

BRAND DRUG MANUFACTURER LAWSUITS PREVENT BIOSIMILAR LAUNCHES IN THE U.S.

Reference Biologic	Biosimilars on Market	Biosimilars FDA Approved But Not Launched	FDA Date of Reference Biologic Licensure	Reference Biologic Patent Applications ¹	Latest Expected Patent Expiration	Date of First FDA Biosimilar Approval
Enbrel (Amgen)	0	2	11/02/1998	57	2029	08/31/2016
Humira (AbbVie)	0	3	12/31/2002	247	2023*	09/23/2016
Avastin (Genentech)	0	1	02/26/2004	219	2019	09/14/2017
Herceptin (Genentech)	0	4	09/25/1998	186	2019	12/03/2017
Rituxan (Genentech/Biogen)	0	1	11/26/1997	204	2018	11/28/2018

Litigation is the primary obstacle to biosimilars launching in the U.S. market.

- **Enbrel:** Amgen has ongoing patent litigation with biosimilar manufacturers. No biosimilar launch date set.
- **Humira:** AbbVie has multiple patent lawsuits ongoing. AbbVie settled lawsuits with seven biosimilar manufacturers to delay launches until 2023.
- **Avastin:** Genentech has ongoing patent litigation with biosimilar manufacturer, no biosimilar launch date set.
- **Herceptin:** Genentech has three patent lawsuits with biosimilar manufacturers ongoing. Genentech settled one patent lawsuit with biosimilar manufacturer with terms unknown, no biosimilar launch date set.
- **Rituxan:** Genentech/Biogen settled patent lawsuit with biosimilar manufacturer with terms unknown, no biosimilar launch date set.

Currently, there are only **7** biosimilars on the market in the U.S. versus **51** approved in Europe.

*2023 is date of expected biosimilar launch, not date of patent expiration.

¹ "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices." I-MAK.