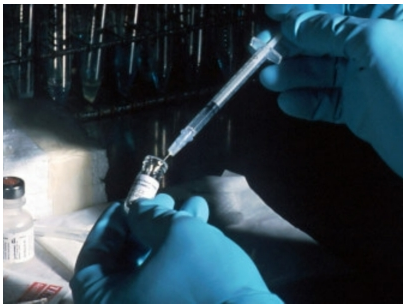
BIOLOGICS HQ

VENABLE LLP

October 11, 2024

LATEST NEWS



Preliminary Injunction Against Amgen's EYLEA® Biosimilar Pavblu™ Denied

By: Robert S. Schwartz, Ph.D.

On September 23, 2024, Regeneron's motion for a preliminary injunction against the commercial launch of Amgen's EYLEA® (aflibercept) biosimilar Pavblu™ (aflibercept-ayyh) was denied in Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). Regeneron filed CAFC Appeal No. 24-2351 on the same day the Order issued. On September 24, 2024, Regeneron filed a motion for a temporary injunction pending appeal. On September 25, 2024, the Federal Circuit issued a temporary injunction preventing Pavblu™'s launch while the Court considers the motion for injunction pending appeal.

Fresenius Kabi and Formycon Announce Approval of Stelara® Biosimilar Otulfi™ in the U.S. and E.U.

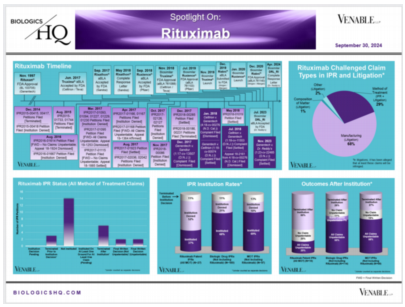
By: Robert S. Schwartz, Ph.D.

On September 27, 2024, the FDA approved a fourth biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab): Fresenius Kabi and Formycon's Otulfi™ (ustekinumab-aauz). Fresenius and Formycon announced Otulfi™'s approval in the E.U. on the same day. Otulfi™'s FDA-approval follows Amgen's Wezlana™ (ustekinumab-auub), approved as an interchangeable biosimilar in October 2023, Alvotech and Teva's Selarsdi™ (ustekinumab-aekn), approved in April 2024, and Samsung Bioepis and Sandoz's Pyzchiva® (ustekinumab-ttwe), approved as interchangeable in June 2024.

PTAB Grants Institution of Eight IPRs challenging The Johns Hopkins University Pembrolizumab Patents

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

Earlier this year, Merck requested *inter partes review* ("IPR") of a number of patents owned by the Johns Hopkins University ("JHU"). The patents are directed to methods of treating cancers in patients with high mutational burdens, such as microsatellite instable ("MSI") cancer, by using anti-PD-1 antibodies, which includes pembrolizumab that is sold by Merck under the trade name Keytruda®. Previously, we reported that in June 2024 the PTAB granted institution of one such IPR – IPR2024-00240 – concerning JHU's U.S. Patent No. 11,591,393 (*see* PTAB Grants Institution of IPR Challenging The Johns Hopkins University Pembrolizumab Patent). The PTAB has now granted institution of all of the remaining IPRs filed by Merck based on similar grounds as the -00240 IPR, for both anticipation (35 U.S.C. § 102) and obviousness (35 U.S.C. § 103) challenges in each IPR.



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®, Riabni™ and DRL_RI), 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 September 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 September 30, 2024.

Read More News

UPDATES

IPRs and PGRs

Soliris® (eculizumab):

- On September 4, 2024, the PTAB terminated **Alexion** and **Samsung Bioepis's** IPR2023-00933 (U.S. Patent No. 9,732,149), IPR2023-00998 (U.S. Patent No. 9,718,880), IPR2023-00999 (U.S. Patent No. 9,725,504), IPR2023-01069 (U.S. Patent No. 10,590,189), and IPR2023-01070 (U.S. Patent No. 10,703,809) due to settlement after institution.

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

- On September 23, 2024, in CAFC Appeal No. 23-1334, the Federal Circuit affirmed the PTAB's finding that all challenged claims of **Novartis's** U.S. Patent No. 9,220,631 are unpatentable in **Regeneron's** IPR2021-00816.

