



## PATENTWATCH

## Bad laboratory practice

The importance of maintaining accurate scientific notebooks has been exemplified by two recent cases brought to the US Court of Appeals for the Federal Circuit (CAFC).

The first case involves establishing priority of invention between patents assigned to Spanish pharmaceutical manufacturers Medichem and Rolabo. The patents concern a method for making the antihistamine drug loratidine (Claritin) from two precursor chemicals via the McMurry reaction, and the only significant difference between the two processes claimed is that Medichem's method "requires the reaction to be carried out in the presence of a tertiary amine" and the Rolabo process permits, but does not require, the presence of a tertiary amine.

Medichem sued Rolabo, claiming priority of invention and seeking invalidation of Rolabo's patent. Because Rolabo has the earlier filing date, Medichem has to establish priority by proving that it was the first to reduce the invention to practice. This complicated case has endured a lengthy period of litigation in which the district court proceedings have been conducted in parallel with consideration of the same case by the Board of Patent Appeals and Interferences (BPAI); the District Court awarded priority to Medichem, but the BPAI resolved the interference in favour of Rolabo, chiefly because of Medichem's failure to provide convincing evidence that the method was 'reduced to practice'.

On Appeal, the Federal Circuit agreed with the BPAI that Medichem did not prove reduction to practice. Medichem's evidence to show reasonable diligence in reducing the invention to practice consisted of a co-inventor's lab book that documented the analysis of a sample claimed to be made using the patented method, NMR spectral data that confirmed the production of loratidine, and a laboratory notebook belonging to one of Medichem's co-inventors. However, the NMR data do not show the process by which loratidine was made, and therefore cannot provide evidence for the claimed process; furthermore, the two lab books were not witnessed and

therefore have minimal corroborative value. Taken together, this evidence was not enough to support Medichem's claim of reduction to practice and, in the absence of reliable testimonial evidence, the Appeals Court reversed the district court's award of priority to Medichem.

By contrast, in a second case, the US CAFC found that a lower court had too readily dismissed the validity of laboratory notebooks when determining priority. Brown and Barbacid are involved in litigation concerning assays for farnesyl transferase inhibitors; Brown has an earlier filing date than Barbacid, but Barbacid claims an earlier reduction to practice. Again, lengthy litigation has ensued, and at a second round of appeal, Brown defended the use of laboratory notebooks as acceptable evidence that he and his coworkers exercised reasonable diligence in reducing his invention to practice before Barbacid's conception date.

However, the issue in this case was whether it was obvious that the experiments outlined in one of the notebooks were carried out for the purpose of moving the inventive process of the assay towards completion. The BPAI had ruled that there was no explanation that made this clear, stating that "we are given a number of laboratory pages, the content of which is never explained." However, the Appeals Court agreed with the testimony of Brown that this work would be understood by persons skilled in the art, and that "a laboratory notebook recording daily experimentation ... need not reproduce on each page a statement of the larger research purpose." The CAFC agreed with Brown and concluded that the Board had erred in its consideration of this evidence, and therefore reversed its decision.

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**Medichem, S.A. v. Rolabo, S.L., No. 05-1179, -1248 (3 Feb 2006):**

<http://www.fedcir.gov/opinions/05-1179.pdf>

**Brown v. Barbacid, No. 05-1119 (3 Feb 2006):** <http://fedcir.gov/opinions/05-1119.pdf>

## Purdue's conduct proves immaterial

The latest chapter in the ongoing case between Purdue Pharma and Endo Pharmaceuticals over Endo's alleged infringement of Purdue's patents for controlled-release painkiller oxycodone (Oxycontin) has been ruled in Purdue's favour.

Both parties lost out in previous decisions which saw the courts decide that Endo had infringed the patents with their generic version of Purdue's drug, but that Purdue's patents were invalid anyway because of inequitable conduct. Now, the CAFC has vacated the ruling on inequitable conduct and affirmed that Endo's drug does infringe Purdue's patents.

Purdue was originally found guilty of inequitable conduct because its claim that Oxycontin is a more easily titratable

analgesic than 'prior art' opioid formulations was subsequently found to be based on insight rather than experimental evidence. However, although the Appeal Court holds that Purdue failed to disclose this lack of experimental evidence for the claim during court proceedings, it stresses that the level of materiality is not especially high. That is, Purdue did not 'expressly misrepresent' to the Patent and Trademark Office that it had obtained such experimental evidence.

When materiality is low, then intent to deceive or mislead the PTO must be high for a ruling of inequitable conduct. But to prove intent, the lower court relied on internal communications disclosing Purdue's lack of experimental evidence for the superior titratability that was part of an application by Purdue to the FDA for approval for a specific labelling claim. The Appeals Court argued that this communication to the FDA does not

prove that Purdue acted with intent to deceive the PTO, and that the court gave this evidence too much weight.

Based on the combined level of materiality and intent, the Court was unable to uphold the verdict of inequitable conduct against Purdue. Moreover, further examination of the claim construction and the prosecution history led the Court to find that there was no limitation in Purdue's patents that excluded the dosage range of Endo's generic product, and as such affirmed the lower court's verdict of infringement.

**Purdue Pharma v. Endo Pharmaceuticals, No. 04-1189, -1347 (1 Feb 2006):** <http://fedcir.gov/opinions/04-1189.pdf>

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