Assessing Factors Behind Biosimilar Uptake And Competition

by Michael Carson, Andree-Anne Fournier, and Pavel Darling; Analysis Group, Inc.

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Michael Carson


Andree-Anne Fournier


Pavel Darling

Recent developments in biosimilar competition have prompted renewed consideration of legal questions related to patent scope, regulatory evidentiary standards, and the influence of pharmacy benefit manager and payor practices.

Competitive assessments in matters involving alleged patent thickets, potential antitrust issues and questions regarding rebate transparency increasingly involve both legal and economic frameworks.

In 2024 and 2025, several large pharmacy benefit managers removed Humira — the branded reference product for adalimumab, an anti-inflammatory biologic used to treat rheumatoid arthritis and other autoimmune conditions — from their national preferred formularies, leaving only adalimumab biosimilars covered.[1]

These exclusions underscore that, even as the U.S. Food and Drug Administration refines its efforts to promote biosimilar uptake, competition between biologics and biosimilars continues to be driven by multiple factors, including PBM and payor strategy.

In October 2025, the FDA released draft guidance that aims to reduce the evidentiary requirements for demonstrating biosimilarity and reflects policymakers' recognition that biosimilar uptake remains uneven.[2]

In particular, the guidance seeks to streamline the process for obtaining interchangeability designations, a change that could make it easier for pharmacists to substitute biosimilars for reference products without a prescriber's involvement in certain situations.

As questions continue to linger over whether the framework established under the Biologics Price Competition and Innovation Act can deliver robust competition between biologics and biosimilars, the experience of Humira and its biosimilars offers a useful real-world test.

A Brief History of the Biosimilar Regulatory Framework

The BPCIA, enacted in 2010, aimed to spur competition by establishing an abbreviated pathway for biologic follow-on products analogous to the Hatch-Waxman framework governing small-molecule generics.[3] However, unlike small-molecule drugs, biosimilars are derived from complex living systems, making molecular identity and substitution for branded reference products far less straightforward.

Interchangeability remains a key distinction: While all biosimilars are highly similar to their reference products, only those designated as interchangeable may be substituted at the pharmacy level, subject to state laws.[4]

The FDA's new draft guidance proposes less stringent comparative efficacy study designs to demonstrate interchangeability. This could lower evidentiary and cost barriers for biosimilar developers, potentially accelerating the timing of market entry and further shaping exclusivity and litigation strategies.

However, because multiple factors influence biosimilar uptake, continued analysis of emerging economic trends will be critical to understanding how these regulatory and market dynamics affect competition. Furthermore, these economic conditions also affect legal strategies, especially in light of the changing regulatory landscape.

Humira and Biosimilar Competition: Emerging Economic Trends

Humira's 2023 patent expiry followed years of litigation over an alleged patent thicket.[5] One might have expected that the subsequent entry of multiple adalimumab biosimilars would trigger rapid uptake and steep price declines akin to those that are often observed when small-molecule generics are launched. Yet, as data from early adoption of adalimumab biosimilars show, the reality has been far more nuanced.

According to our research, biosimilar uptake across biologic classes has varied significantly by product and generally lagged behind the pace of generic adoption.[6] These varied patterns in biosimilar uptake can depend on many factors, including payor

strategy, formulary design and vertical integration — all of which play a role in shaping competition between Humira and its biosimilars.

Adalimumab Biosimilar Uptake and the Role of Vertical Integration and Payor Dynamics

