

MONTHLY INJECTION



October 12, 2021



LATEST NEWS



[FDA and USPTO Collaboration to Increase Pharmaceutical Competition](#)

By: [April Breyer Menon](#)

Lowering drug prices in the U.S. has long been discussed with numerous proposals put forward on steps that could be taken to reach that goal. In July 2021, President Biden issued an [Executive Order](#) on Promoting Competition in the American Economy that contained provisions seeking

to lower drug prices and promote innovation through increased competition in the pharmaceutical marketplace.

On September 10, 2021, pursuant to the executive order, Janet Woodcock, acting commissioner of food and drugs at the U.S. Food & Drug Administration (FDA), wrote a [letter](#) to Andrew Hirshfeld, acting director of the U.S. Patent and Trademark Office (USPTO), outlining steps the FDA and USPTO can pursue together to “help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.”



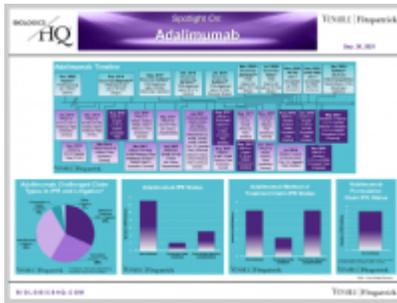
[Senator Leahy Introduces the Restoring the America Invents Act, Ending Discretionary Denials at the PTAB](#)

By: [April Breyer Menon](#)

On September 29, 2021, Senators Patrick Leahy and John Cornyn introduced the Restoring the America Invents Act in the Senate. According to the Senators, the bill seeks to “address problems for small businesses and ordinary Americans caused by poor-quality patents.” It

“builds on and supports the structures that were created ten years ago in the *Leahy-Smith [America Invents] Act*,” bringing “more transparency into the PTO review process, prevent[ing] politicized meddling with PTO decisions, and ensur[ing] that these important PTO proceedings are widely available to the public.”

The bill outlines numerous provisions to address the Senators' concerns, many of which would codify decisions made by the PTAB and Supreme Court.



[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[®] \(adalimumab-fkjp\)](#)

[Spotlight On: Enbrel[®] \(etanercept\) / Erelzi[®] \(etanercept-szsz\) / Eticovo[®] \(etanercept-ykro\)](#)

[Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] \(insulin glargine recombinant\) / Basaglar[®] \(insulin glargine\) / Semglee[®] \(insulin glargine\)](#)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning pegfilgrastim ([Neulasta[®]](#), [Lapelga[™]](#), [Ziextenzo[®]](#), [Udenyca[®]](#), [Fulphila[®]](#), [Nyvepria[™]](#), [MSB11455](#), and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin[®]](#), [Ogivri[™]](#), [Herzuma[®]](#), [Ontruzant[®]](#), [Trazimera[™]](#), and [Kanjinti[®]](#)), rituximab ([Rituxan[®]](#), [Truxima[®]](#), and [Ruxience[®]](#)), adalimumab ([Humira[®]](#), [Amjevita[™]](#), [Cyltezo[®]](#), [Hyrimoz[™]](#), [Hadlima[™]](#), [Abrilada[™]](#), and [Hulio[®]](#)), etanercept ([Enbrel[®]](#), [Erelzi[®]](#), and [Eticovo[®]](#)), and insulin glargine ([Lantus[®]](#) / [Lantus[®] SoloSTAR[®]](#), [Basaglar[®]](#), and [Semglee[®]](#)) have been updated with activity through September 30, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through September 30, 2021.

[Read More News](#)

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On September 7, 2021, [Celltrion](#) filed PGR2021-00117 against [Regeneron](#).

Botox® (onabotulinumtoxinA) / Dysport® (abobotulinumtoxinA):

- On September 17, 2021, [Medy-Tox's](#) request for Director review or panel rehearing of PGR2019-00062 was denied.

Actemra® (tocilizumab):

- On September 24, 2021, [Fresenius Kabi](#) filed IPR2021-01542 against [Chugai Seiyaku Kabushiki Kaisha](#).
-

Litigations

Neupogen® (filgrastim):

- On September 8, 2021, the Court ordered [Amgen](#), [Hospira](#), and [Pfizer's](#) joint stipulations of dismissal in Case Nos. 1:18-cv-01064 (D. Del.) and 1:20-cv-00561 (D. Del.).
-

aBLA Applications and FDA Activity

Byooviz™ (ranibizumab-nuna):

- On September 17, 2021, the FDA approved [Samsung Bioepis](#) and [Biogen's](#) aBLA for [Byooviz™ \(ranibizumab-nuna\)](#), as a biosimilar of [Genentech's Lucentis® \(ranibizumab\)](#).
-

CDER Purple Book Updates

Tivdak™ (tisotumab vedotin-tftv):

- On September 20, 2021, the FDA approved [Seagen's Tivdak™ \(tisotumab vedotin-tftv\)](#).
-

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

Onbevzi® (bevacizumab):

- On September 1, 2021, Boryung Pharmaceutical announced it launched [Onbevzi® \(bevacizumab\)](#), a biosimilar of [Genentech's Avastin® \(bevacizumab\)](#), in South Korea.

Bambevi® (bevacizumab):

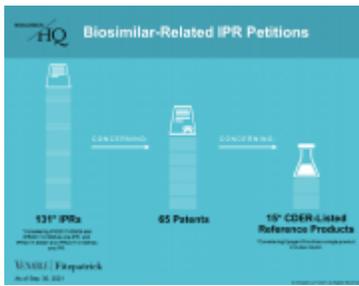
- On September 27, 2021, [Apobiologix](#) (a division of [Apotex](#)) announced approval of [Bambevi® \(bevacizumab\)](#), a biosimilar of [Genentech's Avastin® \(bevacizumab\)](#), in Canada.

