

ASTELLAS PHARMA, INC. v. SANDOZ INC., Appeals Nos. 2023-2032, -2063, -2089 (Fed. Cir. September 18, 2024). Before Lourie, Prost, and Reyna. Appealed from D. Del. (Judge Bataillon).

### Background:

Astellas developed a sustained-release formulation of a drug used to relax the bladder and improve bladder function. The sustained-release formulation solved "food effect" problems that had been encountered with the immediate-release formulation, where the bioavailability of the drug was affected by the presence or absence of food in a patient's stomach.

Astellas filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA), and the FDA approved the NDA for the sustained-release formulation for the treatment of an overactive bladder. Astellas also obtained a patent directed to the sustained-release formulation and methods of using it to treat an overactive bladder. Astellas then immediately sued its competitor Sandoz based on the Abbreviated New Drug Application (ANDA) that Sandoz had submitted to get FDA approval to market and sell a generic version of the sustained-release formulation.

Before the district court, Sandoz raised initial claims of invalidity under each of 35 U.S.C. §§ 102 (for anticipation), 103 (for obviousness), and 112 (for each of written description, enablement, and indefiniteness). It later agreed to limit its invalidity defenses to only those arising under § 112. The parties never discussed any invalidity issues under 35 U.S.C. § 101, either during trial or in the post-trial briefing.

Although the issue of invalidity under § 101 was never raised by either party, the district court decided that the asserted claims were invalid under § 101. Specifically, the court held that the claimed invention "reflects merely the discovery of the food-effect-resolving dissolution profile," and thus the claims were directed to "a natural law applied via routine, conventional, and well-known methods." The court interpreted some of Astellas's arguments to be effectively conceding invalidity on these grounds, and concluded that it would be a "fundamental flaw" of the legal system to allow for parties to consent around patent ineligibility. Thus, the court considered patent eligibility under §101 to be a threshold inquiry that it had a duty to consider.

Sandoz anticipated that Astellas would appeal, and moved for the district court to make additional findings of fact and conclusions of law on the issues that had been presented at trial. The district court denied the motion.

### Issue/Holding:

Did the district court err in deciding, *sua sponte*, that patent claims were invalid under 35 U.S.C. §101? Yes, vacated and remanded.

### Discussion:

The Federal Circuit held that the district court had abused its discretion by disregarding the principle of "party presentation," in which the parties present the issues for decision and the court then decides on those issues. This principle is particularly strong in the context of patent litigation, where a patent is presumed to be valid and the burden of establishing invalidity rests with the party that is asserting invalidity. The Federal Circuit vacated the district court's decision and remanded the case for decision on the issues that were raised by the parties.

## NON-FEDERAL CIRCUIT HIGHLIGHTS FOR OCTOBER 9, 2024

### I. Miscellaneous

- A. On October 1, the U.S. Patent and Trademark Office released a notice announcing that the After Final Consideration Pilot Program 2.0 (AFCP 2.0) will soon be discontinued. The last day to submit a request for participation under the AFCP 2.0 is December 14, 2024. Any AFCP 2.0 Requests submitted on December 15 or later will not be accepted.

The reasons for discontinuing the program are purely economic. The PTO estimates that for the 2022 fiscal year alone, it incurred more than \$15 million in costs associated with examiners considering the merits of AFCP 2.0 submissions. In April 2024, the PTO proposed a new \$500 fee for participating in the AFCP 2.0; however, public commentary reflected that the public was not receptive to paying a fee for the program.

The notice can be found [here](#).