

February 24, 2023

The Honorable Katherine Tai
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Ambassador Tai,

We write to share concerns about trade policy and access to a groundbreaking treatment for cystic fibrosis (CF). Vertex, a company based in Boston, makes and sells the combination drug elexacaftor/tezacaftor/ivacaftor and ivacaftor under the brand name Trikafta. This drug will be patent protected in the United States, and in many other countries, through 2037. In the United States, the list price for this drug hovers around \$322,000 for a year of treatment.¹ The development of this combination drug built off the findings of research funded by the National Institutes of Health.²

Independent reviews have determined that Trikafta is the most efficacious treatment for CF.³ Use of this drug is associated with a dramatic increase in life expectancy for patients with the condition.⁴ According to a patient registry, Americans born with CF since 2017 have a life expectancy of 52 years; a decade ago, their counterparts faced a life expectancy of only 38 years.⁵

Worldwide, only an estimated 12% of people with CF use Trikafta.⁶ Throughout the Global South, the treatment is currently not accessible because of Vertex's profiteering. Vertex does not sell and has not registered the product in India, South Africa, or Ukraine, even though it has filed patents in these countries, thereby preventing other manufacturers from distributing in these markets.⁷

Vertex has registered the drug in Brazil⁸ and is undergoing an assessment process to determine whether it will be made available in the public health system. Brazilian patient organizations fear that Trikafta's extraordinarily high price point makes access extremely unlikely.^{9,10}

¹ <https://collections.nlm.nih.gov/txt.nlm.nlmuid-101769589-pdf>

² <https://www.nhlbi.nih.gov/research/cystic-fibrosis>

³ https://icer.org/wp-content/uploads/2020/08/ICER_CF_Evidence_Report_042720.pdf

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7255286/>

⁵ <https://www.cff.org/community-posts/2022-08/people-cf-are-living-longer-what-does-mean-our-care>

⁶ [https://www.cysticfibrosisjournal.com/article/S1569-1993\(22\)00031-5/fulltext](https://www.cysticfibrosisjournal.com/article/S1569-1993(22)00031-5/fulltext)

⁷ <https://www.nytimes.com/2023/02/07/health/cystic-fibrosis-drug-trikafta.html>

⁸ [https://www.thelancet.com/journals/lanam/article/PIIS2667-193X\(23\)00008-X/fulltext](https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(23)00008-X/fulltext)

⁹ <https://pubmed.ncbi.nlm.nih.gov/31570318/>

¹⁰ <https://www.nytimes.com/2023/02/07/health/cystic-fibrosis-drug-trikafta.html>

Earlier this month, CF patients and their families, supported by civil society organizations and access to medicines experts, filed compulsory license requests for the patents on Trikafta in Brazil, South Africa, and Ukraine.¹¹ In India, patients requested the government revoke Vertex's patents on the drug. If this request in India is not granted, patient advocates are prepared to submit a compulsory license application.¹²

In response to such petitions, the governments of Brazil, India, South Africa, and Ukraine can claim the right to grant compulsory or government use licenses pursuant to national law. The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) preserves this right. Article 31 of the Agreement explicitly states that countries may grant compulsory or government use licenses, thereby allowing generic licensees to supply a product if mandated procedures are followed and if adequate remuneration is paid.

We ask that the United States Trade Representative (USTR) produce a letter providing assurances that the office will not sanction Brazil, India, South Africa, or Ukraine if their governments issue compulsory or government use licenses and thereafter permit the registration and sale of authorized generic versions of Trikafta. Furthermore, if the aforementioned countries issue or even merely explore issuing compulsory or government use licenses, we ask that USTR not place them on the 301 Report's Watch List.

Historically, the United States government has pressured other countries not to utilize the flexibilities protected by TRIPS. In 2018, the United States threatened to block Colombia's accession to the Organisation for Economic Co-operation and Development because the South American country had considered granting a compulsory license for drugs to treat Hepatitis C.¹³ In 2007, USTR placed Thailand on the 301 Report Priority Watch list, following the implementation of government use licenses for patented pharmaceutical products.¹⁴ And in 1998 and 1999, South Africa appeared on the 301 Report Priority Watch List, in response to efforts to allow compulsory licenses for expensive AIDS drugs.¹⁵ Following pressure from advocates, however, President Clinton signed an executive order that supported the rights of sub-Saharan African countries to produce and import generic HIV treatments.¹⁶

In signing this letter, we ask that USTR once again respect the rights of other country governments to exercise TRIPS flexibilities and to defend public health.

¹¹ <https://www.statnews.com/pharmalot/2023/02/07/vertex-cystic-fibrosis-parents-india-brazil-ukraine-south-africa-license/>

¹² <https://www.statnews.com/pharmalot/2023/02/07/vertex-cystic-fibrosis-parents-india-brazil-ukraine-south-africa-license/>

¹³ <https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf>

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3176479/>

¹⁵ <https://cyber.harvard.edu/people/ffisher/South%20Africa.pdf>

¹⁶ <https://www.govinfo.gov/content/pkg/FR-2000-05-12/pdf/00-12177.pdf>

Sincerely,

American Medical Student Association
Health GAP
Initiative for Medicines, Access & Knowledge (I-MAK)
Justice is Global
NETWORK Lobby for Catholic Social Justice
Partners In Health
Public Citizen
T1International
Trade Justice Education Fund
Treatment Action Group
Universities Allied for Essential Medicines North America

Cc: The Honorable Joe Biden, President of the United States of America
The Honorable Xavier Becerra, Secretary, Department of Health and Human Services
The Honorable Tom Carper, United States Senator from Delaware, Chair of the Senate Subcommittee on International Trade, Customs, and Global Competitiveness
The Honorable Bob Menendez, United States Senator from New Jersey, Chair of the Senate Committee on Foreign Relations
The Honorable Bernie Sanders, United States Senator from Vermont, Chair of the Senate Committee on Health, Education, Labor, and Pensions
The Honorable Loyce Pace, Assistant Secretary, Office of Global Affairs, Department for Health and Human Services
The Honorable Gary H. Gibbons, Director, National Heart, Lung, and Blood Institute