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Collaboration vs Competition: Patent Cliffs

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The biosimilar business is growing increasingly fragmented among smaller firms, even as larger corporations are merging. Biosimilars are being developed by more than 40 smaller companies, many of which have no prior experience in the field. Long-term viability and supply reliability are threatened by this fragmentation.



Patent cliffs will be one of the originator's biggest pain points in the next 3-5 years. Between the originator and biosimilar developer, competition is generally more than collaboration. It depends on the different markets and biosimilar developers' volume/growth stage. It's a commercial decision with ROI.

In mature EU markets, stakeholders are well-educated so that we can see biosimilars' deeper and quicker market penetration. Sufficient competition causes lower prices and a limited profit margin. Biosimilar developers also have the ambition to establish their brands, and some have been trying to expand to novel biological products.

To effectively counter biosimilar competition, originator companies are implementing various proactive strategies, including developing second-generation products, product reformulations, improvements in dosing methods, and advancements in supporting devices.

The entry of Humira biosimilars had a profound impact on the European adalimumab market. Following the launch of biosimilars in 2018, Humira sales in Europe saw a remarkable decline, with adalimumab biosimilars capturing approximately 60 per cent volume share within three years. AbbVie has adopted an aggressive approach to mitigate biosimilar competition, implementing price reductions of up to 80 per cent in specific European markets, offering discounts ranging from 10 per cent

to 80 per cent during government tender processes, and securing settlement agreements with biosimilar manufacturers for early entry in Europe, while strategically delaying US launches until 2023.

Despite these efforts, adalimumab biosimilars achieved significant market penetration in Europe, although adoption rates varied widely among countries. The UK reached an impressive 90 per cent market share for adalimumab biosimilars, while Denmark achieved nearly 97 per cent and Norway surpassed 90 per cent. In contrast, France has seen lower adoption rates, with a market share of around 41 per cent.

Interestingly, AbbVie's heavy discounting and the influx of potential competitors have resulted in several adalimumab biosimilars approved in Europe not launching or being withdrawn. For example, Sandoz withdrew its adalimumab biosimilar Halimatoz post-approval for commercial reasons. Similarly, Boehringer Ingelheim withdrew Cyltezo before its market entry, focusing its efforts on the US market and halting biosimilar development activities outside the United States. Other approved adalimumab biosimilars, such as Pfizer's Amsparity, which received European Commission market authorization in February 2020, have also been sidelined due to "unfavorable market conditions."

However, in the uneducated market or some impacted by policy or access barriers, we may see some cooperation between originators and biosimilar developers in the short term. The originator can obtain surplus value after patent cliffs and defend the other competitors in the market. Biosimilar developers can enter the market quickly and with lower promotion and marketing costs. In the US, the IRA (Inflation Reduction Act of 2022) may increase partnerships to let biosimilars access the market before the patent cliff to avoid price negotiation. In China, biosimilar's VBP (volume-based procurement) is coming. A lower price is expected. China already has many well-known and commercialised biopharma companies with biosimilar pipelines, transforming from traditional generic companies and emerging biotech.

Another observation is that biosimilar developers have more partnerships across different regions/countries. In China, we see both licenses in and out. 3S Biopharma was licensed to develop and commercialise Samsugn Bioepis' multiple biosimilar products in Mainland China. Henlius has more than ten partners to develop and commercialise biosimilar products globally. There are also more partnerships among local biosimilar developers and big local pharma with strong marketing and sales teams or distribution channels.

Strategic partnerships and collaborations between these originator companies and biosimilar developers are on the rise, with many leading pharmaceutical companies adopting a hybrid strategy that involves the development of both originator biologics and biosimilars. Industry giants such as Amgen, Merck & Co., and Pfizer exemplify this approach, leveraging their biologic development and manufacturing expertise to create powerful synergies.

Originator companies are increasingly forming alliances with biosimilar developers to co-develop and commercialise biosimilars, especially in emerging markets. A prime example is mAbxience, a Spanish biosimilar manufacturer majority-owned by Fresenius Kabi and partially owned by Insud Pharma. They have established significant agreements with Teva Pharmaceuticals to develop an anti-PD-1 oncology biosimilar candidate. They are collaborating with Egis on commercialising two biosimilar candidates across eight Central and Eastern European countries, with plans for further expansion. Furthermore, they are working with Abbott to launch several biosimilars targeting oncology, women's health, and respiratory diseases in Latin America, Southeast Asia, and Africa.

These strategic partnerships empower originator companies to sustain a strong presence in the biosimilar market while granting biosimilar developers access to well-established commercial networks and regulatory expertise.

Additionally, a notable trend of mergers and acquisitions is taking place, enabling companies to consolidate resources and capitalise on synergies. Viatris, for instance, has made a strategic decision to sell its biosimilar business to Biocon, allowing it to focus on its core brand business. This consolidation is essential for achieving the scale and efficiency required to thrive in an increasingly competitive marketplace.

While larger companies are consolidating, the biosimilar market is becoming more fragmented among smaller players. Over 40 smaller companies are developing biosimilars, and many possess limited experience in the field. This fragmentation poses challenges to long-term viability and supply reliability.

The complexity and cost of biosimilar development may lead to a "biosimilar gap" where certain biologics with expiring patents lack corresponding biosimilar initiatives.

We believe multi-level roles (global, regional and by country) and diversified cooperation will enhance the ecosystem's long-term and healthy development.

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