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

July 15, 2013

This is a joint letter from civil society and advocacy organizations that work on access to medicines, intellectual property and trade policy, human rights, and other social/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, including 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 is problematic because the patent applicant already has a de facto monopoly even with respect to a pending patent application and then gets an addition period of guaranteed monopoly once the delayed patent has been granted. This extra period of monopoly extend 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. Brazil nonetheless encourages and welcomes modifications in existing medicines that provide real therapeutic benefits to patients.
- Article 3 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 means that Brazil might not grant patents on me-too drugs and minor variations of earlier medicines that don't provide significant health benefits.
- Article 3 allows opposition procedures by any interested party, which would include patients, civil society groups, and others, 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 provides limited data protection, but 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. We applaud Brazil for clarifying that it will not grant data monopolies.
- Articles 3 and 5 also ensures that the National Sanitary Agency will continue to have input into accessing 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 allows the government of Brazil to permit public non-commercial use of a patent. Frankly, this is something that we think 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.

We urge quick passage and effective implementation of the proposed reforms despite 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 past civil society campaigns, Brazil is exercising its lawful right to use TRIPS-compliant flexibilities to fulfill its human right obligations to its people.

Very truly yours

Gestos - HIV, Communication and Gender

LACCASO - Latin America and the Caribbean Council of Aids Organizations

Health GAP (Global Access Project), USA

Treatment Action Campaign, South Africa