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Abbott Labs v. Gardner, 387 U.S. 136 (1967)

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ABBOTT LABS V. GARDNER, 387 U.S. 136 (1967)

Abbott Labs v. Gardner, 387 U.S. 136 (1967) is a leading Supreme Court case dealing with the “ripeness doctrine,” which prevents courts from ruling on matters that have not yet developed into a form that is appropriate for judicial resolution. In the federal courts, the ripeness doctrine derives in part from Article III of the Constitution, which gives the federal courts jurisdiction over “cases and controversies” but not over abstract questions or hypothetical disputes. Although ripeness concerns can arise in many contexts, one recurring issue—and the one at the heart of the Abbott Labs litigation—is whether a person can seek a review of an administrative regulation before the administrative agency attempts to enforce it.

The *Abbott Labs* case concerned a new Food and Drug Administration (FDA) regulation implementing a federal statute that required drug labels and advertisements to prominently display the drug’s generic name. The main purpose of the statute was to inform doctors and patients that many expensive drugs were identical to cheaper generic products. As the FDA interpreted the statute through this new regulation, the generic name had to appear every time the brand name appeared. Several dozen drug companies and their trade association filed a lawsuit against the FDA, contending that the regulation required more extensive use of the generic name than the authorizing statute contemplated. The government argued that the regulation’s validity could not be challenged until the agency enforced it against a violator. That is, the government contended that the suit was not “ripe.”

The Supreme Court, in an opinion by Justice John Marshall Harlan II, allowed the drug companies’ challenge to proceed. The Court first considered whether the specific statutes governing the FDA barred pre-enforcement review. Statutory provisions expressly allowed pre-enforcement judicial review in certain types of situations, but this did not persuade the Court that Congress meant to preclude pre-enforcement review in cases in which the FDA statutes did not mention such review. Having determined that there was no implicit statutory bar to review, the Court turned to more general principles of the ripeness doctrine. The Court stated that the ripeness inquiry has “a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.”

By applying these standards, the Court determined that the companies’ challenge to the regulation could be decided without waiting for any further factual development, because it presented a purely legal question regarding the agency’s statutory authority to issue the regulation. Further, turning to the consideration of hardship, the Court stated that the regulation was harming the companies even before enforcement, because in order to comply they would have to spend a great deal of money to prepare new labels. Yet if they did not comply and waited to be cited for a violation, they faced serious penalties. Given the dilemma facing the companies, the Court decided it would be inappropriate to delay a ruling.

Three justices, led by Justice Abe Fortas, sharply dissented. They argued that the statutory scheme did not allow for pre-enforcement review, and that these FDA regulations had to be challenged in the context of an

Abington Township v. Schempp, 374 U.S. 203 (1963)

enforcement action. They also contended that even if review were otherwise available under the governing statutes, this particular case did not present a concrete dispute ripe for review. The dissenters warned that the decision would endanger the public by allowing regulated entities to delay for years the implementation of regulations meant to protect public health and safety, a harm that far outweighed the hardship on the drug companies.

Abbott Labs v. Gardner was decided at the same time as two other related cases involving FDA regulations. One of those cases, *Toilet Goods Assn. v. Gardner*, 387 U.S. 158 (1967), provides a useful contrast. Here, the Court dismissed the suit on ripeness grounds. The lawsuit involved a challenge to the validity of an FDA regulation that required manufacturers of color additives to provide FDA inspectors with access to their facilities and formulas. The Court determined that a proper resolution of the case required further factual development regarding how and why the FDA would carry out the inspections, which the agency had not yet conducted. Turning to the issue of hardships, the Court stated that the regulation did not require the manufacturers to change any of their present processes in order to comply, and that the risk of hardship was too speculative.

The *Abbott Labs* litigation marked an important turning point. Before the case, pre-enforcement review of agency action was rare. Afterwards, it became a familiar feature of the administrative state. In addition, while *Abbott Labs* arose in the particular context of administrative law, its two-part ripeness inquiry is commonly cited in other contexts as well.

SEE ALSO *Article III; Case or Controversy; Ripeness*

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