UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

Before the Honorable Robert L. Barton, Jr. Administrative Law Judge

In the Matter of

CERTAIN MODIFIED VACCINIA ANKARA ("MVA") VIRUSES AND VACCINES AND PHARMACEUTICAL COMPOSITIONS BASED THEREON

Inv. No. 337-TA-550

ORDER 46: CONCLUSIONS OF LAW

- 1. The Commission has subject matter, in rem, and in personam jurisdiction.
- 2. There has been an importation of certain modified vaccinia viruses, which are the subject of the alleged unfair trade allegations.
- 3. A domestic industry exists in the United States, as required by subsection (a)(2) of Section 337, that exploits the certain modified vaccinia viruses that are covered by U.S. Patent No. 6,761,893 and U.S. Patent No. 6,913,752.
- 4. MVA-BN practices U.S. Patent No. 6,761,893 and U.S. Patent No. 6,913,752.
- 5. Respondent Acambis's accused product infringes claims 1, 4, 5, and 34 of U.S. Patent No. 6,761,893 and claims 1-9 and 13-16 of U.S. Patent No. 6,913,752.
- 6. Claims 1 and 34 of U.S. Patent No. 6,761,893 are invalid as anticipated by MVA viruses MVA-572, MVA-575, MVA-F6-580 and multiple publications disclosing and describing these viruses. Claims 4 and 5 of U.S. Patent No. 6,761,893 are invalid as anticipated by the Mayr and Mayr et al. publications. All of these claims are invalid as obvious in light of the same prior art MVA viruses and publications which invalidate these claims, alone or in combination; and are invalid under 35

U.S.C. § 102(f).

7. Claims 1, 4, 5, and 34 of U.S. Patent No. 6,761,893 are not invalid for lack of

enablement, lack of written description under 35 U.S.C. § 112, failure to disclose the

best mode, or indefiniteness.

8. Claims 1-9 and 13-16 of U.S. Patent No. 6,913,752 are invalid for lack of

enablement, lack of written description under 35 U.S.C. § 112 and under 35 U.S.C.

§ 102(f).

9. Claims 1-9 and 13-16 of U.S. Patent No. 6,913,752 are not invalid as anticipated, or

obvious in light of, MVA viruses MVA-572, MVA-575, MVA-F6-580 and multiple

publications disclosing and describing these viruses; for failure to disclose the best

mode; or for indefiniteness.

10. Respondent has failed to prove that the patents-in-suit are unenforceable because of

inequitable conduct.

11. There is no violation of 19 U.S.C. § 1337.

If a violation were found, the record does not support issuance of a limited exclusion 12.

order and a bond during Presidential review, or the issuance of a cease and desist

order.

SO ORDERED.

Robert L. Barton, Jr.

Administrative Law Judge