You Can't (Always) Claim What You Didn't Describe: U.S. and European Perspectives on Chemical Patents

Authors:
Kimberly Vines Ph.D., Stites & Harbison, Huntsville, Alabama, USA
Prof. Dr. Aloys Hüttermann, Michalski Hüttermann & Partner, Düsseldorf, Germany.

The Federal Circuit's decisions in *Duke* and *Seagen* underscore a simple but recurring truth in chemical and biotech patenting: you may be able to obtain broad claims that sweep far beyond what you actually described, but you may not be able to enforce them. Both cases illustrate how expansive genus formulas and long substituent lists can unravel when a patentee later seeks to capture a specific species—whether it is a long-used commercial drug or a competitor's breakthrough antibody drug conjugate (ADC). And while the U.S. outcomes turned on written description and enablement, the same fact patterns would have collided even earlier—and more decisively—with Europe's strict added-matter regime, raising the question of how these disputes would have unfolded had they been examined or litigated in Europe.

The U.S. View

1. Duke v. Sandoz: The Perils of Never Naming the Species

In *Duke v. Sandoz*,[1] the Federal Circuit invalidated a species-level claim of US 9,579,270 directed to the prostaglandin-F analog used in Allergan's product Latisse®, an FDA-approved 0.03% bimatoprost solution for treating eyelash hypotrichosis. Duke University and Allergan Sales, LLC ("Allergan") jointly own the '270 patent and related patents. After Sandoz launched a generic version, Allergan sued in 2018, asserting infringement of claim 30 of the '270 patent. The district court jury rejected Sandoz's invalidity defenses—including written description—and awarded Allergan $39 million in damages. The Federal Circuit reversed, on the grounds that the '270 patent lacked adequate written description.

How a Known Drug Became Prior Art Against Its Own Patentee

Although bimatoprost had been known, used, and commercially exploited by the patentee for years, the '270 patent did **not** disclose the specific compound. The first application in the patent family was filed in 2000, but the '270 patent itself was not filed until 2015, long after bimatoprost had become the active ingredient in Latisse®, which received FDA approval in December 2008 and entered the market in 2009. Because no earlier application in the priority chain ever identified the structure of bimatoprost or any species within claim 30's narrow subgenus, the drug's own public disclosure later became prior art against the patentee.

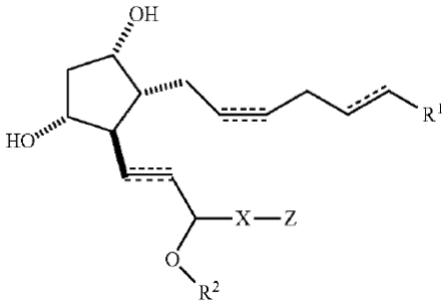
[1] Duke Univ., Allergan Sales, LLC v. Sandoz Inc., 160 F.4th 1305 (Fed. Cir. 2025)

Structural Features Aren't Enough: Blaze Marks Still Required

Without literal (ipsis verbis) support, written description turns on whether the specification demonstrates possession of the claimed invention, usually through a representative number of species or through common structural features that meaningfully define the claimed sub-genus.

Claim 30 recites a method of growing hair via topical application of a composition containing a prostaglandin F analog of a particular structure.

> A method of growing hair, wherein the method comprises topically applying to mammalian skin a safe and effective amount of a composition comprising:
>
> ... an active ingredient selected from the group consisting of a prostaglandin F analog of the following structure:



> wherein
> R^1 is C(O)NHR^3;
> R^2 is a hydrogen atom;
> R^3 is methyl, ethyl, or isopropyl;
> X is selected from the group consisting of —C≡C—, a covalent bond, —CH═C═CH—, —CH═CH—, —CH═N—, —C(O)—, —C(O)Y—, —$(CH_2)_n$—, wherein n is 2 to 4, —CH_2NH—, —CH_2S—, and —CH_2O—;
> Y is selected from the group consisting of a sulfur atom, an oxygen atom, and NH; and
> Z is phenyl.

