

MONTHLY
INJECTION

March 12, 2024



LATEST NEWS



Ha Kung Wong Discusses the Biosimilar Patent Legal System with The Center for Biosimilars

Ha Kung Wong Discusses Patent Shift Predictions and Legal Landscapes of Biosimilars with The Center for Biosimilars

In interviews with the Center for Biosimilars, [Ha Kung Wong](#):

- Answers the question, “Can you explain the patent legal system biosimilars are required to undergo and why this process is important to their development?” including a summary and statistics relating to BPCIA patent dance proceedings for biosimilars thus far.
- Examines proposed patent law changes that could significantly impact the biosimilars sector, including limitations on asserted patents, elimination of interchangeability requirements, and heightened oversight of pharmacy benefit managers.



Chugai, Genentech, and Hoffmann-La Roche Dismiss Appeals of Actemra® Patent IPR Final Written Decisions

By: [Damineh Morsali, Ph.D.](#) and [Robert S. Schwartz, Ph.D.](#)

On February 12, 2024, [Chugai](#), [Genentech](#), and [Hoffmann-La Roche \(Roche\)](#) filed a [motion to voluntarily dismiss CAFC Appeals 24-1111](#) and [24-1115](#), appealing the Final Written Decisions in [IPR2022-00578](#) and [IPR2022-00579](#), brought by [Celltrion](#).

Seagen Requests Director Review of Unpatentability Decision in Adcetris® Patent PGR

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



On February 14, 2024, Seagen requested director review of the PTAB's January 16th Final Written Decision in PGR2021-00030 finding antibody-drug conjugate claims in U.S. Patent No. 10,808,039 unpatentable.

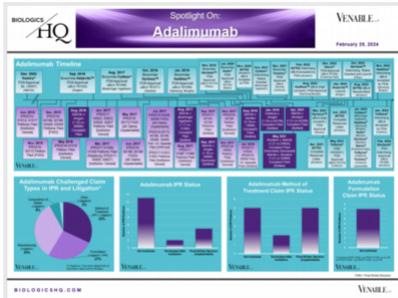


First High-Concentration Humira® Interchangeable, Alvotech and Teva's Simlandi®, Approved in the U.S.

By: Robert S. Schwartz, Ph.D.

On February 23, 2024, the FDA approved Alvotech and Teva's Simlandi® (adalimumab-ryvk) as biosimilar to and interchangeable with AbbVie's Humira® (adalimumab). Simlandi® is the tenth Humira® biosimilar to be approved, and the third interchangeable, following Boehringer Ingelheim's Cyltezo® (low-concentration adalimumab-adbm) and Pfizer's Abrilada™ (low-concentration adalimumab-afzb).

Simlandi® is the first high-concentration, citrate-free Humira® biosimilar to be designated as interchangeable in the U.S.



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

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

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) / 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-szszs](#)) / [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](#)[™], [MSB11456](#), and [CT-P47](#)), pegfilgrastim ([Neulasta](#)[®], [Fulphila](#)[®], [Udenyca](#)[®], [Ziextenzo](#)[®], [Nyvepria](#)[®], [Fylnetra](#)[™], [Stimufend](#)[®], [Lapelga](#)[™], and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin](#)[®], [Ogivri](#)[®], [Herzuma](#)[®], [Ontruzant](#)[®], [Trazimera](#)[®], [Kanjinti](#)[®], [TX-05](#), [EG12014](#), and [HLX02](#)), 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 February 29, 2024.

BiologicsHQ's "[Spotlight On Biosimilar Litigations](#)" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through February 29, 2024.

Read
More
News

UPDATES

IPRs and PGRs

[Actemra](#)[®] ([tocilizumab](#)):

- On February 12, 2024, [Chugai](#), [Hoffmann-La Roche](#), and [Genentech](#) filed a motion to voluntarily dismiss Fed. Cir. Appeal Nos. 24-1111 and 24-1115, appealing the final written decisions in IPR2022-00579 finding all challenged drug delivery device claims of U.S. Patent No. 10,874,677 unpatentable and IPR2022-00578 finding all challenged method of treatment claims of U.S. Patent No. 8,580,264 unpatentable.

