

**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs**[222A2100DD/AAKC001030/  
AOA501010.999900]**HEARTH Act Approval of Tule River Indian Tribe of the Tule River Reservation, California Leasing Ordinance****AGENCY:** Bureau of Indian Affairs, Interior.**ACTION:** Notice.

**SUMMARY:** The Bureau of Indian Affairs (BIA) approved the Tule River Indian Tribe of the Tule River Reservation, California Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into agriculture, business, residential, wind and solar, and wind energy evaluation leases without further BIA approval.

**DATES:** BIA issued the approval on December 16, 2021.

**FOR FURTHER INFORMATION CONTACT:** Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, [sharlene.roundface@bia.gov](mailto:sharlene.roundface@bia.gov), (505) 563-3132.

**SUPPLEMENTARY INFORMATION:****I. Summary of the HEARTH Act**

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the

HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Tule River Indian Tribe of the Tule River Reservation, California.

**II. Federal Preemption of State and Local Taxes**

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447-48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation v. Thurston County*, 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because "tax on the payment of rent is indistinguishable from an impermissible tax on the land." See *Seminole Tribe of Florida v. Stranburg*, 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of "traditional notions of Indian self-government," requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* balancing test from the preamble to the surface leasing regulations, 77 FR at 72447-48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to "allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities." 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes "flexibility to adapt lease terms to suit [their] business and cultural needs" and to "enable [Tribes] to approve leases quickly and efficiently." H. Rep. 112-427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. See *Michigan v. Bay Mills Indian Community*, 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that "[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding"). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. See *id.* at 810-11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. See 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including

terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Tule River Indian Tribe of the Tule River Reservation, California.

**Bryan Newland,**

*Assistant Secretary—Indian Affairs.*

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## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1296]

### Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same; Notice of Institution of Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 17, 2021, under section 337 of the Tariff Act of 1930, as amended, on behalf of AbbVie Inc. of Chicago, Illinois; AbbVie Biotechnology Ltd. of Bermuda; and AbbVie Operations Singapore Pte. Ltd. of Singapore. A supplement to the complaint was filed on January 4, 2022. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States and the sale of certain adalimumab, processes for manufacturing or relating to same, and products containing same by reason of the misappropriation of trade secrets and tortious interference with contractual relations, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

**ADDRESSES:** The complaint, except for any confidential information contained

therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

#### SUPPLEMENTARY INFORMATION:

*Authority:* The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2021).

*Scope of Investigation:* Having considered the complaint, the U.S. International Trade Commission, on January 25, 2022, Ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States or in the sale of certain products identified in paragraph (2) by reason of the misappropriation of trade secrets and tortious interference with contractual relations, the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "adalimumab (drug substance and drug product), vials, prefilled syringes, autoinjectors or other presentations containing same, and the methods of manufacturing and processes for making the same";

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064

AbbVie Biotechnology Ltd, Harbour Fiduciary Services Limited, Thistle House, 4 Burnaby Street, Hamilton HM11, Bermuda  
AbbVie Operations Singapore Pte. Ltd., 23 Tuas South Avenue 6, Singapore 637022

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Alvotech hf., Sæmundargata 15-19, 101 Reykjavik, Iceland  
Alvotech Germany GmbH, Karl-Heinz-Beckurts-Str. 13, 52428, Jülich, Nordrhein-Westfalen, Germany  
Alvotech Swiss AG, Thurgauerstrasse 54 Zürich, 8050 Switzerland  
Alvotech USA Inc., 1201 Wilson Blvd., Ste 2130, Arlington, VA, 22209  
Ivers-Lee AG, Kirchbergstrasse 160, Burgdorf, Bern, 3400 Switzerland  
Teva Pharmaceutical Industries Ltd., 5 Basel Street, Petach Tikva, 49131 Israel  
Teva Pharmaceuticals USA Inc., 1090 Horsham Road, North Wales, PA 19454

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a/the respondents to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing