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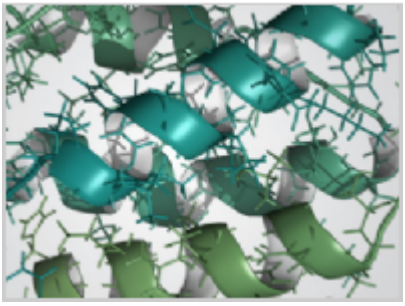
December 9, 2019

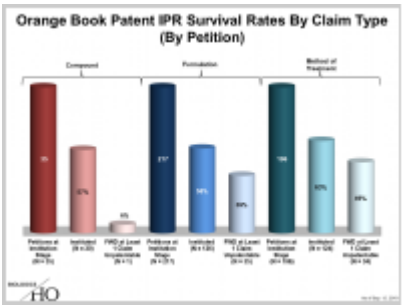
LATEST NEWS



Will Authorized Biologics Disrupt the Market for Biosimilars?

By: Ha Kung Wong and Erica Norey

In an article for Biosimilar Development, Ha Kung Wong and Erica Norey discuss the potential impact of authorized biologics on the developing biosimilars market. The article draws upon experience with authorized generics in the small molecule drug market and discusses the role interchangeability designations for biosimilars could play in prompting authorized biologic development.

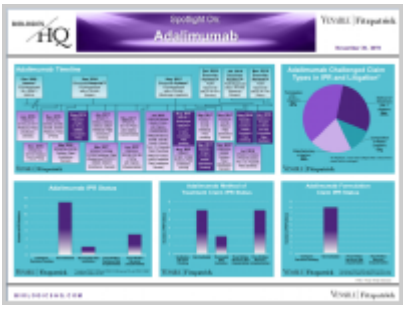


Seven Years of Orange Book Patent IPRs: Where Are We Now?

By: Corinne Atton and April Breyer Menon

Heralded as a less expensive, faster way to challenge patents, inter partes review (IPR) before the US Patent Trial and Appeal Board (PTAB) has proven remarkably popular. IPR was first available on September 12, 2012, and within days, the first petitions challenging patents listed in the U.S. Food and Drug Administration Orange Book (small molecule drug patents) were filed. Seven years on and close to 500 such petitions have been filed. The data is insightful: the number of petitions filed per fiscal year peaked in 2015 and has since fallen; the institution rate has dropped from 87% in fiscal year 2013 to 62% in fiscal year 2019; survival rates vary by claim type – with compound claims, unsurprisingly, proving the strongest; novelty challenges have been few and generally unsuccessful; and 63% of final written decisions have been appealed to the U.S. Court of Appeals for the Federal Circuit, which has affirmed almost all of them.

Spotlight On: Biosimilar Litigations



Spotlight On: Rituxan® (rituximab) / Truxima® (rituximab-abbs) / Ruxience® (rituximab-pvvr)

Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo® (adalimumab-adbm) / Hyrimoz™ (adalimumab-adaz) / Hadlima™ (adalimumab-bwwd) / Abrilada™ (adalimumab-afzb)

Spotlight On: Enbrel® (etanercept) / Erelzi® (etanercept-szzs) / Eticovo™ (etanercept-ykro)

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, and Abrilada™), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) have been updated with activity through November 30, 2019.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through November 30, 2019.

Read More News

UPDATES

IPRs and PGRs

Lantus® (insulin glargine recombinant):

- On November 19, 2019, in ***Mylan*** *v.* ***Sanofi***, Fed. Cir. Appeal No. 19-1368 and consolidated appeal 19-1369, the Federal Circuit affirmed the PTAB's determinations that all challenged claims were unpatentable in IPR2017-01526 and IPR2017-01528.

Litigations

Ultomiris® (ravulizumab-cwvz):

- On November 12, 2019, **Chugai** filed Case No. 1:19-cv-02120 (D. Del.) against **Alexion**.

Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):

- On November 15, 2019, the Court dismissed ***Amgen*** *v.* ***Accord***, Case No. 0:18-cv-61828 (S.D. Fla.) at the parties' request.

Neupogen® (filgrastim):

- On November 25, 2019, the Court dismissed ***Amgen*** *v.* ***Kashiv BioSciences***, Case No. 2:18-cv-03347 (D.N.J.) at the parties' request.

Amjevita™ (adalimumab-atto):

- On November 26, 2019, the Court dismissed ***Coherus*** *v.* ***Amgen***, Case No. 1:19-cv-00139 (D. Del.) at the parties' request.

aBLA Applications and FDA Activity

Ziextenzo® (pegfilgrastim-bmez):

- On November 4, 2019, the FDA approved **Sandoz's** **Ziextenzo® (pegfilgrastim-bmez)**, a biosimilar of **Amgen's** **Neulasta® (pegfilgrastim)**. On November 15, 2019, **Sandoz** launched **Ziextenzo®**.

Truxima® (rituximab-abbs):

- On November 7, 2019, **Celltrion** and **Teva** announced **Truxima® (rituximab-abbs)**, a biosimilar of **Genentech's** **Rituxan® (rituximab)**, would be launched on November 11, 2019 at a 10% discount.

Abrilada™ (adalimumab-afzb):

- On November 15, 2019, the FDA approved **Pfizer's** **Abrilada™ (adalimumab-afzb)**, a biosimilar of **AbbVie's** **Humira® (adalimumab)**.

SB8 (bevacizumab):

- On November 19, 2019, **Samsung Bioepis** announced that the FDA accepted for review its aBLA for **SB8 (bevacizumab)**, a proposed biosimilar of **Genentech's** **Avastin® (bevacizumab)**.

CDER Purple Book Updates

Reblozyl® (luspatercept-aamt):

- On November 8, 2019, the FDA approved **Celgene's** **Reblozyl® (luspatercept-aamt)**.

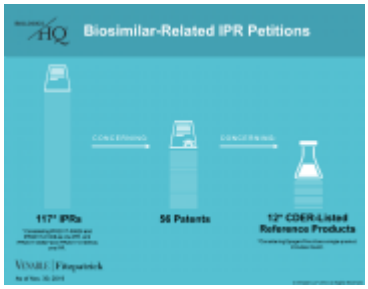
Non-U.S. Biosimilars / Follow-On Biologics

Remsima®SC (subcutaneous infliximab):

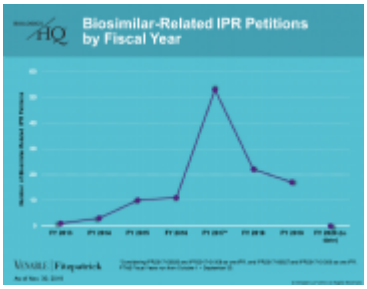
- On November 25, 2019, **Celltrion** announced it received approval in the E.U. for its subcutaneous version of **infliximab**. This is the world's first subcutaneous formulation of **infliximab**. The intravenous formulation of **Remsima®** (called **Inflectra®** in the U.S.) is a biosimilar of **Janssen's** **Remicade® (infliximab)**.

STATISTICS

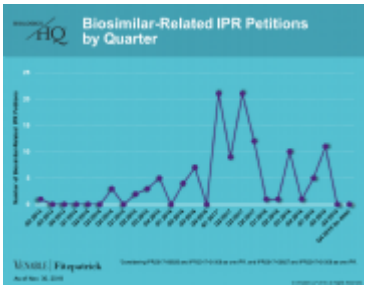
Biosimilar-Related IPR Petitions	Biosimilar-Related IPR Petitions by Fiscal Year	Biosimilar-Related IPR Petitions by Quarter



