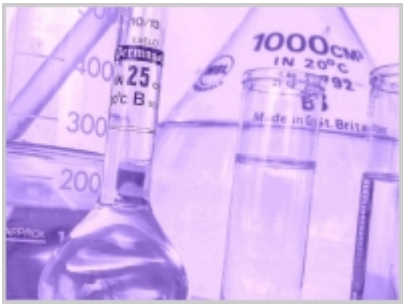
BIOLOGICS HQ

VENABLE | Fitzpatrick

March 8, 2022

LATEST NEWS



A Survey of PGR Outcomes

By: April Breyer Menon and Robert S. Schwartz

***Inter Partes* reviews (IPRs) and post grant reviews (PGRs) are procedures for challenging the validity of patents at the U.S. Patent and Trademark Office (PTO). IPRs and PGRs went into effect as a result of the America Invents Act (AIA) on September 15, 2012, and were intended to replace *inter partes* reexamination.**

In the nine years since their inception, hundreds of PGRs and thousands of IPRs have been filed. When the procedures were initiated, institution and invalidation rates were high, leading Chief Judge Rader to call the PTAB "death squads" for patents. Much has changed since then with institution rates falling, claim construction standards changing (from the broadest reasonable interpretation to the *Phillips v. AWH Corp.* standard used in federal courts), an increase in allowance of motions to amend, and an increase in discretionary denials based on parallel litigations.

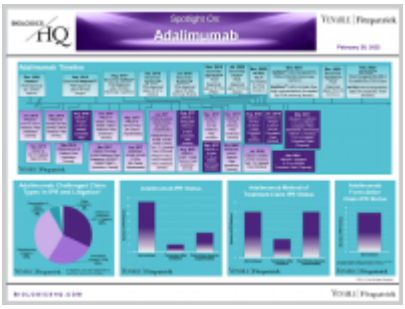
While most of the focus on post grant proceedings at the PTAB has been on IPRs, PGRs are increasingly being filed. Petitioners considering post grant reviews have a wealth of data from the large number of IPR decisions to examine statistical trends. The same is not true for PGRs given the fewer number of PGRs filed to date.

To address this, we analyzed PGR outcomes for the nine years since their inception through December 31, 2021 and compared them to IPR outcomes and 35 U.S.C. § 112 challenge outcomes in district court litigations. With a focus on pharmaceutical and biotechnology patents, we analyzed PGR outcomes for patents on small molecule drugs listed in the FDA's "Orange Book," biologic drugs listed in the Center for Drug Evaluation and Research (CDER) "Purple Book," and patents falling under the PTO's Tech Center 1600 (TC 1600), which includes patents for biotechnology, chemistry, small molecule drugs, and a larger set of biologics that also includes drugs regulated by the Center for Biologics Evaluation and Research (CBER) such as vaccines.

What Does USPTO Director Review Really Change?

By: Ha Kung Wong and April Breyer Menon

Ha Kung Wong and April Breyer Menon discuss the practical implications of the U.S. Supreme Court's ruling in U.S. v. Arthrex, including the outcomes of requests for director review, time to decision on the requests, and potential future issues with the director review process.



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 February 28, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through February 28, 2022.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On February 9, 2022, the PTAB instituted **Celltrion's** IPR2022-00257 and **Apotex's** IPR2022-00301 against **Regeneron** and granted joinder of both IPRs with IPR2021-00880.
- On February 9, 2022, the PTAB instituted **Celltrion's** IPR2022-00258 and **Apotex's** IPR2022-00298 against **Regeneron** and granted joinder of both IPRs with IPR2021-00881.

Botox® (onabotulinumtoxinA):

- On February 18, 2022 **Revance** filed requests for rehearings of the decisions denying institution of IPR2021-01203 and IPR2021-01204.

