ALM Law Journal Newsletters
Intellectual Property Strategist

By Sarah Brand and Jeff Ginsberg
June 30, 2025

Federal Circuit: District Court Did Not Err In Declining to Find Infringement By Moderna's Activities Involving COVID-19 Vaccine

On June 4, 2025, a Federal Circuit panel consisting of Judges Taranto, Chen, and Hughes issued a unanimous opinion, authored by Judge Taranto, in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc*., Case No. 2023-2357. The panel affirmed the U.S. District Court for the District of Delaware's decision that appellee's activities involving its mRNA-based COVID-19 vaccine SPIKEVAX® did not infringe appellant's U.S. Patent Nos. 11,246,933 ('933 patent) or 11,382,979 ('979 patent). Slip Op. at 2–3.

Alnylam Pharmaceuticals, Inc., (Alnylam) owns the '933 and '979 patents. *Id*. at 2. The '979 patent is the child of the '933 patent. *Id*. Both patents are directed to biodegradable lipids and their use for the delivery of active agents, such as nucleic acids. *Id*. at 3. Specifically, the '933 and '979 patents disclosed a cationic lipid with at least a branched alkyl terminal hydrophobic chain in at least one biodegradable hydrophobic tail. *Id*. at 5. In March 2022, Alnylam sued Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively Moderna) in the U.S. District Court for the District of Delaware, alleging that Moderna infringed the '933 patent through activities involving the SM-102 lipid in SPIKEVAX®. *Id*. at 6. In July 2022, after the '979 patent issued, Alnylam sued Moderna in the same forum for alleged infringement of the '979 patent through activities involving SPIKEVAX®. *Id*. The two pending actions were consolidated. *Id.*

The parties submitted joint claim construction briefing in June 2023. *Id*. Alnylam requested the court construe "branched alkyl" and "branched C10-C20 alkyl" as "a saturated hydrocarbon moiety that is not a straight chain," with an additional requirement that a "branched C10-C20 alkyl" contains 10 to 20 carbon atoms. *Id*. at 6–7. Moderna requested a construction that accorded with an alleged "definitional sentence" in the specification: "Alkyl in which one carbon atom in the group (1) is bound to at least three other carbon atoms, and (2) is not a ring atom of a cyclic group." *Id*. at 7. The district court agreed with Moderna, finding that Alnylam had engaged in "clear and unequivocal lexicography." *Id*. Accordingly, the district court construed "branched alkyl" to mean "[a] saturated hydrocarbon moiety group in which one carbon atom in the group (1) is bound to at least three other carbon atoms, and (2) is not a ring atom of a cyclic group." *Id*. at 7–8. The parties stipulated to noninfringement of all asserted claims under the district court's claim constructions, as Moderna's SM-102 lipid had branching without a carbon atom connected to at least three other carbon atoms. *Id*. at 8, 12. Instead, the branching involved a secondary carbon in the alpha position. *Id*. at 12. The district court entered a final judgment to that effect. *Id*. at 8. Alnylam appealed. *Id*.

The Federal Circuit began its analysis by explaining that it would review the district court's claim construction "without deference" because "the intrinsic evidence alone determines the

proper claim construction." *Id*. Following that standard, the Federal Circuit explained that Alnylam had acted as a lexicographer and "clearly" defined "branched alkyl" in its specification. *Id*. at 9. The Federal Circuit referenced multiple reasons for finding that Alnylam had acted as a lexicographer, including that: 1) the definition in question appears under a heading titled, "Definitions"; 2) the term "branched alkyl" is set in quotation marks in the specification; (3) the section in question uses the term "refer to," which indicates definitional intent; and (4) the phrase "unless otherwise specified" in the section in question indicates general applicability of the previously stated rule or definition. *Id*. at 9-10. Accordingly, the Federal Circuit affirmed the district court's finding that Alnylam had acted as a lexicographer in defining "branched alkyl." *Id*. at 10.

