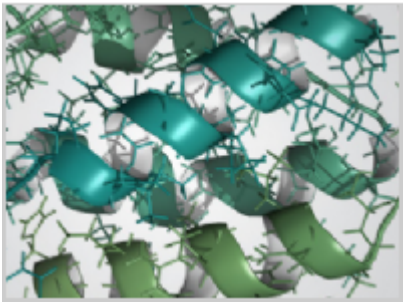
BIOLOGICS HQ

VENABLE | Fitzpatrick

November 8, 2021

LATEST NEWS



FDA Approves Boehringer Ingelheim's Cyltezo® as Interchangeable with Humira®

By: April Breyer Menon

On October 15, 2021, the FDA approved Boehringer Ingelheim's Cyltezo® (adalimumab-adbm) as interchangeable with AbbVie's Humira® (adalimumab) for many of Humira's approved indications. As an interchangeable, Cyltezo can be automatically substituted for Humira at the pharmacy, subject to individual state laws. Grant of interchangeability status was based on the phase III VOLTAIRE-X study, which evaluated switching patients with moderate-to-severe chronic plaque psoriasis between Cyltezo and Humira and back again, and found that those who switched had similar clinical outcomes in terms of safety, efficacy, pharmacokinetics, and immunogenicity to those who did not switch.

U.S. Patent Legal Landscape Outlook

By: Ha Kung Wong

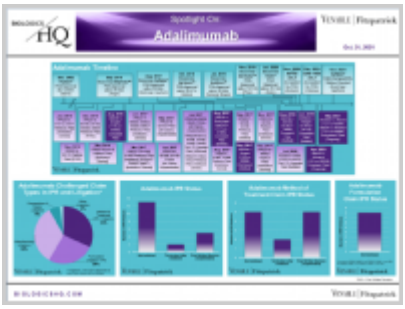
Ha Kung Wong, Wei Campbell, and Christine Cochran gave a LSPN Live presentation titled "US Patent Legal Landscape Outlook: What are the Main Challenges Facing the US Patent System and how do we Prepare for them?" where they discussed recent Supreme Court cases and the current IP system in the U.S.

2021 Patent Caselaw Roundup – Lawline CLE

By: Christopher Loh

Christopher Loh taught a Lawline CLE updating in-house and outside counsel on the latest developments in patent case law. The CLE includes a review of the Supreme Court's *Arthrex* decision and its effects on the

logistics of *inter partes* review proceedings, the Supreme Court's *Minerva* decision and its effects on the assignor estoppel doctrine, a roundup of key Federal Circuit decisions, and recent developments in the Western District of Texas concerning jurisdiction and venue disputes.



Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria™ (pegfilgrastim-apgf)

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) / Hulio® (adalimumab-fkjp)

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 pegfilgrastim (Neulasta®, Lapelga™, Ziextenzo®, Udenyca®, Fulphila®, Nyvepria™, MSB11455, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri™, Herzuma®, Ontruzant®, Trazimera™, and Kanjinti®), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™, and Hulio®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, and Semglee®) have been updated with activity through October 31, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through October 31, 2021.

Read More News

UPDATES

IPRs and PGRs

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

- On October 4, 2021, **Amgen** filed a request for Director review of the final written decision in IPR2016-01542.

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On October 26, 2021, the PTAB instituted IPR2021-00816 filed by **Regeneron** against **Novartis**.

Litigations

Botox® (onabotulinumtoxinA):

- On October 1, 2021, **Allergan** filed Case No. 1:21-cv-01411 (D. Del.) against **Revance Therapeutics** related to **Revance's** daxibotulinumtoxinA (not yet FDA approved).

Forteo® (teriparatide):

- On October 1, 2021, consent judgment of noninfringement was entered in ***Amphastar Pharmaceuticals*** *v.* ***Eli Lilly***, Case No. 1:21-cv-01922 (S.D. Ind.).

