BIOLOGICS HQ

VENABLE LLP

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-aekn)	Alvotech / Teva	4/16/2024	2/21/2025
Pyzchiva' (ustekinumab-ttwe)	Samsung Bioepis / Sandoz	6/28/2024 (Interchangeable)	2/22/2025
Otulfi™ (ustekinumab-aauz)	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, Pend 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

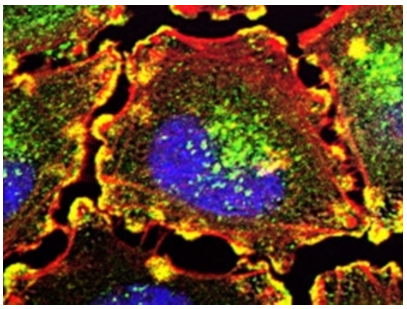
Accord BioPharma's Stelara® Biosimilar Imuldosa™ Approved by FDA

By: Robert S. Schwartz, Ph.D.

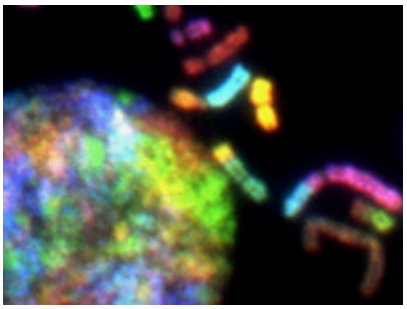
On October 10, 2024, the FDA approved Accord BioPharma's Imuldosa™ (ustekinumab-srlf), the fifth biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab). Imuldosa™ was developed by Dong-A ST in collaboration with Meij Seika Pharma, and Accord is responsible for commercialization in the U.S. 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.



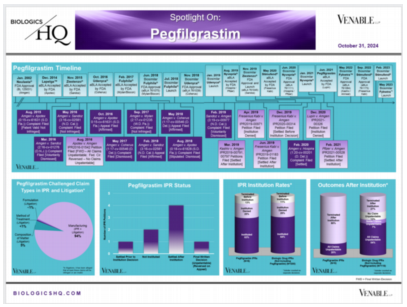
On October 22, 2024, the Federal Circuit (CAFC Case No. 24-2351) denied Regeneron's request for an injunction pending appeal for Amgen's EYLEA® (aflibercept) biosimilar Pavblu™ (aflibercept-ayyh). The appeal concerns the District Court's (Case No. 1:24-cv-00039 (N.D.W. Va.) / 1-24-md-2103 (N.D.W. Va.)) 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-szzs) / 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.

Read 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

Hympavzi™ (marstacimab-hncq):

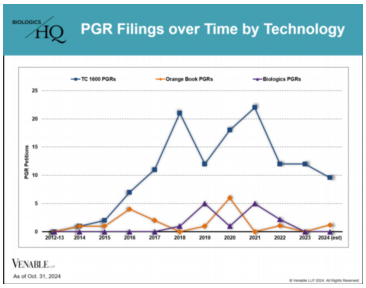
- On October 11, 2024, the FDA approved **Pfizer's Hympavzi™ (marstacimab-hncq)**.

Vyloy™ (zolbetuximab-clzb):

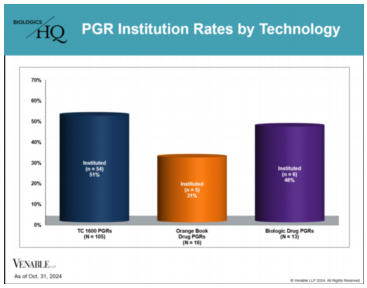
- On October 18, 2024, the FDA approved **Astellas's Vyloy™ (zolbetuximab-clzb)**.

STATISTICS

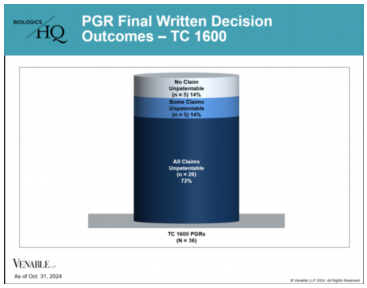
PGR Filings Over Time by Technology



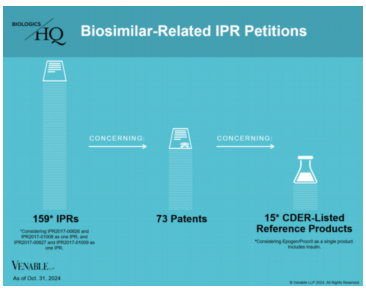
PGR Institution Rates by Technology



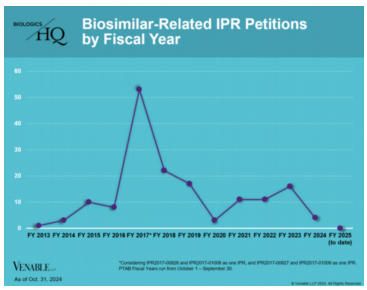
PGR Final Written Decision Outcomes – TC 1600



