

# GIBSON DUNN

Appellate & Constitutional Law and  
Intellectual Property Update

January 7, 2025

## Federal Circuit Update

This edition of Gibson Dunn's Federal Circuit Update for November-December 2024 summarizes the current status of petitions pending before the Supreme Court and recent Federal Circuit decisions concerning inherency, the on-sale bar, vicarious liability, and the listing provision in the Hatch-Waxman Act.

## Federal Circuit News

### **Noteworthy Petitions for a Writ of Certiorari:**

There were a few potentially impactful petitions filed before the Supreme Court in November and December 2024:

- [\*\*Celanese International Corp. v. International Trade Commission\*\*](#) (US No. 24-635): The question presented is “Whether the sale of an end product made by secret use of a later-patented process places ‘the claimed invention’—that is, the process itself—on sale and thus invalidates the patent on that process, even where the claimed process was not disclosed by the sale and cannot be discovered by studying the end product.” A response is due February 10, 2025.
- [\*\*Lighting Defense Group LLC v. SnapRays, LLC\*\*](#) (US No. 24-524): The question presented is “Whether a defendant subjects itself to personal jurisdiction anywhere a plaintiff operates simply because the defendant knows its out-of-forum other conduct ‘would necessarily affect marketing, sales, and activities’ within the forum, Pet.App.11a—

even though the defendant has no contacts with the plaintiff or the forum whatsoever.” After SnapRays waived its right to respond, the Court requested a response. The response is due February 10, 2025.

- [\*\*Parker Vision, Inc. v. TCL Industries Holdings Co., et al.\*\*](#) (US No. 24-518): The question presented is “Whether 35 U.S.C. § 144, which requires the Federal Circuit to issue ‘opinion[s]’ in PTAB appeals, is a reason-giving directive that prohibits the Federal Circuit’s practice, under Federal Circuit Rule 36(a), of summarily affirming PTAB decisions without issuing opinions.” After the respondents waived their right to respond, the Court requested a response, which is due February 14, 2025. Eight amicus curiae briefs have been filed.

We provide an update below of the petitions pending before the Supreme Court, which were summarized in our [October 2024 update](#):

- The Court will consider the petition in **Edwards Lifesciences Corporation, et al., v. Meril Life Sciences Pvt. Ltd., et al.** (US No. 24-428) at its January 10, 2025 conference.
- The Court denied the petitions in **Norwich Pharmaceuticals Inc. v. Salix Pharmaceuticals, Ltd.** (US No. 24-294) and **Zebra Technologies Corporation v. Intellectual Tech LLC** (US No. 24-114).

#### **Federal Circuit En Banc Petitions:**

**Percipient.ai, Inc. v. United States**, No. 23-1970 (Fed. Cir. Nov. 22, 2024): The Federal Circuit granted the United States’s petition for rehearing en banc limited to the question of “Who can be ‘an interested party objecting to . . . any alleged violation of statute or regulation in connection with a procurement or a proposed procurement’ under the Tucker Act, 28 U.S.C. § 1491(b)(1)?”

## **Upcoming Oral Argument Calendar**

The list of upcoming arguments at the Federal Circuit is available on the court’s [website](#).

## **Key Case Summaries (November-December 2024)**

**Cytiva Bioprocess R&D AB v. JSR Corp., JSR Life Sciences, LLC**, Nos. 23-2074, 23-2075, 23-2191, 23-2192, 23-2193, 23-2194, 23-2239, 23-2252, 23-2253, 23-2255 (Fed. Cir. Dec. 4, 2024): JSR filed petitions for *inter partes* reviews (IPR) challenging Cytiva’s patents relating to affinity chromatography, which is a process by which compounds in a mixture are separated. The challenged independent claims recite a composition with an amino acid

substitution, and the dependent claims add certain antibody binding properties. Specifically, one set of dependent claims recites the composition's capability of binding to a particular region of an antibody called the Fab region, and a second set of dependent claims recites the process by which the composition binds to the Fab region. The Board held that the dependent composition claims were unpatentable because they claimed an inherent property, but that the dependent process claims were not unpatentable because even though Fab-binding was an inherent property, JSR had not shown a reasonable expectation of success. Cytiva appealed as to the composition claims, and JSR cross-appealed as to the process claims.

The Federal Circuit (Prost, J., joined by Taranto and Hughes, J.J.) [affirmed the appeal, and reversed the cross-appeal](#). The Court first held that the dependent composition and process claims must rise and fall together and therefore the Board's inherency finding should have applied to both sets of claims. The Court determined that the Board did not err in concluding that the dependent claims recite only a natural result of the composition recited in the independent claims, and thus, all the dependent claims were invalid as inherent.

