BIOLOGICS HQ

VENABLE LLP

January 13, 2025

LATEST NEWS

Most Read BiologicsHQ News in 2023

In case you missed them, catch up on the BiologicsHQ most read news articles in 2023:

- Implications of Loper Bright for FDA-Regulated Products
- Ha Kung Wong Discusses the Biosimilar Patent Legal System with The Center for Biosimilars
- Amgen Plans At-Risk Launch of EYLEA® Biosimilar Pavblu™ After Federal Circuit Lifts Temporary Injunction
- Amgen Launches Pavblu™ as the First EYLEA® Biosimilar in the U.S.
- Chugai, Genentech, and Hoffmann-La Roche Dismiss Appeals of Actemra® Patent IPR Final Written Decisions
- PTAB Issues Final Written Decision Finding Seagen's Adcetris® Patent Claims Unpatentable

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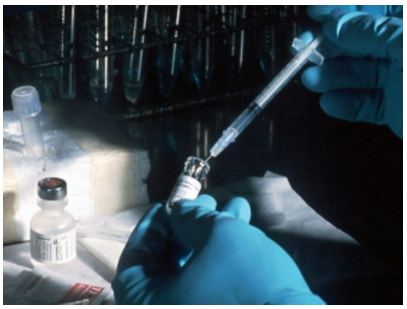
Gedeon Richter and Hikma's aBLA for Proposed Prolia® / Xgeva® (denosumab) Biosimilar RGB-14 Accepted by FDA

By: Robert S. Schwartz, Ph.D.

On December 12, 2024, Gedeon Richter and Hikma announced the FDA acceptance of their aBLA for RGB-14 (denosumab), a proposed biosimilar of Amgen's Prolia® / Xgeva® (denosumab). This is the eighth publicly disclosed aBLA submission for a Prolia® / Xgeva® biosimilar.

Blincyto® Found to Infringe Lindis Biotech's Patents



By: Robert S. Schwartz, Ph.D.

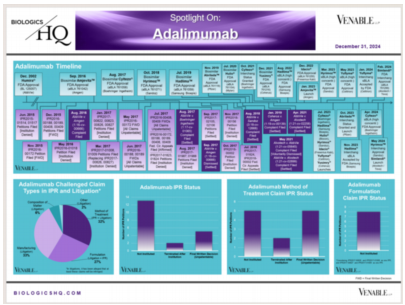
On December 17, 2024, after a seven-day jury trial in Case No. 1:22-cv-00035 (D. Del.), the jury returned its verdict, finding Lindis Biotech's U.S. Patent Nos. 8,709,421 (claims 3, 8, and 15) and 10,071,158 (claims 1, 12, and 20) willfully infringed by Amgen's Blincyto® (blinatumomab). The jury found both direct and induced infringement. The jury also found the patents had not been shown to be obvious, or invalid for lack of written description or enablement.

aBLA Updates: Stelara® Biosimilar Steqeyma™ (ustekinumab-stba) FDA-Approval; Lucentis® Biosimilar Xlucane™ (ranibizumab) aBLA Resubmission

By: Robert S. Schwartz, Ph.D.

On December 17, 2024, the FDA approved Celltrion's Steqeyma™ (CT-P43) (ustekinumab-stba) as the seventh biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab). Celltrion previously reached a settlement agreement allowing Steqeyma™ to enter the U.S. market by March 7, 2025. Under a settlement agreement with Amgen, Wezlana™ (ustekinumab-auub), the first FDA-approved Stelara® biosimilar was able to launch as of January 1, 2025 (previously reported First Biosimilar and Interchangeable of Stelara® (ustekinumab) Approved in the U.S.), however no launch has been announced to date.

On December 31, 2024, Xbrane announced the resubmission of its aBLA for Xlucane™ (ranibizumab), a proposed biosimilar of Genentech's Lucentis® (ranibizumab). The aBLA was previously withdrawn from FDA consideration in May 2022, resubmitted in April 2023, and received a Complete Response Letter in April 2024 (previously reported Biosimilar Launch and Approval Updates – Tyenne® (tocilizumab-aazg), Xlucane™ (ranibizumab), Hercessi™ (trastuzumab-strf)).



