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November 12, 2018

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MONTHLY INJECTION



LATEST NEWS



Fitzpatrick, Cella, Harper & Scinto Officially Joins Venable Forming Venable Fitzpatrick

Venable LLP, an *American Lawyer* Global 100 firm, announced that Fitzpatrick, Cella, Harper & Scinto, a leading intellectual property firm, has successfully joined Venable. The Fitzpatrick lawyers will practice as Venable Fitzpatrick, effective November 1, 2018. Joining from Fitzpatrick are 97 attorneys and 70 staff members who will be in the New York, Washington, DC, and Los Angeles offices.



VIDEO: Changes to IPRs and PGRs for Biologics

By: [Ha Kung Wong](#)

[Ha Kung Wong](#) addresses recent changes to inter partes review (IPR) and post-grant review (PGR) proceedings with respect to biologic drugs as part of a video series for the Center for Biosimilars.

View Additional New Videos from Ha Kung Wong:

- [The BPCIA One Year After *Sandoz v. Amgen*](#)
- [Biosimilar Manufacturer's Approach to the Patent Dance](#)
- [The Importation of Biologics and Biosimilars](#)
- [FDA and FTC Cooperation to Address Anticompetitive Behavior](#)
- [The FDA's Biosimilar Action Plan](#)

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UPDATES

IPRs and PGRs

- **Neupogen[®] (filgrastim) / Neulasta (pegfilgrastim):** On October 1, 2018, [Apotex](#) and [Adello](#) filed PGR2019-00001.
- **Ajovy[™] (fremanezumab-vfrm) / Emgality[™] (galcanezumab-gnlm):** On October 1, 2018, [Eli Lilly](#) filed IPR2018-01711 and IPR2018-01712.
- **Herceptin[®] (trastuzumab):**
 - On October 3, 2018, Final Written Decisions finding all instituted claims unpatentable were entered in IPR2017-00737 filed by [Hospira](#) and [Pfizer](#) and joined IPR2017-01960 filed by [Samsung Bioepis](#), and in IPR2017-01122 filed by [Celltrion](#) and [Teva](#).
 - On October 3, 2018, Final Written Decisions finding no instituted claims unpatentable were entered in IPR2017-00804 filed by [Hospira](#) and [Pfizer](#) and joined IPR2017-01958 filed by [Samsung Bioepis](#), and in IPR2017-01139 filed by [Celltrion](#) and [Teva](#).
 - On October 3, 2018, Final Written Decisions finding no instituted claims unpatentable were entered in IPR2017-00805 filed by [Hospira](#) and [Pfizer](#) and joined IPR2017-01959 filed by [Samsung Bioepis](#), and in IPR2017-01140 filed by [Celltrion](#) and [Teva](#).
 - Final Written Decisions were issued in IPR2017-00731 filed by [Hospira](#) and [Pfizer](#), IPR2017-01121 filed by [Celltrion](#) and [Teva](#) and joined IPR2017-02063 filed by [Pfizer](#), but the decisions have not yet been posted to the dockets.
- **Rituxan[®] (rituximab):**
 - On October 4, 2018, a Final Written Decision finding all instituted claims unpatentable was entered in IPR2017-01095 filed by [Celltrion](#) and [Teva](#).
 - On October 30, 2018, IPR2018-01019 filed by [Celltrion](#) and [Teva](#) was instituted. [Celltrion](#) and [Teva's](#) motion for joinder with IPR2017-01923 was granted.
 - On October 31, 2018, [Biogen](#) and [Pfizer](#) filed a joint motion to terminate IPR2018-00186 after it was instituted.
 - On October 31, 2018, a Final Written Decision finding all instituted claims

unpatentable was entered in IPR2017-01168 filed by [Pfizer](#).

- **Humira® (adalimumab):** .
 - On October 15, 2018, [Sandoz](#) and [AbbVie](#) requested termination due to settlement of IPR2017-01987, IPR2017-01988, IPR2017-02105, and IPR2017-02106.
 - On October 18, 2018, [Sandoz](#) and [AbbVie](#) voluntarily dismissed the appeal of the decisions not to institute in IPR2017-01824 (Federal Circuit Case No. 18-2142) and IPR2018-00002 (Federal Circuit Case No. 18-2143) after signing a global settlement agreement.
- **Erbitux® (cetuximab):** On October 17, 2018, The Trustees of the University of Pennsylvania requested a panel rehearing and rehearing *en banc*, in Case No. 17-2397, of the Federal Circuit's decision affirming the PTAB's final written decision finding all instituted claims unpatentable in IPR2016-00458 filed by [Eli Lilly](#).
- **Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant):** On October 29, 2018, [Mylan](#) and [Biocon](#) filed IPR2019-00122.

