Intellectual Property Watch
http://www.ip-watch.org/

Panellists: Global Health Justice Needs Government Commitment, New Innovation Models

Published on 15 October 2012 @ 12:46 pm

By Catherine Saez, Intellectual Property Watch

Global health needs innovation but also to ensure equitable access for the world population, panellists at a roundtable said last week. At issue is the capacity of the pharmaceutical industry to innovate, and the potential barriers to access in a context of widespread diseases that blur the boundaries between developed and developing countries. Most panellists concluded that governments should hold primary responsibility for the health of their populations.

The Geneva-based Graduate Institute of International and Development Studies and Washington, DC-based Georgetown Law School organised a joint roundtable on global health law, innovation, access and justice on 10 October. Perspectives of the World Health Organization, academia and the pharmaceutical industry were presented.

"Medical innovation is basically innovation of medical technologies," said Zafar Mirza, coordinator for the Department of Public Health, Innovation and Intellectual Property at the WHO. Medical innovation stands apart from other types of innovation for several reasons, he said, some of which are that: health development is not possible without innovation and has a public good dimension; drug development is an expensive, risky and lengthy process; equitable access is an important factor; and end products are strictly and heavily regulated.

The pipelines for medical innovations are not very promising, he said, as the blockbusters are losing their patent rights, the costs of research and development (R&D) are going up, and the results going down. Developing countries have an additional concern with a lack of R&D for treatments for neglected diseases (those afflicting primarily poor populations for which there is little commercial market), he said. One of the reasons is the lack of interest of the private sector, for understandable reasons, he added.

However, in the last 10 years, the situation has changed and some progress has been made on neglected diseases, he said. Discussion about R&D for those diseases started in 1996 at the WHO, after the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into effect in 1995. Two dedicated working groups have been addressing the issue, with the current working group, the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), making a number of recommendations, one of which is for a global framework on R&D.

The recommendations of the CEWG were presented to the World Health Assembly in May (*IPW*, WHO, 25 May 2012) and member states have requested more time to discuss the recommendation on the global framework. They will meet from 26-28 November to further the discussion, Mirza said.

Ellen 't Hoen, lawyer and a research fellow at the School for Social Science Research at the University of Amsterdam and former director of the Medicines Patent Pool, and Suerie Moon, research director of the Forum on Global Governance for Health at the Harvard Global Health Institute recently published a joint article on the global R&D treaty. http://www.the-scientist.com/?articles.view/articleNo/32664/

Exclusive Rights v. Access: Old Debate but Changing Rules

"Access to medicines has been a major bone of contention between developed and developing countries since the late 1970s," said Frederick Abbott, professor at Florida State University College of Law, and governments and health policymakers are balancing strong patent systems by potentially weakening patent rights, he said.

One of the most common ways to mitigate the social welfare costs of patents in developed countries is through social insurance schemes, he said. Developing countries can subsidise medicines. They can also use

mechanisms like compulsory licences or recalibration of their patent laws. However, compulsory licensing, which is fully permitted under the TRIPS agreement and reinforced by the Doha Round, is reluctantly used by developing countries. This is mainly because when governments use compulsory licences they are often threatened with political retaliation and investment-related sanctions even though the governments making those threats know full well that that action is legal, he said.

Calibrating the patent system includes heightening inventive step standards, or making companies demonstrate improvement in efficacy of their new medicines, Abbott said, but those types of calibration can be rather difficult for developing countries to implement because they would need sophisticated knowledge in areas such as chemistry, biochemistry and biological engineering, he said. They need to be able to understand the difference between truly inventive biological mechanisms and the ones that are not, and have patent examiners able to understand this difference. According to Abbott, the calibration model used successfully by India is not really a model that can be applied to most developing countries.

The distribution of diseases has shifted, and patients in developing countries are as much affected by non-communicable diseases such as coronary diseases, cancer, diabetes, or psychiatric diseases, he said. The US Federal Reserve Bank of St. Louis (Missouri) published a report entitled "The Case Against Patents," [pdf] in which they advise just getting rid of patents, he said, adding that it is doubtful this report will have a large impact.

