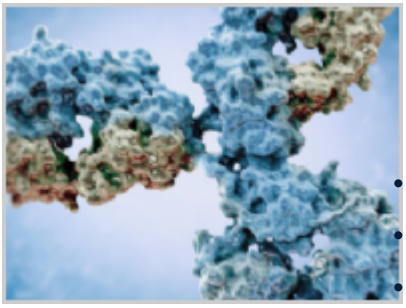
BIOLOGICS HQ

VENABLE LLP

January 10, 2023

LATEST NEWS



Most Read BiologicsHQ News in 2022

In case you missed them, catch up on the BiologicsHQ most read news articles in 2022:

- A Survey of PGR Outcomes
- Biosimilars Approved in the EU are Considered Interchangeable
- PTAB Director Review Updates
- First Interchangeable FDA Approval without a Switching Study
- The Trouble With IP for Digital Health and Precision Medicine
- Senator Mike Lee Introduces the Biosimilar Red Tape Elimination Act to Eliminate Switching Study Requirement for Biosimilar Interchangeability

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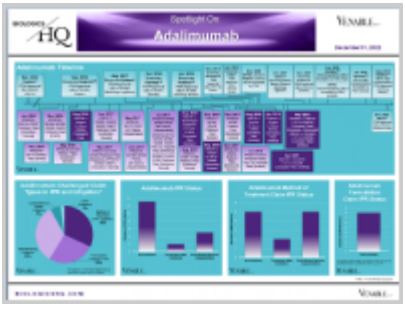


Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria®(pegfilgrastim-apgf) / Fylnetra™ (pegfilgrastim-apgf) / Stimufend® (pegfilgrastim-fpgk)

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)

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 pegfilgrastim (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria®, Fylnetra™, Stimufend®, Lapelga™, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri®, Herzuma®, Ontruzant®, Trazimera®, Kanjinti®, TX-05, and EG12014), rituximab (Rituxan®, Truxima®, Ruxience®, and Riabni™), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™, Hulio®, Yusimry™, Idacio®, AVT02, and Yuflyma®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, Semglee®, and Rezvoglar™) have been updated with activity through December 31, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through December 31, 2022.

Read More News

UPDATES

IPRs and PGRs

Skyrizi® (risankizumab-rzaa):

- On December 7, 2022, **Sandoz** requested rehearing of the PTAB's decision denying institution in PGR2022-00037 against **Boehringer Ingelheim**.

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

- On December 23, 2022, **Novartis** filed a notice of appeal of the final written decision finding all challenged claims unpatentable in IPR2021-00816 against **Regeneron**.

Opdivo® (nivolumab):

- On December 29, 2022, Dana-Farber Cancer Institute filed IPR2023-00249 and IPR2023-00252 against **Bristol-Myers Squibb**.

aBLA Applications and FDA Activity

BIIB800 (tocilizumab):

- On December 9, 2022, **Biogen** and **Bio-Thera Solutions** announced the FDA acceptance of the aBLA for **BIIB800 (tocilizumab)**, a proposed biosimilar of **Genentech's Actemra® (tocilizumab)**.

Idacio® (adalimumab-aacf):

- On December 13, 2022, the FDA approved **Fresenius Kabi's Idacio® (adalimumab-aacf)**, a biosimilar of **AbbVie's Humira® (adalimumab)**.

Remsima® SC (infliximab):

- On December 23, 2022, **Celltrion** announced the submission of a BLA for **Remsima® SC (infliximab)**, a subcutaneous version of its biosimilar infliximab, **Inflectra® (infliximab).**

CDER Purple Book Updates

Lunsumio™ (mosunetuzumab-axgb):

- On December 22, 2022, the FDA approved **Genentech's Lunsumio™ (mosunetuzumab-axgb).**

NexoBrid™ (anacaulase-bcdb):

