BIOLOGICS HQ

VENABLE | Fitzpatrick

March 12, 2020

LATEST NEWS

FDA Updates Relating to Biosimilars

February was a busy month for the FDA in the field of biosimilars:

- **On February 3, 2020, the FDA and FTC issued a joint statement regarding their enhanced collaboration to support the adoption of biosimilars and interchangeables.**
- **On February 3, 2020, the FDA published a draft guidance, "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers." Comments will be accepted until April 2, 2020.**
- **On February 3, 2020, the FDA and FTC announced a public workshop on a competitive marketplace for biosimilars, to take place on March 9, 2020.**
- **On February 6, 2020, the FDA issued a draft guidance, "Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed." Comments will be accepted until April 6, 2020.**
- **On February 21, 2020, a final rule on the definition of "biological product" was published. This rule defines "protein" as "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size." The FDA is using this "bright line" approach to reduce uncertainty regarding whether products will be regulated as drugs or biological products. Under the final definition, "insulin clearly is a 'protein' ... because the total number of amino acids exceeds 40" and thus will be regulated as a biological product.**
- **On February 21, 2020, the FDA issued frequently asked question documents for patients and health care providers relating to the transition of biological products approved under the Food, Drug, and Cosmetic Act, such as insulin and human growth hormone, from being regulated as drugs to being regulated as biological products, as of March 23, 2020.**
- **On February 24, 2020, the FDA launched its revised version of the "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," also known as the Purple Book, that is now searchable. This initial phase of the searchable database includes information on licensed biosimilar and interchangeable products and their reference products.**

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)

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® and Basaglar®) have been updated with activity through February 29, 2020.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through February 29, 2020.

Read More News

UPDATES

IPRs and PGRs

Myozyme® / Lumizyme® (alglucosidase alfa):

- On February 3, 2020, the Federal Circuit denied Duke University's request for en banc rehearing of its decision in Federal Circuit Case No. 18-1696, affirming the PTAB's obviousness decision on remand of IPR2013-00535.

Lantus® (insulin glargine recombinant):

- On February 6, 2020, the Federal Circuit denied **Sanofi's** motion to stay its mandate pending a forthcoming Supreme Court writ of certiorari in consolidated Federal Circuit Case Nos. 19-1368 and 19-1369, appealing the final written decisions in IPR2017-01526 and IPR2017-01528.

- On February 10, 2020, in Case No. 19A886, the Supreme Court issued an order staying the issuance of the Federal Circuit's mandate in consolidated Federal Circuit Case Nos. 19-1368 and 19-1369. On February 14, 2020, the Supreme Court vacated its order and denied **Sanofi's** application for a stay pending a Supreme Court decision on a forthcoming writ of certiorari.

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

- On February 18, 2020, the PTAB issued final written decisions in ***Eli Lilly*** *v.* ***Teva*** IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427 finding all instituted claims unpatentable.

Taltz® (ixekizumab):

- On February 24, 2020, **Genentech** filed requests for adverse judgment after institution in PGR2019-00043, filed by **Eli Lilly**, and PGR2019-00044, filed by **UCB** on the same patent.

Litigations

Neulasta® (pegfilgrastim):

- On February 11, 2020, **Amgen** filed Case No. 1:20-cv-00201 (D. Del.) against **Hospira** and **Pfizer** related to their proposed biosimilar **PF-06881894**.

Taltz® (ixekizumab):

- On February 26, 2020, **Genentech** filed a motion to voluntarily dismiss Case No. 3:18-cv-01518 (S.D. Cal.).

aBLA Applications and FDA Activity

FYB201 (ranibizumab):

- On February 4, 2020, **Formycon** and **Bioeq** announced that they withdrew their aBLA for **FYB201 (ranibizumab)**, a proposed biosimilar of **Genentech's Lucentis® (ranibizumab)**, after the FDA requested additional data. They plan to resubmit the application after providing the requested data.

Trazimera™ (trastuzumab-qyyp):

- On February 15, 2020, **Pfizer** launched **Trazimera™ (trastuzumab-qyyp)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, at a 22% discount.

CDER Purple Book Updates

Vyepti™ (eptinezumab-jjmr):

- On February 21, 2020, the FDA approved **Lundbeck Seattle BioPharmaceuticals' Vyepti™ (eptinezumab-jjmr)**.

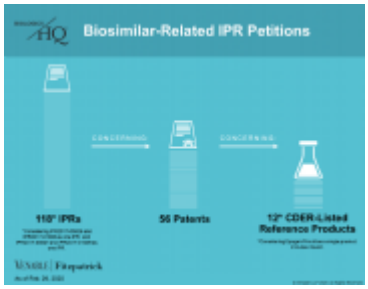
Non-U.S. Biosimilars / Follow-On Biologics

Amsparity™ (adalimumab):

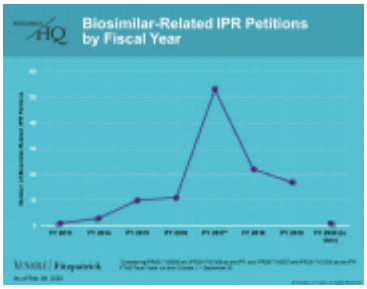
- On February 13, 2020, **Pfizer's Amsparity™ (adalimumab)**, a biosimilar of **AbbVie's Humira® (adalimumab)** was approved in the E.U.

