Major Project Report
on

‘Fault lines in the Indian Patent Regime

relating to

pharmaceutical sector and challenges to sustainable access to affordable medicines to poor - a possible way out.’

Submitted for the award of the degree of Executive MBA

by

Mohinder. S. Grover
DTU/13/MBA/512

Under the Supervision of

Dr. Rajan Yadav, Associate Professor

Delhi School of Management

Delhi Technological University

May 2015

CERTIFICATE

This is to certify that Mr. Mohinder Singh Grover, Roll No. 2K/13/MBA/512, a student of Executive MBA Batch 2013-15 Delhi School of Management, DTU has worked on the Major Project entitled 'Fault lines in the Indian Patent Regime relating to pharmaceutical sector and challenges to sustainable access to affordable medicines to poor-a possible way out' at Delhi School of Management, DTU in the year 2015, in partial fulfilment of the requirement for the award of degree of Executive MBA. The Report embodies the original work, primary research and studies carried out by the student himself.

(Dr. Rajan Yadav)

Associate Professor, DSM, DTU

May 2015

Declaration

This is to certify that I , Mohinder Singh Grover , a student of the Executive MBA Program batch 2013-15 of Delhi School of Management, Delhi Technological University have worked on the Major Project Report entitled 'Fault lines in the Indian Patent Regime relating to pharmaceutical sector and challenges to sustainable access to affordable medicines to poor-a possible way out' at Delhi School of Management, DTU in the year 2015, in partial fulfilment of the requirement for the award of degree of Executive MBA. The Report embodies the original work, primary research and studies carried out by me

(Mohinder Singh Grover)

2K13/MBA/512.

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(Mohinder Singh Grover)

2K13/MBA/512.

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Executive Summary

Right to good health and wellbeing is an inalienable basic human right and is recognized in a number of national and international legal instruments. Part IV of the Constitution of India, which enshrines 'Directive Principles of the State Policy' makes a reference to Constitutional commitments in Articles 39(f) and 47, to provide for health care Provision of universal healthcare for its people is a fundamental duty of every nation, more so, of the signatories to the 1948 'Universal Declaration of Human Rights', and the 'International Covenant on Economic, Social, and cultural Rights'India is a signatory to both the Declaration and the Covenant, and its track record on human rights, is periodically subjected to peer review by member states of the UN Human Rights Committee, as part of United Nations' Universal Periodic Review process in Geneva.at periodic intervals. Article 18 of the Constitution of the World Health Organization (WHO) a specialized agency of the United Nations, concerned with international public health. declares that 'the enjoyment of the highest attainable standard of healthis one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition', and recognizes that the objective of the WHO shall be the attainment by all peoples of the highest possible level of health

Following India's accession to the World Trade Organization (WTO), India was required to comply with Trade Related Intellectual Property Rights (TRIPS) which sets out minimum standards, of intellectual property protection. As a developing country India was granted a transition period of 10 years and had to amend its patents law inter-alia, to make patents available for pharmaceutical products by January 1, 2005. The Patents (Amendment) Act of 2005, removed the prohibition of product patent for pharmaceutical compounds, and allowed both product and process patents in India. The 2005 Amendment in Section 3 clearly delineates what is not patentable, and has introduced provisions, to restrict frivolous patents that are only trivial modifications of existing inventions. Section 3(d) in particular, and compatibility of amended Indian Patents Act with TRIPS has been challenged by pharmaceutical MNCs as well as the US Trade Representative (USTR).

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CHAPTER 1

Introduction

1.1Brief background of Patents Act, 1970, prior to 2005 amendments

Patent[1] system in India is not new. India's first patent statute, India's Act of 1856 was based on the British patent law of 1852.The law provided certain exclusive privileges to inventors of new manufacturers for a fourteen year term. In 1911, the British enacted the Indian Patent and Designs Act, which created a Controller of Patents to oversee patent administration in India. Despite these developments and the emergence of an industrialized economy, patent filing in India remained slow. Almost 85per cent of medicines were supplied by multi-national companies. Kefauver Committee of the USA which deliberated extensively on availability of medicines worldwide and the role of the MNCs pointed out that the prices of antibiotics and other medicines in India were the highest in the world. . After independence the Indian government wanted a patent system that was more conducive to national interests. Two Committees were appointed, one headed by Justice Bakshi Tek Chand in 1950, which revealed the need to "stimulate invention and encourage exploitation of new inventions for industrial purposes" and recommended changes such as introducing compulsory licensing provisions, and the other by Justice Rajagopal Ayangar in 1959, which found that multinational companies were exploiting India's patent system to achieve monopolistic control and that foreigners held about 80-90% of Indian patents, but practiced less than 10% of those patents in India. It recommended "radical" modifications to India's patent law, which became the foundation of the modern Indian patent system after a decade long negotiations and debates in the Indian Parliament in 1970.

[1]A patent is a territorial right, a monopoly, for a limited period, granted at the request of the individuals/ corporations, by the patent office of the respective country, for technological or other inventions, by preventing others from using the patented technology/invention. A patent may be product patent, or a process patent. A process patent grants monopoly on the process of manufacturing the product and not on the product per se., A product patent, on the other hand, grants a monopoly on the product which that prevents others to manufacture, sell, distribute and import the patented product without authorization of the patent holder. Hence, a product patent on drugs means that only the patent holder can produce the patented drug in the normal circumstances. Monopolies generally lead to high prices

The main features of the Patents Act, 1970[2] were as follows:

- There was no product patent[3] for pharmaceuticals, food and chemical based products. These industrial sectors were covered by process patent only.
- The term of the patent was 7 years from the date of application or 5 years from the date of sealing of patent which ever period was lower.
- In order to ensure pronounced role of the domestic enterprises in the patented product a system of 'licensing of right' was also provided for the sectors covered by the process patent.
- There was no constraints on exports.
- The patent holder was under obligation to use the patent. There was also provision for revocation of patent for non-use.
- For licenses of right the royalty ceiling was stipulated at 4 per cent.

Through the 1970 Act, the Indian government made a deliberate choice to stimulate the lagging Indian economy by promoting domestic drug manufacturing. By explicitly abolishing patents for pharmaceutical products, the 1970Act generated immediate and dramatic results. Because pharmaceutical products patented outside of India could be reverse engineered and manufactured, India developed a capable generic drug manufacturing industry reputed for producing generic versions of branded drugs at low cost. Over the ensuing years, India developed a worldwide reputation as a producer of low-price generic drugs.India is currently the biggest producer of generic drugs by volume and the leading exporter of medicine to developing countries,and it supplies a large percentage of AIDS medicines used in developing countries.

Initially, India was one of the most vocal opponent of Trade Related Intellectual Property Rights (TRIPS) and played a key role along with Brazil, in resisting the American pressure and preventing inclusion of IPRs (Intellectual Property rights) in GATT (General Agreement on Trade and Tariffs). India and Brazil were able to articulate that GATT's jurisdiction was limited to tangible goods and that GATT lacked the legal competence to address an issue within the IP area. It was also contended that counterfeit goods belonged to the exclusive jurisdiction of WIPO

[2]Even after amendment in 2005, it retains the title as Patents Act, 1970.

[3]Before TRIPS, most developing countries did not have pharmaceutical patents. Surprisingly, many industrialized countries excluded pharmaceutical products from patentability in early phases of their development. Pharmaceutical patents were first authorized in Japan in 1976, Switzerland in 1977 and Italy in 1978, and were unavailable in Finland, Greece, Iceland, Monaco, Norway, Portugal and Spain as late as 1988.

(World Intellectual Property Organization). Under the onslaught of persistent US pressure, the developing countries could not prevent inclusion of the IPRs in the GATT Ministerial Declaration in 1986, but managed to ensure that until 1988 that no substantive discussions on IPRs became part of GATT or a major role of IPRs in GATT. Developing nations, had however hoped that they could limit negotiations to trade in counterfeit goods and other trade related aspects. In 1989 India made a surprising move and gave up its opposition to inclusion of IPRs in GATT negotiations. Analysts have drawn linkages to threat of US Special 301 law against India, and also the vulnerability of India to seek support from the US to borrow from the IMF and the World Bank to meet the depleting foreign exchange crises caused during the first Gulf War. The US position was that India could object to any aspect of the proposed agreement/treaty but did not need to refuse discussion on the issue of IPRs altogether. The appeared to be a rational, plausible and pragmatic approach at that time.

The TRIPS Patents System is based upon a joint position paper presented by the multinational associations of USA, Europe and Japan to the GATT Secretariat in June 1988 during the Uruguay Round Negotiations. The main features of the TRIPS system are as follows:

- TRIPS provides for patent protection 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;
- The foreign patent holders have been absolved from working of their patents and imports by them are to enjoy the same patent rights without discrimination as to the place of invention, field of technology and whether the products are imported or locally produced;
- The term of all patents shall not end before the expiration of 20 years from the date of application;
- There is no 'licensing of right' provision; and
- The compulsory licensing provisions are subject to tight conditionalities with constraints on exports.

Post 1970, the Indian domestic pharmaceutical industry flourished in the absence of product patents.[4] The competitive generic market resulted in production of generic versions of blockbuster drugs at very low prices.[5]These generic drugs cost about 5% of the price of similar drugs sold by US and EU pharmaceutical firms.[6]Apart from the large domestic consumption, cheap Indian generic drugs have been favored by many millions of AIDS patients across the Third World. Generic drugs from India played a key role in lowering the price of antiretroviral treatment by as much as 98%, making it feasible to scale up treatment more rapidly for 3.7 million Africans with AIDS lacking access to treatment.[7]

On March 23, 2005, the Indian Parliament passed the Patent (Amendment) Bill2005.It was the third amendment to the Indian Patent Act 1970). The amended Patent Act conforms to requirements set forth by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Since the new law came into effect on January 1, 2005, there have been serious concerns regarding the role of the domestic Indian generic industry in the new product patents regime,[8]and the continued availability of essential medicines at affordable prices.[9]The 2005 amendments to the Indian patent law have the potential to considerably upset the existing state of affairs. In this context, it is not surprising that the TRIPS-imposed changes to

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[4]**S.** Mukherjee, The Journey of Indian Patent Law towards TRIPS Compliance, 35 IIC125 (2004).
4 Jean O**.** Lanjouw, The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation

[6] Intl. Ctr. for Trade and Sustainable Dev., Indian Parliament Approves Controversial Patents Bill (Mar. 23, 2005). (Available at http://www.ictsd.org/weeklv/05-03-23/storvl.htm).
[7]**5** Africa Focus Bull. India/Africa: Threat to Generic Drugs, (Mar. 7, 2005) (available at http:i'ww.africafocus.or2/docs05/indO5O3.php).
[8] Health GAP (Global Access Project) & Medicines Sans Frontiers, India's Patent Act to Block Access to Low-Cost Generic AIDS Drugs,
http://www.healthgap.org/press releases/04/121504_HGAPMSF transcript india.doc
(Dec. 15, 2004) (Civil society proponents have argued that undermining Indian generic drug manufacturers is not good for the long-term economic interest of India, and that when one examines the tremendous impact that lack of access would have on India and on importing countries, the speculated benefits, such as increased foreign direct investment, would not actually counterbalance the costs).

[9]Health GAP (Global Access Project), Factsheet: Changes to India's Patents Act and Access to Affordable Generic Medicines after January 1, 2005,
http:'www.healthgap.org/press releases/04/ 121404 HGAP FS INDIA patent.pdf (Dec. 14, 2004)
(Civil society proponents have expressed fears about a steep rise in drug prices owing to the introduction of product patents in pharmaceuticals. While analyzing the impact of the new Indian Patent Act on access to essential medicines, it has to be pointed out that medicines patented prior to 1995 - medicines not protected by product patents in India - would remain available at the same prices. India would still be able to market generic versions of these drugs. The cause of concern would be the "drugs in the mailbox" (transitional period from 1995-2005), and for the new drugs approved post-2005).

India's patent law and their effects on public health prompted many constituencies to voice concerns, including those from multinational pharmaceutical companies,domestic Indian pharmaceutical manufacturers,Western governments,groupsconcerned with access to medicine,and lawyers and commentators from around the world.Finding a practical balance between long-term investments in the pharmaceutical industry and keeping essential medicines affordable is therefore a continuing point of tension.

1.11 Right to good health as an inalienable human right

Right to good health and wellbeing is an inalienable basic human right and is recognized in a number of national and international legal instruments. Part IV of the Constitution of India, which enshrines 'Directive Principles of the State Policy'makes a reference to Constitutionalcommitments in Articles 39(f) and 47, to provide for health care[10].Provision of universal healthcare for its people is a fundamental duty of every nation, more so, of the signatories to the 1948 'Universal Declaration of Human Rights', and the 'International Covenant on Economic, Social, and cultural Rights'[11]. India is a signatory to both the Declaration and the Covenant, and its track record on human rights, including these and other relevant instruments, is periodically subjected to peer review by member states of the UN Human Rights Committee, as part of its Universal Periodic Review, in Geneva. The World Health Organization (WHO) is a specialized agency of the United Nations, concerned with international public health. Article 18 of the Constitution of the WHO declares that 'the enjoyment of the highest attainable

[10] Article 39(f) states that 'The State shall, in particular, direct its policy towards securing that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.'
Article 47 states that 'The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and……'

[11] Article 1(1) of the Universal Declaration of Human Rights states that 'Everyone has the right to a standard of living adequate for the for the wellbeing of himself and of his family , including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment , sickness, disability , widowhood, old age or other lack of livelihood in circumstances beyond his control'
Article 12 of the International Covenant on Economic, Social and Cultural Rights mandates the states parties to to the Covenant 'to recognize the right of everyone to enjoyment of the highest attainable standard of physical and mental health and to take steps to achieve full realization of this right including , the prevention, treatment, and control of epidemic , endemic , occupational and other diseases; and creation of conditions which would assure to all medical service and medical attention in the event of sickness etc. '

standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition', and recognizes that the objective of the WHO shall be the attainment by all peoples of the highest possible level of health. World Health Assembly (WHA), an organ of the WHO, has been conferred with the authority, among others, to adopt regulations concerning various standards in relation to the trade in pharmaceutical drugs as per Article 21 of the WHO Constitution. WHA has the authority to adopt and implement agreements with respect to any matter within the competence of the WHO. In an important endeavor in 1998, the WHO revising its drug policy urged member states to reaffirm their commitment to develop, implement, and monitor national drug policies to ensure equitable access to essential drugs and to ensure that public health, rather than commercial interests, have primacy in pharmaceutical and health policies, and to review their options under the Agreement on Trade related Aspects of International Property Rights to safeguard access to essential drugs[12]. In another policy initiative; 'Health for All in the 21st Century', it mentions a number of obligations the WHO need to fulfil using international law to ensure universal access to medicine[13]. The UN Committee on Economic, Social and Cultural Rights, referring to the social function of the intellectual property, has in a Joint Report of the WHO, World Intellectual Property Organization, (WIPO), and World Trade Organization (WTO) , in 2012 has emphasized on the duty of States to prevent unreasonably high costs of essential medicines as well as to prevent the use of scientific and technological progress for purposes contrary to human rights and dignity, including the right to life and health.[14]

Access to affordable medicines and medical procedures is imperative to maintain and sustain good health. Inability to access requisite medicines may, inter-alia, be related to lack/ inadequacy of disposable income, low purchasing power, high and unaffordable price of medicines, or even non-availability of medicines, or a combination of both. Primary objectives of India's National Pharmaceutical Policy are to ensure accessibility, availability of drugs at reasonable prices, and to promote further research and development of low priced innovative drugs. Under the Drug Price Control Order, 1995, the National Pharmaceutical Pricing Authority (NPPA) has been

[12] WHO Document EB102.R24.
[13] WHO Doc A 51/5 (1998) http://apps.who.int/gb/archive/pdf_files/WHA51/ea5.pdf (para52)
[14] Promoting access to medical technologies and innovation intersections between public health, intellectual property , and trade, Joint Report if the WHO, WIPO, and WTO, 2012, p. 41.

mandated to control and fix the maximum retail prices of a number of scheduled/listed bulk drugs and their formulations, in accordance with well-defined criteria and methods of accounting, relating to costs of production and marketing. Notably therefore, the prices of these medicines have remained quite stable and affordable. Apart from the scheduled medicines under the Drug Price Control Order (DPCO) 1995, the NPPA monitors prices of other medicines not listed in the DPCO schedule, such that they do not have a price variation of more than 10% per annum. The government has decided to launch a country wide Jan Aushadhi Campaign to ensure that easy access to essential medicines throughout the country at easily affordable prices

1.12 Reasons attributed for high prices of medicines

Manufacturers justify high prices for medicines, among others, on the following:

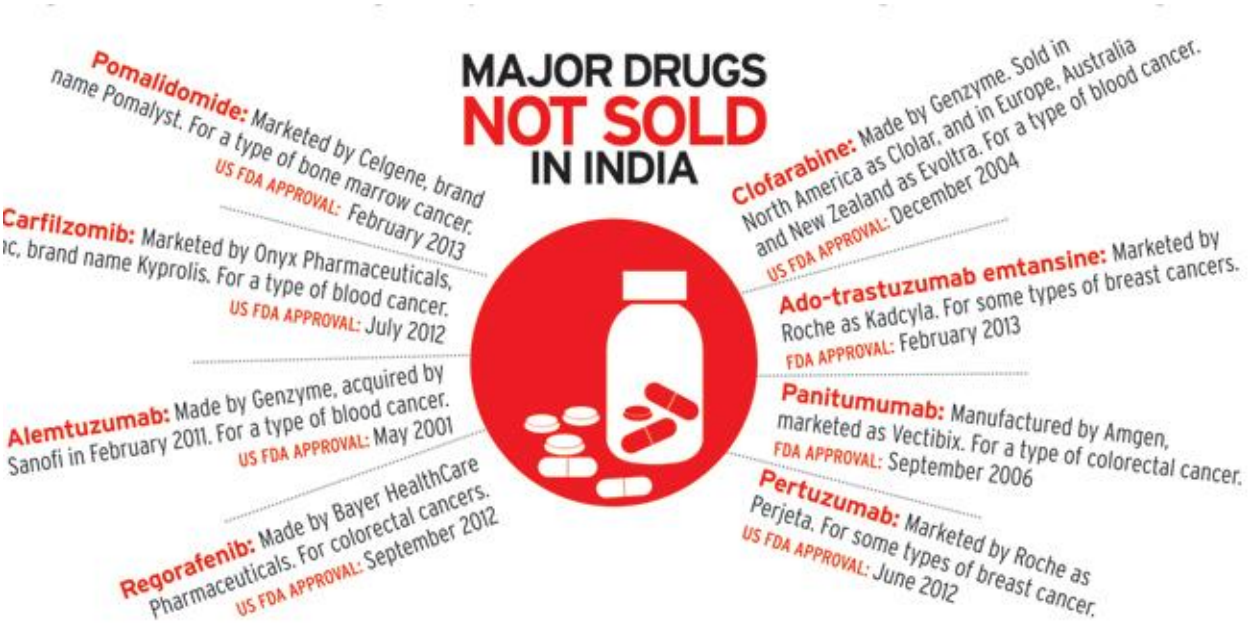
- High costs and long periods involved in drug discovery and development process.
- Low productivity in research and development of new molecules.
- Long periods and multiple phases of testing and trials to secure regulatory approvals.
- Short shelf life, high rates of obsolescence, of even established drugs due to adverse drug reactions,& emergence of better drugs.
- High investments to set up manufacturing facilities, particularly those involved with new technology areas.
- High costs involved in marketing, promotion, and distribution of drugs.
- To provide for ability to meet class action suits and hefty liability claims attributable to adverse effects attributable to drugs.

The exclusive intellectual property right claimed in the form of a patent on the medicine provides the platform to recover these costs, and perhaps much more, through the sale of drugs. Rand D of drugs is a highly capital intensive and uncertain activity. On an average it may take more than 10-12 years to discover, develop, and market a new drug, It is a risky venture too as one out of a thousand may reach human clinical trial stage and one out of five may finally be approved for human usage. It is for reason that pharmaceutical companies ride on a few blockbuster drugs to maximize their revenue streams.

Over two-thirds of the population in developing and poor countries are not able to afford modern medicines, largely developed by major global multinational pharma companies. Thus inability of

around 75 percent of world's population to access affordable medicines is a matter of serious concern for the future of healthcare. For millions of people suffering from HIV/AIDS the unaffordable price of antiretroviral (ARV) came down from US$ 10,000-12,000 a month to US $140 when CIPLA , an Indian company produced and marketed the generic version of the medicine. Gleevec, an anti-cancer drug marketed by Novartis, an MNC, costs INR 1, 20,000 per month while the generic version produced and marketed by NATCO, an Indian company costs less than one tenth of this price even after payment of royalty of 8 percent to the patent holder Novartis. Because of inability of the patients to afford high prices of latest generation of drugs, the big pharma companies do not market their latest drugs in poor countries. Number of patients who can afford them, total revenue that might be generated, requirement of confirmatory clinical trials to establish safety and efficacy on Indians, drug price controls, and threat of grant of compulsory licenses, are some of the factors considered by the big pharma companies to launch their latest medicines in India. Total pharma sales of Pfizer in India are a little more than the global market for just one blockbuster anti-cholesterol drug Lipitor. India does not figure among priority markets for major Pharma companies. The US Food and Drug Administration (US FDA) approved 39 new medicines in 2012, a large number of them for treatment of cancer. More than a dozen drugs essential for important cancer areas are not available in India.

Figure 1.1 Major Drugs neither patented nor sold in India



(Sourcehttp://media2.intoday.in/btmt/images/stories//December2013/cancerdrugsnotinindia_120213030815.jpg)

The way to procure such medicines is for doctors to write to the company concerned and get the medicine under the patients personal import license,or through the drug manufacturer's patient assistance program ,- with patient securing import clearances and duty exemptions. This modality is obviously neither scalable, nor efficient, or expedient.

1.13 Major factors that have affected States'authority to design and implement their healthcare policies and programs include:

- Patent monopoly. Around 97per cent of all the patents belong to owners in the developed world.
- Globalization of intellectual property, with TRIPS as an instrumentality, and WTO as a forum to address intellectual property issues.
- Endlessly protracted, largely frivolous, patent litigations.
- Non fulfilment of the spirit of 'Doha Declaration'
- Focus of the discourse on trade/commercial interests rather than the human right to health. Whether the WHO, or the WTO should assume leadership role and drivethe global governance for access to health, and coordinate global health Rand D financing.is an issue.

1.20 DOHA Declaration Saga and failure of Doha spirit

Non availability and non-affordability to essential HIV/AIDS drugs to million in Africa became a major human health issue and led to discussions in the WTO, which paved the way for Doha Declaration in 2001. Doha Declaration represents an important milestone in evolution of the patent regime to define, interpret, and marginally expand the scope of flexibilities available to member states under the TRIPS to meet their primary responsibility of protecting public health, which was ingeniously and systematically scuttled by vested and powerful entrenched pharma interests.In order to understand and appreciate the import of the Doha Declaration, one has to examine the following WTO Documents.

- Declaration on the TRIPS Agreement and Public Health. .Adopted on 14 November 2001. (Doha WTO Ministerial 2001: TRIPS, WT/MIN (01)/DEC/2). Placed at **Annexure A1.**
- The separate Doha Declaration explained. WTO explanation on the Doha Declaration. Placed at **Annexure A2**

- Decision removes final patent obstacle to cheap drug imports. (Press Release No Press/350/Rev.1 issued on 30 August 2003). Placed at **Annexure A3**
- Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. (Document No. WT/l/540 and Corr1. Decision of the General Council of 30 August 2003). Placed at **Annexure A4**

1.21 Doha Declaration emerged in response to huge public outcry of national and international NGOs and media, and strong reaction of coalition of likeminded developing countries including India, Brazil, South Africa, against aggressive and abusive tactics used by mighty pharma companies and developed countries to restrict application of existing flexibilities under the TRIPS by the developing countries. Trigger came to the fore when Brazil was taken to the WTO Disputes Settlement Body and South Africa was slapped with an infringement case for making use of the so called TRIPS flexibilities, to provide access to medicines to thousands of HIV/Aids patients. It shocked the public conscience. It fundamentally transformed the character of the dispute from one between private intellectual property rights and its violators as presented by the MNCs while negotiating the TRIPS Agreement, to one between the rights of the states to protect public health , and power of patent monopoly as articulated by the NGOs. It elevated the expected role of the TRIPS to act and operate as a facilitating instrument in aid of developing countries to meet and fulfil their basic and primary responsibility to protect public health. It is very instructive to examine the text of paras 4-6 of the 'Doha Declaration on the TRIPS Agreement and Public Health' reproduced below:

"4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing[15] under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

1.23 The documents (Doha Declaration and related explanatory documents), inter-alia, declare, clarify, interpret,and emphasize that:

- The TRIPS Agreement does not and should not prevent members from taking measures to protect public health , and that the TRIPS flexibilities 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.
- The TRIPS flexibilities include :

  -Not only rights but also the obligations of the WTO members to interpret and implement the TRIPS Agreement in a manner supporting the protection of public health trough access to needed drugs.

[15]A Compulsory License under the patents system is described as an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state. As per the WTO a compulsory license is when a government allows someone else to produce the patented product or process without the consent of the patent owner.

-Mandate to read each provision of the TRIPS Agreement in the light of object and purposes of the Agreement, as expressed in its objectives and principles;
-Each member states' right to grant compulsory licenses, with freedom to determine the grounds on which such licenses should be granted;
-Each member states' right to determine what constitutes a national emergency which has to be understood to represent public health crisis, including those related to HIV/AIDS. Tuberculosis, malaria and other epidemics, and that in these circumstances there is no need to try to obtain a voluntary license before resorting to compulsory licensing;
-Each member states' right to determine its own exhaustion regime and consequently amember's right to allow parallel imports cannot be challenged under the WTO dispute settlement system, and
-Each member states' right to determine the scope and extent of limitations and exceptions in its patent regime, standards of patentability, and freedom to refuse data exclusivity.

1.24 In the negotiations to define contours for use of compulsory licenses under the TRIPS Agreement by members with no or insufficient manufacturing capacities, as mandated in Para 6 of the Doha Declaration, while the United States and other developed countries tried to restrict the compulsory licensing to most severe public health problems, the developing member states firmly rejected the idea restricting the grant of compulsory license to a limited scope of diseases. While the developing countries succeeded in their efforts, but what ultimately emerged was lengthy, complex, bureaucratic procedure divorced completely from the realities of commercial life. For instance, an exporting country is obliged to obtain a license to export the product, produce the drug in batches of required quantity, label it with specially, and color coded for the purpose and to stop production once the demand is met. There is a requirement to post this information on the website of the manufacturer. The member exporting country has to provide details of compulsory license granted to the exporter manufacturer. These requirements defeat the very purpose for which these provisions have been made in the first instance, and make it impossible to use them. It took Canada , through its 'Canada's Access to Medicines Regime' more than two years to clear the grant of export to Rwanda in Africa , a combination of anti-HIV drug, in spite of being permitted by the patentee to do so. This has been the only case of compulsory license under para 6 provisions so far. The experience of Indian and private

companies to supply anti-HIV/AIDS drugs have been far from satisfactory. This explains the complexity of the process.

1.25 As pointed out by various NGOs like CP Tech, MSF, OXFAM, Health Action International amendment of Article 30 the TRIPS Agreement, which has much potential to create new exceptions, could have been so drafted that the WTO members could simply agree in cases where a member state lacked manufacturing capacity and needed medicines, Article 30 would permit the creation of an exception to the restriction imposed by Article 31(f). However, major pharma lobbies worried that Article 30 route solution might result in a broad and automatic exception to allow the exporting country to manufacture and export without compulsory license at all, they strived and secured a complex and commercially unworkable outcome.

1.26 It has been argued that since the language of para 4 of the Doha Declaration, has been written in the form of an agreement, and adopted by consensus of Ministers in the Ministerial meeting of the member countries, it could be interpreted as a decision of the Members under Article IX:I of the WTO Agreement, and that under Article 31(3) of the Vienna convention on Law of Treaties , the status of Doha Declaration is substantively equivalent to that of the TRIPS Agreement[16].

1.27 Every attempt by the developing countries to pursue the Doha Declaration was met with strong resistance from the developed countries and the big pharma with threats of political and trade sanctions. While the most prominent clarification under the Doha Declaration related to grant of compulsory licenses by the developing countries, no compulsory license was granted in India till 2003. The period from 2003to 2005 saw the greatest volume of compulsory licensing activity and a substantial decline thereafter. It is surprising that after the 2005 amendment of the Patent Act and introduction of product patents, compulsory licensing activity should have been used more frequently to tap the promising opportunity to manufacture generic medicines. Concern about provoking retaliatory actions including market withdrawal by the patent owning pharma companies and trade sanctions from the developed countries representing those countries

[16] Abbot Fredrick M. The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a dark corner at the WTO, Journal of International Economic Law, 5(2)(2002) 469-505.

seem to have dissuaded and discouraged various developing countries to seek recourse to grant of compulsory licensing. This has been substantiated by:

- The South Centre , a think tank of the developing countries located in Geneva, in its Policy Brief to mark the 10th anniversary of the WTO Ministerial Doha Declaration on TRIPS and Public Health has brought out that brought out over the ten year period since the Doha Declaration the developing countries continued to be subjected to commercial and political pressures from the multinational pharmaceutical companies and the developed countries not to make use of the TRIPS flexibilities for public health . [17]
- Intimidation of the Thai Minister for Commerce by the EU Commissioner for External Trade warning that Thailand's action, in 2007, of issuing compulsory licenses for Abbot Laboratories antiretroviral drug Kaletra could lead to isolation of Thailand from the global biotechnology investment community[18]. Abbott laboratories responded by withdrawing application to market 7 new drugs in Thailand[19]. . US responded, in concert, to place Thailand on its 'Special 301Priority Watch List' for reason for lack of transparency and due process exhibited by Thailand in issuing compulsory licenses[20]. Thailand concerned that issuing compulsory licenses for heart disease, cancer, and other life-style diseases might provoke and be criticized as impermissible, on the grounds inter-alia, of absence of national emergency, (though legitimate under the Doha declaration) restrained itself.[21]Not surprisingly, there were very few compulsory licenses after the Thai incident.
- India faced similar reactions both from the US Govt. and the pharmaceutical industry after it issued its first compulsory license under the TRIPS regime for Bayer's anti-cancer drug Nexavar (sorafenib tosylate) to NATCO, on the grounds that neither the reasonable

[17] The Doha Declaration on TRIPS and Public Health Ten Years Later: The state of implementation, Policy Brief, South Centre ,2011 Http://www.college-de-france .fr/media/dominique-_Ten_Years-Later krouedan/UPL2843447343329281495_The _Doha _Declaration_on _TRIPS__and_Public _Health_Ten_Years_Later_The_State__of _implementation.pdf.

[18] www://keionline.org/misc-docs/thai/070710-PM-MOC.pdf

[19] Drug Access-Abbott to stop launching new drugs in Thailand in response to country's compulsory license for antiretroviral Kalketra, 14 March 2007.

[20] http://www.ustr.gov/about-us/press-office/reports-and-publications/archives/2007/2007-special301-report.

[21] Bangkok's drug war goes global, The Wall Street Journal Asia 7 March 2007, 13 Http://online .wsj.com/article/SBI117322181443628799.html.

requirements of public in respect of patented invention had been satisfied, nor was it made available at a reasonable cost, as well as non-working of the patent in India
This is in striking contrast to the US threatening Bayer with compulsory license for Ciprofloxacin during the anthrax scare in the US[22].

1.28 While the TRIPS Agreement and para 5(b) of the Doha Declaration provide freedom to the member countries to adopt their own regimes for defining scope of 'exhaustion' the EU and the US want to limit 'international exhaustion' to marketing with the consent of the patent holder[23] and in violation of the TRIPS agreement and the Doha Declaration often attempt to defeat this flexibility by seizing goods in transit between two countries which follow the principle of international exhaustion. This action is also contrary to 'freedom of transit' guaranteed under Article V of GATT. The impact of seizure would be shocking if the importing country might have legally and legitimately manufactured the generic drug. Such situations could be possible for a number of reasons including lack of patent protection in a member state, which could be due to if no patent were ever sought; or patent was sought and rejected; or patent has expired;or the claimed invention failed to meet the criteria of patentability. Seizure in transit would impact on TRIPS flexibilities and the territorial nature of patent protection if as a result of high patentability criteria fixed by a member state it rejects patents and the generic manufacturer's goods are seized. Subsequent to high rates of seizure in transit Brazil and India have initiated dispute resolution procedures against the EU in the WTO in 2010.[24] EU have resorted to bilateral arrangements with India to address this issue. India and EU have reached an 'Understanding' in July 2011, concerning a pending WTO complaint challenging EU custom measures that had been used to justify seizure of Indian generic medicines in transit through Europe to destinations in Latin America, Oceania and Africa. While India has assured that it will not seek establishment of a dispute settlement panel at the WTO, but reserved the right to revive the dispute if the EU does not abide by the core principles agreed to in the Understanding.[25] Developing countries have also been pressed to follow a restrictive interpretation of TRIPS flexibilities related to, scope of patent protection, standard of patentability, and data exclusivity.

[22] Supra note 6
[23] Supra note 6
[24] Request for consultations by India , EU- Seizure of generic drugs in transit , WT/DS408(11 May 2011)
[25] India and EU reach an Understanding on issue of Seizure of Indian Generic drugs in transit, Ministry of Commerce and Industry, Govt.of India, 28 July 2011, http://pib.nic.in/newsite/erelease.aspx?relid=73554.

As per Article 39.3 of the TRIPS Agreement member states are not required to provide exclusive rights to originator of data , but only to provide protection of undisclosed data against 'unfair' and 'non –commercial' use. TRIPS does not provide for data protection, as data exclusivity , is an independent right and creates an independent monopoly, and protection beyond what is provided under the TRIPS might lead to 'ever greening' of patents and can prevent entry of generic medicines even on compulsory license. It may thus confer monopolistic property right for drugs which are not protected by patents and thus have drastic adverse impact on access to medicines. Tendency among developed countries to link patent protection to regulatory data and denial of regulatory approval for generic medicines in cases where originator medicines are still under patent protection , blocks market approval till the end of the term of the patent , and consequently affects the development, marketing and of access to cheaper generic versions . Patent linkage is one of the strategies adopted to extend paten monopoly. It involves linking generic drug marketing approval with the originator drug's patent status and refusing marketing approval until the relevant patent expires. It is based on the premise that grant of marketing approval to a generic product prior to expiry of the patent term tantamount to violation of the patent. Patent linkage due to its widening scope and geographical coverage has global impact. Its effect in jurisdictions with data protection and data exclusivity have the virtual effect of shutting out prospects of entry of generic drugs due to non-availability of the clinical trials data on the original drug from the regulatory authorities. In 2011, sixteen countries including Chile, Singapore, South Korea, Bahrain, Oman, Jordan, Colombia, Peru, Guatemala, El Salvador, Nicaragua, Costa Rica, Dominican Republic, signed bilateral agreements with the US for patent linkage , and many more are expected to join soon. Since in the pharmaceutical sector basic unit of patent is a molecule, there is a greater dominance on the basis of patents as an independent development of the same molecule is not possible during the life term of the patent. Patent linkage facilitates ever greening of pharmaceutical patents Competitors can invent around the patent but cannot make the same molecule, because of the patent exclusivity, which may at times lead to abuse of dominance. Patent linkage is a feature of many free trade agreements between generic drug producing developing countries and the developed countries, to circumvent and restrict the usage of TRIPS flexibilies by developing countries. Indian Patent Act seeks to control ever greening of drug patents, inter-alia, through patentability criteria of efficacy under section 3(d), and pre-grant opposition under section 25(1) (a) of the Patents Act.

