BIOLOGICS HQ

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July 9, 2020

LATEST NEWS

Biosimilar Law Experts Discuss Potential Bills and Chances for Passage

Ha Kung Wong and April Breyer Menon Discuss Promising and Not-so-Promising Biosimilar Legislation

By: Ha Kung Wong and April Breyer Menon

Despite the United States having had a biosimilar pathway for a decade now, the industry has launched just 17 biosimilars, well behind the pace in Europe and India. Several pieces of legislation have been introduced in Congress to help boost uptake, generate savings for payers and patients, and increase biosimilar access. However, not every bill is likely to become a law, as politics and money can often get in the way.

In interviews with the Center for Biosimilars, Ha Kung Wong and April Breyer Menon discuss potential bills to improve biosimilar uptake, including the Hatch-Waxman Integrity Act, Stop STALLING Act, Biologic Patent Transparency Act, Affordable and Safe Prescription Drug Importation Act, Biosim Act, and their chances for passage. They also discuss additional issues that may affect biosimilar legislation such as COVID-19, upcoming elections, and biosimilar uptake in the US.

It's a New Set of Rules for Insulin Products Under 351(k)

By: Ha Kung Wong

Based on a June 2020 announcement, the longtime generics manufacturer Lannett would become among the first to file for insulin glargine product approval under the 351(k) Biologics License Application pathway.

Ha Kung Wong discusses previous and future approval processes for insulin biosimilars, including clinical testing and the possibility of receiving an interchangeability designation.

Spotlight On: Herceptin® (trastuzumab) / Ogivri™ (trastuzumab-dkst) / Herzuma® (trastuzumab-pkrb) / Ontruzant® (trastuzumab-dttb) / Trazimera™ (trastuzumab-qyyp) / Kanjinti™ (trastuzumab-anns)

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) / Abrilada™ (adalimumab-afzb)

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

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine) / Semglee™ (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 trastuzumab (Herceptin®, Ogivri™, Herzuma®, Ontruzant®, Trazimera™, and Kanjinti™), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, and Abrilada™), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, and Semglee™) have been updated with activity through June 30, 2020.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through June 30, 2020.

Read More News

UPDATES

IPRs and PGRs

Soliris® (eculizumab):

- On June 1, 2020, the PTAB granted **Alexion** and **Amgen's** joint motions to terminate due to settlement after institution in IPR2019-00739, IPR2019-00740 and IPR2019-00741.

Lantus® (insulin glargine recombinant):

- On June 10, 2020, **Sanofi** filed Federal Circuit Appeal No. 20-1871, appealing the final written decision in IPR2018-01670 finding the 1 challenged claim unpatentable.

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On June 11, 2020, **Eli Lilly** filed Federal Circuit Appeal Nos. 20-1876, 20-1877, and 20-1878, appealing the final written decisions finding no instituted claim unpatentable in IPR2018-01710, IPR2018-01711, and IPR2018-01712 respectively.

Neulasta® (pegfilgrastim):

- On June 19, 2020, the PTAB granted **Amgen** and **Fresenius Kabi's** joint request to terminate IPR2020-00314 prior to an institution decision due to settlement.

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

- On June 23, 2020, the PTAB granted **Amgen** and **Fresenius Kabi's** joint request to terminate IPR2019-01183 after institution due to settlement.

Litigations

Eylea® (aflibercept):

- On June 19, 2020, **Novartis** filed Case No. 1:20-cv-00690 (N.D.N.Y.) against **Regeneron** related to **Regeneron's Eylea® (aflibercept)**.

Avastin® (bevacizumab):

- On June 28, 2020, **Genentech** filed Case No. 1:20-cv-00859 (D. Del.) against **Samsung Bioepis** related to **Samsung Bioepis's** proposed biosimilar **SB8 (bevacizumab)**.

aBLA Applications and FDA Activity

Nyvepria™ (pegfilgrastim-apgf):

- On June 10, 2020, the FDA approved **Pfizer** and **Hospira's Nyvepria™ (pegfilgrastim-apgf)**, a biosimilar of **Amgen's Neulasta® (pegfilgrastim)**.

