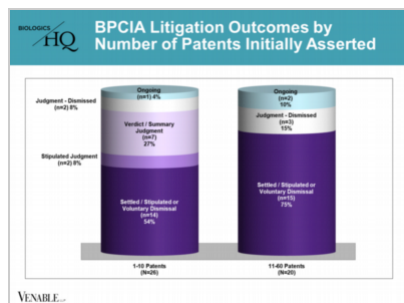




April 10, 2023



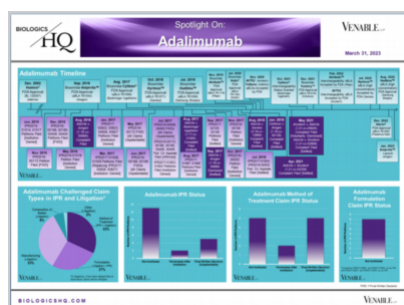
LATEST NEWS



The State of Biosimilars in 2023

By: [April Breyer Menon](#) and [Ha Kung Wong](#)

It has been 13 years since the Biologics Price Competition and Innovation Act (BPCIA) was enacted and biosimilars had a pathway to enter the U.S. market. While there have been challenges over this time, the U.S. biosimilar market has come a long way and has overcome many hurdles. We explore some of the issues biosimilars have faced when entering the U.S. market, with a particular focus on the impact of *inter partes* reviews (IPRs), post grant reviews (PGRs), and the BPCIA litigation patent dance, as well as challenges to gaining market share after launch.



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)

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-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 BII800), 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[®], AVT02, and Yuflyma[®]), etanercept (Enbrel[®], Erelzi[®], and Eticovo[®]), and insulin glargine (Lantus[®] / Lantus[®] SoloSTAR[®], Basaglar[®], Semglee[®], and Rezvoglar[™]) have been updated with activity through March 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 March 31, 2023.

Read
More
News

UPDATES

IPRs and PGRs

Eylea[®] (afibercept):

- On March 1, 2023, the PTAB denied institution of Mylan's IPR2023-00099 against Regeneron due to disclaimer of all challenged claims.
- On March 22, 2023, the PTAB instituted Celltrion's IPR2023-00532 and granted joinder with IPR2022-01225 against Regeneron. The PTAB also instituted Celltrion's IPR2023-00533 and Samsung Bioepis's IPR2023-00566 and granted motions for joinder with IPR2022-01226, against Regeneron.
- On March 26, 2023, Samsung Bioepis filed IPR2023-00739 against Regeneron.

aBLA Applications and FDA Activity

Rezvoglar[™] (insulin glargine-aglr):

- On March 1, 2023, Eli Lilly announced it will be launching Rezvoglar[™] (insulin glargine-aglr), a biosimilar and interchangeable of Sanofi's Lantus[®] (insulin glargine recombinant), on April 1, 2023 at a 78% discount.

Udenyca® (pegfilgrastim-cbqv):

- On March 6, 2023, **Coherus** announced the FDA approval of a single-dose prefilled autoinjector version of **Udenyca® (pegfilgrastim-cbqv)**, a biosimilar of **Amgen's Neulasta® (pegfilgrastim)**.

Hyrimoz™ (adalimumab-adaz):

- On March 21, 2023, **Sandoz** announced the FDA approval of a citrate-free, high-concentration version of **Hyrimoz™ (adalimumab-adaz)**, a biosimilar of **AbbVie's Humira® (adalimumab)**.

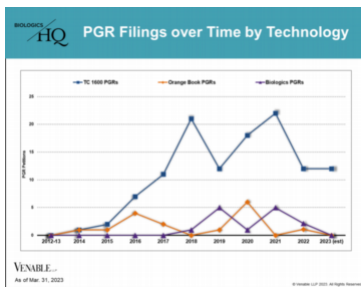
CDER Purple Book Updates

Zynyz™ (retifanlimab-dlwr):

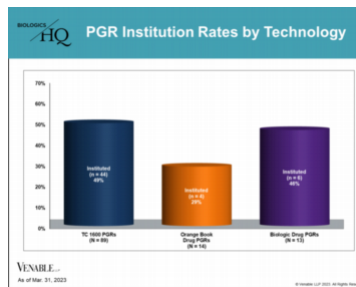
- On March 22, 2023, the FDA approved **Incyte's Zynyz™ (retifanlimab-dlwr)**.

