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Korean Co. Can't Be First To Invent CRISPR, PTAB Told

By **Britain Eakin**

Law360 (September 12, 2022, 10:07 PM EDT) -- The Patent Trial and Appeal Board is again considering who was first to invent the CRISPR-Cas9 gene-editing technology, this time hearing arguments Monday from Korean biotechnology company ToolGen Inc. that it was first to use the technology in plants and animals.

The interference proceedings mark the latest chapter of determining who was first to get CRISPR-Cas9 to work, with ToolGen arguing that it beat the Broad Institute and the Massachusetts Institute of Technology, along with the University of California and the University of Vienna, in reducing the invention to practice. The hearings came after the board decided in February that Broad and MIT were **first** to reduce to practice the use of CRISPR-Cas9 in eukaryotic cells over UC Berkeley's Jennifer Doudna and the University of Vienna's Emmanuelle Charpentier, collectively referred to by the board as CVC.

That decision, however, did not resolve the interferences involving ToolGen, largely because CVC lodged an appeal of the board's decision to the Federal Circuit in March, which means the PTAB decision isn't final yet. The board declared these interferences — which are PTAB proceedings initiated when an invention is claimed in more than one patent application or patent — in December 2020, and it named ToolGen the senior party. In interference proceedings, the senior party is given the benefit of the earliest filed patent application, meaning the burden of proof in both cases is on CVC and Broad to show they reduced CRISPR-Cas9 to practice before that.

During Monday's hearing, CVC attorney Keith R. Hummel of Cravath Swaine & Moore LLP told the board that ToolGen shouldn't be entitled to the October 2012 filing date the board gave it, saying the company should be stuck with statements it made to the U.S. Patent and Trademark Office as it considered ToolGen's patent application.

Hummel said that while ToolGen told the USPTO that CRISPR-Cas9 has to be codon-optimized to work, which it contended during prosecution wasn't routine, it's arguing the opposite now in the interference proceeding. CVC said in case filings that means ToolGen can't prevail here because there is no written description support for codon optimization, which is used for improving gene expression, in the October 2012 application.

"ToolGen now agrees with us that codon optimization is routine. But they made a strategic decision during prosecution, and they are now stuck with that decision," Hummel said during the hearing, adding later that ToolGen should be stopped from relying on a version of the invention in the interference

proceeding that contradicts what it told the USPTO during prosecution.

The panel, however, pushed back on that argument. Administrative Patent Judge Sally Gardner Lane asked Hummel if CVC even attempted to show that the earlier ToolGen application doesn't "contain an embodiment that falls in the CVC side of the count."

The so-called count in an interference proceeding is based on patent claims, usually one from each party, that defines the scope of the invention at issue. Here, ToolGen's side of the count requires codon optimization, while CVC's side does not.

Hummel said ToolGen isn't permitted to bring forward any proof that doesn't show a codon-optimized sequence.

"And what authority are you basing that position on?" Judge Lane asked.

Hummel cited the doctrine of party admission and judicial estoppel.

The panel had no questions for ToolGen attorney Anthony M. Insogna of Jones Day, who contested CVC's estoppel argument during the hearing.

"The count is the count, regardless of how the parties secured their claims. CVC ... did not even attempt to show that ToolGen's [2012 application] lacked an embodiment within the CVC half of the count. For this reason alone, their motion should be denied," he said.

CRISPR, which stands for Clustered Regularly Interspaced Short Palindromic Repeats, has been called a major breakthrough in gene editing that is much faster, simpler, cheaper and more efficient than previous technologies. The technology has been subject to several interference proceedings, which predate the 2012 America Invents Act. Rather than declare one large, multiparty interference, the PTAB instead broke it up.

In February, the board determined that Broad and MIT were first to reduce the invention to practice, before the Nobel Prize-winning scientists at the University of California and University of Vienna, who took home the 2020 Nobel Prize in chemistry for their work on CRISPR.

During the other interference proceeding Monday involving Broad, Raymond N. Nimrod of Quinn Emanuel Urquhart & Sullivan LLP, who represents the institute, urged the board to broaden the count.

He argued that Broad has generic RNA claims that correspond to the count, and unless the count is broadened, then his client risks losing those claims.

Both proceedings are in the initial, or motions stage, of the interferences, in which the board will determine constructive reduction to practice. If they advance, the board will dig into the scientists' notebook from their experiments to determine who actually reduced the invention to practice first.

Broad is represented by Raymond N. Nimrod and Matthew D. Robson of Quinn Emanuel Urquhart & Sullivan LLP and Steven R. Trybus of Locke Lord LLP.

CVC is represented by Eldora L. Ellison, Eric K. Steffe, David H. Holman, Byron L. Pickard, John C. Rozendaal, Paul A. Ainsworth and Michael E. Joffre of Sterne Kessler Goldstein & Fox PLLC, Li-Hsien Rin-

Laures of RinLaures LLC, Sandip H. Patel of Marshall Gerstein & Borun LLP, and Keith R. Hummel of Cravath Swaine & Moore LLP.

ToolGen is represented by Anthony M. Insogna, Nikolaos C. George, S. Christian Platt, Timothy J. Heverin and Roger C. Rich of Jones Day.

The case is The Regents of the University of California v. Toolgen Inc., interference number 106,127, before the Patent Trial and Appeal Board.

--Additional reporting by Dani Kass. Editing by Adam LoBelia.
