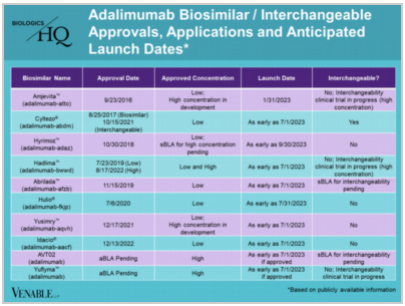
BIOLOGICS HQ

VENABLE LLP

February 8, 2023

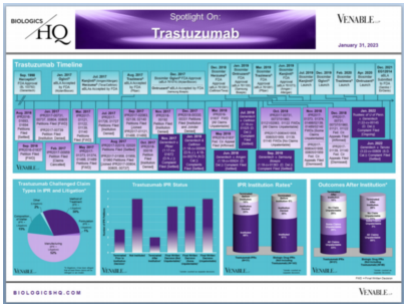
LATEST NEWS



First Humira Biosimilar Enters the U.S. Market

By: April Breyer Menon and Ha Kung Wong

On January 31, 2023, Amjevita™ (adalimumab-atto) entered the U.S. market as the first biosimilar of Humira® (adalimumab), after receiving approval in September 2016. Amjevita will be available in a low-concentration, citrate-free formulation (40 mg/0.8mL and 20mg/0.4mL) in prefilled syringes and for autoinjectors.



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)

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

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On January 5, 2023, **Novartis** filed Appeal No. 23-1334, appealing the final written decision finding all challenged claims unpatentable in IPR2021-00816 against **Regeneron**.

Eylea® (aflibercept):

- On January 6, 2023, **Samsung Bioepis** filed IPR2023-00442 against **Regeneron**.
- On January 13, 2023, **Regeneron** filed Fed. Cir. Appeal Nos. 23-1395 and 23-1396, appealing the final written decisions finding all challenged claims unpatentable in IPR2021-00880 (IPR2022-00257, IPR2022-00310 joined) and IPR2021-00881 (IPR2022-00258, IPR2022-00298 joined) respectively, against **Mylan**, **Celltrion**, and **Apotex**.
- On January 11, 2023, the PTAB instituted ***Mylan*** *v.* ***Regeneron*** IPR2022-001225 and IPR2022-001226.
- On January 17, 2023, **Celltrion** filed IPR2023-00462 against **Regeneron**.

Litigations

Herceptin® (trastuzumab):

- On January 6, 2023, **Genentech** and **Tanvex** submitted a joint notice of settlement in Case No. 3:22-cv-00809 (S.D. Cal.).

Yervoy® (ipilimumab) / Imjudo® (tremelimumab-actl):

- On January 23, 2023, **Bristol-Myers Squibb** filed Case No. 1:23-cv-00079 (D. Del.) against **AstraZeneca**.

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aBLA Applications and FDA Activity

AVT04 (ustekinumab):

- On January 6, 2023, **Alvotech** and **Teva** announced the FDA acceptance of an aBLA for **AVT04 (ustekinumab)**, a proposed biosimilar of **Janssen's Stelara® (ustekinumab)**.

Insulin-R (human insulin):

- On January 7, 2023, **Biocon Biologics** announced receipt of a complete response letter from the FDA for **Insulin-R (human insulin)**, a proposed biosimilar of **Eli Lilly's Humulin® R (human insulin)**.

CDER Purple Book Updates

Leqembi™ (lecanemab-irmb):

- On January 6, 2023, the FDA approved **Eisai's Leqembi™ (lecanemab-irmb).**

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

Vegzelma® (bevacizumab-adcd):

- On January 3, 2023, **Celltrion** announced the approval of **Vegzelma® (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, in Canada.

Hadlima™ (adalimumab-bwwd):

- On January 3, 2023, **Samsung Bioepis** announced the approval of citrate-free, high-concentration **Hadlima™ (adalimumab-bwwd)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, in Canada.

