BIOLOGICS HQ

VENABLE LLP

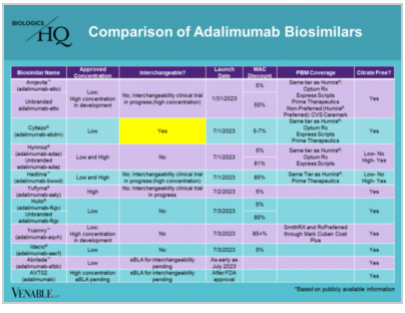
August 10, 2023

LATEST NEWS

PTAB Eliminates POP Review and Expands Director Review to Institution Decisions

By: April Breyer Menon and Ha Kung Wong

As of July 24, 2023, the United States Patent and Trademark Office (USPTO) revised the interim Director Review process and replaced the Precedential Opinion Panel (POP) with the Appeals Review Panel process, which will review decisions in *ex parte*, re-examination, and reissue appeals, and the Delegated Rehearing Panel (DRP), which will review decisions from America Invents Act (AIA) proceedings, such as *inter partes* reviews (IPRs) and post grant reviews (PGRs). Most notably, requests for Director Review will now be accepted for institution decisions and decisions granting rehearing in addition to final written decisions. Additionally, requests for Director Review may now be decided by the DRP instead of directly by the PTO Director.



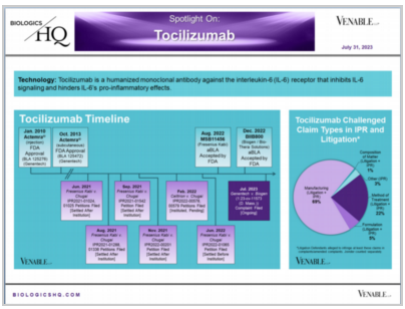
What Do the Humira Biosimilar / Interchangeable Launches Mean for the Adalimumab Market?

By: April Breyer Menon and Ha Kung Wong

At the beginning of July, seven additional Humira® (adalimumab) biosimilars, including one interchangeable, joined Amjevita™ (adalimumab-atto) in the US marketplace. Humira brought in over $21 billion in the US in 2022, and biosimilars have long hoped to gain a share of that market, while bringing costs down for patients and payers.

Many have hoped to gain insight into the workings of the biosimilar market through these biosimilar launches, but several unique aspects of the adalimumab market may make it difficult to extrapolate insights from this market to the biosimilars industry as a whole.

The adalimumab market is unique in a number of ways, and we discuss how that may impact biosimialr uptake.



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 July 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 July 31, 2023.

Read More News

UPDATES

IPRs and PGRs

Keytruda® (pembrolizumab):

- On July 6, 2023, **Genentech** filed disclaimers and requested termination of PGR2021-00036 and PGR2021-00039 filed by **Merck Sharp & Dohme**, which were awaiting decisions on **Merck's** requests for rehearing of the decisions denying institution. On July 20, 2023, the PTAB denied the requests for rehearing because the claims had been disclaimed and denied the motions to terminate as moot.

Eylea® (aflibercept):

- On July 19, 2023, the PTAB instituted **Samsung Bioepis's** IPR2023-00442 against **Regeneron**.
- On July 20, 2023, the PTAB instituted **Celltrion's** IPR2023-00462 against **Regeneron**.

Litigations

Actemra® (tocilizumab):

- On July 13, 2023, **Genentech**, **Chugai**, and **Hoffmann-La Roche** filed Case No. 1:23-cv-11573 (D. Mass.) against **Biogen** and **Bio-Thera Solutions** related to proposed biosimilar **BIIB800 (tocilizumab)**.

Yervoy® (ipilimumab) / Imjudo® (tremelimumab-actl):

- On July 31, 2023, the Court dismissed Case No. 1:23-cv-00079 (D. Del.) pursuant to the stipulated dismissal filed by **Bristol-Myers Squibb** and **AstraZeneca**.

Opdivo® (nivolumab) / Imfinzi® (durvalumab):

- On July 31, 2023, the Court dismissed Case Nos. 1:22-cv-00346 (D. Del.) and 1:23-cv-00459 (D. Del.) pursuant to the stipulated dismissals filed by **Bristol-Myers Squibb** and **AstraZeneca**.

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aBLA Applications and FDA Activity

Cyltezo® (adalimumab-adbm):

- On July 1, 2023, **Boehringer Ingelheim** announced the launch of **Cyltezo® (adalimuma-adbm)**, a low-concentration biosimilar and interchangeable of **AbbVie's Humira® (adalimumab)**. **Cyltezo** is the first interchangeable of **Humira** to launch and is priced at 5-7% less than **Humira's** wholesale acquisition cost.

