BIOLOGICS HQ

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December 9, 2022

LATEST NEWS

Senator Mike Lee Introduces the Biosimilar Red Tape Elimination Act to Eliminate Switching Study Requirement for Biosimilar Interchangeability

By: April Breyer Menon and Ha Kung Wong

On November 17, 2022, Senator Mike Lee (R-UT) introduced the "Biosimilar Red Tape Elimination Act" to increase biosimilar competition and reduce patient costs by prohibiting the FDA from requiring switching studies to approve a biosimilar as interchangeable.

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 November 30, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through November 30, 2022.

Read More News

UPDATES

IPRs and PGRs

Skyrizi® (risankizumab-rzaa):

- On November 7, 2022, the PTAB denied institution in ***Sandoz*** *v.* ***Boehringer Ingelheim*** PGR2022-00037.

Eylea® (aflibercept):

- On November 9, 2022, the PTAB issued final written decisions in IPR2021-00880 (IPR2022-00257 and IPR2022-00301 joined) and IPR2021-00881 (IPR2022-00258 and IPR2022-00298 joined) between **Regeneron** and **Mylan**, **Celltrion**, and **Apotex**, finding all challenged claims unpatentable.

Litigations

Praluent® (alirocumab) / Repatha® (evolocumab):

- On November 2, 2022, the Supreme Court granted certiorari in ***Amgen*** *v.* ***Sanofi*** Case No. 21-757, appealing the Federal Circuit's affirmance (Case No. 20-1074) of grant of judgment as a matter of law that claims lacked enablement in Case No. 1:14-cv-01317 (D. Del.).

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On November 9, 2022, the jury verdict in ***Teva*** *v.* ***Eli Lilly*** Case No. 1:18-cv-12029 (D. Mass.) was entered, finding **Teva's** patents valid and infringed.

Keytruda® (pembrolizumab):

- On November 29, 2022, **Merck Sharp & Dohme** filed a declaratory judgment action, Case No. 1:22-cv-03059 (D. Md.), against The Johns Hopkins University related to a collaboration agreement.

Stelara® (ustekinumab):

- On November 29, 2022, **Janssen** filed Case No. 1:22-cv-01549 (D. Del.) against **Amgen** related to proposed biosimilar **ABP 654 (ustekinumab)**.

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aBLA Applications and FDA Activity

ABP 654 (ustekinumab):

- On or before November 3, 2022, **Amgen** submitted an aBLA to the FDA for **ABP 654 (ustekinumab)**, a proposed biosimilar of **Janssen's Stelara® (ustekinumab)**.

Rezvoglar™ (insulin glargine-aglr):

- On November 16, 2022, the FDA approved **Eli Lilly's Rezvoglar™ (insulin glargine-aglr)** as interchangeable with **Sanofi's Lantus® (insulin glargine recombinant)**.

Releuko™ (filgrastim-ayow):

- On November 22, 2022, **Amneal** and **Kashiv BioSciences** announced the launch of **Releuko™ (filgrastim-ayow)**, a biosimilar of **Amgen's Neupogen® (filgrastim)**.

CDER Purple Book Updates

Elahere™ (mirvetuximab soravtansine-gynx):

- On November 14, 2022, the FDA approved **ImmunoGen's Elahere™ (mirvetuximab soravtansine-gynx)**.

Tzield™ (teplizumab-mzwv):

- On November 17, 2022, the FDA approved **Provention Bio's Tzield™ (teplizumab-mzwv)**.

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

Ximluci® (ranibizumab):

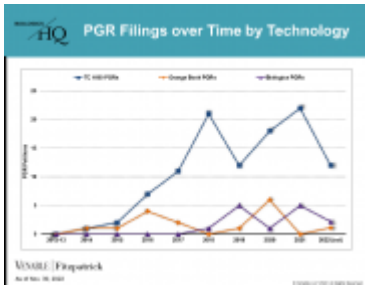
- On November 21, 2022, **STADA** and **Xbrane** announced the approval of **Ximluci® (ranibizumab)**, a biosimilar of **Genentech's Lucentis® (ranibizumab)**, in the E.U.

