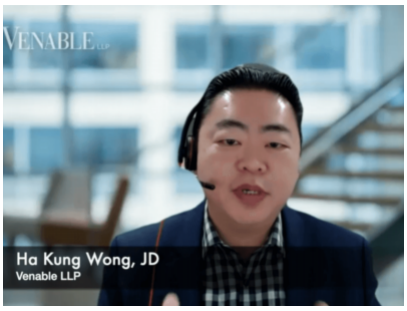
BIOLOGICS HQ

VENABLE LLP

April 9, 2024

LATEST NEWS

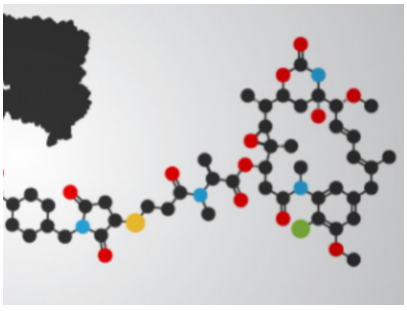


Ha Kung Wong Discusses Biosimilars vs. Bad Patents: Accessibility, Key Court Cases with The Center for Biosimilars

Ha Kung Wong Discusses Decoding the Patent Puzzle: Navigating the Legal Landscape of Biosimilars with The Center for Biosimilars

Ha Kung Wong Discusses Antitrust Lawsuits on Increasing Biosimilar Accessibility with The Center for Biosimilars

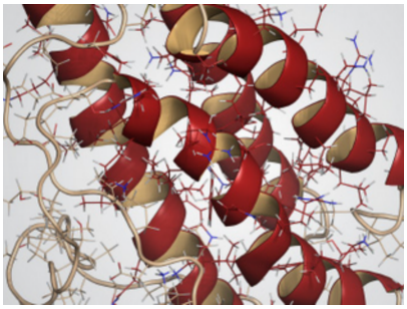
In a series of interviews with The Center for Biosimilars, Ha Kung Wong discusses various topics relating to biosimilars, including concerns about whether "bad patents" are hindering biosimilar access, biosimilar cases to watch (including those for Eylea®, Soliris®, and Tysabri® biosimilars), the U.S. patent system legal landscape and how it can be improved, and Congressional action on anticompetitive practices (including cases involving Humira® (adalimumab) and Remicade® (infliximab) biosimilars and the CareFirst BlueCross BlueShield lawsuit involving delays for Stelara® (ustekinumab) biosimilars).



Stelara® Biosimilar Updates: Settlement of IPR and FDA Review of Proposed Biosimilar

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

On March 4, 2024, the PTAB granted Biocon and Janssen's joint motion to terminate IPR2023-01444 due to a settlement reached prior to an institution decision. The parties announced in a press release that their settlement and license agreement allows Biocon to commercialize Bmab 1200, its proposed biosimilar to Stelara® (ustekinumab), in the U.S. by February 2025, subject to FDA approval. This IPR was the last pending biosimilar patent proceeding related to Stelara®.



Merck Files Four IPRs Challenging The Johns Hopkins University Pembrolizumab Patents

Four Additional IPRs Filed by Merck Challenging The Johns Hopkins University Pembrolizumab Patents

By: Robert S. Schwartz, Ph.D.

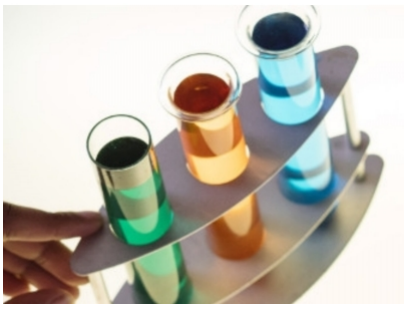
On March 4, 2024, Merck filed four IPRs challenging The Johns Hopkins University ("JHU") patents covering methods of treatment using pembrolizumab, which Merck sells under the trade name Keytruda®. The four IPRs are IPR2024-00622 challenging U.S. Patent No. 10,934,356; IPR2024-00623 challenging U.S. Patent No. 11,325,974; IPR2024-00624 challenging U.S. Patent No. 11,325,975; and IPR2024-00625 challenging U.S. Patent No. 11,339,219, as being anticipated by and obvious over the prior art.

On March 13, 2024, Merck filed four additional IPRs challenging JHU patents covering methods of treatment using pembrolizumab, including IPR2024-00647 challenging U.S. Patent No. 11,649,287; IPR2024-00648 challenging U.S. Patent No. 11,643,462; IPR2024-00649 challenging U.S. Patent No. 11,629,187; and IPR2024-00650 challenging U.S. Patent No. 11,634,491, also as being anticipated by and obvious over the prior art.

Fresenius Kabi's Actemra® biosimilar Tyenne® (tocilizumab-aazg) Approved in the U.S.

By: Robert S. Schwartz, Ph.D.

On March 5, 2024, the FDA approved Fresenius Kabi's Tyenne® (tocilizumab-aazg) as a biosimilar of Chugai, Genentech and Hoffman-La Roche's Actemra® (tocilizumab). This is the second Actemra® biosimilar to be approved in the U.S., following the approval of Biogen and Bio-Thera's Tofidence™ (tocilizumab-bavi) in September 2023, but it is the first biosimilar to be approved with both an intravenous and subcutaneous formulation. Celltrion has a pending aBLA for its proposed Actemra® biosimilar, CT-P47.



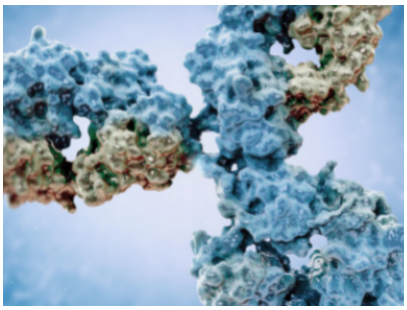
The First Prolia® / Xgeva® Biosimilar Approvals in the U.S.

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

On March 5, 2024, the FDA approved Sandoz's Jubbonti® and Wyost® (denosumab-bddz) as the first biosimilars of Amgen's Prolia® and Xgeva® (denosumab). The launch date for these biosimilars has not been announced as Amgen and Sandoz continue their BPCIA litigation in the district of New Jersey.

Celltrion Submits aBLA for CT-P39, Proposed Interchangeable Biosimilar of Xolair® (omalizumab)

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



On March 10, 2024, Celltrion announced in a press release that it submitted an abbreviated Biologics License Application (aBLA) for FDA approval of CT-P39 (omalizumab), a proposed interchangeable biosimilar of Genentech's / Novartis' Xolair® (omalizumab). This is the first publicly announced aBLA for a proposed biosimilar of Xolair®. No patent proceedings related to any proposed Xolair® biosimilar have been filed to date.

Biden FY25 HHS Budget Eliminates the Separate Interchangeability Designation for Biosimilars

By: Robert S. Schwartz, Ph.D.

On March 11, 2024, the White House released President Biden's FY 2025 Department of Health and Human Services (HHS) Budget in Brief, which outlines $130.7 billion in discretionary funding for HHS. Included in the budget proposal is a provision that would eliminate the separate biosimilar and interchangeable designations, deeming all approved biosimilars to be interchangeable with their reference product, without the need for switching studies. This change is an attempt to alleviate confusion about safety and efficacy differences between biosimilars and interchangebles that stems from having two separate categories of drugs.

EYLEA® IPR Appeals Filed

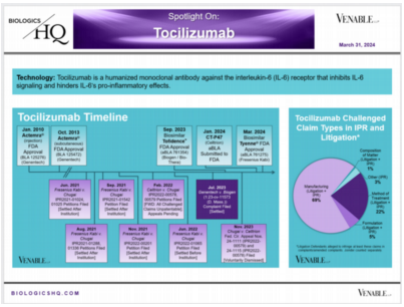
By: Damineh Morsali, Ph.D. and Robert S. Schwartz, Ph.D.

On March 13, 2024, Regeneron appealed the PTAB Board's ("the Board") recent Final Written Decisions ("FWDs") that found claims of two Regeneron patents related to EYLEA® (aflibercept) unpatentable. In CAFC 24-1564 Regeneron appeals the Board's FWD in IPRs brought by Mylan and Biocon (IPR2022-01225) and Celltrion (IPR2023-00532, joined), and in CAFC 24-1567 Regeneron appeals the Board's FWD in IPRs brought by Mylan and Biocon (IPR2022-01226), Celltrion (IPR2023-00533, joined), and Samsung Bioepis (IPR2023-00566, joined).

PTAB Denies Seagen's Request for Director Review of Unpatentability Decision in Adcetris® Patent PGR

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

On March 27, 2024, the PTAB summarily denied Seagen's February 14, 2024 request for Director Review of the PTAB's January 16, 2024 Final Written Decision ("FWD") in PGR2021-00030 related to Adcetris® (brentuximab vedotin). In the FWD, the PTAB held that the antibody-drug conjugate claims in U.S. Patent No. 10,808,039 were unpatentable.



