



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.

Comparison of Adalimumab Biosimilars

Biosimilar Name	Approved in development?	Interchangeable?	Launch Date	IPR Pending?	Patent Challenge?	Cost Price?
Adalimumab-atto	Low	No, interchangeable clinical trial in progress (high concentration)	1/3/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-epo	Low	Yes	7/1/2023	0-7%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low and High	No	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Low/No, High/Yes
Adalimumab-eyo	Low and High	No, interchangeable clinical trial in progress (high concentration)	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Low/No, High/Yes
Adalimumab-eyo	High	No, interchangeable clinical trial in progress	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low	No	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low	High concentration in development	7/1/2023	0-1%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low	No	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low	High concentration in development	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes
Adalimumab-eyo	Low	High concentration in development	7/1/2023	0%	Excluded from "Patent Challenge" (Patent Expiry)	Yes

*Based on publicly available information

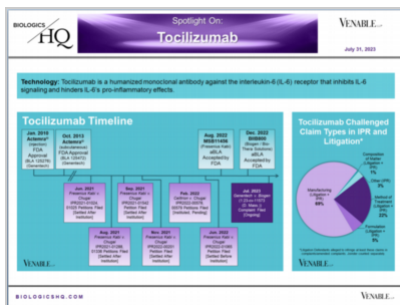
What Do the Humira Biosimilar / Interchangeable Launches Mean for the Adalimumab Market?

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 biosimilar uptake.



[Spotlight On: Actemra[®] \(tocilizumab\)](#)

[Spotlight On: Neulasta[®] \(pegfilgrastim\) / Fulphila[®] \(pegfilgrastim-jmdb\) / Udenyca[®] \(pegfilgrastim-cbqv\) / Ziextenzo[®] \(pegfilgrastim-bmez\) / Nyvepria[®] \(pegfilgrastim-appgf\) / Fylnetra[™] \(pegfilgrastim-appgf\) / 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[®] \(etanercept-szsz\) / Eticovo[®] \(etanercept-ykro\)](#)

[Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] \(insulin glargine recombinant\) / Basaglar[®] \(insulin glargine\) / Semglee[®] \(insulin glargine-yfgn\) / Rezvoglar[™] \(insulin glargine-agrl\)](#)

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 BIB800), 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.

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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**.

aBLA Applications and FDA Activity

Cyltezo[®] (adalimumab-adbm):

- On July 1, 2023, **Boehringer Ingelheim** announced the launch of **Cyltezo[®] (adalimumab-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)**.

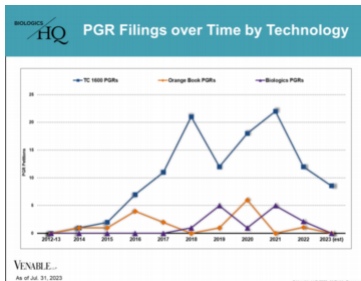
CDER Purple Book Updates

Beyfortus[™] (nirsevimab-alip):

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

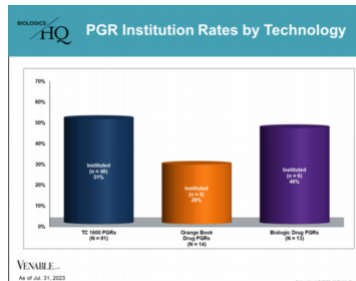
STATISTICS

PGR Filings Over Time by Technology



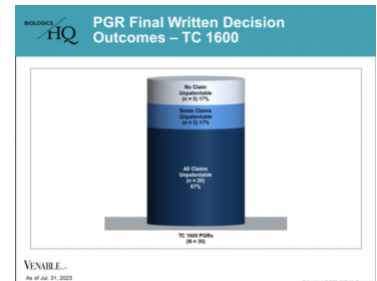
Biosimilar-Related IPR Petitions

PGR Institution Rates by Technology

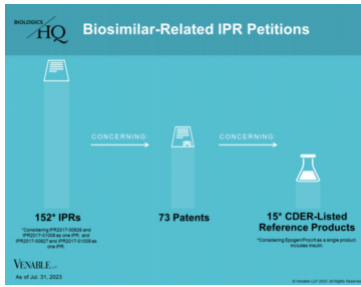


Biosimilar-Related IPR Petitions by Fiscal Year

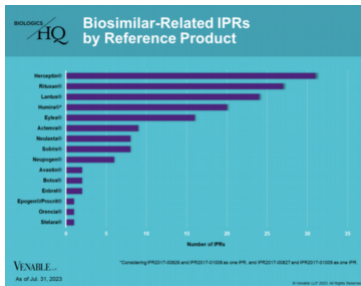
PGR Final Written Decision Outcomes – TC 1600



