BIOLOGICS HQ

VENABLE LLP

July 9, 2024

LATEST NEWS

Permanent Injunction Issued Preventing Launch of EYLEA® Biosimilar Yesafili™

By: Robert S. Schwartz, Ph.D.

On June 11, 2024, the Court in Case No. 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) issued a permanent injunction against the launch of Biocon and Mylan's Yesafili™ (aflibercept-jbvf), a recently approved interchangeable biosimilar of Regeneron's EYLEA® (aflibercept).

PTAB Grants Institution of IPR Challenging The Johns Hopkins University Pembrolizumab Patent

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

On June 13, 2024, the PTAB granted institution of IPR2024-00240 that Merck filed in November 2023 challenging claims 1-42 of The Johns Hopkins University's U.S. Patent No. 11,591,393 ("the '393 patent") on anticipation and obviousness (35 U.S.C. §§ 102 and 103) grounds. The '393 patent is directed to treating cancer patients with high mutational burdens, such as microsatellite instable (MSI) cancer, by using anti-PD-1 antibodies, which includes pembrolizumab, sold by Merck under the trade name Keytruda®.

PTAB Issues Final Written Decision Invalidating Regeneron's EYLEA® Patent (IPR2023-00442)

By: Damineh Morsali, Ph.D. and Robert S. Schwartz, Ph.D.

On June 14, 2024, the PTAB issued a Final Written Decision in Samsung Bioepis's IPR2023-00442 determining that the challenged claims of Regeneron's U.S. Patent No. 10,130,681 ("the '681 patent) that covers EYLEA® (aflibercept) are unpatentable as obvious. The '681 patent is directed to methods for treating angiogenic eye disorders by sequentially administering multiple doses of a vascular epithelial growth factor (VEGF) antagonist to a patient.

FDA Revises Guidance on Switching Studies for Biosimilar Interchangeability

By: Robert S. Schwartz, Ph.D.

On June 20, 2024, the FDA issued a draft guidance, "Considerations for Demonstrating Interchangeability with a Reference Product: Update" that revises the need for switching studies to demonstrate a biosimilar is interchangeable. The initial guidance on interchangeability was published in 2019, before the FDA had received and reviewed any applications for interchangeable biosimilars. The update is based on the FDA's experience gained in approving 13 interchangeable biosimilars and current scientific thinking and analytical assessment techniques.

Under the updated draft guidance, instead of conducting a switching study "Applicants may choose to provide an assessment of why the comparative analytical and clinical data provided in the application or supplement support a showing that the switching standard set forth in section 351(k)(4)(B) of the PHS Act has been met."

Preliminary Injunctions Issued Preventing Launch of EYLEA® Biosimilars

By: Robert S. Schwartz, Ph.D.

In June 2024, the Court granted preliminary injunctions against the commercial launch of three EYLEA® (aflibercept) biosimilars, Samsung Bioepis's Opuviz™ (aflibercept-yszy), Formycon's Ahzantive® (aflibercept-mrbb), and Celltrion's CT-P42 (aflibercept) (FDA-approval pending).

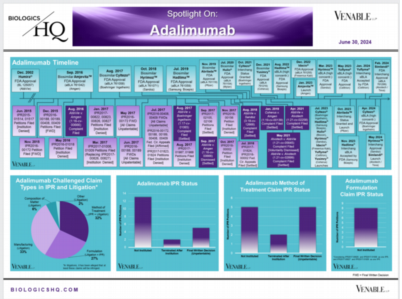
While the preliminary injunction orders for Ahzantive® and CT-P42 currently remain sealed, on June 24, 2024, the Court unsealed portions of its preliminary injunction relating to Opuviz™.

FDA Approves Three Biosimilars – Ahzantive® (aflibercept-mrbb), Nypozi™ (filgrastim-txid), and Pyzchiva® (ustekinumab-ttwe)

By: Robert S. Schwartz, Ph.D.

On June 28, 2024, the FDA approved three new biosimilars, Formycon and Klinge Biopharma's Ahzantive® (aflibercept-mrbb), a biosimilar of Regeneron's EYLEA® (aflibercept); Tanvex Biopharma's Nypozi™ (filgrastim-txid), a biosimilar of Amgen's

Neupogen® (filgrastim); and Samsung Bioepis and Sandoz's Pyzchiva® (ustekinumab-ttwe), an interchangeable biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab).



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®, and Riabni™), 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 June 30, 2024.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through June 30, 2024.

Read More News

UPDATES

IPRs and PGRs

Keytruda® (pembrolizumab):

- On June 13, 2024, the PTAB instituted **Merck Sharp & Dohme's** IPR2024-00240 against method of treatment claims of The John's Hopkins University's (JHU) U.S. Patent No. 11,591,393. On June 27, 2024, JHU filed a request for rehearing of the institution decision.

Eylea® (aflibercept):

- On June 14, 2024, the PTAB issued a Final Written Decision in **Samsung Bioepis's** IPR2023-00442 finding all challenged method of treatment claims of **Regeneron's** U.S. Patent No. 10,130,681 unpatentable.

Zynteglo® (betibeglogene autotemcel):

- On June 26 and 27, 2024, ***bluebird bio*** filed CAFC Appeal Nos. 24-2010 and 24-2016, appealing the Final Written Decisions in IPR2023-00070 and IPR2023-00074 finding the challenged claims of Sloan Kettering's U.S. Patent Nos. 7,541,179 and 8,058,062 are not unpatentable.

Litigations

Eylea® (aflibercept):

- On June 11, 2024, the Court entered a permanent injunction against the commercial launch of **Mylan** / **Biocon's Yesafili™ (aflibercept-jbfv)** in Case No. 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). On June 25, **Mylan** / **Biocon** filed CAFC Appeal No. 24-2002.
- On June 14, 2024, the Court granted a preliminary injunction against the launch of **Samsung Bioepis's Opuviz™ (aflibercept-yszy)** in Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). On June 20, 2024, **Samsung Bioepis** filed CAFC Appeal Nos. 24-1965 and 24-1966.
- On June 21, 2024, the Court granted a preliminary injunction against the commercial launch of **Formycon's Ahzantive® (FYB203) (aflibercept-mrbb)** in Case No. 1:23-cv-00097 / MDL 1:24-md-03103 (N.D.W. Va.). On June 28, 2024, **Formycon** filed CAFC Appeal No. 24-2019.
- On June 28, 2024, the Court granted a preliminary injunction against the commercial launch of **Celltrion's** proposed biosimilar **CT-P42 (aflibercept)** in Case No. 1:23-cv-00089 / MDL 1:24-md-03103 (N.D.W. Va.).

Keytruda® (pembrolizumab):

- On June 29, 2024, the Court stayed ***Merck Sharp & Dohme*** *v. The Johns Hopkins University* Case No. 1:22-cv-03059 (D. Md.) pending the outcome of IPR2024-00240 that was instituted on June 13, 2024.

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aBLA Applications and FDA Activity

Ahzantive® (aflibercept-mrbb):

- On June 28, 2024, the FDA approved **Formycon** and **Klinge Biopharma's Ahzantive® (aflibercept-mrbb)**, a biosimilar of **Regeneron's Eylea® (aflibercept)**.

Nypozi™ (filgrastim-txid):

- On June 28, 2024, the FDA approved **Tanvex Biopharma's Nypozi™ (filgrastim-txid)**, a biosimilar of **Amgen's Neupogen® (filgrastim)**.

Pyzchiva® (ustekinumab-ttwe):

- On June 28, 2024, 2024, the FDA approved **Samsung Bioepis** and **Sandoz's Pyzchiva® (ustekinumab-ttwe)** as an interchangeable biosimilar of **Janssen's Stelara® (ustekinumab)**.

CDER Purple Book Updates

PiaSky™ (crovalimab-akkz):

- On June 20, 2024, the FDA approved **Genentech's PiaSky™ (crovalimab-akkz).**

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

Steqeyma™ (CT-P43) (ustekinumab):

- On June 13, 2024, **Celltrion** announced the approval of **Steqeyma™ (ustekinumab)**, a biosimilar of **Janssen's Stelara® (ustekinumab)**, in South Korea.

