BIOLOGICS HQ

VENABLE LLP

December 11, 2024

LATEST NEWS

Amgen Launches Pavblu™ as the First EYLEA® Biosimilar in the U.S.

By: Robert S. Schwartz, Ph.D.

Amgen announced during its Q3 2024 Earnings Call that it had launched Pavblu™ (aflibercept-ayyh) as the first biosimilar of Regeneron's EYLEA® (aflibercept) to be marketed in the U.S. The launch follows the Federal Circuit's decision on October 22, 2024 (CAFC Appeal No. 24-2351) to deny a temporary injunction that would prevent Pavblu™ from launching at-risk while Regeneron appeals an earlier District Court (Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.)) denial of a preliminary injunction against Pavblu™ (previously reported Amgen Plans At-Risk Launch of EYLEA® Biosimilar Pavblu™ After Federal Circuit Lifts Temporary Injunction). The litigation and appeal remain ongoing.

BPCIA Lawsuit Against Accord's Proposed Prolia® / Xgeva® Biosimilar Filed by Amgen

By: Robert S. Schwartz, Ph.D.

On November 13, 2024, Amgen filed Case No. 5:24-cv-00642 (E.D.N.C.) against Accord BioPharma and Intas Pharmaceuticals, alleging INTP23, their proposed Prolia® / Xgeva® (denosumab) biosimilar, would infringe 34 of Amgen's patents. The patents asserted include two with composition claims, four with composition of matter claims, 32 with manufacturing claims, and one with claims directed to host cells.

Biosimilar Updates: EYLEA® IPR Filings, Herceptin® Biosimilar Hercessi™ Launch, Stelara® Biosimilar Yesintek™ Approval

By: Robert S. Schwartz, Ph.D.

Two IPRs Filed Against Regeneron's EYLEA® (aflibercept) Patent

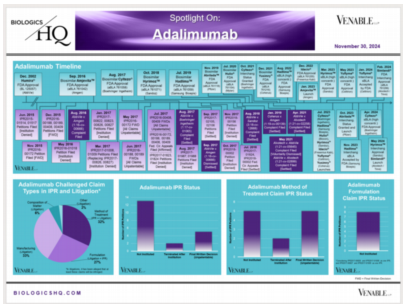
- **On November 20, 2024, Samsung Bioepis filed IPR2025-00176 against Regeneron's U.S. Patent No. 11,084,865 ("the '865 patent"), challenging as obvious 48 claims (claims 1-12, 14-17, 19-20, 22-36, 39-42, 44-45, and 47-55) covering ophthalmic formulations of a vascular endothelial growth factor (VEGF) in vials and prefilled syringes. On December 2, 2024, Formycon filed IPR2025-00233 against the same patent, requesting joinder with Samsung Bioepis's petition if it is instituted.**

Herceptin® (trastuzumab) Biosimilar Hercessi™ Launch Announced

- **On November 29, 2024, Henlius announced that the first commercial shipment of Hercessi™ (trastuzumab-strf), a biosimilar of Genentech's Herceptin® (trastuzumab), had been sent to the U.S.**

Sixth Stelara® (ustekinumab) Biosimilar Approved: Biocon's Yesintek™

- **On November 29, 2024, the FDA approved Biocon's Yesintek™ (ustekinumab-kfce) as the sixth biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab). Biocon previously settled with Janssen, agreeing to a launch date for Yesintek™ as early as February 22, 2025 (previously reported Stelara® Biosimilar Updates: Settlement of IPR and FDA Review of Proposed Biosimilar).**



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 November 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 November 30, 2024.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On November 20, 2024, **Samsung Bioepis** filed IPR2025-00176 **Regeneron's** U.S. Patent No. 11,084,865.

Litigations

Prolia® / Xgeva® (denosumab):

- On November 13, 2024, **Amgen** filed Case No. 5:24-cv-00642 (E.D.N.C.) against **Accord** and **Intas's** proposed biosimilar **INTP23 (denosumab)**.

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

- On November 13, 2024, the Court granted **Novartis** and **Regeneron's** stipulation of dismissal of Case No. 1:20-cv-00690 (N.D.N.Y.), after the claims of the sole asserted patent (U.S. Patent No. 9,220,631) were found unpatentable in IPR2021-00816.

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aBLA Applications and FDA Activity

Pavblu™ (ABP 938) (aflibercept-ayyh):

- On its Q3 2024 Earnings Call, **Amgen** announced the launch of **Pavblu™ (aflibercept-ayyh)** as the first marketed biosimilar of **Regeneron's Eylea® (aflibercept)** in the U.S.