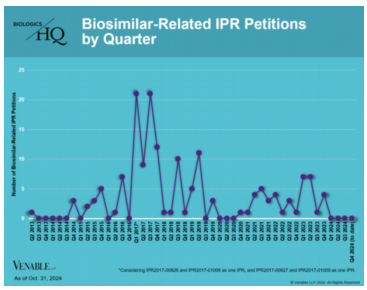
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



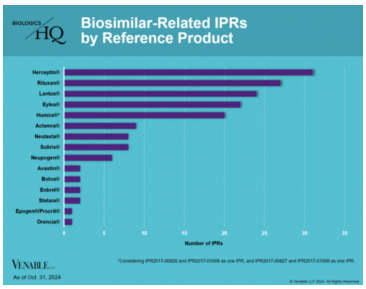
Biosimilar-Related IPR Petitions by Quarter



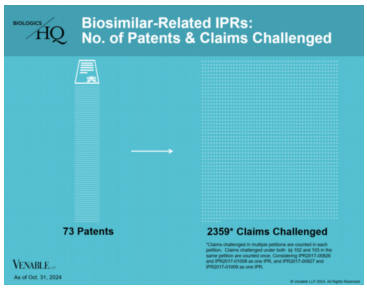
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

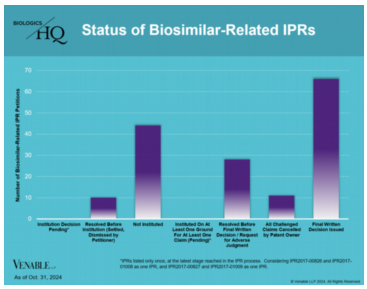
Status of Biosimilar-Related IPRs



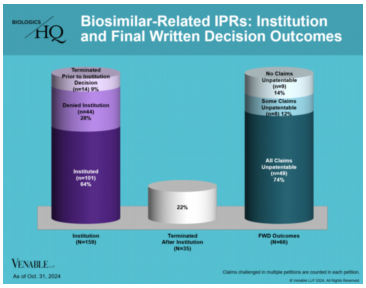
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



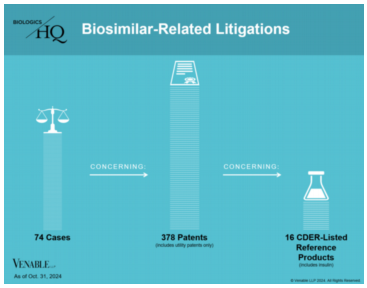
[Biosimilar-Related Litigations]



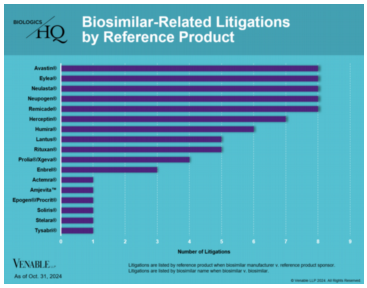
[Biosimilar-Related Litigations by Reference Product]



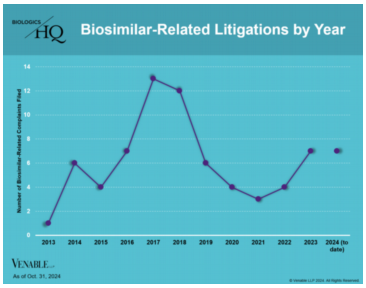
[Biosimilar-Related Litigations by Year]



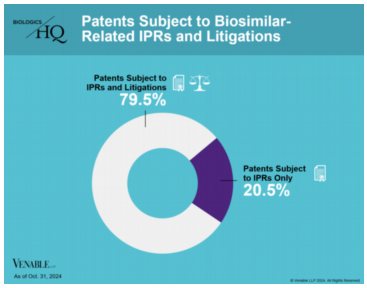
[Patents Subject to Biosimilar-Related IPRs and Litigations]



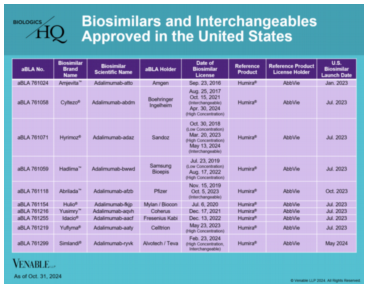
[Biosimilars and Interchangeables Approved in the United States]



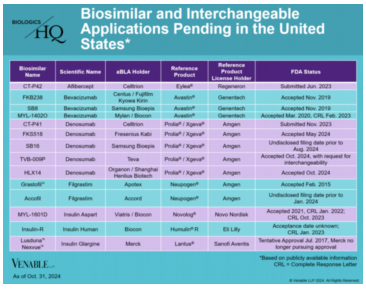
[Biosimilar and Interchangeable Applications Pending in the United States]