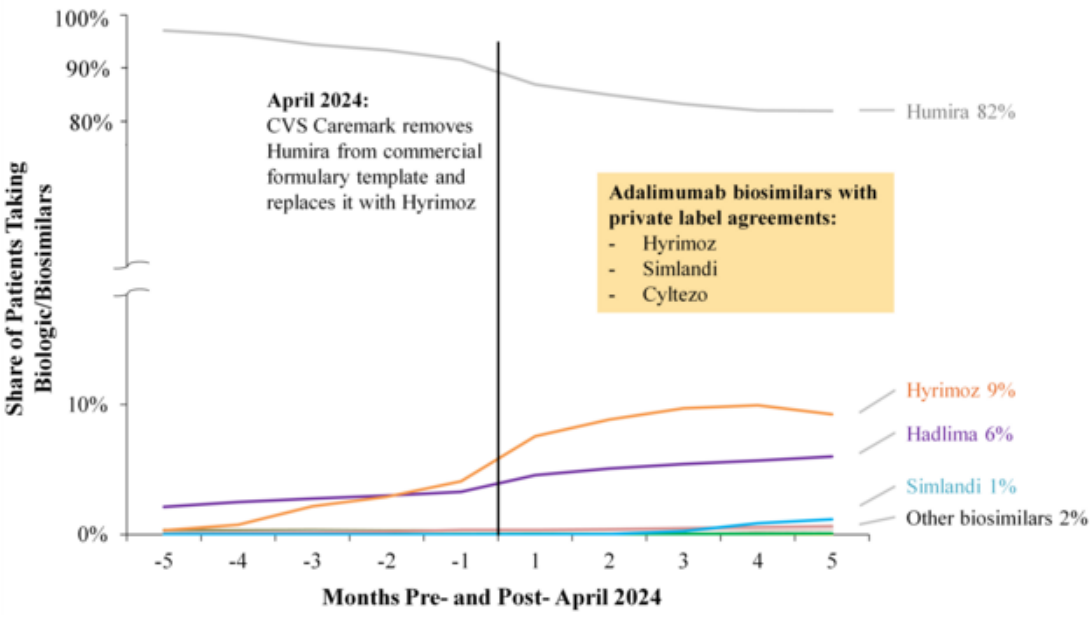
A notable development has been the rise of private-label distributed biosimilars and biologics in recent years.

A private-label distributor, often a PBM or retailer, markets and distributes a manufacturer's biosimilar under its own brand. For example, in 2023, CVS Health launched Cordavis, a subsidiary focused on bringing biosimilar products to the U.S. and which now serves as the private-label distributor for the adalimumab biosimilar Hyrimoz.[7]

Meanwhile, in April 2024, CVS Caremark revised its commercial formulary to exclude Humira while maintaining Cordavis' Hyrimoz as a covered treatment.[8]

These developments illustrate how private-label arrangements may reshape competitive dynamics between Humira and its biosimilars, and how legal practitioners will need to stay abreast of further changes due to both regulatory and economic factors.

