

Patent rulings knock Acorda and Forward



[Jonathan Gardner](#)



Acorda and Forward have been bashed by unfavourable US patent verdicts in multiple sclerosis, while Steadymed got a boost.

It was a bloody Friday for two biotechs that ended up on the wrong side of US patent court decisions. Verdicts handed down by the Patent Trial and Appeal Board (PTAB) mean that Acorda Therapeutics is on track to see generic competition for its multiple sclerosis drug Ampyra as early as next year. Separately, Forward Pharma could miss out on a substantial royalty stream owing to a negative decision on its claims on Biogen's multiple sclerosis pill Tecfidera.

A third decision sparked a share gain in the microcap Steadymed Therapeutics, which won a favourable judgement on treprostinil, the active ingredient in United Therapeutics' pulmonary arterial hypertension treatment Remodulin. United will be facing further legal action on its biggest seller later this year, and analysts are forecasting a sales decline starting next year.

Falling accordingly

Shares in Acorda and Forward fell a similar amount, 21% and 20% respectively. However, the former is in a more difficult position as Ampyra is its only marketed product and the group will see new sales only if its Parkinson's disease asset CVT-301 is approved next year.

The group said it had developed contingency plans in the event of the loss of Ampyra's exclusivity, and would disclose them when it had decided to implement them. Acorda ended 2016 with \$159m of cash; with the potential entry of generics in 2018 at around the time when CVT-301 could be expected to be launch, the group will need to watch its operating expenses, which it expects to amount to at least \$380m in 2017.

Although its shares took on water Friday, Denmark-based Forward is in a more enviable position since it had already signed a deal with Biogen in which the Massachusetts-based biotech paid \$1.25bn to settle part of a long-running dispute. The PTAB decision on patent interference cuts Forward out of royalties that could have amounted to \$300m a year and potentially sets Tecfidera generic entry back by three years to 2028.

Still, Forward, whose main asset appears to be the claim that it filed its patent on dimethyl fumarate a year and a half before Biogen, is in a pretty good position. Its shares are still up 15% since before it signed the deal, and it has a significant war chest.

Assault on three fronts

Steadymed, meanwhile, prevailed in its *inter partes* review against United Therapeutics over manufacturing

patents relating to trestoninil sodium, the active ingredient in Remodulin, Tyvaso and Orenitram. California-based Steadymed wants to deliver trestoninil via a “patchpump” device technology called Treyvent.

The group’s shares rocketed 47% on Friday and were up another 41% this morning. United’s stock was little moved on Friday, but fell 6% this morning following news of a delay in the launch of a new Remodulin delivery technology.

EvaluatePharma’s consensus of sellside forecasts sees United’s revenues, which consist primarily of the three trestoninil-based products, peaking this year at \$1.7bn.

United’s intellectual property estate faces further challenges in the form of patent suits on Tyvaso and Orenitram filed by Watson and Actavis respectively – presumably, these cases would now be owned by Teva Pharmaceutical Industries, but it is not clear from regulatory filings. The Watson trial is due to begin in September 2017, and the Actavis case in February 2018.

As such United could have more pain to come, while Acorda faces a tough year ahead. Forward, however, thanks to deal-making before the patent decision, could have life left in it yet.

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