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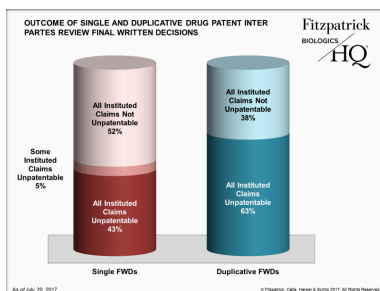
November 3, 2017

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MONTHLY INJECTION



LATEST NEWS



Two Bites of the Apple: Five Interesting Facts about Drug Patent IPR Final Written Decisions

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

As of July 20, 2017, there have been at least 363 IPR petitions filed against patents that were listed in the FDA Orange Book, and 74 IPR petitions filed against patents that have been identified as reading on FDA Purple Book (CDER) listed biologic drugs. Of these 437 drug patent IPRs, 116 resulted in a final written decision (“FWD”).

Highlights of our findings are:

- 85% of drug patent FWDs concerned patents that are also litigated;
- >50% of drug patent FWDs resulted in claims being found unpatentable;
- 62% of drug patent FWDs concern multiple challenges to the same patents;
- Drug patents subject to multiple challenges are more likely to be found unpatentable; and
- Biologic drug patents are more likely to be found unpatentable than Orange Book drug patents.



VIDEO: Biosimilar Interchangeability and Market Share

By: Ha Kung Wong

As part of the *The Center for Biosimilars™ Peer Exchange®*, Ha Kung Wong and panelists Amanda Forsys and Molly Burich discuss the question, "Will biosimilar manufacturers seeking interchangeability have an effect on how reference product sponsors attempt to protect market share?"



VIDEO: Interchangeability and Rheumatology Prescribing Practices

By: Ha Kung Wong

As part of the *The Center for Biosimilars™ Peer Exchange®*, Ha Kung Wong and panelists Angus Worthing, Amanda Forsys, and Molly Burich discuss questions regarding physician prescribing of biosimilars and interchangeables, including how the designation of a product as interchangeable will affect prescribing practices and how interchangeability designations will affect the uptake of biosimilars and interchangeables in the market.

View Additional Videos by Ha Kung Wong:

- [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 October 2, 2017, [Sandoz](#) filed IPR2018-00002.
- **Herceptin® (trastuzumab):**
 - On October 3, 2017, [Pfizer](#) filed IPR2018-00016.
 - On October 4, 2017, IPR2017-01121, IPR2017-01122, IPR2017-01139, and

- IPR2017-01140 filed by [Celltrion](#) and [Teva](#) were instituted.
- On October 26, 2017, a request for rehearing in IPR2017-00731, filed by [Hospira](#) and [Pfizer](#), was granted, reversing a previous denial and instituting trial.
- **Rituxan[®] (rituximab):**
 - On October 2, 2017, institution was denied for IPR2017-01094 filed by [Celltrion](#) and [Teva](#).
 - On October 6, 2017, institution was denied in IPR2017-01093 filed by [Celltrion](#) and [Teva](#).
 - On October 6, 2017, institution was granted-in-part and denied-in-part in IPR2017-01095 filed by [Celltrion](#) and [Teva](#).
 - On October 6, 2017, [Pfizer](#) filed IPR2017-02126 and IPR2017-02127.
 - On October 12, 2017, institution was denied in IPR2017-01230 filed by [Celltrion](#) and [Teva](#).
 - On October 23, 2017, institution was denied in IPR2017-01227 and IPR2017-01229 filed by [Celltrion](#) and [Teva](#).
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LITIGATIONS

