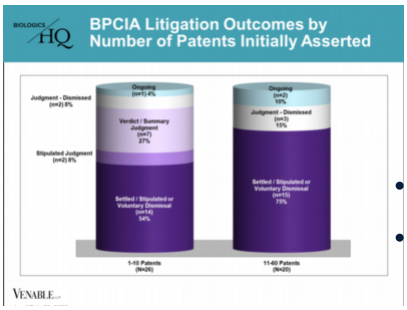
BIOLOGICS HQ

VENABLE LLP

January 12, 2024

LATEST NEWS



Most Read BiologicsHQ News in 2023

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

- The State of Biosimilars in 2023
- Supreme Court Affirms Lack of Enablement in *Amgen v. Sanofi* Antibody Patent Dispute
- First Humira Biosimilar Enters the U.S. Market
- What Do the Humira Biosimilar / Interchangeable Launches Mean for the Adalimumab Market?
- BPCIA Litigation Related to Proposed Eylea Biosimilar CT-P42 Filed
- EYLEA® (aflibercept) IPR and BPCIA Litigation Updates
- New FDA Guidance Removes Interchangeability Statement from Product Labels
- First List of Drugs for Medicare Price Negotiations Published Includes Three Biologics
- Senators Tillis and Coons Reintroduce Patent Eligibility Reform Legislation
- PREVAIL Act Reforms at the PTAB
- PTAB Eliminates POP Review and Expands Director Review to Institution Decisions

Celltrion Completes Application for FDA Approval of CT-P41, Biosimilar of Prolia® / Xgeva®

By: Monica Chou and Robert S. Schwartz, Ph.D.

On November 30, 2023, Celltrion announced that it filed for an abbreviated Biologics License Application (aBLA) for FDA approval of CT-P41 (denosumab), a proposed biosimilar of Amgen's Prolia® /

Xgeva® (denosumab). There is currently another pending aBLA for a proposed biosimilar of Prolia® / Xgeva® from Sandoz for GP2411, which was accepted by the FDA in February 2023. A litigation involving GP2411 was filed in May 2023 and is currently pending. *Amgen, Inc. et al v. Sandoz, Inc. et al*, No. 1:23-cv-02406 (D.N.J.). No patent disputes related to Celltrion's CT-P41 have been filed yet.

EYLEA® (aflibercept) and Soliris® (eculizumab) IPR and BPCIA Litigation Updates

By: Robert S. Schwartz, Ph.D., Monica Chou, and Dameneh Morsali, Ph.D.

On December 8, 2023, the PTAB instituted three of Samsung Bioepis's pending IPRs against Alexion's Soliris® (eculizumab), IPR2023-00933, IPR2023-00998, and IPR2023-00999. The challenged patents include composition of matter, formulation, and method of treatment claims.

On December 19 and 20, 2023, the PTAB instituted two additional IPRs by Samsung Bioepis against Alexion's Soliris® (eculizumab), IPR2023-01070 and IPR2023-01069. The challenged patents include method of treatment claims.

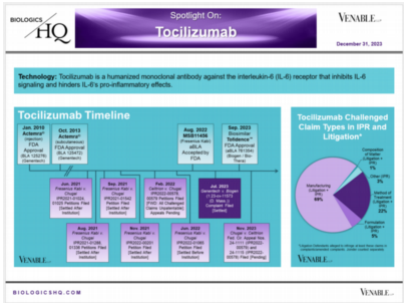
Samsung Bioepis has a pending aBLA for its Soliris® biosimilar candidate SB12.

The PTAB activity for EYLEA® (aflibercept) from November (see EYLEA® (aflibercept) IPR and BPCIA Litigation Updates) has continued into December, with the PTAB granting institution of Samsung Bioepis's IPR2023-01312 against Regeneron and its motion for joinder with Celltrion's IPR2023-00462 on December 8, 2023.

