STANFORD v. CHINESE UNIVERSITY OF HONG KONG, Appeal No. 2015-2011 (Fed. Cir. June 27, 2017). Before O'Malley, Reyna and Chen. Appealed from N.D. Cal. (Judge Illston).

Background:

In February 2007, Stanford patented a method for detecting genetic abnormalities in fetuses by analysis of the mother's serum. The claims recited detection of "targeted sequences" by obtaining maternal tissue containing both maternal and fetal genetic material and measuring the presence of different target sequences.

In 2008, CUHK filed an application for a random sequencing method that does not require the detection of specific target sequences. In response to CUHK's application, Stanford amended claims of a pending continuation application, which later became a patent, to cover random sequencing methods. This caused an issue as to whether there was support for these claims.

Both parties filed requests for interferences to determine who invented the random sequencing method. CUHK argued that the Stanford patent was invalid because it lacked written description for the random sequencing. Stanford countered that the random sequencing is disclosed in the specification. The PTAB agreed with CUHK's argument, primarily on the basis of expert testimony. Stanford appealed to the Northern District of California, who had to pass the appeal to the Federal Circuit due to a jurisdictional issue.

Issue/Holding:

Did the PTAB err in relying on the expert testimony to hold that the Stanford patent lacked sufficient written description for random sequencing? Yes, vacated and remanded.

Discussion:

The key issue was to determine whether the Stanford specification lacked written description for random sequencing. Stanford pointed to columns 19-20 that recite "a methodology useful in the present invention platform is based on massively parallel sequencing of millions of fragments using attachment of randomly fragmented genomic DNA…to create a high density sequencing flow cell…*See, products offered by Illumina*." Stanford argued that the Illumina products used random sequencing.

CUHK's expert witness argued, based on various published references, that the above passage does not preclude targeted sequencing, and accordingly, those of skill in the art could have considered the references in the Stanford patent to Illumina products to indicate targeted sequencing. Based on this, the PTAB held that the Stanford patent did not support random sequencing.

The Federal Circuit found the PTAB's conclusion illogical, because it was not up to the PTAB to determine if the description could indicate targeted sequencing, but rather, if it could also disclose random sequencing. Further, there was no discussion of whether the Illumina platform used targeted or random sequencing. Thus, the Federal Circuit vacated the PTAB decisions and remanded for the Board to consider whether Stanford's patents satisfy the written description requirement.