Though the Doha Declaration assured freedom to the member states to interpret all the TRIPS flexibilities in a way to meet their needs to provide healthcare to its people, it did not foresee and thus could not prohibit the WTO members from entering into bilateral or regional agreements which may run contrary to the objectives of Doha Declaration outside the TRIPS forum. The developed countries by insisting and implanting TRIPS plus obligations in bilateral and regional Free Trade Agreements with developing countries, have effectively negated the freedoms guaranteed under both the TRIPS and Doha Declaration.[26] The Thai-US FTA has provisions for patent term extension, 5 year data exclusivity, patent registration linkage etc. Likewise the EU-Ukraine FTA also reveals that much more sweeping responsibilities have been assumed by Ukraine.[27]

1.29 It reveals how the provisions of the Doha Declaration and the TRIPS flexibilities available to developing countries to promote health care and ensure access to cheaper medicines to their people have been systematically subverted and scuttled at the altar of commercial and trade interests of major pharma companies by the developed countries and highlighted weakness of the WTO as a trade fora to harmonize commercial interests with basic human right of access to affordable medicines and healthcare .

The aggressive tactics employed by major pharma companies and developed countries through various modalities and mechanisms strived, and largely succeeded, to ensure that the TRIPS flexibilities had a very limited application or utility for the developing countries. All kinds of pressures including threats of political and trade sanctions, threat to subject the country to the US 'Special 301 Priority Watch List', insistence on TRIPS plus obligations in bilateral and regional free trade agreements, frivolous and imaginary infringement litigations (multiple litigations in some cases), protracted, exorbitantly costly, obstructive with unnecessary adjournments extending over 4-5 years to tire out generic companies to prevent them from seeking regulatory approvals ,or compulsory licenses, insistence on and application of limiting international exhaustion to marketing with the consent of the patent holder, despite the fact that both the

[26] Drahos Peter, four lessons for developing countries from the trade negotiations over access to medicines, Liverpool Law Review, 28(1)(2007)11-39 DOI 10.1007/s100991-007-9014-5

[27] Association Agreement between the EU and its member states of one part and Ukraine of the other part, Nov 2012, http://static.euractiv.com/sites/all/euractiv/files/EU%20Ukraine%20Associatio%20agreement%20English.pdf.

TRIPS Agreement and the Doha Declaration had provided freedom to the member states to decide their own regime of such exhaustion, linking patent protection to regulatory data, denial of regulatory approval for generic medicines in cases where the original medicines are still under patent protection, insistence on data exclusivity, and restrictive interpretation of TRIPS flexibilities related to scope of subject matter of patent protection, standard of patentability , are employed by developed countries acting on behest of major pharma companies, both inside and outside the TRIPS forum, have made a mockery of the Doha Declaration and the TRIPS flexibilities, to ensure that the developing countries had only a restricted and very limited practical utility, if at all, to protect public health. Doha Declaration looks lofty in intentions on paper turned into a cruel joke on the developing and poor countries by the developed countries pressurized by mighty pharma interests, to ensure that the TRIPS flexibilities have only an extremely restricted application. It also vividly highlights and reaffirms the inability and inexpediency of the WTO, from the perspective of developing countries, as a fora to handle issues related to public health, which has been accepted as a basic human right, to be protected and promoted by all UN Organizations.

1.3 Objective of research

- To examine the nature of challenges to the Indian Patent regime, validity of the challenges, its impact on the Indian Pharmaceutical industry, and challenges confronting the Indian government and Indian Pharmaceutical industry that might impact on sustainable access to affordable medicines to poor in India and abroad.
- To identify whether any TRIPS plus obligations are sought to be read into India's TRIPS obligations indirectly by lobbying through powerful vested interests to gain unfair market access in India to the detriment of Indian pharmaceutical sector.

1.4 Scope of research

- To examine from a legal perspective evolution and development of the Indian Patent regime, its compatibility with the TRIPS and other international obligations, and the unexplored/unexploited flexibilities under the TRIPS still available to India that may be utilized to enhance effectiveness of the Indian Patent regime and facilitate development of the Indian Pharmaceutical sector.

- To examine the rationale, justification, and validity of the US Trade Representative's:

a. Listing India regularly on the Priority Watch List;
b. Initiating an Out-of-Cycle Review (OCR) of India's intellectual property (IP) laws, the mandate which it gave itself in the 2014 Special 301 Report; and
c. The threat of designating India as a Priority Foreign Country (PFC).

- Examination of implications of India's patent regime on development of Indian Pharmaceutical sector, and exploration of a multi-pronged strategy to ensure sustainability of the Indian Pharmaceutical industry to retain its leadership as a provider of generic medicines to the poor in India and abroad.

1.5 Methodology of research

- Analysis of the objections levelled against the Indian patent regime both on substantive aspects based on legality, patentability, compatibility with the TRIPS, as well as procedural aspects related to data exclusivity, confidentiality of data, exclusive marketing rights pending completion of mandatory drug trials.
- To assess challenges confronting the Indian Pharmaceutical sector to meet the existing and emerging needs of people in India and the developing countries.
- Explore possibilities of a multi-pronged strategy to ensure sustainability of accordable access to medicines.
- Critical evaluation of the' proposed way out'

1.6 Literature Review

Critical review of the vast corpus of relevant literature on this subject, which has bearing on defining and clarifying the core issues. In particular it is intended to study and review the following:

- Commission on Intellectual Property, Innovation, and Public Health Report (CIPIH): Public health, innovation and intellectual property rights, WHO, April 2006.
- Role and responsibility of World Health Organization in promoting affordable access to essential medicines, particularly follow up action on the recommendations of the CIPIH Report.

- Follow up action on the Sixty-first World Health Assembly, Resolution WHA 61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. May 2008, WHO.
- Revised Report submitted Institute of Economic Growth, University of Delhi. In August 2010 to the UNCTAD on 'Effects of the New Patents Regime on Consumers and Producers of Drugs/ Medicines in India '
- Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks May 2004. South Centre.
- Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks May 2004. South Centre. Impact of TRIPS on Indian Pharmaceutical Industry. Journal of Intellectual Property Rights. Nair G.G (2008) 432-441
- Strengthening of the Patent regime for developing countries –A survey
  Ruchi Sharma and K.K Saxena, Journal of Intellectual property Rights. Vol.17 March 2012.

Chapter 2

India and the TRIPS: A saga of protracted, frivolous, abusive, and exorbitantly costly litigation to tire out those who seek compulsory license, or regulatory approvals.

2.10 Like all other developing countries all efforts by India and Indian pharma industry to make use of flexibilities available under the TRIPS have been derailed and denied through pressures and subtle threats.

The Indian Patents Act 1970, which came into force in 1972, was a highly diluted patent system- it disallowed product patents on medicines, food, and agro-products; reduced validity of patents from 14 to 7 years for all sectors from the date of filing or five years from the date of sealing; the patent whichever was shorter; included a provision for automatic licenses of right in addition to compulsory licenses for non-working of the patent; it put onus of burden of proof in cases of infringement of process patents on the patent holder-which virtually decimated the patent system as far as the pharmaceutical patents were concerned . Consequently, all the R&D based MNCs stopped filing product patent applications in India , and the only applications they filed related to process patents and that too with little expectations of their exploitation through own use or through licensing to third parties. In the absence of product patents Indian companies were free to manufacture and market product patent protected drugs so long as they used a different (non- patent protected) process. Helped by a strong chemical technology base, India developed strong capabilities to produce the most sophisticated active pharmaceutical intermediates (API) or bulk drugs, within a short period of time, and emerged as a major supplier of APIs to both the developed and the developing countries. India became a major outsourcing hub for bulk drugs to major MNCs. This diluted Patent system enabled India to provide access to provide better access to essential, (generic version of patent protected) medicines at affordable prices to people at home and abroad. India thus earned the sobriquet of 'pharmacy of the world'. In such a situation there was no need of compulsory licenses. India amended its Patent Act, 1970 in 2005

to make it TRIPS compliant. As a developing India had time till end 2004 to bring its intellectual property regime in compliance with TRIPS Agreement from 1.1.2005.

2.11 The (Indian) Patents Act, 1970 underwent three major amendments in 1999, 2002, and the last one in 2005, to fulfil India's obligations under the WTO and to make it TRIPS compliant. TRIPS compliance is evident from the provisions of Sections 83(c), (d), and (f), which is verbatim reproduction of Articles 7, 8(1) & (2) of TRIPS. Doha Declaration in Para 5 were incorporated by India into the provisions of Compulsory License (CL) under Chapter XVI and section 83-92 of the Act. Para 6 of the Doha Declaration was incorporated by India through Section 92A of the Patents Act 1970. The compulsory licensing provisions in the amended Patents Act 1970 are, therefore, to be understood as specifically relating to affordable access to essential and lifesaving medicines. Prior to the 2005 amendment the erstwhile provisions of the Act only permitted grant of process patents. The 2005 amendment extended protection to product and process patents in the area of drugs, pharmaceuticals, and agriculture, reversing the 1970 amendment. The 2005 amendment was in consonance with Article 27(1) of the TRIPS which stated that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an innovative step, and are capable of industrial application.

