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LATEST NEWS

Trends and Predictions for Serial Biologic Drug IPR Petitions

By: Frederick C. Millett and Robert S. Schwartz, Ph.D.

Two decisions over the past year could have significant implications in how serial inter partes review petitions are handled by the Patent Trial and Appeal Board going forward. The first, *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, which laid out a seven-factor test to determine whether the PTAB will use its discretion not to review serial IPR petitions, was recently designated “precedential” by the PTAB. The second, the U.S. Supreme Court’s April 24, 2018, decision in *SAS Institute Inc. v. Iancu*, where the court held that the PTAB must determine the patentability of all challenged claims in a petition and can no longer issue final written decisions on only a partial list of challenged claims, could also have implications for how serial petitions are considered by the PTAB going forward. This article reviews how serial IPRs on patents covering biologic drugs could be affected by these decisions, based on trends over the last few years.

Biosimilars and the Biologics Price Competition and Innovation Act (BPCIA)

By: Michael Enzo Furrow, Ph.D. and Whitney L. Meier

The Biologics Price Competition and Innovation Act (BPCIA) provides an abbreviated pathway for companies to bring biologic drugs to market that are “biosimilar” to previously approved branded reference products by relying on clinical studies that were performed by the reference product sponsor (RPS).

This note introduces biosimilars, the litigation process set up by the BPCIA to facilitate resolution of patent disputes between reference product sponsors and biosimilar manufacturers, and touches on related trends, such as the potential use of inter partes review proceedings by biosimilar manufacturers as an alternative or in addition to litigation.

Federal Circuit Rejects Assertion of Sovereign Immunity by Saint Regis Mohawk Tribe in Inter Partes Review Proceedings

By: Christopher Loh

On July 20, 2018, a Federal Circuit panel (Dyk, Moore, Reyna) affirmed a denial by the Patent Trial and Appeal Board of a motion by the Saint Regis Mohawk Tribe to dismiss, on the basis of sovereign immunity, inter partes review (“IPR”) proceedings against patents that had been assigned to the Tribe by Allergan.

In 2015, Allergan sued Mylan, Teva and Akorn for infringement of patents covering Allergan’s Restasis® dry eye treatment. Mylan, Teva and Akorn petitioned for IPR of those patents. The Board instituted and consolidated the IPRs. Before the oral hearing for the consolidated IPRs took place, Allergan assigned the patents to the Tribe. The Tribe subsequently moved to terminate the IPRs on the basis of tribal sovereign immunity, and Allergan moved to withdraw. The Board denied the motions.

In a decision by Judge Moore, the Federal Circuit affirmed the Board’s denial, holding that “tribal sovereign immunity cannot be asserted in IPRs.”

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UPDATES

IPRs

- **Humira® (adalimumab):** On July 10, 2018, Sandoz filed appeals of the decisions not to institute in IPR2017-01824 (Federal Circuit Case No. 18-2142) and IPR2018-00002 (Federal Circuit Case No. 18-2143).

- **Rituxan® (rituximab):**
  - On July 9, 2018, IPR2018-00285 filed by Pfizer was instituted.
  - On July 10, 2018, Genentech's request for rehearing of the decision to modify the institution decision in IPR2017-01923 after the Supreme Court decision in *SAS* to institute on all grounds was denied.

- **Herceptin® (trastuzumab):** On July 9, 2018, institution was denied in IPR2018-00330 and IPR2018-00331 filed by Pfizer. Pfizer's requests for joinder with its previously filed IPR2017-02019 and IPR2017-02020 were also denied.

- **Enbrel® (etanercept):** On July 13, 2018, Coherus's requests for rehearing of the decisions denying institution of IPR2017-01916 and IPR2017-02066 were denied.

LITIGATIONS

- **Herceptin® (trastuzumab):**
  - On July 11, 2018, Genentech filed Case No. 1:18-cv-01025 (D. Del.) against Celltrion and Teva.
  - On July 16, 2018, an appeal was filed in *Celltrion v. Genentech*, Case No. 4:18-cv-00274 (N.D. Cal.), Federal Circuit Case No. 18-2160.

