BIOLOGICS HQ

VENABLE | Fitzpatrick

November 11, 2019

LATEST NEWS

U.S. Patent System Crimps Drug Innovation for Toughest Diseases

In an article for Bloomberg Law, Ha Kung Wong discusses how the U.S. patent system and *inter partes* review (IPR) proceedings affect pharmaceutical innovation.

Why is Biosimilar Adoption Slow in the U.S., and Can Something Be Done to Boost Uptake?

In an article for MedCity News, Ha Kung Wong discusses reasons for the slow uptake of biosimilars in the U.S.

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)

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 rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, and Hadlima™), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus®/ Lantus® SoloSTAR® and Basaglar®) have been updated with activity through October 31, 2019.

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

Read More News

UPDATES

IPRs and PGRs

Taltz® (ixekizumab):

- On October 7, 2019, PGR2019-00043 filed by **Eli Lilly** was instituted. PGR2019-00044 on the same patent, filed by **UCB**, was also instituted on October 7, 2019.

Myozyme® / Lumizyme® (alglucosidase alfa):

- On October 11, 2019, in Fed. Cir. Appeal No. 18-1696, the Federal Circuit issued a Rule 36 affirmance of the PTAB's decision on remand in Duke University v. **BioMarin**, IPR2013-00535.

Neulasta® (pegfilgrastim):

- On October 16, 2019, IPR2019-00971 filed by **Fresenius Kabi** was denied institution.

Litigations

Enbrel® (etanercept):

- On October 8, 2019, in ***Amgen*** *v.* ***Sandoz***, Case No. 2:16-cv-01118 (D.N.J.), the District Court entered final judgment in favor of **Amgen** and issued a permanent injunction. **Sandoz** filed Federal Circuit Appeal No. 20-1037 on October 15, 2019.

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

- On October 24, 2019, **Amgen** filed Fed. Cir. Appeal No. 20-1074, appealing the final judgment in ***Amgen*** *v.* ***Sanofi***, Case No. 1:14-cv-01317 (D. Del.) and related cases 1:14-cv-01349 (D. Del.), 1:14-cv-01393 (D. Del.), and 1:14-cv-01414 (D. Del.).

aBLA Applications and FDA Activity

Bonsity™ (teriparatide injection):

- On October 4, 2019, the FDA approved **Pfenex's** **Bonsity™ (teriparatide injection)**, a follow-on of **Eli Lilly's Forteo® (teriparatide)**, under the 505(b)(2) pathway.

Zirabev™ (bevacizumab-bvzr) / Ruxience® (rituximab-pvvr) / Trazimera™ (trastuzumab-qyyp):

- On October 29, 2019, **Pfizer** announced its plans for launching three biosimilars in the coming months:
  - **Zirabev™ (bevacizumab-bvzr)**, a biosimilar of **Genentech's** **Avastin® (bevacizumab)**, on December 31, 2019
  - **Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's** **Rituxan® (rituximab)**, in January 2020
  - **Trazimera™ (trastuzumab-qyyp)**, a biosimilar of **Genentech's** **Herceptin® (trastuzumab)**, on Feb 15, 2020

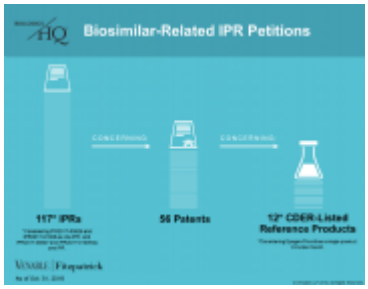
CDER Purple Book Updates

Beovu® (brolucizumab-dbll):

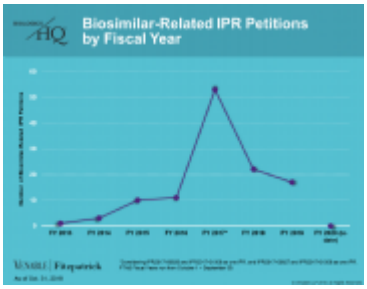
- On October 7, 2019, the FDA approved **Novartis's** **Beovu® (brolucizumab-dbll)**.