Ciptune™ / Ardalicip™ (adalimumab):

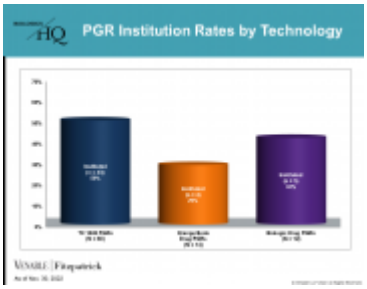
- On November 14, 2022, **Alvotech** and **Cipla** announced the approval of **Ciptunec™ / Ardalicip™ (adalimumab)**, a high-concentration biosimilar of **AbbVie's Humira® (adalimumab)**, in Australia.

STATISTICS

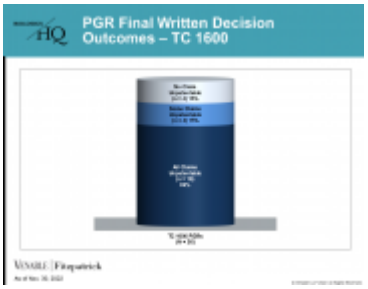
PGR Filings Over Time by Technology	PGR Institution Rates by Technology	PGR Final Written Decision Outcomes – TC 1600



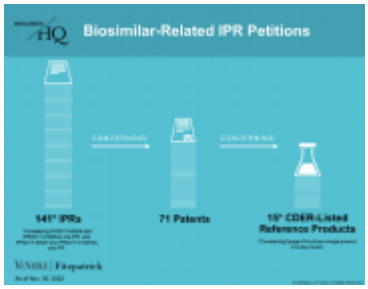
Biosimilar-Related IPR Petitions



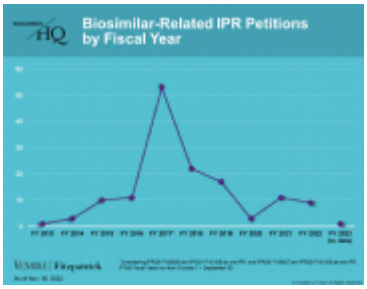
Biosimilar-Related IPR Petitions by Fiscal Year



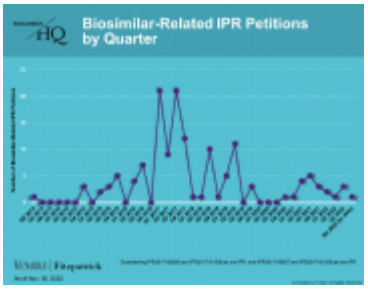
Biosimilar-Related IPR Petitions by Quarter



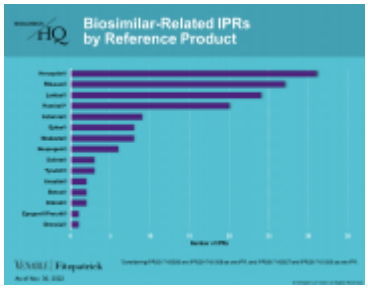
Biosimilar-Related IPRs by Reference Product



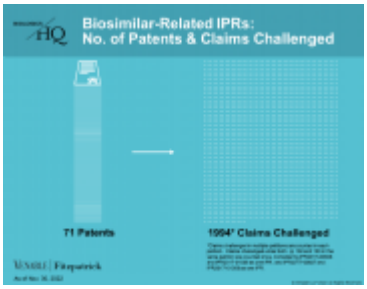
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



