

Client Alert

November 2015

Will Patentees Receive Patent Term Adjustment After *Novartis* and *Gilead*?

Recent Federal Circuit decisions permit the US Patent and Trademark Office (“Patent Office”) to reduce, even deny, Patent Term Adjustment (“PTA”) due to common prosecution practices by its interpretation of *Novartis AG v. Lee*, 740 F.3d 539 (Fed. Cir. 2014) (“*Novartis*”), *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014) (“*Gilead I*”), and *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) (“*Gilead II*”). Patentees may lose PTA if they file a Request for Continued Examination (RCE) prior to the “3-year date,” or by being required to file Terminal Disclaimers over earlier-issued patents, or they may lose PTA for supplemental filings after a reply is filed. The Patent Office’s interpretation of these three court decisions may effectively eviscerate the statute Congress passed to compensate patentees for Patent Office delays in examination.

The term of a US patent is 20 years from filing, but the effective life is reduced by USPTO delays. 35 U.S.C. § 154 compensates for these USPTO delays by PTA. The statute maximizes applicant correction and minimizes USPTO delay.

Novartis—The Timing of an RCE Filing May Negate B Delay PTA

A patent application may begin to accrue PTA if the patent application pends longer than three years, but does not include “any time consumed by continued examination” (i.e., RCE); this is referred to as “B Delay.” 35 U.S.C. § 154(b)(1)(B)(i). The question of how the time consumed by an RCE was tolled was the subject of *Novartis*, in which the Federal Circuit held that:

[T]he PTO argues that “any time consumed by continued examination,” id. § 154(b)(1)(B)(i), no matter when initiated, does not count toward depleting the allotment of three years the PTO has before any adjustment time begins to accrue. In the PTO’s view, no adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing. On this point, we agree with the PTO.

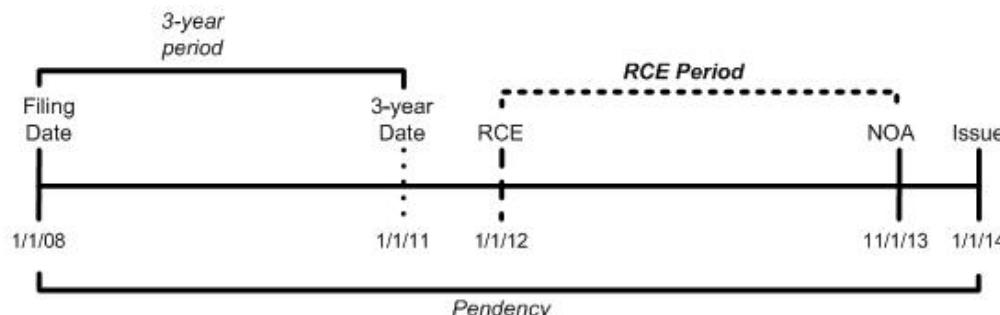
The Federal Circuit continues:

The better reading of the language is that the patent term adjustment time should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years. Such a reading ensures that applicants recover for any “delay[s] due to the failure of the [PTO],” without allowing the applicant to recover for “any time consumed by continued examination,” as the statute requires. Id. § 154(b)(1)(B)(i). Novartis has not given any persuasive reason that this reading of the statute is incorrect.

The Federal Circuit held that an RCE only *pauses* the accrual of B-Delay PTA during the pendency of a patent application. The accumulation of PTA *resumes* after the mailing of a Notice of Allowance until the date the patent issues. An applicant is entitled to a B-Delay PTA only to the extent that there is an excess of three years of pendency minus any time consumed by an RCE. This appeared to offer patentees a reprieve from the Patent Office's previous complete denial of any B-period PTA earned after the filing of an RCE.

Accordingly, the USPTO has applied the holding in *Novartis* as follows:

- (1) Calculate the number of days the patent application is pending, i.e., the period from the filing date to the issue date ("pendency");
- (2) Calculate the number of days "any time consumed by continued examination," i.e., from the date an RCE is filed until the mailing of a Notice of Allowance ("RCE period");
- (3) Calculate the number of days from the filing date to the three-year date ("3-year period");
- (4) Subtract the RCE (2) from the pendency (1) = pendency minus RCE period; and
- (5) Subtract the pendency minus RCE period (4) from the three-year period (3) = B-period.

