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Vanderbilt V. ICOS And Proving Joint Inventorship

Law360, New York (June 23, 2010) -- On April 7, 2010, the U.S. Court of Appeals for the Federal Circuit in Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297 (Fed. Cir. 2010), clarified the legal standards for determining joint inventorship when a patentee allegedly uses information from a third party as the basis to derive an invention.

The two patents at suit were originally assigned to Glaxo Inc. and then assigned to ICOS. The district court found that Vanderbilt University ("Vanderbilt") failed to prove that several of Vanderbilt's scientists (collectively the "Vanderbilt Scientists") were joint inventors on two patents for tadalafil, a PDE5 inhibitor and the active ingredient of the drug Cialis.

On appeal, Vanderbilt raised two arguments why the inventorship on the patents should be corrected to name the Vanderbilt Scientists. First, Vanderbilt argued that the disclosure of certain Vanderbilt structural features to Glaxo led to the identification of a lead compound, the GR30040x molecule, incorporating the same molecular scaffold.

Second, Vanderbilt argued that the key modification of the lead compound that resulted in tadalafil was based on the work of the Vanderbilt scientists. The Federal Circuit held that Vanderbilt failed to prove joint inventorship under the legal standard that clear and convincing evidence is required to establish joint inventorship.

Vanderbilt Univ. v. ICOS Corp. is significant because it deals with the issue of proving joint inventorship when there are interactions between two parties and one of the parties files a patent for an "improvement" allegedly based on the ideas of the other party.

This situation occurs, for example, in the context of sponsored research where one party seeks financing from the other party. It also occurs in the context of a variety of business relationships, such as licensing discussions, contractor/supplier discussions, or other business relationships in which one party obtains information from the other party and then allegedly

files patents for refinements or improvements on the ideas that it received.

The patent statute in 35 U.S.C. § 116 states that joint inventorship may occur even though inventors "did not physically work together or at the same time" and "did not make the same type or amount of contribution." In Vanderbilt v. ICOS, the Federal Circuit reaffirmed and emphasized earlier case law that a primary focus of § 116 is on collaboration and joint behavior, citing previous decisions such as Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352 (Fed. Cir. 2004), Fina Oil & Chem. Co., v. Ewen, 123 F.3d 1466 (Fed. Cir. 1997), and Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co., Inc., 973 F.2d 912 (Fed. Cir. 1992).

The Federal Circuit also clarified the application of its previous holding in Bd. Of Educ. ex. rel. Bd. of Trustees of Fla. State Univ. v. Am. Bioscience Inc., 333 F.3d 1330 (Fed. Cir. 2003) ("American Bioscience").

A joint inventor can be someone that provides written materials or ideas that another person uses to reach the complete invention.

The Federal Circuit provided the example from Kimberly-Clark, which held that collaboration can occur if one inventor builds upon another's suggestion at a meeting or builds upon information presented in another's report. Under Fina there is no "explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor."

However, Kimberly-Clark mandates that individuals are not joint inventors if they are completely ignorant of what each other has done when the claimed invention is conceived.

Vanderbilt admitted that it had no direct evidence to support its claims to joint inventorship. The district court noted that Vanderbilt admitted that the Vanderbilt scientists never had any direct communication with Dr. Daugan, the named inventor on the patents.

However, Vanderbilt argued that joint inventorship should be inferred from the sequence of events, and also pointed out weaknesses in the credibility of ICOS' evidence of independent invention.

Vanderbilt presented evidence at the district court that demonstrated that there was a transfer of information to Glaxo's subsidiary in the United Kingdom (Glaxo U.K.) and that a lead compound, GR30040x, was developed by Glaxo shortly afterward.

In November 1991, the Vanderbilt Scientists synthesized, outside of Glaxo-sponsored

research, a new PDE5 inhibiter based on an IBMX analog. Between December 1991 and February 1992, the Vanderbilt scientists had several discussions and submitted proposals to Glaxo U.K. for a new research agreement.

On Feb. 24, 1992, the Vanderbilt Scientists sent a detailed research proposal to Glaxo U.K. that disclosed the exact design of the Vanderbilt IBMX analog. The listed compounds in the research proposal included what Vanderbilt described as the "Vanderbilt Structural Features" of Vanderbilt's IBMX analog.

On April 8, 1992, Glaxo U.K. forwarded copies of Vanderbilt's February 24, 1992, proposal to Dr. Labaudiniere, the leader of the PDE5 project at Glaxo's research facility in France (Glaxo France). On April 23, 1992, Glaxo France tested 29 compounds for PDE5 inhibition, including a compound designated GR30040x.

