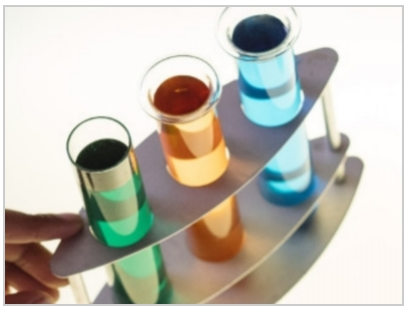
BIOLOGICS HQ

VENABLE LLP

October 10, 2023

LATEST NEWS



New FDA Guidance Removes Interchangeability Statement from Product Labels

By: Robert S. Schwartz, Ph.D.

On September 18, 2023, the FDA issued a new draft guidance "Labeling for Biosimilar and Interchangeable Biosimilar Products," updating the previous labeling guidance "Labeling for Biosimilar Products" from July 2018. In the most recent guidance, the FDA changed its recommendation of inclusion of an interchangeability statement in the labeling for interchangeable products rather than a biosimilarity statement. It now recommends both biosimilars and interchangeables include a biosimilarity statement, regardless of whether the product is a biosimilar or interchangeable.

Complimentary Life Sciences Webinar Series

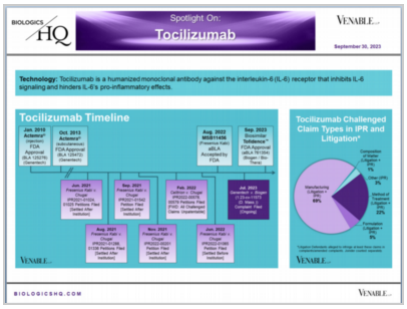
We are excited to announce Venable's inaugural Life Sciences Webinar Series. This month-long series will explore the intricacies and latest developments that shape the life sciences industry. Join us as we hear from our seasoned attorneys across various practices who will share insights and provide a framework for navigating the relevant legal landscape.

Join us on Tuesday, October 17, 2023, from 1:00 p.m. - 2:00 p.m. ET for "IPRs, PGRs, and the BPCIA."

This presentation will provide an update on PTAB challenges to biologics patents and their interplay with district court litigation. We will discuss recent IPR and PGR decisions, focusing on those most relevant to biologics patents. We will explore how challengers in the biologics space are using PTAB proceedings as a tool and how their use of PTAB proceedings has changed over time, compare outcomes at the PTAB vs. district courts, and look at how the Board and district courts are currently approaching parallel proceedings and motions to stay litigation pending IPRs or PGRs.

Speakers:

Ha Kung Wong, Partner, Venable LLP
Christina Schwarz, Partner, Venable LLP



Spotlight On: Actemra® (tocilizumab) / Tofidence™ (tocilizumab-bavi)

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®, Tofidence™, and MSB11456), 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 September 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 September 30, 2023.

Read More

News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On September 1, 2023, the PTAB issued a decision denying institution in ***Celltrion*** *v.* ***Regeneron*** IPR2023-00620 because all challenged claims had been cancelled by **Regeneron**.

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On September 25, 2023, the PTAB issued final written decisions in ***Eli Lilly*** *v.* ***Teva*** IPR2022-00738 and IPR2022-00739 finding all challenged claims unpatentable.

Litigations

Hemlibra® (emicizumab-kxwh):

- On September 20, 2023, the Federal Circuit affirmed the District Court's summary judgment of invalidity and found the District Court did not err by finding a lack of enablement in ***Baxalta*** *v.* ***Chugai***, Appeal No. 22-1461, appealing Case No. 1:17-cv-00509 (D. Del.).

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

- On September 26, 2023, Federal Circuit Appeal No. 23-2424, appealing ***Seagen*** *v.* ***Daiichi*** Case No. 2:20-cv-00337 (E.D. Tex.), was filed by **Daiichi**.

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On September 26, 2023, the Court granted judgment as a matter of law in ***Teva*** *v.* ***Eli Lilly*** Case No. 1:18-cv-12029 (D. Mass.), finding the asserted claims of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908 invalid for lack of written description and enablement. At trial, the jury found the claims infringed. The parties previously stipulated to dismissal of all other challenged patents.

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aBLA Applications and FDA Activity

Tofidence™ (tocilizumab-bavi):

- On September 29, 2023, the FDA approved **Biogen** and **Bio-Thera's** **Tofidence™ (tocilizumab-bavi)**, a biosimilar of **Genentech's** **Actemra® (tocilizumab)**.

CDER Purple Book Updates

Pombiliti™ (cipaglucosidase alfa-atga):

- On September 28, 2023 the FDA approved **Amicus Therapeutics'** **Pombiliti™ (cipaglucosidase alfa-atga)**.

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

Vegzelma® (bevacizumab-adcd):

- On September 4, 2023, **Celltrion** announced the approval of **Vegzelma® (bevacizumab-adcd)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, in Australia.

Tyenne® (tocilizumab):

- On September 19, 2023, **Fresenius Kabi** announced the approval of **Tyenne® (tocilizumab)**, a biosimilar of **Genentech's RoActemra® (tocilizumab)**, in the E.U.

Yesafili® (aflibercept):

- On September 20, 2023, **Biocon Biologics** announced the approval of **Yesafili® (aflibercept)**, a biosimilar of **Regeneron's Eylea® (aflibercept)**, in the E.U.

Tyruko® (natalizumab-sztn):

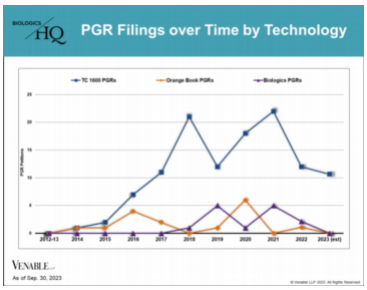
- On September 22, 2023, **Sandoz** and **Polpharma** announced approval of **Tyruko® (natalizumab-sztn)**, a biosimilar of **Biogen's Tysabri® (natalizumab)**, in the E.U.

AVT04 (ustekinumab):

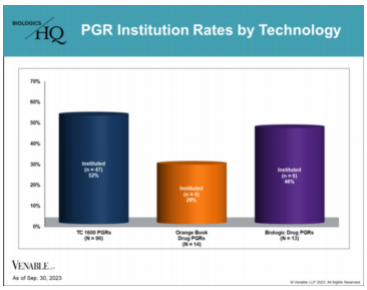
- On September 25, 2023, **Alvotech** and **Fuji Pharma** announced approval of **AVT04 (ustekinumab)**, a biosimilar of **Janssen's Stelara® (ustekinumab)**, in Japan.

STATISTICS

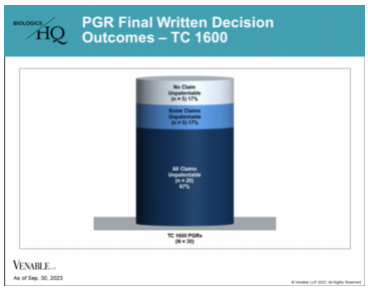
PGR Filings Over Time by Technology



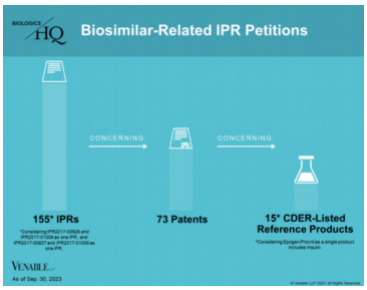
PGR Institution Rates by Technology



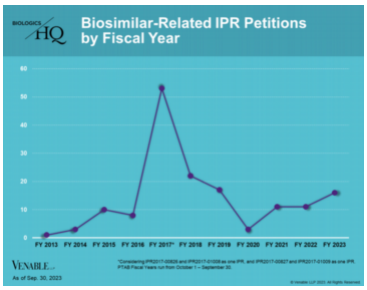
PGR Final Written Decision Outcomes – TC 1600



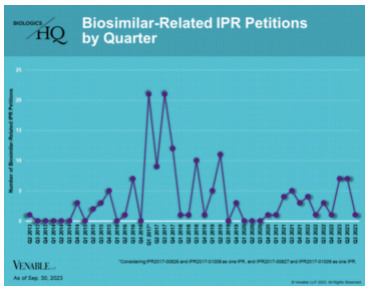
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



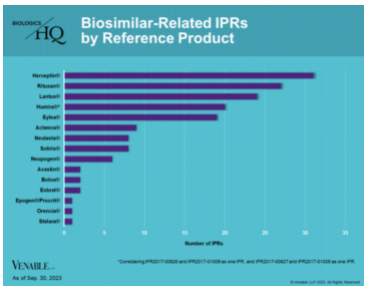
Biosimilar-Related IPR Petitions by Quarter