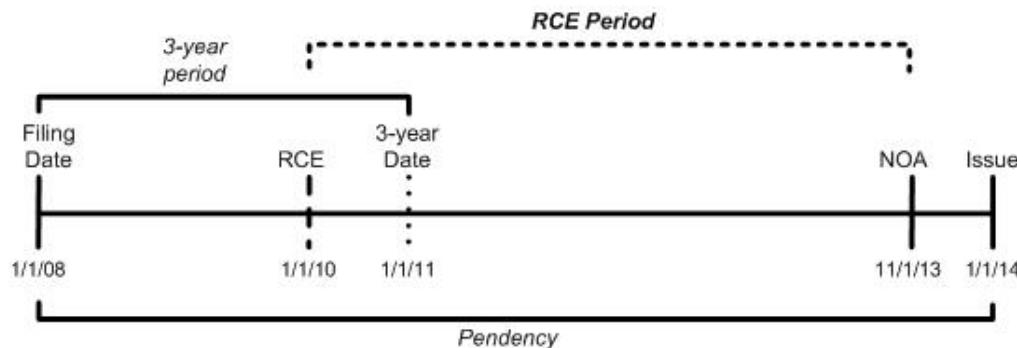


In this example, the RCE is filed *after* the three-year date; the PTA is calculated as:

$$\begin{aligned} &(\text{Pending} - \text{RCE Period}) - \text{three-year period} = \text{B delay} \\ &(2,192 \text{ days} - 679 \text{ days}) - 1,096 \text{ days} = 417 \text{ days} \end{aligned}$$

Thus, if an RCE is filed *after* the three-year date, an Applicant can be rewarded with additional B-Delay PTA from the Notice of Allowance to Issuance (usually approximately 90–120 days).

However, if the RCE is filed *prior* to the three-year date, the RCE period may negate the entire B-period.



In this example, the RCE is filed *before* the three-year date; the PTA is calculated as:

(Pendency – RCE Period) – three-year period = B delay

(2,192 days – 1,401 days) – 1,096 days = 0 days

In this second example, an RCE filed prior to the three-year date may offset any potential PTA that may have been earned under *Novartis*.

The Patent Office rationale may lie in the policy behind a 20-year patent term. Under the pre-GATT regime, a patent received a 17-year term at grant. This allowed applicants to perpetually file continuing patent applications, maintaining patent application pendency indefinitely without losing patent term. (The most successful patentee who maximized this strategy was Jerome Lemelson, who, in one example, maintained continuations of a patent application first filed in 1954, which finally was granted in 1992 as US Patent No. 5,144,421, and did not expire until 2009, 55 years after filing.) In 1995, with the adoption of GATT, patent term was limited to 20 years from filing, in part to harmonize US patent law with our trade partners. However, between 1995 and 2000, Patent Office delays cost patentees years of patent term. To remedy this, Congress created Patent Term Adjustment in 2001, which, in part, awarded extra patent term if a patent application pended longer than three years (e.g., restoring the 17-year term). This became known as “B Delay.”

However, RCEs presented a problem because they allowed applicants to indefinitely maintain a patent application as pending and, thereby, accrue unlimited “B Delay.” To prevent this, Congress specified that the “any time consumed by continued examination” was to be excluded from the calculation of B Delay. Thus, an applicant may file multiple RCEs, but they lose patent term that they cannot recover through B Delay. Under *Novartis*, the Federal Circuit interpreted that the rules allowed the Patent Office to subtract the “RCE period” (see above) regardless of when the RCE was filed. This is based on the concept that the filing of an RCE was a “failure to engage in reasonable efforts to prosecute”. 35 U.S.C. § 154(b)(2)(C). Even if awarded the B Delay running from the mailing of a Notice of Allowance to Issue, this is more often offset by the deduction for the time from filing an RCE to the 3-year period date. With this in mind, practitioners should take into consideration the 3-year date when filing the first RCE as it may adversely affect the potential B-Delay PTA a patentee may be awarded under *Novartis*.

