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# Patent expiry dates for best-selling biologicals

Biosimilars have been approved in Europe since 2006. With patents on originator biologicals expiring and ever-tightening healthcare budgets biosimilars are likely to take an increasing share of the biologicals market. In light of these facts, this article gives estimated patent expiry dates for just some of the best-selling biologicals.

**Keywords:** Biological, biosimilar, patent

Biosimilars are now a reality. The European Medicines Agency (EMA) approved its first biosimilar Omnitrope (somatropin) back in 2006 [1]. Since then, EMA has approved more than 20 biosimilars within the product classes of human growth hormone, granulocyte colony-stimulating factor, erythropoiesis stimulating agent, insulin and tumour necrosis factor (TNF)-inhibitor, for use in the European Union (EU).

Many blockbuster biologicals have already or will soon face competition from biosimilars due to patent expiries and loss of exclusivity. There are also more than 200 new biotechnology

products in the pipeline (phase II to registered), all of which could be future targets for biosimilars. With the increasing price of new biologicals and continuing pressure on healthcare budgets, biosimilars are expected to make up an increasing share of the biologicals market.

There has been significant harmonization across the globe with respect to patents, mainly as a result of the World Trade Organization's TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights). This has resulted in most patent laws nowadays, giving the term of a patent as 20 years from the filing date of the application.

The European Patent Convention requires all jurisdictions to give a European patent a term of 20 years from the actual date of filing an application for a European patent or the actual date of filing an international application under the Patent Cooperation Treaty (PCT) designating the European Patent Office.

In the US, for utility patents filed on or after 8 June 1995, the term of the patent is 20 years from the earliest filing date of the application on which the patent was granted and any prior US or PCT applications from which the patent claims priority. For patents filed prior to 8 June 1995, the term of patent is either 20 years from the earliest filing date as above (excluding provisional applications) or 17 years from the issue date, whichever is longer.

For both Europe and the US exclusivity periods should also be considered.

Estimated patent and exclusivity period expiry dates for just some of the best-selling biological molecules are shown in Figure 1.

(Continued)

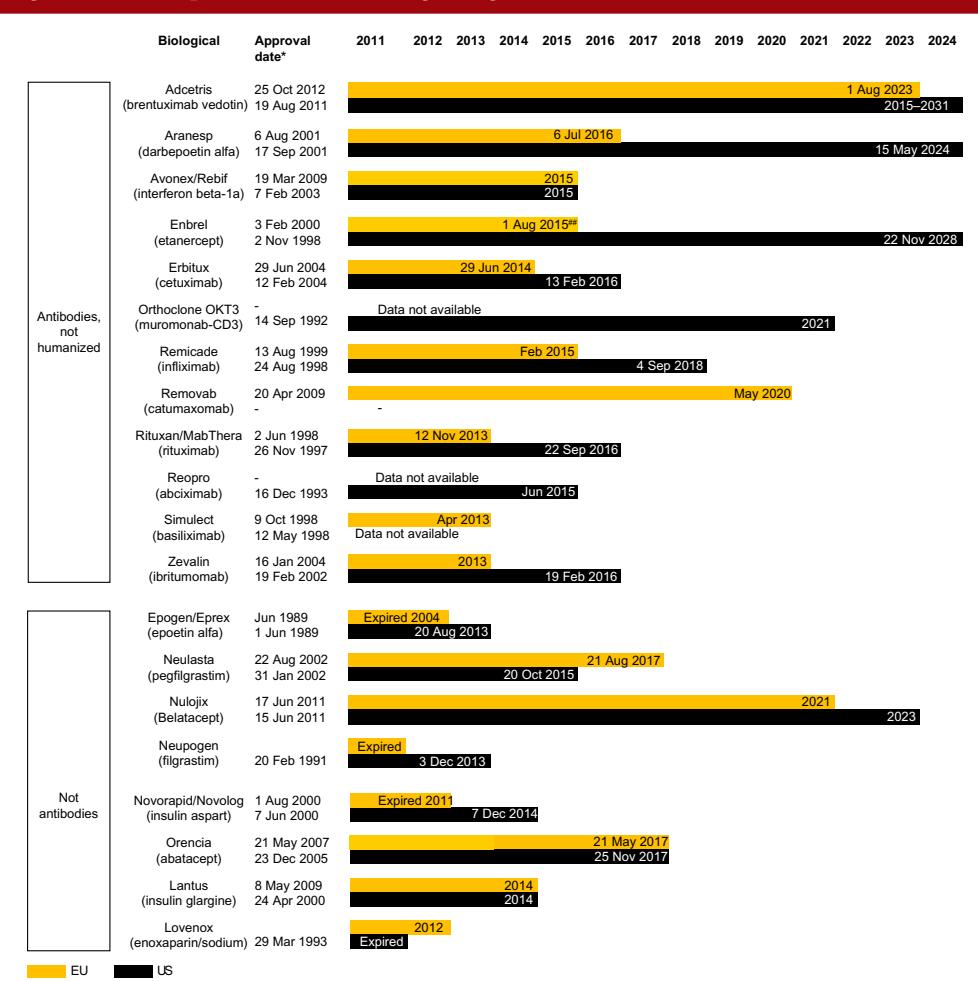
Although the EU previously defined a period of 10 years data exclusivity,

