SUTHERLAND

LEGAL ALERT

April 14, 2010

Decision Clarifies Joint Inventorship Requirements

The recent decision of the United States Court of Appeals for the Federal Circuit in *Vanderbilt University v. ICOS Corporation* contains rulings regarding joint inventorship that should be of interest to all participants in sponsored research. First, the case reaffirms the rule that joint inventorship must be proven by clear and convincing evidence. No. 2009-1258, Slip Op. at 14-15 (Fed. Cir. April 7, 2010). It also holds – by a vote of two out of three judges – that Vanderbilt failed to carry that burden, *id.* at 19-20, and for that reason the case could be viewed as a hindrance to such claims. But the decision also emphasizes that determining joint inventorship is a fact specific inquiry, not easily subject to bright-line tests. This portion of the decision – which was unanimous – could ultimately support claims under the Patent Act to add joint inventors, assuming the existence of clear and convincing evidence that the co-inventors "collaborate[d] and work[ed] together to collectively have a definite and permanent idea of the complete invention." *Id.* at 19.

The statutory requirements for joint inventorship are found in 35 U.S.C. §116, which codified the principles in *Monsanto Co. v. Kamp,* 269 F. Supp. 818, 824 (D.D.C. 1967) (stating that a joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts); *see Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc.*, 973 F.2d 911, 916 (Fed. Cir. 1992) (stating that there must be some element of joint behavior, such as collaboration or working under common direction). Thus, a primary focus of joint inventorship has always been on collaboration and joint behavior. A person must contribute to the conception of the claimed invention to qualify as a joint inventor. Yet, each contributor need not have a contemporaneous picture of the final claimed invention in order to qualify as a joint inventor. Rather, the qualitative contribution of each collaborator is the key – each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.

The Federal Circuit applied these principles to the facts of this case, which can be summarized as follows. In 2005, Vanderbilt University ("Vanderbilt") filed suit against ICOS Corporation. ("ICOS") to correct inventorship of two U.S. patents which were assigned to Glaxo Inc. ("Glaxo") and later to ICOS. The patents involve the compound known as tadalafil, the active ingredient in (Cialis®), a PDE5 inhibitor. Through research that was only partially funded by Glaxo, Vanderbilt scientists worked on PDE5 inhibitors and identified certain compounds containing "structural features" that had the effect of inhibiting PDE5.. Vanderbilt contended these scientists should be added as joint inventors because the Glaxo scientists could not identify and modify the lead compound to arrive at the final tadalafil compound without their reliance on Vanderbilt's work. Relying on *American BioScience* (333 F.3d 1330, Fed. Cir. 2003, where the court found no evidence of conception within a group of scientists at Florida State University and declined to add them as joint inventors), the district court concluded there was no evidence that the Vanderbilt scientists ever conceived the specific chemical structure of the compound claimed, or the compound with all of its components, or communicated that compound to Glaxo. Rather, the district court recognized the Vanderbilt scientists' contributions as "prosaic" contributions because they did not conceive the invention as claimed. Viewing both plaintiff's and defendant's stories as "equally plausible," the district court further concluded that Vanderbilt failed to demonstrate by clear and convincing evidence that its scientists are co-inventors of the patents at issue.

Vanderbilt raised two arguments on appeal before the Federal Circuit: (1) one Glaxo scientist used Vanderbilt's structural features to identify the lead compound, and (2) another Glaxo scientist, the named inventor, also used the work of the Vanderbilt scientists to modify the lead compound to arrive at the final

claimed compound. Apparently, no testimony or documentary evidence was introduced demonstrating a link between the Vanderbilt scientists and the Glaxo inventor prior to the identification of the claimed compound. Indeed, Vanderbilt admitted that it had no direct evidence to support its view of the facts. The Federal Circuit decision ultimately focused on the lack of record evidence to support Vanderbilt's claim, and the majority (Michel, C.J., and Clevenger, J.) affirmed for that reason.

The whole panel recognized, however, that the district court made some erroneous statements regarding the law of joint inventorship and misapplied the holding in *American BioScience* to the facts of this case. The Federal Circuit agreed with Vanderbilt that the district court erred in reading *American BioScience* to hold that each co-inventor must have an independent mental picture of the complete compound claimed in the patent. Instead, the correct standard requires that a group of co-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention. Furthermore, the Federal Circuit found that the district court's statement that "the contribution of a molecular scaffold in the context of one molecule could never rise to the level of joint inventorship for a different family of molecules containing the same scaffold" is in error. The Federal Circuit emphasized that determining whether a person is a joint inventor is fact specific, and no such bright-line standard will suffice in every case.

Nevertheless, the majority found that the district court's legal error was harmless, and does not affect the outcome of this appeal because the district court correctly noted that conception requires identification of the specific chemical structure of the compound, and the parties agreed that the Glaxo inventor was the first to conceive the claimed compound. Furthermore, in view of the district court's conclusions that the parties' respective stories about the Vanderbilt scientists' contributions to the identification of the lead compound were "equally plausible," and that Vanderbilt failed to produce any evidence of joint invention of the final claimed compound, the majority concluded that Vanderbilt failed to carry its burden of proof by clear and convincing evidence. *But see* Dyk, J., concurring in part and dissenting in part.[1]

This case addresses a situation in which sponsored university research was related to the sponsor's final invention, but was deemed not to rise to the level of joint inventorship for patent purposes. In reaching that conclusion, however, the Federal Circuit emphasized that these inquiries are fact specific, and not amenable to resolution using bright-line tests. This conclusion could make it easier for such claims to reach trial. Furthermore, all participants in sponsored research may benefit from examining how they conduct and record their work, bearing in mind the burden of presenting clear and convincing evidence to support joint inventorship if the issue arises.

■ ■ ■

If you have any questions regarding this alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

Ann G. Fort	404.853.8493	ann.fort@sutherland.com
William L. Warren	404.853.8081	bill.warren@sutherland.com
Lei Fang Ph.D, M.D.	404.853.8662	lei.fang@sutherland.com

[1] Judge Dyk concluded that the district court's findings were either directly contradictory with respect to the identification of the lead compound, or tainted by legal error. Because the district court found that the Vanderbilt scientists made some contribution, but did not provide exactly what that contribution was or why that contribution was not enough to make the Vanderbilt scientists joint inventors under the correct standard, Judge Dyk would have vacated the district court's judgment and remanded for the district court to make factual findings under the proper law. Slip op., dissent at 4-6.