BIOLOGICS HQ

VENABLE LLP

August 9, 2024

LATEST NEWS

Implications of Loper Bright for FDA-Regulated Products

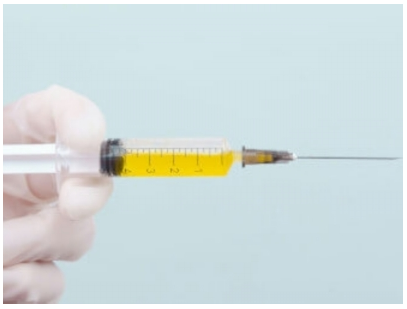
By: Todd Harrison, Claudia Lewis, Justin Coen, and Jeremiah Kelly

After the Supreme Court's reversal of the long-standing *Chevron* deference principle in *Loper Bright*, Venable's FDA Group offers some of its thoughts on the potential impact on the FDA.

FDA Approves Second Soliris® (eculizumab) Interchangeable Biosimilar – Samsung Bioepis's Epysqli® (eculizumab-aagh)

By: Robert S. Schwartz, Ph.D.

On July 19, 2024, the FDA approved the second biosimilar of Alexion / AstraZeneca's Soliris® (eculizumab), Samsung Bioepis's Epysqli® (eculizumab-aagh), approximately one year after Samsung Bioepis announced the FDA acceptance of its aBLA. Epysqli® was approved as an interchangeable.



Regeneron Dismisses IPR Appeals and Disclaims EYLEA® (aflibercept) Patents

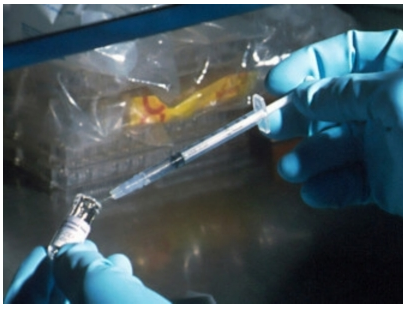
By: Robert S. Schwartz, Ph.D.

On July 8, 2024, Regeneron, Mylan, Celltrion, and Apotex jointly stipulated to the dismissal of CAFC Appeal Nos. 23-1395 and 23-1396, appealing the

Final Written Decisions finding all challenged claims of U.S. Patent Nos. 9,254,338 and 9,669,069 unpatentable in IPR2021-00880 (IPR2022-00257 and IPR2022-00301 joined) and IPR2021-00881 (IPR2022-00258 and IPR2022-00298 joined). The patents recite method of treatment claims for the use of a VEGF antagonist such as EYLEA® (aflibercept) in angiogenic eye disorders.

On July 23, 2024, the PTAB granted Regeneron's request for adverse judgment after disclaiming the claims of U.S. Patent No. 11,253,572 challenged by Samsung Bioepis in IPR2023-00884 (and joined IPR2024-00260 (Celltrion) and IPR2024-00298 (Biocon)). The patent also recited method of treatment claims using aflibercept to treat angiogenic eye disorders.

On July 30, 2024, the PTAB granted Regeneron's request for adverse judgment after disclaiming claims 10-12, 17-19, 21, 25-28, and 33 of U.S. Patent No. 10,888,601, challenged by Samsung Bioepis in IPR2023-00739 (Biocon IPR2024-00201 joined). Similar to the other patents, this patent recited method of treatment claims using aflibercept to treat angiogenic eye disorders.



FDA Accepts Bio-Thera's aBLA for Proposed Stelara® (ustekinumab) Interchangeable BAT2206

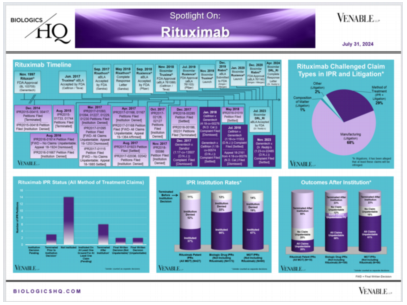
By: Robert S. Schwartz, Ph.D.

On July 24, 2024, Bio-Thera Solutions announced the FDA acceptance of its aBLA for BAT2206 (ustekinumab), a proposed biosimilar of Janssen and Johnson & Johnson's Stelara® (ustekinumab), with a request for interchangeability. This aBLA is the seventh publicly announced aBLA filing for a Stelara® biosimilar. There are currently no pending patent disputes related to BAT2206.

