BIOLOGICS HQ

VENABLE | Fitzpatrick

January 9, 2019

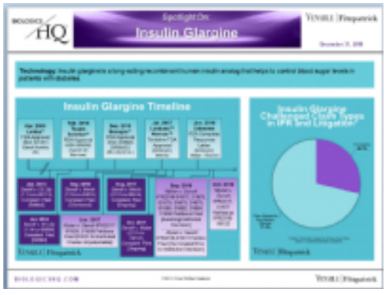
LATEST NEWS

Stakeholders Weigh In on the Key Biosimilar Developments of 2018

The Center for Biosimilars asked experts from across stakeholder groups—and from the United States and abroad—what they felt were the most notable moments in biosimilars during 2018, and what they hope the new year holds for this developing industry. Venable Fitzpatrick partner Ha Kung Wong weighed in.

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 Importation of Biologics and Biosimilars
- The FDA's Biosimilar Action Plan



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. A new dashboard concerning insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) is now available.

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

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

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

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®), and etanercept (Enbrel® and Erelzi®) have been updated with activity through December 31, 2018.

READ MORE NEWS

UPDATES

IPRs and PGRs

Rituxan® (rituximab):

- On December 4, 2018, Biogen filed Federal Circuit Appeal No. 19-1253 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-01095. On December 12, 2018, Celltrion notified the court it would not participate due to settlement. The case is ongoing awaiting the Attorney General's notification of whether the U.S. will intervene.
- On December 10, 2018, IPR2018-01019 was dismissed after institution due to settlement at the joint request of Celltrion and Genentech.

Herceptin® (trastuzumab):

- On December 6, 2018, Celltrion and Teva filed Federal Circuit Appeal No. 19-1258 appealing the Final Written Decision finding no instituted claim unpatentable in IPR2017-01139. On December 20, 2018, the appeal was dismissed due to settlement.
- On December 6, 2018, Celltrion and Teva filed Federal Circuit Appeal No. 19-1259 appealing the Final Written Decision finding no instituted claim unpatentable in IPR2017-01140. On December 20, 2018, the appeal was dismissed due to settlement.
- On December 7, 2018, Genentech filed Federal Circuit Appeal No. 19-1263 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-00731.
- On December 7, 2018, Genentech filed Federal Circuit Appeal No. 19-1265 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-00737.
- On December 7, 2018, Genentech filed Federal Circuit Appeal No. 19-1267 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-01121.
- On December 7, 2018, Genentech filed Federal Circuit Appeal No. 19-1270 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-01122.
- On December 7, 2018, Pfizer and Hospira terminated their involvement in Federal Circuit Appeal Nos. 19-1173 appealing the Final Written Decision in IPR2017-01959, and 19-1174 appealing the Final Written Decision in IPR2017-01958.
- On December 20, 2018, IPR2017-02019 and IPR2017-02020 were terminated after institution due to settlement at the joint request of Genentech and Pfizer.

Erbitux® (cetuximab):

- On December 12, 2018, the Federal Circuit denied The Trustees of the University of Pennsylvania's request for a panel rehearing and rehearing *en banc* in Case No. 17-2397, of the Federal Circuit's decision affirming the PTAB's Final Written Decision finding all instituted claims unpatentable in IPR2016-00458, filed by Eli Lilly.

Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant):

- On December 12, 2018, Final Written Decisions finding all instituted claims unpatentable were entered in IPR2017-01526 and IPR2017-01528, filed by Mylan and Biocon.
- On December 19, 2018, IPR2018-01677 was dismissed at the request of Mylan and Biocon due to a clerical error in filing.

The petition was refiled as IPR2019-00122.

LITIGATIONS

Herceptin® (trastuzumab):

- On December 4, 2018, *Genentech v. Pfizer,* Case No. 1:17-cv-01672 (D. Del.) was dismissed due to settlement.
- On December 27, 2018, Case Nos. 1:18-cv-00095 (D. Del.). and 1:18-cv-01025 (D. Del.) were dismissed due to settlement at the request of Genentech, Celltrion, and Teva.