Adalloce™ (adalimumab-bwwd):

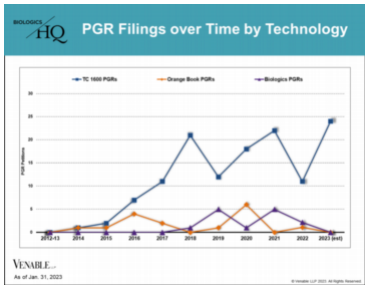
- On January 5, 2023, **Samsung Bioepis** announced the approval of citrate-free, high-concentration **Adalloce™ (adalimumab-bwwd)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, in South Korea.

Ximluci® (ranibizumab):

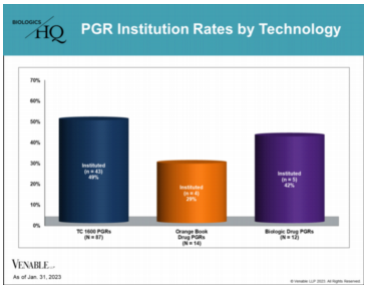
- On January 17, 2023, **STADA** and **Xbrane** announced the approval of **Ximluci® (ranibizumab)**, a biosimilar of **Genentech's Lucentis® (ranibizumab)**, in the U.K.

STATISTICS

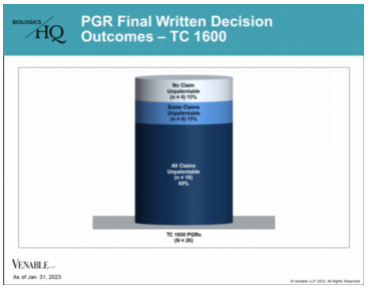
PGR Filings Over Time by Technology	PGR Institution Rates by Technology	PGR Final Written Decision Outcomes – TC 1600



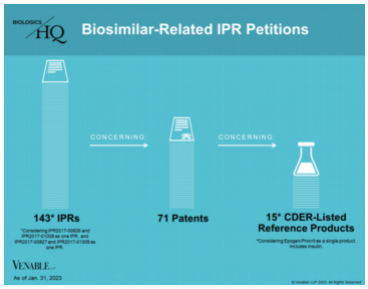
[Biosimilar-Related IPR Petitions]



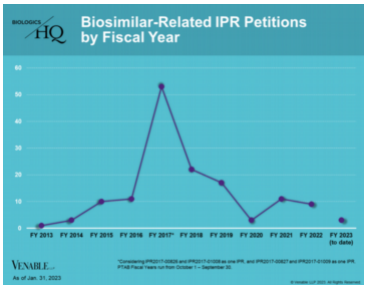
[Biosimilar-Related IPR Petitions by Fiscal Year]



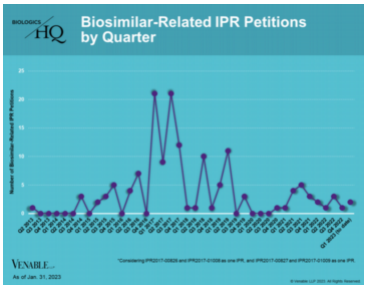
[Biosimilar-Related IPR Petitions by Quarter]



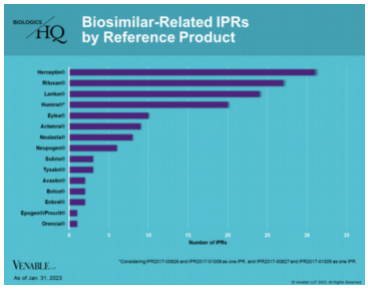
[Biosimilar-Related IPRs by Reference Product]



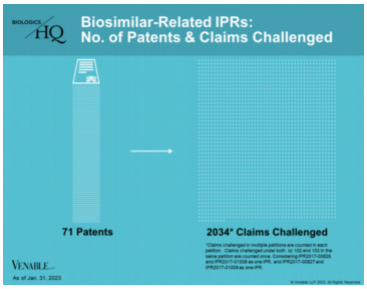
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



