

MONTHLY
INJECTION

June 7, 2022



LATEST NEWS

**PTAB Director Review Updates**By: [April Breyer Menon](#)

On May 27, 2022, the Federal Circuit upheld the ability of Acting Director Hirshfeld to issue Director review decisions, despite being a temporary leader who was not appointed by the President and confirmed by the Senate. On the same day, the PTAB also argued that institution decisions are not subject to the Director review procedure.



Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria® (pegfilgrastim-apgf)

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)

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\)](#)

[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 pegfilgrastim ([Neulasta®](#), [Lapelga™](#), [Ziextenzo®](#), [Udenyca®](#), [Fulphila®](#), [Nyvepria®](#), [MSB11455](#), and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin®](#), [Ogivri®](#), [Herzuma®](#), [Ontruzant®](#), [Trazimera®](#), [Kanjinti®](#), and [EG12014](#)), rituximab ([Rituxan®](#), [Truxima®](#), and [Ruxience®](#)), adalimumab ([Humira®](#), [Amjevita™](#), [Cyltezo®](#), [Hyrimoz™](#), [Hadlima™](#), [Abrilada™](#), [Hulio®](#), and [Yusimry™](#)), etanercept ([Enbrel®](#), [Erelzi®](#), and [Eticovo®](#)), and insulin glargine ([Lantus®](#) / [Lantus® SoloSTAR®](#), [Basaglar®](#), [Semglee®](#), and [Rezvoglar™](#)) have been updated with activity through May 31, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through May 31, 2022.

Read
More
News

UPDATES

IPRs and PGRs

[Skyrizi® \(risankizumab-rzaa\):](#)

- On May 2, 2022, [Sandoz](#) filed PGR2022-00037 against [Boehringer Ingelheim](#).

[Enhertu® \(fam-trastuzumab deruxtecan-nxki\):](#)

- On May 11, 2022, [Seagen](#) filed a request for adverse judgment after canceling the challenged claims in PGR2021-00042.

aBLA Applications and FDA Activity

[Fylnetra™ \(pegfilgrastim-pbbk\):](#)

- On May 26, 2022, the FDA approved [Kashiv Biosciences](#) and [Amneal's Fylnetra™ \(pegfilgrastim-pbbk\)](#), a biosimilar of [Amgen's Neulasta® \(pegfilgrastim\)](#).

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

[Amelivu™ \(ranibizumab\):](#)

- On May 16, 2022, [Samsung Bioepis](#) received approval for [Amelivu™ \(ranibizumab\)](#), a biosimilar of [Genentech's Lucentis® \(ranibizumab\)](#), in South Korea.

Ongavia (ranibizumab):

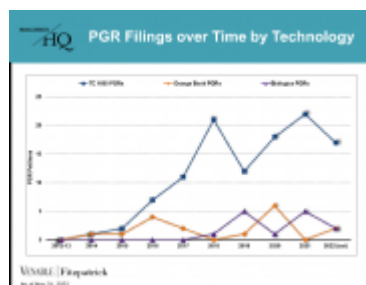
- On May 17, 2022, Teva received approval for Ongavia (ranibizumab), a biosimilar of Genentech's Lucentis® (ranibizumab), in the U.K.

Abevmy™ (bevacizumab):

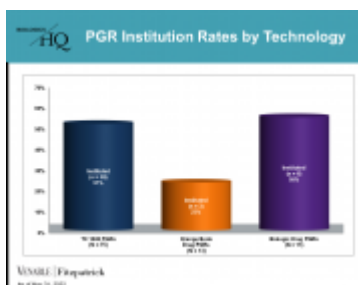
- On May 19, 2022, Biocon and Viatris announced the launch of Abevmy™ (bevacizumab), a biosimilar of Genentech's Avastin® (bevacizumab), in Canada.