INTP23 (denosumab):

- A November 13, 2024 BPCIA litigation Complaint (Case No. 5:24-cv-00642 (E.D.N.C.)) noted that the FDA accepted **Accord** and **Intas's** aBLA for **INTP23 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**, on an undisclosed date.

Hercessi™ (trastuzumab-strf):

- On November 29, 2024, **Henlius** announced the commercial launch of **Hercessi™ (trastuzumab-strf)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**.

Yesintek™ (Bmab 1200) (ustekinumab-kfce):

- On November 29, 2024, the FDA approved **Biocon's Yesintek™ (ustekinumab-kfce)** as a biosimilar of **Janssen** / **Johnson & Johnson's Stelara® (ustekinumab)**.

CDER Purple Book Updates

Auctazyl® (obecabtagene autoleucel):

- On November 8, 2024, the FDA approved **Autolus's Aucatzyl® (obecabtagene autoleucel).**

Kebilidi® (eladocagene exuparvovec-tneq):

- On November 13, 2024, the FDA approved **PTC Therapeutics' Kebilidi® (eladocagene exuparvovec-tneq).**

Regenecyte™ (HPC, Cord Blood):

- On November 20, 2024, the FDA approved **StemCyte's Regenecyte™ (HPC, Cord Blood).**

Ziihera® (zanidatamab-hrii):

- On November 20, 2024, the FDA approved **Jazz Pharmaceuticals' Ziihera® (zanidatamab-hrii)**.

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

Afqlir® (aflibercept-abzv):

- On November 15, 2024, **Sandoz** announced the approval of **Afqlir® (aflibercept-abzv)**, a biosimilar of **Regeneron's Eylea® (aflibercept)**, in the E.U.

Opuviz™ (aflibercept-yszy):

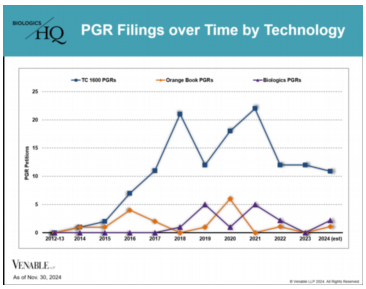
- On November 18, 2024, **Samsung Bioepis** and **Biogen** announced the approval of **Opuviz™ (aflibercept-yszy)**, a biosimilar of **Regeneron's Eylea® (aflibercept)**, in the E.U.

Stoboclo® / Osenvelt® (CT-P41) (denosumab):

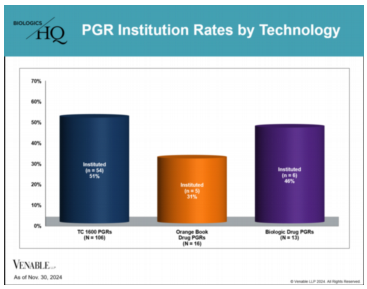
- On November 22, 2024, **Celltrion** announced the approval of **Stoboclo® / Osenvelt® (CT-P41) (denosumab)**, biosimilars of **Amgen's Prolia® / Xgeva® (denosumab)**, in South Korea.

STATISTICS

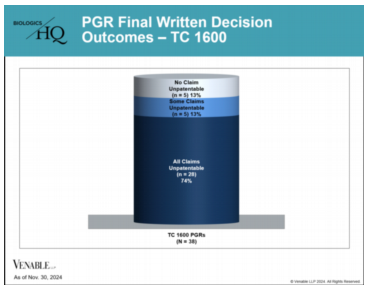
PGR Filings Over Time by Technology



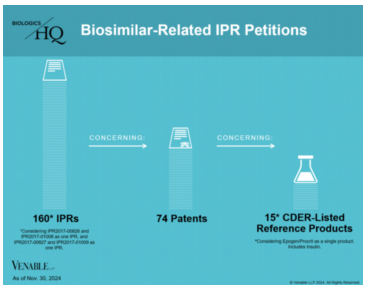
PGR Institution Rates by Technology



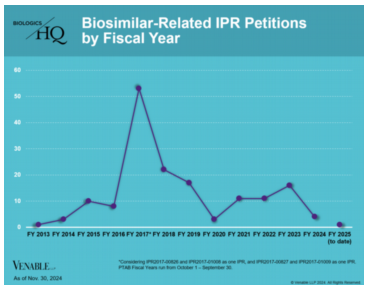
PGR Final Written Decision Outcomes – TC 1600



