BIOLOGICS HQ

VENABLE | Fitzpatrick

May 12, 2021

LATEST NEWS

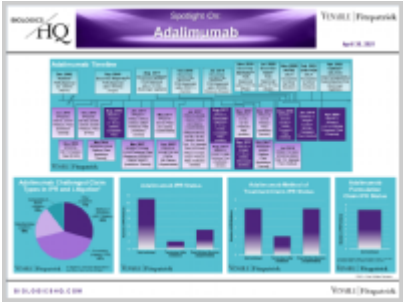
Two Bills Designed to Lower Drug Prices Signed into Law

Two bipartisan bills, the Advancing Education on Biosimilars Act and the Ensuring Innovation Act, were signed into law by President Biden on April 23, 2021. According to U.S. Senator Bill Cassidy, MD (R-LA) who introduced the bills, they "both work to lower the price patients pay for their prescriptions" by increasing competition.

Boehringer Ingelheim Applies for Interchangeability Designation for Cyltezo® (adalimumab-adbm)

On April 23, 2021, Boehringer Ingelheim announced results from the VOLTIRE-X Phase III randomized study that evaluated switching patients with moderate-to-severe chronic plaque psoriasis between reference product Humira® (adalimumab) and biosimilar Cyltezo® (adalimumab-adbm).

According to Boehringer Ingelheim, the results of the study support its application for interchangeability between Cyltezo® and Humira®. If approved, Cyltezo® will be the first interchangeable product licensed in the U.S.



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)

Spotlight On: Enbrel® (etanercept) / Erelzi® (etanercept-szzs) / Eticovo® (etanercept-ykro)

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine) / Semglee® (insulin glargine)

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™, and MSB11455), trastuzumab (Herceptin®, Ogivri™, Herzuma®, Ontruzant®, Trazimera™, and Kanjinti®), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™, and Hulio®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, and Semglee®) have been updated with activity through April 30, 2021.

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, 2021.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On April 16, 2021, **Regeneron** filed IPR2021-00816 against **Novartis**.

Lantus® (insulin glargine recombinant):

- On April 23, 2021, **Mylan** withdrew cross-appeal Fed. Cir. Appeal No. 20-2139, appealing the final written decision in IPR2018-01684 (and joined IPR2019-00987).

Litigations

Avastin® (bevacizumab):

- On April 14, 2021, **Genentech** and **Centus Biotherapeutics** filed a joint motion to stay deadlines and notice of settlement, with the plan to file a motion to dismiss within 30 days, in Case No. 2:20-cv-00361 (E.D. Tex.).

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

- On April 14, 2021, **Amgen** filed a request for an en banc rehearing of the Federal Circuit's affirmation in Fed. Cir. Appeal No 20-1074, appealing the district court determination in Case No. 1:14-cv-01317 (D. Del.) and consolidated Case Nos. 1:14-cv-01349 (D. Del.), 1:14-cv-01393 (D. Del.), and 1:14-cv-01414 (D. Del.) against **Regeneron**.

Taltz® (ixekizumab):

- On April 22, 2021, **Eli Lilly** filed Fed. Cir. Appeal No. 21-1874, appealing the denial of attorney fees in Case No. 3:18-cv-01518 (S.D. Cal.).

Humira® (adalimumab):

- On April 27, 2021, **AbbVie** filed Case No. 1:21-cv-02258 (N.D. Ill.) against **Alvotech** related to its proposed biosimilar **AVT02 (adalimumab)**.

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aBLA Applications and FDA Activity

Cyltezo® (adalimumab-adbm):

- On April 23, 2021, **Boehringer Ingelheim** announced results from a Phase III switching study between **Cyltezo® (adalimumab-adbm)** and **Humira® (adalimumab)** to support its supplemental BLA to designate **Cyltezo® (adalimumab-adbm)** as an interchangeable biosimilar to **AbbVie's Humira® (adalimumab)**. The action date on the supplemental BLA is the 4th quarter of 2021.

CDER Purple Book Updates

Jemperli™ (dostarlimab-gxly):

- On April 22, 2021, the FDA approved **GlaxoSmithKline's Jemperli™ (dostarlimab-gxly)**.

Zynlonta™ (loncastuximab tesirine-lpyl):

- On April 23, 2021, the FDA approved **ADC Therapeutics' Zynlonta™ (loncastuximab tesirine-lpyl)**.

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

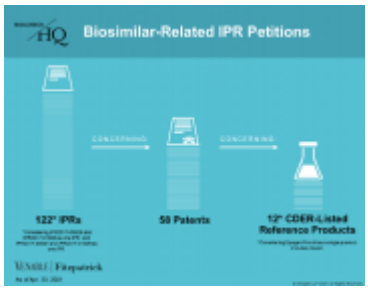
Abevmy (bevacizumab):

- On April 26, 2021, **Biocon Biologics** and **Viatris** announced **Abevmy (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, was approved in the E.U.