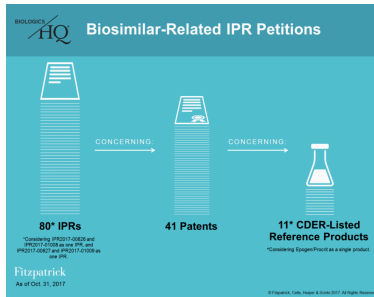
- **Repatha[®] (evolocumab) / Praluent[®] (alirocumab):** On October 5, 2017, the Federal Circuit reversed-in-part, affirmed-in-part, vacated-in-part, and remanded *Amgen v. Sanofi*, Case No. 17-1480.
 - **Avastin[®] (bevacizumab):**
 - On October 6, 2017, Case Nos. 1:17-cv-01407 (D. Del.) *Genentech v. Amgen* and 2:17-cv-07349 (C.D. Cal.) *Amgen v. Genentech* were filed.
 - On October 18, 2017, Case No. 1:17-cv-01471 (D. Del.) *Genentech v. Amgen* was filed.
 - **Darzalex[®] (daratumumab):** On October 11, 2017, U.S. Patent No. 9,758,590 was added to the *MorphoSys v. Janssen* Case No. 1:16-cv-00221 (D. Del.).
 - **Kadcyla[®] (ado trastuzumab emtansine):** On October 13, 2017, [Genentech](#) filed a cross-appeal in *Phigenix v. Genentech* Case No. 5:15-cv-01238 (N.D. Cal.): Fed. Cir. No. 18-1042.
 - **Lantus[®] (insulin glargine recombinant):** On October 24, 2017, [Sanofi](#) filed litigation No. 2:17-cv-09105 (D.N.J.) against [Mylan](#) relating to its proposed insulin glargine products.
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aBLA APPLICATIONS AND APPROVALS

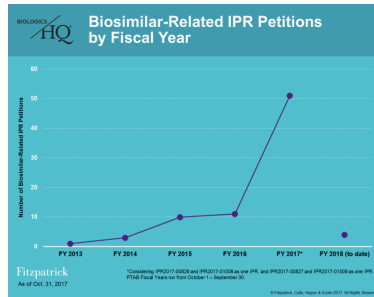
- **MYL-1401H (pegfilgrastim):** On October 10, 2017, [Mylan](#) and [Biocon](#) announced that the FDA had issued a complete response letter relating to their proposed biosimilar of [Neulasta[®] \(pegfilgrastim\)](#).

STATISTICS

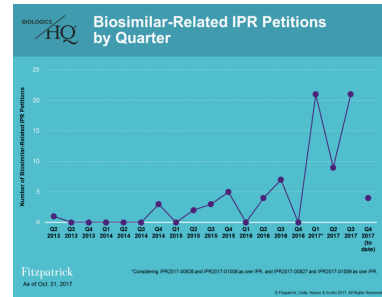
Biosimilar-Related IPR Petitions



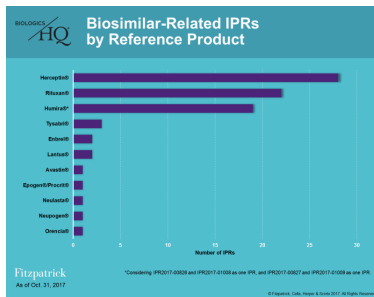
Biosimilar-Related IPR Petitions by Fiscal Year



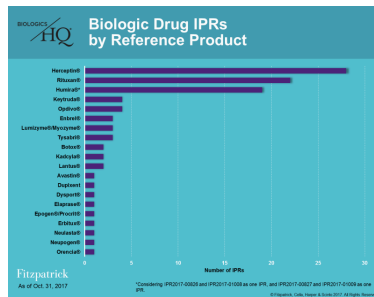
Biosimilar-Related IPR Petitions by Quarter



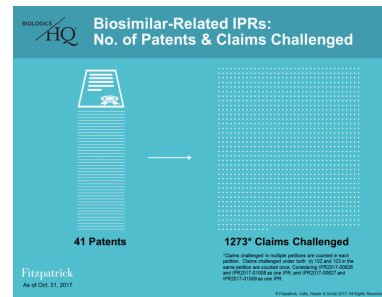
Biosimilar-Related IPRs by Reference Product