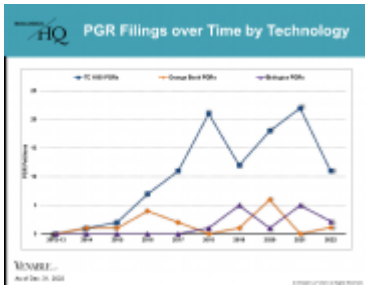
- On December 28, 2022, the FDA approved **Mediwound's NexoBrid™ (anacaulase-bcdb).**

Briumvi™ (ublituximab):

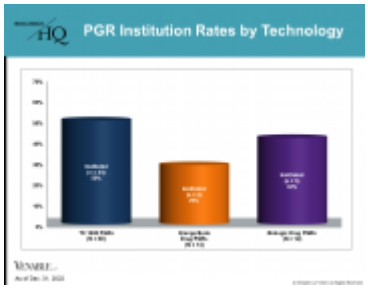
- On December 28, 2022, the FDA approved **TG Therapeutics' Briumvi™ (ublituximab).**

STATISTICS

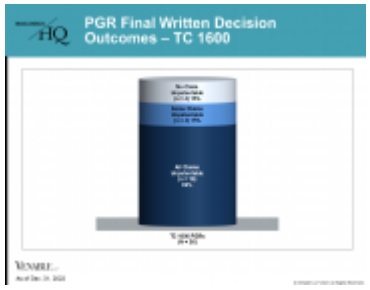
PGR Filings Over Time by Technology



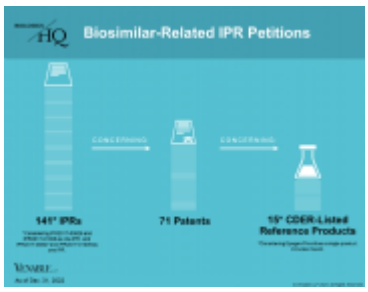
PGR Institution Rates by Technology



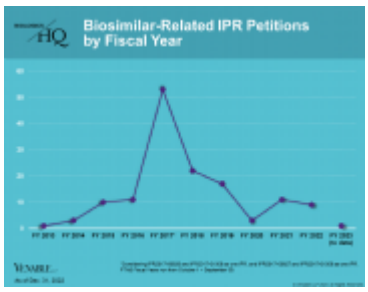
PGR Final Written Decision Outcomes – TC 1600



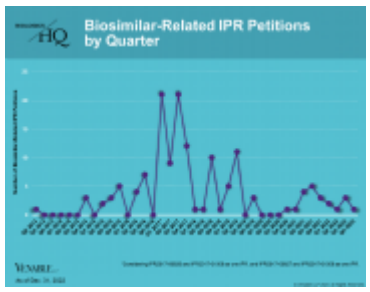
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



Biosimilar-Related IPR Petitions by Quarter

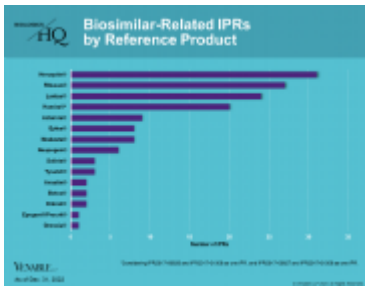


Biosimilar-Related IPRs by Reference

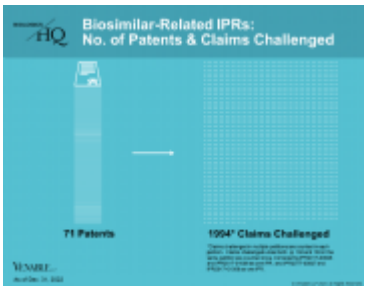
Biosimilar-Related IPRs: Number of Patents