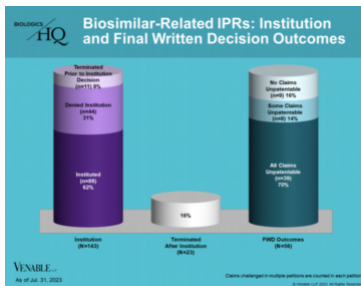
Biosimilar-Related IPR Petitions by Quarter



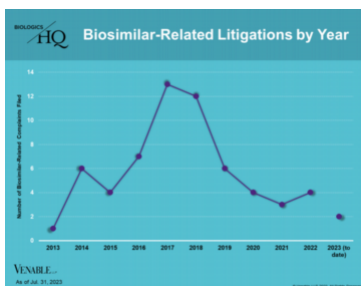
Biosimilar-Related IPRs by Reference Product



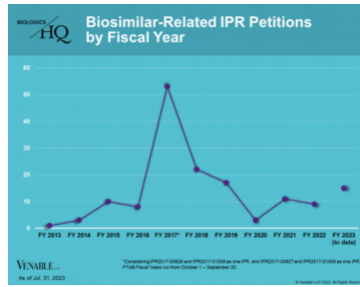
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



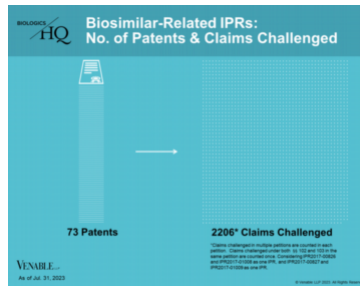
Biosimilar-Related Litigations by Year



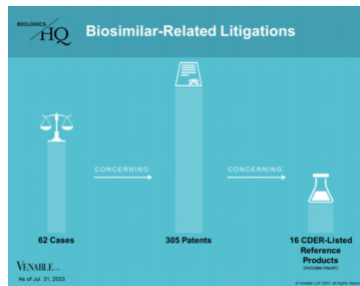
Biosimilar and Interchangeable Applications Pending in the United States



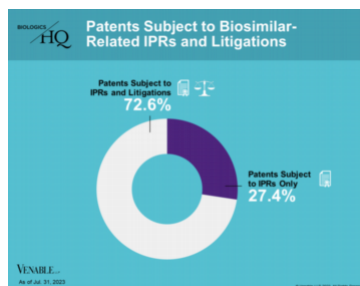
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



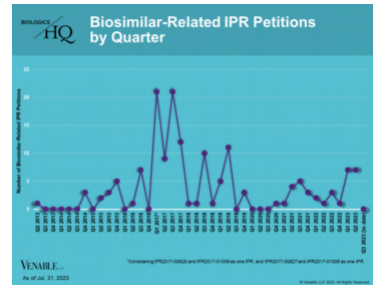
Biosimilar-Related Litigations



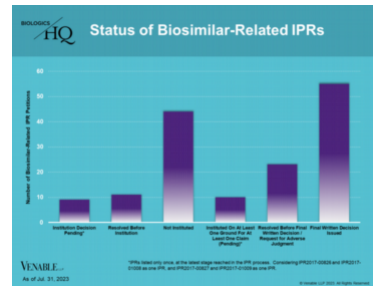
Patents Subject to Biosimilar-Related IPRs and Litigations



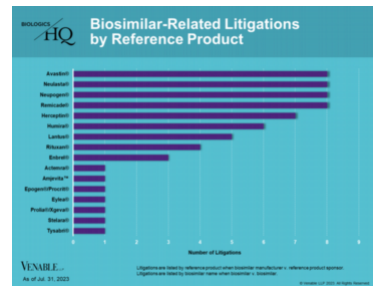
Biologic Drug IPR Petitions



Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States

Biosimilars and Interchangeables Approved in the United States

USDA No.	Reference Product	Reference Product	USDA No.	Reference Product	Reference Product	USDA No.	Reference Product
USDA 701026	Humira	Humira	USDA 701026	Humira	Humira	USDA 701026	Humira
USDA 701027	Humira	Humira	USDA 701027	Humira	Humira	USDA 701027	Humira
USDA 701028	Humira	Humira	USDA 701028	Humira	Humira	USDA 701028	Humira
USDA 701029	Humira	Humira	USDA 701029	Humira	Humira	USDA 701029	Humira
USDA 701030	Humira	Humira	USDA 701030	Humira	Humira	USDA 701030	Humira
USDA 701031	Humira	Humira	USDA 701031	Humira	Humira	USDA 701031	Humira
USDA 701032	Humira	Humira	USDA 701032	Humira	Humira	USDA 701032	Humira
USDA 701033	Humira	Humira	USDA 701033	Humira	Humira	USDA 701033	Humira
USDA 701034	Humira	Humira	USDA 701034	Humira	Humira	USDA 701034	Humira
USDA 701035	Humira	Humira	USDA 701035	Humira	Humira	USDA 701035	Humira
USDA 701036	Humira	Humira	USDA 701036	Humira	Humira	USDA 701036	Humira
USDA 701037	Humira	Humira	USDA 701037	Humira	Humira	USDA 701037	Humira
USDA 701038	Humira	Humira	USDA 701038	Humira	Humira	USDA 701038	Humira
USDA 701039	Humira	Humira	USDA 701039	Humira	Humira	USDA 701039	Humira
USDA 701040	Humira	Humira	USDA 701040	Humira	Humira	USDA 701040	Humira
USDA 701041	Humira	Humira	USDA 701041	Humira	Humira	USDA 701041	Humira
USDA 701042	Humira	Humira	USDA 701042	Humira	Humira	USDA 701042	Humira