Keytruda® (pembrolizumab):

- On September 23, 2024, the PTAB instituted **Merck's** IPRs against The John's Hopkin's University, including IPR2024-00622 (U.S. Patent No. 10,934,356), IPR2024-00623 (U.S. Patent No. 11,325,974), IPR2024-00624 (U.S. Patent No. 11,325,975), and IPR2024-00625 (U.S. Patent No. 11,339,219).
- On September 27, 2024, the PTAB instituted **Merck's** IPRs against The John's Hopkin's University, including IPR2024-00647 (U.S. Patent No. 11,649,287), IPR2024-00649 (U.S. Patent No. 11,629,187), and IPR2024-00650 (U.S. Patent No. 11,634,491).

Litigations

Soliris® (eculizumab):

- On September 3, 2024, the Court ordered **Alexion** and **Samsung Bioepis's** joint motion to voluntarily dismiss Case No. 1:24-cv-00005 (D. Del.) and terminated the case. On September 3, 2024, the Court ordered **Alexion** and **Samsung Bioepis's** joint motion to voluntarily dismiss the related CAFC Appeal No. 24-1829 appealing the preliminary injunction issued against the commercial launch of **Epysqli® (eculizumab-aagh)**.

Eylea® (aflibercept):

- On September 23, 2024, the Court denied **Regeneron's** motion for a preliminary injunction against **Amgen's** biosimilar **Pavblu™ (aflibercept-ayyh)** in Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). On the same day, **Regeneron** filed CAFC Appeal No. 24-2351 appealing the denial, along with a motion for

an injunction pending appeal. On September 25, 2024, the Federal Circuit issued a temporary injunction while it considers the injunction pending appeal motion.

aBLA Applications and FDA Activity

Otulfi™ (ustekinumab-aauz):

- On September 27, 2024, the FDA approved **Fresenius Kabi** and **Formycon's Otulfi™ (ustekinumab-aauz)**, a biosimilar of **Janssen** and **Johnson & Johnson's Stelara® (ustekinumab)**.

CDER Purple Book Updates

Ebglyss™ (mosunetuzumab-axgb):

- On September 13, 2024, the FDA approved **Eli Lilly's Ebglyss™ (lebrikizumab-lbkz)**.

Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq):

- On September 13, 2024, the FDA approved **Genentech's Ocrevus Zunovo™ (ocrelizumab and hyalronidase-ocsq).**

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

Tuznue™ (trastuzumab):

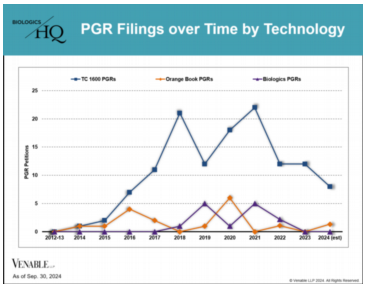
- On September 23, 2024, **Prestige BioPharma** announced the approval of **Tuznue™ (trastuzumab)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, in the E.U.

Otulfi™ (ustekinumab-aauz):

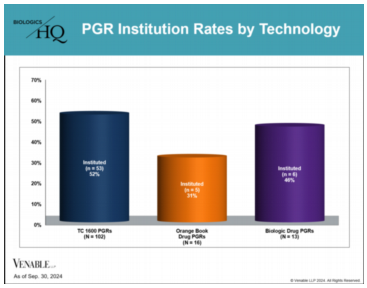
- On September 27, 2024, **Fresenius Kabi** and **Formycon** announced the approval of **Otulfi™ (ustekinumab-aauz)**, a biosimilar of **Janssen** and **Johnson & Johnson's Stelara® (ustekinumab)**, in the E.U.

STATISTICS

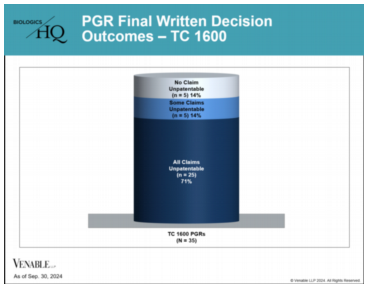
PGR Filings Over Time by Technology



PGR Institution Rates by Technology



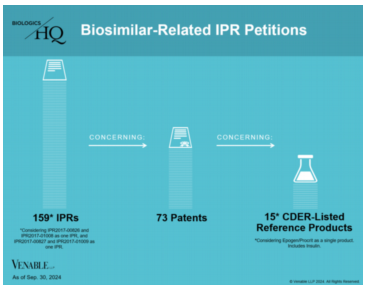
PGR Final Written Decision Outcomes – TC 1600



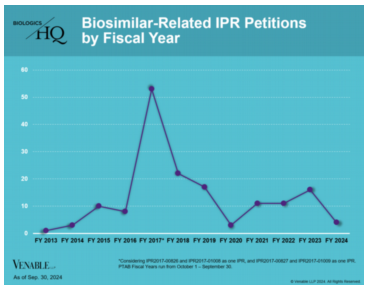
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