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 December 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 December 31, 2024.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On December 2, 2024, **Formycon** filed IPR2025-00233 against **Regeneron's**, U.S. Patent No. 11,084,865, along with a motion for joinder with **Samsung Bioepis's** IPR2025-00176.

Litigations

Blincyto® (blinatumomab):

- On December 18, 2024, the jury entered a verdict in Case No. 1:22-cv-00035 (D. Del.) finding **Lindis Biotech's** U.S. Patent Nos. 8,709,421 and 10,071,158 valid and willfully infringed by **Amgen's** **Blincyto® (blinatumomab)**.

aBLA Applications and FDA Activity

Udenyca® (pegfilgrastim-cbqv):

- On December 3, 2024, **Coherus** announced the sale of **Udenyca® (pegfilgrastim-cbqv)**, a biosimilar of **Amgen's Neulasta® (pegfilgrastim)**, to **Intas Pharmaceuticals**.

RGB-14 (denosumab):

- On December 12, 2024, **Gedeon Richter** and **Hikma** announced the FDA acceptance of their aBLA for **RGB-14 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**.

Steqeyma™ (CT-P43) (ustekinumab-stba):

- On December 17, 2024, the FDA approved **Celltrion's Steqeyma™ (ustekinumab-stba)** as a biosimilar of **Janssen** / **Johnson & Johnson's Stelara® (ustekinumab)**.

Xlucane™ (ranibizumab):

- On December 31, 2024, **Xbrane** announced the resubmission of its aBLA for **Xlucane™ (ranibizumab)**, a proposed biosimilar of **Genentech's Lucentis® (ranibizumab)**, after receiving a Complete Response Letter from the FDA in April 2024.

CDER Purple Book Updates

Bizengri® (zenocutuzumab-zbco):

- On December 4, 2024, the FDA approved **Merus's Bizengri® (zenocutuzumab-zbco)**.

Unloxcyt™ (cosibelimab-ipdl):

- On December 13, 2024, the FDA approved **Checkpoint Therapeutics' Unloxcyt™ (cosibelimab-ipdl).**

Ryoncil® (remestemcel-L-rknd):

- On December 19, 2024, the FDA approved **Mesoblast's Ryoncil® (remestemcel-L-rknd)**.

Symvess™ (acellular tissue engineered vessel-tyod):

- On December 19, 2024, the FDA approved **Humacyte Global's Symvess™ (acellular tissue engineered vessel-tyod)**.

Alhemo® (concizumab-mtci):

- On December 20, 2024, the FDA approved **Novo Nordisk's Alhemo® (concizumab-mtci)**.

Opdivo Qvantig™ (nivolumab; hyaluronidase-nvhy):

- On December 27, 2024, the FDA approved **Bristol-Myers Squibb's Opdivo Qvantig™ (nivolumab; hyaluronidase-nvhy)**.

Non-U.S. Biosimilars / Follow-On Biologics

Omlyclo® (CT-P39) (omalizumab):

- On December 9, 2024, **Celltrion** announced the approval of **Omlyclo® (omalizumab)**, a biosimilar of **Genentech's Xolair® (omalizumab)**, in Canada.

Imuldosa® / Absimky (ustekinumab-srlf):

- On December 12, 2024, **Accord** announced the approval of **Imuldosa® / Absimky (ustekinumab-srlf)**, a biosimilar of **Janssen** and **Johnson & Johnson's** **Stelara® (ustekinumab)**, in the E.U.

