

Life Sciences Newsletter

UPDATES AND NEWS FROM THE BAKERHOSTETTLER LIFE SCIENCES TEAM

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Dear Colleagues,

Welcome to the first issue of the BakerHostetler Life Sciences Newsletter! Within it you will find an overview of noteworthy developments in the life sciences space and at BakerHostetler.

The U.S. Court of Appeals for the Federal Circuit has had a busy start to 2025, rendering decisions on a number of patent cases in the life sciences space, including those related to written description and enablement, motivation to combine prior art references, and inherency in the obviousness context. The Federal Circuit also addressed the scope of the International Trade Commission's domestic industry requirement. 2025 also brings several changes to key intellectual property positions within the new administration.

RON KERN, Ph.D., partner, Intellectual Property Practice Group and Life Sciences Industry team

Patent Law Updates

A Later-Discovered Improvement to an Invention Cannot Be Used to Reach Back and Invalidate an Earlier-Filed Patent

Novartis, which markets and sells a combination therapy of valsartan and sacubitril under the brand name Entresto®, sued MSN Pharmaceuticals Inc. (MSN) for infringing U.S. Patent No. 8,101,659. The U.S. District Court for the District of Delaware “construed the asserted claims to cover valsartan and sacubitril as a physical combination and as a complex.” *In re Entresto*, 125 F.4th 1090, 1096 (Fed. Cir. 2025). MSN argued that the claims lacked enablement and written description because the patent does not disclose complexes of valsartan and sacubitril. Novartis argued that the patent need not enable or describe complexes of valsartan and sacubitril because such complexes were “an after-arising invention.” (*Id.* at 1096-97). On appeal, the Federal Circuit opined that the district court’s error in interpreting the claim construction “led [the court] astray in evaluating written description.” (*Id.* at 1098). The Federal Circuit stated that the complexes, which were not discovered until four years after the priority date of the patent, “cannot be used to ‘reach back’ and invalidate the asserted claims.” (*Id.* at 1100). Read the full blog post [here](#).

If a Claim Limitation Is Inherent, There Is No Question of a Reasonable Expectation of Success in Achieving It

In *Cytiva BioProcess R&D AB v. JSR Corp.*, the Federal Circuit addressed whether a reasonable expectation of success analysis is required when analyzing a claim that merely recites an inherent property of an otherwise obvious claim. 122 F.4th 876 (Fed. Cir. 2024). The Federal Circuit concluded that this additional showing is not required and stated that “[n]o reasonable expectation of success argument or analysis is required where the sole disputed limitation was an inherent property of the claimed composition already determined to be obvious.” (*Id.* at 890-91). Read the full blog post [here](#).

Evidence Suggesting That a Skilled Artisan Would Be Discouraged from Combining Prior Art References May Be Sufficient to Establish a Lack of Motivation to Combine

Laboratory Corporation of America Holdings (Labcorp) challenged certain claims of U.S. Patent No. 7,332,277 as being obvious over a combination of two references. The Patent Trial and Appeal Board (Board) determined that Labcorp did not demonstrate that a person of ordinary skill in the art would have

Patent Law Updates *continued*

been motivated to combine the references. On appeal, Labcorp argued that the Board's analysis of the references was legally flawed because the Board was "fixated on" one of the reference's disclosures that paraformaldehyde could cause one percent of the cell's DNA to escape. *Laboratory Corporation of America Holdings v. Ravgen, Inc.*, No. 2023-1342, 2025 WL 32904, at *2 (Fed. Cir. Jan. 6, 2025). The Federal Circuit affirmed the Board's ruling and stated that even if evidence does not "rise to the level of teaching away," it is still proper to consider evidence that "suggests reasons that a skilled artisan would be discouraged from pursuing such a combination." (*Id.* at *4; citing *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017)).

IN CASE YOU MISSED IT



BakerHostetler Releases Second Annual IP Perspectives Publication

BakerHostetler released its second annual **BakerHostetler IP Perspectives (BHIPP)** publication, which discusses a number of closely watched topics in the IP space, including artificial intelligence (AI) and IP, trade secret trends, litigation trends, and updates on the obviousness-type double patenting caselaw. For more information and a copy of the publication, please visit bakerlaw.com/insights/bhipp-2025-ip-perspectives/.