- **Rituxan® (rituximab):**
  - On July 11, 2018, Genentech filed Case No. 1:18-cv-11553 (D.N.J.) against Celltrion and Teva.
  - On July 16, 2018, an appeal was filed in *Celltrion v. Genentech*, Case No. 4:18-cv-00276 (N.D. Cal.), Federal Circuit Case No. 18-2161.

- **Neupogen® (filgrastim):** On July 18, 2018, Amgen filed Case No. 1:18-cv-01064 (D. Del.) against Hospira and Pfizer.
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- **Praluent® (alirocumab) / Repatha® (evolocumab):** On July 27, 2018, Amgen's petition for writ of certiorari in *Amgen v. Sanofi*, Case No. 17-1480, was placed on the Supreme Court docket as Case No. 18-127.

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aBLA APPLICATIONS AND FDA ACTIVITY

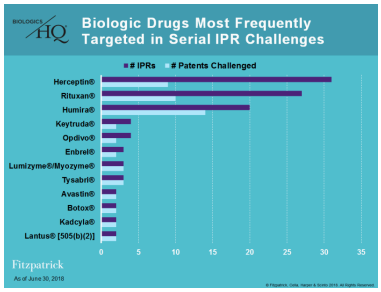
- **Nivestym™ (filgrastim-aafi):** On July 20, 2018, the FDA approved Pfizer's Nivestym™, a biosimilar of Amgen's Neupogen® (filgrastim).

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

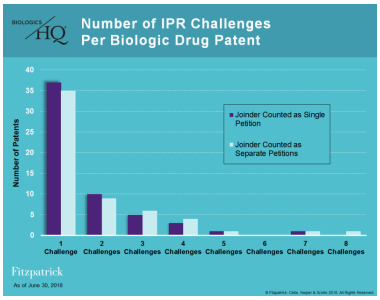
- **Hyrimoz® (adalimumab):** On July 27, 2018, Sandoz announced that Hyrimoz®, its biosimilar of Humira®, was approved in the E.U.
- **Trazimera™ (trastuzumab):** On July 31, 2018, Pfizer announced that Trazimera™, its biosimilar of Herceptin®, was approved in the E.U.

STATISTICS

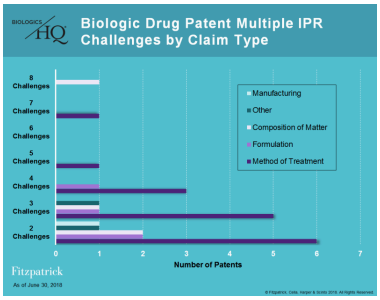
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



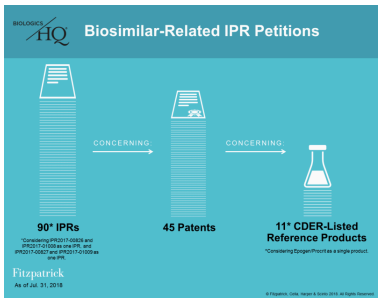
Number of IPR Challenges Per Biologic Drug Patent



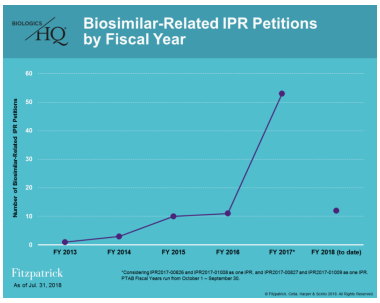
Biologic Drug Patent Multiple IPR Challenges by Claim Type



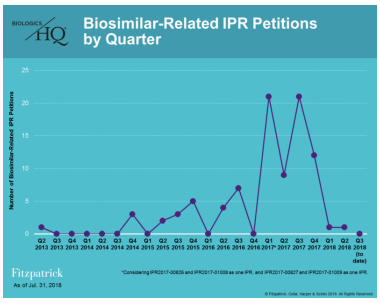
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



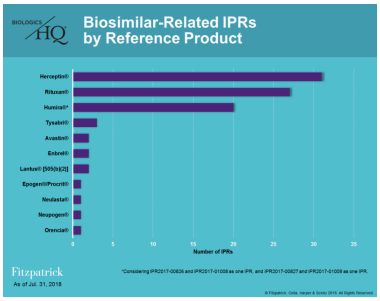
Biosimilar-Related IPR Petitions by Quarter