STATISTICS

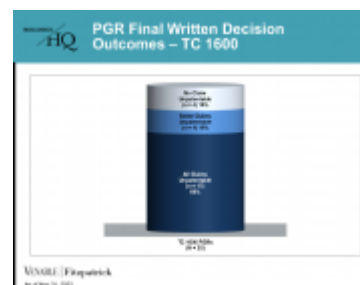
PGR Filings over Time by Technology



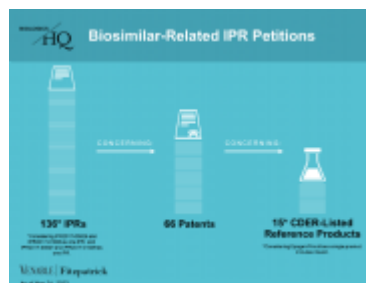
PGR Institution Rates by Technology



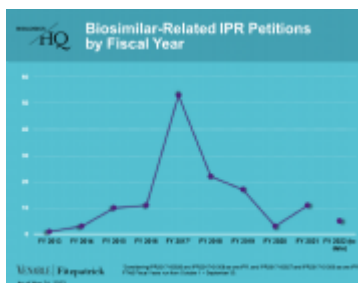
PGR Final Written Decision Outcomes - TC 1600



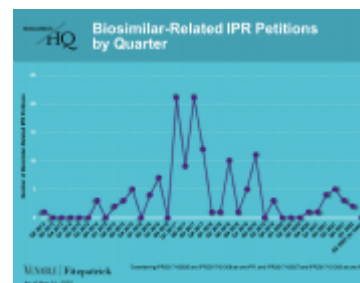
Biosimilar-Related IPR Petitions



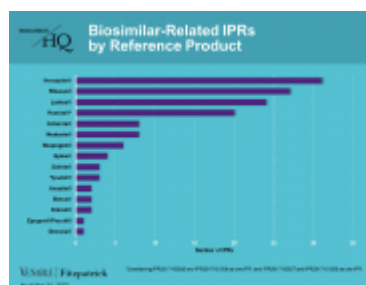
Biosimilar-Related IPR Petitions by Fiscal Year



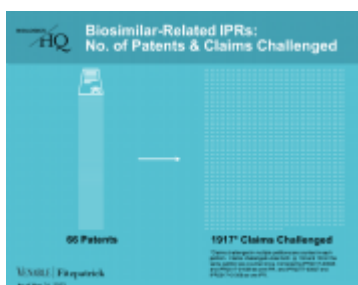
Biosimilar-Related IPR Petitions by Quarter



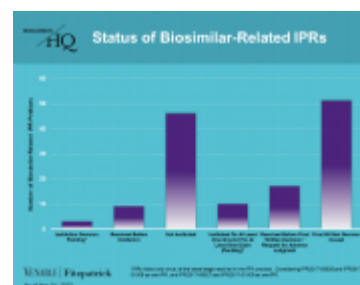
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



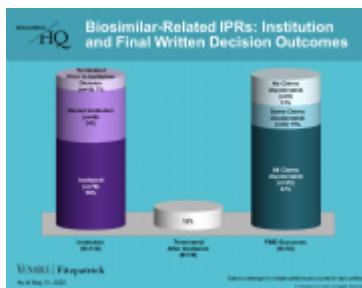
Status of Biosimilar-Related IPRs



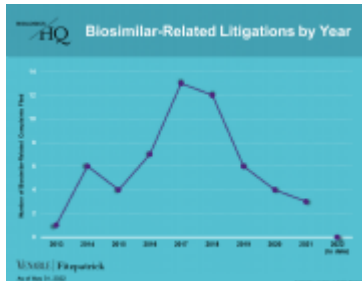
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

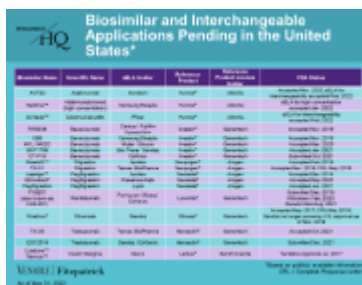
Biosimilar-Related Litigations by Reference Product



