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MONTHLY INJECTION



LATEST NEWS

Update on Biologic Drug
IPRs: Lessons Learned

LEXOLOGY. Webinars

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WEBINAR: Update on Biologic Drug IPRs: Lessons Learned

By: Corinne E. Atton, Whitney L. Meier, and Robert S. Schwartz

Inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB) of the USPTO have been popular since their inception in 2012, and petitions are increasingly being filed against biologic drug patents. Fitzpatrick Cella's award-winning intellectual property attorneys provide you with unique insights and the latest statistics on biologic drug IPRs and the lessons to be learned from recent institution and final written decisions.

Corinne Atton, Whitney Meier, and Robert Schwartz discuss:

- Statistics related to CDER-listed ("Purple Book") biologic drug IPRs including: IPR petitions filed, patents challenged in both IPR and district court litigation, claim types challenged in IPR, IPR outcomes, and comparisons to data on IPRs filed against Orange Book listed patents.
 - Lessons learned from analyzing biologic drug IPRs by claim type: methods of treatment, formulation, composition of matter, and process/manufacturing.
-



FEATURED VIDEO: The Need for Clarity After Sandoz v. Amgen

By: Ha Kung Wong

As part of the *The Center for Biosimilars™ Peer Exchange®*, Ha Kung Wong, Molly Burich, Amanda Forsys, and Angus Worthing highlight unanswered questions surrounding the Supreme Court's ruling in *Sandoz v. Amgen*, which reviewed procedural issues under the Biologics Price Competition and Innovation Act (BPCIA).

View Videos by Ha Kung Wong:

- **Biosimilars and the STRONGER Patents Act**
- **Might Congress Revisit the BPCIA?**
- **The PTAB's Role in Biosimilar Patent Disputes**
- **Upcoming Patent Litigation in Biosimilars**
- **State Laws and Biosimilar Substitution**
- **Healthcare Reform Efforts and the BPCIA**
- **Biosimilar Developers' Concerns About Litigation**
- **Biosimilars, Formularies, Contracting, and PBMs**
- **Reforms at the FDA Level**
- **Inspection Reports and Proprietary Information**
- **Global Reference Products in Biosimilar Development**
- **Biosimilars, Interchangeability, and Perceptions of Safety**
- **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*?**

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UPDATES

IPRs

- **Humira® (adalimumab):** On February 9, 2018, institution was denied in IPR2017-01823 and IPR2017-01824 filed by [Sandoz](#).
- **Dupixent® (dupilumab):** On February 15, 2018, IPR2017-01879 and IPR2017-01884 filed by [Aventisub](#), [Genzyme](#), [Regeneron](#), and [Sanofi](#) were instituted.
- **Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):** On February 15, 2018, a

final written decision finding most instituted claims unpatentable and one claim not unpatentable was issued in IPR2016-01542 filed by [Apotex](#).

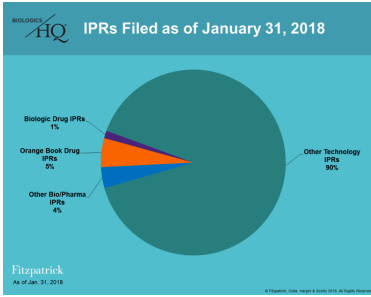
- **Rituxan[®] (rituximab):** On February 21, 2018, a final written decision finding all instituted claims not unpatentable was issued in IPR2016-01614 filed by [Celltrion](#) and [Teva](#), and in joined IPR2017-01115 filed by [Pfizer](#).
- **Herceptin[®] (trastuzumab):**
 - On February 21, 2018, IPR2017-02063 filed by [Pfizer](#) was instituted. [Pfizer's](#) motion for joinder with IPR2017-01121 was also granted.
 - On February 21, 2018, institution was denied in IPR2018-00016 filed by [Pfizer](#).
 - On February 22, 2018, IPR2017-02139 filed by [Samsung Bioepis](#) was instituted. [Samsung's](#) motion for joinder with IPR2017-01488 was also granted.
 - On February 22, 2018, IPR2017-02140 filed by [Samsung Bioepis](#) was instituted. [Samsung's](#) motion for joinder with IPR2017-01489 was also granted.

