

March 31, 2020

Amarin falls at obvious hurdle



[Amy Brown](#)



Amarin's loss of a crucial patent lawsuit shows that potential buyers were right to be wary of the Vascepa opportunity.

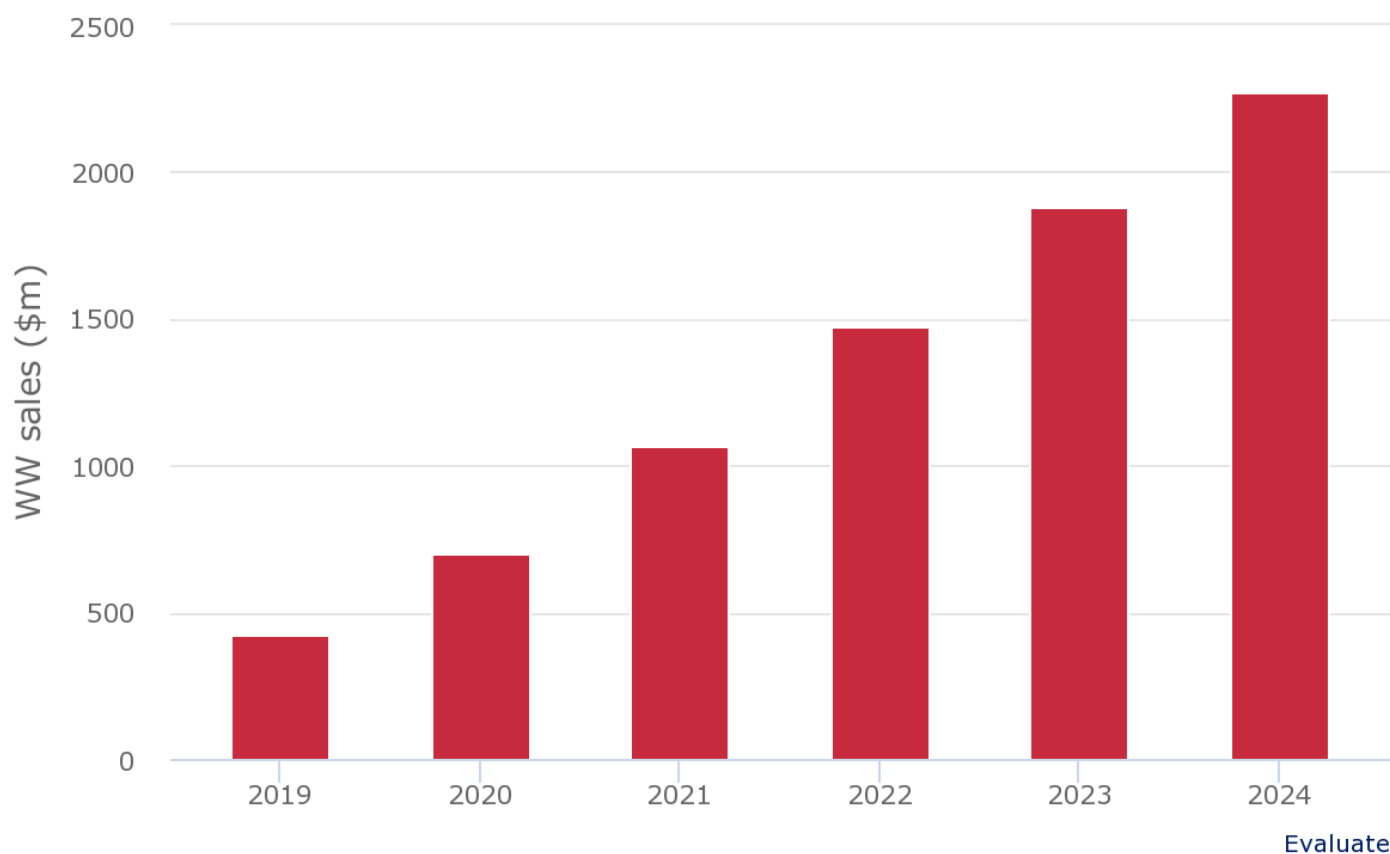
It's the age old story of love lost, found and then lost again. And in this case love really is a drug - Amarin's Vascepa - which had crucial US patents invalidated yesterday.

The [company will appeal](#), so this tale still might have further twists, but the 70% plunge in Amarin's stock today shows that investors have lost interest. Rightfully so - executives gambled on a win, rather than settling with the two remaining generic challengers, a bet that today seems woefully misjudged.

Amarin was not alone in expressing confidence in prevailing in the lawsuit, which had been brought by Dr Reddy's and Hikma. A big majority of analysts also told investors that the company had a good chance of winning, a sellside that today swiftly moved to slash price targets to single digits. Amarin shares were trading at \$24 at the end of last year, but this morning they opened at \$4.

Hopes for a takeout were largely responsible for driving the company's valuation, which reached \$9bn at peak; if any parties were really interested, their decision to hold off will today seem prescient.

Vascepa forecasts



Intellectual property was always thought to be Vascepa's Achilles' heel, and so it seems to have proven ([Litigation risk still overhangs the Amarin takeover thesis, December 16, 2019](#)). The district court decided that, although the generics groups would be infringing Amarin's patents, these patents were invalidated on grounds of obviousness.

Vascepa is the only advanced fish oil product comprising pure eicosapentaenoic acid (EPA); older drugs, like Glaxosmithkline's Lovaza, also contain docosahexanoic acid (DHA), the ingredient that has long been known to raise LDL cholesterol.

Therefore, it would have been obvious to a "skilled artisan" that removing DHA from a fish oil product could have solved the LDL problem, the judge concluded, while retaining an ability to reduce triglycerides. Amarin will seek an injunction to halt any generic launch, a process that some believe could stretch on for years.

The most immediate risk to the company is that an injunction is turned down - the 30-month stay has long expired on the challengers' ANDA filings, so US approval could swiftly be followed by an at-risk launch. Hikma today said it was "evaluating its options" for exactly this course of action, and Dr Reddy's is presumably doing the same.

Another aspect to consider here is what Teva might do; Amarin settled with the Israeli firm over its challenge [back in 2018](#). Under this deal the Israeli firm agreed to stay off the market until August 2029, but "commercial launch by another generic manufacturer under certain circumstances" could bring that date forward.

At an-risk launch elsewhere is surely one of those circumstances, and an agreement to pay Amarin a royalty on any early sales provides a wafer-thin silver lining.

Cold comfort

Still, all three generics firms filed their ANDAs back in 2016, and it is notable that tentative approvals have yet to be granted. Presumably all have had complete response letters issued. Vascepa is a complex product, and approvals anytime soon are far from guaranteed.

Also, this decision only has implications for US sales. Leerink analysts estimate that Canada, Europe and China combined represent at least a \$2bn sales opportunity, though the drug is only launched in the first territory. An EU approval decision, where Amarin was intending to find a partner, is due later this year, while clinical development is still ongoing in China.

But this, and potential delays to generic approvals, are cold comfort to investors, who have seen Amarin

transition from stock market wildcard to developer of a universally lauded lifesaving medicine over a mere 18 months. The US was always the big prize, and sales could start evaporating as soon as next year.

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