

PACIFIC BIOSCIENCES OF CALIFORNIA, INC. v. OXFORD NANOPORE TECHNOLOGIES, INC., Appeal Nos. 2020-2155, 2156 (Fed. Cir. May 11, 2021). Before Lourie, Taranto, and Stoll. Appealed from D. Del. (Judge Stark).

Background:

PacBio owns several patents directed to methods for sequencing nucleic acids using nanopore technology. PacBio sued Oxford for infringement. In March 2020, a jury found all asserted claims infringed but also determined that the claims were invalid under §112 for lack of enablement. PacBio moved for JMOL on the enablement issue. In denying the motion, the district court noted that a statement by one of Oxford's experts that one of ordinary skill in the art would have been able to successfully perform the claimed methods was insufficient to establish enablement.

Issue/Holding:

Did the district court err in denying the motion for JMOL? No, affirmed.

Discussion:

The Federal Circuit adopted a line of reasoning similar to that of the district court. The Federal Circuit noted that what matters is the scope of the claims and it is not enough for enablement that one of ordinary skill in the art knew how to perform some nanopore sequencing before the 2009 priority date of the patents. The Federal Circuit interpreted the claims to recite a method of "determining the sequence of the template nucleic acid," without limiting the character of that "template nucleic acid," by measuring certain electrical properties as the nucleic acid passes through a nanopore. The Federal Circuit found that the jury could have interpreted the statement from Oxford's expert to merely mean that one of ordinary skill in the art could have performed the claimed methods to some extent but not necessarily being able to make and use the full scope of the invention.

The Federal Circuit also noted that there was substantial evidence of non-enablement. For example, the claims broadly recited an "N" limitation (*i.e.*, "measuring a property which has a value that varies for N monomeric units of the template nucleic acid in the pore...wherein N is three or greater"). Oxford's expert stated that this limitation lacked enablement because it was unclear how many nucleotides affect the current measurement during transit of a nucleic acid through the nanopore. Furthermore, PacBio had no evidence of actual reduction to practice to undermine the evidence of non-enablement. PacBio acknowledged that its reduction to practice was constructive only without any accompanying real-world reduction to practice. Another expert testified that the first successful nanopore sequencing of biological DNA molecules was in 2011.

Therefore, the Federal Circuit held that undue experimentation would be required to enable the full scope of the claims and affirmed the district court's denial of JMOL.