The Federal Circuit then turned to Alnylam's alternative argument that the inclusion of "[u]nless otherwise specified" in the passage defining "branched alkyl" covers the disclosure of a secondary carbon at the alpha position. As an initial matter, the Federal Circuit clarified that "a high threshold would have to be met before finding a departure from" a lexicographer's controlling definition. *Id*. at 11. The Federal Circuit then rejected each of Alnylam's arguments, noting that: 1) Alnylam did "not show that the claims make no sense when read in light of the definition, so as to require them to be treated as an exception; 2) the specifications of the '933 and '979 patents did not disclose a secondary carbon in the alpha position, despite hundreds of pages of examples and discussion; and 3) statements made during the prosecution of the '933 and '979 patents suggesting an understanding that "branched alkyls" encompass "an alkyl group with a secondary carbon at the alpha position" were insufficient to override the definition. *Id*. at 11-19. As a result, the Federal Circuit affirmed the lower court's finding that Alnylam "did not otherwise specify" an expansion of the definition of "branched alkyl" to include a secondary carbon in the alpha position. *Id*. at 19.

Federal Circuit: PTAB Did Not Err In Finding that Prior Art Reference Disclosed Negative Limitation Without Stating a Feature's Absence

On June 9, 2025, a Federal Circuit panel consisting of Judges Prost, Reyna, and Chen issued a unanimous per curiam opinion, in *Chian Chiu Li v. Apple Inc.*, Case No. 2024-2148. The panel affirmed the Patent Trial and Appeal Board's (the Board) decision finding that claims 1–6, 8–12, 14–16, and 18–20 of Mr. Li's U.S. Patent No. 11,016,564 ('564 patent) are unpatentable as obvious over the prior art. Slip Op. at 2.

The '564 patent is directed to a method for presenting information on an electronic device when the device senses it has been moved and that a user is looking at the screen. *Id*. Specifically, claim 1 of the '564 patent is directed to a method of performing gaze detection "*only after*" detecting physical contact or movement. *Id*. (emphasis added). Apple, Inc. (Apple) petitioned for *inter partes review* of the '564 patent, claiming that claims 1–6, 8–12, 14–16, and 18–20 were unpatentable as obvious over combinations of previously issued U.S. Patents 10,540,013 (Ryu) and 8,331,992 (Stallings), as well as U.S. Patent Application No. 2010/0079508 (Hodge). *Id*.

Before the Board, Mr. Li argued that the prior art did not anticipate the claims of the '564 patent because the Ryu reference does not disclose that gaze detection is performed only after detecting device movement. *Id*. at 3. Mr. Li's argument was based on the fact that Ryu does not exclude the

possibility of gaze detection after detecting an event using proximity information, rather than after detecting device movement as claimed by the ’564 patent. *Id*. at 4. The Board disagreed, finding that the primary embodiment did not feature triggers other than device movement and that a skilled factfinder could reasonably conclude that “a skilled artisan would read Ryu’s preferred embodiment as performing gaze detection only after motion is detected.” *Id*. at 5. The Board concluded that the challenged claims were unpatentable as obvious over the prior art. *Id*. at 4. Mr. Li appealed. *Id*. at 2.

The Federal Circuit began its analysis with recent Federal Circuit precedent recognizing that prior art references do not need to “state a feature’s absence in order to disclose a negative limitation.” *Id*. at 4 (internal citations and quotations omitted). Since the Ryu reference itself disclosed a device with a proximity censor as “another exemplary embodiment,” the Federal Circuit agreed that substantial evidence supported a finding that the “primary embodiment discloses a device that has a motion sensor and no other sensors.” *Id*. at 5. Additionally, given the fact that no other sensors are disclosed by Ryu, the Federal Circuit agreed that it was reasonable to conclude that Ryu discloses performance of gaze detection only after motion is detected. *Id*.

The Federal Circuit also briefly considered Mr. Li’s additional argument that even if Ryu “inherently” discloses the “only after” limitation, the disclosure was “accidental, unintended, or unappreciated and thus could not form the basis of a finding of anticipation.” *Id*. at 5–6. This argument was swiftly rejected by the Federal Circuit, as the Board’s conclusion did not rely on a conclusion that the “only after” limitation was inherently disclosed by Ryu. *Id*. at 6. Further, the Board’s conclusion did not require a finding of “motivation or explanation” for why Ryu discloses performing gaze detection only after motion detection. *Id*. Accordingly, the Federal Circuit panel affirmed the Board’s finding that the claims are unpatentable. *Id*.

***

Sarah Brand is an Associate with Patterson Belknap Webb & Tyler LLP in New York. She can be reached at sbrand@pbwt.com. Jeff Ginsberg is a Partner at Patterson Belknap Webb & Tyler LLP and Assistant Editor of The Intellectual Property Strategist.
