

Event - Biogen gears up for Tecfidera's day in patent court



[Lisa Urquhart](#)

November 30 is almost certainly circled in red on the calendars of senior executives at Biogen. Key patents on its bestselling product, Tecfidera, are set to suffer a two-pronged attack from Forward Pharma and the Coalition for Affordable Drugs (CAD) during patent interference hearings, representing a defining moment for the company.

If successful Forward Pharma could claim double-digit royalties on future sales of Tecfidera, and a percentage of historic sales stretching back to 2014. If the CAD triumphs the door will be flung open for generic competition from all comers. Conversely, a win for Biogen would remove one of the largest overhangs on the stock and allow the company to protect revenues that last year accounted for just under 40% of total sales.

Company	Biogen
Product	Tecfidera
Market cap	\$68.5bn
Product NPV	\$14.7bn
% of market cap	21%
Event type	Patent interference hearings
Date	November 30

Pay it Forward

As with all matters patent related, the interference hearing is merely a step on a long and torturous legal path. The two decisions are not expected before the first quarter of next year, and each of the parties can appeal. Still, even the hint of a negative decision for Biogen is bound to weigh heavily on its stock, given the potential sums of compensation.

Forward is disputing US and European patents for Tecfidera, and if it finds itself on the winning side it is expected to demand a cash settlement for previous sales of the product starting from 2014 - the date its case first reached court - and royalties on future sales.

Some analysts are forecasting royalties of 10%, which would equate to a \$364m boost to Forward's 2015 revenues based on gross Tecfidera sales in the same year. Worryingly for Biogen, Forward management has in the past talked of royalty rates as high as 20%, creating an even bigger risk to an already fragile MS franchise.

Art and science

Forward Pharma's case relates to the dose patents, with the Danish company arguing that it has much earlier claims over the 480mg daily dose of dimethyl fumarate (DMF), the chief ingredient in Tecfidera.

There have always been tricky IP issues around Tecfidera, mainly owing to the long commercial history of DMF. Jefferies analysts said the dose patents always seemed questionable "given the obviousness of developing and using any drug at an appropriate dose".

And Biogen's separate case against the CAD hinges on arguing against the obviousness of changing the dose of an old drug to work in a new indication, and prior art - that it was not aware of anyone else looking at DMF in MS. The inter partes review (IPR) case was brought by the CAD's founder, Kyle Bass.

Although it is hard to determine Mr Bass's ultimate intentions, the coalition targets drug patents, while

simultaneously shorting the stock of the companies in its crosshairs. Mr Bass argues that his tactics help lower drug prices; however, the fact that they also make him a tidy profit should not be ignored.

While it can be hard to feel sorry for companies protecting patents on very old drugs solely to boost profits, some in the industry have argued that he is abusing a system that was originally designed to help fight patent trolls.

Countdown

Mr Bass's involvement has set important deadlines for proceedings. As the patent court is considering both cases together, many expect the outcome of Forward's interference to be decided by March 22, 2017, the date when a decision on the IPR must be finalised.

If Biogen fails in either of its defences - and IPRs have been shown to succeed in 77% of cases - the already troubled group would be forced to pull the trigger on the acquisitions in the CNS field many have been calling for. As such, the planned spinout of the haemophilia business Bioverativ, due in early 2017, could not have come at a better time.

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