

NOVO NORDISK PHARMACEUTICALS, INC. v. BIO-TECHNOLOGY GENERAL CORP.:
INEQUITABLE CONDUCT

In a recent case discussing the unenforceability of a patent due to inequitable conduct, the United States Court of Appeals for the Federal Circuit (“CAFC”) in *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 04-1581, affirmed a district court holding of inequitable conduct due to the applicant’s failure to disclose to the United States Patent and Trademark Office (“USPTO”) that an example disclosed in a patent application had never actually been performed successfully.

At issue was Novo Nordisk’s U.S. Patent No. 5,633,352 (“the ‘352 patent”), which involved the production of “ripe” human growth hormone (“hGH”) through the use of recombinant DNA techniques. During prosecution of the ‘352 patent, priority was claimed to a PCT application in order to remove anticipating prior art. The PCT application disclosed, in Example 1, the production of hGH using leucine aminopeptidase (“LAP”). However, the ‘352 patent specified the use of a different enzyme, dipeptidyl aminopeptidase I (“DAP I”). The applicants argued that the priority claim was proper, because the production of hGH using DAP I was enabled by Example 1’s production of hGH using LAP. The examiner accepted Novo’s argument relying, in part, on Example 1’s discussion of the experiment in the past tense as having produced hGH with 98% purity and Novo Nordisk’s extensive expert testimony regarding Example 1. However, Example 1 had never actually been performed successfully to produce hGH using the LAP enzyme and had only contained predicted results.

The relevant issue before the CAFC was whether the applicant’s failure to disclose to the USPTO that Example 1 had never been performed successfully constituted a breach of the duty of candor and good faith, rendering the patent unenforceable due to inequitable conduct. Inequitable conduct includes "affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive."

On appeal, the CAFC affirmed the district court's finding of inequitable conduct. The materiality element had been satisfied, because the examiner had relied on Example 1 in order to find enablement and to award a priority date earlier than certain anticipating prior art. In addition, the intent to deceive was found because the applicants knew or should have known that the examiner would have considered the fact that Example 1 had never been performed successfully in determining the enablement issue.

This ruling serves as a warning to the careful drafting of patent applications, in particular, to be aware of consistent tense usage. More generally, the case emphasizes that the duty of candor and good faith applies to the applicant as well as to the applicant’s representatives and includes disclosing information to the USPTO that the applicant knew or should have known to be material.

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