Genzyme Files Complaint Against Sarepta Concerning Gene Therapy Elevidys®

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

On July 26, 2024, Genzyme filed a complaint against Sarepta Therapeutics in the District of Delaware, Case No. 1:24-cv-00882 (D. Del.). In its complaint, Genzyme alleges that Sarepta infringed Genzyme's U.S. Patent Nos. 7,704,721 and 9,051,542 by making, using, offering for sale, and/or selling Elevidys® (delandistrogene moxeparvovec-rokl) in the U.S.



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 July 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 July 31, 2024.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On July 8, 2024, **Regeneron**, **Mylan**, **Celltrion**, and **Apotex** stipulated to the voluntary dismissal of CAFC Appeal Nos. 23-1395 and 23-1396, appealing the Final Written Decisions finding all challenged claims of U.S. Patent Nos. 9,669,069 and 9,254,338 unpatentable in IPR2021-00880 (IPR2022-00257 and IPR2022-00301 joined) and IPR2021-00881 (IPR2022-00258 and IPR2022-00298 joined).

- On July 23, 2024, the PTAB granted **Regeneron's** request for adverse judgement after institution due to disclaimer of the challenged claims of U.S. Patent No. 11,253,572 challenged by **Samsung Bioepis** in IPR2023-00884 (IPR2024-00260 (**Celltrion**) and IPR2024-00298 (**Biocon**) joined).
- On July 30, 2024, the PTAB granted **Regeneron's** request for adverse judgement after institution due to disclaimer of the remaining claims (10-12, 17-19, 21, 25-28, and 33) of U.S. Patent No. 10,888,601 challenged by **Samsung Bioepis** in IPR2023-00739 (**Biocon** IPR2024-00201 joined). **Regeneron** previously disclaimed the other challenged claims (13-16, 20, 22-24, 29-32, and 46-47).

Keytruda® (pembrolizumab):

- On July 31, 2024, the PTAB denied The Johns Hopkins University's (JHU) request for rehearing of the decision instituting **Merck Sharp & Dohme's** IPR2024-00240 against JHU's U.S. Patent No. 11,591,393.

Litigations

Eylea® (aflibercept):

- On July 10, 2024, **Celltrion** filed CAFC Appeal No. 24-2058, appealing the preliminary injunction granted in Case No. 1:23-cv-00089 (N.D.W. Va.) / 1:24-cv-03103 (N.D.W. Va.). On July 31, 2024, **Celltrion** filed a second appeal, CAFC Appeal No. 24-2147, appealing the July 10, 2024 order setting the terms of the preliminary injunction.
- On July 16, 2024, **Samsung Bioepis** filed CAFC Appeal Nos. 24-2082 and 24-2083 appealing the July 10, 2024 orders setting the terms of the preliminary injunctions issued in Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.). / 1:24-md-03103 (N.D.W. Va.).

Elevidys® (delandistrogene moxeparvovec-rokl):

- On July 26, 2024, **Genzyme** filed Case No. 1:24-cv-00882 (D. Del.) against **Sarepta**.

Soliris® (eculizumab):

- On July 29, 2024, in CAFC Case No. 24-1829, the Federal Circuit denied **Alexion's** motion for a temporary injunction pending the appeal of the District Court decision in Case No. 1:24-cv-00005 (D. Del.) to deny a motion for a preliminary injunction against the commercial launch of **Samsung Bioepis's Epysqli® (eculizumab-aagh)**.

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aBLA Applications and FDA Activity

Epysqli® (eculizumab-aagh):

- On July 19, 2024, the FDA approved **Samsung Bioepis's Epysqli® (eculizumab-aagh)** as an interchangeable biosimilar of **Alexion's Soliris® (eculizumab)**.

BAT2206 (ustekinumab):

- On July 24, 2024, **Bio-Thera Solutions** announced the FDA acceptance of an aBLA, with a request for interchangeability, for **BAT2206 (ustekinumab)**, a proposed biosimilar of **Janssen** / **Johnson & Johnson's Stelara® (ustekinumab)**.