[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)]

[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®, TX-05, EG12014, and HLX02), 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 March 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 March 31, 2024.

Read More News

UPDATES

IPRs and PGRs

Keytruda® (pembrolizumab):

- On March 4, 2024, **Merck** filed IPRs against The Johns Hopkins University patents including IPR2024-00622 challenging method of treatment claims of U.S. Patent No. 10,934,356, IPR2024-00623 challenging method of treatment claims of U.S. Patent No. 11,325,974, IPR2024-00624 challenging method of treatment claims of U.S. Patent No. 11,325,975, and IPR2024-00625 challenging method of treatment claims of U.S. Patent No. 11,339,219.
- On March 13, 2024, **Merck** filed IPRs against The Johns Hopkins University patents including IPR2024-00647 challenging method of treatment claims of U.S. Patent No. 11,649,287, IPR2024-00648 challenging method of treatment claims of U.S. Patent No. 11,643,462, IPR2024-00649 challenging method of treatment claims of U.S. Patent No. 11,629,187, and IPR2024-00650 challenging method of treatment claims of U.S. Patent No. 11,634,491.

Stelara® (ustekinumab):

- On March 4, 2024, the PTAB granted **Biocon** and **Janssen's** joint motion to terminate IPR2023-01444 challenging method of treatment claims of U.S. Patent 10,961,307 due to a settlement reached prior to an institution decision. Under the settlement and license agreement, **Biocon** can commercialize **Bmab 1200** by February 2025, subject to FDA approval.

Zolgensma® (onasemnogene abeparvovec-xioi):

- On March 4, 2024, the PTAB granted **Genzyme** and **Novartis's** joint motions to terminate due to settlement after institution in IPR2023-01044 and IPR2023-01045 challenging manufacturing claims of U.S. Patent No. 10,429,288.

Actemra® (tocilizumab):

- On March 6, 2024, **Chugai**, **Hoffmann-La Roche**, and **Genentech's** motions for voluntarily dismissal were granted in Fed. Cir. Appeal Nos. 24-1111 and 24-1115, appealing the final written decisions in IPR2022-00579 finding all challenged drug delivery device claims of U.S. Patent No. 10,874,677 unpatentable and IPR2022-00578 finding all challenged method of treatment claims of U.S. Patent No. 8,580,264 unpatentable.

Eylea® (aflibercept):

- On March 13, 2024, **Regeneron** filed Fed. Cir. Appeal No. 24-1564 appealing the final written decision finding all challenged claims of U.S. Patent No. 10,130,681 unpatentable in IPR2022-01225 by **Mylan** and **Biocon** and IPR2023-00532 (joined) by **Celltrion**.
- On March 13, 2024, **Regeneron** filed Fed. Cir. Appeal No. 24-1567 appealing the final written decision finding all challenged claims of U.S. Patent No. 10,888,601 unpatentable in IPR2022-01226 by **Mylan** and **Biocon**, IPR2023-00533 (joined) by **Celltrion**, and IPR2023-00566 (joined) by **Samsung Bioepis**.

Enhertu® (fam-trastuzumab deruxtecan-nxki) / Adcetris® (brentuximab vedotin)

- On March 27, 2024, **Seagen's** request for Director Review of the Final Written Decision in PGR2021-00030 finding all challenged claims of U.S. Patent No. 10,808,039 unpatentable, was denied.

Litigations

Eylea® (aflibercept):

- On March 8, 2024, the Court granted summary judgment of noninfringement due to disclaimer of U.S. Patent Nos. 10,406,226, 10,464,992, and 10,857,205 in ***Regeneron*** *v.* ***Mylan*** Case No. 1:22-cv-00061 (N.D. W. Va.) and dismissed the relevant causes of action in the complaint.

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aBLA Applications and FDA Activity

Jubbonti® / Wyost® (denosumab-bbdz):

- On March 5, 2024, the FDA approved **Sandoz's** **Jubbonti® (denosumab-bbdz)** as biosimilar to and interchangeable with **Amgen's** **Prolia® (denosumab)** and **Sandoz's** **Wyost® (denosumab-bbdz)** as biosimilar to and interchangeable with **Amgen's** **Xgeva® (denosumab)**.

Tyenne® (tocilizumab-aazg):

- On March 5, 2024, the FDA approved **Fresenius Kabi's** **Tyenne® (tocilizumab-aazg)**, a biosimilar of **Genentech's** **Actemra® (tocilizumab)**.