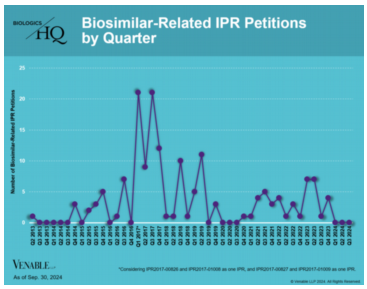
Biosimilar-Related IPR Petitions by Quarter



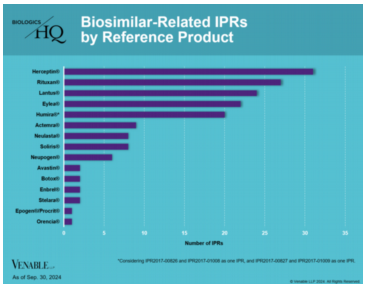
[Biosimilar-Related IPRs by Reference Product]



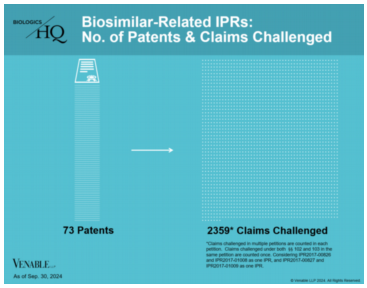
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



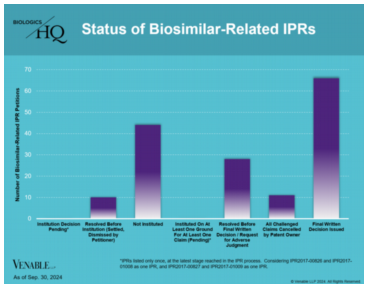
[Status of Biosimilar-Related IPRs]



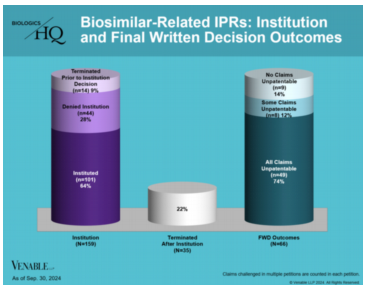
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



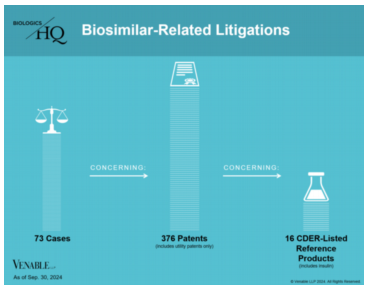
[Biosimilar-Related Litigations]



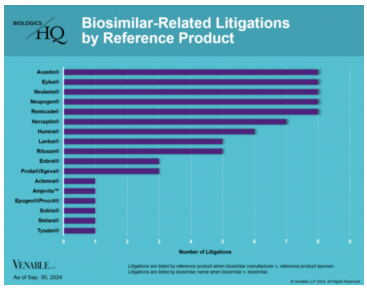
[Biosimilar-Related Litigations by Reference Product]



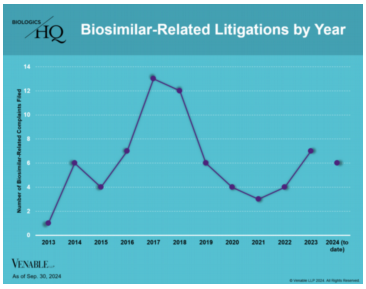
[Biosimilar-Related Litigations by Year]



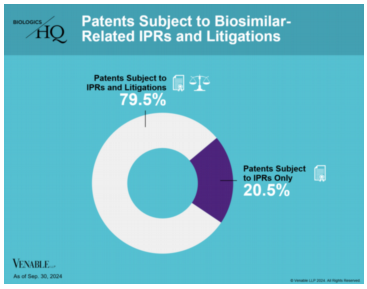
[Patents Subject to Biosimilar-Related IPRs and Litigations]



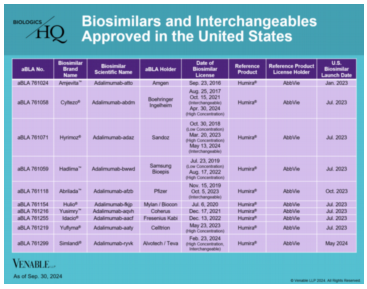
[Biosimilars and Interchangeables Approved in the United States]



