



LEGAL UPDATES

Federal Circuit Upholds Validity of Entresto Patent In Precedential Decision Concerning Written Description and Enablement

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The Importance of the Federal Appeals Court Ruling

In a Jan. 10 precedential ruling by the United States Court of Appeals for the Federal Circuit, the validity of the U.S. patent covering Novartis's blockbuster drug Entresto was upheld, reversing an earlier decision by the U.S. District Court in Delaware that the patent was invalid.

The written description requirement continues to be an issue raised in almost every patent case, with varying results. This decision is a positive result for patentees with broad patent claims that may cover both an original formulation and a subsequent later-developed formulation.

Background

Entresto – marketed by Novartis for the treatment, *inter alia*, of heart failure – comprises a combination of two active agents: valsartan and sacubitril. The Novartis patent (U.S. Patent No. 8,101,659[1]) claims valsartan and sacubitril “administered *in combination*.” Novartis filed suit for patent infringement against MSN Pharmaceuticals and several other defendants that filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to sell generic versions of Entresto.

The district court held the claims of the '659 patent were both enabled and nonobvious, but lacked written description and were therefore invalid. Novartis appealed, and the Federal Circuit reversed the district court's invalidity decision.

Key Issues

Claim Construction

The parties disputed the meaning of the phrase “in combination” recited in the '659 patent. MSN argued that the phrase meant the administration of valsartan and sacubitril as “two separate components,” such as a physical mixture, as opposed to a “complex” of non-covalently bonded components such as found in

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Entresto and the generic drugs. Therefore, MSN argued, the generic drugs were non-infringing. Novartis countered that the phrase should be construed according to its plain and ordinary meaning and was not limited. The district court agreed with Novartis, stating that the record “is silent on whether sacubitril and valsartan must be separate (and not complexed),” and therefore “a person of ordinary skill in the art [] would not read the claims as so limited.”

MSN then argued that the ‘659 patent failed to meet the enablement and written description requirements because the patent does not enable or describe a “complex” such as found in Entresto, which was only developed after the ‘659 patent’s priority date in 2002.

Enablement and Written Description

After a three-day bench trial, the district court held that the ‘659 patent was enabled, because enablement is judged as of the priority date. At the priority date, complexes were unknown and were therefore not required to be enabled. The district court reached the opposite conclusion with respect to written description, finding that since pharmaceutical complexes were unknown in 2002, “[Novartis] scientists, by definition, could not have possession of, and disclose” them.

The Federal Circuit agreed with the district court’s determination regarding enablement but found that its decision on written description “erroneously conflated the distinct issues of patentability and infringement.” The court stated that the ‘659 patent was only required to describe what it claimed (valsartan and sacubitril administered “in combination”), *not* a valsartan-sacubitril “complex,” which was not invented until after the effective filing date of the ‘659 patent. The court stated, “[t]he invention is, for purposes of ‘written description’ inquiry, *whatever is claimed now*.”

Because the disclosures in the specification “plainly show that the inventors had possession of a pharmaceutical composition comprising valsartan and sacubitril administered in combination,” the court determined that the ‘659 patent met the written description requirement. The fact that the ‘659 patent does not describe a “complex” of valsartan and sacubitril, which was only discovered later, does not affect validity because the “complex” is not claimed.

Implications of the Ruling

This decision highlights the importance of the written description requirement. It underscores that patents can remain valid even if they do not describe later-developed formulations, as long as they adequately describe the invention as originally claimed. This ruling emphasizes the need to ensure that patent applications are thoroughly prepared to withstand validity challenges. It also provides a precedent for defending broad patent claims in future disputes.

If you have questions about the impact of this ruling on current or future patent strategy, please contact Nicole Sassu or William Scofield, or reach out to your regular Lathrop GPM attorney.

[1] The ‘659 patent expired January 15, 2025, after additional patent term extension.