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Pharmaceutical & Life Sciences News

MIT, Harvard Face New Challenge to Gene-Editing Patent

By Greg Langlois Posted July 20, 2018, 4:55 PM

- Agricultural tech company Benson Hill asks board to upend CRISPR patent
- Gene-editing technology could revolutionize health care, food, other sectors

A patent on a revolutionary gene-editing technology held by a Massachusetts Institute of Technology and Harvard University group is facing a validity challenge.

Benson Hill Biosystems Inc.'s petition with a U.S. Patent and Trademark office review board challenges all claims of U.S. Patent No. 9,790,490, which describes systems and methods of using a CRISPR technology using a protein referred to as Cpf1. The '490 patent is held by MIT and Harvard and their joint medical research venture, the Broad Institute Inc. Benson Hill offers its customers new CRISPR nucleases that it says can delete, edit, or replace genetic sequences in plants. It says that technology and a data analytic tool it offers can accelerate crop improvement—modifying crops in helpful ways, such as to be more disease-resistant.

CRISPR (clustered, regularly interspaced, short palindromic repeat) technology allows scientists to splice targeted genes, allowing them to disable or remove those associated with diseases such as cancer, among other uses. It has been hailed as one of the most important inventions in history, and its market potential could reach into the billions, so developers are keen to protect patents they've secured.

Agricultural Industry Attack

The technology has potential beyond treating human health conditions. Agricultural uses include developing disease- and drought-resistant crops and boosting their nutritional value.

"There have been thoughts and discussions about the value of CRISPR in modifying the genetics of all types of organisms," Mayer Brown intellectual property partner Brian Nolan told Bloomberg Law in an interview. But the fact that the '490 patent challenge comes from the agricultural space wouldn't limit the scope of a PTO Patent Trial and Appeal Board decision to invalidate it.

"Effectively what these post-grant proceedings are is the Patent Office saying, 'We really should not have issued this claim so that claim can't be applied against anyone," said Nolan, who's based in New York City. "The claim would just be held to be unpatentable, effectively should never have issued because it was determined to fail to comply with one or more of the statutory requirements."

The '490 patent was issued Oct. 17, 2017. Under the USPTO's Patent Trial and Appeal Board post-grant review procedures, a petition to challenge a patent must be filed within nine months after a patent is issued. PGR procedures allow patent claims to be challenged on more grounds than another PTAB proceeding known as inter partes review.

One of those additional grounds falls under Section 112 of the patent laws, which requires a written description specific enough to enable others to replicate it. Benson Hill is challenging all 60 patent claims.

"We believe that the claims are invalid for the written description and enablement in particular that we bring out in our petition," vice president for intellectual property Murray Spruill told Bloomberg Law in an interview. Benson Hill doesn't believe its technology infringes the patent, he said.

"We do have Cpf1 but we also have CRISPR systems as well," he said. "We don't believe these infringe at all. But because the Cpf1s are very, very large group of enzymes, we feel that the patent is way too broad."

Broad itself hasn't had much success in making use of the technology, which indicates the enablement requirement isn't met, he said.

"[T]hey only got a very few number of theirs to work," he said. "The Federal Circuit has said over and over that, particularly if it's nascent technology, I have to describe how to make and use my invention, and the patent from our perspective fails to do that because one doesn't know which Cpf1 you could take from the 40-some that they list and use it in a system and it would work."

Other CRISPR Battles

Broad and the MIT-Harvard team have been engaged in high-stakes litigation over an additional set of patents Broad holds. It has been fighting a challenge to those from the University of California at Berkeley. A PTAB decision in Broad's favor is now on appeal with the U.S. Court of Appeals for the Federal Circuit.

Benson Hill's petition "is entirely without merit," Broad spokesman David Cameron told Bloomberg Law in an email.

"It was filed by a company with competitive interests," he said. "The facts around the discovery and harnessing of Cpf1 [a similar DNA-editing technology] are clear. The patent was issued properly and we are confident the PTAB will reject this baseless claim."

Benson Hill didn't immediately respond to Bloomberg Law's request for comment.

The case is Benson Hill Biosystems, Inc. v. The Broad Institute, Inc., P.T.A.B., PGR2018-00072, petition filed, 7/17/18.

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