Keywords: **literal infringement; about; claim construction; doctrine of equivalents**

General: **The criticality of an "about" limitation may justify not only a narrow construction of the term but also a narrow range of equivalents.**

Ortho-McNeil Pharmaceutical, Incorporated, v. Caraco Pharmaceutical Laboratories, Limited
No. 06-1102 (Fed. Cir. 2007)
January 17, 2007

I. Facts

Ortho-McNeil Pharmaceutical, Incorporated ("Ortho") is the owner of U.S. Patent No. 5,336,691 ("the '691 patent"), which is listed in the FDA's Orange Book as relating to Ultracet. Ortho filed suit in the district court after Caraco Pharmaceutical Laboratories, Limited ("Caraco") filed an ANDA for a generic version of Ultracet, which included a paragraph IV certification with respect to the '691 patent[1]. Caraco's ANDA requested approval for a formulation containing tramadol and acetaminophen with an average weight ratio of tramadol to acetaminophen of 1:8.67, and requiring a weight ratio of no less than 1:7.5. Ortho alleged that Caraco's proposed formulation infringed claim 6 of the '691 patent, which recites (when read in conjunction with the two claims on which it depends): "A pharmaceutical composition comprising a tramadol material and acetaminophen, wherein the ratio of the tramadol material to acetaminophen is a weight ratio of about 1:5."

The only issue in the case was the infringement of claim 6 of the '691 patent, as the parties had previously stipulated to be bound by the patent validity and enforceability decisions in Ortho-McNeil's corresponding Ultracet ANDA litigations against Kali Laboratories, Inc. ("Kali") and Teva Pharmaceutical Industries ("Teva")[2].

Caraco argued that the proper construction of "about 1.5" was "approximately 1:5, subject perhaps to minor measuring errors of, say, 5 or 10%." Ortho argued that the proper construction is "approximately 1:5, and . . . encompasses a range of ratios of at least 1:3.6 to 1:7.1."

On motion for summary judgment, the district court followed Ortho's claim construction and found that Caraco's ANDA formulation did not literally infringe the '691 patent, nor did it infringe under the doctrine of equivalents, based on the doctrine of claim vitiation. The district court concluded that finding infringement by Caraco's formulation with an average weight ratio of 1:8.67 would render meaningless the "about 1:5" limitation.

II. Issue

Was the district court correct in its finding of non-infringement?

[1] Paragraph IV certification requires a certification by the filer of the ANDA that either 1) its generic drug will not infringe patents listed in the Orange Book as related to the nongeneric product or 2) the relevant Orange Book patents are invalid.

[2] On July 20, 2007, Ortho announced a settlement agreement with Kali in which Kali agreed that the '691 patent is valid and enforceable. The Teva case is still pending.

III. Discussion

Yes. The Federal Circuit agreed with the district court's finding of no literal infringement and no infringement under the doctrine of equivalents. The central question of infringement was the claim construction of the term "about 1:5." In reviewing the district court's finding of non-infringement, the Court referred to its approach to the interpretation of the term "about" in other cases:

> [T]he word "about" does not have a universal meaning in patent claims, . . . the meaning depends upon the technological facts of the particular case.
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> The use of the word "about," avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter . . . .

The Federal Circuit agreed with the district court's claim construction, stating that the existence of a separate claim in the '691 patent directed at a ratio of "about 1:1" provided evidence supporting a narrow interpretation of the term "about 1:5." Further, other claims in the '691 patent were directed at ranges of ratios, such as "from about 1:1 to about 1:1600," leading the Court to conclude that the inventors meant something more precise in claim 6, which contained no recitation of a range. The Court also considered expert evidence that a ratio of 1:3.6 up to a ratio of 1:7.1 would be statistically indistinguishable from a ratio of "about 1:5." Because the Caraco formulation had a ratio of tramadol to acetaminophen of no less than 1:7.5, the Federal Circuit affirmed the district court's finding of no literal infringement.

On the question of whether there was infringement under the doctrine of equivalents, the district court determined that a holding that Caraco's product infringed claim 6 of the '691 patent under the doctrine of equivalents would impermissibly vitiate the limitation of claim 1 of a weight ratio of tramadol to acetaminophen of "about 1:5." The Federal Circuit found no error in the lower court's analysis and affirmed its holding and stated, "[a]n infringement analysis that stretches the bounds of the 'about 1:5' limitation beyond those confidence intervals directly conflicts with the patent's express claim to both the 1:1 and the 1:5 ratios."