BIOLOGICS HQ

VENABLE LLP

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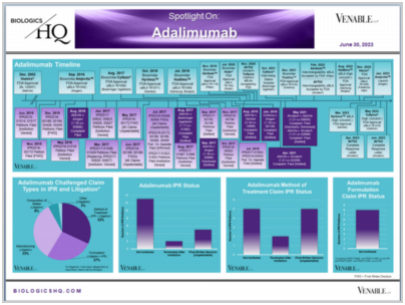
LATEST NEWS

Senators Tillis and Coons Reintroduce Patent Eligibility Reform Legislation

By: April Breyer Menon and Ha Kung Wong

On June 22, 2023, Senators Thom Tillis (R-N.C.) and Chris Coons (D-Del.) announced the reintroduction of legislation to reform the patent eligibility requirements under 35 U.S.C. § 101. The "Patent Eligibility and Restoration Act of 2023" seeks to clarify which inventions are eligible for patenting in the U.S. According to the bill, judicial exceptions to § 101 have rendered an increasing number of inventions ineligible for patent protection, and judicial efforts to interpret the exceptions have led to "extensive confusion and a lack of consistency."

Under the bill, all judicial exceptions to patent eligibility would be eliminated. Any invention or discovery that can be claimed as a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, would be eligible for patent protection, except as explicitly provided in the bill.



Spotlight On: Actemra® (tocilizumab)

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)

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-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®, 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 June 30, 2023.

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, 2023.

Read More News

UPDATES

IPRs and PGRs

Soliris® (eculizumab):

- On June 16, 2023, **Samsung Bioepis** filed IPR2023-01069 and IPR2023-01070 agains **Alexion**.

Stelara® (ustekinumab):

- On June 21, 2023, **Samsung Bioepis** filed IPR2023-01103 against **Janssen**.

Botox® (onabotulinumtoxinA) / Dysport® (abobotulinumtoxinA):

- On June 27, 2023, in Appeal No. 22-1165, the Federal Circuit affirmed the PTAB's final written decision denying the non-contingent motion to amend in PGR2019-00062 between **Medy-Tox** and **Galderma**.

Litigations

Humira® (adalimumab) / Yusimry™ (adalimumab-aqvh):

- On June 14, 2023, **Coherus** filed a **Form 8-K** with the SEC related to a dispute with **AbbVie** over a settlement and license agreement for **Coherus's Yusimry™ (adalimumab-aqvh)**, a biosimilar of **AbbVie's Humira® (adalimumab)**. According to the filing, **AbbVie** alleged **Coherus** breached their settlement and license agreement because **Coherus** announced on June 1, 2023 its pricing agreement with Mark Cuban Cost Plus Drug Company and its plans to offer **Yusimry** to customers beginning in July 2023. **Coherus** filed a motion for a temporary restraining order against **AbbVie** in the Delaware Court of Chancery on June 13, 2023 to prevent **AbbVie** from terminating their agreement. In response, **AbbVie** filed a motion for a preliminary injunction against **Coherus** on the same day. The parties settled their dispute with **AbbVie** agreeing not to terminate the license and settlement agreement, and that it will not terminate the agreement in the future unless it first serves a new notice of breach and affords **Coherus** an opportunity to cure any alleged breach.

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aBLA Applications and FDA Activity

AVT04 (ustekinumab):

- On June 12, 2023, **Alvotech** and **Teva** announced a settlement and license agreement with **Johnson & Johnson** related to **AVT04 (ustekinumab)**, a proposed biosimilar of **Johnson & Johnson / Janssen's Stelara® (ustekinumab)**, granting a license entry date no later than February 21, 2025.

Xlucane™ (ranibizumab):

- On June 22, 2023, **Xbrane** and **STADA** announced the FDA acceptance of an aBLA for **Xlucane™ (ranibizumab)**, a proposed biosimilar of **Genentech's Lucentis® (ranibizumab)**, with a Biosimilar User Fee Amendment (BsUFA) goal date of April 21, 2024.

AVT02 (adalimumab):

- On June 28, 2023, **Alvotech** announced the receipt of a Complete Response Letter from the FDA for its aBLA for an interchangeable designation for **AVT02 (adalimumab)**, a proposed biosimilar and interchangeable of **AbbVie's Humira® (adalimumab)**. **Alvotech** plans to resubmit its aBLA with data to support interchangeability.