LITIGATIONS

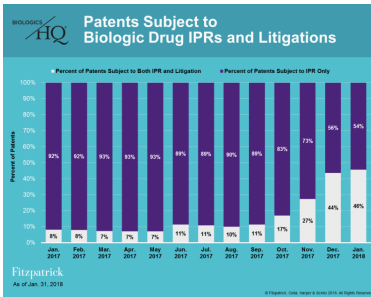
- **Avastin[®] (bevacizumab):** On February 2, 2018, the District Court granted [Genentech's](#) motion to dismiss in [Amgen v. Genentech](#), Case No. 2:17-cv-07349 (C.D. Cal.).
- **Elitek[®] (rasburicase):** On February 2, 2018, the District Court granted [Sanofi](#) summary judgment of noninfringement in [Washington Research Foundation & Genentech v. Sanofi](#), Case No. 2:15-cv-01143 (W.D. Wash.). On February 26, 2018, [Washington Research Foundation & Genentech](#) filed an appeal, Federal Circuit Case No. 18-1612.
- **Humira[®] (adalimumab):** On February 5, 2018, the Federal Circuit affirmed the District Court's dismissal of [AbbVie v. MedImmune](#), in Case No. 17-1689.
- **Neulasta (pegfilgrastim):** On February 12, 2018, [Amgen](#) filed Federal Circuit Case No. 18-1552, appealing [Amgen v. Sandoz](#), Case No. 3:16-cv-02581 (N.D. Cal.).
- **Neupogen[®] (filgrastim):** On February 12, 2018, [Amgen](#) filed Federal Circuit Case No. 18-1551, appealing [Amgen v. Sandoz](#), Case No. 3:14-cv-04741 (N.D. Cal.).
- **Avonex[®] / Betaseron[®] / Extavia[®] / Rebif[®] (interferon beta-1a / interferon beta-1b):** On February 23, 2018, the jury issued a verdict in [Bayer v. Biogen](#), Case No. 2:10-cv-02734 (D.N.J.), finding the patent at issue infringed and invalid for anticipation.
- **Praluent[®] (alirocumab) / Repatha[®] (evolocumab):** On February 23, 2018, [Amgen's](#) petition for rehearing *en banc* in [Amgen v. Sanofi](#), Case No. 17-1480 was denied.

STATISTICS

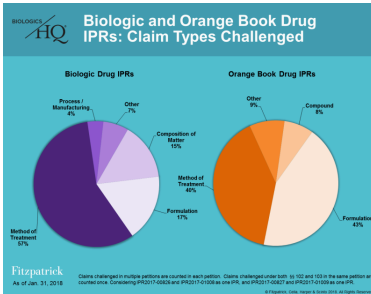
IPRs Filed as of January 31, 2018



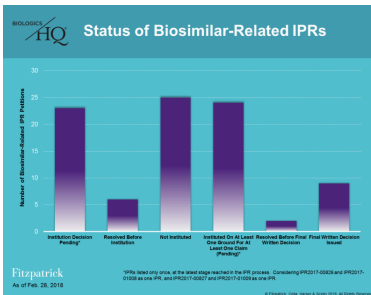
Patents Subject to Biologic Drug IPRs and Litigations



Biologic and Orange Book Drug IPRs: Claim Types Challenged

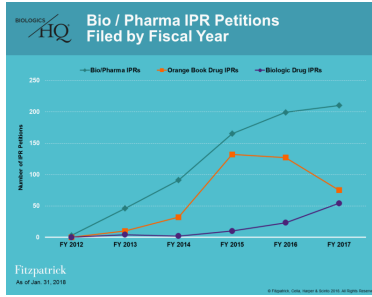


Status of Biosimilar-Related IPRs

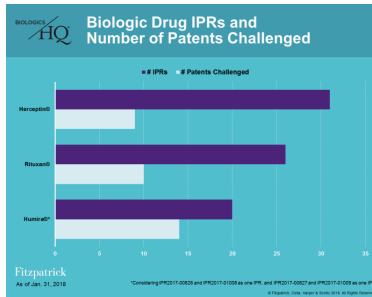


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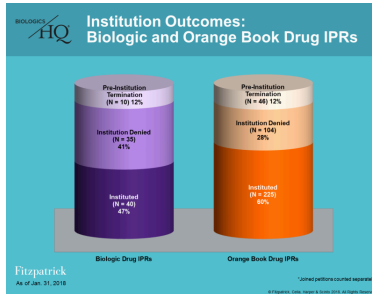
Bio / Pharma IPR Petitions Filed by Fiscal Year



Biologic Drug IPRs and Number of Patents Challenged



Institution Outcomes: Biologic and Orange Book Drug IPRs

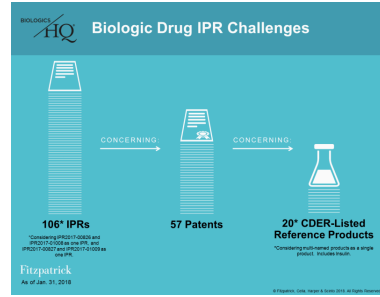


Biosimilars Approved in the U.S.

