BIOLOGICS HQ

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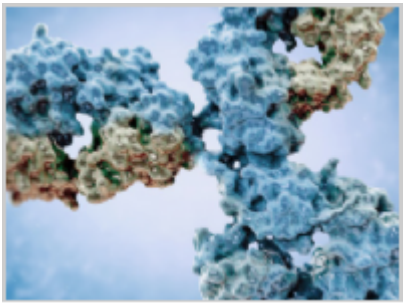
October 8, 2019

LATEST NEWS



Can Congress Speed Biosimilars to Market by Limiting Patent Litigations?

By: Ha Kung Wong and April Breyer Menon

Biosimilar uptake has been low in the United States so far, with market shares for most biosimilars under 10%. Given the cost savings potential, trying to increase biosimilar uptake has been high on Congress' agenda. There are many bills pending in Congress dealing with issues from a variety of angles, such as changes to the FDA Purple Book listing of biologic drugs, limits on patent litigation, changes to patent office proceedings, and ways to combat anticompetitive behavior, such as innovator product sponsors inappropriately withholding samples. But will they actually help bring biosimilars to market more quickly?

Using data compiled for BiologicsHQ.com, we analyzed 2 bills, the Affordable Prescriptions for Patients Act of 2019 (S.1416) and the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act (HR.3991), that propose changes to patent litigation by limiting the number of patents a reference product sponsor can assert in a patent litigation to see how many biosimilar cases they would have impacted so far and whether they would really help bring biosimilars to market sooner.

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 September 30, 2019.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through September 30, 2019.

Read More News

UPDATES

IPRs and PGRs

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

- On September 11, 2019, IPR2019-00791 and IPR2019-00797 filed by **Kashiv BioSciences** and **Amneal** were instituted.

Litigations

Neupogen® (filgrastim):

- On September 3, 2019, in Fed. Cir. Case No. 18-1551 (appealing 3:14-cv-04741 (N.D. Cal.), and consolidated Fed. Cir. Case No. 18-1552 (appealing 3:16-cv-02581 (N.D. Cal.)), **Amgen's** petition for rehearing *en banc* was granted-in-part, removing the sentence from the Court's opinion stating that the doctrine of equivalents "applies only in exceptional cases."

Herceptin® (trastuzumab):

- On September 4, 2019, in ***Genentech*** *v.* ***Amgen***, Case No. 1:18-cv-00924 (D. Del.), **Genentech** added U.S. Patent No. 9,868,760 to its complaint.

Eylea® (aflibercept) / Lucentis® (ranibizumab) / Zaltrap® (ziv-aflibercept):

- On September 5, 2019, in ***Novartis Vaccines and Diagnostics*** *v.* ***Regeneron***, Case No. 1:18-cv-02434 (S.D.N.Y.), the Court issued a judgment of non-infringement and order of dismissal after the parties stipulated to non-infringement and requested dismissal of the case.

Kadcyla® (ado-trastuzumab emtansine):

- On September 5, 2019, in ***Phigenix*** v. ***Genentech***, Fed. Cir. Case No. 17-2617, the Federal Circuit affirmed the District Court's summary judgment of non-infringement in Case No. 5:15-cv-01238 (N.D. Cal.). Because the

opinion was affirmed, the conditional cross appeal, Fed. Cir. 18-1042, was not decided.

Neulasta® (pegfilgrastim):

- On September 16, 2019, **Amgen** and **Mylan** stipulated to non-infringement of U.S. Patent No. 9,643,997 in Case No. 2:17-cv-01235 (W.D. Pa.). The case is now terminated as the parties previously stipulated to non-infringement of U.S. Patent No. 8,273,707.

Avastin® (bevacizumab):

- On September 20, 2019, **Genentech** and **Pfizer's** stipulated dismissal due to settlement in Case No. 1:19-cv-00638 (D. Del.) was ordered.

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

Herzuma® (trastuzumab-pkrb):

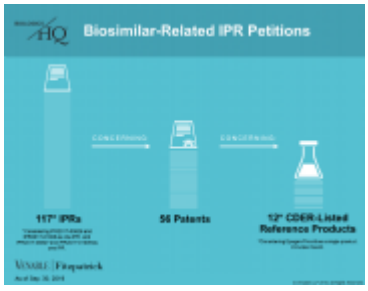
- On September 11, 2019, **Teva** and **Celltrion** announced that **Herzuma® (trastuzumab-pkrb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, was approved in Canada.

Aranesp® (darbepoetin alfa):

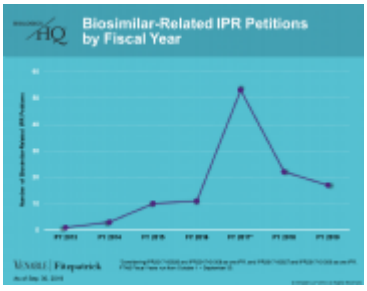
- On September 23, 2019, Dong-A ST and Sanwa Kagaku Kenkyusho (SKK) announced that DA-3880, a biosimilar of **Amgen's Aranesp® (darbepoetin alfa)** was approved in Japan.
- On September 24, 2019, Chong Kun Dang Pharmaceutical announced that CKD-11101, a biosimilar of **Amgen's Aranesp® (darbepoetin alfa)** was approved in Japan.

STATISTICS

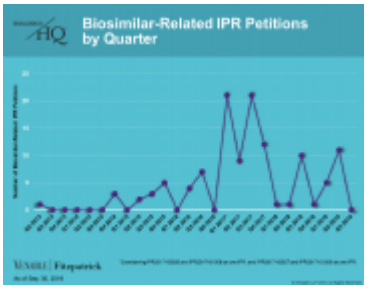
Biosimilar-Related IPR Petitions



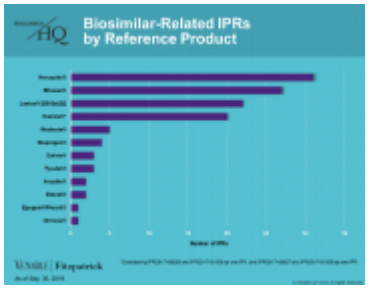
Biosimilar-Related IPR Petitions by Fiscal Year



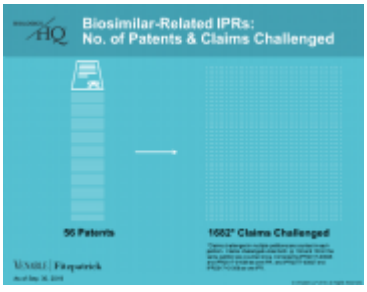
Biosimilar-Related IPR Petitions by Quarter



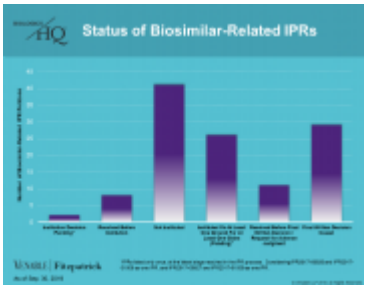
Biosimilar-Related IPRs by Reference Product



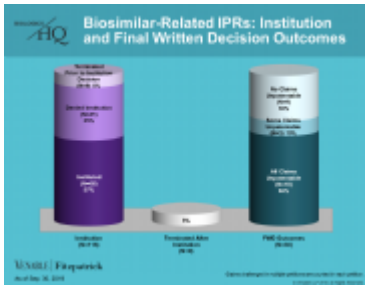
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



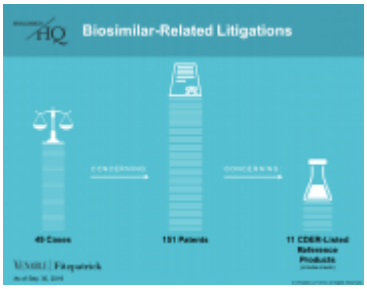
Status of Biosimilar-Related IPRs



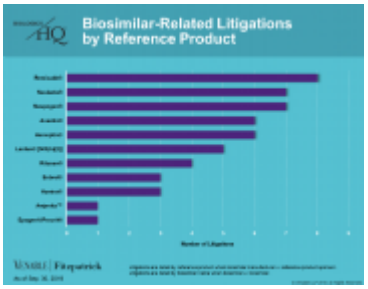
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



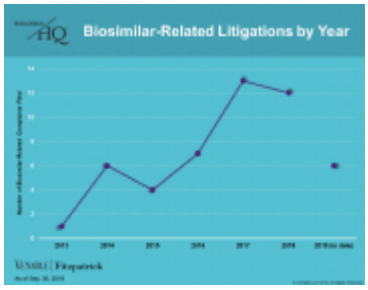
Biosimilar-Related Litigations



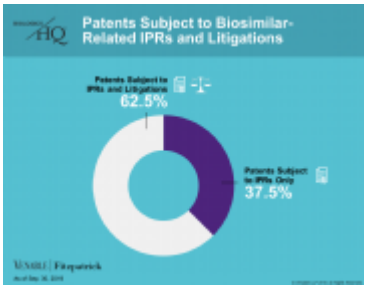
Biosimilar-Related Litigations by Reference Product



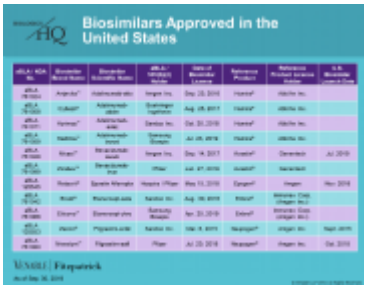
Biosimilar-Related Litigations by Year



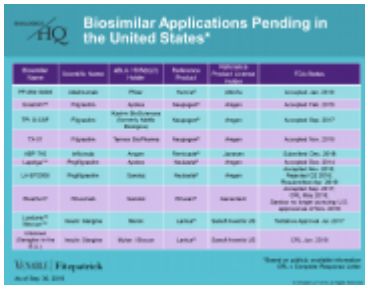
Patents Subject to Biosimilar-Related IPRs and Litigations



