

## **Exhibit 39**

to the Declaration of Cullen N. Pendleton in Support of Amgen's Opposition to Roche's Motion for Summary Judgment that Claim 7 of the '349 Patent is Invalid Under 35 USC §112 and is Not Infringed

NOTICE OF  
CLAIMED INVESTIGATIONAL EXEMPTION  
FOR A NEW DRUG

ERYTHROPOIETIN (EPOCH)

CHUGAI PHARMACEUTICAL CO., LTD.

VOLUME 1.3

Plaintiff's Exhibit 19

CONFIDENTIAL SUBJECT TO  
PROTECTIVE ORDER C.A. NO. 87-  
2617-Y (D.C.MA.) C.A. NO. 87-  
07200 TJH(DC.CA)CHUGAI 639

PLAINTIFF'S  
EXHIBIT  
19

A 119740

Chugai Pharmaceutical Co., Ltd.  
1-9\_Kyobashi 2-chome  
Chuo-ku, Tokyo 104, Japan

4.2.7 (Continued)

Percent  $^{59}\text{Fe}$  uptake (%) =

Body weight (g) x  $^{59}\text{Fe}$  (cpm) in 0.5 ml of blood x 2 x 0.07

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Total amount (cpm) of  $^{59}\text{Fe}$  injected

x100

Using the values for log-dose and response (percent  $^{59}\text{Fe}$  uptake) from each mouse perform a parallel line assay as directed under the Design and Analysis of Biological Assays in the USP XXI, p. 1169 - 1179.

Criteria

One mg of EPOCH polypeptide as determined by the method described in this section shows a specific biological potency ranging between  $130 \times 10^3$  IU and  $250 \times 10^3$  IU. Note that the conversion constant for the specific potency,  $180 \times 10^3$  IU/mg EPOCH polypeptide (see Sections 3 and 4.2.6.8) represents the midpoint in logarithmic expression.

Remarks

\*1 Composition:

Medium

$\alpha$ -MEM (Gibco): 1 pack for liter use/liter  
FCS (High Clone): 20 ml/liter  
Streptomycin sulfate (Majji): 100 mg/liter  
Potassium Penicillin G (Majji):  $100 \times 10^3$  U/liter

Note: Adjust the pH with  $\text{NaHCO}_3$  to 7.2

\*2 Mouse: Use 6 - 12 mice.

\*3  $^{59}\text{Fe}$ :  $^{59}\text{FeCl}_3$  (New England Nuclear) or an equivalent.

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PROTECTIVE ORDER C.A. NO. 87-  
2617-Y (D.C.MA.) C.A. NO. 87-  
07200 TJH(DC.CA)CHUGAI 246

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