July 30, 2020

Anthony S. Fauci, M.D.
NIAID Director
Bethesda MD 20892-2520
Via: Anthony.Fauci@nih.hhs.gov

Dear Dr. Fauci:

We are writing to ask that the National Institute of Allergy and Infectious Diseases (NIAID) *not* extend exclusive rights to a portfolio of federally-owned HIV treatment-related patent grants and applications in countries with lower incomes. Specifically, we request that if NIAID grants the proposed exclusive license to the firm RNAceuticals, the geographic scope of exclusivity does not extend to countries that have a per capita income less than 30 percent of the United States.

The notice and request for comment on the license in question was published in the Federal Register (85 FR 41607) with the title:

> Prospective Grant of Exclusive Patent Commercialization License: N6, a Novel, Broad, Highly Potent HIV-Specific Antibody and a Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains

The proposed licensee is RNAceuticals, a perplexing firm that does not maintain a web page. The company has refused to provide information about its Board of Directors, senior management, and ownership, making it difficult to assess the company's capacity to develop products or to address health and affordability issues in developing countries.

For existing HIV drugs, most companies that currently hold patents on useful antiretroviral drugs have demonstrated a willingness to license on a non-exclusive basis in roughly 115 lower and middle income countries, including South Africa and India, via the Medicines Patent Pool. Instead this proposed license would extend exclusivity to this mystery firm to HIV antibodies already in clinical trials to Brazil, China, India, South Africa, and Russia, and apparently Serbia.

The USAID is aware that most persons living with HIV reside in countries with lower incomes and scarce resources to purchase medicines, and that the role of donors in supporting such areas is constantly at risk and is declining relative to the number of persons needing treatments. While only a handful of developing countries are included in the proposed license, several have large populations of persons living with HIV, and five countries (India, China, Brazil, Russia and South Africa) can play an important role in manufacturing generic versions of products covered by the license. The exclusive license would allow the licensee to prevent that manufacture.

The following table illustrates the disparity of incomes in countries covered by the license.

Country	GNI per capita in 2019 (Atlas method)
United States	$ 65,760
Australia	$ 54,910
Canada	$ 46,370
European Union	$ 35,721
Germany	$ 48,520
Spain	$ 30,390
Italy	$ 34,460
France	$ 42,400
UK	$ 42,370
Sweden	$ 55,840
BRICS Countries	
Brazil	$ 9,130
Russian Federation	$ 11,260
India	$ 2,130
China	$ 10,410
South Africa	$ 6,040
Serbia	$ 7,020

This table only illustrates the income differences among countries in the proposed license, and not the high incidence per capita of HIV in some of the countries. For example, in South Africa, UNAIDS estimates that 19 percent of the population between 15 and 49 years old is living with HIV.

It is also highly relevant that all five of the BRICS countries have some capacity to manufacture generic products and to supply countries with similar or lower incomes, where affordability and access challenges are acute and well known. The expansion of HIV treatments in developing countries would have been impossible without access to HIV generic drugs manufactured in India, China and Brazil, and for biologic drugs or vaccines, all five of the BRICS countries offer potentially important capacity for manufacturing affordable products.

The Bayh-Dole Act requires NIAID to limit the scope of rights to that which is reasonably necessary to induce the investment necessary to bring an invention to practical application, where it is to be made available to the public on reasonable terms. In addition, the Public Health Service's Licensing Policy strives "to promote commercial development of inventions in a way that provides broad accessibility for developing countries." A license that extends exclusivity to resource-poor countries, where exclusivity is not reasonably necessary, is inconsistent with the Bayh-Dole Act and the PHS Licensing Policy.

In the case of HIV drugs, GSK, Pfizer, Abbott, Gilead, BMS, Roche and other companies have already shown a willingness to license openly to allow production and use in India and other countries, and this has been very important in ensuring a supply of cheap generic drugs.

The NIAID should not turn these publicly supported inventions into privately owned monopolies in resource-poor countries.

Sincerely,

Global Humanitarian Progress Corporation, Colombia
Health Global Access Project
Knowledge Ecology International (KEI)
Médecins Sans Frontières (MSF) Access Campaign
Public Citizen
Red de Acceso a Medicamentos Guatemala, RedMedGua
SECTION27
Third World Network (TWN)
Treatment Action Campaign (TAC)
Universidades Aliadas por Medicamentos Essenciais - UAEM Brasil
Universities Allied for Essential Medicines (UAEM)

Professor Brook K. Baker, Northeastern U. School of Law
Christopher Morten, NYU School of Law
Eric Sawyer
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Hernán Núñez Rocha, former Director of the Ecuadorian patent office
Luis Villarroel Villalón, Corporación Innovarte (Chile)
Professor Guillermo Vidaurreta, FLACSO Argentina
Professor Manuel Becerra Ramírez, Universidad Nacional Autónoma de México
Professor Rafael Pérez Miranda, Universidad Autónoma Metropolitana, México