

COMMENT:

Enablement in HIV therapy.

Despite explicit changes introduced back in 1995, PTO Examiners are still requiring in vivo data even though in vitro data is provided. This requirement is especially bothersome in HIV treatment field. Out of thousands issued patents in HIV field, the number of patents supported by human data or even animal data is staggeringly low. At the first glance this may mean that in vitro data are acceptable to the USPTO as enabling examples. ver, there is perceptible variation among Examiners when it comes to accepting in vitro data as enabling. In vitro data is still not accepted by individual Examiners. It appears that the level of acceptance of in vitro data depends on arbitrary criteria set by an individual Examiner who are not persuaded by 1995 rules. Another frequently seen tactic is to compare an anti-HIV drug to a vaccine and then rely on rejection criteria set in the training example "K" in MPEP. eed perhaps yet another explicit guideline to enablement of in vitro data to be conform to enablement criteria under 112 first paragraph.

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