Semglee™ (insulin glargine):

- On June 11, 2020, the FDA approved **Mylan's Semglee™ (insulin gargine)**, a biosimilar of **Sanofi's Lantus® (insulin glargine recombinant)**.

CDER Purple Book Updates

Uplinza™ (inebilizumab):

- On June 11, 2020, the FDA approved **Viela Bio's Uplinza™ (inebilizumab)**.

Lyumjev™ (insulin lispro-aabc):

- On June 15, 2020, the FDA approved **Eli Lilly's Lyumjev™ (insulin lispro-aabc)**.

Phesgo™ (pertuzumab; trastuzumab; hyaluronidase-zzxf):

- On June 29, 2020, the FDA approved **Genentech's Phesgo™ (pertuzumab; trastuzumab; hyaluronidase-zzxf)**.

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

Nepexto™ (etanercept):

- On June 4, 2020, **Mylan** and **Lupin** announced that **Nepexto™ (etanercept)**, a biosimilar of **Amgen's Enbrel® (etanercept)**, was approved in the E.U.

Truxima® (rituximab-abbs):

- On June 5, 2020, the World Health Organization (WHO) preqalified **Celltrion's Truxima® (rituximab-abbs)**, a biosimilar of **Genentech's Rituxan® (rituximab)**.

Ziextenzo® (pegfilgrastim-bmez):

- On June 9, 2020, **Sandoz** announced that **Ziextenzo® (pegfilgrastim-bmez)**, a biosimilar of **Amgen's Neulasta® (pegfilgrastim)**, was approved for marketing in Canada.

Riximyo® (rituximab):

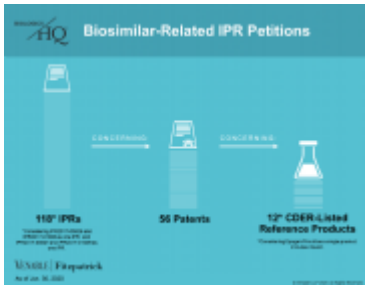
- On June 9, 2020, **Sandoz** announced that **Riximyo® (rituximab)**, a biosimilar of **Genentech's Rituxan® (rituximab)**, was approved for marketing in Canada.

Hulio® (adalimumab):

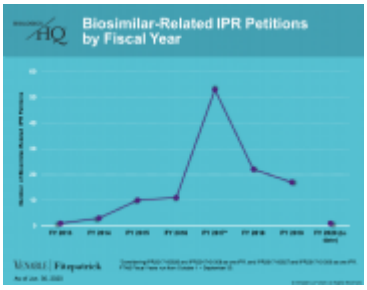
- On June 29, 2020, **Fujifilm Kyowa Kirin Biologics** announced that **Hulio® (adalimumab)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, was approved in Japan.

STATISTICS

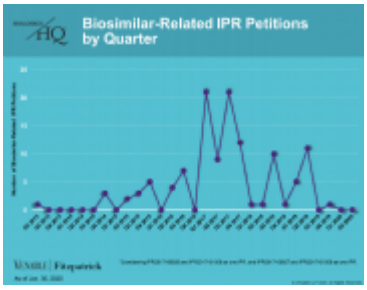
Biosimilar-Related IPR Petitions



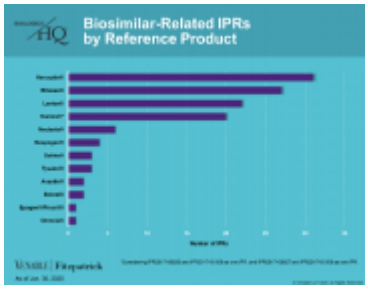
Biosimilar-Related IPR Petitions by Fiscal Year



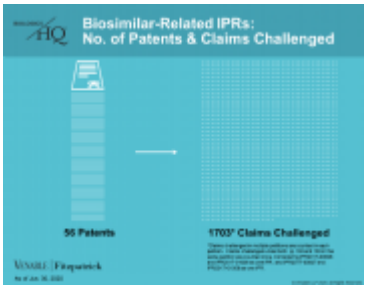
Biosimilar-Related IPR Petitions by Quarter



