**Keywords:** **enablement, undue experimentation**

**General:** **The enablement requirement may be met by animal tests or *in vitro data*. Title 35 does not demand that human testing occur within the confines of Patent and Trademark Office proceedings.**

***Edwards Lifesciences AG v. CoreValve Inc.***
105 U.S.P.Q.2d 1039 (Fed. Cir. November 13, 2012)

## I. Facts

Edwards Lifesciences LLC ("Edwards") sued CoreValve, Inc. ("CoreValve") for infringement of U.S. Patent No. 5,411,552 ("the '552 patent"), relating to a "transcatheter heart valve" that is mounted on a stent and implanted in the heart by catheter, thereby avoiding open heart surgery and its associated risks. CoreValve challenged validity of the patent for lack of enablement, arguing that the '552 patent had only been implanted in pigs, the implants were not always successful, and that design changes were made after the patent application was filed.

Edwards agreed that additional developmental work was required at the time of filing. Indeed, in a contemporaneous report, Knudsen, one of the patent's co-inventors, wrote that "questions such as size reduction, material and design optimization, and stent valve sterilization, remain unsolved," and that "much more work had to be done before anybody ever even contemplated using this for a human." However, Edwards argued that at the time of filing the device was "a device to perform testing on" and "not a device to move in and treat patients."

At district court, the jury found that the '552 was valid and that CoreValve's Generation 3 Re-Valving System infringed claim 1 of the '552 patent, and that the infringement was willful. The district court entered judgment on the verdict.

## II. Issue

A. Did the district court err by holding the '552 patent valid as enabled?

## III. Discussion

A. No. The Federal Circuit affirmed the district court's ruling that the '552 patent was valid because there was substantial evidence to support the jury's verdict. In finding validity, the Federal Circuit stated that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)). Further, the court noted that "[c]ontinuing development is often contemplated and necessary, while early filing is often essential."

Regarding CoreValve's argument that testing in pigs does not enable use in humans, the court focused on an analysis of whether conversion to a human prosthesis would require undue experimentation. The court stated:

> it has long been recognized that when experimentation on human subjects is inappropriate, as in the testing and development of drugs and medical devices, the enablement requirement may be met by animal tests or in vitro data. *See* MPEP §2164.02 ("An in vitro or in vivo animal model example in the specification, in effect, constitutes a 'working

> example' if that example 'correlates' with a disclosed or claimed method invention."). This general rule has been elaborated in various situations, e.g., *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans"); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration. Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office proceedings.").

To determine whether subject matter requires undue experimentation, the Federal Circuit relied on factors mentioned in *In re Wands*. In particular, "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims," should be considered. *In re Wands*, 858 F.2d 737 (Fed. Cir. 1988).

The Federal Circuit reasoned that substantial evidence as to how someone skilled in the art would use pig testing for a human version without undue experimentation had been provided. Specifically, the court mentioned that:

a) there was evidence that the stent/valve prosthetic device was successfully implanted in pigs, in accordance with the procedure described in the '552 specification,

b) there was explanation that pigs were a standard experimental animal for heart valve research,

c) that both sides discussed the vascular anatomies of pigs and the established use of porcine valves in humans, and

d) that witnesses discussed the nature of the ongoing experimentation, in light of the district court's instruction on the enablement requirement.

## IV. Conclusion

The Federal Circuit upheld the district court's ruling that there was substantial evidence supporting the jury's verdict that invalidity on the ground of non-enablement had not been proved by clear and convincing evidence.