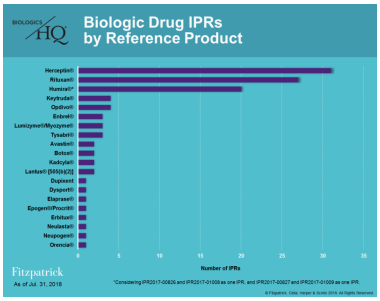
Biosimilar-Related IPRs by Reference Product

Biologic Drug IPRs by Reference Product

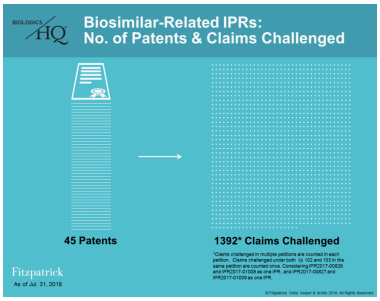
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



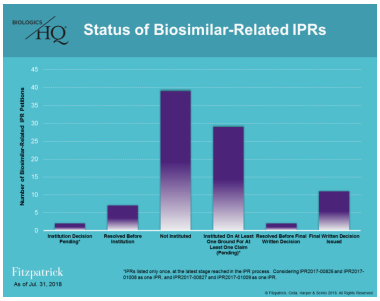
Status of Biosimilar-Related IPRs



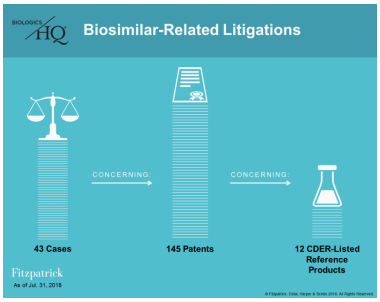
Biosimilar-Related Litigations



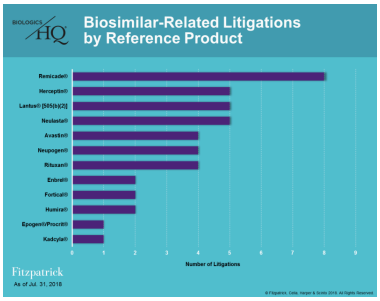
Biosimilar-Related Litigations by Reference Product



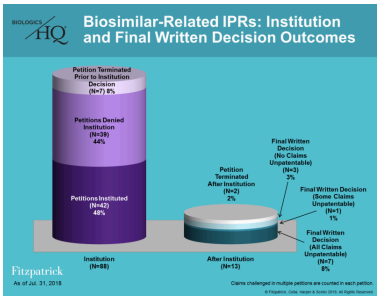
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



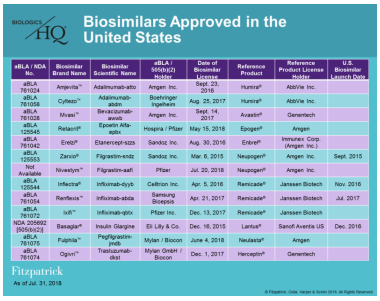
Biosimilars Approved in the U.S.



Biosimilar Applications Pending in the U.S.

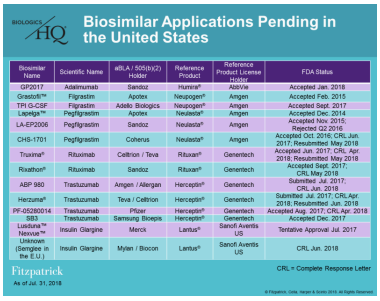


Biologic Drug IPR Challenges



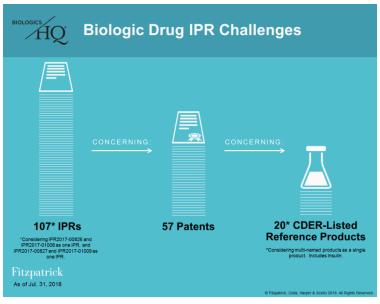
aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	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
Not Available	Nivestym™	Filgrastim-aafi	Pfizer	Jul. 20, 2018	Neupogen®	Amgen Inc.	
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion Inc.	Apr. 5, 2016	Remicade®	Janssen Biotech	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepsis	Apr. 21, 2017	Remicade®	Janssen Biotech	Jul. 2017
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer Inc.	Dec. 13, 2017	Remicade®	Janssen Biotech	
NDA 205992 [505(b)(2)]	Basaglar®	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016
aBLA 761075	Fulphila™	Pegfilgrastim-jmdb	Mylan / Biocon	June 4, 2018	Neulasta®	Amgen	
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan GmbH / Biocon	Dec. 1, 2017	Herceptin®	Genentech	

