

Regulatory Capture and Access to Health Care

India Case Study

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**EMPOWERING CIVIL SOCIETY NETWORKS
IN AN UNEQUAL, MULTI-POLAR WORLD**



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Regulatory Capture and Access to Health Care in India

Section I: Introduction

1. Introduction: Pathways of 'Regulatory Capture' in India

A major pitfall faced by public regulatory agencies is what has come to be known as 'regulatory capture' – a phenomenon where regulatory agencies that are designed to regulate industries for the public interest are 'captured' by the industries they are supposed to regulate. As a consequence regulators end up regulating industries in a way that benefits the regulated industry, rather than the general public.

Proposals to address this phenomenon differ quite radically. George Stigler, one of the first scholars to refer to 'regulatory capture'¹ essentially argued for removal of state controls and regulations, because of the inherent tendency of regulatory agencies to be captured by industry that is sought to be regulated. However a contrary position views regulatory capture as an imperfection, often deliberately introduced, in systems of regulation. Joseph Stiglitz, for example, argues that economies with well-designed regulations can perform better, but the design of regulatory systems need to ensure that they are not captured by those they seek to regulate.²

There are multiple reasons why government regulation is necessary in a market economy. The evidence of 'market failures' is too compelling to ignore, and is a prime reason for government regulation in situations where the market does not work in the best interest of the public but favours those who can manipulate the market through their monopoly power. Regulations are important instruments that governments can use, in situations of budgetary constraint, to promote distributive justice.³

Regulatory capture takes place through several pathways. The regulatory system gets captured by those that are supposed to be regulated because they are the designated 'experts' who understand the system. Such 'experts' often have dual loyalties, i.e. to also represent the interests of those who are being regulated. Such issues of 'conflict of interest' are further augmented by 'Revolving Door' practices, where regulatory bodies include people who have had previous and recent stints in bodies that are the subject of regulation.

One of the most glaring instances of the revolving door phenomenon was seen in the course of a landmark patent case between Swiss TNC Novartis and the Indian government involving the anti-cancer drug imatinibmesylate. Gopal Subramaniam, who was the Solicitor General of India when the case began, took over as the lawyer representing Novartis while the case was underway. He replaced Rohinton Nariman, who was appointed as Solicitor General of India to replace Subramaniam.⁴ In a similar vein, Naresh Dayal, ex-secretary, Ministry of Health and Family Welfare, retired on September 30, 2009, and soon after joined GlaxoSmithKline Consumer Healthcare as a non-official director.⁵ Rather than raising red flags over the implications of the revolving door, recent policy initiatives in the health field appear to move towards their institutionalization. Thus, the 2011 National Health Research Policy (NHRP) seeks to develop *"mechanisms favouring seamless movement of personnel between teaching, research and industry."*⁶

Capture also occurs through the promotion of ideas and in post-1990 India, the virtues of neoliberal reforms, including those of deregulation, are promoted by the Indian state and its vocal proponents. This has had significant impact on regulatory structures, as regulatory capture is more easily accomplished when the voice of those who benefit from lax regulation is significantly stronger than the general public whose interests are supposed to be safeguarded through regulatory structures and mechanisms.⁷ Neo-liberal reforms, undertaken in India since the 1990s, have expanded the scope for private activity and reduced regulation⁸ and the nexus between the state and big business has strengthened.⁹ Regulatory capture has now morphed into what has been described as "...an interlocking dynamic of policymakers, regulatory officials, corporate players and extremely sophisticated industrial lobby groups"¹⁰.

In this paper on Regulatory Capture in India and the Health Sector, we examine how instances of regulatory capture are not an isolated phenomenon but are embedded in the neoliberal economic system itself. We focus on the range of regulatory mechanisms that deal with Access to Medicines. The discussion is divided into two parts. In the first section we look at regulatory mechanisms regarding the pricing and quality of medicines, and the regulation of clinical trials in India. In the second section we examine regulations (and the capture of regulatory mechanisms) related to Intellectual Property (IP) in India. The paper's particular focus on IP is linked to the critical role played by the standard of IP protection in India and the ability of Indian generic companies to produce affordable medicines, not just for Indian patients, but for a range of patients in countries across the world.

SECTION 2: Regulatory Capture in the Domestic Medicines' Market

2. Access to Medicines in the context of India's Health system

A discussion on Access to Medicines in India needs to be understood in the context of the two contrasting trends. On the one hand India has one of most poorly resourced and managed public health system in India, with public investment on healthcare stagnating at around 1% of GDP since the 1990s.¹¹ Neoliberal reforms in India, initiated in 1992-93, led to slashing of the public budget for social sectors, including healthcare and led to a virtual dismantling of large parts of the public health infrastructure. Thus, for example, there was a sharp reduction in capital investment in public hospitals between 1991 and 2001.¹² While there have been sporadic attempts to restore public expenditure on health, these have seldom matched needs or expectations. The National Rural Health Mission (NRHM) launched in 2005 and deigned to strengthen the public system was able to attract just 40% of the funds originally visualized as necessary for a full re-vitalization of the public system.¹³

As a consequence, a largely unregulated private medical sector is the main recourse for treatment for patients in India, with private sector care accounting for 80% of out-patient care and 60% of in-patient care. Private expenditure on healthcare in India is among the highest in the world -- 70% as compared to just 30% of public expenditure.¹⁴ Various studies have consistently shown that within private expenditure on health care, the share of expenditure of medicines ranges from 70-80%.¹⁵ The 55th NSS (National Sample Survey) round on consumer expenditure estimated that 77% of out-of-pocket health expenses on health in rural areas and 70% in urban areas is on medicines alone.¹⁶ A private sector led healthcare system further pushes up healthcare costs with evidence of supplier induced demand and lack of standard treatment practices, leading to aberrations such as unnecessary injections, irrational treatment regimens and excessive medications being provided in the private medical sector¹⁷.

On the other hand India has the most developed indigenous pharmaceutical industry among Low and Medium Income countries (LMICs) – the third largest in the world by volume of production. The ability of Indian companies to market affordable generic versions of new medicines at a fraction of the cost charged by Northern pharmaceutical companies has been a major driver of access to medicines in a range of countries, especially for poor patients in LMICs. Ironically, while India has been termed as the 'Pharmacy of the South', the largest numbers of patients without secure access to medicines reside in the country. According to 2004 World Medicines' report by the World Health Organization (WHO), an estimated 649 million people in India did not have regular access to essential medicines¹⁸. Due to rolling back on elements of regulation in India, such as monitoring and oversight policies, and increasing reliance on market competition, it is now harder to oversee drug policies and to monitor availability and prices¹⁹. Some indication that the situation in India regarding access remains as dire as earlier reported is available through a comparison of medicine consumption, calculated as number of standard units consumed per 10,000 population. India lies at the bottom of 30 countries surveyed, with reported consumption of around 2 units/10,000 population – lower than Pakistan, Indonesia, Colombia and Jordan – and an order of magnitude lower than the best performing countries such as UK, Japan, France and Canada (who report consumption levels of above 15 units/10,000 population²⁰).

The benefits of a developed domestic pharmaceutical industry have not translated into universal access to medicines in India because of the poor capacity and outreach of the public health system, which forces patients to directly pay for medicines while accessing healthcare from private facilities. Thus a major proportion of medicines (in excess of 80%) are procured through out-of-pocket (OoP) payments.

The growth of the domestic industry is also a regulatory challenge given the very large number of manufacturers and products. Poor regulatory oversight has led to the proliferation of a very large number of branded generics –

estimated to be between 60,000 to 85,000²¹. Drugs which should never have been allowed to reach the market are being marketed and many are inherently unsafe and potentially hazardous.²² These products continue to be marketed by companies by relying on dubious and unregulated unethical marketing. As a result expenditure on irrational drugs – largely through out of pocket expenditure – pushes up total treatment costs and also leads to adverse health effects.

In this rather unique situation, which combines a poorly developed, private sector-led healthcare system and a well-developed pharmaceutical industry, the role of government regulation and the negative effects of regulatory capture by industry have a particularly pernicious impact on public health and peoples livelihoods. Out of pocket expenditure on healthcare amongst the poor – a major portion of which is expenditure on drugs -- leads to catastrophic health expenditure (defined as over 10% of consumer expenditure) and over 63 million persons are pushed below the nationally designated poverty line (those whose consumption expenditure is less than USD 0.5/day approx.) every year due to health care costs. The number of households facing catastrophic expenditures due to health costs has risen to 18% of all households in 2011-12 as compared to 15% in 2004-05²³. Evidence indicates that the poorest 10% of the population tend to disproportionately rely on sales of their assets or borrowing to finance inpatient care, having little access to savings or employer reimbursement. This not only erodes their purchasing power in the short term but it also makes them vulnerable to slide into long-term poverty²⁴.

In the following discussion we examine some of the key instances of regulatory capture which seriously compromise access to medicines in India, including those related to prices and rationality of medicines.

2.1. Regulation of Medicine Prices: Prey to Industry Influence

Recognizing the impact of medicine prices on healthcare costs, price control on medicines was first imposed in 1962. Comprehensive price controls were introduced later through the Drug Price Control Order (DPCO) 1979. DPCO 1979 which covered an estimated 80% of drugs expectedly triggered an adverse response from the pharmaceutical industry – both from industry associations representing Transnational Corporations (the Organisation of Pharmaceutical Producers of India – OPPI) and those representing domestic companies (Indian Drug Manufacturers' Association – IDMA). Manufacturers shifted production away from drugs under price control while they mounted a concerted campaign against drug pricing norms. The concerted lobbying by the industry coupled with the shortfalls in the production of essential drugs led to the revision of the drug policy in 1986 and relaxation of price controls in the DPCO of 1987²⁵²⁶(see Table below). The DPCO 1987 drew heavily on a report published by the National Council of Applied Economic Research (NCAER)²⁷ in 1984 that concluded that drug manufacturing in India was non-remunerative as a consequence of price controls. The NCAER report has been critiqued for being dependent on data provided by the industry.²⁸

The DPCO 1987 was again amended in 1995, further reducing the coverage of price controls to just 74 bulk drugs from 142 bulk drugs in 1987. The trajectory of price regulation was now clearly informed by neoliberal economic reforms in the country. Capture of regulations for price control was accomplished through two prominent pathways. The first was the ideological capture of public policy by neoliberal economics, which in turn promoted the logic that markets are self-regulating and need little intervention from governments. The second pathway was the physical capture of committees set up by the government to review regulations on price controls.

