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NEW U.S. COURT RULING COULD ADD TO THE TERM OF U.S. PATENTS

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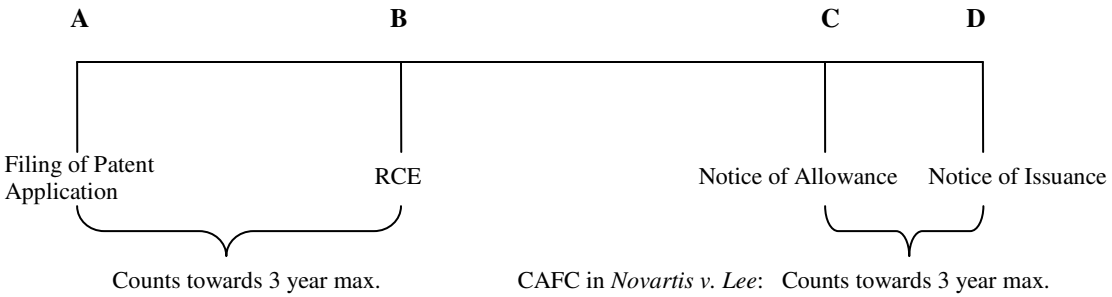
The U.S. Court of Appeals for the Federal Circuit (CAFC) case of *Novartis AG v. Lee*, decided on January 15, 2014, is an appeal by plaintiff Novartis and a cross-appeal by defendant U.S. Patent Office (PTO) of a ruling of the district court regarding the PTO's determination of how much time to add to the patent term of various Novartis patents. The PTO cross-appealed the district court's ruling that the PTO had improperly determined the amount of patent term adjustment to which Novartis was entitled.

By way of background, the enforceable life or "term" of a U.S. patent begins on the date the patent is issued and generally ends 20 years from the date the application was filed. Although 20 years is the general term, additional time may be added under what is known as patent term adjustment (PTA).

Particularly, under 35 U.S.C. §154(b)(1)(B) (the PTA statute), if allowable claimed subject matter is present, an applicant is guaranteed to have a patent issued within 3 years of filing a patent application. If a patent application remains pending longer than 3 years due to delays on the part of the PTO, the applicant is entitled to have the extra time added to the usual 20 year term. In other words, the PTO is allotted a maximum of 3 years to issue a patent from the date an application is filed. The PTA statute was created to compensate for delays in the patent examination process that may significantly reduce the effective term of the patent.

The ruling of the CAFC in *Novartis AG v. Lee* entitles applicants to even more time added to the patent term under the PTA statute. The CAFC held that, contrary to the PTO's previous practice, the time between the Notice of Allowance and the Notice of Issuance of the patent does count towards the 3 year maximum allotted to the PTO (please see the diagram below).



If (time period A to B) + (time period C to D) > 3 years, the patent term is eligible to be adjusted by increasing the term.

Therefore, any delay between the Notice of Allowance and the Notice of Issuance of the patent should be added to the total time period of pendency of the patent application to determine whether the 3 year maximum has been exceeded.

For three of Novartis' patents, the CAFC found that the PTO had improperly refused to count the time from allowance to issuance when determining the total pendency of the respective patent applications, even though the time from allowance to issuance was plainly attributable to the PTO. Furthermore, the CAFC held that the filing by Novartis of an RCE during the course of prosecution did not change the analysis.

Decision: The PTO had erred in calculating the patent term adjustment for three of Novartis' patents because the time between allowance and issuance had been improperly excluded. The district court's judgment is partly UPHELD and partly REVERSED, and the case is REMANDED for redetermination of the proper patent term adjustments.

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