Zymfentra™ (infliximab-dyyb for subcutaneous use):

- On March 20, 2024, **Celltrion** announced the launch of **Zymfentra™ (infliximab-dyyb)**, a subcutaneous version of **Celltrion's** **Inflectra® (infliximab)**. **Zymfentra™** is the first subcutaneous version of infliximab and was approved under a full BLA. **Inflectra®** is a biosimilar of **Janssen's** **Remicade® (infliximab)**.

CT-P39 (omalizumab):

- On March 21, 2024, **Celltrion** announced the submission of an aBLA for **CT-P39 (omalizumab)**, a proposed biosimilar and interchangeable of **Genentech's** **Xolair® (omalizumab)**. This is the first publicly disclosed filing of an aBLA for a **Xolair®** biosimilar.

CDER Purple Book Updates

Letybo® (letibotulinumtoxina-wlbg):

- On March 4, 2024, **Hugel** announced the FDA approval of **Letybo® (letibotulinumtoxina-wlbg)**.

Tevimbra® (tislelizumab):

- On March 13, 2024, the FDA approved **BeiGene's** **Tevimbra® (tislelizumab)**.

Lenmeldy™ (atidarsagene autotemcel):

- On March 18, 2024, the FDA approved **Orchard Therapeutics'** **Lenmeldy™ (atidarsagene autotemcel)**.

Winrevair™ (sotatercept-csrk):

- On March 26, 2024, the FDA approved **Merck's** **Winrevair™ (sotatercept-csrk)**.

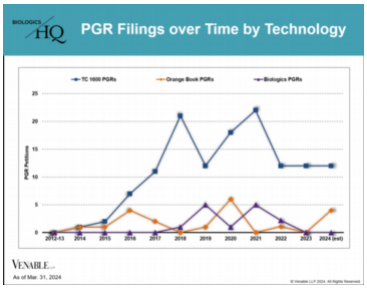
Non-U.S. Biosimilars / Follow-On Biologics

Versavo® (bevacizumab):

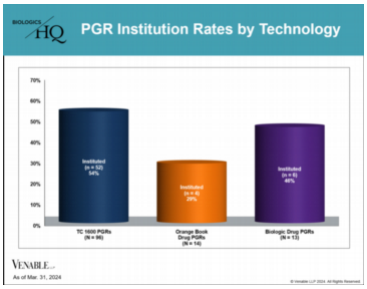
- On March 19, 2024, **Dr. Reddy's** announced the launch of **Versavo® (bevacizumab)**, a biosimilar of **Genentech's** **Avastin® (bevacizumab)**, in the U.K.

STATISTICS

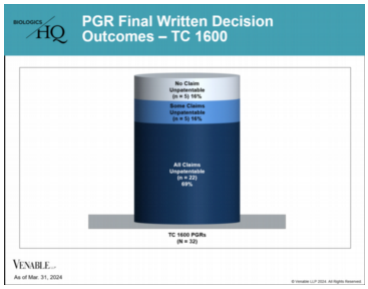
PGR Filings Over Time by Technology



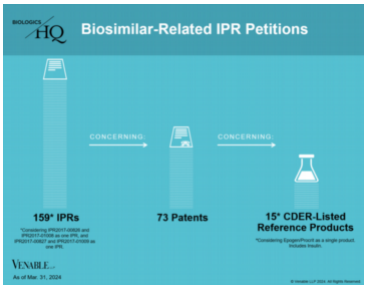
PGR Institution Rates by Technology



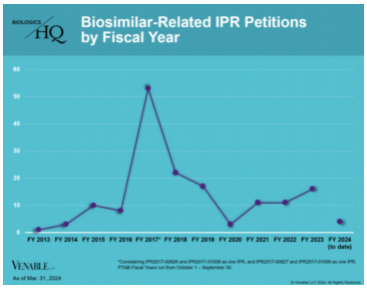
PGR Final Written Decision Outcomes – TC 1600



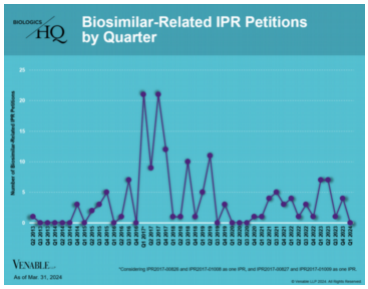
Biosimilar-Related IPR Petitions



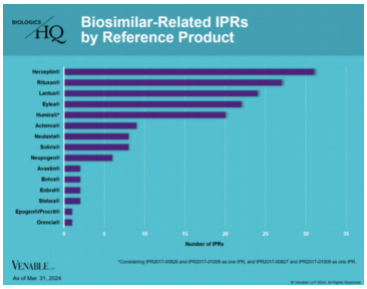
Biosimilar-Related IPR Petitions by Fiscal Year



