

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

7 October 2013

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 set forth by the Patent Act (see Article 3, amending Patent Act Art. 229-C, and Article 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-intensive 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),

Brook K. Baker, Professor of Law,
Northeastern U. School of Law, Program on
Human Rights and the Global Economy,
Honorary Research Fellow, University of
KwaZulu Natal, Durban, S. Africa

Amy Kapczynski, Professor of Law, Yale
Law School

Sean Flynn, Associate Director, American
University Washington College of Law,
Program on Information Justice and
Intellectual Property

Yousuf Vawda, Professor, Faculty of Law,
Head of Public Law, University of KwaZulu
Natal, S. Africa

Rochelle Dreyfuss, Professor, NYU School
of Law, USA

Lisa Forman, Lupina Assistant Professor,
Dalla Lana School of Public Health; Director,
Comparative Program on Health and Society,
Munk School of Global Affairs, University of
Toronto, Canada

David K. Levine, Professor of Economics
and Joint Chair RSCAS; Department of
Economics, European University Institute,

Lawrence Lessig, Professor, Harvard Law
School

Carlos Correa, University of Buenos Aires,
Argentina

Dean Baker, Center for Economic and
Policy Research, United States

Robert Naiman, Policy Director, Just
Foreign Policy, USA

Peter Sainsbury, Associate Professor,
School of Public Health, University of
Sydney, Australia

Mauricio Torres-Tovar, professor Major
Cundinamarca University, President of
International Association of Health Policies,
Columbia

Josep L. Ventura, MD PhD, Former head
(currently retired) of the Intensive Care Unit
of Cardiac Surgery of Hospital Universitari
de Bellvitge, l'Hospitalet de L Barcelona,
Spain

Ricardo Alberto Martínez, Ex Interventor
de ANMAT, Argentina

Italy; John H. Biggs Distinguished Professor, Department of Economics, Washington University, USA

Keith E. Maskus, Arts and Sciences Professor of Distinction, Professor of Economics, University of Colorado, USA

Graham Dutfield, Professor, School of Law, University of Leeds, U.K.

Kevin Outtersen, Professor Boston University School of Law and School of Public Health, USA

Margaret Chon, Donald & Lynda Horowitz Professor for the Pursuit of Justice, Seattle University School of Law, USA

Peter Jaszi, Professor, American University Law School, Washington, D.C.

Gonzalo Moyano, Docente e Investigador de la Cátedra Libre de Salud y DDHH. Facultad de Medicina, UBA, Argentina

Richard Elliott, Executive Director, Canadian HIV/AIDS Legal Network

Matthew Flynn, Professor Georgia Southern University, USA

Prof. Dra. María R. Mazzieri, Dto. de Farmacia, Facultad de Ciencias Químicas, Universidad Nacional de Córdoba, Córdoba, Argentina

Dr Phoebe Li, Sussex Law School, University of Sussex, UK

Charles Ngwena, Centre for Human Rights, University of Pretoria, South Africa

Kannamma Raman, Department of Civics and Politics, University of Mumbai, India

Marciano Sánchez-Bayle, Director, Pharmacy Service, Hospital Universitario Virgen del Rocío, Sevilla, España; President; Asociación para la defensa de la Sanidad Pública de Andalucía; Spokesperson FADSP,

Irene Anne Jillson, Professor Georgetown University, USA

Deborah Gleeson, Professor, School of Public Health and Human Biosciences, La Trobe University, Australia

Soledad Márquez Calderón, Institute for Health Services Research, Spain

José Adelantado Gimeno, Professor of Sociology, Autonomous University of Barcelona, Spain

Dra. Emma Verástegui Avilés, Instituto Nacional de Cancerología (National Cancer Institute), Mexico

María José Otero, Professor, Faculty of Pharmacy- University of Salamanca, Spain

Sergio E Gonorazky, MD, Chief of the Research Department, Hospital Privado de Comunidad, Argentina

Hope Lewis, Professor, Northeastern U. School of Law, USA

Dr. Ingrid Schneider, Center for Biotechnology, Society, and the Environment, University of Hamburg, Germany

Reinaldo Guimaraes, ABIFINA, Brasil

Bona Mazuka, King's College London, UK

Primah Kwagala, Center for Health, Human Rights & Development, Uganda

Gloria Manso, University of Oviedo, Spain

Beverley Snell, Burnet Institute Associate, Australia

Luigi Palombi, PalombiIP, Australia

Paul Ogendi, AIDS Law Project, Kenya

Debashish Das, India

Anthony So, Professor, Duke University, USA

Federación de Asociaciones para la Defensa de la Sanidad Pública, Madrid, España

Shamnad Basheer, Ministry of HRD, Professor in IP Law, National University of Juridical Sciences, India

Caroline B Ncube, Lecturer, University of Cape Town, S. Africa

Malebakeng Forere, Doctoral Research Fellow, World Trade Institute, Switzerland

Ernesto Alfonso Selva Sutter, Professor, Universidad Centroamericana José Simeón Cañas, El Salvador