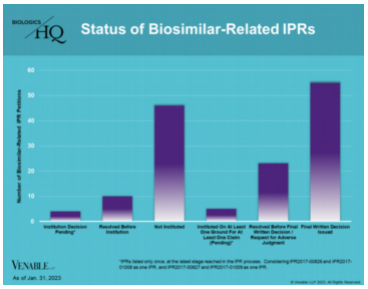
[Status of Biosimilar-Related IPRs]



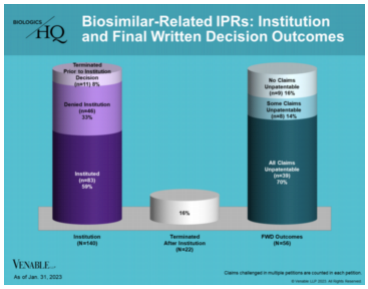
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



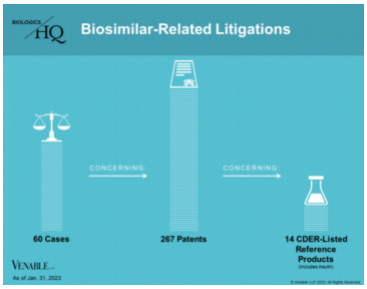
[Biosimilar-Related Litigations]



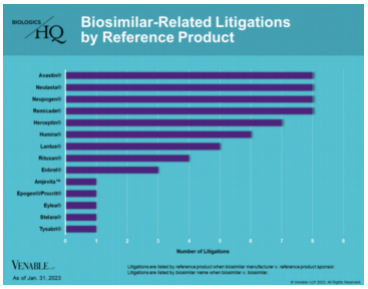
[Biosimilar-Related Litigations by Reference Product]



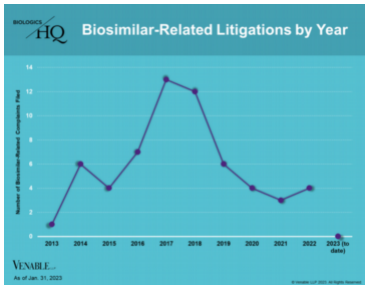
[Biosimilar-Related Litigations by Year]



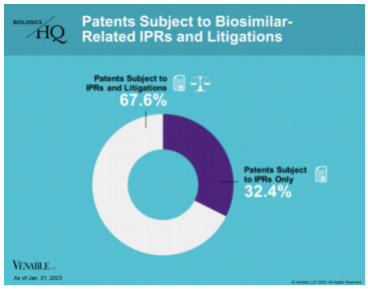
[Patents Subject to Biosimilar-Related IPRs and Litigations]



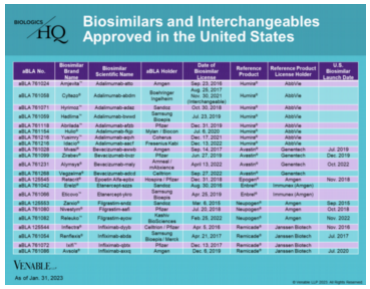
[Biosimilars and Interchangeables Approved in the United States]



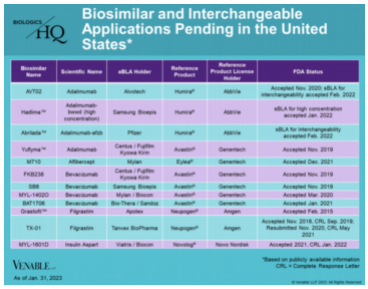
Biosimilar and Interchangeable Applications Pending in the United States



