

EXHIBIT K, Part 13

CONTAINS ROCHE RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL

U.S. PATENT NO. 5,621,080 CLAIM 3		
Claim Limitations	Proposed Claim Construction	Corresponding Structure or Function in Roche's Product
		<p>“Pharmacodynamic results in healthy volunteers showed a potent, does-dependent and long lasting erythropoietic response after both IV and SC administration of RO0503821.” ITC-R-BLA-00000315.</p> <p>“RO0503821 stimulates erythropoiesis thereby increasing the number of RBCs.” ITC-R-BLA-00000316.</p> <p>“RO0503821 was efficacious in correcting anemia associated with CKD in patients who were on dialysis or not on dialysis and who were not currently treated with an ESA, regardless of route of administration (IV or SC). RO0503821 was comparable to both epoetin and darbepoetin alpha reference groups in all study parameters tested with the exception of time to target Hb response in the correction studies, which was longer with RO0503821.” ITC-R-BLA-00000326-27.</p> <p>See also Application Summary for MIRCERA, ITC-R-BLA-00000194-691; Information for Patients and Caregivers, ITC-R-BLA-00000066-77.</p>

U.S. PATENT NO. 5,621,080 CLAIM 4		
Claim Limitations	Proposed Claim Construction	Corresponding Structure or Function in Roche's Product
A pharmaceutical composition	“A composition suitable for administration to humans as a pharmaceutical”	Roche's MIRCERA product is formulated as a pharmaceutical composition.
comprising	“containing at least”	See '933 claim 9 above (pharmaceutical composition).

EXHIBIT A TO PLAINTIFF'S RESPONSE TO FIRST SET OF INTERROGATORIES (1-13)
CASE NO. 05-cv-12237WGY

CONTAINS ROCHE RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL

U.S. PATENT NO. 5,621,080 CLAIM 4		
Claim Limitations	Proposed Claim Construction	Corresponding Structure or Function in Roche's Product
<p>a therapeutically effective amount [of]</p>	<p>“therapeutically effective amount” means either:</p> <p>(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.”</p> <p style="text-align: center;">or</p> <p>(b) “a quantity that produces a result that in and of itself helps to heal or cure. A therapeutically effective amount is one that shares the in vitro biological activity of natural EPO, elicits in vivo biological effects such as those listed in the specification, column 33, lines 24-28: stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes,</p>	<p>Roche’s MIRCERA product contains a therapeutically effective amount of an EPO glycoprotein product.</p> <p>See ‘933 claim 9 above.</p>

⁴ Construction (a) reflects the claim construction adopted by the Federal Circuit in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1303 (Fed. Cir. 2006), with respect to the ‘422 patent. Amgen, however, has not yet exhausted its right to appeal that construction. Amgen, therefore, reserves the right to propose claim construction (b) at trial.

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U.S. PATENT NO. 5,621,080 CLAIM 4		
Claim Limitations	Proposed Claim Construction	Corresponding Structure or Function in Roche's Product
	<p>stimulation of hemoglobin C synthesis, and, as indicated in Example 10, increases the hematocrit level in mammals. Therapeutically effective is to be interpreted as being therapeutically effective with respect to 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.”</p>	
<p>an erythropoietin glycoprotein product according to claim 1, 2, or 3.</p>	<p>“an EPO glycoprotein product according to claim 1, 2, or 3”</p>	<p>Roche's MIRCERA product contains an erythropoietin glycoprotein product according to claim 3. See '868 claim 1 above. See '080 claim 3 above.</p>

U.S. PATENT NO. 5,621,080 CLAIM 6		
Claim Limitations	Proposed Claim Construction	Corresponding Step in Method of Treatment
<p>A method for treating a kidney dialysis patient</p>		<p>Roche's agents have performed this method or Roche has induced or will induce physicians to practice the claimed method for treating a kidney dialysis patients. See '933 claim 11 above.</p>

CONTAINS ROCHE RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL

U.S. PATENT NO. 5,621,080 CLAIM 6		
Claim Limitations	Proposed Claim Construction	Corresponding Step in Method of Treatment
<p>which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.</p>	<p>“administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient”</p>	<p>MIRCERA is administered and will continue to be administered in an amount effective to increase the hematocrit level of patients. See '080 claim 4 above (<i>independent claim</i>) See '933 claim 11 above (<i>effective to increase hematocrit</i>). See also Application Summary for MIRCERA, ITC-R-BLA-00000194-691; Information for Patients and Caregivers, ITC-R-BLA-00000066-77.</p>

**CERTIFICATE OF SERVICE VIA
ELECTRONIC MAIL**

I, William Martinez, hereby declare:

I am a citizen of the United States and a resident of the State of California. I am over the age of eighteen years, and not a party to the within action. My business address is McDermott Will & Emery LLP, 3150 Porter Drive, Palo Alto, California 94304-1212.

On February 10, 2007, I served a copy of **PLAINTIFF'S SUPPLEMENTAL RESPONSE TO FIRST SET OF INTERROGATORIES (NOS. 1-12)** by electronic transmission by attaching the referenced documents to an electronic mail and transmitting the same to the e-mail addresses indicated below:

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed at Palo Alto, California on February 9, 2007.



William Martinez