Gilead I—Terminal Disclaimers Negating Earned PTA

In *Gilead I*, the Federal Circuit held that the absence of a Terminal Disclaimer (TD) in both of two related patents constituted an unfair extension of patent term. This decision did not take into consideration the unusual combination of a pre-GATT and post-GATT patent, which led to a large patent term difference for the particular case.

Gilead is the assignee on US Patent Nos. 5,763,483 (“the ‘483 patent”) and 5,952,375 (“the ‘375 patent”), both directed to antiviral compounds and methods of use. The ‘483 and ‘375 patents share common inventors, but they do not share common priority and have different patent expiry dates. The ‘375 patent

has a priority date of February 27, 1995, issued on September 14, 1999, and expired on February 27, 2015. The '375 patent is a pre-GATT patent and was awarded 17 years of term from issue. The '483 patent was filed on December 27, 1996, has a priority date of December 29, 1995, issued on June 9, 1998 (before the '375 patent), but will expire on December 27, 2016 (after the '375 patent). The '483 patent is a "post-GATT" patent that receives 20 years of term from the filing date, plus days of PTA.

The Federal Circuit held that the principle protected by the obviousness-type double patenting doctrine "is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention," as "is the case here." Slip op. at 11. To remedy this, the assignee would be required to file a Terminal disclaimer over both patents.

Commonly, the first patent in a family pends the longest and accrues the most PTA. This effectively set a "ceiling" for patent term for continuing patents in the family. Later patents generally benefit from the prosecution of the parent and do not pend as long, resulting in less or no PTA. However, after *Gilead I*, a patentee may be required to file a Terminal Disclaimer to limit the term of the patent to the *shortest* of the patent terms, effectively eliminating any PTA earned in the first patent. Also, failure to file the Terminal Disclaimer may be grounds for invalidity under *Gilead I*. Further, the Patent Office may require a Terminal Disclaimer be filed in *all* patent applications subject to a non-statutory double patenting rejection. This holding encourages applicants to file divisional patent applications (directed to claims restricted by the USPTO from the rest of the original claims), because patent applications filed as divisional patent applications may be exempt from nonstatutory double patenting rejections.

Gilead II—Expanded Applicant Delay

In *Gilead II*, the Federal Circuit held that the Patent Office may deduct "Applicant Delay" for the period between the filing of a Reply to Office Action and a subsequent Information Disclosure Statement ("IDS") filed after a reply. In *Gilead II*, the patentee filed an IDS 57 days after they filed a response to a Restriction Requirement. This was treated as "Applicant Delay" by the Patent Office, and the Federal Circuit agreed, that this filing could delay "the processing and examination of other applications before the examiner." 778 F.3d at 1350.

This holding by the Federal Circuit has been broadly interpreted by the Patent Office to allow for "Applicant Delay" deductions for *any* filing after a reply except when expressly requested by the Examiner. 37 C.F.R. § 1.704(c)(8). *Gilead II* may have the practical effect of penalizing patentees for the common practice of filing a Supplemental Reply following a Patent Office Interview. This is regularly done to simplify issues, and often, leads to allowance after the discussion with the USPTO. Practitioners must be careful to make it clear on the record that any supplemental reply was done at the express request of the Examiner. 37 C.F.R. § 1.704(c)(8). It is noted that an IDS filed based on a foreign Office Action, which is allowed by USPTO rules, does not constitute an Applicant Delay if filed within 30 days of receipt by someone involved in preparation and/or prosecution of the patent application (which would not appear to include a foreign agent involved only with prosecution of a foreign counterpart of the patent application). 37 C.F.R. § 1.704(d)(1)(i).

Conclusion

Applicants should take into consideration the three-year date from filing of a patent application before filing an RCE to avoid losing potential B delay PTA under *Novartis*. Additionally, Applicants may favor filing only divisional patent applications to seek "safe harbor protection" under 35 U.S.C. §121, thereby avoiding double patenting rejections and multiple Terminal Disclaimers under *Gilead I*. Further, it should be made clear on the record that any Supplemental Reply was authorized by the Examiner to avoid any Applicant Delays under *Gilead II*.

The lawyers of Hunton & Williams LLP are available to assist patent applicants in their efforts to maximize patent term through patent term adjustment, while also counseling clients on how to proactively avoid problems associated with the court's decision.

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