

5 Sens. Introduce Bill To Bar Tribal Immunity Deals At PTAB

By Steven Trader

Law360 (March 8, 2018, 5:13 PM EST) -- A group of five bipartisan lawmakers led by Sen. Claire McCaskill, D-Mo., formally introduced legislation Wednesday that aims to prevent companies from selling their patents to Native American tribes to use tribal immunity to shield them from America Invents Act reviews at the Patent Trial and Appeal Board.

The Preserving Access to Cost Effective Drugs, or PACED, Act comes on the heels of a controversial deal last year in which Allergan Inc. sold six patents for the dry-eye drug Restasis to the Saint Regis Mohawk Tribe in order to avoid challenges launched by Mylan Inc. and other generics companies, believing the tribe's status as a sovereign entity would shield the patents from PTAB review.

The PTAB ruled in late February that tribal sovereign immunity does not apply to inter partes reviews, and the Saint Regis tribe is currently appealing to the Federal Circuit.

The group of senators, which also included Sen. Tom Cotton, R-Ark., Sen. Pat Toomey, R-Pa., Joni Ernst, R-Iowa, and David Perdue, R-Ga., are looking to etch that notion in stone by introducing legislation that would "restore the power of the PTAB and federal courts, and the International Trade Commission, to review patents regardless of sovereign immunity claims made as part of sham transactions," according to a statement accompanying their proposal.

"We watched a company brazenly try to exploit a potential legal loophole to game the system in an effort to protect their bottom line-and keep Missourians from access to cheaper generic drug options in the process," McCaskill said in the statement. "That should be illegal, and our bipartisan bill would make it so by ending this astounding assertion of sovereign immunity to avoid patent review, before any other companies follow suit."

Allergan transferred the Restasis patents to the tribe in September in exchange for a \$13.8 million upfront payment and the promise of \$15 million in annual royalties — a move that struck some lawmakers as anti-competitive and prompted McCaskill to send a letter on Oct. 3 to trade group Pharmaceutical Research and Manufacturers of America calling the patent transfer "one of the most brazen and absurd loopholes I've ever seen." She followed up with a draft bill around the same time aimed at blocking such maneuvers.

Sen. Ernst said Wednesday that Congress could no longer afford "to look the other way" while pharmaceutical companies "attempt to stifle competition and prevent Americans from accessing affordable generic drugs."

"Failure to act could incentivize other industries to use similar tactics to block competitors," Ernst said in a statement. "Through the PACED Act, we can speed up the entry of safe and affordable generic drugs into the market while maintaining the integrity of the U.S. patent system."

The lawmaker's new legislation received immediate praise from the High Tech Inventors Alliance — made up of a number of technology giants including Amazon, Google and Oracle — which in a statement on Wednesday said it "respects the historical understanding of tribal sovereignty while allowing the patent office to continue unhindered in reexamining its work where appropriate and canceling patent awards that should not have been issued through the IPR program."

The group United for Patent Reform, a coalition of hundreds of companies, also applauded the proposed bill on Tuesday, saying in a statement it would "prevent gamesmanship" while "still insuring that the U.S. government provides absolute protection to the sovereign rights of the tribes themselves."

Back in October when McCaskill first proposed the draft bill, the Saint Regis tribe fired back that it unfairly targeted tribes while still exempting state universities and other sovereign governments also engaged in the patent review process.

The tribe did not immediately return a request for comment on Thursday. Representatives for Allergan declined to comment.

--Additional reporting by Kat Greene and Matthew Bultman. Editing by Alyssa Miller.