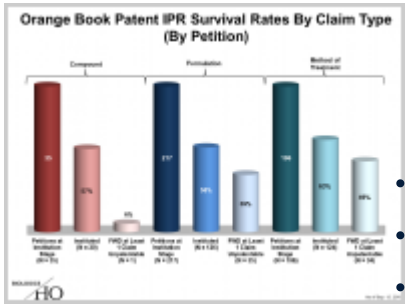
BIOLOGICS HQ

VENABLE | Fitzpatrick

January 7, 2020

LATEST NEWS



Venable Fitzpatrick's 10 Most Read Articles of 2019

In case you missed them, check out Venable Fitzpatrick's most read articles of 2019:

- **Seven Years of Orange Book Patent IPRs: Where Are We Now?**
- **Biosimilar Experts Give Highlights of U.S. Uptake Issues**
- **The Most Important U.S. Patent Cases of 2019 Thus Far**
- **Biosimilars and the BPCIA: Past, Present, and Future**
- **Will Authorized Biologics Disrupt the Market for Biosimilars?**
- **U.S. Patent System Crimps Drug Innovation for Toughest Diseases**
- **More Uncertainty After DOJ Signals Approval of ACA Reversal**
- **Why is Biosimilar Adoption Slow in the U.S., and Can Something Be Done to Boost Uptake?**
- **Can Congress Speed Biosimilars to Market by Limiting Patent Litigations?**
- **How Can Biosimilars Make Headway in the U.S. Market?**

Supreme Court Prohibits United States Patent and Trademark Office from Shifting Attorney's Fees in Certain District Court Proceedings

By: Christopher Loh

The Supreme Court on December 11, 2019 unanimously ruled in *Peter v. NantKwest, Inc.*, No. 18-801, that the United States Patent and Trademark Office (USPTO) cannot shift the fees of its attorneys and paralegals to litigants in district court proceedings brought under 35 U.S.C. §145.

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 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 December 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 December 31, 2019.

Read More News

UPDATES

IPRs and PGRs

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

- On December 6, 2019, the PTAB granted **Kashiv BioSciences** and **Amgen's** joint motions to dismiss IPR2019-00791 and IPR2019-00797 due to settlement.
- On December 6, 2019, the PTAB granted **Kashiv BioSciences** and **Amgen's** joint motion to dismiss PGR2019-00001 due to settlement.
- On December 10, 2019, the PTAB instituted IPR2019-01183 filed by **Fresenius Kabi**.

Myozyme® / Lumizyme® (alglucosidase alfa):

- On December 11, 2019, Duke University filed a petition for en banc rehearing of the Federal Circuit's decision in Appeal No. 18-1696, appealing the final written decision in Duke v. **BioMarin**, IPR2013-00535.

Lantus® (insulin glargine recombinant):

- On December 19, 2019, **Mylan** and **Sanofi** filed petitions for panel rehearings in Fed. Cir. Appeal No. 19-1368 and consolidated appeal 19-1369, where the Federal Circuit affirmed the PTAB's determinations that all challenged claims were unpatentable in IPR2017-01526 and IPR2017-01528. **Sanofi** also filed petitions for en banc rehearing.

Neulasta® (pegfilgrastim):

- On December 20, 2019, **Fresenius Kabi** filed IPR2020-00314.

Litigations

Epogen® / Procrit® (epoetin alfa):

- On December 16, 2019, the Federal Circuit affirmed the jury verdict and denial of JMOL or new trial in ***Amgen*** *v.* ***Hospira***, Fed. Cir. Appeal Nos. 19-1067 and 19-1102, appealing Case No. 1:15-cv-00839 (D. Del.).

Neupogen® (filgrastim):

- On December 20, 2019, the Court granted **Amgen** and **Tanvex's** joint motion to dismiss Case No. 3:19-cv-01374 (S.D. Cal.).

aBLA Applications and FDA Activity

Ogivri™ (trastuzumab-dkst):

- On December 3, 2019, **Mylan** and **Biocon** announced the launch of **Ogivri™ (trastuzumab-dkst)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**.

Avsola™ (infliximab-axxq):

- On December 6, 2019, the FDA approved **Amgen's Avsola™ (infliximab-axxq)**, a biosimilar of **Janssen's Remicade® (infliximab).**

ABP 798 (rituximab):

- On December 19, 2019, **Amgen** and **Allergan** announced the submission of an aBLA for **ABP 798 (rituximab)**, a proposed biosimilar of **Genentech's Rituxan® (rituximab)**.

CDER Purple Book Updates

Padcev™ (enfortumab vedotin-ejfv):

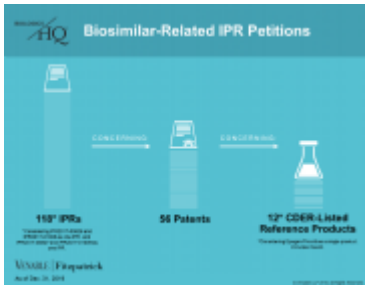
- On December 18, 2019, the FDA approved **Astellas's Padcev™ (enfortumab vedotin-ejfv)**.