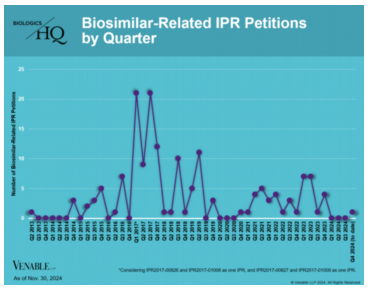
Biosimilar-Related IPR Petitions



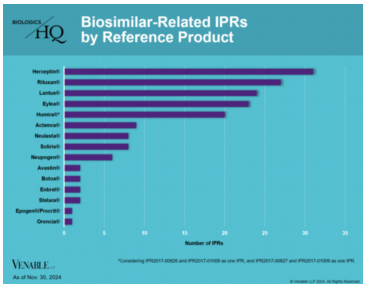
Biosimilar-Related IPR Petitions by Fiscal Year



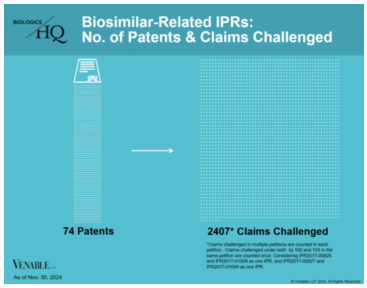
Biosimilar-Related IPR Petitions by Quarter



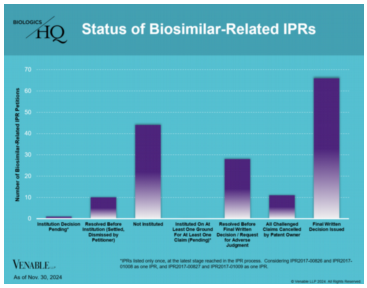
Biosimilar-Related IPRs by Reference Product



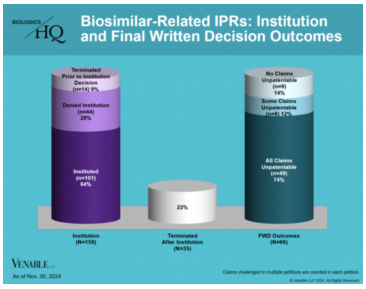
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



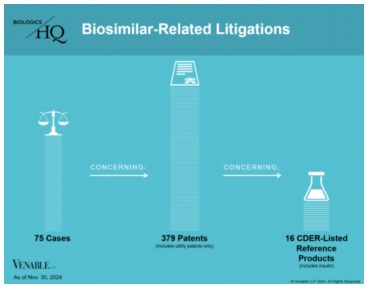
Status of Biosimilar-Related IPRs



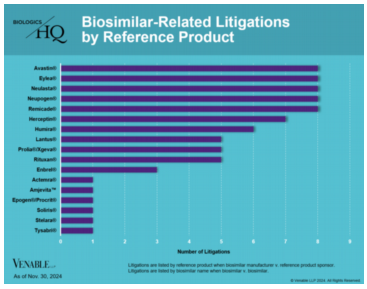
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



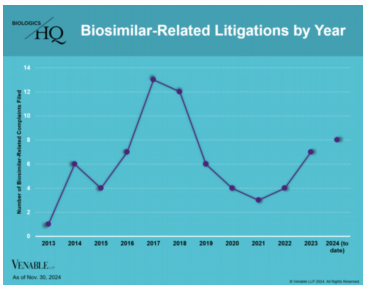
Biosimilar-Related Litigations by Reference Product

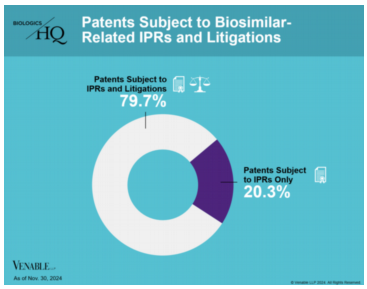


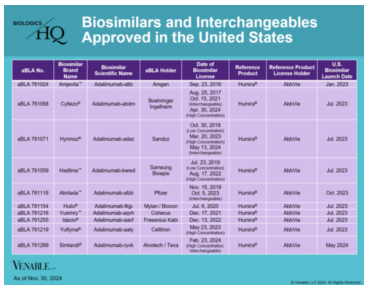
Biosimilar-Related Litigations by Year

Patents Subject to Biosimilar-Related IPRs and Litigations

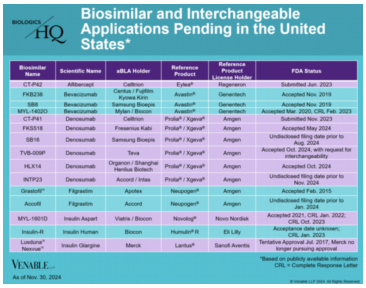
Biosimilars and Interchangeables Approved in the United States



