Carnegie Endowment for International Peace

How the U.S. and India could Collaborate to Strengthen Their Bilateral Relationship in the Pharmaceutical Sector

Second Panel:
Exploring the Gilead-India Licensing Partnership Model

Opening Remarks by Mr D G Shah

1. A sustained and aggressive campaign by the innovator pharmaceutical lobby in the USA has created a *perception* that India's IP regime does not protect their innovation. This is not true.

2. The facts speak otherwise:

   Between 2005 and 2014, India granted about 63,000 patents in 20 different fields. They include chemical, mechanical engineering, electronics, pharmaceuticals, etc. Majority of them, say 52,000 (82%), are granted to foreign companies.

3. Pharmaceuticals and Biotechnology account for only 11% of total patents granted. Their intense lobbying against India's IP regime has been a main source of discord in otherwise mutually beneficial relationship between the two countries. Their dissatisfaction essentially relate to five areas:

   a. Section 3(d) of India's Patent Act;

   b. Use of TRIPs flexibility for public health, viz. Compulsory Licensing;

   c. Interpretation of TRIPs Article 39.3 relating to *protection* of undisclosed test data;

   d. Not linking drug regulatory approval to patent status of the product, commonly known as "patent linkage"; and

   e. Unpredictability of India's patent regime.

   As Sec 3(d) and Compulsory Licensing have been widely debated, I will not dwell upon them. Instead, I propose to focus on the remaining three areas.

4. **TRIPs Article 39.3:**

   India's interpretation of TRIPs Article 39.3 is not only accepted by all countries (as none has gone to Dispute Settlement Body) but is also endorsed by the *WHO Commission on Intellectual Property Rights, Innovation and Public Health*. It has recommended that developing countries should not impose restrictions for the use of or reliance on such data by the drug regulator in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

   India's position is corroborated by an analysis of the new drug approvals by the EMEA for three years (2007-09). The analysis revealed that of 113 drug products approved, 92 were granted data exclusivity. Of these 92, 32 drugs did not have subsisting patents for the actives. The patents had either expired or were not patentable, but they were eligible for data exclusivity. Of the remaining 60 drug products, the data exclusivity for 38 had monopoly beyond expiry of patent. Thus, the data exclusivity period extended beyond patent expiry for 70 of 92 products approved in the EU in 2007-09.

5. **Patent Linkage:**

This is unique to the USA. It is adopted by very few countries. Most countries including EU Member States, Japan and many others do not have this provision. It is important to know that even in the USA, the patent linkage system was devised as a part of the political compromise to ensure passage of the Hatch Waxman Act in 1984 to pave the way for approval of generics.

The innovatory lobby is pushing for the "U.S. Plus" system in India to protect their patents. However, India's patent law has adequate provision to enforce one's rights. It also provides monetary damages to a patentee in case of infringement of a patent. Hence, there is no justification for singling out drug patent holders for exceptionally beneficial treatment.

In this context, it is useful to take note of the *Final Report of European Commission on Pharmaceutical Sector Inquiry*. It has concluded that the "authorization to market a medicinal product is taken on the basis of scientific criteria concerning the quality, safety and efficacy of the medical product concerned" and no other criteria such as patent status should be taken in to account. They should be dealt with as per the patent laws before the competent courts.

The Joint Report of the WTO, WIPO and WHO has also noted that patent linkage "can delay market entry of generics and increase prices of medicines". The possibility of erroneous grant of patents cannot be discounted. The US Federal Trade Commission (FTC) in its report had observed that in 70% of cases of patent challenge, the patent was either revoked or withdrawn by the patentee.

6. **Unpredictability of India's Patent Regime:**

Let me now present to you data about revocation of patents in India and the U.S. You can then decide if the U.S. regime is more predictable than India's regime.

Revocation of Patents - India & the U.S.

Particulars	India (1995-2014*)	U.S.A. (2007-11)
Period - No. of Years	20	5
Patent Revoked	67	253

* Upto 10 October 2014

Source: DIPP GoI and U.S. Patents Invalidity Study 2012: A White Paper presented at the USPTO's Annual Meeting in 2012.

