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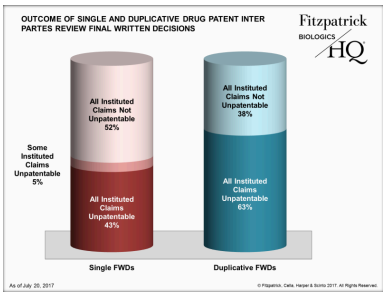
LATEST NEWS



Two Bites of the Apple: Five Interesting Facts about Drug Patent IPR Final Written Decisions

By: Corinne E. Atton, April M. Breyer, and Ha Kung Wong

As of July 20, 2017, there have been at least 363 IPR petitions filed against patents that were listed in the FDA Orange Book, and 74 IPR petitions filed against patents that have been identified as reading on FDA Purple Book (CDER) listed biologic drugs. Of these 437 drug patent IPRs, 116 resulted in a final written decision ("FWD").

Highlights of our findings are:

- 85% of drug patent FWDs concerned patents that are also litigated;
- >50% of drug patent FWDs resulted in claims being found unpatentable;
- 62% of drug patent FWDs concern multiple challenges to the same patents;
- Drug patents subject to multiple challenges are more likely to be found unpatentable; and
- Biologic drug patents are more likely to be found unpatentable than Orange Book drug patents.

VIDEO: Biosimilar Interchangeability and Market Share

By: Ha Kung Wong

As part of the *The Center for Biosimilars*™ *Peer Exchange*®, Ha Kung Wong and panelists Amanda Forys and Molly Burich discuss the question, "Will biosimilar manufacturers seeking interchangeability have an effect on how reference product sponsors attempt to protect market share?"

VIDEO: Interchangeability and Rheumatology Prescribing Practices

By: Ha Kung Wong

As part of the *The Center for Biosimilars*™ *Peer Exchange*®, Ha Kung Wong and panelists Angus Worthing, Amanda Forys, and Molly Burich discuss questions regarding physician prescribing of biosimilars and interchangeables, including how the designation of a product as interchangeable will affect prescribing practices and how interchangeability designations will affect the uptake of biosimilars and interchangeables in the market.

View Additional Videos by Ha Kung Wong:

- **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?**

Read More News

UPDATES

IPRs

- **Humira® (adalimumab):**
  - On October 2, 2017, Sandoz filed IPR2018-00002.
- **Herceptin® (trastuzumab):**
  - On October 3, 2017, Pfizer filed IPR2018-00016.
  - On October 4, 2017, IPR2017-01121, IPR2017-01122, IPR2017-01139, and

IPR2017-01140 filed by Celltrion and Teva were instituted.
    - On October 26, 2017, a request for rehearing in IPR2017-00731, filed by Hospira and Pfizer, was granted, reversing a previous denial and instituting trial.

- **Rituxan® (rituximab):**
    - On October 2, 2017, institution was denied for IPR2017-01094 filed by Celltrion and Teva.
    - On October 6, 2017, institution was denied in IPR2017-01093 filed by Celltrion and Teva.
    - On October 6, 2017, institution was granted-in-part and denied-in-part in IPR2017-01095 filed by Celltrion and Teva.
    - On October 6, 2017, Pfizer filed IPR2017-02126 and IPR2017-02127.
    - On October 12, 2017, institution was denied in IPR2017-01230 filed by Celltrion and Teva.
    - On October 23, 2017, institution was denied in IPR2017-01227 and IPR2017-01229 filed by Celltrion and Teva.

LITIGATIONS

- **Repatha® (evolocumab) / Praluent® (alirocumab):** On October 5, 2017, the Federal Circuit reversed-in-part, affirmed-in-part, vacated-in-part, and remanded *Amgen v. Sanofi*, Case No. 17-1480.