Rituxan® (rituximab):

- On December 6, 2018, Genentech and Sandoz requested dismissal of Case No. 1:17-cv-13507 (D.N.J.).

aBLA APPLICATIONS AND FDA ACTIVITY

Herzuma® (trastuzumab-pkrb):

- On December 14, 2018, the FDA approved Celltrion and Teva's Herzuma®, a biosimilar of Genentech's Herceptin® (trastuzumab).

ABP 710 (infliximab):

- On December 17, 2018, Amgen announced that it submitted an aBLA for ABP 710, its proposed biosimilar of Janssen's Remicade® (infliximab).

CDER PURPLE BOOK UPDATES

Asparlas™ (calaspargase pegol-mknl):

- On December 20, 2018, the FDA approved Servier Pharma's Asparlas™.

Ultomiris™ (ravulizumab-cwvz):

- On December 21, 2018, the FDA approved Alexion's Ultomiris™.

Elzonris™ (tagraxofusp-erzs):

- On December 21, 2018, the FDA approved Stemline Therapeutics' Elzonris™.

NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

CKD-11101 (darbepoetin alfa):

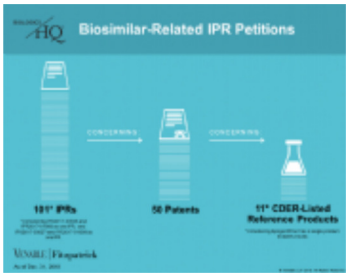
- On December 2, 2018, Chong Kun Dang Pharmaceutical announced that it received approval for CKD-11101, its biosimilar of Aranesp® (darbepoetin alfa) in South Korea.

Ogivri™ (trastuzumab):

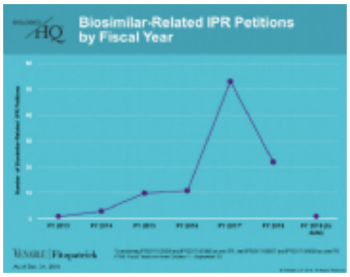
- On December 19, 2018, Mylan and Biocon announced that they received approval for Ogivri™, their biosimilar of Herceptin® (trastuzumab), in the E.U.

STATISTICS

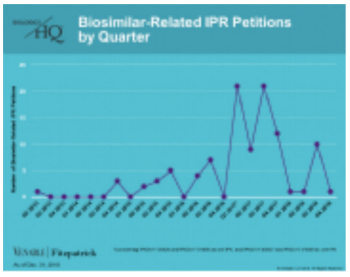
Biosimilar-Related IPR Petitions



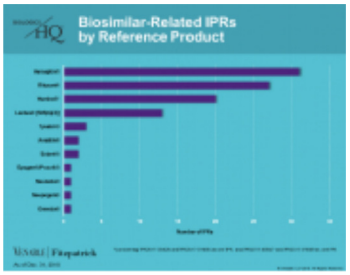
Biosimilar-Related IPR Petitions by Fiscal Year



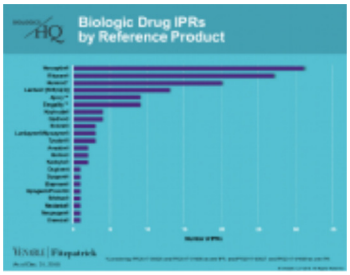
Biosimilar-Related IPR Petitions by Quarter



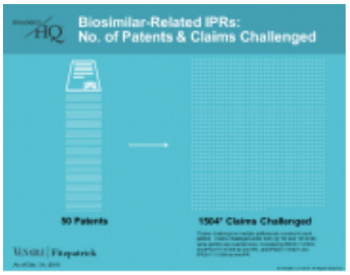
Biosimilar-Related IPRs by Reference Product