Allergan argued that the '270 patent satisfied the common-structural-features prong of the written description test because the specification allegedly identifies three characteristics shared by all members of the claimed subgenus: (i) the prostaglandin "hairpin" structure, (ii) an amide at the R^1 position, and (iii) an unsubstituted phenyl ring as the Z group.

But Formula (I)—the core genus—was disclosed at a *high level of generality* across all applications in the priority chain. It permitted variation at seven positions —R_1, R_2, R_3, R_4, X, Y, and Z—each defined by multiple possible substituents (i.e., Claim 1). This creates an enormous universe of hypothetical compounds. Claim 30 carved out a much narrower subgenus by requiring, among other things, that R_1 is C(O)NHR_3 and Z is phenyl. The question, therefore, was whether the specification provided sufficient guidance—true "blaze marks"—to

lead a skilled artisan from the broad genus of Formula (I) to the narrower subgenus defined in Claim 30.

Why Claim 30 Failed: Preferred Embodiments Pointed Away from the Claimed Subgenus

The Federal Circuit concluded that it did not. The specification's preferred embodiments affirmatively pointed away from the claimed invention. Although Formula (I) in its broadest aspect lists thirteen possible R_1 substituents, only five are identified as preferred—and none included $C(O)NHR_3$, a required feature of claim 30. Similarly, while phenyl is described as a "most preferred" option *within* the category of aromatic groups at the Z position, the patent does not direct a skilled artisan to select an aromatic group in the first place.

Allergan emphasized that ten of the ninety-five exemplified compounds used phenyl at Z. But this did not help: none of those compounds were described as preferred embodiments, and nothing in the specification indicated that the phenyl-bearing examples marked the path to the claimed subgenus. In short, the patent provided **no roadmap** leading from the generic disclosure to the specific structural combination recited in claim 30.

Consequences of Omission: An Undisclosed Preferred Embodiment Becomes Prior Art

Because bimatoprost was never described in any application filed before its public disclosure, the patentee could not claim it years later without written-description support. Once Allergan attempted to claim an undisclosed species, bimatoprost's own marketing history became invalidating prior art.

U.S. Strategy Lesson: How a CIP Could Have Preserved Priority

In the United States, this gap could have been corrected by filing a continuation-in-part (CIP) before bimatoprost became publicly known. A CIP allows the applicant to add new matter—such as the structure of bimatoprost—while preserving the original priority date for subject matter already disclosed. Had bimatoprost been added in a timely CIP, the patentee could have obtained claims directed specifically to that embodiment with a filing date predating the public disclosure.

The dispute in *Duke v. Sandoz* illustrates how a patentee can lose the ability to protect its own commercially successful product when an initially broad disclosure fails to provide blaze marks to a later-favored species. But written description problems are not limited to a patentee's *own* later-developed embodiments. The Federal Circuit's decision in *Seagen v. Daiichi Sankyo* demonstrates the flipside: the written description requirement also prevents applicants from retroactively claiming a competitor's subsequently developed and publicly disclosed product. Together, the cases frame the two ends of the genus–species spectrum—one involving an undisclosed commercial embodiment and the other a later-invented competitor species—and show how the same doctrinal principles operate in both directions.

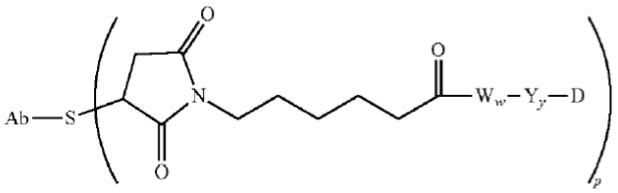
2. Seagen v. Daiichi Sankyo[2]: Attempting to Claim a Competitor's Product

Daiichi Sankyo's Enhertu—an antibody–drug conjugate (ADC) that achieved FDA breakthrough therapy designation—stood at the center of *Seagen v. Daiichi*. After Daiichi publicly disclosed Enhertu's structure, Seagen filed a patent application containing a subgenus claim broad enough to encompass Enhertu and later asserted that claim—issued in U.S. Patent No. 10,808,039 ("the '039 patent")—against Daiichi.

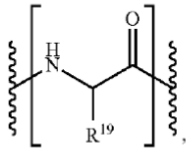
Although a district court jury found the claim valid and infringed, awarding Seagen more than $41 million and rejecting Daiichi's written-description and enablement challenges, the Federal Circuit reversed. The court held that the asserted species-level ADC claim lacked adequate written-description and enablement support, and that judgment as a matter of law should have been entered for Daiichi.

Enhertu and the Asserted ADC Claims in the '039 Patent

Claim 1 of the '039 patent was directed to an antibody-drug conjugate having the formula:



each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl,

wherein Y is a spacer unit; y is 0, 1 or 2; D is a drug moiety, and; p ranges from 1 to about 20, wherein the S is a sulfur atom on a cysteine residue of the antibody, and wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

In Daiichi's Enhertu, Ab is trastuzumab (a HER2-targeting antibody), D is a topoisomerase I inhibitor payload (DXd), y is 0, and W_w is Gly-Gly-Phe-Gly. Enhertu is distinguished by site-specific conjugation and a high, homogeneous drug-to-antibody ratio (DAR ≈ 8), far above the 2–5 DAR typical of earlier ADCs. Its protease-cleavable tetrapeptide linker is stable in circulation but selectively cleaved inside tumor cells, releasing the lipophilic DXd payload. This yields a strong bystander effect—cytotoxic molecules diffuse into neighboring tumor cells with low or heterogeneous HER2 expression—while minimizing systemic toxicity.

Priority Fight: Could the 2004 Application Support a Gly/Phe-Only Tetrapeptide?

Enhertu was publicly disclosed in 2015. Seagen filed the '039 patent in 2019, claiming priority to a 2004 application. Thus the central dispute was whether the 2004 application—or any

[2] Seagen Inc. v. Daiichi Sankyo Co., Ltd., 160 F.4th 1322 (Fed. Cir. 2025)

intervening filing—provided written description support for the specific Gly/Phe-only tetrapeptide linker (Gly–Gly–Phe–Gly) required by the asserted claim.

If the 2004 application adequately described that structure, Seagen would be entitled to the early priority date and Enhertu would represent infringing subject matter. If not, Enhertu's 2015 disclosure would be anticipatory prior art, and the claim would be invalid.

The Broader W_w Definition in 2004: A Genus Too Large to Support the Later Species

Although the 2004 application depicted an ADC of the same general architecture—an antibody, a drug, and a peptide linker—the written description issue centered on how broadly the linker region (W_w) was defined.

In 2004, W was "an amino acid" and w was an integer from 0 to 12, meaning W_w could be any peptide of 1–12 residues—or absent altogether. Nothing in the 2004 disclosure singled out tetrapeptides, glycine/phenylalanine-restricted linkers, or any structural or functional subclass that would direct a skilled artisan toward the specific Gly/Phe-only tetrapeptide later claimed.

By contrast, in 2019, Seagen amended its claims to require a four-residue Gly/Phe motif that mapped precisely onto Enhertu's linker.

Because the priority application described only an extremely broad, undifferentiated genus, the Federal Circuit held that it lacked written description support for the narrow species later claimed. As a result, the '039 patent could not rely on the 2004 priority date, and Daiichi's 2015 publication of Enhertu became anticipatory prior art.

The Crystal-Ball Problem: Why Seagen Could Not Retroactively Claim Enhertu's Linker

A key distinction between *Duke* and *Seagen* is strategic posture. Seagen was not trying to protect its own later-developed embodiment; it was attempting to claim a competitor's product after the competitor publicly disclosed it. Written description doctrine imposes a fundamental constraint: a patentee cannot retroactively claim a specific species unless the original application actually demonstrates possession of that species.

