

16 May 2023 | **Analysis**

Is The Bloom Off The Rose For Big Pharma And Biosimilars?

Landscape Shifts As Originators Signal Waning Interest In Off-Patent Biologics

by **David Wallace**

After a wave of big pharma interest in the biosimilars arena, originator enthusiasm for the sector appears to be waning – potentially opening up an opportunity for newcomers to compete on off-patent biologics.

When biosimilars first started to gain significant momentum, with approvals and launches in Europe and later the US, big pharma interest in the sector soon grew. Major players like Amgen, Biogen, Boehringer Ingelheim, Merck and Pfizer all made moves into biosimilars, joining a market that also included established larger off-patent firms with the capacity to invest in biosimilars – such as Sandoz, Teva and Mylan – as well as a number of dedicated pure-play biosimilars developers.

However, over the years the landscape has evolved, with many originators now being more selective in their commitments to biosimilars – or pulling out of the sector altogether.

Recently, a number of moves have reshaped the competitive landscape considerably, as originators reassess the value of their biosimilars interests, at the same time as certain off-patent players are also rethinking their strategy in this area.

This comes as new dynamics are making themselves felt in the biosimilars arena, whether through the potential impact of price negotiation under the Inflation Reduction Act (Also see "[Unpicking The CMS Guide On Price Negotiation: A Dive Into The US Eylea Biosimilar Landscape](#)" - Generics Bulletin, 30 Mar, 2023.), the complicating behaviors of US pharmacy benefit managers and the lack of confidence that the market can support more than a couple of initial biosimilars

per molecule (Also see "[‘In A Word, Complicated’ – AAM’s Burton Talks US Biosimilars](#)" - Generics Bulletin, 21 Mar, 2023.), or simply competitive pressures from multiple rivals being felt quickly in once-booming categories such as oncology. (Also see "[Amgen Builds Up Future Launches As Oncology Biosimilars Slide](#)" - Generics Bulletin, 2 Feb, 2023.)

Many Originators Have Lost Interest In Biosimilars...

While Boehringer Ingelheim is expected to make a big splash in a couple of months' time with its launch of the first US interchangeable Humira (adalimumab) biosimilar, Cyltezo (Also see "[First Interchangeable Humira Biosimilar Approved In US](#)" - Generics Bulletin, 18 Oct, 2021.), the company as far back as 2018 indicated that it had no interest in biosimilars outside of the US – despite receiving a European approval for Cyltezo – and has since shown little appetite for the sector outside of adalimumab. (Also see "[Boehringer Bails On Biosimilars Outside US](#)" - Generics Bulletin, 4 Dec, 2018.)

Merck was another firm that showed interest in biosimilars only for this to later cool. The firm had a partnership with Samsung Bioepis to market several biosimilars, but eventually took the decision in 2010 to spin off its biosimilars, women's health and legacy brands units into a separate company, Organon. (Also see "[Merck Spins Out Biosimilars And Legacy Brands](#)" - Generics Bulletin, 10 Feb, 2020.)

And Organon itself has suggested a certain amount of long-term uncertainty over biosimilars in recent months, albeit with the business still a significant growth driver for the company as things stand. (Also see "[Organon CEO Uncertain Over Long-Term Future Of Biosimilars Business](#)" - Generics Bulletin, 12 Jan, 2023.)

Pfizer is another major originator who seems to be losing interest in biosimilars, having built up the business for some years, including through assets acquired as part of its takeover of Hospira. Despite biosimilars having brought in sales of over \$2bn for the company for two years in a row (Also see "[Pfizer Quietly Chalks Up Another \\$2bn Year For Biosimilars](#)" - Generics Bulletin, 8 Feb, 2023.), biosimilars now barely warrant a mention during Pfizer's results calls – and the firm last year took the decision to no longer split out biosimilars as a separate reporting segment. (Also see "[Pfizer Interest In Biosimilars Appears To Decline As Firm Ceases To Split Out Segment](#)" - Generics Bulletin, 8 Nov, 2022.)

This is in line with an indication from the firm in 2021 that it would be taking a more "opportunistic" approach to biosimilar investments in future (Also see "[Pfizer Takes ‘Opportunistic’ Approach To Future Biosimilars](#)" - Generics Bulletin, 29 Jul, 2021.), having two years earlier axed several biosimilar development programs in favor of innovative R&D. (Also see "[Pfizer Axes Staff And Five Pre-Clinical Biosimilars To Fund Late-Stage Innovative Programs](#)" - Generics Bulletin, 15 Jan, 2019.)

Biogen, meanwhile, is the latest firm to indicate that it is getting cold feet on biosimilars. In 2022, the firm pulled out of its Samsung Bioepis joint venture with Samsung Biologics through a \$2.3bn buyout. (Also see "[Biogen Sells Samsung Bioepis Stake In \\$2.3bn Buyout](#)" - Generics Bulletin, 28 Jan, 2022.)

Biogen nevertheless said at the time that it would maintain certain interests in biosimilars and that the category still represented “an important value creation opportunity for Biogen.”

However, more recently the company has admitted that biosimilars may not form part of its future. CEO Chris Viehbacher confirmed that a formal process was underway to “evaluate strategic options for our biosimilars business,” having previously hinted that “we are looking at whether we can do more with that business or maybe whether others should own this business” as the company looked to prioritize near-term opportunities and control costs (*see sidebar*).