CDER Purple Book Updates

Kisunla™ (donanemab-azbt):

- On July 2, 2024, the FDA approved **Eli Lilly's Kisunla™ (donanemab-azbt)** for Alzheimer's disease.

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

Lytenava™ (bevacizumab):

- On July 8, 2024, **Outlook Therapeutics** announced the approval of **Lytenava™ (bevacizumab)**, the first biosimilar of **Genentech's** **Avastin® (bevacizumab)** approved for an on-label ophthalmic condition, the treatment of wet AMD, in the U.K.

Omlyclo® (CT-P39) (omalizumab):

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

Avzivi® (bevacizumab-tnjn):

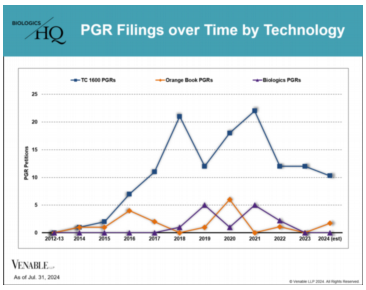
- On July 30, 2024, **Bio-Thera Solutions** announced the approval of **Avzivi® (bevacizumab-tnjn)**, a biosimilar of **Genentech's** **Avastin® (bevacizumab)**, in the E.U.

Steqeyma™ (CT-P43) (ustekinumab):

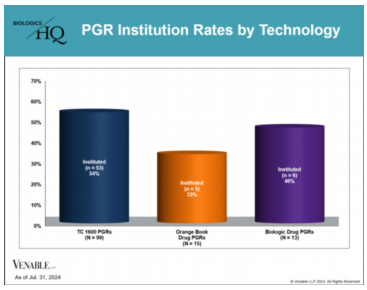
- On July 31, 2024, **Celltrion** announced the approval of **Steqeyma™ (ustekinumab)**, a biosimilar of **Janssen** / **Johnson & Johnson's** **Stelara® (ustekinumab)**, in Canada.

STATISTICS

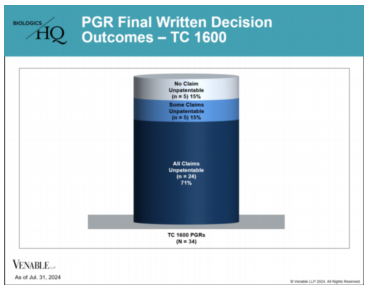
PGR Filings Over Time by Technology



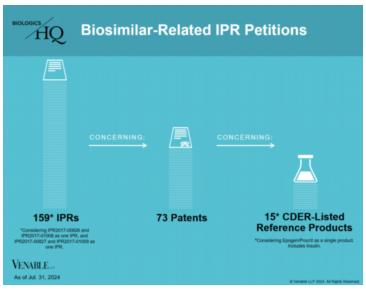
PGR Institution Rates by Technology



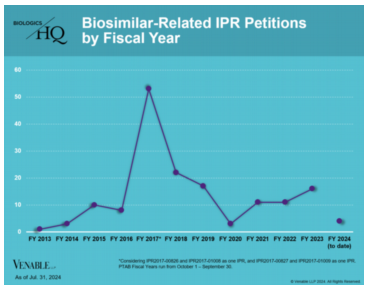
PGR Final Written Decision Outcomes – TC 1600



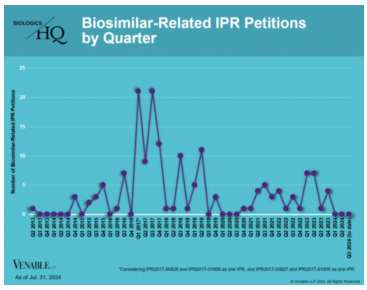
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



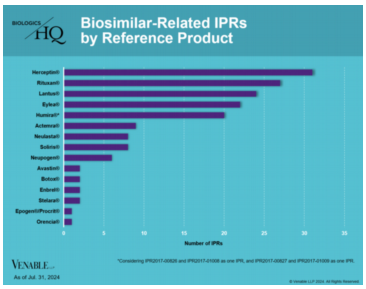
Biosimilar-Related IPR Petitions by Quarter



