Virginia District Court Denies Extra Patent Term Adjustment When National Stage Entry Date Falls On A Holiday

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Some *patent term adjustment (PTA)* cases have broad impact–like *Wyeth v. Kappos* and *Novartis v. Lee*-but *Acetelion Pharmaceuticals, Inc. v. Lee* addresses a more esoteric issue: when does the 14-month clock start to run in a U.S. national stage application when the 30-month national stage entry days falls on a Federal holiday? Judge O'Grady of the U.S. District Court for the Eastern District of Virginia agreed with the USPTO that the clock does not start to run until the next business day.

Type "A" Delay Under The PTA Statute

The PTA statute (35 USC § 154(b)) was created to compensate for delays in the patent examination process that can erode the effective term of a patent, which is measured from the patent's earliest non-provisional U.S. priority date. The statute provides "guarantees" against different types of USPTO delays, and requires a day-for-day deduction of Applicant delays against USPTO delays.

The issue in *Acetelion* relates to "A" delay, which accrues when the USPTO fails to act in accordance with set time frames including failing to issue a "notification under section 132" (*e.g.*, a Restriction Requirement or Office Action) within 14 months of "(I) the date on which an application was filed under section 111(a); or (II) the date of commencement of the national stage under section 371 in an international application."

Starting The 14-Month Clock In U.S. National Stage Applications

Under the America Invents Act Technical Corrections Act (AIA TCA) (effective Jan. 14, 2013), the 14-month clock begins to run in a U.S. national stage application on "the date of commencement of the national stage." Under the PCT, the national stage of examination will not commence until "expiration of 30 months from the priority date," unless an applicant makes an "express request" for early examination. See PCT Article 23. In accordance with PCT rules, if "the expiration of any period" falls on an official holiday for the patent office at issue, then "the period shall expire on the next subsequent [business] day." See PCT Rule 80.5.

The Acetelion National Stage Timeline

The patent at issue in *Acetelion* was granted from a U.S. national stage application filed January 12, 2012. According to the district court decision, the application was filed with "a Form PT0-1390 Transmittal Letter," on which the applicant did *not* check the box indicating that the application was "an express request to begin national examination procedures." However, the application also was filed with a Preliminary Amendment which included a statement that "Applicant earnestly solicits early examination and allowance of these claims. …."

On January 26, 2012, the USPTO issued a Filing Receipt indicating receipt of the "35 U.S.C. §§ 375 (c)(I), (c)(2), and (c)(4) REQUIREMENTS" on January 12, 2012 and designating January 16, 2012 as the "DATE OF COMPLETION OF ALL 35 U.S.C. § 371 REQUIREMENTS[.]" However, January 16, 2012, was Martin Luther King, Jr. Day.Thus, when the USPTO calculated A delay for the patent, it started the 14-month clock on January 17, 2012.

Does The PCT Holiday Rule Impact PTA?

One of Acetelion's arguments was that the USPTO abused its discretion when it started the the 14-month clock on January 17, 2012, instead of January 16, 2012. The USPTO justified this calculation based on PCT Rule 80.5, but Acetelion argued that the rule only should be invoked to help, not hurt, applicants:

[T]he weekend/holiday extension should only apply where a filer's right would be protected by extending the deadline to the next business day whereas here, the length of Plaintiffs PTA and the rights associated with the increased patent term duration are constrained by the extension.

Acetelion also noted that the USPTO did not have to take any action in order for the 30 month period to expire, such that the timing of the holiday was irrelevant. The court rejected these arguments:

Because a filer can take actions on the expiration date, the PTO must be available to receive and take action on such filings–which is not possible on a weekend or federal holiday... Accordingly, [the USPTO's] decision to apply the weekend/holiday exception is consistent with the interpretation of similar statutory provisions and is not a clear error of judgment.

The court therefore granted summary judgment in favor of the USPTO.

What About The Filing Receipt?

One dissatisfying aspect of this decision is the court's failure to address the January 16, 2012 date listed on the Filing Receipt. Another dissatisfying aspect of this decision is the presumption that the USPTO must be able to "receive and take action" on the date submissions are made. Does the court think USPTO personnel review every document on the day it's filed?

A Less Esoteric PTA Issue

Stakeholders following the PTA issues surrounding <u>Information Disclosure Statements</u> filed when an application is awaiting examination after a Request for Continued Examination (RCE) may be interested in Judge Lee's decision in <u>Supernus Pharmaceuticals, Inc. v Lee</u>.

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