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INJECTION



September 12, 2023



LATEST NEWS



**PREVAIL Act Reforms at the PTAB**

By: [Damineh Morsali, Ph.D.](#) and [Ha Kung Wong](#)

The Promoting and Respecting Economically Vital American Innovation Leadership Act (“PREVAIL Act”) was recently introduced in Congress. According to the Act's sponsors, it reforms rules and procedures at the PTAB to promote fair treatment for inventors, improve efficiency, and

ensure that the USPTO has the resources it needs to effectively administer a patent system that incentivizes American innovation and enables U.S. inventors to compete.

[Damineh Morsali](#) and [Ha Kung Wong](#) discuss the provisions of the bill, including changes to standing in IPRs and PGRs, handling of duplicative challenges, transparency, deadlines, and motions to amend.



**First List of Drugs for Medicare Price Negotiations Published Includes Three Biologics**

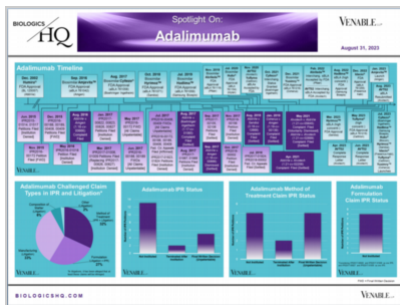
By: [Ha Kung Wong](#)

The Inflation Reduction Act (IRA), signed into law on August 16, 2022, allows the federal government to negotiate prices for some high-cost drugs covered under Medicare. On August 29, 2023, the US Department of Health and Human Services (HHS) published the first list of drugs that will

be subject to price negotiations.

[Ha Kung Wong](#) discusses the IRA provisions affecting pharmaceuticals and the three biologic drugs chosen for the first round of negotiations, including the potential discounts and what they may do to avoid negotiated prices taking effect.

**Spotlight On: Actemra<sup>®</sup> (tocilizumab)**



**Spotlight On: Neulasta<sup>®</sup> (pegfilgrastim) / Fulphila<sup>®</sup> (pegfilgrastim-jmdb) / Udenyca<sup>®</sup> (pegfilgrastim-cbqv) / Ziextenzo<sup>®</sup> (pegfilgrastim-bmez) / Nyvepria<sup>®</sup> (pegfilgrastim-ppgf) / Fylnetra<sup>™</sup> (pegfilgrastim-ppgf) / Stimufend<sup>®</sup> (pegfilgrastim-fpgk).**

**Spotlight On: Herceptin<sup>®</sup> (trastuzumab) / Ogivri<sup>®</sup> (trastuzumab-dkst) / Herzuma<sup>®</sup> (trastuzumab-pkrb) / Ontruzant<sup>®</sup> (trastuzumab-dttb) / Trazimera<sup>®</sup> (trastuzumab-qyyp) / Kanjinti<sup>®</sup> (trastuzumab-anns).**

### **Spotlight On: Biosimilar Litigations**

**Spotlight On: Rituxan<sup>®</sup> (rituximab) / Truxima<sup>®</sup> (rituximab-abbs) / Ruxience<sup>®</sup> (rituximab-pvvr) / Riabni<sup>™</sup> (rituximab-arrx).**

**Spotlight On: Humira<sup>®</sup> (adalimumab) / Amjevita<sup>™</sup> (adalimumab-atto) / Cyltezo<sup>®</sup> (adalimumab-adbm) / Hyrimoz<sup>®</sup> (adalimumab-adaz) / Hadlima<sup>™</sup> (adalimumab-bwwd) / Abrilada<sup>™</sup> (adalimumab-afzb) / Hulio<sup>®</sup> (adalimumab-fkjp) / Yusimry<sup>™</sup> (adalimumab-aqvh) / Idacio<sup>®</sup> (adalimumab-aacf) / Yuflyma<sup>®</sup> (adalimumab-aaty).**

**Spotlight On: Enbrel<sup>®</sup> (etanercept) / Erelzi<sup>®</sup> (etanercept-szsz) / Eticovo<sup>®</sup> (etanercept-ykro).**