Actemra® (tocilizumab):

- On February 21, 2022, **Celltrion** filed IPR2022-00578 and IPR2022-00579 against **Chugai Seiyaku Kabushiki Kaisha**, **Hoffmann-La Roche**, and **Genentech**.
- On February 23, 2022, the PTAB instituted **Fresenius Kabi's** IPR2021-01288 and IPR2021-01336 against **Chugai Seiyaku Kabushiki Kaisha** and **Hoffmann-La Roche**.

Litigations

Hemlibra® (emicizumab-kxwh):

- On February 10, 2022, **Baxalta** filed Appeal No. 22-1461, appealing the summary judgment decision on remand in 1:17-cv-00509 (D. Del.).

---

aBLA Applications and FDA Activity

Abrilada™ (adalimumab-afzb):

- On February 25, 2022, **Pfizer** announced the FDA had accepted its sBLA for interchangeability status for **Abrilada™ (adalimumab-afzb)**, which was approved as a biosimilar of **AbbVie's Humira® (adalimumab)** in November 2019.

Releuko™ (filgrastim-ayow):

- On February 25, 2022, the FDA approved **Kashiv BioScience's Releuko™ (filgrastim-ayow)**, a biosimilar of **Amgen's Neupogen® (filgrastim)**.

AVT02 (adalimumab):

- On February 28, 2022, **Alvotech** announced the FDA had accepted for review its sBLA for interchangeability status for **AVT02 (adalimumab)**, a proposed high-concentration, citrate-free biosimilar of **AbbVie's Humira® (adalimumab)**. **Alvotech** submitted an aBLA for a biosimilar version of **AVT02** in November 2020 and is awaiting FDA approval.

CDER Purple Book Updates

Enjaymo™ (sutimlimab-jome):

- On February 4, 2022, the FDA approved **Bioverativ's Enjaymo™ (sutimlimab-jome)**.

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

Ontruzant® (trastuzumab-dttb):

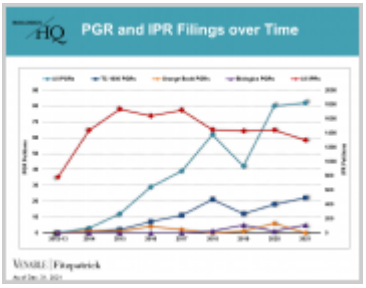
- On February 2, 2022, **Samsung Bioepis** announced the approval of **Ontruzant® (trastuzumab-dttb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, in Canada.

Yuflyma™ (adalimumab):

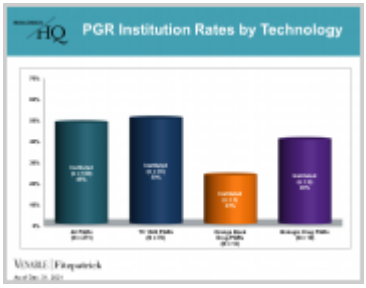
- On February 22, 2022, **Celltrion** announced the approval of **Yuflyma™ (adalimumab)**, a high-concentration, citrate-free biosimilar of **AbbVie's Humira® (adalimumab)**, in the E.U. The lower concentraion version of **Yuflyma™** was approved in the E.U. in February 2021.