LITIGATIONS

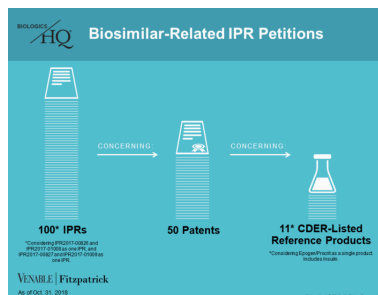
- **Epogen® / Procrit® (epoetin alfa):** On October 11, 2018, [Hospira](#) filed Federal Circuit Case No. 19-1067 appealing the final judgment in [Amgen v. Hospira](#), Case No. 1:15-cv-00839 (D. Del.). On October 23, 2018, [Amgen](#) filed a cross appeal, Federal Circuit Case No. 19-1102.
- **Humira® (adalimumab):** On October 16, 2018, Case No. 3:18-cv-12668 (D.N.J.) was dismissed at the request of [AbbVie](#) and [Sandoz](#).
- **Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant):** On October 29, 2018, [Sanofi v. Merck](#), Case No. 1:16-cv-00812 (D. Del.) was dismissed.
- **Avonex® / Betaseron® / Extavia® / Rebif® (interferon beta-1a / interferon beta-1b):** On October 30, 2018, [Pfizer](#) and [EMD Serono](#) filed Federal Circuit Case No. 19-1133 appealing [Bayer v. Biogen](#), Case No. 2:10-cv-02734 (D.N.J.).

aBLA APPLICATIONS AND FDA ACTIVITY

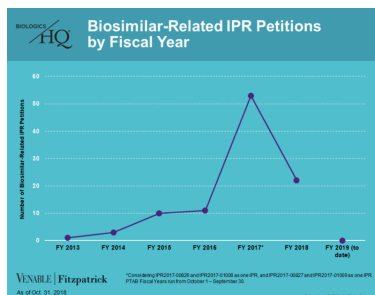
- **Nivestym™ (filgrastim-aafi):** On October 1, 2018, [Pfizer](#) announced that it launched [Nivestym™](#), a biosimilar of [Amgen's Neupogen® \(filgrastim\)](#).
- **TX-01 (filgrastim):** On October 1, 2018, [Tanvex BioPharma](#) announced that it submitted a BLA for [TX-01](#), a proposed biosimilar of [Amgen's Neupogen® \(filgrastim\)](#).
- **Hyrimoz™ (adalimumab-adaz):** On October 30, 2018, the FDA approved [Sandoz's Hyrimoz™](#), a biosimilar of [AbbVie's Humira® \(adalimumab\)](#).

STATISTICS

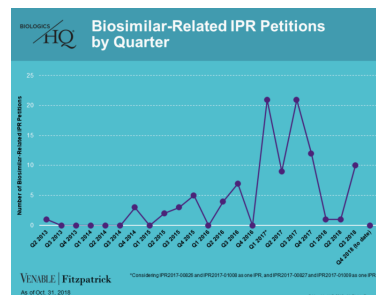
Biosimilar-Related IPR Petitions



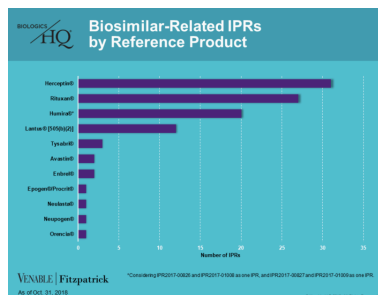
Biosimilar-Related IPR Petitions by Fiscal Year



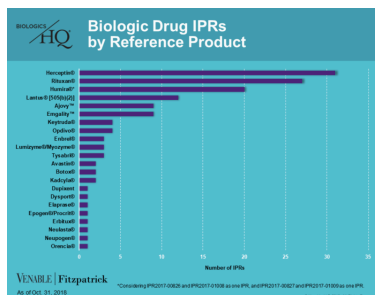
Biosimilar-Related IPR Petitions by Quarter



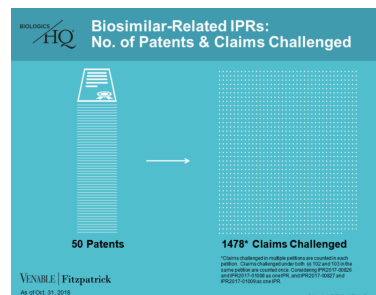
Biosimilar-Related IPRs by Reference Product



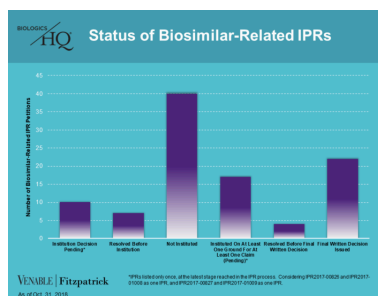
Biologic Drug IPRs by Reference Product



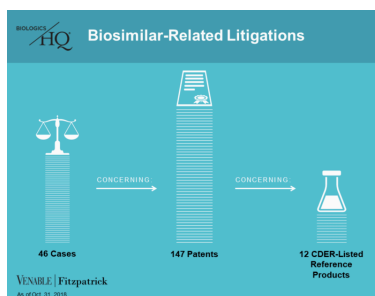
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



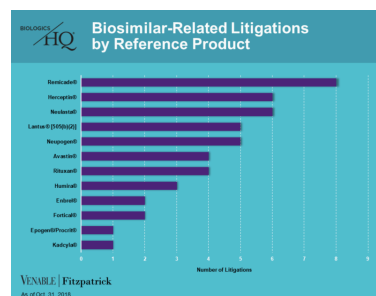
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

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