

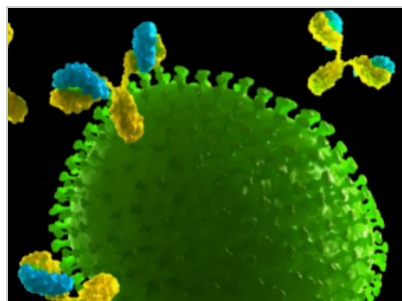
MONTHLY INJECTION



June 12, 2023



LATEST NEWS

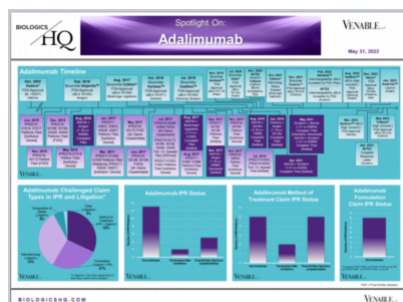


Supreme Court Affirms Lack of Enablement in *Amgen v. Sanofi* Antibody Patent Dispute

By: [Kaitlyn M. Rodnick](#), [Ha Kung Wong](#), and [Megan S. Woodworth](#)

On May 18, 2023, the Supreme Court issued a unanimous decision in [Amgen v. Sanofi](#), construing the statutory enablement requirement.

Agreeing with the lower courts, the Court found that [Amgen](#) failed to enable all that it had claimed, even allowing for a reasonable degree of experimentation.



Spotlight On: Actemra® (tocilizumab)

Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria® (pegfilgrastim-apgf) / Fylmetra™ (pegfilgrastim-apgf) / Stimufend® (pegfilgrastim-fpgk)

Spotlight On: Herceptin® (trastuzumab) / Ogivri® (trastuzumab-dkst) / Hersuma® (trastuzumab-pkrb) / Ontuzant® (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-szsz) / 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 May 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 May 31, 2023.

Read
More
News

UPDATES

IPRs and PGRs

Lantus[®] (insulin glargine recombinant):

- On May 9, 2023, in Sanofi v. Mylan Fed. Cir. Appeal No. 21-1981, the Federal Circuit reversed the PTAB's FWD finding all challenged claims unpatentable in IPR2019-01657.

Soliris[®] (eculizumab):

- On May 18, 2023, Samsung Bioepis filed IPR2023-00933 against Alexion.
- On May 31, 2023, Samsung Bioepis filed IPR2023-00998 and IPR2023-00999 against Alexion.

Litigations

Prolia[®] / Xgeva[®] (denosumab):

- On May 1, 2023, Amgen filed Case No. 1:23-cv-02406 (D.N.J.) against Sandoz related to proposed biosimilar GP2411 (denosumab).

Praluent[®] (alirocumab) / Repatha[®] (evolocumab):

- On May 18, 2023, in **Amgen** v. **Sanofi** Case No. 21-757, the Supreme Court affirmed the Federal Circuit (Appeal No. 20-1074) and District Court's (Case No. 1:14-cv-01317 (D.Del.)) finding of lack of enablement.

Stelara[®] (ustekinumab):

- On May 23, 2023, the court ordered the stipulated dismissal due to settlement between **Janssen** and **Amgen** in Case No. 1:22-cv-01549 (D. Del.). Under the confidential settlement agreement, **Amgen** will be able to sell its proposed biosimilar **ABP 654 (ustekinumab)** no later than January 1, 2025, if approved.

aBLA Applications and FDA Activity

Fylnetra[™] (pegfilgrastim-pbbk):

- On May 16, 2023, **Amneal** and **Kashiv Biosciences** announced the launch of **Fylnetra[™] (pegfilgrastim-pbbk)**, a biosimilar of **Amgen's Neulasta[®] (pegfilgrastim)**.

Cyltezo[®] (adalimumab-adbm):

- On May 22, 2023, the FDA approved an autoinjector version of **Boehringer Ingelheim's Cyltezo[®] (adalimuma-adbm)**, a biosimilar and interchangeable of **AbbVie's Humira[®] (adalimumab)**.

Yuflyma[®] (adalimumab-aaty):

- On May 23, 2023, the FDA approved **Celltrion's Yuflyma[®] (adalimumab-aaty)**, a high-concentration, citrate-free biosimilar of **AbbVie's Humira[®] (adalimumab)**.

CDER Purple Book Updates

Elfabrio[®] (pegunigalsidase alfa-iwxj):

- On May 9, 2023, the FDA approved **Chiesi Farmaceutici's Elfabrio[®] (pegunigalsidase alfa-iwxj)**.

Epkinly[™] (epcoritamab-bysp):

- On May 19, 2023, the FDA approved **Genmab's Epkinly[™] (epcoritamab-bysp)**.

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

Epysqli[™] (eculizumab):

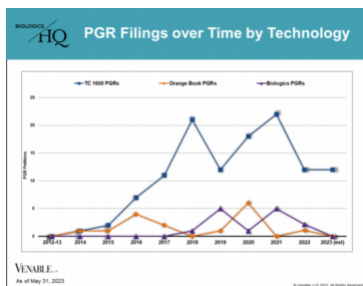
- On May 30, 2023, **Samsung Bioepis** announced the approval of **Epysqli[™] (eculizumab)**, a biosimilar of **Alexion's Soliris[®] (eculizumab)** in the E.U.

