



July 6, 2018

[Forward](#) [Contact Us](#) [Visit Our Website](#) [Download PDF](#)

MONTHLY INJECTION



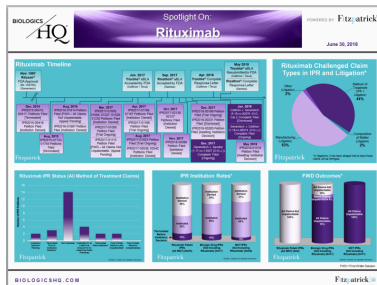
LATEST NEWS



Lost Profits Damages Based on Foreign Acts Under 35 U.S.C. § 271(f)(2)

By: Christopher Loh

On June 22, 2018, the United States Supreme Court issued a 7-2 decision in *WesternGeco LLC v. ION Geophysical Corp.*, No. 16-1011, holding that patent owners can recover lost profits damages under 35 U.S.C. § 271(f)(2) based on acts occurring outside the United States.



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 June 30, 2018.

The dashboard concerning adalimumab ([Humira[®]](#), [Amjevita[™]](#), and [Cyltezo[™]](#)) has also been updated with activity through June 30, 2018.

[Read More News](#)



UPDATES

IPRs

- **Humira[®] (adalimumab):** On June 5, 2018, institution was denied in IPR2018-00156 filed by [Sandoz](#).
- **Rituxan[®] (rituximab):**
 - On June 6, 2018, IPR2018-00231 filed by [Pfizer](#) was terminated prior to an institution decision after [Pfizer](#) requested dismissal with prejudice.
 - On June 14, 2018, institution was granted in IPR2018-00186 filed by [Pfizer](#).
- **Herceptin[®] (trastuzumab):** On June 18, 2018, institution was denied in IPR2018-00192 filed by [Samsung Bioepis](#).

LITIGATIONS

- **Herceptin[®] (trastuzumab):**
 - On June 11, 2018, final judgment of dismissal was entered in [Celltrion v. Genentech](#), Case No. 4:18-cv-00274 (N.D. Cal.).
 - On June 21, 2018, [Genentech](#) filed Case No. 1:18-cv-00924 (D. Del.) against [Amgen](#) related to [Amgen's](#) proposed biosimilar [ABP 980](#).
- **Rituxan[®] (rituximab):** On June 11, 2018, final judgment of dismissal was entered in [Celltrion v. Genentech](#), Case No. 4:18-cv-00276 (N.D. Cal.).

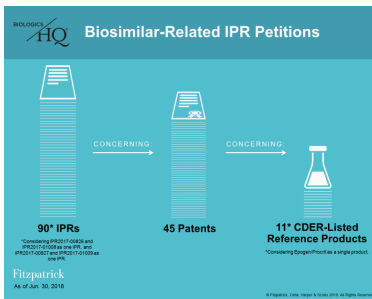
aBLA APPLICATIONS AND FDA ACTIVITY

- **ABP 980 (trastuzumab):** On June 1, 2018, [Amgen](#) and [Allergan](#) announced that they had received a Complete Response Letter from the FDA related to their application for [ABP-980](#), a proposed biosimilar of [Genentech's Herceptin[®]](#) (trastuzumab).
- **Insulin Glargine:** On June 2, 2018, It was announced that [Mylan](#) and [Biocon](#) had received a Complete Response Letter from the FDA related to their 505(b)(2) application for [insulin glargine](#), a follow-on product of [Sanofi's Lantus[®]](#) (insulin glargine).

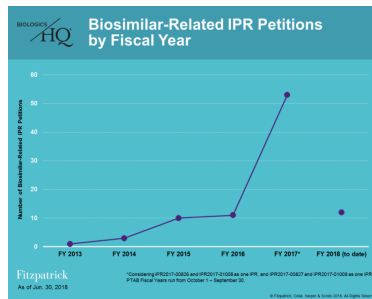
- **Fulphila™ (pegfilgrastim-jmdb):** On June 4, 2018, the FDA approved Mylan and Biocon's Fulphila™, a biosimilar of Amgen's Neulasta® (pegfilgrastim).
- **Herzuma® (trastuzumab):** On June 18, 2018, Celltrion announced that it had resubmitted its application for Herzuma®, a proposed biosimilar of Genentech's Herceptin® (trastuzumab).

STATISTICS

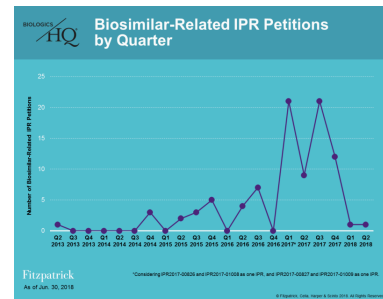
Biosimilar-Related IPR Petitions



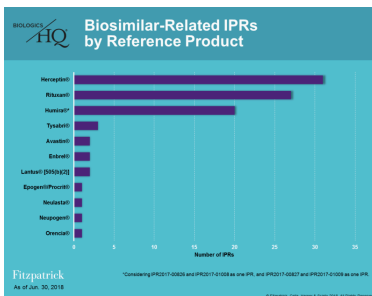
Biosimilar-Related IPR Petitions by Fiscal Year



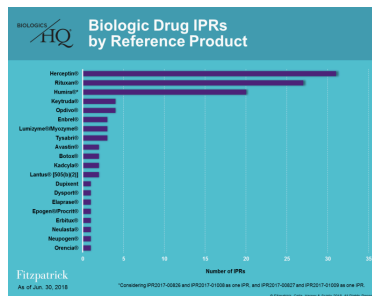
Biosimilar-Related IPR Petitions by Quarter



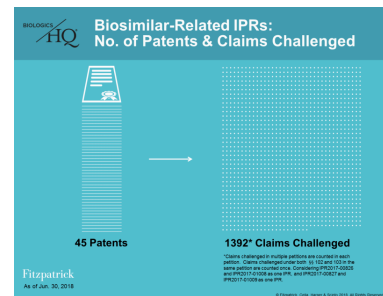
Biosimilar-Related IPRs by Reference Product



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

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



© Copyright 2018 Fitzpatrick, Cella, Harper & Scinto. All Rights Reserved. Attorney Advertising. Prior results do not guarantee a similar outcome. BiologicsHQ Bi-Weekly Injection is published for informational purposes only. This newsletter provides no legal advice, does not create an attorney-client relationship, and neither the information nor any opinion expressed constitutes a solicitation for business. Links or references to third party sites or resources are provided for informational purposes only.

To unsubscribe or change subscription options please [click here](#).