The Precedent: Federal Circuit Provides Further Clarity on Issues Surrounding Patent Validity in *Novartis Pharmaceuticals Corp. v. Torrent Pharma Inc.*

Related Professionals

Michael V. Messinger
Michael M. Stojsavljevic
Aaron M. Williams
Graham D. Christian
Marcel C. Duhamel
Andrew D. Fleming
Bradley A. Hough
Maureen E. Kelly
Lauren A. Kickel
Jason Mueller
Jabari A. Shaw
Mitchell A. Tobias
Brady R. Wilson

Related Services

Intellectual Property
Patents

AUTHORED ARTICLE | 2.21.2025

In this edition of *The Precedent*, we outline the validity of a pharmaceutical patent concerning the patent's written description.

By: Mike Messinger and Mike Stojsavljevic

Overview:

Following an appeal from the United States District Court for the District of Delaware, the Federal Circuit considered challenges to the validity of a pharmaceutical patent concerning the patent's written description, enablement, and obviousness.

Identified Issues

1. **Issue of Written Description**: Did the '659 Patent provide an adequate written description of the claimed invention (a pharmaceutical composition combining valsartan and sacubitril) properly construed to not *cover later-discovered* valsartan-sacubitril complexes?
2. **Issue of Enablement**: Did the '659 Patent sufficiently enable a person skilled in the art to make and use the invention as of its priority date?
3. **Issue of Obviousness**: Was the combination of valsartan and sacubitril obvious in view of prior art?

Holdings on the Issues

1. **Written Description (Reversed)**: The Federal Circuit held that the patent adequately described the claimed invention as a combination of valsartan and sacubitril, reversing the lower court's invalidation for lack of written description.
2. **Enablement (Affirmed)**: The Federal Circuit affirmed that the '659 Patent satisfied the enablement requirement, as it enabled the claimed combination without considering the later-discovered

valsartan-sacubitril complex.

3. **Obviousness (Affirmed)**: The court agreed that the claims were non-obvious, noting the lack of motivation in the prior art to combine valsartan and sacubitril.

Background and Reasoning

The dispute in Novartis *Pharmaceuticals Corp. v. Torrent Pharma Inc*. centers on U.S. Patent No. 8,101,659 (the '659 Patent), which protects the pharmaceutical combination of valsartan and sacubitril, marketed as Entresto®, for treating heart failure. The patent, filed with a priority date of January 2002, describes the unexpected therapeutic benefits of combining valsartan, an angiotensin receptor blocker, with sacubitril, a neutral endopeptidase inhibitor. At the time of the invention, sacubitril had not been tested in humans or animal models for hypertension or heart failure. The combination therapy was later commercialized as Entresto® and approved by the FDA in 2015, becoming a treatment option for heart failure. This legal dispute began when generic manufacturers, including MSN Pharmaceuticals, filed Abbreviated New Drug Applications (ANDA) to produce generic versions of Entresto®. Novartis responded with patent infringement lawsuits, leading to a consolidated multidistrict litigation in Delaware. After a three-day bench trial, the district court ruled that while the patent was not invalid for non-enablement, it failed to meet the written description requirement because it did not explicitly describe the valsartan-sacubitril complex. Novartis appealed this finding, arguing that the patent claimed only the combination of valsartan and sacubitril, not the later-discovered complex.

The Federal Circuit reversed the District Court's finding that the '659 Patent lacked written description of the claimed combination. Here, the complexed form, rather than just the claimed combination of valsartan and sacubitril, was used in the infringing product and determined to be within the scope of the claimed combination. The District Court determined that the claimed combination did not satisfy the written description requirement for failing to disclose the complexed form. On appeal, the Federal Circuit explained that the '659 Patent did not need to describe a complexed form of valsartan and sacubitril because the '659 Patent did not claim the complexed form. Rather, the written description requirement was satisfied because the disclosures showed that the inventors of the '659 Patent had possession of the claimed combination of valsartan and sacubitril. Further, the Federal Circuit held that the District Court erred in conflating the issues of patentability and infringement by considering whether the claims covered the complexed form in its analysis of whether the claims satisfied the written description requirement.

The Federal Circuit affirmed the District Court's decision finding that the later-existing complexes could not be considered in the enablement analysis. That is, later-discovered art, such as the complexes, cannot be used to invalidate earlier-filed claims. Otherwise, the parties did not dispute that the '659 Patent enabled the claimed combination. Furthermore, the Federal Circuit determined the District Court did not make any error that warranted a reversal with respect to obviousness. Specifically, the Federal Circuit found that the cited prior art provided no motivation to combine valsartan and sacubitril or any reasonable expectation of success.