FYB203 (aflibercept):

- On June 29, 2023, **Formycon**, and **Klinge Biopharma** announced the submission of an aBLA to the FDA for **FYB203 (aflibercept)**, a proposed biosimilar of **Regeneron's Eylea® (aflibercept)**.

CT-P42 (aflibercept):

- On June 30, 2023, **Celltrion** announced the submission of an aBLA to the FDA for **CT-P42 (aflibercept)**, a proposed biosimilar of **Regeneron's Eylea® (aflibercept)**.

CDER Purple Book Updates

Columvi™ (glofitamab-gxbm):

- On June 15, 2023, the FDA approved **Genentech's Columvi™ (glofitamab-gxbm)**.

Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc):

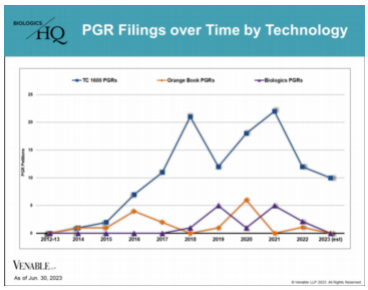
- On June 20, 2023, the FDA approved **Argenx's Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)**.

Rystiggo® (rozanolixizumab-noli):

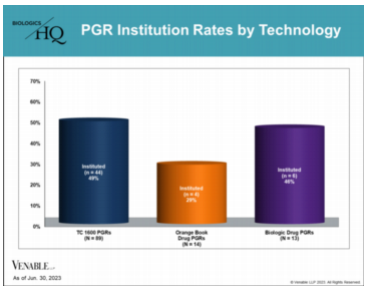
- On June 26, 2023, the FDA approved **UCB's Rystiggo® (rozanolixizumab-noli)**.

STATISTICS

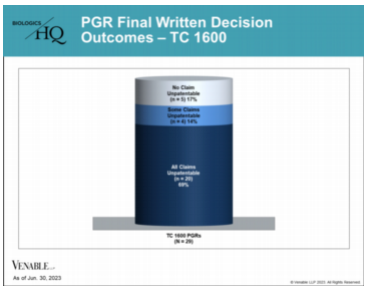
PGR Filings Over Time by Technology



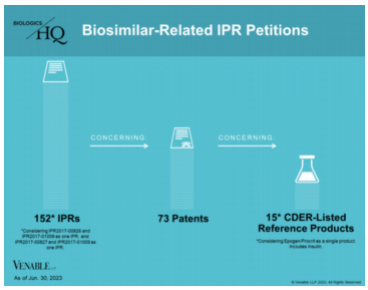
PGR Institution Rates by Technology



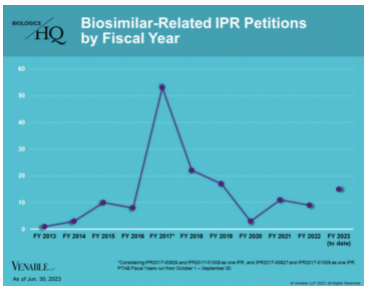
PGR Final Written Decision Outcomes – TC 1600



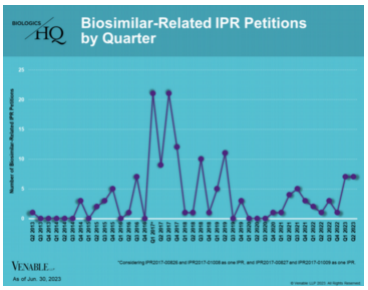
Biosimilar-Related IPR Petitions



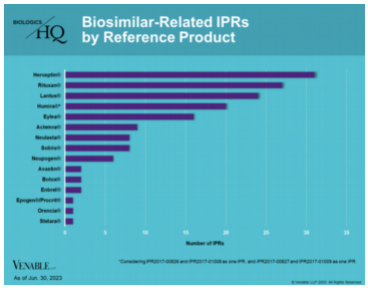
Biosimilar-Related IPR Petitions by Fiscal Year



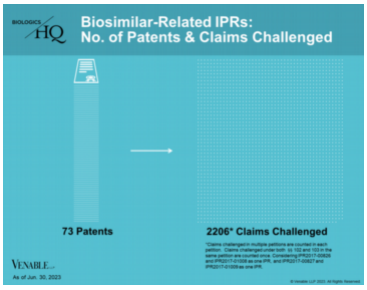
Biosimilar-Related IPR Petitions by Quarter



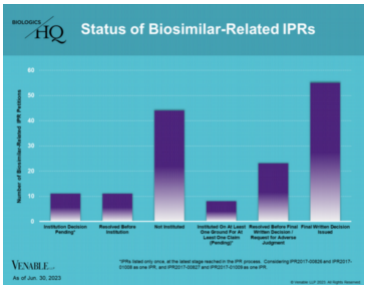
Biosimilar-Related IPRs by Reference Product



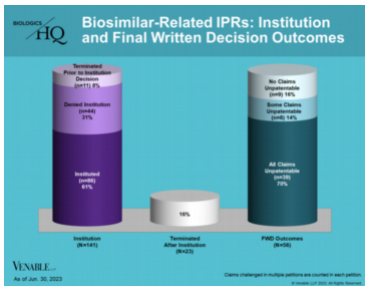
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



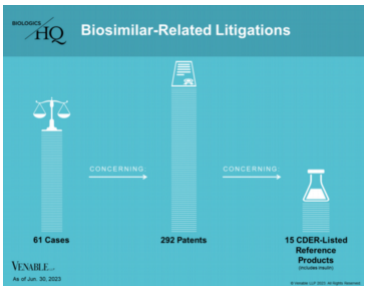
Status of Biosimilar-Related IPRs



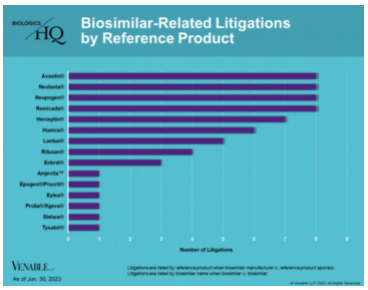
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



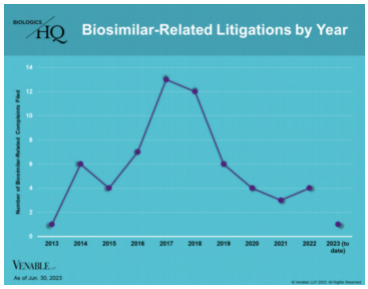
Biosimilar-Related Litigations



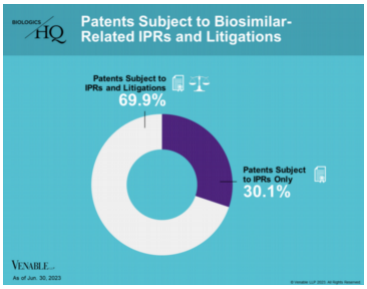
Biosimilar-Related Litigations by Reference Product



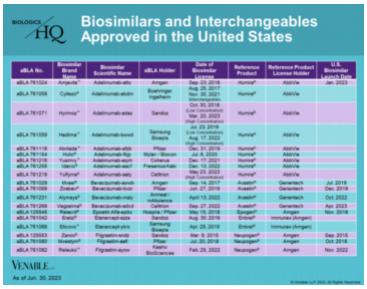
Biosimilar-Related Litigations by Year



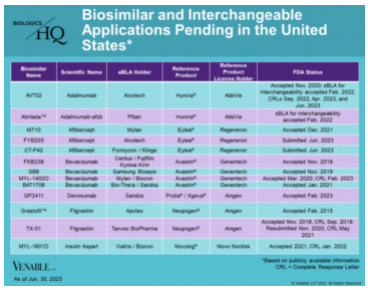
Patents Subject to Biosimilar-Related IPRs and Litigations



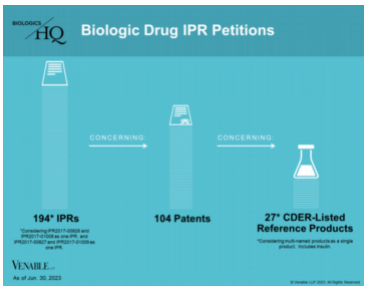
Biosimilars and Interchangeables Approved in the United States



