

GILEAD SCIENCES, INC. v. LEE, Appeal No. 2014-1159 (Fed. Cir. February 26, 2015).
Before Dyk, Wallach, and Hughes. Appealed from E.D. Va. (Judge O'Grady).

Background:

Gilead filed a petition with the PTO challenging the PTO's assessment of a fifty-seven day reduction of patent term adjustment ("PTA") due to Gilead filing an IDS fifty-seven days after filing a response to a restriction requirement and before the examiner issued the next office action. Gilead argued that its filing of the IDS did not cause any actual delay and therefore should not have been subtracted from its PTA. The PTO rejected this argument and denied the petition. Gilead appealed to the district court.

In its appeal to the district court, Gilead argued that the PTO's interpretation and application of the relevant PTA statute was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation." The parties subsequently filed cross-motions for summary judgment, agreeing that only questions of law were in dispute. Finding that Gilead did not succeed in showing the PTO's interpretation was unreasonable, the district court granted the PTO's motion for summary judgment. Gilead appealed.

Issue/Holding:

Is the PTO's interpretation unreasonable that the filing of an IDS after submitting a reply to a restriction requirement constitutes a failure to engage in reasonable efforts to conclude prosecution of the application? No, affirmed.

Discussion:

Gilead argued that the PTA statute only allows for an assessment of Applicant Delay in instances where the applicant's conduct actually delays the conclusion of prosecution. In support of this argument, Gilead cited to the context of the surrounding statutory language and to the legislative history. The Federal Circuit was not persuaded by either line of argument. As to the language of the statute itself, the Federal Circuit concluded that nothing in the plain language of the statute suggests that "reasonable efforts to conclude prosecution of the application" requires the applicant's behavior to have actually caused a delay in concluding prosecution. In regard to the legislative history, the Federal Circuit indicated that Gilead did not contend that any provision in the statute was ambiguous so as to allow consideration of extrinsic materials, such as the legislative history, in interpreting the statute. Also, the House committee reports relied upon by Gilead were for bills that were not enacted. And, the Federal Circuit stated that the House committee reports relied upon by Gilead did not support Gilead's position, and instead further supported the PTO's position.

The Federal Circuit found that a reasonable interpretation of the statute is that Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred. The decision points out that although an applicant's conduct may not actually result in delaying the issuance of that applicant's patent, such conduct may result in delaying the issuance of patents of other patent applicants.