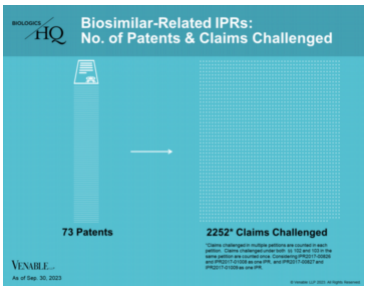
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

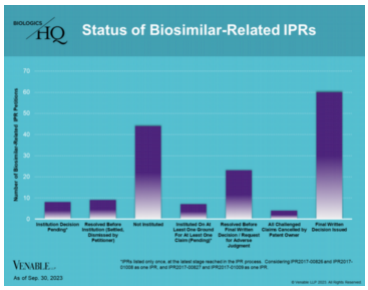
Status of Biosimilar-Related IPRs



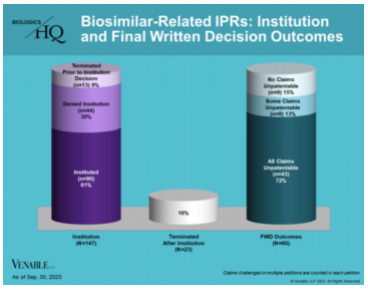
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



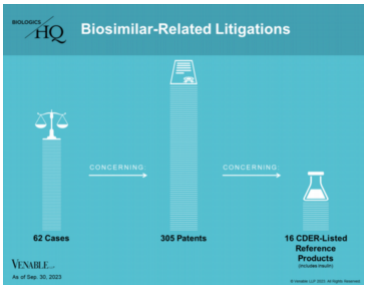
[Biosimilar-Related Litigations]



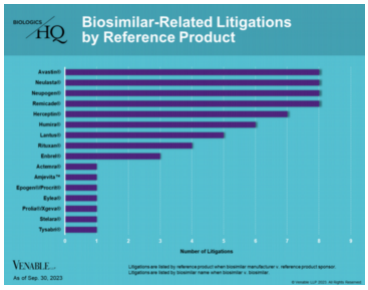
[Biosimilar-Related Litigations by Reference Product]



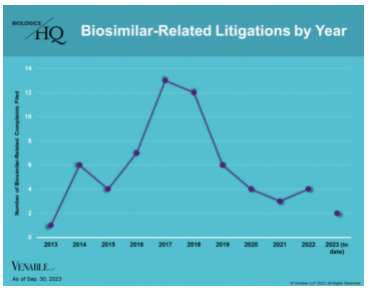
[Biosimilar-Related Litigations by Year]



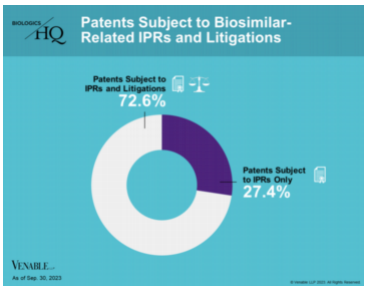
[Patents Subject to Biosimilar-Related IPRs and Litigations]



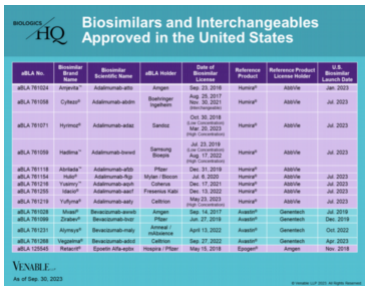
[Biosimilars and Interchangeables Approved in the United States]



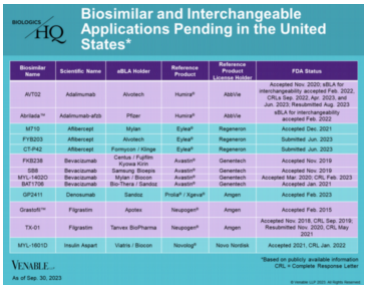
[Biosimilar and Interchangeable Applications Pending in the United States]



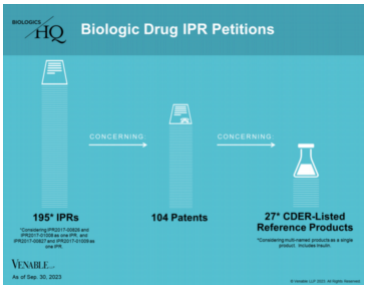
[Biologic Drug IPR Petitions]



