

Civil Society Statement in Support of Brazilian Patent Law Reform to Increase Access to Medicines for All

September 16, 2013

This is a joint statement from civil society and advocacy organizations that work on access to medicines, intellectual property and trade policy, human rights, and other social and economic justice issues from around the world. We are writing to support proposed changes to Brazil's patent law outlined in *Brazil's Patent Reform: Innovation Towards National Competitiveness* and specified in **Bill no. H.R. 5402/2013**. The public purpose behind the proposed reform is to use flexibilities allowable under the WTO TRIPS Agreement so that Brazil can better meet the rights and needs of its people to have increased access to affordable medicines of assured quality. The reforms should also permit Brazil to become more self-reliant with respect to domestic manufacture of medicines by preventing or overcoming patent and data monopoly barriers and allowing more widespread generic competition. In sum, we think these reforms are essential for Brazil to meet its human rights obligations, especially the right to health and the right of access to medicines.

We outline how the proposed patent law reforms will positively impact access to medicines:

- Article 2 of the Bill revokes a provision in the existing Patent Act that allows extension of the patent term beyond 20 years when there has been a 10-year-plus delay, for any cause, in the granting of a patent. This provision on extensions is problematic because the patent applicant already has a de facto monopoly with respect to a pending patent application and yet it gets an additional period of guaranteed monopoly once the delayed patent has been granted. This extra period of monopoly extends the time that the patent holder can charge exorbitant prices and delays competitive generic entry. The consequence is either a drain on public or private resources or patients going without needed, cost-prohibitive treatments.
- Article 3 of the Bill disallows patents on (a) new uses of existing medicines and (b) new forms of known substances (medicines) unless the new form shows a significant improvement in the known efficacy of the medicine. This provision closely follows the standard of patentability that has been used so successfully in India and which was recently upheld by the Supreme Court of India. This provision is especially important, as it will allow Brazil to weed out evergreening claims for new patent monopolies based on routine discovery of new uses and minor modifications to existing medicines. The proposed Bill nonetheless encourages and welcomes modifications in existing medicines that provide real therapeutic benefits to patients.
- Article 3 of the Bill also raises the standard for inventive activity or step by requiring that the invention must represent a significant technical advance with respect to the current state of the art. Again this ensures that patents are not granted on "me-too" drugs and minor variations of earlier medicines that don't provide significant health benefits.
- Article 3 of the Bill allows opposition procedures by any interested party, such as patients and civil society groups, at any time until the end of the patent examination period (when a decision is issued). Through opposition procedures, interested parties can offer relevant evidence challenging the merits of the application. In addition, Brazil can independently seek expert technical opinions on the merit of the

application. Use of such opposition procedures has been very successful in weeding out unmeritorious patent applications in India allowing early generic access to many important medicines.

- Article 3 of the Bill limits data protection and expressly allows the National Sanitary Agency (medicines regulatory authority) to use previously filed test results and other data in approving registration applications of generic equivalents. Multinational pharmaceutical companies and their supporters in the US and EU have long supported monopoly control over regulatory data – what is called data exclusivity, which can prevent generic competition for many years and significantly increase the cost of medicines.
- Articles 3 and 5 of the Bill also ensures that the National Sanitary Agency will continue to provide input into assessing whether a medicine presents a health risk and whether a medicine meets standards of patentability, if that medicine is of interest in light of Brazil’s access to medicines policy or its pharmaceutical care program under its National Health System. Given its expertise on both matters, it is important that the Agency be permitted to perform these roles, which will again help ensure access to safe and affordable medicines.
- Article 4 of the Bill allows the government of Brazil to permit public non-commercial use of a patent. This is a provision that Brazil and other governments should use more often. In a world where more and more medicines are patent protected and where more and more countries are bound by the TRIPS Agreement, it makes sense for governments to allow generic competition on over-priced medicines that are important to public health goals.

In conclusion, we urge quick passage and effective implementation of the proposed reforms despite the expected opposition from the US and EU and from Big Pharma. The Doha Declaration on the TRIPS Agreement and Public Health clarifies that Brazil and other countries can prioritize access to medicines, which is the objective of the proposed patent law reform. By pursuing the patent law reforms outlined above, largely in response to civil society campaigns, Brazil is exercising its lawful right to use TRIPS-compliant flexibilities to fulfill its human right obligations to its people.

