BIOLOGICS HQ

VENABLE LLP

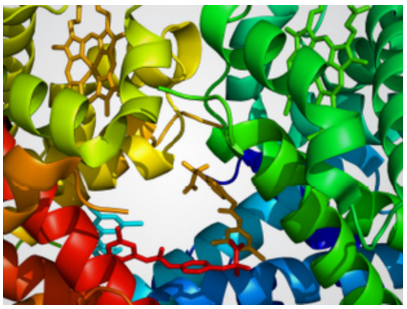
June 10, 2024

LATEST NEWS

FDA Approves High-Concentration Formulation of Boehringer Ingelheim's Humira® Biosimilar Cyltezo® (adalimumab-adbm)

By: Monica Chou and Robert S. Schwartz, Ph.D.

According to a May 1, 2024 press release, the high-concentration (100 mg/mL), citrate-free formulation of Boehringer Ingelheim's Cyltezo® (adalimumab-adbm) was approved by the FDA as interchangeable with AbbVie's Humira® (adalimumab) to treat multiple chronic inflammatory diseases.



Regeneron Files Second BPCIA Complaint Against Celltrion's Proposed EYLEA® Biosimilar CT-P42

By: Robert S. Schwartz, Ph.D.

On May 17, 2024, Regeneron filed a second infringement litigation against Celltrion's proposed EYLEA® (aflibercept) biosimilar CT-P42, Case No. 1:24-cv-00053 (N.D.W. Va.). Regeneron's Complaint listed 25 patents, including 8 patents with method of treatment claims, 5 patents with formulation/composition claims, 4 patents with composition of matter claims, 12 patents with manufacturing claims, one patent with device claims, and one patent with packaging claims.

FDA Approves First Two Interchangeable EYLEA® Biosimilars – Biocon's Yesafili™ (aflibercept-jbvf) and Samsung Bioepis's Opuviz™ (aflibercept-yszy)

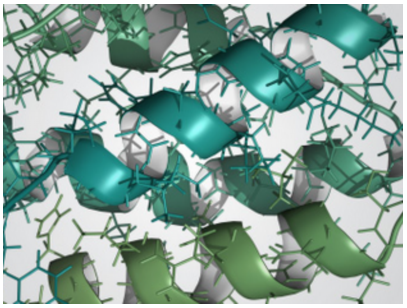
By: Robert S. Schwartz, Ph.D.

On May 20, 2024, the FDA approved the first two interchangeable biosimilars of Regeneron's EYLEA® (aflibercept) – Biocon Biologics and Mylan's Yesafili™ (aflibercept-jbvf) and Samsung Bioepis's Opuviz™ (aflibercept-yszy).

The First Biosimilar Disputes at the Unified Patent Court (UPC)

By: Dameneh Morsali, Ph.D. and Robert S. Schwartz, Ph.D.

The first two biosimilar disputes were filed in Europe's Unified Patent Court (UPC) in March and April. On March 19, 2024, Alexion Pharmaceuticals (a subsidiary of AstraZeneca specializing in rare disease treatment) filed for provisional measures in the Hamburg Local Division against Amgen and Samsung Bioepis, asserting patent application EP 3167888 claiming antibodies corresponding to Alexion's blockbuster Soliris® (eculizumab). On April 9, 2024, Novartis and Genentech applied to the Düsseldorf Local Division of the UPC for provisional measures against Celltrion's proposed Xolair® (omalizumab) biosimilar CT-P39.



Fresenius Kabi Announces FDA Acceptance of aBLA for Prolia® / Xgeva® (denosumab) Biosimilar Candidate FKS518

By: Robert S. Schwartz, Ph.D.

On May 27, 2024, Fresenius Kabi announced the FDA acceptance of its aBLA for FKS518 (denosumab), a proposed biosimilar of Amgen's Prolia® / Xgeva® (denosumab). This is the third publicly announced aBLA for a Prolia® / Xgeva® biosimilar.

Amgen Files BPCIA Lawsuit Against Celltrion's Proposed Prolia® / Xgeva® (Denosumab) Biosimilar CT-P41

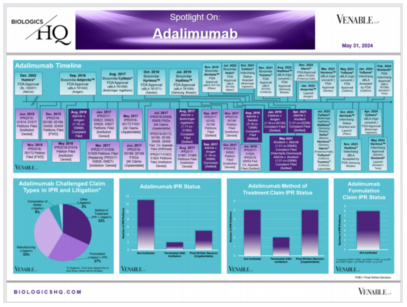
By: Robert S. Schwartz, Ph.D.

