

Federal Circuit Review: *Duke University v. Sandoz Inc.*

April 17, 2026

Trailblazing: *Duke v. Sandoz* and the Written Description Requirement

Introduction

On November 18, 2025, the Federal Circuit Court of Appeals issued its opinion in *Duke University v. Sandoz Inc.*, reversing a 2023 decision out of the District Court for the District of Colorado in which a jury had awarded plaintiffs Duke University and Allergan Sales, LLC, \$39 million in damages for infringing a patent for a hair loss drug.¹ In doing so, the Federal Circuit held that the patent claim that defendant Sandoz Inc. had infringed upon was invalid for lack of adequate written description under 35 U.S.C. § 112. The decision in *Duke v. Sandoz* serves as a reminder to patent practitioners and clients to remain cognizant of the scope of their claims and ensure that skilled artisans have sufficient guidance to practice the claimed invention.

Allegan's "Charming" Claim

Claim 30 of U.S Patent No. 9,579,270 (the "270 patent") was directed to a method of growing hair by topically applying an adaptable chemical compound known as prostaglandin, which the court likened to "a charm bracelet to which different charms can be attached at different points."² Claim 30 identified one such analog of prostaglandin (prostaglandin F, or "PGF") having the structure below where, to continue the court's analogy, R¹, R², X, and Z were places that chemical "charms" of various lengths and complexities may attach.³

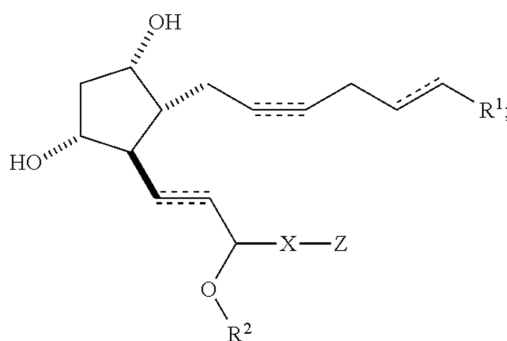


Figure 1 - Prostaglandin F Analog Scaffold

¹ *Duke University v. Sandoz Inc.*, No. 24-1078, slip op. (Fed. Cir. Nov. 18, 2025).

² *Id.* at 2-3.

³ *Id.* at 3-4. Note, R¹ and C¹ are used interchangeably throughout the opinion (see n. 1, pg. 4). All references to C¹ have been amended to reference R¹ for clarity.

Sandoz manufactured and sold a generic version of an Allergan-marketed product containing a specific embodiment of the claimed PGF analog (bimatoprost, illustrated below). During the proceedings, Sandoz stipulated to infringement, but challenged the validity of the claim itself.⁴

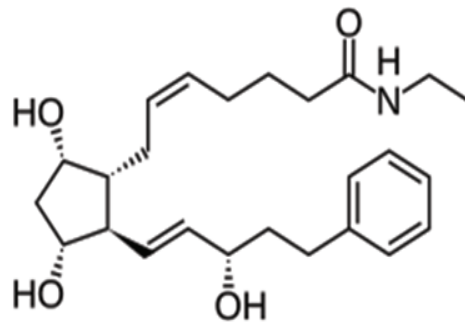


Figure 2 - Bimatoprost

Lost in the Woods

At issue in this case was whether the '270 patent specification disclosed that a person of ordinary skill in the art would conclude that Allergan possessed the full scope of the invention at the time of application, specifically bimatoprost and the full subgenus disclosed by claim 30.⁵ The Federal Circuit has previously held that, when claiming a genus or even sub-genus of chemical compounds, it is necessary to include "description not only of the outer limits of the [sub-]genus but also of either a representative number of members...or structural feature common to the members" that allow a person of ordinary skill in the art to recognize them.⁶

Sandoz argued that the specification not only did not provide an example of the compound taught by claim 30 but also failed to identify sufficient commonalities of structure that would provide sufficient "blaze marks" to lead a skilled artisan to such compounds, with estimates of the claim's scope of compounds ranging from the thousands to the billions.⁷ Allergan countered that the '270 patent provides sufficient "blaze marks" in the disclosure of three features common to the claimed subgenus: "[i] the characteristic prostaglandin hairpin, [ii]...with amides at the [R¹] position...[iii] connected to the unsubstituted phenyl ring at the [Z position]."⁸

⁴ *Id.* at 4.

⁵ *Id.* at 6-7.

⁶ *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023).

⁷ *Id.* at 7. ("Sandoz contends that the specification of the '270 patent is written so broadly that it encompasses a "universe of billions of compounds," while claim 30 is limited to roughly 1,620 of these potential compounds. Based on the vast discrepancy between the written description and the actual scope of the claim, Sandoz continues, the pertinent artisan would conclude that the named inventors did not actually possess the invention claimed in claim 30....Experts for both sides agreed that the number of compounds actually claimed by claim 30 is far smaller: either 4,230, which was Allergan's expert's view, or 1,620, as Sandoz's expert opined.")