[Enhertu](#)[®] ([fam-trastuzumab deruxtecan-nxki](#)) / [Adcetris](#)[®] ([brentuximab vedotin](#))

- On February 14, 2024, [Seagen](#) filed a request for Director Review of the final written decision in PGR2021-00030 filed by [Daiichi](#), finding all challenged composition of matter claims of U.S. Patent No. 10,808,039 unpatentable.

[Eylea](#)[®] ([afibercept](#)):

- On February 21, 2024, the PTAB granted adverse judgment against [Regeneron](#) after disclaimer of all challenged formulation claims of U.S. Patent No. 10,464,992 in [Celltrion's](#) IPR2023-00462 and [Samsung Bioepis's](#) IPR2023-01312 (joined).

[Elevidys](#)[®] ([delandistrogene moxeparvovec-rokl](#)):

- On February 21, 2024, [Sarepta Therapeutics](#) filed IPR2024-00580 challenging formulation and composition of matter claims of The Trustees of the University of Pennsylvania and [REGENXBIO's](#) U.S. Patent No. 11,680,274.

Zolgensma[®] (onasemnogene abeparvovec-xioi):

- On February 26, 2024, **Genzyme** and **Novartis** filed joint motions to terminate due to settlement in IPR2023-01044 and IPR2023-01045 challenging manufacturing claims of U.S. Patent No. 10,429,288.
-

Litigations

Zolgensma[®] (onasemnogene abeparvovec-xioi):

- On February 14, 2024, **Genzyme** and **Novartis's** joint stipulations of dismissal were granted in Case Nos. 1:21-cv-01736 (D. Del.) and 1:23-cv-00554 (D. Del.).
-

aBLA Applications and FDA Activity

Simlandi[®] (adalimumab-ryvk):

- On February 23, 2024, the FDA approved **Alvotech** and **Teva's Simlandi[®] (adalimumab-ryvk)** as a high-concentration, citrate-free biosimilar and interchangeable of **AbbVie's Humira[®] (adalimumab)**.

Bmab 1200 (ustekinumab):

- On February 29, 2024, **Biocon Biologics** announced the FDA acceptance of an aBLA for **Bmab 1200 (ustekinumab)**, a proposed biosimilar of **Janssen's Stelara[®] (ustekinumab)**. **Biocon** also announced a settlement and license agreement with **Janssen** and **Johnson & Johnson**, allowing the commercialization of **Bmab 1200** beginning in February 2025, subject to FDA approval.
-

CDER Purple Book Updates

Amtagvi[™] (lifileucel):

- On February 16, 2024, the FDA approved **Iovance Biotherapeutics' Amtagvi[™] (lifileucel)**.
-

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

Jubbonti[®] (GP2411) (denosumab):

- On February 20, 2024, **Sandoz** announced the approval of **Jubbonti[®] (denosumab)**, a biosimilar of **Amgen's Prolia[®] (denosumab)**, in Canada.

Afilivu (SB15) (afibercept):

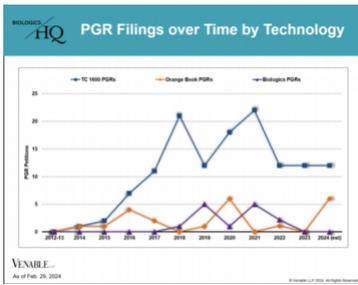
- On February 23, 2024, **Samsung Bioepis** and **Samil Pharmaceutical's Afilivu (afibercept)**, a biosimilar of **Regeneron's Eylea[®] (afibercept)**, was approved in South Korea.

STATISTICS

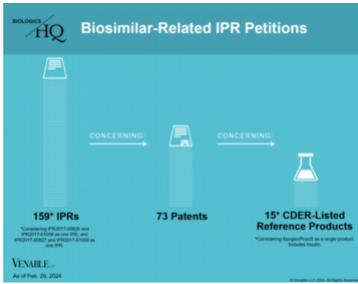
**PGR Filings
Over Time
by Technology**

**PGR Institution
Rates by
Technology**

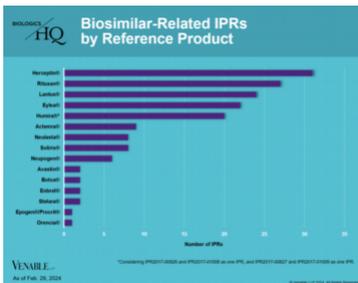
**PGR Final Written
Decision Outcomes –
TC 1600**



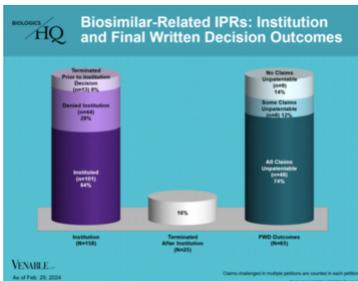
Biosimilar-Related IPR Petitions



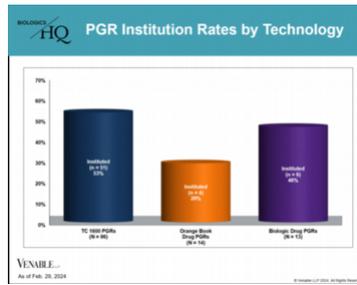
Biosimilar-Related IPRs by Reference Product



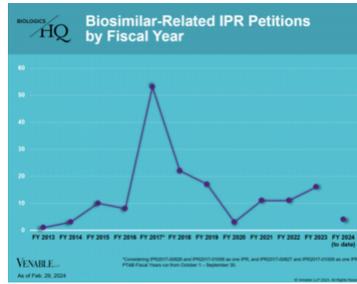
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations by Year



Biosimilar-Related IPR Petitions by Fiscal Year



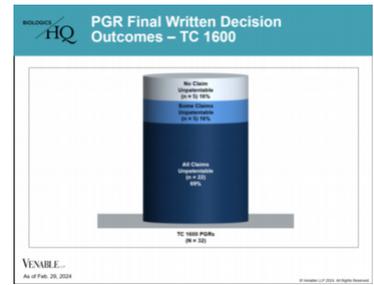
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



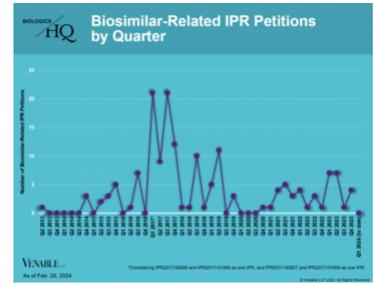
Biosimilar-Related Litigations



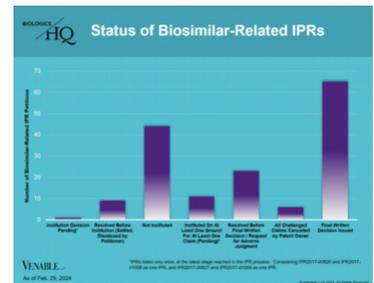
Patents Subject to Biosimilar-Related IPRs and Litigations



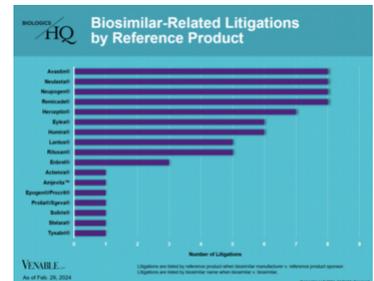
Biosimilar-Related IPR Petitions by Quarter



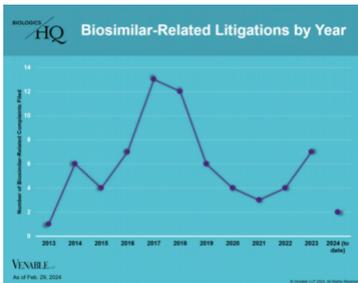
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States



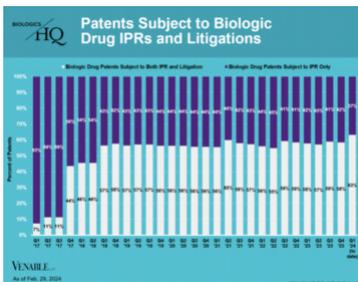
Biosimilar and Interchangeable Applications Pending in the United States