In 2004, Seagen had no way to foresee the exact tetrapeptide linker Gly–Gly–Phe–Gly that Daiichi would introduce in 2015. Without that foresight, the 2004 application could not and did not describe the later Gly/Phe-only motif. A broad genus disclosure does not show possession of a particular, later-developed species simply because the species falls within the genus. Thus the Federal Circuit found written description lacking not only for the specific tetrapeptide but also for the broader subgenus Seagen attempted to claim: the gulf between what was disclosed in 2004 and what Seagen sought to claim 15 years later could not be bridged by high-level structural formulas or expansive amino-acid lists.

Litigation vs. Prosecution: A Written Description Divide

Seagen also highlights a familiar disparity between the Federal Circuit's rigorous written description standard and the far more lenient approach routinely seen during USPTO examination. Examiners rarely undertake the type of detailed structural analysis applied in *Duke* or *Seagen*.

Broad genus disclosures, high-level descriptions, and extensive lists of possible substituents are often accepted as sufficient to show possession, even where the specification contains few concrete examples.

As a result, applicants can obtain claims during prosecution that would not survive the far more demanding scrutiny applied in litigation. The two cases illustrate this mismatch: disclosures that appear "adequate" during examination can unravel completely once the question becomes whether the earlier specification actually provided blaze marks to the specific species asserted years later.

Synthesizing the Lessons of Duke and Seagen

Duke and *Seagen* together underscore the Federal Circuit's increasingly exacting approach to written description in chemical, pharmaceutical, and biologic cases. In both disputes, the patentees attempted to assert species-level claims years after the original filing, long after the relevant compounds or linkers had entered the public domain. And in each instance, the court held that the earlier applications contained no meaningful guidance—no blaze marks—leading a skilled artisan from a broad genus to the specific species later claimed.

Despite the different fact patterns, the doctrinal lesson is the same. A broad genus disclosure defined by numerous variable substituents or amino acid permutations is insufficient standing alone, even if the later-claimed species falls mathematically within that genus. The specification must do more than enumerate possibilities: it must actually teach the path to the later-asserted embodiment, whether it is a patentee's own compound (as in *Duke*) or a competitor's later-developed configuration (as in *Seagen*).

Strategically, the cases highlight two distinct but related risks:

- **Failure to disclose one's own commercial embodiment** (*Duke*) can forfeit patent protection if public disclosures occur before a CIP or other mechanism is used to add the species to the specification.
- **Attempting to claim a competitor's later-publicized species** (*Seagen*) is almost impossible unless the original application already contains a concrete description of that specific structure or a closely related, clearly delineated subgenus.

Both decisions also accentuate the widening gap between patent prosecution and patent litigation. During examination, applicants may obtain broad claims based on generic structural formulas and expansive substituent lists. But in enforcement, the Federal Circuit demands far tighter conformity between the claim's scope and the specification's actual teachings. Practitioners therefore cannot rely on prosecution standards as a predictor of litigation survivability.

Ultimately, *Duke* and *Seagen* reaffirm a core principle of U.S. patent law: written description is about demonstrating possession, not possibility. A patentee must describe the invention it seeks to claim, not simply include it within a vast theoretical universe of chemical or biological permutations. Failing to do so risks losing protection for valuable internal embodiments—and makes it impossible to reach a competitor's later innovations.

The European View

1. Fundamental principle differences

Before the European approach is discussed it is noteworthy to reflect that especially in this area of broad genus claims there is a fundamental principle difference in understanding between Europe, especially the EPO and the US.

In a nutshell, the patent system in Europe is mostly text-based whereas in the US it is inventor based.[3] Of course, as with all rules of thumb, this has its boundaries, but it helps to understand the principal approaches and their differences on both sides of the Atlantic.