- **Avastin® (bevacizumab):**
    - On October 6, 2017, Case Nos. 1:17-cv-01407 (D. Del.) *Genentech v. Amgen* and 2:17-cv-07349 (C.D. Cal.) *Amgen v. Genentech* were filed.
    - On October 18, 2017, Case No. 1:17-cv-01471 (D. Del.) *Genentech v. Amgen* was filed.

- **Darzalex® (daratumumab):** On October 11, 2017, U.S. Patent No. 9,758,590 was added to the *MorphoSys v. Janssen* Case No. 1:16-cv-00221 (D. Del.).

- **Kadcyla® (adotrastuzumab emtansine):** On October 13, 2017, Genentech filed a cross-appeal in *Phigenix v. Genentech* Case No. 5:15-cv-01238 (N.D. Cal.): Fed. Cir. No. 18-1042.

- **Lantus® (insulin glargine recombinant):** On October 24, 2017, Sanofi filed litigation No. 2:17-cv-09105 (D.N.J.) against Mylan relating to its proposed insulin glargine products.

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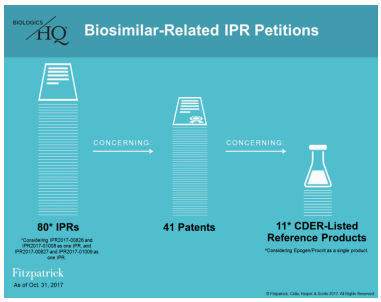
aBLA APPLICATIONS AND APPROVALS

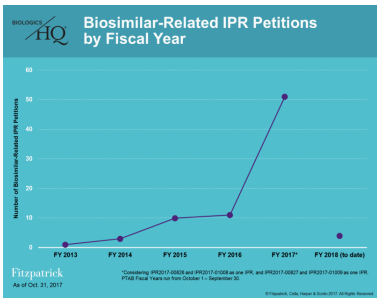
- **MYL-1401H (pegfilgrastim):** On October 10, 2017, Mylan and Biocon announced that the FDA had issued a complete response letter relaing to their proposed biosimilar of Neulasta® (pegfilgrastim).

STATISTICS

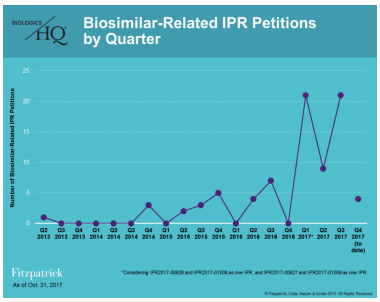
Biosimilar-Related IPR Petitions



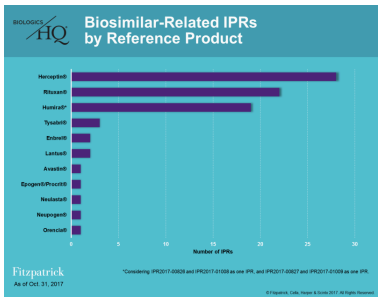
Biosimilar-Related IPR Petitions by Fiscal Year



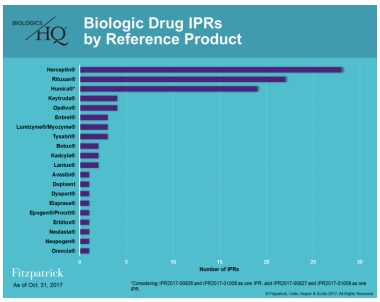
Biosimilar-Related IPR Petitions by Quarter



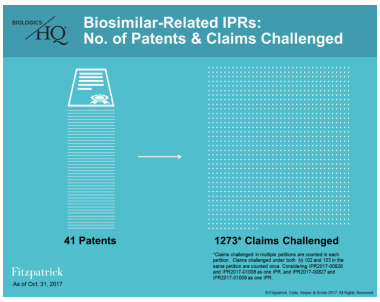
Biosimilar-Related IPRs by Reference Product



