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PTAB Terminates Interference Involving Revolutionary Gene Modification Technology

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CRISPR-Cas9

CRISPR, or clustered regularly interspaced short palindromic repeats, are segments of prokaryotic DNA that combine with small clusters of *cas* genes (CRISPR-associated system) to form a system capable of alternating the genetic sequence of an organism. In nature, CRISPR-Cas systems protect bacteria against infection by viruses–they are not known to occur naturally in eukaryotes, such as plants and animals. However, one CRISPR-Cas9 system, the CRISPR-Cas9 system, is currently being put to use as a tool to modify specific DNA sequences in the genomes of other organisms, including plants and animals. The system functions by linking a DNA-cutting enzyme to a specific site on a target gene, thereby achieving specific, targeted manipulation of DNA. As a result, the CRISPR-Cas9 system may be used to edit, delete, or repair specific gene sequences. As one example, scientists are using the CRISPR-Cas9 system to create animal models of human diseases. Although research remains in the relatively early stages, potential applications for the CRISPR-Cas9 system run from basic scientific research to clinical applications for humans.

The Interference

On April 13, 2015, the Regents of the University of California, University of Vienna and Emmanuelle Charpentier (collectively, UC) suggested an interference between its patent application and multiple patents issued to Broad Institute, Inc., Massachusetts Institute of Technology, and President and Fellows of Harvard College (collectively, "Broad"). On February 11, 2016, the PTAB declared an interference to determine whether Broad's and UC's claims were directed to patentably indistinct subject matter under 35 U.S.C. § 102(g). By way of

background, an interference-in-fact does not exist if the claims of either party are patentably distinct. To determine whether an interference-in-fact exists, the PTAB uses a two-way test that considers whether each party's claims are obvious or anticipated by the other party's claims. Thus, an interference-in-fact could not exist in this case if UC's claims, when treated as prior art, fail to anticipate or render obvious Broad's claims **or** if Broad's claims, when treated as prior art, fail to anticipate or render obvious UC's claims.

In declaring the interference, the PTAB identified claims of both Broad and UC directed to CRISPR-Cas9 systems and methods. Broad's involved claims differed from UC's in one notable respect. All of the Broad claims were limited to methods of systems being used in eukaryotic cells, whereas none of UC's involved claims were limited to any particular environment.

During the motions phase of the interference, Broad filed a motion arguing that no interference-in-fact existed between the parties' claims because a skilled artisan would not have reasonably expected the CRISPR-Cas9 systems described in its claims to work based on the broader disclosures of CRISPR-Cas9 systems in the UC claims. In particular, Broad cited to statements from inventors of the UC patents expressing doubts as to whether the CRISPR-Cas9 system would function in eukaryotes. UC responded that its inventors' statements were merely noting that confirmatory results had not been reported. UC added that its inventors and the prior art established an expectation of success because they predicted the potential to exploit the CRISPR-Cas9 system for RNA-programmable editing.

In its decision on the motion, the PTAB agreed with Broad and held that a person of ordinary skill in the art would have a reasonable expectation of success that the CRISPR-Cas9 system would work in eukaryotes based on UC's claims alone or in view of the prior art. The PTAB noted that, although the prior art gave a reason to try CRISPR-Cas9 systems in eukaryotic cells, there was no way to discern any expectation that it would work before the results to the actual studies were known. The PTAB also rejected UC's argument that, because many independent research groups were able to use the CRISPR-Cas9 systems after the UC inventors published their work, those skilled in the art possessed a reasonable expectation of success. Specifically, the PTAB concluded that "[w]e are not persuaded that a scientist's 'belief' in the success of his or her own experiments is necessarily a reasonable expectation of success that indicates obviousness. Were this true, the requirement for a reasonable expectation of success or predictability in the context of subject matter that would have been obvious to try would be rendered meaningless." The PTAB then turned to the specific disclosures in the prior art and examined whether those disclosures provided instructions

relevant to the use of the CRISPR-Cas9 system such that one skilled in the art would reasonably expect that it would work in eukaryotic cells. Upon review of the prior art, the PTAB determined that failures demonstrated in other systems indicated the opposite. Thus, the PTAB held that UC's claims, if treated as prior art to Broad's claims, would not anticipate or render Broad's claims obvious, and that, as a result, there is no interference-in-fact between Broad's claims and UC's claims.

Based on its finding of no interference-in-fact, the PTAB terminated the interference without entering judgment against either party's claims. UC may now appeal the PTAB's decision to the Federal Circuit.

Broad Institute Inc. et al. v. the Regents of the University of California, Interference No. 106,048 (PTAB Feb. 15, 2017) (Paper No. 893).

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