Avonex® (interferon beta-1a) / Betaseron® (interferon beta-1b) / Extavia® (interferon beta-1b) / Rebif® (interferon beta-1a):

- On October 4, 2021, the Supreme Court denied **Biogen's** writ of certiorari in Supreme Court Case No. 20-1604, appealing from Fed. Cir. Case No. 19-1133 and District Court Case No. 2:10-cv-02734 (D.N.J.).

Cimzia® (certolizumab pegol):

- On October 19, 2021, the Court ordered **UCB Pharma** and **Nektar Therapeutics'** stipulation of dismissal of Case No. 1:20-cv-00650 (D. Del.).

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aBLA Applications and FDA Activity

CT-P16 (bevacizumab):

- On October 1, 2021, **Celltrion** announced submission of an aBLA for **CT-P16 (bevacizumab)**, a proposed biosimilar of **Genentech's** **Avastin® (bevacizumab)**.

Cyltezo® (adalimumab-adbm):

- On October 15, 2021, the FDA approved **Boehringer Ingelheim's** **Cyltezo® (adalimumab-adbm)** as interchangeable with **AbbVie's** **Humira® (adalimumab)**. **Cyltezo® (adalimumab-adbm)** is the second biosimilar to be granted interchangeable status in the U.S.

CDER Purple Book Updates

Susvimo™ (ranobizumab):

- On October 22, 2021, the FDA approved **Genentech's Susvimo™ (ranobizumab)**.

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

Nypozi™ (filgrastim):

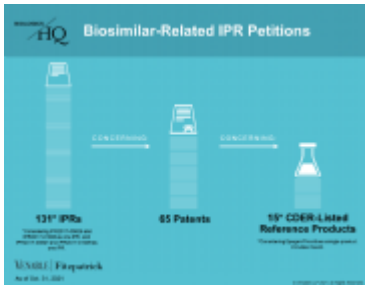
- On October 4, 2021, **Tanvex Biopharma's Nypozi™ (filgrastim)**, a biosimilar of **Amgen's Neupogen® (filgrastim)**, was approved in Canada.

Kirsty (insulin aspart):

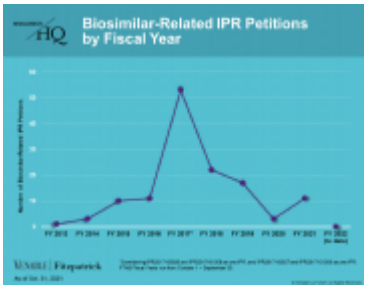
- On October 12, 2021, **BGP Pharma's** (part of **Viatris**) **Kirsty (insulin aspart)**, a biosimilar of **Novo Nordisk's Novolog® (insulin aspart)**, was approved in Canada.

STATISTICS

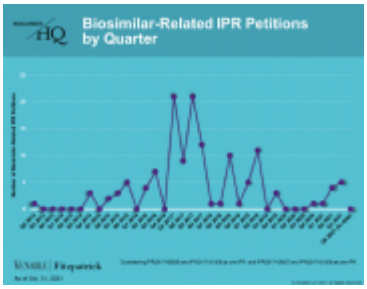
Biosimilar-Related IPR Petitions



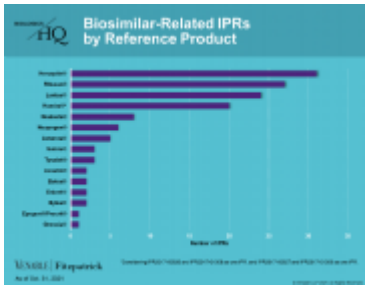
Biosimilar-Related IPR Petitions by Fiscal Year



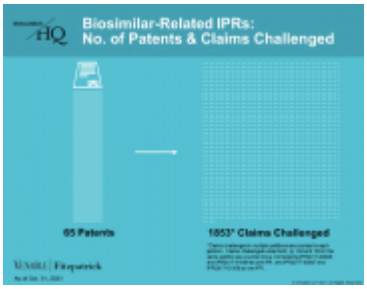
Biosimilar-Related IPR Petitions by Quarter