Status of Biosimilar-

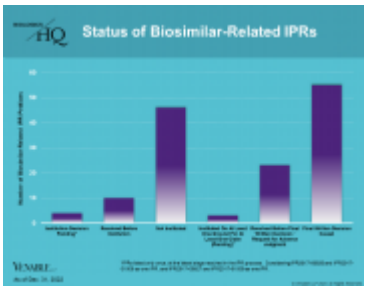
Product



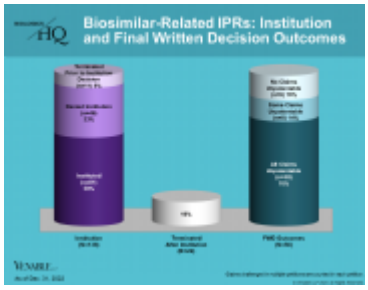
and Claims Challenged



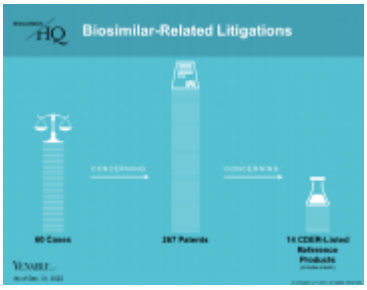
Related IPRs



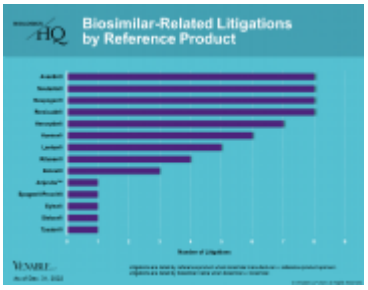
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



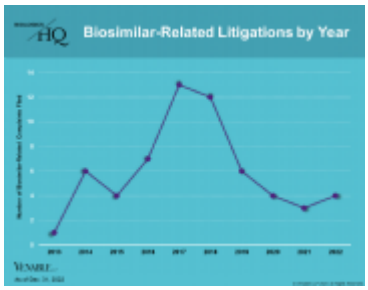
Biosimilar-Related Litigations



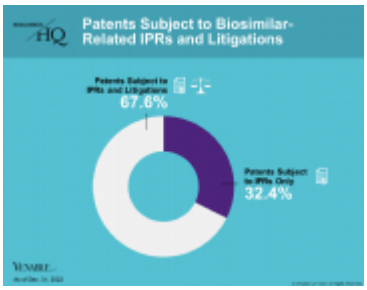
Biosimilar-Related Litigations by Reference Product



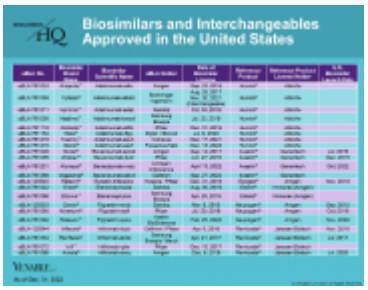
Biosimilar-Related Litigations by Year



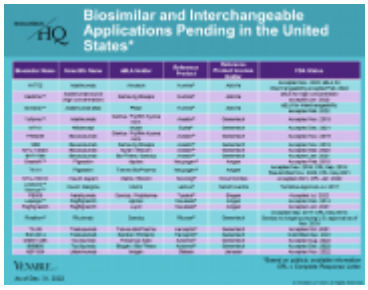
Patents Subject to Biosimilar-Related IPRs and Litigations



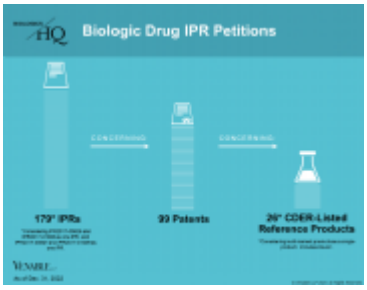
Biosimilars and Interchangeables Approved in the United States



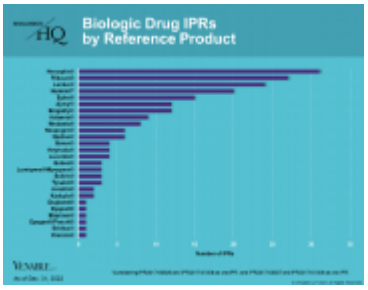
Biosimilar and Interchangeable Applications Pending in the United States



