BIOLOGICS HQ

VENABLE | Fitzpatrick

March 6, 2019

LATEST NEWS

The proposed Affordable Drug Manufacturing Act: Friend or foe for biosimilars?

By: Ha Kung Wong and April Breyer Menon

In an article for Patent Lawyer Magazine, Ha Kung Wong and April Breyer Menon discuss how high barriers to biosimilar market entry may make government development and manufacturing challenging under the Affordable Drug Manufacturing Act.

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

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

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

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® and Erelzi®), and insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) have been updated with activity through February 28, 2019.

Read More News

UPDATES

IPRs and PGRs

Orencia® (abatacept):

- On February 7, 2019, ***Momenta Pharmaceuticals*** *v.* ***Bristol-Myers Squibb***, Federal Circuit Case No. 17-1694, appealing the final written decision in IPR2015-01537, was dismissed for lack of standing/jurisdiction and mootness.

Dupixent® (dupilumab):

- On February 14, 2019, final written decisions were issued in IPR2017-01879 and IPR2017-01884 filed by **Sanofi**, **Regeneron**, and **Genzyme**. The PTAB found no challenged claims unpatentable as anticipated in IPR2017-01879, but found all challenged claims of the same patent unpatentable as obvious in IPR2017-01884.

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

- On February 19, 2019, IPR2018-01422, IPR2018-01423, and IPR2018-01424 filed by **Eli Lilly** were instituted.
- On February 25, 2019, IPR2018-01425, IPR2018-01426, and IPR2018-01427 filed by **Eli Lilly** were instituted.

Soliris® (eculizumab):

- On February 28, 2019, **Amgen** filed IPR2019-00739, IPR2019-00740, and IPR2019-00741.

Litigations

Opdivo® (nivolumab) / Bavencio® (avelumab):

- On February 12, 2019, a stipulation of dismissal due to settlement was granted in ***Bristol-Myers Squibb*** *v.* ***EMD Serono***, Case No. 1:17-cv-01029 (D. Del.)

Hemlibra® (emicizumab-kxwh):

- On February 12, 2019, **Baxalta** filed Federal Circuit Appeal No. 19-1527 appealing the decision in 1:17-cv-00509 (D. Del.) finding **Genentech** did not infringe the patent at issue and dismissing invalidity counterclaims.

Elitek® (rasburicase):

- On February 15, 2019, ***Genentech*** *v.* ***Sanofi***, Federal Circuit Appeal No. 18-1612 appealing summary judgment of noninfringement in 2:15-cv-01143 (W.D. Wash.) was voluntarily dismissed.

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

- On February 21, 2019, **Sandoz** filed declaratory judgment Case No. 5:19-cv-00977 (N.D. Cal.) against **Amgen**.

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

- On February 25, 2019, on remand from Federal Circuit Case No. 17-1480, the jury in ***Amgen*** *v.* ***Sanofi***, Case No. 1:14-cv-01317 (D. Del.), found claims 7 and 15 of U.S. Patent No. 8,829,165 invalid for lack of adequate written description and claims 19 and 29 not invalid. The jury found that claim 7 of U.S. Patent No. 8,859,741 was not invalid.

CDER Purple Book Updates

Cablivi® (caplacizumab-yhdp):

- On February 6, 2019, the FDA approved **Ablynx NV's** **Cablivi® (caplacizumab-yhdp)**.

Herceptin Hylecta™ (trastuzumab; hyaluronidase-oysk):

- On February 28, 2019, the FDA approved **Genentech's** **Herceptin Hylecta™**, a combination of **trastuzumab** and **hyaluronidase**.

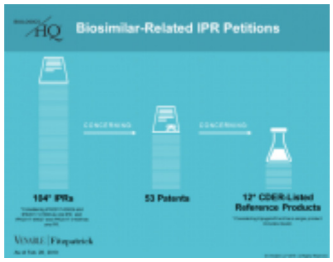
Non-U.S. Biosimilars / Follow-On Biologics

Zirabev™ (bevacizumab):

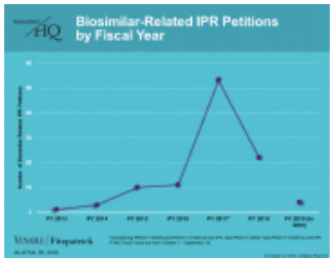
- On February 19, 2019, **Pfizer's Zirabev™ (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, was approved in the E.U.

STATISTICS

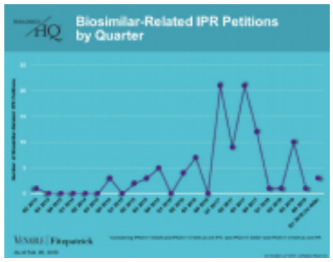
Biosimilar-Related IPR Petitions



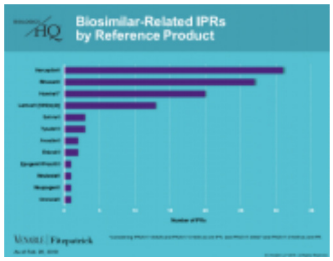
Biosimilar-Related IPR Petitions by Fiscal Year



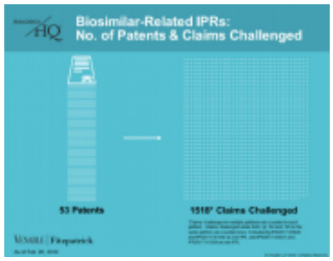
Biosimilar-Related IPR Petitions by Quarter



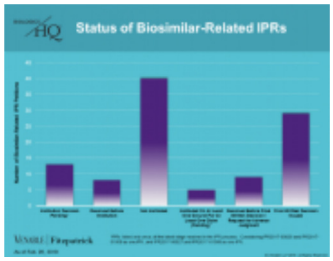
Biosimilar-Related IPRs by Reference Product



