



# THINK FORWARD

## Update on CRISPR Patent Battle

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Discovery of the revolutionary gene editing technology called CRISPR touched off a battle between the University of California (UC) and the Broad Institute (Broad) over control of the associated patent rights. The technology evolved out of research findings that the CRISPR-Cas 9 immune system of prokaryotes (e.g., bacteria) could be harnessed as a gene editing tool with widespread potential commercial applications in the fields of medicine and agriculture.

UC and Broad both filed initial patent applications prior to the effective date of the prior art provisions of the AIA, making their applications subject to pre-AIA law regarding priority of invention. One year ago, on January 11, and at the suggestion of UC, the PTAB declared an interference between UC's pending patent application and a series of patents issued to Broad covering CRISPR technology (interference no. 106,048). UC filed its initial patent application first and also published a preliminary report several months prior to Broad's earliest filing date. However, Broad used the priority examination option at the USPTO to move its applications more quickly to grant.

The claims of the Broad patents relate to use of CRISPR in eukaryotic cells, i.e., cells having a nucleus such as plant or animal cells. UC's pending claims do not recite a specific cell environment, and thus cover the use of CRISPR in either eukaryotic or prokaryotic cells. The PTAB's declaration of interference identified the interfering subject matter (i.e., the count) as the use of CRISPR in eukaryotic cells.

Over the past year, the parties proposed motions in the PTAB on various matters related to the priority contest, as well as the patentability or enforceability of the opposing party's claims. During the initial stage of the contest, however, the PTAB has confined the proceedings to the parties' positions on issues that impact the priority contest, such as whether an interference-in-fact existed, the benefit of priority claims, and the definition of the count. On December 6, 2016, the PTAB heard oral arguments on these issues.

A central issue in the interference concerns whether Broad's claims to CRISPR in eukaryotic cells cover a separate invention from UC's claims that do not specify a particular cell environment. If so, then no interference-in-fact would exist and the PTAB would be expected to dissolve the interference.

Broad argues that the conditions for an interference-in-fact under the two-way test of 37 C.F.R. §41.203(a) are not satisfied because UC's claims do not anticipate or render obvious its claims to CRISPR in eukaryotic cells. According to Broad, the skilled artisan would not have had a reasonable expectation of successfully adapting the UC's published techniques to eukaryotic cells and therefore its claims would not have been obvious over UC's claims and prior publication. UC argues to the contrary and that for the same reason the eukaryotic limitation should be removed from the definition of the count. Doing so would permit UC to rely on its best proofs of earlier invention.

The PTAB now faces the challenge of assessing the competing positions and sorting through the voluminous evidence that includes conflicting interpretations of inventor statements, patent filings from other competing laboratories, and highly technical scientific studies or opinions that are purported to show the relative ease or difficulty of translating techniques developed in prokaryotic to eukaryotic cells. While no firm conclusions can be drawn at this stage, news reports from the December 6 hearing suggest that UC arguments received more scrutiny and probing by the PTAB judges than those of Broad.

If the PTAB were to decide that no interference-in-fact exists and dissolves the interference, Broad would exit with its patents claiming CRISPR in eukaryotic cells and UC's application would return to the examiner for further prosecution. Since many of UC's claims have been allowed, those claims could presumably proceed to issuance. Also, UC's allowed claims are generic to the cell environment, so an end to the interference should not itself deprive UC of patent rights to certain CRISPR uses in eukaryotic cells.

An end to the interference, however, would not necessarily signal an end to the battle over CRISPR. Any granted claims could still be subject to a validity challenge by some form of post-grant proceeding. The PTAB deferred any decision on proposed motions by both UC and Broad on various validity issues that could be revisited in another forum.

If the PTAB were to maintain the interference, the priority contest could continue based on the current count or one of the modified counts suggested by UC. The PTAB could also decide to entertain the patentability or enforceability motions proposed in the first stage of the interference.

Whatever the outcome of the ongoing interference, licensees of the CRISPR technology should expect continued uncertainty over the patent landscape for the foreseeable future, absent a settlement between the parties.

The patent battle over CRISPR also highlights the risks associated with publicly disclosing groundbreaking results when the potentially most valuable applications have yet to be fully reduced to practice. In this case, the initial publication of results outside the eukaryotic cell environment may have altered the competitive playing field among the research groups in the CRISPR field. The current interference might have been avoided or decided on different terms had the initial public disclosures followed, rather than preceded, the successful application of CRISPR to eukaryotic cells.

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