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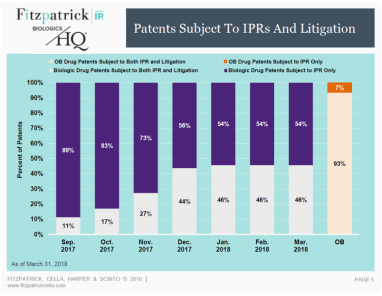
LATEST NEWS



Interplay Between IPR Proceedings & District Court Litigation

By: Corinne E. Atton

At the Managing IP PTAB Forum in May 2018, Corinne Atton presented statistics relating to the interplay between *inter partes* review (IPR) proceedings and district court litigations related to biologic and small molecule drugs.

Statistics include:

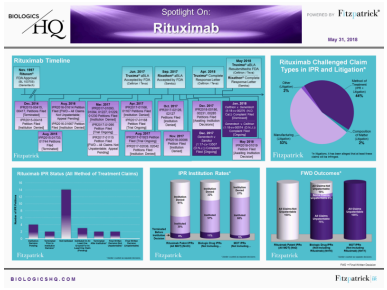
- IPRs Filed as of February 28, 2018
- Percentages of biologic and small drug-related patents subject to IPR only and those subject to both IPRs and litigation
- Inclusion of testimonial evidence in Patent Owner IPR preliminary responses before and after the rule allowing inclusion of new testimonial evidence
- Patent claim types challenged in biologic drug IPRs and IPRs on patents included in the FDA Orange Book
- IPR Institution and Final Written Decision outcomes for biologic drug patents and Orange Book drug patents by claim type, including method of treatment, formulation, and composition of matter claims
- IPRs filed by fiscal year relating to biologic drug and Orange Book drug patents

Federal Circuit Clarifies Venue Issues In Patent Cases

By: Christopher Loh

Two recent Federal Circuit orders have provided answers to certain venue-related questions that have arisen in patent cases:

- Alien corporate defendants remain subject to venue in any judicial district (*In re: HTC Corporation*)
- When a defendant moves to dismiss for improper venue, the burden of proving that venue is proper rests with the plaintiff (*In re: ZTE (USA) Inc.*)



Spotlight On: Rituxan® (rituximab)

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

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboard concerning rituximab (Rituxan®) has been updated with activity through May 31, 2018.

The dashboard concerning adalimumab (Humira®, Amjevita™, and Cyltezo™) has been updated with activity through May 31, 2018.

Read More News

UPDATES

IPRs

- **Humira® (adalimumab):**
  - On May 3, 2018, Sandoz's request for rehearing of the decision denying institution in IPR2017-01824 was denied.

    - On May 3, 2018, institution was denied in IPR2018-00002 filed by Sandoz.

- **Herceptin® (trastuzumab):** On May 8, 2018, Genentech filed an appeal of the Final Written Decision in IPR2016-01837, Federal Circuit Case No. 18-1933.

- **Rituxan® (rituximab):**
    - On May 4, 2018, IPR2018-01019 was filed by Celltrion and Teva.
    - On May 31, 2018, institution was denied in IPR2018-00086 filed by Pfizer.

- **Avastin® (bevacizumab):** On May 11, 2018, Genentech filed an appeal of the Final Written Decision in IPR2016-01771, Federal Circuit Case No. 18-1959.

LITIGATIONS

- **Herceptin® (trastuzumab):** On May 9, 2018, *Celltrion v. Genentech*, Case No. 4:18-cv-00274 (N.D. Cal.), was dismissed with the option to amend the complaint.

- **Rituxan® (rituximab):** On May 9, 2018, *Celltrion v. Genentech*, Case No. 4:18-cv-00276 (N.D. Cal.), was dismissed with the option to amend the complaint.

- **Neulasta (pegfilgrastim):** On May 21, 2018, Amgen filed Federal Circuit Case No. 18-1993, appealing from *Amgen v. Coherus,* Case No. 1:17-cv-00546 (D. Del.).

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aBLA APPLICATIONS AND FDA ACTIVITY

- **Rixathon® (rituximab):** On May 2, 2018, Sandoz announced that it had received a Complete Response Letter from the FDA related to its application for Rixathon®, a proposed biosimilar of Genentech's Rituxan® (rituximab).

- **CHS-1701 (pegfilgrastim):** On May 3, 2018, Coherus announced that it had resubmitted its application for CHS-1701, a proposed biosimilar of Amgen's Neulasta® (pegfilgrastim).

- **Retacrit® (epoetin alfa-epbx):** On May 15, 2018, the FDA approved Hospira's Retacrit®, a biosimilar of Amgen's Epogen® (epoetin alfa).

- **Truxima® (rituximab):** On May 29, 2018, Celltrion announced that it had resubmitted its application for Truxima®, a proposed biosimilar of Genentech's Rituxan® (rituximab).

CDER PURPLE BOOK UPDATES

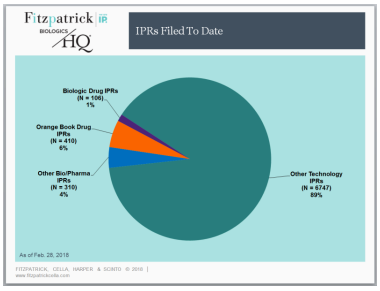
- **Aimovig™ (erenumab-aooe):** On May 17,2017, the FDA approved Amgen's Aimovig™.