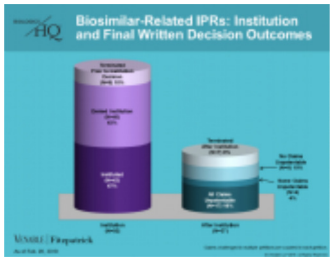
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



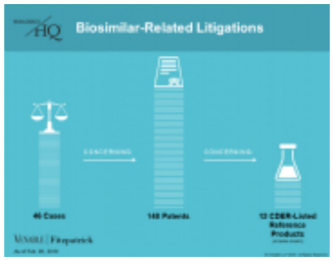
Status of Biosimilar-Related IPRs



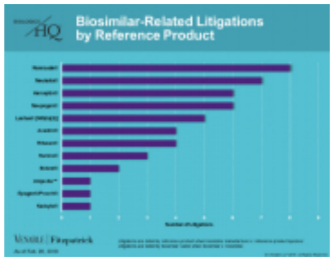
Biosimilar-Related IPRs: Institution and FWD Outcomes



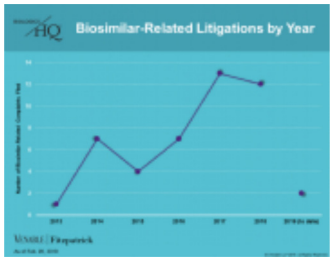
Biosimilar-Related Litigations



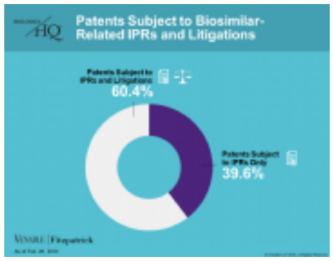
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

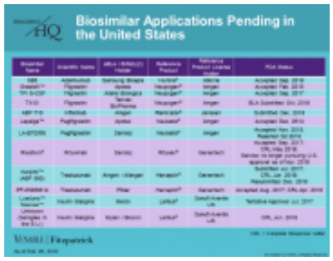


Patents Subject to Biosimilar-Related IPRs and Litigations

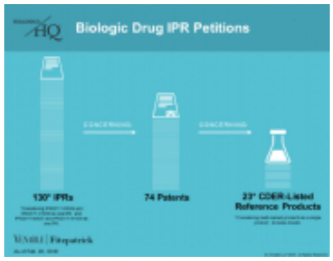


Biosimilars Approved in the United States

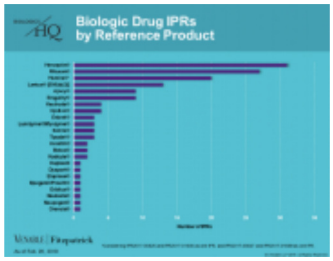
Biosimilar Applications Pending in the United States



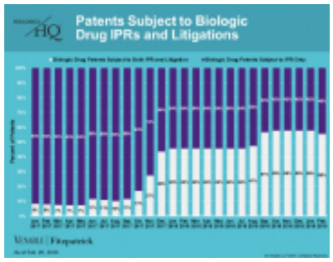
Biologic Drug IPR Petitions



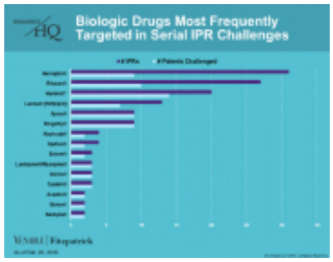
Biologic Drug IPRs by Reference Product



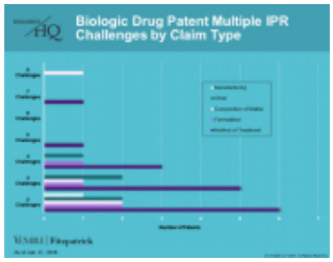
Patents Subject to Biologic Drug IPRs and Litigations



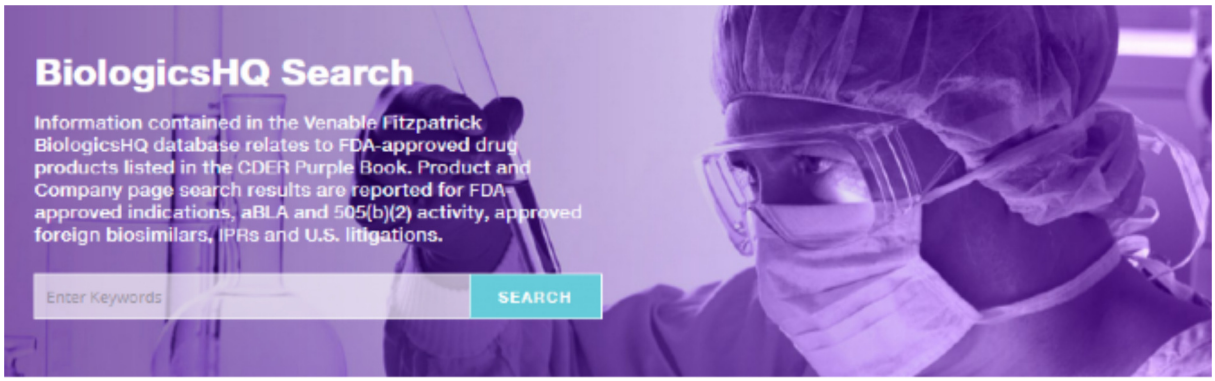
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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

Brendan M. O'Malley, Ph.D.
Vice-Chair
+1 212.218.2249
BOMalley@Venable.com

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