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Federal Circuit Friday

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In *Intra-Cellular Therapeutics v. Iancu* (September 18), the Federal Circuit clarified the rules regarding accounting for applicant delay in calculating patent term adjustment under 35 USC §154(b).

Intra-Cellular responded to a final office action on the three-month deadline by arguing the merits of the examiner's objections and rejections rather than either (i) filing an appeal or an RCE in which to continue arguing the merits or (ii) submitting amendments to the claims. Twenty-one days later, Intra-Cellular filed a second response, this time cancelling and amending claims in accordance with the examiner's positions in the final office action. Intra-Cellular's initial response was not compliant with PTO regulations regarding responses to a final office action, but the subsequent response was compliant.[1]

The issue was whether the 21 days between the initial non-compliant response and the subsequent compliant response should count as "applicant delay" for purposes of reducing the number of days of patent term adjustment.

The statute provides that the period of patent term adjustment "shall be reduced" by periods of time in which "the applicant failed to engage in reasonable efforts to conclude prosecution of the application" and includes, as an example, that "any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request" shall be deemed to be a failure to engage in reasonable efforts to conclude prosecution of the application.[2] The PTO regulations track the statutory language, but include a few additional examples of when an applicant will be deemed to have failed to engage in reasonable efforts to conclude prosecution of the application, none of which is directly relevant to the situation in this case.[3]

The PTO concluded that the 21 days was properly treated as applicant delay and deducted it from the patent term adjustment otherwise due for the patent. Intra-Cellular appealed.

The Federal Circuit concluded that the time between a non-compliant after-final response and a compliant after-final response ***can*** be counted as applicant delay and deducted from any patent term adjustment otherwise applicable to the patent. The court supported the decision with a Chevron administrative deference analysis[4] as follows:

- *Chevron Step 1:* The relevant statute does not answer the precise question because it "does not answer the question of what type of action by an applicant constitutes 'reasonable efforts to conclude prosecution' for purposes of responding to a *final* Office action" (italics in original).

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1 *See* MPEP 714.12 and 37 CFR §§1.113, 1.114.

2 35 USC §154(b)(2)(C)(i).

3 37 CFR §1.704.

4 In *Chevron v. Natural Resources Defense Council*, 467 US 837 (1984), the US Supreme Court provided the framework for determining when a court should defer to an administrative agency's interpretation of a statute governing that agency's activities. In a first step, the court asks whether Congress has, in the statute, spoken to the precise question at issue. If so, then the inquiry ends and the statute is applied as written. If not, then the court proceeds to a second step in which it asks whether the agency's interpretation is a *permissible* reading of the statute – *i.e.,* whether the agency's interpretation contradicts any unambiguous language of the statute or is an unreasonable resolution of ambiguous statutory language.

  - The court noted as part of its Chevron Step 1 analysis that the patent term adjustment statute was passed against an existing backdrop of PTO regulations regarding what is and is not an appropriate response to final office actions – "what may be 'reasonable efforts' in the context of responding to a non-final Office action can be quite different from 'reasonable efforts' for responding to a final Office action."

- *Chevron Step 2:* The Patent & Trademark Office's interpretation of the patent term adjustment statute is a permissible interpretation because it is reasonable to interpret the word "respond" in the statute ("any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request") as a response that is *compliant with PTO regulations*. Thus, because Intra-Cellular's initial reply did not comply with the regulations regarding responding to a *final* office action, that initial reply did not stop the clock from running past the three month mark and Intra-Cellular was accountable for the 21 days after the three-month date before it filed a compliant response.
  - Intra-Cellular argued that "any bona fide attempt to address all rejections and objections in an Office action" should be counted as a "response" under 35 USC §154(b) and should stop the three month clock. The Federal Circuit disagreed because treating a non-compliant response after final as a proper response would effectively "give the applicant the benefits of an RCE (which re-opens prosecution) without the concomitant [patent term adjustment] reduction that comes with an RCE."

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Closing Thoughts

So, why did Intra-Cellular spend the time and money to appeal the loss of a mere 21 days of patent term? Most likely because the patent covers serotonergic chemical compounds believed to be useful for treatment of a variety of central nervous system disorders (*e.g.,* obesity, anorexia, depression, anxiety, psychosis, schizophrenia, migraine, etc.) and therefore is likely to be listed in the Orange Book, the FDA's list of "Approved Drug Products with Therapeutic Equivalence Evaluations."[5]

Listing a patent in the Orange Book generally prohibits generic drug manufacturers from marketing a lower-cost generic version of a brand name prescription drug until the patent expires or is determined to be invalid. Assuming that the patent is valid, each day that the patent term is increased – *i.e.,* each additional day that passes before expiration (and therefore before one or more low cost generics become available in the market) can be worth millions of dollars in brand name drug sales. Thus, those 21 days of patent term extension could be quite valuable.[6]

[5] A quick check of the on-line Orange Book database did not reveal a current listing of US 8,648,077, but that is not surprising as the relevant drug or drugs may well be still in development or working their way through the FDA approval process. Intra-Cellular Therapies has two drug development programs to which the '077 patent might be relevant: ITI-007 (Lumateperon), indicated for treatment of schizophrenia, bipolar depression, and other neuro-psychiatric conditions and currently in phase 3 clinical trials for schizophrenia; and ITI-333, indicated for substance abuse disorder, depression, and pain and currently in pre-clinical phase.

[6] As an example, in 2018 Pfizer had multiple products with revenues above $1 billion per year, representing more than $2.74 million in revenue *per day* for each of those products. According to the FDA, drug prices drop on average by 6% upon the first generic entering the market, 50% upon two generics entering the market, and 75% after six generics are available. Therefore, for a $1 billion per year brand drug, *each day* of patent exclusivity on the tail end – just before generics become available – can be worth anywhere from $164,000 to $2 million depending on how many generics enter the market upon expiration.