In re Entresto: Federal Circuit Reverses Patent Invalidity, Strengthens Pharmaceutical Protection

Overview

In re Entresto. (125 F.4th 1090, Fed. Cir. 2025) involves an appeal from the District Court for the District of Delaware. This case began when Novartis Pharmaceuticals Corporation sued MSN Pharmaceutical, Alembic Pharmaceuticals Limited, and Torrent Pharma alleging that their filing of an Abbreviated New Drug Application ("ANDA") directly infringed claims 1-4 of their '659 patent. In response, MSN argued that Novartis's claims did not satisfy the written description, enablement, or non-obviousness requirement. The district court agreed in part and found Novartis's patent invalid for lack of written description. Novartis appealed this decision.

Case Background

Novartis Pharmaceuticals Corporation is a global player in the innovative healthcare space, known for developing groundbreaking treatments. One of their many drugs, Entresto, a combination of valsartan and sacubitril, was approved by the FDA in 2015 for the treatment of heart failure. Since its approval, Entresto has become a vital option for patients with heart failure, generating over $3 billion in sales in 2023 alone. To protect their invention, Novartis holds several patents for Entresto, including the '659 patent. This patent covers the specific combination of valsartan and sacubitril.

Several prominent generic drug manufacturers, including MSN, Torrent Pharma, and Alembic, filed an ANDA with the FDA in 2019, seeking approval to market a generic version of Entresto. Like other generic manufacturers, these companies aimed to introduce a lower-cost alternative to Entresto, offering more affordable treatment for heart failure patients. However, to stop the generic manufacturers from making and selling a generic version of Entresto, Novartis filed a lawsuit for direct infringement.

The main issues in this case were whether Novartis's patent was valid and whether the opposing parties' generic formulation infringed on Novartis's patent. This case was initially heard by the District Court and was subsequently appealed to the Federal Circuit.

Case Details

Novartis sued the generic manufacturers alleging they directly infringed on claims 1-4 of their '659 patent. The generic manufacturers responded by arguing that the patent was invalid for obviousness, lack of written description, and on enablement grounds. The district court found the patent to be non-obvious and enabled. In particular, the district court found that the prior art did not clearly motivate a skilled person to combine valsartan and sacubitril. The district court also found that the '659 patent did not need to enable the valsartan-sacubitril complex, as it was unknown in 2002.

On the other hand, the district court agreed that the claims do not satisfy the written description requirement. Analyzing the claims, the district court stated that the term "administered in combination" should be interpreted according to its plain meaning. Resulting in

the valsartan-sacubitril combination being considered a complex. However, the court stated it was previously undisputed that these complexes were unknown to a person of ordinary skill in the art. Therefore, Novartis could not have possessed or disclosed these complexes, meaning it failed to meet the written description requirement.

The parties appealed the adverse rulings to the Federal Circuit.

Federal Circuit Ruling

One of the main disputed issues was over the meaning of the term "administered in combination" in the '659 patent. The Federal Circuit stated that the '659 patent "is silent on whether sacubitril and valsartan must be separate." Accordingly, the court said that it must give that term its plain and ordinary meaning. After referring to the specification, the court stated phrases such as "[a] therapeutically effective amount of each of the component[s] of the combination of the present invention may be administered simultaneously or sequentially in any order" disclose the administration of valsartan and sacubitril in combination as a physical mixture. The court concluded the specification plainly shows the inventors had position of this pharmaceutical complex. Therefore, the Federal Circuit concluded there was adequate written description.

Next, the Federal Circuit analyzed the district court's ruling on the enablement and obviousness issues. Regarding enablement, the Federal Circuit affirmed that the '659 patent did not need to enable later-created valsartan-sacubitril complexes. Therefore, the claims were enabled. The Federal Circuit further upheld the district court's ruling of non-obviousness, reasoning that the prior art at the time lacked clear motivation and a reasonable expectation of success in combining valsartan and sacubitril.

Conclusion

The Federal Circuit reversed the district court's ruling on the lack of written description and affirmed the findings that the claims were enabled and non-obvious.

Key Takeaways

This case reinforces and clarifies the requirements of written description, enablement, and obviousness. The Federal Circuit indicated that a patent does not need to enable later-discovered inventions, like the valsartan-sacubitril complex, if they were unknown at the time. This case further emphasized the importance of clearly describing an invention to satisfy the written description requirement, especially when dealing with new combinations or complex compounds.

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