Tofidence™ (tocilizumab-bavi):

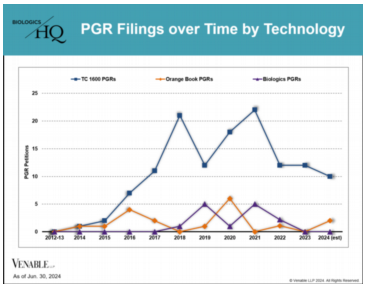
- On June 24, 2024, **Biogen** and **Bio-Thera** announced the approval of **Tofidence™ (tocilizumab-bavi),** a biosimilar of **Genentech's Actemra® (tocilizumab)**, in the E.U.

Omlyclo® (CT-P39) (omalizumab):

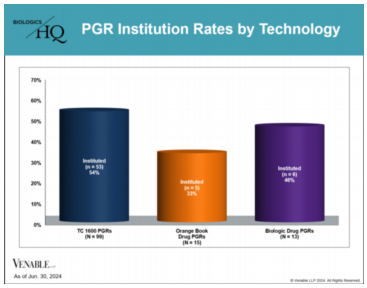
- On June 25, 2024, **Celltrion** announced the approval of **Omlyclo® (omalizumab)**, a biosimilar of **Genentech's Xolair® (omalizumab)**, in South Korea.

STATISTICS

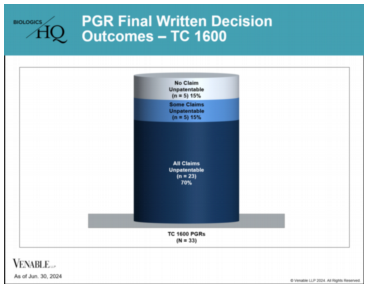
PGR Filings Over Time by Technology



PGR Institution Rates by Technology



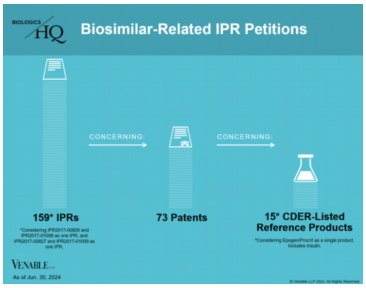
PGR Final Written Decision Outcomes − TC 1600



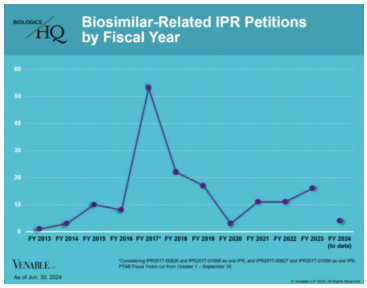
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

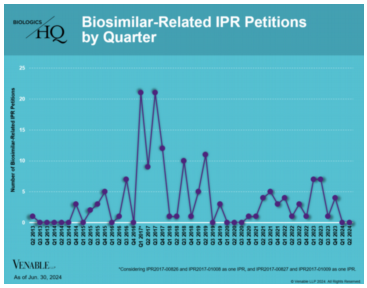
Biosimilar-Related IPR Petitions by Quarter



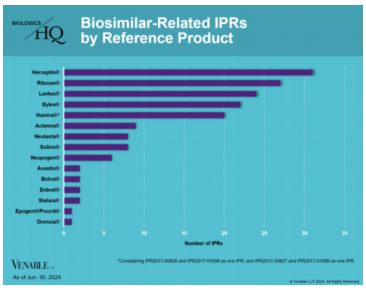
[Biosimilar-Related IPRs by Reference Product]



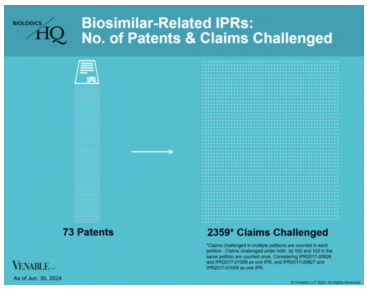
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



