

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN MODIFIED VACCINIA
ANKARA (“MVA”) VIRUSES AND
VACCINES AND PHARMACEUTICAL
COMPOSITIONS BASED THEREON**

Investigation No. 337-TA-550

**NOTICE OF COMMISSION DECISION
TO REVIEW THE FINAL INITIAL DETERMINATION;
EXTENSION OF THE TARGET DATE FOR
COMPLETION OF THE INVESTIGATION;
SCHEDULE FOR BRIEFING ON THE ISSUES ON
REVIEW AND REMEDY, PUBLIC INTEREST, AND BONDING**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in its entirety the final initial determination (“final ID”) issued by the presiding administrative law judge (“ALJ”) in the above-captioned investigation and to extend the target date for completion of the investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on September 23, 2005, based on a complaint filed by Bavarian Nordic A/S (“Bavarian Nordic”) of Denmark. The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain modified vaccinia ankara (“MVA”) viruses and vaccines and pharmaceutical compositions based thereon by reason of infringement of various claims of United States Patent Nos. 6,761,893 (“the ‘893 patent”) and 6,913,752 (“the ‘752 patent”). The complaint also alleged violations of section 337 in the importation of certain MVA viruses and vaccines and pharmaceutical compositions based thereon or in the sale of such articles by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complaint named a single respondent, Acambis PLC (“Acambis”) of the United Kingdom.

On November 30, 2005, the ALJ issued an order (Order No. 10) denying Acambis’ motion to terminate the investigation on the basis of 28 U.S.C. § 1498.

On April 14, 2006, the ALJ issued an ID (Order No. 26) terminating the trade secret portion of this investigation based on an agreement to arbitrate between Bavarian Nordic and Acambis. On May 9, 2006, the Commission declined to review this ID.

On April 17, 2006, the ALJ issued an ID (Order No. 27) granting in part respondent’s motion for summary determination with regard to the conversion claim, on the basis, *inter alia*, that it was insufficiently pled. In a separate notice issued on May 9, 2006, the Commission reviewed the ID on the conversion claim, affirming the dismissal of the conversion claim and taking no position on the ALJ’s finding of no jurisdiction over the conversion claim.

After a hearing and post-hearing briefing, the ALJ issued a final initial determination (“final ID”) on September 6, 2006, finding no violation of section 337. The ALJ held that the patents were infringed but invalid.

Bavarian Nordic, Acambis, and the Commission investigative attorney filed petitions for review of the final ID. By notice of October 20, 2006, the Commission extended the deadline for determining whether to review the final ID to Wednesday, November 22, 2006 and extended the target date for completion of the investigation to Monday, January 8, 2007.

Having examined the relevant portions of the record in this investigation, including the final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in its entirety, as well as Order No. 10. The Commission has also determined to extend the target date for completion of the investigation to January 31, 2007.

The Commission requests briefing based on the evidentiary record on the issues on review. The Commission is particularly interested in responses to the following questions:

Regarding both the ‘893 and ‘752 patents:

(1) Does 28 U.S.C. § 1498(a) constitute an affirmative defense available in section 337 investigations? If so, has Acambis properly and timely raised and maintained this defense? What are the consequences of having successfully raised and maintained this defense in a section 337 proceeding?

Regarding the '893 patent:

(1) As a matter of claim construction, does “virus deposited” in claim 1 refer to an isolated, purified virus?

(2) Can the virus deposited be identified by sequence alone or is replication behavior a limitation of the virus deposited? If two viruses contain identical DNA coding region sequences, are the viral genomes necessarily identical? If not, *e.g.*, if viruses contained different inverted terminal repeats, is replication behavior necessarily the same? What are the consequences of replication behavior for determining anticipation and infringement of “virus deposited ... and derivatives” in claim 1?

(3) May a mixture of viruses containing the claimed virus anticipate claim 1 regardless of the replication behavior of the mixture? Does MVA-572 or MVA-575 inherently anticipate claim 1 even if those prior art viruses were not homogenous?

(4) Is MVA-F6 homogenous and does MVA-F6 *directly* anticipate claim 1?

Regarding the '752 Patent:

(1) Is there any evidence that the terms “non-replicative” and “not capable of reproductive replication” have different meanings, despite the use of different words? Should the terms “non-replicative” and “permit replication” as they appear in the asserted claims of the '752 patent be construed in conformance with the teaching from the specification that “the term ‘not capable of reproductive replication’ means that the virus of the present invention exhibits an amplification ratio of less than 1 in human cell lines, such as 293 (ECACC No. 85120602), 143B (ECACC No. 91112502), HeLa (ATCC No. CCL-2) and HaCat (Boukamp et al. 1988, J Cell Biol 106(3): 761-71) under the conditions outlined in Example 1 of the present specification”? '752 patent, col. 2, lines 53-59.

(2) Would a virus be considered to replicate if it sometimes replicated and other times did not? Is a person of ordinary skill in the art only concerned with mean values to the exclusion of standard error analysis? Would a person of ordinary skill in the art find viral replication if the mean value were above 1 even if the confidence intervals straddled 1? Would a person of ordinary skill in the art find no replication if the mean value were below 1 and the confidence intervals straddled 1?

(3) Is there evidence that MVA-575 possesses a replication ratio of 1 or greater in HaCaT and other human cells? Is there clear and convincing evidence that MVA-575 possesses a replication ratio less than 1 in HaCaT and other human cells?

(4) Given the claim construction in Order No. 31 regarding “replication,” would it matter to enablement, written description, infringement, or domestic industry of the ‘ 752 patent whether MVA-BN replicated less than MVA-575 if MVA-575 still possessed a replication ratio less than 1 in human cells? Is the ALJ’s claim construction of this term correct to a person of ordinary skill in the art? Answers to the above should give precise citations to the record and should take into account the confidence interval.

(5) Figure 1A indicates that the replication rates for certain MVA viruses are different. This is especially apparent at higher replication rates. Does the difference in replication rates indicate that these viruses are not identical? Would the lack of identity be reflected in the genome? If so, what part of the genome would reflect the lack of identity? The coding region? The noncoding region? Both?

In connection with the final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background information, see the Commission Opinion, *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount to be determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation, including references to exhibits and testimony. Additionally, the parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the ALJ's September 6, 2006, recommended determination on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is requested to supply the expiration dates of the patents at issue and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than the close of business on December 12, 2006. Reply submissions must be filed no later than the close of business on December 22, 2006. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original and 12 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R § 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and under sections 210.42 - .46, .51(a) of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42 - .46, .51(a)).

By order of the Commission.

/s/

Marilyn R. Abbott
Secretary to the Commission

Issued: November 22, 2006