

Forecasts tell a tale of two continents for biosimilars



[Madeleine Armstrong](#)

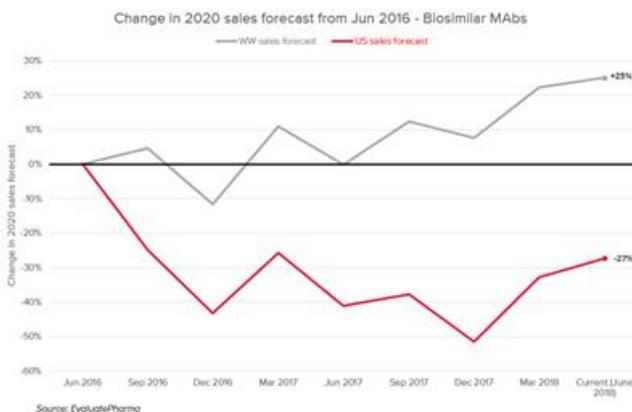


Despite government rhetoric, the US biosimilar market has failed to live up to expectations so far.

Considering the US government's recent rhetoric around lowering drug prices, it seems surprising that companies are exiting the biosimilars market. But in another sign that the space is not turning out to be as attractive as expected, Biogen said last week that it had no long-term interest in Samsung Bioepis, its joint venture with Samsung Biologics.

An analysis of *EvaluatePharma* consensus forecast data suggests a reason for the waning interest: while expectations for the global biosimilars sector have risen, those for the biggest market, the US, have nosedived in the past two years (see charts below).

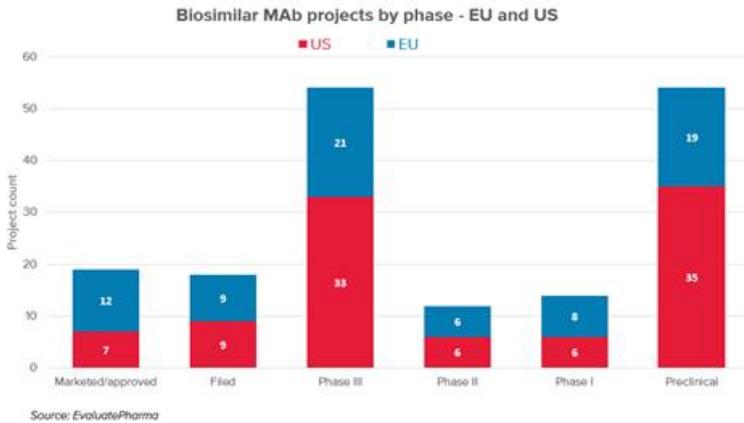
This might just be a function of forecasts shifting as projects are delayed in the US, rather than an actual decline in peak forecasts. But the analysis below still paints a picture of a US biosimilars market that has – so far – failed to live up to expectations.



A tough stance from the FDA has probably not helped the US cause. This was exemplified again on Friday by a US knockback for Amgen and Allergan's ABP 980, a biosimilar version of Roche's Herceptin – the same day that the EMA's Committee for Medicinal Products for Human Use (CHMP) recommended the approval of four

new biosimilars.

A look at the number of biosimilars currently approved in each territory supports the notion of a stricter FDA – although it is worth noting that the European regulatory path for biosimilars was defined much earlier.

