

CASE LAW UPDATE

May 3, 2007

CASE	<i>Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.</i> (Fed. Cir. January 19, 2007)
MAIN ISSUE(S)	What is the proper meaning of the claim limitation, "about 1:5?" Properly construed, was the grant of summary judgment of non-infringement for literal infringement and infringement under the Doctrine of Equivalents proper?
EXECUTIVE SUMMARY	The Federal Circuit affirmed the District Court's construction of the term "about 1:5" to mean a range of ratios of no greater than 1:3.6 to 1:7.1. Thus, in considering the intrinsic and extrinsic evidence, a ratio of no less than 1:7.5 did not infringe either literally or under the doctrine of equivalents. To conclude so would have eviscerated the claim limitation under the doctrine of claim vitiation.
KEY TERM(S)	claim construction, about, doctrine of claim vitiation, infringement
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PROCEDURAL POSTURE	Ortho sued Caraco for infringement of claim 6 of its '691 patent in the U.S. District Court for the Eastern District of Michigan. Caraco moved for summary judgment of non-infringement. The District Court concluded that Caraco's ANDA-defined product, having an average weight ratio of tramadol to acetaminophen of 1:8.67 and expressly requiring a weight ratio of no less than 1:7.5, did not infringe, either literally or under the Doctrine of Equivalents (DOE), claim 6 of Ortho's '691 patent, which claimed an average weight ratio of about 1:5. Ortho appealed.
FACTS	The '691 patent is directed to a pharmaceutical composition comprising certain weight ratios of tramadol and acetaminophen. The only claim at issue, dependent claim 6, is directed to the composition "wherein the ratio of tramadol material to acetaminophen is a weight ratio of about 1:5." Caraco's ANDA expressly requires its pharmaceutical composition have a weight ratio of tramadol to acetaminophen of no less than 1:7.5. Caraco argued that the proper construction of "about 1:5" was approximately 1:5, inclusive of minor measuring errors of 5 or 10%. Ortho argued that the term "about 1:5" means approximately 1:5, encompassing a range of ratios of <u>at least</u> 1:3.6 to 1:7.1.
HOLDING	The Federal Circuit AFFIRMED the district court's grant of summary judgment of non-infringement in favor of the defendant, Caraco.
COURT'S REASONING	Relying on both intrinsic evidence and extrinsic evidence, the Federal Circuit opined that the term "about 1:5" is narrow because the 1:5 weight ratio is distinctly claimed and is distinguished from other broader weight ranges. Further, the specification supported the criticality of the 1:5 ratio, because the ratio was specifically identified, and, if broadened, it would potentially vitiate another claim limitation, namely the 1:1 limitation. Experimental data included in the specification also listed other specific ratios, but the patentee chose to claim the specific ratios of 1:1 and 1:5, when they could otherwise have claimed a range of "about 1:1 to about 1:5." Ortho's expert also concluded, using statistical analyses, that the ratio of 1:5 would not be statistically different from a ratio up to and including 1:7.1 and down to and including 1:3.6. Construing the claim to include these numerical limitations, the court concluded there was no literal infringement by Caraco's formulation requiring a ratio of no less than 1:7.5. Under the DOE, the court opined that the 1:5 parameter was critical, and could not be expanded beyond the patent's stated 95% confidence intervals. In addition, in reissue proceedings related to the '691 patent, the court noted Ortho had admitted it had claimed more than it was entitled to and had narrowed all of its claims, except claim 6, from "comprising" to "consisting essentially of." To broaden the claim now would eviscerate the "about 1:5" claim limitation.
PANEL	Schall, Gajarsa, Federal Circuit Judges and McKinney, Chief Judge of the U.S. District Court for the Southern District of Indiana, sitting by designation.