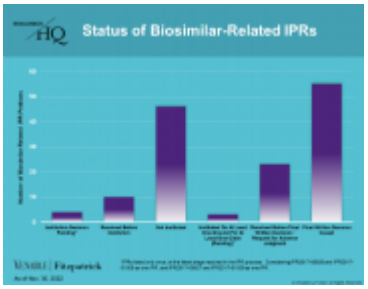
Status of Biosimilar-Related IPRs



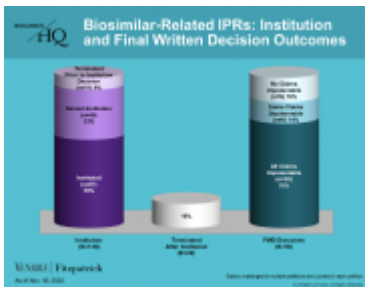
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



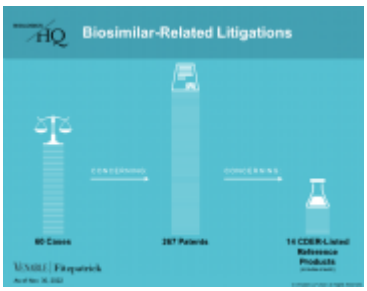
Biosimilar-Related Litigations



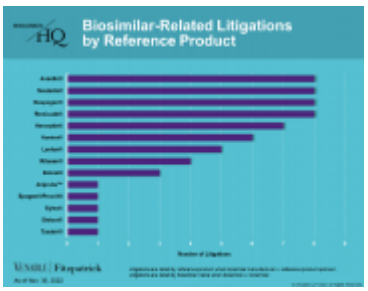
Biosimilar-Related Litigations by Reference Product



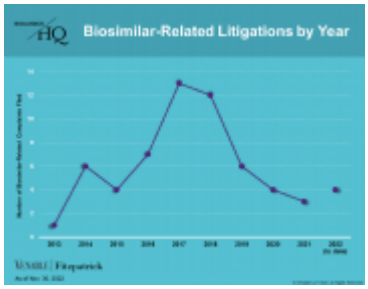
Biosimilar-Related Litigations by Year

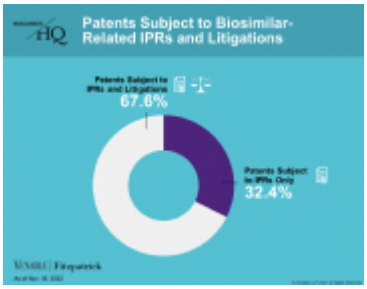


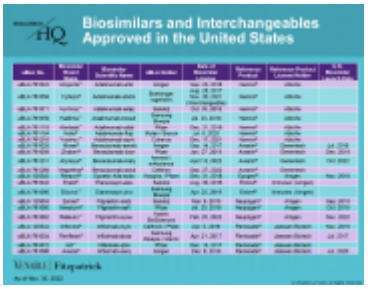
Patents Subject to Biosimilar-Related IPRs and Litigations



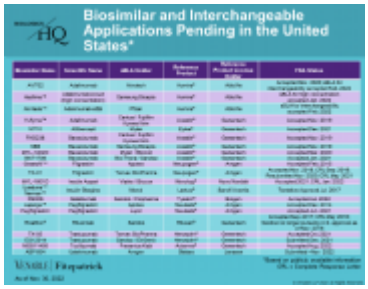
Biosimilars and Interchangeables Approved in the United States



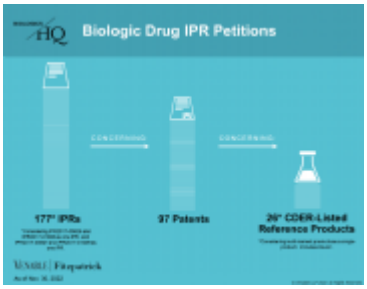




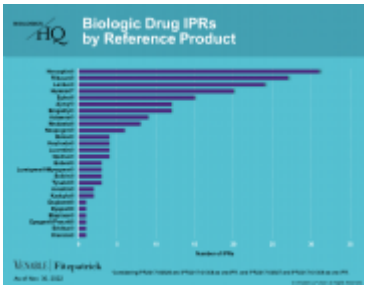
Biosimilar and Interchangeable Applications Pending in the United States



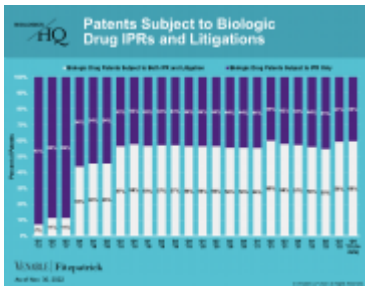
Biologic Drug IPR Petitions



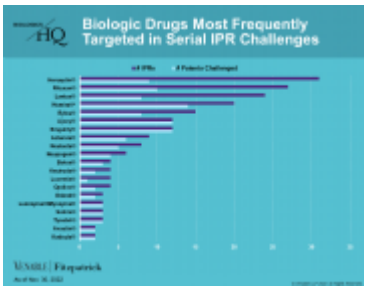
Biologic Drug IPRs by Reference Product



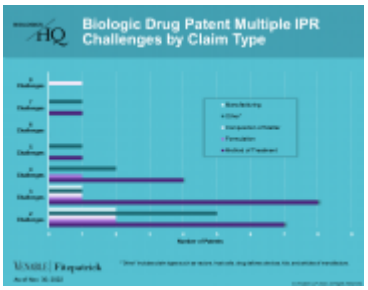
Patents Subject to Biologic Drug IPRs and Litigations



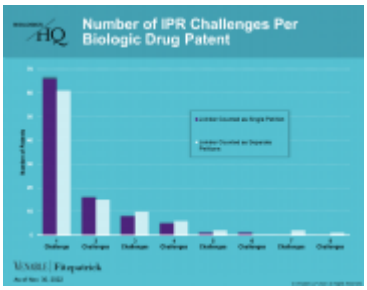
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

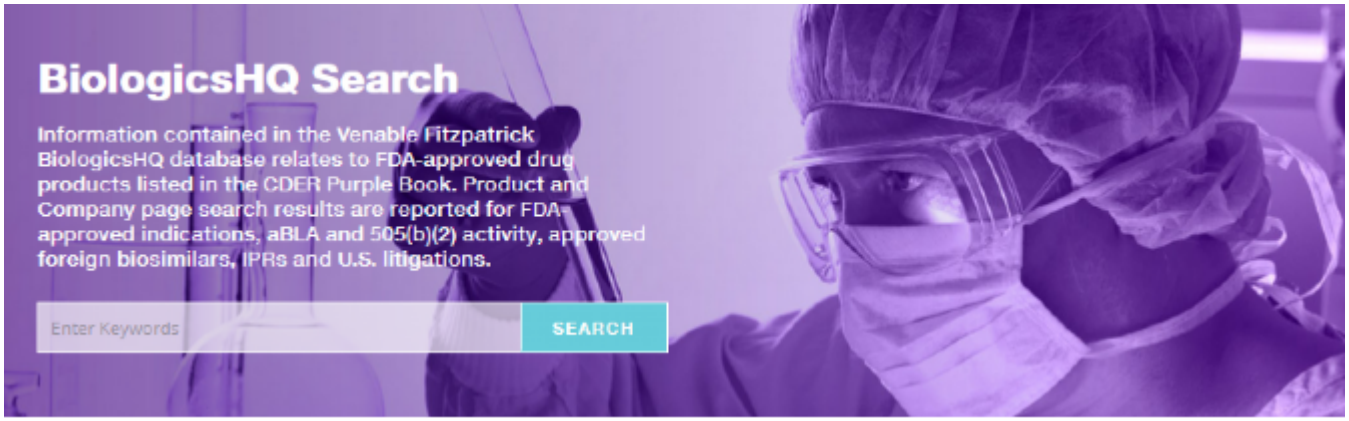


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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