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Publications

January 14, 2026 • Updates

Federal Circuit Strikes Life Sciences Patent Over Insufficient Disclosure of Particular Species

Key Takeaways:

- The Federal Circuit held that general disclosure of any part of a compound may be insufficient to support a priority date for a specific species within the genus.
- The decision underscores that every element of a claimed species, even noncritical components, must be clearly disclosed in the priority application.
- Applicants should identify all elements of all commercially relevant species in drug, protein, and nucleic acid applications and consider filing new provisional or priority applications to cover previously unappreciated compounds within an already disclosed genus.

In *Seagen v. Daiichi Sankyo*[1], the Federal Circuit invalidated claims in a life sciences patent, highlighting the limits of genus-level disclosure to support specific, non-exemplified species. The court found that generic disclosure of a small linker in antibody-drug conjugates (ADCs) of Seagen's application was not enough to describe the particular linker of Daiichi Sankyo's ADC, Enhertu®, and reversed a jury verdict that Enhertu® infringed Seagen's patent. The decision reinforces the demanding written description standard in chemical and life sciences patents, particularly when disclosures describe a genus but do not exemplify a specific species within the genus.

Background: Enhertu® and the Asserted Patent Claims

In late 2011, Daiichi Sankyo developed the drug Enhertu®, an ADC that links the cancer drug deruxtecan with the antibody trastuzumab via the tetrapeptide linker GGFG[2]. Trastuzumab guides the deruxtecan directly to cancer cells (particularly breast cancer). Proteases within the cancer cell cut the linker to release the deruxtecan to kill the cancer. Seagen sued Daiichi, asserting that Enhertu® infringed Seagen's patent US 10,808,039. The '039 patent was filed in 2019, claiming the benefit of prior filed US Pat. App. Ser. No. 10/983,340 having an earliest effective filing date of November 2004 (the "2004 priority document"). Following a jury trial, Seagen was awarded more than $41 million in damages.[3]

Daiichi moved for Judgment as a Matter of Law to set aside the jury award, arguing that

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- Biotechnology & Life Sciences Patent Prosecution
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the claims lacked written description in the 2004 priority document and that the '039 patent should not be accorded the benefit of the 2004 filing date. Though unsuccessful at the district court[4], on appeal, the Federal Circuit agreed with Daiichi, determining that the 2004 priority document lacked sufficient written description of the specific GGFG linker that connects trastuzumab to deruxtecan.[5] Accordingly, the Federal Circuit found that Daiichi had invented Enhertu® *before* the effective filing date of the '039 patent. Thus, Enhertu® did not infringe the '039 patent because its invention antedated Seagen's effective filing date, and worse for Seagen, Enhertu® anticipated the claims of the '039 patent, thus invalidating them.

Disclosure Shortfall: GGFG Linker Not Described in Priority Application

Central to the Federal Circuit's decision was the fact that the Enhertu® linker was not disclosed in the 2004 priority document.[6]

The fact that both the ADCs described in the 2004 priority document and Enhertu® utilized trastuzumab as the antibody and deruxtecan (a topoisomerase inhibitor) as the drug was not disputed. The core factual issue was whether the specific tetrapeptide linker GGFG that connects deruxtecan to trastuzumab was sufficiently described in Seagen's 2004 application. The priority document generally disclosed a linker from two to twelve amino acids[7], with one exemplified tetrapeptide linker being GFLG.[8] The Federal Circuit found that general disclosure of a tetrapeptide linker and a specific embodiment of GFLG was insufficient to show that Seagen was in possession of an ADC with GGFG connecting deruxtecan and trastuzumab (e.g., Enhertu®): "claims to a particular species or subgenus require 'reasonably specific supporting disclosure' to show that the inventor possessed the specific compound."[9]

Takeaway: No Part of a Compound is Too Small to Describe

While previous decisions have consistently decided that broad disclosure of a genus does not necessarily support specific compounds[10], it is notable that Seagen's patent was invalidated due to insufficient disclosure for the GGFG linker in the priority document.[11] The portion of the ADC lacking support in the priority document represents less than 0.3% of the whole molecule and it neither targets the ADC to a cancer cell nor kills the cancer cell. This decision highlights that no part of a compound, no matter how small or trivial in relation to the whole compound, is safe from the disclosure requirement.

Functional Disclosure Remains an Open Question

When a genus is claimed, the written description requirement can be satisfied if a "representative number of species" is disclosed such that the artisan would "recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the species."[12] It is conceivable that, particularly in the chemical and biological arts, a functional argument could be made to describe the "necessary common attributes or features" for showing possession. Would the Federal Circuit have arrived at the same decision if the record contained evidence that targeting and cytotoxicity of an ADC containing trastuzumab and deruxtecan could have been achieved irrespective of the linker sequence? Unfortunately, this concept was neither argued by Seagen nor addressed by the Court.

What This Means for Patent Drafters in Chemical and Life Sciences

For future chemical and life sciences (e.g., peptides and nucleic acids) applications, the patent drafter should be careful with how they describe the broadest scope of the invention. Generic and/or boilerplate disclosure of possible identities for variable regions

of a genus of compounds may not satisfy the written description requirement for particular species within the genus. Patent owners cannot rely on nonspecific definitions, even at minor or noncritical locations of the molecule, for support for individual species that are not specifically identified or exemplified in the disclosure.

Practitioners should collaborate with inventors to identify and disclose specific chemical moieties or amino acid or nucleic acid sequences as early as possible in the drafting process. Any current or potentially commercially relevant compounds, proteins, and nucleic acids should be fully disclosed in the provisional or priority applications. And if, during pendency of an application, the inventor discovers that a previously unappreciated portion of the genus not exemplified in the pending application is commercially relevant, they may consider filing a separate provisional application to cover the new compounds rather than rely on the original disclosure and continuation applications.

For issues regarding written description in pending applications and current patents, the practitioner *may* have success if they can show that the asserted utility of the compound does not depend on a specific identify of the variable moiety for which a written description rejection has been raised. The Court's decision did not hinge on the linker's function and Seagen did not make any arguments related to the functional relevance of the linker. It remains to be determined whether generic disclosure of a variable coupled with disclosure that the purpose or function of the variable does not depend on a specific identity could satisfy the written description requirement.

[1] No. 2023-2424.

[2] Glycine (G)-glycine (G)-phenylalanine (F)-glycine (G).

[3] *Seagen* slip op. at 8.

[4] *Id.*

[5] The motion for JMOL also argued that the full scope of the claims was not enabled with respect to antibodies and drugs that can be used in the ADC. The Federal Circuit also agreed with Daiichi that the patent was invalid for lack of enablement. The enablement portion of the decision is beyond the scope of this post.

[6] *Seagen* slip op. at 12.

[7] The asserted claims and 2004 priority document referred to the linker as "–W_w–".

[8] Glycine (G)-phenylalanine (F)-leucine (L)-glycine (G).

[9] *Id.* (citing *In re Ruschig* 379 F.2d 990 (CCPA 1967)).

[10] See *e.g., In re Ruschig* (379 F.2d 990 (CCPA 1967)) and *Regents of the University of Minnesota v. Gilead Sciences, Inc.* (61 F.4th 1350 (Fed. Cir. 2023)).

[11] *Seagen* slip op. at 12.

[12] *Carnegie Mellon University v. Hoffman-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008). See also Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (January 5, 2001).