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July 26, 2017

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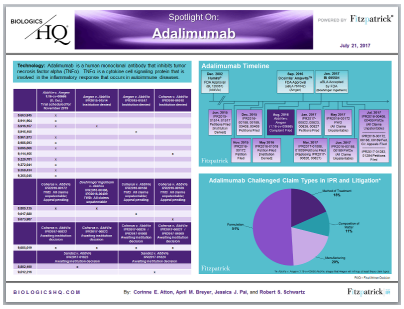
LATEST NEWS



Spotlight On Adalimumab

By: Corinne E. Atton, April M. Breyer, Jessica J. Pai, and Robert S. Schwartz

BiologicsHQ's "Spotlight On" dashboard provides, at a glance, an overview of the status of U.S. patent proceedings concerning adalimumab (Humira® and Amjevita™).

Drug Patents May Fare Better Than Other Technologies In IPR Proceedings

By: Corinne E. Atton and April M. Breyer

On March 31, 2017, the United States Patent Trial and Appeal Board ("PTAB") released updated statistics showing the fate of resolved inter partes review ("IPR") proceedings. These statistics show that a total of 4,563 IPR petitions were resolved as of March 31, 2017 including 1,577 final written decisions. In 81% of these final written decisions (27% of the total number of petitions filed), at least some instituted patent claims were found

unpatentable. This statistic has contributed to concerns that PTAB is a patent "death squad."

Fitzpatrick's BiologicsHQ reports that such concern is not justified for drug patents. On the contrary, IPR statistics for this subset of patents are significantly more favorable: a smaller percentage of drug patent IPRs are instituted; and of those that reach a final written decision, a higher percentage of patents survive with at least some claims remaining patentable. This is welcome news to the pharmaceutical industry.

Supreme Court Rules That Biosimilars Makers Can Give Notice Of Commercial Marketing Before FDA Licensure

By: Christopher E. Loh

In a June 12, 2017 decision authored by Justice Clarence Thomas, the United States Supreme Court in Sandoz v. Amgen ruled that, under the Biologics Price Competition and Innovation Act (BPCIA), biosimilar makers can give notice of commercial marketing before the United States Food and Drug Administration (FDA) licenses their biosimilar products. The Sandoz ruling resolves an ambiguity in the text of the BPCIA, which gave rise to a presumption by some (and a holding by the Federal Circuit at 794 F.3d 1347, 1358 (2015)) that biosimilar makers had to wait until 180 days after FDA licensure of their biosimilar products before providing notice of the commercial marketing of those products—thereby potentially extending by an additional six months the BPCIA's statutory 12-year exclusivity period for innovator biologics. The Sandoz ruling makes clear that an additional six-month period of exclusivity was not contemplated by the BPCIA.

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UPDATES

IPRs

- **Lantus® (insulin glargine recombinant):** On June 5, 2017, Mylan and Biocon filed IPR2017-01526 and IPR2017-01528.
- **Herceptin® (trastuzumab):** On July 5, 2017, Pfizer filed IPR2017-01726 and IPR2017-01727.
- **Humira® (adalimumab):**
  - On July 6, 2018, Final Written Decisions issued for IPR2016-00408 and IPR2016-00409, filed by Boehringer Ingelheim.
  - On July 14, 2017, Coherus filed appeals in IPR2016-00172 (Fed. Cir.

17-2304), IPR2016-00188 (Fed. Cir. 17-2305), and IPR2016-00189 (Fed. Cir. 17-2306).
    - On July 20, 2017, Sandoz filed IPR2017-01823 and IPR2017-01824.
- **Erbitux® (cetuximab):** On July 13, 2017, a Final Written Decision issued for IPR2016-00458 filed by Eli Lilly, ImClone, and Bristol Myers Squibb.
- **Rituxan® (rituximab):** On July 18, 2017, IPR2017-01115 was instituted and joined with IPR2016-01614.

LITIGATIONS

- **Botox® (onabotulinumtoxinA):** On June 5, 2017, a stipulation of dismissal with prejudice was granted in 1:15-cv-03372 (N.D. Ill.).
- **Neupogen® (filgrastim):** On June 12, 2017, the Supreme Court issued a decision in *Amgen v. Sandoz* (Case Nos. 15-1039 (U.S.) and 15-1195 (U.S.) appealed from 3:14-cv-04741 (N.D. Cal.)) on June 12, 2017 vacating-in-part, reversing-in-part, and remanding the case to the Federal Circuit.
- **Lantus® (insulin glargine recombinant):** On June 28, 2017, U.S. Patent No. 9,604,008 was added to litigation 1:16-cv-00812 (D. Del.).

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aBLA APPLICATIONS AND APPROVALS

- **CT-P10 (rituximab):** On June 29, 2017, Celltrion and Teva announced that the FDA has accepted their aBLA for CT-P10 as a proposed biosimilar of Rituxan®.
- **Lusduna™ Nexvue™ (insulin glargine):** On July 20, 2017, Merck and Samsung Bioepis announced the FDA had tentatively approved their biosimilar of Lantus®.
- **Renflexis™ (infliximab-abda):** On July 24, 2017, Merck and Samsung Bioepis announced the U.S. launch of their biosimilar of Remicade®.

CDER PURPLE BOOK UPDATES

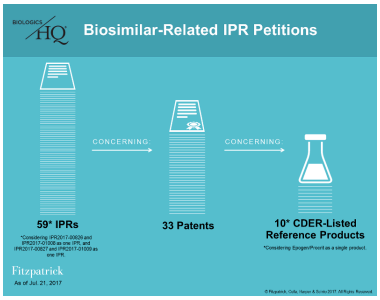
- **Rituxan Hycela™ (rituximab; hyaluronidase):** On June 22, 2017, the FDA approved Genentech's Rituxan Hycela™.
- **Tremfya™ (guselkumab)**: On July 13, 2017, the FDA approved Janssen's Tremfya™.

