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OFFICE OF THE ALJ

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UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.

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

Order No. 3: Granting Complainant's Motion No. 568-2 For Extension, Setting Procedural Schedule For The Section 271(e)(1) Defense And Rescheduling Preliminary Conference To July 18

On May 24, 2006, complainant moved for extension of the briefing schedule to June 26, 2006 for any response to respondents' Motion No. 568-1 for summary determination of no violation of section 337 because any importations of the accused products to date were solely for uses reasonably related to the Food and Drug Administration approval process and thus within the safe harbor created by 35 U.S.C. § 271(e).<sup>1</sup> (Motion Docket No. 568-2.)

In responses filed May 25, 2006, respondents opposed Motion No. 568-2 while the staff supported said motion and "seeks a similar extension" as moved for by complainant.

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<sup>1</sup> Pursuant to Section 271(e)(1):

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

As Motion No. 568-2 states, Motion No. 568-2 was based on Commission rule 210.15. Commission rule 210.15(d) permits the administrative law judge to rule upon motions for extensions ex parte. However, the administrative law judge did allow for responses to be filed in view of the Commission's direction in the notice of investigation that the administrative law judge consider any motion for summary determination under 271(e)(1) at an early date.

Respondents, in opposing 568-2, argued for the most part the merits of their Motion No. 568-1. However, it was also argued that Motion No. 568-2 is based on Commission rule 210.18(d) and complainant failed to submit an affidavit pursuant to said rule. Commission rule 210.18(d) however, refers to a party "opposing the motion." Neither complainant in Motion No. 568-2 nor the staff in its response to Motion No. 568-2 took a position on the merits of respondents' Motion No. 568-1. Hence the administrative law judge rejects respondents' argument that Motion No. 568-2 should be denied for failure to submit an affidavit.

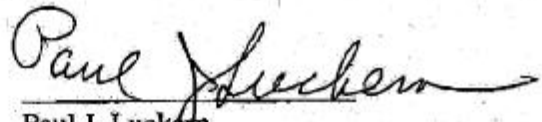
The staff, who represents the public interest, in its response to Motion No. 568-2 argued that an opportunity to conduct discovery is particularly important as to Motion No. 568-1 because the "declarations filed in support of Roche's motion are conclusory in nature." The administrative law judge is making no finding as to said declarations. However, in view of the nature of Motion No. 568-1 and a need to develop a complete record relating to Motion No. 568-1, Motion No. 568-2 is granted and the procedural schedule set forth in Exhibit 2 of Motion No. 568-2 is in effect for the private parties and the staff.

The parties are put on notice that no further extensions regarding the June 26 date set for the filing of any "response" to Motion No. 568-1 will be entertained. Moreover, the administrative law judge has made no decision as to whether he will grant any motion by

respondents for leave to file a reply on June 29.

In view of the briefing schedule on Motion No. 568-1, the June 21, 2006 date for the preliminary conference (Order No. 1) is changed to July 18 at 1:45 PM in Hearing Room A (Room 100).

On May 26, 2006 each of the private parties and the staff received a copy of this order.



Paul J. Luckey  
Administrative Law Judge

Issued: May 26, 2006

**PAUL J. LUCKERN  
ADMINISTRATIVE LAW JUDGE  
UNITED STATES INTERNATIONAL TRADE COMMISSION  
500 E STREET, S.W.  
SUITE 317  
WASHINGTON, D.C. 20436**

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**FACSIMILE COVER SHEET**

**DATE SENT: May 26, 2006**

**REFERENCE: 337-TA-568 Order 3**

**TOTAL NUMBER OF PAGES BEING SENT, INCLUDING THIS COVER SHEET**

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