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Prof. Mohanan B Pillai



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Editorial

The present issue addresses the conflict between the global trade governance regime led by WTO and the Indian domestic regimes, in the light of the implementation of WTO TRIPS Agreement. This volume contains five articles to assess the impact of WTO on India's health sector.

The Uruguay Round negotiations has seen the West imposing WTO's TRIPS regime on the developing nations, despite the stiff resistance from the latter. The trading world was polarised into two hostile camps during Uruguay Round negotiations - the developed nations led by the United States that were worried about the 'free-riding' issue in the developing countries; and the developing world led by India and Brazil opposing incorporation of TRIPS in WTO Agreement. As most of the developing countries were yet to have a patent regime in their domestic legal systems, they feared that the inclusion of TRIPS would make them a frequent defendant before the WTO dispute settlement system for deficiencies in domestic legislations. In his article on WTO's Global IP governance, Girish Kumar addresses this issue.

Reji Joseph stretches the argument further. Joseph studies the political economy of India's engagement with WTO and analyses the contest between WTO and Indian domestic patent regime, i.e., the amendment of the Patents Act 1970 following WTO ruling. Indian subscription to WTO has led to globalization of domestic issues arising out of each of its Agreements and has subsequently resulted in the emergence of the globalization of civil society groups. These groups exert their pressure through various channels such as the Parliament, media, judiciary, political parties, etc, he argues.

In the third article Geethika examines the implications of the new global IPR regime on access to medicines and discusses the Glivec case. The paper assesses the implications of the new global IPR regime on access to affordable and essential medicines in the context of India being portrayed as the 'pharmacy of the world'. The paper also tries to undertake a review of the changing dimensions of IPR legislations in India in the process of achieving TRIPS compliance. It concludes with a detailed examination of the Section 3(d) provision of Indian Patent Act and examines how the TRIPS flexibilities could be made use of to ensure better access to medicines in the post TRIPS world.

The effect of stringent patent regime is a rise in the health expenditure of the public. This becomes more explicit due to the lesser investment of the government in health sector leading to a dominance

of the private sector. The paper by Nagarajan Naidu evaluates the growing private expenditure for health care facilities and studies how this pushes the poor further to poverty, deprivation and restricts their access to better health facilities. For the social protection of the general mass for their health care facilities, the paper calls for expansion of the role of government.

Having constructed a salubrious environment for the pharmaceutical corporates, the TRIPS regime facilitates more foreign investment in the domestic health sector in recent years. Through mergers and acquisitions foreign firms find it easier to improve revenue, profitability, growth in scale and accessibility to wider market. The Indian pharmaceutical sector experiences a boom in M&A-led restructuring strategies in the post-TRIPS period on the domestic firms. The contention that the rise of FDI strengthens R&D investment, needs further probe. The paper by Syama Muralidharan examines the impact of mergers and acquisitions on R&D activities in Indian Pharmaceutical industry. The paper discusses the Ranbaxy-Daiichi acquisition as a case study.

Mohanan Pillai

Editor

Global IP Governance: Disciplining the South through WTO Regime

Girish Kumar R*

Abstract

Most of the developing countries did not have a strong intellectual property regime in their domestic legal system prior to the establishment of WTO. The thrust of TRIPS initiative was to force the developing countries to move toward effective protection of intellectual property and hence much of the WTO litigation in this area, the South feared, would be between developed nation as complainants and developing nations as respondents. But finally developing countries succumbed to pressure of the developed world and acquiesced to incorporate the TRIPS Agreement under WTO purview. Consequently, a complainant Member nation could invoke WTO's dispute settlement procedures for violation of TRIPS provisions. Bringing TRIPS into the WTO Agreement dragged them into frequent litigation by the first world before the WTO dispute settlement system for deficiencies in domestic legislation but also for absence of strong enforcement measures. The GATT, WTO's predecessor, was devoid of a strong adjudicative or enforcement mechanism to address IPR issues. In this paper we will be discussing IPR disputes that have come up before WTO panel/appellate body for adjudication and involving developing nations. The paper is divided into three sections.

Key Words: IPR, WTO TRIPS, GATT, Patents, Trademarks

1. INTRODUCTION

Law is moving from 'localism to transcendentalism'. 'Transcendentalization' involves a supranational regulatory or conflict resolution regime, and is premised upon the concept of 'singularity of law'. The final Act comprised 28 Agreements, in addition to 26000 pages of national

* Girish Kumar R is WTO Chair Professor & Head of the Department of International Relations, Central University of Kerala , Kasargod, Kerala

tariff and service schedules. WTO Agreements included General Agreement on Trade in Goods, General Agreement on Trade in Services (GATS); Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS) covering a very broad area pertaining to trade law. In fact it is a network of treaty agreements (Legrand 2006). It is beyond the control of any government, its agreements/ determinations are applicable to all equally, irrespective of a sovereign nation's economic, social or political power in the comity of nations. It is consistently argued that the WTO through a multitude of agreements under one umbrella and a single dispute settlement mechanism to adjudicate on them established 'perceptual commonalities across laws' and have given sanctity to the singularity of law. "[T]he German, the American, and the Frenchman ... are addressing a problem that arises in each of their own countries but neither the problem nor its solution are any more German than American or French" (Legrand 2006). It could neither be an Indian nor a Brazilian solution. The solution, if it is a trade dispute, whose subject matter is contained in any of the WTO agreements, lie obviously at Geneva, where WTO Dispute Settlement Mechanism is situated. The Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) incorporated in WTO Agreement is responsible for this transformation from power-oriented dispute resolution to law-oriented conflict settlement or from "pragmatism" to "legalism" and has often been referred as "quantum leap" in the history of international trade law. Article 64 of the TRIPS Agreement states that Articles XXII and XXIII of GATT 1994 as elaborated by DSU shall apply to TRIPS cases as well. Member nations are also obliged to maintain "transparency" by publishing and notifying all laws and regulations, and final judicial decisions and administrative rulings to the TRIPS Council. This would enable the Council to examine the implementation of the TRIPS Agreement.

The application of DSU to intellectual property rights, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) received stiff resistance. The trading world was polarised into two hostile camps during Uruguay Round negotiations - the first world led by the United States aggressively pursuing the incorporation of TRIPS into the WTO agenda for they were worried about the 'free-riding' issue in the developing countries; and the third world led by India and Brazil opposing incorporation of TRIPS in WTO Agreement. The developing countries were net importers of intellectual property, relying heavily on the technology transfer from the first world for technological development and preferred a relatively low level of protection of intellectual property. Since most of the developing countries did not have a strong intellectual property regime in their domestic legal systems, bringing TRIPS into the WTO Agreement would drag them into frequent litigation by the first world before the WTO dispute settlement system not only for deficiencies in domestic legislation but also for absence of strong enforcement measures. The thrust of TRIPS initiative is to force the developing countries to

move toward effective protection of intellectual property and hence much of the WTO litigation in this area will be between developed nation as complainants and developing nations as respondents (Cooper and Lowenfeld 1997). But finally developing countries succumbed to pressure of the developed world and acquiesced to incorporate the TRIPS Agreement under WTO purview. Consequently, as explained by Article 64 of TRIPS Agreement, a complainant Member nation could invoke WTO's dispute settlement procedures for violation of TRIPS provisions. The GATT, WTO's predecessor, was devoid of a strong adjudicative or enforcement mechanism to address IPR issues. Albeit the stillborn ITO did have an entire chapter on restrictive business practices that included provisions relating to rights under patents, trademarks and copyrights (Havana Charter 1948). In this paper we will be discussing IPR disputes that have come up before WTO panel/appellate body for adjudication. Before enumerating the IPR disputes invoked under Article 64 of the TRIPS Agreement, it would be helpful to elucidate the major articles of TRIPS Agreement first. This would be followed by TRIPS disputes involving developing nations that reached mutually agreed solutions and disputes that reached Panel/Appellate body stage. The paper will also discuss the possibility of using TRIPS as a tool for cross-sectoral retaliation.

2 TRIPS: GENERAL PROVISIONS AND BASIC PRINCIPLES

The WTO Agreement embodying the results of the Uruguay Round contains the Agreement on Trade-related Aspects of Intellectual Property in Annex IC. The Agreement, intending to reduce impediments to international trade and promote adequate protection of intellectual property rights, emphasises the need for proper enforcement of intellectual property rights and provides effective and expeditious procedures for the multilateral settlement of disputes between the governments. Part I of the Agreement enumerates general provisions and basic principles, especially the obligation to provide 'national treatment' (Article 3). Accordingly, each country shall accord to the nationals of other countries treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property. The most noteworthy clause is the provision of most favoured nation treatment (Article 4) – a novelty in the history of international intellectual property rights treaties. Under this provision, any advantage or favour granted by a country to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other countries. The objective of this Agreement is to promote technological innovation (Article 7) and international transfer of technology. To achieve this objective, the Agreement categorises intellectual property rights into seven and builds on the main existing international conventions and specifies a number of standards of protection.

We will deal with each of the TRIPS categories and the minimum standard of protection as required by TRIPS Agreement (Article 9-40).

Classification

1. Copyright and Related Rights

The Agreement stipulates that parties should comply with the substantive provisions of Berne Convention² for the Protection of Literary and Artistic Works signed in 1886 and as revised in 1971 (Article 9); however, they are not obliged to protect the moral rights as provided in the Convention.² Copyright protection is extended to expressions such as a literary or artistic work, and not to ideas, procedures, and methods of operation or mathematical formulae. Computer programmes would be getting protection like literary works under the Berne Convention. It also lays down the conditions under which compilations of data should be protected by copyright. The Agreement also provides for rental rights, under which the titleholders of computer programmes and cinematographic works are eligible to authorise or prohibit the commercial rental of their works to the public. There are provisions to protect performers from unauthorised recording and broadcasting of live performance (bootlegging) as well. The term of protection for performers and producers of phonograms is 50 years (Article 10-14). However, limitations imposed by Rome Convention of 1961 do apply. These conditions will enable countries to impose reciprocity in some respects or to permit both private use and use for the purposes of teaching and scientific research with remuneration (UN 1995). For the proper protection of copyright, the Agreement also provides for “criminal procedures and penalties in cases of copyright piracy on commercial scale” (Article 61).

2. Trademarks

The Agreement provides equal protection to trade and service marks. Any sign, or any combination of signs, capable of distinguishing goods or services of one enterprise from those of others will be eligible for registration as a trademark. For registration, signs should be visually perceptible. Marks that are well known in a particular nation shall enjoy additional protection. For determining whether a trademark is well known, public knowledge of the mark in the relevant sectors is taken into account, including knowledge resulting from promotion, i.e. advertising. Registration of a trademark is for seven years (Article 15-18). However, the registration could be renewed indefinitely. The Agreement prohibits the requirement that foreign marks be used in conjunction with local marks.

3. Geographical Indications

The Agreement contains provisions that protect geographical indications. It is defined as indications that identify a good as originating in a country, or a region or locality where a given quality reputation or other characteristic of the good is essentially attributable to its geographical origin. Nations are required to provide local means to prevent the use of any indication in the designation or presentation of a good that misleads the public as to the origin of the goods as well as to prevent any use that constitutes an act of unfair competition. Additional protection is given for geographical indications for wines and spirits (Articles 22, 23). However, exceptions are given for names that have already become generic terms, but a nation using such an exception must negotiate to protect the geographical indication in question. TRIPS council shall hold further negotiations to establish a multilateral system of notification and registration of geographical indications for wines.

4. Industrial Designs

The Agreement assures protection for independently created industrial designs that are new or original. However, such protection shall not extend to designs dictated by technical or functional considerations. The owner of a protected design would be able to prevent third parties from the manufacture, sale or importation of articles bearing a design, which is a copy of the protected design. A special provision for new designs in the textile sector is incorporated apparently because of their short life cycle and sheer number. However, the Agreement also provides for “limited exceptions” as well (TRIPS Agreement, Articles 25, 26).

5. Patents

Perhaps the most important part of this agreement contains those provisions dealing with patents covered in eight articles (Articles 27-34.). Accordingly, protection will be available for any invention, whether products or processes in all fields of technology. However, the invention should be ‘new’ involve an ‘inventive step’ i.e. non-obvious and ‘capable of industrial application’. Patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced (Article 27). But for reasons of or republic or morality or for protecting human, animal or plant life or health or to avoid serious prejudice to environment, inventions may be excluded from patentability.

Besides, members may also exclude from patentability (Article 27.3):

- (a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b)Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, members should promulgate provisions that provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. These provisions would be reviewed four years after the date of entry into force of the WTO Agreement³The patent confers upon the owner the right to prevent others from making, selling or importing a patented product without his consent - be it process or product patent. However, nations could provide exceptions to patent; but these exceptions should be “limited” because they should not unreasonably conflict with a normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, and should take into account the legitimate interests of the third parties (Article 30).

The provisions relating to compulsory licensing are enumerated in Article 31 entitled ‘Other Use Without Authorisation of the Right Holder’ (Article 31). Accordingly, if a patent holder fails to ‘work’ a patent within a reasonable period of time, the concerned government could use the patent without the authorisation of the patent holder. However, certain conditions are attached before invoking Article 31. Thus in situations of national emergency, public non-commercial use, anti-competitive practices, etc., this provision could be invoked. Public health and nutrition are some other grounds. However, before granting a compulsory license, efforts should be made to obtain authorisation from the patent holder. It should include paying adequate remuneration and giving a reasonable period of time. And if such efforts fail within a reasonable period of time, compulsory license could be granted. But, when ‘the circumstances that led to it cease to exist and are unlikely to recur’ the license could be revoked. Besides, the granting of compulsory license must be subjected to judicial review. The Agreement provides for a 20-year patent protection.

6. Lay-out designs of Integrated Circuits

Regarding the protection of topographies of integrated circuit, the Agreement relies on Intellectual Property in Respect of Integrated Circuits (the Washington Treaty) signed in 1989 and administered by World Intellectual Property Organisation (WIPO). Thus selling, importing or distributing a protected design without the authorisation of the right holder is treated as unlawful. However, innocent purchasers of infringing products are not treated as infringers, but they should pay a reasonable royalty for the remaining goods sold after receiving notice of infringement. The term of protection is 10 years from first commercial exploitation(Articles 35-38).

7. Trade Secrets

The Agreement provides for protection of trade secrets or know-how against unfair competition as provided in Article 10 *bis* of the Paris Convention (1967). However, such know-how must be secret and have a commercial value, and the person who has the know-how must be in lawful possession of it. Thus the test data submitted by pharmaceutical or agricultural chemicals to the governments for obtaining marketing approval are also protected against unfair commercial use (Articles 35-38).

8. Anti-competitive Practices

The final section of this part recognizes the existence of anti-competitive practices in contractual licenses that impede the transfer and dissemination of technology. Under this section, a nation could legislate to prevent such practices that constitute an abuse of intellectual property rights. It also provides for consultations between governments on such cases (TRIPS Article 40).

Enforcement of Intellectual Property Rights

The TRIPS Agreement obliges countries to take effective action to prevent infringement for the enforcement of intellectual property rights. It calls for fair and equitable procedures, appropriate judicial mechanism, criminal and civil procedures, damages etc. The TRIPS Agreement outlines civil and criminal procedures for the proper enforcement of intellectual property rights. Aggrieved party would be allowed to be represented by independent counsel. If necessary, evidence presented before the judicial authorities should be kept confidential. If an imported good involves infringement of an intellectual property right, the judicial authorities could order to prevent its entry into the channels of commerce. The authorities could also order the infringer to pay adequate damages, which should cover the costs of injury and litigation. If the allegation is wrongly levelled and an abuse of enforcement procedures is proved the court could order that the defendant should be indemnified. If there is a delay in imparting justice that could result in irreparable harm to the right holder, the judicial authorities could initiate provisional measures. Here again the defendant could be indemnified if the complaint is proved wrong. A right holder could request the customs authorities to suspend importation of counterfeit trademark or pirated copyrighted goods. However, in such cases adequate evidence should be provided to the competent authorities. Besides, the authorities could also demand security from the complainant. The TRIPS Agreement provides for criminal procedures and penalties in two cases - willful trademark counterfeiting or copyright piracy on a commercial scale. In such cases, remedies could include imprisonment and/or monetary fine sufficient to provide a deterrent; seizure, forfeiture and destruction of the infringing goods.⁴

Transitional Arrangements

Even though the TRIPS Agreement does not differentiate between countries vis-a-vis their stage of technological development, it provides for “transitional arrangements: regarding implementation. Accordingly, when the WTO Agreements took effect on 1 January 1995, developed nations were given one year to promulgate law and practices that conform to TRIPS Agreement. Developing countries along with countries in the process of transformation from a centrally planned to a free-enterprise economy would have a five-year transition period; and the least developed countries would get a eleven-year transition period. Developing countries that do not have a product patent regime would get an additional five years (i.e. ten years *in toto*) to provide patent protection (Article 65). However, in such cases they should accept the filing of patent applications for pharmaceutical and agricultural chemical products from 1 January 1995. This is popularly known as the ‘pipeline’ protection. Thus developing nations that do not have product patent regime should create a “mail box” system to receive patent applications. After the expiration of the transitional period, they should provide patent protection to such products for the rest of the period (Article 70.8). During this period ‘exclusive marketing rights’ should be granted to such products for a period of five years.

The TRIPS Council

The Agreement also establishes a Council for Trade-related Aspects of Intellectual Property Rights. This Council is supposed to monitor the operation of this Agreement. It shall also provide a venue for the nations to discuss TRIPS matters. The Council shall also oversee the compliance of countries with their TRIPS obligations. Under Article 63, every country is supposed to notify its laws and regulations to TRIPS Council. The Council shall also provide assistance to needy nations in matters related to TRIPS provisions in the context of dispute settlement procedures. The Council will also work hand in hand with other organisations like World Intellectual Property Organisation (WIPO).

3. TRIPS DISPUTES

Those cases that have reached mutually satisfactory solution and cases that have been adjudicated by the Panel/Appellate body would be discussed in this section. This study will focus on those TRIPS cases filed during the first five years of WTO i.e., from 1 January 1995 to 31 December 1999. There were eight cases that were solved through consultations - two of them regarding patents; two on copyright and four on enforcement of TRIPS provisions. Seven disputes reached the Panel/Appellate stage. The rest of the five cases did not reach the panel; neither was

a mutually satisfactory solution found. A summary of all these cases is presented in the following table.

<i>Sl. No</i>	<i>Dispute No</i>	<i>Complainant</i>	<i>Defendant</i>	<i>Category</i>
1	WT/DS 28	US	Japan	Copyrights
2	WT/DS 36	US	Pakistan	Patents
3	WT/DS 37	US	Portugal	Patents
4	WT/DS 42	EU	Japan	Copyrights
5	WT/DS 50	US	Japan	Patents
6	WT/DS 59	US	Indonesia	Trademarks
7	WT/DS 79	EU	India	Patents
8	WT/DS 82	US	Ireland	Copyrights/Enforcement
9	WT/DS 83	US	Denmark	Enforcement
10	WT/DS 86	US	Sweden	Enforcement
11	WT/DS 114	EU	Canada	Patents
12	WT/DS 115	US	EU	Copyrights/Enforcement
13	WT/DS 124	US	Greece	Enforcement
14	WT/DS 125	US	EU	Enforcement
15	WT/DS 153	Canada	EU	Patents
16	WT/DS 160	EU	US	Copyrights
17	WT/DS 170	US	Canada	Patents
18	WT/DS 171	US	Argentina	Patents
19	WT/DS 174	US	EU	Trademarks/ GI
20	WT/DS 176	EU	US	Trademarks
21	WT/DS 186	US	EU	Enforcement
22	WT/DS 196	US	Argentina	Patents
23	WT/DS 199	Brazil	US	Patents
24	WT/DS 224	Brazil	US	Patents
25	WT/DS 290	Australia	EC	Trademarks
26	WT/DS 362	US	China	Enforcement
27	WT/DS 372	EU	China	Financial information service
28	WT/DS 408	India	EU, Netherlands	Patents
29	WT/DS 409	Brazil	EU, Netherlands	Patents
30	WT/DS 434	Ukraine	Australia	Trademarks
31	WT/DS 435	Honduras	Australia	Trademarks, GI
32	WT/DS 441	Dominican Republic	Australia	Trademarks, GI
33	WT/DS 458	Cuba	Australia	Trademarks, GI
34	WT/DS 467	Indonesia	Australia	Trademarks, GI

GI – Geographical Indications

The Table shows that 34 disputes related to intellectual property were between 1995 and 2013 (as of August) The European communities (five times) and Canada shared rest of the 6 disputes (once). However, the developing nations were brought before the dispute settlement mechanism, five times as defendants. They include India, Pakistan, Argentina and Indonesia. The United States and the European Communities brought two disputes against India on identical grounds. Both of them related to transitional measures relating to patents. A similar complaint was brought by the United States against Pakistan as well. But the complaint brought against Indonesia was a nonsensical one and was without any merit. All these complaints are dealt with separately. The discussion begins with cases that reached mutually satisfactory solutions.