⁸ *Id.*

Regarding the first asserted feature, the Court concluded that the '270 patent "at best disclosed two prostaglandin hairpin structures and a menu of available atoms, moieties, and functional groups from which a skilled artisan could populate the R¹, R²...X...and Z positions of those structures."⁹ Both parties' experts concluded that the prostaglandin hairpin structures are found in "billions of compounds," and as such Allergan could not identify how it was unique to the claimed subgenus and how a person of ordinary skill in the art would be able to visualize or identify the thousands of compounds of claim 30 from the billions that were disclosed.¹⁰

Furthermore, the Court concluded that such a structure did not account for the variation at the R¹ and Z positions. First, what Allergan asserted to be only thirteen possible options for the R¹ position were more accurately described as thirteen categories, each with their own myriad options.¹¹ Notably, the options that Allergan identified as preferred (five of thirteen) did not include all of the requisite elements of claim 30, meaning that these blaze marks actually directed a person of ordinary skill in the art away from the claimed compound.¹² Similarly, regarding Allergan's second asserted feature, the Court determined that, while the specification did teach the use of amides, there was no indication that they were preferred at the R¹ position.¹³ Finally, regarding Allergan's third asserted feature, the Court determined that the specification disclosed eight categorical options for the Z position.¹⁴ Of those eight categories, a phenyl group was a preferred member of an unpreferred category, and the Court determined that this was insufficient to guide a person of ordinary skill to the claimed compound.¹⁵

In summary, Federal Circuit precedent provided that, when claiming a genus or even sub-genus of chemical compounds, Allergan must provide "sufficient indication as to how a skilled artisan would narrow the disclosed universe of billions of compounds described in the specification to the subset of just 1,620 – 4,230 compounds actually claimed."¹⁶ Based on the above analysis, the Court concluded that no such indication existed, and the claim was invalidated.¹⁷

⁹ *Id.* at 10.

¹⁰ *Id.* at 10-11.

¹¹ *Id.* at 11. ("In reality, the specification's guidance with respect to the [R¹] position resembles a path with 13 branches, and most of those branches lead to additional branches, yielding in the end a vast number of options for [R¹].")

¹² *Id.* at 13-14.

¹³ *Id.* at 14.

¹⁴ *Id.* at 15. ("Z is selected from the group consisting of a carbo-cyclic group, a heterocyclic group, *an aromatic group*, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group.")

¹⁵ *Id.* at 15-16. ("While the specification does identify phenyl as the most preferred aromatic group,...guidance is only pertinent once the artisan selects an aromatic group from among the eight initially described options, which nothing in the specification directs such an artisan to do.")

¹⁶ *Id.* at 8.

¹⁷ *Id.* at 17-18.

Blazing a Trail – Guidance for Practitioners and Inventors

In travel and patent prosecution, it can be easy to disregard the journey in favor of the destination. While it is admirable for practitioners to seek broad claims that protect as much subject matter as possible, it is always worth confirming that genus claims have the requisite support and structural guidance in the specification. It is worth noting that at no point in its decision did the Court declare that 1,620 compounds or 4,230 compounds were too many to be afforded protection by the single claim. Instead, quoting its decision in two earlier cases, it reaffirmed that “one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say ‘here is my invention’.”¹⁸ Rather, one must direct a person of ordinary skill in the art “to the proposed tree in particular and...teach the point at which [they] should leave the trail to find it.”¹⁹ This may take the form of guidance, particularly in instances where one decision or selection may beget several more. Additionally, this may include identifying representative species (or preferred embodiments), particularly those that are specifically claimed. Doing so may provide a backstop in litigation that allows clients to clearly identify—and by extension protect—their most well-defined embodiments.

When drafting, patent practitioners and inventors must work together to ensure that the application is sufficiently detailed and descriptive to lead a person of ordinary skill in the art through the proverbial woods and to the claimed invention. This requires finding a balance between the depth of the disclosure and the breadth of the claims—a balance that differs with each application. A depth of disclosure regarding a select number of preferred embodiments may be viewed as evidence of teaching away from different, but related, claimed embodiments. Such an imbalance may inadvertently result in only leading people of ordinary skill to a single tree rather than the entire grove. However, this imbalance may also be observed in reverse, as providing a breadth of information without the requisite depth of teaching may obscure the claimed species in a forest of unrelated (and potentially unprotectable) embodiments. The result then may be an inability to clearly demonstrate a protectable path to the grove at all.

In conclusion, patent practitioners need not unnecessarily narrow the scope of their claims beyond what is necessary. Rather, they must ensure that the scope of their claim is only as broad as the scope of the explanation reasonably supporting it.

This case summary is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions about this case summary should be directed to:

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¹⁸ *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000).

¹⁹ *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996).