Dr. Labaudiniere identified GR30040x as a lead compound for further research and assigned Dr. Daugan, the named inventor on the patents, to perform further research. Dr. Daugan discovered tadalafil based on testing various modifications of GR30040x.

Vanderbilt argued at the district court that it was logical, given the sequence of events, to infer that tadalafil was derived by Glaxo France based on the research of the Vanderbilt Scientists. Vanderbilt claimed that all of the compounds tested by Dr. Labaudiniere in April 1992 made use of the Vanderbilt Structural Features such that GR30040x could not have been identified without the use of the Vanderbilt Structural Features. Vanderbilt also argued that tadalafil could not have been identified by Dr. Daugan without reliance upon the research of the Vanderbilt Scientists.

However, ICOS presented evidence that the scientists at Glaxo France independently discovered the compounds that led to the identification of GR30040x. ICOS argued that Dr. Labaudiniere identified two potential PDE-5 inhibiters in March 1992 as potential PDE5 inhibiters, including a compound known as GR35273x.

At trial, ICOS argued that Dr. Labaudiniere took GR35273x from another Glaxo program. ICOS claimed that Dr. Labaudiniere then used this compound and his knowledge from a published article to identify GR30040x. ICOS's evidence included documentary evidence and testimonial evidence from Dr. Labaudiniere and Dr. Daugan.

The district court found that each party's versions of events were equally plausible. However, the Federal Circuit held that Vanderbilt failed to satisfy its burden under the clear and

convincing evidence standard. The Federal Circuit stated that Vanderbilt failed to present clear and convincing evidence that the work of the Vanderbilt Scientists was appropriated by Dr. Labaudiniere for his substructure search leading to GR30040x.

The Federal Circuit stated that Vanderbilt failed to present clear and convincing evidence that that the modifications of GR30040x made by Dr. Daugan made use of the research of the Vanderbilt Scientists.

The Federal Circuit also provided additional clarification on how to apply earlier case law on the type of contribution required to be a joint inventor. The district court had interpreted American Bioscience to require that each co-inventor must have an independent mental picture of the complete invention that is claimed. The Federal Circuit expressly overruled the district court's interpretation. In particular, the Federal Circuit clarified that, under the holding of American Bioscience, a group of co-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention.

Additionally, the Federal Circuit also reaffirmed early case law that the determination of whether a person is a joint inventor is fact specific and that "no bright-line standard will suffice in every case." In particular, the Federal Circuit held that the district court erred when it stated that contributing a molecular scaffold could not rise to the level of joint inventorship for a different family of molecules containing the same scaffold.

Vanderbilt Univ. v. ICOS Corp. indicates the enormous difficulties in proving joint inventorship when information is exchanged with another entity. From a litigation perspective, the case is important because it demonstrates that strong circumstantial evidence may not be enough in many cases to prove joint inventorship under the clear and convincing evidentiary standard.

From a counseling perspective, it demonstrates the risks of disclosing information without considering other safeguards, such as filing one's own patents or obtaining contractual protections on the use of intellectual property.

Additionally, Vanderbilt Univ. v. ICOS Corp. demonstrates some of the potential dangers to a patent owner when there are interactions with third parties prior to the filing of a patent. The Federal Circuit has again stated that there is no bright-line standard to determine whether a third party's contributions are qualitative enough to constitute joint inventorship of the complete invention. A patentee that pursues broad claims may leave themselves open to

potential allegations of improper inventorship if their patent is filed after a third party discloses information to them that is not in the public domain and is related to the subject matter of the patent.

These risks can be minimized through various strategies. It may be desirable, when practical, to impose limitations on the internal dissemination of materials received from a third party to eliminate unnecessary access by potential inventors. The patentee should encourage its inventors to keep careful records to demonstrate what was independently invented.

Other patent prosecution strategies may be considered if there is a concern that the inventors came into contact with the disclosed information. For example, since inventorship is determined with respect to the claimed subject matter, careful drafting of the claims may make it harder for a third party to claim joint inventorship.

Additionally, consideration should be given to disclosing the received information to the patent office. Information that is not in the public domain can be submitted to the U.S. Patent and Trademark Office as 35 U.S.C. § 102(f) type secret prior art for consideration in making prior art rejections. As a result, any issued patent claims would be considered in light of the disclosed information and hence would be presumed to be patentably nonobvious over the disclosed information. This reduces (but may not completely eliminate) the likelihood that a third party can successfully seek joint inventorship for the claimed subject matter.

Additionally, in many fact patterns submitting the information received from the third party as 102(f) prior art may also be necessary under USPTO rules of candor.

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