Mutually Agreed Solutions

Pakistan - Patent Protection for Pharmaceutical and Agricultural Chemical Products
This case was initiated by the United States against Pakistan due to the latter's absence of either patent protection for pharmaceutical and agricultural chemical products or a system to permit the filing of applications for pharmaceutical and agricultural chemical product patents and a system to grant exclusive marketing rights in such products. Under Article 65, certain transition arrangements are made by which a developing country member is entitled to delay the implementation of TRIPS Agreement for a period of five years from the date of entry into force of the WTO Agreement (January 1, 1995). However, such members are obliged to establish 'a means by which applications for patents could be filed (70.8)⁵ and grant exclusive marketing rights (EMRs) (70. 9).⁶ Article 70.9, reads: Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent. These obligations were to be fulfilled on the date of entry into force of the WTO Agreement. But Pakistan's law did not provide product patent protection for pharmaceutical or agricultural chemical inventions, or a system that conformed to Articles 70.8 and 70.9 of the TRIPS agreement with regard to the filing and examination of application and the grant of EMRs, thereby creating inconsistency vis-à-vis Articles 27,⁷ 65 and 70 of the TRIPS Agreement. Pakistan reached a mutually agreed solution with the United States. President Farooq Ahmed Khan Leghari issued an Ordinance, which provided that all applications filed after 1 January 1995 shall be considered validly filed. Accordingly, the Government of Pakistan would issue regulations implementing the Ordinance providing that any person who would first file an application for patent protection for pharmaceutical or agricultural chemical product in another WTO member after the date of Ordinance was issued would be able to file an application with

Pakistan's patent authorities and, until 1 January 2000, have as their filing date the date of application as received by such authorities, or after 1 January 2000, have the right to claim priority under the rules laid down in Article 4 of the Paris Convention for the Protection of Industrial Property. The Ordinance also stipulated measures to implement obligations in Article 70.9 that provides EMRs. Thus EMRs will be granted where: (i) the applicant is granted a patent and marketing approval on the product that is the subject of application in another WTO member; and (ii) the applicant is granted marketing approval in Pakistan. The period of EMRs, shall be five years after these conditions are met or until a product patent is granted or rejected in Pakistan, whichever term is shorter. Under no circumstances will the EMRs be subject to any limitation or exception, including the imposition of a compulsory license. Thus no party will be granted marketing approval for a product that is the subject of EMRs without the express consent of the holder of such EMRs. Based on this Ordinance, the U.S. withdrew the complaint.

1. Patent Protection in Argentina

Argentina provided ten-year term of protection against unfair commercial use for undisclosed test data or other data submitted to Argentinean authorities in support of application for marketing approval for agricultural chemical products. However, on August 1998, the Government of Argentina issued a regulation (Regulation 440.98). This regulation *inter alia* revoked all earlier regulations. But it did not contain any provision that provide effective protection for test data submitted in support of application for getting exclusive marketing rights (EMRs) under 70.9. Hence, the United States alleged that Argentinean legal system did not provide a system that conformed to Article 70.9 of the TRIPS. Hence it was violative of Article 39.3 of the TRIPS Agreement. The United States also alleged that this change in law resulted in lesser degree of consistency with the provisions of Article 65.5. In a subsequent complaint, the United States contended that Argentinean patent law was inconsistent with TRIPS provisions regarding compulsory licenses (Article 31(k), exclusive marketing rights (Article 70.8 and 70.9), import restrictions (Articles 6 and 28.1), product by process patent protection (Article 28.2(b)), burden of proof in process infringement cases (Article 34), injunctions (Article 50), patentability of micro-organisms (Article 27) and transitional patents (Articles 70.4 and 70.7). Consequently, both parties reached a mutually agreed solution when Argentina agreed to change its law accordingly. Argentina agreed that the Argentinean National Congress would pass a bill to this effect.

2. Brazil — Measures Affecting Patent Protection

The US requested consultations with Brazil vis-à-vis provisions of Brazil's 1996 industrial property law, which establish a 'local working' requirement for the enjoyability of exclusive patent

rights. But the US says that the local working requirement can only be satisfied by the local production — and not the importation — of the patented subject-matter. Besides, the local working requirement stipulates compulsory licensing if the subject-matter of the patent is not ‘worked’ in the territory of Brazil. A compulsory license refers to a license issued by a government for use of a patent by a party other than the patentee without the consent of the patentee. Developing nations who are technologically backward and are net importers of intellectual property are desirous to strengthen their local manufacturing base. In fact, TRIPS agreement itself, be it the negotiating history and the *travaux préparatoires* of the agreement or the Preamble, supports technological transfer to the developing world (Champ and Attaran 2002). However, the declaratory nature of special and differential treatment principles make those provisions ineffective. To the US, Brazil’s law violates TRIPS Agreement, because it authorizes compulsory licensing on the ground of the patentee’s failure to work locally, a provision detrimental to the interests of the US pharmaceutical companies. Brazil, however, expressed its willingness to hold prior talks with the U.S. Government, if the Brazilian Government would grant compulsory license on patents held by the U.S. companies. On 5 July 2001, the parties to the dispute notified to the DSB a mutually satisfactory solution on the matter (WTO 2001).

3. China-Measures Affecting Financial Information Services and Foreign Financial Information Suppliers

The European Communities challenged Chinese measures affecting financial information services and foreign financial information services suppliers in China, violative of GATS and Article 39.2 of TRIPS agreement. They empowered the “Xinhua News Agency”, the State news agency in China, to act as the regulatory authority for foreign news agencies and for foreign financial information providers. Consequently, the foreign suppliers can only operate in China through an agent designated by Xinhua and hence could not solicit subscriptions for their services directly in China. Only China Economic Information Service (CEIS), a branch of Xinhua, was designated as an agent. However, EC and China reached an agreement in relation to this dispute in the form of a Memorandum of Understanding (WTO 2008).

Patent Disputes

1. India Patent Protection for Pharmaceutical and Agricultural Chemical Products

This was one of the most sensitive cases in the WTO dispute settlement history vis-à-vis TRIPS Agreement because of the following reasons: It was the first case related to TRIPS issue that reached panel/AB stage for adjudication. It involved the United States, a developed nation and a net exporter of IPRs and, India a developing nation and a net importer of IPRs. United States lodged a similar complaint against Pakistan invoking the same provisions but Pakistan settled the matter at the consultation stage itself (DS 36). The subject matter of the case was

fought again, with the defendant being India, although the complainant was different - European Communities (DS 79). This was because of the failure of the defendant to implement DS13 decision in the previous case. The issue related to transitional arrangements, which a developing nation has to take before the complete implementation of TRIPS Agreement on or before 1 January 2005. This was also the case, in which India was brought before the WTO's dispute settlement mechanism for the first time. Now the case would be discussed in detail.

Following the failure to yield a mutually satisfactory solution, the United States requested to DSB to establish a panel to examine the following sections of TRIPS Agreement: (a) Article 70.8 of the TRIPS Agreement, which necessitates a developing country to establish a 'means'⁸ to receive patent applications during the transitional period; (b) Article 70.9 that provides 'exclusive marketing rights' for a period of five years; (c) Article 63 that insist on 'transparency' by notifying all laws and regulations to the Council for TRIPS. As a developing nation, India was expected to implement the TRIPS provision of WTO Agreement only before 1 January 2005. This privilege is granted under Article 65 of TRIPS Agreement as a 'transitional arrangement'. However, India will have to comply with Article 70.8 and 70.9 contained in 'Protection of Existing Subject Matters' of the TRIPS Agreement. In order to comply with these TRIPS provisions the President of India promulgated the Patent (Amendment) Ordinance⁹ of 1994 to provide a 'mail box' system and the grant of exclusive marketing rights (EMRs),¹⁰ as required by 70.8 and 70.9 of TRIPS respectively. But the ordinance, which became effective on 1 January 1995, lapsed on 27 March 1995. The attempts to give permanent legislative effect to the provisions of the Ordinance by passing the Patent (Amendment) Bill 1995 could not materialise because of the then political inability. But India informed the panel that patent offices were instructed to receive patent applications.

Failure to bring a new legislation after the constitution of Eleventh Lok Sabha forced the United States to initiate this litigation before the dispute settlement mechanism of WTO. The United States contended that since India was not providing product¹¹ See Section 5, in Chapter II 'Inventions not patentable' of the Patents Act, 1970. Section 5 states that in the case of inventions patents to pharmaceutical and agricultural-chemical products and was availing the transitional benefits under Article 65, India was expected to implement Article 70.8 and 70.9 of the TRIPS Agreement. It also requested the Panel to ask India to implement these obligations in a manner similar to the way in which Pakistan indicated.' The United States also contended that if the Panel found that India has a valid mailbox system, India has failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement.

India claimed that even after the lapse of Ordinance, patent applications for pharmaceutical or agricultural chemical products were being received, and allotted a filing date and advertised in the official Gazette with serial number, filing date, name of applicant and title of inventions, because administrative instructions had been given by the executive to this effect. India claimed that such an administrative decision was permissible under Article 73 (1) (a) of the Indian Constitution¹² and the Supreme Court of India in two of its rulings, *J. R. Raghupathy vs. State of Andhra Pradesh* and *Union of India vs. H. R. Patankar and Others*, had opined that administrative action was an available method for the executive. India had thus complied with the requirements of Article 70.8 of TRIPS Agreement. Regarding Article 70.9, India claimed that it did not receive any requests, for granting EMRs, so there was no question of denial so far. Moreover, the events that triggered the obligation of granting EMRs were beyond its control and EMRs could be granted in India only for a product that has satisfied the first four procedures.¹³ Besides, granting EMRs by a developing country like India would frustrate the very purpose of transitional arrangements.

The United States contended that the administrative¹⁴ instructions lost their validity once the Ordinance lapsed. India failed to accord legal sanctity to the Patent Bill afterwards, as a result of which there did not exist any proper mechanism to preserve the novelty and priority in respect of applications for product patents regarding pharmaceutical and agricultural chemical inventions during the transitional period. Consequently, the legal situation in India regarding Article 70.8 was erroneous and largely speculative.

India also rejected the U.S. suggestion to change Indian law in a manner similar to the way in which Pakistan had done saying that it would be inappropriate to transpose the legal system adopted by Pakistan to India. Regarding Article 70.9 the United States argued that the *quid pro quo* for taking advantage of the transition period was to grant EMRs. If India did not want to grant product patents, then it must grant EMRs; conversely if it did not want to grant EMRs, then it must grant product patents. The United States also attributed the non-receipt of request for EMRs to the absence of sufficient mechanism. It claimed that Eli Lilly Corporation that had been granted patent protection and marketing approval was in the process of determining how to apply for EMRs in India. This in effect had destroyed the 'legitimate expectations' which were central for the creation of 'security and predictability' in the multilateral trading system elaborated by the *superfund* panel (WTO 1987).

The panel upheld the U.S. contentions. Regarding Article 70.8, the panel held that Section 15 (2) of the Indian Patents Act authorised the Controller to reject patent applications for pharmaceutical and agricultural products. This makes the administrative instructions given

by the Indian executive redundant and makes the legal situation insecure. The Panel cited *Malt Beverages* case that dealt with a similar issue. It stated:

“Even if Massachusetts may not currently be using its police power to enforce this mandatory legislation, the measure continues to be mandatory legislation, which may influence the decisions of economic operators. Hence, a non-enforcement of a mandatory law in respect of imported products does not ensure that imported beer and wine are not treated less favourably than like domestic products to which the law does not apply” (WTO 1992).

The panel further noted that the legal insecurity is compounded further by lapse of the Patents (Amendment) Ordinance. The Panel supported the United States view vis-à-vis Article 70.9 stating that the executive authority of Indian Government is not bestowed with the authority to grant EMRs so far. This is inconsistent with Article 70.9 of the TRIPS Agreement, which is meant for developing countries availing the transitional benefits under Article 65. The Panel held that India has violated Article 63 of the TRIPS Agreement, because it has not informed the public about the existence of a new system (Para 7.44.) for the filing of mailbox applications. Consequently, the Panel recommended that the DSB request India to bring its transitional regime into conformity with TRIPS Agreement. The Panel adjudicated against India. India appealed against the Panel decision (WTO 1997).

The Appellate Body upheld the Panel’s ruling on Article 70.8 and 70.9 but reversed the Panel’s findings regarding Article 63. India contended that Panel exceeded its authority, for the terms of reference upon which the panel was established did not contain a claim under Article 63. In *United States shirts and blouses* case, it was held that a panel need only address those claims, which must be addressed in order to resolve the matter in issue in the dispute. And all claims must be included in the request for establishment of a panel, because a panel is bound by its terms of reference. In this case, by including Article 63 that was not mentioned in terms of reference, the panel exceeded its authority. One of the unique peculiarities of this case is that the subject matter raised and settled in this dispute constitutes the subject matter of another case.

2. European Communities Vs. India ¹⁵(DS 79)

The European Communities brought a similar complaint against India regarding patent protection for pharmaceutical and agricultural chemical products in India. Interestingly, the Articles invoked remained the same: Article 70.8 and Article 70.9 of the TRIPS Agreement. And in this case, the EC and their member states, which had been a third party in the previous case (DS 50), requested the Panel to extend its finding in the earlier dispute as modified by the AB to this

dispute. And the panel's decision on Articles 70.8 and 70.9 remained the same; still the dispute had raised some procedural issues related to the 'Understanding' on dispute settlement. India requested the Panel to reject the complaints of the EC because it was inconsistent with the rules of the DSU on multiple complaints, in particular Articles 9.1¹⁶ and 10.4.¹⁷ Accordingly, multiple complaints should be submitted to a single panel. India contended that EC should have brought the complaint jointly with the earlier case initiated by the United States as both the complaints are based on the same facts and legal claims India noted that whenever members of the WTO brought complaints on same facts, a single panel was established. The European Community itself had objected to the formation of a panel whose terms of reference remained the same, when Panama requested consultations on its regime for the importation, sale and distribution of bananas in October 1997. India stated that an 'unmitigated right to bring successive complaints on same facts would jeopardise the multilateral trade order'. Quoting Henry H. Herman (1886), India noted:

Interest republicae ut sit finis litium, is an old maxim deeply fixed in the law of fundamentals; that it concerns the state there be an end to litigation.

India also requested that the principles of *res judicata*¹⁸ and *stare decisis*¹⁹ be followed even though the principle of *res judicata* did not apply if the parties to dispute are different and the principles of *stare decisis* not followed much in the WTO jurisprudence (Bhala 1999). India contended that this complaint in all aspects was identical with the previous complaint brought by the United States. But the EC rejected Indian contentions Article 9.3 dealt with complaints related to the same matter. This makes it clear that there is no obligation to constitute a single panel. Besides, the complaint that the EU filed was at a different point of time. Similarly, absence of factual circumstances clearly demonstrated that despite issuing a panel and an AB report India failed to bring forth changes in its domestic law consistent with TRIPS provisions. The European Communities also argued that the principles of *res judicata* did not apply to this case, and the question of *stare decisis* did not arise in WTO jurisprudence. The Panel upheld EU's position and proceeded with the case. It endorsed the rulings of the Panel in the previous case.

Trademarks Disputes

1. Indonesia - Certain Measures affecting the Automobile Industry

This subject of dispute is the National Car Programmes (1993 and 1996) of Indonesia. Against these programmes four complaints²⁰ were filed - one each by the EC and the United States and two by Japan. The complainants invoked innumerable provisions that involved issues under TRIMS, SCM, MFN discrimination, TRIPS and even the participation of private lawyers in panel meetings. But since the subject involved in the complaints remained the same - Indonesian

National Car Programmes - the DSB established a joint panel to review all the four complaints. Here, TRIPS issues that were raised by the United States alone would be isolated. One of the conditions set forth in the Indonesian National Motor Vehicle Programme was the requirement that the “national motor vehicle” must bear a unique Indonesian trademark owned by an Indonesian national to receive benefits of that programme. The United States claimed that this was discriminatory for these benefits resulted in a significant “commercial disadvantage” to owners of foreign-owned trademarks against those of Indonesian trademarks. Hence, United States argued the practice was inconsistent with Articles 3, 20 and 65 of the TRIPS Agreement.

Article 3 obliges “national treatment” in the protection of intellectual property rights. It requires each country to accord the nationals of other countries no less favourable treatment that it accords to its own nationals. The United States contended that under the National Car Programme, only Indonesian companies were eligible, and only Indonesian companies could obtain a “national car” trademark. Secondly, the condition to use a “new” Indonesian trademark as a national car discriminated against owners of existing marks regarding the maintenance of the mark. This might eventually result in the cancellation of global mark for non-use in Indonesia. Article 20²¹ prohibits the imposition of special requirements on the use of a trademark. The United States²² contended that the National Motor Vehicles Programmes requiring producers of a ‘national motor vehicle’ bearing a unique Indonesian trade mark to receive benefits was violative of Article 20 because, these benefits resulted in a significant commercial disadvantage to foreign trade owners and the ineligibility for benefits using an established foreign owned trademark constituted a special requirement on the use of a trademark. The United States also invoked Article 65 that dealt with transitional arrangements. The United States conceded that under Article 65.2 a developing nation could delay the implementation of TRIPS provisions for a period of five years; but this transitional benefits was not applicable to Articles 3, 4 and 5. Consequently, Indonesia violated Article 65.2 as well, due to its measure inconsistent with Article 3. Besides, the United States also argued that as the restrictions of the National Motor Vehicle Programme came into force after 1 January 1995, and hence violated Article 65.5 of the TRIPS Agreement.

Indonesia claimed that the brand name requirement required under the National Car Programme applied to all parties in precisely the same fashion - be it an Indonesian company or a foreign company. Neither may use a pre-existing pre-registered name for a national car. Regarding Article 20, Indonesia argued that it is not relevant to brand-name requirement. Requiring a new trademark to claim subsidies under the national car programme would not confuse the people or encumber the existing trademark with specific requirements. Moreover, as Indonesia is availing a grace period under Article 65.2, it cannot now be found to have violated Article 20.

The Panel rejected all the arguments of the United States and upheld Indonesian measures vis-à-vis trademark. The Panel accepted the U.S. apprehension that the scope for using trademarks owned by US car companies to claim subsidies under National Car Programme is restricted. However, the programme did not pose any problems for the acquisition of trademark rights. And if a foreign company participated in the National Car Programme it would do so voluntarily and was aware of the consequent implications of its inability to maintain pre-existing trademark rights.

2. Copyright Enforcement in China

The US' complaint against China pertained to the protection and enforcement of intellectual property rights related to copyrights in China.²³ The matters raised by US included trademark counterfeiting, copyright piracy, lack of criminal procedures and penalties for commercial scale counterfeiting and piracy in China, etc. Publication or distribution of authors' works would be prohibited if it is not authorised and hence violative of the the minimum standards of protection granted by the Berne Convention. Besides, the pre-publication or pre-distribution review of such works is TRIPS - inconsistent with China's obligations under Article 9.1 of the TRIPS Agreement. Similarly, the related rights to performers and producers of sound recordings during the period of any pre-publication or pre-distribution, were also infringed Agreement. China also failed to make the criminal procedures and penalties applicable to wilful copyright piracy on a commercial scale. Subsequent to panel's adverse determinations, China agreed in 2010 to change its laws. The Standing Committee of the National People's Congress had approved the amendments of the Chinese Copyright Law, and the State Council had adopted the decision to revise the Regulations for Customs Protection of Intellectual Property Rights.

4. TRIPS AS A TOOL OF RETALIATION FOR DEVELOPING COUNTRIES

We would be discussing the decision of WTO Arbitration regarding *European Communities Regime for the Importation, Sale and Distribution of Bananas* (WTO 2000). It is the first time the WTO has authorised trade retaliation affecting the protection of intellectual property right and authorised a developing country to get WTO authorisation to impose retaliatory measures. It is also the first time that WTO allowed 'Cross-retaliation'. The parties to this dispute were Ecuador, the complainant and the European Communities, the defendant. Ecuador's population is 12 million, whereas that of EC is 375 million. Ecuador's share of world merchandise trade is below 0.1 percent, while the EC's world merchandise trade share is approximately 20 percent. Ecuador's GDP at market price in 1998 was US \$20 billion and that of 15 EC member states was

US\$ \$7,996 billion. The per capita income of Ecuador in 1998 was US \$1600, whereas EC's GDP per capita is US \$22,500. The economy of Ecuador revolves around the banana sector. It is the largest exporter of bananas in the world and the largest exporter to the European market. Banana production is the largest source of employment. It is also the largest source of foreign earnings. Approximately 11 percent of Ecuador's population depends on this sector. Banana production represents nearly 5.2 percent of the GDP and its exports (in goods only) is nearly 25.45 percent of Ecuador's total merchandise exports. These facts clearly demonstrate the extremely asymmetrical nature of trade relationship that exists between the two disputants - the European Communities and Ecuador.

EU's failure to implement the AB's recommendation induced Ecuador to move to DSB seeking its authorisation to suspend concessions or other obligations under the TRIPS Agreement, the EATS and GATT 1994 in an amount of US \$450 million under Article 22.2 of the DSU. Ecuador announced that if DSB authorised suspension of concessions, Ecuador would apply this against 13 of the EC member states, European Communities contended that the amount of suspension of concession proposed by Ecuador was excessive. It also alleged that Ecuador failed to follow the principles and procedures set forth in Article 22.3 of DSU that deals with cross sectional retaliation. The DSB referred the matter to arbitration.²⁴ The measures in dispute were regarding the revised EC - banana regime as contained in EC Regulation 1637/98 and 2362/98, which entered into force on 1 January 1999. Based on the panel report, the EC revised its banana regime; but that too was found inconsistent with Articles I and XIII of GATT and Articles II and XVII of GATS. It was the jurisdiction of Arbitrators to determine: (i) whether the level of suspension of concessions or other obligations requested was equivalent to the level of nullification; (ii) whether the principles of procedures concerning the suspension of concessions or other obligations across sectors and/or agreements pursuant to Article 22.3 of the DSU were followed. Accordingly, the minimum requirements for a request for authorisation of suspension of concessions or other obligations pursuant to Article 22.2 of the DSU must contain a specific level of suspension and should specify the agreement and sectors under which concessions would be suspended.²⁵

To meet the first minimum requirement, Ecuador set out the specific amount of US \$ 450 million as the level of proposed suspension of concessions or other obligations. However, it added that the direct and indirect harm and macro economic repercussion of its entire economy amount to altogether US \$1 billion. But the arbitrators concluded that Ecuador could obtain authorisation by the DSB to suspend concessions or other obligations of a level not exceeding US \$201.6 million per year. Article 22.3 of DSU enumerates the principles and procedures to be followed for trade

retaliation. Thus the complaining party should first seek suspension of concessions in *the same sector(s)*, where nullification or impairment was found. If it was not effective it should seek suspension in *other sectors under the same agreement*; and if this was also not effective and the circumstances are serious enough suspension could be brought under *another covered agreement*. The report of the reconvened panel in this dispute found the revised banana regime of EU to be inconsistent with Articles 1²⁶ and XI²⁷ of GATT as well as Articles 11 and XV¹¹ of GATS with respect to EC's commitments on wholesale trade services within the sector of distribution services.