STATISTICS

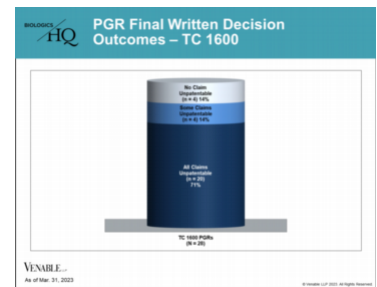
PGR Filings Over Time by Technology



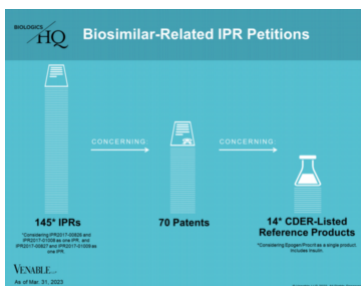
PGR Institution Rates by Technology



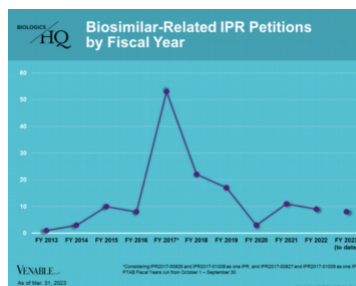
PGR Final Written Decision Outcomes – TC 1600



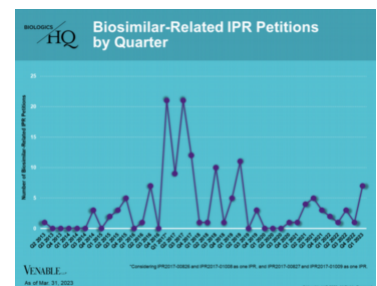
Biosimilar-Related IPR Petitions



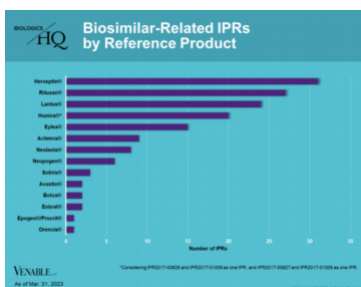
Biosimilar-Related IPR Petitions by Fiscal Year



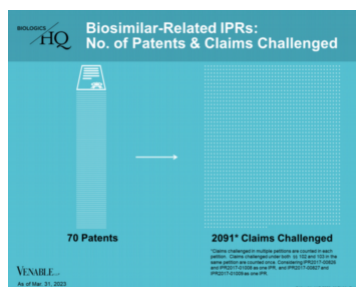
Biosimilar-Related IPR Petitions by Quarter



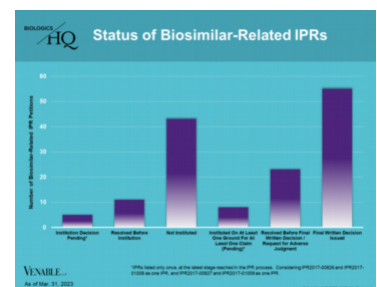
Biosimilar-Related IPRs by Reference Product



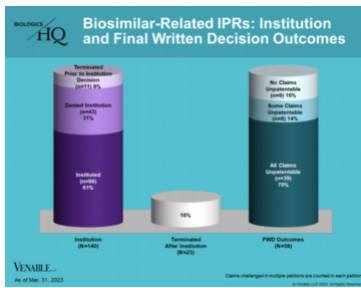
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



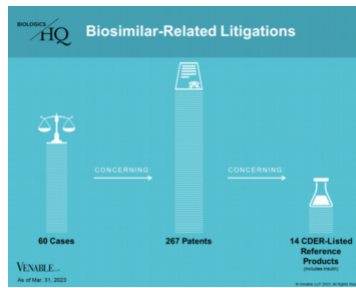
Status of Biosimilar-Related IPRs



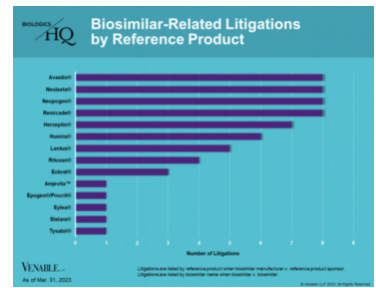
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



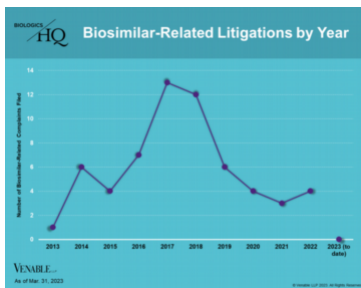
Biosimilar-Related Litigations



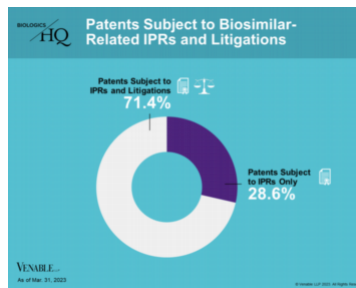
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



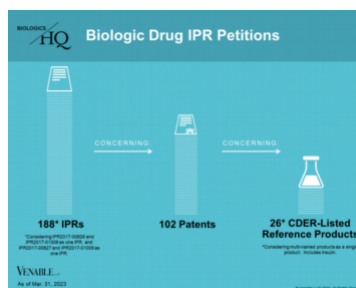
Biosimilars and Interchangeables Approved in the United States