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

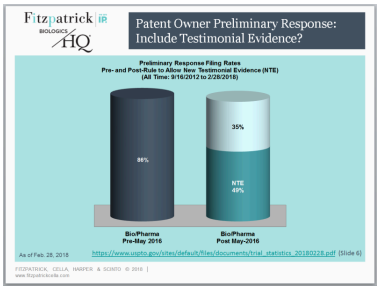
- **Zessly (infliximab):** On May 24, 2018, Sandoz announced that Zessly, its biosimilar of Remicade®, was approved in the E.U.
- **Kanjinti (trastuzumab):** On May 30, 2018 Kanjinti, Amgen's biosimilar of Herceptin® was approved in the E.U.

STATISTICS

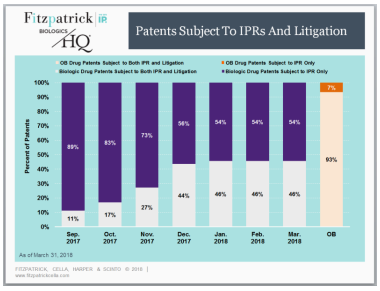
IPRs Filed as of February 28, 2018



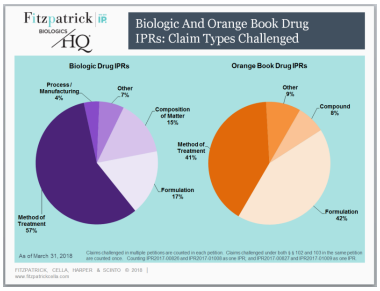
Patent Owner Preliminary Response: Include Testimonial Evidence?



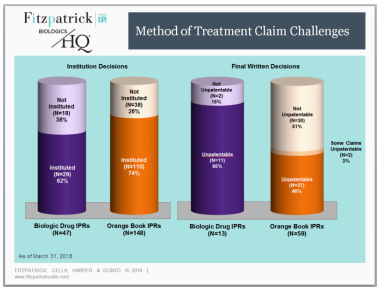
Patents Subject to IPRs and Litigation



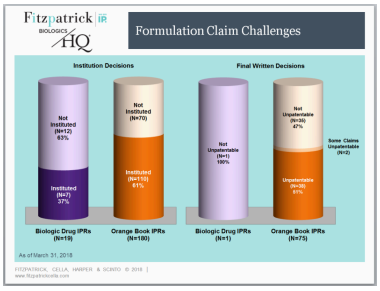
Biologic and Orange Book Drug IPRs: Claim Types Challenged



Biologic and Orange Book Drug IPRs: Method of Treatment Claim Challenges



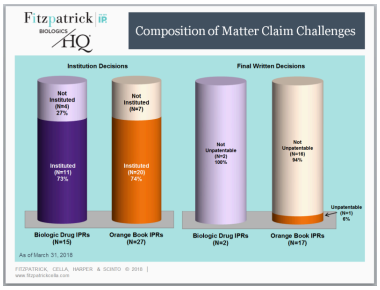
Biologic and Orange Book Drug IPRs: Formulation Claim Challenges

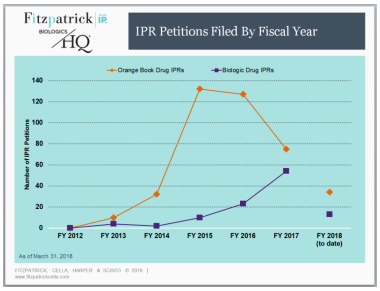


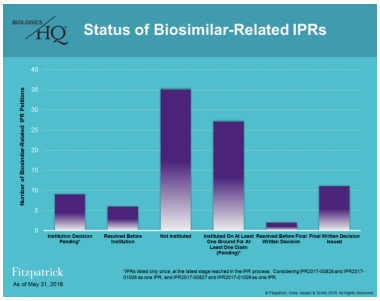
Biologic and Orange Book Drug IPRs: Composition of Matter Claim Challenges

Biologic and Orange Book Drug IPR Petitions Filed by Fiscal Year

Status of Biosimilar-Related IPRs



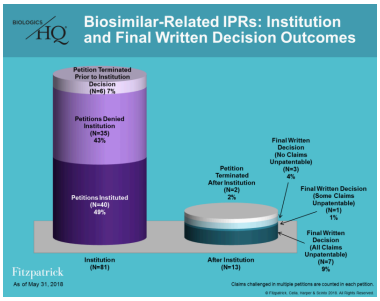


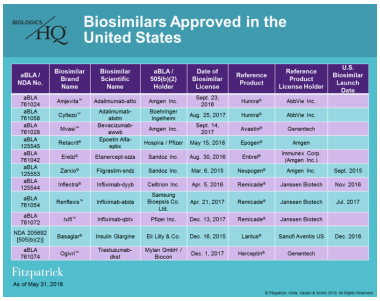


Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

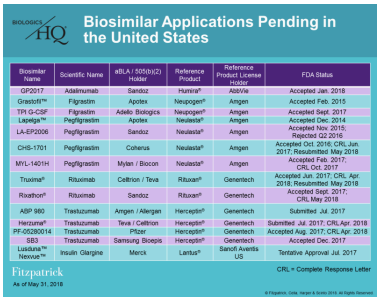
Biosimilars Approved in the U.S.

