

# Latisse Ruling's Lessons On Avoiding Chemical Patent Pitfalls

By **Kimberly Vines** (December 1, 2025)

The U.S. Court of Appeals for the Federal Circuit's Nov. 18 decision in *Duke University v. Sandoz Inc.* delivers a critical warning for chemical and life sciences patents: Broad genus disclosures rarely support later-asserted, narrowly tailored species claims unless the specification clearly demonstrates possession of those species at filing.



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This ruling underscores the central role of the written description requirement under Title 35 of the U.S. Code, Section 112(a), particularly after the America Invents Act rendered the "best mode" requirement unenforceable. While best mode technically survives in the statute, Section 282(b)(3)(A) ensures it cannot serve as a basis for invalidity, leaving written description as the primary doctrine for policing inadequate disclosures in complex chemistries.

## The Dispute and Its Context

The dispute centered on Allergan Inc.'s product Latisse, a topical solution approved by the U.S. Food and Drug Administration for treating eyelash hypotrichosis, or hair loss. Latisse contains bimatoprost, a prostaglandin F analog originally developed for glaucoma treatment but later discovered to promote eyelash growth.

In 2018, Allergan sued Sandoz, a generic pharmaceutical manufacturer, after Sandoz began producing and selling a generic version of Latisse. Although a jury initially awarded Allergan \$39 million for infringement, the Federal Circuit reversed on appeal, holding that Claim 30 of the asserted patent was invalid under Section 112(a) for inadequate written description.

## The Patent and Claims at Issue

The asserted patent, U.S. Patent No. 9,579,270, owned by Duke University and licensed to Allergan, covers methods of promoting hair growth using prostaglandin F analogs. Despite Latisse becoming FDA-approved in December 2008, the structure of bimatoprost was not included in the '270 patent.

## Strategic Lesson

Disclose and claim any lead compound as soon as it is identified — waiting is a costly mistake. Early disclosure provides clear evidence of possession, secures the earliest possible priority date and strengthens enforceability against future challenges.

When claiming specific embodiments, there is no need to label a compound as "preferred" or "best"; simply include it as one example within a broader genus. This approach preserves strategic flexibility while satisfying Section 112(a), reducing the risk that later species claims will be denied priority or invalidated for inadequate written description.

Critically, failing to timely disclose and claim a preferred compound can backfire: Your own nonpatent disclosure may become prior art, blocking you from claiming that compound in a follow-on application.

## **Blaze Marks**

A recurring theme in written description jurisprudence is the need for blaze marks — clear, directional cues guiding a skilled artisan from a broad genus to a narrower subgenus or specific compound.

As the court explained in its 2000 decision in *Purdue Pharma LP v. Faulding Inc.*, "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.'" [1] Without such blaze marks, a narrowed claim often appears as after-the-fact claiming rather than evidence of contemporaneous possession.

## **Why Allergan Fell Short**

Formula (I) in the '270 patent is disclosed in its broadest form, encompassing multiple variables —  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ , X, Y and Z — each capable of representing several different chemical groups, creating an enormous number of potential compounds.

Claim 30 depends on Claim 17, which claims a subgenus. Claim 17 specifies:

- $R_1 = C(O)NHOH$ ,  $C(O)NHR_3$  or  $C(O)NHS(O)_2R_4$ ;
- $R_2 =$  hydrogen;
- $R_3 =$  methyl, ethyl or isopropyl;
- X = selected from eight linkers with variable Y groups (Y = S, O or NH); and
- Z = very broad, e.g., "Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, an aromatic group, a heteroaromatic group, and substituted versions thereof."

## ***The Issue***

Does the specification provide sufficient guidance to lead a skilled artisan from Formula (I) to the subgenus of Claim 30, wherein  $R_1$  is  $C(O)NHR_3$  and Z is phenyl?

The court said no. The blaze marks in the '270 patent point away from  $C(O)NHR_3$  because none of the preferred  $R_1$  groups included it. The patent lists 13 possible  $R_1$  options, but only five are identified as preferred — and two as "more preferred." Similarly, for Z, although phenyl is described as most preferred among aromatic groups, nothing in the patent directs a skilled artisan to select an aromatic group in the first place.

Allergan's argument that 10 of the 95 example compounds included phenyl was unpersuasive because none were described as preferred embodiments.

## ***Strategic Lesson***

When preparing follow-on applications, it is advisable to review the specification to ensure that preferred embodiments for each variable encompass the compounds you intend to protect. Prepare subgenus structures of varying scope to create clear blaze marks that lead from the genus to the species you may later assert.

## **If the Preferred Compound Isn't Yet Known**

Obviously, Duke/Allergan knew the structures of their preferred compounds long before filing the application that led to the '270 patent. But what if the applicant doesn't yet know which compounds will succeed?

As research and development progresses and preferred embodiments emerge, applicants should consider filing follow-on applications that disclose those specific compounds — along with subgenus formulas of varying scope that encompass them — to prevent easy design-arounds. This proactive approach ensures evolving discoveries are captured and protected, reducing vulnerability to competitors that might exploit gaps in claim coverage.

## **Why This Matters**

Securing claims to a broad genus does not guarantee enforceability against potential infringers.

In litigation, genus claims often face intense scrutiny under Section 112(a) for written description and enablement. To satisfy written description, a specification claiming a genus of chemical compounds must do more than define boundaries — it must either disclose a representative number of species or identify structural features common to the genus. The disclosure should enable a skilled artisan to visualize or recognize the compounds within that scope.

## **Commercial Perspective**

Including claims that cover the marketed product is critical for meaningful protection. Duke v. Sandoz illustrates this point: The patentee failed to adequately disclose or claim its own commercial compound, relying instead on a broad genus defined by Formula (I) of the specification. If the inventors knew their preferred compound — such as bimatoprost, the active ingredient in Latisse — why didn't they disclose it?

Patent applicants often hesitate to disclose preferred compounds too soon, fearing that revealing the lead compound compromises competitive secrecy by giving rivals a road map to replicate or design around the product. Before the America Invents Act, failure to disclose the best mode could invalidate a patent. Today, while best mode remains in Section 112(a), it is no longer enforceable. The U.S. Patent and Trademark Office cannot reject an application for lack of best mode, and courts cannot invalidate a patent on that ground.

Yet best mode still matters. As a drafting discipline, it can prevent written description pitfalls — especially when commercial embodiments are known at filing. In practice, the enforcement vacuum shifts consequences to doctrines that remain potent: written description and enablement. Omitting a preferred embodiment can support arguments that the specification fails to show possession or fails to teach how to make and use the full scope without undue experimentation.

## **Conclusion**

The Federal Circuit's decision in Duke v. Sandoz reinforces a fundamental truth in chemical patent strategy: Broad genus claims rarely survive without clear evidence of possession of specific embodiments.

For innovators, the mandate is clear: Disclose and claim lead compounds early, provide blaze marks that guide a skilled artisan from genus to species, and update filings as R&D progresses. These steps secure priority, strengthen enforceability and protect against competitors exploiting gaps in claim coverage.

In a landscape where precision matters, proactive drafting remains the best defense.

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[1] *Purdue Pharma LP v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000).