STATISTICS

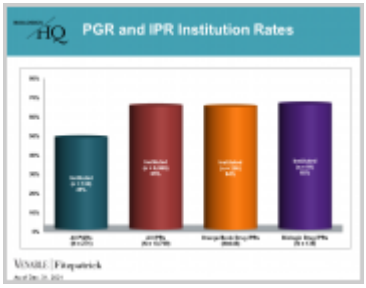
PGR and IPR Filings over Time



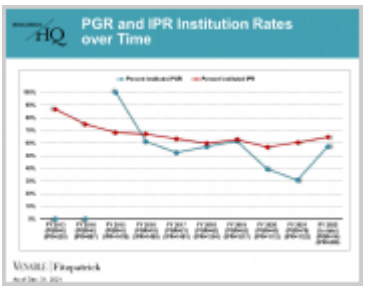
PGR Institution Rates by Technology



PGR and IPR Institution Rates

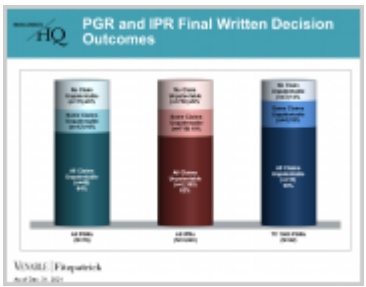


PGR and IPR Institution Rates over TIme



PGR Institution Rates by Invalidity Challenge Type

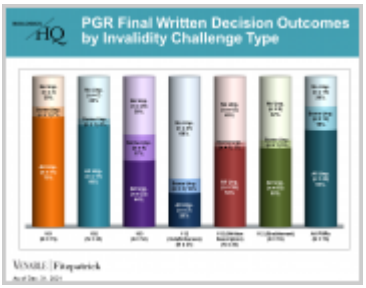
PGR and IPR Final Written Decision Outcomes



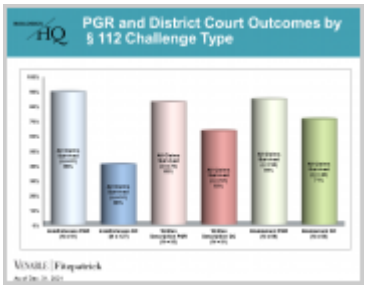
PGR Final Written Decision Outcomes by Invalidity Challenge Type

PGR and District Court Outcomes by § 112 Challenge Type

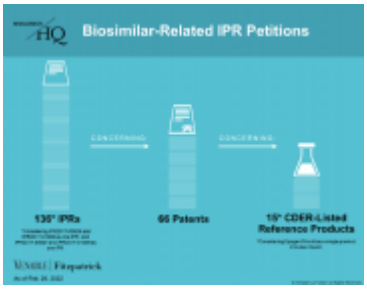
Biosimilar-Related IPR Petitions



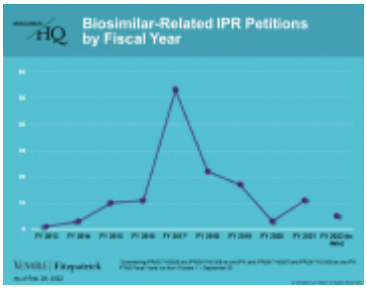
[Biosimilar-Related IPR Petitions by Fiscal Year]



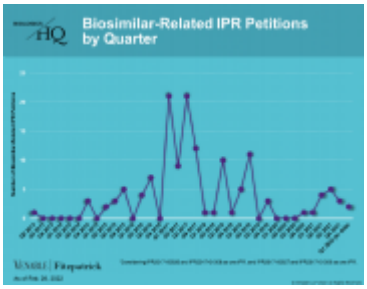
[Biosimilar-Related IPR Petitions by Quarter]



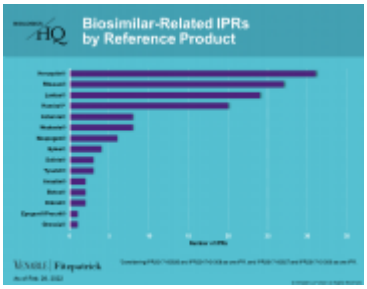
[Biosimilar-Related IPRs by Reference Product]



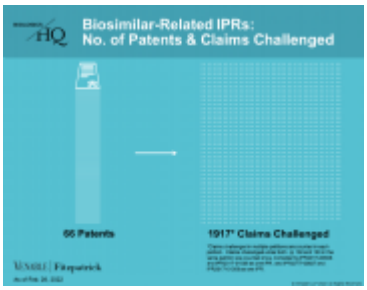
[Biosimilar-Related IPRs: Number of Patents and Claims Challenged]



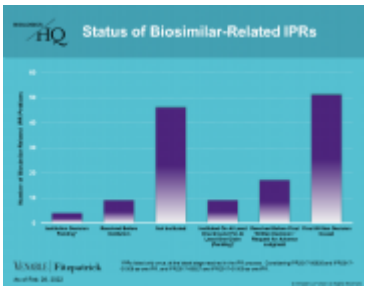
[Status of Biosimilar-Related IPRs]



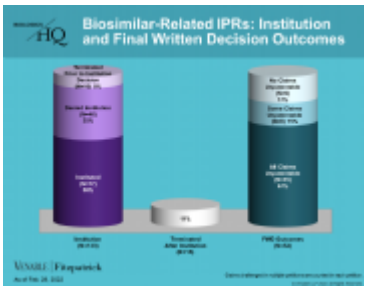
[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



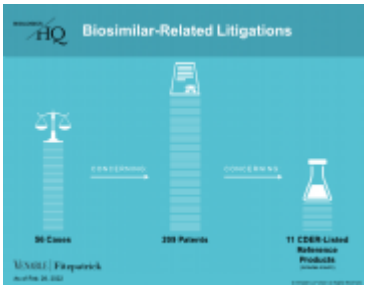
[Biosimilar-Related Litigations]



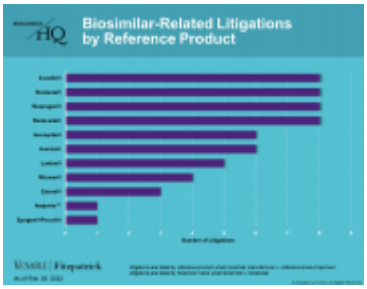
[Biosimilar-Related Litigations by Reference Product]



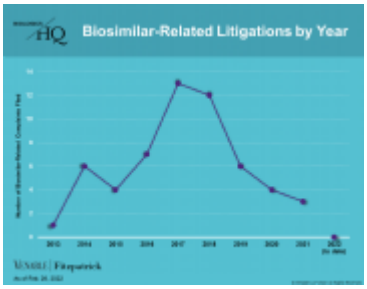
[Biosimilar-Related Litigations by Year]



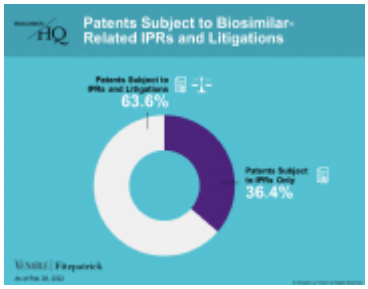
[Patents Subject to Biosimilar-Related IPRs and Litigations]



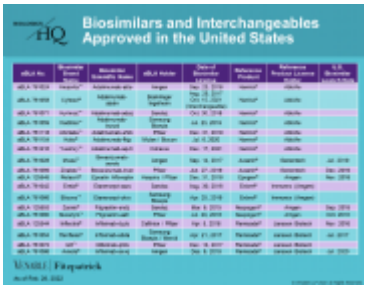
[Biosimilars and Interchangeables Approved in the United States]



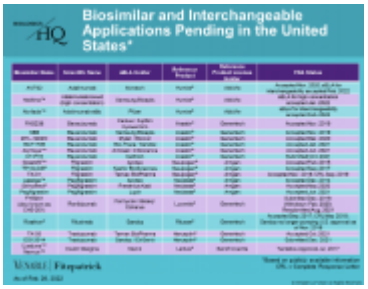
[Biosimilar and Interchangeable Applications Pending in the United States]



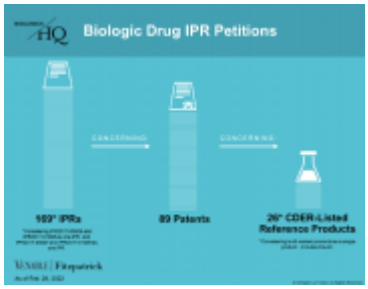
[Biologic Drug IPR Petitions]



[Biologic Drug IPRs by Reference Product]