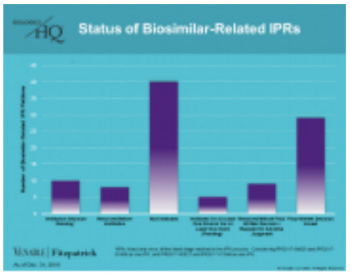
Biologic Drug IPRs by Reference Product



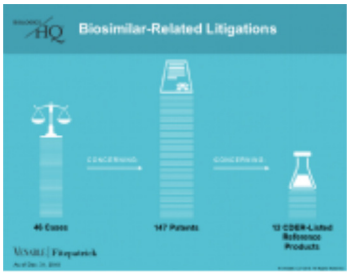
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs

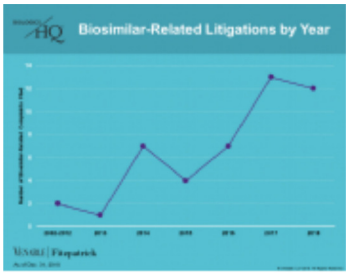


Biosimilar-Related Litigations

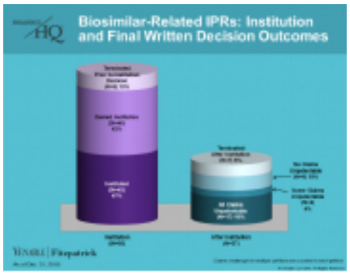


Biosimilar-Related Litigations by Reference Product

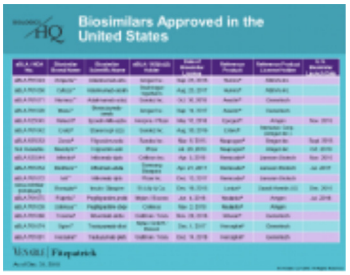
Biosimilar-Related Litigations by Year



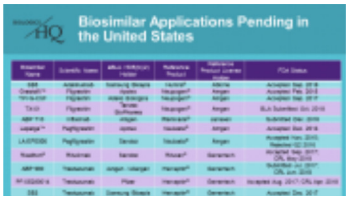
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilars Approved in the United States

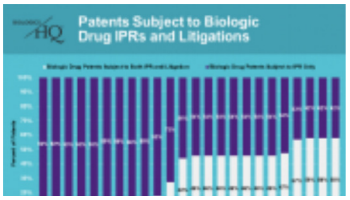


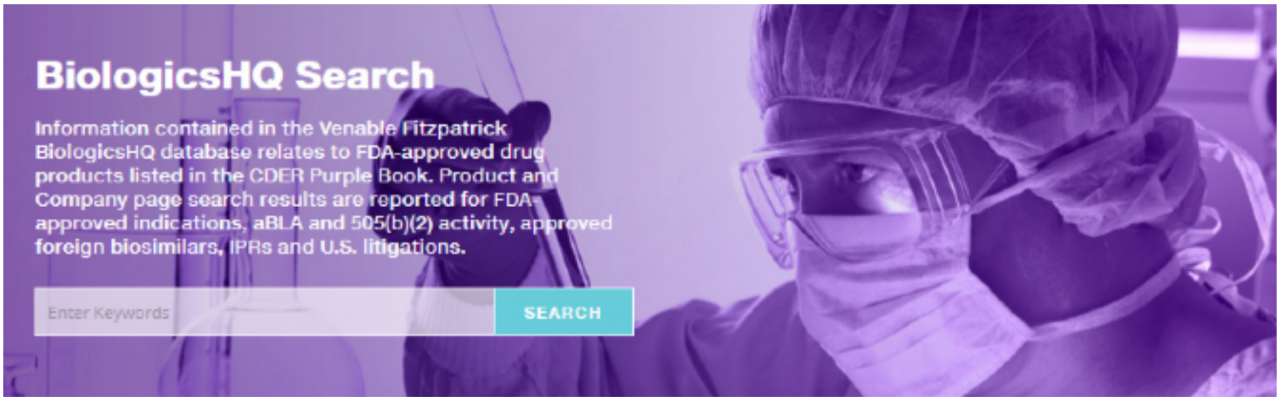
Biosimilar Applications Pending in the United States



Biologic Drug IPR Petitions

Patents Subject to Biologic Drug IPRs and Litigations





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