***Crown Packaging Technology, Inc. v. Belvac Production Machinery, Inc.***, Nos. 22-2299, 22-2300 (Fed. Cir. Dec. 10, 2024): Crown sued Belvac for infringing patents related to "necking," a process used for manufacturing metal beverage cans. Belvac raised the affirmative defense of invalidity under the on-sale bar of pre-AIA 35 U.S.C. § 102(b) based on a letter that Crown sent to a third party named Complete before the critical date. The letter provided a quotation for Crown's necking machine, including a description, price, and delivery terms. The parties cross-moved for summary judgment on the issue of the on-sale bar. The district court determined that Crown's letter to Complete was an invitation to make an offer, not an offer itself, and therefore granted Crown's motion and denied Belvac's.

The Federal Circuit (Dyk, J., joined by Hughes and Cunningham, JJ.) [reversed and remanded](#). The Court determined that Crown's letter to Complete qualified as a commercial offer for sale because it was sufficiently definite as to the terms of the offer, including a detailed description of the machine, pricing, and delivery terms. The Court also held that the offer was "made in this country" as required under § 102(b), as it was directed to a United States entity at its United States place of business, and rejected Crown's argument that the letter did not trigger the on-sale bar because it was sent from England. The Court therefore held that the asserted claims are invalid under § 102(b).

***CloudfChange, LLC v. NCR Corp.***, No. 23-1111 (Fed. Cir. Dec. 18, 2024): CloudfChange sued NCR alleging that its NCR Silver product infringed CloudfChange's patents directed to an online web-based point-of-sale (POS) system for managing business operations. In the district court, CloudfChange argued that under the Federal Circuit's precedent in *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279 (Fed. Cir. 2011), NCR "used" the claimed system because NCR controls and benefits from each recited component of the system. A jury found that NCR directly infringed all the asserted claims. NCR moved for judgment as a matter of law (JMOL) of no infringement arguing that the entire system was not "used" until the customers put Silver into service. The district court denied NCR's motion reasoning that although NCR's customers control Silver by putting the system into service, "NCR directs its customers to perform by requiring them to obtain and maintain internet access," which is required to use Silver, and concluded that NCR was vicariously liable.

The Federal Circuit (Stoll, J., joined by Dyk and Reyna, JJ.) [reversed](#). The Court held that while the district court correctly determined that NCR’s customers, and not NCR, used the system because they put the system into service, the district court erred in concluding that NCR was vicariously liable for its customers’ use of the claimed system. The Court reasoned that NCR did not direct or control its customers to subscribe to Silver, download the application, or put Silver into use, and the district court erred by focusing its direction and control analysis on only one element of the system—Internet access.

***Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Amneal Pharmaceuticals of New York, LLC, et al.***, No. 24-1936 (Fed. Cir. Dec. 20, 2024): Teva sells a ProAir® HFA inhaler device, which delivers albuterol sulfate for treatment of bronchospasm, a condition that causes the airways in the lungs to contract. Teva listed nine patents in the Orange Book covering various aspects of its inhaler, including improvements to the metered dose counter, but not the active ingredient, albuterol sulfate. Amneal filed an abbreviated new drug application (ANDA) seeking approval to market a generic version of Teva’s ProAir® HFA that uses the same active ingredient. Amneal filed a paragraph IV certification asserting that it did not infringe Teva’s nine patents. Teva then sued Amneal for infringement of five of the patents. Amneal moved for judgment on the pleadings on the ground that Teva improperly listed the asserted patents in the Orange Book. The district court granted Amneal’s motion concluding that Teva’s patents do not claim the drug for which the applicant submitted the application and ordered Teva to delist its patents from the Orange Book.

The Federal Circuit (Prost, J., joined by Taranto and Hughes, JJ.) [affirmed](#). The Court explained that to list a patent in the Orange Book, the patent must “claim[] the drug for which the applicant submitted the application” as required by the Hatch-Waxman Act. The Court interpreted this to mean that the patent must “particularly point[] out and distinctly claim[] the drug,” which must include at least the active ingredient. Thus, patents claiming just device components of the product do not meet the listing requirement, and so the district court did not err in ordering Teva to delist its patents from the Orange Book.

**The following Gibson Dunn lawyers assisted in preparing this update: Blaine Evanson, Jaysen Chung, Audrey Yang, Hannah Bedard, Evan Kratzer, and Julia Tabat.**

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