BIOLOGICS HQ

VENABLE LLP

September 12, 2023

LATEST NEWS

PREVAIL Act Reforms at the PTAB

By: Damineh Morsali, Ph.D. and Ha Kung Wong

The Promoting and Respecting Economically Vital American Innovation Leadership Act ("PREVAIL Act") was recently introduced in Congress. According to the Act's sponsors, it reforms rules and procedures at the PTAB to promote fair treatment for inventors, improve efficiency, and ensure that the USPTO has the resources it needs to effectively administer a patent system that incentivizes American innovation and enables U.S. inventors to compete.

Damineh Morsali and Ha Kung Wong discuss the provisions of the bill, including changes to standing in IPRs and PGRs, handling of duplicative challenges, transparency, deadlines, and motions to amend.

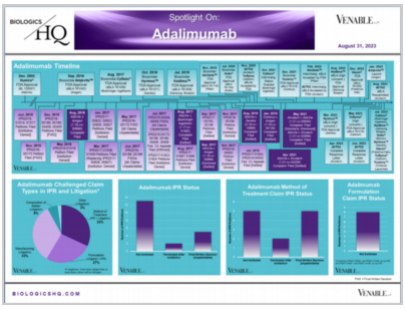
First List of Drugs for Medicare Price Negotiations Published Includes Three Biologics

By: Ha Kung Wong

The Inflation Reduction Act (IRA), signed into law on August 16, 2022, allows the federal government to negotiate prices for some high-cost drugs covered under Medicare. On August 29, 2023, the US Department of Health and Human Services (HHS) published the first list of drugs that will be subject to price negotiations.

Ha Kung Wong discusses the IRA provisions affecting pharmaceuticals and the three biologic drugs chosen for the first round of negotiations, including the potential discounts and what they may do to avoid negotiated prices taking effect.

Spotlight On: Actemra® (tocilizumab)



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®, MSB11456, and BIIB800), 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 August 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 August 31, 2023.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On August 8, 2023, **Regeneron** filed a statutory disclaimer and request to terminate IPR2023-00620 filed by **Celltrion** prior to an institution decision.
- On August 18, 2023, **Samsung Bioepis** filed IPR2023-01312 against **Regeneron** and a request for joinder with IPR2023-00462.

Stelara® (ustekinumab):

- On August 9, 2023, the PTAB granted **Samsung Bioepis** and **Janssen's** joint request to terminate IPR2023-01103 due to settlement before institution decision.

Botox® (onabotulinumtoxinA):

- On August 28, 2023, the PTAB denied institution of Hugel's IPR2023-00604 against **Medy-Tox**.

Actemra® (tocilizumab):

- On August 29, 2023, final written decisions were issued in **Celltrion's** IPR2022-00578 and IPR2022-00579 against **Chugai**, **Hoffmann-La Roche**, and **Genentech**, finding all challenged claims unpatentable.

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aBLA Applications and FDA Activity

FYB202 (ustekinumab):

- On August 7, 2023, **Formycon** and **Fresenius Kabi** announced a settlement agreement with **Johnson & Johnson** related to FYB202 (ustekinumab), a proposed biosimilar of **Johnson & Johnson** / **Janssen's** **Stelara® (ustekinumab)**, which is currently in development. The settlement agreement grants a license beginning no later than April 15, 2025, subject to FDA approval. According to the press release, submission of an aBLA to the FDA is planned for later in 2023.

Tyruko® (natalizumab-sztn):

- On August 24, 2023, the FDA approved **Sandoz** and **Polpharma's** **Tyruko® (natalizumab-sztn)**, a biosimilar of **Biogen's** **Tysabri® (natalizumab)**.

CT-P43 (ustekinumab):

- On August 25, 2023, **Celltrion** announced a settlement agreement with **Johnson & Johnson** related to **CT-P43 (ustekinumab)**, a proposed biosimilar to **Johnson & Johnson** / **Janssen's** **Stelara® (ustekinumab)**. The settlement agreement allows **CT-P43** to enter the US market on March 7, 2025, subject to FDA approval. **Celltrion** submitted an aBLA to the FDA for **CT-P43** in June 2023.

