BIOLOGICS HQ

VENABLE | Fitzpatrick

September 9, 2019

LATEST NEWS

The Most Important U.S. Patent Cases of 2019 Thus Far

By: Christopher Loh

Thus far 2019 has been an eventful year for patent law in the United States. Over the past seven months, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit (the U.S. appellate court tasked with reviewing all district court patent decisions) have issued several significant rulings that may affect the rights of patent owners. This article reviews the most important of these rulings.

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 August 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 August 31, 2019.

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UPDATES

IPRs and PGRs

Herceptin® (trastuzumab):

- On August 1, 2019, the USPTO Director filed a notice of intervention in Fed. Cir. Case No. 19-1265, appealing the final written decision in IPR2017-01960. **Hospira** and **Samsung Bioepis** previously terminated their involvement in the appeal.

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

- On August 8, 2019, **Apotex** filed a motion for adverse judgment in PGR2019-0001. This does not affect the other petitioner **Adello**, who will continue the proceeding as the sole petitioner.

Lantus® (insulin glargine recombinant):

- On August 15, 2019, IPRs filed by **Pfizer** were instituted and joined with IPRs previously filed by **Mylan**, including:
  - IPR2019-00977 joined with IPR2018-01675
  - IPR2019-00978 joined with IPR2018-01676
  - IPR2019-00980 joined with IPR2018-01678
  - IPR2019-00981 joined with IPR2018-01679
  - IPR2019-00982 joined with IPR2019-00122
  - IPR2019-00987 joined with IPR2018-01684
  - IPR2019-00979 was instituted, but joinder with IPR2018-01670 was denied.
- On August 19, 2019, IPR2019-01022 filed by **Pfizer** was instituted and joined with IPR2018-01680 previously filed by **Mylan**.
- On August 20, 2019, IPR2019-01023 filed by **Pfizer** was instituted and joined with IPR2018-01682 previously filed by **Mylan**.

Soliris® (eculizumab):

- On August 30, 2019, IPR2019-00739, IPR2019-00740, and IPR2019-00741 filed by **Amgen** were instituted.

Litigations

Herceptin® (trastuzumab):

- On August 7, 2019, the Federal Circuit denied **Genentech's** request for an injunction against **Amgen** pending resolution of Fed. Cir. Case No. 19-2156 and **Genentech's** request to expedite the appeal.

Enbrel® (etanercept):

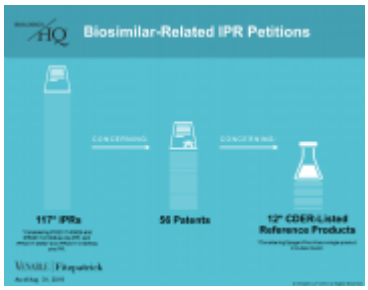
- On August 9, 2019, the District Court in ***Immunex*** *v.* ***Sandoz***, Case No. 2:16-cv-01118 (D.N.J.), determined that claims 11-23 and 35-36 of U.S. Patent No. 8,063,182 and claims 3, 8, and 10 of U.S. Patent No. 8,163,522 were not invalid. The parties previously stipulated to infringement.

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

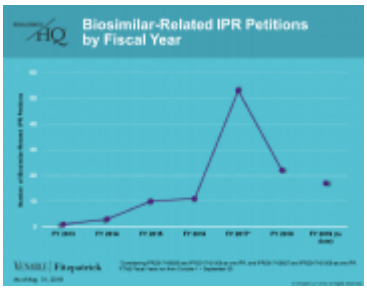
- On August 28, 2019, **Sanofi's** motion for judgment as a matter of law was denied as to written description, but granted as to enablement in Case No. 1:14-cv-01317 (D. Del.) (and consolidated cases 1:14-cv-01414 (D. Del.), 1:14-cv-01393 (D. Del.), and 1:14-cv-01349 (D. Del.)). Because the patent claims at issue were found to lack enablement, **Amgen's** motion for a permanent injunction was denied as moot.

