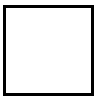
Federal Circuit overturns jury win for Labcorp in dispute with Qiagen



Aug. 19, 2025By Mark McCarty

The U.S. Court of Appeals for the Federal Circuit has overturned a jury finding that Labcorp Inc. was entitled to damages of $4.7 million in a dispute with Qiagen Inc. The case presented another test of the doctrine of equivalents and affirmed that this doctrine has its limits where accusations of infringement are concerned.

The Federal Circuit hearing revolved around Labcorp's allegations that Qiagen had infringed on two of the former's patents for in vitro diagnostics. The 10,017,810 ('810) and the 10,450,597 ('597) patents overlap considerably, but Labcorp had initially sued in 2018 solely for the '810 patent. That lawsuit, which was heard in a Delaware district court, was later amended to include the '597 patent, but the associated jury trial did not convene until August 2021. The five-day trial concluded with a jury determination that Qiagen owed Labcorp $4.7 million for infringement, but the jury's decision was a complicated one.

District court denied Qiagen's first petition for JMOL

The jury had determined that Qiagen had infringed on three claims of the '597 patent but cited the doctrine of equivalents to determine infringement on three claims found in the '810 patent. Qiagen had petitioned the district court for a judgment as a matter of law (JMOL) of non-infringement, but the judge in the case declined.

The debate in this case over infringement of both patents hinged on methods used to prepare DNA fragments for sequencing by means of enrichment of the genomic regions of interest. The '810 patent describes a method for attaching a universal adaptor to DNA fragments, a process followed by two runs of amplification that employ distinct primer pairs. In contrast, the '597 patent replaced one adaptor with a set of primers that attach at different sites, which allows selective amplification of target DNA strands. This feature of the '597 patent was intended to reduce superfluous amplification and to provide greater compatibility with commercially available sequencing systems.

Labcorp's position during the district court hearing was that the doctrine of equivalents provided a demonstration of infringement for some of the sample index primers described in the cited patents. The U.S. Supreme Court affirmed this doctrine in a case decided in 1997, although this doctrine has not been a routine feature of patent litigation in the intervening 28 years.

Stan Gibson, chairman of the patent litigation group at Jeffer Mangels Butler & Mitchell LLP, told *BioWorld* that the doctrine of equivalents allows an imputation of infringement without having to demonstrate a point-by-point match. As an alternative to literal infringement, the doctrine of equivalents allows courts to determine infringement in a manner that is not directly supported by the patent.

Consequently, the doctrine of equivalents is typically narrowly construed, Gibson said, adding that this doctrine presents another hazard. Gibson said that by allowing an argument regarding the doctrine "to be expanded too far, you allow someone to have a monopoly on something that they didn't invent." An associated risk is that an entity might obtain something as effective as an explicit patent for an article for which the entity in question could not obtain a patent.

Gibson noted that courts typically employ the function-way-result test to determine whether an argument for the doctrine of equivalents has merit, which he noted was cited by the Federal Circuit. "You really need to have very specific testimony to support" a recitation of the

doctrine, he added, noting that the district court and the Federal Circuit came to very different conclusions regarding the validity of that expert testimony.

One of the confounders for Labcorp where the Federal Circuit hearing was concerned was largely procedural in nature. Gibson said the judge in the district court hearing allowed the jury to do its own work regarding an analysis of the patents' claims, a process required to determine infringement as a matter of law. Gibson said the district court judge determined that some of the terms found in the patents should be interpreted in the plain meaning of the terms found in the patents, thus negating the need for a formal claims construction process.

The meaning of 'identical' a key factor

This became a problem at the Federal Circuit in connection with the term "identical" because of the scope of the application of the word. Gibson said the Federal Circuit determined that the jury should not have used the term "identical" to apply to a portion of a DNA sequence, but rather should have applied the term to the entire sequence of interest. He said that once the term "identical" was applied to the entire sequence, there was no reasonable assertion of infringement.

Gibson said the four years that elapsed between the district court outcome and the Federal Circuit decision is perhaps a bit longer than one might ordinarily expect, but noted that many courts came out of the COVID-19 pandemic with a backlog. Procedural tactics can also add to the amount of time needed to process an appeal, but in any event, this case has been found for Qiagen. Gibson noted that the Federal Circuit remanded the case back to the district court with instructions to find non-infringement, which he said "should be the end of the case." This case serves as a reminder that the doctrine of equivalents "is a very narrow doctrine" and requires a close analysis if its use is to survive an appeal.

"The biggest takeaway is that these types of patents are going to be very narrowly construed and interpreted," Gibson said, adding that such technologies may require more than a couple of patents to survive what some in the medical device industry might see as the inevitable legal challenge.