BIOLOGICS HQ

VENABLE | Fitzpatrick

May 6, 2020

LATEST NEWS

Wong Discusses Strength of Regulatory Actions

Venable Fitzpatrick partner Ha Kung Wong discussed with the Center for Biosimilars recent regulatory actions to promote biosimilars, including the recent FDA/FTC collaboration to fight anticompetitive practices for biosimilars, and the March 23, 2020 transition of regulation of certain small molecule drugs, including insulins, to regulation as biologics. He addressed the questions:

- **Will manufacturers be motivated to bring products to market under the newly established biologics approval pathway under the Biologics Price Competition and Innovation Act?**
- **Is it possible that the newly announced FDA/Federal Trade Commission (FTC) collaboration to fight anticompetitive practices will improve the marketplace for biosimilars?**

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)

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

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (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 trastuzumab (Herceptin®, Ogivri™, Herzuma®, Ontruzant®, Trazimera™, and Kanjinti™), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, and Abrilada™), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) have been updated with activity through April 30, 2020.

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, 2020.

Read More News

UPDATES

IPRs and PGRs

Lantus® (insulin glargine recombinant):

- On April 2, 2020, the PTAB issued a final written decision in ***Mylan*** *v.* ***Sanofi*** IPR2018-01670, finding the 1 challenged claim unpatentable.

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

- On April 28, 2020, **Teva** filed Federal Circuit Appeal Nos. 20-1747, 20-1748, 20-1749, 20-1750, 20-1751, and 20-1752 appealing the final written decisions finding all challenged claims unpatentable in IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427 respectively.

Litigations

Neupogen® (filgrastim):

- On April 24, 2020, **Amgen** filed Case No. 1:20-cv-00561 (D. Del.) against **Pfizer** and **Hospira** related to their biosimilar **Nivestym™ (filgrastim-aafi)**.

aBLA Applications and FDA Activity

Ontruzant® (trastuzumab-dttb):

- On April 15, 2020, **Merck** announced the launch of **Ontruzant® (trastuzumab-dttb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, at a 15% discount.

CDER Purple Book Updates

Trodelvy™ (sacituzumab govitecan-hziy):

- On April 22, 2020, the FDA approved **Immunomedics Inc.'s** **Trodelvy™ (sacituzumab govitecan-hziy)**.

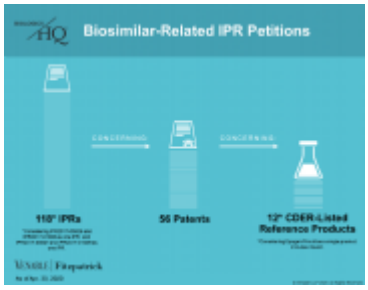
Non-U.S. Biosimilars / Follow-On Biologics

Ruxience® (rituximab-pvvr):

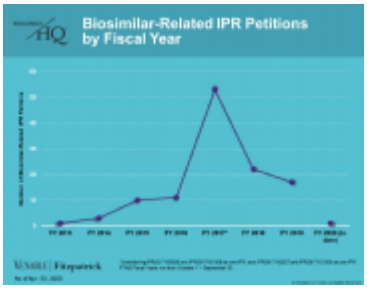
- On April 2, 2020, **Pfizer** announced that **Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's** **Rituxan® (rituximab)**, was approved in the E.U.

STATISTICS

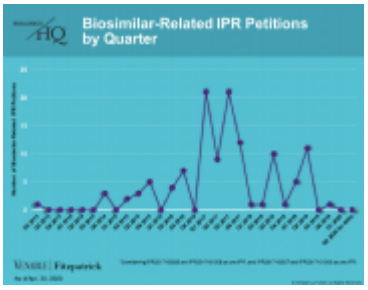
Biosimilar-Related IPR Petitions



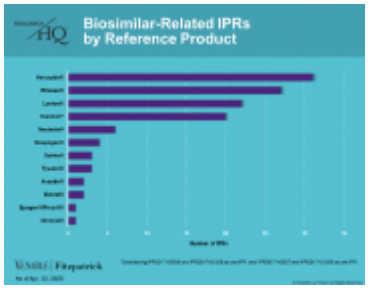
Biosimilar-Related IPR Petitions by Fiscal Year



