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The Top 10 Drugs Losing US Exclusivity in 2025

Source: An article by Eric Sagonowsky, Angus Liu, Fraiser Kansteiner, Andrea Park, Kevin Dunleavy, Zoey Becker for FiercePharma)

While each year features high-profile losses of exclusivity in the pharma industry, this year's list is significant.

Johnson & Johnson's *Stelara* is already facing off against several biosimilars, and several more are yet to come as the year plays out. With US$6.72 billion in U.S. sales in 2024, the drug is the largest U.S. loss of exclusivity since AbbVie's mega blockbuster *Humira* suffered the patent cliff in early 2023. Johnson & Johnson had previously warned of a "late 2023" patent cliff for *Stelara*, but the company was able to squeeze more life out of its key immunology moneymaker through a series of legal settlements.

Johnson & Johnson's not alone in losing U.S. market exclusivity on a key sales driver this year. Also facing ongoing or future declines for their top revenue generators are Regeneron with eye drug *Eylea*, Amgen with bone medicines *Prolia/Xgeva* and Novartis with heart failure therapy *Entresto*.

Eylea already faces its first U.S. biosimilar after Amgen launched *Pavblu* in November. *Eylea* is included in this report—despite the biosimilar launch happening last year—because the commercial situation is still playing out for Regeneron and to not exclude a key development in an important market.

Amgen, for its part, collected US$4.39 billion in revenue from its key bone medicines *Prolia* and *Xgeva* last year. While the company has built its own impressive biosimilar business over the years, it'll have to play an unfamiliar role and watch copycat drugs eat away at the market for its originators starting in late May and early June.

Novartis, meanwhile, has warned of a "mid-2025" loss of U.S. exclusivity for *Entresto* as a key combination patent nears its expiration this summer. Besides *Entresto*, Novartis has two other big-selling products on this list - *Promacta* and *Tasigna*.

Moving down the list, readers will likely notice two high-profile drugs from AstraZeneca. Rare disease medicine *Soliris*, picked up in AZ's buyout of Alexion, is set to face its first biosimilar from Amgen sometime in the second quarter. And *Brilinta*, a cardiometabolic drug once pegged to be a key blockbuster but that never quite met expectations, is also running out of its U.S. patent protections in the near future.

For one measure of the high-profile nature of the drugs on this list, 2024's report gives a number of examples. With US$1.45 billion in prior-year U.S. sales, Bristol Myers Squibb's *Sprycel* led the 2024 group. But, if compared against the 2025 class of patent expirations, *Sprycel* would rank No. 6.

There are always uncertainties in compiling this report due to the unpredictable nature of patent litigation and regulatory interactions. This year, the drug with the most apparent uncertainty is J&J's *Simponi* and *Simponi ARIA*. That medicine's inclusion hinges on a potential fourth-quarter approval—and

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In Brief...

- **Johnson & Johnson** announced that it will invest US$55 billion in US manufacturing facilities and other domestic infrastructure over the next four years. The disclosure followed plans revealed by other pharma companies in recent weeks, including **Eli Lilly's** February announcement that it will more than double its planned investment in US manufacturing to US$50 billion and **Merck & Co.'s** recent pledge to invest US$8 billion in US manufacturing facilities by 2028 on top of US$12 billion spent since 2018.
- **Sanofi** has taken another step on the path to becoming the world's leading immunology company by paying US$600 million to acquire **Dren Bio's** *DR-0201*, an early-stage bi-specific myeloid cell engager. .
- **AstraZeneca** and **Alteogen Inc.** have entered into an exclusive license agreement for *ALT-B4*, a novel hyaluronidase utilizing *Hybrozyme™* platform technology. Under the terms of the agreement, AstraZeneca will acquire worldwide rights to use ALT-B4 to develop and commercialize subcutaneous formulations of several oncology assets. Alteogen will be responsible for clinical and commercial supply of ALT-B4 to AstraZeneca.
- **Cardinal Health's** board of directors has elected *Robert Musslewhite,* former CEO of Definitive Healthcare, and *Sudhakar Ramakrishna,* president and CEO of SolarWinds Corporation, as independent directors, effective March 7. With more than 20 years of leadership experience, Musslewhite brings to the board unique expertise in advanced analytics, data and technology across the healthcare

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Sven Seidel, CEO of PHOENIX group, Joins IFPW Board of Directors

IFPW is pleased to announce that Sven Seidel has been appointed to the IFPW Board of Direcctors as a Director-at-Large for Europe, the Middle East and Africa regions.

Sven is CEO of the PHOENIX group. Prior to 2019, Sven served as an Executive Board Member of the OTTO Group, CEO of LIDL from 2014 to 2017, having previously held the position of Executive Board Member responsible for the group's corporate development. Before his executive board roles, Sven was a partner at Porsche Consulting (2003-2011). He has extensive experience in consumer products and consumer health, omnichannel commerce, and corporate transformation.

IFPW congratulates Sven on his appointment and looks forward to working with him as an integral member of IFPW's Board of Directors.

