

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.*

Plaintiffs,

v.

SANDOZ INC., *et. al.*

Defendants.

1:20CV1589

ORDER

Defendants move the Court to supplement a prior ruling, [D.I. 571](#), with findings of fact and conclusions of law favoring defendants' preferred theory of the case. Specifically, they invite the Court to further rule in their favor by finding several asserted patent claims, which recite ineligible subject matter, to also lack sufficient written description and enablement. [D.I. 576](#).

Politely put, defendants worry the parties inadequately raised the matter of subject-matter eligibility at trial or in briefing. The Court disagrees. Certainly, in the ordinary course, courts defer to parties' framing of issues—particularly when resolving questions of law. [United States v. Sineneng-Smith](#), 590 U.S. ___, 140 S. Ct. 1575 (2020). But it prizes form over substance to conclude that a party must utter either magic words or a page number in the United States Reports to invoke a settled point of foundational patent law, as patent owner did repeatedly here.

The Court senses a more fundamental flaw in the assertion that patent litigants may, in essence, consent around the bounds of patent eligibility. By the Hatch-Waxman Act of 1984, Congress sought to remedy the dysfunctional market for pharmaceutical drugs, [New York ex rel. Schneiderman v. Actavis PLC](#), 787 F.3d 638, 645–47 (2d Cir. 2015), enacting a scheme of interlocking incentives to speed low-cost generic drugs to

market, while still driving new (brand) drug development, *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013). The pharmaceutical industry, to put it mildly, has perverted this intent. With alarming regularity since, brand and generic drug manufacturers have colluded to protect weak or invalid patents and share in the startling profits. *E.g.*, *In re Glumetza Antitrust Litig.*, No. C 19-05822 WHA, 2021 WL 1817092 (N.D. Cal. May 6, 2021).

This case is not about a patent claiming an active ingredient. Those have already begun to expire. See *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-cv-905, D.I. 1. This case is about the pharmaceutical industry's long-standing "innovation" of patenting extended-release formulas for soon-to-expire active-ingredient patents. Despite the obviousness implications, 35 U.S.C. § 103, the USPTO has accommodated this practice. Astellas went a step further here, specifying the dissolution profile that it *discovered* would address the troublesome food effect. Or, as Astellas put it: "The inventive concept of the '780 Patent was discovering the dissolution rate that would address the food effect and achieving it using previously known formulation technology." D.I. 541 at 5. Yet the claims remain invalid. The Court could not have better invoked *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012).

To be sure, this admission hardly surprised the Court since it was the fundamental theme of the Astellas case. Defendants challenged the asserted claims as insufficiently enabled and not adequately described. And across five days of trial, Astellas proclaimed that its asserted claims were so easy anyone of ordinary skill in the art could do it without any more explanation than a general description coupled with a laundry list of compatible compounds. What *did* surprise the Court was defendants' failure to articulate this critical defense despite Astellas's clear and repeated admission that the asserted claims were

invalid as a matter of settled, basic patent law. Accordingly, and to no avail, the Court made explicit its concern about validity.

The Court of Appeals for the Federal Circuit has a sufficient record to disagree. But the subsequent history of the Hatch-Waxman Act cautions that if there be only one realm in which courts ought to tack closer to Congress's word than to the parties' presentation of the case, it is pharmaceutical-patent cases arising under the Hatch-Waxman Act.

The Court notes this matter is currently on appeal to the Federal Circuit. To the extent this Court has any jurisdiction to supplement its earlier ruling, this order supplements the Court's prior ruling, [D.I. 571](#), otherwise the Defendant's motion, [D.I. 576](#), is denied.

Dated this 27th day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge