Lawyers Provide Update on Written Description Requirement in Patent Lawyer Magazine

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Haynes Boone Partners David McCombs, Eugene Goryunov and Alan Wang and Associate Li Yang authored an article in *The Patent Lawyer.* Read an excerpt below:

Introduction

In our earlier article – "Negative Limitations and the Written Description Requirement" – we examined the state of law on the written description requirement for negative limitations in view of *Novartis Pharmaceuticals v. Accord Healthcare Inc.*, No. 2021-1070 (Fed. Cir. Jan. 3, 2022). On June 21, 2022, the U.S. Court of Appeals for the Federal Circuit vacated its decision in Novartis and further refined the standard for when a silent specification can meet the written description requirement.

The Panel Rehearing in Novartis

The dispute in *Novartis* involves U.S. Patent No. 9,187,405 ("the '405 patent"). Each independent claim recites a negative limitation, "absent an immediately preceding loading dose regimen." This no-loading-dose limitation was added during prosecution of the '405 patent's parent application. Importantly, the '405 patent (like its parent) does not mention any loading dose in its specification—whether to be used or not. The district court found that the claims were not invalid for inadequate written description. In January 2022, the Federal Circuit affirmed the district court's judgement, and HEC petitioned for a panel rehearing. The new panel vacated the January 2022 decision and reversed the district court.

Majority Opinion

The majority held that the written description requirement "cannot be met through simple disregard of the presence or absence of a limitation." It may, however, "be satisfied when a skilled artisan would understand the specification as inherently disclosing the negative limitation."

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Excerpted from *The Patent Lawyer*. To read the full article, click here. (page 76)

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