BIOLOGICS HQ

VENABLE | Fitzpatrick

November 14, 2022

LATEST NEWS

Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria®(pegfilgrastim-apgf)

Spotlight On: Herceptin® (trastuzumab) / Ogivri® (trastuzumab-dkst) / Herzuma® (trastuzumab-pkrb) / Ontruzant® (trastuzumab-dttb) / Trazimera® (trastuzumab-qyyp) / Kanjinti® (trastuzumab-anns)

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) / Hulio® (adalimumab-fkjp) / Yusimry™ (adalimumab-aqvh)

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

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine) / Semglee® (insulin glargine-yfgn) / Rezvoglar™ (insulin glargine-aglr)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning pegfilgrastim (Neulasta®, Lapelga™, Ziextenzo®,

Udenyca®, Fulphila®, Nyvepria®, MSB11455, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri®, Herzuma®, Ontruzant®, Trazimera®, Kanjinti®, and EG12014), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™, Hulio®, and Yusimry™), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus®/ Lantus® SoloSTAR®, Basaglar®, Semglee®, and Rezvoglar™) have been updated with activity through October 31, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through October 31, 2022.

Read More News

UPDATES

IPRs and PGRs

Actemra® (tocilizumab):

- On October 4, 2022, **Fresenius Kabi** and **Chugai Seiyaku Kabushiki Kaisha** requested to terminate IPR2021-01024, IPR2021-01025, IPR2021-01288, IPR2021-01336, IPR2021-01542, IPR2022-00201, and IPR2022-01065 due to settlement.

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On October 14, 2022, the PTAB instituted **Eli Lilly's** IPR2022-00796 against **Teva.**

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On October 25, 2022, the PTAB issued a final written decision finding all challenged claims unpatentable in ***Regeneron*** *v.* ***Novartis*** IPR2021-00816.

Eylea® (aflibercept):

- On October 28, 2022, **Mylan** filed IPR2023-00099 against **Regeneron**.

Litigations

Forteo® (teriparatide):

- On October 14, 2022, **Eli Lilly** filed Case No. 1:22-cv-01355 (D. Del.) against **Dr. Reddy's**.

aBLA Applications and FDA Activity

Cimerli™ (ranibizumab-eqrn):

- On October 3, 2022, **Coherus** announced the launch of **Cimerli™ (ranibizumab-eqrn)**, an interchangeable biosimilar of **Genentech's Lucentis® (ranibizumab)**.

Alymsys® (bevacizumab-maly):

- On October 3, 2022, **Amneal** and **mAbxience** announced the launch of **Alymsys® (bevacizumab-maly)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**.

CDER Purple Book Updates

Imjudo® (tremelimumab-actl):

- On October 21, 2022, the FDA approved **AstraZeneca's Imjudo® (tremelimumab-actl)**.

Tecvayli™ (teclistamab-cqyv):

- On October 25, 2022, the FDA approved **Janssen Biotech's Tecvayli™ (teclistamab-cqyv).**

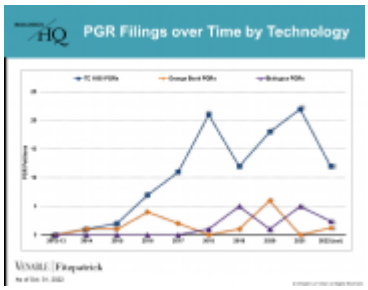
Non-U.S. Biosimilars / Follow-On Biologics

LucenBS (ranibizumab):

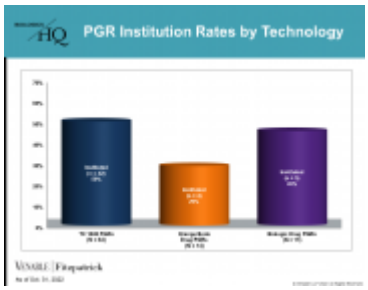
- On October 21, 2022, **Chong Kun Dang Pharmaceutical** announced the approval of **LucenBS (ranibizumab)**, a biosimilar of **Genentech's Lucentis® (ranibizumab)**, in South Korea.

STATISTICS

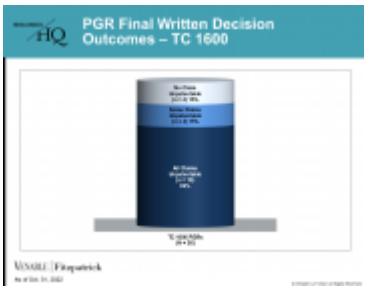
PGR Filings over Time by Technology



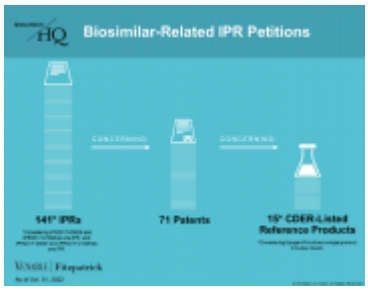
PGR Institution Rates by Technology



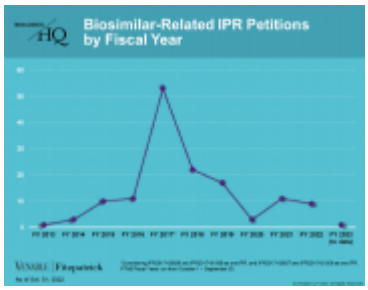
PGR Final Written Decision Outcomes - TC 1600