STATISTICS

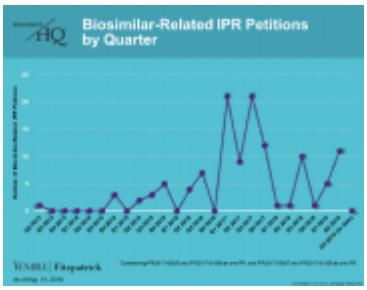
Biosimilar-Related IPR Petitions



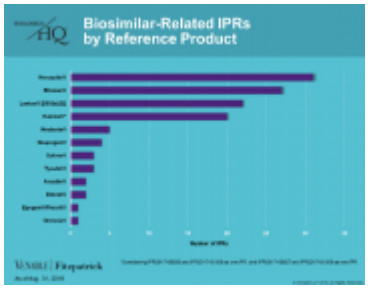
Biosimilar-Related IPR Petitions by Fiscal Year



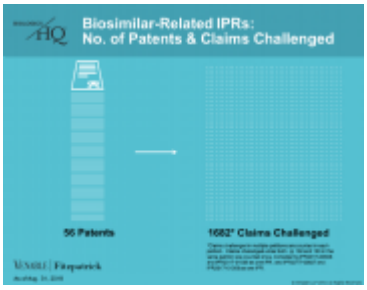
Biosimilar-Related IPR Petitions by Quarter



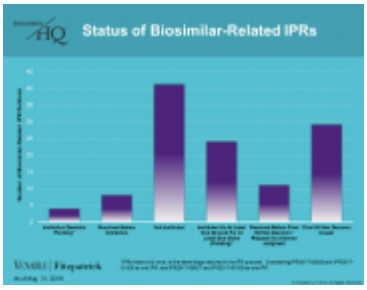
Biosimilar-Related IPRs by Reference Product



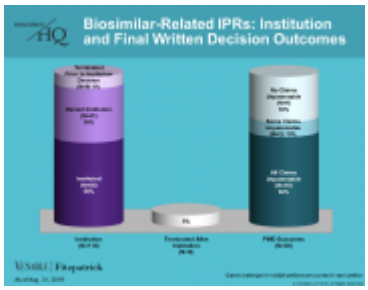
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



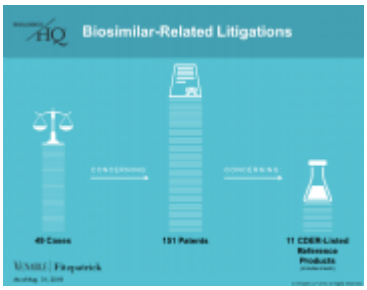
Status of Biosimilar-Related IPRs



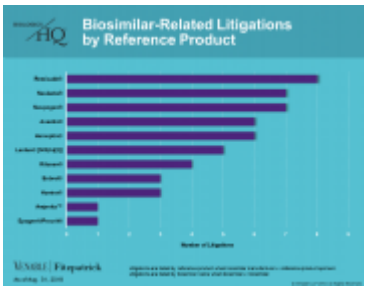
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



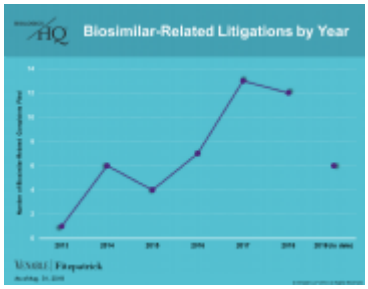
Biosimilar-Related Litigations



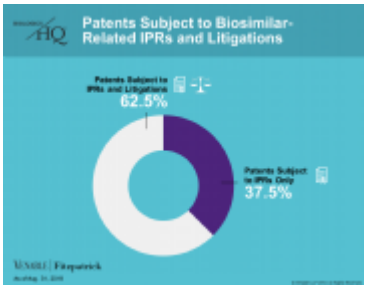
Biosimilar-Related Litigations by Reference Product



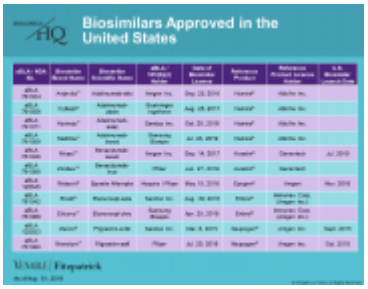
Biosimilar-Related Litigations by Year



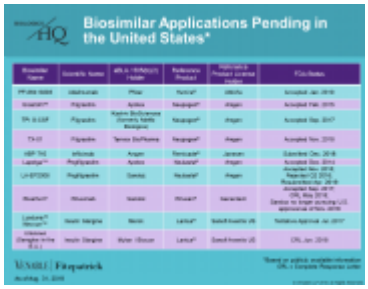
Patents Subject to Biosimilar-Related IPRs and Litigations



