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**Declarations under Rule 4.17:**

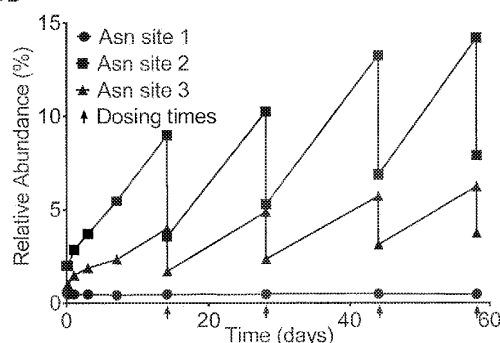
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
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(54) **Title:** QUANTITATION AND MODELING OF QUALITY ATTRIBUTES OF THERAPEUTIC MONOCLONAL ANTIBODIES

Figure 3B



(57) **Abstract:** Methods of predicting an *in vivo* serum concentration of an antibody with a post-translational modification of interest after administration of the antibody are provided, as are methods for predicting a subject's exposure to post-translational variants of the antibody. The methods include predicting a percentage of the antibody with the post-translational modification of interest using an *in vivo* rate constant determined for the post-translational modification, and multiplying the predicted percentage of the antibody with the post-translational modification of interest by the *in vivo* concentration of the antibody to determine the concentration of the antibody with the post-translational modification of interest.