**Spotlight On: Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine recombinant) / Basaglar<sup>®</sup> (insulin glargine) / Semglee<sup>®</sup> (insulin glargine-yfgn) / Rezvoglar<sup>™</sup> (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<sup>®</sup>, MSB11456, and BIIB800), pegfilgrastim (Neulasta<sup>®</sup>, Fulphila<sup>®</sup>, Udenyca<sup>®</sup>, Ziextenzo<sup>®</sup>, Nyvepria<sup>®</sup>, Fylnetra<sup>™</sup>, Stimufend<sup>®</sup>, Lapelga<sup>™</sup>, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin<sup>®</sup>, Ogivri<sup>®</sup>, Herzuma<sup>®</sup>, Ontruzant<sup>®</sup>, Trazimera<sup>®</sup>, Kanjinti<sup>®</sup>, TX-05, EG12014, and HLX02), rituximab (Rituxan<sup>®</sup>, Truxima<sup>®</sup>, Ruxience<sup>®</sup>, and Riabni<sup>™</sup>), adalimumab (Humira<sup>®</sup>, Amjevita<sup>™</sup>, Cyltezo<sup>®</sup>, Hyrimoz<sup>®</sup>, Hadlima<sup>™</sup>, Abrilada<sup>™</sup>, Hulio<sup>®</sup>, Yusimry<sup>™</sup>, Idacio<sup>®</sup>, Yuflyma<sup>®</sup>, and AVT02), etanercept (Enbrel<sup>®</sup>, Erelzi<sup>®</sup>, and Eticovo<sup>®</sup>), and insulin glargine (Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup>, Basaglar<sup>®</sup>, Semglee<sup>®</sup>, and Rezvoglar<sup>™</sup>) have been updated with activity through August 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 August 31, 2023.

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## UPDATES

IPRs and PGRs

### **Eylea® (aflibercept):**

- On August 8, 2023, **Regeneron** filed a statutory disclaimer and request to terminate IPR2023-00620 filed by **Celltrion** prior to an institution decision.
- On August 18, 2023, **Samsung Bioepis** filed IPR2023-01312 against **Regeneron** and a request for joinder with IPR2023-00462.

### **Stelara® (ustekinumab):**

- On August 9, 2023, the PTAB granted **Samsung Bioepis** and **Janssen's** joint request to terminate IPR2023-01103 due to settlement before institution decision.

### **Botox® (onabotulinumtoxinA):**

- On August 28, 2023, the PTAB denied institution of Hugel's IPR2023-00604 against **Medy-Tox**.

### **Actemra® (tocilizumab):**

- On August 29, 2023, final written decisions were issued in **Celltrion's** IPR2022-00578 and IPR2022-00579 against **Chugai**, **Hoffmann-La Roche**, and **Genentech**, finding all challenged claims unpatentable.

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## **aBLA Applications and FDA Activity**

### **FYB202 (ustekinumab):**

- On August 7, 2023, **Formycon** and **Fresenius Kabi** announced a settlement agreement with **Johnson & Johnson** related to FYB202 (ustekinumab), a proposed biosimilar of **Johnson & Johnson / Janssen's Stelara® (ustekinumab)**, which is currently in development. The settlement agreement grants a license beginning no later than April 15, 2025, subject to FDA approval. According to the press release, submission of an aBLA to the FDA is planned for later in 2023.

### **Tyruko® (natalizumab-sztn):**

- On August 24, 2023, the FDA approved **Sandoz** and **Polpharma's Tyruko® (natalizumab-sztn)**, a biosimilar of **Biogen's Tysabri® (natalizumab)**.

### **CT-P43 (ustekinumab):**

- On August 25, 2023, **Celltrion** announced a settlement agreement with **Johnson & Johnson** related to **CT-P43 (ustekinumab)**, a proposed biosimilar to **Johnson & Johnson / Janssen's Stelara® (ustekinumab)**. The settlement agreement allows **CT-P43** to enter the US market on March 7, 2025, subject to FDA approval. **Celltrion** submitted an aBLA to the FDA for **CT-P43** in June 2023.