2.12 TRIPS Agreement, as agreed and administered by the WTO, provides the minimum agreed level of protection to intellectual property rights and the members are free to provide higher level of protection through their national legislations. Prior to signing of the GATT in April 1994 and setting up of the WTO, there were different standard of protection of intellectual property in the pharmaceutical sector ranging from no protection through patents to restriction to process patents only , and periods ranging from 7 years in India to 17 years in the US. While most countries provided for compulsory licenses, India had a provision of license of right under stipulated conditions. Developed countries provided the highest levels of protection where besides patents, innovations of products, processes, and new utilities of existing products were also provided protection under the patent system. The system prevailing in the US and some developed countries favored the rights of inventors over those of infringers. The advocatedrationale in favour of TRIPS was that the IPR protection encourages innovation

leading to new useful products, newer technology, higher investments in production,manufacturing, andmarketing and consequently stimulating economic growth and development. TRIPS was also expected to usher in a globally harmonized IPR regime, free market access, enhanced cross border investments, liberal transfers of technology, MFN status among member states, and a rule based global trade order implemented by the member states and overseen by the WTO . This has led to evolution of the WTO as the most important instrument for protection of intellectual property rights and resolution of disputes. It must be clearly understood that the real primary purpose of TRIPS is to stronger private property rights and promotion of free trade in goods and services embodying IPRs and neither the promotion of innovation, nor the promotion of public access to products of innovation. The entire TRIPS is built on the premise that strong IP protection is essential for innovation and technological development and that the lack of strong IP protection is barrier to free trade. The preamble and the stated objectives and principles pay only a lip service and are not concerned about how strong IP protection mandated by it affects affordable access to public goods such as public health ormedicines protected by patents.It is a paradox and irony that while recent strides and developments in biotechnology, bioinformatics, nanotechnology, genomics etc. aided by strong IP protection afforded by TRIPS have rejuvenated R&D in the pharmaceutical sector and enabled it to develop latest generation of innovative lifesaving medicines, millions of poor in the developing world continue to suffer for want of such products because of their inability to afford them .Neither is there enough R&D andinnovation in relation to diseases which disproportionately afflict people in developing countries. Paradoxically, intellectual property rights are directly and indirectly have contributed to such a situation. While the major pharma companies, who were the main players to push for the TRIPS and are now major beneficiaries, are also involved in systematic scuttling of whatever little flexibilies are provided by TRIPS to the developing countries. Major public health concerns of the developing countries, apart from affordable access to medicines include lack of preventive, diagnostic, and curative pharmaceutical products, insufficient research and development into special needs of developing countries, little transfer of promised technology, and little assistance in capacity building in areas of drug discovery, development and delivery

Chapter 3

World Health Organization loses its legitimate turf and authority to the WTO

3.1 Against the backdrop of the international debate on relationship between IP rights innovation, and public health, the World Health Assembly in May 2003 decided to task an independent Commission to analyze this key issue. The Commission was set up in Feb.2004. The operative part of the text of the resolution establishing the Commission (WHA56.27) reads as follows:

"…collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries…"

It is perhaps the first and the most in depth study of inter-relation of IP rights, innovation, and public health. The recommendations, inter-alia, emphasized that:

- -the developing countries should focus on research in areas of their need ; allocate progressively more resources, and accord higher priority to combat rapidly growing impact of type 1 diseases; consider appropriate level of exemptions for research , to foster health related research involving Universities and other public research institutions , using patent pools of upstream technologies; and consider making use of compulsory licensing within flexibilities available under TRIPS to address the specific and relevant health related problems. It also cautioned developing countries not to undertake TRIPS + obligations.

- emphasizing Public-private partnership, including pharmaceutical industry, it urged the existing donors to contribute more over longer timeframe, employing open source methods to motivate involvement of more scientists; WHO should evolve mechanisms to support public-private

partnerships, assist in strengthening clinical trials and regulatory infrastructure and fill the identified gaps in developing countries;

- underlining the need for an international mechanism to increase global coordination and funding of medical R&D, it talked about a medical R&D Treaty urged that its sponsors should undertake further work to develop the idea ;

- govts. should invest in health delivery infrastructure, train the health care workers, remove tariff and taxes on health care products, monitor supply and distribution chain, and that developing countries with manufacturing and export capacity should take necessary legislative steps , consist with TRIPS, to provide in their legislation for compulsory license for exports;

- that pharmaceutical companies should avoid filing patents in low income developing countries and grant voluntary licenses to facilitate greater access to medicines and to accompany this with transfer of technology; developing should retain the possibility of benefiting from differential pricing and parallel imports , and avoid barriers to legitimate competition;

- govts. should establish networks, both national and international, formal and informal, involving universities, institutions and educational bodies in developed and developing countries to intensify collaborations and capacity building;

- That developed countries and their regulatory institutions need to provide greater financial and technical assistance, including transfer of technology to assist in setting up of minimum standard of regulatory protocols;

- govts. should consider compliance with the objectives of the Convention on Biological Diversity through establishment of appropriate national regimes for prospecting for genetic resources, their subsequent utilization, and commercialization with requisite disclosures of sources in patent applications and sharing of benefits with owning communities;

- Incorporation of digital libraries of traditional knowledge into minimum search documentation lists of patent offices to prevent misuse of traditional knowledge;

- The WHO should develop a global plan of action to secure increased and sustainable funding for developing and producing accessible products to address diseases that affect disproportionately the developing countries, and that WHO should continue to monitor, from a public health perspective, the impact of intellectual property rights , and other factors.

  The recommendation are generic in nature, without any specific mandate, plan of action, timelines , funding mechanism, or identifications of the institutions who would provide resources; or measurable objectives, or even differentiating between developing and least developed countries.

  Terms of reference and recommendations of the Commission are placed at Annexure B

  Report of the Commission may be perused at the following link (http://www.who.int/intellectualproperty/documents/thereport/en/).

3.21 Some members of the Commission havemade some very pertinent observations/comments and reservations on the recommendations of the Commission. These are as follows;

3.22 Professor Carlos Correa&Professor Pakdee Pothisiri[28]
Both commented that:

- While endorsing the Commission's view on irrelevance of patents for development of products needed to address the diseases prevailing in developing countries, and acknowledging that the pharmaceutical companies countries shape the global R&D agenda, underlined the need to promote generics competition to drive down prices and improve access to medicines to all, and to ensure a pro-competitive implementation of TRIPS Agreement through utilization of compulsory licenses and govt. use provisions when needed.
- Need for further analysis of negative impact on public health of TRIPS+ provisions such as data exclusivity contained in free trade agreements. WHO should assess this and alert developing countries.

[28]Professor Carlos Correa, lawyer and economist, Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law at the University of Buenos Aires.) Professor Pakdee Pothisiri (Senior Deputy Permanent Secretary of Health, Government of Thailand, and Secretary General of the Thai Food and Drug Administration

- Need for more analysis to examine drastic decline in the capacity of pharmaceutical industry to innovate in spite of availability of new powerful scientific and technological tools.
- Noted that changes in the industry structure to focus on highly profitable products and a relaxation of patentability, contributing to industry's emphasis on modification of existing products rather than on development of genuinely new compounds.
- Remarked that while the Report addressed, but has not sufficiently elaborated, on the profound distortions in the functioning of the patent system which allows proliferation of patents on trivial developments which are used to obstruct generics competition.
- Data on quantities, duration, and other conditions of supplies and the implications for the sustainable access to medicines need to be better examined in the appropriate context.

Full text of the comments is placed at **Annexure C1**

3.23 Professor Trevor Jones[29] remarked that:

- While he supported a large portion of the Report, he did not agree with the Report's implication that there was a direct link between patent ownership, product price, and access in the developing world. Companies set prices largely on the ability/willingness to pay, also taking into account the country, the disease, and regulation. There are differential prices based on volume, country/market, public or private supply, level of competition, and schemes for medically indigent, and company donation schemes, he emphasized.
- Concerning access patents are not the issue, but the overwhelming poverty of individuals, absence of state health- care financing, lack of medical personnel, transport and distribution infrastructure plus supply chain charges which can make affordable originator or generic products unaffordable In many countries, medicines are unaffordable from whatever source, price or patent status. He wondered why the cheap generics of medicines in the WHO essential list which are off –patent are not available.
- Countries should have the right to enact TRIPS compliant compulsory licensing but should only use this when all other reasonable steps have been taken.
- The report confuses so-called "evergreening" with incremental innovation, which is life blood of innovation and requires strong IPR to stimulate further innovation.

Full text of the comments is placed at **Annexure C 2.**

3.24 Professor Fabio Pammolli[30]commented that:

[29]Former Director-General, Association of British Pharmaceutical Industry and former Director of Research and Development at the Wellcome Foundation Limited.,

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- The term "developing country" encompasses very different countries which experience different levels of economic development and disease burdens. In order to design relevant solutions relevant macro-economic and institutional features need to be taken into account. An analytical work that should be performed to assess which policy is relevant to which type of developing country is fully articulated in the report.
- As for IPR, an undifferentiated recommendation as the one the reader might infer from the Report that all developing countries should lower IP standards, is not supported by analysis.
- Patent protection per se does not create monopoly positions in the final market . the legal definition of relevant market for competition purposes in the pharmaceuticals is a difficult and case specific analysis.
- Countries that do not protect pharmaceuticals does not necessarily experience higher rates of access, even if generic products are manufactured locally.

Text of the comments is placed at **Annexure C3**

3.25 Professor Hiroko Yamane[31] commented that:

- The Report should have provided more evidence based analyses of different patent policy options for developing countries considering both their short and long- term consequences. The report deals with all developing countries in an undiffertiated manner.
- The recommendations cover drug discovery, development, and access for all Types I, II, and III indiscriminately, without a clear picture of what type of medicines, old or new, are actually needed and which policy tools and incentives are specially required.. Type III (truly neglected) diseases which offer no commercial incentive should have received more attention.
- The actual level of patenting, scope of protection, and effect of such factors on price and competition were not adequately examined.
- The assignment of IP rights may lead to more efficient use of resources (information etc.) and licensing can promote transfer of technology.

[30] Professor of Economics and Management, Faculty of Economics, University of Florence; Director of IMT Lucca Institute for Advanced Studies

[31] Professor at the National Graduate Institute for Policy Studies, Japan

- Small patents around basic technology can work as a barrier against monopolization and help local businesses or applied research enter the market.
- The Report should have indicated possible consequences of adopting recommended policy tools on the entry of drugs, , investment, and ultimately the access and innovation. will generally benefit

Text of the comments is placed at **Annexure C4**

3.26 As a follow up on the Commissions 'recommendations, the subsequent adoption of the WHO Global Strategy and Plan of Action on Public Health , Innovation, and Intellectual Property (GSPA-PHI), the World Health Assembly vide Resolution WHA61.21 required the WHO to establish a result oriented and time-limited expert working group under the auspices of WHO and link up with other relevant groups to examine the current financing and coordination of research and development , as well as proposals for new and innovative source of funding to stimulate R&D in Type II and Type III diseases ,and the specific R&D needs of developing countries in relation to Type I diseases .Two WHO expert working groups (Expert Working Group(EWG) and Consultative Expert Working Group (CEWG), examined the current state of financing as well as the new and innovative sources of financing to stimulate R&D directed at specific needs of developing countries. The CEWG recommended adoption of a binding agreement based on Article 19 of the Constitution of WHO for providing effective financing and coordination mechanism to promote R&D focused on health needs of developing countries. While the content of the proposed agreement was left to the member states, CEWG set out the principles and objectives to support the negotiation process. It suggested that the objectives of the proposed Convention could,inter-alia, include:

- Implementing states' obligations under international human rights instruments related to national health;
- Delinking R&D costs and prices of products;
- Enhancing innovative capacity in developing countries and transfer of technology to these countries;
- Securing sustainable funding for identified priorities in developing countries;
- Generating R&D outcomes as public goods freely available for further research and production;

- Core elements the proposed convention to focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries in relation to Type I diseases.

3.27 The CEWG[32] required all member countries to commit 0.01% their GDP on government funded R&D devoted to meet the health needs of developing countries.. The CEWG suggested a Global Health R&D Observatory, with relevant advisory mechanisms, under the auspices of the WHO to monitor financial flows to R&D and to identify gaps to avoid unnecessary duplication. The major challenges currently faced by the global health R&D are sustainable funding; priority setting, and equitable distribution of R&D funds; ensuring accountability, transparency and affordability of R&D outputs; coordinationand continuous monitoring; delinking cost of R&D from cost of products; contribution of a fixed percentage of GDP; and R&D outcomes' relation with TRIPS.At present there is no reliable and sustainable mechanism to generate sufficient funds for research and priority of R&D is most often set by those invest in R&D. While an international treaty with binding obligations on states to contribute to R&D to facilitate an equitable sharing of burden of R&D, to ensure a robust and sustainable flow of funds and an authority to set norms, priorities, and ensuring accountability, transparency and affordability is a must, the ground reality is that market incentives and not the health needs or public priorities largely drive the private R&D investments. The developed countries while paying a lip service to the need for affordable access to medicines for the poor in the developing countries are neither in favour of committing more funds, nor enthusiastic about dilution of TRIPS provisions. Discussions on proposed treaty have been put of till 2016.The paradox is that while the WHO has been unable to show strong leadership to contend with and overcome political and economic agendas of the developed member states, strong pharma lobbies, and vested interests of some donors, the WHO, despite its weaknesses, remains the most appropriate body in the UN system to play a critical role in agenda setting, consensus building, ratification and implementation of the proposed treaty, monitoring of the priority decision making related to R&D and to take forward the idea of ensuring affordable access of medicines to all. May be a charismatic, committed, and a leader with a vision could someday lead the WHO to enable to fulfil its mission of highest possible standard of health for all.

