

MONTHLY
INJECTION

May 8, 2023



LATEST NEWS



Spotlight On: Actemra[®] (tocilizumab)

Spotlight On: Neulasta[®] (pegfilgrastim) / Fulphila[®] (pegfilgrastim-jmdb) / Udenyca[®] (pegfilgrastim-cbqv) / Ziextenzo[®] (pegfilgrastim-bmez) / Nyvepria[®] (pegfilgrastim-appgf) / FyInetra[™] (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 [BIB800](#)), pegfilgrastim ([Neulasta](#)[®], [Fulphila](#)[®], [Udenyca](#)[®], [Ziextenzo](#)[®], [Nyvepria](#)[®], [Fynetra](#)[™], [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 April 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 April 30, 2023.

Read
More
News

UPDATES

IPRs and PGRs

[Opdivo](#)[®] ([nivolumab](#)):

- On April 10, 2023, Dana-Farber Cancer Institute's IPR2023-00249 and IPR2023-00252 against [Bristol-Myers Squibb](#) were terminated due to settlement prior to institution decisions.
- On April 18, 2023, Dana-Farber Cancer Institute's IPR2023-00501 against [ER Squibb & Sons](#) was terminated due to settlement prior to an institution decision.

[Eylea](#)[®] ([aflibercept](#)):

- On April 27, 2023, [Samsung Bioepis](#) filed IPR2023-00884 against [Regeneron](#).

Litigations

[Evenity](#)[®] ([romosozumab-aqqg](#)):

- On April 21, 2023, [OssiFi-Mab](#) filed Case No. 1:23-cv-10861 (D. Mass.) against [Amgen](#).

[Opdivo](#)[®] ([nivolumab](#)) / [Imfinzi](#)[®] ([durvalumab](#)):

- On April 25, 2023, [Bristol-Myers Squibb](#) filed Case No. 1:23-cv-00459 (D. Del.) against [AstraZeneca](#).

aBLA Applications and FDA Activity

[Rezvoglar](#)[™] ([insulin glargine-aglr](#)):

- On April 1, 2023, [Eli Lilly](#) launched [Rezvoglar](#)[™] ([insulin glargine-aglr](#)), a biosimilar and interchangeable of [Sanofi's Lantus](#)[®] ([insulin glargine recombinant](#)) at a 78% discount.

[AVT02](#) ([adalimumab](#)):

- On April 13, 2023, **Alvotech** and **Teva** announced receipt of a Complete Response Letter from the FDA related to **AVT02 (adalimumab)**, a proposed biosimilar of **AbbVie's Humira® (adalimumab)**.

Vegzelma® (bevacizumab-adcd):

- On April 17, 2023, **Celltrion** announced the launch of **Vegzelma® (bevacizumab-adcd)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**.

Xlucane™ (ranibizumab):

- On April 24, 2023, **Xbrane** announced the resubmission of an aBLA for **Xlucane™ (ranibizumab)**, a proposed biosimilar of **Genentech's Lucentis® (ranibizumab)**.

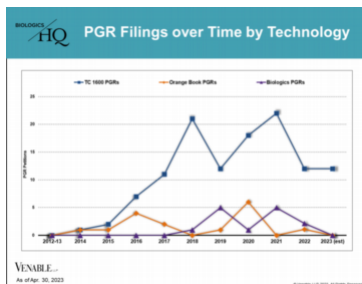
Non-U.S. Biosimilars / Follow-On Biologics

Hyrimoz® (adalimumab-adaz):

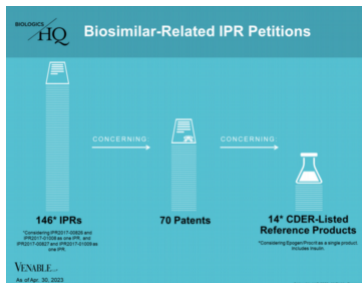
- On April 3, 2023, **Sandoz** announced the approval of citrate-free, high-concentration **Hyrimoz® (adalimumab-adaz)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, in the E.U.

STATISTICS

PGR Filings Over Time by Technology

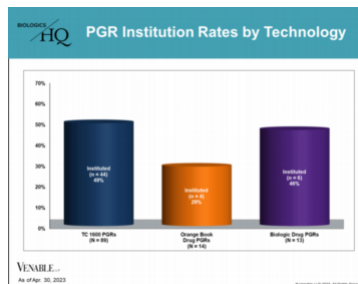


Biosimilar-Related IPR Petitions

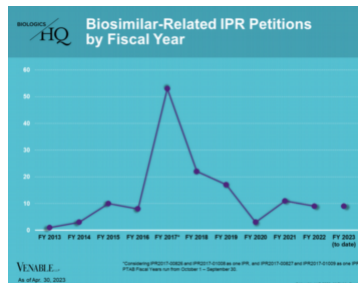


Biosimilar-Related IPRs by Reference Product

PGR Institution Rates by Technology

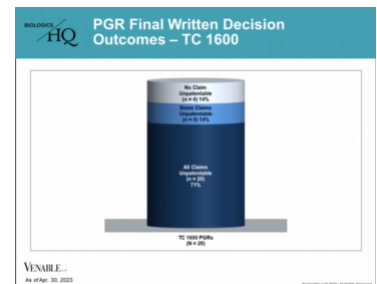


Biosimilar-Related IPR Petitions by Fiscal Year

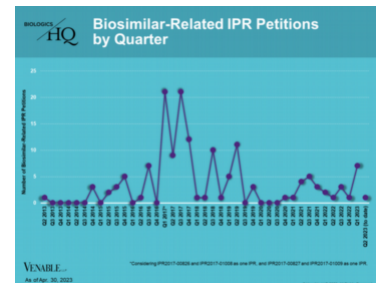


Biosimilar-Related IPRs: Number of Patents and Claims Challenged

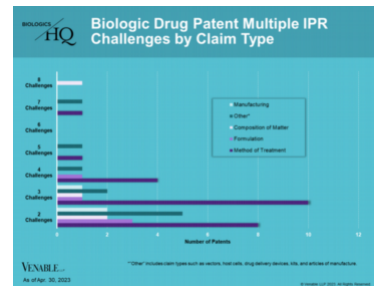
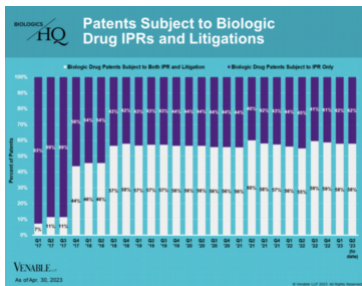
PGR Final Written Decision Outcomes – TC 1600



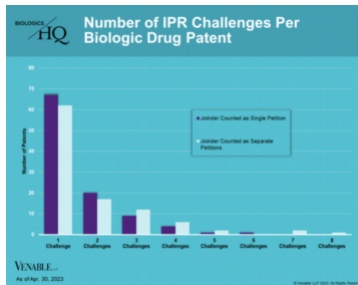
Biosimilar-Related IPR Petitions by Quarter



Status of Biosimilar-Related IPRs



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

© 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.