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LATEST NEWS

Amgen Obtains $70 Million Damages Award Against Hospira For Infringement Of Amgen's Erythropoetin Patent

By: Christopher E. Loh

On September 22, 2017, a District of Delaware jury in the matter *Amgen v. Hospira,* 15-cv-839-RGA (D. Del.) returned a verdict awarding Amgen $70 million for Hospira's infringement of an Amgen patent covering the manufacture of Amgen's erythropoetin product Epogen®. That verdict is the first instance in which a patent owner has recovered significant infringement damages under the Biologics Price Competition and Innovation Act (BPCIA). It is also the first time a patent owner has recovered damages under the BPCIA for acts of infringement by a competitor conducted prior to the commercial marketing of the competitor's biosimilar product.

Pharma at the PTAB

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

April Breyer, Corinne Atton and Ha Kung Wong reveal that PTAB decisions have been consistent but drug patents challenged multiple times are more likely to be found unpatentable.

There has been some concern regarding the statistics periodically issued by the Patent Trial and Appeal Board ("PTAB") of the US Patent and Trademark Office, that the numbers reported overlook multiple inter partes review ("IPR") challenges to the same patents, and potentially, different outcomes in those challenges. We have monitored IPRs filed on drug patents – patents that are listed in the Food and Drug Administration's (FDA) Orange Book ("Orange Book patents"), and patents that have been identified in proceedings as reading on FDA Purple Book listed biologic drugs ("Biologic Drug Patents") – and report here that while certain drug patents have been challenged in *multiple* IPR petitions, concern as to different outcomes, at least in the final written decisions ("FWDs") that have been issued to date, appears to be unfounded. These FWDs have been consistent: either all instituted claims have been held unpatentable, or all instituted claims have been held not unpatentable. The biggest news is that drug patents challenged in multiple IPRs – at least those that reach FWD – have a much greater chance of being found unpatentable than drug patents that have been challenged in only one IPR. The percentage is 63% for what we have described in this article as "duplicative FWDs", compared to 44% for non-duplicative FWDs.

VIDEO: How Important is Inter Partes Review to Biosimilars?

By: Ha Kung Wong

In an interview with The Center for Biosimilars, Ha Kung Wong discusses the importance of IPRs to biosimilars. He notes that we have not seen as many IPRs in the biosimilar space as one might expect, and whether an IPR is used in a biosimilars context is, at the moment, more related to the parties involved than any type of significant industry-wide trend. Reasons for this may include standing, the breadth of patents in the biologics space, and estoppel.

View Additional Videos by Ha Kung Wong:

- **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

- **Herceptin® (trastuzumab):**
  - On July 27, 2017, institution was denied for IPR2017-00731 and IPR2017-00739 filed by Hospira and Pfizer.
  - On July 27, 2017, institution was granted for IPR2017-00737, IPR2017-00804, and IPR2017-00805 filed by Hospira and Pfizer.
  - On August 25, 2017, Samsung Bioepis filed IPR2017-01958 with a motion for joinder with IPR2017-00804; IPR2017-01959 with a motion for joinder with IPR2017-00805; and IPR2017-01960 with a motion for joinder with IPR2017-00737.
  - On August 29, 2017, Pfizer filed IPR2017-02019 and IPR2017-02020.
  - On August 31, 2017, Boehringer Ingelheim filed IPR2017-02031 and IPR2017-02032.
  - On September 7, 2017, Pfizer filed IPR2017-02063 with a motion for joinder with IPR2017-01121.
  - On September 11, 2017, the PTAB granted Genentech's request for adverse judgment and cancellation of claims in IPR2017-00959.
  - On September 29, 2017, Samsung Bioepis filed IPR2017-02139 with a motion for joinder with IPR2017-01488; and filed IPR2017-02140 with a motion for joinder with IPR2017-01489.

- **Humira® (adalimumab):**
  - On July 31, 2017, AbbVie filed appeals in IPR2016-00408 (Fed. Cir. 17-2362) and IPR2016-00409 (Fed. Cir. 17-2363).
  - On August 21, 2017, Sandoz filed IPR2017-01987 and IPR2017-01988.
  - On September 7, 2017, institution was denied for IPR2017-00822, IPR2017-00823, IPR2017-01008, and IPR2017-01009 filed by Coherus.
  - On September 14, 2017, Sandoz filed IPR2017-02105 and IPR2017-02106.
  - On October 2, 2017, Sandoz filed IPR2018-00002.

