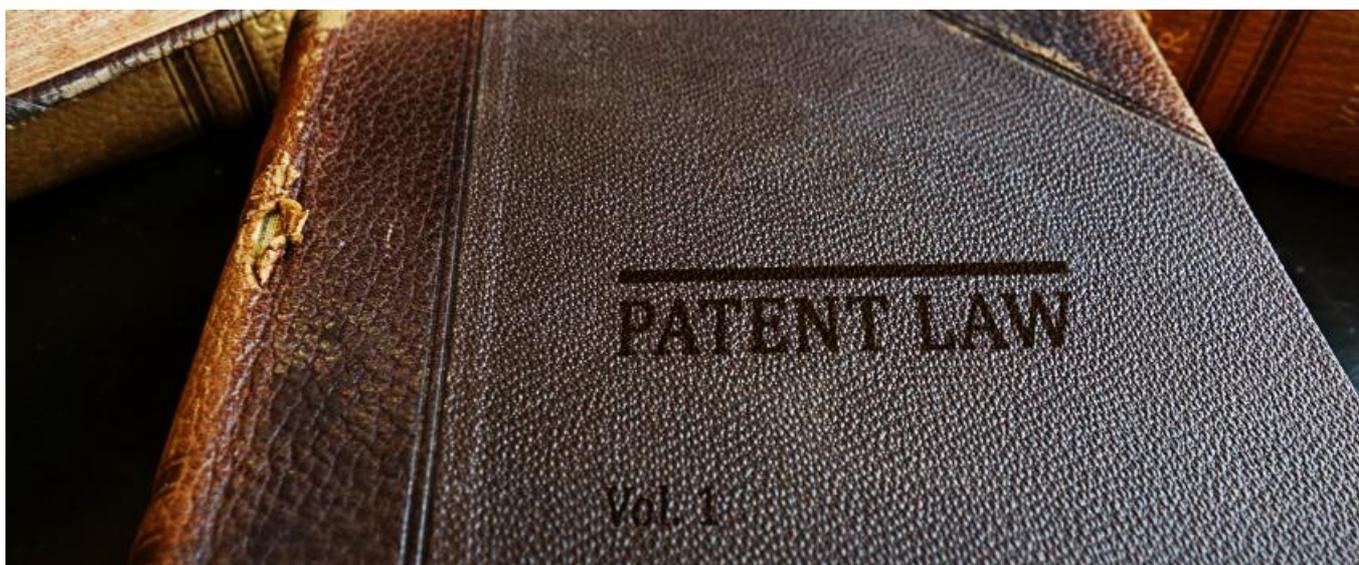


After Alzheimer's collapse, Biogen must win Tecfidera patent challenge



[Jonathan Gardner](#)



A successful Mylan challenge would see generic entry within two years - though Biogen has fought off copycats before.

Biogen's aducanumab disaster has raised the stakes for the next major valuation-shifting catalyst in the company's calendar: a US decision on Tecfidera's intellectual property, due in 2020.

At stake are eight extra years of Tecfidera sales, which would equate to around \$4bn in valuation, or a quarter of what the company lost on last week's news that aducanumab had failed a futility test in Alzheimer's disease. Uncertainty over the shelf life of Biogen's biggest product might keep bigger players from bidding on the company, at least at its current valuation. In the meantime, Biogen has a chance to strike its own deals. If the worst-case scenario with Tecfidera comes to pass for the company, and its valuation plummets again, the group could become even more at risk of a low-ball takeout.

The good news for the Massachusetts-based group is that Tecfidera has survived challenges before, although its six decades of use as a human therapeutic should raise questions about the strength of its patent estate.

2021 or 2028

A victory for Mylan's 2020 *inter partes review* (IPR) of the Tecfidera '514 patent could see launch of a generic as soon as the end of 2020 or early 2021. Should Biogen prevail, generic entry would be delayed to 2028.

The difference is worth billions in sales and valuation to Biogen. Assuming entry of a Tecfidera generic at the beginning of 2021, *EvaluatePharma's* NPV analyser suggests the multiple sclerosis pill has a net present value of \$5.6bn and Biogen a market capitalisation of \$40.6bn. Stretching the intellectual property to 2028 adds just over \$4bn to these figures.

The possibility that the company's biggest marketed product could face generic erosion in the near future might have contributed to Biogen's decision today to add \$5bn to the share buyback programme it initiated in August 2018. This had \$1.7bn remaining.

Tecfidera scenarios			
	Current model	Mylan wins	Biogen wins
Generic entry	Mid-2023	End 2020/Beginning 2021	2028*
Tecfidera NPV	\$7.6bn	\$5.6bn	\$9.7bn
Biogen market cap**	\$42.6bn	\$40.6bn	\$44.8bn

**Assumes mid-year patent expiry. **Based on March 22 market close.
Source: EvaluatePharma*

The longer Biogen can delay generic entry, the more time it will have to get Tecfidera follow-on Vumerity (BIIB098) established. Now being reviewed by the FDA, Vumerity probably will not save the Biogen oral MS franchise if Tecfidera generics launch sooner rather than later, however.

EvaluatePharma's consensus shows sales reaching \$111m in 2024. Bernstein analyst Ronny Gal points out that Biogen probably will not be able to engage in a patient-switching strategy for Vumerity, as it is a different active ingredient, and patients stable on Tecfidera will want to continue.

Battle-tested

For a molecule that has been used as a drug in humans since 1959, Tecfidera's active ingredient, dimethyl fumarate, has been remarkably resilient to intellectual property challenges. The latest came in February with Mylan's IPR challenge to the '514 patent on the basis of obviousness. The method patent claims protection for a method of treating patients with 480mg a day of fumaric acid esters.

Biogen has already prevailed in two IPRs from the Coalition for Affordable Drugs, led by the hedge fund manager Kyle Bass. All of the IPRs so far have centred on a 2006 publication of phase II data showing that dimethyl fumarate showed efficacy at 720mg a day but not at 360mg a day.

These data came before Biogen filed the 480mg patent. The previous IPRs argued that 480mg daily, Tecfidera's maintenance dose, was obviously efficacious because it is between the 360mg and 720mg tested in phase II. This case was rejected because the magnitude of the efficacy at the 480mg daily dose used in phase III would not have been obvious.

Mylan's new claim adds that post hoc analyses of the phase II data would have revealed the 480mg dose's efficacy, an argument Biogen rejects because of a lack of statistical significance.

Analysts reviewing the Mylan challenge have noted that because Tecfidera's IP has survived previous challenges, there is a good chance that it will do so again. However, the fact the PTAB judges decided to institute a new review, rather than rejecting Mylan's request outright, might mean they have seen something worth studying.

Mylan has little to lose in its new legal assault on Tecfidera. While Biogen is now touted as an acquisition target thanks to its post-aducanumab valuation, the legal wrangling will probably keep buyers on the sideline until its true value becomes clearer. The group now needs to do something more decisive than share buybacks – its investors want deals, and soon.

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