AVT02 (adalimumab):

- On August 31, 2023, **Alvotech** announced the resubmission of its aBLA for **AVT02 (adalimumab)**, a proposed interchangeable biosimilar of **AbbVie's** **Humira® (adalimumab)**, after receiving a Complete Response Letter from the FDA in June.

CDER Purple Book Updates

Talvey™ (talquetamab-tgvs):

- On August 9, 2023, the FDA approved **Janssen's** **Talvey™ (talquetamab-tgvs)**.

Elrexfio™ (elranatamab):

- On August 14, 2023, the FDA approved **Pfizer's** **Elrexfio™ (elranatamab)**.

Veopoz™ (pozelimab-bbfg):

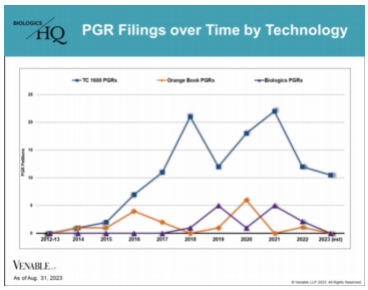
- On August 18, 2023, the FDA approved **Regeneron's** **Veopoz™ (poselimab-bbfg)**.

Eylea® HD (aflibercept):

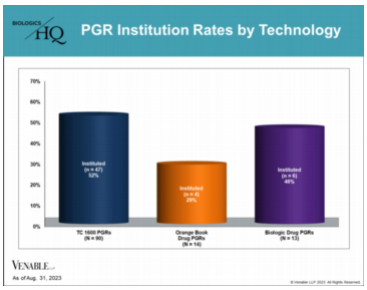
- On August 18, 2023, the FDA approved **Regeneron's** **Eylea® HD (aflibercept)**, a high dose version of **Eylea® (aflibercept)**.

STATISTICS

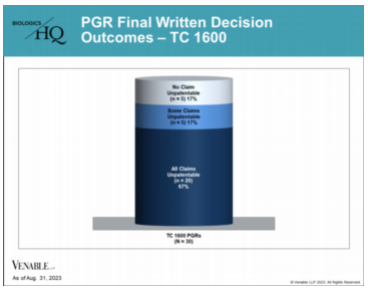
PGR Filings Over Time by Technology



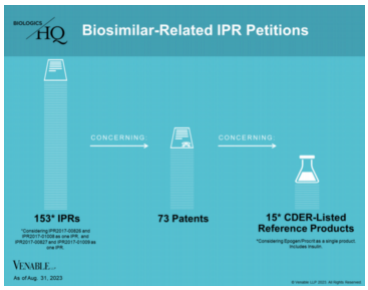
PGR Institution Rates by Technology



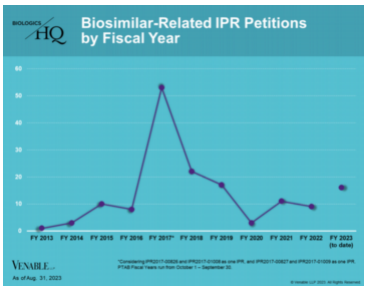
PGR Final Written Decision Outcomes – TC 1600



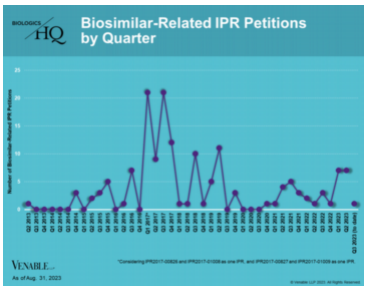
Biosimilar-Related IPR Petitions



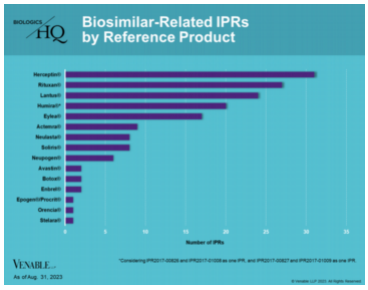
Biosimilar-Related IPR Petitions by Fiscal Year



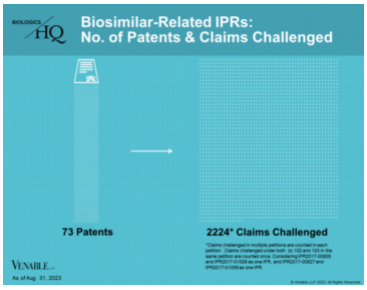
Biosimilar-Related IPR Petitions by Quarter



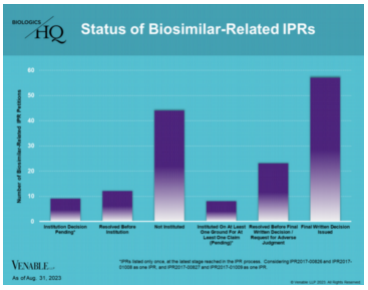
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



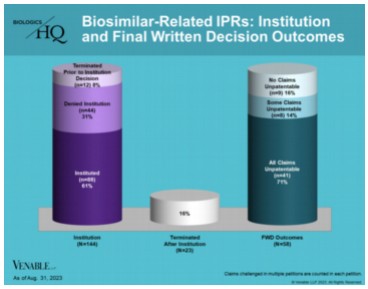
Status of Biosimilar-Related IPRs



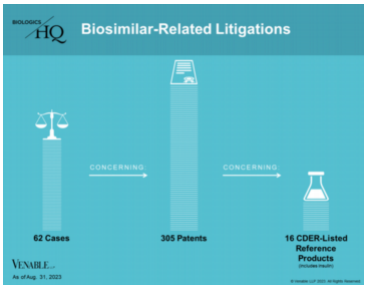
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

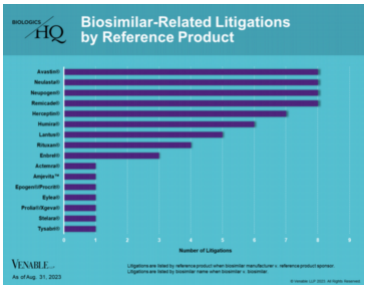
Biosimilar-Related Litigations by Reference Product



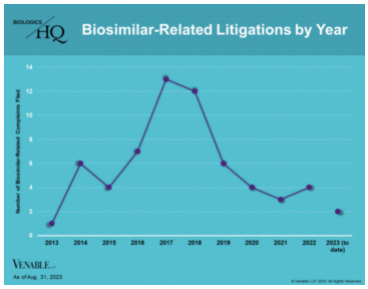
[Biosimilar-Related Litigations by Year]



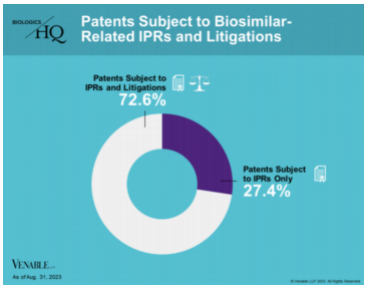
[Patents Subject to Biosimilar-Related IPRs and Litigations]



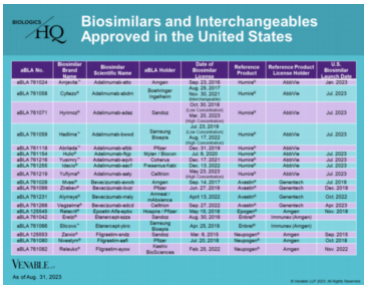
[Biosimilars and Interchangeables Approved in the United States]



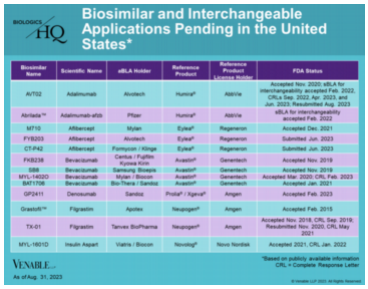
[Biosimilar and Interchangeable Applications Pending in the United States]



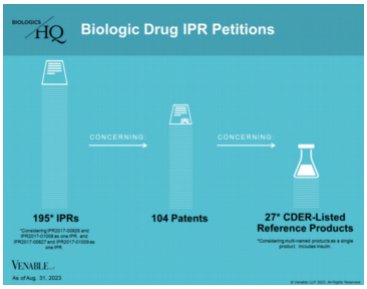
[Biologic Drug IPR Petitions]