Regulatory capture and its consequence were clearly evident from the constitution of a Drug Price Control Review Committee (DPCRC) in 1999, tasked, *inter alia*, to: review the current Drug Price Control Mechanism and suggest alternative models, if any; and to suggest the criteria of market competition and monopoly and turnover for inclusion of drugs under price control. The 12 member committee included 8 government officials, one representative from civil society, two representatives from the pharmaceutical industry and one representative from the confederation of Indian industries²⁹. The DPCRC's recommendations were echoed in the text of the

2002 Pharmaceutical Policy: “The DPCRC’s recommendations ... to move away from the “controlled regime” to a “monitoring regime” is in the present context an extremely important recommendation...”³⁰ The shift away from the regime of price control was reflected in the 2002 Policy’s effect of retaining only 39 bulk drugs under price control. See Table 1 which shows the progressively reducing coverage of drug price controls since comprehensive controls were imposed in 1979.

Table 1: Change in Overall Price Control Parameters (1979-2002 **)³¹

DPCO Year	No. of Drugs under Price Control	Percent of Market Covered in Price Controlled Category (approx.)	Mark-up (profitability) allowed
1979	347	80 - 90%	40%, 50% and 100% in three categories termed “life saving”, “essential” and “non essential”.
1987	142	60 - 70%	75% and 100% in two categories, subsequently one category with 100% mark up.
1995	74	25 - 30%	100%
2002*	39*	10 - 20%	100% or more

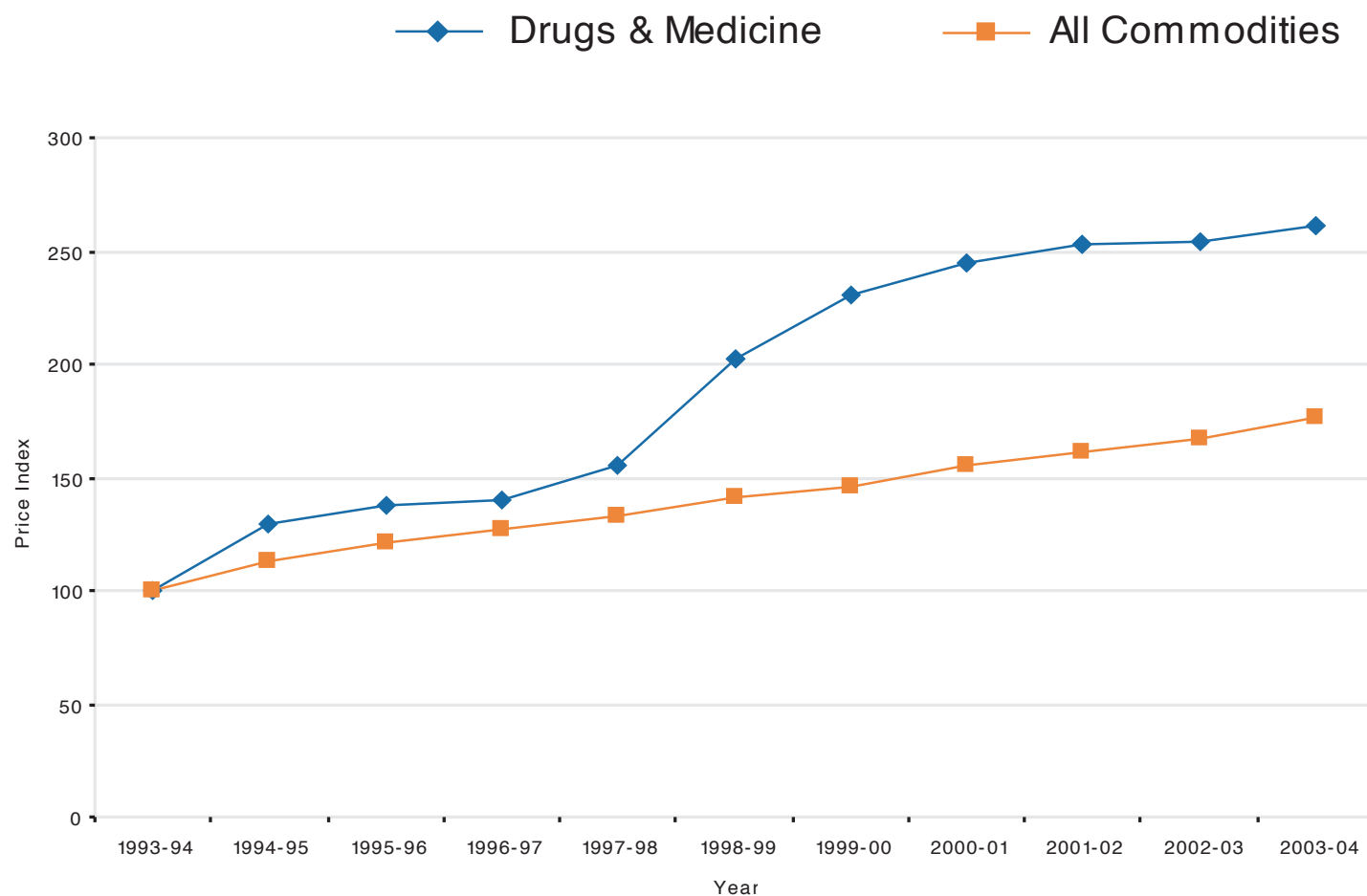
* The 2002 DPCO wasn’t enforced as a Supreme Court order stayed its implementation

** See discussion on DPCO 2012 later (not included in the table as parameters for ceiling price calculation were changed

Source: Successive DPCOs and 2002 Policy Document. Calculation of market share is approximate and based on ORG data for relevant period – a range is given as the market share changes with companies shifting production away from price controlled categories

Progressive and accelerated decontrol of drug prices since 1995 had expected consequences, with drug prices clearly outstripping the general increase in prices as depicted by the Wholesale Price Index³² (see Chart 1).

Chart 1: Comparison of Price Index on Drugs and Medicines and All Commodities 1993-2004³³



However, a public interest litigation filed by K. S. Gopinath and B. V. Bhaskar in the High Court of Karnataka at Bangalore resulted in an Order dated 12.11.2002 which stopped the Government from implementing the price control regime of the Pharmaceutical Policy 2002³⁴. The Court issued a directive to expeditiously put in place a mechanism to control the prices of all essential drugs. The case was later appealed by the Union of India in the Supreme Court of India. Responding to this appeal the All India Drug Action Network (AIDAN) and other co-petitioners (AIDAN and ors. versus Union of India in the Supreme Court – WP (Civil) 423/ 2003) in its prayer before the Supreme Court asked for the issuance of a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 (Union of India) to ensure that the medicines/ drugs set out in the National Essential Medicines List 2003 are available and at affordable prices for the poor by bringing all of them under price control³⁵. Subsequently the Supreme Court of India in its Order dated 10.03.2003 in SLP No. 3668/2003 (Union of India Vs. K.S. Gopinath and others) directed the government to: *“..consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control..”* India³⁶

In the light of the Court’s intervention, the Department of Chemicals and Petrochemicals constituted a Joint Committee of Government and Industry³⁷. Thus we see a clear shift towards regulatory capture, with Industry now being seen as at least an equal partner in determining regulatory policy. The Joint Committee, thus constituted, had four members from different government departments and two members each from the Indian Pharmaceutical Alliance (IPA), Organisation of Pharmaceutical Producers of India (OPPI), Indian Drugs Manufacturers Association

(IDMA), Confederation of Indian Pharmaceuticals Industries (CIPI), Federation of Indian Chamber of Commerce and Industry (FICCI), and the Confederation of Indian Industries (CII). The industry segment in the committee continued to press for ‘monitoring’ rather than ‘regulation’.³⁸ Subsequent to this the issue remained in limbo for six years and the 1995 DPCO remained in operation as no new price control order was issued till 2012. Finally, in 2012, the government imposed price control on 348 drugs listed as essential³⁹.

BOX: Chronology of events: Drug price control in India

1978-79: Drug Policy of 1978 and Drug Price Control Order (DPCO) of 1979 notified. For the first time comprehensive price control imposed on drugs. 347 bulk drugs brought under price control covering an estimated 80-90% of drugs in the market. Mark up (including profits) over production costs capped at 40%, 50% and 75% on different categories of price controlled drugs

1980-85: Manufacturers shift production away from price controlled drugs creating shortages and putting pressure on government to attend the DPCO

1986-87: New Drug Policy of 1986 and DPCO of 1987 notified. Drugs under price controlled category slashed to 142, reducing span of coverage to 60% of drugs in the market. Mark ups increased to 75% and 100%

1994-95: Drug Policy 1994 and DPCO 1995 notified. Drugs under price control slashed to 74 and a uniform markup of 100% allowed. Only 25-30% of drugs now under price control

2002: Drug Policy of 2002 proposes reducing drugs under price control to just 39 covering 10-20% of drugs in the market

2002: Karnataka High Court, responding to a Public Interest Litigation, stays implementation of Drug Policy 2002

2003: Drug Price case taken over by Supreme Court which asks governments to take steps to ensure affordable access to all essential drugs

2012: Government announces DPCO 2012. All essential drugs (348) brought under price control but system of identification of drugs to be placed under price control and of price fixation changed radically. Price fixation is now based on average of existing costs in the market and not on production cost. As a result price reduction is meager (overall less than 3% impact on overall drug market) and price control extends to less than 17% of the market.

2012 - : Supreme Court continues to hear a PIL asking for switch back to cost based pricing of drugs.

However, there will only be a marginal effect on the prices of essential drugs, because the new DPCO fixes ceiling prices based on an average of the prices of all brand with a turnover in excess of 1% of the total market for a particular drug (a departure from the earlier practice of fixing based on manufacturing cost). This methodology would largely reflect the price of the brand leaders, serving to legitimize the rampant overpricing of drugs today. It disregards evidence that many top-selling brands in the market are priced 10-50 times higher than similar unbranded formulations. In fact, in several categories, top-selling drugs tend to be the most expensive⁴⁰ – sustained by aggressive promotion. Thus the ceiling prices of price controlled drugs now reflect the high prices of top-selling brands, and have no real link with the actual cost of production. See Table below which compares the prices of a select list of commonly used drugs with the price of the top selling brand prior to DPCO 2012, ceiling price as per DPCO 2012, the calculated price if a cost-plus formula was used and the Tamil Nadu Medical

Sales Corporation (TNMSC) procurement price. As we can see ceiling prices as per DPCO 2012 are 300-800% higher than what they would have been if the earlier cost plus formula was applied. Further they are 800-2000% higher than the procurement price of TNMSC.

Table 2: How Overpricing will continue based on DPCO 2012⁴¹

Prices for 10 Tabs (unless otherwise specified) in Indian Rs.