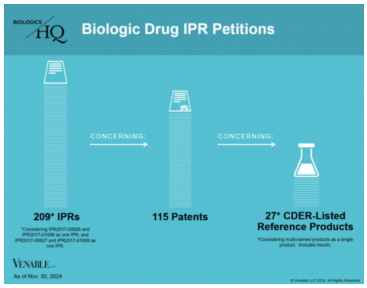




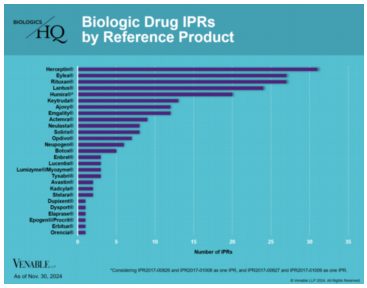
Biosimilar and Interchangeable Applications Pending in the United States



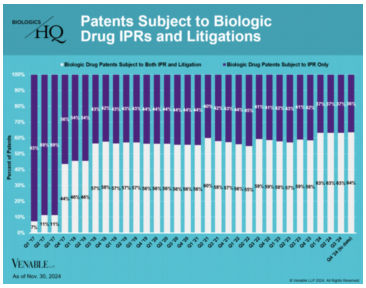
Biologic Drug IPR Petitions



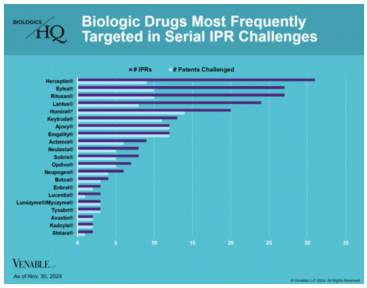
Biologic Drug IPRs by Reference Product



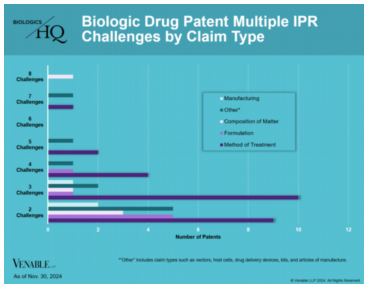
Patents Subject to Biologic Drug IPRs and Litigations



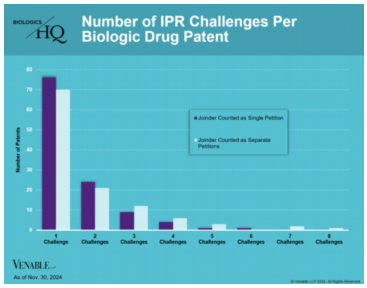
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

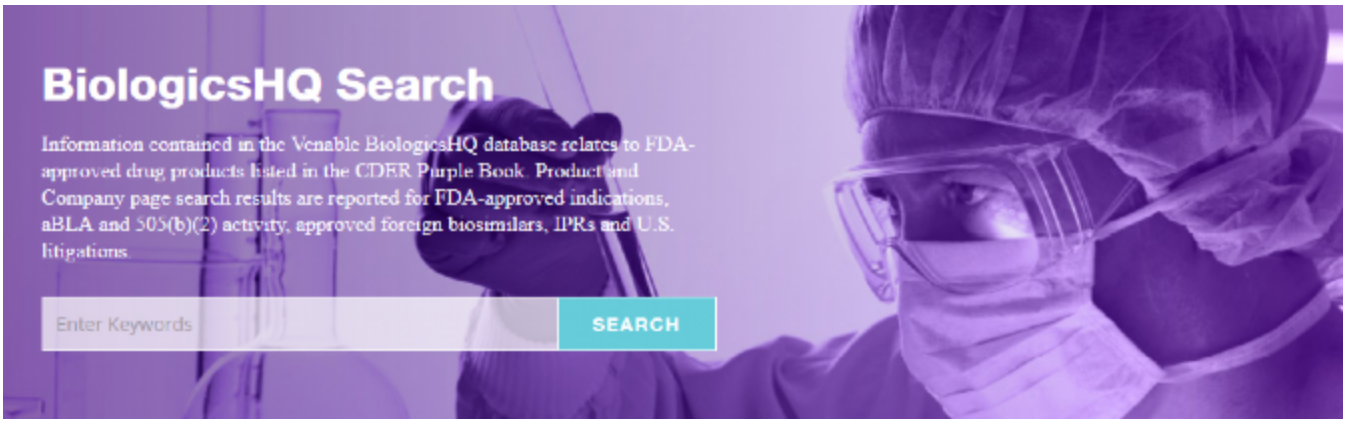


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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