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Top Ten *(cont'd.)*...

launch—of Teva and Alvotech's *AVT05*. The medicine was included in the report because a key patent has already expired, and a reputable biosimilar team is marching through the regulatory process.

To compile this report, company filings, presentations and conference call transcripts were considered, along with published research from pharmacy benefit manager OptumRx and healthcare services firm Cardinal Health. The report ranks the top U.S. losses of exclusivity based on U.S. sales from the prior year.

Top Ten U.S. Drugs Losing Exclusivity in 2025

Drug	Company	2024 Sales (in US$ Billions)
1. Stelara	Johnson & Johnson	6.72
2. Eylea	Regeneron	4.77
3. Prolia/Exgeva	Amgen	4.39
4. Entresto	Novartis	4.05
5. Soliris	AstraZeneca	1.52
6. Promacta	Novartis	1.18
7. Simponi/Simponi Aria	Johnson & Johnson	1.08
8. Tysabri	Biogen	0.92
9. Tasigna	Novartis	0.848
10. Brilina	AstraZeneca	0.751

Survey Finds Improvement in Price Revision Rates for Generic Players

(Source – An article by Takashi Ebisawa for Pharma Japan)

Japan's generic manufacturers are seeing an improvement in revision rates in the FY2025 drug price revision following the 3% hike in minimum NHI prices and the companies' pricing strategies vis-á-vis wholesalers, according to a JIHO survey.

Five generic makers responded to the survey, conducted in March in conjunction with the Ministry of Health, Labor and Welfare's (MHLW) announcement regarding new NHI prices which will take effect April1, 2025. The five companies that realized the improved revision rates are Sawai Pharmaceutical, Towa Pharmaceutical, Nichi-Iko Pharmaceutical, Nipro and Nissin Pharmaceutical.

Nissin's products will see a positive revision upwards of 3%. "This is probably the first time our revision rate has turned positive," the company commented. "The hike in minimum NHI prices and our tenacious price negotiations paid off." For confidentiality reasons, the company did not further elaborate.

Towa will see a negative revision, but at a narrower rate of -2.7%, compared to its FY2024 revision rate of -5.2%. By using this number as its "final defense line," the company has introduced a new strategy to raise the ratio of wholesaler purchase prices (WPPs; invoice prices to wholesalers) trying to narrow the gap between market prices and NHI prices. The company's success using this strategy, coupled with the increase in minimum prices, helped halve its revision rate.

Adversely, Sawai's and Nipro's negative revision rates will widen by more than 2 points compared to FY2024 to -3.1% and -2.5% respectively. Both companies attribute this mainly to a reduction in the number of products subject to unprofitability re-pricing in FY2025. Nichi-Iko's revision rate is -1.0%.

Considering that the market environment will toughen in the future, some of these companies plan to continue strengthening their pricing strategies through measures such as raising WPPs. The five companies also largely agreed on the need to further expand price support rules such as increases in minimum NHI prices of essential medicines and unprofitable products. Nissin pointed out that the current unprofitable product re-pricing rule does not use a calculation formula that appropriately reflects rising personnel costs.

In Brief (cont.)

ecosystem. Ramakrishna is an experienced CEO and global technology leader with more than two decades of technology and business expertise.

- **Dr. Reddy's** is selling a portfolio of 14 abbreviated new drug applications to **Senores Pharmaceuticals**. The acquired portfolio consists of 13 ANDAs already approved by the **U.S. Food and Drug Administration** and one pending approval. The estimated market for these ANDAs in the U.S. is estimated between US$421 million and US$1.3 billion.
- **Mallinckrodt plc** and **Endo, Inc.** announced they have entered into a definitive agreement to combine in a stock and cash transaction to create a global, scaled, diversified pharmaceuticals company. The companies plan to combine their generic pharma business and Endo's sterile injectables business after the close of the transaction, with the intention of separating that business from the combined company at a later date (subject to the combined company's board of directors' approval and other conditions.)
- **Sumitomo Pharma** is to divest its Asia pharma businesses to major Japanese trading house **Marubeni** for a total consideration of ¥72 billion (US$480.3 million), with the first part of the transaction due to occur by the end of September. The agreement marks another move by one of Japan's major business conglomerates to draw down its pharma interests
- The government of Japan is investing ¥55.3 billion (US$369.7 million) in initiatives aimed at the repatriation of active pharmaceutical ingredients (APIs) for certain antibiotics essentials in the treatment of infectious diseases and preventing infections during surgery. Four companies are currently working with the government to build systems for API manufacturing in Japan, including **Meiji Seika Pharma, Fujifilm Toyama Chemical, Otsuka Chemical** and **Shionogi Pharma.** According to sources, the Japanese government has subsidized 50% of the costs of new construction and renovation of production facilities with the goal of supplying finished products by 2030. One point of concern is that domestic production will bring the issue of higher manufacturing costs, since Japan-produced APIs would mainly be supplied domestically without economies of scale for limited production. Estimates show that manufacturing costs would be three to ten times higher than if produced overseas.

(Sources: Company Press Releases, Drug Store News, FiercePharma, PharmaVoice and Pharma Japan)