Avtozma® (CT-P47) (tocilizumab):

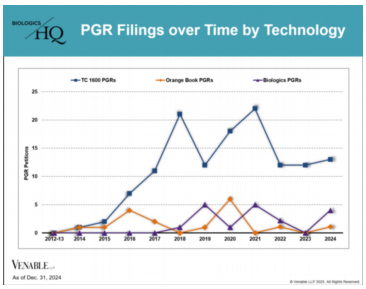
- On December 23, 2024, **Celltrion** announced the approval of **Avtozma® (tocilizumab)**, a biosimilar of **Genentech's** **Actemra® (tocilizumab)**, in South Korea.

Bevqolva® (bevacizumab):

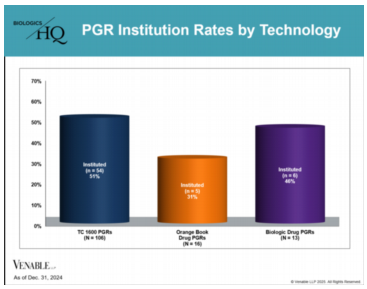
- On December 26, 2024, CuraTeQ Biologics announced the approval of **Bevqolva® (bevacizumab)**, a biosimilar of **Genentech's** **Avastin® (bevacizumab)**, in the U.K.

STATISTICS

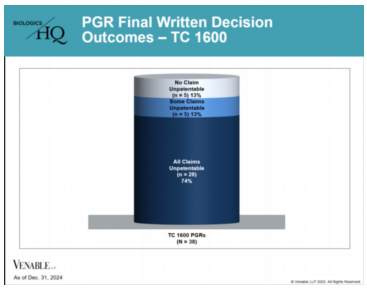
PGR Filings Over Time by Technology



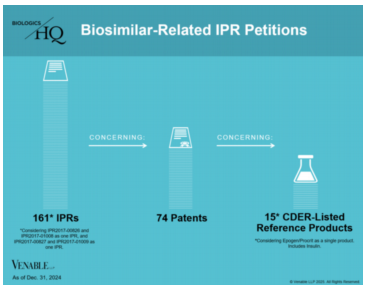
PGR Institution Rates by Technology



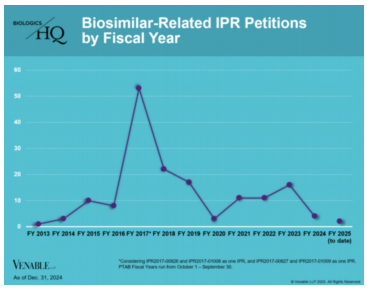
PGR Final Written Decision Outcomes – TC 1600



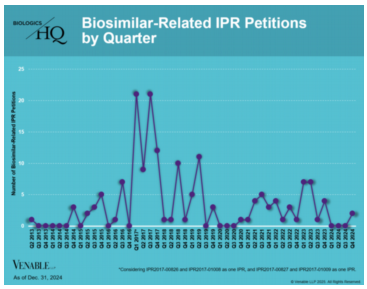
Biosimilar-Related IPR Petitions



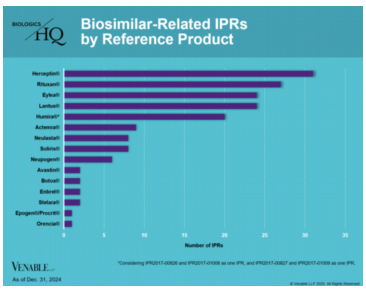
Biosimilar-Related IPR Petitions by Fiscal Year



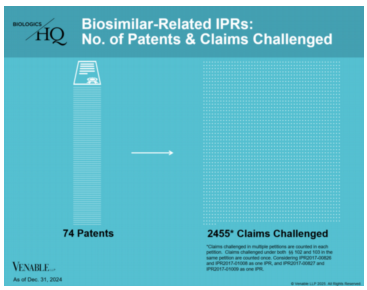
Biosimilar-Related IPR Petitions by Quarter



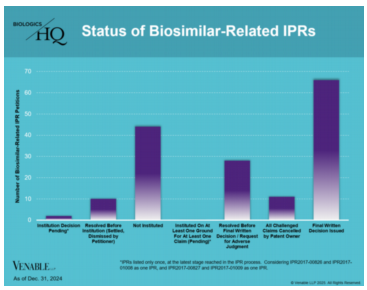
Biosimilar-Related IPRs by Reference Product