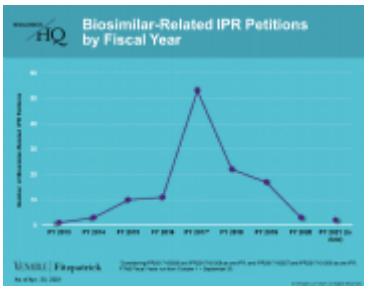
STATISTICS

Biosimilar-Related IPR	Biosimilar-Related IPR Petitions	Biosimilar-Related IPR Petitions

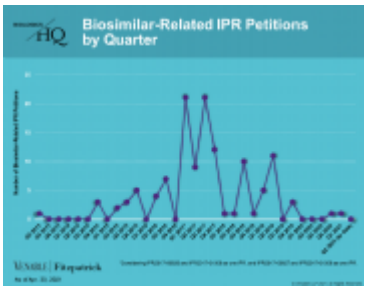
Petitions



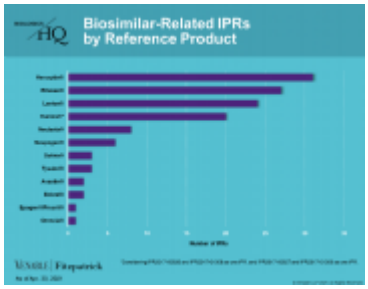
by Fiscal Year



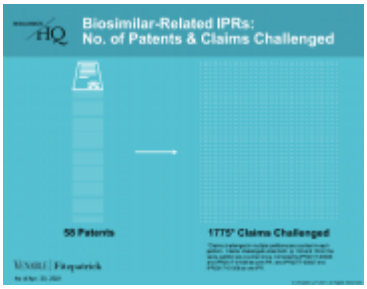
by Quarter



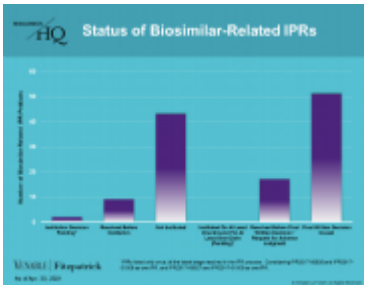
Biosimilar-Related IPRs by Reference Product



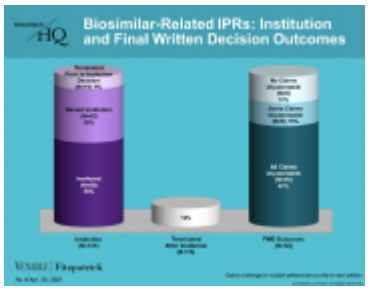
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



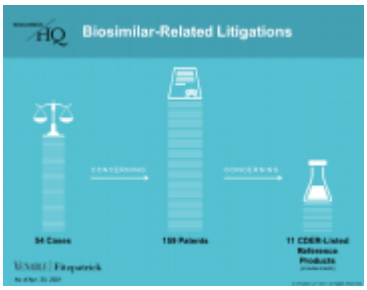
Status of Biosimilar-Related IPRs



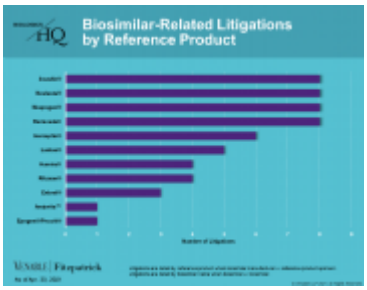
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



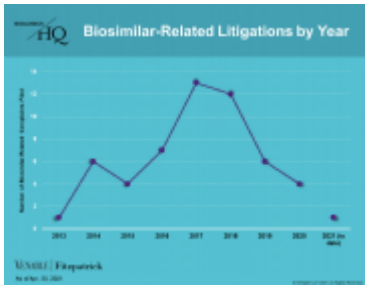
Biosimilar-Related Litigations



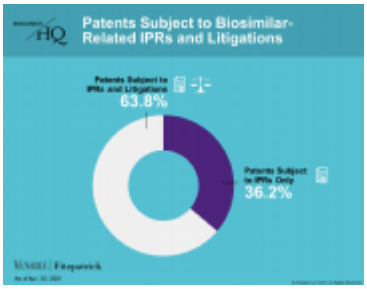
Biosimilar-Related Litigations by Reference Product



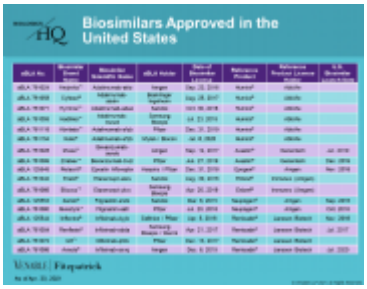
Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



