IP Alert: Patent Wars: Genome Editing

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By Sarah A. Kagan

The hotly contested patent rights to CRISPR-Cas9 “genome editing” technology are still unsettled, as two groups of inventors await a decision from the U.S. Court of Appeals for the Federal Circuit on appeal from the Patent Trial and Appeal Board (PTAB). A panel of the Federal Circuit, consisting of Chief Judge Prost, Judge Schall, and Judge Moore, heard oral arguments April 30. The parties sparred over whether the PTAB was correct to shut down an interference between (a) patents relating to use of the CRIPSR-Cas9 enzyme complex in eukaryotic cells and (b) patent applications relating to use of the CRISPR-Cas9 enzyme complex in any environment (including in prokaryotic cells, in eukaryotic cells, and in a cell-free system). Each of the parties is a group of inventors from multiple academic institutions. The group with the broader claims (in any environment) comprises the Regents of University of California, the University of Vienna, and Emmanuelle Charpentier, collectively “UC.” The group with the narrower claims (in eukaryotic cells) comprises the Broad Institute, Inc., the Massachusetts Institute of Technology, and the President and Fellows of Harvard

College, collectively “Broad.” Although the PTAB designated UC as the senior party in the interference because it has an earlier priority date than Broad, the designation does not play any role in the issue on appeal.[1]

UC suggested an interference to the U.S. Patent and Trademark Office (USPTO) between UC’s generic application claims (in any environment) and Broad’s species patent claims (in eukaryotic cells). During the motion phase of the interference conducted by the PTAB, Broad moved to dissolve the interference on the basis of no-interference-in-fact, i.e., that the claims of the two parties are not directed to the same invention. The USPTO’s rules define interfering subject matter as existing when the claims of each party are obvious or not novel over the claims of the other party, and vice versa. 37 C.F.R. § 41.203(a). The PTAB decided in its February 15, 2017 decision on motions that the subject matter of Broad (in eukaryotic cells) was not obvious over the subject matter of UC (in any environment). This determination is not a determination of patentability of either party’s claims. Rather, it only decides the narrow question of whether the parties claim the same invention. Although obviousness is a key determinant in the assessment of an interference-in-fact, it is not the same obviousness as under 35 U.S.C. § 103 for patentability, because the scope of what is considered prior art is much more limited in the interference-in-fact context.

On appeal, a party wishing to reverse a PTAB decision must show that substantial evidence did not support the decision or that the decision was based on an error of law. In its oral argument, UC urged that the PTAB did not look at the evidence as a whole or give proper weight to inventor statements. Judge Moore interjected that UC’s problem with this argument was that the PTAB did cite evidence supporting its decision; UC could not prove error merely by showing that there was also evidence supporting UC’s desired result.

UC then pivoted to asserting two alleged legal errors. First, the PTAB had erroneously deemed irrelevant evidence of six lab groups’ essentially simultaneous achievement of using CRISPR-Cas9 in eukaryotic cells. The PTAB concluded that this evidence was irrelevant to the existence of a reasonable expectation of success, a key element of the obviousness assessment. UC urged that this was the best contemporaneous evidence of the expectation of a person of skill in the art. Second, the PTAB erroneously required that in order to make a case of obviousness, the prior art must contain specific instructions of how to practice the invention, which is inconsistent with the Supreme Court’s KSR decision[2] and the Federal Circuit’s Kubin decision.[3] UC pointed to the same six lab groups and the similar known techniques they used as evidence that the person of skill in the art had a reasonable expectation of success, with no obstacles anticipated.

Broad argued that UC had focused on the wrong point in time for assessing reasonable expectation of success by looking at the techniques used by the six lab groups. That view used

hindsight, knowing what turned out to be successful, rather than the expectations before the groups performed the experiments.

Chief Judge Prost in her questioning of both sides seemed concerned that the PTAB had used the wrong legal standard. Was the PTAB requiring that there be a guarantee of success in the prior art for the subject matter to be obvious? Broad urged that the PTAB had repeatedly enunciated the correct standard (reasonable expectation of success) and had not required a guarantee of success.

In its rebuttal time, UC returned to the evidence of the six lab groups that essentially simultaneously achieved CRISPR-Cas9 activity in eukaryotic cells and the fact that they used the same straightforward techniques without the need to innovate techniques or design-around. This was evidence of a reasonable expectation of success that the PTAB disregarded as such, UC urged. Judge Moore strongly disagreed with UC's interpretation of the evidence. Judge Moore stated that the behavior of the six lab groups reflects the real-life way scientific inquiry proceeds. One first tries the simple, cheap experiment; only when that does not work does one innovate to find a way to make it work. The fact that the six groups all did this does not reflect that they all had a reasonable expectation of success, but rather that they were doing what scientists do.

If the Federal Circuit affirms the decision of the PTAB, the interference will end. Each party will be able to continue to pursue its applications and maintain its issued patents. Given that possible outcome, Broad raised an interesting jurisdictional issue in its Brief for Appellees: what injury-in-fact would UC incur based on the PTAB's decision of no interference-in-fact? The decision would not preclude UC from pursuing its involved patent applications. Given the court's recent interest in defining appellant standing in appeals from America Invents Act-created post-grant proceedings,[4] one might have expected some discussion on this issue. However, appellant UC did not respond to the issue in its Reply Brief, and neither the parties nor the judges raised it at the oral argument.[5] Is changing the competitive patent landscape sufficient injury to generate standing under Article III of the U.S. Constitution? Must the injured party show some commercial activity to obtain standing? Must the scope of a party's claims be narrowed to show injury? Other future litigants might try to use this issue in the no-interference-in-fact context.

Broad holds 12 patents and one allowed application that were involved in the interference. If the appeal affirms the PTAB decision and the interference is dissolved, we are still likely to hear more about the interactions of these two parties and their patent portfolios. While the main commercial activities with CRISPR-Cas9 will likely be in the area of eukaryotic cells, covered by Broad patents, UC may obtain generic claims.

Click here to listen to oral arguments in University of California v. Broad Institute, Inc.

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[1] Only if the court rules that an interference-in-fact exists will the case proceed to the priority phase of the interference at the PTAB.

[2] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)

[3] In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009)

[4] The America Invents Act created post-grant review, inter partes review, and review of covered business methods. See our discussions of jurisdictional issues on appeals from the PTAB here (January 9, 2018), and here (March 26, 2018). The next Spring/Summer IP Update, scheduled for late July, will also discuss these issues.

[5] The lack of interest in the standing issue may be due to the failure of Broad to raise it before briefing began.

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