UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before The Honorable Paul J. Luckern
Administrative Law Judge

In the Matter of **CERTAIN PRODUCTS AND PHARMACEUTICAL COMPOSITIONS CONTAINING RECOMBINANT HUMAN ERYTHROPOIETIN**	)	**Inv. No. 337-TA-568**

MEMORANDUM OF LAW IN SUPPORT OF RESPONDENTS' MOTION FOR SUMMARY DETERMINATION OF NO VIOLATION OF SECTION 337

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INTRODUCTION

In its Notice of Investigation, the Commission directed the Administrative Law Judge "to consider at an early date any motions for summary determination based upon 35 U.S.C. § 271(e)." The present motion demonstrates the merit in taking up this issue now.

This memorandum and the accompanying declarations demonstrate that respondents (collectively "Roche") have imported the accused product (called "CERA") solely for uses reasonably related to the approval process of the Food and Drug Administration. This activity is specifically exempted from infringement liability by 35 U.S.C. §271(e)(1) and has consistently been held to be noninfringing by the Supreme Court and the Federal Circuit. This memorandum and the supporting declarations also show that Roche has engaged in no activities beyond the scope of the §271(e)(1) safe harbor that would warrant continuing this investigation. Roche has not sold CERA for importation into the United States or sold CERA within the United States after importation. Indeed, Roche has not even offered to sell CERA in the United States. Accordingly, since there has been no infringing importation or sale of an allegedly infringing product, there has been no violation of §337 and this investigation should be terminated.

Much of Amgen's amended complaint is directed to future activities that Roche may engage in after FDA approval is obtained. In this respect, the complaint effectively seeks an advisory opinion that Roche's commercial activities after the FDA's approval of CERA will infringe its patents. The Commission obviously considered such future actions to be not subject to review, since they are not included in the Notice of Investigation. Roche respectfully submits that the ALJ need not even consider those allegations in granting this motion for summary determination.

However, if the ALJ chooses to go beyond the Notice of Investigation and consider the alleged future acts, it will quickly be seen that they provide no ground for relief.

The ITC investigates future activities only in the unusual circumstance where importation of an infringing product is legally "imminent." The few cases that have proceeded under an "imminent" importation theory have involved importers who had already entered into an actual contract to sell the infringing product to a commercial customer, thus constituting a "sale for importation" within the meaning of §337. As noted previously, Roche has not made any agreement to sell CERA in the United States to any entity either prior to or after FDA approval. It could not do so, since the product has not been approved by the FDA. 21 U.S.C. §355(a).

Under similar circumstances, federal courts have observed that it would be nonsensical to permit drug makers to be protected from direct suits for infringement under §271(e)(1) but to allow them to be subject to suit in a declaratory judgment action, since one of the purposes of §271(e)(1) is to insulate companies seeking FDA approval from "expensive, resource-draining, and personnel-distracting litigation." Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1290 (N.D. Cal. 1991), aff'd, 991 F.2d 808 (Fed. Cir. 1993). Roche respectfully submits that these concerns apply with equal force in the context of §337 investigations.

Because Amgen has no case here that warrants proceeding with this investigation, this investigation should be summarily terminated.

DECLARATIONS SUPPORTING THIS MOTION

This motion is supported by the following declarations:

- Jean-Pierre Buch. (Attachment 1 to this Memorandum). Mr. Buch, an employee of F. Hoffmann-La Roche Ltd. ("Roche Switzerland"), is the Global Technical Team Leader for CERA. Mr. Buch states that CERA has not been approved by the FDA. Mr. Buch further states that CERA has not been sent to the United States for sale. Rather, Mr. Buch explains,

CERA has been sent to scientists in the United States for clinical and non-clinical study to develop information for FDA approval of the product.

