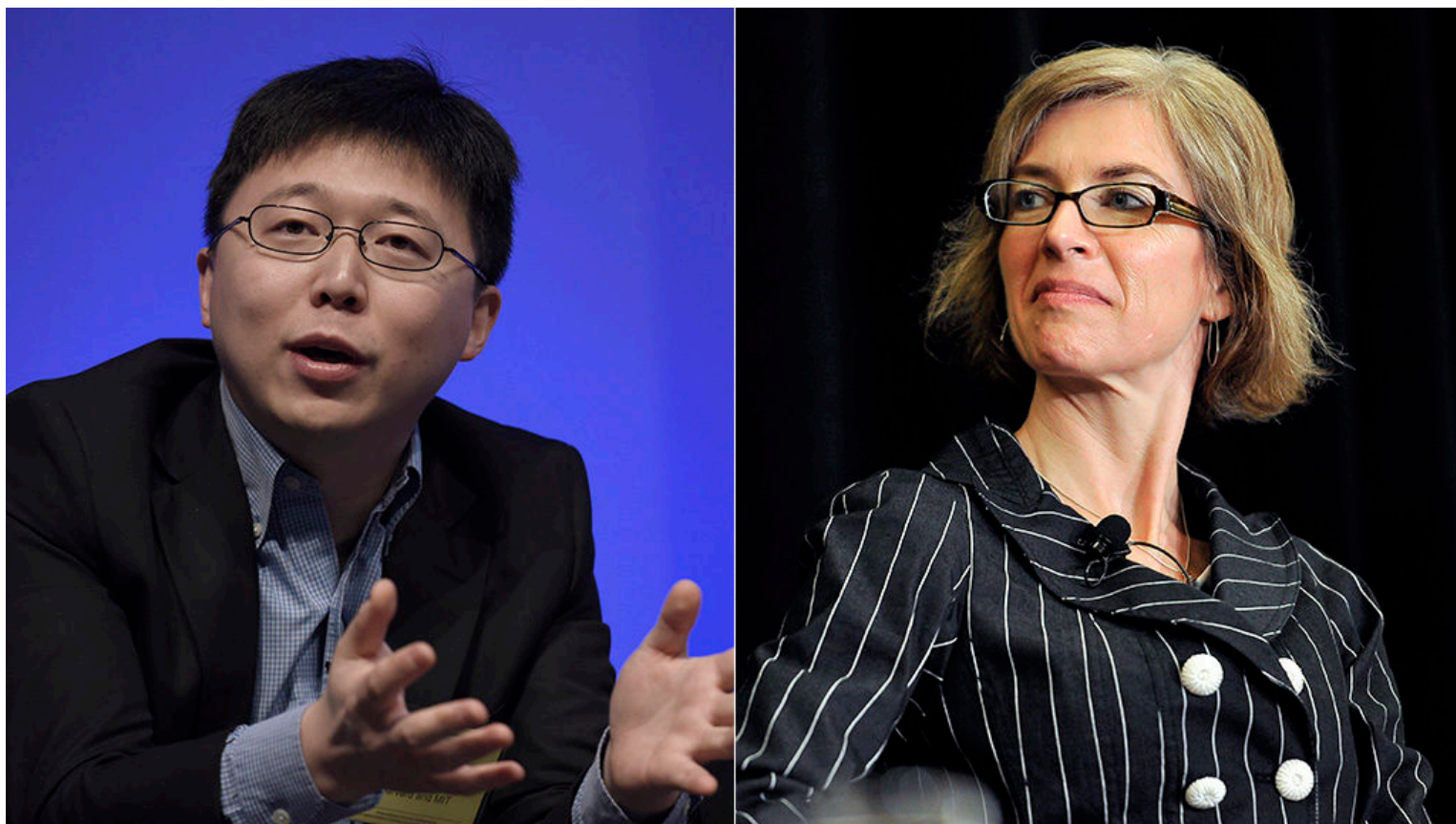


## Waiting for the CRISPR patent decision? Here's what we know



AP, Getty Images Feng Zhang of the Broad Institute, left, and Jennifer Doudna of the University of California

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February 6, 2017

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t's been 61 days since the one and only [oral argument](#)<sup>1</sup> in the CRISPR patent case. Where's the decision?