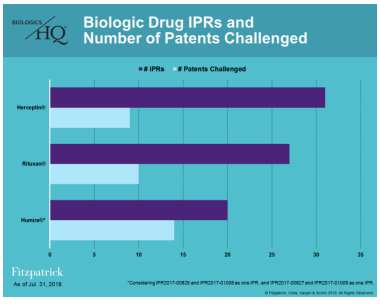
Biologic Drug IPRs and Number of Patents Challenged

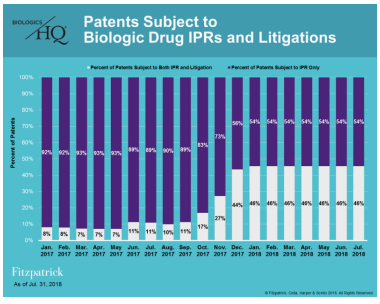


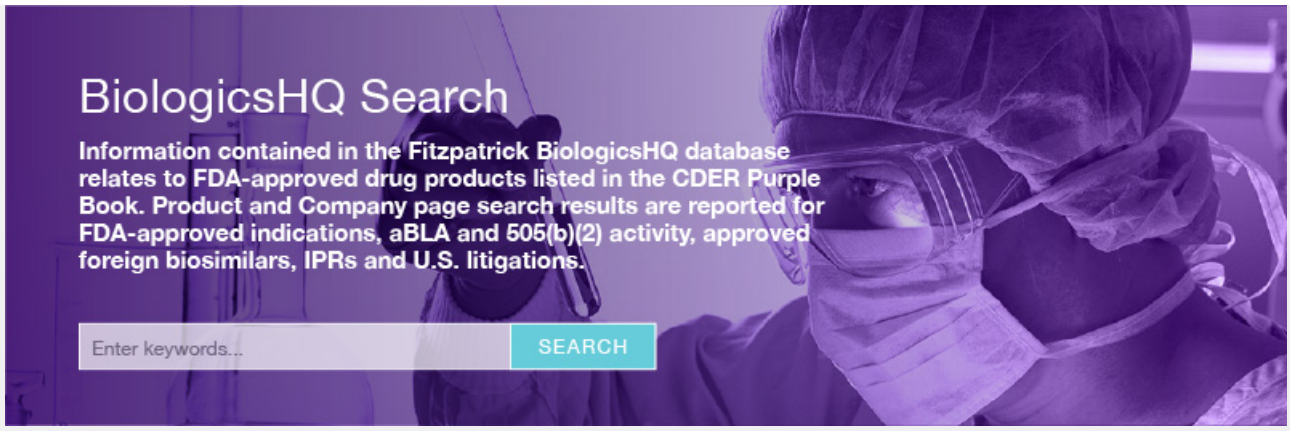
Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License Holder	FDA Status
GP2017	Adalimumab	Sandoz	Humira®	AbbVie	Accepted Jan. 2018
Grastofil™	Filgrastim	Apotex	Neupogen®	Amgen	Accepted Feb. 2015
TPI G-CSF	Filgrastim	Adello Biologics	Neupogen®	Amgen	Accepted 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
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; CRL Jun. 2018
Herzuma®	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017; CRL Apr. 2018; Resubmitted Jun. 2018
PF-05280014 SB3	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017; CRL Apr. 2018
Ustuzna™ Nexvia™ Unknown (Semglee in the E.U.)	Trastuzumab	Samsung Bioepis	Herceptin®	Genentech	Accepted Dec. 2017
	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017
	Insulin Glargine	Mylan / Biocon	Lantus®	Sanofi Aventis US	CRL Jun. 2018

Patents Subject to Biologic Drug IPRs and Litigations









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