Drug/ Use	Market leader Price (2012)	Ceiling Price based on Market Based calculation in DPCO 2012	Ceiling price if cost plus formula was used	TNMSC Price (2012-13)
Diclofenac 50mg Painkiller	45.00	12.20	2.81	1.20
Atorvastatin 10 mg Cholesterol Lowering	104.00	42.40	5.60	2.10
Atenolol 50 mg (14 Tabs) Anti hypertensive	51.40	17.50	3.50	1.50
Fluconazole 50 mg Antifungal	204.40	65.00	16.80	8.90
Metformin 500 mg Anti-diabetic	24.80	11.70	4.75	2.00
Cetirizine 10 mg Anti allergic	27.80	13.60	1.00	0.90

The new DPCO, it is estimated, affected only about 17 per cent of the drugs in the market. The impact on prices will be about Rs 1,300 crore, i.e. a mere 2 per cent of the Rs 75,000 crore domestic market. Further, of the 100 top selling brands, 55 of fall outside the scope of price control (calculations based on a study by the Public Health Foundation of India in 2014⁴²). This is a far cry from the spirit of the directive of the Supreme Court, which had called for institution of measures that would lead to significant decrease in prices of drugs.

2.2 Regulation of Drugs: Therapeutic Relevance and Quality

It has been estimated that at least 50% of the average family spending on medicines in India is incurred on irrational or unnecessary drugs and diagnostic tests.⁴³ Of the estimated 60-85,000 brands of different drugs in the market only a small proportion offer real therapeutic value. The proliferation of brands places an inordinate burden on drug regulatory agencies. Compounding this is evidence that a significant number of available drugs are either hazardous or irrational and useless.⁴⁴ Such a situation adds to expenses incurred by patients who

are also unnecessarily exposed to side effects. Further, in the case of anti-microbials, resistance is a growing problem and a cause for concern. For example, India has the largest number of multi-drug resistant TB cases in the world, requiring treatment with second-line drugs that can be 10 times more expensive than first-line ones⁴⁵. The irrational proliferation of combination products is particularly responsible for the situation.⁴⁶ Patients are adversely affected as an estimated 80-85% of drugs consumed in India are procured from retail outlets, compared to the dominant pattern of institutional procurement in countries with developed health systems.⁴⁷ Of further concern is the incapacity of the drug regulatory agencies to oversee the quality of medicines in the market⁴⁸.

Here we refer to only a selection of evidence available that points to clear regulatory capture by pharmaceutical companies – both Indian and Foreign – of the state and national drug regulatory agencies. One of the best documented reports was compiled by the Justice Lentin Commission, set up by the Maharashtra Government. The Commission was set up to investigate the death of 14 patients in Bombay's (now Mumbai) J. J. Hospital in 1988 after being administered glycerol adulterated with diethylene glycol. The Commission exposed a clear nexus between influential doctors, politicians, the state (Maharashtra) Food and Drugs Administration (FDA) and drug manufacturers. The report stated: *"The entire structure of FDA, at one time a prestigious body famous in all Asia, has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a sense of non-accountability all round."*⁴⁹. The report revealed the protection pharmaceutical companies received from the FDA, the flagrant violation of laws in issuing licences, deferring prosecution of errant manufacturers and ministerial interference at every stage. Prior to the publication of the Commission Report, the Health Minister, BhaiSawant resigned saying the Commission had drawn un-permissible conclusions. In an unprecedented show of solidarity, MLAs from the opposition and the ruling party joined hands in criticising the Commission's findings regarding the role of the politicians in the scandal⁵⁰.

That this situation of extensive regulatory capture continues to be grim - as a consequence of nexus between regulatory agencies, 'experts' and pharmaceutical companies - was documented by the 59th Report of the Parliamentary Standing Committee of Health and Family Welfare in its report published in 2012⁵¹. The report documents clear evidence of doctors providing 'expert' opinion of a dubious nature in collusion with drug companies to allow the introduction of new drugs in the market. Part of the report was based on data available with the Central Drugs Standards Control Organisation (CDSCO – the apex drug regulatory agency in India) regarding marketing approval granted for the introduction of 39 new drugs in the market. The report pointed to the non-application of existing regulations while approving new drugs. For several drugs mandated Phase III trials were not conducted before approval even though these drugs did not address medical needs in the country. It also pointed to evidence of a perverse nexus between the regulatory agency, empanelled 'experts' and drug companies. In a damning indictment of the entire system of marketing approval for new drugs the report said that expert "opinions were actually written by the invisible hands of drug manufacturers and experts merely obliged by putting their signatures"⁵².

2.3 Regulation of Clinical Trials

Changes in the regulatory environment for clinical trials were initiated through the constitution of a 'Pharmaceutical Research and Development Committee' (PRDC) by the Ministry of Chemicals & Fertilizers. The committee submitted its report in 1999. In a clear signal that the regulation of clinical trials would be tailored to the needs of the pharmaceutical industry, the 15 member committee included 5 members from industry (Anji Reddy of Reddy's Laboratories, Parvinder Singh of Ranbaxy, Y.K. Hameed of Cipla, Swati A. Piramal of Piramal Pharmaceuticals and AmitMitra of the Federation of Indian Chambers of Commerce and Industry). The terms of reference of the Committee included: To appraise the current status of R&D in the Indian pharmaceutical sector and to suggest measures to boost it in the context of drug price control regime and changes in laws on

Intellectual Property Rights; and to suggest new and innovative fiscal and non-fiscal measures for boosting R&D in pharmaceutical sector⁵³.

The committee, *inter alia*, citing the unique opportunity for India to become a leading centre for clinical trials, called for basic changes in the legislation allowing import of animals, contract research and a legal status for institutional ethics committees⁵⁴. In 2005 the Indian Patents Act was amended to align it to the requirement of TRIPS agreement under the WTO. This was seen by international pharmaceutical companies as an opportunity to exploit the Indian market. The PRDC committee's report echoed the view of pharmaceutical companies that the changed industrial environment (consequent to the change in India's Patent Act, which was anticipated by the committee's report) could be leveraged to draw in investments into the pharmaceutical sector.

In 2005 the Indian Government acted on the committee's recommendations and amended a key clause in the Drugs and Cosmetics Act (DCA) that had been specifically designed to protect the interests of trial subjects. Prior to the 2005 amendment to the DCA, foreign sponsors were permitted to conduct clinical trials with a "phase lag": the trial in India had to be conducted one phase earlier than elsewhere. This meant that, for example, if the Phase 3 of a trial was completed outside the country, trials within India had to commence from Phase 2. However, amendments to 'Schedule Y' of the Drugs and Cosmetics Rules, in January 2005, allowed "concurrent phase" trials in the country. Thus, the 2005 amendments made it easier for drug companies to do research that involved Indian participants⁵⁵⁵⁶.

Trial sponsors and contract research organisations (CROs) utilized the liberalized regime to scale up conduct of clinical trials in India. From 40 to 50 trials in 2003, the country saw around 1850 trials registered with the government registry in June 2011⁵⁷. Regulatory structures were unable to cope with the sudden rise in trials and there continued to be a persisting regulatory lag. Thus, for example, while the new law was notified in January 2005, registration of clinical trials was made mandatory (with full disclosure of trial data with the Clinical Trials Registry) only from June 15, 2009⁵⁸.

Deaths of clinical trial subjects also rose exponentially, and an estimated 3,458 research participants died during clinical trials conducted in the period, January 1, 2005, to December 31, 2012⁵⁹. Out of these, 89 deaths were found to be attributable to the clinical trials. Given the very poor level of regulatory oversight, these numbers are likely to be under-estimates. Belying claims that liberal norms governing drug trials would fast track approval of necessary drugs, in this period, trials on 475 new drugs were conducted and only 17 drugs were approved for marketing in India.⁶⁰

Numerous instances have now been documented of gross ethical violations as a result of the precipitous change in domestic law on clinical trials and the wide gaps in regulatory mechanisms. A prominent instance is the trial on a vaccine against the Human Papilloma Virus (HPV) by the US based NGO called Program for Appropriate Technology in Health (PATH). PATH's trial was funded by the Bill and Melinda Gates Foundation and the vaccines were provided free of cost by Merck and Glaxo Smith Kline (GSK). Several thousand adolescent girls were vaccinated in Andhra Pradesh and Gujarat as part of the trial, which PATH called a 'demonstration project'⁶¹.

Chronology of Events: Unethical Clinical Trials in India

2005: Amendment of 'Schedule Y' of the Drugs and Cosmetics Rules, in January 2005, allowed "concurrent phase" trials in the country. This made it easier for drug companies to do research that involved Indian participants

2003-2011: From 40 to 50 trials in 2003, the country saw around 1850 trials registered with the government registry in June 2011

2007-2009: Registration of clinical trials introduced as a voluntary measure in 2007 and made mandatory (with full disclosure of trial data with the Clinical Trials Registry) from June 15, 2009

2004-2008: Around ten firms, including Pfizer, GlaxoSmithKline and Astra Zeneca, conducted unethical clinical trials in the hospital in Bhopal reserved for victims of industrial genocide. The trials were called off in 2008 on the orders of the hospital's management.

2010: A US based NGO called Program for Appropriate Technology in Health (PATH) was given approval for a trial that they called a 'demonstration project' on the HPV vaccine. Gross ethical violations in the manner in which trial participants were recruited.

2013: The Parliamentary Standing Committee on Health found several instances of ethical and procedural violations in the manner in which the HPV trials were conducted

2008-2010: Government and private doctors in Indore, Madhya Pradesh, reportedly carried out clinical trials of various medicines on some 233 patients who had gone to them seeking psychiatric treatment. The trials, which included gross ethical violations

2013: The Supreme Court, taking cognizance of the issue after a public interest litigation was filed by the Indore based Swasthya Adhikar Manch (health rights platform) imposed a stay on clinical trials in country.

2013: The Supreme Court stopped the country's drug regulatory agency from approving any new drug trials on humans. The court banned clinical trials for new drugs unless they were personally verified and cleared by the health secretary.

2014: Government admits before the Supreme Court that an estimated 3,458 research participants died during clinical trials conducted in the period, January 1, 2005, to December 31, 2012. Out of these, 89 deaths were found to be attributable to the clinical trials. In this period, trials on 475 new drugs were conducted and only 17 drugs were approved for marketing in India.

2013-2014: After a rather hasty exercise in 2013, further amendments to the Drugs and Cosmetics Act undertaken in 2014. Norms for compensating those suffering adverse effects of clinical trials still being discussed.

There were gross ethical violations in the manner in which trial participants were recruited. In Andhra Pradesh, consent was not taken either from the girls or from their parents or guardians. Hostel wardens signed up to give consent for hundreds of girls in their charge. The district health systems were in no position to monitor the health of the trial subjects or to follow up on possible adverse effects. The story broke when four deaths were reported among trial subjects in Khammam in Andhra Pradesh⁶². Till this day the cause of death and its possible link with the vaccine has not been established or disproved as there were no systems in place to follow up trial participants.

