

## A Costly “Error”: Federal Circuit Affirms Invalidity of Enanta Patent Due to the Provisional Application’s Lack of Written Description

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The U.S. Court of Appeals for the Federal Circuit’s recent precedential decision in *Enanta Pharms. Inc. v. Pfizer Inc.*, No. 2025-1427 (June 23, 2026) emphasizes the importance of thoroughly reviewing provisional applications for accuracy and proper written description support.

In *Enanta*, the Federal Circuit held that earlier filed applications must satisfy the written description requirements of 35 U.S.C. § 112 to have a valid priority claim. An inventor can only be given credit for inventing what was disclosed in the application, and even slight differences in disclosures, such as closely related structures, do not necessarily meet the requirements of § 112.

### Detailed Analysis

In June 2022, *Enanta* sued Pfizer in the U.S. District Court for the District of Massachusetts, alleging Pfizer’s coronavirus treatment product, Paxlovid®, infringed the claims of U.S. Patent No. 11,358,953 (“the ‘953 Patent”) directed to compounds and methods for inhibiting coronavirus replication. Pfizer counterclaimed that the asserted claims were invalid as anticipated by Pfizer’s April 6, 2021 public disclosure of nirmatrelvir, which was incorporated into Paxlovid®.

The ‘953 Patent issued from a non-provisional patent application filed on November 9, 2021, and claimed earliest priority to a provisional patent application filed on July 20, 2020. The claims of the ‘953 Patent recite an “optionally substituted C<sub>1</sub>-C<sub>8</sub> alkyl.” The provisional and non-provisional applications, however, define “substituted” differently. The provisional application recites “-NCH(O)-C<sub>2</sub>-C<sub>12</sub>-alkyl,” while the ‘953 patent’s specification recites “NCH(O)-C<sub>1</sub>-C<sub>12</sub>-alkyl.”

Pfizer asserted that the ‘953 Patent was not entitled to the July 2020 priority date of the provisional application because “C<sub>1</sub>” was not supported by the provisional application’s disclosure of a C<sub>2</sub>-C<sub>12</sub> alkyl. *Enanta* argued that the provisional application contained an obvious typographical error, and the “C<sub>2</sub>” should have been “C<sub>1</sub>.” *Enanta* alleged it realized the error in July 2021 and fixed it in subsequently filed non-provisional applications, including the application that issued as the ‘953 Patent.

The district court granted Pfizer’s motion for summary judgement based on the invalidity of the ‘953 Patent, concluding that “C<sub>2</sub>” was not an obvious typographical error the district court had the power to correct. Thus, the district court found that the ‘953 Patent impermissibly broadened the scope such that it was not entitled to the provisional filing date.

Seeing no error in the ‘953 Patent, the Federal Circuit considered whether the provisional application provided adequate written description support for “C<sub>1</sub>” disclosed and claimed in the ‘953 Patent.

As the Federal Circuit explained, 35 U.S.C. § 112 requires that the earlier application of a priority claim describe the claimed invention in sufficient detail such that a POSITA can clearly conclude that the inventor was in possession of the claimed invention as of the priority date.

Here, the Federal Circuit held that the provisional application did not convey to a POSITA that the inventors possessed “C<sub>1</sub>” at the time of the provisional application’s filing date, as “C<sub>2</sub> is simply different from C<sub>1</sub>.” The Court was unpersuaded by Enanta’s expert testimony because the expert did not point to any disclosure of “C<sub>2</sub>” in the provisional application that provided support for “C<sub>1</sub>.” There was no genuine issue of material fact because there was no disclosure of “C<sub>1</sub>” in the provisional application.

The Federal Circuit explained that “they did not invent what they did not disclose.” Ultimately, a disclosure of one chemical compound (or integer) “cannot necessarily be a disclosure of another, even one close by structurally.” The Court analogized the difference between two-carbon ethanol, which is regularly consumed by people, to one-carbon methanol, which is highly toxic.

Thus, the Federal Circuit affirmed the district court’s grant of summary judgement, concluding that the provisional application did not disclose “C<sub>1</sub>” and did not provide written description support for the claims of the ’953 Patent.

## Takeaways

Given that claims are typically not finalized at the provisional stage, care should be taken to ensure that at least the inventive aspects are accurately and sufficiently described in a provisional application. Moreover, the *Enanta* decision demonstrates the importance of reviewing draft non-provisional claim language to ensure that the claim language has sufficient support in the earliest priority application. Otherwise, patent practitioners or inventors risk losing the earliest priority date during prosecution or litigation. As demonstrated by *Enanta*, the loss of a priority date during litigation can be catastrophic, resulting in an invalidated patent.

The *Enanta* decision suggests that “napkin” or limited disclosure provisionals may be (or perhaps should be) relics of the past. Such provisional applications can be an invalidity death sentence laden with written description issues. Moreover, *Enanta* demonstrates that courts will closely scrutinize whether an earlier application provides adequate written description support for later-claimed subject matter.

In sum, the disclosure of a provisional application matters. Extra time and money spent during the drafting process could save your patent from significantly more costly invalidation during litigation.

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