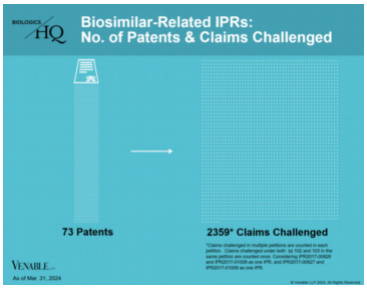
Biosimilar-Related IPR Petitions by Quarter



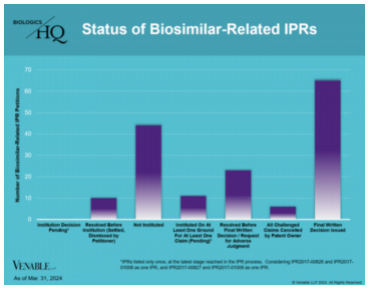
Biosimilar-Related IPRs by Reference Product



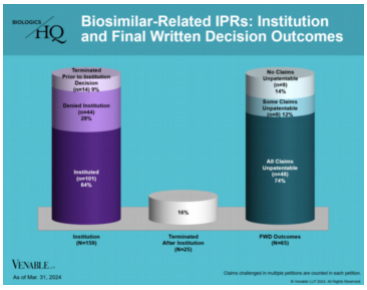
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



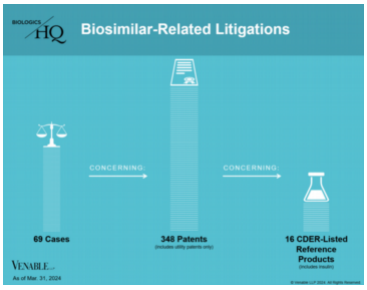
Status of Biosimilar-Related IPRs



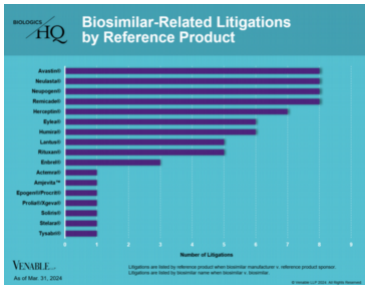
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



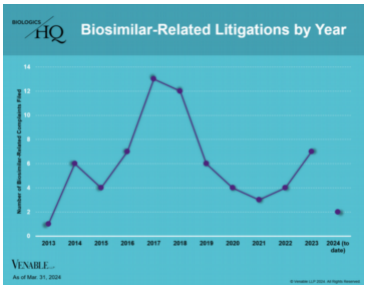
Biosimilar-Related Litigations



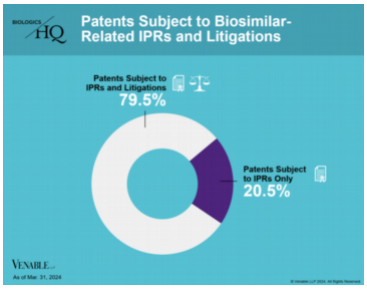
Biosimilar-Related Litigations by Reference Product



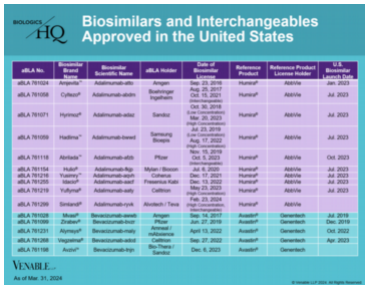
Biosimilar-Related Litigations by Year



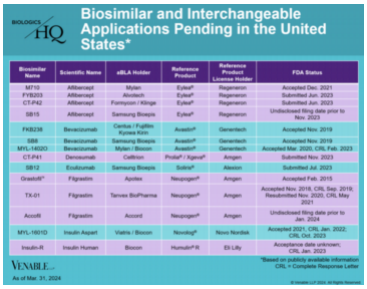
Patents Subject to Biosimilar-Related IPRs and Litigations