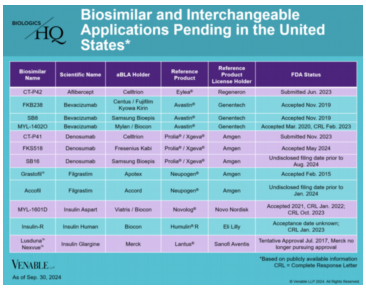
[Biosimilar and Interchangeable Applications Pending in the United States]



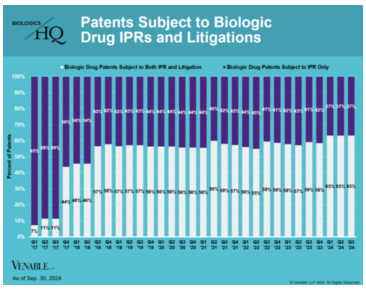
[Biologic Drug IPR Petitions]

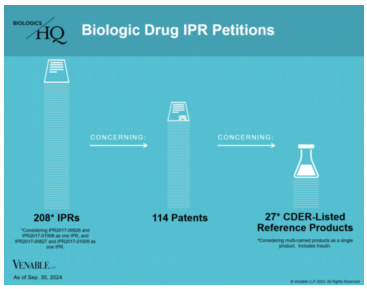


[Biologic Drug IPRs by Reference Product]

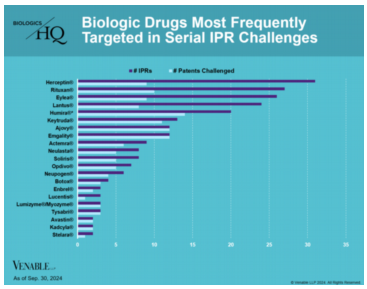


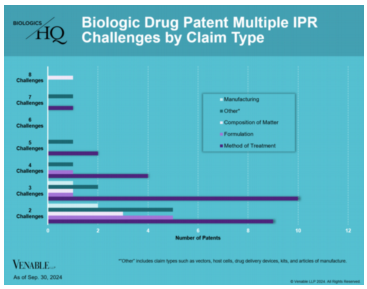
Patents Subject to Biologic Drug IPRs and Litigations



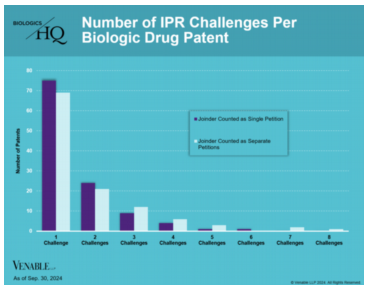


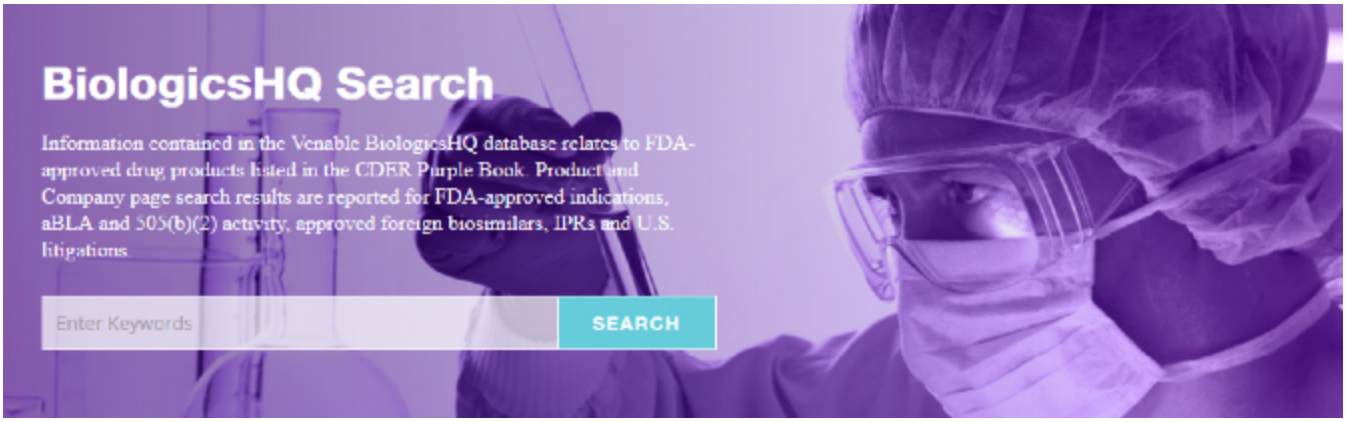
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges





Number of IPR Challenges Per Biologic Drug Patent





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