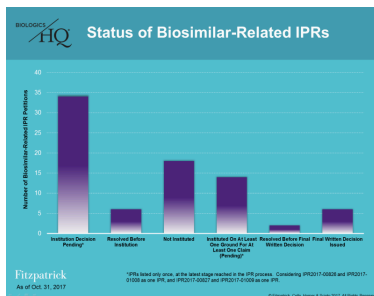
Biologic Drug IPRs by Reference Product



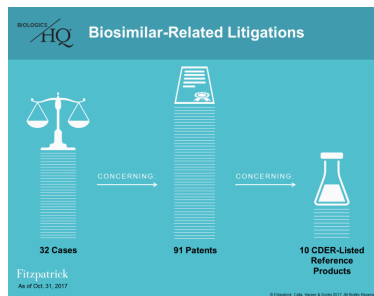
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



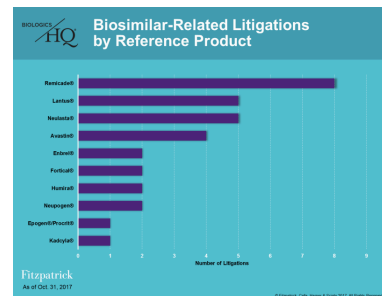
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product



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 781024	Anjevia™	Adalimumab-ahp	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 781058	Cylteco™	Adalimumab-ahbm	Amgen Inc.	Aug. 25, 2017	Humira®	AbbVie Inc.	
aBLA 781028	Mvasi™	Bevacizumab-awwb	Amgen Inc.	Sept. 14, 2017	Avastin®	Genentech	
aBLA 781042	Erelzi®	Etanercept-ssz	Sandoz Inc.	Aug. 30, 2016	Enbrel®	Genzyme Corp. (Amgen Inc.)	
aBLA 125503	Zarxio®	Filgrastim-sndz	Sandoz Inc.	Mar. 5, 2016	Neupogen®	Amgen Inc.	Sept. 2015
aBLA 125544	Infectra®	Infliximab-dyyr	Celtrion Inc.	Apr. 5, 2016	Remicade®	Centocor Inc.	Nov. 2016
aBLA 781054	Renflexis™	Infliximab-abda	Samsung Bioparis Co. Ltd.	Apr. 21, 2017	Remicade®	Centocor Inc.	Jul. 2017
NDA 205892 (505b)(2)	Basaglar	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016

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Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License Holder	FDA Status
Relacor®	Epoetin Alfa	Hospira / Pfizer	Eprex® Procrit®	Amgen	Accepted Jan. 2015, Rejected (a 2015, Resubmitted Dec. 2016, Complete Response Letter Jan. 2017)
Grastin™	Filgrastin	Apotex	Neupogen®	Amgen Inc.	Accepted Feb. 2015
Urelason	Filgrastin	Adamo Biologics	Neupogen®	Amgen Inc.	Accepted Sept. 2017
532	Infliximab	Shenyang Biotech	Remicade®	Centocor Inc.	Accepted May 2016
Lapiga™	Pegfilgrastim	Apotex	Neulasta®	Amgen	Accepted Dec. 2014
LA-22008	Pegfilgrastim	Sandoz	Neulasta®	Amgen	Accepted Nov. 2016, Rejected (Q2 2016)
CRS-1701	Pegfilgrastim	Cohesion	Neulasta®	Amgen	Accepted Oct. 2016, Complete Response Letter Jan. 2017
MPL-1401H	Pegfilgrastim	Mylan / Bioson	Neulasta®	Amgen	Accepted Feb. 2017, Complete Response Letter Oct. 2017
CR-PT8	Rituximab	Celtrion / Teva	Rituxan®	Genentech	Accepted Jan. 2017
Riuxon	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sept. 2017
ADP-860	Trastuzumab	Amgen / Alkermes	Herceptin®	Genentech	Submitted Jul. 2017
CT-PE	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017
MPL-1401D	Trastuzumab	Mylan / Bioson	Herceptin®	Genentech	Accepted Jan. 2017
Lodona™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Resubmitted Jul. 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.

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