BIOLOGICS HQ®

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LATEST NEWS

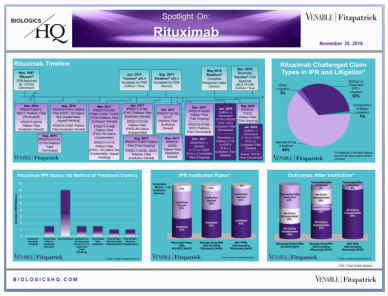
VIDEO: Noteworthy Ongoing Biosimilar Litigation

By: Ha Kung Wong

Ha Kung Wong addresses ongoing biosimilar cases that stakeholders are watching closely as part of a video series for the Center for Biosimilars.

View Additional New Videos from Ha Kung Wong:

- **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**
- **FDA and FTC Cooperation to Address Anticompetitive Behavior**
- **The FDA's Biosimilar Action Plan**



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

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

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™, Cyltezo™, and Hyrimoz™), and etanercept (Enbrel® and Erelzi™) have been updated with activity through November 30, 2018.

Read More News

UPDATES

IPRs and PGRs

- **Humira® (adalimumab):** On November 2, 2018, IPR2017-01987, IPR2017-01988, IPR2017-02105, and IPR2017-02106 filed by Sandoz were terminated due to settlement.

- **Rituxan® (rituximab):**
  - On November 6, 2018, Federal Circuit Appeal No. 18-1924 filed by Celltrion appealing the Final Written Decision in IPR2016-01614 was dismissed.
  - On November 8, 2018, IPR2018-00186 was dismissed after institution at the joint request of Biogen and Pfizer.

- **Herceptin® (trastuzumab):**
  - On November 8, 2018, Hospira and Samsung Bioepis filed Federal Circuit Case No. 19-1174 appealing the Final Written Decisions finding no instituted claims unpatentable in IPR2017-00804 and joined IPR2017-01958.
  - On November 8, 2018, Hospira and Samsung Bioepis filed Federal Circuit Case No. 19-1173 appealing the Final Written Decisions finding no instituted claims unpatentable in IPR2017-00805 and joined IPR2017-01959.
  - On November 29, 2018, Final Written Decisions finding some instituted claims unpatentable were entered in IPR2017-01488 filed by Pfizer and joined IPR2017-02139 filed by Samsung Bioepis.
  - On November 29, 2018, a Final Written Decision finding some instituted

claims unpatentable was entered in IPR2017-01374 filed by Celltrion and Teva.
    - On November 30, 2018, Genentech filed Notices of Appeal in IPR2017-00731, IPR2017-00737, IPR2017-01121, and IPR2017-01122.

- **Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant):** On November 8, 2018, Mylan and Biocon requested dismissal of IPR2018-01677.

LITIGATIONS

- **Rituxan® (rituximab):**
    - On November 1, 2018, dismissal due to settlement was requested in *Genentech v. Celltrion* Case Nos. 1:18-cv-11553 (D.N.J.) and 1:18-cv-00574 (D.N.J.).
    - On November 30, 2018, Federal Circuit Case No. 18-2161 appealing *Celltrion v. Genentech* Case No. 4:18-cv-00276 (N.D. Cal.) was voluntarily dismissed.

- **Herceptin® (trastuzumab):** On November 30, 2018, Federal Circuit Case No. 18-2160 appealing *Celltrion v. Genentech* Case No. 4:18-cv-00274 (N.D. Cal.) was voluntarily dismissed.

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aBLA APPLICATIONS AND FDA ACTIVITY

- **Udenyca™ (pegfilgrastim-cbqv):** On November 2, 2018, the FDA approved Coherus's Udenyca™, a biosimilar of Amgen's Neulasta® (pegfilgrastim).

- **Retacrit® (epoetin alfa-epbx):** On November 14, 2018, Pfizer announced it launched Retacrit®, its biosimilar of Amgen's Epogen® (epoetin alfa) on November 12, 2018.

- **Truxima® (rituximab):** On November 28, 2018, the FDA approved Celltrion and Teva's Truxima®, a biosimilar of Genentech's Rituxan® (rituximab).

CDER PURPLE BOOK UPDATES

- **Gamifant® (emapalumab-lzsg):** On November 20, 2018, the FDA approved Novimmune's Gamifant®.

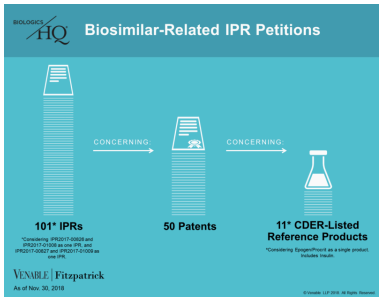
NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

- **Pelmeg (pegfilgrastim):** On November 23, 2018, Cinfa Biotech and Mundipharma announced that Pelmeg, their biosimilar of Neulasta® (pegfilgrastim) was approved in the E.U.

