

United States

BioPharma Patents

QUICK TIPS & NEWS

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QUICK TIPS

A. FOUR TIPS FOR OVERCOMING U.S. OBVIOUSNESS REJECTIONS:

- 1) **Advantages:** Do not argue an advantage unless the advantage is attributable to a claim limitation. Otherwise, see if it is possible to recast the "advantage" as an unexpected result. Remember to explain why the result is unexpected.
- 2) **Claim Limitations:** Only argue limitations which are present in the claims.
- 3) **Compound Claims:** For compound claims, remember the Examiner must support a

QUICK NEWS

A. PATENT TERM ADJUSTMENT (PTA) UPDATE:

TAKE AWAY

Patentee is now entitled to part B delay PTA from the time of Notice of Allowance until the issue date of the patent regardless of when an RCE is filed.

In *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) the Federal Circuit held in favor of the USPTO's interpretation of the PTA statute that filing an RCE at any time results in reduction of part B delay. However, the Federal Circuit held that the amount of reduction in PTA is the period from the day the RCE was filed to the

reason to (1) select the closest prior art compound, and then (2) modify the closest prior art compound to arrive at the claimed compound. Separately argue why (1) and (2) are not satisfied.

- 4) **Product-by-Process Claims:** Do not argue process limitations in product-by-process claims. Patentability is determined on product structural limitations.

B. TIPS FOR AVOIDING REQUEST FOR CONTINUED EXAMINATION (RCE) FILINGS:

- 1) Prepare claims early for U.S. entry.
- 2) Interview examiners early and often as needed.
- 3) Use the USPTO After-Final Consideration Pilot Program 2.0 (AFCP 2.0). No USPTO fee and program is extended until 30 September 2014.
- 4) A final office action will be withdrawn as incomplete if a restriction requirement made earlier in prosecution was improper. More than 70% of petitions against restriction requirements from bio/pharma art units are successful. One may only petition if the restriction requirement was traversed, so remember to traverse. It is important, however, not to say anything in the traversal argument that disclaims claim scope. *See, Uship LLC v. United States*, 714 F.3d 1311 (Fed. Cir. 2013).

period from the day the RCE was filed to the day a Notice of Allowance was sent (not to the day the patent issued as currently calculated by the USPTO), unless exceptional circumstances arise. **Therefore, many U.S. patents may be entitled to additional PTA.**

REMEMBER: The deadline to file a request for reconsideration of PTA is 2 months after the patent issues, which is extendible for up to 5 additional months with payment of fee(s).

B. PATENT LAW TREATY IMPLEMENTATION (EFFECTIVE 18 DEC 2013):

- 1) Claims no longer required in non-provisional application (other than design patent) to secure filing date (although this is not a recommended practice because adding new matter after the filing date is prohibited).
- 2) Allows for restoration of patent rights via revival of abandoned applications and acceptance of delayed maintenance fee payments.
- 3) Permits restoration of priority to foreign/provisional application in subsequent application filed within 2 months of expiration of 12-month filing period.
- 4) Revises PTA provisions to provide for reduction of PTA if application is not in condition for examination within 8 months of filing or commencement date.

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