Ecuador did not seek withdrawal of concession in the goods sector. But requested the suspension of concessions in other sectors in the following orders – Trade in services (GATS) and TRIPS. The EC alleged that while seeking suspension of concession, Ecuador failed to follow the principles and procedures. The arbitrators rejected the contention of the European communities stating that owing to the existence of considerable economic differences between a developing WTO Member and the world's largest trader, suspension of commitments under GATT or GATS alone would not be practicable or effective. Hence Ecuador was authorised to cross-retaliate in TRIPS.

Why TRIPS turned out to be the best tool of retaliation?

In its submission, Ecuador had made a distinction between 'primary' and 'investment' goods on the one hand, and 'consumer' goods on the other. Ecuador argued that its imports of primary and investment goods amount to approximately 85 percent. Consequently, suspension of concessions regarding the goods was not practicable and effective for they were used as inputs in the domestic manufacturing process. Similarly, imposing prohibitive tariffs on EC imports of such goods would increase the cost of domestic production and would harm Ecuador more than the European communities. Besides, Ecuador, being a developing country, accounts for a negligible proportion of the EC's exports of those goods, the suspension of concessions would only have a negligible effect on EC exports.²⁸ Regarding GATS within the sector of distribution services Ecuador proposed suspension of concession, only in 'wholesale trade services'. According to the Services Sectoral classification List, the principal sector of distribution services comprises the subsectors of 'commission agents' services', 'whole trade services', 'retailing services, 'franchising' and 'others'. Ecuador entered into specific commitments on market access or national treatment only on 'wholesale trade services' and hence it could propose retaliation only in this sector, which was not effective or practicable. Regarding suspension of commitments in sectors other than distribution services, Ecuador

has made commitments on market access and/or national treatment in business services, communications, construction and engineering, financial services, health and social services, different types of transport services, tourism, travel, recreational and cultural services, etc. However, in many of these sectors Ecuador's specific commitments exclude supply mode one (cross border supply) i.e., Article 1:2 (a). Consequently, Ecuador's suspension of concession would be oriented to commitments concerning commercial presence (i.e., Article I:2(c)) of EC service suppliers, or in other words, foreign direct investment. Suspension of commitments concerning commercial presence would destroy the investment climate in Ecuador. Hence trade retaliation in this sector would be ineffective in this sector and could prove detrimental to a developing country like Ecuador. It would also force the existing EC service suppliers to transfer investment from Ecuador. Hence retaliation in service sector was not effective and practicable.

After concluding that retaliation in goods (GATT) and services (GATS) were ineffective and not practicable, the Arbitrators emphasized that the "circumstances are serious enough" to authorize suspension of concessions. The Arbitrators underlined the importance of banana trade to Ecuador and supported Ecuador's claim that:

...The banana sector is the lifeblood of its economy. Ecuador is the largest exporter of bananas in the world and the largest exporter to the European market. Banana production is also the largest source of employment and the largest source of foreign earnings. Nearly 11 percent of Ecuador's population is totally dependent on this sector. Banana exports (in goods only) represent 25.45 percent of Ecuador's total merchandise exports. Banana production represents nearly 5.2 percent of the GDP. In Ecuador's view, the banana industry is of greater importance to its economy than the whole agricultural sector in most developed countries.

The Arbitrators also considered Ecuador's arguments plausible that WTO - inconsistent aspects of the EC's import regime aggravated its economic problems. Ecuador in its submission noted that it was facing the worst economic crisis in its history. Its economy shrunk by 7 percent in 1999 and total imports decreased by 52 percent unemployment rose to 17 percent. Accepting Ecuador's contention relating to the broader economic consequences of EC's actions, the Arbitrators authorised DSB to suspend certain obligations under the TRIPS Agreement. Given these circumstances, the Arbitrators told that suspension of concessions in TRIPS was imperative to make retaliation effective and practicable. Ecuador sought to

limit its suspension of concession in three areas of intellectual property protection: (a) copyright and related rights, Article 14 on Protection of sound recordings and broadcasting organizations; (b) geographical indications; and (c) industrial designs.

5. DOHA ROUND AND AFTER

In November 2001, WTO Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha. It emphasized on TRIPS flexibilities for better access to essential medicines. It attempted to address the concern that patent rules create a price rise and restrict access to affordable medicines for populations in developing countries. This creates a public health crisis for governments to contain diseases of public health importance, like HIV, tuberculosis and malaria. The Declaration aimed to address this. The Doha Declaration affirmed that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. Paragraph 4 of Doha declaration declares that the TRIPS agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”. Paragraph 5 reaffirms a nation’s right to opt ‘compulsory licensing’ and the freedom to determine the grounds upon which such licences are granted. It also affirms the right of a member with insufficient or no manufacturing capacities in pharmaceutical sector to import from other nations without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder’s consent (parallel importation). The transition period for LDCs for implementation of the TRIPS obligations relating to patents and marketing rights, and data protection for pharmaceutical products was extended from 2006 to 2016.

The seizure of Indian Generic drugs in Transit

The nearly ten year lull post Doha Round Declaration on TRIPS and Public Health was ceased with the repeated seizures of generic drugs originating in India but transiting through ports and airports in the Netherlands to third country destinations on patent infringement grounds. Two consultations requests were filed one by India (WT DS408) and the other by Brazil (WTDS 409) against, the European Union, and Netherlands.

6. CONCLUSION

A perusal of these cases demonstrates that it is primarily a rich nation’s affair. Only the developed nations - the United States, European Communities, Canada and Australia - used WTO’s judicial mechanism to settle TRIPS disputes during the transitional period. The developing nations were involved in five TRIPS disputes. They included India, Pakistan,

Indonesia and Argentina - but every time as respondent. During the transition period, barring the case of Indonesia, complainants against the developing nations were on expected lines, i.e., litigating with them for their failure to implement Articles 70.8 and 70.9. This was because a developing country member was exempted from implementing the rest of TRIPS provisions for a period of ten years i.e., till December 31, 2004 under the transitional arrangements. But the TRIPS Agreement insisted they create a mail-box system and grant exclusive marketing rights, if they decide to avail of this grace period. They were equally expected that after the lapse of this grace period, they were supposed to implement the domestic IPR regimes akin to the developed nations.

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End Notes

- ¹ Under GATT, after the Tokyo Round there were two streams for dispute adjudication - one under Articles XXII and XXIII of GATT 1947; the others presented by respective NTB codes.
- ² Article 6bis of Berne Convention extends protection to moral rights as well. TRIPS Agreement stipulates that parties should comply with the substantive provisions of Berne Convention for the Protection of Literary and Artistic Works signed in 1886 and as revised in 1979; however, they are not obliged to protect the moral rights as provided in the Convention.
- ³ The TRIPS Agreement regarding the protection of plant varieties offers a choice to the members - must be protectable either by patents, or a *sui generis* system or by any combination of the two. This choice reflects the existing disparity between the law in the United States and that of European countries. In the former, plant varieties are patentable; whereas the latter protects by a *sui generis* system. Negotiators also granted a transitional period regarding the intellectual property protection in the area of living matter, apparently because this issue is still at an embryonic stage.
- ⁴ Part III of the TRIPS Agreement is concerned with 'Enforcement of Intellectual Property Rights'. It is divided into five sections (each one dealing with 'General Obligation', 'Civil and Administrative Procedures and Remedies', 'Provisional Measures', 'Special Requirements Related to Border Measures' and 'Criminal Procedures' and contained in twenty one articles.
- ⁵ TRIPS Agreement, Article 70.8 states that if a Member does not make patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, the Member shall (a) provide ... a means by which applications for patents for such inventions can be filed; (b) apply to these applications, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

- ⁶ Article 70.9, reads: Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.
- ⁷ Article 27 states that: 1.... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Patent rights should be made enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because tire exploitation is prohibited by their law. 3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
- ⁸ Also termed as “mailbox system” created for the filing and handling of patent applications for pharmaceutical and agricultural products as required by Article 70.8. See TRIPS Agreement, Article 70.8,
- ⁹ According to clause (1) of Article 123 of the Indian Constitution, the President could legislate when Parliament is not in session by issuing an ordinance. However, the ordinance shall cease to apply at the expiration of six weeks from the re-assembly of Parliament.
- ¹⁰ The Bill was passed by the Lok Sabha and was introduced in the Rajya Sabha. While it was pending before the Select Committee of the House, Lok Sabha was dissolved on 10 May 1996. With the dissolution of Lok Sabha, the Bill lapsed.
- ¹¹ See Section 5, in Chapter II ‘Inventions not patentable’ of the Patents Act, 1970. Section 5 states that in the case of inventions
- (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug or
- (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds); no patent shall be granted in respect for the substances themselves, but claims for the methods or processes or manufacture shall be patentable.
- ¹² Article 73(1)(a) of the Indian Constitution states that the executive power of the Union shall extend to the matters to which Parliament has the power to make law.
- ¹³ Thus for a product to receive EMR, in India, it must meet the following conditions.

- (a) A mailbox application has been filed in India in respect of a pharmaceutical or agricultural chemical product;
- (b) A patent application has been filed in respect of that product in another WTO member after 1 January 1995;
- (c) The other member has granted the patent;
- (d) The other member has approved the marketing for the product; and
- (e) India has approved the marketing of the product.

¹⁴ In *India-Patents (EU)*, the Panel noted that the administrative instructions India relied upon were “unwritten and unpublished”

¹⁵ In the *India-Patents (US)*, EU was the third party.

¹⁶ Article 9.1 which states that: “where more than one member requests the establishment of a panel related to the same matter, a single panel may be established to examine these complaints taking into account the rights of all members concerned. A single panel should be established to examine such complaints whenever feasible”.

¹⁷ Article 10.4 which states that: “If a third party considers that a measure already the subject to a panel proceeding nullifies or impairs benefits occurring to it under any covered agreement that member may have recourse to normal dispute settlement Procedures under this Understanding. Such a dispute shall be referred to the original panel wherever possible”.

¹⁸ The term ‘res judicata’ means “a matter adjudged” or a matter settled by judgement. ‘Res jurisdiction is ‘a rule that final judgement or decree on merits by court of jurisdiction is conclusive of rights of parties or their privies in all later suits on points and matters determined in former suit.”

¹⁹ *Stare decisis* means ‘to abide by or adhere to decided cases’. To *Black’s Law Dictionary*, it is the “Policy of courts to stand by precedent and not to disturb settled point”.

²⁰ On October 3, 1996, the European Communities requested consultations with Indonesia (WT/DS 54); on October 4, 1996 Japan requested consultations with Indonesia (WT/DS 55)(Japan also requested additional consultations with Indonesia (WT/DS 64)); and on October 8, 1996 the United States requested consultations with Indonesia (WT/DS 59).

²¹ *TRIPS Agreement*, Article 20 states that the use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

²² The United States says that the TRIPS negotiators tried to stop this practice of linking two trademarks to be used on a single product. It cites out the examples of “Lahali-Pepsi” and “Modi-Xerox”, a prior practice of India that required such linkages.

²³ Panel, China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WTO Doc., WT/DS362 dtd. 10 April 2007

- ²⁴ Members of the arbitration panel were Stuart Harbinson (Chairman), Kym Anderson and Christian Baberli (Members).
- ²⁵ *EC-Hormones* case which sets the minimum requirements as follows:(i) the quest must set out a specific level of suspension, i.e. a level equivalent to the nullification and impairment caused by the WTO - inconsistent measure, pursuant to Article 22.4; and (ii) the request must specify the agreement and sector(s) under which concessions or other obligations would be suspended to Article 22.3
- ²⁶ GATT Article on *General Most- Favoured -Nation Treatment* says: With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation,... any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties
- ²⁷ This Article enables a Member to impose restrictions on imports to “safeguard its external financial position and its balance of payments. However, such restrictions shall not damage the commercial or economic interests of other members or unreasonably prevent the imports. (See GATT Article XII OM “Restrictions to Safeguard the Balance of Payments”)
- ²⁸ However, with respect to consumer goods the arbitrators held that Ecuador has not followed the principles and procedures of Article 22.3 in considering suspension of concession on consumer goods is not practicable or effective. Here, Ecuador argued that its import is only 15%. Arbitrators decided that Ecuador could not conclude that suspension in this area was not effective.

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Political Economy of India's Engagement with the WTO: An Analysis in the Context of Amendment of India's Patent Act

Reji K. Joseph*

Abstract

Many developing countries like India were forced to take on commitments under TRIPS agreement due to the principle of 'either take it all leave all' during the Uruguay Round of trade negotiations. It was feared that strengthening of the IPR regime would lead to rise in medicine prices and would adversely affect not only the access to medicine issues but the very existence of the generic pharma industry in India which was the sole source of good quality cheap medicines in India and other developing countries. However, the policy makers during the early years of this decade seemed to have come to the realization, which is reflected in the Bill introduced in the Parliament of India for the amendment of the Patents Act 1970, that strengthening of the IPR regime is good for the country and did not bother to exercise the freedom to incorporate TRIPS flexibilities into the Act. But the Government had to face various hurdles in the form of resistance from left parties and civil society groups while amending the Act and was forced to incorporate substantial changes to the provisions – narrowing the scope of patentability to prevent evergreening, strengthening the compulsory license provisions, facilitating export of medicines produced under compulsory license, strengthening the pre-grant opposition provisions and protecting the production of generics of the 'mail-box' patented medicines - in the Bill amending the Patents Act.

Key Words: WTO, Indian Patent Act, TRIPS, NWGPL

1. THE BACKGROUND

At the Ministerial conference held at Marrakesh in 1994, the Government of India (GoI) ratified the Final Act of 1986-1994 Uruguay Round of trade negotiations establishing the World

* Associate Professor at Institute for Studies in Industrial Development (ISID), New Delhi. Email - rejikjoseph@gmail.com. This paper was presented during the international conference on 'World Trade, World Poverty', organized by Institute of Human Rights, Indiana University-Purdue University, Fort Wayne, USA, on 18-19 November 2009.

Trade Organization (WTO) and it became obligatory for India to implement various Agreements incorporated in the Final Act. The Trade Related aspects of Intellectual Property Rights (TRIPS) Agreement, an important agreement of the WTO covering various forms of IPRs, had to be implemented by amending various IPR laws of the country. The IPR laws covered by TRIPS relate to:

- (a) Copyrights and related rights
- (b) Trademarks
- (c) Geographical Indications
- (d) Industrial Designs
- (e) Patents (also includes sui generis protection for plant varieties)
- (f) Layout Designs of Integrated Circuits
- (g) Protection of Undisclosed Information.

While the Members are obliged to enforce the minimum standards of IPR protection prescribed by the Agreement, they have the leeway in framing the working of IPR provisions such as scope of patentability, compulsory licensing provisions, etc. All the laws on IPRs in India except Patents have been amended without much debate in the Parliament or protests from the public¹. Amendment of the Patents Act 1970 has been crucial issue especially for the general public and the pharmaceutical industry (NWGPL, 2003). It was feared that the implementation of product patent rights in pharmaceuticals would give monopoly rights to the innovators of new medicines for a period of 20 years, resulting in sharp increase in the price of medicines. The new patent regime under the TRIPS was also perceived as a threat to the sustenance of Indian generic pharmaceutical industry, which supplied cheap and quality medicines to patients in India as well as foreign countries. This industry, which has thrived under the process patent regime under the Patents Act 1970, would no longer be able to continue with their modus operandi of reverse engineering and continue the production of cheap medicines. Thus, amending the Patents Act of 1970 was the most important hurdle in making Indian IPR system, TRIPS compliant.

TRIPS Agreement provided some transitional arrangements to developing country Members. Though the provisions of the Agreements are expected to be in force by 1st January 1996, developing countries which had process patent regimes were given time, if they wanted, to extend the period for further four years, i.e., till 1st January 2000². However, the Agreement

required these Members to make provisions for receiving patent applications³. And for developing countries which are obliged to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of the Agreement, i.e., 1st January 1996, could delay the application of the provisions for an additional period of five years, i.e., till 1st January 2005. India was having process patent regime in pharmaceuticals and agro-chemicals and had the time till 1st January 2005 to extend product patent rights in pharmaceuticals and agro-chemical products, though in other areas it had to meet its obligations by 1st January 2000.

India complied with its obligations under the TRIPS Agreement in three steps. The first step was the Patents (Amendment) Act of 1999, which provided for receiving of patent applications (mail-box applications) and for exclusive marketing rights⁴. The Patents (Amendment) Act 2002 introduced comprehensive amendments to bring together various provisions of the Patents Act 1970 into conformity with the TRIPS Agreement⁵. For the third and most important amendment aimed at introducing product patent rights along with already existed process patent rights in pharmaceuticals and agro-chemicals, a Bill amending the Patents Act was introduced in 2003 by the National Democratic Alliance (NDA) government led by the Bharatiya Janata Party (BJP). The Bill lapsed owing to a change in government at the centre and the consequent dissolution of the Lok Sabha. The new Congress-led UPA coalition government, established with the external support of left parties, pushed the 2003 Bill to amend the Patents Act so as to meet the TRIPS time line of 1st January 2005. But the UPA could not gather the necessary support particularly owing to the disagreement of left parties on the provisions of the Bill and hence passed as a Presidential Ordinance on 26th December 2004 to meet the deadline. The government had six months to codify this Ordinance by obtaining the approval of the Parliament. The Government in March 2005 introduced a substantially revised Bill which was passed in the Parliament and became the Patents (Amendment) Act, 2005. The modifications to the Ordinance were not incorporated voluntarily by the Government but were the outcome of a hard bargain that the civil society groups and left political parties had with the Government. This paper is an analysis of the out come of this bargain and the process of co-ordination among the national and international civil society groups and with the political parties.

2.SALIENT FEATURES OF THE PATENT ACT OF INDIA

High Criteria for Patentability

There were serious concerns that a broad definition of what is patentable would lead to 'evergreening' of patents, that is the continuation of patent rights beyond the stipulated 20 years by acquiring patents on small changes made to the original invention. The third amendment restricted

the chances of 'evergreening' by defining pharmaceutical substance and clarifying what is meant by an 'invention' and 'inventive step', which is the most important criterion determining the patentability of a subject matter. Indian Patents Act now defines new invention and inventive step as

“New invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art” (Section 2.L) and “inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art” (Section 2Ja).

Whereas in the ordinance “invention” and “inventive step” were defined as

“invention means a new product or process involving an inventive step and capable of industrial application” (Section 2.J) and “inventive step means a feature that makes the invention not obvious to a person skilled in the art” (Section 2.Ja).

The scope of patentability has also been restricted by defining inventions that are not patentable. Section 3 of the Patents Act is on inventions not patentable. Section 3(d) is noteworthy. It reads inventions are not patentable if ;

“the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”.

Whereas section 3(d) in the Ordinance was ambiguous. It read that “the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in new product or employs at least one new reactant”.

This section has been a powerful instrument in preventing frivolous patents, often inviting the ire of pharma MNCs. Novartis' case in India would be the best pointer in exposing how effective is this section in preventing frivolous patents. Novartis had applied for patents through the 'mailbox' for crystalline form of 'imatinib mesylate', for the treatment of chronic myeloid leukaemia. This molecule in original form has been patented in 1992 in Switzerland and subsequently in other countries. The original molecule is not patentable in India as there is prior publication of the invention in pre-1995 period and hence the company has sought for patent on the crystalline form. In 2003 Novartis secured an Exclusive Marketing Right for its drug Glivec (Imatinib mesylate) and obtained injunctions against Natco, the only producer of generic version Glivec and against six other potential manufacturers of the generic version of Glivec. However, amendment of Section 3(d) in 2005 using TRIPS flexibilities prevented patenting of 'salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives' of already known substance unless they significantly enhance the efficacy of the already existing substance. After the 2005 amendment, generic companies and patient groups challenged the patent over Imatinib mesylate on various grounds and the Patents Office rejected Novartis' patent application on beta crystalline salt of Imatinib mesylate in January 2006. Pharma majors with their advanced technical capabilities are able to incorporate incremental innovations to the original invention and thus able to prolong the life of patent even after the expiry of original patent.

Opposition to Grant of Patents

The Patents Act provides for pre-grant⁶ and post-grant⁷ opposition to the grant of patents. There are 11 grounds under which any entity can register opposition to the grant of a patent. Though the Ordinance has also provided for the opposition of grant of patent, it made the pre-grant opposition weak as the grounds on which opposition can be made were restricted to mere two. After the amendment, the all the 11 grounds for the post grant opposition were made grounds for pre-grant opposition as well.

The recent rejection of Gilead's patent application for 'tenofovir', an antiretroviral drug, is a very good example of how useful is the pre-grant opposition provision in preventing frivolous patents, especially from a public health perspective. This drug has been patented by Gilead Science (valid till 2018) and was licensed Indian pharmaceutical companies for the production and marketing. However, the patent holder in the recent past sought to obtain a patent in India for the medicine and this move had been immediately met with large-scale opposition and ire from activist groups and associations such as The Indian Network for People Living with HIV and the Delhi.

Network of Positive People, who were quick to file pre-grant oppositions against said application. The major legal ground of opposition has been that tenofovir is created by the addition of a salt (fumaric acid) to an existing compound (tenofovir disoproxil) and should therefore be granted no patent. Granting of patents would have eliminated the competitive producers and escalated the cost of drug in India. In developed countries, the drug costs \$5,718 per patient per year, while Cipla has been marketing a generic version called Tenvir, at a cost of \$700 per person per year in India. The Patent office of India rejected the patent application on grounds of violations of Section 3(d).