A Parliamentary Standing Committee on Health clearly indicted PATH and commented:⁶³ *“PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers.”*

Another prominent instance of abject regulatory failure related to trials conducted between January 2008 and October 2010 by government and private doctors in Indore, Madhya Pradesh. Trials were conducted on some 233 psychiatric patients who had gone to them seeking psychiatric treatment. Following media reports the government responded by imposing a mere 5,000 rupees fine on 12 doctors for not informing the parent hospital about the conduct of the trials and for ignoring protocols.⁶⁴ There were 18 deaths during the course of these trials, none of which was investigated by any independent agency.⁶⁵ Matters finally came to a head when a civil society organisation, SwasthyaAdhikarManch (health rights platform), filed a Public Interest Litigation in the Supreme Court of India.⁶⁶ The Court, in January 2013, stopped the country’s drug regulatory agency from approving any new drug trials unless they personally verified and cleared by the health secretary.

Ten years after the Indian law was amended to facilitate clinical trials by foreign sponsors, regulatory agencies have only now started putting in place regulations regarding clinical trials that span issues such as informed consent, ethics committees, compensation norms, reporting of serious adverse events during trials, etc. After a rather hasty exercise in 2013, further amendments to the Drugs and Cosmetics Act have been undertaken in 2014.⁶⁷

The clinical trials industry now claims that the clampdown by the Supreme Court and new regulations have slowed down the growth of the industry. However almost all the clinical trials suspended after 2013 have been subsequently approved. The ‘industry slowdown’ argument is an industry ploy to further weaken regulations.⁶⁸ In fact, several important areas of regulations remain untouched, including areas related to the regulation of Contract Research Organizations (CROs), Targeting of Marginalized Populations and the accountability of Ethics Committees⁶⁹.

The huge regulatory lapses related to clinical trials need to be seen as part of a trajectory beginning with liberalized norms based on a committee’s report that had a strong corporate presence. This was followed by reluctance to put in place adequate regulatory structures even though evidence of ethical violations kept mounting. The nexus – between policy makers, regulators and industry -- which we refer to as characteristic of an evolved system of regulatory capture is clearly in evidence in the case of the recent developments in the clinical trial sector in India.

Section III: Multiple Influences on India's IP Policy

3.1 Shifting Positions on Intellectual Property Protection

Capitulation during GATT negotiations

In 1986, at the Uruguay Round of negotiations under the General Agreement on Trade and Tariffs (GATT, the predecessor of the World Trade Organization) developed countries introduced a number of issues on the agenda, which were hitherto not considered as trade issues. Prominent among these were Intellectual Property Rights, Investment and Services. In the initial 3 years of negotiations, developing countries led by India and Brazil were able to stall the introduction of these new issues⁷⁰. The US, its European allies and Japan continued to press for the inclusion of these new issues in subsequent negotiations. The US, had an interest in protecting its IP-dependent industries where its corporation held global ascendancy specifically the pharmaceuticals, software and mass media sectors⁷¹.

India's pharmaceutical sector had flourished in the wake of its 1970 Patent Act, which did not allow product patents in the case of medicines and agro-chemicals. The post 1970 growth of a generic industry in India was to have far reaching effects, not just in India, but across the world. The Indian generic company Cipla, changed the entire landscape of HIV treatment in 2001 when it offered the same combination of anti-retrovirals at USD 350 for a year's treatment⁷² that MNCs were offering at USD 10439 (discounted price). The US, during the Uruguay round of negotiations, had clearly anticipated this trajectory of the Indian generic industry and its potential to challenge the domination of US based companies in the global pharmaceutical market. By the early 2000s India came to be termed the "Pharmacy of the South" and Indian generics were supplying affordable medicines to over a hundred countries in Africa, Latin America and Asia. A 2010 study of donor-funded HIV medicines found that as of the end of 2009, "among paediatric ARV and adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets, Indian-produced generics accounted for 91% and 89% of 2008 global purchase volumes, respectively."⁷³

Domestic Policy Shifts affect position on IP

At the beginning of 1989 both Brazil and India were plagued by domestic economic problems, and bilateral pressure by the US resulted in the two main hold-outs changing their position on inclusion of IP issues in the negotiations. India went to the extent of replacing India's chief negotiator at GATT, S P Shukla because of his strong opposition to the inclusion of IP issues in the negotiating agenda⁷⁴. In 1991 the then Congress government embarked on a formal policy to introduce neoliberal reforms⁷⁵. This led to a significant shift in public policy, which had its impact on the government's official view on IP rights. From an earlier position that India was forced to concede ground in the GATT negotiations, there was now an attempt to argue that strong IP protection would actually further domestic interests in India. India finally became a founder member of the WTO and signed on to the TRIPS Agreement.

Legislative History of India's 2005 Patent Act

When a new government came to power in 2004 there was a clear consensus among major political parties (the BJP and the Congress) on the need to continue and strengthen neoliberal reforms. In consonance with this overall consensus, the government circulated the Third Patents (Amendment) Bill draft for discussion as the 2005 deadline for India's compliance with TRIPS obligations loomed. This draft, promulgated as an ordinance in December 2004 (but requiring ratification within 6 months by Parliament) did not make use of safeguards available in the TRIPS agreement. However, in late 2004, for entirely extraneous political compulsions, the principal opposition party (BJP) signaled its opposition to the draft⁷⁶.

Given the change in circumstances the government was forced to seek support from smaller parties which stood

towards the left of the political spectrum and who had been arguing for incorporation of pro-health safeguards in the amended Act. The deliberations in Parliament in March 2005 were held in the backdrop of protests across the country, as well as in different parts of the world – all demanding that the ‘pharmacy of the South’ should not be jeopardized. The Indian generic industry too put pressure on the government to incorporate amendments that would safeguard their interests. A snapshot of these provisions and their impact in the past 10 years is in Box 1.

The relatively progressive and pro-public health amendments to the 2004 ordinance, leading to the amended 2005 Patents Act need to be seen in the context of the extraordinary circumstances which forced the hand of the government, as should the use of these safeguards over the past decade. Saddled with a law that the UPA government did not entirely wish upon itself, the government has never pushed for a complete realization of the possible benefits of the flexibilities in the Indian Act.⁷⁷ The development and use of the public health safeguards in the Indian patent law over the past decade arose largely out of the mobilization and hard work of public health and public interest groups and their constant and consistent holding of government institution to account for positions taken in court cases and international trade negotiations.

BOX: Select Public Health Safeguards in India’s Patent Law

Restriction on evergreening: One of the key provisions of the Patents Act 1970 specifies what products and processes cannot be patented. These include discoveries, plants and animals, business methods, traditional knowledge and so on. Of particular note is Section 3(d), which guards against the common pharmaceutical-industry practice of ‘evergreening’ – i.e. extending patent terms by making modifications to original molecules (also known as ‘new chemical entities’) or finding new uses or new forms of existing medicines.

Pre and post-grant oppositions to patents: Pre- and post-grant patent oppositions are aimed at assisting the Patent Office with all available information on the product or process on which a monopoly is sought. Ultimately, it is the responsibility of the Patent Office to ensure that patents are granted only to genuine applications; but with tens of thousands of applications to examine, the role of oppositions has been critical in bringing frivolous or tendentious applications to light. People living with HIV, cancer and hepatitis C as well as generic companies have successfully used India’s strict patentability criteria including Section 3(d) and the patent opposition system to ensure that key medicines have not been patented in India.

Recognition of standing of public interest groups in patent oppositions: India’s patent law allows any person to file a pre-grant opposition. The vital importance of the role of public interest and health groups in opposing patents and patent applications and not restricting this to generic companies has been underscored in cases where generic companies have taken voluntary licenses from patent holders and subsequently withdrawn their patent oppositions. The tenofovir and sofosbuvir voluntary licenses are cases in point. In the case of the latter, for instance, generic company Natco which was successful in the first round of opposing the patent on sofosbuvir subsequently took a license from Gilead and withdrew its patent opposition. The pre-grant opposition system has also been used by groups outside India as in the case of the opposition filed by [ABIA]. While post-grant is open only to a person “interested,” the Intellectual Property Appellate Board (IPAB) has ruled that in the case of an NGO working with drug users that challenged a patent Roche had on pegylated interferon “...public interest is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve. We therefore hold that the appellant who works for a community which needs the medicine is definitely a ‘person interested.’”

Bolar and Research Exemptions: The Indian patent law specifically recognizes various exceptions to patent rights including the bolar and research exceptions. The Bolar exception allows generic companies to make all preparations use and even manufacture a patented medicine in order to get marketing approval. This is an important safeguard so that as soon as a patent expires, is revoked or a compulsory licence is issued, the generic version can be put on the market. The research exception allows the use of a patented medicine for the purposes of research.

Parallel Imports and International Exhaustion: Parallel imports and the international rule of exhaustion are recognized under the Indian law which means that a medicine patented in India, put on the market anywhere in the world by the patent holder can be imported into India without the patent holder's permission.

Compulsory Licensing and government use: The Indian patent law has extensive provisions on compulsory licensing. Under the law, a manufacturer interested in making a patented medicine must wait for three years after a patent has been granted and then apply for a compulsory licence on various grounds, including that the patented medicine is not available or is not reasonably priced. This application can only be made after negotiations with the patent holder have failed. A compulsory licence may also be issued by the Central government where there is a circumstance of national emergency, extreme urgency or public non-commercial use. This specifically includes public-health crises related to HIV, TB, malaria and other epidemics. There is no requirement for negotiations with patent holders in these cases. A compulsory license for export may also be issued if another country with limited manufacturing capability issues a compulsory licence, or in any other way allows the import of medicines that are patented in India. The Act also authorises the government to use a patented medicine for its own purposes (including its provision in public-health institutions). In March 2012 the Indian Patent Office issued India's first compulsory licence on sorafenibtosylate, a drug used in the treatment of kidney and liver cancer and which is patented in India by the multinational German company, Bayer Corporation. Bayer was selling the drug at Rs. 2,88,000 or approximately USD 5200 per person per month. The generic equivalent made by NatcoPharma Limited which applied for and received the compulsory licence is sold at Rs. 8,800 or USD 160 while the version made by another Indian generic company, Cipla Limited (that has chosen to challenge Bayer's patent instead of pursuing the compulsory licence route) is priced at Rs. 6780 or USD 124.⁷⁹

Regulatory Capture in formulation of IP Policy

Regulatory capture of the formulation of IP policy in India needs to be understood in the above context. The first link in the chain is the capture of IP legislation at the global level by multinational corporations acting through the aegis of developed country governments at the Uruguay Round of negotiations. The second link in the chain is the capture of public policy in India as a result of its adoption of neoliberal policies in the 1990s. The logical consequence of these trends would have been the formulation of an IP policy that provided higher standards of IP protection with weak safeguards. This did not happen because of fortuitous circumstances, which we briefly describe earlier. While the Indian Patent Act provides the enabling platform for pro-public health measures, it is out of sync with the overall neoliberal vision of the Indian government, and has been so for quite some time.

