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Timing of PTO Disclosures: A Trap for the Unwary

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Every day counts when it comes to patent protection for blockbuster pharmaceuticals. A recent decision from a U.S. District Court in Virginia affirming the Patent and Trademark Office's 57-day reduction in Patent Term Adjustment has the potential to ensnare unwary patent applicants and their attorneys, which could result in significant financial ramifications for the holder of the patent that eventually issues. *Gilead Sciences, Inc. v. Rea*, 1:12cv1090 (E.D. Va.).

The term of a United States patent is measured as 20 years from its earliest claimed U.S. non-provisional priority date. Because the clock measuring the patent term begins at application filing, rather than at patent issuance, the length of time in which a patent is in force depends upon the PTO's diligence in examining the application. Because PTO examination delay has the potential to shorten the effective life of a patent, applicants are compensated for such delay by adding extra days of term to the end of a patent that has undergone delayed issuance. This is determined by calculating the period of PTO delay (if any) and subtracting from it the period of applicant delay (if any). Applicant delay is defined in the statute as "the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

A patent applicant has a duty to disclose to the PTO all material information that is known to the applicant. *Therasense, Inc. v. Becton Dickinson and Co*., 649 F.3d 1276 (Fed. Cir. 2011) (en banc). An applicant's failure to disclose such material information can lead to a finding that the patent is unenforceable due to inequitable conduct. *Id*. The PTO regulations encourage submission of information before commencement of examination on the merits, so that all information can be considered when the examiner mails the first office action on the merits. This is usually done in an Information Disclosure Statement, or IDS.

At the same time, if the PTO determines that two or more independent and distinct inventions are claimed in one application, it may require the application to be restricted to one of the inventions. When that happens, the Examiner requires the patent applicant to elect an invention to which the claims will be restricted. This official action, or restriction requirement, will normally be made before any action on the merits.

The ***Gilead*** Case

In *Gilead Sciences, Inc. v. Rea*, an IDS was submitted before the PTO mailed a first office action on the merits, but *Gilead* was assessed applicant delay because the IDS was submitted *after* Gilead had filed a response to a restriction requirement. In explaining why it believed that this IDS constituted applicant delay, the PTO said that under the PTA regulation 37 C.F.R. § 1.704(c)(8), the submission of a supplemental reply or other paper after a reply has been filed is "a failure to engage in reasonable efforts to conclude prosecution." As a result, Gilead's PTA was reduced by the 57-day period between the response to the restriction requirement and the submission of the IDS.

After the PTO denied Gilead's petition that it reconsider its decision, Gilead filed suit in Virginia, arguing that the IDS regulations and PTA applicant delay regulations are intended to serve complementary purposes. In particular, the IDS regulations encourage applicants to submit an

IDS promptly and the PTA regulations are intended to ensure that applicants do not gain a term extension for delay resulting from their failure to take such prompt action. As a result, said Gilead, the conflict caused by the PTO's application of the regulations is that only a particular category of IDS submissions—an IDS before a first office action on the merits, but after a response to restriction requirement—that is considered promptly submitted by the IDS regulations and does not *actually* delay examination was being treated by the PTO as late for purposes of PTA calculations.

The district court concluded that the PTA regulation was a reasonable interpretation of the controlling PTA statute. Specifically, the court held that the governing stated the "explicit focus of the statute . . . is on whether the applicant's efforts were reasonable, not whether the outcome of those efforts caused actual delay." Thus, the PTO's assessing applicant delay for an IDS filed after a response to restriction requirement was deemed an acceptable practice by the court. Gilead is appealing this decision to the Court of Appeals for the Federal Circuit.

Practical Consequences

The manner in which the PTO applies 37 C.F.R. § 1.704(c)(8) to one category of IDS' filed before the receipt of a first office action on the merits—those submitted after a restriction election—has an effect that subverts the statutory purpose of encouraging diligent actions by the PTO and applicants. Because the PTO assesses an applicant delay penalty for submitting an IDS before a first office action on the merits if a reply to restriction requirement has been filed, this PTO practice, now blessed by the court, encourages applicants in need of submitting an IDS at this juncture to delay submitting the information until after receipt of the first office action on the merits. Submitting material in this manner (*i.e.*, after receipt of a first office action on the merits and with or before a response to that office action, together with the required fee under 37 C.F.R. § 1.97(c)(2)) will avoid an applicant suffering a PTA penalty, even though it will extend prosecution if it causes the examiner to raise a new rejection based upon the newly submitted material.

Scrupulous patent applicants (and their counsel) should be well aware of this incongruous result, as *not* filing an IDS after a restriction election but before a first office action could result in tens of millions in revenue based on PTA that was not unwittingly forgone. At the same time, those same individuals should balance their approach to ensure that they satisfy their duty of candor and submit information material to patentability promptly to the PTO.