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Complex or Not Written Description Is Evaluated Against Claims

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The US Court of Appeals for the Federal Circuit reversed a district court's ruling of invalidity for lack of written description, finding that the district court erred in its analysis of written description because patents must be evaluated based on the claims themselves, not on their construction. *In re Entresto*, Case No. 23-2218 (Fed. Cir. Jan. 10, 2025) (**Lourie**, Prost, Reyna, JJ.)

Novartis owns an approved new drug application (NDA) for a combination therapy of valsartan and sacubitril that Novartis markets under the brand name Entresto®. The term "combination therapy" is used to describe pharmaceuticals where two or more active pharmaceutical ingredients are combined in a single method of treatment. Entresto® is protected by several patents, including the patent at issue. Several generic pharmaceutical manufacturers, including MSN, filed abbreviated new drug applications (ANDAs) seeking to market generic versions of Entresto® prior to the expiration of Novartis' patent. Novartis sued for infringement.

A unique property of Entresto® is the specific form taken by the active pharmaceutical ingredients, valsartan and sacubitril. The valsartan and sacubitril in Entresto® are present in what is known as a "complex," meaning the two drugs are bonded together by weak, noncovalent bonds. At issue before the district court was the construction of the claim term "wherein said [valsartan and sacubitril] are administered in combination." The inquiry focused on whether "in combination" required the valsartan and sacubitril to be chemically separated molecules (not in the form of a complex). The district court adopted Novartis' proposal to give the term its plain and ordinary meaning because the intrinsic record was silent as to whether the molecules must be separate and not complexed. The complexed form of valsartan and sacubitril was not developed until four years after the priority date of the patent.

After the district court declined to adopt MSN's "complexed" claim construction, MSN stipulated to infringement. The case proceeded to a bench trial on the issue of validity. The district court found the patent not invalid for obviousness, lack of enablement, and indefiniteness. However, the district court ruled that because the patent did not disclose the complexed form of valsartan and sacubitril, it was invalid for lack of written description. Novartis appealed.

Novartis argued that a complex of valsartan and sacubitril was an after-arising invention that need not have been enabled or described. The Federal Circuit agreed, finding that because the patent did not

claim the complexed form of valsartan and sacubitril, those complexes need not have been described. The Court cited its “long-recognized” rule that “the invention is, for purposes of the written description inquiry, whatever is now claimed.” All that was required to meet the written description requirement was a disclosure sufficient to show that the inventors possessed a pharmaceutical composition comprising valsartan and sacubitril administered in combination. The Federal Circuit found that by considering what the claims were “construed to cover,” the district court improperly conflated the distinct issues of patentability and infringement. The Federal Circuit reversed the district court’s finding of invalidity for lack of written description.

Having found no reversible error, the Federal Circuit affirmed the district court’s finding that the patent was not invalid for obviousness or lack of enablement. The parties did not address definiteness on appeal.

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