Antonio Ugalde, Professor Emeritus, University of Texas-Austin, USA

Nuria Homedes, Salud y Farmacos, USA

Srividhya Ragavan, Professor of Law, University of Oklahoma College of Law, USA

Eva M Moya, Assistant professor, University of Texas at El Paso, USA

Susy Yeshika Olave Quispe, Agencia Española de Medicamentos y productos Sanitarios (Spanish Agency for Pharmaceuticals and other health products), Spain

Hugo Spinelli, Director del Departamento de Salud Comunitaria de la Universidad Nacional de Lanús (Director of Community Health, Lanus National University), Argentina

Corina Bontempo Duca de Freitas, Fundação de Ensino e Pesquisa em Ciências da Saúde - SESDF (foundation for research and education in health sciences), Brasil

Mariella B. D. Freitas, Professor, Departamento de Biologia Animal – Universidade Federal de Viçosa (Federal University of Vicoso, Animal Biology), Brasil

Ines Galvão, ICS-UL, Portugal

Jane Ndagire, Center for Health and Human Rights, Uganda

Carlose Eugenio Monteiro Cardoso, CODESIRA, Guine-Bissau

Riaz Tayob, Southern And East African Trade Institute (SEATINI), South Africa

Rosemary Galli, Observatorio das Nacionalidades, uEce, UK

Ashwin Parthasarathy, University of Mumbai, India

Pamela Samuelson, Professor, University of California, Berkeley Law School, USA

Lonias Ndlovu, Professor, University of Zululand, South Africa

Graeme Austin, Professor, Victoria University of Wellington, New Zealand

Jorge Contreras, Professor, American University Washington College of Law, USA

Lieve Vanleeuw, Treatment Action Campaign, South Africa

Patrick Bond, University of KwaZulu Natal, South Africa

Kevin Outterson, Professor, Boston University Law School and School of Public Health, USA

Jonathan Edwin, MPH, University of British Columbia, Canada

William Aldis, MD FACP, Asst.Prof., School of Global Studies, Thammasat University, Thailand

Nguyen Tien Lam, Head of Viral, Parasitic and HIV/AIDS Department, National Hospital of Tropical Diseases (NHTD), Vietnam

Liza Vertinsky, Associate Professor, Emory Law School, USA

Tahir Amin, Director of Intellectual Property, Initiative for Medicines, Access & Knowledge, USA

Priti Radhakrishnan, Director of Treatment Access, Initiative for Medicines, Access & Knowledge, USA

Professor José Terán, Health Action International, Ecuador

Sudip Chaudhuri, Professor of Economics, Indian Institute of Management, India

Carlos Zamora, Caja Costarricense de Seguro Social, Costa Rica

Maria Elena Lopez Nunez, Physician, Costa Rica

Rafaela Sierra, Professor (retired), University of Costa Rica, Costa Rica

Jaime Breilh, Md.MSc.PhD., Universidad Andina Simón Bolívar, Ecuador

Michael Geist, Canada Research Chair in Internet and E-commerce Law, University of Ottawa, Canada

Suerie Moon, MPA, PhD, Research Director and Co-Chair, Forum on Global Governance for Health, Harvard Global Health Institute; Lecturer, Dept. of Global Health & Population, Harvard School of Public Health; Project Co-Director, Innovation and Access to Technologies for Sustainable Development, Harvard Kennedy School of Government, USA

Michael Perlman, Professor of Economics, Chico California State University, USA

Joan Rovira, Professor, Department of Economics, University of Barcelona, Spain

Terry Dwyer, chartered tax advisor, Australia

Monica Martins, universidade estadual do Ceará, Brazil

Rasigan Maharajh, Institute for Economic Research on Innovation, South Africa

Kenneth Mwehonge, Coalition for Health Promotion and Social Development (HEPS Uganda)

Emmanuel Kamonyo, Open Society Institute for South Africa, Kenya

Nirmal Gurbani, Professor Pharmaceutical Management at IIHMR, Jaipur, India

Katherine J. Strandburg, Alfred B. Engelberg Professor of Law, New York University, USA

Anna George, Professor, Murdoch University, Australia

Robert Cook-Deegan, Professor, Duke University, USA

Adriana Nilsson, Professor, Copenhagen Business School, Denmark

Volnei Garrafa, University of Brasília, Brazil

Marcelo Lalama, Universidad Central, Ecuador

Lily Gordillo, Ministerio de Salud, Guatemala

Miguel Kottow, Universidad de Chile, Chile

Rogelio Fernandez, Universidad Autónoma de Nayarit, Mexico

Jaime Sepulveda, Asociación Latinoamericana de Medicina Social, Chile

Shubha Ghosh, University of Wisconsin, USA

Pedro Marcos Nunes Barbosa, IP Law and Civil Law Professor at PUC-Rio, Brazil

León Felipe Sánchez Ambía, Facultad de Derecho UNAM, Mexico

Tido von Schoen-Angerer, MD, MPH,
Fribourg Hospital, Switzerland, NGO Board
Member, UNITAID