On May 28, 2024, Amgen filed a BPCIA litigation, Case No. 1:24-cv-06497 (D.N.J.), against Celltrion's proposed Prolia® / Xgeva® (denosumab) biosimilar CT-P41 alleging infringement of 29 of Amgen's patents, including one patent with formulation/composition claims, three patents with composition of matter claims, and 27 patents with manufacturing claims.

FDA Approves First Interchangeable Biosimilar of Alexion's Soliris® (eculizumab) – Amgen's Bkemv™ (eculizumab-aeeb)

By: Robert S. Schwartz, Ph.D.

On May 28, 2024, the FDA approved Amgen's Bkemv™ (eculizumab-aeeb), the first interchangeable biosimilar of Alexion's Soliris® (eculizumab). Bkemv™ was approved with a skinny label for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS).



Spotlight On: Actemra® (tocilizumab) / Tofidence™ (tocilizumab-bavi) / Tyenne® (tocilizumab-aazg)

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

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

Spotlight On: Biosimilar Litigations

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

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) / Idacio® (adalimumab-aacf) / Yuflyma® (adalimumab-aaty) / Simlandi® (adalimumab-ryvk)

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 tocilizumab (Actemra®, Tofidence™, Tyenne®, and CT-P47), pegfilgrastim (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria®, Fylnetra™, Stimufend®, Lapelga™, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri®, Herzuma®, Ontruzant®, Trazimera®, Kanjinti®, Hercessi™, TX-05, and EG12014), rituximab (Rituxan®, Truxima®, Ruxience®, and Riabni™), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz®, Hadlima™, Abrilada™, Hulio®, Yusimry™, Idacio®,

Yuflyma®, and Simlandi®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, Semglee®, and Rezvoglar™) have been updated with activity through May 31, 2024.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through May 31, 2024.

Read More News

UPDATES

IPRs and PGRs

Enhertu® (fam-trastuzumab deruxtecan-nxki) / Adcetris® (brentuximab vedotin):

- On May 28, 2024, **Seagen** filed CAFC Appeal No. 24-1878 appealing the final written decision in PGR2021-00030 finding all challenged composition of matter claims of U.S. Patent No. 10,808,039 unpatentable.

Litigations

Soliris® (eculizumab):

- On May 6, 2024, the Court denied **Alexion's** motion for a preliminary injunction against **Samsung Bioepis's SB12 (eculizumab)**, a proposed biosimilar of **Alexion's Soliris® (eculizumab)**, in Case No. 1:24-cv-00005 (D. Del.). The Court found that each of the asserted claims for which **Alexion** sought a preliminary injunction (U.S. Patent No. 9,447,176, claim 1 and U.S. Patent No. 10,590,189, claim 1) faced a substantial question of validity, and therefore **Alexion** failed to demonstrate a reasonable likelihood of success.
  - On May 20, 2024, **Alexion** filed CAFC Appeal No. 24-1829, appealing the decision denying the preliminary injunction.

Eylea® (aflibercept):

- On May 17, 2024, **Regeneron** filed Case No. 1:24-cv-00053 (N.D.W. Va.) against **Celltrion** alleging infringement of 25 patents by **Celltrion's** proposed biosimilar **CT-P42**.
- On May 17, 2024, the Court granted Temporary Restraining Orders against **Mylan** / **Biocon's Yesafili™ (aflibercept-jbfv)** in Case No. 1:22-cv-00061 (N.D.W. Va.) and against **Samsung Bioepis's Opuviz™ (aflibercept-yszy)** in Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.). On May 30, 2024, the Court extended the Temporary Restraining Orders through June 14, 2024.

Prolia® / Xgeva® (denosumab):

- On May 28, 2024, **Amgen** filed Case No. 1:24-cv-06497 (D.N.J.) alleging infringement of 29 patents by **Celltrion's** proposed **Prolia® / Xgeva® (denosumab)** biosimilar **CT-P41 (denosumab)**.

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aBLA Applications and FDA Activity

Hyrimoz® (adalimumab-adaz):

- On May 13, 2024, the FDA approved **Sandoz's** sBLA for **Hyrimoz® (adalimumab-adaz)**, deeming it interchangeable with **AbbVie's Humira® (adalimumab)** for the 10 mg/0.1 mL, 20 mg/0.2 mL, and 80 mg/0.8 mL

strengths. A provisional determination was also made for 40mg/0.4 mL strength due to interchangeable exclusivity of **Alvotech** and **Teva's Simlandi® (adalimumab-ryvk)**.