STATISTICS

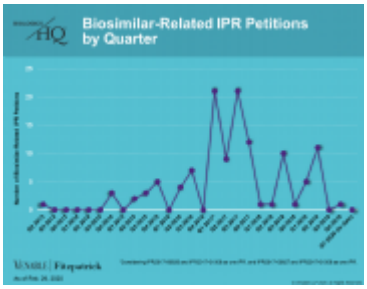
Biosimilar-Related IPR Petitions



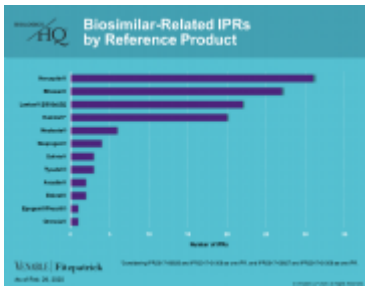
Biosimilar-Related IPR Petitions by Fiscal Year



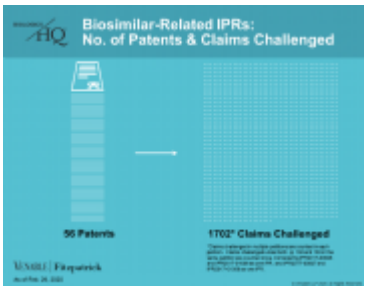
Biosimilar-Related IPR Petitions by Quarter



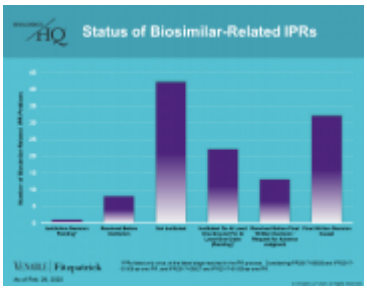
Biosimilar-Related IPRs by Reference Product



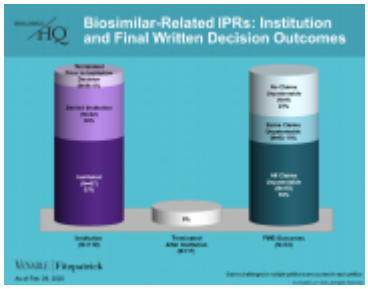
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



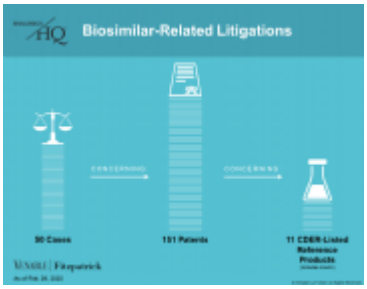
Status of Biosimilar-Related IPRs



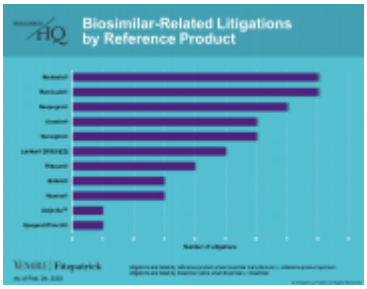
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



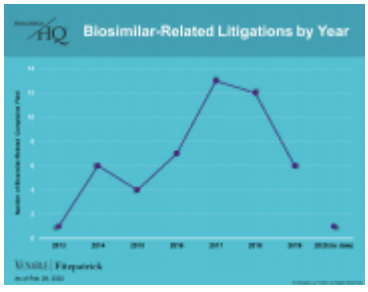
Biosimilar-Related Litigations



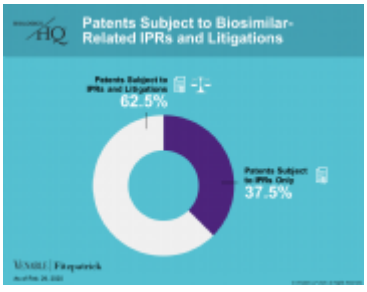
Biosimilar-Related Litigations by Reference Product



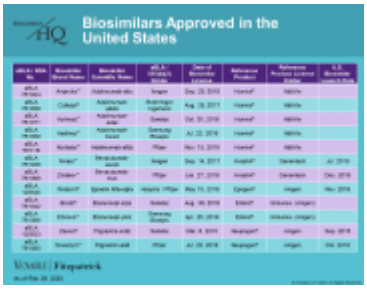
Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars Approved in the United States