- **Dupixent® (dupilumab):**
  - On July 28, 2017, Genzyme, Regeneron, and Sanofi filed IPR2017-01879.
  - On July 31, 2017, Genzyme, Regeneron, and Sanofi filed IPR2017-01884.

- **Enbrel® (etanercept):**

- On August 4, 2017, Coherus filed IPR2017-01916.
- On September 7, 2017, Coherus filed IPR2017-02066.

- **Erbitux® (cetuximab):** On August 7, 2017, The Trustees of the University of Pennsylvania filed an appeal in IPR2016-00458 (Fed. Cir. 17-2397).

- **Rituxan® (rituximab):**
  - On August 18, 2017, Celltrion and Teva's Request for Rehearing of the decision denying institution in IPR2016-01667 was denied.
  - On August 29, 2017, Pfizer filed IPR2017-01923.
  - On August 31, 2017, Sandoz filed IPR2017-02036 and IPR2017-02042.
  - On October 2, 2017, institution was denied for IPR2017-01094 filed by Celltrion and Teva.

LITIGATIONS

- **Opdivo® (nivolumab):** On July 26, 2017, Bristol Myers Squibb, owner of Opdivo® (nivolumab) filed the following litigations:
  - Case No. 1:17-cv-01027 relating to Genentech's Tecentriq® (atezolizumab).
  - Case No. 1:17-cv-01028 relating to AstraZeneca's Imfinzi™ (durvalumab).
  - Case No. 1:17-cv-01029 relating to EMD Serono / Merck / Pfizer's Bavencio™ (avelumab).

- **Humira® (adalimumab):**
  - On August 2, 2017, AbbVie filed case No. 17-cv-01065 (D. Del.) against Boehringer Ingelheim.
  - On September 28, 2017, *AbbVie v. Amgen*, case No. 1:16-cv-00666 (D. Del.) was dismissed.

- **Remicade® (infliximab):** On August 7, 2017, *Janssen v. Celltrion*, case No. 1:16-cv-11117 (D. Mass.) was dismissed.

- **Lantus® (insulin glargine recombinant):** On August 8, 2017, Sanofi filed litigation 2:17-cv-05914 (D.N.J.) relating to Merck's Lusduna™ Nexvue™ (insulin glargine).

- **Epogen® / Procrit® (epoetin alfa):**
  - On August 10, 2017, the Federal Circuit dismissed Amgen's appeal in Fed. Cir. 16-2179 and denied its motion for writ of mandamus.
  - On September 26, 2017, a jury verdict in favor of Amgen issued in *Amgen v. Hospira*, case No. 1:15-cv-00839 (D. Del.).

- **Kadcyla® (adotrastuzumab emtansine):** On August 23, 2017, *Phigenix v. Genentech*, case No. 5:15-cv-01238 (N.D. Cal.), was terminated after summary judgment. On September 27, 2017, Phigenix appealed the case to the Federal Circuit (No. 17-2617).

- **Neulasta® (pegfilgrastim):** On September 22, 2017, Amgen filed case No. 2:17-cv-01235 (W.D. Pa.) against Mylan.

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aBLA APPLICATIONS AND APPROVALS

- **ABP 980 (trastuzumab):** On July 31, 2017, Amgen and Allergan announced that they submitted an aBLA to the FDA for ABP 980, a proposed biosimilar of Herceptin® (trastuzumab).
- **CT-P6 (trastuzumab):** On July 31, 2017, Celltrion and Teva announced that they submitted an aBLA to the FDA for CT-P6, a proposed biosimilar of Herceptin® (trastuzumab).
- **Cyltezo (adalimumab-adbm):** On August 25, 2017, Boehringer Ingelheim's biosimilar of Humira® (adalimumab) was approved by the FDA.
- **Filgrastim:** On September 11, 2017, Adello Biologics announced the FDA had accepted its aBLA for its proposed biosimilar of Neupogen® (filgrastim).
- **Rixathon (rituximab):** On September 12, 2017, Sandoz announced the FDA had accepted its aBLA for its proposed biosimilar of Rituxan® (rituximab).
- **Mvasi (bevacizumab-awwb):** On September 14, 2017, Amgen's biosimilar of Avastin® (bevacizumab) was approved by the FDA.

CDER PURPLE BOOK UPDATES

- **Besponsa® (inotuzumab ozogamicin):** On August 17, 2017, the FDA approved Wyeth's Besponsa®.
- **Mylotarg® (gemtuzumab ozogamicin):** On September 1, 2017, the FDA approved Wyeth's Mylotarg®.

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

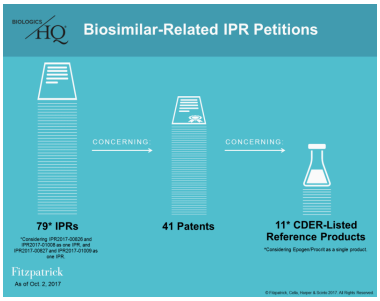
- **Imraldi (adalimumab):** On August 25, 2017, Samsung Bioepis announced that Imraldi, its biosimilar of Humira®, was approved in the E.U.

STATISTICS

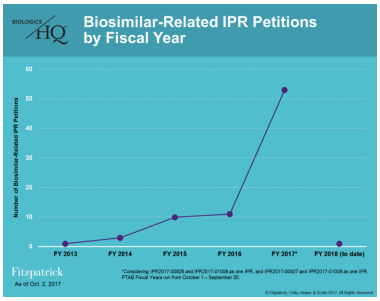
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

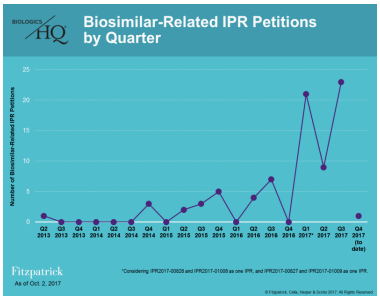
Biosimilar-Related IPR Petitions by Quarter



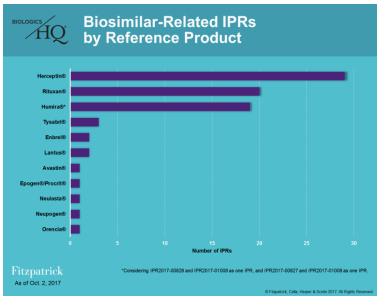
Biosimilar-Related IPRs by Reference Product



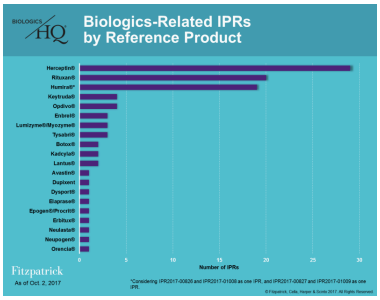
Biologics-Related IPRs by Reference Product



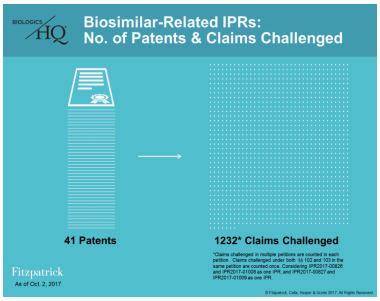
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



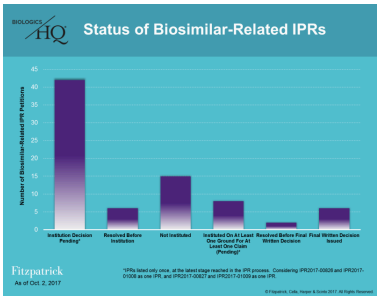
Status of Biosimilar-Related IPRs



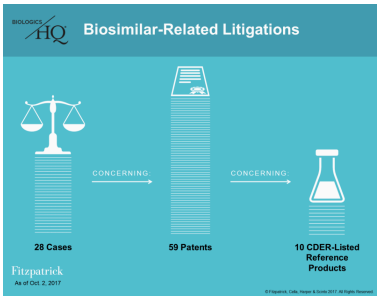
Biosimilar-Related Litigations



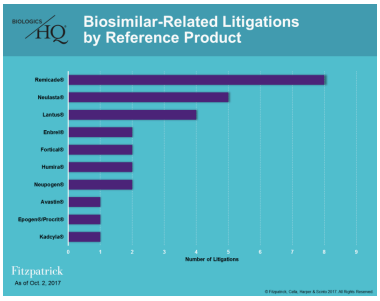
Biosimilar-Related Litigations by Reference Product

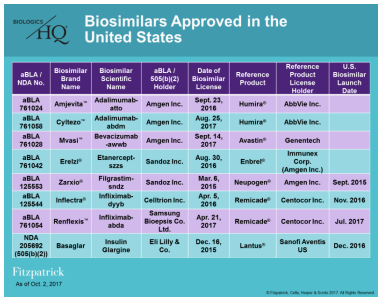


Biosimilars Approved in the U.S.