As may be seen from the above table, India revoked only 0.1% of patents in 20-year period. Whereas in the USA, the patents were revoked for 253 out of 283 (89%) cases identified for patent validity in five years.

The White Paper further mentions that:

- The number of cases of invalidity in the USA has increased over 10 years between 2002 and 2012. In the first six months of 2012 alone, the number of patents invalidated was more than in the whole year of 2002, 2003 or 2004.

- Pharmaceutical and mechanical devices sectors saw most invalidations in the USA.

- The number of cases appealed in the U.S. Supreme Court between 2002 and 2012 has been increasing and it may be mentioned that between 2006 and 2012, six cases have been held invalid by the U.S. Supreme Court.

India has a well-established legislative, administrative and judicial framework to safeguard IPRs. It meets India's obligations under TRIPS, while utilizing the flexibilities provided under the international regime to address its developmental concerns. The U.S. also has well established legal provisions for challenging patent validities. The increasing number of cases being decided by the U.S. Supreme Court relating to patents also brings out the fact that patent infringement, revocation and other disputes relating to IPRs is subject of contests in the U.S. as much as they are in India.

7. It is against this background that I wish to commend a bold and innovative approach from Gilead to establish that IP and Access can co-exist. Gilead saw in a short period what many foreign companies, operating in India for more than 50 years, have overlooked. Gilead recognized opportunity for a new equilibrium that creates a win-win situation both for the innovator and the patient. Gilead has also implicitly acknowledged through its action that innovation has no value if it cannot be used to save lives of people. This model is new for many innovator companies, but not so for generics. They have been working on the "volume" play, whereas traditionally the innovator companies have refused to look beyond "margin" play.

8. To conclude, I hope and desire that Gilead succeeds in this bold initiative. The success is to be measured not only in terms of access and lives saved, but also in terms of winning investor confidence by generating greater *volume of profits, not margins*. Gilead's success will be a new milestone in the history of pharmaceutical industry. I sincerely hope that it paves the way from acrimony to amiability between the two great democracies of the world and promote stronger ties in all fields of economy.

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Summary of Patents Granted & Revoked by India

(1 January 2005 to 10 October 2014)

Sr No	Field of Invention	Granted				Revoked	
		Indian	Foreign	Total	% of Total	No	% of Granted
1	CHEMICAL	3,354	9,506	12,860	21	4	0.03
2	MECHANICAL ENGINEERING	2,168	10,398	12,566	20	28	0.22
3	ELECTRONICS	384	4,937	5,321	8		
4	PHARMACEUTICALS	1,039	3,575	4,614	7	24	0.52
5	ELECTRICAL ENGINEERING	557	3,688	4,245	7	4	0.09
6	GENERAL ENGINEERING	833	2,749	3,582	6		
7	BIO-CHEMISTRY	506	2,955	3,461	6		
8	COMMUNICATION TECHNOLOGY	243	2,896	3,139	5	1	0.03
9	BIOTECHNOLOGY	339	2,236	2,575	4		
10	COMPUTER SCIENCE	150	1,709	1,859	3		
11	POLYMER TECHNOLOGY	168	1,434	1,602	3		
12	PHYSICS	199	1,306	1,505	2		
13	MICRO BIOLOGY	210	999	1,209	2		
14	METALLURGY	197	771	968	2		
15	TEXTILES	135	815	950	2	3	0.32
16	CIVIL ENGINEERING	121	526	647	1	1	0.15
17	BIO-MEDICAL ENGINEERING	41	543	584	1		
18	FOOD	312	208	520	1	2	0.38
19	AGROCHEMICALS	109	240	349	1		
20	AGRICULTURE ENGINEERING	16	41	57	0		
	Total	**11,081**	**51,532**	**62,613**	**100**	**67**	**0.11**
	% of Total	**18**	**82**	**100**			