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3 Big Battles in Biosimilars to Watch

The global biosimilars market is forecast to grow to \$24 billion by 2019. A few major contenders -- Hospira, Novartis, and Mylan -- could profit from that growth.

Leo Sun ([TMFSunLion](#))
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The global market for biosimilars, or generic versions of biologic medical products, is expected to soar to \$24 billion by 2019, according to a recent report from Frost & Sullivan -- not bad for a fledgling industry that currently only consists of a handful of drugs.

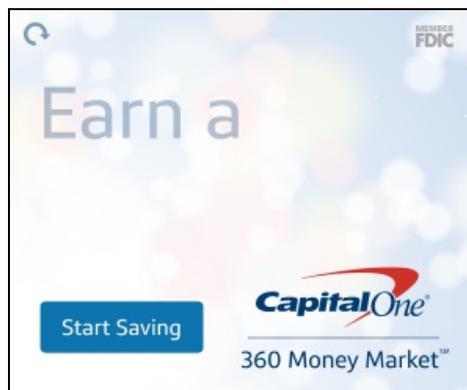
Biosimilars have appeared in response to the patent cliff now facing some of the top-selling biologic drugs of the past decade. In this article, we'll examine biosimilar versions of **Johnson & Johnson** ([NYSE:JNJ](#)) and **Merck's** ([NYSE:MRK](#)) Remicade, **Amgen's** ([NASDAQ:AMGN](#)) Enbrel, and **Roche's** ([NASDAQOTH:RHHBY](#)) Herceptin, and look at just how much these new contenders matter to patients and investors.

Generic Remicade

The blockbuster rheumatoid arthritis treatment Remicade is a core source of revenue for J&J ([NYSE:JNJ](#)) and Merck ([NYSE:MRK](#)), which co-market the drug globally:

Company	2013 Remicade sales	YOY growth	Percentage of total revenue
J&J	\$6.67 billion	8.7%	9.4%
Merck	\$2.27 billion	9%	5.2%

SOURCE: COMPANY ANNUAL REPORTS.



Remicade's European patent will expire in February 2015, although its U.S. patent will last until September 2018.

That's where **Hospira** ([NYSE:HSP](#)), a maker of injectable drugs and medical devices, comes in. Hospira is no stranger to biosimilars -- two of its newer drugs, Retacrit and Nivestim, are respective generic versions of J&J's ([NYSE:JNJ](#)) anemia drug Procrit/Eprex and Amgen's ([NASDAQ:AMGN](#)) neutropenia treatment Neupogen.

Hospira's ([NYSE:HSP](#)) biosimilar version of Remicade, known as Inflectra, last September became the first biosimilar monoclonal antibody ever approved in the European Union. Hospira ([NYSE:HSP](#)) co-developed the drug with South Korean company **Celltrion**, which will market the product as Remsima.

Hospira ([NYSE:HSP](#)) plans to launch Inflectra across Eastern Europe this year, and subsequently into larger Western European markets in 2015 as more of Remicade's patents expire. If patent litigation doesn't halt the early launch of Inflectra and Remsima, the drug could generate annual sales of \$560 million in Europe, according to Barclays analyst Mark Purcell.

This could provide Hospira ([NYSE:HSP](#)), which generated \$4 billion in 2013 sales, with a considerable boost in 2015 and beyond. More importantly, it could offset the double-digit decline of its medication management business, which was hurt by an FDA ban that prevented the company from importing several of its top-selling medical devices from Costa Rica.

Generic Enbrel: Amgen vs. Novartis

Amgen's ([NASDAQ:AMGN](#)) Enbrel, another blockbuster arthritis drug, could also soon be threatened by a biosimilar version developed by **Novartis'** generics unit Sandoz. Amgen and **Pfizer** ended their co-marketing agreement for the drug last October.

Company	2013 Enbrel sales	YOY growth	Percentage of total revenue
Amgen	\$4.55 billion	7%	24.4%
Pfizer (outside U.S. & Canada)	\$3.78 billion	1%	7.3%

SOURCE: COMPANY ANNUAL REPORTS.

Amgen's ([NASDAQ:AMGN](#)) patent on Enbrel will not expire in the U.S. until 2028, thanks to new patents issued in 2011 and 2012, but it already faces generic competition overseas.