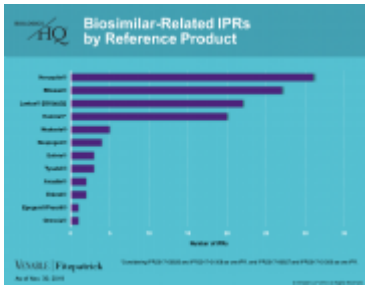
[Biosimilar-Related IPRs by Reference Product]



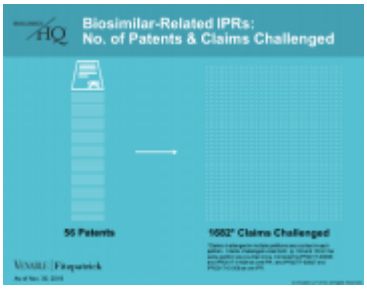
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



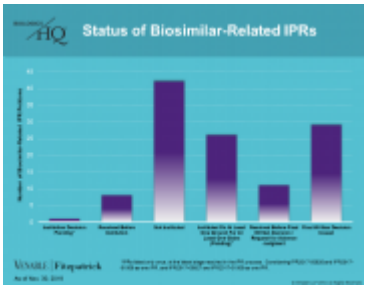
[Status of Biosimilar-Related IPRs]



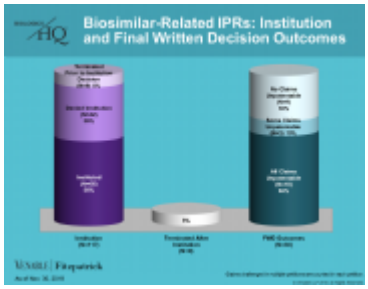
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



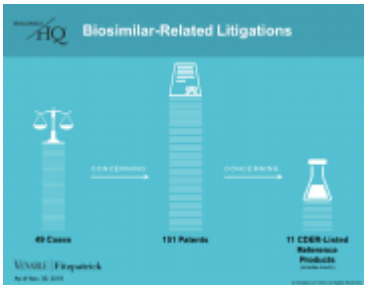
[Biosimilar-Related Litigations]



[Biosimilar-Related Litigations by Reference Product]

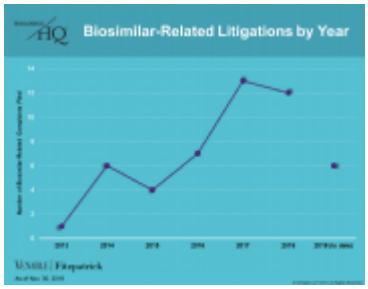


[Biosimilar-Related Litigations by Year]

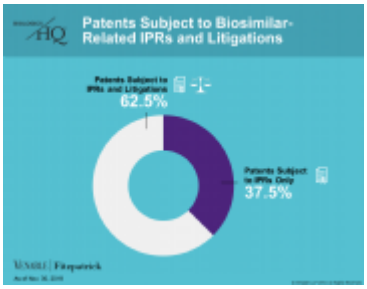


[Patents Subject to Biosimilar-Related IPRs and Litigations]

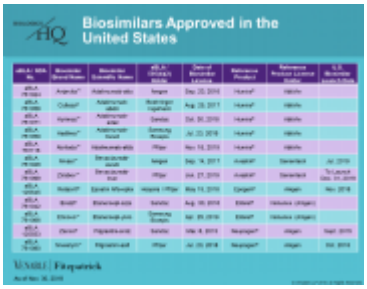
[Biosimilars Approved in the United States]



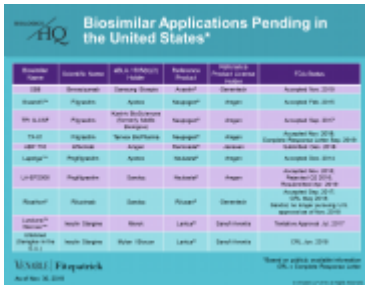
[Biosimilar Applications Pending in the United States]