VENABLE LLP
As of Jul. 31, 2023

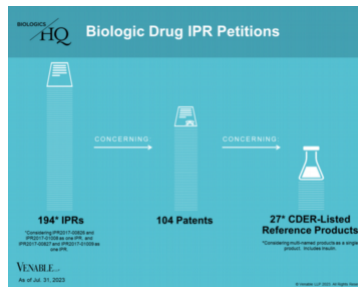
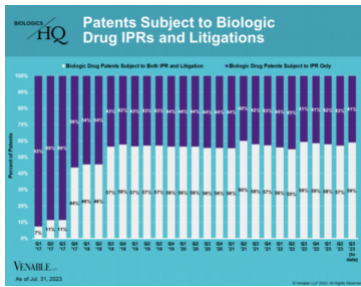
Biologic Drug IPRs by Reference Product

Biosimilar and Interchangeable Applications Pending in the United States*

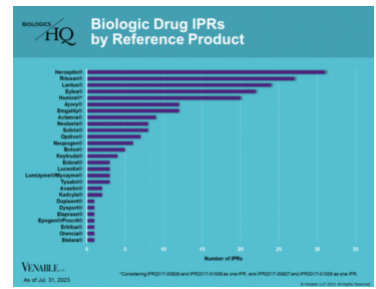
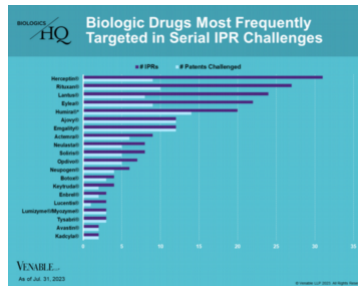
Biosimilar Name	Scientific Name	aBLA Holder	Reference Product	Reference Product Listing Status	FDA Status
AT22	Adalimumab	AbbVie	Humira®	Active	Approved Nov. 2009; BLA for interchangeability accepted Feb. 2021; CMA Feb. 2022; Apr. 2023, and Jun. 2023
Abraxis™	Abiraterone	Merck	Zytiga®	Active	BLA for interchangeability accepted Feb. 2022
AT10	Abiraterone	Merck	Zytiga®	Repealed	Accepted Dec. 2021
FT203	Abiraterone	Merck	Zytiga®	Repealed	Submitted Jan. 2023
CT242	Abiraterone	Paragard Village	Zytiga®	Repealed	Submitted Jan. 2023
FD238	Abiraterone	Cardinal Pharma	Zytiga®	Completed	Accepted Nov. 2018
BB	Biosimilar	Shimadzu Biotech	Avastin®	Completed	Accepted Nov. 2018
MTL14023	Biosimilar	Merck Serono	Avastin®	Completed	Accepted Mar. 2020; CMA Feb. 2023
MTL176	Biosimilar	Merck Serono	Avastin®	Completed	Accepted Jan. 2021
QF241	Denosumab	Sandoz	Prograf® / Xgeva®	Active	Accepted Feb. 2023
Granix™	Pegaptanib	Aptivis	Macugen®	Active	Accepted Feb. 2015
TX-01	Pegaptanib	Tanaka BioPharma	Macugen®	Active	Accepted Nov. 2018; CMA, CMA, Dec. 2019; Re-submitted Nov. 2020; CMA, May 2021
MTL14010	Insulin Aspart	Vanitas Biotech	Novolog®	Novo Nordisk	Accepted 2012; CMA, Jan. 2022

*Based on publicly available information: CMA = Complete Response Letter

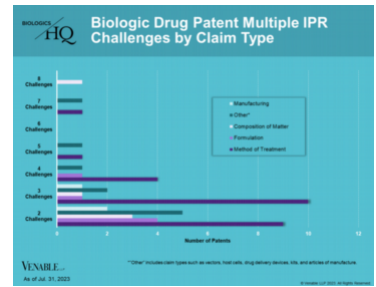
Patents Subject to Biologic Drug IPRs and Litigations



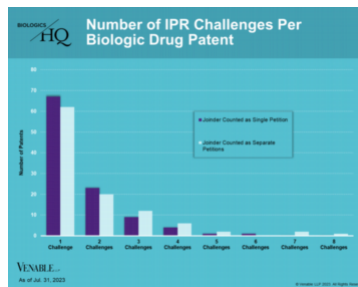
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent



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.

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