Action against AIDS, Germany

International Treatment Preparedness Coalition
in Eastern Europe and Central Asia

Act Up Paris, France

Hivos, The Netherlands

Afro Global Alliance, Ghana

HIV Prevention Justice Alliance, USA

AidsFonds, The Netherlands

Housing Works, USA

AIDS Foundation of Chicago, USA

Initiative for Social and Economic Rights (ISER),
Uganda

AIDS-Free World, USA

AIDS Law Project, Kenya

Intellectual Property Left, S. Korea

African Services Committee, USA

International community of women living with
HIV -Eastern Africa-Kenya chapter

AFROCAB, Zambia

International Federation of Medical Students

Alianza LAC - Global por el Acceso a Medicamentos
 - ABIA-GTPI (Brasil)
 - Acción Internacional por la Salud – AIS América Latina y el Caribe
 - Acción Internacional por la Salud – AIS Bolivia
 - Acción Internacional por la Salud – AIS Colombia
 - Acción Internacional por la Salud – AIS Ecuador
 - Acción Internacional por la Salud – AIS Nicaragua
 - Acción Internacional por la Salud – AIS Perú
 - Farmamundi (España)
 - Federación Médica Colombiana
 - Fundación IFARMA (Colombia)
 - Fundación GEP (Argentina)
 - Health Action International
 - HAI EUROPE
 - International Treatment Preparedness Coalition LATCA Guatemala
 - KEI – Knowledge Ecology International (USA)
 - Misión Salud (Colombia)
 - Políticas Farmacéuticas (Chile)
 - Public Citizen (USA)
 - Red Ge (Perú)
 American Medical Student Association, USA

 Amore Healthcare Foundation, Inc., Nigeria

 Asha Kiran Samudayak Samiti, India

 Asia Pacific Network of People Living with HIV (APN+)

 Asia Pacific Network of Sex Workers, Thailand

 Asian Network of People Who Use Drugs, Thailand

 Asociación de Consumidores y Usuarios en Acción - FACUA (Association of Consumers and Users in Action-FACUA), Spain

 Association of Korean Doctors for Health Rights, South Korea

 BUKO Pharma- Kampagne, Germany

 Bolivian Network of People Living with HIV/AIDS (REDBOL), Bolivia

 Bread for the World, Germany

 Canadian HIV/AIDS Legal Network, Canada

 Association of Brazil

 International HIV/AIDS Alliance

 Korean Pharmacists for Democratic Society

 LACCASO - Latin America and the Caribbean Council of Aids Organizations

 Lean on Me Foundation, Kenya

 Lhak-Sam (BNP+), Bhutan

 Manipur Network of Positive People (MNP+), India

 Mariam Foundation, Uganda

 Marilia Bernardes Marques, Brazil

 Maryknoll Office for Global Concerns, USA

 Medecins Sans Frontiere/Doctors Without Borders, Int'l

 Médicos del Mundo, Argentina - América Latina y el Caribe

 Minnesota AIDS Project, Inc.

 National Care Centre, Uganda

 National Empowerment Network of People living with HIV/AIDS in Kenya

 National Forum of People Living with HIV and AIDS Networks in Uganda (NAFOPHANU)

 NGO "АГЕР'С"/Директор ОФ "АГЕР'С", Kazakhstan

 Network Of Maharashtra by People Living with HIV/AIDS (NMP+), India

 Network of Association of People Living with HIV in Lao PDR

 Oxfam, International, UK

 PATAM, Pan African Treatment Access Movement

 Pakistan Network of Positive People, Pakistan

 People's Health Movement, Global

Cebes – Centro Brasileiro de Estudos de Saúde, Brazil	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
Center for Epidemiological Surveillance, Brazil	Proclade, Cameroon
Center for Health Human Rights and Development (CEHURD), Uganda	Salud por Derecho, Spain
Coalition for Health Promotion and Social Development (HEPS Uganda)	Salud y Farmacos, Spain
Coalition Plus, France	Salud y Farmacos, USA
DADO-Pakistan	Section27, South Africa
DoginRyun, S. Korea	Sociedade Brasileira de Bioética, Brazil
East African research and Legal Chambers, Rwanda	Solidarity for HIV/AIDS Human Rights-NANURI+, S. Korea
East African Health Platform (EAHP), Tanzania	Southern and East African Trade Institute (SEATINI), Uganda
Ethiopian Drug Information Network, Ethiopia	Stichting Health Action International (HAI), The Netherlands
European AIDS Treatment Group (EATG)	Stop AIDS Alliance, Int'l
FIOCRUZ, Brasil	Stop AIDS Campaign, UK
Foundation for Integrative AIDS Research (FIAR), USA	Stop AIDS Now!, The Netherlands
Gestos - HIV, Communication and Gender	Soa Aids, Netherlands
Global Justice Institute, USA	TASO - The Aids Support Orgainsation of Uganda
Global Network of People Living with HIV (GNP+), The Netherlands	Third World Network, Int'l
The Global Network of Sex Work Projects, UK	Treatment Action Campaign, South Africa
The Good Neighbor, Nigeria	Universidad de Costa Rica, Costa Rica
Grandmothers Advocacy Network, Canada	VOCAL-NY (formerly NYC AIDS Housing Network), USA
Health Access Network, Ghana	WEDNET-Africa, Uganda
Health Digest Foundation, Ghana	Women`s health, HIV and AIDS Southern Africa, Zimbabwe
Health GAP (Global Access Project), USA	World AIDS Campaign and Africa Regional Platform on Health, South Africa
Interagency Coalition on AIDS and Development (ICAD), Canada	