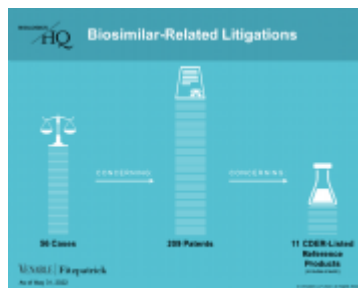
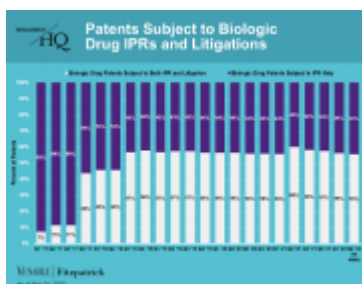
Biosimilar-Related Litigations by Year



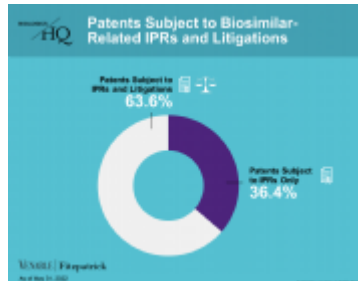
Biosimilar and Interchangeable Applications Pending in the United States



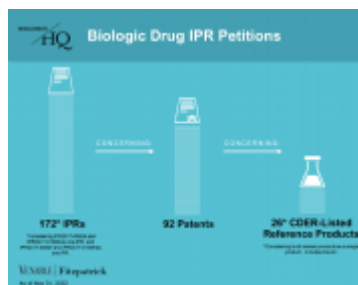
Patents Subject to Biologic Drug IPRs and Litigations



Patents Subject to Biosimilar-Related IPRs and Litigations



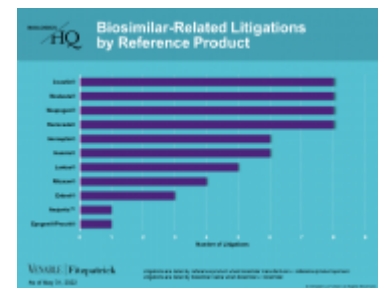
Biologic Drug IPR Petitions



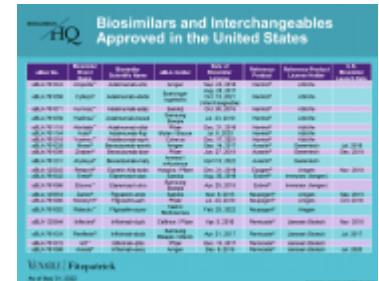
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



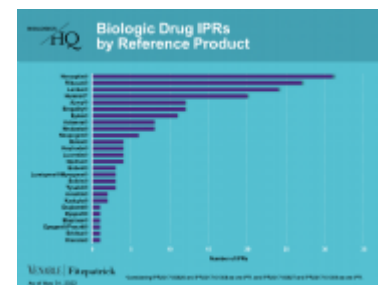
Number of IPR Challenges Per Biologic Drug Patent



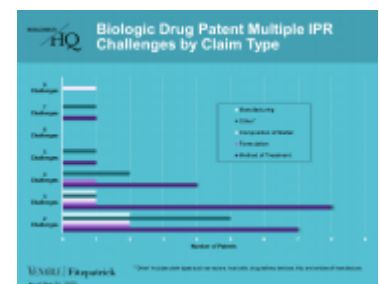
Biosimilars and Interchangeables Approved in the United States

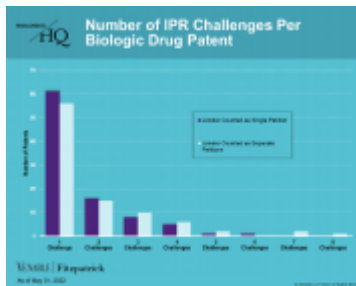


Biologic Drug IPRs by Reference Product



Biologic Drug Patent Multiple IPR Challenges by Claim Type





BiologicsHQ Search

Information contained in the Venable Fitzpatrick 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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