The Federal Circuit Provides a Cautionary Tale for Preparing Inventor Declarations

The Federal Circuit recently issued an opinion that highlights Applicants’ duty of candor and good faith with the United States Patent and Trademark Office ("USPTO").

In *Novo Nordisk*, the Federal Circuit held that Novo Nordisk’s US Patent No. 6,677,358 ("the ‘358 patent") was invalid as obvious and reversed the district court’s finding of inequitable conduct. *Novo Nordisk v. Caraco Pharma.*, 2011-1223, June 18, 2013. The ‘358 patent involved orally delivered anti-diabetic drugs. Specifically, claim 4 is directed to treating a patient by administering two drugs, repaglinide with metformin.

The Court provided useful guidance for the preparation of inventor declarations filed under 37 CFR § 1.132 (“ Declarations”) and attorney arguments.

Inequitable conduct may occur when: (1) material information is not provided to the USPTO; (2) with intent to deceive. In *Therasense*, the Federal Circuit clarified that the deception is material if the USPTO would not have allowed the claim if it had been aware of the information. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011)(en banc).

One of Caraco’s assertions of inequitable conduct was based on trial testimony by the inventor, Dr. Sturis, that seemed to be inconsistent with a Declaration that Dr. Sturis provided during prosecution of the patent application. During the trial, Dr. Sturis conceded that he withheld certain information from the USPTO. For example, Dr. Sturis testified that when he conducted a study described in his Declaration, he planned to only calculate the statistical significance (p value) of the data as a whole. This analysis showed that the results were not statistically significant. He then provided a second statistical analysis based on one data point that was statistically significant. He had stated in his declaration that the data “indicated” and “strongly suggest[ed] synergy.” However, during trial he admitted that he was not completely convinced of the synergy.

Caraco’s other argument for finding inequitable conduct involved statements attorney Bork made about Dr. Sturis’ Declaration. For example, Bork made a statement that the Declaration provided “clear evidence of synergy.” However, the Declaration just stated that the data “indicated” and “strongly suggest[ed] synergy.” Further, the presence of synergy was doubtful, as noted in an email that Dr. Sturis sent to attorney Bork after the Declaration was submitted to the USPTO.
The district court found the materiality prong of the inequitable conduct satisfied because the Examiner withdrew the obviousness rejection based on the Sturis Declaration.

The Federal Circuit reversed. The Court stated that the "but for" test was not satisfied because a reasonable examiner would have understood that synergy in humans was not definitively proven. The Court found it redeeming that the non-favorable results of Dr. Sturis’ original statistical analysis were disclosed to the USPTO and that this disclosure provided the patent examiner the opportunity to determine the significance of the data. Thus, the adverse test results were not hidden in favor of more promising data. However, the Court said that the original protocol “ideally would have been disclosed to the PTO.”

While the Federal Circuit found the conduct of attorney Bork in characterizing the Declaration “troubling,” it ultimately found no inequitable conduct because: (1) the Declaration itself used the term “strongly suggest” instead of stating that there was synergy; and (2) the attorney said that the declaration was “evidence” rather than “proof” of synergy.

Although inequitable conduct was not found in this situation, this case serves as a valuable reminder to always be forthright with information or data when working with the USPTO. The following practices will help ensure compliance with your duty of honesty with the USPTO: (1) don’t cherry pick data to obtain statistically significant synergistic results; (2) don’t omit parts of the test protocol or hide adverse test results; and (3) don’t overstate the significance of the results. Regarding the data, it is probably best to say that data is “evidence” of synergy rather than “proof.”

Wood Phillips has a long history of evaluating information and helping our clients deal with the USPTO. Please contact us if you have questions regarding your duty to disclose when prosecuting a patent application with the USPTO.