Thus, the "written description" requirement therefore does not really exist in Europe because the text-based approach does not require actually possession of the invention.[4] The discussion whether in the context of "plausibility" such a requirement would be introduced through the back door[5] became obsolete after the G 2/21 was issued by the Enlarged Board of Appeal of the EPO, which made it clear that "plausibility" is no patentability requirement.

Thus in principle, broad genus claims are not a problem in Europe *as such*. They can be attacked (or the Office can bring forward objections), of course, but not on the basis of a lack of possession of the invention but on the basis of sufficiency or – more relevant – on the basis of alleged lack of inventive step, i.e. bringing forward arguments or, if you are an opponent, experimental data showing that not all subspecies of the broad genus claim would solve the problem of the invention.[6]

The issue of sufficiency, however, should not be confused with broadness. A claim is sufficient, if the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The claims that were subject of the Duke and Seagan case undoubteldy cover a broad range of compounds – however, as these are described by their chemical structure, there is no reason to doubt that a skilled person in the art cannot carry them

---

[3] Cf A Hüttermann, Zur Gemeinsamkeit von Literatur und Patenten, Mitt. dt. Patentanw. 2013, 3, S. 113-121

[4] As a side remark: This is to some extent different in the UK after the issuance of the "Warner Lambert" decision UKSC 2016/0197 . However, the UK will not be further discussed.

[5] Cf T. Exner, A. Hüttermann, Führt das EPA mit Hilfe der "Plausibilität" den Erfindungsbesitz als Patentierungskriterium ein?, GRUR Int. 2018, 97

[6] Whether post-filed data can then be filed by the patentee/applicant to support the claims is an issue that is in flux post the G2/21 and will not be discussed here.

out or does not know what falls under the claims and what not. Sufficiency is then an issue when general, functional terms like an "inhibitor" etc. are part of the claims.

The tension surrounding broad genus claims and subspecies generally emerges only when (1) the patentee must amend the claim in light of prior art, or (2) it becomes clear that not all embodiments within the genus "work."

2. Europe's Approach: Strict Added-Matter, Intermediate Generalization, and No CIPs

Although *Duke* and *Seagen* reflect the Federal Circuit's increasingly exacting approach to written description under § 112(a), Europe has long applied a similarly strict—arguably even stricter—standard when it comes to added-matter and support for amended claims.

Because the EPC employs a text-based framework, applicants may not deviate from the application as filed. Under Article 123(2) EPC, an application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. According to the "gold standard" regime of the EPO, now followed by the UPC as well, this means that no amendments are possible that a skilled person would not directly and unambiguously derive from the original disclosure. The skills of said "skilled person" awarded by the case law actually are surprisingly limited if one may be a little cynical.

This standard is applied with particular rigor in chemical and biotech cases and prohibits both broadening and narrowing amendments that stray beyond what is expressly or implicitly disclosed. Both EPO and UPC are especially wary of intermediate generalizations, which occur when an applicant removes a feature from its disclosed context and inserts it into a claim without the accompanying limitations originally associated with it.

Because the specific combination was not disclosed as filed, such amendments are almost always treated as added matter. In this respect, the Europe's approach to written description is unforgiving—more rigid than USPTO examination practice and much closer to the Federal Circuit's litigation-level scrutiny.

The Two-List Principle: No New Combinations Without Explicit Disclosure

One of the clearest examples of Europe's strict added-matter jurisprudence is the two-list principle, which prevents applicants from creating new combinations by selecting one element from a first list and another element from a second list unless that specific pairing was directly and unambiguously disclosed in the original application. For example, selecting A_1 from List A and B_1 from List B is therefore treated as impermissible added matter under Article 123(2) EPC unless the application clearly teaches that exact combination.

This doctrine is frequently applied in chemical and biotech filings, where lists of possible substituents, residues, or components are common, and it reflects Europe's strict stance on added matter and intermediate generalization: combinations not originally disclosed cannot be

introduced later. This stands in contrast to the more flexible U.S. approach, where a continuation-in-part (CIP) may be used to introduce new embodiments prior to their public disclosure, preserving some priority rights—an option that does not exist under the EPC framework.