Fixed the negotiation period for the CL to be 6 months

Compulsory licensing, which allows third parties to produce and market patented medicines on certain grounds and the Government to override patent rights in situations of national emergency or other circumstances of extreme urgency or for public non-commercial purposes, was another issue of concern. In the case of a third party, it was required before making an application to the Controller of Patents for compulsory license, to enter into negotiations with the patent holder for a license on reasonable terms and conditions and such efforts have not been successful within a reasonable period. But, the Ordinance did not specify what is the reasonable period within which such negotiations should be completed, resulting in widespread concerns that compulsory licenses may take too long and thus defeat the whole purpose of the vary provision. The third amendment addressed this concern by specifying that the reasonable time period is six months.

Compulsory licensing for export

The other issue in this context was the export of medicines from India produced under compulsorily license to other countries which do not have manufacturing capacities. The TRIPS Agreement (Article 31.f) originally provided that compulsory license can be used predominantly for the supply of the domestic market of the Member authorizing such license. This required domestic manufacturing capacity as a pre-requirement for the exercise of compulsory license and a number of developing and least developed countries raised this matter in the WTO ministerial and the Doha Declaration clarified that countries without sufficient or no manufacturing capacities can import from any country which has issued a compulsory license. Import from India of medicines produced under compulsory license was a major concern for the health activists and governments in developing countries because these countries benefit from import of cheap and good quality medicines from India. The ordinance had provided that patented drugs, which are produced through compulsory licenses in the country, can be exported to developing countries with in insufficient or no manufacturing capacity subject to the condition that the importing country grants a compulsory

license. Globally this clause had attracted widespread criticism owing to the procedural hurdles for such countries to grant compulsory license. The third amendment clarified that the country can import from India if 'provided compulsory license has been granted by such country or such country has by notification or otherwise allowed importation of the patented pharmaceutical product from India'.

The Ordinance provided "Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country" (Section 92.A(1)). This section has been amended as "compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India".

The term 'shall' implies that compulsory license will be granted automatically without separate scrutiny or procedural requirements in India. In addition, section 90 also allows the export of medicines that are produced under compulsory license for the supply within India to countries where an export market exists that is not being supplied or developed (Hoen 2009).

Politicians, UN officials and international NGOs called on Indian policy makers to take into account India's responsibility as a supplier of affordable medicines. A New York Times editorial called upon the Indian Parliament to ensure that India could continue to play its role as leading supplier of low-cost medicines and to ensure that the amended patent law protected India's ability to make AIDS medicines available. This editorial received serious attention in India and was read out in the parliament during the debate on the Patents Act in March 2005.

Production of generic versions of 'mail-box' patented drugs

Possibly the biggest concern expressed after the Ordinance was on the continued production of drugs for which applications were pending in the mail-box. It was apprehended that generic medicines that are already produced and marketed in India for which patent application are pending in the mail-box, would go off the market once the patent is granted, leading to a quantum jump in drug prices. The Glivec case, the anti-cancer drug (Imatinib mesylate) for which the Swiss MNC Novartis obtained exclusive marketing rights in 2003 would be the best pointer to the concerns on the drug price. The price of Glivec was more than 10 times higher than that of its generic

counterparts: Novartis charged \$27000 per person for one year whereas the price of Indian generic equivalents was \$2700 per person for one year. These generic drugs going off the market would mean that patients have no other choice but to buy highly expensive patented medicines or continue with the disease without taking required medication. The third amendment clarified that those Indian companies already producing medicines for which applications are filed in the mailbox can continue to produce them even after patent is granted to the drug, after paying a royalty to the patent owner.

Section 11. A.7 provided for the continued manufacture of drugs with application in the mailbox. Mailbox was an arrangement mandated by the TRIPS agreement for those countries availed the transitional period of 10 years. The applications in the mail box would be examined only after 1st January 2005. India incorporated this provision into its Patents Act through the amendment in 1999. Many Indian companies started producing medicines for which applications were filed in the mailbox as it was legally permissible to do so. It was apprehended that after the final amendment of the Patents Act to allow for product patents from 2005, drugs which are produced by Indian companies and for which applications are pending in mail box would go off the market once patents are granted. But the final amendment provided that

“patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprise”.

Even if an application in the mail box is granted patent rights, those generic firms producing that drug will not be prevented from doing so. If there are Indian producers, the incentive of foreign firms to import that drug into India will be less due to the cost advantage that Indian firms are having.

3. HOW DID THESE FLEXIBILITIES GET INCORPORATED INTO THE PATENT ACT?

The GoI, in the early years of this decade did not seem to be keen on exerting the flexibilities available under the TRIPS agreement. Provisions in the 2003 Bill and the Ordinance are clear evidences for this. The TRIPS flexibilities were got incorporated into the Act only because of the pressure from left political parties and civil society groups. When the 2003 bill was introduced by the NDA led by the BJP, which had a very broad patentability criteria, weak pre-grant opposition,

weak compulsory license regime, restrictions on the export of drugs produced under compulsory license and no provision for the protection of generics of 'mail-box' patented medicines the then major opposition party, the Congress party, did not offer any resistance in the Parliament. It was only the small group of left parties who opposed the bill despite the fact that they did not have adequate number of Members in the Parliament to prevent the Bill. However, the Bill lapsed owing to a change of Government at the Centre. The new UPA Government led by the Congress party took up the same Bill which the NDA presented and introduced in the Parliament for the amendment of the Patents Act. However, by this time, the mood in the NDA camp had changed due to political concerns and not because of the desire to bring in the TRIPS flexibilities into the Bill, and opposed the Bill in the Parliament. For the UPA, it had become impossible to get the amendment done without the support of the left parties. In order to secure the support of left parties, the UPA had to make substantial changes in the Bill. In the mean time, the UPA passed an Ordinance with the 2003 Bill to meet the time line of 1st January 2005 for the full implementation of the TRIPS Agreement.

The left parties, i.e., CPI(M), CPI, Forward Bloc and RSP said "the left parties have been consistently of the view that TRIPS was and continues to be an iniquitous agreement balanced heavily in favour of multinational corporations" (People's Democracy 2005). The interventions that these parties made were based on this perspective. The left parties intervened in a major way in the third amendment of the Patents Act.

There were eight areas where the left parties wanted the Government to review the provisions in the Ordinance. The eight areas are: (1) patentability criteria, (2) pre-grant opposition to patent applications, (3) compulsory licensing provision, (4) export of drugs produced under compulsory license, (5) production of drugs for which applications were pending in the mail-Box, (6) patenting of software, (7) exclusion of micro-organisms from patenting, and (8) defining what is a new chemical entity (people's Democracy, 2005). All their demands except the exclusion of micro-organisms from patenting and defining what is a new chemical entity were met to appease the left parties and in these two areas, an expert committee was to set up. A case in point is the 'inventive step' clause, which was copied verbatim with an addition of just two words from the list of recommendations by the CPI(M), which in turn appears to be based on a report by a prominent civil society initiative – the National Working Group on Patent Law (NWGPL). The recommendations sent by CPI(M) to GoI defined an inventive step as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance and that makes the invention not obvious to a person skilled in the art" and the

CPI(M) has copied this verbatim from the Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970, commissioned by NWGPL.

The civil society groups like the NWGPL, Medicines San Frontiers (MSF), Gene Campaign, etc. have been a decisive force in the formulation of WTO consistent domestic policies from a perspective of protecting the interests of the people of the country. These organizations though do not have any official representation, act as pressure groups. The role played by the civil society groups especially the NWGPL during the final amendment of Patents Act is praise worthy and would be the best example of civil society groups successfully pressurizing the government to review its stance.

The NWGPL, which is a network of 12 organizations⁸, began its work on WTO issues as early as 1988 during the mid-term review of Uruguay Round negotiations. The positive impact of the Patents Act 1970 was widely visible at this time as India had a vibrant generic pharmaceutical industry which brought down the prices of medicines in India from one of the highest in the world⁹ to one of the lowest in the world in a matter of few decades. The Ayyangar Committee Report and the Report of the Patents Enquiry Committee which formed the basis of the Patents Act 1970 had already generated a lively discussion in India and other developing countries about the merits of the process patent regime. So it was quite natural for the people working in this area to come together in a group to convince the government on the importance of continuing with the Patents Act 1970. NWGPL held that India should continue with protecting the processes and not the products and there should be a strong compulsory license system (Dhar and Murali 2007).

The NWGPL established Peoples' Commissions, members of which constituted eminent personalities from diverse fields in the country like bureaucracy, academics, industry, law, etc., to study various facets of new patent regime and come out with reports. The Fourth Peoples' Commission established in 2003 to study the provisions of the '2003 Bill' with I.K Gujral, former Prime Minister of India as Chairman and Prof. Yaspal, former chairman of University Grants Commission, Prof. Muchkund Dubey, former Foreign Secretary, B.L Das, former India's ambassador to GATT, Dr. Yusuf Hamied, Chairman and MD Cipla, S.P Shukla, former member, Planning Commission, Prof. Prabhat Patnaik, Professor in Jawaharlal Nehru University, Dr. Rajeev Dhavan, senior advocate at supreme court of India and Prof. Ashok Parthasarathi, former secretary of GoI as members and B.K Keayla, former commissioner of payments as convener submitted its report in October 2004. The Recommendations of the Commission became the breeding ground for the protests from various corners when the UPA attempted to introduce the final amendment Bill in December 2004.

The report of the Fourth Peoples' Commission has dealt with each of the important provisions of the proposed Patents (Amendment) Bill and made concrete recommendations for the consideration by the GoI. The report clearly states the objective of the exercise. It says:

“... we must ensure that the exercise of making our Patent Act WTO – compliant does not end up contravening or jeopardizing the fundamental rights that the Constitution guarantees to our people....A sound and balanced national patent system is of crucial importance for the autonomous development of any economy and for meeting public demand for drugs, pharmaceuticals and other essential commodities. It is, therefore, extremely important that every provision of the amending Bill should be formulated with utmost care and attention and with clarity and precision” (pages 6,14).

The recommendations of the Peoples' Commission were spread into six broad areas; most of them were raised also by the left parties. The major issues raised by the commission were: (a) Scope and Patentability, (b) Compulsory licensing, in order to enable the domestic enterprises to ensure abundant availability at competitive prices, of pharmaceuticals and other products covered by the patent regime, (c) The terms of patent i.e. period of patent and licenses, (d) Royalty parameters, (e) Export of patented products; and (f) Pre-grant opposition to patent claims. Most of these recommendations were accepted by the GoI, as we have seen earlier in this section. One specific issue which the Commission raised was to limit the reasonable period after which the applicant can approach the Controller of Patents for compulsory license to 150 days. The third amendment clarified it by saying that “reasonable period shall be construed as a period not ordinarily exceeding a period of six months”. A brief analysis of the working of NWGPL, which is given below, would show the efforts of the Group in sensitizing the policy makers and concerned stakeholders the method adopted by them for the sensitization.

When the NWGPL was formed, the first task they undertook was to evolve some kind of a program. They focused on sensitizing the people on the impact of changes in the patent law by organizing national and international conferences. The first national seminar organized by the group in 1998 was attended by eminent scientists, jurists, economists, technocrats, industrialists, journalists, representatives of government and various organizations. A clear cut position got established with the unanimous adoption of a resolution in the concluding session of this conference which was addressed by K R Narayanan, then Minister of State for Science and Technology, P N Haksar, former vice Chairman, Planning Commission, Justice V R Krishna Iyer and Justice D A Desai, former judges of Supreme Court, Dr Surendra Patel, world known economist and senior

scientists like Dr Nitya Anand. The resolution became the basis for the national campaign against change to the patent law. After the seminar, representatives of the Group led by Justice V. R. Krishna Iyer met then Prime Minister Chandra Shekhar to appraise him of their serious concern and the need to protect the national interest during the GATT negotiations. In 1993, an International Conference on Patents Regime proposed in the Uruguay Round of GATT negotiations was organized by NWGPL jointly with ALIFAR (Asociación Latinoamericana de la Industria Farmacéutica or the Latin American association of the pharmaceutical industry) of South America, Canadian Drug manufacturers Association and IDMA. New Delhi Declaration and New Delhi Statement were issued, which became landmark documents for further campaign. Arising out of this conference, a delegation of these industries associations was led by NWGPL to Geneva and met the officials at GATT.

The second major initiative of the Group came in the wake of Dunkel Draft in December 2001. A Peoples' Commission on constitutional issues of Dunkel Draft Text with the Chairman and Members of former Judges of Supreme Court was established in November 1993. The Commission submitted a detailed report which was submitted to the Prime Minister and circulated extensively. The report had looked into the constitutional issues arising out of GoI holding negotiations in the Uruguay Round on agricultural issues without consulting the state governments. The group members approached a number of state governments and held discussion with them about the implications of Dunkel Draft Text. Some of the state governments – Tamil Nadu, Rajasthan and Orissa agreed to file petitions in the Supreme Court⁹. These petitions were drafted by Dr. Rajeev Dhavan, a member of NWGPL.

NWGPL took the lead in establishing a Forum of Parliamentarians on patent law and WTO Issues in 1995. The core group of the forum included Dr. Murli Manohar Joshi as Convener and Dr Ashok Mitra, A B Bardhan, Jaipal Reddy, George Fernandes and Prithviraj Chauhan as members and B K Keayla as convener, S P Shukla as forum advisor. NWGPL and the Parliamentarians Forum jointly organized an international Conference of Parliamentarians in 1996, attended by a number of Parliamentarians from South America, Pakistan, Bangladesh, Sri Lanka, Nepal, etc.

NWGPL established the second Peoples' Commission in 1998 to examine the transitional period obligations in the TRIPS agreement and implementation of the obligation in the TRIPS agreement and submitted its report of the government with recommendations. The Third Peoples' Commission was established during the course of introduction of second amendment. A large number of experts and stakeholders numbering 25 appeared before the commission. The

Commission has also received nine detailed papers from various experts, who could not personally appear before the Commission. The Commission submitted its report in 2003 for the consideration of the Government and Members of Parliament. In December 2003 the Government introduced the final Patents (Amendment) Bill, prompting NWGPL to set up the Fourth Peoples' Commission on Review of Legislations Amending the Patents Act 1970. This Commission went into the depth of various amendments already carried out and the proposed amendments in the final amending Bill. In order to put their views upfront, NWGPL coordinated with the left parties, the king maker of UPA coalition government. S.P Shukla of NWPL acted as the coordinator with left parties during the course of third amendment to the Patents Act 1970.

We have already seen that there are commonalities in the contents of interventions of the left parties and NWGPL in the context of making Indian patent regime compatible to the WTO. These two groups were quite successful in exerting pressure on the government. What is more important is that there is a commonality in the ideology representing both these groups-the left parties and the NWGPL believed that the TRIPS agreement had sought to strengthen the monopoly position of multinational companies. These two non-state actors led by a common ideology turned out to be the most important pressure group in directing India's relations with WTO in the area of IPRs.

4. CONCLUSION

The formulation of India's engagement with the WTO is not an easy task and it requires consensus building among various stakeholders including the civil society groups and small political parties. The implications of WTO agreements being vast and diverse for various segments of the society, India's policy towards the Organization has to take into consideration the concerns of all these segments. In the case of IPRs, it was feared that strengthening of it would adversely impact the survival of the Indian generic pharma industry and access to medicines and the Government of India was forced to take into account concerns raised by patient groups, public health groups and the pharma industry. With the emergence of the WTO, there is a globalization of the issues arising out of each of its Agreements and has subsequently resulted in the emergence of the globalization of civil society groups and these groups exert their pressure through various channels such as the Parliament, media, judiciary, political parties, etc. Given the multitude of issues emerging from the global trading regime and the diversities within the country, India cannot formulate its

external economic policies merely based on its economic reasoning but has to take into account the interests of the public well.

End Notes

- ¹ There have been concerns expressed from various corners (industry association-Indian Pharmaceutical Alliance, CSOs, Health Activists, Academics, etc.) in the case of protection of pharmaceutical test data. GoI appointed an inter-ministerial Committee to study the issue and the Committee submitted its report in 2007. GoI is yet to take an official decision on the issue.
- ² Article 65.2 of TRIPS Agreement.
- ³ Article 70.8 of TRIPS Agreement.
- ⁴ An ordinance was issued on 31st December 1994 amending the Patents Act 1970 to introduce the mail-box provisions. But the amendment was not passed by the Parliament. The United States dragged India into a dispute in the WTO (WT/DS50) on the failure of providing mail-box facility where the decision went against India. Exclusive Marketing Rights brought with them a five-year, patent-like monopoly for products covered by the product patent applications made under the mailbox system. The company securing an exclusive marketing right has the exclusive right to sell or distribute the article or substance covered in a patent application in a country.
- ⁵ It introduced 64 amendments (Basheer 2005).
- ⁶ Where an application for a patent has been published but a patent has not been granted
- ⁷ Any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent
- ⁸ The 12 organizations are: (a) Public Interest, Legal Support and Research Centre, (b) CSIR Scientific Workers Association, (c) Delhi Science Forum, (d) Academy of Young Scientists, (e) Consumers' Forum, (f) National Confederation of Officers' Association of Public Sector Undertakings, (g) Forum of Financial Writers, (h) All India Drug Action Network, (i) Forum for Preservation on Indian Patents Law, (j) National Campaign Committee on Drug Policy, (k) All India Lawyers Union, and (l) Indian Drug Manufacturers Association.
- ⁹ The United States' Senate Committee on Drug Prices, the 'Kefauver Committee' reported in 1962 that 'in drugs, India ranks amongst the highest priced nations of the world'.
- ¹⁰ In the course of time there were changes in the leadership in these state governments and the writ petitions were withdrawn.

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The *Glivec* Case & Section 3(D) of Indian Patent Act, 2005: New Avenues to Access Essential Medicines

G. Geethika*

Abstract

*Indian pharmaceutical industry plays a vital role in the global public health setting. The new global IPR regime which began with the introduction of the Agreement on Trade Related Intellectual Property Rights (TRIPS) by the World Trade Organisation (WTO) necessitated crucial changes in the Indian Patent Act of 1970 and the resultant scenario has not been favourable for the public health sector especially with respect to access to medicines, for various reasons. Developing countries have been eagerly searching for alternatives to overcome the hurdles posed by the new global IPR regime and, in this context, the *Glivec* case and the Supreme Court judgement against Novartis is noteworthy. This paper examines the implications of the new global IPR regime on access to medicines and discusses about the *Glivec* case as a new avenue for developing countries as a leeway over the WTO imposed TRIPS regime.*

Key Words: Glivec, IPR, Section 3D, WTO

1. INTRODUCTION

Indian pharmaceutical industry plays a vital role in the global public health setting. The Indian Patent Act of 1970 and some other well thought out legislations related to industrial and trade policy had aided the pharmaceutical industry to become the 'pharmacy of the world' by flourishing in various aspects of drug development. The growth of the industry to this stature has not been free of barriers and the new global IPR regime is emerging to be challenging at multiple realms.

* Author is Teacher Fellow at School of International Relations, Mahatma Gandhi University, Kottayam & Assistant Professor in Political Science, Union Christian College, Aluva.

The new global IPR regime was launched by the inclusion of the Agreement on Trade Related Intellectual Property Rights (TRIPS) under the auspices of the World Trade Organisation (WTO). It was after years of deliberations in the Uruguay round of GATT negotiations that intellectual property rights was introduced into the ambit of the trade related discourse. The most consequential of the institution of the TRIPS Agreement has been the impact on the pharmaceutical sector and the post-TRIPS scenario has further aggravated the situation to that of contention of interests between pharmaceutical corporate giants and millions of poor people who have been denied access to affordable essential medicines.

The rising apprehensions about the new patent regime was addressed at the WTO through the Doha Declaration on TRIPS Agreement and Public Health which drew the attention of the developing countries to some of the flexibilities available in the Agreement. Yet, the global scenario presented an unfriendly environment for the developing countries like India and their generic drug industries, especially with the inclusion of provisions to implement stringent intellectual property norms in the various bilateral free trade agreements initiated by the US and the EU. The circumstance has compelled the developing countries to explore all possible avenues to overcome the hurdles posed by the new global IPR regime and, in this regard, India has once again kept up its reputation as the 'pharmacy of the world' with successfully rejecting patents to new drugs on the grounds of efficacy.

On April 1, 2013, the Supreme Court of India pronounced a historic judgement rejecting patent rights to Novartis for their cancer drug '*Glivec*' on the grounds of lack of efficacy as stipulated by Section 3(d) of the Indian Patent Act, 2005. The landmark judgement has opened up a plethora of discourses on pharmaceutical patents and the implications of the new global IPR regime on access to affordable medicines. In this context, this paper proposes to examine the new windows of opportunities for India to protect and promote access to medicines while assessing the multidimensional implications of the new global intellectual property rights (IPR) regime.

This discussion in this paper shall proceed as follows: first, an analysis of the implications of the new global IPR regime on access to affordable and essential medicines is conducted in the context of India being the 'pharmacy of the world'. Subsequently, the paper tries to understand the factors contributing to this situation by undertaking a review of the changing dimensions of IPR legislations of the country in the process of achieving TRIPS compliance. Finally, the study concludes with the detailed examination of the Section 3(d) provision and the new avenues it reveals in appropriating the flexibilities of the TRIPS Agreement in favour of accessing medicines, with the *Glivec* case as an illustration.

2. THE NEW GLOBAL IPR REGIME & ITS IMPLICATIONS ON ACCESS TO MEDICINES

By signing the Uruguay Round Agreements on April 15, 1994, Indian became a founder-signatory of the WTO. Associated with the membership was the ‘single undertaking’ requirement that obliged us to agree to change our outlook towards association of stringent intellectual property protection norms with pharmaceutical innovations. India was put under the contractual obligation to honour the Agreement and amend the 1970 Act in compliance with its provisions (Correa 2000).