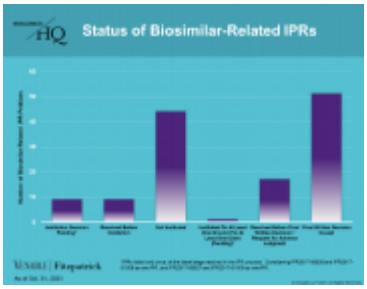
Biosimilar-Related IPRs by Reference Product



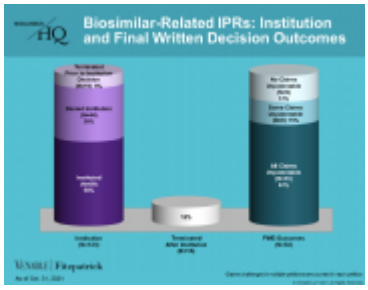
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



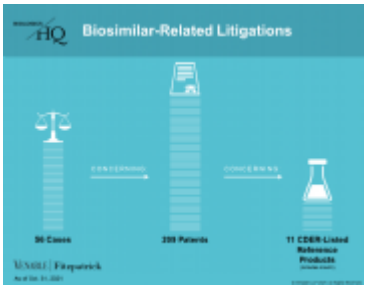
Status of Biosimilar-Related IPRs



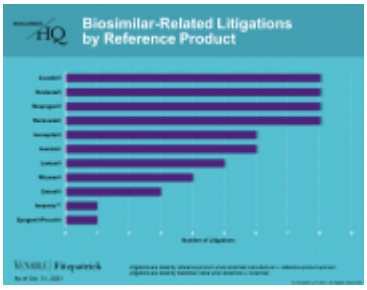
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



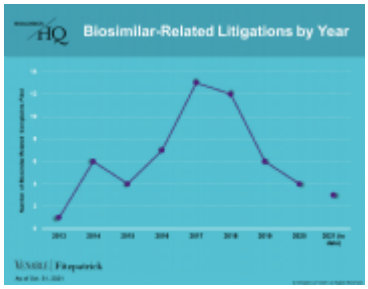
Biosimilar-Related Litigations



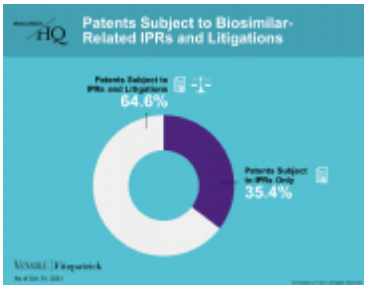
Biosimilar-Related Litigations by Reference Product



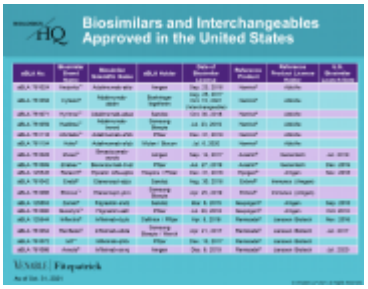
Biosimilar-Related Litigations by Year



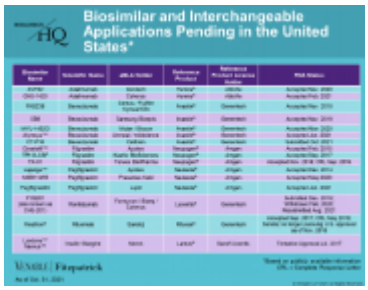
Patents Subject to Biosimilar-Related IPRs and Litigations



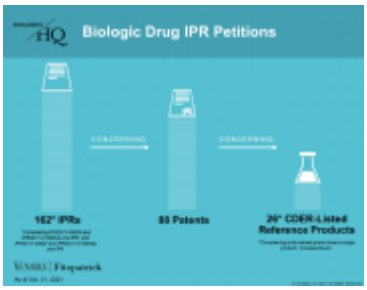
Biosimilars and Interchangeables Approved in the United States



