

Turning Up the Heat: Federal Circuit Sets the Temperature for pH Measurements in Precedential Opinion

3 MIN READ

May 21, 2026, 3:00 PM

By: Matthew S. Murphy, Sara Natour, Jerome P. David

The Federal Circuit recently affirmed a Northern District of West Virginia decision finding no literal or doctrine of equivalents infringement of product-by-process claims requiring a minimum pH level.

In *Actelion Pharms. Ltd v. Mylan Pharms. Inc.*, No. 2024-1641 (May 13, 2026), the Federal Circuit considered infringement of two patents with product-by-process claims directed to a lyophilized composition containing epoprostenol and formed from a bulk solution with “a pH of 13 or higher.” As the patents did not define the term “pH,” the district court construed the recited range to mean a pH of 12.98 or higher measured at $25\pm 2^{\circ}\text{C}$, a standard temperature used in the field. The parties did not dispute in the trial proceeding that Mylan’s bulk solution had a pH below 12.98 when measured at $25\pm 2^{\circ}\text{C}$. Actelion instead argued that the relevant person of skill in the art would measure the solution’s pH at a colder “operating temperature,” which would be conducive to a higher pH result. The district court rejected this argument, finding that a POSA would measure the bulk solution at the standard temperature in view of the intrinsic record and extrinsic evidence.

A core question on appeal was whether the district court’s determination of the scope of measurement temperature was correct. The Federal Circuit agreed with the district court’s finding that the intrinsic record supported interpreting “a pH of 13 or higher” as invoking measurement at standard temperature. For instance, the specification defined “an alkaline

environment” as having a pH greater than 7, which is only accurate at $25\pm 2^{\circ}\text{C}$. To determine how a POSA would understand the disputed phrase, the Federal Circuit also considered the district court’s review of extrinsic evidence. The United States Pharmacopeia (an influential collection of standards for the pharmaceutical industry) reported that pH measurements are made at standard temperature “unless otherwise specified” and the parties’ experts agreed that the “vast majority of the pH measurements” disclosed in the asserted patents’ shared specification were conducted at standard temperature. In view of this evidence, the Federal Circuit found no clear error in the district court’s fact conclusions and affirmed its determination of no literal infringement.

The Federal Circuit similarly affirmed the district court’s determination of no infringement under the doctrine of equivalents, finding that both prosecution history estoppel and the disclosure-dedication doctrine barred Actelion from asserting equivalents. Notably, the Federal Circuit reasoned that the latter doctrine does not require a disclosed alternative to be mutually exclusive with the relevant claimed matter, as disclosed but unclaimed matter may be dedicated to the public even if it overlaps in scope with relevant claim limitations.

This opinion highlights how extrinsic evidence about conventional practices in the relevant field can sway a court’s understanding of the POSA’s claim interpretation. Litigants should be aware that both intrinsic and extrinsic evidence contour the scope of common terms, and litigants should analyze how such evidence could convey meaning to disputed terms. As we previously discussed concerning another Federal Circuit opinion about pH levels, *Enviro Tech Chemical Services, Inc. v. Safe Foods Corp.*, No. 2024-2160 (May 4, 2026), the record evidence can weigh heavily on the scope of phrases that might appear simple on their face.

“Evidence that relevant artisans use a claim term in an established and consistent way, including evidence of a [w]ell known industry standard[],’ . . . can be persuasive of the term’s meaning.”

 www.cafc.uscourts.gov/...



Related People

Matthew S. Murphy
Jerome P. David
Sara Natour

Related Services

Intellectual Property

To subscribe to our publications, [click here](#).

News & Insights

- The Empty Chair in Antitrust Conspiracy Cases
WEBINAR ANTITRUST
- USC Gould/Analysis Group Global Competition Law Thought Leadership Conference
SPEAKING ENGAGEMENT ANTITRUST
- 17th ACI Summit on Biosimilars & Innovator Biologics
SPEAKING ENGAGEMENT INTELLECTUAL PROPERTY
- GCR Live: Europe 2026
SPEAKING ENGAGEMENT ANTITRUST
- 20th Annual IBA Competition Mid-Year Conference
SPEAKING ENGAGEMENT ANTITRUST
- Axinn Represents Tecomet in Closing of Merger with Orchid Orthopedic
DEALS & CASES ANTITRUST
- Recent Benchmarking Suits Highlight DOJ Enforcement Risks
BYLINE ARTICLES ANTITRUST
- “Old Crime, New Code” – DOJ Outlines its Views on When Software and AI Can Facilitate Collusion
AXINN VIEWPOINTS ANTITRUST
- From Listings to Litigation: Zillow and Redfin Face Continued Litigation with the FTC and States
AXINN VIEWPOINTS ANTITRUST
- Informa CompLaw Antitrust West Coast Conference 2026
SPEAKING ENGAGEMENT ANTITRUST