Biosimilar and Interchangeable Applications Pending in the United States*

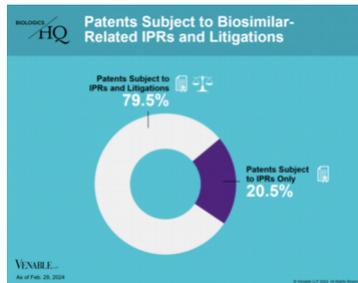
Biosimilar Name	Reference Product	USDA Number	Reference Product	Reference Product	FDA Status
SB110	Abiraterone	Abiraterone	Abiraterone	Abiraterone	Approved Dec. 2011
PT0203	Abiraterone	Abiraterone	Abiraterone	Abiraterone	Submitted Jan. 2013
CT192	Abiraterone	Abiraterone	Abiraterone	Abiraterone	Submitted Jan. 2013
SB15	Abiraterone	Abiraterone	Abiraterone	Abiraterone	Unpublished filing date prior to Nov. 2023
FB0238	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Approved Nov. 2019
089	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Approved Nov. 2019
MF11820	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Approved Mar. 2020, CRL Feb. 2023
0P141	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Approved Feb. 2023
CT141	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Approved Feb. 2023
SB02	Bevacizumab	Bevacizumab	Bevacizumab	Bevacizumab	Submitted Jul. 2023
04040*	Figitumab	Figitumab	Figitumab	Figitumab	Approved Feb. 2015
TX11	Figitumab	Figitumab	Figitumab	Figitumab	Approved Nov. 2018, CRL Dec. 2019
04040*	Figitumab	Figitumab	Figitumab	Figitumab	Submitted Nov. 2020, CRL May 2021
04040*	Figitumab	Figitumab	Figitumab	Figitumab	Unpublished filing date prior to Jul. 2021
MF11810	Insulin Aspart	Insulin Aspart	Insulin Aspart	Insulin Aspart	Approved 2012, CRL Jan. 2022
04040*	Insulin Human	Insulin Human	Insulin Human	Insulin Human	Approved 2003, CRL Jan. 2022

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Patents Subject to Biologic Drug IPRs and Litigations



Number of IPR Challenges Per Biologic Drug Patent



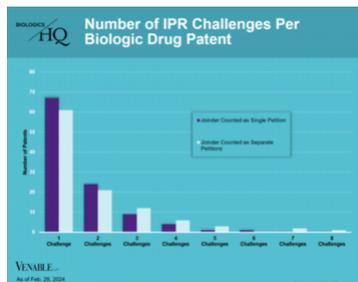
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent

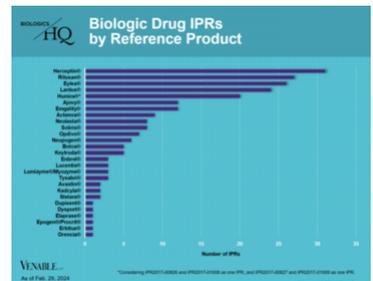


Biosimilars and Interchangeables Approved in the United States

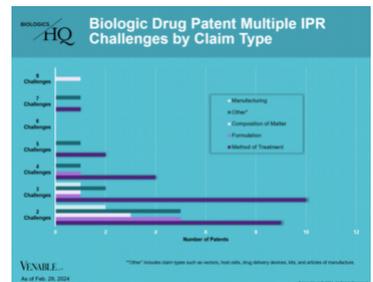
USDA No.	Reference Product	Reference Product	USDA Number	Date of Approval	Reference Product	Reference Product	U.S. Marketing
USDA 701001	Abiraterone	Abiraterone	Abiraterone	Dec. 23, 2011	Abiraterone	Abiraterone	Jan. 2012
USDA 701008	Cetuximab	Abiraterone	Abiraterone	Dec. 23, 2011	Abiraterone	Abiraterone	Jan. 2012
USDA 701011	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701009	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701018	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701019	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701020	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701021	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701022	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701023	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701024	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701025	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701026	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701027	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701028	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701029	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701030	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701031	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701032	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701033	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701034	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701035	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701036	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701037	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701038	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701039	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701040	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701041	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701042	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701043	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701044	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701045	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701046	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701047	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701048	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701049	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012
USDA 701050	Humirax	Humirax	Humirax	Dec. 23, 2011	Humirax	Humirax	Jan. 2012

VENBLE. As of Feb. 29, 2024.

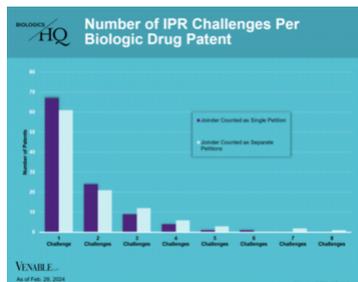
Biologic Drug IPRs by Reference Product



Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent



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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