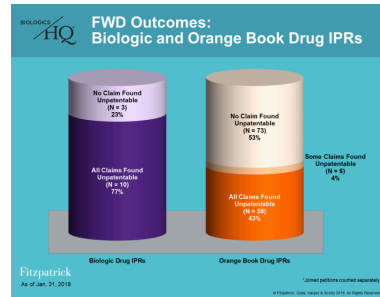
Biologics AHA No.	Biosimilar Brand Name	Biosimilar Scientific Name	Biologics AHA No.	Date of Biologics License	Reference Product	Reference Product License Holder	U.S. Reference Product
ABLA 71024	Ampligen	Adifenbutolol	ABLA 71024	Sept. 23, 2016	Humira	AbbVie Inc.	Humira
ABLA 71025	Cytexa	Adalimumab	ABLA 71025	Aug. 25, 2017	Humira	AbbVie Inc.	Humira
ABLA 71026	Mvasi	Becaplermin	ABLA 71026	Sept. 14, 2017	Avastin	Genentech	Avastin
ABLA 71027	Evolri	Elesclerone	ABLA 71027	Aug. 30, 2016	Enbrel	Janssen Corp. (Amgen Inc.)	Enbrel
ABLA 71028	Zarvio	Filgrastim	ABLA 71028	Nov. 4, 2016	Neupogen	Amgen Inc.	Neupogen
ABLA 71029	Infecta	Infliximab	ABLA 71029	Apr. 5, 2016	Remicade	Janssen Biotech	Remicade
ABLA 71030	Renflexis	Infliximab	ABLA 71030	Apr. 21, 2017	Remicade	Janssen Biotech	Remicade
ABLA 71031	Infliximab	Infliximab	ABLA 71031	Dec. 18, 2017	Remicade	Janssen Biotech	Remicade
ABLA 71032	Humira	Infliximab	ABLA 71032	Dec. 18, 2017	Remicade	Janssen Biotech	Remicade
ABLA 71033	Benevolin	Infliximab	ABLA 71033	Dec. 18, 2017	Remicade	Janssen Biotech	Remicade
ABLA 71034	Oglin	Infliximab	ABLA 71034	Dec. 1, 2017	Remicade	Genentech	Remicade

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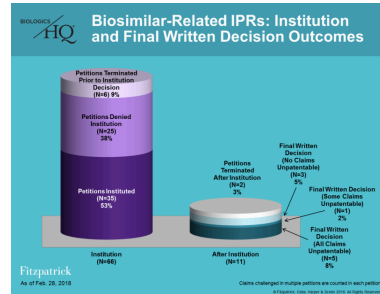
Biologic Drug IPR Challenges



FWD Outcomes: Biologic and Orange Book Drug IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar Applications Pending in the U.S.

Biosimilar Name	Chemical Name	Biologics AHA No.	Reference Product	Reference Product License Holder	FDA Status
AMN017	Adalimumab	ABLA 71025	Humira	Janssen Biotech	Accepted Jan. 2018; Rejected Oct. 2015; Complete Response Oct. 2016; Complete Response Oct. 2017
Retrovir	Epoetin Alfa	ABLA 71024	Epogen / Procrit	Amgen	Accepted Jan. 2017
Onasemnogene	Onasemnogene	ABLA 71026	Avastin	Genentech	Accepted Feb. 2017; Complete Response Aug. 2017
Leqembi	Pegfilgrastim	ABLA 71028	Neupogen	Amgen	Accepted Dec. 2014
L4497006	Pegfilgrastim	ABLA 71028	Neupogen	Amgen	Accepted Nov. 2015; Rejected Q2 2016
CT-5101	Pegfilgrastim	ABLA 71028	Neupogen	Amgen	Accepted Oct. 2017; Complete Response Later Jul. 2017
MPL-14019	Pegfilgrastim	ABLA 71028	Neupogen	Amgen	Accepted Feb. 2017
CT-5101	Pegfilgrastim	ABLA 71028	Neupogen	Amgen	Accepted Aug. 2017
IBI-198	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-302	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-303	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-304	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-305	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-306	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-307	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-308	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-309	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-310	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-311	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-312	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-313	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-314	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-315	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-316	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-317	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-318	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-319	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-320	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-321	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-322	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-323	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-324	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-325	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-326	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-327	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-328	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-329	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017
IBI-330	Infliximab	ABLA 71029	Remicade	Janssen Biotech	Accepted Aug. 2017

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BiologicsHQ Search

Information contained in the Fitzpatrick BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

Contact Us

(212) 218-2100 New York
(714) 540-8700 California
(202) 530-1010 Washington DC

BiologicsHQ@fchs.com
www.fitzpatrickcella.com
www.postgranthq.com



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