- Iris Kingma-Johnson, M.D., Ph.D. (Attachment 2). Dr. Kingma-Johnson is Medical Director at Roche Laboratories, a wholly owned subsidiary of respondent Hoffmann-La Roche Inc. ("Roche U.S."). Dr. Kingma-Johnson describes the FDA approval process for biological products, current trends affecting the FDA's approval of such products, the status of Roche's ongoing clinical trials involving CERA for the FDA approval process, and the timing of possible FDA approval.
- Philippe Van der Auwera, M.D. (Attachment 3). Dr. Van der Auwera is Global Head, Anemia Management Business, and Director, Anemia Franchise Pharmaceuticals, at Roche Switzerland. Dr. Van der Auwera states that the Roche entities in Europe do not sell CERA. Dr. Van der Auwera also explains that Roche does not sell or offer to sell CERA for importation into the United States because the product is not approved and because of the inherent uncertainties of whether the product will be approved, what uses the product will be approved for, when the product will be approved, and what form the product will take when and if it is approved.
- Chrys Kokino. (Attachment 4). Mr. Kokino is Vice President, Anemia Products, at Roche U.S. His declaration shows that Roche does not sell or offer to sell CERA in the United States for the same reasons. The product is not approved for sale by the FDA and there is uncertainty concerning

whether the product will be approved, what uses the product will be approved for, when the product will be approved, and what form the product will take when and if it is approved.

- Lisa M. Marcopulos. (Attachment 5). Ms. Marcopolus is Senior Manager, Global Investigational Product Supply, at Roche U.S. Ms. Marcopulos describes how CERA received from Europe for clinical trials is sent to clinical investigators.
- Hing W. Char. (Attachment 6). Dr. Char is Research Leader in the Department of Pharmaceutical and Analytical Research and Development at Roche U.S. Dr. Char describes the non-clinical studies conducted by Roche for purposes of securing the approval of CERA by the FDA.
- Eric G. Wright, Esq. (Attachment 7). Mr. Wright's declaration provides verified copies of several documents describing the FDA approval process, current issues facing applicants and the FDA, and statistics regarding the FDA's examination of Biologic License Applications and New Drug Applications.

BACKGROUND

A. Erythropoietin

Erythropoietin is a naturally occurring hormone that stimulates red blood cell production as well as the division and differentiation of progenitor cells in the bone marrow. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 339 F. Supp. 2d 202, 214 (D. Mass. 2004). Erythropoietin, its production by the kidney, and its functions and beneficial attributes have been widely known for decades. Id. Several years after its purification from human urine in 1977, the

human erythropoietin gene was isolated, sequenced and cloned, enabling the expression of recombinant human erythropoietin ("rHuEPO"). Id.

Since 1989, Amgen and its licensee, Johnson & Johnson, have been the exclusive sellers of rHuEPO products in the United States. Outside the United States, Roche affiliates have manufactured and marketed an rHuEPO product known as NeoRecormon®. NeoRecormon® is used to treat anemia in Europe. Roche does not sell NeoRecormon® in the United States.

B. Roche's Novel Drug CERA

Responding to the need for improved anemia drugs and patient choice, Roche over seven years ago embarked upon an extensive research program directed at developing superior anemia treatments. CERA (an acronym for Continuous Erythropoiesis Receptor Activator) was invented by Roche as a result of this research. The U.S. Patent and Trademark office has recognized CERA as a novel and patentable product.

CERA is a unique molecule that differs considerably from rHuEPO in its physical, chemical, and biological properties. CERA is substantially more complex, and has almost twice the molecular weight and physical size of rHuEPO. CERA has a considerably longer circulating lifetime in the human body, is more soluble, and its formulation is more stable at room temperature than formulations of rHuEPO marketed by Amgen.

C. The State Of Development Of CERA

CERA is a new chemical entity. It contains "no active moiety that [previously] has been approved by [the] FDA." 21 C.F.R. §314.108(a) (Apr. 1, 2005). Therefore, Roche must receive approval of an "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use" before the product can be offered for sale in the United States. Id.; see also 21 C.F.R. §314.50 (providing requirements for a New Drug Application). The approval process is