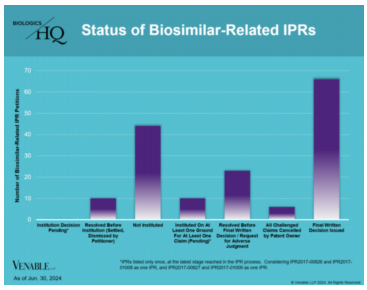
[Status of Biosimilar-Related IPRs]



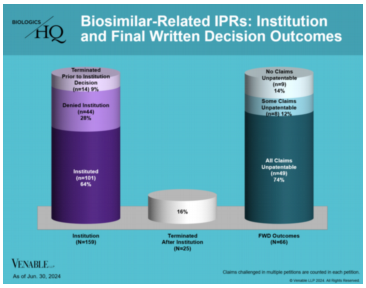
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



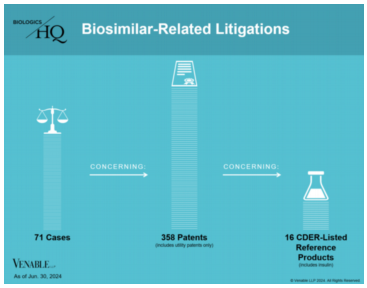
[Biosimilar-Related Litigations]



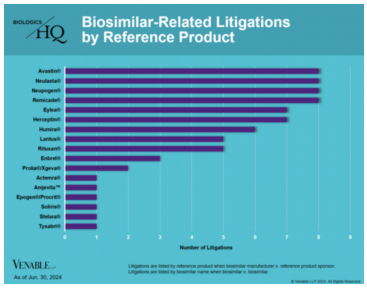
[Biosimilar-Related Litigations by Reference Product]



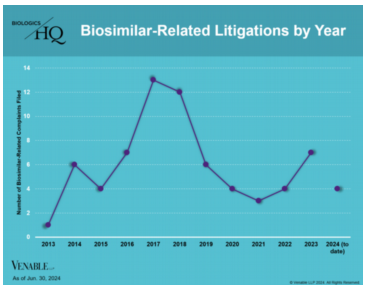
[Biosimilar-Related Litigations by Year]



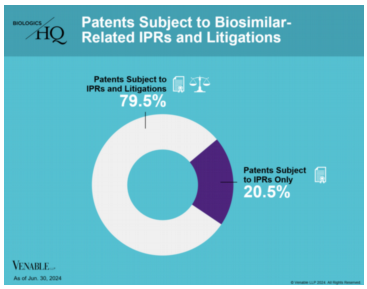
[Patents Subject to Biosimilar-Related IPRs and Litigations]



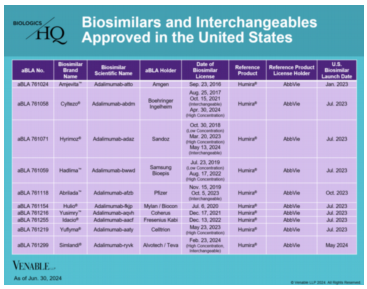
[Biosimilars and Interchangeables Approved in the United States]



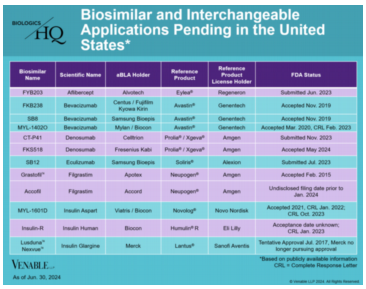
[Biosimilar and Interchangeable Applications Pending in the United States]

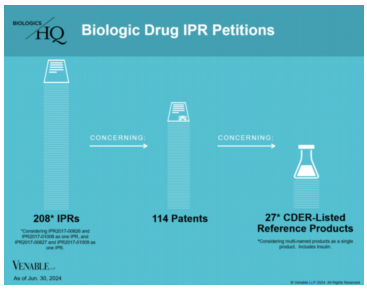


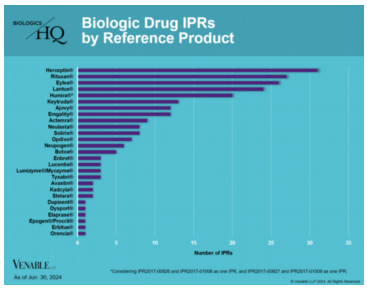
[Biologic Drug IPR Petitions]



