BIOLOGICS HQ

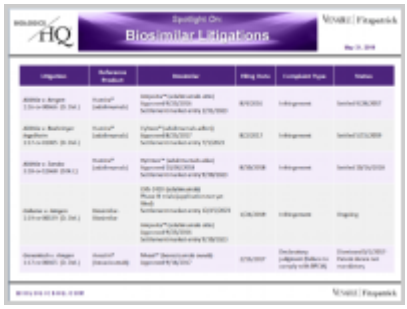
VENABLE | Fitzpatrick

June 6, 2019

LATEST NEWS

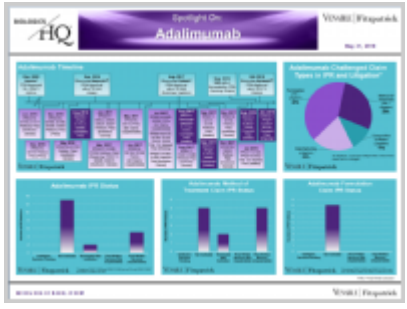
Biosimilar Experts Give Highlights of US Uptake Issues

Venable Fitzpatrick partner Ha Kung Wong spoke at the ISPOR 2019 annual meeting as part of a panel that reviewed the current state of the biosimilar market and challenges to biosimilar uptake in the U.S. His comments on pending Congressional action relating to the Purple Book, including the "Purple Book Continuity Act of 2019" in the House of Representatives and the "Biologic Patent Transparency Act" in the Senate, were included in an article in The American Journal of Managed Care (AJMC).



Spotlight On: Biosimilar Litigations

BiologicsHQ's new "Spotlight On" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through May 31, 2019.



Spotlight On: Rituxan® (rituximab) / Truxima® (rituximab-abbs)

Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo® (adalimumab-adbm)

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" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning rituximab (Rituxan® and Truxima®), adalimumab (Humira®, Amjevita™, and Cyltezo®), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) have been updated with activity through May 31, 2019.

Read More News

UPDATES

IPRs and PGRs

Lantus® (insulin glargine recombinant):

- On May 2, 2019, **Hospira** and **Pfizer** filed the following IPRs and requested joinder with IPRs previously filed by **Mylan** and **Biocon**:
  - IPR2019-00977 requesting joinder with IPR2018-01675
  - IPR2019-00978 requesting joinder with IPR2018-01676
  - IPR2019-00979 requesting joinder with IPR2018-01670
  - IPR2019-00980 requesting joinder with IPR2018-01678
  - IPR2019-00981 requesting joinder with IPR2018-01679
  - IPR2019-00982 requesting joinder with IPR2019-00122
  - IPR2019-00987 requesting joinder with IPR2018-01684
  - IPR2019-01022 requesting joinder with IPR2018-01680
  - IPR2019-01023 requesting joinder with IPR2018-01682

Humira® (adalimumab):

- On May 15, 2019, **Boehringer Ingelheim** withdrew as a party from Federal Circuit Appeal Nos. 17-2362 and 17-2363, appealing the final written decisions finding all challenged claims unpatentable in IPR2016-00408 and IPR2016-00409 respectively. The appeals remain ongoing with the U.S. as intervenor.

Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):

- On May 20, 2019, **Apotex's** request for rehearing of the final written decision in IPR2016-01542 finding all challenged claims, except for claim 18, unpatentable was denied. However, the PTAB sua sponte reversed its prior decision finding claim 18 not unpatentable, after changing its prior claim construction.

Litigations

Neulasta® (pegfilgrastim):

- On May 2, 2019, **Amgen** and **Coherus** announced that they had settled their trade secret case No. 56-2017-00493553-CU-BT-VTA (CA Sup. Ct.).

Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):

- On May 5, 2019, the Federal Circuit in consolidated appeal Nos. 18-1551 and 18-1552 affirmed the district court's summary judgment of non-infringement in ***Amgen*** v. ***Sandoz*** Case Nos. 3:16-cv-02581 (N.D. Cal.) and 3:14-cv-04741 (N.D. Cal.).
- On May 13, 2019, **Sandoz** voluntarily dismissed ***Sandoz*** *v.* ***Amgen***, Case No. 5:19-cv-00977 (N.D. Cal.).

Humira® (adalimumab):

- On May 15, 2019, **Boehringer Ingelheim** and **AbbVie's** stipulated dismissal due to settlement was granted in Case No. 1:17-cv-01065 (D. Del.).

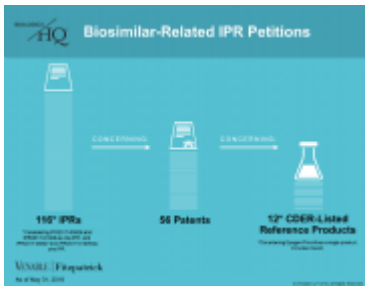
Non-U.S. Biosimilars / Follow-On Biologics

Ogivri™ (trastuzumab-dkst):

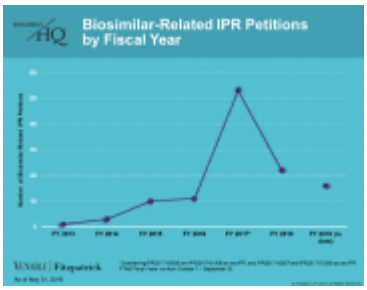
- On May 22, 2019, **Mylan** and **Biocon** announced that **Ogivri™ (trastuzumab-dkst)**, a biosimilar of **Genentech's** **Herceptin® (trastuzumab)**, was approved in Canada.