On December 14, 2023, Celltrion filed IPR2024-00260 along with a motion for joinder with Samsung Bioepis's IPR2023-00884, which was instituted in November. On December 18, 2023, Biocon Biologics, and the related parties in-interest Janssen, Johnson & Johnson, Viatris, Momenta, and Mylan, filed IPR2024-00298 along with a motion for joinder with the same Samsung Bioepis IPR2023-00884.

In the ongoing Northern district of West Virginia litigation (1:22-cv-00061), judgment against Mylan's proposed biosimilar M710 issued on December 27, 2023 after a bench trial. Also on December 27, 2023, Regeneron filed a second lawsuit against Samsung Bioepis, 1:23-cv-00106 (N.D.W. Va.).

Samsung Bioepis, Celltrion, and Biocon have filed aBLAs for their EYLEA® biosimilar candidates SB15, CT-P42, and M710 respectively.



Spotlight On: Actemra® (tocilizumab) / Tofidence™ (tocilizumab-bavi)

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)

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)

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™, and MSB11456), pegfilgrastim (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria®, Fylnetra™, Stimufend®, Lapelga™, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri®, Herzuma®, Ontruzant®, Trazimera®, Kanjinti®, TX-05, EG12014, and HLX02), rituximab (Rituxan®, Truxima®, Ruxience®, and Riabni™), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz®, Hadlima™, Abrilada™, Hulio®, Yusimry™, Idacio®, Yuflyma®, and AVT02), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, Semglee®, and Rezvoglar™) have been updated with activity through December 31, 2023.

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, 2023.

Read More News

UPDATES

IPRs and PGRs

Soliris® (eculizumab):

- On December 8, 2023, the PTAB granted institution of **Samsung Bioepis's** IPR2023-00933, IPR2023-00998 and IPR2023-00999 against **Alexion**.
- On December 19, 2023, the PTAB granted institution of **Samsung Bioepis's** IPR2023-01070 against **Alexion**.
- On December 20, 2023, the PTAB granted institution of **Samsung Bioepis's** IPR2023-01069 against **Alexion**.

Eylea® (aflibercept):

- On December 8, 2023, the PTAB granted institution of **Samsung Bioepis's** IPR2023-01312 against **Regeneron** and granted its motion for joinder with **Celltrion's** IPR2023-00462.

- On December 14, 2023, **Celltrion** filed IPR2024-00260 against **Regeneron** along with a motion for joinder with **Samsung Bioepis's** IPR2023-00884.
- On December 18, 2023, **Biocon Biologics**, and the related parties in-interest **Janssen**, **Johnson & Johnson**, **Viatris**, **Momenta**, and **Mylan** filed IPR2024-00298 against **Regeneron** along with a motion for joinder with **Samsung Bioepis's** IPR2023-00884.

Litigations

Eylea® (aflibercept):

- On December 27, 2023, the Court issued a sealed judgment in ***Regeneron*** *v.* ***Mylan***, Case No. 1:22-cv-00061 (N.D.W. Va.), finding claims 4, 7, 9, 11, and 14-17 of U.S. Patent No. 11,084,865 valid and infringed, and claims 6 and 25 of U.S. Patent No. 11,253,572 patent and claims 11 and 19 of U.S. Patent No. 10,888,601 infringed, but invalid as obvious.
- On December 27, 2023, **Regeneron** filed a second lawsuit against **Samsung Bioepis**, 1:23-cv-00106 (N.D.W. Va.) related to its proposed biosimilar **SB15**.

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aBLA Applications and FDA Activity

Avzivi® (bevacizumab-tnjn):

- On December 6, 2023, the FDA approved **Bio-Thera Solutions** and **Sandoz's** **Avzivi® (bevacizumab-tnjn)**, a biosimilar of **Genentech's** **Avastin® (bevacizumab)**.

