

Disputes Continue over Foundational Patents for Gene Editing

by Jennifer K. Wagner

[caption id="attachment_13549" align="alignleft" width="300"]_CRISPR-Cas9 editing of the genome[/caption]

As we noted early last year, a major dispute over patent rights to CRISPR-Cas systems broke out in January 2016 between Feng Zhang, the Broad Institute, and MIT on one side and Jennifer Doudna and the University of California-Berkeley as well as Emmanuelle Charpentier, Krzysztof Chylinski, and the University of Vienna on the other. [CRISPR-Cas systems](#) are powerful tools for genome editing that allow researchers to activate or deactivate target genes. As a reminder of this patent dispute, at issue is whether Zhang was first to invent the application of CRISPR-Cas9 in mammalian and human cells or whether Doudna's invention of CRISPR-Cas9 was broad enough to encompass application in both prokaryotic and eukaryotic cells (including mammalian and human cells).

A few noteworthy events have occurred since [our last coverage in February 2016](#). The two sides are engaged in what is called an interference proceeding. The U.S. Patent and Trademark Office (USPTO) determined preliminarily that the two sides were claiming patent rights to the same technology and initiated the interference to let them fight over who had priority. Under the pre-2013 version of the Patent Act that applies here, the key question would be who invented first.

Oral arguments in the interference were held on December 6, 2016 at the USPTO office in Alexandria, Virginia. Then, on February 15, 2017, the U.S. Patent Trial and Appeal Board (PTAB) granted the Broad Institute's motion and entered judgment of "no interference-in-fact." PTAB explained that the Broad Institute had successfully rebutted the presumption of interference by showing the claims of the two parties are drawn to distinctly patentable subject matter—in other words, the parties aren't claiming the same invention. The PTAB concluded that the University of California's claims, even if prior art, would not have rendered the Broad Institute's an obvious extension of that art (therefore setting it up as interfering with the University of California's patent claims). To reach that conclusion, the PTAB relied heavily on the statements of UC-B's Doudna, which showed that at the time of the respective inventions there was not a reasonable expectation of success in eukaryotic cells and, thus, the technology claimed by the Broad Institute's Zhang was not obvious. A thorough explanation of PTAB's rationale has been provided elsewhere by [Kevin Noonan](#). The ruling effectively lets the patent already issued to the Broad Institute stand, with the University of California's patent application still pending. On April 12, 2017, the University of California-Berkeley filed notice of appeal. PTAB appeals are heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C.

The competitions for CRISPR-related patents are only getting more interesting. On March 24, 2017, the European Patent Office (EPO) [reportedly](#) announced its intention to grant a patent to the University of California, reaching a conclusion opposite of that reached by PTAB, thereby highlighting the fine lines that authorities are forced to draw here. More recently, [the Wall Street Journal reported](#) that the USPTO gave notice to Vilnius University in Lithuania (Virginijus Siksnys) that it would be issuing an expansive patent related to CRISPR as well. And back in September 2016—despite being previously [unsuccessful with its applications in the United States](#)—ToolGen [obtained](#) two CRISPR patents from the Korea Intellectual Property Office.

It is clear the drama over foundational IP for CRISPR inventions will continue for the foreseeable future and will play out on a global stage. All the while, the exciting science will [march on](#).

For additional reading:

- Joe Stanganelli, "[Interference: A CRISPR Patent Dispute Roadmap](#)," *Bio-IT World*, January 9, 2017
- Sharon Begley, "[Broad Institute prevails in heated dispute over CRISPR patents](#)," *STAT*, February 15, 2017
- Sarah Zhang, "[What the CRISPR Patent Decision Means for Gene Editing](#)," *The Atlantic*, February 15, 2017
- Kevin Noonan, "[PTAB Decides CRISPR Interference in Favor of Broad Institute—Their Reasoning](#)," *Patent Docs Biotech & Pharma Patent Law & News Blog*, February 16, 2017
- Lisa M. Krieger, "[How UC-Berkeley's CRISPR license could limit innovation](#)," *Mercury News*, February 16, 2017
- Jon Cohen, "[CRISPR patent ruling leaves license holders scrambling](#)," *Science*, February 24, 2017
- Jorge L. Contreras and Jacob Sherkow, "[CRISPR, surrogate licensing, and scientific discovery](#)," *Science*, February 17, 2017
- Lawrence Horn, "[Patent Pools for CRISPR Technology](#)," *Science*, March 27, 2017 (letter and response by Contreras and Sherkow)
- Sharon Begley, "[University of California's CRISPR patent win in Europe likely to be challenged](#)," *STAT*, March 28, 2017
- Sy Mukherjee, "[The Patent Battle Over Revolutionary CRISPR Gene-Editing Tech Just Went Global](#)," *Fortune*, March 28, 2017
- Sharon Begley, "[University of California Appeals CRISPR Patent Setback](#)," *STAT*, April 13, 2017
- Sarah Zhang, "[Why the University of California Is Appealing the CRISPR Patent Decision](#)," *The Atlantic*, April 13, 2017
- Amy Dockser Marcus and Joe Palazzolo, "[Group Seeks to Overturn Patent Ruling on Breakthrough Gene Technology](#)," *The Wall Street Journal*, April 13, 2017