This underlying contradiction is now being laid bare as evidenced by significant departures in public positions by the current Indian government. The appointment of Arvind Subramaniam as the Chief Economic Adviser to the Ministry of Finance was an indication of a qualitative shift in public policy. In March 2014, in a written testimony submitted during the process of review by the US of intellectual property (IP) protection of various countries including India, Subramaniam wrote, *"If India does not address the problems created by Section 3(d) of the patent legislation or by compulsory licensing for nonworking, the United States should consider initiating WTO disputes against India."*⁸⁰ The formal shift in positions became evident in the numerous interactions between the Indian and the US government. Shortly thereafter, a joint communiqué at the end of Prime Minister Modi's visit to the

US in 2014, stated *“Agreeing on the need to foster innovation in a manner that promotes economic growth and job creation, the leaders committed to establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and technical-level meetings as part of the Trade Policy Forum”*.⁸¹

In September 2014, the Minister of Commerce, Nirmala Sitharamiah stated: *“India does not have an IPR policy. This is the first time we are coming out with an IPR policy. We are very strong in IPR and we certainly want to protect our interest. IPR policy issues have been hanging for quite a long time and the new policy will give direction in terms of protecting IPRs of India. With the US we have (certain) issues. India has become a brand in terms of pharma. Because India does not have any policy, developed nations are picking holes in India’s IPR laws”*.⁸² To draft this IPR policy, the government established an ‘IP Think Tank’ that was, *inter alia*, tasked to unfold India’s new vision on Intellectual Property Rights. As the membership of this think tank became public, questions arose over its composition that included legal representatives of industry including the pharmaceutical industry.⁸³

In January 2015, the think tank released the ‘Draft Intellectual Property Policy’ with a vision of *“intellectual property led growth in creativity and innovation”*. The draft policy enunciates a vision that proactive promotion of IP protection is in harmony with India’s developmental goals, and says: *“An all-encompassing IP Policy will promote a holistic and conducive ecosystem to catalyze the full potential of intellectual property for India’s economic growth and socio-cultural development”*. The policy further resolves to: *“Stimulate large corporations, both Indian and foreign, that have R&D operations, to create, protect and utilize IP in India”*; and to: *“Strengthen IP teaching, research and training in collaboration with WIPO, WTO, other International Organizations and reputed foreign universities”*. Nowhere in the policy is a mention of the possible negative effective of strong IP protection on access to health services and other basic needs or of the benefits of open innovation systems and non-exclusive licenses⁸⁴.

The draft was criticized widely as making *“...a categorical and critical mistake of promoting intellectual property as an end in itself rather than as a means for achieving social and economic progress through enhanced production of and access to the fruits of creativity and innovation”*.⁸⁵ While the Department of Industrial Policy and Promotion announced a call for public comments which was followed by hearings by the think tank, most notable was the specific invitation to the US government to comment on the draft after the US President’s visit in January 2015. According to the Commerce Minister, *“We have invited the Americans to look at the draft policy (on IPR) and give their inputs. We will then see what we can do with it.”*⁸⁶ The draft IPR policy has been warmly welcomed by the US pharmaceutical industry with some representatives of the industry noting that the changes indicated by the current government could, *“translate into significant new market opportunities for right holders.”*⁸⁷ The final draft of the IPR policy is now reportedly under inter-ministerial consultation.⁸⁸

3.2 Case Studies on Regulatory Capture

Regulatory capture in the field of intellectual property as it relates to pharmaceuticals takes many forms. In Section 2, several instances of regulatory capture have been highlighted that indicate capture of domestic regulatory structures by the domestic pharmaceutical industry in India. The case studies in this section focus on the strategies and tactics of regulatory capture employed by the multinational pharmaceutical industry and developed countries, in their attempts to influence Intellectual Property related laws and policies. Multinational companies have employed multiple strategies including advocacy through industry associations like the Organization of Pharmaceutical Producers of India (OPPI), litigation, and arguably takeovers and deals with the generic industry.

MNCs have achieved high level interactions with Indian law and policy makers and often these have resulted in policy positions that are at least initially favourable to big pharma till the inevitable push back from civil society. As we discuss below, they have been particularly successful in influencing developed country positions and encouraged them to influence India’s policies as regards intellectual property protection. Initially, the US and

EU and now Japan are using multiple forums and mechanisms to pressure and influence Indian law and policy makers to undermine the use of TRIPS flexibilities in India. This pressure cannot be seen in isolation from the actions of the MNC pharma industry in these countries in pushing their governments to use state machinery of diplomacy and trade pressure against the Indian government to force changes in India's patent regime.

The first two case studies examine the role of pharma MNCs in setting the agenda for the EU-India FTA negotiations on intellectual property and in the pressure created by the US government on India. The third case study on patent linkage in India exemplifies the multitude of strategies employed by MNC pharma to implement TRIPS-plus provisions in India. The final case study examines technical assistance provided by developed countries and MNC pharma to the Indian patent office and the Indian judiciary as a strategy to harmonise the examination and adjudication of patents away from the pro-public health and public interest basis adopted by these institutions.

3.2.1. Bogey of Counterfeit to Criminalise Generic Drugs

Transnational pharmaceutical companies and some developed countries have been using the bogey of 'counterfeits' to delegitimize generic medicines. The issue came to a head in a major international incident in 2009 when generic drugs from India, being exported to Latin America and Africa, were confiscated in transit in several European ports⁸⁹ on the suspicion that they were 'counterfeit'. The term counterfeit is used in the context of trademark violations. The confiscation of legal generic drugs by claiming they were 'counterfeit' points to a motivated attempt by developed countries and TNCs to conflate the issues related to generic drugs, quality of drugs and counterfeits. The industry associations of MNCs in the pharmaceutical sector, IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) and its US based counterpart, PhRMA (Pharmaceutical Research and Manufacturers of America) have been at the forefront of a global campaign to criminalize generic drugs by labeling them as counterfeit⁹⁰.

PhRMA and IFPMA have been instrumental in setting up the global 'Partnership for Safe Medicines' (PSM). The US Department of state lists the PSM as one of its worldwide partners in the combat of 'counterfeit' medicines⁹¹. The 'Partnership for Safe Medicines' was launched in India in 2010 and its first planning meeting saw the presence of the US patent office chief and representatives from the US FDA⁹².

Scott A. LaGanga, who serves as executive director of the global Partnership for Safe Medicines also serves as vice president of public affairs and alliance development at PhRMA⁹³. LaGanga was instrumental in the creation of the Partnership for Safe Medicines India. While PSM India claims to be a civil society organisation, LaGanga writes in a publicly available paper: *"PSM representatives actually met PSM-India's future founder and executive director, MrBejonMisra, on one of our first visits but did not realize that he was the perfect candidate until 2 years later"*. He further writes that *"Mr. Misra continues his advocacy through disseminating PSM-India success at speaking around the globe, and is involved in a variety of initiatives across India to promote safe medicines to patients. He is in regular communication with the Drug Controller General in India, as well as US Government officials in India, to further both domestic and international cooperation"*⁹⁴.

Investigations reveal that 45% of PSM-India's funding is from PSM-Washington, about 15% from the pharma industry and individuals, about 20% from other NGOs and another 20% from the Indian government⁹⁵.

PSM India has been a co-collaborator in organizing several high profile meetings which purport to discuss 'safe medicines' but generally focus on 'counterfeits'. This includes an 'International Workshop on Patient Safety and Drug Detection Technology' in New Delhi in September 2012 in collaboration with the Ministry of Health and Family Welfare, Government of India, and the World Health Organization (WHO) Country Office for India⁹⁶. A more recent exercise was a 'National conference on Patient Safety and Drug Regulatory Scenario in India', in May 2015, in collaboration with Government of India & Government of Jammu & Kashmir⁹⁷.

The collaboration of this so called partnership for ‘safe medicines’ with the government of India is a clear attempt by pharmaceutical MNCs through its Indian front organisation, to influence public policy regarding generic drugs. It is curious that the Indian regulatory agencies continues to give space to PSM-India in spite of its position regarding counterfeit drugs in the WHO, where India has clearly opposed the conflation of ‘counterfeit’, which is an issue related to trademark infringement, with the issue of quality of generic medicines⁹⁸.

3.2.2 EU-India FTA and the Role of Industry Organisations

Since 2007, India and the European Union (EU) have been negotiating a free trade agreement (FTA) that has attracted global concern over its potential impact on the manufacture, supply and distribution of generic medicines from India. The European Commission’s (EC) aggressive approach to trade negotiations commenced in 2006 with the release of the Global Europe Strategy, *“after enormous pressure from business groups to support EU businesses in competing globally.”*⁹⁹ The EC’s new approach to intellectual property obligations in FTAs has been revealed in the FTAs concluded with Korea, Colombia and Peru since the launch of the Global Europe trade strategy. These FTAs contain several TRIPS-plus obligations including longer patent terms, data exclusivity and enforcement measures. Leaked versions of the EU-India FTA negotiation texts in 2009, 2010 and 2011 confirm that the EU is making similar demands of India that would require significant changes in the domestic patent regime.

Influence of European industry on EC: In 2010, Corporate Europe Observatory (CEO) and India FDI Watch released a report¹⁰⁰ which details instances of links between the European pharmaceutical industry and the EC. In early 2007, before the negotiations were formally launched, the EC circulated a questionnaire to business lobbies in the EU asking for their inputs following which Business Europe was given the names of all the chief EU FTA negotiators. It didn’t take long for Business Europe to contact them. On 22 May 2007, four weeks before the official negotiations with India began, EU DG Trade’s Lisa Mackie, Annette Grünberg and Frauke Sommer met with three Business Europe lobbyists to specifically discuss negotiation tactics: Carlos Gonzalez-Finat, an advisor at the time for Business Europe, Gisela Payeras from the European pharmaceutical lobby EFPIA and Robert Court, the then vice president of pharma giant GlaxoSmithKline and chair of Business Europe’s India commission¹⁰¹.

TRIPS-plus measures demanded by EU: An examination of the demands of the European MNC pharma industry and their replication in the EU-FTA negotiating texts reveals the close links between industry and the EC. The EFPIA in its demands made of the EC said: *“The absence of Regulatory Data Protection is a vital gap in India’s intellectual property regime to promote pharmaceutical innovation [...] EFPIA, therefore, stresses the importance of the inclusion of an effective Regulatory Data Protection framework in the final FTA.”*¹⁰² This demand was echoed in the EU’s demand for data exclusivity in the EU-India FTA negotiations. It may be underlined here that Data Exclusivity is a ‘TRIPS plus’, i.e. it is a measure that is not required by the TRIPS agreement. If Data Exclusivity is provided for, drug regulators when approving generic versions of medicines cannot rely on data already generated by the originator to determine if the medicine is safe and effective. This would force generic manufacturers to conduct fresh clinical trials on medicines already introduced in the market or wait till a specified exclusivity period is over (5 to 11 years) before they can get marketing approval. Duplicate clinical trials on human populations for a medicine whose safety and efficacy is already proven are unethical and add considerably to the cost of generic production. Introduction of data exclusivity, thus, creates an additional layer of beyond patent protection and applies even to medicines that are off-patent or where a compulsory licence is issued.