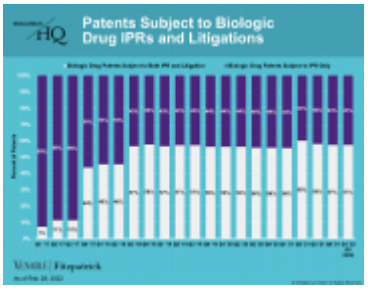


[Patents Subject to Biologic Drug IPRs and Litigations]

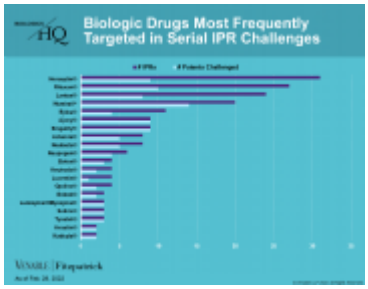


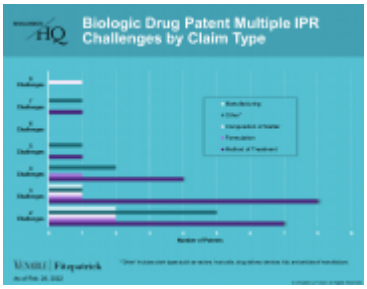
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]

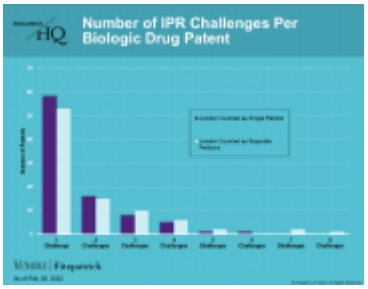
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

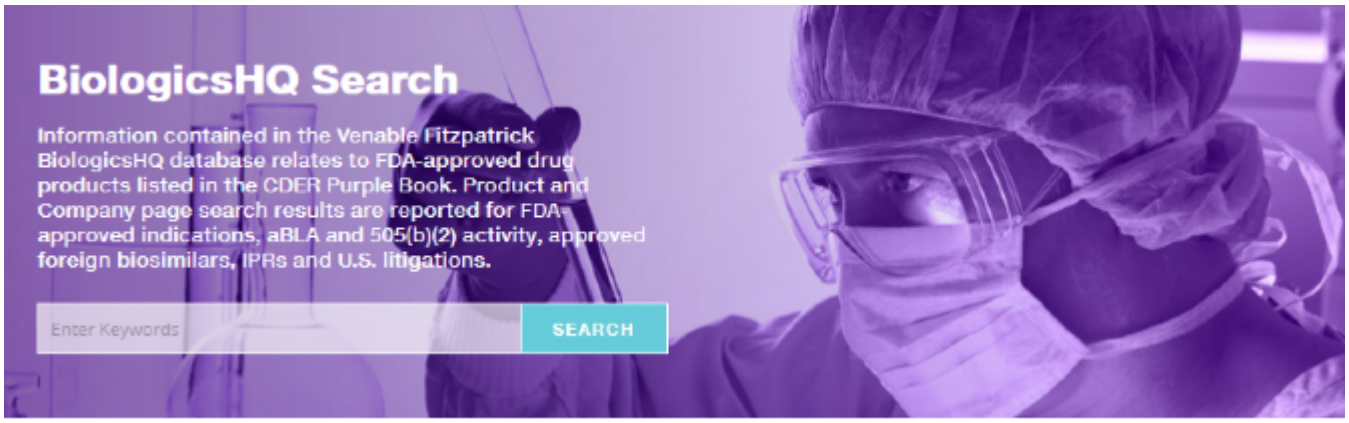


[Number of IPR Challenges Per Biologic Drug Patent]









Contact the BiologicsHQ Team

Robert S. Schwartz, Ph.D.
Chair
+1 212.218.2298
RSchwartz@Venable.com

Ha Kung Wong
Partner
+1 212.218.2571
HWong@Venable.com