Backgrounder for Indo-US Dialogue
January 2015

A. India's IP Regime:

1. Pharmaceuticals in India spend more on R&D than all other industries put together.[1] It therefore not only respects intellectual property (IP) but also actively supports an IP regime that meets India's commitment to the WTO as per Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) 1994.

2. A *section* of the U.S. pharmaceutical industry represented mainly by Mr Ajay Banga (USIBC) and Mr John Castellani (PhRMA) may express concern about India's regime, in particular about protection and enforcement of patents in the field of pharmaceuticals. However, these concerns are misplaced on two counts:

> *Firstly*, they are using the US regime as benchmark to evaluate India's IP regime. But India has never agreed to conform to the US standards. India has accepted international standards as embodied in the TRIPS Agreement. The US is a signatory to the TRIPs Agreement. India is fully compliant with it. Hence, these concerns are misplaced.
>
> *Secondly*, a cursory glance at patents granted in various fields (Annexure-A) including pharmaceuticals, from 1 January 2005 to 10 October 2014 show that 82% of patents granted are to foreign companies. Thus, it would be incorrect to say that India does not recognize patents or it discriminates against foreign companies.

They argue that protection and enforcement is inadequate in India. This is not true. India has adequate laws for protection and an independent judiciary for the enforcement of IP.

3. It may be noted that several US corporations (Boeing, Pepsico, Abbot, Gilead & Others) academics (from Columbia, Oklahoma & Others) and civil society organizations (KEI, MSF, UACT and Others) have expressly supported India's IP regime. Gilead is working on a model that shows that IP and Access can co-exist.

B. Unpredictable IP Environment in the U.S.:

1. The IP regime, even in the US is litigious and more unpredictable than India as may be seen from the U.S. Supreme Court's decisions invalidating patents (Annexure-B). India is no different.

2. A white paper report with respect to *United States Patents Invalidity Study* conducted in 2012 and presented at the USPTO's annual meeting in 2012 brings out clearly that there are multiple avenues available under the US patents systems to challenge the validity of an issued US patent. One avenue to challenge patent validity is through the Federal Courts in the United States while the other is to utilize the ex-party or an inter party re-examination procedures in the US Patent & Trade Mark Office (USPTO).

[1] Capitaline Plus

3. The following findings of the report on court decisions in the United States brings out the fact that patent validity is an important issue even in the US and the US court system is grappling with a number of cases challenging the validity of patents:-

- Between 2007 and 2011, 283 cases were identified in US Federal District Courts where patent validity was determined. Of these, only in 39 cases was the patent held valid and enforceable. In 253 cases, therefore, the patent was held to be invalid.

- With respect to patent invalidity in the Federal Circuit Courts, the report mentions that the number of cases of invalidity has increased over ten years (2002 and 2012). Particularly since 2007, the number of patents invalidated by the Federal Circuit Courts has remained consistently higher than the previous year. Further in the first 6 months of 2012, more patents were invalidated than in whole year of 2002, 2003 or 2004.

- Of the invalidation cases that came to the US Federal Courts in 2012, 26% were invalidated.

- The report also states that patents directed towards mechanical devices and pharmaceutical drugs were most susceptible to patent invalidity. Cases characterized as pharmaceuticals were patents directed to traditional drugs as well as chemical molecules and food supplements.

- During the period between 2002 and 2012, 20 cases relating to pharmaceuticals were invalidated by the Federal District Courts as compared to 34 for mechanical devices, 10 in respect of medical devices.

4. As against this, the Intellectual Property Appellate Board (IPAB) and the High Courts in India have revoked only 29 patents (10 of Indian Companies and 19 of Foreign Companies) during the 10-year period.

C. Role of the U.S. FDA:

1. In 2012, while introducing the generic drug user fees, the U.S. FDA had indicated that the waiting period for approval will be brought down to about half from 36 months over a period of three years. It had further stated that the user fees will be used to augment its resources to improve its services to the generic industry. It was then estimated that India being a major supplier of generics to the USA, will contribute about 60% of the total collection of user fees estimated at US $ 400 Mn.

However, the waiting period has not declined as may be seen from the Annexure-C showing approval rate for foreign filings. The inordinate delays not only deprives Indian companies of opportunity to market their products, but also deprives India of its share of exports and the U.S. patients of access to low priced quality medicines.

2. India has sanctioned 19 posts for the food and drug inspectors of the U.S. FDA. Several of these posts, particularly of the drug inspectors, are lying vacant. Instead, the drug inspectors come on short term visa. They are assigned the role and responsibility of inspections in the country. This practice causes some problems during the inspections because of cultural differences. The shop floor operators, not used to American English, find it difficult to understand their questions/observations; and likewise the inspectors, not used to Indian English, do not fully grasp the explanation provided by the operators. Thus, cultural differences act as barriers to communication. This results in inadequate appreciation of the cGMP and other measures for compliance with the U.S. FDA standards and practices. Hence, India should request that these posts are fully utilized and those posted in India are exposed to cultural differences, including fright and nervousness of the inspections.