The EFPIA also demanded that: *“The EU must address the scourge of counterfeiting and piracy in its bilateral relations with key strategic partners (e.g. China, Russia, India and Brazil) and in the framework of the Anti-Counterfeiting Trade Agreement (ACTA) negotiations”*¹⁰³. This demand was echoed in provisions suggested by the EU in the negotiating text of the EU-India FTA negotiations. Among these are provisions relating to the ability of patent holders to get court orders against generic companies. Indian courts have held that in the case

of medicines or other public interest matters, courts would be extremely careful before granting an injunction that would prevent a generic medicine from reaching the market at a stage when it is not even proven that the generic medicine infringes a patent. However, the EU's demands would broaden the circumstances in which patent holder can ask courts for such orders. In addition, the EU is also seeking what is known as 'third party liability' which would allow patent holders to involve the entire manufacture, supply and distribution chain in patent disputes. This could include API manufacturers, truckers, pharmacies and even NGOs that are treatment providers and would impact their willingness to work with generic companies.

Both the examples cited above are of TRIPS-plus measures introduced in the negotiating text of the EU-India FTA at the behest of industry. The ability of pharma MNCs to influence the EC was instrumental in overriding multiple European Parliament directives to the EC not to demands TRIPS-plus provisions in FTAs¹⁰⁴.

Selective access to negotiating texts: The lack of public access to the negotiating texts of the EU-India FTA has resulted in legal battles in both jurisdictions that are telling of the reach of the MNC pharma industry and the business lobbies more generally. In 2011 CEO challenged the secrecy around the negotiations and the access given to business and trade associations before the General Court of the EU. In 2013, the General Court dismissed the case finding in response to CEO's argument that they should have received equal treatment with the trade associations, that, *"...the documents requested by the applicant were provided to trade associations and companies participating as experts in the work of the advisory committee and of its working groups on access to markets of a third State and for the sole purpose of enabling all of the participants to fulfil their roles as advisers to the Commission...Suffice it to state that the applicant objectively lacks the abovementioned status, whatever the alleged importance of its role in international negotiations or its reliability as an organisation entered in the Commission's interest group register."*¹⁰⁵ In June 2015, the European Court of Justice declined to allow CEO's appeal against the decision of the General Court.

In India, access to these texts for industry appears to be selective. The Confederation of Indian Industries (CII) has taken positions more in line with the MNC pharma industry and the documents of the European Commission indicate that the EC was also sharing information with CII. However the same facility has been denied to one of generic industry bodies in India -- the Indian Pharmaceutical Alliance (IPA) -- which is currently involved in a legal battle under India's Right to Information Act to gain access to the negotiating texts.¹⁰⁶

3.2.3 US pressure on India: Role of MNC lobbying in the US

There is considerable pressure on India from the US to modify the pro-public health provisions of the Indian Patents Act. The irony of these attacks from a government that procures the majority of AIDS treatment provided by it across the developing world from Indian generic producers appears lost on the US administration. The US Government's President's Emergency Plan for AIDS Relief (PEPFAR) procures 90% of its AIDS medicines from generic manufacturers and estimated that it saved US\$215 million in 2008 alone through the use of generic ARVs. Today nearly 14 million people in developing countries are on ARVs. A 2010 study estimated that between 2003 and 2008, over 80% of ARVs accessed by people living with HIV across these countries were supplied by Indian generic companies.¹⁰⁷ Indian companies are able to produce safe, effective and affordable generic medicines thanks to the use of health safeguards in India's patent law. The US government is however pushing India to roll back these safeguards and adopt intellectual property protection higher than what is required in TRIPS i.e. TRIPS-plus provisions through a variety of strategies and mechanisms.

US Special 301 and the US International Trade Commission Investigations: The US Special 301 Report that has been released annually since 1989 identifies countries that, the US government believes, do not adequately protect intellectual property and marks them either for heightened engagement or trade sanctions. At the urging of the pharmaceutical and copyright industries, Section 301 was amended in 1984 and 1988 to expand the policy

into intellectual property. The US placed many of the leading countries opposing TRIPS in the first Special 301 Report in 1989, including India. Between 1991 and 1994, India was designated a Priority Foreign Country and in 1992 lost the Generalised System of Preferences (GSP) benefits on matters related to pharmaceutical patents.¹⁰⁸

The GSP benefits were restored in 2005 when India amended its patent law but India continues to feature on the Priority Watch List of the Special 301 on an annual basis. These reports echo the demands of industry led by the Pharmaceutical Research and Manufacturers of America (PhRMA). Of the forty-eight countries PhRMA requested to be included in watch lists in 2008, thirty six, or 75%, of the requests were honored by USTR.¹⁰⁹

In 2014, the US used the Special 301 processes to escalate pressure on the Indian government by announcing an out-of-cycle review.¹¹⁰ In 2013 and 2014, the US International Trade Commission announced two sets of investigations into India's trade policies that included IP law and policy.¹¹¹ These actions were preceded by a sustained campaign by US pharma¹¹² that eventually roped in US law and policy makers into demanding that the US government initiate strict actions against India over its IP policies. This included a letter by the US Senate Committee on Finance to the US Secretary of State asking him to raise concerns over India's compulsory license and the Supreme Court of India's decision in the Novartis case on his visit to India¹¹³ and a letter signed by 170 members of the US Congress to the US President criticizing India's IP climate and asking the President to, "send a strong signal to the Indian government that these actions are inconsistent with India's international obligations and set a precedent."¹¹⁴

USPTO's IPR attaché in its embassy in India: The US embassy in India is directly involved in lobbying on IP issues through its IPR attaché. Dominic Keating, the former IPR attaché in India noted, "*My key role is to promote high standard Intellectual Property protection and enforcement in India.*"¹¹⁵ Mr. Keating has also stated that the U.S. Mission is working with governments and industry associations to promote high standards of intellectual property protection and enforcement in South Asia.¹¹⁶

The IPR attaché was a regular participant at the highly controversial George Washington University's India Project's "IP Summits". These summits were heavily funded by Multinational Pharmaceutical Companies and featured US judges in the promotion of greater intellectual property protection in India.¹¹⁷ The US embassy also puts out 'IPR toolkits' challenging the health safeguards in India's law such as India's refusal to provide data exclusivity.¹¹⁸

US regulatory bodies lobbying for IP in India: In 2009, the United States Patents and Trademark Office (USPTO) and Pfizer held joint meetings for NGOs and media in India which featured lobbying against key safeguards in India's patent regime including on Section 3(d) and on data exclusivity.¹¹⁹ The USPTO later acknowledged that holding joint meetings with regulated companies was not part of their practice – however there has been no information of how these meetings were allowed and what action was taken against USPTO and US embassy officials on these meetings.¹²⁰

The George Washington University's "IP Summits" featured the active participation of US Judges such as Randall R. Rader, U.S. Court of Appeals for the Federal Circuit.¹²¹ These events were heavily funded by US industry. For instance PhRMA, Microsoft, Qualcomm and others were key sponsors of the 2009 IP Summit.¹²² As with the USPTO, the participation of a senior US judge in such a heavily industry funded event and promotes through his sessions greater intellectual property protection raises questions of the line between the regulator and the regulated.

High level access for industry bodies: Just before President Obama's visit to India in 2009 the US administration was actively engaged in lobbying for an intellectual property rights (IPR) regime in India that "protects American patents."¹²³ President Obama also participated in programmes organized by the US-India Business Council (USIBC). USIBC is actively lobbying against the issuance of compulsory licences by the Indian government and against a key health safeguard of India's patent law. The sponsors of USIBC's Coalition for a Healthy India included most of the big multinational pharmaceutical companies - Pfizer, Merck, Johnson and Johnson, Abbott

Laboratories, Novartis, Sanofi-Aventis and Eli Lilly. The Indian arms of some of these companies approached the Indian Prime Minister's Office to push for amendments to Section 3(d) of the Indian Act (that bars patents on trivial innovations), data exclusivity and patent linkage. (see case study on patent linkage below). In 2009, USIBC announced the launch of its report against Section 3(d). This report was circulated when United States Trade Representative (USTR) Ron Kirk traveled to India for the first time; Kirk attended the meeting where the report was launched. In 2015, both the Indian Prime Minister and the US President jointly attended a USIBC closed doors meeting where the US President specifically raised the issue of intellectual property rights in India.¹²⁴

3.2.4 Pushing Patent Linkage in India

A patent linkage system requires that drug regulatory agencies refuse to register generic versions of patented medicines. A patent linkage system would undermine several health safeguards in the Indian law. The Indian law allows generic companies to take all actions necessary to comply with regulatory requirements so that a generic medicine can be launched immediately on patent expiry, if the patent is revoked or if a compulsory license is issued. Further, generic companies often 'launch at-risk' generic versions of patented drugs where they believe that the existing patent is likely to be overturned and/or that their version of the medicine does not infringe the patent granted.

The preamble to the TRIPS agreement recognizes that intellectual property rights are "*private rights*". The implementation of a patent linkage system fundamentally alters the nature of these private rights by burdening their enforcement on a public body. Under such a system, the drug regulator's office -- a government body meant to ensure the safety, quality and efficacy of medicines for the public -- is required to enforce patents on behalf of the patent holder. The UN Special Rapporteur on the Right to Health has accordingly cautioned developing and least developed countries against adopting patent linkage.¹²⁵ The negative impact of a patent linkage system has also been cited in the report of the WHO's Commission on Intellectual Property, Innovation and Public Health (CIPiH).¹²⁶

Lobbying India's Regulatory Authority: The attempt by MNCs to impose patent linkage in India started with lobbying India's Drug Controller General of India (DCGI). In 2008, to the surprise of many observers, the then DCGI, Surinder Singh, announced that, "*We are going to seek the list of the drugs from innovator companies that have received patent in India. Once we have the database of the drugs which have been granted patent, we will not give any marketing approval to their generic versions.*"¹²⁷

That this announcement was a result of lobbying was confirmed by the head of the Organisation of Pharmaceutical Producers (OPPI), who stated, "*OPPI has been trying to impress upon the need of 'patent linkage' to the government, since quite sometime. In April last year, the DCGI acceded to our request. Unfortunately, due to some reason, this assurance did not get translated into reality...*"^{128,129} The 'reason' may have been the swift reaction of public health organisations and the domestic generic industry which brought the fact that patent linkage was not within the legislative framework of the country to the notice of the government and the DCGI.

Litigation to pursue patent-linkage: Determined to push ahead with their attempts to secure patent linkage in India, MNCs resorted to litigation. US company Bristol Myers Squibb (BMS) in an ex-parte hearing before a single judge of the Delhi High Court requesting an injunction against the Indian generic manufacturer, Hetero, launching a generic version of the anti-cancer drug *dasatinib*. The single court issued an order supporting BMS¹³⁰ and the order was widely viewed as giving impetus to the DCGI's plans for introducing patent linkage.

