BIOLOGICS HQ

VENABLE | Fitzpatrick

February 11, 2019

LATEST NEWS

Featured Video: Upcoming Changes to Biologics Regulation

Ha Kung Wong discusses how upcoming changes to the regulation of biologics are generating industry uncertainty with his answer to the question, "*By 2020, some products that are currently regulated as drugs, like insulin, will be regulated as biologics. Does this fact pose any challenges—or opportunities—from the patent litigation standpoint?*" as part of a video series for the Center for Biosimilars.

View Additional Commentary on Biosimilars from Ha Kung Wong:

- The Center for Biosimilars Most Watched Biosimilars Interview of 2018: **FDA and FTC Cooperation to Address Anticompetitive Behavior**
- **Noteworthy Ongoing Biosimilar Litigation**
- **Changes to IPRs and PGRs for Biologics**
- **The BPCIA One Year After** ***Sandoz v. Amgen***
- **Biosimilar Manufacturer's Approach to the Patent Dance**
- **The Importance of Biologics and Biosimilars**
- **The FDA's Biosimilar Action Plan**

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 January 31, 2019.

Read More News

UPDATES

IPRs and PGRs

Rituxan® (rituximab):

- On January 3, 2019, Biogen filed Federal Circuit Appeal No. 19-1364 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-01168.
- On January 16, 2019, the PTAB granted Pfizer's request to withdraw its request for rehearing of the decision not to institute in IPR2017-01166.

Herceptin® (trastuzumab):

- On January 10, 2019, Hospira was dismissed from Federal Circuit Appeal No. 19-1265 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-00737, due to settlement. The appeal remains ongoing for Samsung Bioepis.

Humira® (adalimumab):

- On January 31, 2019, Coherus was dismissed after settlement from consolidated Federal Circuit Appeal Nos. 17-2304, 17-2305, and 17-2306 appealing the Final Written Decisions finding all instituted claims unpatentable in IPR2016-00172, IPR2016-00188, and IPR2016-00189. The appeals remain ongoing between AbbVie and the U.S. as Intervenor.

Litigations

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

- On January 7, 2019, the Supreme Court denied the writ of certiorari in ***Amgen*** *v.* ***Sanofi***, Case No. 18-127.

Herceptin® (trastuzumab):

- On January 17, 2019, Genentech added U.S. Patent No. 10,160,811 to ***Genentech*** *v.* ***Amgen***, Case No. 1:18-cv-00924 (D. Del.).

Amjevita™ (adalimumab):

- On January 24, 2019, Coherus filed Case No. 1:19-cv-00139 (D. Del.) against Amgen.

Hemlibra® (emicizumab-kxwh):

- On January 25, 2019, final judgment of non-infringement was entered and invalidity counterclaims were dismissed in ***Baxalta*** *v.* ***Genentech***, Case No. 1:17-cv-00509 (D. Del.).

Darzalex® (daratumumab):

- On January 31, 2019, stipulated dismissal was entered in *MorphoSys v.* ***Janssen***, Case No. 1:16-cv-00221 (D. Del.).

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aBLA Applications and FDA Activity

Udenyca™ (pegfilgrastim-cbqv):

- On January 3, 2019, **Coherus** confirmed it had launched **Udenyca™ (pegfilgrastim-cbqv)**, its biosimilar of **Neulasta® (pegfilgrastim)**.

Ontruzant® (trastuzumab-dttb):

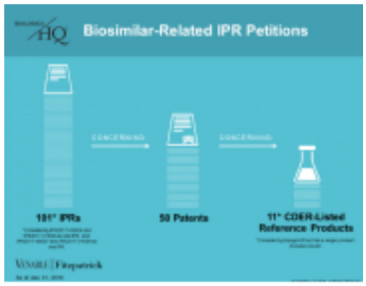
- On January 18, 2019, the FDA approved **Samsung Bioepis's** **Ontruzant® (trastuzumab-dttb)**, a biosimilar of **Genentech's** **Herceptin® (trastuzumab)**.

Kanjinti™ (ABP 980) (trastuzumab):

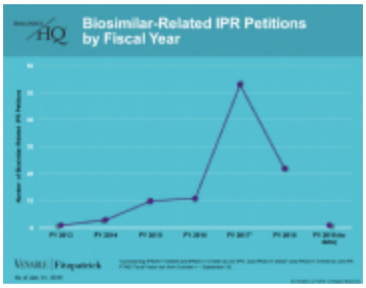
- On January 29, 2019, **Amgen** announced that it resubmitted its aBLA for **Kanjinti™ (ABP 980) (trastuzumab)**, it's proposed biosimilar of **Genentech's** **Herceptin® (trastuzumab)**, to the FDA in December 2018.