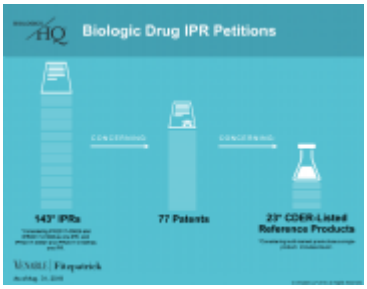
Biosimilars Approved in the United States



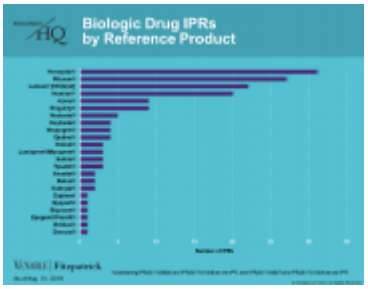
Biosimilar Applications Pending in the United States



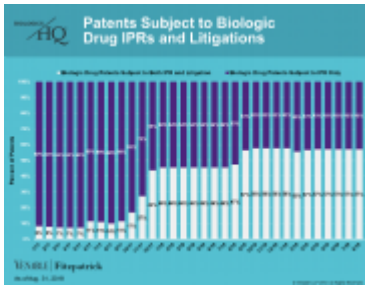
Biologic Drug IPR Petitions



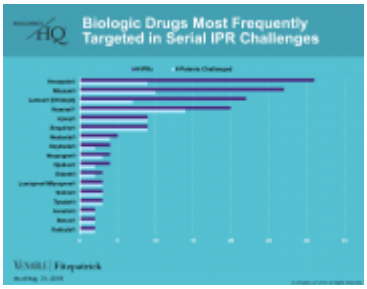
Biologic Drug IPRs by Reference Product



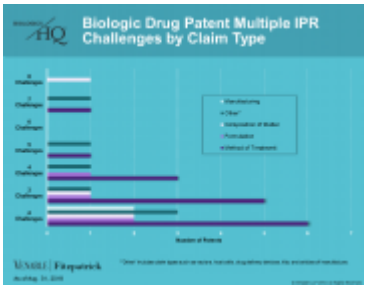
Patents Subject to Biologic Drug IPRs and Litigations



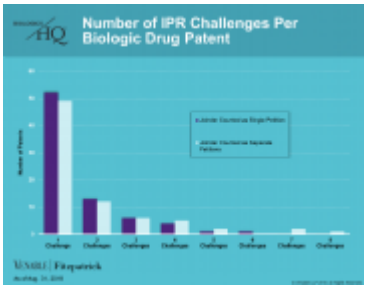
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

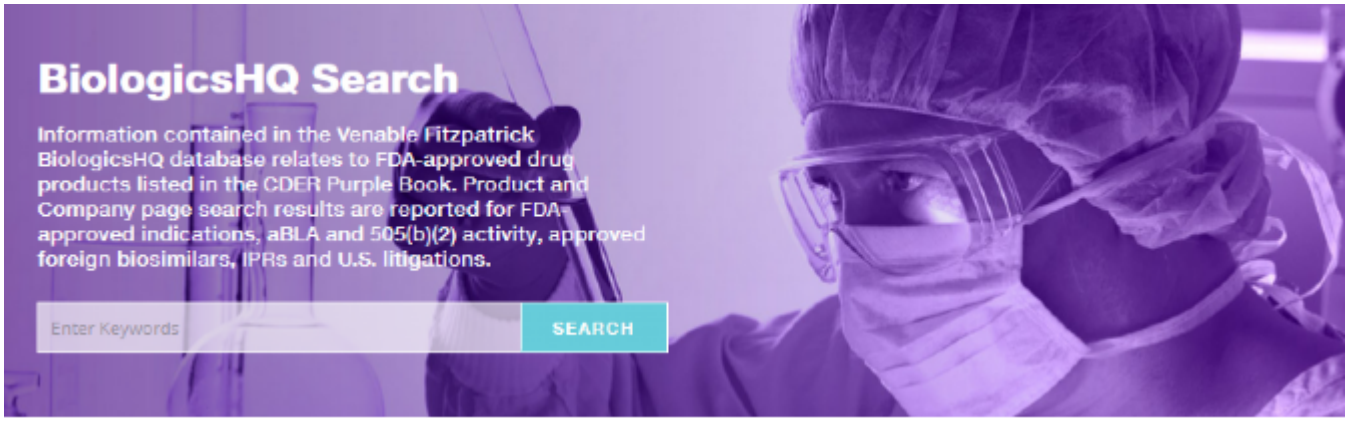


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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