Biosimilar Applications Pending in the U.S.



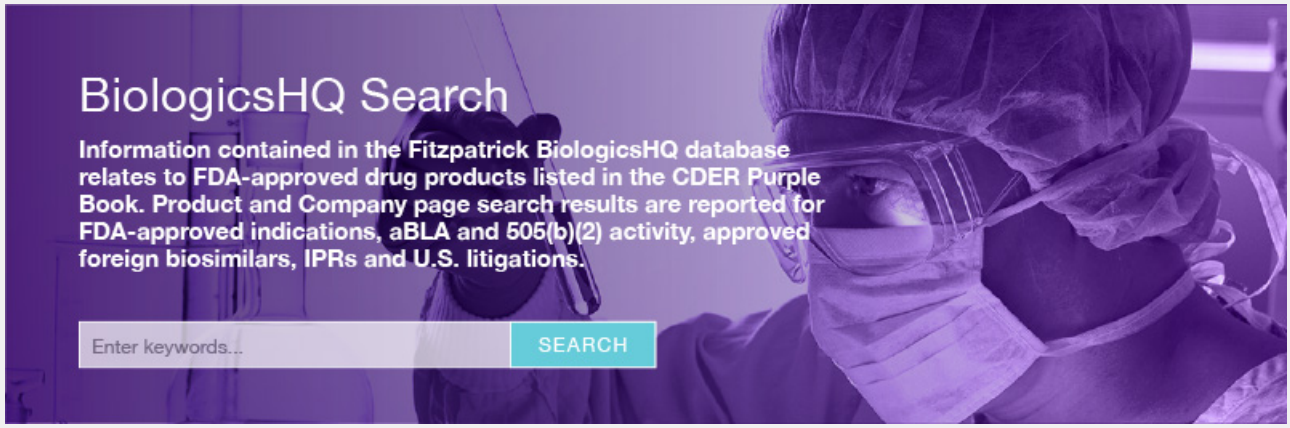


aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	Boehringer Ingelheim	Aug. 25, 2017	Humira®	AbbVie Inc.	
aBLA 761028	Mvasi™	Bevacizumab-awwb	Amgen Inc.	Sept. 14, 2017	Avastin®	Genentech	
aBLA 125545	Retacrit®	Epoetin Alfa-epbx	Hospira / Pfizer	May 15, 2018	Epogen®	Amgen	
aBLA 761042	Erelzi®	Etanercept-szzs	Sandoz Inc.	Aug. 30, 2016	Enbrel®	Immunex Corp. (Amgen, Inc.)	
aBLA 125553	Zarxio®	Filgrastim-sndz	Sandoz Inc.	Mar. 6, 2015	Neupogen®	Amgen Inc.	Sept. 2015
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion Inc.	Apr. 5, 2016	Remicade®	Janssen Biotech	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepis Co. Ltd.	Apr. 21, 2017	Remicade®	Janssen Biotech	Jul. 2017
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer Inc.	Dec. 13, 2017	Remicade®	Janssen Biotech	
NDA 205692 [505(b)(2)]	Basaglar®	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan GmbH / Biocon	Dec. 1, 2017	Herceptin®	Genentech	



Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License Holder	FDA Status
GP2017	Adalimumab	Sandoz	Humira®	AbbVie	Accepted Jan. 2018
Grastofil™	Filgrastim	Apotex	Neupogen®	Amgen	Accepted Feb. 2015
TPI G-CSF	Filgrastim	Adello Biologics	Neupogen®	Amgen	Accepted Sept. 2017
Lapelga™	Pegfilgrastim	Apotex	Neulasta®	Amgen	Accepted Dec. 2014
LA-EP2006	Pegfilgrastim	Sandoz	Neulasta®	Amgen	Accepted Nov. 2015; Rejected Q2 2016
CHS-1701	Pegfilgrastim	Coherus	Neulasta®	Amgen	Accepted Oct. 2016; CRL Jun. 2017; Resubmitted May 2018
MYL-1401H	Pegfilgrastim	Mylan / Biocon	Neulasta®	Amgen	Accepted Feb. 2017; CRL Oct. 2017
Truxima®	Rituximab	Celltrion / Teva	Rituxan®	Genentech	Accepted Jun. 2017; CRL Apr. 2018; Resubmitted May 2018
Rixathon®	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sept. 2017; CRL May 2018
ABP 980	Trastuzumab	Amgen / Allergan	Herceptin®	Genentech	Submitted Jul. 2017
Herzuma®	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017; CRL Apr. 2018
PF-05280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017; CRL Apr. 2018
SB3	Trastuzumab	Samsung Bioepis	Herceptin®	Genentech	Accepted Dec. 2017
Lusduna™ Nexvue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017

CRL = Complete Response Letter



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