However, Novartis is intent on challenging Amgen ([NASDAQ:AMGN](#)) in the U.S., and initiated a late-stage trial of its biosimilar version of Enbrel last June. Novartis then sued Amgen ([NASDAQ:AMGN](#)), claiming that the new patents were invalid and unenforceable. However, a court ruled that a biosimilar manufacturer couldn't sue a branded company unless a new drug application for the biosimilar had already been filed with the FDA. Novartis appealed the decision in December.

Regardless of the outcome of the appeal, Novartis has a steep uphill climb ahead. When Amgen ([NASDAQ:AMGN](#)) received those new patents, Merck ([NYSE:MRK](#)) completely abandoned its efforts to create a biosimilar version of Enbrel.

Despite these stateside challenges, Novartis could manufacture the biosimilar overseas, where generic versions of Enbrel are already available from Pfizer's Wyeth division and Indian company Taj Pharmaceuticals.

Either way, a market approval of Novartis' generic Enbrel could further boost sales at its Sandoz division, which posted a 5%

year-over-year jump in sales in 2013. Sandoz accounts for 16% of Novartis' top line.

Generic Herceptin: Roche vs. Mylan and Biocon

Last but not least, we'll look at **Mylan** and **Biocon's** biosimilar version of Roche's ([NASDAQOTH:RHHBY](#)) blockbuster breast cancer drug Herceptin, which was approved last November. Herceptin, a targeted treatment for HER2+ breast cancer (25% of breast cancer cases), is one of the lead contributors to Roche's top line.

Roche Herceptin sales, 2013	YOY growth	Percentage of total revenue
6.08 billion CHF (about \$6.84 billion)	6%	13%

SOURCE: ROCHE 2013 ANNUAL REPORT.

Roche's ([NASDAQOTH:RHHBY](#)) patents for Herceptin will expire in 2014 in Europe and 2019 in the U.S. However, it faces a unique situation in India, due to the Indian government's practice of pushing pharmaceutical companies to either lower their prices or allow local pharmaceutical companies to produce generic versions of their patented drugs. Those practices caused Roche ([NASDAQOTH:RHHBY](#)) to lower the price for Herceptin from \$4,500 per month in the U.S. to \$1,366 in India, and to abandon its patent altogether last August in India.

Mylan, the third largest generics maker by revenue in the world, and Indian biopharmaceutical company Biocon then pursued the market approval of Hertraz, their biosimilar version of Herceptin.

On Feb. 10, however, Roche ([NASDAQOTH:RHHBY](#)) secured an injunction in India against Mylan and Biocon to ban any direct comparisons between Hertraz and Herceptin. Roche's ([NASDAQOTH:RHHBY](#)) reasoning was that there were no public records for the phase 1 and 2 trials demonstrating that Hertraz was a valid biosimilar version of Herceptin. As long as the injunction is active, Hertraz can only be promoted as an alternative treatment for HER2+ breast cancer instead of a biosimilar version of Herceptin.

Biocon called Roche's ([NASDAQOTH:RHHBY](#)) strategy "shocking but not unexpected," and highlighted the challenges that generic-drug makers can face while developing biosimilars in developing countries.

The Foolish takeaway

The biosimilars market is a key one to watch in the health care industry as blockbuster biologic drugs start going off patent. Companies such as Hospira, Novartis, and Mylan are all poised to profit from these losses at Johnson & Johnson ([NYSE:JNJ](#)), Merck ([NYSE:MRK](#)), Amgen ([NASDAQ:AMGN](#)), and Roche ([NASDAQOTH:RHHBY](#)) over the next few years.

10 stocks we like better than Merck and Co.

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David and Tom just revealed what they believe are the [ten best stocks](#) for investors to buy right now... and Merck and Co. wasn't one of them! That's right -- they think these 10 stocks are even better buys.

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*Stock Advisor returns as of Nov. 7, 2016

Leo Sun has no position in any stocks mentioned. The Motley Fool recommends Johnson & Johnson. The Motley Fool owns shares of Johnson & Johnson. Try any of our Foolish newsletter services [free for 30 days](#). We Fools may not all hold the same opinions, but we all believe that [considering a diverse range of insights](#) makes us better investors. The Motley Fool has a [disclosure policy](#).

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