

PTA Strategies: Wyeth, RCE's and the PCT*

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Roughly *half* of all patents granted today are eligible for Patent Term Adjustment (PTA); more could have been, but for strategic procurement choices.

New strategies must be considered in view of (a) the *Wyeth* case; (b) backlog growth; and (c) the new Kappos RCE policies.

Corporate principals need to provide counsel informed direction keyed to business objectives to permit proper crafting of procurement strategies to maximize protection while minimizing procurement expenses.

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Contents

- Nominating Corporate Procurement Objectives 5
- Continuations, Continuations-in-part
and Divisionals 9
- RCE's versus Continuations, CIPs and Divisionals 10
- The "A", "B" and "C" Types of PTA 11
- The Critical "B" Period 12
- Post-RCE: No "B" Period 13
- RCE's should be filed late in the Process 14
- Divisionals Should be Filed Early in the Process 15

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Contents (con'd)

| | |
|---|----|
| ● PCT Priority and the PTA | 16 |
| ● PCT Should not Enter U.S. via Continuation | 20 |
| ● <i>Wyeth v. Kappos</i> Federal Circuit Appeal | 21 |
| ● Minimizing Procurement Expenses | 29 |
| Double Patenting | 31 |
| Explicit Written Instructions | 32 |
| Endnote – authorship and contact information | 33 |

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Nominating Corporate Patent Procurement Objectives

1. Is the *latest expiration date* very important?
2. Is an *early grant date* important?
3. Is procurement *cost minimization* of greater importance than term maximization or an early grant date?

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Nominating Objectives (*con'd*)

Corporate objectives should be spelled out *in writing* so counsel will implement a procurement strategy consistent with corporate objectives.

(Counsel *today* may understand corporate objectives, but what happens when counsel picks the case up for action, say, three years from now?)

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- Where deferral of patent term expiration date is important, then the strategies must be tailored to meet this objective.
- ***Dual patenting strategies*** should be considered where *both* an early grant of a patent ***and*** a latest patent termination date are important. See slides 15-16.

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Costs! “No” Answer to Questions (1) and (2)

If a patent term adjustment* is unimportant and if there is no need seen for PTA vis a vis saving prosecution costs, an RCE-based deferral of examination should be considered. See slides 29-30.

*Note: Throughout this presentation, patent term *adjustment* is referred to as opposed to a patent term *extension* to distinguish the PTA law from a Patent Term Extension (PTE) granted based upon a regulatory delay.)

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Continuations, CIPs and Divisionals

1. A continuation, continuation-in-part or divisional filing ***extinguishes*** any right to patent adjustment for any period prior to the filing of such continuation, continuation-in-part or divisional .
2. Therefore, any divisional (or other continuing) application should be filed ***as soon as possible*** because there is ***no PTA credit for pendency prior to the actual divisional application filing date.***

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RCE's versus Continuations, CIPs and Divisionals

1. An RCE filing does *not* extinguish any ***already earned*** adjustment periods for “A” or “B” or “C” adjustments prior to a first RCE.
2. An RCE filing ***blocks any*** future “B” adjustment credits.
3. The right to earn continued adjustment periods continues for both “A” and “C” events after any RCE filing.

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The “A”, “B” and “C” Types of PTA:

“A” Period: PTO Examination and Processing Delays
Balanced Against Applicant Prosecution Delays

“B” Period: Extensions for Pendency Greater than Three Years (exclusive of “C” delays and exclusive of applicant’s diligence adjustments).

“C” Period: Patentability Merits Appeal (and Interference or Secrecy Order) Delays.

Mandamus and Other non-“C” Court Actions:
Actions other than “C” actions are “B” Adjustments.

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The Critical “B” Period

Because of the enormous patent application backlog of 800,000 applications, a patent will generally have a pendency of greater than three years, i.e., **every** patent will have a “B” adjustment for the period beyond three years pendency absent diligence deductions (unless an RCE is filed within the first three years or the patent is keyed to a continuing application granted in less than three years).

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Post-RCE: No "B" Period

Any RCE filed within the first three years from pendency *kills* any **subsequent** "B" Period extension *beyond the RCE filing date*.

Thus, any extended pendency period that is not subject to an "A" or "C" adjustment **must** take place before any RCE is filed or such pendency period is forfeited for adjustment purposes.

Regardless of when an RCE is filed, however, a patent still may earn A adjustment and/or C adjustment.

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RCE filings late in the Process

Because B delay is not credited until three years from the filing date, it may be beneficial to refrain from filing an RCE until after the 3 year date has passed, if you can do so without accumulating Applicant delay.

Prosecution diligence is important during the “B” period as deductions will be made, e.g., for responses filed more than three months after an Office Action.

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Divisionals Should be Filed Early in the Process

If a divisional application will be necessary and if patent adjustment for the divisional is important, the divisional should be filed as soon as possible because the PTA adjustment clock for the divisional commences only as of the *actual filing date*:

The entire pendency of the original application before the divisional is filed is *irrelevant* to the patent term of the divisional.

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Any divisional application generally should be filed *after* a restriction requirement to permit the divisional to enjoy the statutory shield of 35 USC 121 against double patenting.

