

NOVARTIS AG v. LEE, Appeal Nos. 2013-1160, -1179 (Fed. Cir. January 15, 2014). Before Newman, Dyk, and Taranto. Appealed from D.D.C. (Judge Huvelle).

### Background:

Novartis filed a civil action in the district court, claiming that the USPTO had improperly determined the amount of B-delay patent term adjustment (PTA). Novartis argued that 35 U.S.C. §154(b)(1)(B) was contrary to the USPTO's interpretations that (1) any time consumed by an RCE is excluded from the B-delay PTA determination, even if a first RCE is filed after the three-year window allotted to the USPTO to issue a patent has closed, and (2) "time consumed by" an RCE includes the time from allowance to issuance of the patent. The district court held that the USPTO's reduction of B-delay PTA when a first RCE is filed after the three-year period is contrary to law. Because of this holding, the district court did not address Novartis' alternative argument regarding the proper interpretation of "time consumed by" an RCE. The USPTO appealed.

### Issues/Holdings:

Did the district court err in holding that the USPTO's reduction of B-delay PTA when a first RCE is filed after the three-year period is contrary to law? Yes. Is the USPTO's interpretation that "time consumed by" an RCE includes the time from allowance to issuance of the patent contrary to law? Yes. Affirmed in part, reversed in part, and remanded for a redetermination of the proper PTA.

### Discussion:

The Federal Circuit agreed that the USPTO's reading of 35 U.S.C. §154(b)(1)(B) was correct, i.e., no B-delay PTA is available for any time consumed in continued examination, even if the first RCE was filed after the three-year window allotted to the USPTO to issue a patent has closed. The Federal Circuit reasoned that this is consistent with (i) the statutory text, which does not set a time-of-initiation restriction for RCEs, and (ii) the underlying policy in PTA calculations that if delays are not "due to the failure" of the USPTO, then they should not count toward the three-year period allotted to the USPTO to issue a patent.

The Federal Circuit nonetheless agreed with Novartis on the issue of when "time consumed by" an RCE ends. In particular, the Federal Circuit rejected the USPTO's argument that the time between allowance and issuance is "time consumed by" an RCE and should be excluded from B-delay PTA. The Federal Circuit pointed out that the allowance-to-issuance time would count toward the USPTO's three-year allotment in a case not involving an RCE, and concluded that there was no basis for treating an RCE case differently. The Federal Circuit also noted that the common-sense understanding of "time consumed by" an RCE is time up to allowance, but not later, unless examination on the merits is reopened.