

## MONTHLY INJECTION

February 9, 2024



### LATEST NEWS



#### **BPCIA Complaint Against Proposed Soliris<sup>®</sup> (eculizumab) Biosimilar SB12 Filed**

By: [Monica Chou](#) and [Robert S. Schwartz, Ph.D.](#)

On January 3, 2024, [Alexion](#) filed a [BPCIA litigation](#) in the District of Delaware (Case No. 1-24-cv-00005 (D. Del.)) against [Samsung Bioepis's](#) proposed [Soliris<sup>®</sup> \(eculizumab\)](#) biosimilar [SB12](#), alleging infringement of six patents, including four claiming methods of treating atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria, one claiming pharmaceutical compositions, and one claiming an antibody.



#### **Accord's aBLA for Proposed Biosimilar DMB-3115 Accepted by FDA**

By: [Monica Chou](#) and [Robert S. Schwartz, Ph.D.](#)

According to a January 2024 [press release](#) from [Accord](#), the FDA accepted [Accord's](#) abbreviated Biologics License Application (aBLA) for [DMB-3115 \(ustekinumab\)](#), a proposed biosimilar to [Janssen's](#) (a [Johnson & Johnson](#) company) [Stelara<sup>®</sup> \(ustekinumab\)](#). According to [Accord's](#) [press release](#), [Accord](#) also publicly disclosed for the first time that it previously submitted aBLAs for a [filgrastim \(Neupogen<sup>®</sup>\) biosimilar](#) and a [pegfilgrastim \(Neulasta<sup>®</sup>\) biosimilar](#).

#### **PTAB Issues Final Written Decision Finding Seagen's Adcetris<sup>®</sup> Patent Claims Unpatentable**

By: [Monica Chou](#) and [Robert S. Schwartz, Ph.D.](#)



## Spotlight On: Biosimilar Litigations

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

Spotlight On: Humira<sup>®</sup> (adalimumab) / Amjevita<sup>™</sup> (adalimumab-atto) / Cyltezo<sup>®</sup> (adalimumab-adbm) / Hyrimoz<sup>®</sup> (adalimumab-adaz) / Hadlima<sup>™</sup> (adalimumab-bwwd) / Abrilada<sup>™</sup> (adalimumab-afzb) / Hulio<sup>®</sup> (adalimumab-fkjp) / Yusimry<sup>™</sup> (adalimumab-aqvh) / Idacio<sup>®</sup> (adalimumab-aacf) / Yuflyma<sup>®</sup> (adalimumab-aaty)

Spotlight On: Enbrel<sup>®</sup> (etanercept) / Erelzi<sup>®</sup> (etanercept-szsz) / Eticovo<sup>®</sup> (etanercept-ykro)

Spotlight On: Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine recombinant) / Basaglar<sup>®</sup> (insulin glargine) / Semglee<sup>®</sup> (insulin glargine-yfgn) / Rezvoglar<sup>™</sup> (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<sup>®</sup>, Tofidence<sup>™</sup>, MSB11456, and CT-P47), pegfilgrastim (Neulasta<sup>®</sup>, Fulphila<sup>®</sup>, Udenyca<sup>®</sup>, Ziextenzo<sup>®</sup>, Nyvepria<sup>®</sup>, Fylnetra<sup>™</sup>, Stimufend<sup>®</sup>, Lapelga<sup>™</sup>, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin<sup>®</sup>, Ogivri<sup>®</sup>, Herzuma<sup>®</sup>, Ontruzant<sup>®</sup>, Trazimera<sup>®</sup>, Kanjinti<sup>®</sup>, TX-05, EG12014, and HLX02), rituximab (Rituxan<sup>®</sup>, Truxima<sup>®</sup>, Ruxience<sup>®</sup>, and Riabni<sup>™</sup>), adalimumab (Humira<sup>®</sup>, Amjevita<sup>™</sup>, Cyltezo<sup>®</sup>, Hyrimoz<sup>®</sup>, Hadlima<sup>™</sup>, Abrilada<sup>™</sup>, Hulio<sup>®</sup>, Yusimry<sup>™</sup>, Idacio<sup>®</sup>, Yuflyma<sup>®</sup>, and AVT02), etanercept (Enbrel<sup>®</sup>, Erelzi<sup>®</sup>, and Eticovo<sup>®</sup>), and insulin glargine (Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup>, Basaglar<sup>®</sup>, Semglee<sup>®</sup>, and Rezvoglar<sup>™</sup>) have been updated with activity through January 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 January 31, 2024.