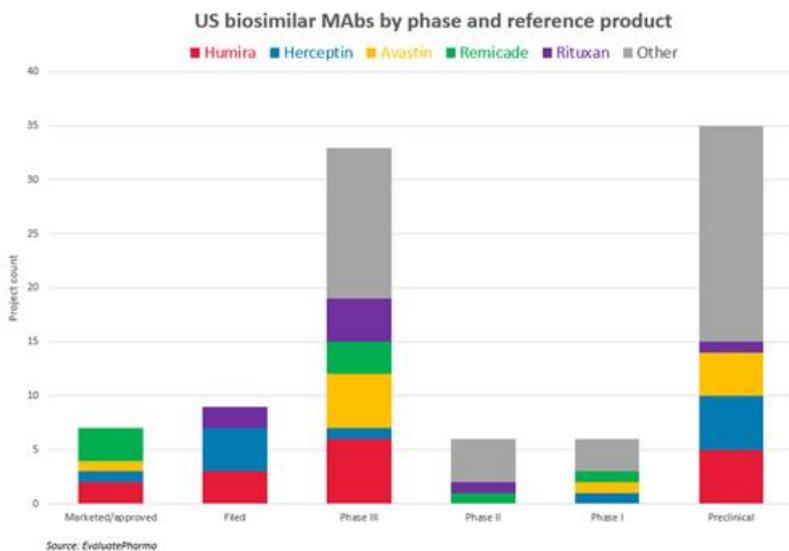


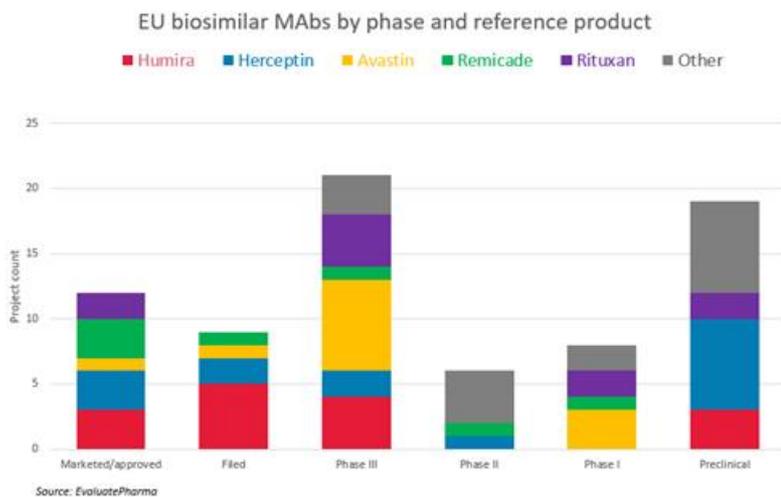
Herceptin is a case in point. Only one copycat version of Roche’s drug – Mylan and Biocon’s Ogivri – has received the US thumbs up, while the FDA rejected Celltrion’s Herzuma and Pfizer’s PF-05280014 in April.

Meanwhile, in Europe, Herzuma has been approved and launched, as has Samsung Bioepis’s Ontruzant, while Amgen’s Kanjinti got the go-ahead in May. And PF-05280014, also known as Trazimera, could soon also get the nod after a positive opinion from the CHMP on Friday.

Still, it is not all plain sailing: Mylan withdrew its European application for Ogivri in September. It has since refiled.

Showing that it can change its mind, the FDA yesterday approved Mylan and Biocon’s Fulphila, the first biosimilar of Amgen’s neutropenia therapy, Neulasta, after issuing a complete response letter in October. Fulphila is not covered by this analysis, which only includes monoclonal antibodies.





If getting approval is more difficult in the US, reaching the market is harder still. Patent wrangling has meant that only two biosimilar MAbs are currently marketed in the country: Pfizer's Inflectra and Samsung Bioepis's Renflexis, both versions of Johnson & Johnson's Remicade.

And these have not taken off as hoped, as J&J has managed to hold off competition by offering discounts on Remicade. During its first-quarter results, J&J said that Remicade had a 95% volume share of the infliximab market, despite an aggressive pricing strategy from Samsung Bioepis ([Samsung leaps into its first US biosimilars battle](#), July 25, 2017).

There are also structural barriers to biosimilars in the US healthcare system, according to Mike Thompson, medical research director at Aurora Health Care in Milwaukee. At this week's Asco meeting he listed several factors that can hold back biosimilar uptake, including delays in their inclusion in formularies and hospital treatment pathways.

He added that there can also be logistical issues – for example, if there are four or five biosimilars marketed for each branded drug, pharmacies might have to stock them all.

Biogen out

This uncertain environment might be one reason for Biogen executives saying at the Bernstein Strategic Decisions Conference last Wednesday that the company did not intend to stay in the joint venture for the long haul.

Biogen currently has an option, which expires at the end of June, to increase its stake in Samsung Bioepis to 50%, from around 5% currently. It is unclear whether it would take this step and then sell off the stake later – either way, Samsung Biologics is apparently keen to increase its holding in the joint venture, [according to Korean media reports](#).

Biogen has made it clear, however, that in the long term the biosimilars joint venture is a distraction from its core neuroscience business – echoing comments made by Merck KGaA when it [sold its biosimilars business to Fresenius last year](#), saying it wanted to focus on innovative medicines.

Some big companies remain confident that the US biosimilar market will eventually take off, especially with pricing pressure unlikely to go away.

Novartis's chief executive, Vas Narasimhan, said during the group's first-quarter conference call that the broad use of biosimilars will happen "because it's the right thing for the healthcare system, right thing for patients and right thing for physicians".

The big questions now are when use of biosimilars will pick up, and whether the rewards will be as great as originally expected.

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