



Another Round in the US CRISPR Patent Dispute

September 17, 2019

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A further chapter in the ongoing US patent battle between the University of California, Berkeley and the Broad Institute in their bids to obtain foundational patents to the CRISPR/Cas9 system of gene editing has begun.

The initial dispute dates back to at least May 2012 when a patent application was filed by the University of California, Berkeley and other applicants (collectively “UC Berkeley”) in the United States Patent and Trademark Office (USPTO) based on work showing a CRISPR/Cas9 system that could cut DNA *in vitro*. Later in 2012, a second group of applicants led by the Broad Institute (collectively “the Broad Institute”) filed a patent application in the USPTO claiming the use of CRISPR/Cas9 in eukaryotic cells to modify DNA *in vivo*.

The Broad Institute’s US application issued to patent first in April 2014, with claims covering methods of using CRISPR/Cas9 to edit genes in eukaryotic cells. In early 2016, UC Berkeley requested that a patent interference be initiated (these proceedings are now obsolete under the current “first to file” system in the United States) between the Broad Institute’s issued claims and UC Berkeley’s pending applications. UC Berkeley claimed that they invented the CRISPR/Cas9 system and that the Broad Institute’s claims to the use of CRISPR/Cas9 in eukaryotic cells were no more than an obvious extension of UC Berkeley’s early work in cell-free and prokaryotic systems.

In a February 2017 decision, the United States Patent Trial and Appeal Board (PTAB) rejected UC Berkeley’s argument, holding that the Broad Institute’s claims, which are all limited to CRISPR-Cas9 systems in a eukaryotic environment, are not directed to the same invention as UC Berkeley’s claims, which are all drawn to CRISPR-Cas9 systems not restricted to any environment. As a result, the Broad Institute’s patents remained valid, and UC Berkeley was free to pursue their pending claims. As we reported [here](#), this decision was upheld by the United States Federal Court of Appeals in September 2018.

UC Berkeley has subsequently obtained several issued US patents with claims directed to CRISPR/Cas9 systems without regard to the cells in which it is used, and they have also recently filed multiple patent applications with claims specifically directed to CRISPR/Cas9 based methods and systems [in eukaryotic cells](#). As a result, on June 24, 2019, the PTAB initiated a new patent interference proceeding to look at the question of who invented the use of CRISPR/Cas9 in eukaryotic cells. The interference is between 10 pending UC Berkeley applications, all of which include claims reciting CRISPR/Cas9 in eukaryotic cells, and 13 issued Broad Institute patents and one pending Broad Institute application.

Following the initiation of the new interference proceeding, an unrelated party, Sigma-Aldrich (now MilliporeSigma; referred to herein as “Sigma”) has entered the picture by filing a self-described “extraordinary” petition on July 18, 2019 asking that the USPTO declare a parallel interference between itself and UC Berkeley. Sigma has recently been granted a CRISPR related patent and has a number of pending patent applications directed to CRISPR/Cas9 based methods in eukaryotic cells. Sigma’s earliest application was filed before the first Broad Institute application (but after two of the earliest UC Berkeley applications) but the USPTO Examiner responsible for Sigma’s applications has continued to reject their pending claims as obvious in view of UC Berkeley’s applications. Sigma argues that as the PTAB and Federal Circuit have both already held that eukaryotic claims are patentable over UC Berkeley’s applications, the Examiner’s position is incorrect.

It is unlikely that any of these matters will be resolved any time soon. The new UC Berkeley-Broad Institute interference is still at an early stage. The parties are due to file motions in October 2019. There is no specific time frame for consideration of Sigma’s petition and progress in the interference could potentially be delayed until the petition is resolved. In the meantime, the CRISPR/Cas9 patent landscape has become even more complex and uncertain for parties interested in



licensing the technology.

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