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## UPDATES

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### IPRs and PGRs

#### **Eylea<sup>®</sup> (aflibercept):**

- On January 9, 2024, the PTAB issued final written decisions in IPR2022-01225 by **Mylan** (and joined IPR2023-00532 by **Celltrion**) and IPR2022-01226 by **Mylan** (and joined IPR2023-00533 by **Celltrion** and IPR2023-00566 by **Samsung Bioepis**) finding all challenged claims of **Regeneron's** U.S. Patent No. 10,130,681 (Claims 1, 3-11, 13-14, 16-24, and 26) and U.S. Patent No. 10,888,601 (Claims 1-9, 34-39, 41-43, and 45) unpatentable as anticipated (obviousness challenges not decided).
- On January 16, 2024, the Board instituted **Biocon's** IPR2024-00201 against **Regeneron**, and granted **Biocon's** motion for joinder with **Samsung Bioepis's** IPR2023-00739.
- On January 22, 2024, **Regeneron** requested termination of IPR2023-00462 by **Celltrion** and joined IPR2023-01312 by **Samsung Bioepis** due to disclaimer of all challenged claims.

- On January 30, 2024, the Board instituted **Celltrion's** IPR2024-00260 against **Regeneron**, and granted **Celltrion's** motion for joinder with **Samsung Bioepis's** IPR2023-00884.
- On January 31, 2024, the Board instituted **Biocon's** IPR2024-00298 against **Regeneron**, and granted **Biocon's** motion for joinder with **Samsung Bioepis's** IPR2023-00884.

#### **Enhertu<sup>®</sup> (fam-trastuzumab deruxtecan-nxki) / Adcetris<sup>®</sup> (brentuximab vedotin)**

- On January 16, 2024, the PTAB issued a final written decision in **Daiichi v. Seagen** PGR2021-00030 finding all challenged claims of U.S. Patent No. 10,808,039 (claims 1-5, 9, and 10) invalid for lack of written description and enablement and as anticipated. The claims were not found unpatentable for failure to set for the subject matter of the invention.

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## Litigations

#### **Soliris<sup>®</sup> (eculizumab):**

- On January 3, 2024, **Alexion** filed Case No. 1:24-cv-00005 (D. Del.) against **Samsung Bioepis** related to its proposed biosimilar **SB12 (eculizumab)**.

#### **Eylea<sup>®</sup> (aflibercept):**

- On January 10, 2024, **Regeneron** filed Case No. 1:24-cv-00264 (C.D. Cal.) against **Amgen** related to its proposed biosimilar **ABP 938 (aflibercept)**.
- On January 26, 2024, **Regeneron** filed Fed. Cir. Appeal No. 24-1402 and **Biocon** filed cross Appeal No. 24-1405, appealing the judgment in Case No. 1:22-cv-00061 (N.D.W. Va.) finding claims 4, 7, 9, 11, 14-17 of **Regeneron's** U.S. Patent No. 11,084,865 valid and infringed, and claims 6 and 25 of U.S. Patent No. 11,253,572 and claims 11 and 19 of U.S. Patent No. 10,888,601 invalid and infringed.

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## aBLA Applications and FDA Activity

#### **DMB-3115 (ustekinumab):**

- On January 4, 2024, **Accord BioPharma** announced the FDA acceptance of an aBLA for **DMB-3115 (ustekinumab)**, a proposed biosimilar of **Janssen's Stelara<sup>®</sup> (ustekinumab)**. Also noted in its press release, **Accord** has submitted aBLAs to the FDA for **Accofil<sup>®</sup>**, a proposed biosimilar of **Amgen's Neupogen<sup>®</sup> (filgrastim)**, and **Pelgraz**, a proposed biosimilar of **Amgen's Neulasta<sup>®</sup> (pegfilgrastim)**, on undisclosed dates.

#### **Yuflyma<sup>®</sup> (adalimumab-aaty):**

- On January 10, 2024, **Celltrion** announced the filing of an sBLA for an interchangeability designation for **Yuflyma<sup>®</sup> (adalimumab-aaty)**, a high-concentration biosimilar of **AbbVie's Humira<sup>®</sup> (adalimumab)**.

#### **CT-P47 (tocilizumab):**

- On January 28, 2024, **Celltrion** announced the submission of an aBLA to the FDA for **CT-P47 (tocilizumab)**, a proposed biosimilar of **Genentech's Actemra<sup>®</sup> (tocilizumab)**.

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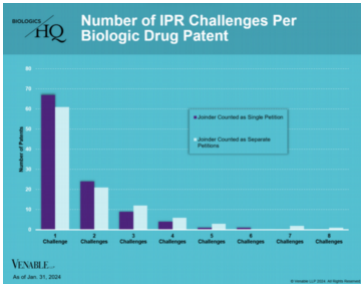
## Non-U.S. Biosimilars / Follow-On Biologics

#### **Uzpruvo<sup>®</sup> (AVT04) (ustekinumab):**









## BiologicsHQ Search

Information contained in the Venable BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

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