[32] Research and development to Meet Health Needs in developing Countries: Strengthening Global Finance and Coordination, report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), world Health Organization, April 2012, p.15, 110-112, 123.

Chapter 4

Study[33] by the Institute of Economic Growth, University of Delhi for the United Nations Conference on Trade and Development UNCTAD

4.1 A study on 'Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India' was undertaken by the Institute of Economic Growth of the University of Delhi, and submitted to the United Nations Conference on Trade and Development(UNCTAD) in August 2010. Link to the full report is at the footnote. Salient points made by the Principal investigators Bishwanath Goldar (bng@iegindia.org) and Indrani Gupta (indrani@iegindia.org) are as follows.

- The Indian pharmaceuticals industry grew rapidly in the period 1970 to 1995 in a protective regime which reduced the dominance of the MNCs to about 20-25% and prices from the highest in the world to very low compared to the prices prevailing elsewhere in the world by mid-2000

- It has been acknowledged that the Indian pharmaceuticals industry adopted a successful strategy and has emerged as a major supplier of cheap and quality generics in the regulated market. The level of R&D activity undertaken by the Indian pharma has been reflected in the applications for patents and that the Indian firms have acquired manufacturing facilities abroad , entered into alliances and been engaged in contract manufacturing, contract research, product development and in clinical trials.

- The consumers have not also suffered much because of the new patent regime. The price increase in the post-1995 period faster than the general rate of inflation, was mostly attributable

[33]Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India Revised Report Submitted to the UNCTAD by Institute of Economic Growth wtocentre.iift.ac.in/UNCTAD/09.pdf

to the relaxation of price control and that the prices of drugs/medicine in India remained low relative to the prices prevailing in other countries,

- India has exploited the flexibilities in the TRIPS Agreement, keeping the national in mind and denied patents to frivolous inventions through use of compulsory licensing, pre and post grant opposition, parallel imports, Bolar exception and not allowing extension of patent period beyond twenty years and also made use of sec 3(d) and sec 84 (1) of the amended Patent Act.

- Despite the recognition of intellectual property rights, the MNCs had not undertaken research at the basic level, but the big domestic firms had a large number of molecules to treat diabetes, malaria, cancer, inflammation and other metabolic disorders in their research pipeline. The Schumpeterian link between size and innovative activity was reflected in increased filing of patents by large firms. There is econometric evidence is to indicate that the TRIPS Agreement strongly stimulated R&D activities in pharmaceutical firms in India, which in turn had shown up in patent applications.

- While the large firms have been strategizing to cope up with the challenges of the patent regime, SMEs are most vulnerable, inter-alia, due to lack of expertise, training and finance for technological up gradation and adoption of good manufacturing practices (GMP); limited application of IT in in production and processes; limited expertise on IPR issues; inability to raise finance on easy terms for import of capital goods and undertaking promotional marketing activities.

- While the govt. has planned several supportive measures, the SMEs will have to upgrade their production facilities to the international GMP levels failing which they would lose both the domestic and the international market to larger firms which would jeopardize their very existence.

- To study the impact of product patent regime on drug prices, an econometric analysis has been carried out for eight therapeutic segments. The analysis brings out that:

i. the price elasticity of demand for drugs belonging to the eight segments studied is not high (about -l.1 on average);

ii. the cross-price elasticity of the products of foreign and domestic firms based on the same molecule is low, which may be in a large measure to the differences in the marketing networks of foreign and domestic firms, and the fact that the marketing reach of foreign firms is less, and that even if the foreign firms have the exclusive right to supply a particular patented drug, its availability may remain restricted because of the limited marketing reach of foreign firms;

- Prices charged by foreign firms could go up by 250% if they had the full freedom to price the patented product and the govt. does not resort to compulsory licensing. In that event there will be a loss of consumers' welfare of about Rs 6 billion per segment in respect of the eight segments and the overall loss of about Rs 220 billion per year due to product patenting of all the pharmaceuticals. The expected gain of about Rs 27 billion (or about $0.6 billion) per year would be too small for major global pharma companies to redirect their R&D efforts to meet specifically India's health requirements.

- Despite this major change in the patent regime, the market share of foreign companies has declined during 2004-08 in eight of the eleven segments studied. The drug price control does have an impact on the market shares and the market share of the drugs under price control tends to get reduced over time, though there are exceptions. While the price control tends to reduce the market shares of both domestic and foreign companies, and this factor alone should not have caused the relative share of foreign companies to decline. The main reason for the new patent regime not contributing to an increase in the market share of foreign companies is that the existing foreign companies have mostly been operating in the generic segments only where the domestic companies dominate. Despite price relaxations and the 2005 Act making it favorable to launching of patented drugs, the foreign companies have not yet launched (Report was submitted in 2010) launched many of their patented products in India. Most of the MNCs pharma companies have stopped launching latest products in India after 1995 though they have been introducing them in other parts of the world.

- The patent applications which are filed in India are not found to be consistent with the disease burden of the country. Overall, the top five causes of disease, are lower respiratory infections, diarrheal diseases, and childhood-cluster diseases, tuberculosis and HIV & AIDS. Clearly India has been dealing with the dual burden of communicable and non-communicable diseases, with vaccine preventable diseases, still being an important source of DALYs lost. Communicable diseases segment accounting for 13% of the total patent applications and the non-communicable diseases taking 86% share of the total patent applications, while both these types of diseases comprise approximately 43% each of the total burden of disease reflected a bias in patent applications for diseases which are more global in nature, rather than those which are tropical and afflict the developing countries.
- As much of these patented applications/drugs are very similar to the off-patent drugs and offer possibilities of substitution, there may be no immediate danger of price rise due to the new patent system but there may be some medium to long run price effects of the new patent system, when far superior patent protected drugs come into the market, whether from Indian or foreign firms, which may result in significant loss of consumer welfare. Besides, if there was a sudden jump in research into the diseases affecting the developing world like water-borne diseases, vector-borne diseases like malaria & dengue, pneumonia, TB etc. and better and more effective new patented drugs become available in the global market, it would certainly impact both on prices and availability, but, given the pattern of R&D, it seemed unlikely in the near future.

- While there was no cause of immediate major concern on adverse impact of the new patent regime, but to safeguard against future eventualities, the government must be open and explore all the possibilities of furthering the cause of public health by exercising the many flexibilities of the TRIPS, like compulsory licensing, government use, parallel imports, price control, etc. and to address the deficiencies in the policy and institutional framework which might obstruct implementation of the TRIPS flexibilities, and guard against dilution of the TRIPS flexibilies through various bilateral and free trade agreements. It advocates India's cooperative, pro-active engagement with the multilateral institutions, pharmaceutical companies, and various govts. to promote cooperation in R&D, especially in neglected health diseases, and to ensure that more suitable drugs come into the market for diseases, and that these are available, affordable and accessible for the vast majority of the population.

Chapter 5

Patent buyout proposal

5.1 Both the Commission on Intellectual Property Rights, Innovation and Public Health, and the Consultative Expert Working Group (CEWG[34]) , set up in pursuance of the Resolutions of the World Health Assembly, have recommended establishing a global R&D treaty to address the health needs of the developing countries. The CEWG had recommended adoption of a binding agreement based on Article 19 of the Constitution of the WHO for providing effective financing and coordination mechanism to promote R&D focused on health needs of developing countries, and had required all member countries to commit 0.01% their GDP on government funded R&D devoted to meet the health needs of developing countries., and delinking R&D costs and prices of products. The CEWG had also recommended that R&D outcomes be treated as public goods freely available for further research and production. But divergent views of the developed member states on sustainable funding, priority setting, and equitable distribution of R&D funds, priority setting, , ensuring accountability, transparency and affordability of R&D outputs, coordination and continuous monitoring, delinking cost of R&D from cost of products, R&D outcomes' relation with TRIPS, and their reluctance on contribution of a fixed percentage of GDP to fund the proposed global R&D treaty ,forced the WHO to postpone further deliberations on the proposed treaty till 2016. While the deliberations on the proposed global R&D treaty/agreement have bogged down, Prof Kevin Outtterson, of the West Virginia University, proposed a 'Patent Buy-Outs for Global disease Innovations for Low- and Middle - Income Countries' which addresses the challenge of providing access to patented medicines at marginal (generic) pricing, while ensuring innovation by reimbursing the innovator companies for all lost R&D cost recoveries.

[34] Research and development to Meet Health Needs in developing Countries: Strengthening Global Finance and Coordination, report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), world Health Organization, April 2012, p.15, 110-112, 123.

5.2 Kevin Outterson, Associate Professor of Law at the West Virginia University , in a paper entitled 'Patent Buy-Outs For Global disease Innovations For Low- and Middle -Income Countries' available at http://www.who.int/intellectualproperty/submissions/en/has articulated a 'Patent Buy Out Proposal' which has the beauty of providing access to patented medicines at marginal (generic) pricing, while ensuring innovation by reimbursing the innovator companies for all lost R&D cost recoveries , while minimizing risks as the present IP system is retained for more than 80% of the global patent –based cash flow of the pharmaceutical companies. Salient features of the proposal are as follows.

- The purchaser which could be a government, inter-governmental organization, (such as UNAID, Global Fund, WHO etc.) , or a donor (such a Gates foundation) acquires the patent and exclusive marketing rights for a patented global medicine from the patent owner , limited to a particular geographical market , say non-OECD countries, while the patent owners retains all the rights in OECD countries.
- The purchaser offers an open, non-exclusive, no royalty license to any legitimate generic manufacturer, but only for sale in target markets. Negotiations will not be required, and transaction costs will be minimal. Normal patent-based pricing remains in all OECD countries, while generic pricing through multiple manufacturers prevails in all non-OECD countries.
- The patent owner is compensated under a buy –out formula which mimics the lost cost R&D recovery from the foregone sales.
- This proposal divides the world into two groups- rich OECD group and all the other countries.
- Drugs licensed under this system which are pre-qualified by the WHO should be granted automatic marketing approval in all the target countries, a form of reference approval in lieu of a country by country ANDA process.
- The buy-out price, based on expected profits rather than sales or costs must be such that it is high enough to optimize global pharmaceutical innovation and yet low enough to be affordable for all global diseases. He has suggested a formula for the buyout price as

BOP = NPVt (d) (U * M) p

BOP is the buy-out price;
NPV is the net present value over the patent period

t at discount rate d;
U is the number of generic units sold in the target markets by all sellers during t;
M is the marginal cost of production per unit, estimated as the lowest sustained actual price per unit during t;
p is a profit adjustor, reflecting the percentage of profits allocated to R&D cost recovery (17% in the simple models above).
Estimated payments could be made at buy-out, subject to periodic and retrospective adjustment as actual data developed on u and m, and perhaps for changes in d.

Since the license would encourage any pharmaceutical company to sell the drug generically in any or all the target markets, competition would ensure the lowest marginal cost of production, which would maximize 'u' to minimize 'm' which would translate into greatest access at a market determined low price, and overcome battle over TRIPS and essential medicines could be avoided.

Text of the proposal is placed at **Annexure D**

Chapter 6

Growth and development of Indian pharmaceutical sector- the driver and the catalyst in promoting access to affordable drugs

6.1 The growth and development of the Indian pharma sector has been phenomenal and has been the mainstay in Indian quest to ensure access to affordable medicines to millions of its citizens and the poor in developing countries. Indian pharmaceutical sector is highly fragmented with about 24,000 players, including 330 in the organized sector, with the top ten making up more than a third of the market. The market valued at INR 750 bn. for 2014 is largely dominated by branded generics accounting for 70-80% of the market .Despite over 350 drugs under price control, the Indian pharma market remains one of the fastest growing markets in the world, and is expected to grow to US$ 85 bn. by 2020.Life style segments including cardiovascular, anti-diabetes, anti-depressants, and anti-cancer drive the market. Biopharmaceuticals is becoming increasingly important area of interest because of the complexity in manufacture and limited competition.