3. The U.S. FDA wants to ensure that Indian companies export safe, effective and quality products for its citizens. Likewise, the Indian companies also want to ensure that they meet the U.S. FDA norms all the time. Thus, there is congruity in goals of both, the U.S. FDA and the Indian manufacturers. This can be leveraged by attitudinal change in the way inspections are carried out. It is therefore suggested that drug inspectors, instead of being perceived and acting as “investigators”, should assume the role of "enabler" to meet the common goal of ensuring safe, effective and quality products are exported from India. To this end, the industry and the U.S. FDA can work together by focussing on the capacity building workshops, which may help bring about the requisite change in behavior and attitude.

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Annexure A

Report on Patents Granted by India
(FROM 1-1-2005 to 10-10-2014)

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

Annexure B

US Supreme Court's Decisions Invalidating Patents

Sr No	Case	Year	Case History	Decision of the US Supreme Court
1	eBay Inc vs. MercExchange, LLC	2006	The case was related to a patent owned by MercExchange which covered eBay's 'Buy it now' function. MercExchange had sued eBay for patent infringement.	Overturned the Federal Circuit court's approval for injunction noting the fact that nothing in the patent Act eliminated the traditional reliance on weighing the equitable factors to be determined while imposing an injunction. The Federal District Courts were directed to weigh 4 factors before deciding upon an injunction - a) that the petitioner has suffered an irreparable injury, b) that the remedies available in the law are inadequate to compensate for that injury, c) balance of hardship between the petitioner and the respondent and d) that public interest would not be disserved by a permanent injunction.
2	KSR International Co. Vs. Teleflex Inc.	2007	Teleflex sued KSR International claiming that the KSR's products infringed Teleflex's patent on connecting an adjustable vehicle control pedal through an electronic throttle control.	Held that the claim by Teleflex Inc. was obvious under the requirements of the Patent Act and therefore not patentable.
3	Microsoft Corporation Vs. AT&T Corpn.	2007	AT&T held a patent on a programme that could digitally encode and compress recorded speech on computer. Microsoft's Windows operating system had the potential to infringe that system because Windows incorporated software called NetMeeting that when installed enabled a computer to process speech in the same manner as claimed by AT&T's patent. Microsoft shipped abroad a master version of Windows to foreign manufacturers. These manufacturers first used the master version of Windows to generate copies and then they installed the copies on to the computer they sold to users abroad. AT&T accused Microsoft of infringing the patent.	Supreme Court ruled that abstract software code was an idea lacking physical embodiment and it could not be useable, combinable part of a computer. They also held that copies of Windows used to install on foreign computers could not be considered as supplied from the US.

4	Quanta Computers Inc. Vs. LG Electronics Inc.	2008	Quanta Computers owned several patents on methods and systems for processing information. It entered into two contracts with Intel. In the license agreement, LG authorized Intel to make and sell microprocessor product using the invention. But the license agreement also expressly stated that no license was granted to any third party for combining licensed products with other products (i.e. combing the microprocessor products with other parts of a computer). At the same time the agreement also stated that patent exhaustion would apply when a party sells its licensed product. Quanta computers purchased Intel's licensed microprocessor product containing the patented technology. LG sued Quanta for infringement.	Supreme Court reversed the Federal Circuit Court's decision and reaffirmed the validity of the patent exhaustion doctrine which implied that LG did not have the patent right on the micro processor product whch was duly produced under license by Intel and then sold to Quanta. The Supreme Court held that the patent right had been exhausted on the unit of the product that was sold to Quanta.
5	Bilski Vs. Kappos	2010	An application was made by Bilski seeking patent on a method for hedging risk in t eh commodities market. The patent was not granted by the USPTO and then it went through a series of challenge right upto the SC	SC affirmed the decision that it was not amenable for patent as it was not patent eligible subject matter.
6	Mayo Collaborative Services Vs. Prometheus Laboratories Inc.	2012	Claims were related to method of giving a drug to a patient with a view to optimize therapeutic efficacy. Prometheus Laboratories Inc. had filed a patent infringement case against Mayo Collaborative Services.	The Supreme Court held that claims directed to a diagnostic method that involve observing a natural correlation were not patentable subject matter.
7	Association for Molecular Pathology Vs. Myriad Genetics	2013	The case relates to challenging the validity of gene patents in the US. Myriad Genetics was granted a patent that covers methods to diagnose propensity to cancer by looking for mutated DNA sequences and methods to identify drugs using isolated DNA sequences.	The US Supreme Court in a unanimous decision invalidated Myriad's claim to isolated genes. The Court held that merely isolating genes that are found in nature does not make them patentable.

Annexure C

USFDA & Global Generics

Global Generic Drug Applications & Approvals

	FY01	FY05	FY10	FY11	FY12	FY13	FY14
ANDAs Submitted	307	766	813	893	1,103	968	1,473
Approvals (incl. tentative)	310	467	426	458	517	440	406
% Approval	101	61	52	51	47	45	28

***FY means year ending October 30**

Source: JP Morgan

2001-2014: Applications ↑380% & Approvals ↑31%