Hadlima™ (adalimumab-bwwd):

- On July 1, 2023, **Samsung Bioepis** and **Organon** announced the launch of **Hadlima™ (adalimumab-bwwd)**, a low and high-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Hadlima** is priced at 85% less than **Humira's** wholesale acquisition cost.

Hyrimoz™ (adalimumab-adaz):

- On July 1, 2023, **Sandoz** announced the launch of **Hyrimoz™ (adalimumab-adaz)**, a low and high-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Sandoz** launched a branded version of **Hyrimoz**, priced at 5% less than **Humira's** wholesale acquisition cost, and an unbranded version priced at an 81% discount.

Yuflyma® (adalimumab-aaty):

- On July 2, 2023, **Celltrion** announced the launch of **Yuflyma® (adalimumab-aaty)**, a high-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Yuflyma** is priced at 5% less than **Humira's** wholesale acquisition cost.

Hulio® (adalimumab-fkjp):

- On July 3, 2023, **Biocon** and **Viatris** announced the launch of **Hulio® (adalimumab-fkjp)**, a low-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Biocon** launched a branded version of **Hulio**, priced at 5% less than **Humira's** wholesale acquisition cost, and an unbranded version priced at an 85% discount.

Idacio® (adalimumab-aacf):

- On July 3, 2023, **Fresenius Kabi** announced the launch of **Idacio® (adalimumab-aacf)**, a low-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Idacio** is priced at 5% less than **Humira's** wholesale acquisition cost.

Yusimry™ (adalimumab-aqvh):

- On July 3, 2023, **Coherus Biosciences** announced the launch of **Yusimry™ (adalimumab-aqvh)**, a low-concentration biosimilar of **AbbVie's Humira® (adalimumab)**. **Yusimry** is priced at more than an 85% discount to **Humira's** wholesale acquisition cost.

DRL_RI (rituximab):

- On July 12, 2023, **Dr. Reddy's** announced the FDA acceptance of an aBLA for **DRL_RI (rituximab)**, a proposed biosimilar of **Genentech's Rituxan® (rituximab)**.

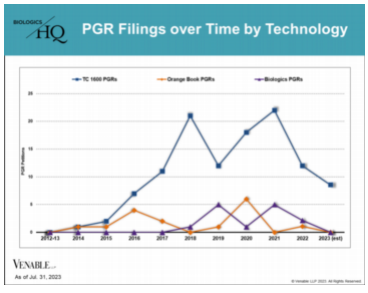
CDER Purple Book Updates

Beyfortus™ (nirsevimab-alip):

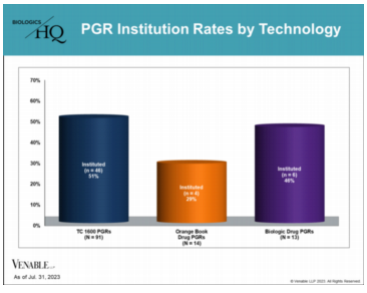
- On July 17, 2023, the FDA approved **AstraZeneca's Beyfortus™ (nirsevimab-alip)**.

STATISTICS

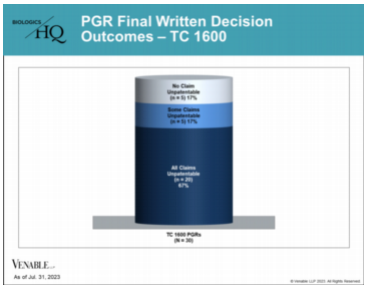
PGR Filings Over Time by Technology



PGR Institution Rates by Technology



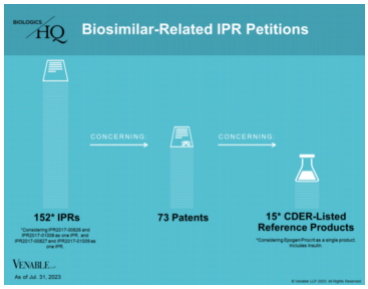
PGR Final Written Decision Outcomes – TC 1600



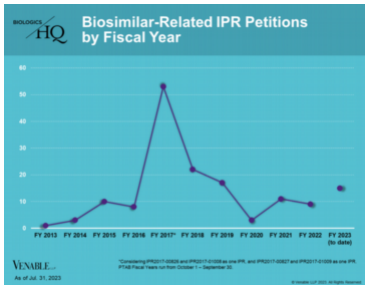
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