### **AVT02 (adalimumab):**

- On August 31, 2023, **Alvotech** announced the resubmission of its aBLA for **AVT02 (adalimumab)**, a proposed interchangeable biosimilar of **AbbVie's Humira® (adalimumab)**, after receiving a Complete Response Letter from the FDA in June.

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## **CDER Purple Book Updates**

### **Talvey™ (talquetamab-tgvs):**

- On August 9, 2023, the FDA approved **Janssen's Talvey™ (talquetamab-tgvs)**.

### **Elrexfio™ (elranatamab):**

- On August 14, 2023, the FDA approved **Pfizer's Elrexfio™ (elranatamab)**.

**Veopoz™ (pozelimab-bbfg):**

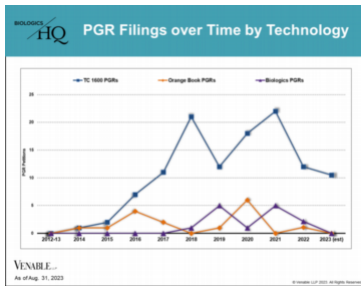
- On August 18, 2023, the FDA approved **Regeneron's Veopoz™ (poselimab-bbfg)**.

**Eylea® HD (afibercept):**

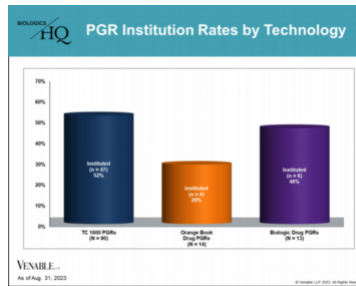
- On August 18, 2023, the FDA approved **Regeneron's Eylea® HD (afibercept)**, a high dose version of **Eylea® (afibercept)**.

**STATISTICS**

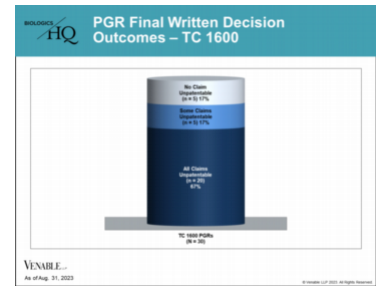
**PGR Filings Over Time by Technology**



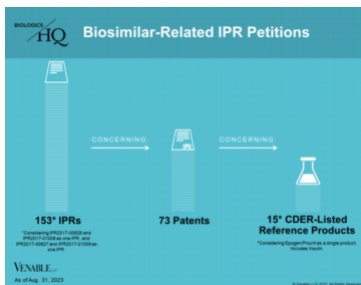
**PGR Institution Rates by Technology**



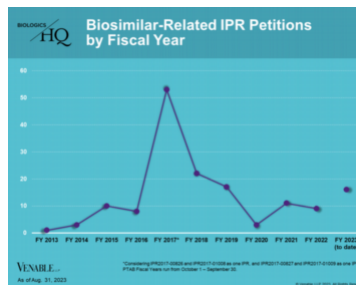
**PGR Final Written Decision Outcomes – TC 1600**



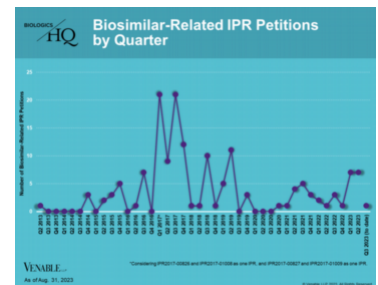
**Biosimilar-Related IPR Petitions**



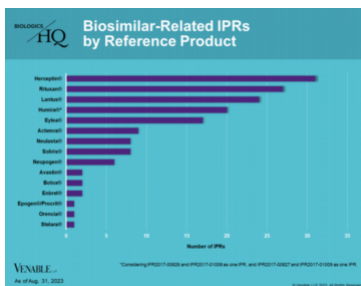
**Biosimilar-Related IPR Petitions by Fiscal Year**