Investors, lawyers, patent agents, biotech executives, and scientists have been anxiously waiting for the Patent Trial and Appeal Board to decide whether foundational CRISPR-Cas9 patents awarded to the Broad Institute of Harvard and MIT beginning in 2014 “interfered” with a patent application filed in 2012 by the University of California. Based on the time it usually takes PTAB to hand down a decision, this one should arrive “any day now,” said Jacob Sherkow of New York Law School, an expert on intellectual property law.

But while CRISPR groupies have been compulsively checking PTAB's electronic docket for every twist and turn in the case since the case began in January 2016, they shouldn't expect to stumble upon the decision there. PTAB is notoriously ... well, unhurried about posting motions, orders, and other case files. It posted the transcript of the Dec. 6 oral arguments on January 19. The expectation is that once the

three PTAB judges hearing the CRISPR case have their decision, they will inform the attorneys representing the Broad and UC. The attorneys will inform their clients. Their clients will inform reporters.

In other words, forget the docket. Check STAT early and often.

But don't count on a final, nothing-more-to-do, the fight-is-over decision. Remember, the question before PTAB is whether the CRISPR-Cas9 patent application that UC filed in May 2012, but which the patent office has not acted on, claimed essentially the same invention as the patent awarded to the Broad in April 2014. If so, the Broad's patent "interfered" with UC's application.

The case has therefore turned in large part on whether what UC Berkeley biochemist Jennifer Doudna and her colleagues invented is essentially the same as what the Broad's Feng Zhang and his colleagues invented. If so, then giving a patent to the latter interfered with the pending application of the former.

There are two main possibilities:

- The judges can rule there was not interference in fact. That would be a big win for the Broad, which has argued that what Team Zhang did (making CRISPR-Cas9 edit the genomes of eukaryotic cells) was so different from what Team Doudna did (making CRISPR cut DNA in a test tube) that the claims in each institution's patent applications are different and distinct. No interference would mean that the Broad can keep its patents on eukaryotic uses. UC's pending patents would likely also be granted. "That would be the equivalent of [PTAB] washing their hands of this," said biotechnology patent attorney Kevin Noonan, a partner at the Chicago law firm McDonnell Boehnen Hulbert & Berghoff. "It's like saying, 'you each get patents.'" Unfortunately for UC, the value of the Broad's patents on CRISPR'ing human cells, lab animals, and the like is expected to dwarf the value of UC's, which licensees might feel they do not need to move ahead with medical uses of CRISPR. But UC could [appeal](#)<sup>2</sup> the PTAB decision to the US Court of Appeals for the Federal Circuit.
- The judges can rule that there *was* interference, as UC contends. This would suggest that what Zhang did was an obvious extension of what Doudna did. The Broad, too, could appeal to the circuit court. But even if they don't, it is not game over: If we get an interference-in-fact ruling, said Noonan (who is — fun fact — the ex-husband of Supreme Court justice Sonia Sotomayor), "it sets up the priority phase." That's when PTAB would have to decide who discovered what first.

If you thought the case has been entertaining so far, just wait until Doudna, Zhang, and their colleagues testify (probably in writing, but a fan can hope not) on just what that scribble in the lab notebook means. It would be the genomic version of the iconic Watergate question, but "what did Zhang (or Doudna) discover and when did s/he discover it?"

If cooler heads wonder at this point what it would take for the parties to settle, Noonan was not sanguine: "I would predict that if they've gone this far, they're going to go all the way" through the legal system.

## Links

1. <https://www.statnews.com/2016/12/06/crispr-court-hearing-broad-california/>
2. <https://www.uspto.gov/web/offices/pac/mpep/s1216.html>

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