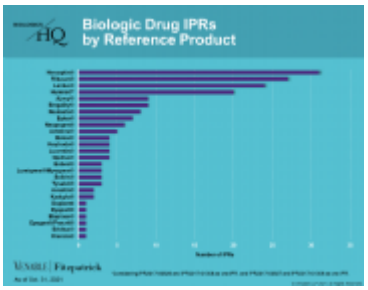
Biosimilar and Interchangeable Applications Pending in the United States



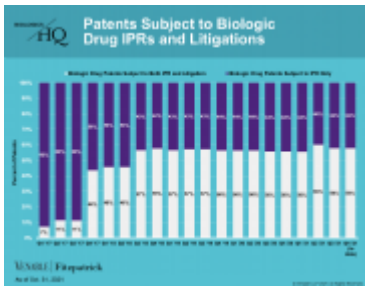
Biologic Drug IPR Petitions



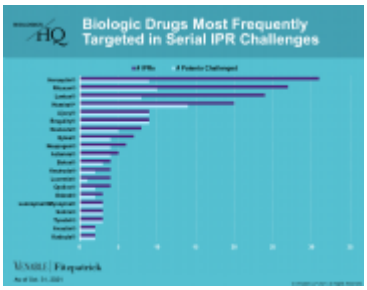
Biologic Drug IPRs by Reference Product



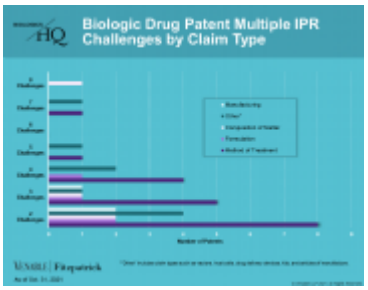
Patents Subject to Biologic Drug IPRs and Litigations



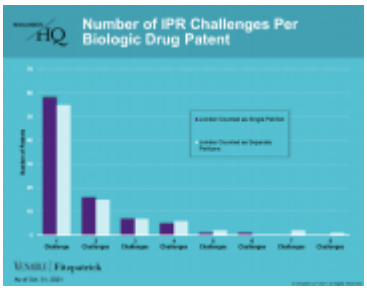
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

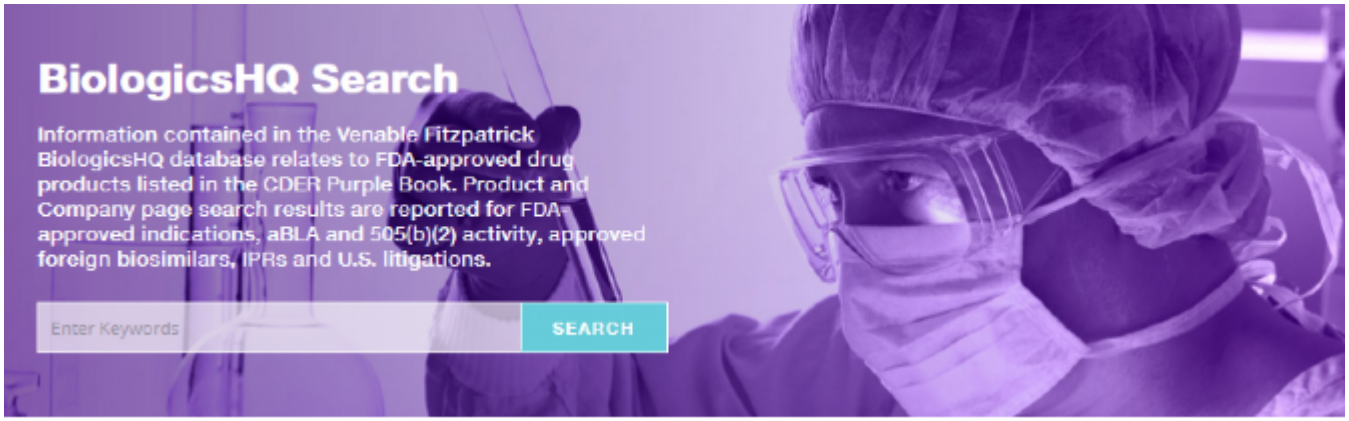


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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