

DUKE UNIVERSITY v. SANDOZ INC., Appeal No. 2024-1078 (Fed. Cir. November 18, 2025). Before Dyk, Stoll, and Stark. Appealed from D. Colo. (Judge Moore).

Background:

The patent at issue is directed toward a method of treating hair loss using a specific chemical composition. Sandoz offered a generic version of the drug for sale and was sued by Duke and Allergan (collectively “Allergan”) for patent infringement. Sandoz stipulated to infringement but asserted that the claim at issue was invalid for lack of an adequate written description. At trial, a jury found the patent was valid and awarded Allergan approximately \$39 million in damages.

Sandoz filed a motion for judgment as a matter of law and argued that no reasonable jury could have found that the written description was sufficient. In doing so, the Sandoz argued that the independent claim of the patent is directed toward billions of possible combinations, as admitted by Allergan’s own expert. Further, Sandoz argued that claim 30, the dependent claim relied upon for infringement, is directed toward over a thousand combinations and that none of these combinations are demonstrated in the specification. The court denied Sandoz’s motion by asserting that the jury instructions, to which Sandoz agreed, state that neither examples nor a reduction to practice are required to provide an adequate written description and that Sandoz failed to meet its burden in convincing the jury that the full scope of the invention was not set out in the specification. Sandoz appealed.

Issue/Holding:

Did the district court err in denying Sandoz’s motion for judgment as a matter of law. Yes, reversed.

Discussion:

The Federal Circuit reversed, stating that a patent claiming a genus or subgenus of chemical compounds must satisfy the written description requirement by showing either (1) a representative number of species within the claimed group or (2) structural features common to all members that allow a skilled artisan to “visualize or recognize” the claimed compounds.

Here, Allergan argued that condition (2) was met. Allergan’s argument relied on the fact that, even though there were over a thousand combinations in dependent claim 30, the specification is directed toward and gives sufficient guidance for particular subcomponents. Once these subcomponents are realized, Allergan argued that there are only 13 remaining options. However, the Federal Circuit held that each of these “13 options” are themselves large categories with numerous choices for each option. For instance, one “option” was choosing a compound with group R₃. Even if this option were selected, one must still choose from a list of twelve broad categories for R₃ such as “a carbocyclic group, a heterocyclic group, an aromatic group...” The Federal Circuit analogized this to disclosing a forest and then later picking a single tree to claim as your invention.

The Federal Circuit also found that the specification would lead one away from the combination recited in claim 30, as it is not described in any of the “preferred” or “more preferred” embodiments. Based on this, the Federal Circuit found that the written description requirement was not met and vacated the verdict.