STATISTICS

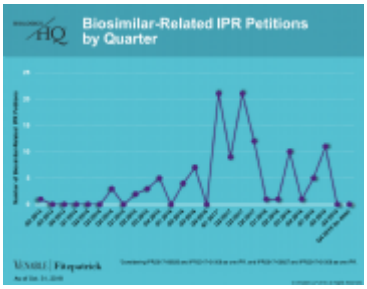
Biosimilar-Related IPR Petitions



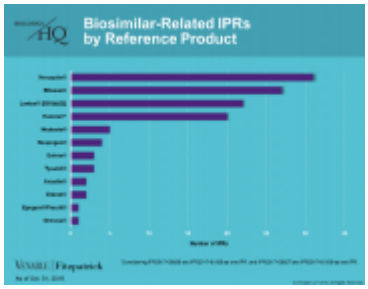
Biosimilar-Related IPR Petitions by Fiscal Year



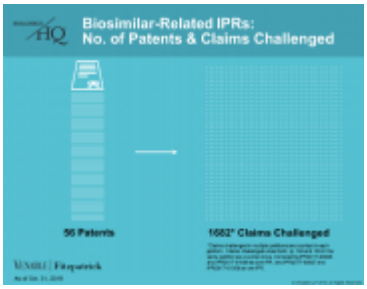
Biosimilar-Related IPR Petitions by Quarter



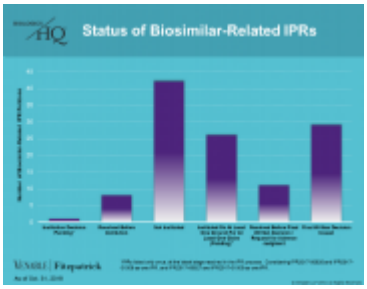
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs

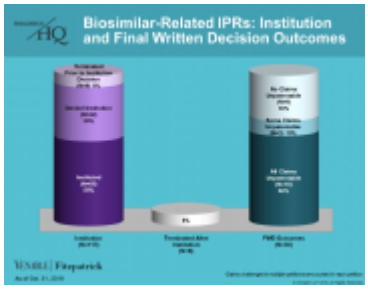


Biosimilar-Related IPRs:

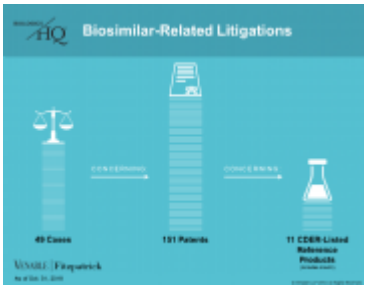
Biosimilar-

Biosimilar-Related

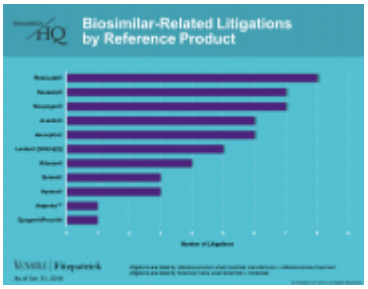
Institution and Final Written Decision Outcomes



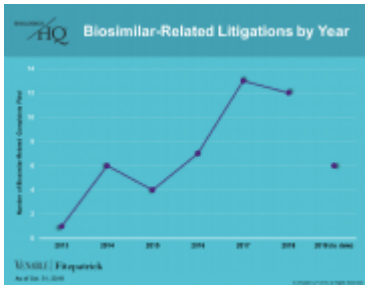
Related Litigations



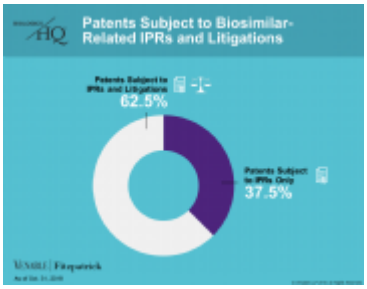
Litigations by Reference Product



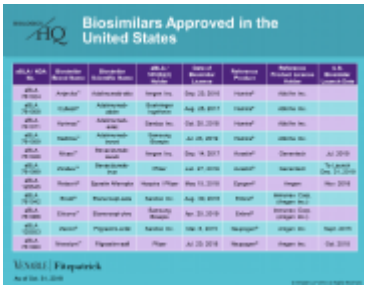
Biosimilar-Related Litigations by Year



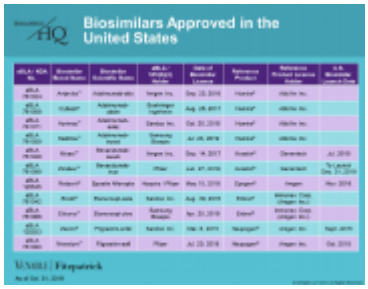
Patents Subject to Biosimilar-Related IPRs and Litigations



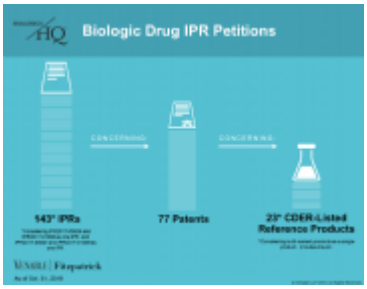
Biosimilars Approved in the United States



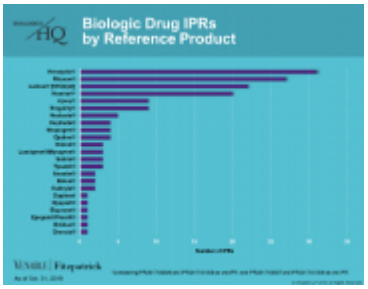
Biosimilar Applications Pending in the United States



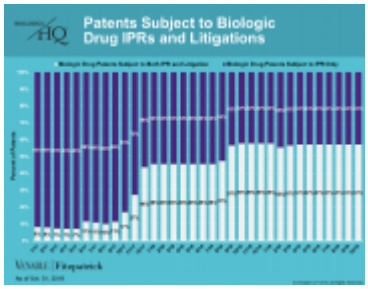
Biologic Drug IPR Petitions



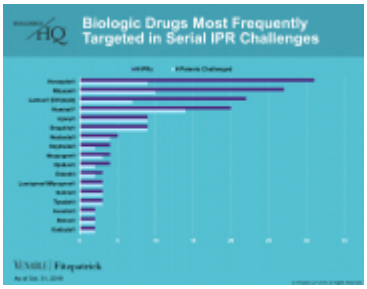
Biologic Drug IPRs by Reference Product



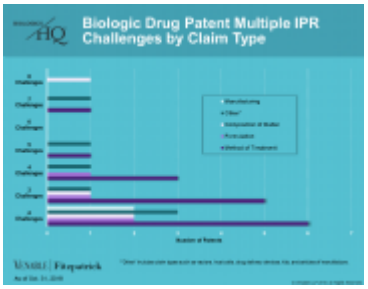
Patents Subject to Biologic Drug IPRs and Litigations



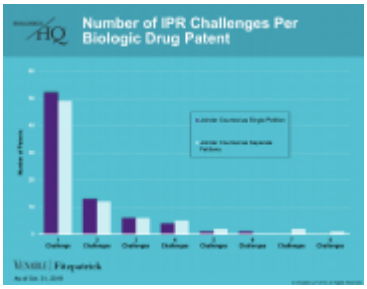
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

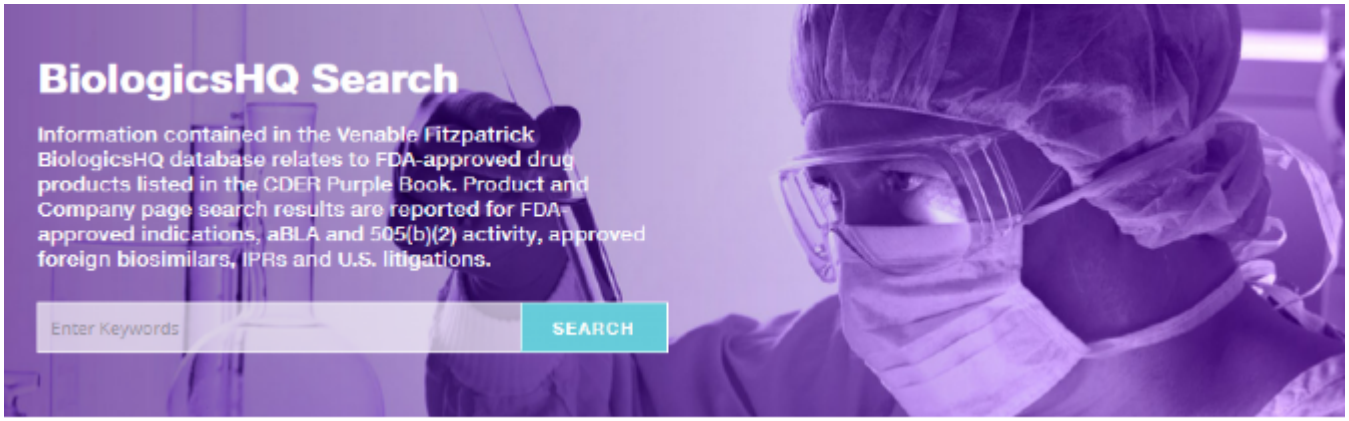


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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