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Thou Shall Describe a Reason for Negative Claim Limitations

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In addressing a written description issue relating to the adequacy of support in the specification for including a “negative limitation” in the claims, the U.S. Court of Appeals for the Federal Circuit established a standard requiring the specification to describe a reason for the negative limitation. *Santarus, Inc., et al., v. Par Pharmaceutical, Inc.,* Case No. 10-1360 (Fed. Cir., Sept. 4, 2012) (per curiam) (Newman, J., concurring-in-part and dissenting-in-part).

The patent-at-issue was one of several patents asserted by Santarus against Par Pharmaceuticals after Par filed an Abbreviated New Drug Application (ANDA) for **FDA** approval to sell a generic counterpart to Santarus’ Zegerid® products. The claims of the asserted patent were directed to a method for treating an acid-caused gastrointestinal disorder by administering to a subject suffering from such disorder a solid composition of omeprazole and sodium bicarbonate, *wherein the composition contains no sucralfate*. The only support in the specification of the asserted patent for this negative limitation was the statement that “omeprazole represented an advantageous alternative to the use of H2 antagonists, antacids, and sucralfate as a treatment for complications related to stress-related mucosal damage.” The priority document on which the asserted patent is based was a continuation-in-part that had even less direct support for the negative limitation, merely mentioning that the only patient whose death was attributed to stress-related upper gastrointestinal bleeding was in the sucralfate arm.

The district court found that neither the priority application nor the specification of the asserted patent supported the no sucralfate limitation, stating that the disclosures did not show why a person of ordinary skill in the art reading the application would believe that sucralfate was contraindicated, making treatment inadvisable, in the claimed composition. The lower court held that the asserted parent was invalid on written description grounds.

The Federal Circuit reversed. The Court disagreed that the specification must include evidence of contraindication. Rather, in what appears to be a new rule for negative claim limitations, the Court stated that negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support need not rise to the level of disclaimer. The Court stated that it is possible for the patentee to support both the inclusion and exclusion of the same material. The Court found that the claim limitation directed to the lack of sucralfate is adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate.

In dissent, Judge Newman agreed that the district court had clearly erred in its finding. However, the dissent criticized the majority for setting a new rule, calling it a “gratuitous fillip … that creates a new and far-reaching ground of invalidity, a ground that received no deliberation and advice from the concerned communities.

Practice Note: The Manual of Patent Examining Procedure (MPEP), in relevant part at §2173.05(i), states that a negative limitation must have “a basis” in the original disclosure. Whether the difference between a basis, in the MPEP, and “a reason” will have an impact on the jurisprudence in this area remains to be seen. In the meantime, practitioners should provide a reason in the original disclosure to support a negative limitation. The Court explained in this case that a listing of the disadvantages of a negative limitation element can be a reason that supports the negative limitation.

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