U.S. No.	Reference Product	U.S. Brand Name	U.S. Approval Date
1	Humira	Humira	Jan 2013
2	Humira	Humira-CTP	Jan 2013
3	Humira	Humira-CTP2	Jan 2013
4	Humira	Humira-CTP3	Jan 2013
5	Humira	Humira-CTP4	Jan 2013
6	Humira	Humira-CTP5	Jan 2013
7	Humira	Humira-CTP6	Jan 2013
8	Humira	Humira-CTP7	Jan 2013
9	Humira	Humira-CTP8	Jan 2013
10	Humira	Humira-CTP9	Jan 2013
11	Humira	Humira-CTP10	Jan 2013
12	Humira	Humira-CTP11	Jan 2013
13	Humira	Humira-CTP12	Jan 2013
14	Humira	Humira-CTP13	Jan 2013
15	Humira	Humira-CTP14	Jan 2013
16	Humira	Humira-CTP15	Jan 2013
17	Humira	Humira-CTP16	Jan 2013
18	Humira	Humira-CTP17	Jan 2013
19	Humira	Humira-CTP18	Jan 2013
20	Humira	Humira-CTP19	Jan 2013
21	Humira	Humira-CTP20	Jan 2013

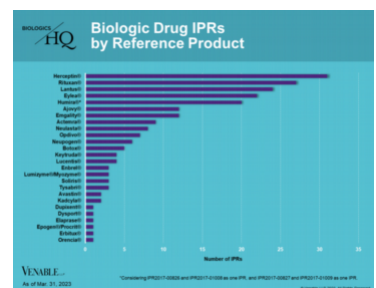
Biosimilar and Interchangeable Applications Pending in the United States

Biosimilar Name	Reference Product	U.S. Brand Name	U.S. Approval Date
Abatacept	Humira	Humira	Jan 2013
Bevacizumab	Humira	Humira	Jan 2013
Humira-CTP	Humira	Humira	Jan 2013
Humira-CTP2	Humira	Humira	Jan 2013
Humira-CTP3	Humira	Humira	Jan 2013
Humira-CTP4	Humira	Humira	Jan 2013
Humira-CTP5	Humira	Humira	Jan 2013
Humira-CTP6	Humira	Humira	Jan 2013
Humira-CTP7	Humira	Humira	Jan 2013
Humira-CTP8	Humira	Humira	Jan 2013
Humira-CTP9	Humira	Humira	Jan 2013
Humira-CTP10	Humira	Humira	Jan 2013
Humira-CTP11	Humira	Humira	Jan 2013
Humira-CTP12	Humira	Humira	Jan 2013
Humira-CTP13	Humira	Humira	Jan 2013
Humira-CTP14	Humira	Humira	Jan 2013
Humira-CTP15	Humira	Humira	Jan 2013
Humira-CTP16	Humira	Humira	Jan 2013
Humira-CTP17	Humira	Humira	Jan 2013
Humira-CTP18	Humira	Humira	Jan 2013
Humira-CTP19	Humira	Humira	Jan 2013
Humira-CTP20	Humira	Humira	Jan 2013

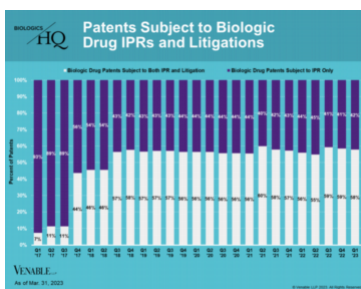
Biologic Drug IPR Petitions



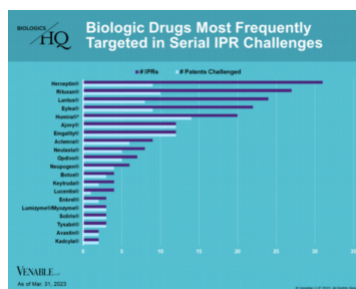
Biologic Drug IPRs by Reference Product



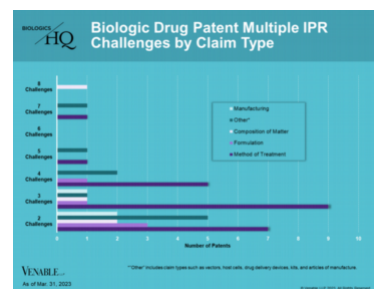
Patents Subject to Biologic Drug IPRs and Litigations



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

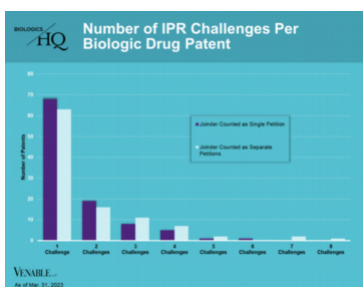


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR

Challenges Per Biologic Drug Patent



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.

Contact the BiologicsHQ Team



Robert S. Schwartz, Ph.D.
Chair
+1 212.218.2298
RSchwartz@Venable.com



Ha Kung Wong
Partner
+1 212.218.2571
HWong@Venable.com

CALIFORNIA | DELAWARE | FLORIDA | ILLINOIS | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC

© 2023 Venable LLP. This email is published by the law firm Venable LLP. It is not intended to provide legal advice or opinion. Such advice may be given only when it is related to specific fact situations that Venable has accepted an engagement as counsel to address. ATTORNEY ADVERTISING.

Venable.com | Manage Preferences | Unsubscribe | If you are having trouble viewing this email, click here to view it in the browser or contact us by mail at Venable LLP, 600 Massachusetts Avenue, NW, Washington, DC 20001.