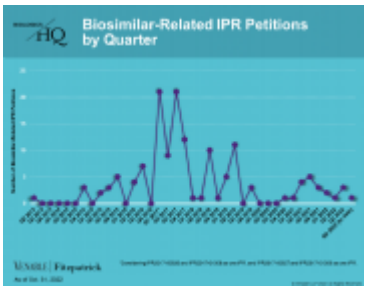
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



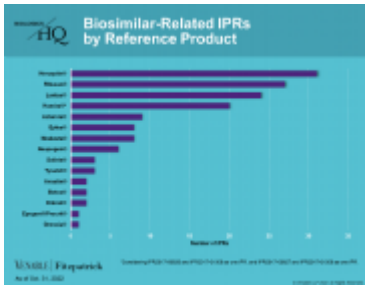
Biosimilar-Related IPR Petitions by Quarter



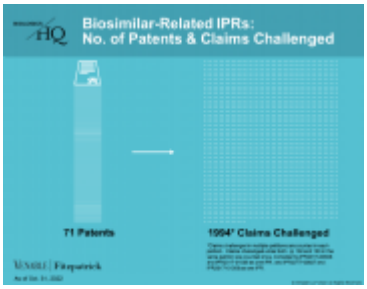
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

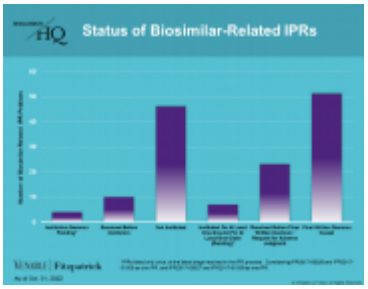
Status of Biosimilar-Related IPRs



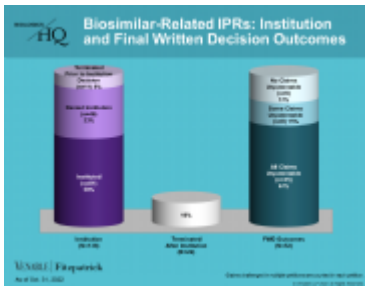
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



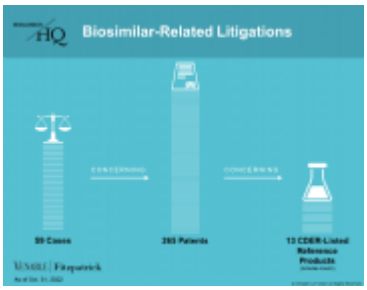
Biosimilar-Related Litigations



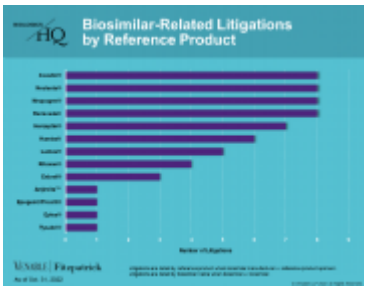
Biosimilar-Related Litigations by Reference Product



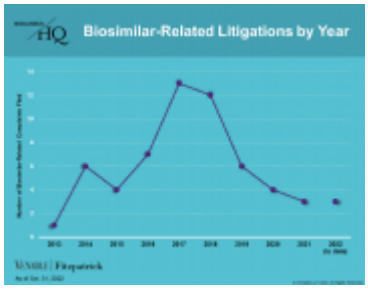
Biosimilar-Related Litigations by Year



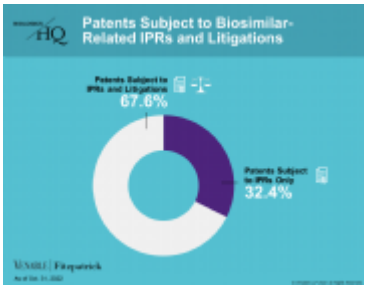
Patents Subject to Biosimilar-Related IPRs and Litigations



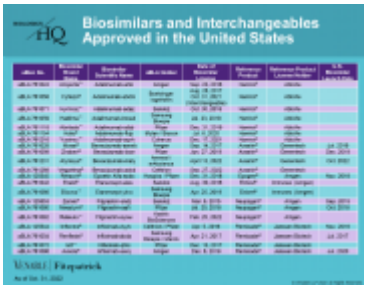
Biosimilars and Interchangeables Approved in the United States