6.2 Indian pharma companies are exporting to virtually all the countries in the world. Currently, the US is the biggest customer, accounting for nearly 22% of the sectors exports, while Africa accounts for 16% and the Commonwealth of Independent States (CIS) about 8% of the total exports. Latin America is an important and attractive target market for Indian pharma producers. There are about 175 US FDA and 90 UK-MHRA approved pharma manufacturing plants in India which can supply high quality pharma products globally. While some Indian companies are focusing on generics market in the US, Europe, and semi-regulated markets, others are focusing on custom manufacturing for innovator companies. Currently India produces around one -third of the generic medicines for HIV/AIDS and one- fourth of all the generic medicines. India ranks third in terms of volume and seventh in terms of value in manufacture of pharmaceuticals. Indian exports account for around 10% of global pharma production and around 20% of global generic market. Innovations in drug classes and treatment categories such

as antihistamines, beta-blockers, non-steroid anti-inflammatory drugs, anti-diabetic drugs, anti-psychotics, treatment for hepatitis C , rheumatoid arthritis, treatment, and oral contraceptives; and R&D in specialized segments like anti-infective, cardiovascular, or CNS drugs for improved potency, enhanced efficacy, and drug delivery system etc. have helped Indian pharma companies in seeking and sustaining market access in domestic and global markets.

6.3 Indian pharma companies have addressed the challenge of the post-TRIPS regime by exploring and exploiting all options of expanding their market share both at home and abroad. Now the pharma industry spends around 5% of its sales on R&D compared to 1% in 1994-95. The R&D profile of Indian pharmaceutical industry includes development of generics, new drug delivery systems and new drugs development. However, new products account for only 5% and the rest has been on new processes, new dosage forms, and drug delivery systems and the R&D activities of the Indian pharma companies are increasingly getting concentrated on life style diseases of the global nature, and not on local diseases such as tuberculosis and malaria. . Most of the patenting activity is carried out by large pharma companies, largely on new or improved processes, rather than on products, and even the product related applications are concerned with intermediates and formulations with maximum contribution in modified release dosage forms. The model adopted by Indian pharma companies including Ranbaxy, Dr. Reddy Labs (DRL) and Lupin, which started investing in R&D for New Chemical Entities (NCE), was to develop new molecules up to a certain stage and then license it out to partners from developed countries , primarily MNCs as they lacked the skills and the funds required for development and marketing of a new drug , Post-TRIPS major thrust of the Indian pharma companies is reflected by:

- During 2007-11 Indian pharma companies obtained 31% (694) of the of the total (2244) US Abbreviated New Drug Application(ANDA) approvals, largest for any single country;
- Rising number of active Drug Master Files (DMFs) by Indian pharmaceutical companies from 271 in 2009 to 417 in 2012. Indian companies top the list in global DMF (type II active) owning almost a third of them;
- Steep increase in US-FDA, MHRA-UK, EDQM, EMA-EU, TGA-Australia , MCC-South Africa and other , inspections and approvals to Indian pharma companies lifting India to second position after the USA. India currently exports drugs intermediaries active pharmaceutical ingredients (APIs) finished dosage formulations (FDFs), bio-pharmaceuticals and clinical

services. Some of the Indian companies faced challenge on the US regulatory front for inability to maintain prescribed GMPs and were slapped with hefty fines ;

- Compliance by Indian pharma companies with the global regulatory framework based on advanced GMP (good manufacturing practices), GCP (good clinical practices), GLP (good laboratory practices) ;
- Increase in domestic as well as international patenting activities;
- Thrust in the US and EU markets with an eye on expected patent expiry of pharmaceutical products;
- Increased spending on R&D activities; and
- Increased collaboration and cooperation with major global pharma companies including joint ventures, alliances, mergers and acquisitions.

6.4 Despite various constraints, Indian pharma companies made rapid strides. Biocon has come up with a new drug, Alzumab, the first in its class globally developed through biological process for treatment of Psoriasis; Cedilla Pharmaceuticals launched a new cancer drug Mycidac-C- injection for New Small Cell Lung Cancer (NSCLC); Zydus Cadila launched a new class of anti-diabetic drug, Saroglitazar which has been branded as Lipaglyn; and Ranbaxy obtained a fixed dose combination for arterolane maleate and piperaquine phosphate marketed as Synriam..

6.5 Growth rate of India's pharmaceutical exports has outweighed the corresponding growth rate of all other merchandise products, and despite being one of the major producers of generic drugs only one Indian pharma company figures in the top ten generic producers in the world. The increased R&D expenditure has helped in steady increase in patent filings, largely for incremental innovations, as well as increase in growth of exports through lagged effect. The increased exports in turn have had a positive impact on increased allocation for R&D activities. Indian pharma sector is expected to witness greater rural penetration, increased merger and acquisition activity. and strategic tie-ups, to consolidate the market, widen geographical reach, strengthen distribution network, expand portfolio of new therapeutic segments , and mitigate generic competition, as an inorganic growth strategy. A few top Indian pharma companies are Cipla, Cadila, Sun Pharma (which recently acquired Ranbaxy), Dr. Reddy's labs, Lupin ltd.,

Aurobindo Pharma, Piramal Health, Cadila Health, matrix labs, Wockhardt, Glenmark, IPCA, Torrent, and Unichem. Recent M&A activities included:

- A joint venture between Sun Pharma and Merck to develop, manufacture and commercialize new combinations and formulations of innovative, branded generics in the Emerging Markets. Sitagliptin and Sitagliptin+Metformin have already been launched in the Indian. Market;
- A joint venture between Lupin and Eli-Lily to promote and distribute Lilly's Huminsulin range of products in India and Nepal;
- A joint venture between Cadila and Bayer to sell brands from both the companies in Indian markets;
- A joint venture between Biocon and Pfizer JV to give Pfizer exclusive rights to commercialize Biocon products globally, including co-exclusive rights with Biocon in Germany, India and Malaysia; and
- Acquisition of Universal Medicines by Aventis.

6.6 There were 72 outbound acquisitions in 2012 by Indian pharma companies' worth over US$ 11 bn. compared to US$ 6 bn. in 2011. Internally Sun Pharma acquired Ranbaxy for US$ 3.2 bn. and the last regulatory hurdle was cleared by the Punjab and Haryana High Court recently. Some of the Indian companies which were also acquired by MNCs. included Matrix labs by Mylan; Shantha Biotech by Sanofi Aventis; Orchid Chemicals by Hospira; and Piramal Healthcare by Abbott Labs.

6.7 The policy reform has facilitated globalization of Indian pharmaceutical industry. Participation of Indian pharma companies in the global network has been, largely, barring a few large companies with a vision of a global footprint, stimulated, and sustained primarily by a quest to build an income generation opportunity, and secondarily as ameans for competence building. The Indian companies undertaking contract research, , collaborative research projects, ,out licensing and in-licensing partnerships, have willingly become partners of subordinate status who undertake piecemeal projects in drug research and are not exposed to the whole process of new drug development . The scope of joint ownership and transfer of technology in such collaborations is also very limited, with the consequence of the subordinate status of the Indian

partner resulting in a status of dependency on the foreign partner. Despite, public-private partnerships, soft loans, grants, and other incentives for R&D activities, private companies have not been very enthusiastic not receptive to invest in development of new drugs for neglected diseases, largely on account of heavy financial commitments for longer durations, with uncertain outcomes. The success of Open Source .Development Programme of the CSIR is also contingent on willingness of the industry in taking the product to the market. As the private sector is shying away, the only way is to find ways and means of discovering, developing and delivering new drugs for the neglected disease through R&D funded through public resources. Liberalization of the FDI regime has attracted investment in pharmaceutical R&D in India. But the bulk of the FDI in the pharma sector has been in the clinical phase, particularly in phase III trials, and not in the biological or chemistry research for new drug development. Phase III clinical trials require a large number of human subjects. MNCs are attracted to India because:

- Amendments to Schedule Y of the Drug and Cosmetic Rules, 1945 has removed restrictions on foreign players conducting clinical trials in India. The amended rules require that clinical trials should be conducted in accordance with principles of the Declaration of Helsinki, Indian Good clinical Practice Guidelines, and the Ethical Guidelines for Biomedical Research on Humans, prescribed by the ICMR.
- Availability of ethnically diverse population suffering from diverse ailments as target subjects.
- English speaking human resources, good communication network, and IT capabilities to facilitate trials.
- Ease to subvert and sidestep various restrictions on clinical trials. There have been instances of trials being conducted on women without prior informed consent, and at times exploitation of the poor and the venerable, in flagrant disregard of Declaration of Helsinki
- Ability to get away with paltry compensation in case of accidents or injury, damage or death in clinical trials.

6.8 Some Indian companies have been developing niche portfolios in various segments for both domestic and international markets. For the high margin niche segments in injectable, dermatology, respiratory, bio generics, etc.in the US market some companies have been preparing for requisite approvals for a basket of products to be launched soon after the patent cliff when these products go off patent .generic penetration in the US is going to peak after the

patent cliff in 2018 when a large number of patents are due to expire. Likewise the pharma companies are trying to focus on what they call “limited competition” and “differential products”. Limited competition drugs are generic drugs which are either difficult to make and thus cannot be manufactured by many companies. Differential products are existing molecules but have different dosage and/or administration mechanism. This is a strategy to exploit incremental innovation. Dr. Reddy’s labs, Lupin Ltd, and Sun Pharma are adept at this business strategy. Thus despite significant share in output and employment the future of small scale units is threatened by increasing competition and requirement of compliance with GMPs, GCPs, and GLPs.

6.8 Permission of 100% FDI in health and medical services under the automatic route, extension of weighed deduction of 200% for R&D expenditure in an in-house facility until 31 March 2017, and exemptions from price controls for products that are produced domestically using domestic R&D and resources and are patented in India, has contributed to increasedaccess to affordable medicines and healthcare facilities for the poor.. While the availability of generic medicines brings down prices of patented drugs, the Indian companies would follow their business strategy which ensures the highest return. R&D activities and priorities of the Indian companies are not aligned with the need to discover, develop, and deliver relevant to disease burden of the poor in India. Making generics available at cheaper prices vis a vis the innovator price, is a prudent commercial business model and not a philanthropic endeavor. It is the responsibility of the state to find ways and means to ensure access to affordable to its poor citizens and to share/underwrite financial and commercial risks inherent in discovery, development and delivery of New Molecular Entities, specifically relevant for the disease burden of the poor in India, as this is not an attractive opportunity for the MNC pharma companies because of the inability of the poor in Indi to afford them. The unguarded comment made by the CEO of Bayer, that “Bayer had not invented the Nexavar for the poor people of India but for Western patients who can afford it”, is a bitter truth. We have to accept that it is our responsibility to develop specific drugs for our specific disease burden.

Chapter 7

Saga of protracted litigation to frustrate Indian pharma industry to make use oflegitimate and permissible TRIPS flexibilities incorporated in the Patents Act, 1970.