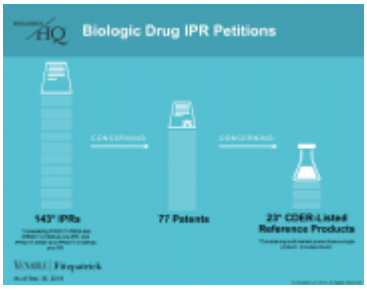
Biosimilars Approved in the United States



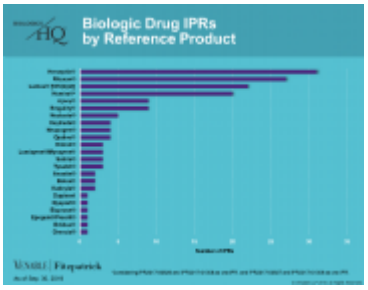
Biosimilar Applications Pending in the United States



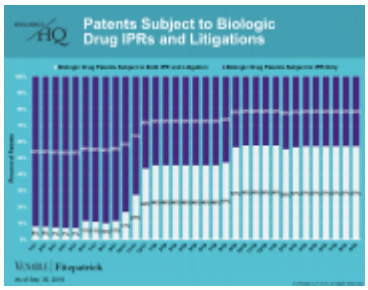
Biologic Drug IPR Petitions



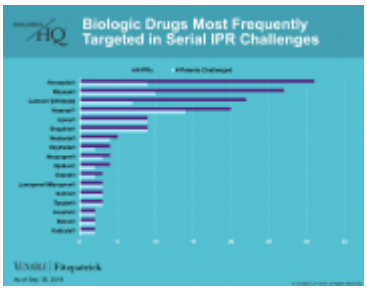
Biologic Drug IPRs by Reference Product



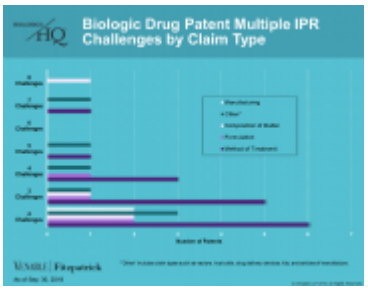
Patents Subject to Biologic Drug IPRs and Litigations



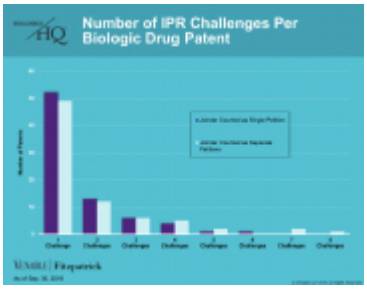
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

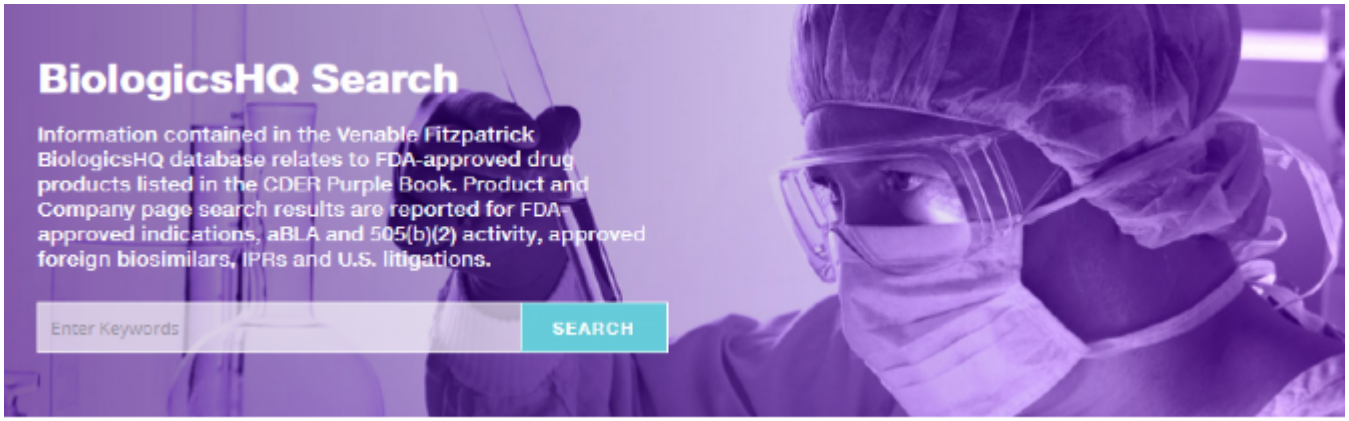


Biologic Drug Patent Multiple IPR Challenges by Claim Type



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

Ha Kung Wong
Partner
+1 212.218.2571
HWong@Venable.com

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