WHERE PATENTS include "prophetic" or "paper" examples, patent applicants should make clear that no underlying work has been performed, or results have actually been achieved, in order to avoid later allegations of inequitable conduct. Two recent Federal Circuit decisions, one of which is now on remand to the district court, illustrate this principle.

In *Purdue Pharma L.P. v. Endo Pharm., Inc.* the Federal Circuit, on petition for rehearing, vacated the trial court’s inequitable conduct judgment and remanded with instructions to reconsider both materiality and intent findings. In *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, Novo’s failure to disclose the prophetic nature of an example in a patent application was sufficiently material to infer deceptive intent and support a finding of inequitable conduct.

Prophetic Examples and Inequity

Applicants for a patent are subject to a "duty of candor" that requires them to disclose all “material information" to the PTO. A breach of the duty of candor may constitute inequitable conduct.

Inequitable conduct may arise when a patent applicant makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information, combined with an intent to deceive the PTO. Both materiality and intent must be proven by clear and convincing evidence.

In certain instances, allegations of inequitable conduct can arise from the use of prophetic examples. Prophetic examples, often called “paper examples," "describe the manner and process of making an embodiment of the invention that has not actually been conducted.

Section 608.01(p) of the Manual of Patent Examining Procedure (MPEP) authorizes the use of prophetic examples, stating that simulated or predicted test results and prophetic examples are permitted in patent applications. However, the MPEP makes clear that prophetic examples should not be represented as work actually done, and that no results should be represented as actual results unless they have actually been achieved. Prophetic examples may be used in chemical and biotech patent applications, and may help satisfy the enablement requirement under 35 U.S.C. §112, as well as overcome prior art objections.

As the following cases illustrate, patentees must be careful not to misleadingly describe prophetic examples as actual working examples.

The ‘Purdue’ Case

In the *Purdue* case, Purdue sued Endo Pharmaceuticals alleging that Endo’s proposed generic version of Purdue’s prescription chronic pain relief medication OxyContin® infringed three of Purdue’s patents. Endo filed counterclaims seeking, among other things, a declaration that Purdue’s patents were unenforceable for inequitable conduct based on a prophetic example in the asserted patents.

Specifically, the specifications of the patents-in-suit repeatedly note that the inventors “surprisingly discovered” that a particular controlled release oxycodone
Purdue repeatedly relied on this disclosure to overcome the examiner’s prior art obviousness rejections. However, at the bench trial, a named inventor, Dr. Kaiko, testified that he had “no scientific proof” at the time the patent application was filed that the inventions of the patents provided pain relief for most patients over a four-fold dosage range, leading to easier titration, i.e., adjusting of dosages in order to provide acceptable pain control without unacceptable side effects.

Instead, Dr. Kaiko testified that he had an “insight...that the range around the oral bioavailability of oxycodone had to be narrower than the range around the oral bioavailability of morphine.” (emphasis added). With this “insight,” Dr. Kaiko “envisioned [a]...proposed controlled-release oxycodone product...having an approximate four-fold range.” Purdue does not dispute that no clinical studies existed to support the patents’ disclosure of a four-fold range of doses that treat approximately 90 percent of patients.

In considering the materiality prong of the inequitable conduct defense, the district court found that a reasonable examiner would have considered important the fact that Purdue did not have “scientific proof” that the claimed invention actually provided adequate pain relief for most people over a four-fold dosage range. According to the district court, Purdue “repeatedly and convincingly” stated to the PTO that it had discovered an oxycodone formulation that controlled pain over a “four-fold” range of doses for “approximately 90 percent” of patients and that this “result” was of “extreme clinical importance.”

The district court stated that such definitive statements would be undercut if the PTO were aware that the statements lacked any support beyond Dr. Kaiko’s assertions and insight. Thus, the district court found these statements material. Regarding the intent prong of the inequitable conduct defense, the district court found that Purdue made a “deliberate decision” to misrepresent to the PTO a “theoretical argument” as a precisely quantified “result” or “discovery.”

On appeal, the Federal Circuit initially concluded that “the trial court’s findings on materiality and intent were well-founded” and upheld the conclusion that the patents-in-suit were unenforceable due to inequitable conduct. This was not the end of the story, however. On a petition for rehearing, the Federal Circuit further examined the issues in the case.

With respect to materiality, the Federal Circuit agreed that Purdue’s arguments to the PTO provided enough of a suggestion that clinical trials had been performed that the failure to disclose to the PTO that the “surprising discovery” was based on insight, and not scientific proof, was a failure to disclose material information. The Federal Circuit emphasized that this case was unusual, and that a failure to tell the PTO that a “surprising discovery” was based on insight, rather than scientific data, did not alone amount to a material omission.

However, here, “Purdue did much more than characterize the four-fold dosage range of the claimed oxycodone formulation as a surprising discovery.” Instead, “Purdue repeatedly relied on that discovery to distinguish its invention from other prior art [] while using language that suggested the existence of clinical results supporting the reduced dosage range.” The Federal Circuit further noted that “the level of materiality is not especially high.” Purdue did not make an affirmative misrepresentation, but instead, made statements implying that an empirical basis existed for its discovery, and then failed to disclose that the discovery was based only on insight, i.e., that the discovery was a predicted test result, not a working example.

The Federal Circuit found two problems with the trial court’s intent analysis. First, the trial court relied on evidence that related to Purdue’s attempt to gain FDA approval for a claim on the product label, instead of its attempt to gain allowance of its patent claims. Second, according to the Federal Circuit, the trial court failed to properly consider the level of materiality.

Specifically, “[i]t appears that the trial court perceived the level of materiality to be high and inferred deceptive intent from that high materiality, combined with the court’s erroneous finding that any good faith on the part of Purdue was undercut by its admitted inability to prove the ease of titration claim.” Here, since “the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone.”

Consequently, the Federal Circuit vacated the inequitable conduct judgment and remanded the case to give the trial court “an opportunity to reconsider its intent finding.” The Federal Circuit further directed that “[i]f the trial court still finds that a threshold level of intent to deceive has been established, the court should reweigh its materiality and intent findings to determine whether the sanction of unenforceability due to inequitable conduct is warranted.”

The ‘Novo Nordisk’ Ruling

In another recent inequitable conduct case involving a prophetic example, the Federal Circuit affirmed the district court’s conclusion that the patent in suit was unenforceable based on the applicant’s failure to disclose the prophetic nature of the example. Novo Nordisk involved a lengthy dispute between Novo and Bio-Technology General (BTG) regarding a process of producing human growth hormone (hGH) in microorganisms such as E. Coli bacteria using recombinant DNA techniques. According to the process disclosed in Novo’s patent, “ripe” or mature hGH can be obtained by cleaving (cutting) off the bacterial protein sequence from the fusion protein produced by the bacterial host cell with a proteolytic enzyme.

The prophetic example at issue was included in a PCT application that Novo filed on Dec. 9, 1983 (1983 PCT application). Using the past tense, Example 1 described a process for making hGH with leucine aminopeptidase (LAP) as the cleavage enzyme. Example 1 also provided a result for the purification step.
However, despite being written in the past tense, the cleavage and purification steps described in Example 1 had not been successfully performed prior to the filing of the 1983 PCT application. Further, Novo scientists subsequently learned that LAP did not work as described in Example 1, but that another enzyme, DAP I, did work. Based on this discovery, Novo filed another PCT application on Feb. 6, 1986 (1986 PCT application) that disclosed DAP I as the cleaving enzyme. Novo filed a continuation application, Novo responded by identifying the enabling disclosure in the 1983 PCT application, Novo filed a continuation application, and amended the priority statement to disclose DAP I as the cleaving enzyme.

In patent applications in the series that eventually issued as the patent-in-suit, Novo had claimed priority to the 1986 PCT application. However, to overcome the examiner's prior art obviousness rejections, Novo filed a continuation application and amended the priority statement to reach back to the 1983 PCT application. When the examiner asked Novo to identify the enabling disclosure in the 1983 PCT application, Novo responded by identifying Example 1 as being “specifically directed to hGH.”

The district court found the asserted patent unenforceable because a claim misconduct caused during patent prosecution and also during an interference with BTG regarding company had first invented the claimed invention.

The district court found that Novo had committed inequitable conduct during patent prosecution by failing to disclose the prophetic nature of Example 1 to the examiner. This non-disclosure was material because the examiner relied upon Example 1 in evaluating whether [the priority application] enabled the invention and therefore was entitled to an earlier priority date than the prior art reference cited by the examiner. The district court found intent to deceive based on the fact that Novo knew or should have known that the examiner would have considered the fact that Example 1 was prophetic, particularly when Novo knew that it had never successfully produced hGH using the methodology described in Example 1.

The district court also found that Novo committed inequitable conduct during the interference proceeding with BTG, likewise finding as material Novo's failure to inform the Board of Patent Appeals and Interferences (the Board) that Example 1 was a prophetic, rather than actual working example. The district court found that Novo had an intent to deceive because Novo knew or should have known that the Board would consider both Example 1 and the expert opinion provided by Novo regarding Example 1 “material to the question of enablement, particularly since this question was the sole focus of the interference.”

On appeal, Novo argued that the withheld information about Example 1 was cumulative, and thus immaterial, because during prosecution Novo had submitted a declaration by three of the named inventors that disclosed that pure LAP enzyme did not work. The Federal Circuit rejected this argument, concluding that the declaration did not establish that the Example 1 methodology did not work because the testing conditions in Example 1 differed from the testing conditions of the examples in the inventors' declaration.

Novo further argued that the intent prong had not been satisfied because there was no evidence that (a) the co-inventor who wrote Example 1 knew that the drafting of a prophetic example in the past tense was contrary to PTO rules, or (b) he subsequently told any of Novo's attorneys that Example 1 was prophetic. Novo asserted that "because it is impossible to disclose the unknown, the district court's finding of inequitable conduct is reversible error." The Federal Circuit dismissed this argument as a "circular logic" that it had previously rejected.

Purdue and Novo demonstrate that prophetic examples improperly written in the past tense so as to appear to be actual examples may give rise to a finding of inequitable conduct if the patentee relies on the disclosure without explicitly informing the PTO of the prophetic nature of the example.

Lessons for the Future

Given that Purdue is now back at the district court following remand, it is premature to say whether Purdue and Novo will ultimately win up with different outcomes. What is clear, however, is that patent applicants should exercise due care when incorporating examples into patent applications, and should make clear whether they are actual or prophetic examples.

This is especially important given the Federal Circuit's ruling that a prosecuting attorney's lack of knowledge regarding the prophetic nature of an example is not a valid excuse. Likewise, defendants in patent litigation would be well advised to carefully inquire into the nature of examples in patents to evaluate what reliance, if any, was placed on those examples during patent prosecution or interference proceedings and whether the examples described were ever actually performed successfully.