TRIPS Agreement administers provisions not only extended rights to new aspects like geographical indications, integrated circuits and trade secrets, but also made it mandatory for its signatory countries to amend or incorporate the following provisions in their national legislations: (i) restoration of patent term to 20 years; (ii) introduction of product patents and reversal of the burden of proof; (iii) dilution of compulsory licensing provisions; (iv) removal of ‘licences of right’ clause; (v) extension of patentability to biotechnology, agricultural or horticultural inventions; and extend the protection to geographical indications, integrated circuits and trade secrets for which India had no legislation until then (Nair 1996).

It was propagated that the product patent regime would benefit five industries, namely, pharmaceuticals, organic chemicals, plastic materials, inorganic chemicals, and steel mill products. Levin et al. (1987) showed that patents are the most effective means of protecting process and product innovations in the drug industry. Mansfield (1981) found that around 65% of pharmaceutical innovations would not have taken place if patent protection were not available. Yet, much of the global experience has been that product patent can benefit a country in terms of innovation only when its industrial capabilities have reached a certain level (May & Sell 2006). In almost all lesser circumstances the new global IPR regime has affected the pharmaceutical sector in multiple ways.

It is interesting to look at the views of Parvinder Singh, vice-chairman and managing director of Ranbaxy, about the impact of changes in the Patent Act of 1970, who observed, “...no new products would be introduced by Indian companies...the country will become entirely dependent on imports and at exorbitant prices the export activity would receive major setback, worsening our balance of payment position...monopolistic regimes will get established and competitive forces would get totally eliminated..” (P. Singh 1988).

Assessing the implications of TRIPS compliance on the Indian pharmaceutical sector, four issues concerning access to medicines caught the attention of scholars: (i) studies projected

a 242% rise in medicine prices in India; (ii) the panic that Indian firms would not be able to produce generics loomed large; (iii) the impact of TRIPS on R&D in the Indian pharmaceutical sector, especially in tropical diseases; and (iv) the impact on the developing countries (especially LDCs) who depended massively on cheap generic drugs exported by Indian firms. The apprehension in this regard has not thus far escalated to a major problem in lieu of the leniency transition period available to the LDCs till 2016 (Attaran & Gillespie 2001; CIPR 2002; Dhar & Rao 1995; Keayla 1995, Lanjouw 1998).

The situation has not been bright and shiny in the area of patenting also. Not only has India fallen back in the total filings, but the performance of the pharmaceutical sector is abysmally poor. A study report of TIFAC reported certain important findings in this regard: (i) a country like the US filed nearly 45,000 patent applications in 2006; India's contributions being 650, (ii) no Indian company is included among the top ten; the top most being IBM with 3,300 PCT applications (Damodaran 2008). The share of foreign applicants in total patent filings increased from 74 to 79 percent between 2001 and 2011. Of the 79% applications those pertaining to drugs constituted 9% in 2011, but it was 21% in 2000. Lack of full capacity to conceptualise, develop and market a drug has prompted Indian companies to discover candidate drugs¹: a compound (small molecule, antibody, etc.) with strong therapeutic potential, best in potency and selectivity and whose activity and specificity have been optimised. End result of lead compound optimisation.

To better understand the circumstances, it is imperative to conduct a review of the history of intellectual property protection system of the country. The intention shall be to comprehend the nature and scope of the legislations that were prevalent in the country prior to implementing the amendments as prescribed by the TRIPS Agreement and the implications of the same on the Indian pharmaceutical sector.

3. INTELLECTUAL PROPERTY LEGISLATIONS IN INDIA & THE PHARMACEUTICAL SECTOR

India cannot boast of a long history of intellectual property legislations. While the long history of colonisation may be a reason for the delay in the introduction of an intellectual property protection system, the basic characteristic of the Indian approach to the concept of property rights could be another significant factor. Unlimited individual property was looked down upon and common property or shared property was approvingly acclaimed as part of the national ethos. The way ownership of the entire body of traditional knowledge was conceived by society is a standing example of this outlook.

The first step in the direction of incorporating intellectual property into national legislation was initiated by the British administration and was drafted in line with the regulations followed by Britain. Over time three laws relating to patents were implemented in India, namely, the Patents & Designs Protection Act, 1872; The Protection of Inventions Act, 1883, later consolidated as The Inventions & Designs Act, 1888, and The Indian Patents & Designs Act 1911 (Thadikkaran 2013).

The Indian Patents & Designs Act 1911 needs special mention as it not only consolidated and replaced the existing statutes but was also the first to bring patent administration under the management of the Controller of Industrial Patents and Designs for the first time (Ragavan 2001). It created a form of intra-British Empire priority system wherein an applicant of an Indian patent was entitled to the benefit of the earlier United Kingdom filing date. The Patent term was for sixteen years with extensions of up to seven additional years. Like its predecessor Acts, the 1911 Act permitted patenting of pharmaceutical products. The 1911 Act underwent three further amendments in 1920, 1930 and 1945 (Mueller 2007, Blocker 2007).

The aforesaid intellectual property legislations had limited but crucial influence on the early stage of growth of the Indian drug enterprise. The product patent system instituted by the Patents and Designs Act, 1911, had become an obstacle to the development of the indigenous drug industry and the post-independence period called for a strong intervention by the Indian government. The government realised that the strong patenting provisions (for 16 years since 1930) not only led to exorbitant prices for medicines made by foreign-owned firms but also discouraged the indigenous firms from R&D. Multinational corporations took a very long time to launch their patented drugs in India and severely challenged our public health needs. The prices in India for the broad spectrum *antibiotics*, *aureomycin* and *achromycin*, were amongst the highest in the world earning India the reputation of being ‘the lower per capita income country with highest drug prices’ in the world as observed by Kefauver Committee 1961 (Pradhan 2006). As a newly independent developing country, doing justice to increasing public health needs of the poor by providing medical infrastructure and affordable medicines became one of its biggest challenges. Comprehending the gravity of the situation, the government designed a multifaceted strategy of policy measures, including revision of the patent system (Mueller 2007).

The first strategy used by the government was to keep aside import substitution in the pharmaceutical sector and encourage foreign capital. Foreign companies eagerly established subsidiaries in India but denied technology transfer. The failure of the strategy led the government to constitute several committees to study and recommend ways to rejuvenate the domestic drug

sector. The Patent Enquiry Committee, 1948, chaired by Dr. Bakshi Tek Chand, the Pharmaceutical Enquiry Committee of 1954 headed by General Bhatia, the Committee on the Revision of Patents Law, 1957, chaired by Justice N. Rajagopala Ayyangar; the 1974 Hathi Committee to study the various facets of drug industry, among others produced reports with valuable policy recommendations that transformed the national legislations in favour of the domestic drug sector of India (Ekbal 2013).

Growth of the industry was further guided by policy interventions in various spheres: industrial licensing policy led to production of essential drugs; the Foreign Exchange Regulation Act (FERA) encouraged the public sector and indigenous private sector and kept foreign sector at bay with the decision to keep foreign equity shares below 40%; the Monopolies and Restrictive Trade Practices (MRTP) Act, 1969, checked the anti-competitive practices of not only foreign firms but also large Indian firms; the drug policies balanced the needs of controlling prices and providing sufficient profits to manufacturers; indigenous research and development efforts encouraged by setting up CSIR and providing exemptions from price control; and the Drugs (Control of Prices) Order, 1970 also was crucial in price control. Through these policy interventions Indian pharmaceutical industry became self-reliant in the production of the entire range of formulations and about 70% of bulk drugs (Ekbal 2013).

Over and above all the afore mentioned measures, it was the historic Indian Patent Act of 1970 which eliminated product patents in pharmaceuticals and enabled Indian companies to engage in reverse engineering. The provisions of the Indian Patent Act, 1970 (hereinafter referred to as the “1970 Act”) govern the procurement and grant of patents in India (non-substantive procedural issues relating to the procurement & granting of patents are governed by the Patent Rules and not the 1970 Act). Section 159 of the Act, requires the Central Government to frame rules to administer and carry out the intent of the Act. The Act was kept in abeyance till the formulation of rules. The rules came into force on April 20, 1972. Thus, the 1970 Act (except for certain sections) came into force on April 20, 1972. The remaining sections of the Act came into force on April 1, 1978. Since its enactment, the Act has been amended on five occasions: (a) the Repealing and Amending Act, 1974 (Act 56 of 1974); (b) the Delegated Legislation Provisions (Amendment) Act, 1985 (Act 4 of 1985); (c) the Patents (Amendment) Act, 1999 (Act 17 of 1999); (d) the Patents (Amendment) Act, 2002 (Act 38 of 2002); and (e) the Patents (Amendment) Act, 2005 (Act 15 of 2005) (Thadikkaran 2013).

The first two amending Acts referred above were driven by the changes within India, while the later three amending Acts were made to meet India’s obligations under the TRIPS. At

present, the 1970 Act is a collection of 23 chapters each dealing with various principles/aspects involved in the grant of patents in India (Blocker 2007).

The 1970 Act is unique and is recognised as one of the best ever patent laws drafted in India and elsewhere. This Act is known for its pro-public approach because of some carefully crafted features. For instance, potential abuse of the exclusive rights by the patentee can be restricted through provisions like compulsory license and license of rights with stipulation of quantum of royalty payable. Also, the term of patent in respect of inventions relating to food, drug or medicine has been reduced to seven years from the date of patent and five years from the date of sealing whichever is earlier; and the patents must be worked within three years of filing. The endorsement of the patents with the word 'license of right', after three years from the date of sealing, in fact is an invitation to the interested persons to seek licenses to exploit the patented invention commercially to meet the reasonable requirements of the public and to make them available to the public at reasonable prices (Chandran et.al. 2005).

In comparison to Patent Act 1911, provisions under the 1970 Act led to a substantial rise in the number of applications filed by Indian applicants. Remarkably, by 1978-79, the number of foreign owned patent applications filed in India had decreased to 1010, which is less than one quarter of the 4248 applications filed ten years prior in 1968. The filing trend in the field of pharmaceuticals has been that its filing rate was 6% in 1986-87 and 7% in 1993-94 but recorded an average of 6.7% during 1986-87 to 1993-94. The major contributors to the patent applications in India are USA, UK, Germany, France, Switzerland, Japan and USSR (Ekbal 2013).

The most revolutionary provision in the 1970 Act was undoubtedly the process-only patents framework for substances useable as food or medicine. It favoured Indians in many other ways. Products developed by advanced nations with their legacy of outstanding S&T calibre and financial resources could be indigenized and produced locally (through alternative and economical processes) to meet India's needs both on the strategic (e.g. specialty chemicals including polymers and propellants, advanced materials and metal alloys) as well on the civilian (drugs and pharmaceuticals, agrochemicals, catalysts and so on) side. This has indirectly promoted our growth in most of these sectors in the past decades (Damodaran 2008).

Yet another feature intended to serve public interest was that under Section 146(2) it has been made mandatory on the part of the patentee to furnish the statement every year as to the extent to which the patented invention has been commercially worked in India (Khader 2009).

Similar to India, some other developing countries also incorporated unique provisions in their patent laws intended to safeguard their national interests. It was generally acknowledged

that these discriminatory provisions were transitory in nature leading to a fuller and more rigid patent system as these countries moved upwards in development and international competitiveness (Nair 1996).

Indian Patent Act 1970 and Access to Medicines

The policy reforms of the 1970s revolutionised the Indian pharmaceutical industry. Through the use of indigenous raw materials and appropriate technology the industry achieved self-reliance and self-sufficiency. Comprising of a large family of more than 24,000 registered units, the industry could boast that out of the 465 main bulk drugs used in India, around 425 bulk drugs were manufactured in India and 60 of them were exported too. The share of the domestic sector in total production increased from 27% in 1975 to 52% in 1980 and the revenue rocketed from a meagre Rs. 100 million in 1947 to Rs. 94,530 million in 1995. In the 1980s the industry had growth at a rapid rate of 11% per year, which further accelerated to 17% per annum during 1990s. Similarly investment has also increased from Rs. 225 crore in 1973 to Rs. 1000 crore in 1993. The leading 250 pharmaceutical companies controlled 70% of the market, with market leaders holding nearly 7% of the market share. Formulations accounted for 81.5% of the market and bulk drugs account for the remaining 18.5%. The production of bulk drugs had reached 82% by the end of 1980s. India's total exports of pharmaceutical products had risen from 06% in 1970-71 to 4% in 1999-2000 (Kardam 1997, Chandran et.al. 2005, Pradhan 2006).

An interesting observation about this period is that process patents and reverse engineering helped ensure unrestricted supply of all new drugs into the Indian market with very little 'drug lag'. Possibilities of accessing pre-clinical documentation helped Indian drug companies launch many medicines far ahead of their original innovators. Some good examples are *Atenolol*, *Diclofenac*, *Alprazolam*, *Cimetidine*, *Ranitidine*, *Famotidine* etc. Further, this scenario has been thought to contribute to self reliance in technology for conventional formulations and bulk drugs (Nair 1996). India became a world leader in the manufacture and export of basic drugs such as *Ethambutol* and *Ibuprofen*. The industry has also contributed to the development of new drugs such as *Tromovill*, *Cibenid* and *Centbucridines* as well as the development of innovative process technologies for known drugs. Thus, the highly watered down 1970 Act is directly responsible for the tremendous growth of pharmaceutical industry, which has made the country self sufficient in this field (Kardam 1997). The biggest contribution of the Indian generic drug industry is that since 2001 India has been able to supply generic anti-retroviral drugs to many countries and the prices have since then reduced significantly. When Cipla introduced the triple cocktail of antiretroviral drugs (*stavudine* + *lamivudine* + *nevirapine*) in 2001 at US\$350 per

person per year, the originator company's price for the drug in developing countries fell from US\$10,000 to US\$727. The originator's price came down further as more Indian generic companies began to produce the triple cocktail drug. Patients in all continents, except maybe Europe and Australia, rely on India for exported medicines and the United States of America is the largest importer in terms of value (Ekbal 2013).

Adopting an open avenue for patent protection through the promotion of process patents has not been free of downfalls. It is no secret that in the absence of a truly forward-looking and self-reliant S&T-cum-industrial policy approach, the 'permissive' IPR policy did not promote innovation through original patentable inventions of consequence: no new material, ally, polymer, drug, catalyst, and so on, not even any new competitive technology! India lagged behind the developed countries and even the East Asian Countries in the realm of Pharmaceutical R&D (just nine firms spending more than Rs. One crore in R&D, in 1982-83). Even while total allocation for R&D by the pharmaceutical sector in India was at a dismal level of 1.5 to 2 % of its turnover, the bulk of it was being spent on process and technology development. With such relatively low or sub-critical investment in new drug research, the number of patents filed annually remained stagnant at around 3500 and it steadily lost even adequate professional recognition in the research community (Nair 1996, Chandran et.al.2005).

In other words, Mueller (1997), Chandran et.al. (2005), Damodaran (2008) and others opine that the 1970 Act gave the nation 'a quick and assisted take off' but with technology transfer continuing by and large to be the major accepted strategy of industrial development in public and private sectors, patents never got to be a true instrument for developing professional expertise in new chemical entity development, conducting advanced clinical trials and most importantly in drafting patents and patent related litigation in the areas of new chemical entities, genetic engineering, combinational chemistry, natural products, agro-chemicals and agricultural products.

The 1990s was a significant period in the history of independent India. On the one end of the spectrum at the political front experienced the assassination of the Prime Minister and emergence of new actors into leadership. At the economic front, the new government decided to get in tune with the international neo-liberal revolution and adopted some liberalisation policies which had, and continues to have, unfathomable repercussions in all spheres of the Indian society. The socialist outlook fostered by the leaders until then suddenly became less significant and the public health sector also felt the tremors. These domestic changes were soon followed by the TRIPS Agreement. Nair (1996) and Ekbal (2013) pointed out that the dilemma that India faced with the start of TRIPS era, given the then envious status of the Indian pharmaceutical industry

shaped by the protective industrial and patent policies, was how to adopt TRIPS compliance and break out of the image of a copy-cat industry to an R&D industry without compromising on the public health needs of a very large domestic and international patient pool.

Changing Dimensions of Patent Laws in India under the New IPR Regime

The Statement on Industrial Policy of 24 July 1991 formally launched a new era of liberalisation in the Indian economy following which industrial licensing was abolished and FERA was amended and later abolished. The Drug Policy of 1986 was also modified and the drug pricing mechanism based on 'market competition' and 'annual turnover' brought down the number of drugs under price control from 142 to 74 (Ekbal 2013). Over and above these policy incongruencies, the amendments in the Indian patent legislation in compliance with the TRIPS Agreement has drastically affected the capacity of the Indian pharmaceutical industry, especially the generic firms, in supplying affordable drugs to the world. Several studies (Dhar & Rao 1995, Nayyar 1992, Lanjouw 1998, Mashelkar 2009, Mishra 2001, Kumar 2003, Pradhan 2006 and several others) point out the effect of transformation of Indian patent regime on Indian pharmaceutical industry and public health interests of the people.

The Patents (Amendment) Act, 1999

The first amendment came in 1999, with retrospective effect from January 1, 1995. Article 65 of TRIPS allowed India until 2005 to establish its product patent regime. Being a country with no history of awarding product patents to pharmaceuticals and chemical inventions, Article 65 of TRIPS allowed India until 2005 to establish its product patent regime. But in the mean time TRIPS (Article 65(2) & (4) along with 70(8)) required the inclusion of provisions to accept 'mail box' applications, grant exclusive marketing rights (EMR), shift the burden of proof to alleged infringer and extend protection to imported materials and products (Chandran et.al. 2005, Ragavan 2001).

The Patents (Amendment) Act, 2002 and Patent Rules, 2003

India amended its Patents Act again in 2002 to meet with the second set of obligations (20 years term of patent, reversal of burden of proof etc.), which had to be effected from January 1, 2000. It came into force on 20th May, 2003. The amendment included provisions to formally integrate the Act with Paris Convention and PCT terminology. India became party to both the treaties on December 7, 1998 (Pillai 2005).

The Patents (Amendment) Act, 2002, required substantial changes in the procedural laws which lead to the repeal of the Patent Rules, 1972. The Patents Rules, 2003 was enacted on May

2, 2003 after being published and circulated for over six months in order to receive public comments. The Rules were further amended by the Patents (Amendment) Rules, 2005 and the Patents (Amendment) Rules, 2006, to introduce flexibility and reduce processing time for patent applications and to simplify and rationalize the procedures for granting of patents (Thadikkaran 2013).

The Indian Patents (Amendment) Act, 2005

The Third Amendment of the Patents Act 1970, by way of the Patents (Amendment) Ordinance 2004 came into force on 1st January, 2005 incorporating the provisions for granting product patent in all fields of technology including chemicals, food, drugs & agrochemicals and this Ordinance was replaced by the Patents (Amendment) Act 2005 which is in force now (Blocker 2007).

An attempt has been made by the drafters of the third amendment to increase the threshold of patentability by setting higher standards of ‘novelty’ and ‘inventive step’ and by excluding additional categories of subject matters of patentability. The new definition for ‘new invention’ [Section 2(1)(l)], the amended definition for ‘inventive step’ [Section 2(1)(ja)], the amended definition for ‘pharmaceutical substance’ [Section 2(1)(ia)], and exclusion of patentable subject matter as per Section 3 & 4 through the addition of the new explanation to Section 3(d) in general were all aimed at stepping up the threshold of patentability in general (Pillai et.al. 2006, Khader 2009).

Another feature relevant to pharmaceutical patents is with respect to filing of the application: a) claim or claims can now relate to single invention or group of inventions linked to form a single inventive concept; b) patent application will be published 18 months after the date of filing; and c) applicant can request for examination 12 months within publication or 48 months from date of application, whichever is later (Saha 2006).

The introduction of amendments in compliance with TRIPS had made the public health activists and human rights advocates look at the Indian Patents Act with suspicion for various reasons. The next section examines the new avenues explored by the nation in overcoming the concerns raised by the new IPR regime by studying the case of appropriation of the efficacy provision as illustrated in the *Glivec* case.

4. NATIONAL INITIATIVES TO PROTECT ACCESS TO AFFORDABLE MEDICINES

The implementation of the amendments to our patent system has not produced appropriate results in favour of the public health needs of the country. Since the inception of the TRIPS

Agreement the generic industry has had to effectively overcome multiple levels of obstacles to survive and sustain their reputation as the most reliable source of affordable medicines (Musungu & Oh 2005). At another level, the Doha Declaration on the TRIPS Agreement and Public Health urges the government to scout for appropriate TRIPS flexibilities to address the public health concerns. In this regard, it is interesting and motivating that the Indian patent authorities and judiciary have been able to explore few possibilities which are nothing less than milestones.

Section 3(d), Efficacy and the Glivec Case

One of the most infamous strategies employed in pharmaceutical innovations during the past few decades has been the patenting of drugs that are mere modifications of known substances, thus saving hugely on R&D spending, saving time on clinical trials, and more importantly, eliminating competition, extending monopolies and making drugs unaffordable. Studies by institutions like the National Institute for Health Care Management (NIHCM) reveal that over 75% of the drugs patented today, even in the US, are of this nature (Grover 2013). This strategy of securing sequential and overlapping patents on a single product through trivial changes is called 'evergreening'. In pharmaceuticals, this may involve changes in size, colour, dosage, delivery mechanism and composition (Rangnekar 2013).

One of the first illustrations of this kind of evergreening is 'Zidovudine' (AZT, previously *Azidothymidine*), which was a known cancer drug and GlaxoSmithKline procured a patent as an antiretroviral drug for HIV (Chandra 2011). Novartis' *Glivec*, Merck's *Efavirenz*, Gilead Sciences' *Tenofovir* and *Amprenavir*, Roche's *Pegasys*, Abbott's *Kaletra* and *Aluvia* etc are new drugs made by combining pre-1995 drugs (Menghaney 2013).

During processing of many 'mailbox' applications, India also came across a large number of 'evergreening' patent claims. A single medicine was being presented under many secondary applications with alterations in one or more features including formulations, combinations and derivatives (Menghaney 2013). Intellectual property experts and public health activists maintain this as a damaging scenario that would in the long run adversely affect our right to health concerns as well as pharmaceutical export potential. This state of affairs necessitated the need for inclusion of safeguards while amending the patent system. It was in this context that the Section 3(d) was incorporated into Chapter II of the Indian Patents Act, 1970 under the amendments of 2005. Under Section 3 of Chapter II titled 'inventions not patentable', a number of exclusions such as frivolous inventions, methods of agriculture, traditional knowledge etc have been listed. The clause (d) goes a step further and prevents patenting of substances that do not enhance known efficacy (Rangnekar 2013).

According to Section 3(d), a substance is not patentable if it is “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new product or employs at least one new reactant” (Srinivasan 2007). Explanation to Section 3(d): “Salts, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”. The primary objective of Section 3(d) patentability criteria is to prevent ‘evergreening’ and tweaking of known and patented formulations to extend patent claims. The interesting aspect here is that our legislation is now relying on utility and efficacy to differentiate between patentable and non-patentable inventions. The critical part here is that the novelty is derived from the use, not the product (Chandra 2011).

The idea of incorporating Section 3(d) into the Act was suggested by the Indian Drug Manufacturer’s Association (IDMA) and was developed on the basis of the report submitted by a Technical Expert Group (chaired by R.A. Mashelkar, former Director General of CSIR) constituted by the Government (Sengupta 2012). Interestingly, it was first incorporated in 2004 that the European Parliament in a directive relating to drug regulation of medicinal products for human use (Chandra 2010).

Section 3(d) & Compliance with TRIPS

Patent laws are national laws and, therefore, what is patentable in India may not be so in other countries. Moreover, the definition of invention as incorporated in the TRIPS Agreement is vague and inconclusive. These parameters provides for a leeway for countries like India to reframe the scope of ‘patentable subject matter’ to suit the domestic interests and to protect the provisions under its Constitution. The efficacy criterion as mentioned in Section 3(d) may be read in this light. The interpretative criteria codified by the Vienna Convention on the Law of Treaties (Article 31 & 32) also permit such diversions (Correa 2013). Moreover, Article 30 of the TRIPS and the Doha Declaration of 2001 approve the implementation of exceptions and provisions that support WTO members’ rights to protect public health and access to medicines (Chandra 2011).

The Section 3(d) can also be understood as a precautionary principle intended to protect the right to health. This principle, formalised at the 1992 UN Conference on Environment and Development, requires that precaution should prevail whenever questions of human and environmental health are involved. As a precautionary principle, 3(d) is expected to prevent a

health emergency, which could arise out of removal of affordable, life-saving generic drugs from the market and thereby, limiting access to these drugs. This is where this principle scores over the compulsory licensing provision implied in Article 31(c) of TRIPS which provides measure of addressing health emergencies and not preventing them. Therefore, the value of 3(d) is not limited to settling the debate on what constitutes inventions, what is novel and what is useful (Chandra 2011).

In other words, it is evident that Section 3(d) cannot be implicitly seen as violation of any regulations set aside by TRIPS. But the United States Trade Representative (USTR) stated that Section 3(d) may be incompatible with two aspects of Article 27.1 of the TRIPS Agreement: (a) the non-discrimination clause, and (b) the obligation to grant a patent when the three patentability criteria specified in that article (novelty, inventive step/non-obviousness, industrial applicability/utility) are met, without imposing additional substantive conditions. But this allegation is only because USTR is reluctant to see the complete picture with respect to interpretation of the term 'discrimination'. Section 3(d) cannot be accused of discrimination since it does not take place on the basis of any of the following grounds: the place of invention or the field of technology (Correa 2013).

An investigation has been initiated by the ITC (International Trade Commission) on 'Trade, Investment and Industrial Policies in India: Effects on the US Economy'. This investigation no. 332-543 by ITC appears to cover Section 3(d) of the Patents Act, 1970 also among 'IP intensiveness' in India (Nair, Fernandes & Nair 2014).

The 'Glivec' Case: Lessons for All

Imatinib Mesylate, commonly known as *Glivec* (or *Gleevec*), is the second best selling drug marketed by Novartis which is a Swiss pharmaceutical company with its sales spanning across the continents. Interestingly, patenting of this drug caused a pandemonium in India and the case is often referred to as the 'Mother of all product patent litigations'. *Glivec* is a tyrosine kinase inhibitor and it is prescribed to patients with Chronic Myeloid Leukaemia (CML, a form of blood cancer) since it effectively controls the cellular action that allows the cancer to grow. Though not a cure, the drug must be taken for the rest of the life of the patient. Over 30,000 cases of CML are reported in India every year (Correa 2013).

Novartis procured the patent for *imatinib*, and other derivatives of the compound, from the United States (Zimmermann patent no. 5,521,184A,10 in April 1994). The patent was named after the inventor, Jurg Zimmermann (Chaudhuri 2013). In the US since the Zimmermann patent

covered all its derivatives, Novartis did not apply for a separate patent for *imatinib mesylate* and it has been granted patent in 40 countries (Menghaney 2013).

Since the 1970 Act did not entertain pharmaceutical patents, on 17th July 1998, Novartis filed a patent application in the Chennai Patent Office for the beta crystalline form of *imatinib mesylate* and the application was accepted as a 'mailbox' application (no. 1602/MAS/1998 for the invention titled 'crystal modification of a N-phenyl-2-primidineamine derivative, processes for its manufacture and its use). On 10th November 2003, the Mailbox application was processed and based on section 92A of the Patents Act, Novartis was granted an EMR for marketing *Glivec* in India (Nair et.al. 2014).

On procuring the EMR, Novartis obtained an injunction order from the Madras High Court impeding six (Cipla, Ranbaxy, Natco, Hetero etc.) of the nine generic producers from manufacturing, selling and distributing generic versions of *imatinib mesylate* (Chandra 2010). This move by Novartis instantly resulted in upsetting the market price of the drug making it unprocurable for most patients- *Glivec* cost Rs 1000 per 100mg capsule, approximately Rs 1.2 lakh per month and generic drugs at around about Rs 90 per 100mg capsule amounting to Rs 8000 per month (Chandra 2011).

Generic manufacturers like Natco pharmaceuticals joined hands with organisations like Alternative Law Forum, Lawyers Collective and the Cancer Patients Aid Association and filed a pre-grant opposition (Writ petition no.24759 of 2006 in the Madras High Court) against Novartis' patent application on *Glivec* when it came up for examination in 2005 (Grover 2013). Section 3(d) was invoked contending that *imatinib mesylate* was only a modification of an already existing drug and granting of patent to *Glivec* was plain violation of the health rights of the CML patients. In addition, they claimed that the non-availability and non-affordability of the drug is violative of the patients' rights under Article 14 (right to equality) and Article 21 (right to life and personal liberty) of the Constitution of India (Chandra 2011). Meanwhile, on examining the patent application filed by Novartis, the Assistant Patent Controller of Chennai Patent Office agreed with the arguments of the pre-grant opposition and observed that the drug *imatinib mesylate* was only a beta crystalline form of the salt form of *imatinib* and was neither novel nor inventive and was, therefore, not patentable according to Section 3(d) of Indian Patents Act, 2005 (Grover 2013).

Challenging the decision of the Patents Controller at Chennai, in May 2006 Novartis filed a writ petition in the Chennai High Court against the Government of India and the opponents. The three main issues contended were: patentability of *Glivec*, section 3(d)'s compliance with the TRIPS Agreement, and constitutional validity of section 3(d) (Chandra 2010). The Counsel for

Novartis (Shanti Bhushan and Soli Sorabjee) argued that the inherent ambiguity, vagueness and arbitrariness of Section 3(d) made it difficult to interpret accurately and therefore violated the Fundamental Right Article 14 (right to trade) of the Indian Constitution (Srinivasan 2007). But the Court, on 23 February 2007, stated that the first issue vis-à-vis TRIPS compliance was outside its jurisdiction and suggested it to be settled via mechanisms under Article 64 of the TRIPS, namely, Dispute Settlement Body. With regard to the second contention, the Court could not find any violation of Article 14 and the petition by Novartis was dismissed (Grover 2013).

The Intellectual Property Appellate Board (IPAB) (on 26 June 2009) also rejected patent to *Glivec* for lack of clarity that the 30% increase in bioavailability is an enhanced efficacy and the beta crystalline form of the mesylate salt is not an 'obvious' form of the free base form. Thus the transfer of court proceedings to IPAB as per Section 117G of the Patent Act also did not favour Novartis (Nair et.al. 2014). Until now, *Glivec* was denied patent by the Chennai Patent Office (2006), the Chennai High Court (2007) and the IPAB (2009) (Chandra 2011).

Seeking a favourable judgement and unwilling to yield to the rejections, Novartis filed the Special Leave Petition under Article 136 of the Constitution in the Supreme Court of India in 2009 (Appeal no. 20539-549). Novartis was represented in the Court by ex-Solicitor General of India Gopal Subramaniam and the aim was to prove before the Court that *Glivec* was a result of two inventions- from *imatinib* to *imatinib mesylate* and then from the latter to beta crystalline form (Grover 2013). However, on 1 April 2013, the Supreme Court of India produced an epic judgement rejecting patent to *Glivec*. Justice Aftab Alam and Justice Ranjana Prakash Desai ruled that *imatinb mesylate* was a known substance as per the Zimmermann patent and therefore does not qualify as an invention in terms of clauses (j) and (ja) of Section 2(1) of Indian Patents Act, 2005 (SCI 2013). Further, as concluded by Chennai Patent Office, Chennai High Court and the IPAB, the beta crystalline form did not satisfy the Section 3(d) criterion (Chandra 2010).

The judgement is historic since it clearly brings out the pharmaceutical sector as one which merits a justified differentiation while being dealt with under the patents regime. This has definitely ignited the hopes of the global civil society fighting for the human right to health. Secondly, the section 3(d) is observed by the legal community as a useful technical provision to catalyse decisions relating to drug patents.

A cause for failure of Novartis could be that when it applied for a patent for the beta crystalline form in India in 1998, it did not claim any therapeutic benefit since it was not required to do so at that stage because the Section 3(d) efficacy criterion was introduced much later. Since 2004, Novartis made some vain attempts to file affidavits to satisfy the requirement of Section

3(d) but it was not accepted (Chaudhuri 2013). Also, if instead of in April 1994, Novartis had filed the patent in the US a few months later after 1 January 1995 when TRIPS came into effect, the anti-cancer drug would have been eligible for a patent in India as a new substance and Section 3(d) would not have been applicable, till that patent expired. If Novartis does not introduce new drugs in the country that would be a good ground for issuing compulsory licence (Chaudhuri 2013).

It is a hopeful turn of events to note that Section 3(d) is being emulated by a number of countries including Argentina, Australia, Canada and Thailand, among others (Rangnekar 2013).

5. CONCLUSION

The major objective of this paper has been to examine the challenges and opportunities for India in addressing the issues of access to medicines in the context of the new global IPR regime. The recent Supreme Court judgement on the *Glivec* case exposed some new avenues in interpreting and appropriating the flexibilities in the TRIPS Agreement as upheld by the Doha Declaration.

It has been appreciated the world over that the Indian Patent Act of 1970 with its unique features like process patent, subject specific patent term, exclusion of subject matters of relevance to social/human rights like pharmaceuticals etc and provisions like compulsory licensing etc, was vital to the development of a flourishing generic drug industry in India. The Act was amended thrice to incorporate provisions in compliance with the TRIPS Agreement, permitting product patents in all fields of technology including food, chemicals, drugs and agrochemicals. During this amendment the Committee took some decisive measures to protect the interest of the nation. They increased the threshold of patentability by setting higher standards of 'novelty' and 'inventive step'. In this regard, the addition of Section 3(d) has emerged to be a crucial parameter in balancing pharmaceutical patenting with public health interests of the country.

The case of '*Glivec*' is an interesting illustration. Section 3(d) is being understood as a precautionary principle, expected to prevent a health emergency, with a stature above compulsory licensing and the developing countries are adopting the provision into their legislations. But many developed countries and pharmaceutical companies complain that it is non-compliant with TRIPS. The USTR maintains that it is incompatible with Article 27.1 of the TRIPS Agreement. It will henceforth be more difficult to indulge in evergreening in India with new forms of non-patented drugs or patent-expired drugs unless therapeutic efficacy is demonstrated. Few other successful cases of patent refusals also can be identified. The Gilead was rejected patent for Tenofovir on

the basis of pre-grant opposition based on Section 3(d). Erlotinib is another interesting case which is still being contented in Supreme Court. Other examples are Sitagliptin and Valganciclovir cases.

In brief, India has had a unique experience vis-à-vis intellectual property protection and generic drug industries. While the liberal outlook of the Indian polity and economy could not decline the TRIPS Agreement from being drafted and adopted under the WTO, the social and humanitarian commitments forced the country to devise ingenious ways around the new IPR regime that shall help sustain and promote the generic drug industry. It is not illogical to state that the Indian polity is suffering extreme degrees of compulsions from the global economy to modify national IPR regulations to better suit the developed country interests and it is only through a concerted effort from the generic companies, the national and international human rights and public health advocates, various organisations and beneficiary populations across the developing world that many of the anomalies could be restrained, if not removed altogether.

End Note

- ¹ a compound (small molecule, antibody, etc.) with strong therapeutic potential, best in potency and selectivity and whose activity and specificity have been optimised. End result of lead compound optimisation.

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Trends in Health Care Expenditure and Its Implications in India

V.Nagarajan Naidu*

Abstract

Healthy life of individuals as outcome in the society is determined by the amount and the way by which the allotted amount are spent in the society. In a society where the majority are deprived, the health outcome is influenced by the intervention of the government via various projects and schemes. The trends of expenditure on health care in India highlights the fact that it is not growing much in tune with the requirements on the one hand and on the other hand health expenditure is increasingly dominated by private sector. The growing private expenditure for health care facilities particularly the private out of pocket expenditure eats away the resources needed for other essential items of individuals and this may push them to poverty and deprivation. For the social protection of general mass for their health care facilities, the expansion of the role of government is warranted.

Key Words: Health expenditure, out-of-pocket expenditure, catastrophic expenditure, health insurance

1. INTRODUCTION

The globalisation of neoliberal development agenda has been taking place with renewed interest and support from multifarious global institutions in the recent past. The withdrawal of public or government from the provision of various basic services in the society is being witnessed. In many cases, the government institution is replaced by profit and market oriented private sector to meet the needs of society. Health is one of the vital services where from the withdrawal of

* Nagarajan Naidu is Associate Professor and Head, Department of Economics, University College Thiruvananthapuram, Kerala.

state is very prominent in the recent past both at global and national level. The withdrawal of the state from the provision of health care increases the out-of-pocket health care expenditure by individuals which adversely affect the living conditions of people particularly, the marginalised and downtrodden sections in the society. This issue has become more serious in a country like India where a good section of people have low purchasing power which prevent them from accessing the most essential services such as health care.

The paper is structured into five sections. The first section gives an introduction. The second section gives an outline on the various sources of financing of health care and a comparison of health care expenditure of India with other countries. The third section shows the trends in health expenditure at national level and state level in India. The fourth section shows the analysis of health care expenditure source wise. It also takes into account the various dimensions of health care expenditure including out of pocket expenditure. The fifth section gives the conclusion.

Expenditure on health is an inevitable factor to improve the health status with in a country. India has worked continuously to improve the health care system in the last several decades and considerable progress has been made in expanding the public health system and reducing the burden of disease. All the achievements or improvements made in the health system are always backed by huge investments in the health system of the country. The financing of the health care system takes place from various sources: (1) The tax based public sector that comprises local, state and central government (2) The private sector including the not-for-profit sector, organising and financing, directly or through insurance, the health care of their employees, and target population(3)Households through the out of pocket expenditure including user fees paid for public facilities (4) Other insurance- socialand community based and (5) External financing through grants or loans

Health expenditure of India at the global level

India's performance in the health sector requires much improvement in comparison with other emerging economies, including most comparable nations of the region. Deficiencies persist with respect to access, affordability, efficiency, quality and effectiveness, despite the high level of overall private and public expenditure on health. Table 1 shows the health expenditure and health indicators in selected countries.

Table 1: Health Expenditure and Health Indicators in Selected Countries

HDI Rank	Country	Health Expenditure as % of GDP		Per capita Expenditure on Health (PPP US \$)	Out of Pocket Expenditure as % of Private Expenditure	Life expectancy at birth	Infant Mortality Rate per 1000 live birth	Per capita GDP (\$)
		Public	Private					
1	Norway	6.9	1.2	2920	96.8	87.7	4	36974
2	Iceland	7.6	1.6	2643	55.2	79.6	3	27032
3	Sweden	7.5	1.3	2270	100	70.9	3	23680
4	Australia	6.2	3	2532	59.6	79	6	19054
7	USA	6.2	7.7	4887	26.5	76.9	7	34946
8	Canada	6.8	2.8	2792	52.3	79.2	5	22385
9	Japan	6.2	1.8	2131	74.9	81.3	3	32540
11	Denmark	7	1.5	2503	90.8	76.4	4	30265
13	UK	6.2	1.4	1989	55.3	77.9	6	24186
18	Germany	6.3	2.1	2204	82.1	78	4	22418
21	Italy	6.2	1	229	76.8	78.6	4	18928
52	Cuba	2.7	3.4	544	92.8	76.5	7	2234
55	Mexico	2.1	1.8	345	92.8	73.1	24	6150
58	Malaysia	2.2	2.2	458	81.2	72.8	8	3748
65	Brazil	3.2	4.4	573	64.1	87.8	37	2888
69	Azerbaijan	1.1	0.5	48	97.7	71.8	77	679
96	Turkey	3.6	1.5	204	98.8	70.1	36	2131
99	Srilanka	1.8	1.9	122	95	72.3	17	849
104	China	2	3.4	224	95.4	70.6	31	918
109	Vietnam	1.5	3.7	134	87.6	68.6	30	413
112	Indonesia	0.6	1.8	77	91.8	66.2	33	678
127	India	0.9	4.2	80	100	63.3	67	462
131	Myanmar	0.4	1.7	26	99.6	57	77	1027
139	Bangladesh	1.6	2	58	93.2	60.5	51	332
143	Nepal	1.5	3.6	63	93.3	59.1	66	231
144	Pakistan	1	3	85	100	60.4	84	401
169	Ethiopia	1.4	2.1	14	84.7	45.7	116	93

Source: World Health Report, 2009

The Table highlights the fact that there is close association between the level of health expenditure and the health status. In countries where the HDI and other indices of health improvement such as life expectancy are higher, the higher is the percapita health expenditure. In HDI ranking, Norway stands first followed by Iceland, Sweden, Australia, USA, Canada, Japan,

Denmark, UK, Germany etc. India's HDI ranking is 127th which indicate the poor performance in Human Development Indicators.¹

Health expenditure in terms of Gross Domestic Product (GDP) shows that it is very high among developed countries as compared to developing country like India. Also, the contribution of public sector in health expenditure is higher in developed countries, while the major portion of health expenditure of underdeveloped countries are met by the private sector. The public expenditure on health as per cent of GDP is highest in Denmark which is sevenper cent and lowest in Myanmar which is 0.4 per cent. In the case of India, the private expenditure on health as per cent of GDP is on the higher side i.e. of 4.2 per cent, whereas that of public expenditure is only 0.9 per cent. This brings out low public sector contribution in providing health facilities in India. The Table clearly shows that in most of the developed countries the public participation via expenditure on health is high. These countries are also characterized by good performance with regard to health indicators like life expectancy rate, infant Mortality Rate (IMR), per capita gross domestic product etc. On the other hand, less developed countries are characterized by high private expenditure, less per capita expenditure on health, high out of pocket expenditure etc. The human development indicators of LDC's have also shown poor performance.

2. TRENDS IN HEALTH EXPENDITURE IN INDIA

Among various sources of spending on health, the public sector spending has the leading and strategic role. Greater the public expenditure on health, greater will be the improvement in health standard of the people within the country. The data shows that, the expenditure on health constitute about 4.8 per cent of the total expenditure in 2009-2010 which is 1.38 per cent of the total GDP (*Economic Survey* 2011). Another important feature of the health spending in India is that, health expenditure in India is dominated by private spending. This would mean inadequate public spending on health (Chandrasekharar C.P and Jayati Ghosh 2006). In India, the fund flow to the health sector is dominated by the private funds, that is, about 71.62 per cent of the total health expenditure in 2008-09, while the public fund was only 26.70 per cent (Health Profile of India 2010). Another important feature of the health sector in India is that, the expenditure on health is not distributed equitably across the country. There are inter-state and inter regional disparities in the expenditure on health. The problem of unequal spending on health could be minimised only through the increased government spending, which is now only around twenty sixper cent of the total health expenditure. In the post reform period, greater initiatives have been taken by the governments (local, state and central) to promote health status of the citizens and effectively maintain and manage the policies formed for the purpose. The launching of the National

Rural Health Mission (NRHM) in 2005 is considered as a milestone in the health sector of the country. The NRHM was launched to provide, accessible, affordable and accountable quality health services to rural areas with emphasis on poor persons and remote areas. It is being operationalized throughout the country with special focus on eighteen states, which include eight empowered action group states (Bihar, Orissa, Jharkhand, Madhya Pradesh, Chhattisgarh, Uttar Pradesh, Uttarkhand and Rajasthan) and eight North Eastern states i.e., Himachal Pradesh and Jammu and Kashmir. The NRHM also aims to provide an over reaching umbrella to the existing programmes of Health and Family Welfare including the Reproductive Child Health project, Malaria, Blindness, Iodine deficiency, Filariasis, T.B., Leprosy and Integrated Disease Surveillance Programmes.