No CIP "Fix" before the EPO

As described before, in the Duke v. Sandoz case there could have been a potential fix by filing a CIP application.

Europe, however, does not permit this approach. Under the EPC's strict prohibition on adding subject-matter (Article 123(2) EPC), any attempt to introduce bimatoprost into the application after the initial filing would be considered impermissible new matter.

Unlike a U.S. CIP, a European divisional must be fully supported by the original disclosure and cannot contain added embodiments. Thus, in Europe, the patentee would have had no procedural mechanism to "add" bimatoprost to an existing application after the first filing. The only path to protect that compound would have been to disclose it from the outset or to file a new, separate application before the compound entered the public domain.

3. Duke and Seagen in Europe

Taken together, *Duke* and *Seagen* underscore that the Federal Circuit's recent decisions do not reflect a shift in doctrine, but rather a faithful application of long-standing written description principles to challenging fact patterns. Both cases turned on the fundamental requirement of demonstrating possession of the claimed invention as of the priority date—whether by expressly disclosing the species or by providing blaze marks that lead the skilled person to it.

However, as described before, broad claims *as such* are no problem in Europe, and some of the family members of the patents that were subject of the *Duke* and *Seagen* cases, were actually granted with quite broad claims.[7]

So the question whether a court would have ruled similar in Europe actually boils down to the question: Would the defendant in a counterclaim or the potential nullity claimant have brought the patent owner in a position where it would have been necessary to amend/limit their claims?

As presented earlier, possible reasons to do so could be

a) Relevant prior art

b) Lack of sufficiency – which, however, in the present cases seems not really given, since although the claims are allegedly broad, they are written in a way that a skilled person can understand them.

c) Lack of inventive step due to "non-working" embodiments

[7] E.g. EP 1 267 806 (Duke family member) or EP 2 486 933 B1 (Seagan family member)

If an opponent presented convincing prior art or experimental evidence showing non-working embodiments, both patentees in *Duke* and *Seagen* could have faced significant pressure to amend their claims. Under Europe's strict added-matter regime, such amendments may well have been impossible. This would likely have led to revocation—but for reasons different from the U.S. written description doctrine.

Comparative Conclusion: U.S. vs. Europe

Common problem, different gatekeepers. *Duke* and *Seagen* expose the same structural vulnerability in chemical/biotech claiming: broad genus-level disclosures without blaze marks to later-asserted species. In the U.S., the failure surfaces during enforcement under § 112(a) (written description and, at times, enablement). In Europe, the failure is often stopped earlier under Article 123(2) EPC (added matter), with sufficiency (Art. 83 EPC) and inventive step (Art. 56 EPC) providing additional checks.

Doctrine vs. procedure. The U.S. system can allow broad, lightly supported claims to issue, only to subject them to stringent litigation-level scrutiny later. Europe imposes litigation-level scrutiny during prosecution/opposition, preventing unsupported claims from ever maturing into enforceable rights.

Strategic implications.

- U.S.: Preserve optionality with timely CIPs to add later-favored species before public disclosure; ensure early filings contain credible blaze marks toward foreseeable commercial embodiments. Expect litigation to probe for representative species and common structural features that genuinely point to the accused species.

- Europe: Draft with explicit combinations and avoid reliance on recombining lists later; anticipate two-list and intermediate-generalization traps; recognize there is no CIP and divisional filings cannot add new matter. If later data show non-working embodiments, be prepared for inventive-step attacks and limited room to amend.

Bottom line. Across jurisdictions, the message is consistent: possession beats possibility. In the U.S., that means written description must point the way from genus to species. In Europe, that means the text as filed must expressly (or directly and unambiguously) support the claim—*as amended or granted*. Failing either test risks losing protection for valuable internal embodiments and makes it nearly impossible to reach a competitor's later innovations.