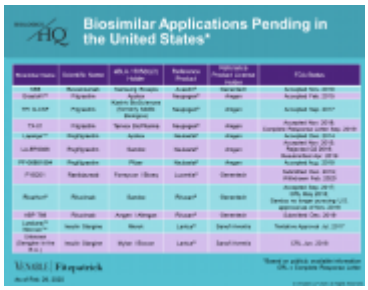


Biosimilar Applications

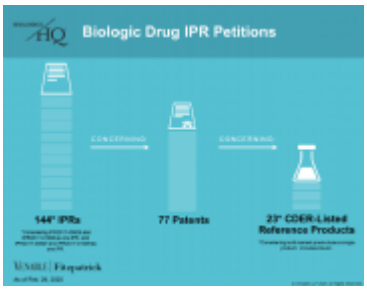
Biologic Drug

Biologic Drug

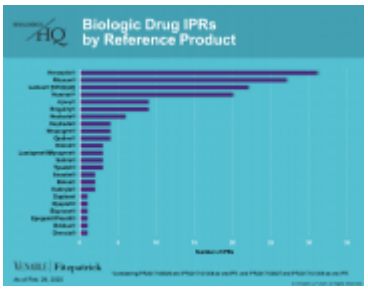
Pending in the United States



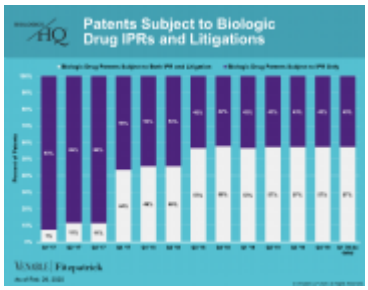
IPR Petitions



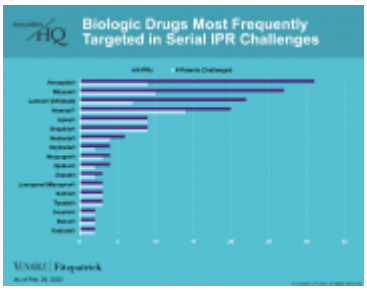
IPRs by Reference Product



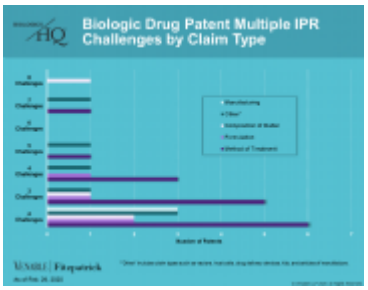
Patents Subject to Biologic Drug IPRs and Litigations



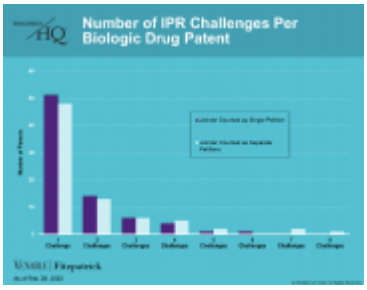
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

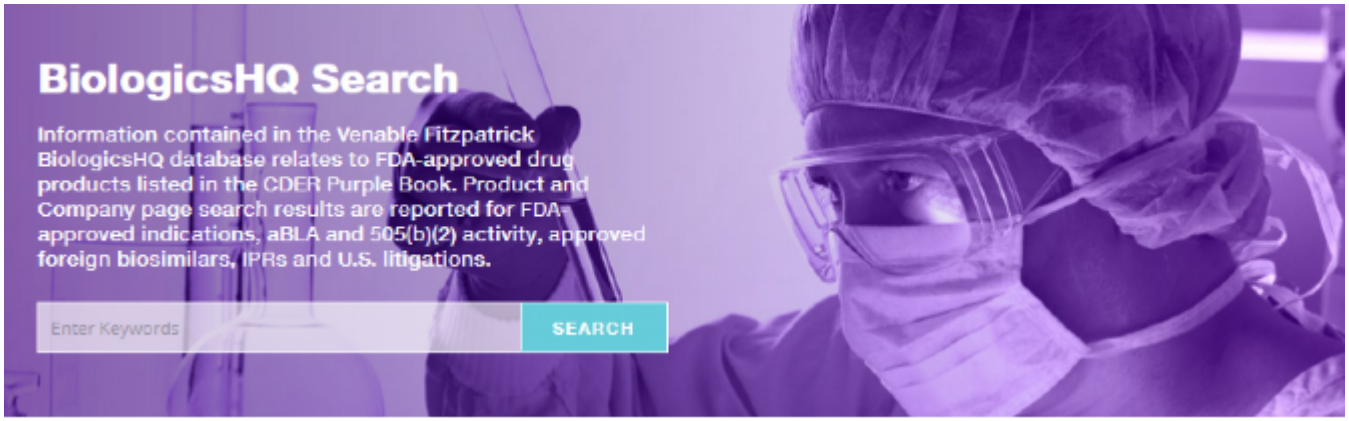


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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