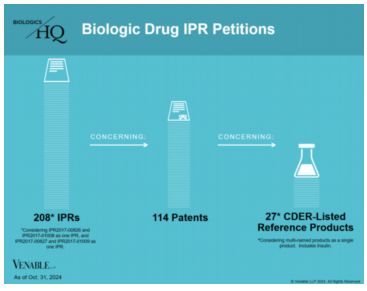
[Biologic Drug IPR Petitions]



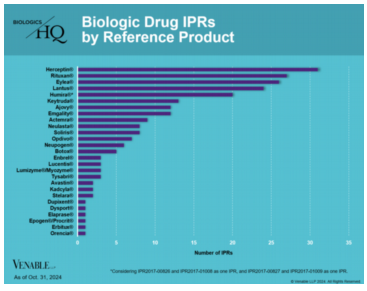
[Biologic Drug IPRs by Reference Product]



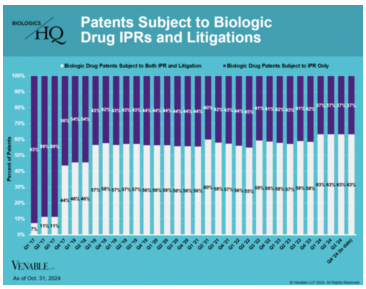
[Patents Subject to Biologic Drug IPRs and Litigations]

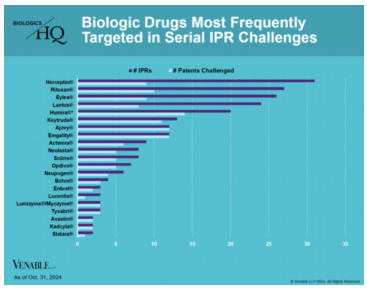


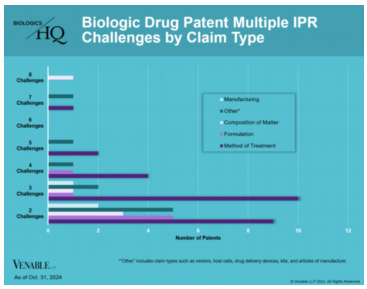
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]



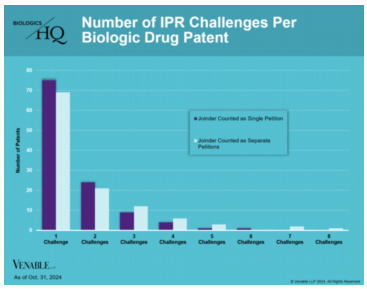
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

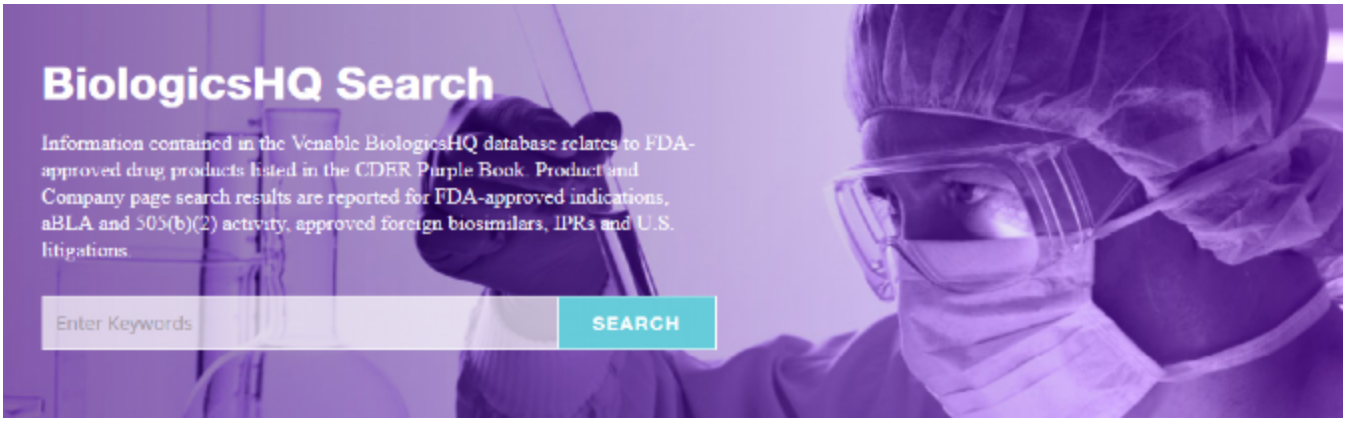






Number of IPR Challenges Per Biologic Drug Patent





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