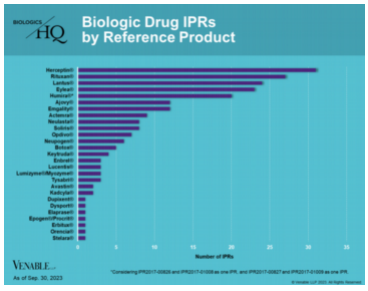
[Biologic Drug IPRs by Reference Product]



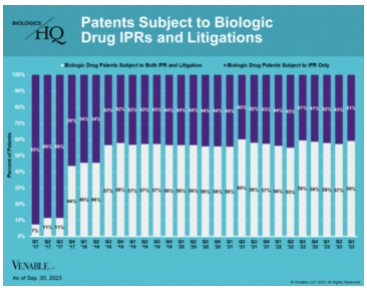
[Patents Subject to Biologic Drug IPRs and Litigations]

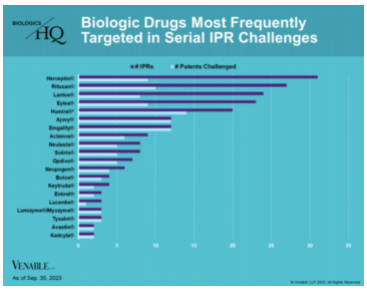


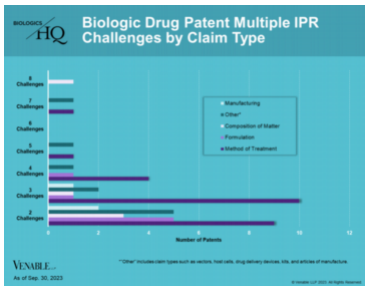
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]



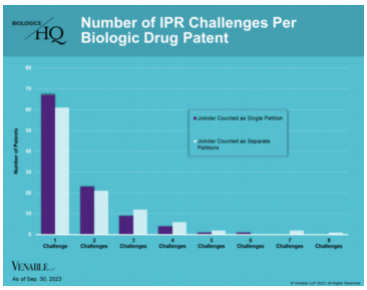
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

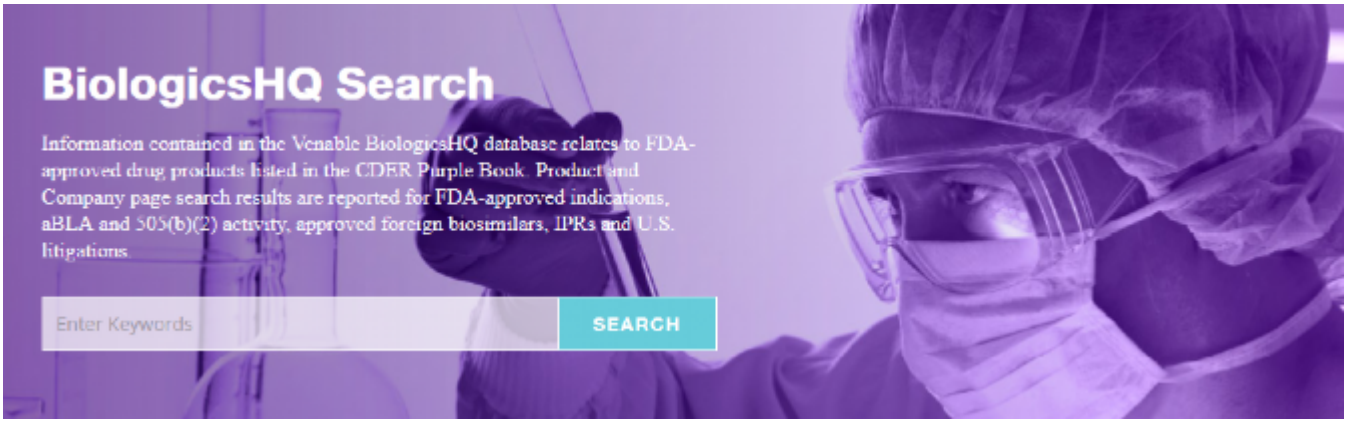






Number of IPR Challenges Per Biologic Drug Patent





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