STATISTICS

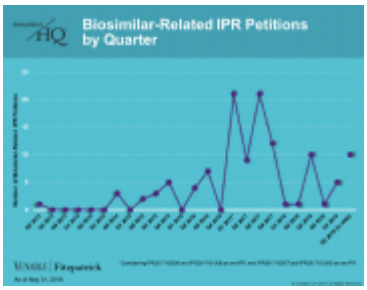
Biosimilar-Related IPR Petitions



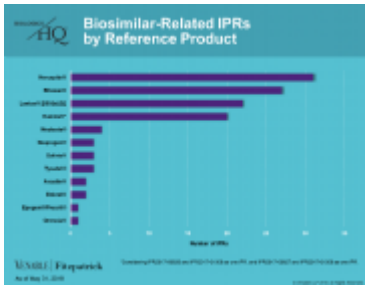
Biosimilar-Related IPR Petitions by Fiscal Year



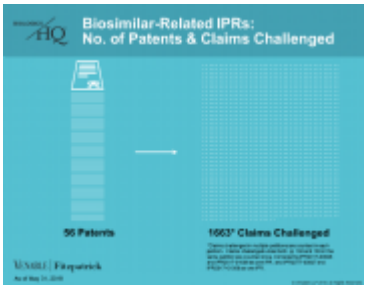
Biosimilar-Related IPR Petitions by Quarter



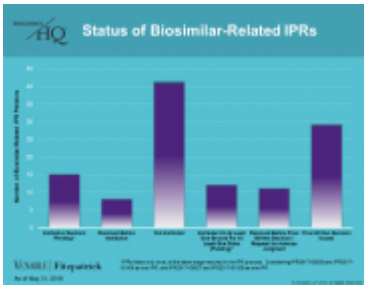
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



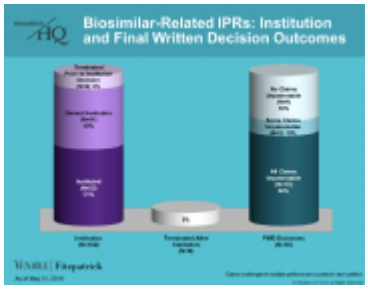
Status of Biosimilar-Related IPRs



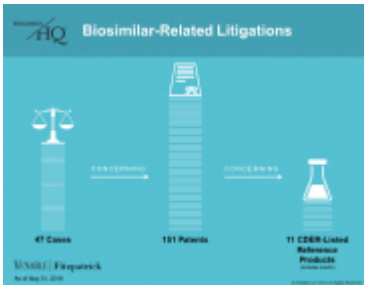
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

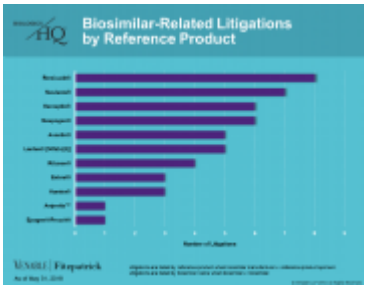
Biosimilar-Related Litigations by Reference Product



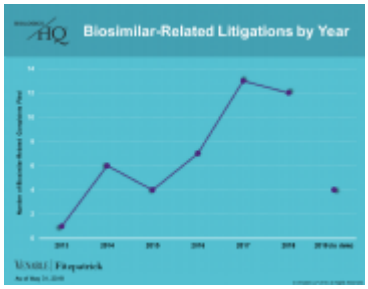
[Biosimilar-Related Litigations by Year]



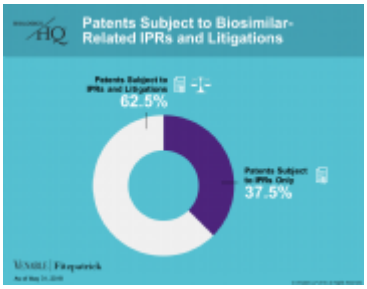
[Patents Subject to Biosimilar-Related IPRs and Litigations]



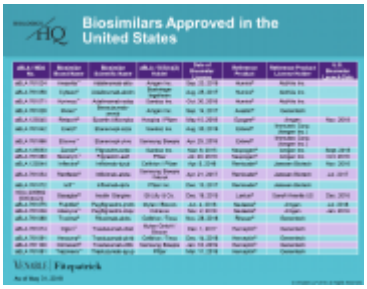
[Biosimilars Approved in the United States]