Table 2: Trends in Expenditure on Health 1950-51 to 2009-10

Sl. No.	Year	Health expenditure as per cent of GDP			Per Capita Public Expenditure on Health (Rs.)
		Revenue	Capital	Total	
1	1950-51	0.22	NA	0.22	0.61
2	1960-61	0.63	NA	0.63	2.48
3	1970-71	0.74	NA	0.74	6.22
4	1975-76	0.73	0.08	0.81	11.15
5	1980-81	0.83	0.09	0.91	19.37
6	1990-91	0.89	0.06	0.96	64.83
7	1990-96	0.82	0.06	0.88	112.21
8	2001-02	0.79	0.04	0.83	183.56
9	2003-04	0.86	0.06	0.91	214.62
10	2009-10	1.28	0.09	1.38	320.10

Note: GDP is at market price, which base year 1993-94

Source: (1) *Report on Currency and Finance*, RBI, Various Issues

(2) *Statistical Abstract of India*, Government of India, various issues

(3) *Handbook of Statistics of India*, RBI, various issues

(4) *Financing and Delivery of Health care services in India* (2005), NCMH.

The trends in health expenditure show that the expenditure on health as per cent of GDP is very meagre and negligible. The latest data shows that in India, the expenditure on health is only 1.38 per cent of the total GDP, which is comparatively low. During 1950-51 periods the expenditure on health was only 0.22 per cent of GDP and the whole expenditure was revenue in nature. Till the period 1970-71, the whole expenditure was revenue expenditure and there was no capital expenditure in health sector. Even today, a major chunk of health expenditure is in the form

revenue expenditure and meagre allocation to capital outlay adversely affects the health infrastructure facilities of the country.¹Though there has been increase in percapita health expenditure from Rs 6.22 in 1970-71 to Rs 320 in 2009-10, the amount is too inadequate as compared to actual requirement of the society.

Health expenditure of major states

The health sector falls under the concurrent list. Thus, the provision of public health care in India is a responsibility shared by both the central and state governments. The state governments very often account for more than two-third of the total public expenditure on health in India. The state government's expenditure on health includes expenditure on the medical, public health and family welfare. The Table3 gives the health expenditure in various states and union territories of the country.

Table 3: Total Expenditure on Public Health (Rs. in Millions)

State/Year	1981	1987	1991	1996	1998	2000	2006	2008
Andhra Pradesh	420.00	1400.56	629.18	1098.70	1410.23	1475.02	3946.6	11148.5
Arunachal Pradesh	25.00	28.39	23.17	70.04	70.12	NA	375.5	101.8
Assam	171.00	671.69	192.61	305.43	463.78	337.78	392.3	1609.5
Bihar	211.00	173.35	422.89	478.59	484.79	556.16	1770.4	671.0
Delhi	652.00	1298.15	414.92	1018.35	1836.88	3530.55	7205.0	NA
Goa, Daman & Diu	16.00	168.16	20.80	38.64	47.11	NA	NA	NA
Gujarat	251.00	1430.99	443.95	870.79	1160.69	NA	3865.7	8447.8
Haryana	206.00	496.78	136.93	221.25	499.71	499.31	4852.9	1638.5
Himachal Pradesh	112.00	417.01	84.74	175.80	238.55	289.01	2267.1	1324.4
Jammu & Kashmir	76.00	711.32	44.65	194.15	919.83	462.37	3029.4	2034
Karnataka	205.00	595.74	178.54	331.07	404.06	NA	3953.9	9643.8
Kerala	125.00	502.21	175.57	346.07	412.90	502.75	814.1	1153.6
Madhya Pradesh	638.00	1585.23	433.09	644.43	838.75	1428.67	1779.6	2631
Maharashtra	747.00	3387.95	1988.86	3653.10	4670.36	4808.10	3312.3	11015
Manipur	24.00	251.97	38.24	62.53	122.20	NA	98.1	678.6
Meghalaya	27.00	161.09	42.72	64.36	76.98	NA	473.6	670
Mizoram	36.00	154.70	22.19	48.58	NA	NA	240	1061.2
Nagaland	59.00	193.99	35.54	104.76	35.35	NA	156.3	330.3
Orissa	234.00	614.82	228.52	390.96	453.32	595.22	318.2	1895.6
Pondicherry	13.00	36.77	19.77	43.33	48.42	50.41	1133.2	995.7
Punjab	165.00	435.69	194.14	239.31	402.63	426.65	54.9	954.4
Rajasthan	345.00	1891.95	267.60	565.48	696.25	715.59	1985.4	3006.2
Sikkim	11.00	30.70	9.25	16.97	17.38	25.30	176.7	350.5
Tamil Nadu	243.00	975.80	559.21	972.17	1294.37	1743.82	4104.5	6686.7
Tripura	4.00	83.57	49.15	34.30	62.92	NA	370.3	1052.6
Uttar Pradesh	625.00	1578.41	1155.97	1771.26	104.95	NA	19466	18455.2
West Bengal	391.00	669.98	563.85	752.42	NA	1377.27	2687.1	5041.4
All INDIA	6032.00	21046.97	8376.05	14512.84	16772.53	18823.98	75712.7	102923.7

Note: NA - Not Available; Data for Chhattisgarh, Jharkhand, Uttaranchal are included in their parent state.

Sources: Govt of India (various years), *Finance and Revenue Accounts*, Comptroller and Auditor General of India

The trends indicate that most of the states and union territories experienced increase in the expenditure on health. It reveals two things. Firstly, the growth of public expenditure of different states is not in tandem with the rate of growth of population. Secondly, there exists a wide inequality in the health expenditure levels of various states located in different regions. Though there has been increase in health expenditure in absolute amount in all states over the period, except a few states, the actual growth rate of health expenditure was less than the population growth rate. As compared to other states in India, the growth of health expenditure was lower for all North Eastern states in India. The widening inequality in the percapita spending on health care is a serious issue in India. Also, the volume of money spent on health alone does not make the sufficient condition for the improved health status rather, what is also important is, improvement in the per capita health expenditure and development of infrastructure facilities, which is more accessible to the ordinary people.

3. SOURCES OF HEALTH EXPENDITURE

As per the flow of funds of health statistics, the important sources of health expenditures are broadly public, private and external sources. The public funds include the funds of centre, state and local government. The private funds include households, firms, social insurance and NGOs. The external sources comprise of central government, state government and NGOs. In India major share of the expenditure on health sector comes from the private sector. The data on health expenditure shows that, about seventy two per cent of the expenditure on health comes from the private sector (*Health Information of India 2011*). The largest source of funds coming from the private sector is households. The other sources of private funds are social insurance, firms and NGOs. Out of the total private expenditure on health sector, 71.13 per cent contributed by households, and firms share is 5.73 per cent, while the NGO's share is very meagre, i.e. 0.07 per cent. External flows contribute only a small portion of the health expenditure. It constitutes only 2.27 per cent of the total health expenditure. A study conducted by Dedes Mukhopadhyay, (Mukhopadhyay 2008) in India shows that, about ninety per cent of hospitals and sixty four per cent of the beds are in private sector. Less than ten per cent of the population enjoy the health facilities provided by the government. Roughly eighty per cent of the health care is sought in the private sector and almost same number of allopathic doctors working in this sector. He further explains that, even the under privileged poor people prefer to go to the private health providers, because no one want to trade off between one's health needs and financial ability.¹

Various sources of expenditure on health in relation to the total health expenditure and to GDP are good indicators for a comparative analysis. Trends in all these indicators are given in the Table 4.

Table 4: National Expenditure on Health in India (Indian Rupee)

SELECTED RATIO INDICATORS	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
1.Expenditure ratios														
(Total expenditure on health (THE) as % of GDP)	4.1	4.0	4.3	4.4	4.2	4.4	4.8	4.6	4.4	4.2	4.2	4.1	4.1	4.0
Financing sources measurement														
External sources of health as % of THE	1.3	0.2	1.6	1.6	1.3	0.5	2.3	0.3	0.7	2.3	1.4	1.3	1.4	1.7
Financing agents measurements														
General government expenditure on health (GGHE) as % of THE	26.2	25.1	24.7	25.3	26.2	24.5	23.8	22.8	23.2	22.5	23.8	24.9	26.2	28.0
Private expenditure on health (PvtHE) as % of THE	73.8	74.9	75.3	74.7	73.8	75.5	76.2	77.2	76.8	77.5	76.2	75.1	73.8	72.0
GGHE as % of general government expenditure	4.3	4.0	4.2	4.2	3.9	3.8	3.9	3.7	3.6	3.5	3.8	3.8	3.7	4.1
Social security funds as % of GGHE	15.2	16.2	15.2	15.4	16.4	16.9	16.4	17.6	18.2	18.7	17.2	16.9	17.2	15.6
Private insurance as % of PvtHE	1.1	1.2	1.1	1.1	1.1	1.0	1.0	1.4	1.8	2.1	2.1	2.1	2.1	2.2

Since 1991, the health expenditure as per cent of GDP was almost stable. It varied between only 4.0 per cent to 4.8 per cent. In 2008, the total health expenditure as per cent of GDP was just 4 per cent while the contribution of external sources was only 1.7 per cent. The general government expenditure (both centre and state) in total health expenditure was 26.2 per cent in 1995 and it remains almost steady at 28 per cent in 2008. The general government expenditure on health from the total expenditure was just 4.1 per cent in 2008 while it was 4.3 per cent in 1995. It implies that

the total government health expenditure from its total budgeted outlay has declined over this period. The contribution of social security fund in health expenditure witnessed wide fluctuation during this period. In 2008, the contribution of social security fund as per cent of general government expenditure on health was only 15.6 per cent. The private insurance as per cent of total private expenditure on health, though very low, has witnessed slight improvement over this period. It was increased from 1.1 per cent in 1995 to 2.2 per cent in 2008.

The pattern of health expenditure between public and private or household is not uniform across various states in India. The Table 5 provides the state/ UTs wise spending on health from different sources. The figures in the Table prove that the State level trend is similar to the Centre.

Table 5: Health Care Spending from Different Sources By State / UT Wise in India, 2004-05(as per cent)

Per cent spent by State	Household	Public	Other
Andhra Pradesh	73.4	19.4	7.2
Arunachal Pradesh	86.5	13.5	0
Assam	80.8	17.8	1.4
Bihar	90.2	8.3	1.5
Delhi	56.4	40.5	3.1
Goa	79.2	17.5	3.3
Gujarat	77.5	15.8	6.7
Haryana	85	10.6	4.4
Himachal	86	12.4	1.6
Jammu & Kashmir	77.3	20.7	2.0
Karnataka	70.4	23.2	6.4
Kerala	86.3	10.8	2.9
Madhya Pradesh	83.4	13.6	3.0
Maharashtra	73.3	22.1	4.6
Manipur	81.2	17.2	1.6
Meghalaya	36.5	58.4	5.2
Mizoram	39.4	60.6	0
Nagaland	91.7	7.60	0.7
Orissa	79.1	18.0	2.9
Punjab	76.1	18.0	5.9
Rajasthan	70.0	24.5	5.5
Sikkim	56.9	43.1	0
Tamil Nadu	60.7	26.6	12.7
Tripura	69.0	27.4	3.6
Uttar Pradesh	84.3	13.0	2.7
West Bengal	78.4	17.3	4.3
Union Territories	85.1	8.8	6.1

Source: *National Health Profile, 2010*

The general trend shows that, in most of the states and Union territories, the major share of the health care spending comes from the households (private sector). The data for the period 2004-05 shows that, Meghalaya and Mizoram are only two states in which the public spending on health is greater than the private spending. In all other states the household spending on health dominates over the public spending. In Meghalaya and Mizoram, the household spending on health was 36.5 per cent and 39.4 per cent respectively of the total expenditure on health while the public spending was 58.4 per cent and 60.6 per cent respectively in these states.

Among various states, some states have household expenditure on health above 90 per cent of the total health expenditure. In states like Bihar and Nagaland, the households spend more than ninety per cent of the total health spending i.e., 90.2 and 91.7 respectively. In states like Arunachal Pradesh, Assam, Haryana, Himachal Pradesh, Kerala, Madhya Pradesh, Manipur, Uttar Pradesh and Union Territories, the household expenditure varies between eighty per cent and ninety per cent respectively. In states, like Arunachal Pradesh, Goa, Gujarat, Jammu and Kashmir, Karnataka, Maharashtra, Orissa, Punjab, Rajasthan and West Bengal, the household expenditure on health vary between seventy per cent and eighty per cent of the total expenditure on health. In states like Tripura and Tamil Nadu, the household expenditure on health varies between sixty per cent and seventy per cent. In Tamil Nadu, the public expenditure on health is 26.6 and household spending is 60.7 per cent of the total expenditure on health in the state. Thus, throughout the country, the private share in health spending is higher.¹

Health insurance in India

The role of insurance in health sector has been increasing at a rapid scale since 1991. There are different types of health coverage prevail in India. Based on the ownership of the existing health insurance schemes, this can be broadly divided into four categories (Mavalavakar, Dileep and Ramesh Bhat 2000). (1) Government or health base systems (2) Market based systems (Private or Voluntary) (3) Employer provided insurance schemes and (4) Member organisation (NGO or corporative) based systems. The government or state based systems include Central Government Health Schemes (CGHS) and Employees State Insurance Schemes (ESIS). In the market based system, there are voluntary and private participation. The employer provided insurance schemes are seen in both public and private sector. These are common for large public and private enterprises. In the NGO or corporative based insurance system, the members repay a set of amount each year for specified services. The premium are usually at flat rate (not income related) and therefore, not progressive.

At present both the private and public insurance companies play equally important role in providing health insurance in India. The result is expanded coverage of health insurance and more insured against the financial loss due to bad health. At the same time the expenditure on the health insurance scheme have also increased. The Table 6 gives a trend in the expansion of coverage under health insurance in India since 2007.

Table 6: Coverage Under Health Insurance in India 2007-08 to 2009-10

Sl. No.	Insurer	Premium (Rs.in Lakh)			Policies		
		2007-08	2008-09	2009-10	2007-08	2008-09	2009-10
1	Royal Sundaram	10860.61	11445.55	11611.00	252258	242182	255136
2	TATA-AIG	6890.50	7895.30	8339.00	361687	393702	293905
3	Reliance	27561.96	31082.85	23874.80	693339	766114	973004
4	IFFCO Tokio	11402.43	14098.88	16421.60	63002	77442	69603
5	ICICI Lombard	88461.07	103170.00	91180.93	933446	808701	633007
6	Bajaj Allianz	24325.35	33201.85	29539.01	899851	2182676	1588019
7	HDFC ERGO	2810.09	4549.76	26874.10	693	2826	134245
8	Cholamandalam	10938.39	16588.88	14951.22	21001	22128	29530
9	Future Genrali	0.00	4125.36	6932.41	0	9854	44234
10	Universal Sompo	0.13	324.20	1740.02	2	4524	36184
11	Shriram General		0.00	0.00		0	0
12	Bharti Axa General		150.72	3519.50		280	9771
	Sub Total (Private)	183250.53	226633.35	234983.59	3225279.00	4510429.00	4066638.00
13	New India	120942.17	135584.97	154190.27	1534833	1555784	1446268
14	National	68470.40	85401.78	102171.36	852094	928555	1150405
15	United India	69494.46	90072.09	125614.00	2374428	2926342	3253338
16	Oriental	54743.82	71345.00	106350.66	650617	741251	745013
	Sub Total (Public)	313650.85	382403.84	488326.29	5411972.00	6151932.00	6595024.00
	Total (Public+private)	496901.38	609037.19	723309.88	8637251.00	10662361.00	10661662.00
17	Star Health	15295.49	49073.29	96552.54	149837	292971	562386
18	Apollo DKV	298.10	4435.34	10642.91	3260	39570	1301201
19	Max BUPA			12.74			253
	Grand Total	512494.97	662545.82	830518.07	8790348.00	10994902.00	12525502.00

Source: IRDA, Hyderabad, Andhra Pradesh

The Table depicts the premium and policies obtained by various insurers. It can be well understood from the Table that, the public sector units lead in the number of premium and policies. In the case of number of policies, the public sector units together hold the first position. Among the public sector units, New India Insurance leads in the number of premium and, United India Insurance leads in the number of policies. On the other hand, among the private sector insurance companies ICICI Lombard lead in the number of policies. If we compare the companies in both the public sector and private sector individually, in the case of premium, New India Insurance occupies the first position and United India Insurance holds second position. On the other hand, with regard to

policies United India Insurance occupies the first position and Bajaj Allianz has taken the second position. Another important trend we find in the Table is that, in some companies the amount of premium has declined, though the number of policies had increased whereas some companies experienced rise in number of premium and decline in number of policies. In total, the trend shows that the health insurance has an increasing trend both with respect to amount of premium and number of policies.

Out of pocket expenditure

The out of pocket expenditure is the part of the private health expenditure. In India, it is the single largest share in the total health expenditure (National Health Account 2004-05). The out of pocket expenditure will take into account the patient side cost of treatment for diagnosis, consultation, drugs, transportation, hospital stay, and food and escort. Out of pocket payments are expenditure borne directly by a patient, where insurance does not cover the full cost of the health good or service (OECD 2009). The out of pocket expenditure become catastrophic, when it exceed certain limit of the disposable income. In OCED study (OCED 2009) the catastrophic health expenditure is commonly defined as payments for health services exceeding 40 per cent of the household disposable income after subsistence needs to meet.

Table 7: Out Pocket Expenditure as Per Cent of Private Health Expenditure, 1995 to 2008

Sl. No	Year	Out of Pocket Expenditure as per cent of Pvt. HE.
1	1995	91.4
2	1996	91.0
3	1997	92.0
4	1998	91.9
5	1999	91.3
6	2000	92.2
7	2001	92.7
8	2002	92.3
9	2003	91.7
10	2004	89.6
11	2005	90.1
12	2006	90.0
13	2007	89.9
14	2008	89.5

Source: *National Health Accounts Report*, MOHFW, GOI

Table 7 provides trend in out of pocket expenditure as per cent of private health expenditure in India. It is clear from the Table that more than ninety per cent of the private health expenditure is out of pocket expenditure. In 1995, it was 91.4 per cent and in 1996 and it declined to 89.5 per cent in 2008. The declining trend in out of pocket expenditure means more is spent on consumption and improvement in the health status of the people. Since private sector contributes more than seventy five per cent of the health expenditure and within the private sector, out of pocket expenditure constitutes ninety per cent, we can broadly say that, out of pocket expenditure is the major component in the health expenditure of India.

Now, let us have a glance at out of pocket expenditure on India on various health care services like out-patient care, in-patient care, delivery, antenatal and post natal care, abortion and still births, immunisation and family planning services. This is given in the Table 8.

*Table 8: Out Of Pocket Expenditure on Health Care by Households 2004-05
(in Rs. 1000)*

Expenditure on Health Care	Total	% Distribution	Per Capita Expenditure (in Rs.)
Out-Patient Care	614,774,538	66.10	564.53
In-Patient Care	218,333,032	23.48	200.49
Delivery care	31,925,528	3.43	29.32
Post Natal Services	5,808,715	0.62	5.33
Anti Natal care services	12,543,534	1.35	11.52
Abortion and Still births*	40,220	0.00	0.04
Immunization	4,851,318	0.52	4.45
Family Planning Services**	26,279,373	2.83	24.13
Medical attention at Death***	15,446,918	1.66	14.18
Total Expenditure on Health	930,003,177	100.00	853.99

Notes:

*Estimates based on the total number of pregnant women and number of deliveries

** Data available from NFHS-3 on family planning and their average expenditure

*** Health expenditure incurred by households on the members who died during the previous year.

Source: *National Health Accounts Report 2004-05*, MOHFW, GOI

The Table 8 gives the detailed idea regarding the out of pocket expenditure on various health care services during 2004-05. Out of various health care services, the expenditure on outpatient care stands first. The expenditure on outpatient care constitutes 66.10 per cent of the total out of pocket expenditure in India. The second position goes to inpatient care which constitutes 23.48 per cent of the total out of pocket expenditure on health. Out of the total out of pocket expenditure in India, 3.43 per cent on delivery care, 0.62 per cent in post natal services, 1.35 per cent on Anti natal care services, 0.52 per cent in Immunisation 2.83 per cent on family planning

services and 1.66 per cent is expenditure on medical attention at birth. The Table also gives the per capita out of pocket expenditure on various health care services. Thus, based on the data given on out of pocket expenditure on health of 2004-05, it can be understood that out of pocket expenditure constitute more than two third of the health expenditure in India.

In some cases the out of pocket expenditure become catastrophic, which in turn may have an adverse impact upon the level of consumption of the people. Therefore, people who live below poverty line may find difficult to meet their survival needs, if they have to make huge out of pocket expenditure. Thus, the out of pocket expenditure which is more catastrophic in nature may have a tendency to make people poor and the poor people to become poorer. This problem is very critical in the rural part of the country, which constitute more than sixty two per cent of the out of pocket expenditure in India (*Health Account of India 2004-05*). This situation necessitates more government funding for health programmes to prevent people from acute poverty driven by catastrophic health care spending.

4. CONCLUSION

A well developed health care system is an asset to every nation, because it plays an inevitable and strategic role in the development process. In order to maintain a good health status, it is essential to make huge investment on health related aspects. Expenditure can improve the health status of the population directly by reducing mortality, fertility and morbidity. At the individual level, spending on health care is a major factor which not only determines the physical health status of individuals but also the economic status of the concerned individuals for future sustenance. Health expenditure consists of all expenditures or outlays for medical care, prevention, promotion, rehabilitation, community health activities, health administration and regulation and capital formation with the predominant objective of improving health.

Globalisation and transition from a planned economy to a market economy has increased the distress of the poor sections. Many health care markets in transitional countries are insufficiently regulated. As a consequence, some healthcare providers exploit patients to the extent that they are pushed into poverty. Most governments fail to fund their health sector adequately because of limited budgets, excessive faiths in market forces or other priorities. Consequently, many public care facilities are run down or they generate revenue by charging patients. Due to increasing cost of health care, the health expenditure becomes catastrophic, which is cited as one important reason for households to fall into poverty.

