the wherewithal for determining the extent to which any sequence of amino acids may function, in vivo, as though it were the sequence encoded by the erythropoietin gene in the human genome. No impermissible vagueness attends claiming glycoproteins which share that amino acid sequence to an extent sufficient to allow the products to function, in vivo, as erythropoietin hematopoietic agents. Thus, the term "sufficiently duplicative of" as applied to amino acid sequence needed for the specified in vivo biological activity is not violative of the requirements of the second paragraph of 35 U.S.C. §112.

The same reasoning applies to reference in claim 41 to glycosylation sufficiently duplicative of that of naturally occurring erythropoietin. At the time of the invention, the art knew that erythropoietin isolated from urine was a glycoprotein and that treatment to remove its carbohydrate would destroy in vivo biological activity. Applicant was the first to provide for a glycoprotein which is both different from previously isolated urinary erythropoietin in its glycosylation and yet sufficiently like the natural product (previously isolated in the art) in terms of its glycosylation to allow it to fill the long-felt need (unsatisfiable by urinary isolates) for life-sustaining human therapeutic agents for, e.g., the anemia associated with dialysis in renal failure patients.

The precise nature of the differences in the carbohydrate structures of products of the present invention and urinary-derived human erythropoietin are only now starting to be understood, as evidenced by the results of the experimental procedures detailed in the attached Declaration of Thomas W. Strickland. Briefly put, the procedures demon-