BIOLOGICS HQ®

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LATEST NEWS

VIDEO: Biosimilars and the STRONGER Patents Act

By: Ha Kung Wong

Ha Kung Wong discusses how the STRONGER Patents Act could affect biosimilars in a video for the Center for Biosimilars, including changing inter partes review (IPR) burdens and claim construction standards to match those in district court litigations, standing in IPRs, and appeals of IPR institution decisions.

VIDEO: Might Congress Revisit the BPCIA?

By: Ha Kung Wong

Ha Kung Wong discusses whether Congress might revisit and amend the Biologics Price Competition and Innovation Act (BPCIA) in a video for the Center for Biosimilars.

View Additional Videos by Ha Kung Wong:

- **The PTAB's Role in Biosimilar Patent Disputes**
- **Healthcare Reform Efforts and the BPCIA**
- **Biosimilars, Formularies, Contracting, and PBMs**

- **Reforms at the FDA Level**
- **Inspection Reports and Proprietary Information**
- **Global Reference Products in Biosimilar Development**
- **Biosimilars, Interchangeability, and Perceptions of Safety**
- **How Important is *Inter Partes* Review to Biosimilars?**
- **Might the FDA Clarify Its Stance on the BPCIA?**
- **Might PTAB Invalidate More Method of Treatment Patents?**
- **Will Biosimilar Applicants Still Participate in the Patent Dance?**
- **What Questions Did SCOTUS Leave Unresolved in Sandoz v. Amgen?**

Wi-Fi One, LLC v. Broadcom Corp.: En Banc Federal Circuit Holds That Time-Bar Determinations for Petitions for Inter Partes Review May Be Appealed

By: Justin J. Oliver and David D. Leege

On January 8, 2018, the Court of Appeals for the Federal Circuit, sitting *en banc*, issued a majority opinion holding that a determination made by the PTO concerning whether a petition for *inter partes* review (IPR) is time-barred under 35 U.S.C. § 315(b) is subject to judicial review. Specifically, the Federal Circuit majority held that the limit on judicial review in 35 U.S.C. § 314(d), pertaining to institution decisions, does not apply to time-bar determinations under 35 U.S.C. § 315(b).

Read More News

FCHS UPCOMING EVENTS

Update on Biologic Drug IPRs: Lessons Learned

Lexology Webinar
February 22, 2018

Inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) of the USPTO have been popular since their inception in 2012, and petitions are increasingly being filed against biologic drug patents. Fitzpatrick Cella's award-winning intellectual property attorneys provide you with unique insights and the latest statistics on biologic drug IPRs and the lessons to be learned from recent institution and final written decisions.

Corinne Atton, Whitney Meier, and Robert Schwartz will discuss:

- Statistics related to CDER-listed ("Purple Book") biologic drug IPRs including: IPR petitions filed, patents challenged in both IPR and district court litigation, claim types

challenged in IPR, IPR outcomes, and comparisons to data on IPRs filed against Orange Book listed patents.
- Lessons learned from analyzing biologic drug IPRs by claim type: methods of treatment, formulation, composition of matter, and process/manufacturing.

This webinar is perfect for life sciences professionals interested in understanding how IPRs are being used to challenge biologic drug patents.

Join us on Thursday, February 22, 2018 at noon EST for this complimentary webinar.

Click here to register.

UPDATES

IPRs

- **Rituxan® (rituximab):** On January 2, 2018, Celltrion and Teva's requests for rehearing of institution decisions in IPR2017-01094 and IPR2017-01095 were denied.

- **Avastin® (bevacizumab):** On January 5, 2018, Pfizer filed IPR2018-00373.

- **Herceptin® (trastuzumab):**
  - On January 11, 2018, institution was granted in IPR2017-01488 filed by Pfizer.
  - On January 23, 2017, institution was denied in IPR2017-01726 and IPR2017-01727 filed by Pfizer.

LITIGATIONS

- **Forteo® (teriparatide):** On January 10, 2018, *Eli Lilly v. Teva*, Case No. 1:16-cv-00596 (S.D. Ind.), was dismissed after settlement.

- **Herceptin® (trastuzumab):**
  - On January 11, 2018, Celltrion and Teva filed Case No. 3:18-cv-00274 (N.D. Cal.) against Genentech and Hoffmann-La Roche related to Celltrion and Teva's proposed Herceptin® biosimilar.
  - On January 12, 2018, Genentech and Hoffmann-La Roche filed Case No. 1:18-cv-00095 (D. Del.) against Celltrion and Teva related to Celltrion and Teva's proposed Herceptin® biosimilar.

- **Rituxan® (rituximab):**
  - On January 11, 2018, Celltrion and Teva filed Case No. 5:18-cv-00276 (N.D. Cal.) against Genentech, Biogen, and Hoffmann-La Roche related to Celltrion and Teva's proposed Rituxan® biosimilar.

- On January 12, 2018, Genentech, Biogen, and Hoffmann-La Roche filed Case No. 1:18-cv-00574 (D.N.J.) against Celltrion and Teva related to Celltrion and Teva's proposed Rituxan® biosimilar.

- **Remicade® (infliximab):** On January 23, 2018, *Janssen v. Celltrion* Federal Circuit appeal No. 2017-1120 was dismissed as moot.

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aBLA APPLICATIONS AND APPROVALS

- **GP2017 (adalimumab):** On January 16, 2018, Sandoz announced the FDA accepted its aBLA for GP2017, its proposed biosimilar of AbbVie's Humira® (adalimumab).

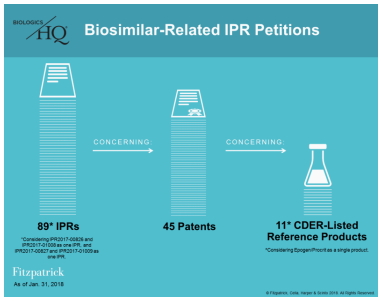
NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

- **Mvasi™ (bevacizumab-awwb):** On January 18, 2018, Amgen and Allergan announced that Mvasi, their biosimilar of Avastin®, was approved in the E.U.

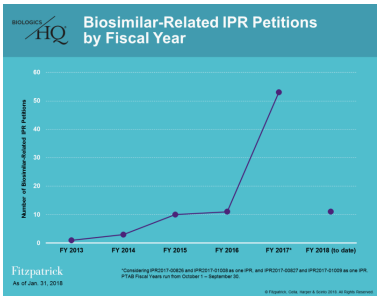
- **LBEC0101 (etanercept):** On January 19, 2018, LG Chem announced that LBEC0101, its biosimilar of Enbrel®, was approved in Japan.

STATISTICS

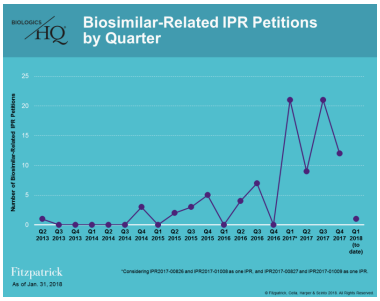
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



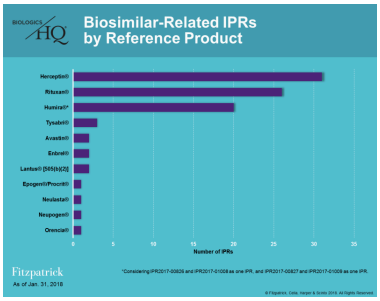
Biosimilar-Related IPR Petitions by Quarter



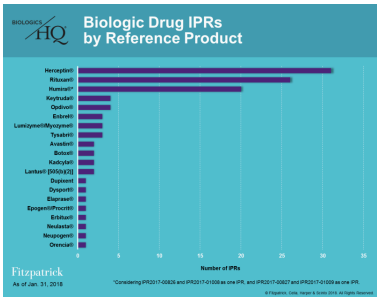
Biosimilar-Related IPRs by Reference Product

Biologic Drug IPRs by Reference Product

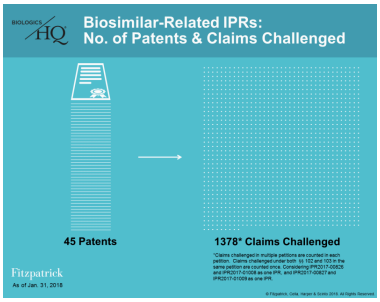
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