Yesafili™ (aflibercept-jbvf):

- On May 20, 2024, the FDA approved **Mylan** and **Biocon's Yesafili™ (aflibercept-jbfv)** as an interchangeable biosimilar of **Regeneron's Eylea® (aflibercept)**.

Opuviz™ (aflibercept-yszy):

- On May 20, 2024, the FDA approved **Samsung Bioepis's Opuviz™ (aflibercept-yszy)** as an interchangeable biosimilar of **Regeneron's Eylea® (aflibercept)**.

Simlandi® (adalimumab-ryvk):

- On May 21, 2024, **Alvotech** and **Teva** announced the launch of **Simlandi® (adalimumab-ryvk)**, a high-concentration, citrate-free interchangeable biosimilar of **AbbVie's Humira® (adalimumab)**.

FKS518 (denosumab):

- On May 27, 2024, **Fresenius Kabi** announced the FDA acceptance of an aBLA for **FKS518 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**.

Bkemv™ (eculizumab-aeeb):

- On May 28, 2024, the FDA approved **Amgen's Bkemv™ (eculizumab-aeeb)** as an interchangeable biosimilar of **Alexion's Soliris® (eculizumab)**.

CDER Purple Book Updates

Imdelltra™ (tarlatamab-dlle):

- On May 16, 2024, the FDA approved **Amgen's Imdelltra™ (tarlatamab-dlle).**

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

Jubbonti® / Wyost® (denosumab-bbdz):

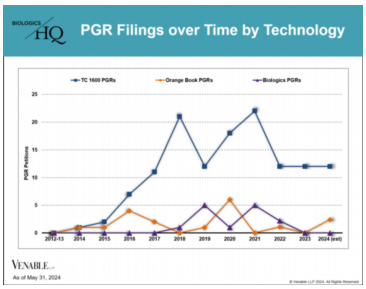
- On May 22, 2024, **Sandoz** announced the approval of **Jubbonti®** and **Wyost® (denosumab-bbdz)**, biosimilars of **Amgen's Prolia® / Xgeva® (denosumab)**, in the E.U.

Omlyclo® (CT-P39) (omalizumab):

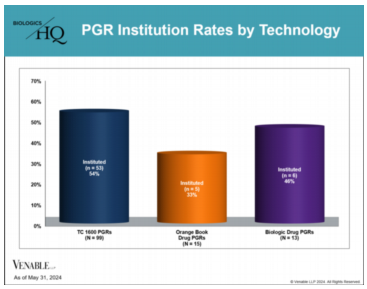
- On May 23, 2024, **Celltrion** announced the approval of **Omlyclo® (omalizumab)**, a biosimilar of **Genentech's Xolair® (omalizumab)**, in the E.U.

STATISTICS

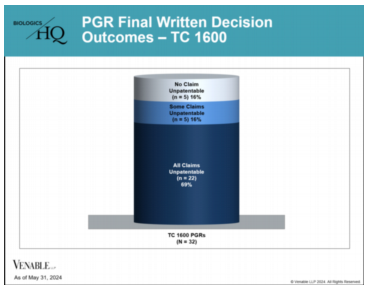
PGR Filings Over Time by Technology	PGR Institution Rates by Technology	PGR Final Written Decision Outcomes – TC 1600



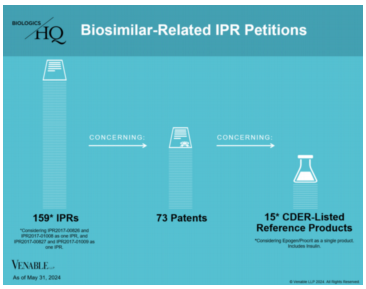
Biosimilar-Related IPR Petitions



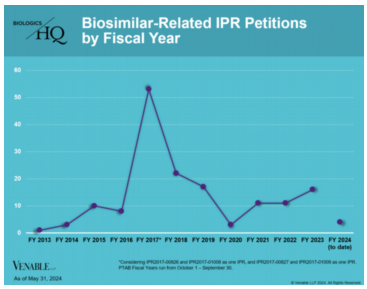
Biosimilar-Related IPR Petitions by Fiscal Year



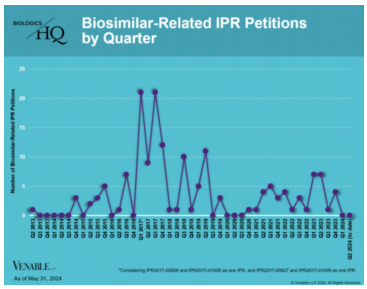
Biosimilar-Related IPR Petitions by Quarter