STATISTICS

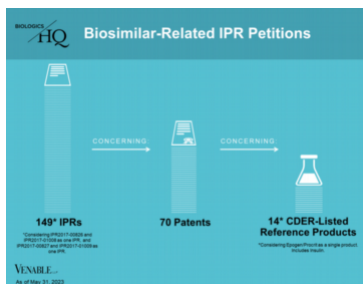
**PGR Filings
Over Time
by Technology**

**PGR Institution
Rates by
Technology**

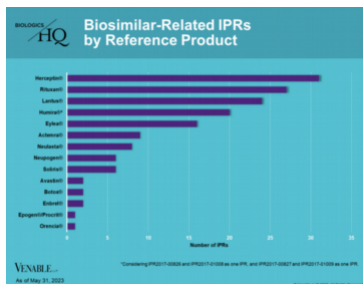
**PGR Final Written
Decision Outcomes –
TC 1600**



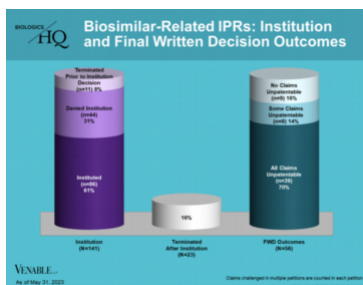
Biosimilar-Related IPR Petitions



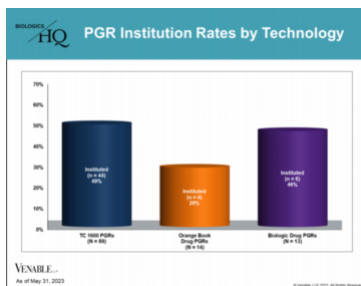
Biosimilar-Related IPRs by Reference Product



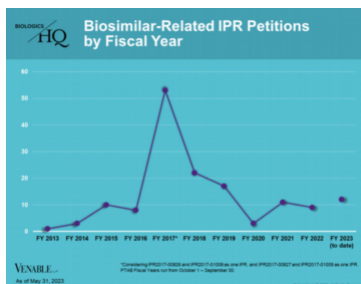
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



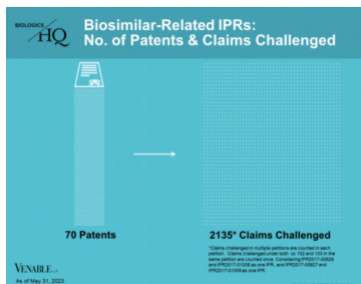
Biosimilar-Related Litigations by Year



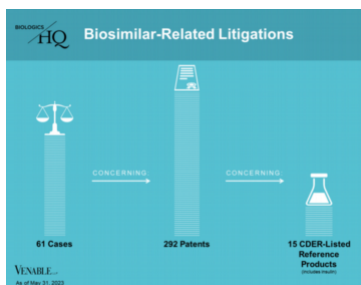
Biosimilar-Related IPR Petitions by Fiscal Year



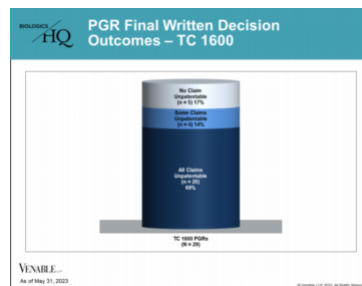
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



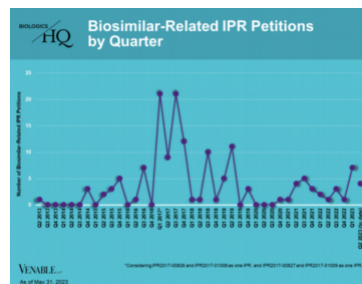
Biosimilar-Related Litigations



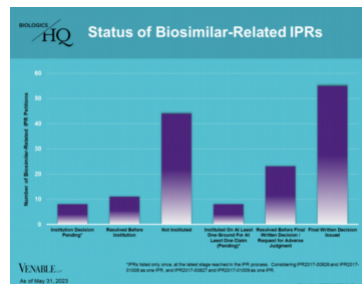
Patents Subject to Biosimilar-Related IPRs and Litigations



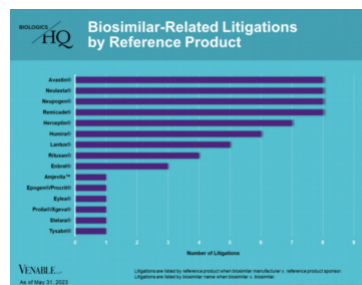
Biosimilar-Related IPR Petitions by Quarter



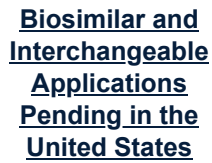
Status of Biosimilar-Related IPRs



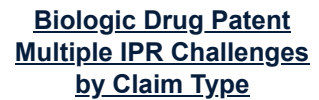
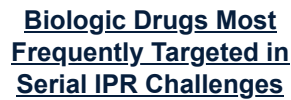
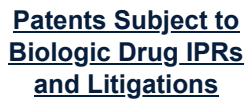
Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States



Biologic Drug
IPRs by Reference
Product



BiologicsHQ Search

Information contained in the Venable BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

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