

**LEGAL UPDATES**

# Claim Construction Matters: Federal Circuit Decision Highlights the Significance of Lexicography in Patent Drafting

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A precedential ruling by the U.S. Court of Appeals for the Federal Circuit on June 4 affirmed that Moderna’s mRNA-based COVID-19 vaccine SPIKEVAX® does not infringe two patents owned by Alnylam Pharmaceuticals, upholding a prior decision by the U.S. District Court in Delaware.

Many patents include a “Definitions” section in the specification where terms may be defined in a manner that differs from their ordinary meaning. This decision highlights the impact that definitional language in the specification has on claim interpretation, as well as the importance of clearly establishing any deviations from these controlling definitions.

## Background

Moderna’s SPIKEVAX® COVID-19 vaccine employs lipid nanoparticles for the delivery of mRNA. One lipid present in the formulation is the cationic lipid SM102. In 2021, Alnylam filed two Track One applications claiming priority to a 2011 provisional application. The applications granted as US Patent Nos. 11,246,933 and 11,382,979 in February and July of 2022, respectively, with claims that generically cover cationic lipid structures. Upon grant, Alnylam immediately enforced the two patents against Moderna, alleging that Moderna’s use of SM102 infringed both patents.

The claims of both of the asserted patents include the limitation that the cationic lipid comprises a “hydrophobic tail [that] is a branched alkyl, where the branching occurs at the  $\alpha$ -position relative to” a biodegradable group, such as an ester. In SM102, the alpha-position relative to the ester group is a carbon atom bound to a hydrogen atom, two carbon atoms, and the oxygen atom of the ester group.

By contrast, the definition of “branched alkyl” in the specification of the asserted patents provides that “unless otherwise specified,” the group “refer[s] to...an alkyl group...in which one carbon atom in the group...is bound to at least three other carbon atoms.” The district court construed the meaning of “branched alkyl” in a

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manner consistent with the definition in the specification. Under this claim construction, Moderna did not infringe the asserted patents. Alnylam appealed, arguing that the record showed that it did not intend to so limit the term “branched alkyl,” and the Federal Circuit affirmed the district court’s decision.

## Key Issue – Claim Construction

### Establishing Definitional Language

The Federal Circuit agreed with the district court’s determination and held that Alnylam acted as lexicographer in the “Definitions” section of the patent, where it stated that “[u]nless otherwise specified, the term[ ] ‘branched alkyl’ ... refer[s] to...” In arriving at this determination, the court considered the following factors:

- **The location of the passage in question.** Here, the paragraph describing branched alkyl groups was within a section under the title “Definitions.”
- **The use of quotation marks around the term in question.**
- **The use of the phrase “refer to,”** which the Federal Circuit determined “generally ‘conveys an intent for [that sentence] to be definitional.’” Additionally, the court reasoned that the use of this phrase, “rather than a non-limiting term,” indicated that the description of a “branched alkyl” in the specification was definitional.
- **Contrasting language elsewhere in the “Definitions” section;** the court specifically drew a distinction between the “refer to” language at issue and non-limiting language (e.g., “for example” and “include”) used to clarify the scope of other technical terms in the specification.
- **The inclusion of the phrase “[u]nless otherwise specified” within the lexicographic sentence,** which the Federal Circuit reasoned “suggests that the rest of the sentence lays out a generally applicable rule or definition.”

### Deviating from Definitional Language

Upon finding that “the high threshold for lexicography” was met in the asserted patents for the term “branched alkyl,” the court reasoned that “a high threshold would have to be met before finding a departure from that controlling definition.”

The phrase “[u]nless otherwise specified” that precedes the definition of “branched alkyl” left open the possibility of a broader reading of the term. In evaluating whether a departure from the definition was supported, the court emphasized the meaning of “specified” in the context of “unless otherwise specified” as requiring one to “name or state explicitly or in detail.” Any exception to the general definition must, therefore, be clear and explicit. Interestingly, the court quoted an earlier decision [1] that contrasted the term “specified” with the more general term “indicated,”

suggesting that the latter may give rise to a more lenient standard. The court's stance highlights the importance of semantics and word choice during the drafting process.

To determine whether Alnylam had "otherwise specified" a meaning for "branched alkyl," the court looked to the claims, the specification and the prosecution histories of the patents. The claims on their face did not require a deviation from the definitional language and, therefore, did not support the finding of one. In its analysis of the specification, the court took note of a generic formula that purportedly deviated from the definitional language in a manner that supported Alnylam's position. However, the court held that a redefinition of the term "branched alkyl" in relation to the generic formula did not necessarily support a redefinition of the term in the asserted claims because there was no link between the formula and the claims (Alnylam had previously argued that the generic formula fell outside the scope of the claims).

Finally, while Alnylam provided a structural representation of branching at the alpha position during prosecution to differentiate the claims over the prior art, the court held that the representation, which had a secondary carbon at the alpha position, merely constituted an example of what branching at the alpha position could look like and did not override the general definition in the specification.

## Implications of the Ruling

The Federal Circuit articulated the public policy rationale underpinning the decision: "[p]ublic notice is a central policy...the applicant has ample control over provision of definitions, so when a definition is expressly stated, the public is generally entitled to expect clear notice of exceptions." Thus, where a patentee has acted as lexicographer, the public is justified in assuming that the definitional language is comprehensive, absent the explicit disclosure of exceptions.

This decision underscores the importance of meticulous definition drafting in patent applications and the value of critically reviewing and redefining terms. The ruling highlights best practices for establishing definitional language and the importance of clearly and explicitly describing exceptions. It also sets a precedent for future disputes over the definition of terms.

If you have questions about the impact of this ruling on current or future patent strategy, please contact [Vinay Trivedi-Parmar](#) or [Christine Greene](#), or reach out to your regular Lathrop GPM attorney.

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[1] *HRE, Inc. v. United States*, 142, F.3d 127, 1276 (Fed. Cir. 1998).