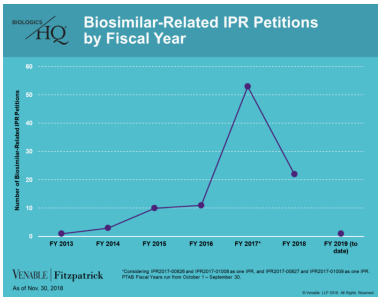
- **Ziextenzo® (pegfilgrastim):** On November 27, 2018, Sandoz announced that Ziextenzo®, its biosimilar of Neulasta® (pegfilgrastim) was approved in the E.U.

STATISTICS

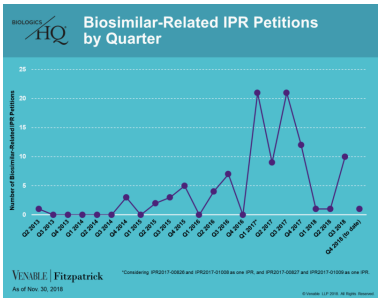
Biosimilar-Related IPR Petitions



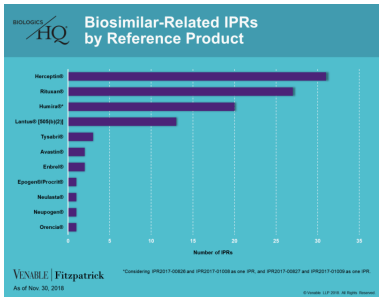
Biosimilar-Related IPR Petitions by Fiscal Year



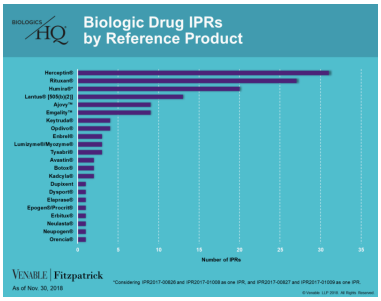
Biosimilar-Related IPR Petitions by Quarter



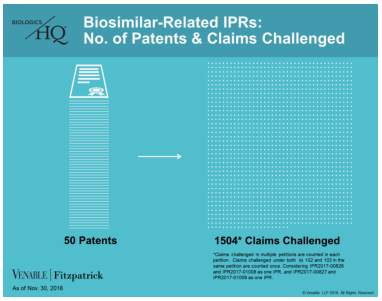
Biosimilar-Related IPRs by Reference Product



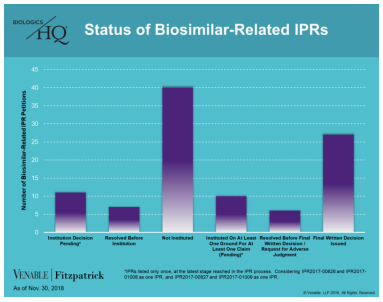
Biologic Drug IPRs by Reference Product



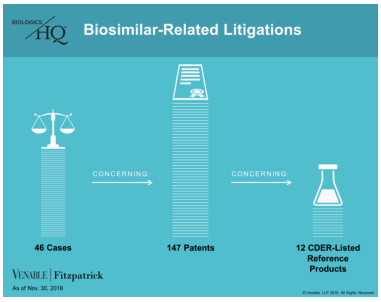
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



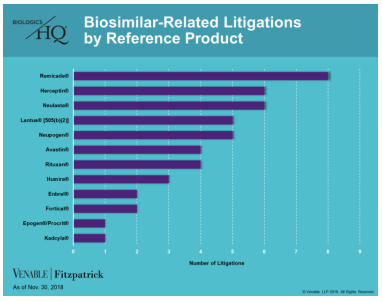
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations



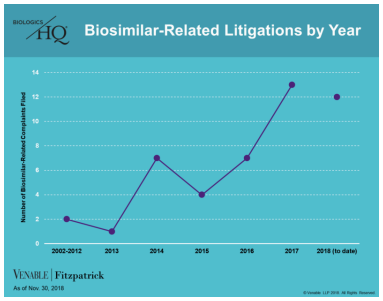
Biosimilar-Related Litigations by Reference Product

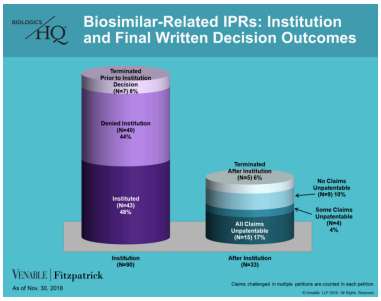


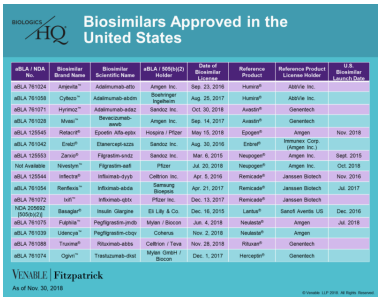
Biosimilar-Related Litigations by Year

Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilars Approved in the U.S.



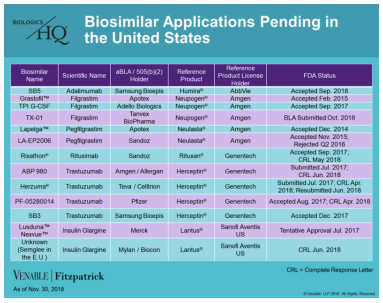


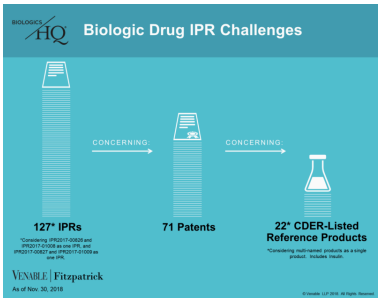


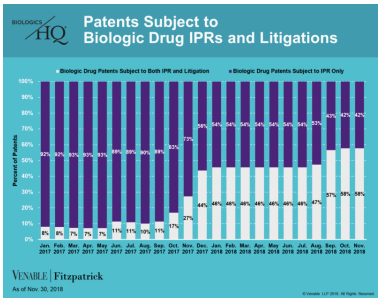
Biosimilar Applications Pending in the U.S.

Biologic Drug IPR Challenges

Patents Subject to Biologic Drug IPRs and Litigations



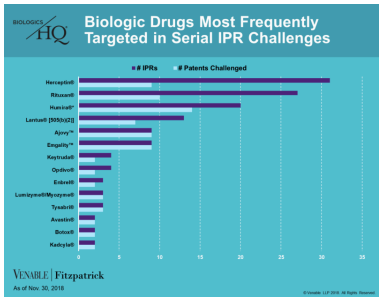


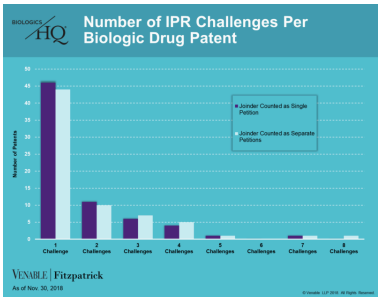


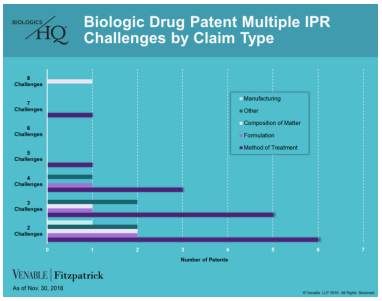
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

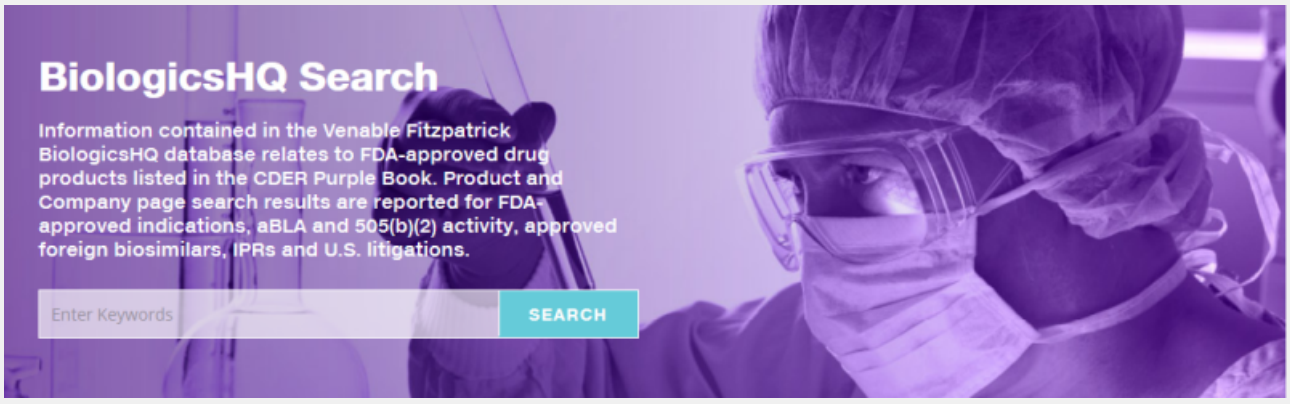
Number of IPR Challenges Per Biologic Drug Patent

Biologic Drug Patent Multiple IPR Challenges by Claim Type









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