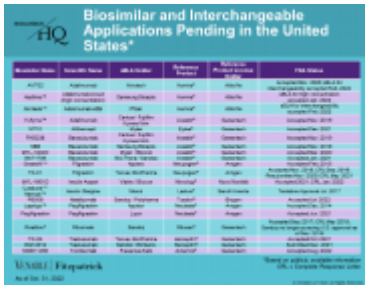
Biosimilar and Interchangeable Applications Pending in the United States



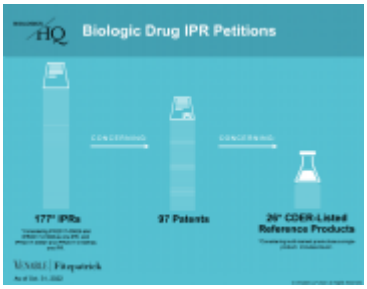
Biologic Drug IPR Petitions



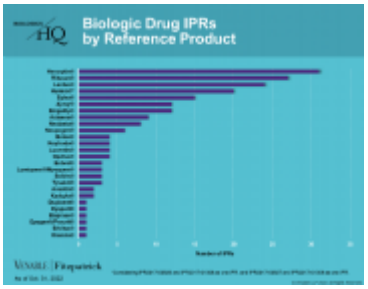
Biologic Drug IPRs by Reference Product



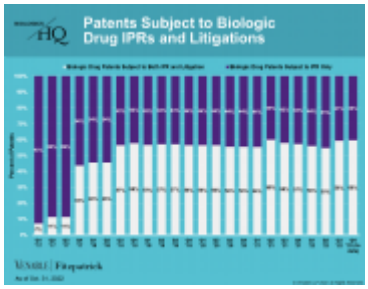
Patents Subject to Biologic Drug IPRs and Litigations

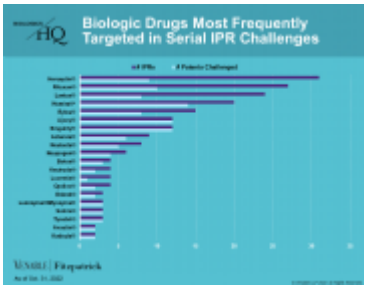


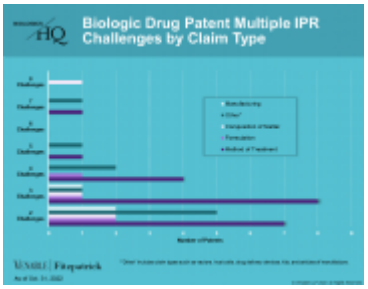
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



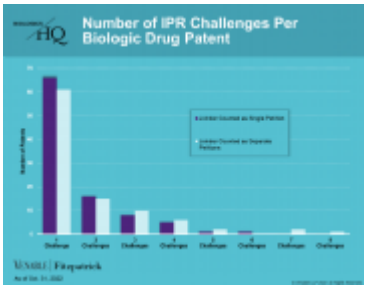
Biologic Drug Patent Multiple IPR Challenges by Claim Type

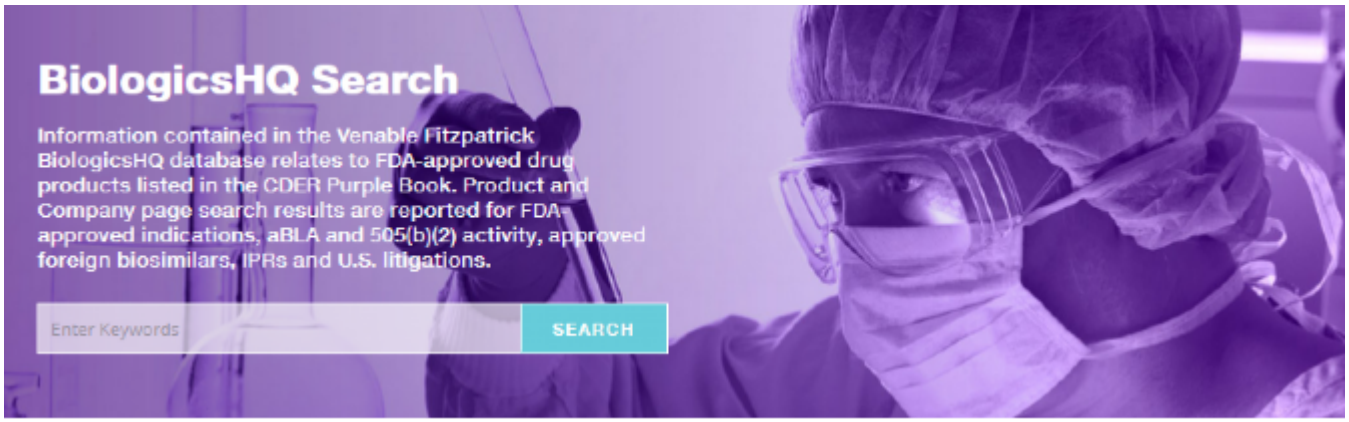






Number of IPR Challenges Per Biologic Drug Patent





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