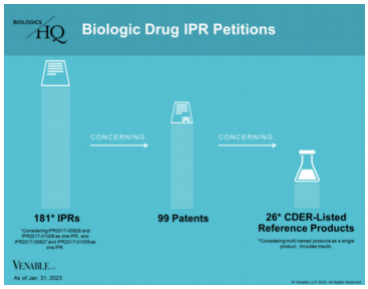
Biologic Drug IPR Petitions



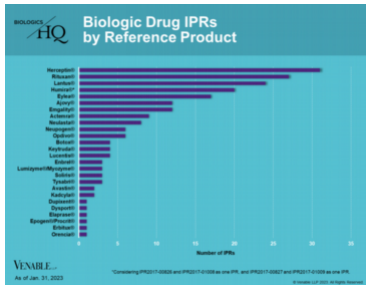
Biologic Drug IPRs by Reference Product



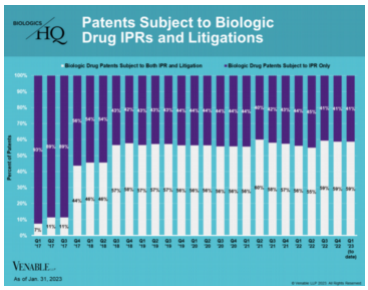
Patents Subject to Biologic Drug IPRs and Litigations

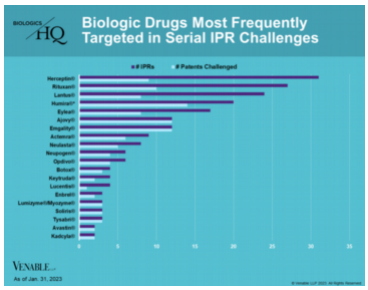


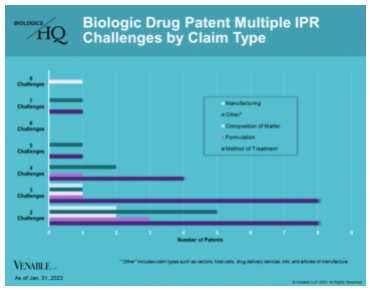
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



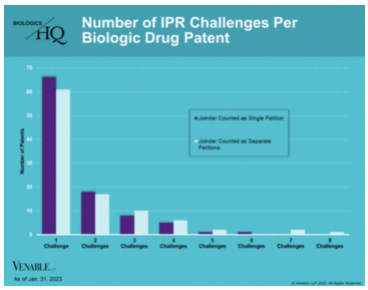
Biologic Drug Patent Multiple IPR Challenges by Claim Type

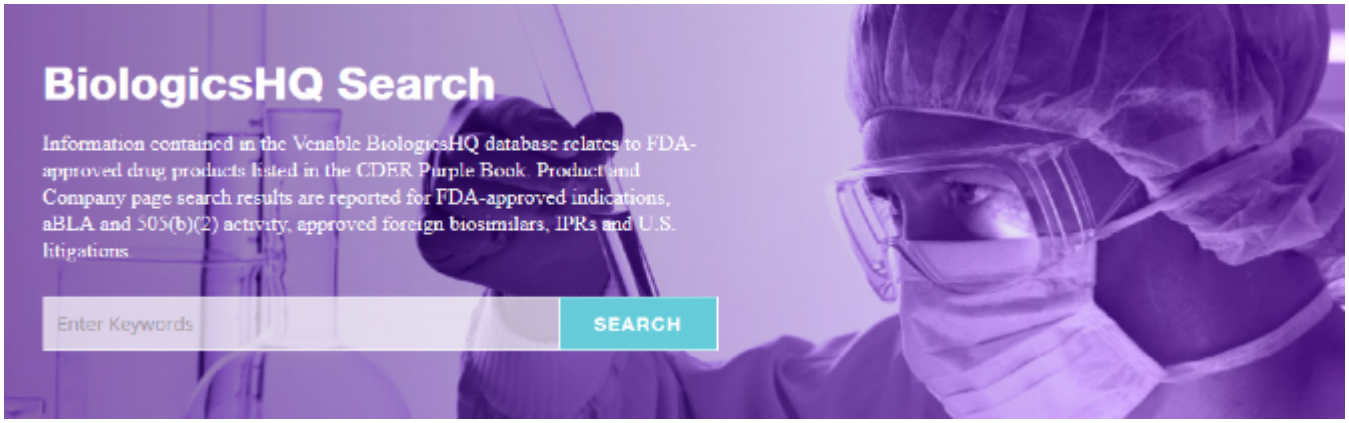






Number of IPR Challenges Per Biologic Drug Patent





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