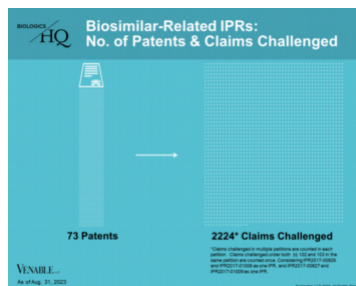
**Biosimilar-Related IPR Petitions by Quarter**



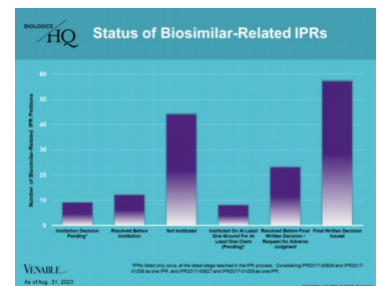
**Biosimilar-Related IPRs by Reference Product**



**Biosimilar-Related IPRs: Number of Patents and Claims Challenged**



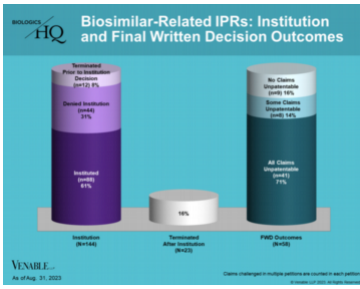
**Status of Biosimilar-Related IPRs**



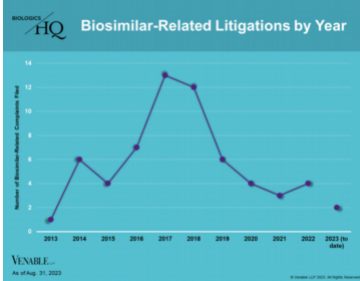
**Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes**

**Biosimilar-Related Litigations**

**Biosimilar-Related Litigations by Reference Product**



## Biosimilar-Related Litigations by Year

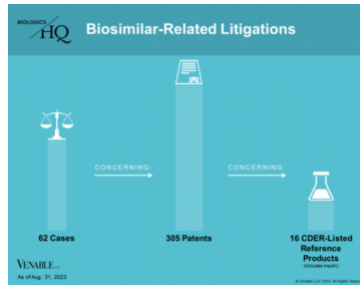
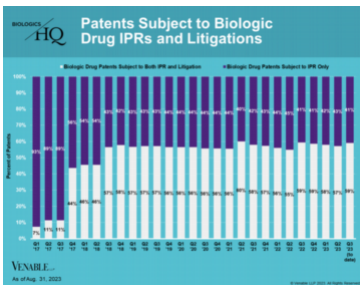


## Biosimilar and Interchangeable Applications Pending in the United States

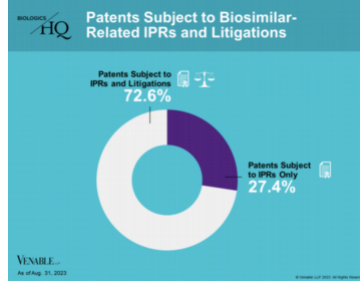
Biosimilar Name	Scientific Name	U.S. Holder	Reference Product	Reference Product U.S. Holder	FDA Status
AV52	Adalimumab	Abbott	Humira®	AbbVie	Interchangeability accepted Feb. 2023. OTC for 2023, Apr. 2023, and Jun. 2023. Interchangeability accepted Feb. 2022
Atkora™	Adalimumab-ask	Pfizer	Humira®	AbbVie	U.S. for interchangeability accepted Feb. 2022
MS16	Adalimumag	Sandoz	Etanercept	Regeneron	Accepted Dec. 2021
PT9203	Adalimumag	Alkermes	Etanercept	Regeneron	Submitted Jan. 2023
CT242	Aflibercept	Roche/Genentech	Eylea®	Regeneron	Submitted Jan. 2023
F0238	Biosimilars	Cartus / Pfizer	Aucor®	Genentech	Accepted Nov. 2019
BB	Biosimilars	Roche/Genentech	Aucor®	Genentech	Accepted Nov. 2019
MLV4000	Biosimilars	Roche/Genentech	Aucor®	Genentech	Accepted Nov. 2019
MS176	Biosimilars	Roche/Genentech	Aucor®	Genentech	Accepted Nov. 2019
QF411	Canakinumab	Sandoz	Procris®/Iguratig	Amgen	Accepted Feb. 2023
Granix™	Filgrastim	Amgen	Neupogen®	Amgen	Accepted Feb. 2023
TX-01	Filgrastim	Tanaka BioPharma	Neupogen®	Amgen	Accepted Nov. 2018, OTC, Sep. 2019. Resubmitted Nov. 2020, OTC, May 2021
MLV18010	Insulin Aspart	Novo Nordisk	Novolog®	Novo Nordisk	Accepted 2021, OTC, Jan. 2022