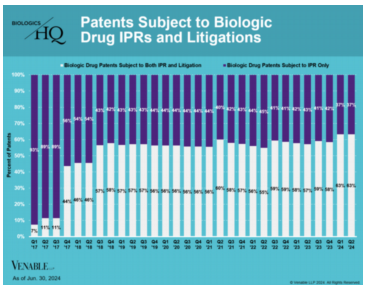
[Biologic Drug IPRs by Reference Product]



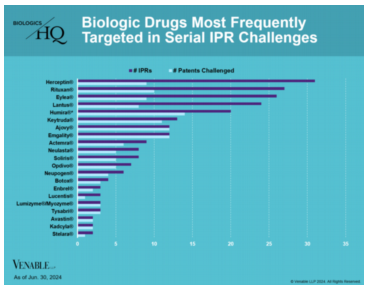




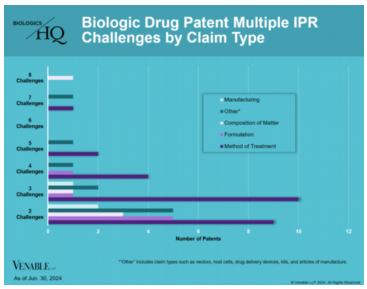
Patents Subject to Biologic Drug IPRs and Litigations



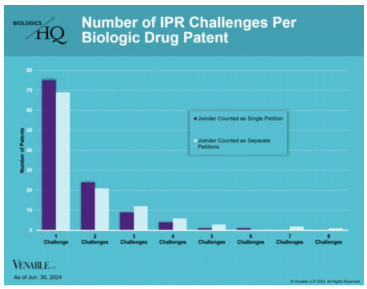
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

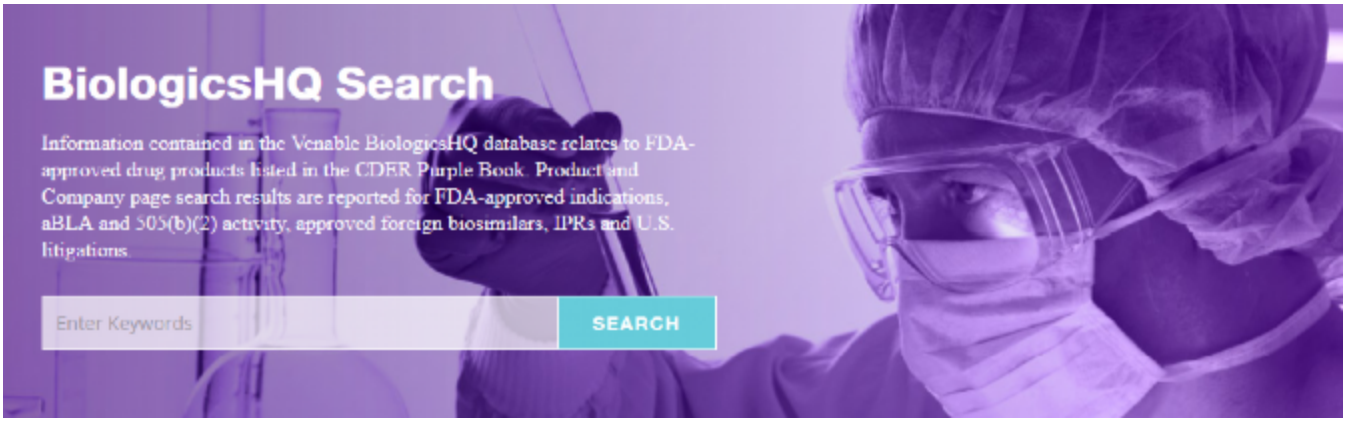


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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