

## Federal Circuit Patent Bulletin: *Gilead Scis., Inc., v. Lee*

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February 27, 2015

*"[With respect to Patent Term Adjustment,] 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."*

On February 26, 2015, in *Gilead Scis., Inc., v. Lee*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Wallach,\* Hughes) affirmed the district court's summary judgment that the Director of the U.S. Patent & Trademark Office (PTO) properly calculated the Patent Term Adjustment (PTA) period for U.S. Patent No. 8,148,374, which related to a compound and method for inhibiting cytochrome P450 monooxygenase in a patient. The Federal Circuit stated:

In 1994, Congress changed the method of how a patent term is calculated. Under the previous statute, a patent's term ran from the date the patent issued until the end of a period measured from that date—generally seventeen years, subject to certain extensions. Under the 1994 statutory provision, the patent term still begins on the date of issuance, but generally ends twenty years after the patent application was filed. Under the new statute, because the duration of a patent is no longer solely predicated on its date of issuance, delays in the patent examination process decrease the length of an applicant's patent term. In order to address this issue, in 1999, Congress enacted provisions under which patent applicants may seek PTAs for delays caused by the PTO between the filing and issuance dates of the patent application. . . .

Gilead argues the PTA statute only allows for adjustments in instances where the applicant's conduct "actually delays the conclusion of prosecution." . . . "[T]he 'starting point in every case involving construction of a statute is the language itself.'" "Absent a clearly expressed legislative intention to the contrary, [the statute's plain] language must ordinarily be regarded as conclusive." Here Gilead's contention is problematic because nothing in the plain language of the statute suggests reasonableness requires the applicant's behavior to have an effect on when the prosecution ends. Furthermore, Gilead emphasizes the term "conclude prosecution," while ignoring that the statute's "reasonable efforts" language focuses on applicant conduct as

opposed to the results of such conduct. Finally, Gilead does not point to any language in the statute equating "reasonable efforts to conclude prosecution of the application" as described by § 154(b)(2)(C)(i) to applicant conduct requiring actual delay.

Gilead next argues "[a]nother statutory provision confirms Congress's intent to tie the 'reasonable efforts' clause to applicant behavior that causes actual delay." Specifically, Gilead contends "Congress identified one specific type of applicant behavior as a failure 'to engage in reasonable efforts to conclude processing or examination' of the application—taking over 3 months to respond to an office action." According to Gilead, by including a specific timeframe, this statutory provision requires actual delay. Therefore, Gilead argues Congress must have intended for the PTO to penalize only applicant behavior causing actual delay. Gilead urges this court to apply the rule of ejusdem generis to § 154(b)(2)(C)(ii) in finding that Congress intended the results of the applicant behavior described in that provision applies generally to § 154(b)(2)(C)(i). . . .

Here, ejusdem generis is inapplicable to this statutory provision. Subsection 154(b)(2)(C)(ii) provides one instance where Congress provided an example of applicant delay. However, the third subsection of the statute does not provide a general word or phrase, but rather employs broad language in directing the PTO to prescribe other instances in which applicant behavior that "constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." Therefore, the plain language of the statutory text does not support Gilead's contention that Congress meant to restrict such conduct solely to applicant conduct causing delay. . . .

Adoption of Gilead's interpretation of the statute necessarily leads to an illogical distinction between applicants whose conduct is intended to cause delay, but who nonetheless fail, from those whose conduct incidentally results in causing actual delay. In such a scenario, egregious and obvious delay tactics would remain unsanctioned merely because they do not result in actual delay. Thus, because the legislative history of the statute does not support the finding that Congress aimed to distinguish between patent applicants whose conduct attempts to delay issuance of a patent from those whose conduct actually results in a delay, this court rejects Gilead's attempt to read it into the statute. . . .

[T]his court is required to accept the agency's construction of the statute even if the agency's reading differs from what the court believes is the best statutory interpretation. . . . Congress expressly delegated authority to the PTO by granting authority to "[t]he Director [to] prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." As permitted by statute, the PTO promulgated 37 C.F.R. § 1.704(c)(8), which encompasses the

precise situation in this case—the filing of a supplemental IDS after submission of a reply to a restriction requirement. Such broad language demonstrates Congress intended the PTO to employ its expertise in identifying applicant conduct demonstrating a lack of "reasonable efforts to conclude processing or examination of an application." Therefore, this court finds 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 statute expressly requires the PTO to respond to a reply under 35 U.S.C. § 132 within four months after the date the reply is filed. Because the PTO characterizes restriction requirements as § 132 notifications, it has a significantly reduced window of time to reply to the patent applicant. . . . The regulation is a reasonable interpretation of the statute because the filing of a supplemental IDS after an initial reply to a restriction requirement further adds to the list of documents the PTO must consider before responding to the restriction requirement. Therefore, the additional documents make it increasingly difficult for the PTO to satisfy the statutorily-mandated time requirement stipulated in § 154(b)(1)(A)(ii).