

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN GABAPENTIN
IMMUNOASSAY KITS AND TEST
STRIPS, COMPONENTS THEREOF, AND
METHODS THEREFOR**

Investigation No. 337-TA-1239

LIMITED EXCLUSION ORDER

The United States International Trade Commission (“Commission”) has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by respondent Kappa City Biotech, SAS of Montlucon, France (“Respondent”) of certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor (as defined in paragraph 2 below) that infringe one or more of U.S. Patent Nos. 8,828,665 (“the ’665 patent”) and 10,203,345 (“the ’345 patent”) (collectively, “Asserted Patents”).

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of infringing certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor manufactured by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(g)(1) do not preclude the issuance of the limited exclusion order, and that the

bond during the period of Presidential review shall be in the amount of 100 percent (100%) of the entered value of the entered value of the articles subject to this Order.

Accordingly, the Commission hereby **ORDERS** that:

1. Certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor that infringe one or more of claims 1-3, 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 patent and claims 1, 2, 7, 8, 11, 12, 19, 20, 26, and 27 of the '345 patent and are manufactured abroad by, or on behalf of, or imported by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license from, or with the permission of, the patent owner or as provided by law.

2. The certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor subject to this exclusion order (*i.e.*, "covered articles") are as follows: gabapentin immunoassays kits, gabapentin-specific test strips, multi-drug test kits and strips that test for gabapentin among other drugs, and components of such kits and test strips.

3. Notwithstanding paragraph 1 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of 100 percent (100%) of their entered value, pursuant to subsection (j) of section 337 (19 U.S.C. § 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order

is approved or disapproved but, in any event, not later than sixty (60) days after the receipt of this Order. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection (“CBP”), in advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

5. In accordance with 19 U.S.C. § 1337(1), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

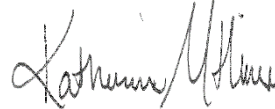
6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 210.76).

7. The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR §§ 201.16(a), 210.7(a)(1)), the

Commission orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Katherine M. Hiner". The signature is fluid and cursive, with the first name being the most prominent.

Katherine M. Hiner
Acting Secretary to the Commission

Issued: July 25, 2022