Pharmaceutical Industry Facing Patent Cliffs, Cooperating

For Andrew Jenner, director of intellectual property and trade at the International Federation of Pharmaceutical Manufacturers and Associations, the pharmaceutical industry has to face three main challenges. The first is that innovation is getting more difficult. The pipelines seem to be drying up and one-size-fits-all medicines are very difficult and complex to find. The second challenge is that the patients' demands in regulatory requirements are changing. There is a change in people's attitude toward lower tolerance of side effects, for example.

The last challenge is patent cliffs. This is the period of history when the highest number of patents will expire, Jenner said. "Profits are disappearing from one day to the next," he said, adding that the pharmaceutical industry had suffered the highest private sector job loss in the last two years.

"There is an ever-pressing need for us to continue to innovate," Jenner said, as there are "no more low hanging fruits in the small molecule models." It is not a matter of putting smart people in a room any more, he said, but rather about generating networks where one company may have expertise, another know-how like clinical trials, and yet another the knowledge. An example of such a network is TransCelerate BioPharm. According to a report in PharmaTimes, ten of the world's leading pharmaceutical companies have set up a non-profit organisation to collaborate and develop new medicines. Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, Roche and Sanofi. The companies have come together to "identify and solve common drug development challenges with the end goals of improving the quality of clinical studies."

Political commitment is key in the access process, Jenner said. It is a driver for success because political commitment drives the strengthening of healthcare systems with the establishment of healthcare centres and the training of healthcare professionals. Medicine is a fundamental part of access but getting medicines to patients is a complex process, he said. Among efforts of the pharmaceutical industry, Jenner cited tiered pricing, technology transfer, voluntary licences, and just recently the product development partnership (PDP) process, which brings together various private, public and academic stakeholders for R&D.

Now there needs to be more focus on non-communicable diseases and prevention, coordination and alignment with different initiatives and activities, he said, and the pharmaceutical industry needs to coordinate and collaborate more effectively. This needs to happen not only with other companies, as it is "always difficult for companies to work together because they are fiercely competitive," but also with governments, academia, healthcare professionals and NGOs.

Jenner said a general message for governments is to emphasise better coherence between their innovation, economic and health policies. "It is perfectly legitimate for countries to interpret IP laws in one way or another, but as industry we need to know what the playing field is and then we can decide whether or not we want to go there," he said. "We need to have stability. We need to have legal certainty." Governments wanting to create a pro-innovative environment need to consider it as a long term objective and need to ensure that it aligns fully with their health objectives, he said.

Global Health – More than Eradicating Specific Diseases

Currently writing a book on global health law soon to be published, Prof. Larry Gostin, faculty director at the Georgetown University O'Neill Institute for National and Global Health Law, said that what makes people healthy "is really not access to medicines and not even access to a doctor," but safe and nutritious food, clean water, sanitation, hygiene, vector control, tobacco control and the like. "It is nowhere to be found in global health debates," he said, including at the WHO.

The global health community should not obsess over the eradication of specific diseases, even as "terribly important" as is it, as eradicating those diseases will not make the population healthy, he said.

Global health justice needs a body of hard and soft laws, he said. "When I first entered global health, I thought global health was mostly about making rich countries devote resources to those who lack the capacity to do it," he said. This "is a northern view based upon guilt, but it is really the wrong view," he said. The primary responsibility for health must be governments, and they cannot rely on external funding,

although external funding can close the capacity gaps, he said. There needs to be a basic commitment at the national level. There are still residual international responsibilities, but they are based on a flawed idea of international development assistance for health, which is "very much charitable-based, with a benefactor and a recipient." It is not justice-based, he said, and lacks a sense of shared responsibility, adding, "We need to change this paradigm."

Change is in the national interest of developed and developing countries, said Gostin. For developed countries, it gives them a sense of requiring responsibility on the part of the developing countries, and "seeing a long-term end to global health aid as we know it once we get to sustainable development."

Related Articles:

Public Health In 2012: A Busy Crossroads Of Partnership, Innovation, And Trade
Agricultural Innovation Needed In Africa, With Farmers' Participation, WTO Panellists Say
IFPMA Report, Panel, Examine Rise Of Industry Global Health Partnerships

Catherine Saez may be reached at info@ip-watch.ch.

Categories: Features, Access to Knowledge, Development, Education/ R&D/ Innovation, English, Human Rights, Lobbying, Patent Policy, Public Health, WHO