And then there are other firms, like AbbVie, that have simply shown no interest in biosimilars whatsoever. Biosimilars, said AbbVie vice chairman and president Rob Michael late last year, were “something we looked at, but what we’re pursuing is really an innovation model that elevates the standard of care. And so we’re not really interested in pursuing a biosimilar strategy.” (Also see "[AbbVie: ‘We Looked At Biosimilars, We Are Not Interested’](#)" - Generics Bulletin, 19 Dec, 2022.)

...But Amgen Is Committing To Another Decade

With so many originators retreating from the biosimilars sector, Amgen remains something of an outlier, recently reaffirming an earlier commitment to double its biosimilar revenues to \$3.5bn-\$4bn between 2021 and 2030. (Also see "[Amgen: We Expect To Double Biosimilar Sales By 2030](#)" - Generics Bulletin, 6 Dec, 2021.)

“We do feel strongly that we will continue to be able to deliver” on this target, said Murdo Gordon, Amgen’s executive vice-president for global commercial operations, maintaining that biosimilars are “still a very important part of our business.”

Biogen Is ‘Evaluating Strategic Options’ For Its Biosimilars Business

By [David Wallace](#)

26 Apr 2023

Biogen revealed that a formal process is now underway to “evaluate strategic options” for its biosimilars business, pointing to a potential transfer of the unit to a new owner.

[Read the full article here](#)

Amgen Reveals First Figures For US Humira Rival

By [David Wallace](#)

Gordon was speaking as Amgen reported initial results for its Amjevita (adalimumab-atto) biosimilar, the first US rival to Humira that was launched at the end of January this year (*see sidebar*).

While sales of Amgen's oncology biosimilars fell by 27% in the first quarter – continuing a downward trend that had been seen last year – the company pointed to products such as Stelara (ustekinumab), Eylea (aflibercept) and (eculizumab), along with adalimumab, as providing significant biosimilar opportunities in the years to come. (Also see "[As Biosimilar Revenues Fall, Amgen Looks To Next Wave For Growth](#)" - Generics Bulletin, 8 Nov, 2022.)

So What Does This Mean For The Biosimilars Market?

It would be wrong to imagine that the only upheaval in biosimilars has been on the originator side. Notably, Mylan's 2020 merger with Pfizer's Upjohn business to create Viartis soon led the firm to reconsider its interests in biosimilars, ultimately selling off the segment entirely to its partner Biocon Biologics (*see sidebar*).

Another biosimilars firm to have shown waning interest in investing in early-stage biosimilar development is Coherus, which in 2021 executed a strategic shift that included shelving development of its own Eylea biosimilar. (Also see "[Coherus Shelves Eylea Biosimilar And Rules Out Early-Stage Biosimilar Development](#)" - Generics Bulletin, 2 Feb, 2021.)

However, other major firms in the sector are standing firm in their commitment to biosimilars.

Sandoz has recently announced a number of deals and investments as it looks to strengthen its capabilities ahead of its upcoming spinoff from parent Novartis. (Also see "[Sandoz Makes Major Moves To Bolster Biosimilars Ahead Of Spinoff](#)" - Generics Bulletin, 10 May, 2023.) (Also see "[Sandoz Unveils \\$400m+ Investment In Slovenian Biosimilars Plant](#)" - Generics Bulletin, 9 Mar, 2023.)

28 Apr 2023

As Amgen and AbbVie reveal first-quarter results, a clearer picture is beginning to emerge of the dynamics for biosimilar competition to Humira in the US. But Amgen is cautioning that Q2 sales of Amjevita may not match initial uptake in Q1.

[Read the full article here](#)

Biocon Pays \$3.3bn For Viartis Biosimilars Business

By [David Wallace](#)

28 Feb 2022

Biocon Biologics will pay up to \$3.3bn to acquire the global biosimilars business of Viartis, in a long-rumored deal that will create a vertically-integrated biosimilars giant with annual sales approaching \$1bn.

[Read the full article here](#)

And Teva has also signalled a continuing interest in biosimilars as a significant growth driver for the company, including existing partnerships with Celltrion, Alvotech and Formycon/BioEq, as well as its own in-house development.

But the exit of so many originators from the market could make extra room for those firms that are more firmly rooted in the off-patent sector to compete more effectively on biosimilars.

And there is still plenty of competition in the market. As smaller developers ally with more established off-patent companies to get their products on the market – such as Hikma (Also see "[Hikma Highlights Long-Term Importance Of Biosimilars](#)" - Generics Bulletin, 24 Jan, 2022.) – larger biosimilars firms are also ramping up operations.

Alvotech is now starting to deliver on bringing its substantial pipeline of products to market (Also see "[Stada And Alvotech Launch Higher-Strength Adalimumab In Europe](#)" - Generics Bulletin, 9 Jun, 2022.); Celltrion's business is continuing to expand, with the firm now marketing its own products directly in the US (Also see "[Building A US Business: Celltrion's New CCO Talks Strategy](#)" - Generics Bulletin, 28 Mar, 2023.); and even relatively new entrants to the market such as Amneal are feeling confident enough to announce ambitions of eventually being among the top five players in biosimilars. (Also see "[Amneal Continues To See Value In Complexity](#)" - Generics Bulletin, 16 Mar, 2023.)

This suggests that while many originators may not see sufficient value in biosimilars, there will be no shortage of competitors in the market in the coming years – especially as off-patent opportunities increasingly shift towards biologics. (Also see "[Scale Of Off-Patent Savings Ramps Up As Impact Of Biologic LOEs Increases](#)" - Generics Bulletin, 24 Jan, 2023.)