

A Closer Look at EPA's Updated Part 152 Subpart E Regulations and Related Guidance

On February 5, 2014, EPA issued a Final Rule updating its Part 152 subpart E regulations concerning procedures to protect data submitters' compensation and exclusive use rights. (79 Fed. Reg. 6819). Among other changes, EPA amended 40 C.F.R. § 152.84 to require submission of all data compensation compliance information and materials, including evidence of any offers to pay, at the time of application, rather than "at any later time prior to EPA's approval of the application," as the regulation had previously provided.

In comments on the rulemaking, CPDA had urged the Agency to retain the flexibility provided in the then-existing version of § 152.84. EPA, however, concluded that the amendment was required by FIFRA § 33(f)(4), added by PRIA 2, which directs EPA to ensure that each application include "all the necessary forms." EPA also concluded that requiring all compliance materials, including the offer-to-pay certification, at the time of application would promote the efficient and effective review of applications.

EPA's rejection of CPDA's proposal to retain § 152.84 as written may have been a disappointment to some, but we have a different perspective. While we understand the desire to withhold compensation offers until substantial similarity is determined, we do not consider the elimination of this option a significant loss.

In fact, this practice was never widely followed and was being sharply curtailed by EPA as a matter of administrative procedure in any event. Counterbalancing this minor change are several positive features of EPA's Final Rule and related guidance issued at the same time. Overall, EPA's Final Rule and new guidance are welcome developments that should assist post patent applicants to achieve fair and appropriate resolutions of their data compensation obligations.

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