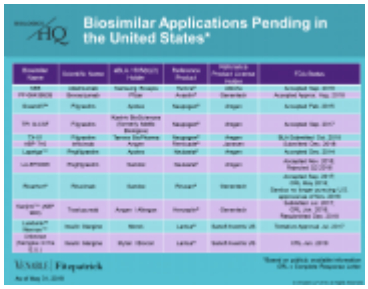
[Biosimilar Applications Pending in the United States]



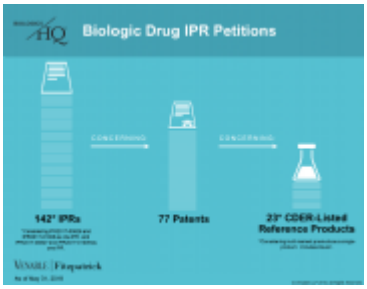
[Biologic Drug IPR Petitions]



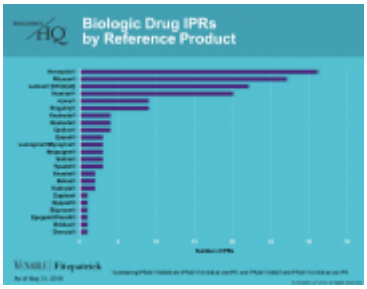
[Biologic Drug IPRs by Reference Product]



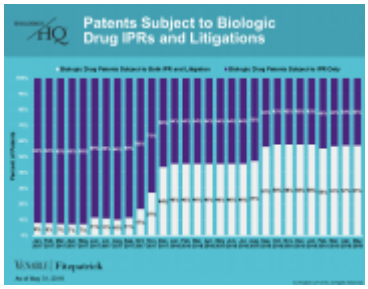
[Patents Subject to Biologic Drug IPRs and Litigations]



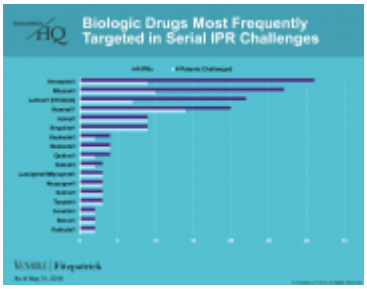
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]

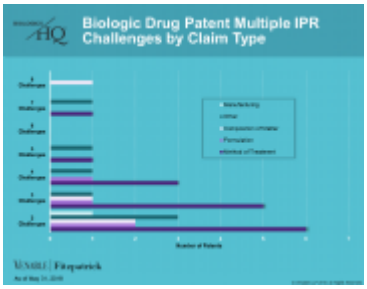


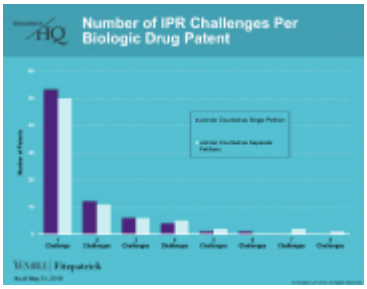
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

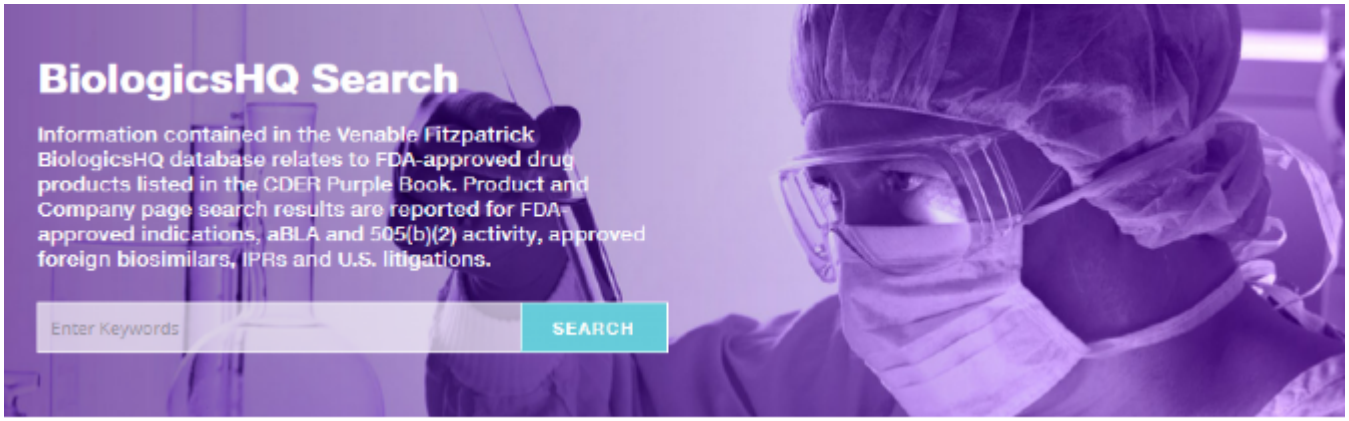


[Number of IPR Challenges Per Biologic Drug Patent]









Contact the BiologicsHQ Team

Robert S. Schwartz, Ph.D.
Chair
+1 212.218.2298
RSchwartz@Venable.com

CALIFORNIA | DELAWARE | MARLAND | NEW YORK | VIRGINIA | WASHINGTON, DC