Enhertu® (fam-trastuzumab deruxtecan-nxki):

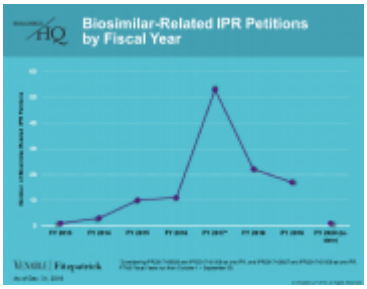
- On December 20, 2019, the FDA approved **Daiichi's Enhertu® (fam-trastuzumab deruxtecan-nxki)**.

STATISTICS

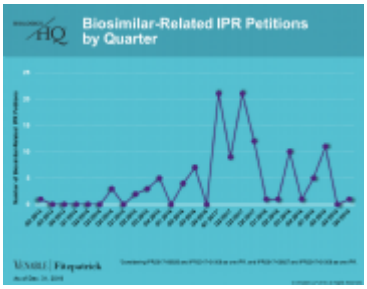
Biosimilar-Related IPR Petitions	Biosimilar-Related IPR Petitions by Fiscal Year	Biosimilar-Related IPR Petitions by Quarter



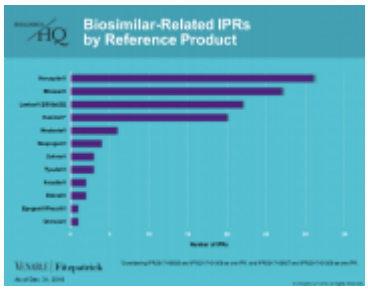
[Biosimilar-Related IPRs by Reference Product]



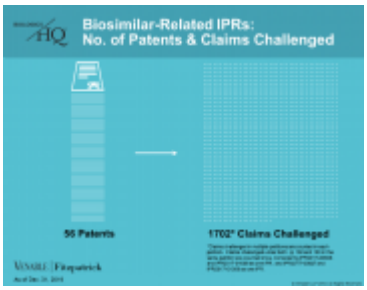
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



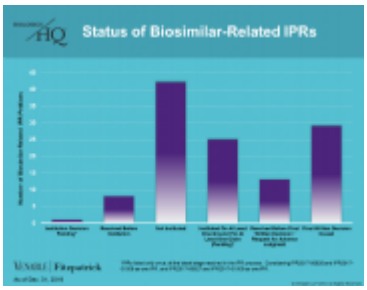
[Status of Biosimilar-Related IPRs]



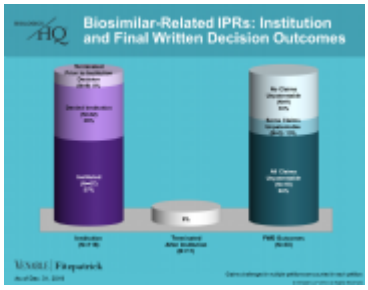
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



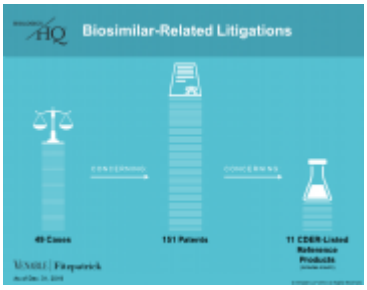
[Biosimilar-Related Litigations]



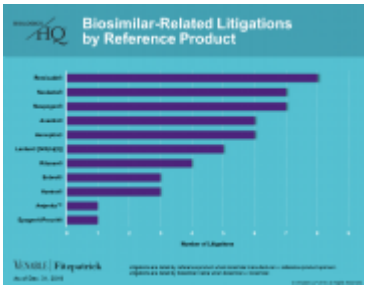
[Biosimilar-Related Litigations by Reference Product]



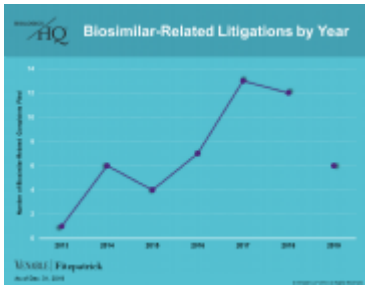
[Biosimilar-Related Litigations by Year]



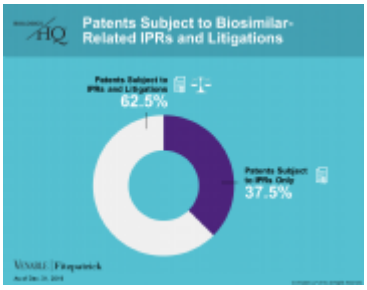
[Patents Subject to Biosimilar-Related IPRs and Litigations]



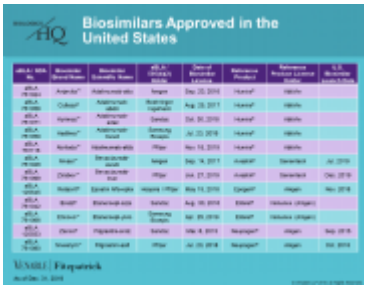
[Biosimilars Approved in the United States]