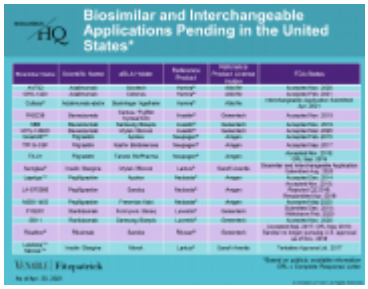
Biosimilars Approved in the United States

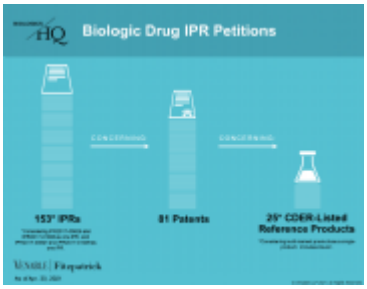


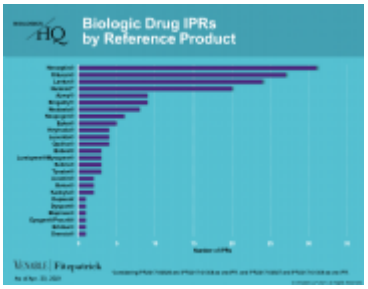
Biosimilar and Interchangeable Applications Pending in the United States

Biologic Drug IPR Petitions

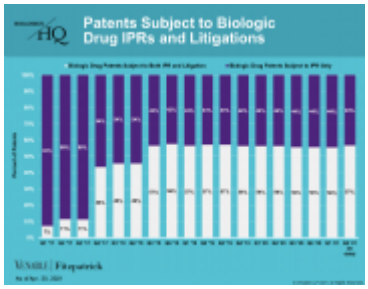
Biologic Drug IPRs by Reference Product



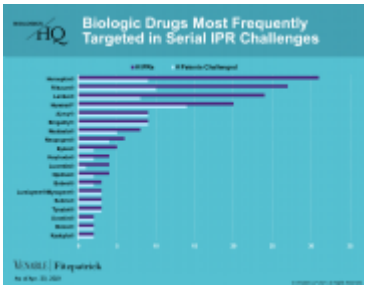




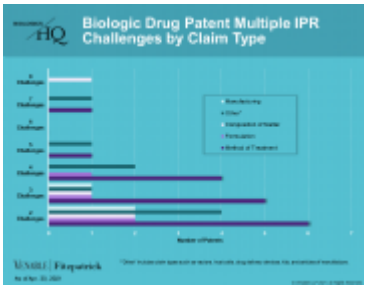
Patents Subject to Biologic Drug IPRs and Litigations



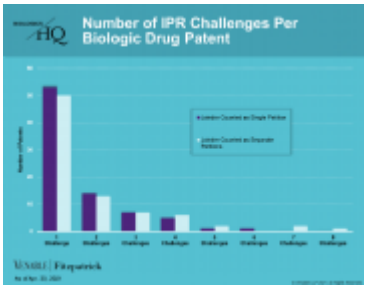
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

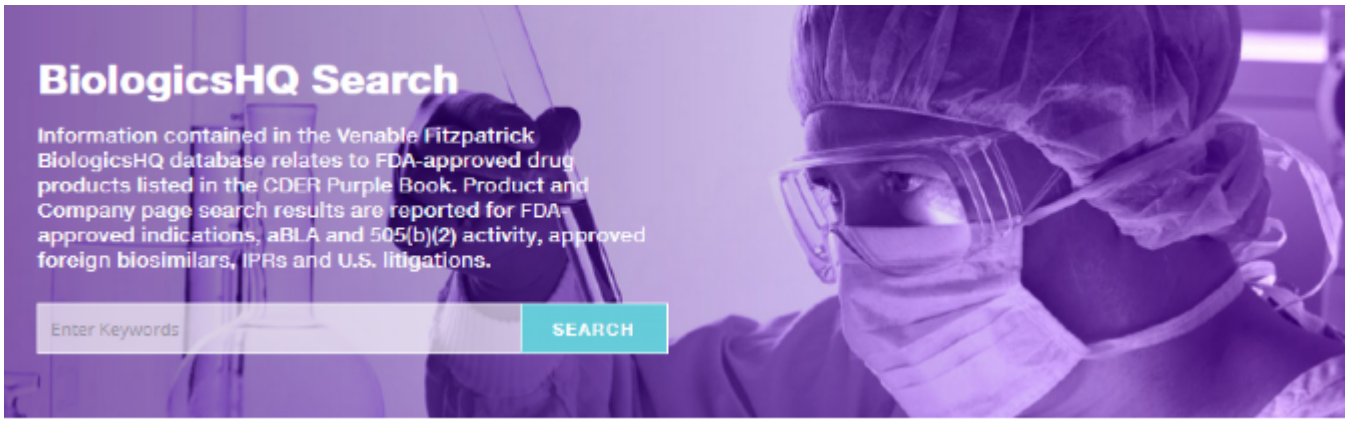


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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