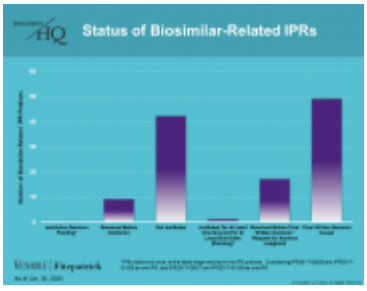
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs

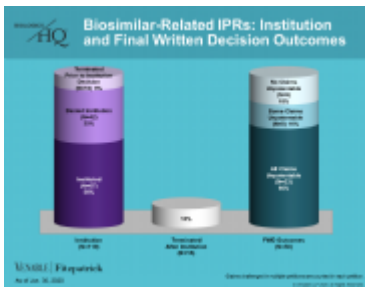


Biosimilar-Related IPRs:

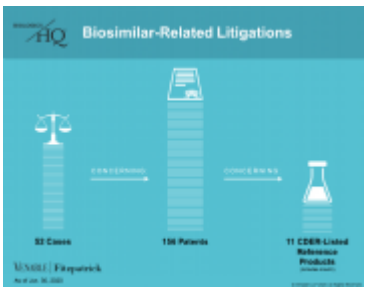
Biosimilar-

Biosimilar-Related

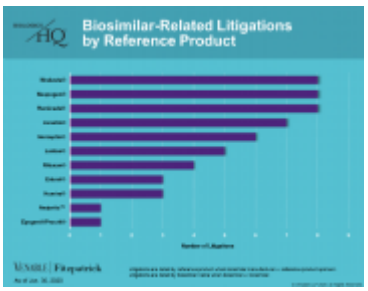
Institution and Final Written Decision Outcomes



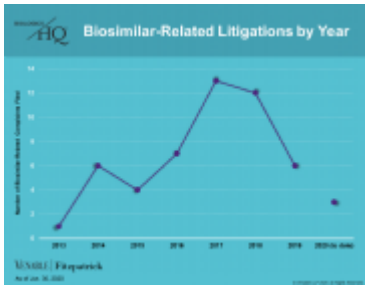
Related Litigations



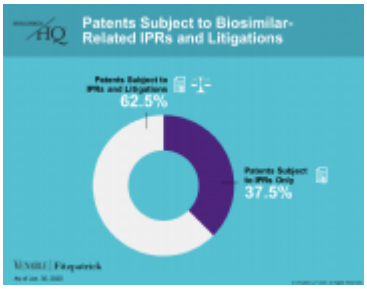
Litigations by Reference Product



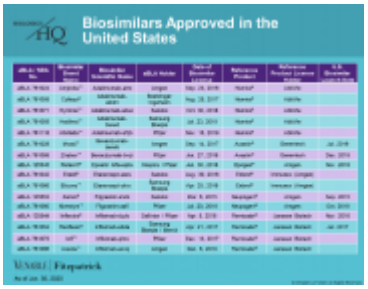
Biosimilar-Related Litigations by Year



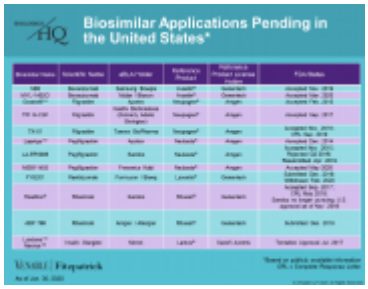
Patents Subject to Biosimilar-Related IPRs and Litigations



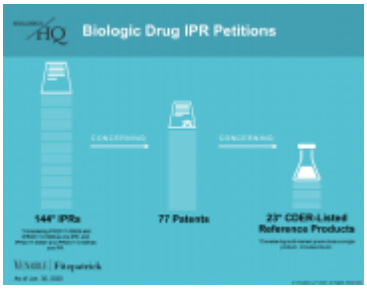
Biosimilars Approved in the United States



