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Federal Circuit Patent Bulletin: *Cadence Pharm., Inc. v. Exela PharmSci Inc.*

March 25, 2015

"The determination of equivalence depends not on labels like 'vitiation' and 'antithesis' but on the proper assessment of the language of the claimed limitation and the substantiality of whatever relevant differences may exist in the accused structure."

On March 23, 2015, in *Cadence Pharm., Inc. v. Exela PharmSci Inc.*, the U.S. Court of Appeals for the Federal Circuit (Reyna, Linn,* Wallach) affirmed the district court's judgment that Exela infringed U.S. Patents No. 6,028,222 and No. 6,992,218, which related to aqueous phenol formulations such as paracetamol marketed by Cadence as Ofirmev®, and that the '218 patent was not invalid. The Federal Circuit stated:

The district court construed the terms "aqueous solution" and "solution" in claim 1 of the '218 patent as "[a] composition containing water as a solvent and an active ingredient susceptible to oxidation." The district court thus concluded that the claimed step of "deoxygenation of the solution" required that an active ingredient already be dissolved. In other words, the district court interpreted the claim to directly cover only the method of first dissolving an active ingredient to form a solution and then deoxygenating the solution. Exela's accused process, by contrast, first deoxygenates a solvent and only then adds an active ingredient. Accordingly, the district court found that Exela did not literally infringe claim 1. Nevertheless, the district court found that Exela's ANDA formulation infringed claim 1 under the doctrine of equivalents. It found that the timing of the addition of the active ingredient did not matter and ruled that the differences between the claimed steps and Exela's method were insubstantial.

[We] find no clear error in the district court's finding of infringement under the doctrine of equivalents. The district court relied on the testimony of Cadence's expert, Dr. Orr, "that adding acetaminophen before or after the deoxygenation step would have no impact on the stability of the final product." Dr. Orr explained that this was so because "in both cases you're trying to deoxygenate your solution. In both cases, you're employing bubbling to do that. And the results that you achieve under this prolonged period of-of bubbling is still a solution of less than two parts per million." This testimony supports the district court's finding that changing the

timing of the deoxygenation step was an insubstantial difference. The correctness of this conclusion is confirmed by the district court's finding and Exela's accession that its formulation is, in fact, stable. Exela's speculation that other differences between its formulation and the claimed formulation may be responsible for stability is insufficient to create a definite and firm conviction that the district court made a mistake.

The district court also did not accept Exela's argument that this scope of equivalents would vitiate a limitation of the claim. Exela challenges that determination and contends that deoxygenating after adding the active ingredient is the "antithesis" of deoxygenating before adding the active ingredient and that because such a substitution would "vitiate" the claimed limitation, there can be no finding of equivalence. . . .

Exela fundamentally misunderstands the doctrine of claim vitiation. "Vitiation" is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted. We have repeatedly reaffirmed this proposition. Characterizing an element of an accused product as the "antithesis" of a claimed element is also a conclusion that should not be used to overlook the factual analysis required to establish whether the differences between a claimed limitation and an accused structure or step are substantial vel non. The determination of equivalence depends not on labels like "vitiation" and "antithesis" but on the proper assessment of the language of the claimed limitation and the substantiality of whatever relevant differences may exist in the accused structure.

Since a reasonable trier of fact could (and, in fact, did) conclude that Exela's process is insubstantially different from that recited in the claims, the argument that a claim limitation is vitiated by the district court's application of the doctrine of equivalents is both incorrect and inapt. Therefore, we affirm the district court's determination of infringement of claim 1. . . .

Exela bears a difficult burden in this case on the question of obviousness. First, since the Examiner initially rejected the claims of the '218 patent for essentially the same reasons as defendants now raise, the Patent Office is "'presumed to have properly done its job'" when it ultimately allowed the '218 patent. Second, patents are presumed to be valid, so defendants must prove invalidity by clear and convincing evidence. Third, we will only overturn the district court's underlying factual determinations if we believe they are clearly erroneous.

Exela has not met its burden. The district court found the teachings of the '222 patent and the cited Palmieri article lacking, as do we. The district court found that skilled artisans understood acetaminophen to be primarily degraded via hydrolysis. . . . The district court thus was correct in concluding that it would not have been obvious to combine the Palmieri article with the '222 patent, because the Palmieri article addressed the degradation of pyrogallol-which degrades primarily by oxidation-and did not address the degradation of acetaminophen-which, as noted above-degrades primarily by hydrolysis. . . . Regarding secondary considerations, we agree with the district court that secondary considerations related to the marketing of Ofirmev® are not per se irrelevant to the non-obviousness of the claims of the '218 patent, despite the fact that the claims do not literally cover Ofirmev®.