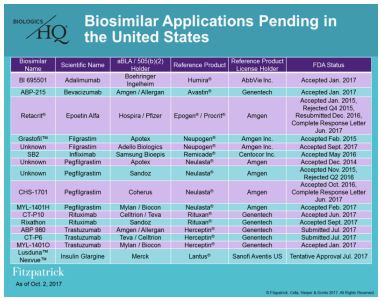
Biosimilar Applications Pending in the U.S.





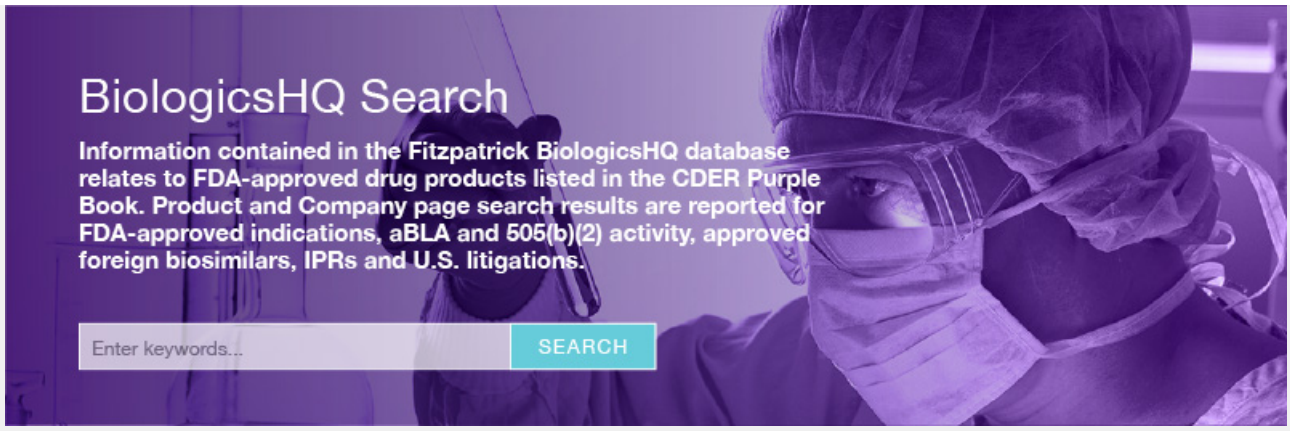
Biosimilars Approved in the United States

aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	Amgen Inc.	Aug. 25, 2017	Humira®	AbbVie Inc.	
aBLA 761028	Mvasi™	Bevacizumab-awwb	Amgen Inc.	Sept. 14, 2017	Avastin®	Genentech	
aBLA 761042	Erelzi®	Etanercept-szzs	Sandoz Inc.	Aug. 30, 2016	Enbrel®	Immunex Corp. (Amgen Inc.)	
aBLA 125563	Zarxio®	Filgrastim-sndz	Sandoz Inc.	Mar. 6, 2015	Neupogen®	Amgen Inc.	Sept. 2015
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion Inc.	Apr. 5, 2016	Remicade®	Centocor Inc.	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepsis Co. Ltd.	Apr. 21, 2017	Remicade®	Centocor Inc.	Jul. 2017
NDA 205692 (505(b)(2))	Basaglar	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016



Biosimilar Applications Pending in the United States

Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License 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
Grastofil™	Filgrastim	Apotex	Neupogen®	Amgen Inc.	Accepted Feb. 2015
Unknown	Filgrastim	Adello Biologics	Neupogen®	Amgen Inc.	Accepted Sept. 2017
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
Rixathon	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sept. 2017
ABP 980	Trastuzumab	Amgen / Allergan	Herceptin®	Genentech	Submitted Jul. 2017
CT-P6	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017
MYL-1401O	Trastuzumab	Mylan / Biocon	Herceptin®	Genentech	Accepted Jan. 2017
Luxturna™ Nexvua™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017



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