

FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Medichem, S.A. v. Rolabo, S.L., 05-1179 (Fed. Cir. Feb. 3, 2006) (Gajarsa, J.)

In a second appeal from an interference proceeding by the district court, the court affirmed the finding of an interference-in-fact. Both prongs of the two-way test were met, including the finding that Rolabo's genus claim rendered Medichem's species claim obvious. The technology was a method to prepare an antihistamine used in Claritin®. The court, however, reversed the award of priority to Medichem because it could not sufficiently corroborate its inventors' testimony as to date of actual reduction to practice. The foundation was insufficient for the non-inventor notebooks offered for corroboration, and some entries may have been from an inventor.

Each party to the interference had a patent to a process for the preparation of Loratadine, an antihistamine that is the active pharmaceutical ingredient in the allergy medication Claritin®.

Both patents involve chemical reactions generally known in the art as "McMurry" reactions.

The only significant difference between the processes claimed by Medichem and Rolabo is that Medichem's process requires the reaction to be carried out in the presence of a type of chemical known as a tertiary amine. In contrast, the Rolabo process permits by not excluding, but does not require, the presence of a tertiary amine. Conceptually, therefore, the Medichem invention, which requires a tertiary amine, is a species within the genus of the Rolabo invention.

The court affirmed the finding of an interference-in-fact. In the earlier appeal it held that the first prong of the "two-way test" for interference had been met.

[W]e remanded to the district court for a determination of whether the second prong was also satisfied—namely, whether Rolabo's genus claim, if prior art, would either anticipate or render obvious Medichem's species claim.

The court affirmed the obviousness determination, while noting that the anticipation finding below was unsupported. Regardless, the obviousness determination satisfied the interference-in-fact requirement by meeting the second prong of the test. Under the motivation-to-combine element of obviousness, there were conflicting statements in the prior art about positive or negative effects from adding a tertiary amine to the reaction, but this did not render the district court's finding erroneous in consideration of the prior art as a whole. Moreover, the situation was not that the subject matter was "obvious to try" but not obvious.

In the present appeal, the court also noted that the same interference was adjudicated before the U.S. PTO's Board in early 2005. The Board reached a decision in favor of Rolabo, which was opposite the district court's award of priority to Medichem.

As to priority of invention, the court disagreed with the district court.

Because the Medichem '100 patent issued from an application that had a later effective filing date than did Rolabo's '827 patent application . . . Medichem bears the burden of establishing priority by a preponderance of the evidence. . . . Here, because neither party relied on a date of conception, priority is properly awarded to the party that was the first to

reduce its invention to practice, either actually or constructively. Rolabo relies on its date of constructive reduction to practice, namely its February 26, 1997 effective filing date. Medichem, on the other hand, alleges that it achieved an actual reduction to practice in the spring of 1996, a date which if proven would antecede Rolabo's filing date, and thereby entitle it to priority.

Medichem could not prove reduction to practice because its evidence to corroborate the inventor's testimony on its supposed reduction was insufficient.

Sufficiency of corroboration is determined by using a "rule of reason" analysis, under which all pertinent evidence is examined when determining the credibility of an inventor's testimony. . . . The requirement of independent knowledge [excluding co-inventors] remains key to the corroboration inquiry. . . . [C]orroboration is fundamentally about "credibility . . ."

The court analyzed documentary corroborating evidence from Medichem's inventors and non-inventors.

[For the inventor's notebooks,] the problem with the dated NMR data is that at most they corroborate that the inventors were in possession of the chemical loratadine as of that date; they do not, in themselves, adequately corroborate the claimed process, as they do not establish whether the sample that was analyzed was actually produced by that process. . . .

It is clear to this court, therefore, that Medichem's claim of corroboration stands or falls with the modicum of additional corroborative value that can properly be assigned to non-inventor Casas' notebook. However, Casas did not testify regarding the notebook or the genuineness of its contents. In addition, although Casas' notebook was dated, it was neither signed nor witnessed, and inventor Rodriguez testified that she and Casas had made entries in each others' notebooks. Rodriguez characterized these occasions as not out of the ordinary. As a result, the district court was clearly reliant on the inventor to help to identify the author of specific entries made in Casas' notebook, because in a reduction to practice inquiry, only those passages of the unsigned, unwitnessed notebooks authored by non-inventor Casas could possess significant corroborative value. In addition, without testimony from Casas, the court lacked any non-inventor testimony regarding the genuineness of the notebook's contents.