Figure 1

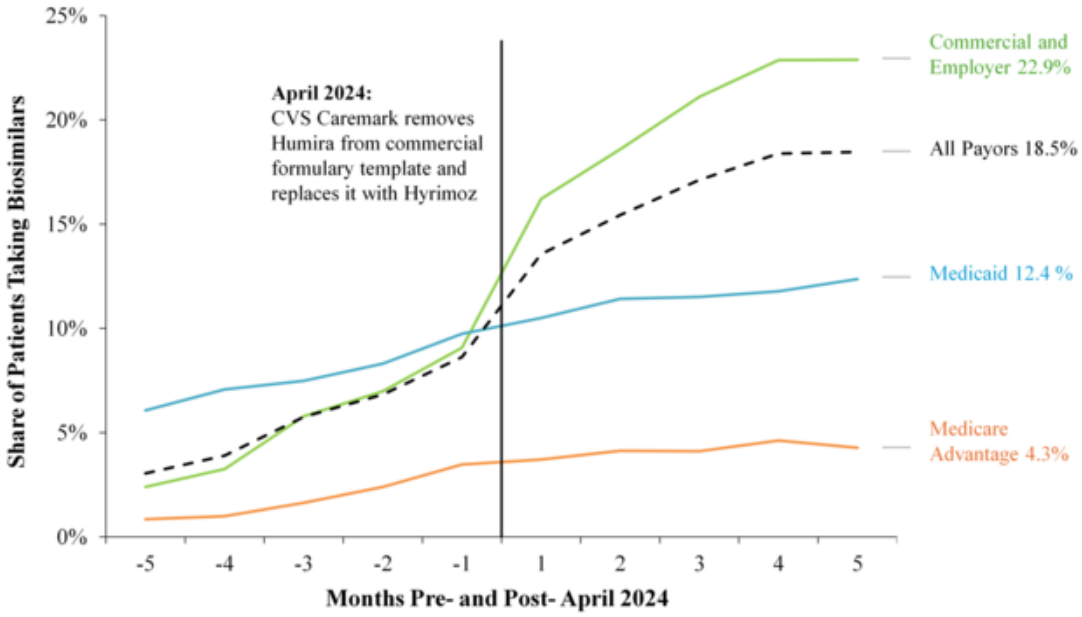


For example, uptake for Hyrimoz rose to approximately 9% in the five months following the April 2024 formulary update, up from an average of about 2% in the five months prior to the formulary change.

These trends highlight that biosimilar uptake can be affected by formulary decisions made by PBMs — especially when those PBMs also distribute private-label biosimilars.

Although biosimilar adoption percentages may appear modest, the underlying dollars are substantial. Given the magnitude of Humira's U.S. sales — more than $18 billion in 2022, its final full year without biosimilar competition — each percentage point in biosimilar share corresponds to meaningful changes in spending.[9]

Figure 2



Variation in payor reimbursement and formulary strategy can also influence biosimilar uptake. As shown in Figure 2, adalimumab biosimilar adoption has been meaningfully higher among commercial and employer health plan beneficiaries (approximately 23%), particularly after the April 2024 formulary change, than among those covered by government-funded health plans (4%-12%).

Within government-funded health plans, uptake has been higher for Medicaid beneficiaries than for those enrolled in Medicare Advantage plans. One potential reason is that Medicare Part D plan sponsors have traditionally preferred drugs with higher list prices and correspondingly larger rebates, reducing incentives to prioritize biosimilar alternatives.[10]

These differences underscore that competition between biologics and biosimilars can vary materially across payor channels.

Although numerous adalimumab biosimilars now compete with Humira, each product has unique characteristics that can influence its uptake and pricing. For example, adalimumab biosimilars differ in whether they are offered in low- or high-concentration formulations, marketed through private-label distributors, or hold interchangeability designations.[11]

Even as the FDA's October 2025 draft guidance aims to reduce evidentiary requirements for obtaining an interchangeability designation, variation in state substitution laws means that uptake could remain uneven across the U.S. — including for biosimilars deemed interchangeable with Humira.[12]

Forward-Looking Implications for Biologic and Biosimilar Competition

Humira's experience illustrates how many factors, including but not limited to policy, payor reimbursement and formulary strategy, and vertical integration, can collectively shape competition between biologics and biosimilars.

The adalimumab landscape shows that heterogeneity — in rates of adoption, pricing trajectories and contracting structures — may well persist, making continued study essential rather than assuming the existence of a one-size-fits-all model of competition.

As new biosimilars launch and the FDA's evolving guidance potentially lowers barriers to interchangeability and substitution, several legal and regulatory questions may take center stage in future biosimilar litigation, such as:

- Patent and process protection: How do alleged patent thickets and trade secret protections over manufacturing processes and other inventions affect entry timing, market access and the scope of lawful competition?
- Exclusivity and self-preferencing: Could vertically integrated private-label models lead to allegations of antitrust or favoritism concerns if linked to PBM formulary control?
- Transparency: How might rebate structures and net pricing arrangements affect claims around transparency, fair competition and potential exclusionary conduct?

As the FDA and courts continue to define the balance between innovation and competition, the Humira experience underscores that biosimilar success — and the legal disputes surrounding it — will be driven not only by scientific progress, but also by economic and market forces.

Michael Carson is a vice president, and Andrée-Anne Fournier and Pavel Darling are managing principals, at Analysis Group, Inc.

Endnotes

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