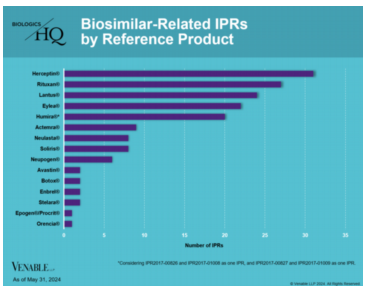
Biosimilar-Related IPRs by Reference Product



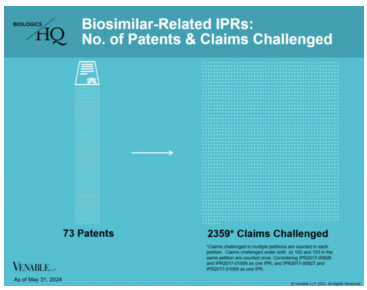
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



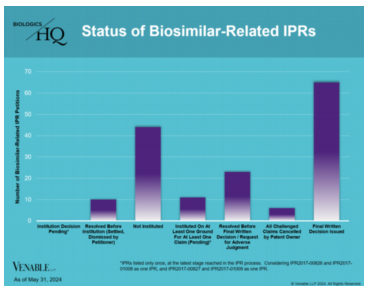
Status of Biosimilar-Related IPRs



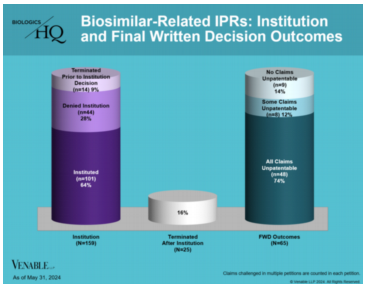
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



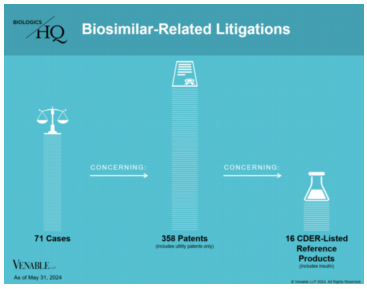
Biosimilar-Related Litigations



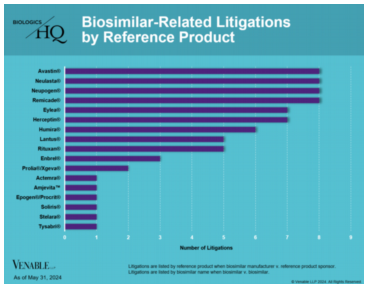
Biosimilar-Related Litigations by Reference Product



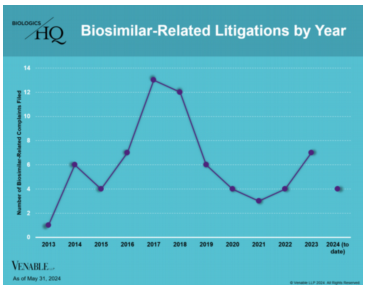
Biosimilar-Related Litigations by Year



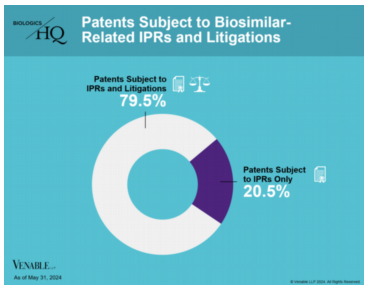
Patents Subject to Biosimilar-Related IPRs and Litigations



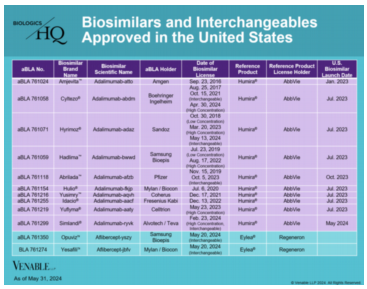
Biosimilars and Interchangeables Approved in the United States



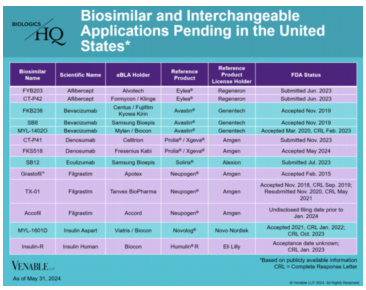
[Biosimilar and Interchangeable Applications Pending in the United States]