**Figure 1: Patent expiry dates on best-selling biologicals**

Biological	Approval date*	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Humanized antibodies	Actemra/RoActemra (tocilizumab)	16 Jan 2009 8 Jan 2010						23 Apr 2017#							
	Avastin (bevacizumab)	12 Jan 2005 26 Feb 2004							21 Jan 2022						
	Arzerra (ofatumumab)	19 Apr 2010 26 Oct 2009						Data not available				2023			
	Benlysta (belimumab)	13 Jul 2011 9 Mar 2011								2021		2023			
	Campath/Lemtrada (alemtuzumab)	12 Sep 2003 7 May 2001							7 May 2021		6 Jul 2021				
	Cimzia (certolizumab pegol)	1 Oct 2009 22 Apr 2008						Data not available				2024			
	Herceptin (trastuzumab)	28 Aug 2000 25 Sep 1998					28 Jul 2014**			18 Jun 2019					
	Humira (adalimumab)	8 Sep 2003 31 Dec 2002							15 Oct 2018		31 Dec 2016				
	Ilaris (canakinumab)	23 Oct 2009 17 Jun 2009					Data not available								
	Lucentis (ranibizumab)	22 Jan 2007 30 Jun 2006								30 Jun 2020		2022			
	Prolia/Xgeva (denosumab)	26 May 2010 1 Jun 2010					Data not available				2016				
	Simponi (golimumab)	1 Oct 2009 24 Apr 2009										Oct 2024		Feb 2024	
	Soliris (eculizumab)	20 Jun 2007 16 Mar 2007							1 May 2020			16 Mar 2021			
	Stelara (ustekinumab)	16 Jan 2009 25 Sep 2009											Jan 2024	Sep 2023	
	Synagis (palivizumab)	13 Aug 1999 19 Jun 1998						9 Aug 2015							
	Tysabri (natalizumab)	27 Jun 2006 23 Nov 2004							Aug 2015		Mar 2015				
	Vectibix (panitumumab)	3 Dec 2007 27 Sep 2006							2018		8 Apr 2020				
	Xolair (omalizumab)	25 Oct 2005 20 Jun 2003								Aug 2017		20 Jun 2017			
	Yervoy (ipilimumab)	13 July 2011 25 Mar 2011									2021				2023
	Zenapax (daclizumab)	26 Feb 1999 10 Dec 1997						Mar 2013							
								Data not available							

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**Figure 1: Patent expiry dates on best-selling biologicals (Continued)**



\*EU provides 10 years of exclusivity (8 years data exclusivity and 2 years market exclusivity + 1-year possible extension), US BPCI Act provides 12 years exclusivity (4 years data exclusivity and 8 years market exclusivity); #Based on Supplementary Protection Certificate; \*\*In the UK. Other major EU markets follow on 28 August 2015; patent protecting the cells that make certain levels of erythropoietin lasts until 26 May 2015; ##includes 6-month paediatric extension.

Source: GaBI Online ([www.gabionline.net](http://www.gabionline.net)), Sheppard et al. [1], Bernstein Research [2].

this was revised at the latest review of pharmaceutical EU legislation to the following:

Ten years if the reference product is centrally approved or application to the centralized procedure has been made before 20 November 2005. Or eight years data exclusivity + 2 years market exclusivity + 1 year possible extension if a full dossier is submitted on or after 30 October 2005 via a national procedure or after 20 November 2005 via the centralized procedure [3].

The expiration of patents and other intellectual property rights for originator biologicals over the next decade opens up opportunities

for biosimilars to enter the market and increase industry competition. Price reduction strategies should increase adoption among physicians and patients alike, spurring increases in the biosimilars market share.

According to a report by Frost and Sullivan the global market for biosimilars will rapidly expand more than 20-fold from 2013 to 2019. The biosimilars market is expected to increase from just US\$1.2 billion during 2013 to US\$23 billion in 2019. Demand is being fuelled by governments around the world turning to biosimilars as a cheaper option to reduce healthcare costs. Government initiatives, strategic collaborations and increasing incidents of new diseases are also increasing the value of the market. Deeper penetration into the markets in Europe, Japan and the US, as well as emerging economies in Asia and Latin America is also helping to increase the biosimilars market share.

Major companies investing in the biosimilars market include Amgen, Biocon, Biopartners, Hospira, Intas Biopharmaceutical, Mylan, Dr Reddy's Laboratories, Sandoz and Teva.

**Competing interests:** None.

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