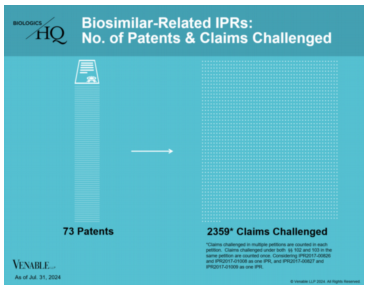
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

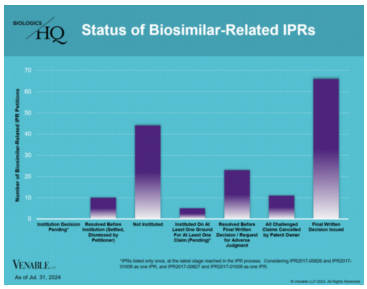
Status of Biosimilar-Related IPRs



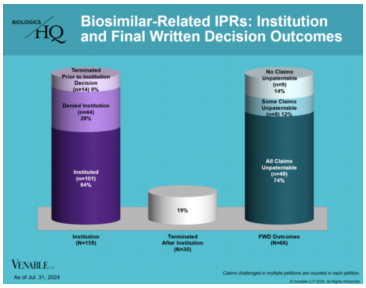
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



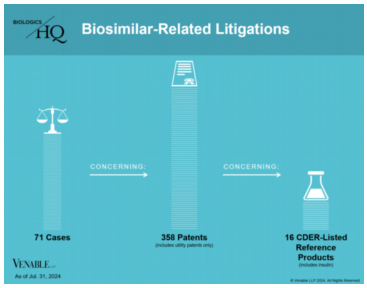
[Biosimilar-Related Litigations]



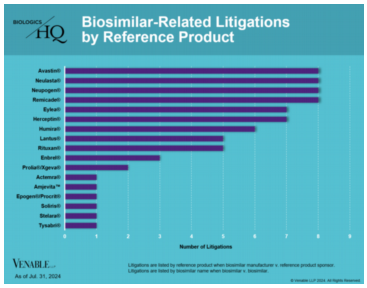
[Biosimilar-Related Litigations by Reference Product]



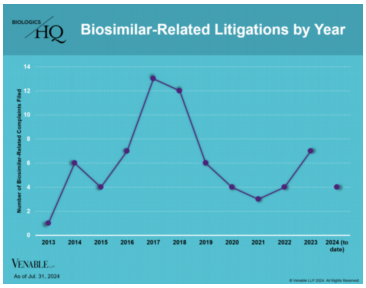
[Biosimilar-Related Litigations by Year]



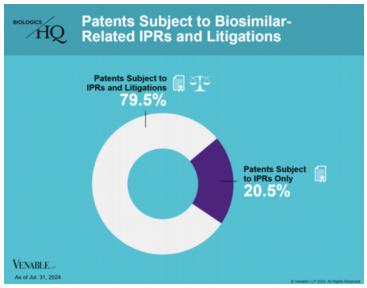
[Patents Subject to Biosimilar-Related IPRs and Litigations]



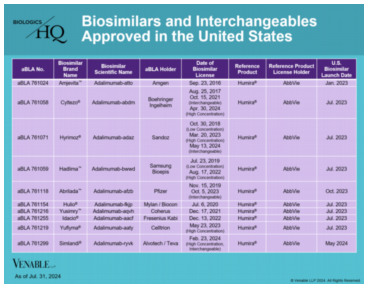
[Biosimilars and Interchangeables Approved in the United States]



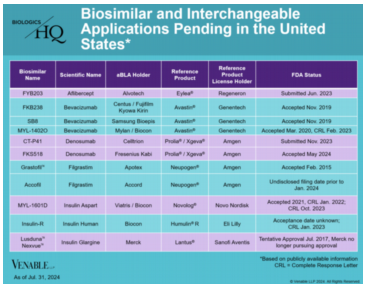
[Biosimilar and Interchangeable Applications Pending in the United States]



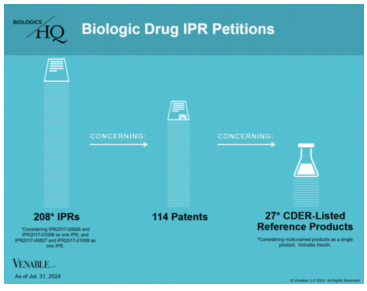
[Biologic Drug IPR Petitions]