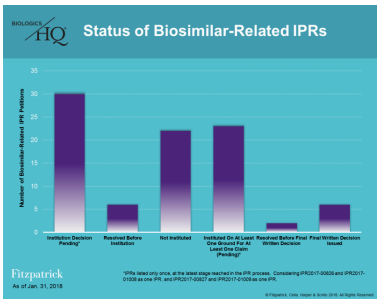
Status of Biosimilar-Related IPRs

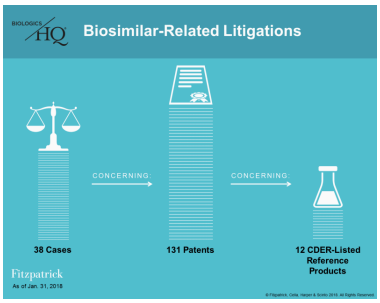


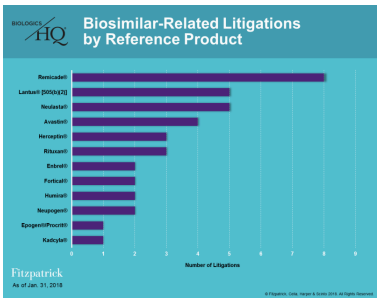
Biosimilar-Related Litigations



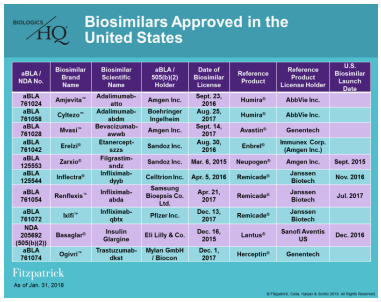
Biosimilar-Related Litigations by Reference Product



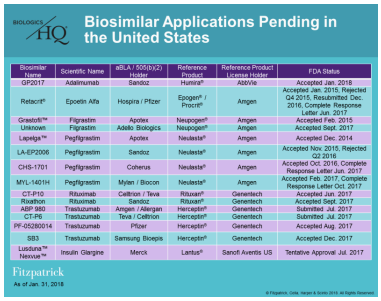


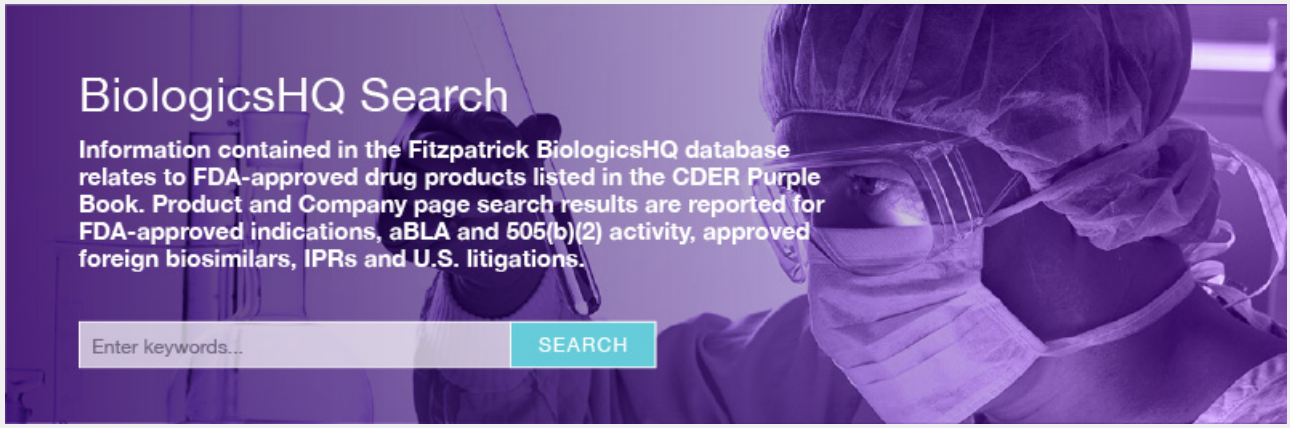


Biosimilars Approved in the U.S.



Biosimilar Applications Pending in the U.S.





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