

## USPTO Cannot Count Time During Which Applicant Is Unable to Take Action As Applicant Delay

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*Supernus Pharmaceuticals, Inc. v. Iancu*, No. 2017-1357 (Fed. Cir. Jan. 23, 2019)

During prosecution of its U.S. patent application, the patent owner filed a request for continued examination (RCE) after a final Office Action. After filing the RCE, the patent owner learned that an opposition had been filed against the corresponding European patent. One hundred days after receiving notification of the opposition, the patent owner filed a supplemental information disclosure statement (IDS). The U.S. application ultimately issued as a patent, and the U.S. Patent and Trademark Office (USPTO) decided that the patent should receive 1,260 days of Patent Term Adjustment (PTA). The PTA time included an assessment of 646 days of applicant delay for the time between the filing of the RCE and the submission of the IDS. The patent owner filed a request for reconsideration of the PTA but the USPTO rejected the request, concluding that the prior Federal Circuit decision in *Gilead Sciences, Inc. v. Lee* applied and the reduction in PTA was proper.

In the district court, the patent owner argued, in part, that 37 C.F.R. § 1.704(c)(8) and (d)(1) are arbitrary, capricious, and contrary to the PTA statute and, further, that it was entitled to 546 days of the 646-day delay. The district court granted summary judgment in favor of the USPTO finding that the USPTO did not err in its PTA calculation and, further, that the *Gilead* decision foreclosed the patent owner's arguments. The patent owner appealed to the Federal Circuit.

In addressing whether the USPTO may reduce PTA by a period that exceeds the "time during which the applicant failed to engage in reasonable efforts to conclude prosecution" under 35 U.S.C. § 154(b)(2)(c)(i), the Federal Circuit held that the district court erred when it granted summary judgment on the basis of *Gilead*. The Federal Circuit found that *Gilead* was not controlling because *Gilead* involved different facts and a different legal question. The court noted that, unlike *Gilead*, this case was not about whether the patent owner's efforts, or those it could have taken, resulted in actual or potential delay. Rather, the patent owner could not have taken any actions to conclude prosecution until the filing of the opposition to the European patent.

Because this case involved a question of statutory interpretation, the Federal Circuit applied a Chevron analysis, and found the first step of Chevron was met because the pertinent language of the PTA statute was clear and unambiguous. Noting that "the statute expressly requires that any reduction to the PTA **be equal** to the period of time during which an applicant fails to engage in reasonable efforts" and "the statute expressly ties reduction of the PTA to the specific time period during which the applicant failed to engage in reasonable efforts," the Federal Circuit

concluded that the USPTO could not “count as applicant delay any period of time **during which** there were no efforts in which the applicant could have engaged to conclude prosecution of the patent.” *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1359-60 (Fed. Cir. 2019) (emphasis in original).

Accordingly, the Federal Circuit held that the PTA reduction here was inconsistent with the statute, accorded no deference to the USPTO’s application of the regulations at issue, and reversed and remanded the district court’s grant of summary judgment.

[A copy of the opinion can be found here ►](#)

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[Mike Rueckheim](#)

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