IBSA Academic Forum

Session Briefing Note
Health Innovation, IPR & Access to Essential Drugs:
Experiences of and Emerging Options for the IBSA countries
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In the IBSA: Delhi Summit Declaration, 15 October 2008, IBSA leaders agreed on the need for establishing trilateral cooperation in the field of intellectual property rights with the aim of promoting a balanced international intellectual property regime and to making a meaningful contribution to the economic and social progress of developing countries, ensuring access to ***knowledge, health care and culture****.*

The objective of this session is to facilitate knowledge sharing between the three countries on strategies to promote universal and affordable access to essential drugs - particularly for HIV/AIDS - and to promote innovation in R&D and production capabilities in this sector. The strategies in question range from making effective use of health-related TRIPS flexibilities to exploring different modalities and models to encourage innovation for the manufacture and delivery of essential drugs and delivery of healthcare.

A second objective is to develop a work programme for 'between the summit periods' to both inform IBSA's contribution to global policy debates and to facilitate further exchange between the three countries on priority issues. In the future, if it is considered useful, the discussion may also encompass other IPR and innovation themes such as access to technologies relevant for the response to climate change and issues relating to sustainable and inclusive approaches to leveraging and conserving biodiversity and developing biotechnologies

While there are a number of barriers to achieving universal and affordable access to the essential drugs, one of the most critical is the international property rights regime. It has had significant implications for the form taken by domestic intellectual property laws, licensing agreements and the terms on which manufacture and/or import of essential medications could be undertaken.

To date, the primary foci have been on identifying how to leverage health-related TRIPS flexibilities (which provide countries with the space to introduce compulsory licensing and/or organize parallel imports where adequate domestic capacities do not exist to ensure access to essential drugs) and how to resist the insertion of TRIPS-plus obligations in regional and bilateral agreements. Emerging evidence suggests that use of these flexibilities have been decisive for reducing the cost of essential drugs and related expenditures in health care budgets. In this regard, there are a number of issues for a knowledge exchange across the three countries.

An additional issue that is of interest is how to support innovation in a post-TRIPS world. A concerted focus on innovation and R&D is central to reducing the cost of existing drugs over the long term and promoting a focus on new drugs and diseases that are of more relevance to the countries of the South. Here again emerging evidence suggests that introducing TRIPS compliant legislation has not helped to promote R&D or innovation in developing countries. In those few instances where a strong domestic industry already existed and/or where the country's domestic market could be of interest to global firms and required a focus on localization, there has been some dynamism. However, even in these instances, the global pharmaceutical market, which has already been characterized by high levels of concentration, has seen additional mergers and acquisitions including with previous independent and well known

developing country generic and bulk drug producers. These developments have potentially significant implications for the types of drugs produced (decline in independent generic industry?), their cost and their market focus.

Further, established global producers (e.g. Novartis) appear to have been much quicker to embrace 'open innovation' models to leverage economies of scale from pooling and outsourcing research and development resources through setting up of global development networks focused on innovation and building up capabilities to be better positioned for new markets and drugs related to biotechnologies. However, cooperation between developing countries and, in particular, IBSA country firms with strong capabilities in these and related areas appear to be less explored to date. Another related approach to explore in this context is patent pools.

The session is expected to focus on the case of HIV/AIDS related access and IPR issues related to pharmaceuticals. However, the discussion can concentrate on this issue within a broader framework of how to promote universal and affordable access to essential medicines (such as for HIV/AIDS but not limited to this) and facilitate R&D, innovation and production capabilities over the medium term Themes that can be addressed by speakers can include:

- The role for joint public financing, manufacturing and procurement and collaboration across countries for orphan diseases;
- How to promote a closer alignment between healthcare and industrial policies: e.g., to date, industrial capabilities and innovation in India have allowed for a low-cost generic drug industry to emerge but this has not been accompanied by strong health and regulatory policies that would ensure that such drugs are also widely accessible to the poor in India itself.
- High priority areas of collaboration with regard to leveraging TRIPS flexibilities: e.g. sharing of information and establishing joint databases and a possible three-way network to monitor patent applications and patent status; sharing of experiences regarding capacity building of patent officers and their sensitization to approaches to assess applications in line with health care priorities; pooled procurement, collaboration on testing facilities and processes; collaboration on addressing so–called 'counterfeit' issues;
- Promising high priority areas of collaboration in new areas/new approaches to innovation: e.g. establishment of a joint API (Active Pharmaceutical Ingredients) Management Initiative along the lines of Chemicals Management initiative in the context of addressing climate change; open innovation networks led by IBSA country producers?
- Identifying complementarities across the IBSA countries that may play a critical role when it comes to South-South cooperation: e.g. Brazil has been more effective in aligning its management of patent applications with promoting its access to health care objectives and India's generic drug manufacturing capacities and R&D have been able to withstand the introduction of domestic IPR legislation which is also TRIPS-compliant.
- Explore whether it would be useful to also make cross-thematic/disciplinary linkages and alliances relating to IPR and innovation issues with regard climate change technologies, information technology innovation models and approaches (e.g. collaboration on open source) and support for inclusive approaches to biodiversity and biotechnologies?