

APPENDIX A

<p><i>“human erythropoietin”</i></p> <p>(‘422 claim 1, ‘933 claims 3, 7-9, 11-12, and 14, ‘868 claims 1 and 2, ‘349 claim 7)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine	a glyco protein having the amino acid sequence of erythropoietin isolated from human urine having the structure that would be produced in mammalian cells as of the invention date
<p><i>“purified from mammalian cells grown in culture”</i></p> <p>(‘422 claim 1)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
wherein the protein is obtained in substantially homogeneous form from mammalian cells grown in culture, such that it originates in mammalian cells, but need not be taken directly out of the interior of the cells	obtained in substantially homogeneous form from mammalian cells, using the word “from” in the sense that it originates in mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture <i>This limitation cannot define the structure of the claimed product.</i>
<p><i>“a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin”</i></p> <p>(‘933 claims 3, 7-9, 11-12 and 14)</p>	
Amgen’s Proposed Construction	Defendants’ Proposed Construction
A glycoprotein product not occurring in nature that is expressed in a mammalian cell from a DNA sequence that does not originate in the genome of the host and comprises a DNA sequence encoding human erythropoietin	a protein [not occurring in nature] that is the expression product of the mammalian host cell having the amino acid sequence of human erythropoietin which is glycosylated naturally by the host cell at specific amino acids

<p><i>“a pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier”</i></p> <p>(‘422 claim 1, ‘933 claims 9 and 12)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
a composition suitable for administration to humans containing at least a diluent, adjuvant or carrier	a mixture having in addition to the active ingredient (as defined in the claim), an additional distinct and separate ingredient that acts as a diluent, an adjuvant or a carrier
<p><i>“a process for the production of a glycosylated erythropoietin polypeptide... comprising the steps of”</i></p> <p>(‘868 claims 1 and 2, ‘698 claims 4-9)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
a process for the production of an erythropoietin polypeptide having one or more carbohydrate groups attached to the polypeptide . . . containing at least the following steps	process for the production of a glycosylated erythropoietin polypeptide having the amino acid sequence and carbohydrate modifications obtainable through process steps (a) and (b) of these claims
<p><i>“wherein said cells are CHO cells”</i></p> <p>(‘868 Claim 2, ‘933 claim 8)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
A cell derived from the ovary of a Chinese hamster.	A cell from the ovary of a Chinese hamster.
<p><i>“cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin”</i></p> <p>(‘868 claims 1 and 2)</p>	
<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
cells receiving purified genetic instructions for human erythropoietin	introduction of purified exogenous DNA molecules encoding the genetic instructions for human erythropoietin into a host cell

“isolating said glycosylated erythropoietin polypeptide expressed [therefrom] [by said cells]”

(‘868 claims 1 and 2, ‘698 claims 4-9)

<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
recovering in pure form said glycosylated erythropoietin polypeptide	separating the glycosylated erythropoietin polypeptide having the defined activity from the growth medium, cellular lysates or cellular membrane fractions of the cells that produce it

“a process for producing erythropoietin comprising the step of”

(‘349 claim 7)

<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
a process for producing erythropoietin containing at least the step	process for producing a glycoprotein having the amino acid sequence and glycosylation structure of a naturally occurring hormone that is produced in a cell and secreted from that cell, and that controls the formation of red blood cells in bone marrow

“effective amount of a glycoprotein product effective for erythropoietin therapy”

(‘933 Claims 9, 10 and 11)

<i>Amgen’s Proposed Construction</i>	<i>Defendants’ Proposed Construction</i>
A quantity of a glycoprotein product according to claim 1, 2, 3, 4, 5 or 6 that produces a result that in and of itself helps to heal or cure a patient in the class of patients listed in the specification, column 33 lines 31 through 36: patients generally requiring blood transfusions and including trauma victims, surgical patients, renal disease patients including dialysis patients, and patients with a variety of blood composition affecting disorders, such as hemophilia, sickle cell disease, physiologic anemias, and the like	A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals