CRISPR Decision Highlights the Importance of Strategic Claims Drafting

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The battle over CRISPR (Clustered regularly-interspaced short palindromic repeats) patents highlights the importance of having a sound patent strategy before filing the first disclosure. The *University of California v. Broad Institute, Inc.*[1] is an excellent example of the difference a well-executed strategy can make. In 2013, teams from UC Berkeley and the Broad Institute filed applications seeking patents for the process of editing genetic information using the CRISPR-Cas9 protein. This came only months after both parties published scientific articles[2, 3] and filed provisional patents. Their strategies when filing their patent applications were distinct and the results decisive.

The UC Berkeley team, led by Jennifer Doudna, is largely credited with the discovery and invention of the method of editing genetic information using the CRISPER-Cas9 protein; however, there is a difference between being an industry-recognized inventor and a legally-recognized inventor. In 2013, the United States implemented a first inventor to file system, which means that an inventor does not need to prove that they were the first person to invent something to be able to patent it, they simply need to file first. This makes prompt filing of a patent application especially important, and indeed, UC Berkeley was first to file; however, all of the patents and applications at issue in the dispute were filed before these new rules took effect.

Because the teams from both UC Berkeley and the Broad Institute were working on similar research, the USPTO Patent Trial and Appeal Board (PTAB) applied a test for simultaneous inventions. Because the UC Berkeley team filed first, their applications could have been considered prior art which then would have precluded the Broad Institute from patenting their inventions; however, their initial disclosure did not adequately define the scope of the invention. UC Berkeley limited their disclosure to prokaryotic cells and failed to include provisions for applying their technology to eukaryotic cells, leaving the door open for the Broad Institute's team to file their own patents.

Writing a high-quality patent disclosure is not a task to be underestimated. Too much detail could unintentionally limit the scope of the invention, whereas too little information could make success nearly impossible without submitting a new disclosure. This creates a dilemma in that, not only can an applicant not disclose the same invention twice, if a new disclosure is needed to fill in missing detail, to fill in missing detail is needed, it will set a new priority date. This priority date is now of particular importance as it is the date the USPTO uses under the first to file rule. The Broad Institute successfully walked this

tightrope, took advantage of the openings left in UC Berkeley's disclosures, and carefully drafted a disclosure and patent claims that maximized the potential value of the patents.

The Federal Circuit recently upheld the PTAB's decision affirming that the patents should remain with the Broad Institute. While the UC Berkeley team were working on developing the same technology, they failed to demonstrate that their technology could be used in eukaryotic cells, which was the claim made by the Broad Institute's team. This is a crucial distinction as there is enough of a difference between the structure of prokaryotic and eukaryotic cells that being successful in manipulating DNA in one did not ensure success applying the same process in another. As a result, the Broad Institute's claims utilizing CRISPR-Cas9 in eukaryotic cells were both novel and non-obvious in view of the UC Berkeley team's disclosures applying the protein in prokaryotic cells.

The well-written disclosure was not the only part of the Broad Institute's patent strategy that stood apart from UC Berkeley's. The Broad institute was also timely in their filings, doing so not long after UC Berkeley, but they also elected for accelerated examination. Between well-drafted claims and taking advantage of the accelerated process, nearly all of the Broad Institute's US applications became granted patents before the dispute began, whereas UC Berkeley has yet to have a single US application referencing CRISPR-Cas9 granted, even at the conclusion of the case. While UC Berkeley could still appeal to the US Supreme Court, it is unlikely the case will be heard given the soundness of the previous decisions.

The Broad Institute's patent strategy was clear. They filed a carefully-crafted disclosure in a timely manner to secure an early priority date. From the initial disclosure they filed a number of applications to create a landscape of patent rights providing comprehensive coverage of a wide range of applications of the technology. Finally, they took advantage of the accelerated examination process, which along with their well written claims, allowed them to secure granted patents quickly. By comparison, UC Berkeley's patent strategy was far less clear, and the results speak for themselves.

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