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

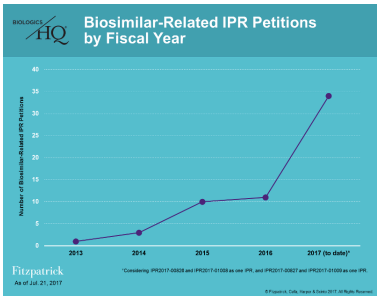
- **Erelzi® (etanercept-szzs):** On June 27, 2017, Sandoz announced that Erelzi, its biosimilar of Enbrel®, was approved in the E.U.

STATISTICS

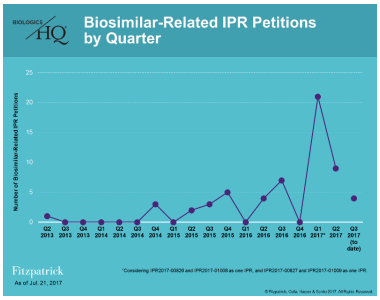
Biosimilar-Related IPR Petitions



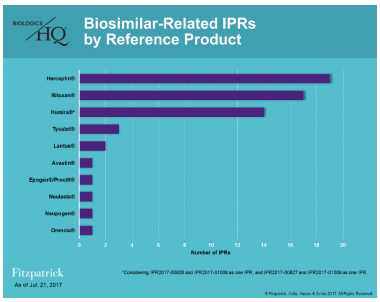
Biosimilar-Related IPR Petitions by Fiscal Year



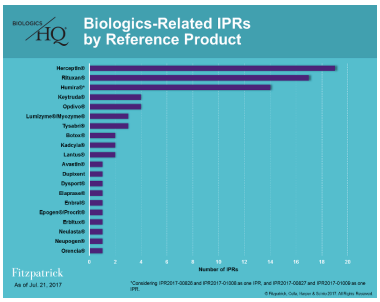
Biosimilar-Related IPR Petitions by Quarter



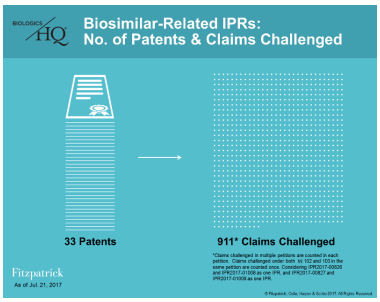
Biosimilar-Related IPRs by Reference Product



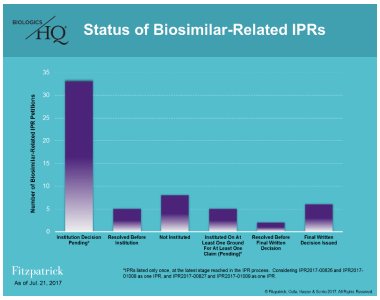
Biologics-Related IPRs by Reference Product



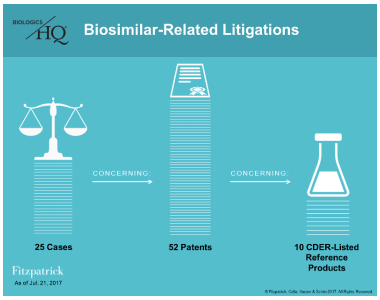
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



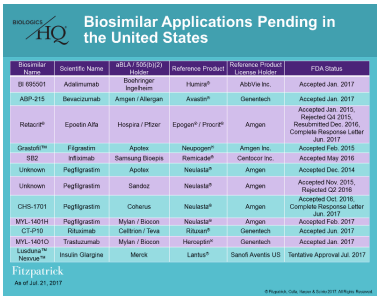
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations



Biosimilar Applications Pending in the U.S.



Biosimilar Name	Scientific Name	aBLA/ 505(b)(2) Holder	Reference Product	Reference Product Licensee Holder	FDA Status
BI 695501	Adalimumab	Boehringer Ingelheim	Humira®	AbbVie Inc.	Accepted Jan. 2017
ABP-215	Bevacizumab	Amgen / Allergan	Avastin®	Genentech	Accepted Jan. 2017
Retacrit®	Epoetin Alfa	Hospira / Pfizer	Epogen® / Procrit®	Amgen	Accepted Jan. 2015, Rejected Q4 2015, Resubmitted Dec. 2016, Complete Response Letter Jun. 2017
Grastofi™	Filgrastim	Apotex	Neupogen®	Amgen Inc.	Accepted Feb. 2015
SB2	Infliximab	Samsung Bioepis	Remicade®	Centocor Inc.	Accepted May 2016
Unknown	Pegfilgrastim	Apotex	Neulasta®	Amgen	Accepted Dec. 2014
Unknown	Pegfilgrastim	Sandoz	Neulasta®	Amgen	Accepted Nov. 2015, Rejected Q2 2016
CHS-1701	Pegfilgrastim	Coherus	Neulasta®	Amgen	Accepted Oct. 2016, Complete Response Letter Jun. 2017
MYL-1401H	Pegfilgrastim	Mylan / Biocon	Neulasta®	Amgen	Accepted Feb. 2017
CT-P10	Rituximab	Celltrion / Teva	Rituxan®	Genentech	Accepted Jun. 2017
MYL-1401O	Trastuzumab	Mylan / Biocon	Herceptin®	Genentech	Accepted Jan. 2017
Lusduna™ Nexvue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017

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As of Jul. 21, 2017

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