The German multinational company, Bayer, followed by suing the DCGI to enforce a patent linkage system in India. (It is of note that Bayer does not benefit from such a system in the EU.) Unlike in the BMS case, here the court dismissed Bayer's plea in August 2009 holding that "*Bayer's argument of inferring drug agencies' role in patent policing or enforcement is unacceptable*".¹³¹ Appeals by Bayer to a division bench of the Delhi High

Court¹³² and then finally before the Supreme Court of India were unsuccessful.¹³³

US embassy's involvement in lobbying: As Bayer's case in India received global attention from public health groups, the US increased its lobbying and advocacy efforts for patent linkage in India. In 2009, the USPTO's IPR attaché in the US embassy in New Delhi co-organised meetings with US MNC pharma company Pfizer for NGOs and media in Mumbai and Delhi (Documents obtained as a result of an application under the US Freedom of Information Act revealed that USPTO and Pfizer each paid \$3,190 for the two meetings). One of the key areas highlighted by Dominic Keating, the IPR attaché at the time was that of patent linkage. According to notes taken by civil society representatives who attended the meeting, the discussion on patent linkage was reportedly as follows:¹³⁴

"Talking about linkage Mr. Keating explained the system of patent linkage and the provisions in US Hatch Waxman Act relating to linkage. He pointed out that this system helps generics to know about the patent status. When asked about WHO briefing note that advises developing countries not to implement DE or Linkage, Mr. Keating replied that he is not impressed with WHO recommendation and the WIPO is the organisation to recommend policy on intellectual property. A participant raised the report of Henry Waxman, a co-author of the US law, which recommends against the imposition of patent linkages provisions in FTA s with developing countries however Mr. Keating stated that the statement was only relating to FTAs and is not relevant to discuss here."

Prime Minister's Office falls prey to MNC pressure: Even as Bayer's case was pending before the Indian Supreme Court, high level lobbying of government officials by the MNCs for patent linkage continued. In July 2010, the Prime Minister's Office (PMO) circulated a note submitted by OPPI asking for key changes in the Indian legislative framework including: the amendment of Section 3(d), the introduction of data exclusivity and patent linkage.¹³⁵ The circulation of the note followed a meeting held on 24 May 2010 between PMO officials, an official of the Department of Pharmaceuticals (DOP) and MNC pharma reps. According to the record of the discussion, the participants at the meeting included Mr. Ranjit Shahani MD, Novartis India and President OPPI, Mr. Alok Sonig, MD, Bristol Myers Squibb India and Executive Member OPPI, Mr. Tapan Ray, DG, OPPI, Mr. Sandeep Gupta, CMD Eli-Lilly & Co (India) Pvt Ltd and VP, OPPI, Mr. Keval Handa, MD, Pfizer Ltd., Mr. Shailesh Iyengar, MD, Sanofi Aventis and Mr. GK Raman, Director Corporate & Govt Affairs, Bristol Myers Squibb India Pvt. Ltd.¹³⁶ The decision taken by the PMO after this meeting was that OPPI would prepare notes on the various IP issues concerning them that would then be circulated to the various ministries for their views which would be collated by the DOP. At the time this note was prepared by OPPI and circulated by the PMO, the appeal by Bayer against the Delhi High Court order was pending in the Supreme Court. With the primary respondent in the case being the Union of India, such a high level intervention by the PMO was clearly a breach of accepted practice.

Over 50 public health and public interest organisations and several individuals wrote to the PMO and the various ministries strongly protesting the circulation of the OPPI note by the PMO.

The PMO note received considerable attention in the media and the unusual action of the PMO was widely commented on.¹³⁷ On 1 December 2010, news reports indicated that all three ministries (Health, Commerce and Chemicals) had rejected the demands made by the MNCs in the note circulated by the PMO.¹³⁸ It may be fair to surmise that this outcome was the result of the public revelation of the PMO note and while the public spotlight may have resulted in the ministries sticking to their previous positions on India's law being TRIPS compliant and the rejection of TRIPS-plus measures, the ability of the MNC pharma industry to effect an intervention from the highest government office is in itself revealing of the level of regulatory capture accomplished by pharma MNCs.

The story is not over and in 2015, the absence of a system of patent linkage in India featured among the many complaints listed by the USTR to justify India's position as a Priority Watch Country in the 2015 Special 301 Report.¹³⁹

3.2.5 “Technical Assistance” from developed countries and MNC pharma

The offer of technical assistance by developed countries and MNC pharma to patent offices and judicial officers in developing countries is increasingly emerging as an area of concern. Patent offices are considered to be administrative bodies, applying patentability standards as part of their examination of patent applications. However, the manner in which the examination takes place determines whether the intent behind the public health safeguards of the Indian patent law is fulfilled in practice. In India’s case, the desire of MNCs to influence patent examination would be understandable given that patent oppositions by public interest groups and generic companies on critical medicines have been successful. The table below provides a snapshot of the successes of public interest groups in this regard.

Table 3: Patent oppositions by public interest groups

MEDICINE/ Therapeutic Category	Patent Applicant/ Patent Office	Opposition filed by	Status of patent application
Imatinibmesylate <i>Anti-Cancer</i>	Novartis Chennai	Cancer Patients Aid Association	Patent Application Rejected
Zidovudine/ lamivudine <i>First-line ARV</i>	GSK Kolkata	Manipur Network of People living with HIV/AIDS, Indian Network for People living with HIV/AIDS	Patent Application Withdrawn
Nevaripine Hemihydrate (syrup) <i>First-line ARV</i>	BoehringerIngelheim Delhi	Positive Womens Network and Indian Network for People living with HIV/AIDS	Patent Application Rejected
TenofovirFumarate or TDF (two applications) <i>Preferred first -line ARV</i>	Gilead Sciences Delhi	Delhi Network of Positive People and Indian Network for People living with HIV/AIDS; Brazilian Interdisciplinary AIDS Association (ABIA) and Sahara (Centre for Residential Care and Rehabilitation)	Patent Application Rejected
Amprenavir <i>Second-line ARV</i>	GSK Delhi	Uttar Pradesh Network of Positive People and Indian Network for People living with HIV/AIDS	Pending
Atazanavir <i>Second-line ARV</i>	Novartis Chennai	Karnataka Network for People Living with HIV and AIDS and Indian Network for People living with HIV/AIDS	Abandoned
Valgancyclovir <i>For opportunistic infections in HIV patients</i>	F Hoffmann-La Roche Chennai	Tamil Nadu Network of Positive People and Indian Network for People living with HIV/AIDS	Patent overturned
Abacavir <i>Second-line ARV</i>	GSK Kolkata	Indian Network for People living with HIV/AIDS	Application withdrawn
Lopinavir <i>Second-line ARV</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, Network of Maharashtra by People living with HIV and AIDS and Indian Network for People living with HIV/AIDS	Patent application rejected

Lopinavir/Ritonavir (Soft Gel) <i>Second-line ARV</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Patent Application Deemed Abandoned
Lopinavir/Ritonavir (Tablet) <i>Second line ARV</i>	Abbott Laboratories	I-MAK	Patent application rejected
Tenofovir or td <i>First-line ARV</i>	Gilead Sciences Delhi	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Pending
Ritonavir <i>Second-line ARV</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Patent application rejected
Efavirenz (post-grant opposition) <i>First-line ARV</i>	Bristol Myers Squibb Mumbai	Delhi Network of Positive People	Pending
Valgancyclovir (post-grant opposition) <i>For opportunistic infections in HIV patients</i>	F Hoffmann-La Roche Chennai	Delhi Network of Positive People	Patent overturned
Pegylated Interferon alpha 2b <i>Hepatitis C</i>	F Hoffmann-La Roche Chennai	Sankalp Rehabilitation Trust	Patent overturned

Technical assistance from developed country patent offices can be a powerful tool to effect change that may be viewed as merely administrative through what has been called “technocratic trust” which “influences decision-making processes of trust-giving offices”.¹⁴⁰ Generally developed countries have lower patentability standards. For countries like India which use relatively high standards of patentability to restrict patents in public interest the challenge is to mitigate against the imposition of developed country standards of patentability and thus avoid granting low-quality patents on trivial innovations.¹⁴¹

India has signed several memorandums of understanding (MoUs) with developed countries on assistance and cooperation on IP generally and some specifically with the patent offices of developed countries such as the European Patent Office (EPO) and the Japan Patent Office (JPO).¹⁴² A 2013 report of an Indian patent examiner¹⁴³ who participated in a training conducted by the JPO is illustrative of the manner in which such trainings are conducted. According to a report submitted by Mangesh L. Mokashi, Examiner of Patents & Designs, Patent Office, Mumbai, the objective was to offer insights into best practices of JPO, sharing experiences and perspectives from companies, research institutes and Intellectual Property Attorneys. The impact of such training needs careful monitoring as the patentability standards in India and Japan are different as is the strictness with which they are applied.

The report cited above highlights the level of involvement and interaction with representatives of industry. The first phase of the training, featuring lecturers from the Nissan Motor Co. Ltd., discussed the anti-counterfeiting measures taken by them in various countries. The third phase of the training, described by the patent examiner as “really interesting and mind blowing” featured exchanges with the Japan Intellectual Property Association (JIPA). JIPAA is described in the report as “a non-profit, non-governmental organization”. JIPA’s website indicates its list of regular members from across industries including Pfizer, Novartis and multiple

Japanese pharmaceutical companies.¹⁴⁴ It is of note that the provisions that featured in the questions to the patent examiners, during the training, also feature in Japan's IP text for the Regional Comprehensive Economic Partnership (RCEP) trade agreement negotiations. In the text, Japan specifically demands that Section 3(d) be reversed, that foreign filing reporting requirements not result in the rejection of a patent and that there be no reporting requirements for working of patents¹⁴⁵ (all of which are contrary to the health safeguards in India's Patent Act).

Attempts to influence the judiciary: Judicial trainings in developing countries appear to be emerging as a method for MNCs to influence the manner in which courts apply or interpret patent rights. It is an attractive avenue to influence the judiciary in India given past record of several pro public health judgments by Indian courts – viz. the rejection of Novartis' patent application for its anti-cancer drug *imatinib*, the rejection of the plea to introduce a patent linkage system (described earlier), the upholding of the grant of a compulsory license for Bayer's anti-cancer drug *sorafenib*, rejection of the challenge to Section 3(d) of the Indian Act, etc.

In a landmark move of sorts Justice Dalveer Bhandari, recused himself from the Supreme Court bench hearing the case filed by Novartis against the rejection of its patent application of the anti-cancer drug, *imatinib*. The recusal of Justice Bhandari came in the background of concerns raised by public health groups over judicial conferences attended by the hon'ble justice¹⁴⁶. The conferences attended by Justice Bhandari in 2009 and 2011 were conducted by an organization known as the Intellectual Property Owners Education Foundation (IPOEF) established by the Intellectual Property Owners Association (IPOA). IPOEF's 2011 International Judges Conference was funded (\$450,000) by the United States Patents and Trademark Office (USPTO).