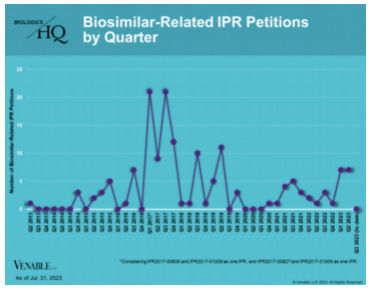
Biosimilar-Related IPR Petitions by Quarter



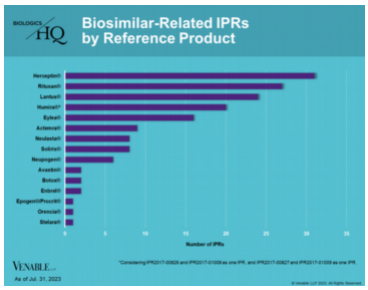
[Biosimilar-Related IPRs by Reference Product]



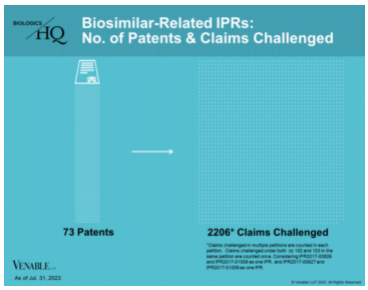
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



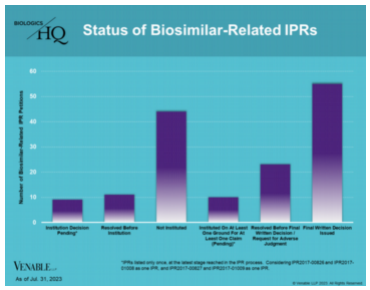
[Status of Biosimilar-Related IPRs]



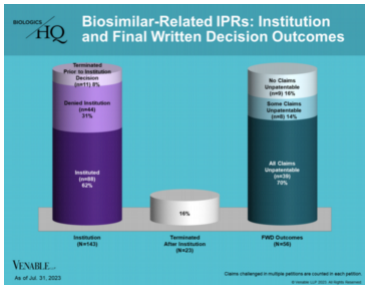
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



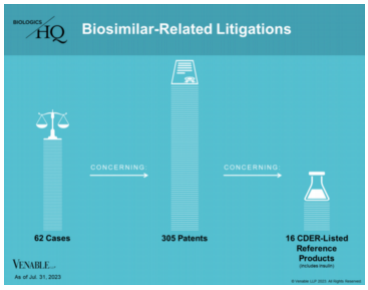
[Biosimilar-Related Litigations]



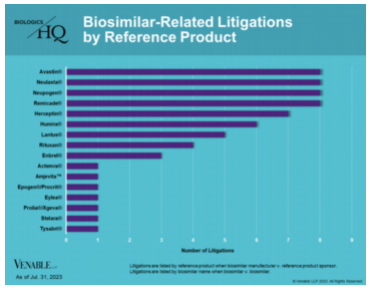
[Biosimilar-Related Litigations by Reference Product]



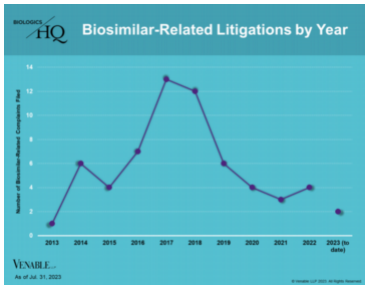
[Biosimilar-Related Litigations by Year]



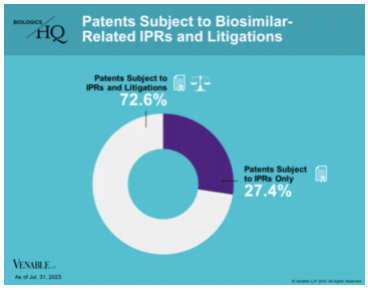
[Patents Subject to Biosimilar-Related IPRs and Litigations]



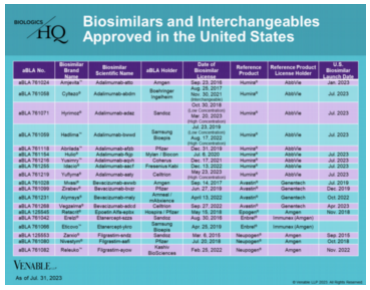
[Biosimilars and Interchangeables Approved in the United States]



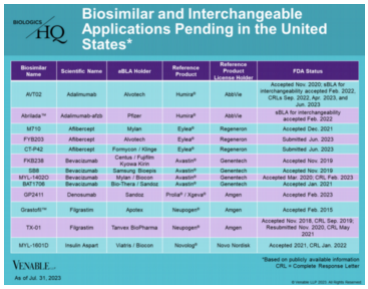
[Biosimilar and Interchangeable Applications Pending in the United States]