Since independence, the health scenario in India started to change rapidly. India built up a vast health infrastructure and health personnel at primary, secondary and tertiary care in public, voluntary and private sectors. At present the life expectancy in the country has doubled and infant mortality rate and crude death rate have been greatly reduced. India has successes in the complete abolition of mass killing diseases like plague, cholera, small pox and substantial control over diseases such as malaria, tuberculosis etc. However, these improvements can only be seen in a relative sense because the absolute health status of the Indian population remains poor, which partly reflects supply side constraints. A comparison with Brazil, Russia, India, and China (BRIC) economies shows that India has the highest child mortality and the proportion of women receiving antenatal care at least once is far lower compared to China and the Latin American and Caribbean

nations. The most striking weakness of our public health system has been its failure to reach the bottom of the pyramid, that is, to almost 300 million poor people of the country. These people are mostly live in rural areas and in urban slums and are forced to incur high costs for private healthcare. High out of pocket expenditure is one of the most important reasons why people are pushed into poverty. The case of SCs, STs, and OBCs, which account for 70 per cent of the total population, is no different. They are in fact, more prone to poor health outcomes, particularly due to their low socio-economic status.

In India, the health care sector is constituted by both public and private sector. The larger share of the health expenditure comes from private individuals. The health services in the public sector, that can be assessed free or for nominal fee are grossly inadequate. As a result, most Indians access private health care that is expensive, unaffordable, unreliable and impoverishing. The greater dependence on private health care sector has increased the out of pocket expenditure and may ultimately impose a financial burden on individuals. For the attainment of better health standard what we require is increase in government spending. The trends in health expenditure show that the expenditure on health as per cent of GDP is very meagre and negligible.

In India, out of pocket expenditure is the single largest share in the total health expenditure. Out of pocket payments are expenditure borne directly by a patient, where insurance does not cover the full cost of the health good or service. In some cases the out of pocket expenditure become catastrophic, which in turn may have an adverse impact upon the level of consumption of the people. Therefore, people who live below poverty line may find it difficult to meet their survival needs, if they have to make huge out of pocket expenditure. Therefore, the out of pocket expenditure which is more catastrophic in nature may have a tendency to make people more poor and poor people to make further poorer. This problem is very critical in the rural part of the country, which constitute more than sixty two per cent of the out of pocket expenditure in India. Therefore, government need to finance many programmes, which would effectively regulate or reduce the catastrophic spending of the people in India.

End Notes

- ¹ The close association between HDI and health sector improvement is applicable, also at sub-national level in India. For example, the state of Kerala has recorded a very high HDI status along with significant improvement in health sector indicators such as child mortality rate, maternal mortality rate, death rate etc.
- ² Along with the quantity of health expenditure, focus must be given for the quality of expenditure. The quality of health expenditure is influenced mainly by the pattern of health expenditure between revenue and capital components. The increase in revenue component highlights the increased spending towards the recurring items such as salary, which adversely affects the accumulation of productive capacity of this sector. Spending will have to be diverted for capital components for enhancing the productive capacity of the society and in turn which may provide more services to achieve the societal ends.

- ³ This highlights the fact that not only there must be an increase in public expenditure on health sector infrastructure facilities but also enhancing the quality of these spending.
- ⁴ One interesting inference derived from this is that the public expenditure does not influence much on the present level of health status of many states. In those states where there is high HDI and health status, the private health expenditure is also very high.

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Impact of Cross Border Mergers and Acquisitions (M&A) in Pharmaceutical R&D: A Case Study of Ranbaxy Laboratories

Syama Muralidharan

Abstract

The pharmaceutical industry has been one of the innovative industries, which have remained relatively fragmented for a long period of time. But in recent years, there have been an increasing trend of concentration through mergers and acquisitions as firms consider Mergers and Acquisitions (M & A) as an effective ways to grow rapidly. The three main objectives necessitating any M & A transaction for corporate were found to be improving revenue and profitability, faster growth in scale and quicker time to market, and acquisition of new technology or competence. The Indian pharmaceutical sector experienced a boom in M&A-led restructuring strategies especially after liberalization due to the presence of big MNCs and post TRIPS pressure on the domestic firms. The Pharmaceutical industry in India has witnessed considerable consolidation with mergers and acquisition by foreign companies in India and Indian companies abroad mainly for strategic marketing reasons. This paper examines the impact of mergers and acquisitions on R&D activities in Indian Pharmaceutical industry taking Ranbaxy-Daiichi acquisition as a case study.

Key Words: Mergers & Acquisitions, Ranbaxy Laboratories, Daiichi Sankyo, R&D, Patent.

1. INDIAN PHARMACEUTICAL INDUSTRY- AN OVERVIEW

The Indian pharmaceutical industry is one of the largest and most innovative industries with more than 20000 registered units. It meets around 70 percent of the countries demand for bulk drugs, drug intermediaries, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. India is one of the largest suppliers of generic drugs¹ abroad. The growth of generic drug market in India could be seen after the introduction of Indian Patent Act 1970².The Patents

* Author is a faculty member at St. Thomas College, Ranni, Kerala. Email – syama989@gmail.com

Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972. The Act was the result of the two committees namely Patent Enquiry Committee³ and the Ayyangar Committee⁴. One of the major recommendations of the Act was the introduction of process patents with regard to inventions relating to drugs, medicines, food and chemicals. This replaced the existing Patent and Designs Act 1911⁵, which followed product patent. In the absence of product patent protection, the Indian pharmaceutical industry was able to introduce generic version of the patented drugs in the Indian market and abroad within a short period of time at a fraction of the originator's price. This had contributed to widespread growth of generic pharmaceutical industries after 1970s, also making available medicines to the public at very low cost.

India became signatory to the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization in 1995. Membership in WTO was expected to result in free flow of trade, investment and technical know. In order to fully comply with the TRIPs agreement India had to amend the Patents Act 1970 thrice. The first two amendments to the patent legislation took place in 1999 and 2002 to accommodate 'exclusive marketing rights' (EMRs) and to extend the patent protection for the 20 years respectively. It was amended again in 2005. A significant change in intellectual property protection in India was the reinstatement of product patents for the first time since 1972. The legislation took effect on the deadline set by the TRIPs agreement, which mandated patent protection on both products and processes for a period of 20 years. For developing countries like India, the deadline for complying with TRIPs was 2000. In addition, Article 65.4 of TRIPs provided a special transitional provision for those countries that did not grant product patents. The provision provided an additional five years (until 2005), from the initial TRIPs transitional period to introduce product patent protection. (Chaudhari 2005) The reintroduction of product patentability takes away the freedom of Indian pharmaceutical companies to introduce generic versions of new chemical entities (NCEs) in the normal course because NCEs often come with product patent protection. The product patent regime was believed to encourage global multinationals to outsource some of their drug manufacturing and clinical trials to India and enter into appropriate partnerships with Indian companies.

2. M&A IN INDIAN PHARMACEUTICAL INDUSTRY

The reform process started in India during 1990s has influenced the functioning of Indian companies, and has resulted in the adoption of different growth strategies by the corporate enterprises. Thus, the importance of Mergers and Acquisitions has undergone a transformation since liberalization in India. The MRTP Act⁶ and other legislations implemented in India has been amended paving way for large business groups and foreign multinational companies to turning to the M&A route for growth. Apart from these changes India amended its patent law in 2005,

bringing them into conformance with the WTO TRIPs agreement. This law forced Indian firms to change their business strategies and they focus on the generics market in Europe and the USA, invest more in innovative R&D and target contract manufacturing market. All these developments have contributed to corporate control in India. In the Indian pharmaceutical industry, a number of companies have entered into merger and acquisition agreements. Multinational companies like GlaxoSmithKline (GSK) Baxter, Aventis, Pfizer, Novartis, Wyeth, and Merck were active in India's pharmaceutical market mainly through subsidiaries especially after the new patent law of 2005. Many big Indian pharmaceutical companies were taken over by foreign firms. In Indian pharmaceutical industry 322 M&A deals took place between 2001 and 2013. Out of the total deals, the number of mergers is 125 (38.82 percent) and number of acquisitions is 197 (61.12percent). Share of pharmaceutical industry is also highest among all the other industries participating in M&A in manufacturing sector during this period. The largest ever acquisition in Indian pharmaceutical sector was Ranbaxy- Daiichi Sankyo deal.

3. THE RANBAXY- DAIICHI ACQUISITION DEAL

Ranbaxy Laboratories Ltd is the largest pharmaceutical company in India founded by Gurbax Singh and Ranbir Singh. It develops, and markets generic, branded generic, value-added and Over-the-Counter (OTC) drugs⁷, anti-retrovirals⁸ (ARVs), Active Pharmaceutical Ingredients⁹ (APIs), and intermediates. Ranbaxy is a research-based international pharmaceutical company having a strong talent pool dedicated to conduct research on generic medicines and also has a research foundation by the name RLL Research Foundation. Ranbaxy has its presence felt not only in the domestic market but also in the international pharmaceutical market with operations in over 49 countries and customers in above 150 countries.

Daiichi Sankyo is the second largest pharmaceutical company in Japan and twenty second largest in the world. Daiichi Sankyo uses its knowledge and expertise in the fields of cardiovascular disease, cancer, metabolic disorders, and infection as a foundation for developing a rich product line-up and R&D pipeline.

Ranbaxy Laboratories Ltd was bought by Daiichi Sankyo for a sum of \$4.9 billion on 11 June, 2008. The rationale for such an acquisition was simple synergy that could benefit both the pharmaceutical giants to gain a firm foothold in the international market. With the acquisition, Daiichi got access to Ranbaxy's basket of 30 drugs for which the company had approvals in the US, including 10 drugs for which Ranbaxy had exclusive sales right to sell for six months after the expiry of their patents. It also helped in better planning of inventory, launch quantities and supply agreement.

4. IMPACT OF ACQUISITION ON R&D IN RANBAXY LABORATORIES

Research activity in Ranbaxy was initiated in 1973. It established the first R&D centre in 1994. It has a multidisciplinary research centre at Gurgaon with facilities for generic research and innovative research. Between 1996-97 and 2002, the total R&D expenditure of Ranbaxy was Rs. 5.46 billion. In 1998, Ranbaxy became the first company from India to launch prescription products under its own label in the United States. It has been the leader in the Indian markets since then and was among the top ten globally.

Ranbaxy's research and development activities are focused towards five areas, viz., New Drug Discovery Research (NDDR), Pharmaceutical Research, Chemical & Fermentation Research, Herbal Drug Research, and Novel Drug Delivery Systems (NDDS). Ranbaxy's NDDR research program focuses on four therapeutic segments viz. metabolic diseases, respiratory diseases, oncology and infectious diseases. The R&D expenditure of Ranbaxy was negligible during the pre-TRIPS period (Rs. 35.01 crores in 1995) (Geetanjali & Sahastabudhe 2012). This was because the Patents Act of 1970 did not grant product patents and recognized only process patents. Consequently, the Indian pharmaceutical industry did not invest highly on R&D of drugs as the legal provisions allowed production of generic drugs. However, with the TRIPS Agreement, change in patent laws and policy scenario, the industry was forced to change its business strategy thereby recognizing the importance of R&D and gradually started increasing its investments in R&D in order to ensure long term sustainable growth and remain competitive at the global level. The company steadily increased its R&D expenditure from Rs.35 crores in 1995 to Rs. 45.64 crores in 2000, which is a percentage increase of over 30% within a period of five years (Geetanjali & Sahastabudhe 2012).

Table 1: R & D Expense of Ranbaxy before Acquisition

Year	R&D Expenses (Million)	R&D expenditure as a percentage of total expenditure
2002	1,686.29	5.64
2003	2380.49	8.57
2004	3313.85	10.81
2005	4863.60	14.55
2006	3863.34	11.33
2007	4139.44	10.91

Source: Various Annual Reports of Ranbaxy Laboratories Ltd.

An analysis of R&D expenditure of Ranbaxy Laboratories Ltd. from 2002 to the acquisition year reveals that the R&D expenses as a percentage of total expenditure increased over the year. In the year 2002, it was only 5.64 percentage of total expenses of the company, which gradually increased and reached 14.55percentage in 2005. During the year, the Company accelerated its drug discovery programs in the therapeutic areas of Infectious Diseases (Anti-bacterials and Anti-fungals), Urology (Benign Prostatic Hyperplasia and Urinary Incontinence), Metabolic Diseases (Type 2 Diabetes ,Hyperlipidemia) and Inflammatory / Respiratory Diseases (Asthma, Chronic Obstructive Pulmonary Disease [COPD]and Rheumatoid Arthritis). To provide the requisite growth momentum to the research activity, a state-of-the-art R&D center, dedicated to New Drug Discovery Research, was commissioned during the year. Ranbaxy made significant progress in its NDDS programs in 2005. The Company launched 4 products in India in the area of Oral Controlled Release Systems, of which 3 were developed in-house and 1 was outsourced. These were : Contiflo OD(Tamsulosin 0.4 mg + Finasteride 5 mg)Capsules; Desval ER(Divalproex Sodium 750 mg) Tablets; Pioglar MF(Pioglitazone30 mg + MetforminS R500 mg) Tablets; Selzic OD(Oxcarbazepine150 / 300 / 600 mg) Tablets. After 2005, R&D expenditure of Ranbaxy in proportion to total expenditure has decreased and reached 10.91 percentage in 2007. During these years company face some crisis related to U.S FDA inspection at its manufacturing facility at Paonta Sahib in Himachal Pradesh and consequent issuance of warning letter citing violation of FDA regulations at the facility. In spite of all these problems, company's R&D expenditure in proportion to total expenditure in the pre-acquisition period has remained more than 10 percentage in almost all years.

Table 2: Intellectual Property Generated by Ranbaxy before Acquisition

Year	Application Filed				Granted			
	India	US	Others	Total	India	US	Others	Total
2002	61	19	56	136	7	8	20	35
2003	108	17	23	148	61	6	-	67
2004	157	15	12	184	36	5	-	41
2005	185	-	-	185	7	5	-	12
2006	125	2	-	127	5	4	-	9
2007	122	-	-	122	3	4	-	7

Source: Various Annual Reports of Ranbaxy Laboratories Ltd.

Data regarding Intellectual Property generated by Ranbaxy before acquisition reveals the fact that the number of application filed as well as patent granted were high, depicting strong innovation initiatives undertaken by the company. But after 2005 it showed a declining trend. By the end of 2007, it had “first to file” (FTF)¹⁰ status for 18 drugs and 98 Abbreviated New Drug Applications (ANDA)¹¹ filings that are awaiting approval. Ranbaxy’s Herbal Drug Discovery division also successfully launched two products (Chericof Herbal and Chyawan Active) in the Indian market and three products in the international market. Ranbaxy’s Herbal Drug Discovery division alone filed 11 patents in 2007. Ranbaxy has been honoured with several titles such as “Most Respected Company of the Year” and was one of the “Most Innovative Company of the Year” in 2007.

Table 3: R&D after Acquisition

Year	R&D Expenses (Million)	R&D expenditure as a percentage of total expenditure
2008-09	4713.74	8.97
2009-10	4943.82	11.94
2010-11	4978.90	9.74
2011-12	4529.22	6.2
2012-13	4490.41	7.07

Source: Various Annual Report of Ranbaxy Laboratory Ltd.

R&D expenditure of Ranbaxy was 4713.74 million in the acquisition year. In 2008, Ranbaxy launched 54 new products in the domestic market of which 19 were developed in-house, 28 were out sourced and seven were in-licensed. In USA, six ANDAs including one PEPFAR-ANDA and one potential Para-IV FTF were submitted. R&D expenditure increased to Rs. 4943.82 million in the year 2009, i.e., 11.94% of total expenditure. It declined to 9.74% of total expenditure in 2010 and further declined to 6.2% in 2011. The reason behind this drop is that after the first successful NDDS product Ciprofloxacin, there were hardly any other returns from the huge R&D investments Ranbaxy was making. In 2012 there was a slight increase in R&D expenditure to 7.07%. Ranbaxy in 2012 launched Synriam™, India’s first new drug for the treatment of malaria. Ranbaxy created differentiation product through R&D to offer significant patient benefits and gain competitive advantage. Absorica™ is a successful example of a differentiated product by Ranbaxy that was approved by the US FDA and launched during 2012. In short, R&D expenditure as a percentage of total expenditure of Ranbaxy Laboratories was high in the initial years of acquisition but it showed a declining trend in the remaining years.

Table 4: Intellectual Property Generated by Ranbaxy after Acquisition

Year	Application Filed	Granted			Total
	Total	India	US	Others	
2008	79	-	6	-	6
2009	120	-	9	-	9
2010	85	-	5	-	5
2011	73	-	4	-	4
2012	84	-	4	9	13

Source: Various Annual Reports of Ranbaxy Laboratories Ltd

During the initial years of acquisition, the number of Intellectual Property generated by Ranbaxy Ltd was marginal. In 2008 only 6 were granted permission out of 79 applications. It increased to 9 in 2009. In 2012, 13 applications got approval out of 84. IP generated as well as granted was low as compared to the pre acquisition period which reveals the fact that company's performance in R&D activities was severely affected and it challenged the general assumption that R&D intensity of merged firms would be higher than non-merged firms in the industry. An analysis of R&D expenditure and number of Intellectual Property generated by Ranbaxy Laboratories Ltd before and after acquisitions reveals the fact that R&D activities of the company hardly made any progress after acquisition.

5. CONCLUSION

Initially the Ranbaxy deal seemed a win-win strategy, which allowed both companies to use each other's networks and technological power. The deal seemed very lucrative for Daiichi Sankyo due to the access to best FTF pipeline, access to the generics product line, access to new markets and an opportunity to diversify away from Japan into the emerging markets. It helped Daiichi to utilise its innovative drug making capabilities and R&D expertise with Ranbaxy's low cost manufacturing abilities to achieve a competitive position in the world generic drug market. The Global Hybrid Business model was launched by Ranbaxy and Daiichi Sankyo with collaborating on the front end in key markets as well as the back end in R&D, supply chain, IT and social contribution in order to realise synergies and save costs for both the companies. But this acquisition deal has made no such significant changes in innovation activities in Ranbaxy in the following years (except the launch of Synriasm™, Absorica™). In short firms pursuing growth through Mergers & Acquisition strategies reduce their commitment to innovation by purchasing businesses in less R&D-intensive environments. Firms use acquisitions as a substitute for innovation since they can move into markets that are new to the firm but that do not require innovation.

End Notes

- ¹ Generic drugs are copies of brand name drugs that have exactly the same dosage, intended use, effects, route of administration, risks, safety, and strength as the original drug.
- ² Provisions of Patent Act 1970 are (1) only process patent and not product patent to be allowed in food, medicines & chemicals, (2) term of Patent is 14 years and for chemicals and drugs, it is 5-7 years (5 years from it is being granted / 7 years from application, whichever is shorter) and (3) automatic licenses of right could be issued 3 years after granting of the patent.
- ³ This Committee was presided over by Dr. Bakshi Tek Chand, a retired Judge of the High Court of Lahore, and consisted of six others with Shri K. Rama Pai, former Controller of Patents as a Member-Secretary. The Committee submitted an interim report in August, 1949 suggesting the immediate amendment of the Patents and Designs Act, 1911 with a view to counteract the misuse or abuse of patent monopolies in India by the enactment of provisions for compulsory licensing. The Government accepted this recommendation which resulted in the amended sections 22, 23 and 23A to 23G of the Indian Patents and Designs Act, 1911 (vide Act 32 of 1950).
- ⁴ In 1957, the Government of India appointed Justice N. Rajagopala Ayyangar Committee to examine the question of revision of the Patent Law and advise government accordingly. The report of the Committee, which comprised of two parts, was submitted in September, 1959. The first part dealt with general aspects of the Patent Law and the second part gave detailed note on the several clauses of the lapsed bills 1953. The first part also dealt with evils of the patent system and solution with recommendations in regards to the law. The committee recommended retention of the Patent System, despite its shortcomings.
- ⁵ In the Indian Sub-continent, the Patents and Designs Act was enacted in 1911 mainly on the basis of the principles laid down in the Statute of Monopolies, Patents, Design and Trade Marks Act, 1883 and Patents and Designs Act, 1907. It recommended product patent for all inventions, including foreign inventions, for a period of 16 years from the date of application.
- ⁶ The Monopolies and Restrictive Trade Practices Act (MRTP Act) was passed by Parliament of India on 18 December 1969 and got president's assent on December 27, 1969. But it came into force from June 1, 1970. It aims to prevent concentration of economic power to the common detriment, provide for control of monopolies and probation of monopolistic, restrictive and unfair trade practice, and protect consumer interest. The threshold limit for describing a unit as monopolistically large was fixed at Rs. 200 million. The prior approval of the Central government became mandatory for the establishment of new undertakings, expansion of new undertakings, mergers, amalgamations and takeovers, and the appointment of directors in certain cases. It was amended in 1991 and was then replaced by the Competition Act, 2002.
- ⁷ OTC drugs are medicines sold directly to a consumer without a prescription from a health professional.
- ⁸ An agent or process effective against a retrovirus.

- ⁹ WHO defined API as “any substance or combination of substance used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in resorting, correcting or modifying physiological functions in human beings”.
- ¹⁰ Under first to file system, the right to the grant of a patent for a given invention lies with the first person to file a patent application for protection of that invention, regardless of the date of actual invention.
- ¹¹ ANDA is an application for a U.S. generic drug approval submitted to U.S Food and Drug Administration for an existing licensed medication or approved drug. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

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 - 1) Hoffmann, Steven (1990): *India and the China Crisis*, Oxford University Press, Delhi.
 - 2) Bhalla and Hazell (2003): "Rural Employment and Poverty: Strategies to Eliminate Rural Poverty within a Generation", *Economic and Political Weekly*, Vol.33, No.33, August 16, pp.3473-84.

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E-mail: ijsaspu@gmail.com; mohapillai@gmail.com