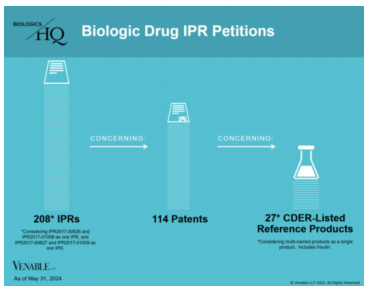
[Biologic Drug IPR Petitions]



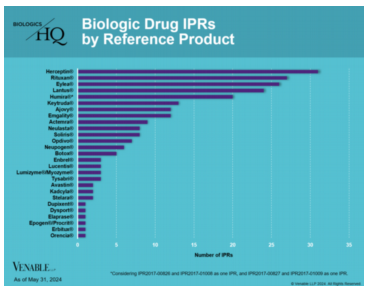
[Biologic Drug IPRs by Reference Product]



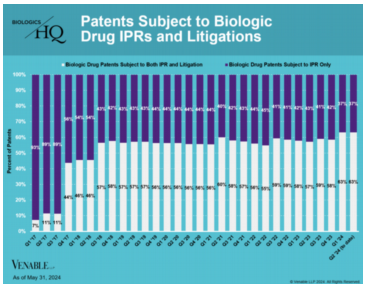
[Patents Subject to Biologic Drug IPRs and Litigations]



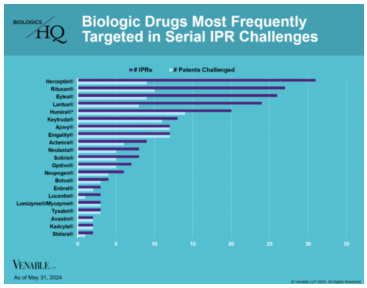
[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]

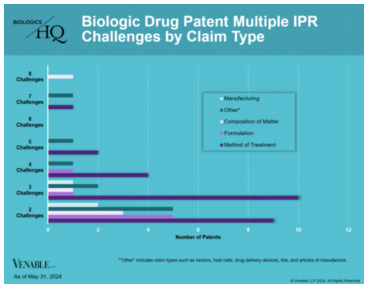


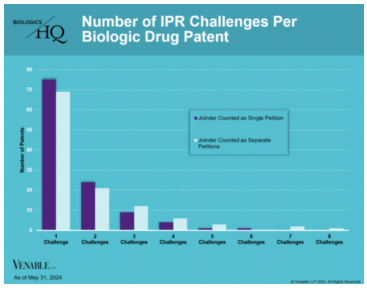
[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

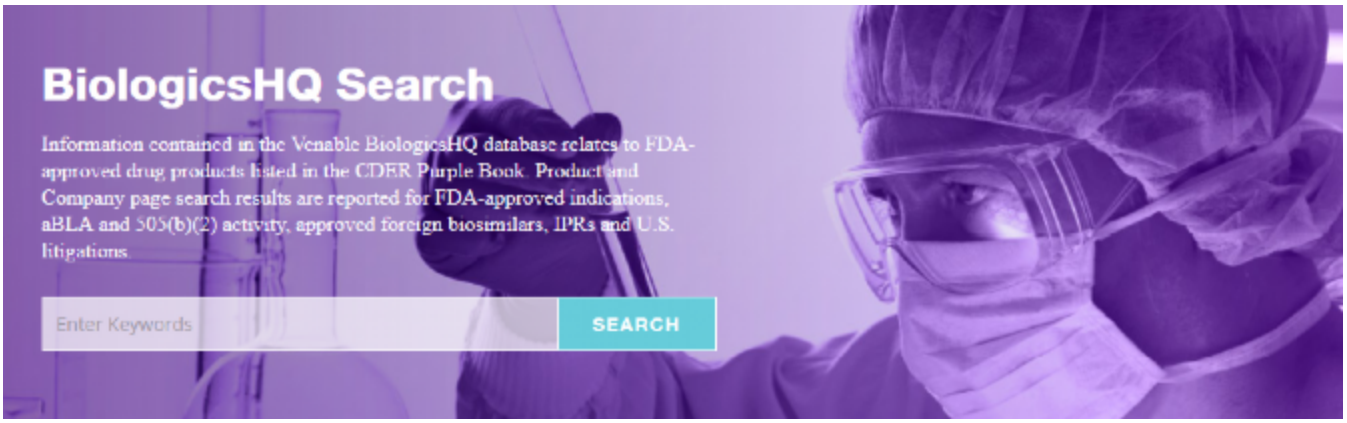


[Number of IPR Challenges Per Biologic Drug Patent]









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