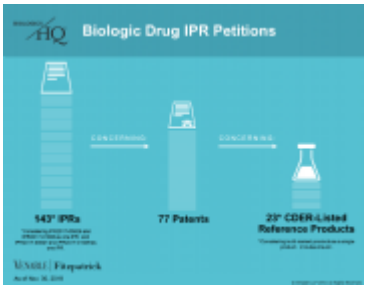


[Biologic Drug IPR Petitions]

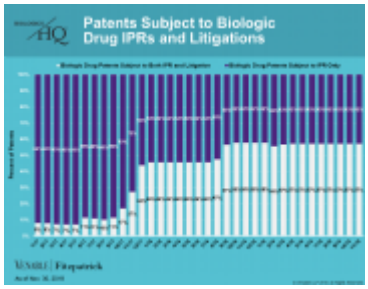


[Biologic Drug IPRs by Reference Product]

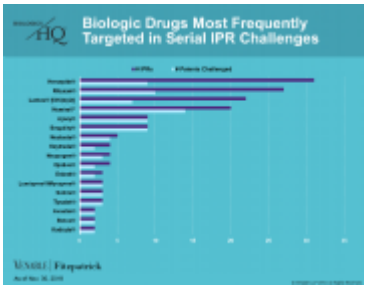




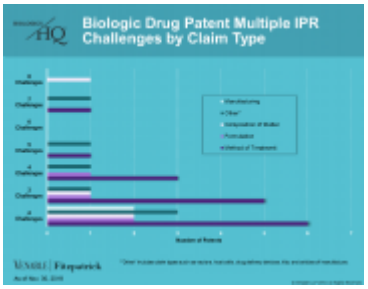
Patents Subject to Biologic Drug IPRs and Litigations



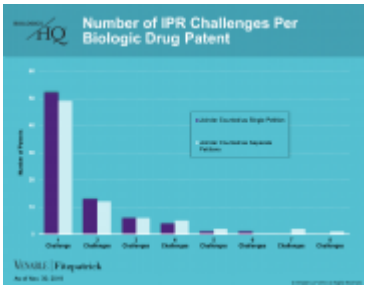
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

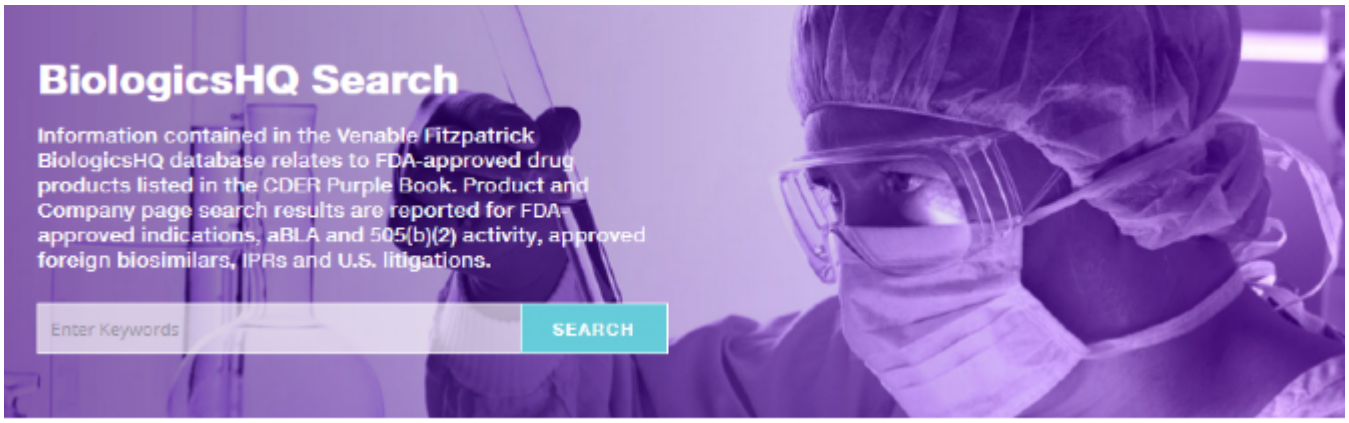


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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