STATISTICS

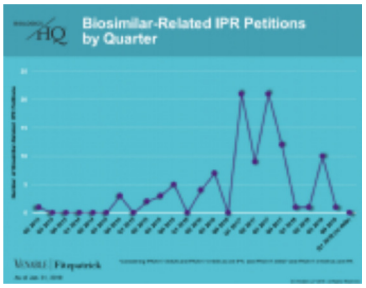
Biosimilar-Related IPR Petitions



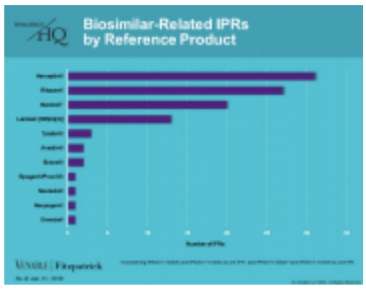
Biosimilar-Related IPR Petitions by Fiscal Year



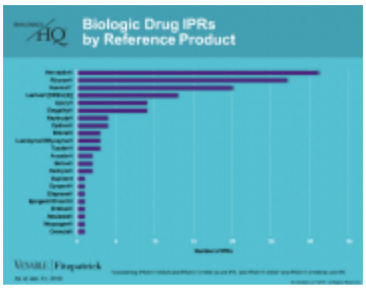
Biosimilar-Related IPR Petitions by Quarter



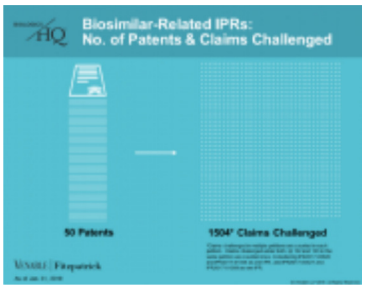
Biosimilar-Related IPRs by Reference Product



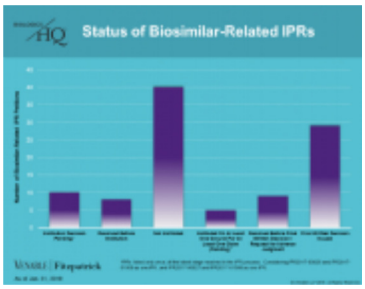
Biologic Drug IPRs by Reference Product



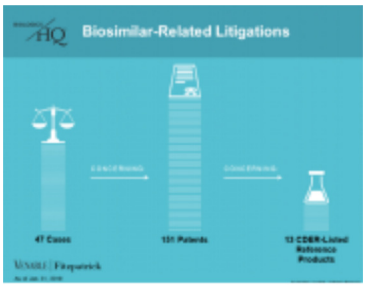
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



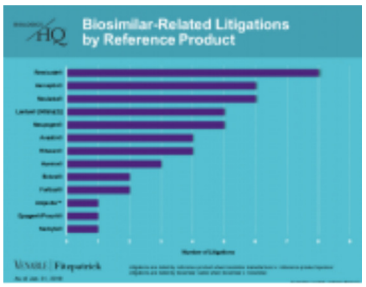
Status of Biosimilar-Related IPRs



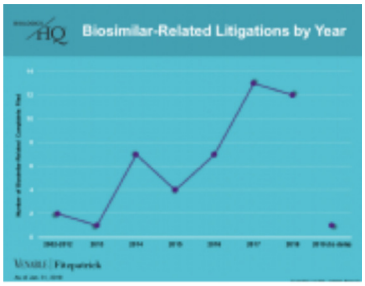
Biosimilar-Related Litigations



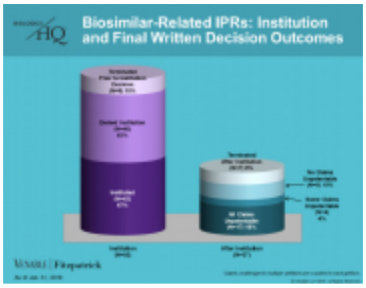
Biosimilar-Related Litigations by Reference Product