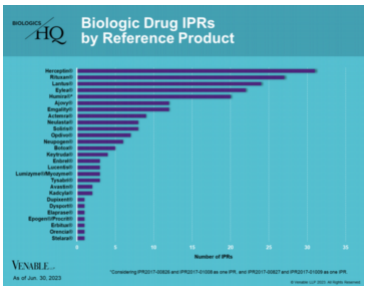
Biosimilar and Interchangeable Applications Pending in the United States



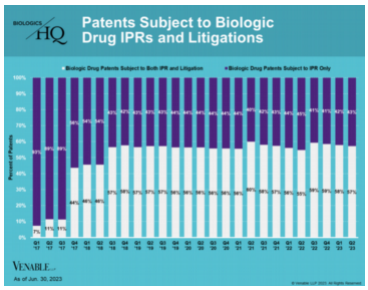
Biologic Drug IPR Petitions



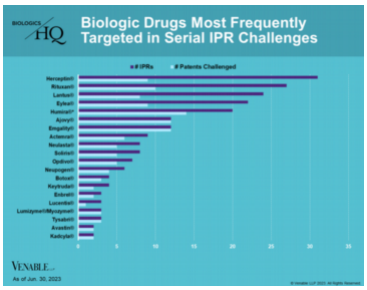
Biologic Drug IPRs by Reference Product



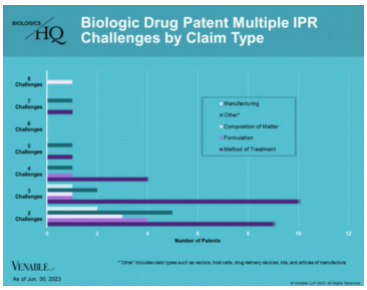
Patents Subject to Biologic Drug IPRs and Litigations



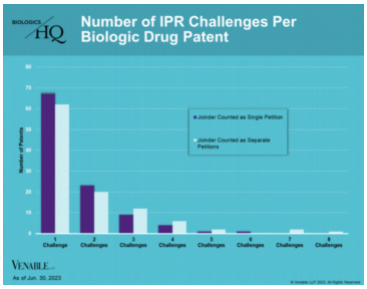
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

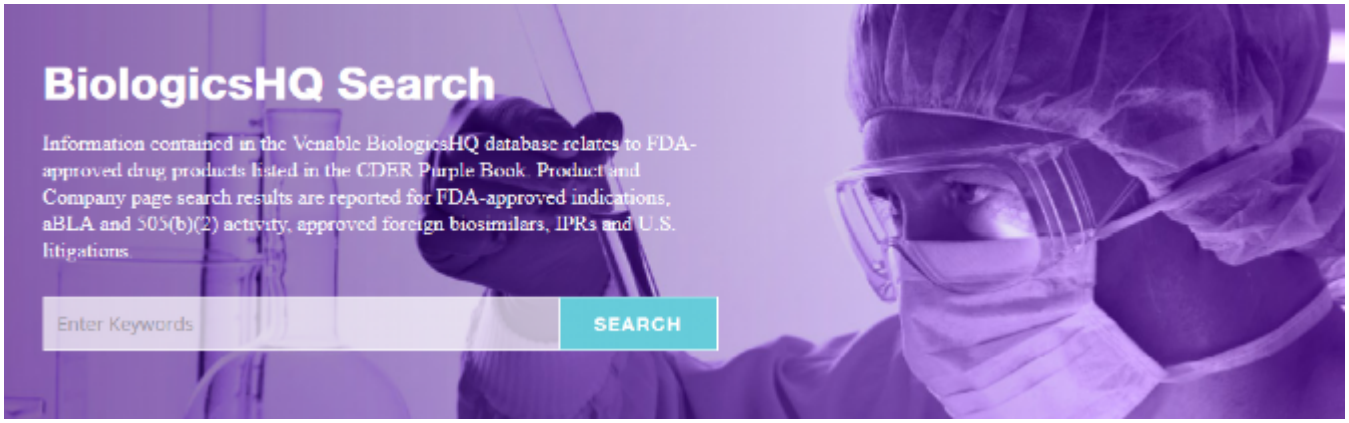


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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