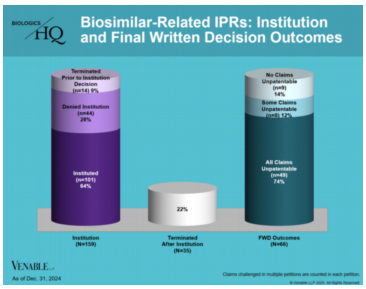
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



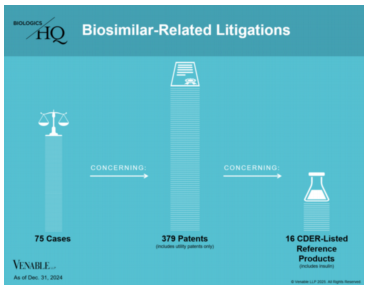
Status of Biosimilar-Related IPRs



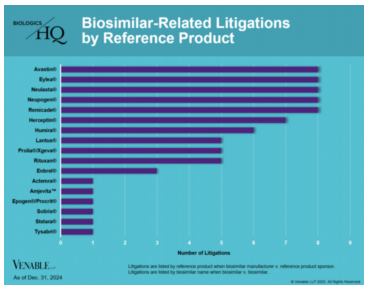
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



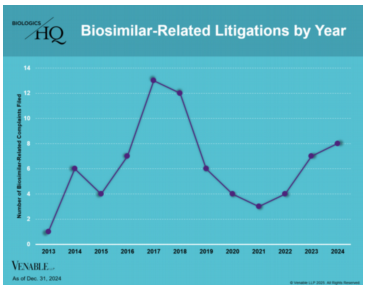
Biosimilar-Related Litigations



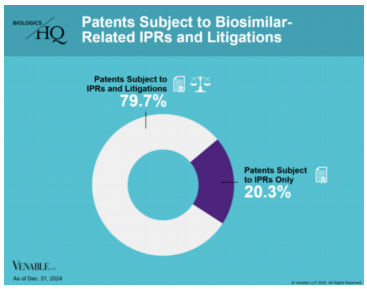
Biosimilar-Related Litigations by Reference Product



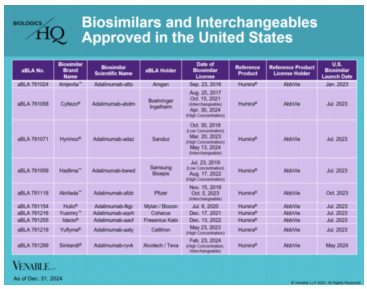
Biosimilar-Related Litigations by Year



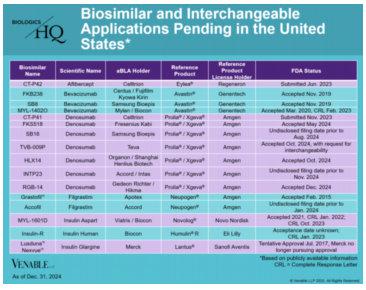
Patents Subject to Biosimilar-Related IPRs and Litigations



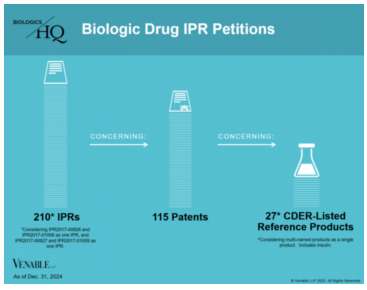
Biosimilars and Interchangeables Approved in the United States



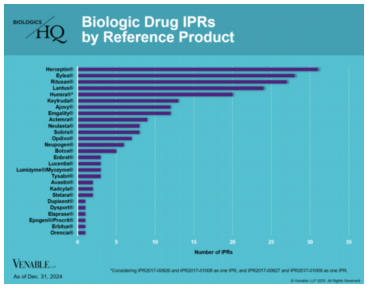
Biosimilar and Interchangeable Applications Pending in the United States