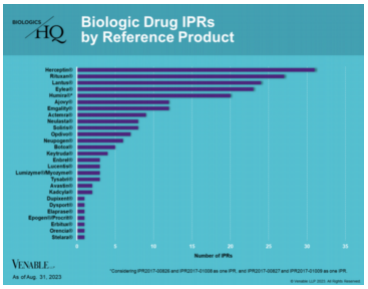
[Biologic Drug IPRs by Reference Product]



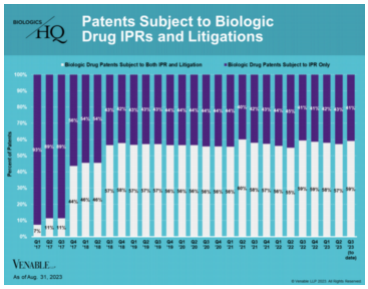
[Patents Subject to Biologic Drug IPRs and Litigations]



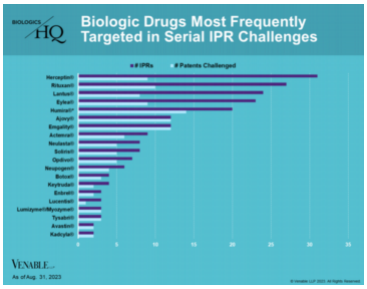
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]

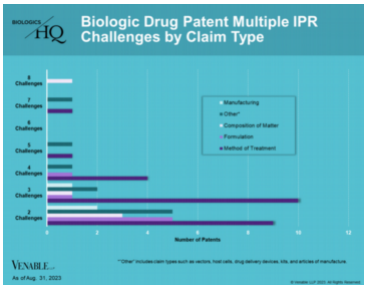


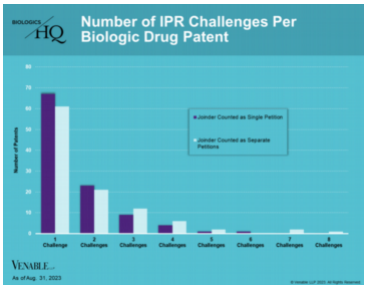
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

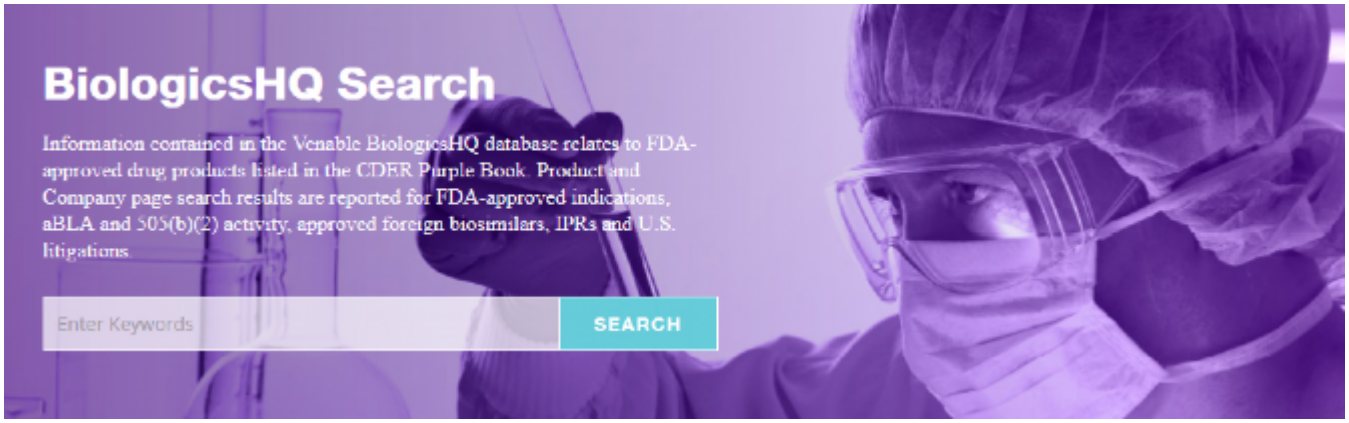


[Number of IPR Challenges Per Biologic Drug Patent]









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