



# Federal Circuit Patent Watch

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## In re Gabapentin Patent Litig.

No. 06-1572, Federal Circuit (*Lourie*, Linn, Moore)

***[S]cientific theories utilized must establish the presence of the limitations recited in the claim.***

On September 21, 2007, the Federal Circuit, inter alia, reversed and remanded the district court's summary judgment that the defendants did not infringe U.S. Patent No. 6,054,482, which related to gabapentin formulations used to treat cerebral disorders such as epilepsy and is marketed by Warner Lambert as Neurontin®. The Federal Circuit stated:

On appeal, Warner Lambert argues that the district court erred by resolving factual disputes on summary judgment. According to Warner Lambert, the parties proffered conflicting expert opinions, based on different evidence and different methods of testing, regarding whether Teva's samples infringed the '482 patent. As such, Warner Lambert argues that genuine issues of material fact exist in the record, and thus summary judgment was not appropriate. Warner Lambert further argues that the district court applied the wrong legal standard. Warner Lambert argues that the court, instead of determining whether it was more likely than not that a particular sample could meet the 20 ppm claim limitation, improperly determined whether it was possible that that sample could exceed the 20 ppm limitation.

Appellees respond that the court properly granted summary judgment for several reasons. First, appellees challenge the accuracy and reliability of the pH testing method. Appellees assert that the pH testing method yielded inaccurate results because, inter alia, Warner Lambert's expert failed to calibrate the standards used for the test. Second, appellees argue that pH testing is not competent proof of infringement in light of the test's lack of precision. Because the pH testing method cannot quantify the level of acidic chloride in a gabapentin sample, as Warner Lambert purportedly conceded, appellees argue that that evidence was insufficient to raise a genuine issue of material fact. As such, appellees contend that summary judgment was proper because appellees' evidence showing that the samples contained more than 20 ppm of acidic chloride stood un rebutted.

We agree with Warner Lambert that genuine issues of material fact exist in the record, and thus that the court erred in granting summary judgment. In support of its motion for summary

judgment, appellees adduced evidence demonstrating that the Teva samples contained over 20 ppm of acidic chloride. To counter that evidence, Warner Lambert submitted results from pH tests that were performed by Warner Lambert's analytical expert, Dr. Martin C. Davies. In conducting the comparative pH testing, Dr. Davies measured pH levels of the Teva samples against standards with known levels of acid. Dr. Davies prepared the standards by first preparing a baseline sample that contained no detectable chloride. Various known amounts of acid were then added to the baseline sample, and the pH measurements of the standard samples were recorded. The pH measurements of the standards generally decreased as the amount of mineral acid increased. Conversely, the pH measurements increased as the amount of mineral acid decreased. The pH values of numerous Teva samples were then measured. The record contains a chart prepared by Dr. Davies that compares those values to the pH measurements of the standard samples. . . . Drawing all reasonable inferences in favor of Warner Lambert as the nonmovant, we conclude that Warner Lambert adduced sufficient evidence to create a genuine issue of material fact regarding whether Teva's samples met the 20 ppm claim limitation of the '482 patent. Accordingly, the district court erred in granting summary judgment. the 20 ppm claim limitation. . . .

It is important to note for the record that Defendants strongly dispute the capability of pH testing to make any scientifically meaningful distinctions between gabapentin samples at the trace levels of acidity relevant to the '482 patent. However, for purposes of this motion, Defendants have placed that dispute to one side (as they must), and focused on the undisputed limitations on the precision of such comparative pH measurements. . . . Thus, appellees limited their summary judgment motion to the issue of the undisputed limits of the test's precision, viz., the  $\pm 5$  ppm margin of error, which we have considered. As such, appellees waived any argument challenging the validity, including challenges to the accuracy or reliability, of the pH testing method for purposes of summary judgment.

Moreover, we are not persuaded by appellees' argument that summary judgment was proper because Warner Lambert failed to prove infringement in quantitative terms. Appellees [contend] that infringement must be proven using a test that can quantify the level of acidic chloride in a gabapentin sample because Warner Lambert chose to draft its claims in quantitative terms. . . . Here, in order to prove infringement, Warner Lambert is required to demonstrate that the Teva samples contain less than 20 ppm of anions of a mineral acid, as recited in the claims. Based on the record before us, the comparative pH testing allows for this showing.

For more information on these issues or other intellectual property law matters, please contact **Lawrence M. Sung, Ph.D.** at [lsung@nixonpeabody.com](mailto:lsung@nixonpeabody.com) or 202-585-8221.

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