STATISTICS

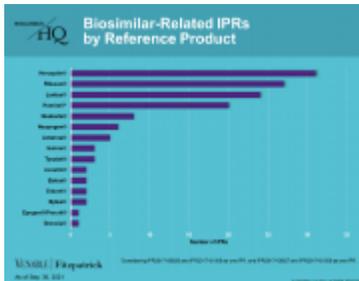
**Biosimilar-
Related IPR
Petitions**

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

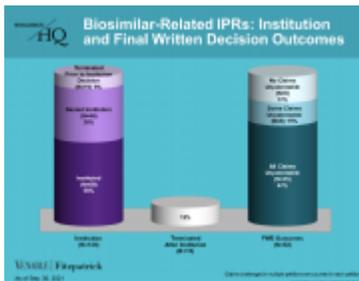
**Biosimilar-Related
IPR Petitions
by Quarter**



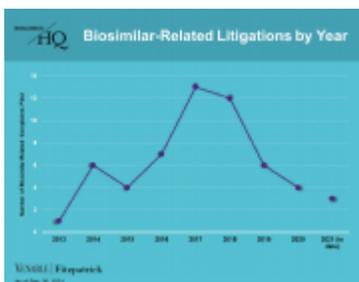
Biosimilar-Related IPRs by Reference Product



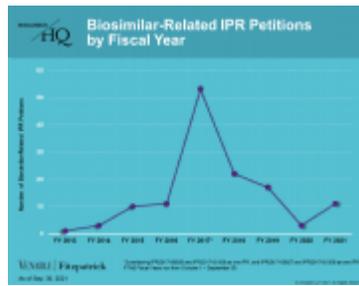
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



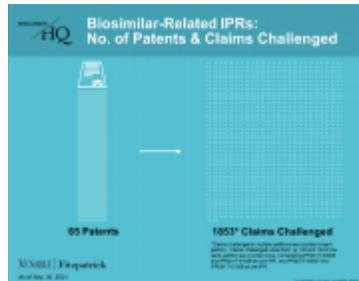
Biosimilar-Related Litigations by Year



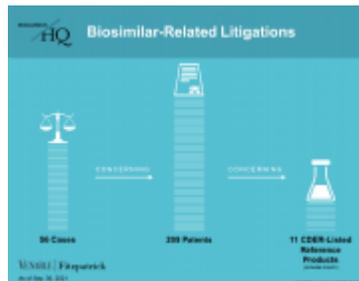
Biosimilar and Interchangeable Applications Pending in the United States



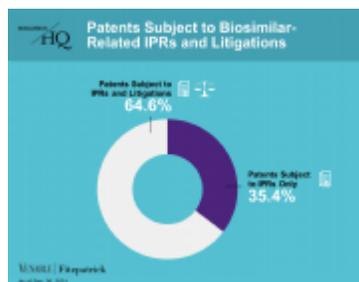
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



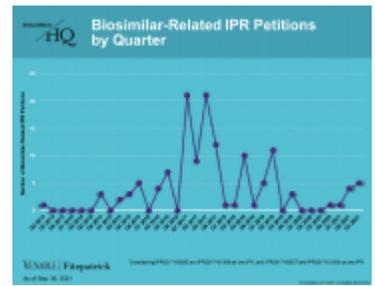
Biosimilar-Related Litigations



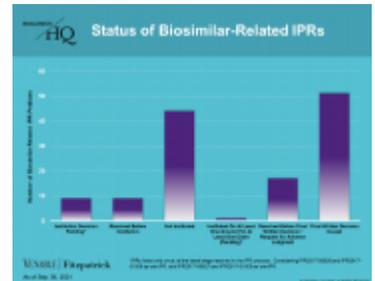
Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPR Petitions



Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States

Biosimilars and Interchangeables Approved in the United States

ANDA No.	Generic Name	Reference Product	USDA Name	Approval Date	Approval Status	Reference Product	USDA Name	Approval Date
ANDA 76124	Insulin	Humalog	Humalog	Mar 22, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76125	Insulin	Humalog	Humalog	Mar 28, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76126	Insulin	Humalog	Humalog	Apr 16, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76127	Insulin	Humalog	Humalog	May 11, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76128	Insulin	Humalog	Humalog	May 25, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76129	Insulin	Humalog	Humalog	Jun 8, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76130	Insulin	Humalog	Humalog	Jun 22, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76131	Insulin	Humalog	Humalog	Jul 6, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76132	Insulin	Humalog	Humalog	Jul 20, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76133	Insulin	Humalog	Humalog	Aug 3, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76134	Insulin	Humalog	Humalog	Aug 17, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76135	Insulin	Humalog	Humalog	Aug 31, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76136	Insulin	Humalog	Humalog	Sep 14, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76137	Insulin	Humalog	Humalog	Sep 28, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76138	Insulin	Humalog	Humalog	Oct 12, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76139	Insulin	Humalog	Humalog	Oct 26, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76140	Insulin	Humalog	Humalog	Nov 9, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76141	Insulin	Humalog	Humalog	Nov 23, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76142	Insulin	Humalog	Humalog	Dec 7, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76143	Insulin	Humalog	Humalog	Dec 21, 2011	Approved	Humalog	Humalog	Mar 2011
ANDA 76144	Insulin	Humalog	Humalog	Jan 4, 2012	Approved	Humalog	Humalog	Mar 2011
ANDA 76145	Insulin	Humalog	Humalog	Jan 18, 2012	Approved	Humalog	Humalog	Mar 2011
ANDA 76146	Insulin	Humalog	Humalog	Feb 1, 2012	Approved	Humalog	Humalog	Mar 2011

UNMRI | Fitzpatrick
 April 16, 2021

Biologic Drug IPRs by Reference Product



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