accepted 2012, CRL Oct. 2023
Neuro®	Health Affairs	Bristol	Neuro®	Novartis	Accepted 2012, CRL Oct. 2023

VENABLE LLP
As of Oct. 31, 2024

Biologic Drug IPR Petitions



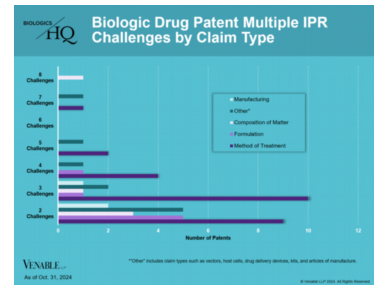
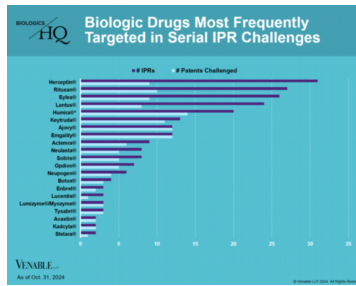
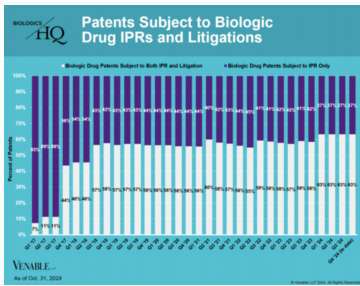
Biologic Drug IPRs by Reference Product



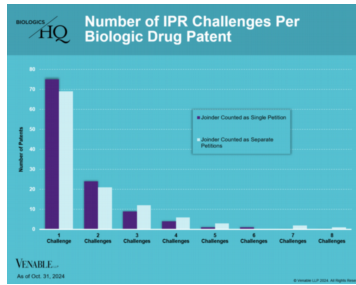
Patents Subject to Biologic Drug IPRs and Litigations

Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent



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.

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