OPEN LETTER FROM INTERNATIONAL INTELLECTUAL PROPERTY SCHOLARS AND EXPERTS SUPPORTING BRAZIL’S PROPOSED PATENT REFORM

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We are legal, intellectual property, trade, development, human rights, and other academics and legal experts who are writing in support of the proposed changes to Brazil’s patent law recently released by the Brazilian government and recommended in a report by the Brazilian House of Representative, Center for Strategic Studies and Debates, titled Brazil’s Patent Reform: Innovation Towards National Competitiveness.

The draft law and report propose amending Brazil’s existing patent law to take greater advantage of policy options (aka “flexibilities”) that are permitted by the World Trade Organization’s agreement on Trade Related Aspects of Intellectual Property Rights and that would promote access to affordable medicine in Brazil as well as adherence to Brazil’s national and international human rights obligations. As documented the attached Technical Review, in our judgment each of the described reforms is both TRIPS compliant and desirable in light of Brazil’s human rights obligations and public health goals and in light of its goal of increasing its technological and innovation capacity and self-reliance with respect to knowledge goods.

Bill no. H.R. 5402/2013 proposes the following substantive amendments to the Brazil Patent Act, Law no. 9279, of May 14, 1996:

- limits the patent term at 20 years maximum, as authorized by Article 33 of the TRIPS Agreement (see Article 2, revoking Patent Act Art. 40, sole §);
- clarifies subject matter that is not considered inventive particularly new use patents and patents on new forms of known substances, as allowed by TRIPS Articles 1.1, 7, 8, 27.1 and 27.3(a) and along the lines of Section 3(d) of the India Amended Patents Act 2005 (see Article 3, amending Patent Act Art. 10);
- increases the standard of inventive step, as allowed by TRIPS Articles 1.1, 7, 8, and 27.1 and along the lines of the India Amended Patents 2005, to require a “significant technical advance in regards to the state of the art” in order to heighten the standard for incremental innovation and to discourage ever-greening (see Article 3, adding Patent Act Art. 13 [with respect to patents] and 14 [with respect to utility models]);
- creates a full-fledged pre-grant opposition mechanism, including provision for electronic submission of evidence of related inventions and prior art and for commission of technical opinions from academic and other experts, as allowed by TRIPS Articles 1.1, 7, 8, and 62.4 (see Articles 3 and 4, amending Patent Act Art. 31 and adding Art. 31-A);
- clarifies that the protection of undisclosed pharmaceutical test data in Brazil...
prevents unfair commercial use and unauthorized disclosure, but permits “use, by
government bodies of test results or other undisclosed data, for market approval of
products equivalent to the product for which they were initially presented,” as
allowed by TRIPS Article 39.3 (see Article 3, amending Patent Act Art. 195);

- updates the Sanitary Agency’s (ANVISA) prior consent mechanism for
  pharmaceutical patents, in accordance with the recently adopted ANVISA Resolution
  21/2013 and as allowed by TRIPS Article 1.1, 7, and 8, granting ANVISA the duty to
  analyze, prior to the Patent Office, patent applications involving
  pharmaceutical/chemical (i) products that have previously been rejected by the
  Agency, and thus present health risks, and (ii) compounds that are of interest to
  support Brazil’s National Health System’s access to medicines policy or a
  pharmaceutical care program, and that may not meet the patentability requirements
  5, amending Article 7 of Law no. 9782 of 26 January 1999);

- incorporates within the Patent Act the public non-commercial use mechanism as set
  forth by the WTO TRIPS Agreement Article 31 (see Article 4, adding Patent Act Art.
  43-A).

In pursuing the patent law reforms outlined above, Brazil is exercising its lawful sovereign
right to make use of TRIPS-compliant flexibilities so as to meet its aspirations and needs
with respect to self-reliant and sustainable development, participation in the global
knowledge economy, and fulfillment of its human right obligations to its people. Brazil is
also joining countries like India, the Philippines, Argentina, and Zanzibar, which have
already incorporated legal rules that prevent excessive granting of patents and promote
patent quality, particularly on global public goods such as medicines, and with progressive
civil society movements in other countries like Uganda and South Africa where campaigns
to amend TRIPS-plus patent legislation have recently been launched. Brazil is also relying
on, and has closely documented, a broad array of scholarly research and expert analysis that
supports each of the patent reform initiatives that it is proposing. Indeed, many of the steps
that Brazil is taking to help ensure patent quality and eliminate abusive patents practices
can be understood as locally tailored versions of steps recently taken in high-protection
jurisdictions such as the U.S. and E.U., where increasing concern has been expressed about
the anticompetitive effects of overgrown patent laws. In the US, for example, both Congress
and the Supreme Court have recently imposed new restrictions on patent law and
introduced new measures to improve patent quality.

If history serves as a guide, we can expect that the United States, Europe, and patent-
tensive industries, especially the patent-based multinational pharmaceutical industry, will
oppose the proposed reforms both internally in Brazil and internationally in various
forums. We fully expect that there will be vigorous, even angry protest; claims that Brazil is
undermining pharmaceutical innovation locally and globally; and threats of retaliatory
action. But in our collective and considered view, Brazil’s patent reforms are both modest
and prudent, as well as fully compliant with international norms. Armed with these
reforms, Brazil should be able to reduce the number of weak pharmaceutical (and other)
patents that are filed; weed out poor-quality patents through informed opposition procedures and the involvement of experts in its drug regulatory authority in the review process; prevent evergreening of patent monopolies by restricting secondary patents on new forms and new uses of known substances and by limiting patents to 20 years only; preclude the creation of a new form of monopoly on data submitted to drug regulators; and allow Brazil to have ready access to government-use licenses upon notice and payment of adequate remuneration so as to meet the needs of its patients for affordable medicines.

If adopted and implemented, the proposed reforms will help Brazil to protect, respect and promote human rights, and also help incentivize local production, generic entry, and competition, and lead to greater technological capacity and employment in patent-based industries. We applaud the Brazilian patent reform initiative and hope for its speedy adoption and implementation.

Signed (in personal capacities),

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