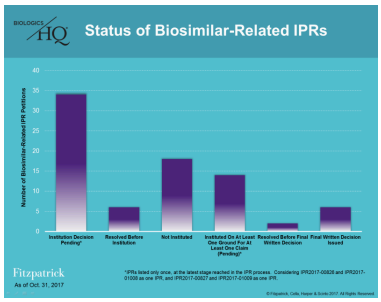
Biologic Drug IPRs by Reference Product



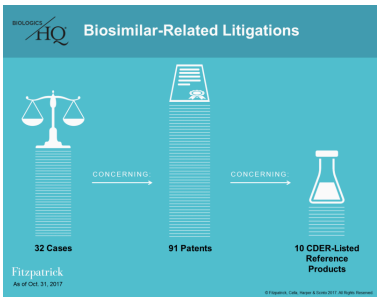
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



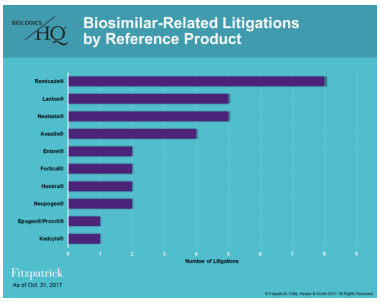
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations

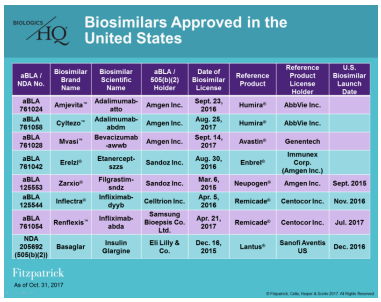


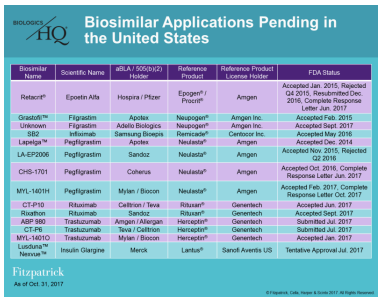
Biosimilar-Related Litigations by Reference Product

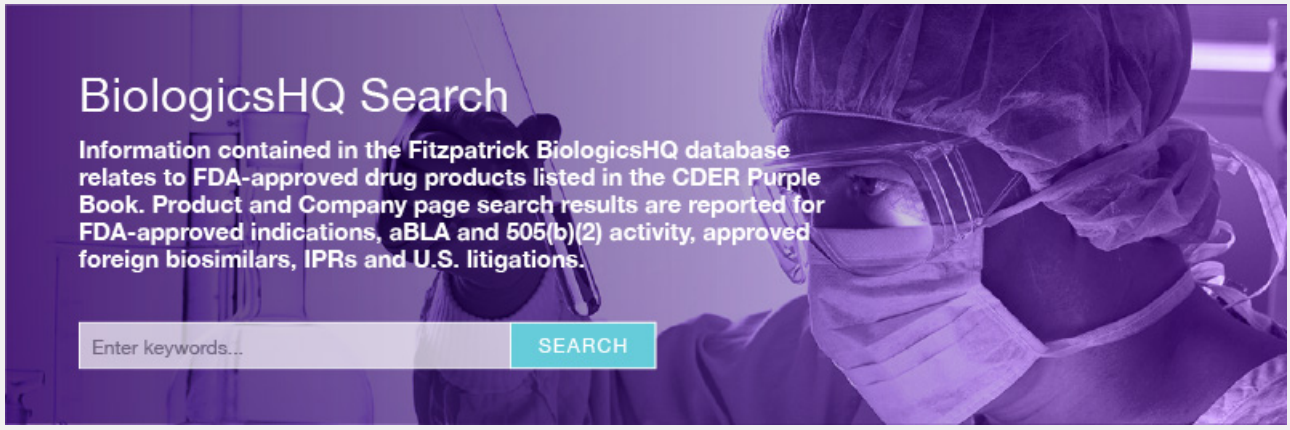


Biosimilars Approved in the U.S.

Biosimilar Applications Pending in the U.S.







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