basis of a large, medium or small quantity purchase? Are different MAC determinations to be made for different classes of providers -- e.g., physicians, hospitals and pharmacies? If not, is the Board to set the MAC at the lowest price at which the drug can be purchased by that class of providers which pays the most for the drug? And what sources or criteria are the Board to consider in determining prices?

Finally, we note that the confusion as to the standard to determine the "lowest unit price" for MAC purposes is compounded, in the case of the proposed Medicare regulation[45/] by the introduction of another undefined and vague concept -- that of "the amount which would be paid by the prudent and cost-conscious provider for such drug if obtained from the lowest-priced source which is widely and consistently available."

Obviously, if these and other uncertainties are not resolved, parties wishing to present evidence with respect to a MAC determination will be seriously disadvantaged by not knowing what evidence will be relevant or persuasive.[46/]

In addition, it is not clear how the proposed regulations would treat patent infringers -- a concern which is raised by the wording of Section 19.2(b). The section provides that a MAC will be applied to a "multiple-source drug", which is defined simply as "a drug marketed or sold by two or more formulators or labelers". There is no recognition of circumstances where one such drug is covered by a valid U. S. patent and formulators or labelers are infringing that patent in the marketing of the same drug. If the MAC is related, in any way, to the price of the infringing drug, the result could be to penalize the patent-holder who has assumed, for the benefit of the public, the research and development costs of the drug. Since it often takes years to conclude patent infringement litigation, such situations