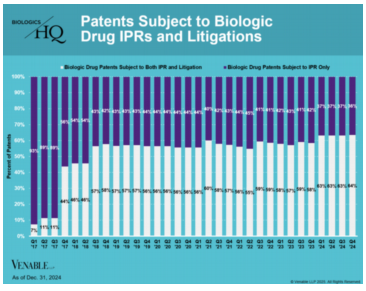
Biologic Drug IPR Petitions



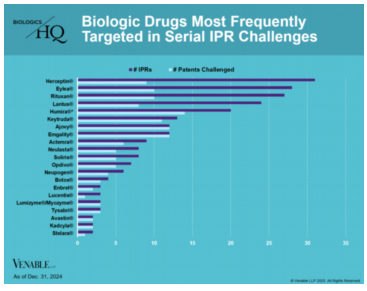
Biologic Drug IPRs by Reference Product



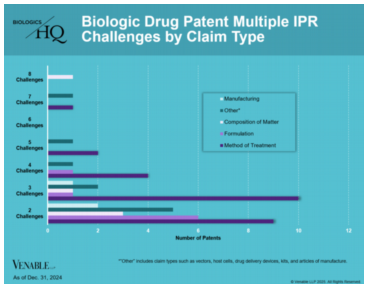
Patents Subject to Biologic Drug IPRs and Litigations



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

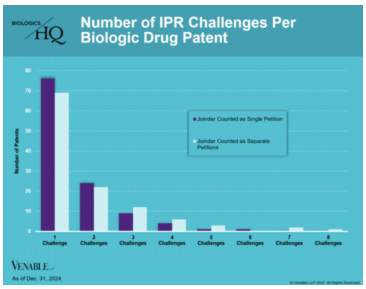


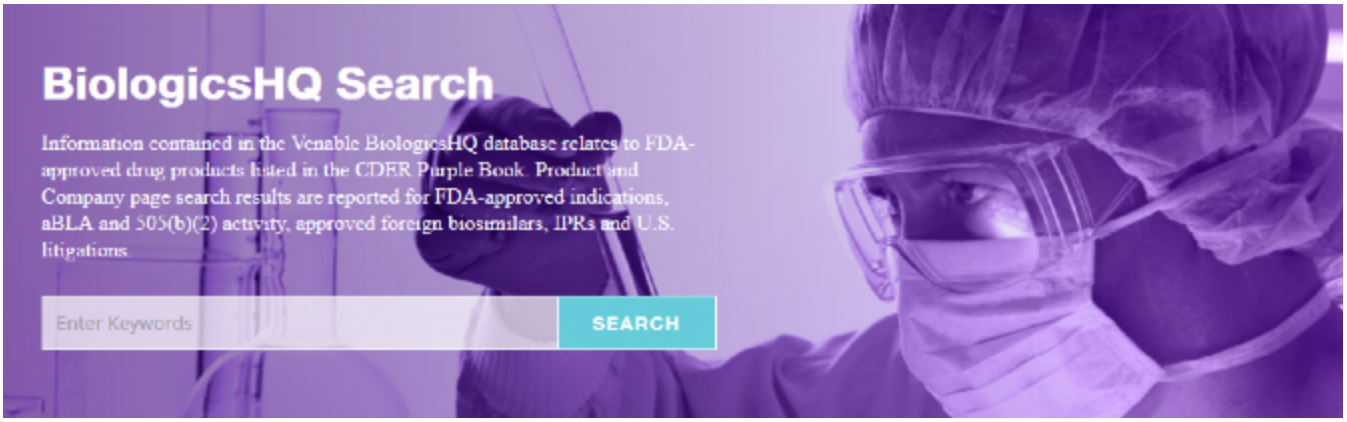
Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR

Challenges Per Biologic Drug Patent





Contact the BiologicsHQ Team

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