Biologic Drug IPR Petitions



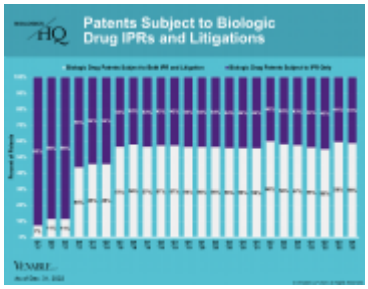
Biologic Drug IPRs by Reference Product

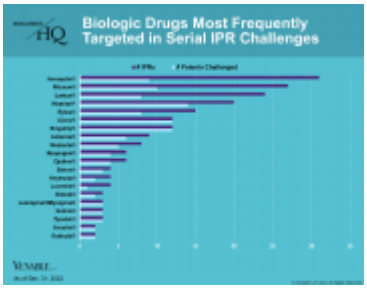


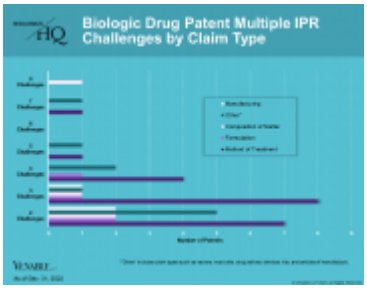
Patents Subject to Biologic Drug IPRs and Litigations

Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

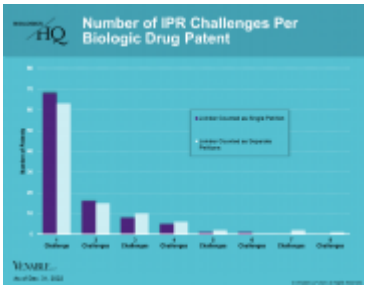
Biologic Drug Patent Multiple IPR Challenges by Claim Type

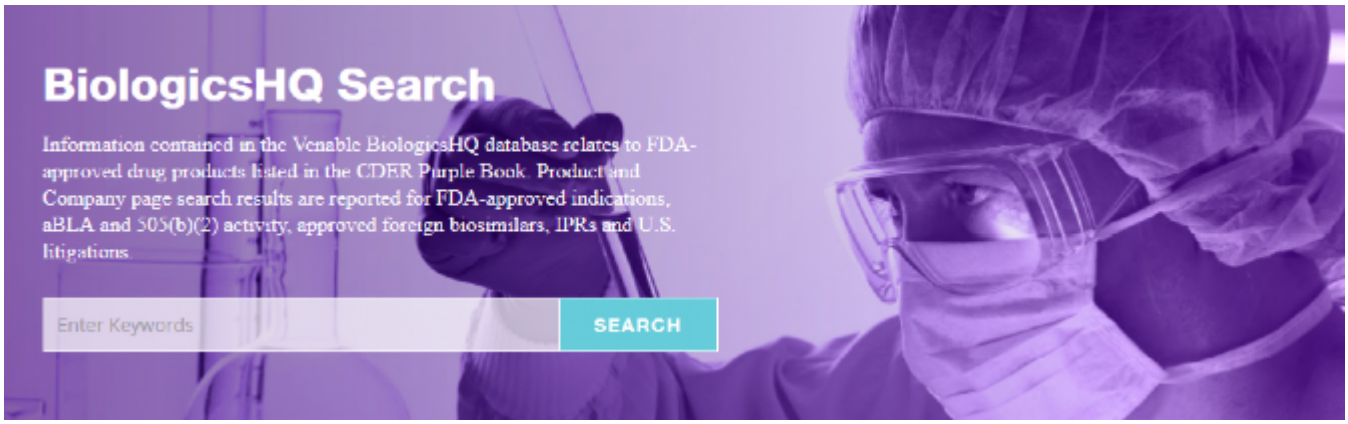






Number of IPR Challenges Per Biologic Drug Patent





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