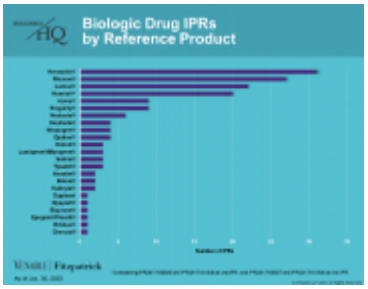
Biosimilar Applications Pending in the United States



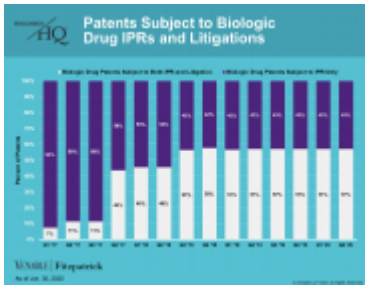
Biologic Drug IPR Petitions



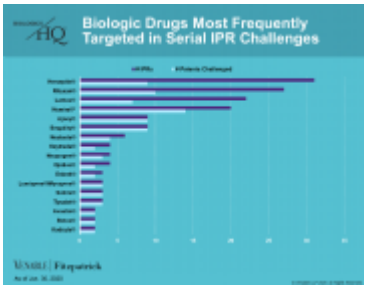
Biologic Drug IPRs by Reference Product



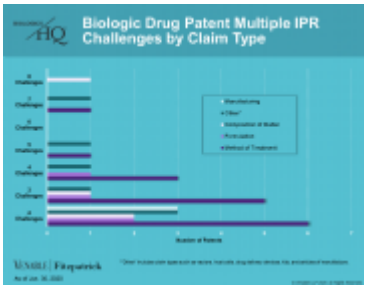
Patents Subject to Biologic Drug IPRs and Litigations



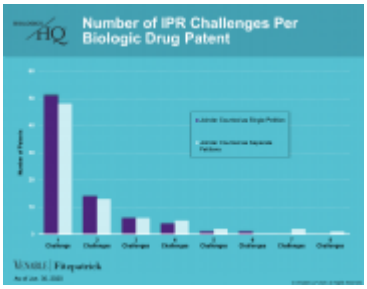
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

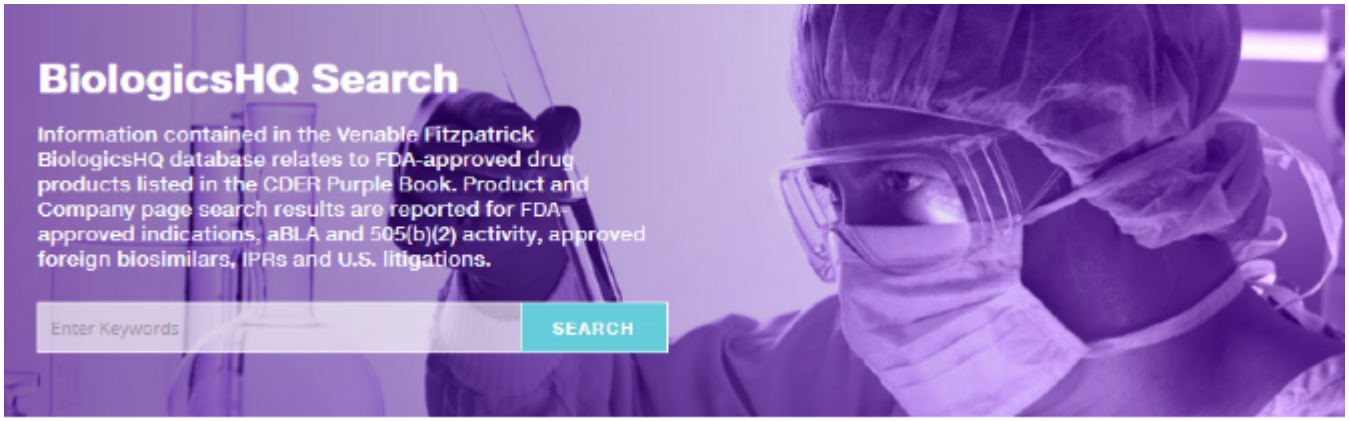


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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