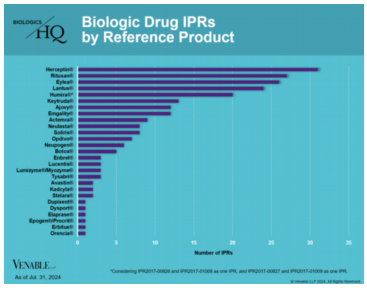
[Biologic Drug IPRs by Reference Product]



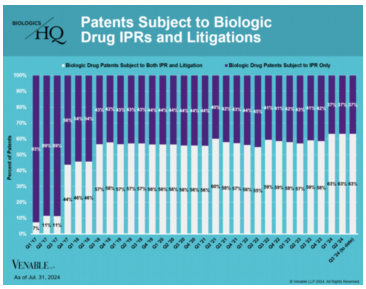
[Patents Subject to Biologic Drug IPRs and Litigations]

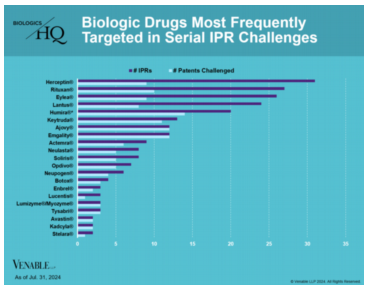


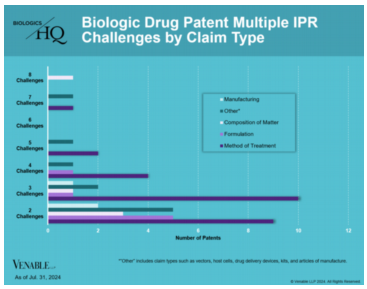
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]



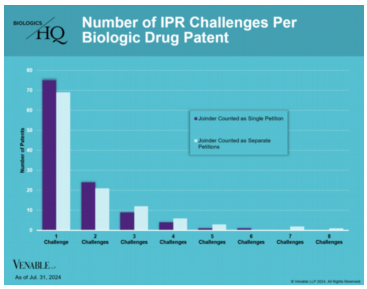
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

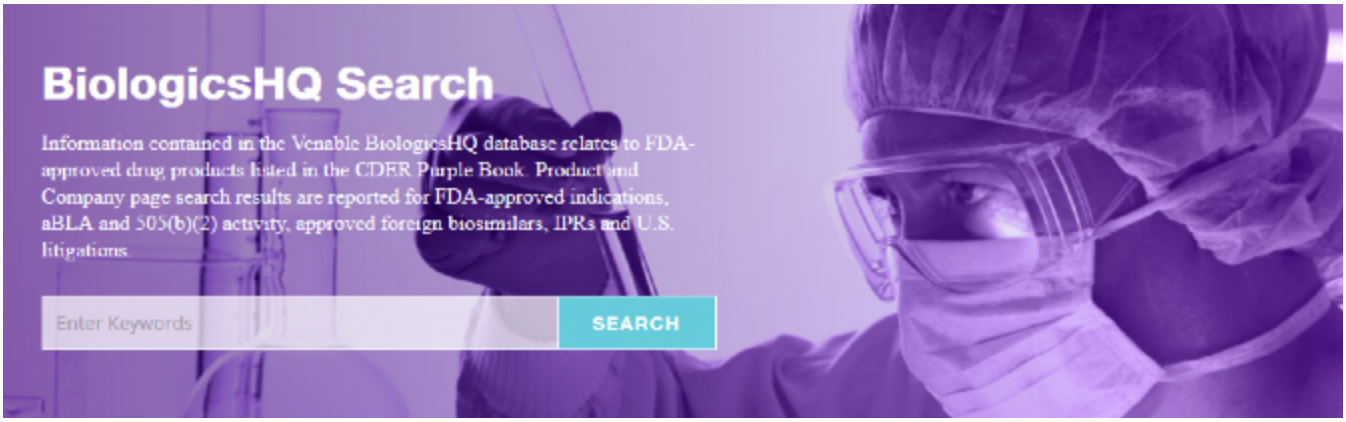






Number of IPR Challenges Per Biologic Drug Patent





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