Interactions between the judiciary and MNC pharma have been reported regularly, albeit designed to appear educational or neutral. In 2010, Federation of Indian Chambers of Commerce and Industry (FICCI) collaborated with the Maharashtra Judicial Academy to hold a 'Judges' Round Table on IP Property Rights Adjudication'. Leaked emails allegedly between FICCI and Microsoft as well as the music industry showed that the funding for the roundtable came from industry which also demanded representation in speaking to the judges and assurances that magistrates empowered to handle copyright cases were invited.¹⁴⁷

In 2003 the George Washington University (GWU) launched its 'India Project' with a focus on intellectual property laws and enforcement in India and has since regularly held IP summits in India sponsored by the pharmaceutical industry among others and that often featured challenges to India's public health safeguards by MNC pharma involved in patent litigation. The 7th IP Summit in 2010 featured an 'Interaction with Judiciary and Moot Court on IPR' at the National Law University in Delhi. Public interest groups in a scathing letter to DIPP that co-sponsored the event pointed out that, according to sources, the moot court problem placed before sitting current judges related to enforcement of intellectual property rights and raised concerns over the placing of issues that were currently being adjudicated by the courts.¹⁴⁸ As stated by GWU staff, *"...one of the goals of the India Project... was to work closely and cooperatively with Indian judges to ensure not just enactment but enforcement of patent laws."*¹⁴⁹

In November 2014, the IPOA planned a trip to India which included meetings with judges from the Delhi High Court and the Intellectual Property Appellate Board.¹⁵⁰ On appeals by public interest groups to the Chief Justice of India, these interactions with the judges were reportedly cancelled.¹⁵¹

Section IV: Change in Policy Space and challenges for Generic Industry

4.1 Liberalized Foreign Direct Investment (FDI) norms and Generic Industry

India can take credit for supporting the development of a self reliant pharmaceutical industry – the largest among Low and Middle income Countries (LMICs). Various factor contributed to this, including the Indian Patents Act of 1970, initiation of basic manufacture of drugs in the public sector in the 1950s and 60s and the Drug Policy of 1978 which imposed several restrictions on the operations of foreign companies and provided preferential treatment to Indian companies. Unfortunately, all these three supportive mechanisms have been reversed in the last two decades. The rollback of measures that promoted the generic industry are a consequence of what we have described as regulatory capture ‘through the promotion of ideas’, in this case the ‘idea’ of neoliberal reforms replacing the previous notion of ‘self reliance’.

Denied support by public policy the Indian generic companies would now rather collaborate than challenge big Pharma. Domestic companies are increasingly looking for tie-ups where domestic facilities will be used for outsourcing of both R&D, manufacture and marketing. See Table detailing some recent alliances between Indian generic companies and MNCs.

Table 4: Select Cases of strategic Alliances of Indian Companies with Foreign Partners

Partnering firms in the India Pharmaceutical sector	Foreign Partner	Description of Alliance	Nature of Alliance
GVK Bio Sciences	INC Research	JV will establish a dedicated resource capability to offer phase I-IV clinical development program in India	R&D alliance
Advinas therapeutics	Merck & co.	Discovery and clinical development collaboration in metabolic disorders	R&D alliance
Pall Pharmed Lab Filtration Pvt Ltd	Euroflow Ltd, UK	Distribution of Euroflow's Chromatography products and technologies in India	Sales and Distribution
Ranbaxy Laboratories Ltd	BlansettPharmaceutical Co., Arkansas, USA	Sales Support to Ranbaxy's DisperMox, amoxicillin tablets for oral suspension in USA	Sales and Distribution
Wockhardt Ltd	Ranbaxy Pharmaceuticals \ Inc., Princeton, New Jersey, USA	Marketing of Wockhardt's bethanecol chloride tablets in USA	Market Development, Sales and Distribution
Orchid Chemicals and Pharmaceuticals Ltd.	Apotex Corp, USA	Sales of Orchid's generic cephalosporin and other injectable products in USA	Market Development, Sales and Distribution

Nicholas Piramal	BioSyntech, Canada	Drug Research and development in Biotechnology area . The collaboration centers on the drug 'BST-Inpod' which is being developed to alleviate chronic heel pain.	R&D alliance
Ranbaxy Laboratories Ltd	Glaxosmithkline, UK	Development of New Chemical entities (NCE's) or new drugs in the area of urology, anti-fungal, anti bacterial and metabolic disorders	R&D alliance
Dabur India Ltd	Abbott Laboratories, USA	Marketing of a number of Dabur products in the USA on an exclusive long term basis	Market Development, Sales and Distribution
Ranbaxy Fine Chemicals Ltd	Mallinckrodt Baker Inc (MBI), USA	RFCL will market MBI JT Baker and Mallinckrodt's range of Scientific Laboratory Products in the Indian market	Market Development, Sales and Distribution
Wockhardt Ltd	Eisai Company Ltd, Japan	Wockhardt markets Methycobal in India	Market Development, Sales and Distribution
Nicholas Piramal	BiogenIdeac, USA	NPIL markets Avonex for multiple sclerosis in	Market Development, Sales and Distribution

Source: KM GopaKumar and MR Santhosh. (2012) *An Unhealthy future for the Indian pharmaceutical industry? Third World Resurgence*. No. 259, March 2012

'Strategic' tie-ups with 'Big-Pharma' have been accompanied by acquisitions of Indian companies by MNCs. Acquisitions have been facilitated by the liberalization of Foreign Direct Investment (FDI) norms for the pharmaceutical sector in 2001. The Industrial Policy Statement of 1991, at the beginning of the phase of industrial liberalisation, claimed that "Foreign investment would bring attendant advantages of technology transfer, marketing expertise, introduction of modern managerial techniques and new possibilities for promotion of exports." However from 2001, the year in which 100% FDI was permitted in the pharmaceutical sector, the exports-sales ratio of MNCs has grown only marginally – from 7% to 11% between 2000-01 and 2008-09¹⁵². Further more than 90 per cent of FDI in pharmaceuticals has gone into Brown-field projects and less than 10 per cent into new ventures¹⁵³.

The government's Department of Industrial Promotion and Planning (DIPP) has pointed to the threat posed by the liberalised FDI norms to domestic companies. An internal DIPP note said *"This has resulted in takeover of key pharmaceutical companies and those with rare facilities and critical verticals, including Ranbaxy, Piramal, Shantha Biotech, AgilaSpecialities and Dabur"*¹⁵⁴. An inter-ministerial group (IMG) on foreign direct investment (FDI), constituted in 2012 had recommended capping of FDI in the pharmaceutical sector at 49%¹⁵⁵. However, both the previous government and the present government have not ratified the IMG's suggestion¹⁵⁶.

The growing collaboration between Indian generic companies and big Pharma put to question the continued survival of an independent and self reliant domestic industry that was seen as the lifeline for poor patients in different parts of the world.

Section V: Conclusions and Recommendations

In spite of being known as the 'Pharmacy of the South' the largest number of people without secure access to medicines is the largest in the world. The most important determinant of poor access is the state of the country's health system, which is largely dependent on a poorly regulated private sector. Out of pocket expenses on healthcare are in the region of 70% of total healthcare costs, and of this, above 70% are spent by patients to procure medicines. This burden can be catastrophic for poor families and an estimated 7 million people in the country fall into the poverty trap every year because of expenses incurred on healthcare.

Not only are medicines not available to a bulk of the population in India, they are also likely to end up procuring medicines that are irrational or hazardous or both. This adds to the cost of treatment and also has a negative effect on health outcomes. India had been recently projected as a lucrative destination for clinical trials, but persistent instances of ethical violations are now being reported during the conduct of clinical trials.

Government regulations can play a major role in mitigating the impact of high drug prices, proliferation of irrational and hazardous drugs and instances of unethical practices in the clinical trials industry. However our study indicates that regulatory capture by the industry, both domestic and foreign, has largely nullified the possible benefits of regulations of the medicines market. Regulatory capture in India is also exercised at the level of public policy with the adoption of neoliberal reforms which places the interest of industry over public health. The impact of neoliberal reforms also extend to continued stagnation of investment in public health, thus compounding the problem of compromised access to medicines for poor patients.

It is imperative that urgent measures be instituted to strengthen regulations on medicines and ensure that they are not shackled through regulatory capture. Specific measures that are necessary include:

- 1) Price control on all essential medicines based on cost of manufacture, which can reduce expenditure on medicines quite significantly. This will need to be accompanied by an expansion of the public health system to significantly reduce the proportion of Out of pocket expenditure on healthcare costs in general and medicines in particular.
- 2) Weeding out of all irrational, unscientific and hazardous drugs from the Indian market and strict adherence to scientific guidelines while approving new drugs.
- 3) Regulation of the clinical trials industry to ensure that drug trials largely address priority public health needs and are conducted in a manner that protects the rights of trial subjects.

Concurrently there are huge concerns regarding the survival of the Indian generic industry as a source for quality low cost medicines, not just for India, but for poor patients across the world. The generic industry faces the prospect of having to work without the protection of India's earlier Patent Act. The health safeguards that are present in the 2005 Patent act are under threat, both as a result of pressures from developed countries and as a consequence of domestic policy shifts. These are now exerting negative pressures on health safeguards in India's Patent Act and on the industrial climate within which generic companies are functioning. As a consequence generic companies are being forced into a situation where they would rather collaborate with big Pharma rather than chart an independent course and continue manufacturing of low-cost generic medicines. Very urgent measures are necessary if the 'Pharmacy of the South' is to be sustained.

- 1) The health safeguards in the Indian Patents Act have to be defended and the Government of India must not fall prey to bilateral, plurilateral or multilateral pressures. The Government must also shun autonomous measures to raise the standards of patentability of medicines.
- 2) Public health concerns need to prevail in all trade negotiations and no TRIP-plus measures should be agreed to in the course of such negotiations.

- 3) The entire system of patent examination, grant of patents, and examination of patent disputes must be secured from influence of industry and foreign governments.
- 4) The government must proactively use the health safeguards in India's Patent Act, including especially the liberal clauses available for grant of compulsory licenses. This could be the single most important measure that can ensure the survival of the generic industry and the continued availability of low-cost generic versions of new medicines for patients in India and across the world.
- 5) The generic industry needs also to be protected from predatory moves by MNCs in the form of FDI caps and other supportive measures that provide them with preferential treatment over MNCs. It is these measures which had led to the growth of the generic industry in the past decade.
- 6) There should not be any dilution of the current resolve of the Indian government in the WHO to resist pressures by developed countries, speaking on behalf of big Pharma, not to conflate the issue of counterfeits with the quality safety and efficacy of generic drugs
- 6) Global solidarity in defense of India's generic industry is important if the 'Pharmacy of the South' is to survive.

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