

The Honorable Dr. Manmohan Singh  
Prime Minister of India  
South Block, Raisina Hill  
New Delhi, India 110 011

December 16, 2004

Sent by Facsimile: +91.11.23019545

Dear Mr. Prime Minister,

We, the undersigned organizations, are gravely concerned that India will trade away its rights to protect the public health of people who need access to low-cost, quality generic medicines—people living with HIV/AIDS and other public health problems in India and around the world. As you know, poor people around the world depend on India as the major source of supply for affordable generic medicines. We are asking you to prioritize the needs of those people while you consider changes to the Indian Patents Act.

By January 1, 2005, India is expected to become compliant with World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and begin to protect and enforce product patents on pharmaceuticals. Product patents will prevent the routine generic production that has been responsible for major reductions in the cost of antiretroviral medicines, as well as other medicines that treat public health problems. As a result, drug prices will increase and lack of access to medicines will worsen—in India and around the world. This will be particularly true for newer, more expensive medicines such as second-line antiretrovirals, which are currently priced out of reach of those who most need them, because of a lack of generic competition.

As a signatory to the Doha Declaration on the TRIPS Agreement and Public Health (the “Doha Declaration”), India promised to implement the TRIPS Agreement “in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>1</sup> We strongly urge you to keep your promise and make full use of your rights under the TRIPS Agreement, as reaffirmed by the Doha Declaration, in order to prioritize public health and access to medicines for all over excessive monopoly rights for pharmaceutical companies.

Draft amendments to the Patents Act currently under consideration by your government could undermine medicines access for people in need—in India and around the world. We call on you to take the following steps in amending the Patents Act:

- **India should delay implementation of the TRIPS Agreement until sufficient pro-public health safeguards are included in the Patents Act.** Many WTO Member Countries—developed and developing countries alike—have been unable to meet artificial deadlines when such deadlines would have pre-empted sound decision making regarding critical public health matters such as access to medicines. India should complete an assessment of the impact of protection and enforcement of product patents on public health before revising the Patents Act. Transparent, public consultation with all sectors of civil society prior to revision and implementation is another necessary prerequisite to amendment of the Patents Act.

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<sup>1</sup> “Declaration on the TRIPS agreement and public health,” WT/MIN(01)/DEC/2, 20 November 2001

- **Simplify and streamline India’s compulsory licensing procedure.** Routine issuance of compulsory licenses after January 1, 2005 in India is critical if the rapid entry of generic versions of important pharmaceuticals is to continue. But compulsory licensing in India is cumbersome and time consuming. The process must be changed to facilitate routine and expedited compulsory licensing of important medicines. A strictly enforced deadline of one to three months should be established for the grant of a compulsory license, and rights of appeal should not include permission for injunctive relief that would impede the use of the license.
- **Retain the pre-grant opposition procedure.** This procedure permits opposition to potentially frivolous patent applications, protecting consumers against high prices on non-innovative pharmaceutical products under consideration for patent protection.
- **Remove draft provisions for new-use or second-use patents, currently described in Section 3(d) of the Patents Act.** TRIPS does not require the granting of additional patents for new uses or new dosage forms for known medicines. New use or second use patents do not reward or encourage true innovation; they will however increase the cost of important medicines, compromise patient access, and extend monopolies over a longer period of time.
- **Fully implement the decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity (the “August 30th Decision”).** The draft amendment to the Patents Act would not permit export of compulsorily licensed medicines from India without a compulsory license granted in the importing country. If the importing countries does not have a patent for the compulsorily licensed medicine in force, it would not be allowed to import compulsorily licensed medicines exported by India, even though the August 30<sup>th</sup> Decision clearly permits this. Despite its flaws, the August 30<sup>th</sup> Decision should be implemented in as complete a manner as possible.

We look forward to your response to this urgent request.

Sincerely,  
<list in formation>

ACT UP Cleveland, USA  
 ACT UP East Bay, USA  
 Act Up-Paris, France  
 Action Against AIDS, Germany  
 Africa Action, USA  
 African Network of People living with HIV/AIDS (NAP+)  
 AGIHAS (PWA Support group), Latvia  
 AIDS and Rights Alliance for Southern Africa (ARASA)  
 AIDS Care Trust, Namibia  
 AIDS Law Unit, Namibia  
 AIDS Policy Project, USA  
 AIDS Treatment Data Network, USA  
 AIDSETI-AIDS Empowerment and Treatment International, USA and Burkina Faso  
 American Jewish World Service, USA  
 American Medical Students Association (AMSA), USA  
 Association African Solidarité, Burkina Faso  
 Association de Lutte Contre le SIDA (ALCS), Morocco

Brazilian Interdisciplinary AIDS Association (ABIA), Brazil  
Brazilian Network for People's Integration (REBRIP), Brazil  
Canadian HIV/AIDS Legal Network, Canada  
Canadian Treatment Action Council (CTAC), Canada  
Center for Health and Gender Equity (CHANGE), USA  
Community Health Media Trust, South Africa  
Community HIV/AIDS Mobilization Project (CHAMP), USA  
Department of Global Health, Loma Linda University, USA  
Essential Action, USA  
Essential Drugs Project, UK  
European AIDS Treatment Group (EATG)  
Forum for Integrative AIDS Research, USA  
Gay Men's Health Crisis, USA  
Gays and Lesbians of Zimbabwe (GALZ), Zimbabwe  
Global AIDS Alliance, USA  
Global Health Interest Group, University of Western Ontario, Canada  
Grupo Português de Activistas sobre Tratamentos de VIH/SIDA, Portugal  
Health GAP, USA  
Hepatitis C Harm Reduction Project, USA  
Human Rights Watch, USA  
India Health Initiative, University of Western Ontario, Canada  
Indian Network of People living with HIV/AIDS (INP+), India  
International Health Action Group, Memorial University Medical School, Canada  
KAIPPG International, USA  
KAIPPG, Kenya  
Lega Italiana per la Lotta contro l'AIDS, Italy  
Living Hope Organization, Nigeria  
McGill International Health Initiative, Canada  
Middle East Children's Alliance, USA  
National Association of People Living with AIDS (NAPWA), USA  
National Forum People living with HIV/AIDS, Uganda  
Pan African Treatment Access Movement (PATAM)  
Positive Living Group, Malaysia  
RESULTS, Seattle, USA  
Rwanda NGOs Forum on HIV/AIDS, Rwanda  
Sida Info Service, France  
SIDACTION, France  
Solidarité Sida, France  
Solidarity and Action Against HIV Infection in India, SAATHI, India  
Southern African Network of AIDS Service Organizations (SANASO)  
Student Global AIDS Campaign, USA  
Tanzanian Network of People Living with HIV/AIDS (TANEPHA), Tanzania  
Thai Treatment Action Group, Thailand  
Toronto Chapter, Physicians for Global Survival, Canada  
Universite de Montreal's Comite d'Action, Sociale et Internationale (CASI), Canada  
Universities Allied for Essential Medicines, USA

cc: The Honorable Minister Kamal Nath, Ministry of Commerce and Industry

The Honorable Minister Ram Vilas Paswan, Ministry of Chemicals and Fertilizers  
The Honorable Union Minister Dr. Anbumani Ramadoss, Ministry of Health and Family Welfare  
The Honorable Ronen Sen, Ambassador of India to the United States of America  
The Honorable Dr. A.P.J. Abdul Kalam, President of India