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

Ranopto® (ranibizumab):

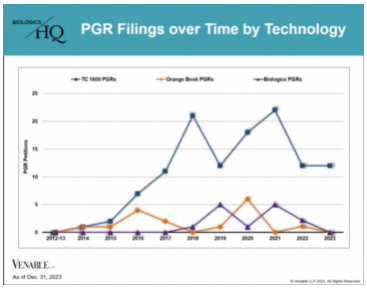
- On December 7, 2023, **Bioeq** and **Teva** announced the approval of **Ranopto® (ranibiziumab)**, a biosimilar of **Genentech's** **Lucentis® (ranibizumab)**, in Canada.

Xelenka® (adalimumab):

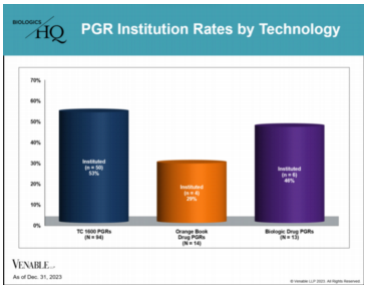
- On December 15, 2023, LG Chem announced the approval of **Xelenka® (adalimumab)**, a high-concentration biosimilar of **AbbVie's** **Humira® (adalimumab)**, in South Korea.

STATISTICS

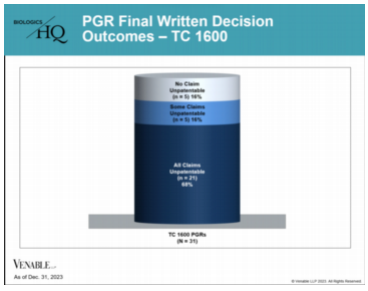
PGR Filings Over Time by Technology



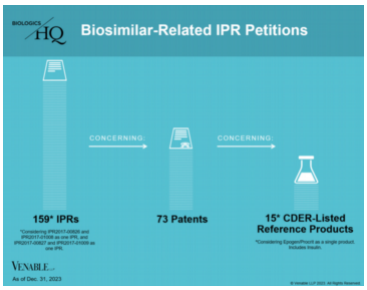
PGR Institution Rates by Technology



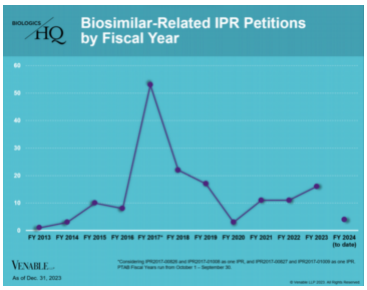
PGR Final Written Decision Outcomes – TC 1600



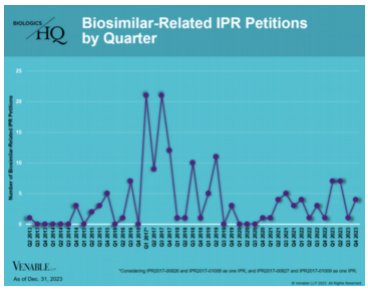
Biosimilar-Related IPR Petitions



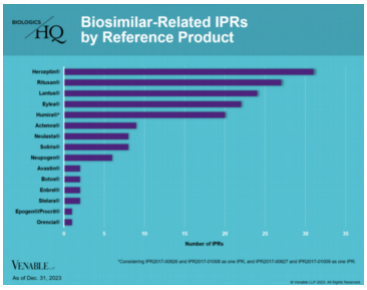
Biosimilar-Related IPR Petitions by Fiscal Year



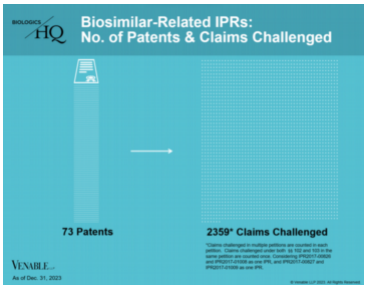
Biosimilar-Related IPR Petitions by Quarter



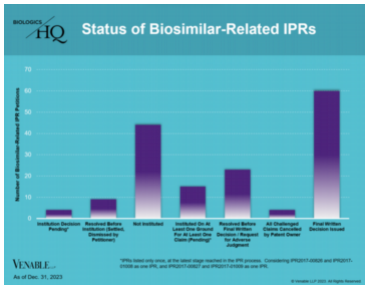
Biosimilar-Related IPRs by Reference Product



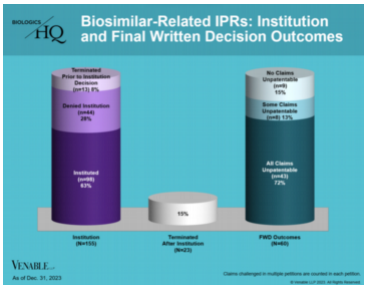
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



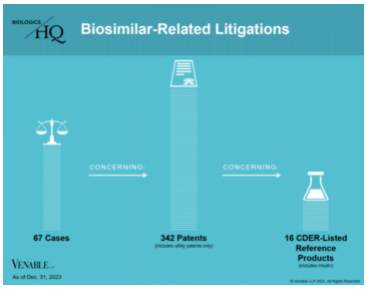
Status of Biosimilar-Related IPRs



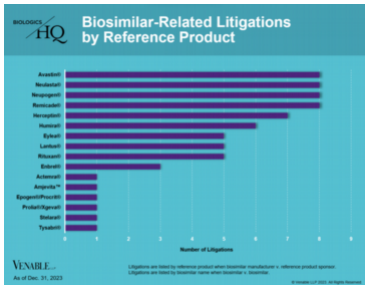
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



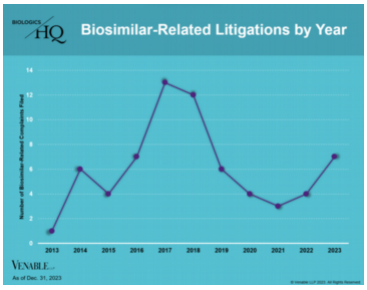
Biosimilar-Related Litigations



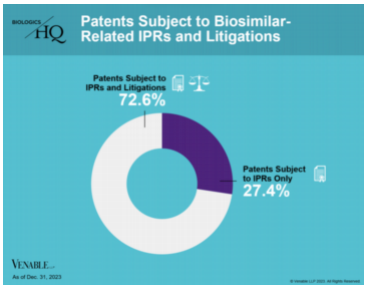
Biosimilar-Related Litigations by Reference Product



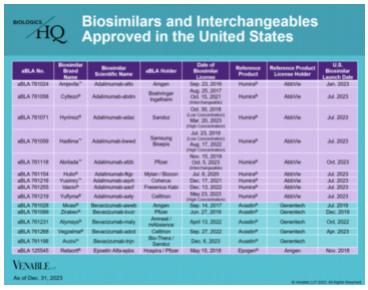
Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars and Interchangeables Approved in the United States

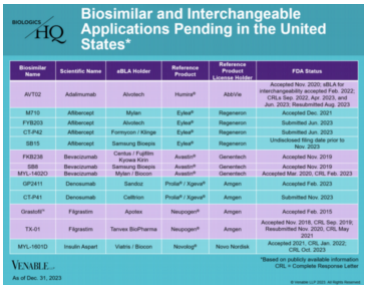


Biosimilar and Interchangeable Applications

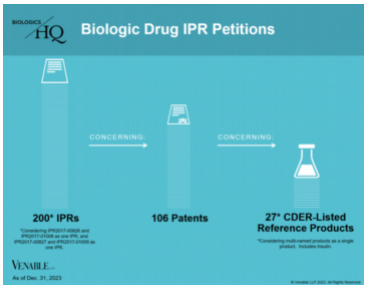
Biologic Drug IPR

Biologic Drug IPRs by Reference

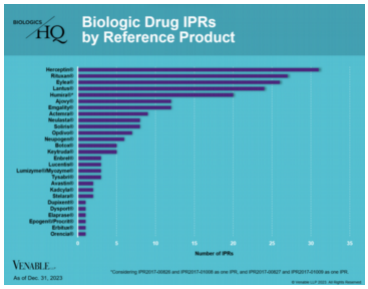
Pending in the United States



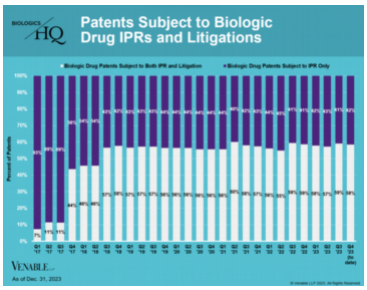
Petitions



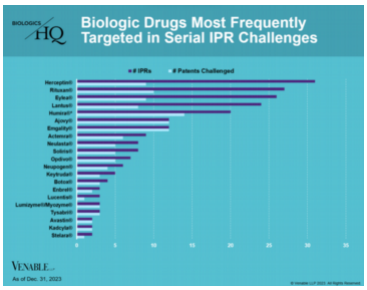
Product



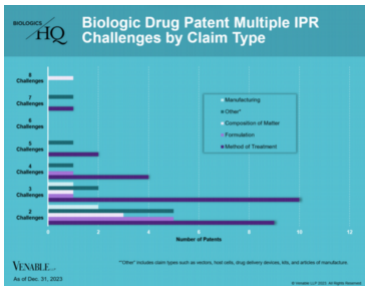
Patents Subject to Biologic Drug IPRs and Litigations



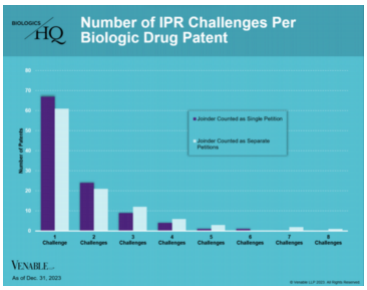
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

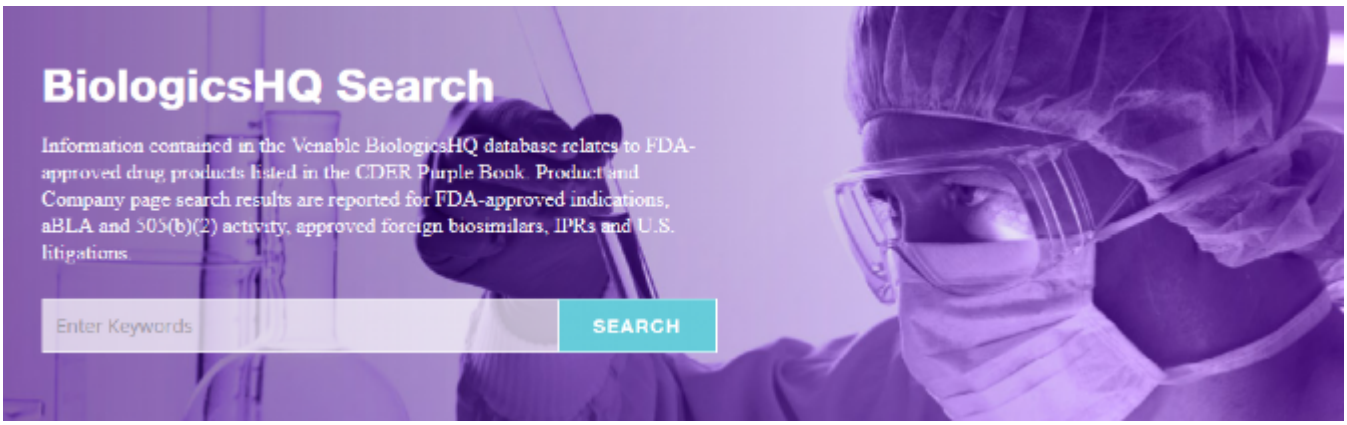


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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