Tesh. W. Dagne, Assistant Professor,
Faculty of Law, Thompson Rivers University,
Canada

Claudia Vaca, Professor, National
University, Colombia

Deborah A Ramirez, Professor,
Northeastern U. School of Law, USA

Melinda Drew, Professor, Northeastern U.
School of Law, USA

Susan Maze-Rothstein, Professor,
Northeastern U. School of Law, USA

Hazel V. J. Moir, Adjunct Associate
Professor, Research School of Social
Sciences, College of Arts & Social Sciences,
The Australian National University

Nancy Sola, Dto de Farmacia - Facultad de
Ciencias Químicas, Universidad Nacional de
Córdoba, Argentina

Daniela Fontana, Dto de Farmacia -
Facultad de Ciencias Químicas, Universidad
Nacional de Córdoba, Argentina

Mark Nichter, Reagents Professor,
University of Arizona, USA

Susan D. Foster, PhD MA, Professor of
International Health, Department of
International Health, Boston University
School of Public Health, USA

Claudio Lorenzo, Professor, Department of
Public Health and the Graduate Program in
Bioethics at the University of Brasilia, Brasil

Ruben Dario Gomez-Arias, Profesor,
Facultad Nacional de Salud Pública,
Universidad de Antioquia, Colombia

Jia Ping, Health Governance Initiative, China

Dr. Joy Fraser, Athabasca University,
Canada

Meri Koivusalo, Senior Researcher,
National Institute for Health and Welfare,
Finland

Jose Gilberto Orozco Diaz, Universidad
Nacional de Colombia, Columbia

Manuel Muñoz, Hospital Nacional Dos de
Mayo, Peru

Maria Clara Sanchez, ICA, Columbia

Lina Patricia Forero Tobaría,
Independiente, Columbia

Maritza Placencia, Universidad Nacional
Mayor de San Marcos, Peru

Rafael Edgardo Mermudez Baston,
Quimico Farmaceutico, Columbia

Claudia Roitter, Universidad Nacional de
Cordoba, Argentina

Pablo Adolfo Elias, Universidad Nacional de
Cuyo, Argentina

Albert Figueras, Universitat Autonoma de
Barcelona, Span

Martin Canas, Universidad Naciona de la
Plata, Argentina

Tapiwanashe Kujinga, Pan-African
Treatment Access Movement, Zimbabwe

Pedro Mizukami, CTS-FGV – Center for
Technology and Society at FVG Law School,
Brazil

Jean-Claude Guedon, Professor, Universite
de Montreal, Canada

Sergiy Kondratyuk, All-Ukrainian Network
of PLWH, Ukraine

Carolina Rossini, Project Director for the
Latin America Resource Center at the
Internet Governance and Human Rights
program at the New America Foundation's

Veronica Fynn, Professor, University of British Columbia, Canada

Donald W. Light, Resident Fellow 2012-2013, E J Safran Center for Ethics, Harvard University, USA

Dr. V. C. Vivekanandan, Ministry of HRD IP Chair Professor, NALSAR University of Law, India

Peter Drahos, Professor & Regulatory Institutions Network Director, Centre for the Governance of Knowledge and Development College of Asia Pacific, The Australian National University, Australia

Warren Kaplan, PhD, JD, MPH, Center for Global Health & Development, Boston University School of Public Health, USA

Margarita María Restrepo G, Profesora, Universidad De Antioquia, Colombia

Guillermo García-Capcha, Peru

Oscar LANZA V. FUNAVI, Foundation for Nature and Life Protection, Bolivia

Sonia Uema, Facultad de Ciencias Químicas - Universidad Nacional de Córdoba, Argentina

Olga Mena, Universidad de Costa Rica Costa Rica

Deborah Tussey, Professor, Oklahoma City University School of Law, USA

Talha Syed, Professor, University of California, Berkeley Law School, USA

OTI, Brazil

Dr. Douglas Ball, Independent pharmaceutical consultant, Public Health and Development, Philippines

Andy Gray, Senior Lecturer, University of KwaZulu Natal, South Africa

Dr. M.R. Santosh, Tata Institute of Social Sciences, India

Roberto López Linares, Acción Internacional para la Salud, Perú

Umunyana Rugege, Lawyer, Section 27, South Africa

Margot Kaminski, Executive Director of the Information Society Project at Yale Law School, USA

Dr. Henning Grosse Ruse – Khan, Senior Research Fellow, Max Planck Institute for Intellectual Property and Competition Law, Germany

Dr Nirmal Gurbani, India

Jon M. Garon, Director, NKU Chase Law + Informatics Institute, Professor of Law, Northern Kentucky University Chase College of Law, USA

Cailin Morrison, LLM Course Leader, School of Law, Social Sciences and Communications, University of Wolverhampton, UK

Mark Weisbrot, Co-Director, Center for Economic and Policy Research, US

Sylvia Kierkegaard, President, Intl. Association of IT Lawyers; Professor, University of Southampton, Denmark, UK