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Federal Circuit: Written Description and Enablement Depend on What a Patent 'Claims,' Not What the Claims Cover

February 12, 2025

Reading Time : **3 min**

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The Federal Circuit recently reversed a district court decision that found a patent that did not describe after-arising technology failed to satisfy the written description requirement. In so doing, the Federal Circuit explained that written description and enablement are evaluated based on the subject matter that is claimed, not the products that practice those claims. As a result, the patentee was not required to describe unclaimed, later-discovered features of the accused products despite the broad language in the claims that undisputedly covered the products.

Several companies filed ANDAs seeking approval to market a generic version of Novartis's drug Entresto®, which consists of the compounds valsartan and sacubitril complexed together through weak noncovalent bonds. In response, Novartis brought suit in the District of Delaware alleging infringement of one of its patents directed to pharmaceutical compositions of valsartan and sacubitril "administered in combination."

At the district court, Defendant MSN argued that the patent was invalid for lack of written description and enablement because it did not include any description of combinations of valsartan and sacubitril where the drugs were complexed. More specifically, MSN argued that by failing to disclose valsartan-sacubitril complexes, the patent failed to describe and enable the full scope of the claims. Novartis responded that because its Entresto® product was developed after the patent was filed—it is after-arising technology—the specification did not need to describe or enable complexed valsartan-sacubitril to satisfy the requirements of Section 112. It need only provide support for then known combinations of valsartan and

sacubitril. Following a three-day bench trial, the district court held that the patent satisfied the enablement requirement, explaining that enablement is judged based on the state of the art at the time of filing, and need not enable later-developed, complexed combinations. But the district court took the opposite approach with respect to written description, reasoning that the same facts were fatal for written description purposes because Novartis could not possibly describe that which it had not yet conceived.

On appeal, the Federal Circuit reversed the district court's written description determination (while affirming its holding on enablement). The court held that the district court "erroneously conflated the distinct issues of patentability and infringement," leading it astray in its evaluation of the written description. The question is not whether the patent adequately described complexed forms of valsartan and sacubitril. Rather, the question is whether the patent adequately describes ***what is claimed***, i.e. a combination of valsartan and sacubitril. In this case, the complexed form found in Entresto® is not "what is claimed." Although products like Entresto® include the claimed combination, they also include unclaimed features (i.e., the valsartan-sacubitril complexes) that were not known at the time. As to the claimed features, however, the specification provided ample disclosures demonstrating the inventors were in possession of a pharmaceutical composition of valsartan and sacubitril administered ***in combination***.

MSN recently petitioned for rehearing focused on the argument that when the broadly construed claims include technology that did not exist at the time of invention (and thus, could not have been described), the written description requirement is not met.

Practice Tip: While it is true that a patent must describe and enable the full scope of the claims, it is important to remember that the scope of what is claimed may differ from the scope of what the claims cover. Thus, when considering what is embraced by the full scope of the claims, and therefore, relevant to a written description or enablement analysis, parties should consider whether there are features present that were developed later in time. Those features may very well fall outside of the scope of the claims for the purposes of written description and enablement, while the product may nevertheless practice the claims as they are written.

In Re: Entresto (Sacubitril/Valsartan), 2023-2218 (Fed. Cir. Jan. 10, 2025).

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