Allergan Inc

Waxman hits out at Allergan patent deal with Mohawk tribe

Democrat accuses US drugmaker of blocking competition from generic rivals



Former congressman Henry Waxman accused Allergan of 'blocking competition that would create price competition and provide patients with a choice'

OCTOBER 8, 2017 by David Crow in New York

The architect of landmark legislation that established the system for generic medicines in the US has hit out at Allergan, accusing the drugmaker of blocking competition by transferring its patents to a Native American tribe.

The intervention by Henry Waxman, the former Democrat congressman, comes amid mounting criticism of Allergan in Washington, after it transferred patents protecting a \$1.5bn eyecare drug to a tribe in an unusual attempt to see off a challenge from generic rivals.

After taking ownership of the patents last month, the Saint Regis Mohawk Tribe applied to have a challenge against the intellectual property thrown out on the grounds that its status as a sovereign nation gave it immunity. The tribe received an upfront payment of \$13.75m from Allergan and a potential \$15m a year in royalties.

Mr Waxman, who was in congress between 1975 and 2015, described Allergan's manoeuvring as "troubling" and said the drugmaker had transferred the "patent to a sovereign nation with the intention of extending the drug's monopoly".

He said the move would have the effect of "blocking competition that would create price competition and provide patients with a choice".

Last week, Senator Claire McCaskill, a Democrat, introduced a bill designed to thwart the Allergan arrangement, which would prohibit tribes from claiming sovereign immunity in patent disputes. Several other prominent politicians, including Republicans, have either requested a probe into the deal or criticised it.

Mr Waxman's criticism is damaging because the <u>bipartisan legislation</u> he passed in 1984 with Senator Orrin Hatch, a Republican, is held up by the pharma industry as a grand compromise that sped up the introduction of generic medicines while protecting intellectual property rights.



"When drafting the Hatch-Waxman Act, Senator Hatch and I worked hard to find a balance that would promote price competition while providing at the same time incentives for manufacturers, such as extending their patent life," Mr Waxman told the Financial Times.

He added: "Now we are seeing efforts that are throwing off the balance we achieved."

Allergan has said it only intends to use the arrangement with the tribe to protect it from a quasi-judicial patent appeals process known as inter-parties review (IPR), which is loathed by the pharmaceutical industry. Legal challenges brought under the Hatch-Waxman process will continue as normal, the company says.

However, intellectual property lawyers have told the FT that there is no legal impediment to prevent pharmaceutical companies from using the same ploy to frustrate copycat rivals challenging their patents in the courts under Hatch-Waxman.

Mr Hatch's office did not return a request for comment, although the senator has been critical of the IPR process in the past.

In a statement, Allergan said: "Respectfully, Mr Waxman is not appreciating the facts of our agreement with the St Regis Mohawk Tribe."

Allergan said the arrangement was "aimed squarely" at removing the "double jeopardy" of having to fight challenges in the courts as well as those brought under the "fatally flawed IPR process". The group said the IPR system had led to a "new generation of stock manipulators and 'reverse trolls' who do nothing to advance patient welfare".

Allergan's patent switch has caused a political furore at a time when the pharmaceutical industry is already under pressure over the cost of its medicines and struggling to repair its reputation after the Martin Shkreli price-gouging scandal.

Chip Davis, president of the Association for Accessible Medicines, the trade group for generic drugmakers, said the "level of scrutiny bordering on outrage in Washington is only starting on this".

However, Mr Davis predicted that Allergan would not bow to the political pressure, describing the company's chief executive, Brent Saunders, as someone "highly engaged in DC" who "understands politics well".

"He didn't enter into this lightly and would not have done so unless he thought they would prevail and withstand the legal and political scrutiny," Mr Davis said.

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