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Illumina Fails To Revive 2 DNA Patents On Appeal

By **Hanna Vioque**

Law360, London (February 14, 2024, 7:12 PM GMT) -- European patent officials have revoked two of Illumina Cambridge Ltd.'s patents for DNA-sequencing techniques, ruling that the patented claims went beyond the original application, in the latest setback for the biotech giant.

The board of appeal concluded in two newly public, Feb. 2 decisions that Illumina's inventions had added material to its claims, meaning they could not be patented. Both inventions related to labeled nucleotides that could be used in DNA sequencing, the judgments say.

Specifically, Illumina's inventions linked a nucleotide molecule to a detachable label via a "cleavable linker group attached to the base," making the molecule useful in DNA labeling techniques, according to the patent descriptions.

The appellate boards agreed that the opposition division had rightly found that the patented method required at least "two independent selections from two lists."

The first selection, of a disulfide bond, needed to be made from a list of "several cleavable linkers." A second selection, of a metal or reducing agent, then had to be made from a list of cleaving agents in order to split the disulfide bond. This combination was "necessary to arrive" at the patented claims, the judgments say.

Without specific pointers, this "combined selection of features pertaining to separate embodiments of the application as filed" was not direct and unambiguous, the judgments say.

Illumina argued that the skilled scientist would automatically use the reducing agents specified in the patent's first claim to remove the disulfide linker, because they were known to result in cleavage of the disulfide bond. But the appellate boards found that the prior art also disclosed other cleavage agents such as by contact with electrophiles.

As a result, it "cannot thus be the case that a skilled person who wanted to cleave a disulfide linkage would ... inevitably use the cleavage agents" in the patented claims, the board wrote in both decisions.

Without a pointer to combine the features, "disulfide linkage" and a "metal or reducing agent," the patents had to fail, the judgments say.

The decisions mark the latest setback for the U.S. biotechnology giant when it comes to new methods of testing for genetic disorders.

In July 2022, Illumina **agreed to pay \$325 million** to Complete Genomics Inc.'s Chinese parent company for willfully infringing the company's DNA sequencing patents. MGI and Illumina agreed to a "three-year period of peace," regarding claims of U.S. patent infringement during which neither would sue.

In April, the genetic testing company settled another suit from Ravgen Inc., a small Maryland biotech startup, which had sued at least seven other companies since 2020 over allegations of patent infringement for a new method of testing genetic disorders.

Last year, Illumina raked in \$4.5 billion in total revenue, according to its latest financial report.

Representatives for Illumina Cambridge Ltd., Qiagen GmbH, Christian Kilger and Hoffmann Eitle did not immediately respond to requests for comment.

The patents-at-issue are EP 1451351 and EP 2338893.

Illumina Cambridge Ltd. was represented in both cases by Cooley LLP.

Christian Kilger, an opponent to patent number EP 1451351A2, was represented by CH Kilger Anwaltspartnerschaft mbB. Qiagen GmbH, an opponent to patent number 2338893, was represented by CH Kilger Anwaltspartnerschaft mbB.

Hoffmann Eitle represented itself in both cases.

The cases are Illumina Cambridge Ltd. v. Christian Kilger and Hoffmann Eitle and Illumina Cambridge Ltd. v. Qiagen GmbH and Hoffmann Eitle, case numbers T 0360/20 - 3.3.02 and T 0426/20 - 3.3.02, in the Boards of Appeal of the European Patent Office.

--Editing by Alyssa Miller.

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