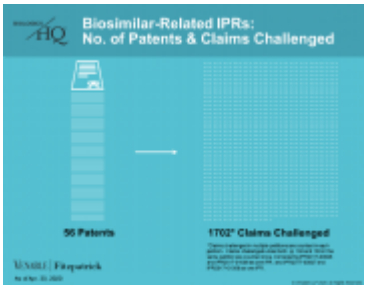
Biosimilar-Related IPR Petitions by Quarter



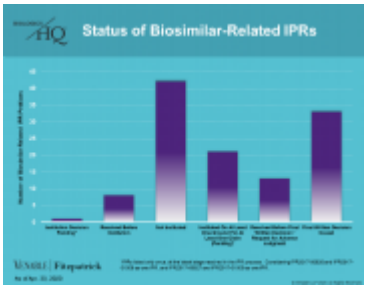
Biosimilar-Related IPRs by Reference Product



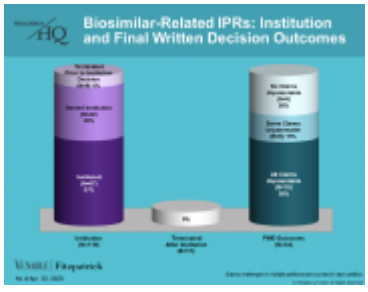
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



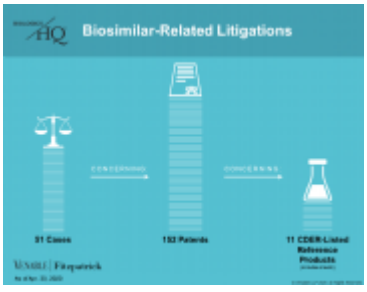
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

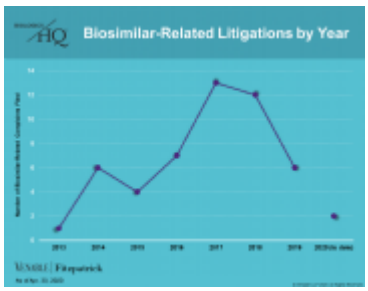


Biosimilar-Related Litigations

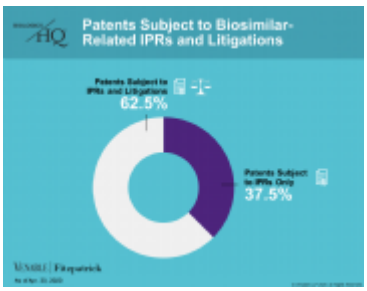


Biosimilar-Related Litigations by Reference Product

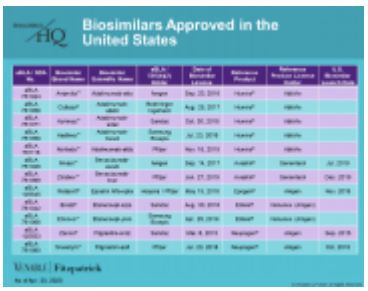
Biosimilar-Related Litigations by Year



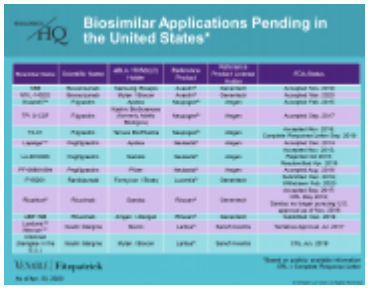
Patents Subject to Biosimilar-Related IPRs and Litigations



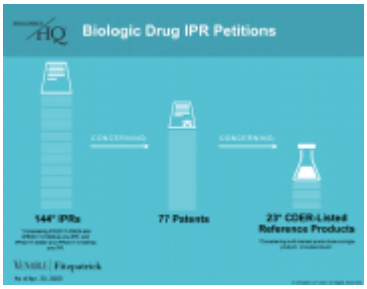
Biosimilars Approved in the United States