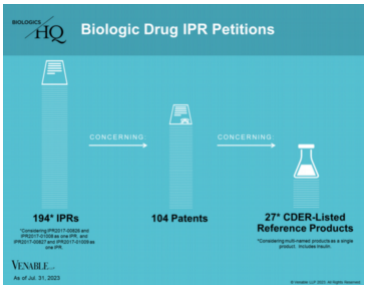


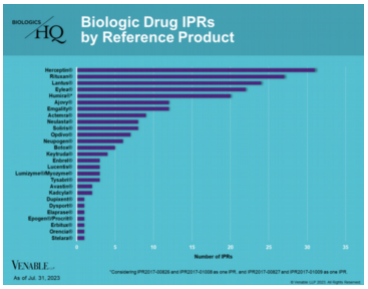
[Biologic Drug IPR Petitions]



[Biologic Drug IPRs by Reference Product]



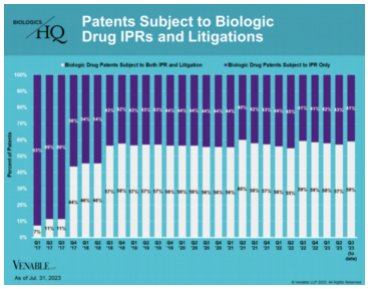


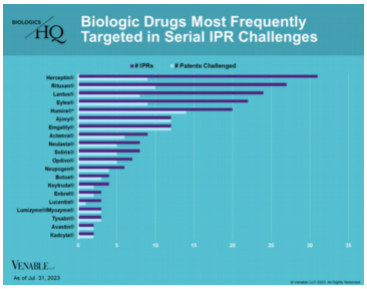


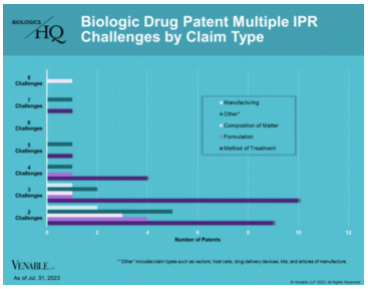
Patents Subject to Biologic Drug IPRs and Litigations

Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

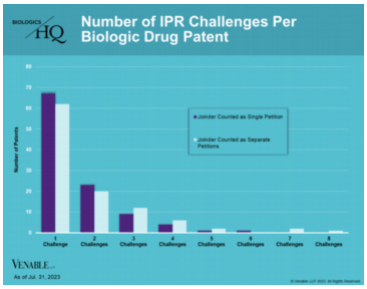
Biologic Drug Patent Multiple IPR Challenges by Claim Type

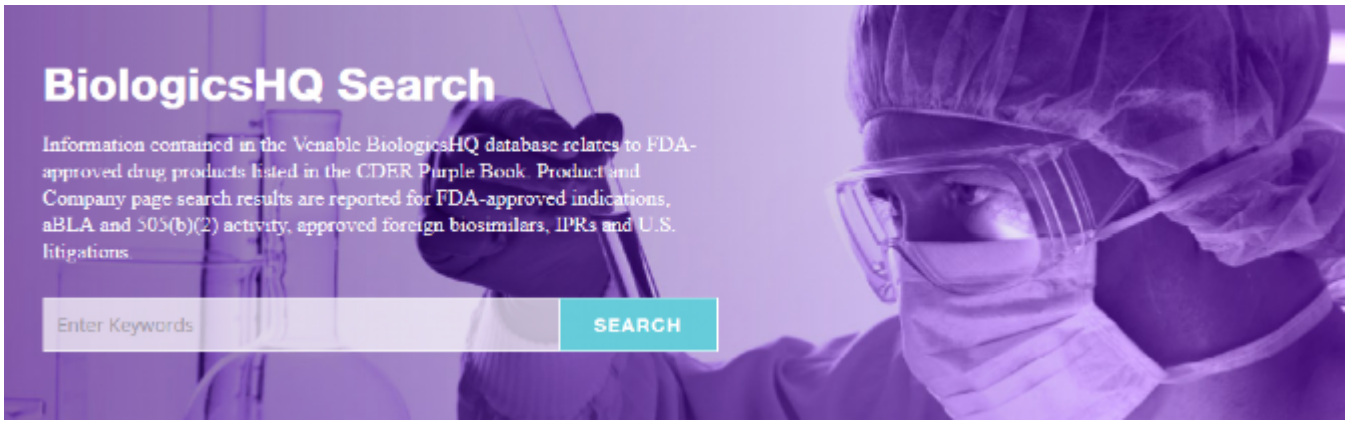






Number of IPR Challenges Per Biologic Drug Patent





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