Earliest possible election is therefore key to employing early divisional filing strategy.

(Filing a divisional at an early date must be weighed against the pros and cons of a later rejoinder possibility.)

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PCT Priority and the PTA

Under the *statutory wording* the “B” period for a patent based upon a PCT filing commences from the PCT *actual filing date* and not the later “national stage” date.

But, under *PTORules* the “B” period commences from the “national stage” filing date which is generally 18 months later.

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PTO is thus routinely depriving PCT-based patentees of at least 18 months of “B” patent term adjustment.

Challenge to PTO failure to follow the statute should involve a request to adjust the term within two months of the initial determination and a civil action within six months of grant.

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Success of a challenge to the PTO interpretation will depend upon whether PTO accepts request for reconsideration (which would mean a repudiation of its existing rules) or a court challenge.

Various factors will influence the chances of success of such a court action.

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PCT Should not Enter U.S. via Continuation

PCT-based patent applicants who enter the national stage by means of a ***continuation*** of the original PCT application may not qualify for a patent adjustment as of the PCT filing date because the continuation is a ***new*** application.

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Wyeth v. Kappos Federal Circuit Appeal

Wyeth v. Kappos, Fed. Cir. No. 2009-1120 (arg. October 7, 2009)(Rader, Plager, Moore, JJ.), is a PTO appeal from a District Court decision, *Wyeth v. Dudas*, 580 F.Supp.2d 138 (D.D.C. 2008)(Robertson, J.), that interpreted the PTA law as giving a longer adjustment than under the PTO calculation method.

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The *Wyeth v. Kappos* Controversy:
Are the “A” and “B” periods additive?

- **Per Wyeth Court Decision**: Yes as to “A” delays within first three years after grant (before the “B” period starts after three years).
- **Per PTO**: No, as to “A” delays in first three years which are “cumulative” to B delays.

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Hypothetical Example to Illustrate Wyeth: A patent application receives a first action 28 months (two years and four months) after filing with no further “A” delays until the grant which is five years from the filing date.

There is a two year “A” delay because a first action or allowance is due within 14 months from filing.

There is a two year “B” delay because a patent is promised to be granted within three years.

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Wyeth Example (con'd):

Under the Wyeth District Court interpretation, the net adjustment is four years, i.e., the two “A” years and the two “B” years. There is no “double counting” because the “B” delay period **starts** after three years.

Per the PTO view on appeal, the total adjustment is two years because the “B” period (per the PTO) starts from **filing**.

(“Double counting is not permitted so the “A” delay period cannot be “double counted.”)

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Wyeth appeal: A Likely Early 2010 Decision

If the patentee-appellee Wyeth wins the appeal, the impact will directly apply **only to Wyeth** (and the other various plaintiffs in pending District Court actions against the PTO that have been suspended pending a decision in *Wyeth v. Kappos*).

(The case law *will* of course apply to future patents and patents granted within 180 days if a timely court action is taken, but the new case law will not be **retroactively** applied for current patentees outside the six month time window for a civil action.)

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The PTO today is not following the District Court decision and continues to provide only for the shorter patent adjustments, contrary to the District Court decision: ***The six month deadline for filing after the grant of the patent should not be missed.***

It is important to now take appropriate action even prior to the Federal Circuit decision in *Wyeth* for others with an allowed application who have not filed an action at the District Court or patentees with a recently granted patent where there is no pending civil action.

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For existing patents granted six-plus months ago:

There is no basis to file a civil action under the PTA law because the six month period is ***statutory***.

There is also no basis to file a request for reconsideration to the PTO under the PTA ***implementing rules***:

But, should a petition to waive the rules be accepted because of the PTO's mistake?

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Prospectively, a party entitled to the longer period under the District Court interpretation should file a request for adjustment of the term within two months of a PTO decision ***in the patentee's own case*** and/or file a civil action within 180 days from grant.

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Minimizing Procurement Expenses

A PTA strategy is relatively **expensive** in terms of up-front costs because of a variety of PTA-driven factors including earliest responses without extensions of time, presentation of declaration or other evidence early in the prosecution process and presentation of broad claims at an early stage before the true **commercial** scope needed for protection can be determined.

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Deferral of Expenses is more important (con'd)

Where minimizing procurement expense is of paramount importance, counsel should be thusly instructed so that PTA maximization is *not* an objective of the procurement exercise while cost deferral *is* of greater importance.

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Double Patenting

If there are two patents granted to related subject matter with differing patent expiration dates, consideration must be given to the effect of a terminal disclaimer.

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Explicit Written Instructions

- Corporate patent objectives should be explicitly spelled out in writing at the outset of prosecution:
- It could be imagined that particularly absent instructions to the contrary, counsel may well be to minimize procurement delays which would maximize patent adjustment but greatly add to costs.
- Counsel “today” may understand corporate objectives, but will this be recalled several years downstream during late prosecution of the application?

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Endnote *

This analysis is based upon the experience of the authors who have representing parties against the Office and counseled on strategies dealing with patent term adjustment.

The opinions expressed herein represent the personal views of the authors and do not necessarily reflect the views of any colleague, organization or client thereof.

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