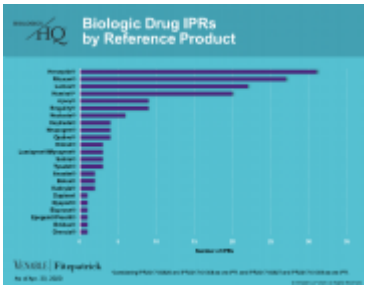
Biosimilar Applications Pending in the United States



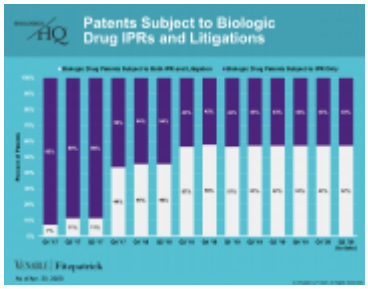
Biologic Drug IPR Petitions



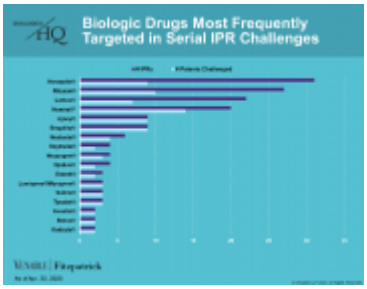
Biologic Drug IPRs by Reference Product



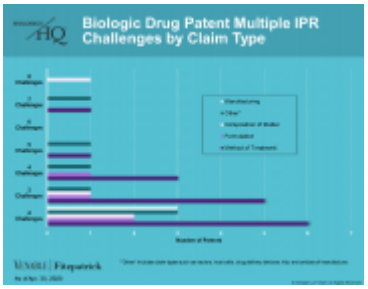
Patents Subject to Biologic Drug IPRs and Litigations



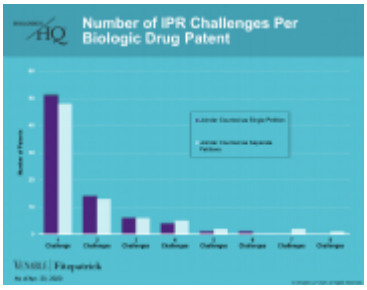
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

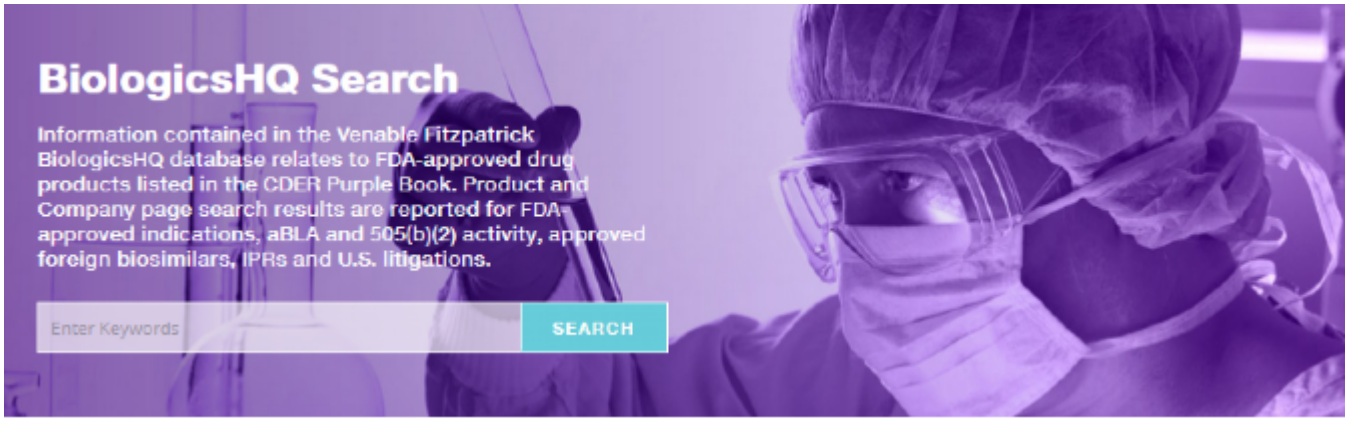


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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