GOVERNMENT UPDATES

Sen. Thom Tillis, R-N.C., Will Serve as Chair of the Senate Judiciary Subcommittee on Intellectual Property for the 119th Congress

Sen. Thom Tillis, R-N.C., announced that he will serve as chair of the Senate Judiciary Subcommittee on Intellectual Property for the 119th Congress and will look to "usher[] in meaningful change within the IP space," including "reforming patent eligibility via the Patent Eligibility Restoration Act." www.tillis.senate.gov/2025/2/tillis-to-chair-senate-judiciary-subcommittee-on-intellectual-property-for-the-119th-congress

John Squires Has Been Nominated to Be the Under Secretary of Commerce for Intellectual Property and Director of the USPTO

The White House announced that John Squires, former chief IP counsel at Goldman Sachs, has been officially nominated to be the under secretary of commerce for IP and director of the U.S. Patent and Trademark Office (USPTO). www.senate.gov/legislative/nom_cmtec.htm

INTERNATIONAL TRADE COMMISSION

US International Trade Commission's Domestic Industry Requirement Has No 'Threshold Dollar Value' and 'Small Market Segments' Apply

Ventria Bioscience Inc. (Ventria), the owner of U.S. Patent No. 10,618,951 (the '951 patent), filed a complaint with the International Trade Commission (Commission) alleging that Wuhan Healthgen Biotechnology Corp.'s (Healthgen) importation of recombinant human serum albumin violated Section 337. The Commission found that Healthgen infringed certain claims of the '951 patent and that Ventria satisfied the domestic industry requirement. *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*, 127 F.4th 1334, 1336 (Fed. Cir. 2025). The Federal Circuit affirmed and stated that although "the dollar amounts of Ventria's [product] investments are small, the Commission found all of the investments are domestic, all market activities occur within the United States, and the high investment-to-revenue ratios indicate this is a valuable market." (*Id.* at 1339). The Federal Circuit noted that an analysis of the domestic industry requirement "requires a holistic review of all relevant considerations that is very context dependent." (*Id.* at 1339). "Small market segments can still be significant and substantial enough," and the analysis "cannot hinge on a threshold dollar value or require a rigid formula." (*Id.*).

IN THE NEWS

- BakerHostetler was recognized in World Intellectual Property Review's 2024 Patent rankings for "Highly Recommended, Non-Contentious – Patents" and "Recommended, Contentious – Patents."
- BakerHostetler's IP Practice Group was named one of the "Top 10 Patent Firms" and was recognized as an "Award Winning Law Firm 2025" by The Patent Lawyer Magazine for North America – Northwest.
- Partner **Felicity Groth**, patent agent **Elizabeth Browning**, partner **Joe Lucci**, partner **Rakesh Mehta**, and partner **Jeff Rosedale** attended the Life Sciences PA 2025 Annual Dinner & Showcase held at the Philadelphia Museum of Art.
- Partner **Winston Kirton**, co-leader of the firm's FDA practice and Life Sciences Industry Team, will present at the 12th Annual Legal, Regulatory and Compliance Forum on Cosmetics and Personal Care Products in New York.



- BakerHostetler will be at the AXS25 Summit from April 27 to May 1, 2025, at the Wynn & Encore Las Vegas. BakerHostetler's FDA team will host off-site office hours and a reception for AXS25 attendees.
- Partner **Lee Rosebush** and associate **Marc Wagner** will be presenting at INTERPHEX, taking place from April 1 to 3, 2025, in New York City. Lee and Marc's presentation, titled "Partnering with 503Bs as a Drug Shortage Channel," will describe the regulatory and market landscape for drug shortages and will occur on April 2 at 11:30 AM ET.

At a Glance

BakerHostetler's life sciences practice is a multidisciplinary practice group spanning intellectual property (IP), litigation, business, regulatory and government compliance, digital assets and data management (DADM), noncompete and trade secrets, tax, and federal policy.