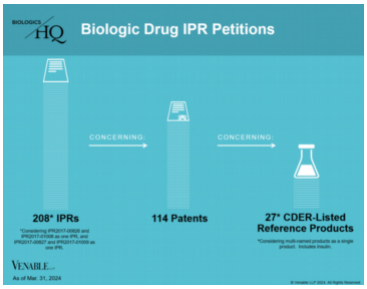
Biosimilars and Interchangeables Approved in the United States



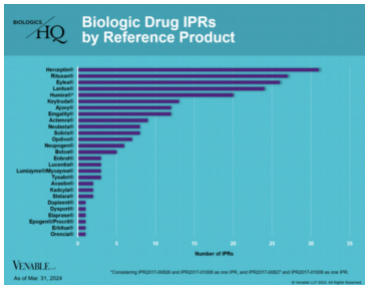
Biosimilar and Interchangeable Applications Pending in the United States



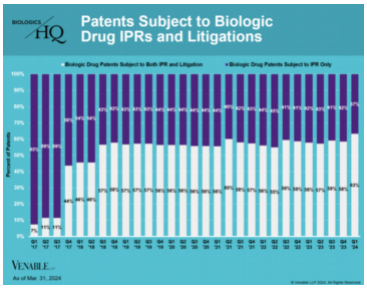
Biologic Drug IPR Petitions



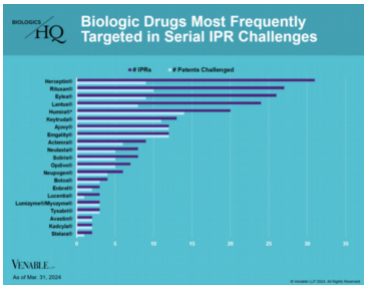
Biologic Drug IPRs by Reference Product



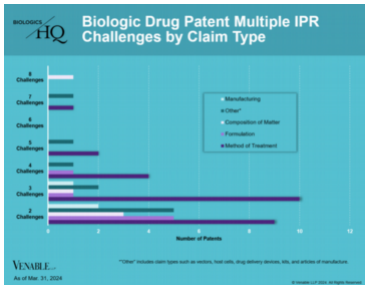
Patents Subject to Biologic Drug IPRs and Litigations



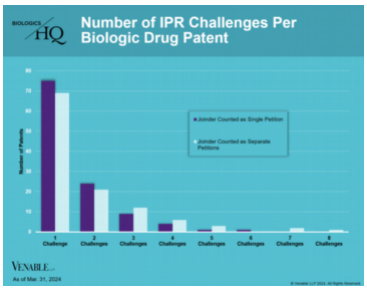
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

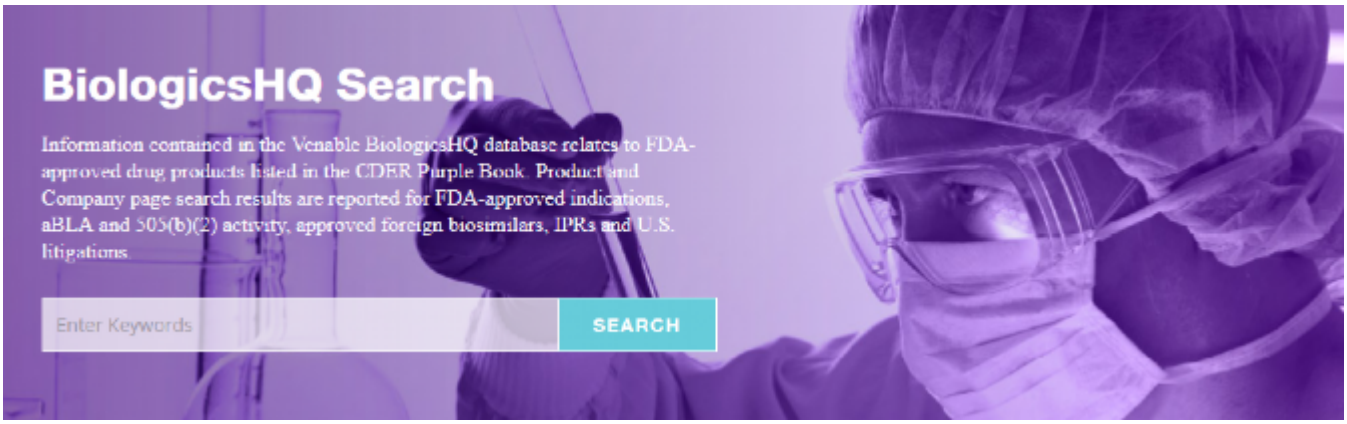


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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