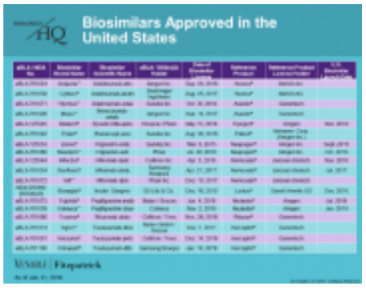
Biosimilar-Related Litigations by Year



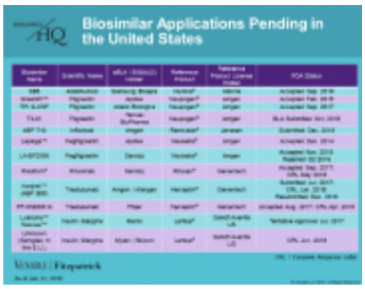
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



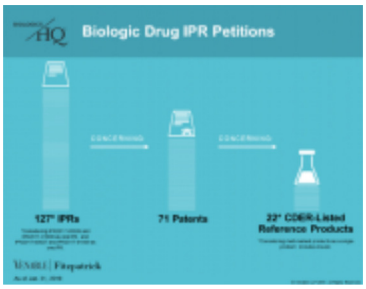
Biosimilars Approved in the United States



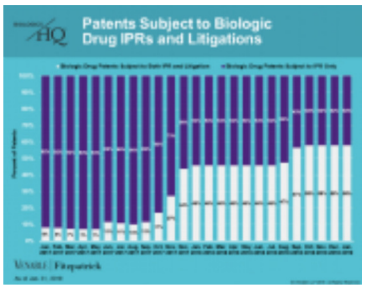
Biosimilar Applications Pending in the United States



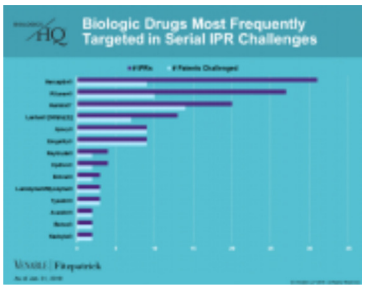
Biologic Drug IPR Petitions



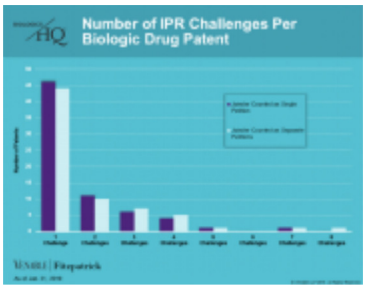
Patents Subject to Biologic Drug IPRs and Litigations



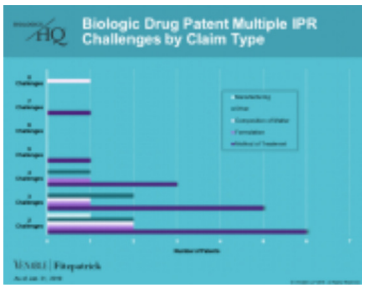
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

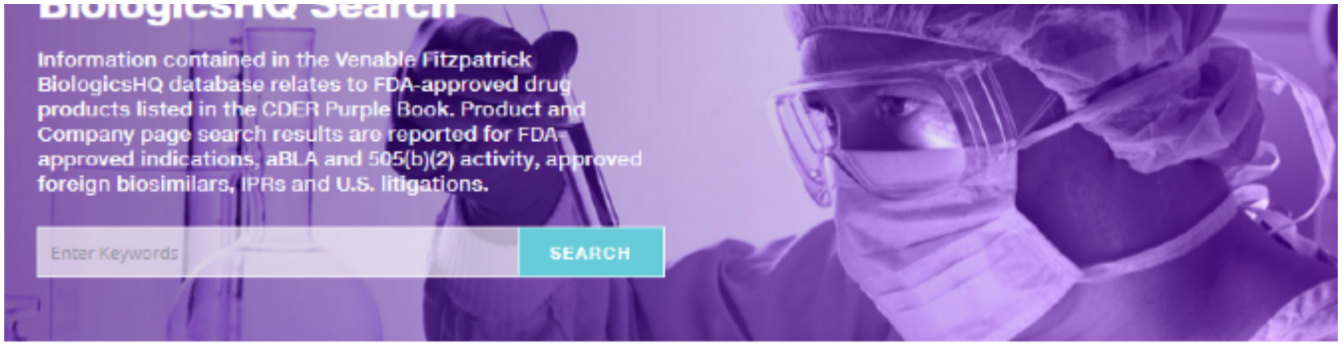


Number of IPR Challenges Per Biologic Drug Patent



Biologic Drug Patent Multiple IPR Challenges by Claim Type





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