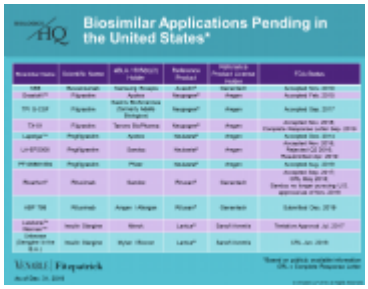
[Biosimilar Applications Pending in the United States]

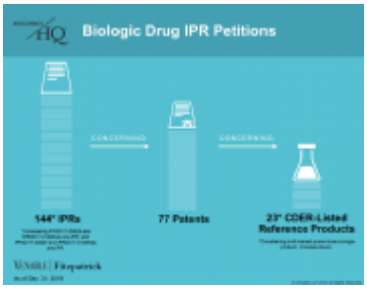


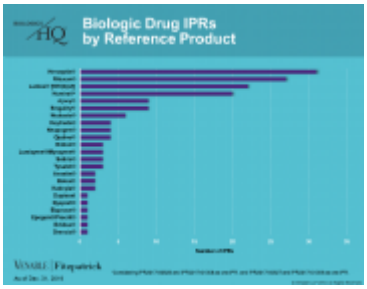
[Biologic Drug IPR Petitions]



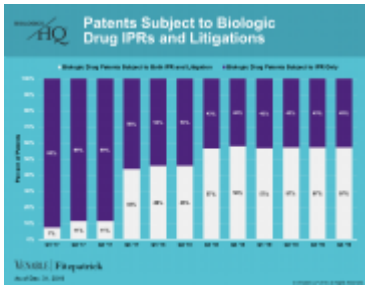
[Biologic Drug IPRs by Reference Product]



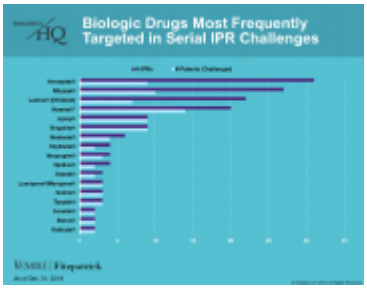




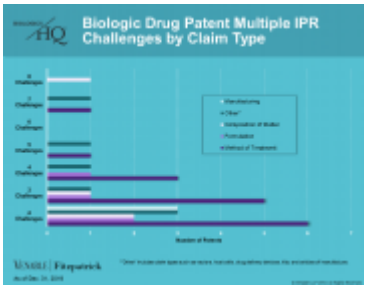
Patents Subject to Biologic Drug IPRs and Litigations



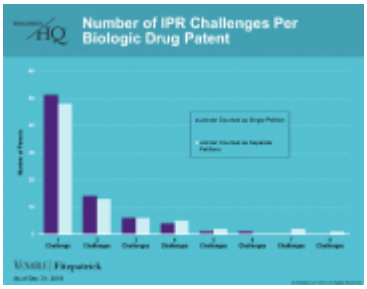
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

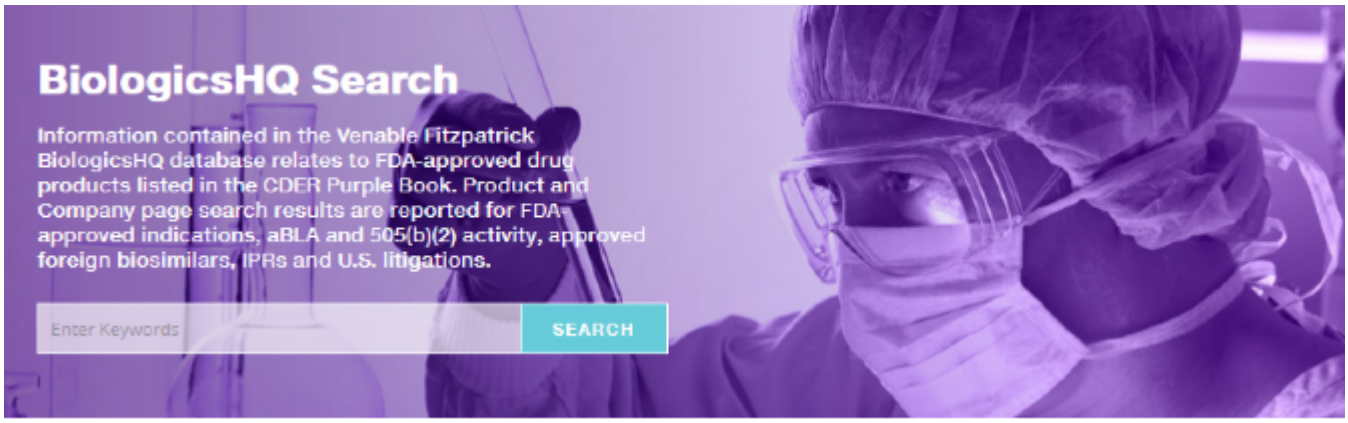


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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