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## Patents Subject to Biologic Drug IPRs and Litigations



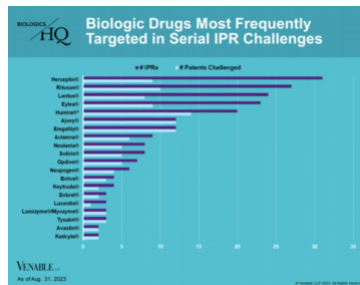
## Patents Subject to Biosimilar-Related IPRs and Litigations



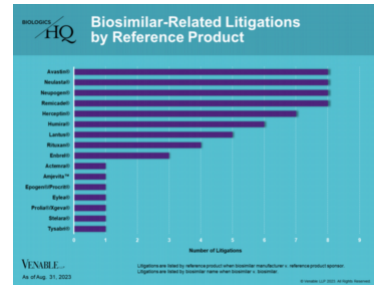
## Biologic Drug IPR Petitions



## Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



## Number of IPR Challenges Per Biologic Drug Patent

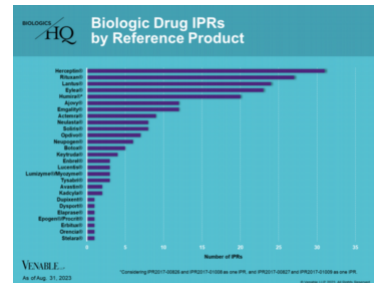


## Biosimilars and Interchangeables Approved in the United States

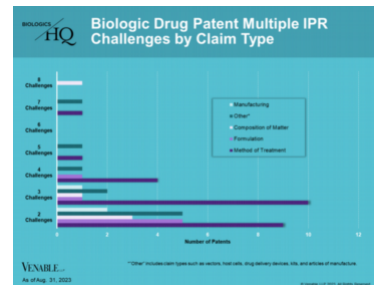
U.S. Holder	Reference Product	Reference Product U.S. Holder	U.S. Approval Date
AbbVie	Humira®	AbbVie	Jul 2023
Amgen	Neupogen®	Amgen	Jul 2023
Amgen	Novolog®	Novo Nordisk	Jul 2023
Amgen	Procris®	Amgen	Jul 2023
Amgen	Humira®	AbbVie	Jul 2023
Amgen	Humira®	AbbVie	Jul 2023
Amgen	Humira®	AbbVie	Jul 2023
Amgen	Humira®	AbbVie	Jul 2023
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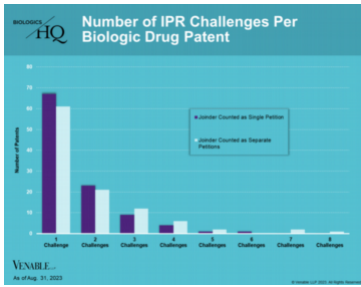
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## Biologic Drug IPRs by Reference Product



## Biologic Drug Patent Multiple IPR Challenges by Claim Type





# BiologicsHQ Search

Information contained in the Venable BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

Enter Keywords

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