7.1 The Indian pharma industry rose to the challenge of TRIPS and successfully strived and succeeded in building capacity and competence, for future growth. It is clear that lack of an effective IPR system would have affected investor confidence in enlarging the scope and resources allocation in innovation, which is essential for discovery and development, including in the pharmaceutical sector. TRIPS Agreement allows grant of compulsory licenses under Article 31 of the Agreement. Many countries including Thailand, Brazil, South Africa, Malaysia, Indonesia, Zambia, Ghana, and Mozambique from the developing world, and Canada and Italy from the OECD, have issued compulsory licenses, mostly for HIV/AIDS drugs, Thailand has been the most successful and effective in exploiting the flexibilities available under the TRIPS Agreement. In 2006, 2007, and 2008 Thailand issued seven compulsory licenses- 2 for HIV/AIDS medicines; 4 for cancer medicines; and 1 for cardio-vascular diseases. Thailand model which aimed at increasing generic competition to reduce prices and improve access and affordability has been used by most of the other developing countries. Strategies adopted by patent holders included voluntary reduction of prices, drugs at concessional prices and in some cases free of cost, and at the other extreme some companies have refused to register their latest generation innovative products.

7.2 Despite an exhaustive Patents Act, 1970, a few provisions and text formulations are yet to be interpreted and clarified through judicial interventions. . Some innovator companies owning patents for new chemical entities have been successful in obtaining injunctive relief in alleged infringement suits, except when the court extended the balance in favour of third parties, in larger public interest to ensure continued affordable access to essential medicines.. Major global pharma companies have engaged the generic Indian pharma companies in protracted, exorbitantly expensive, and frivolous litigations, with a deliberate design to maintain their market share, and to frustrate efforts of India pharma companies to make use of legitimate TRIPS flexibilities and their rights under the Patents Act, 1970.

While post-2005 there have been many patent infringement suits involving Indian pharmaceutical companies , the 'nib' patent wars have been in the limelight- Imatinib (Gleevec), Sorafenib ((Nexavar), Erlotinib and Dasatinib, are subject matters of ongoing litigation on both the infringement related injunctions and damages as well as patent regulatory linkages. While patent –regulatory linkage was contested by Indian pharmaceutical companies successfully, a few cases are still languishing for final orders in High Courts.Erlotinib has been subject matter for many infringement litigations, with Roche v Cipla being the lead one[35]. Patent valid but not infringed judgment was given by the single judge, which was challenged by Roche. The same is in appeal before the Division Bench. In an application for interim injunction of patent granted for Erlotinib (Tarceva), single bench of justice S Ravindra Bhat in the Delhi High Court rejected the application in the interest of third party –public health. This could be interpreted as first Judge made compulsory license in India. This order of the single bench was challenged in a division bench of Delhi High Court who not only upheld the order of the single bench but also imposed costs of INR 5 lakhs on Roche for not disclosing the contents of complete specification and facts concerning the pending divisional application for polymorph B. This was further challenged unsuccessfully by Roche .the hearings between Roche and large number of generic manufacturers with respect to the infringement suit involving Erlotinib patent are in progress in Delhi High Court. Discussion on the litigations involving major international pharma companies, in India would not be complete, unless we look at two famous cases – 'Nexavar' case involving Bayer and the 'Gleevec' case involving Novartis.

7.3 Grant of Compulsory License to manufacture cancer drug Nexavar

The grant of the first compulsory license (CL) to Indian pharma company Natco to manufacture and market the anti-cancer drug Nexavar, a drug patented by Bayer, a German pharmaceutical company, in February 2012 has been an epoch making event in the history of Indian pharma industry, as the implications of the judgment would have far reaching effects on affordable access to patented medicines through the flexibilities available under the TRIPS Agreement. It would have ripple effect since there are a large number of patented drugs needed, primarily in developing countries, with a high disease burden and poor capita income, which are not accessible and affordable. It would also have impact on investment in innovation and new drug

[35] F Hoffmann-La Roche Ltd & Anr v Cipla Ltd, IA 642/2008 in CS(OS) 89/2008dated 19 March 2008.

discovery and development, as well business strategy of major pharma companies to seek patent for their newer drugs in India. Natco filed an application under section 84 of the Patents Act, 1970 for grant of a compulsory license for manufacture of Sorafenib Tosylate (Nexavar) of Bayer which was protected by patent no.215758 granted on 3 March 2008. (Sorafenib Tosylate is a palliative drug for patients suffering from Renal Cell Carcinoma (RCC) and Hepato-Cellular Carcinoma (HCC) stage IV). Natco approached Bayer on 6 Dec.2010, as statutorilyrequiredunder section 87(1) , for a voluntary license to manufacture and market its patented product which was rejected by Bayer. Thereafter Natco filed an application for a CL with the Controller General of Patents, who passed a detailed and reasoned order[36]granting the CL on 9 March 2012. A brief history of the CL is contained in the order. The order was justified on all the three counts of Section 84(1) as follows:

1. That the reasonable requirements of the public have not been satisfied;
2. That the patented invention is not available to the public at a reasonable price; and
3. That the patented invention is not worked in India.

The CL granted was subject to the conditions which fixed the price at INR 8880 for a pack of 120 tablets, (as against INR 2, 80,000 of the patented product) and a royalty of 6% on net sales of the drug on a quarterly basis.

Bayer challenged this order in the Intellectual Property Appellate Board (IPAB), who dismissed the appeal but increased the royalty from 6 to 7%.The IPAB stated that the CL was not in favour of the licensee but to make the medicine reasonably affordable and available to the people. It upheld the Controller's decision to that drugs should be made affordable and available to the public. IPAB found that the Bayer had failed on all the tests of section 84(1) and observed that 'working' may not be interpreted solely as manufacturing in India in all the cases, and that importation may also be treated as 'working' if the full and complete, or at least reasonable requirements of the public or met, at a reasonably affordable price, in India. It is noteworthy and important to underline that justice Prabha Sridevan delivering the decision in the open court on 4 March 2013 said that drugs used for treating kidney and liver cancer should be made available at an affordable price to all needy patients, and that Bayer had not taken any effort to revise the

[36] Natco Pharma v Bayer, C.L.A No. 1/2011,http://wwwipiindia.nic.in/ipoNew/compulsory_license_120320.pdf.

marketing strategy and cut price of the product in the preceding three years after the grant of the patent from the date of filing of CL application by Natco.

Bayer challenged the IPAB order through a writ petition in the Bombay High Court which was heard on 11 October 2013 and has been repeatedly adjourned and is pending to be heard on date without interim relief. Bayer had earlier filed a suit for infringement against Cipla which is pending in Delhi High Court.Cipla had offered the product at even cheaper price than Natco. A suit is also pending against BDR Pharma Ltd. in Bombay High Court. In the meantime, a statement reportedly made by the CEO of Bayer that "Bayer had not invented the Nexavar for the poor people of India but for Western patients who can afford it", has evoked strong reactions from various NGOs and others.

7.4 Refusal of Patent to 'Gleevec' of Novartis

Post -2005 amendment of the Patents Act 1970, India has begun to witness a number of litigations, involving product patents. 'Gleevec case' , which may be termed as 'mother of all product patent litigations in India',has caused a stir ,both inside and outside the pharmaceutical industry in India and abroad as well as among practitioners of intellectual property . This landmark judgment was delivered by the Supreme Court of India on 1 April 2013. This momentous judgment has sustained hopes of millions of poor in the developing world that the MNC pharma companies cannot be the final arbiters of healthcare of the poor, by seeking to patent frivolous incremental inventions and to evergreen their products by extension of patent protection beyond what is permissible . Supreme Court of India has shown the way that Section 3 (d) of the Indian Patent Act, 1970 holds the key. This momentous judgment, perhaps the most important in the annals of Indian patent law jurisprudence, has far reaching implications for the quest of developing countries to provide for affordable access to essential medicines for millions of poor patients, and to stimulate the developed world to reflect, revisit, and review their patent regimes and to free their patent regimes, from the clutches of major international pharma lobbies feeding on tinkering minor innovations and making healthcare unaffordable for their middle class too. It is very instructive to go through the facts and evolution of this case.

- Novartis AG, a pharmaceutical company based in Switzerland, filed a patent application in Chennai Patent Office on 17 July 1998 for a patent for beta- crystalline of Imatinib Mesylate (Gleevec). The patent application no. 1602/MAS/1998 sought patent protection for beta

crystalline form of free base Imatinib, which was covered by an earlier pre-1995 patent no. 5,521,184A, 10 popularly known as 'Zimmerman Patent'. In the'Zimmerman Patent 'many obvious options of salts were discussed and disclaimed. Since the Indian patent application no. 1602/MAS/1998 was filed during the transitional phase ('mailbox transitional system' introduced in compliance with Article 70.8 of TRIPS), , it was kept in the mailbox and not opened for examination until 2005.

- On 10 November 2003, Novartis obtained Exclusive Marketing Right (EMR) for Gleevec in India .In order to enforce its EMR Novartis obtained injunction order from Madras High court to restrain the Indian generic manufacturers from manufacturing, selling , and distributing the generic version of Gleevec. Once the generic manufacturers stopped producing the generic version of Gleevec, after the injunction order,the price of Gleevec increased from INR 10,000 to INR 120,000 for a month's treatment.(From a price of INR 90 to INR 1000per100 mg capsule). However, in a parallel litigation, the Bombay High Court refused to grant the injunction.
- In 2005, following amendment of the Patents Act 1970, section 3(d) is with the requirement of 'efficacy' is introduced, with an explanation to the section3 (d). It was introduced with an objective to prevent evergreening of frivolous patents.
- Following the 2005 amendment of the Indian Patents Act, various generic companies (opponents)[37]and an NGO filed pre-grant oppositions against Novartis 'patent application. Opponents, inter-alia, averred that the alleged invention was neither novel, nor did it involve an inventive step; and further that the alleged invention was merely a 'new form' of a 'known substance 'that did not result in enhancement of efficacy. It was argued that the alleged invention did not meet the criteria of patentability under section 3(d). These arguments were based on the fact that Novartis had already been granted a US patent in 1993 for the free base, Imatinib, including disclaimer salts and processes thereof. It was also averred that the US 1993'Zimmerman patent effectively disclosed both the free base and Imatinib, and the acid-addition salt Imatinib Mesylate. It was further argued that different crystalline forms of Imatinib Mesylate did not differ in properties with respect to efficacy and that thus various forms of Imatinib Mesylate must be considered the 'same substance 'under sec3 (d) and explanation thereof.

[37] Leading the opponents were Cipla, and Cancer Patients Aid Association, whose common orders are available on this link http://www.ipab.tn.nic.in/Orders/100-2009.htm.

- The technical expert representing the Novartis, during the proceedings produced affidavits wherein beta crystalline salt was compared with insoluble Imatinib base, and further stated that the 30% increase in bio-availability is to be expected since the beta-crystalline salt is soluble while the insoluble Imatinib base will not get absorbed in the blood stream readily.
- The opponents contended that the comparison of Imatinib enhanced efficacy should be done between the alpha crystalline salt and the beta crystalline salt and not between Imatinib base and beta crystalline salt.
- Pursuant to this pre-grant opposition hearings, Patent Controller in Chennai refused to grant a patent to Novartis on 25 January 2006, before the Madras and accordingly the EMY got extinguished.
- Novartis filed writ petitions[38] against the Govt. of India, and the opponents before the Madras High court challenging the decision of the Patent Controller and the constitutional validity of sec 3(d) of the Patent Act 1970. Novartis argued that the term efficacy in sec3 (d) was vague and ambiguous; that it violated equity provision guaranteed in Article 14 of the Indian constitution; and further that Sec3(d) was not TRIPS compliant. . Following many adjournments the writ petitions challenging the decision of the Controller were converted into statutory appeals. The first appeal challenging validity of sec 3(d) was heard by the High Court of Madras, who upheld the validity of sec3 (d) and rejected the Novartis appeal on 6 August 2007.The High Court Order stated that;

a. "We state that in this case we have already found, analyzing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve, namely to prevent evergreening; to provide easy access to citizens of this country to lifesaving drugs and to discharge their constitutional obligations of providing good health care to its citizens"
b. Further the High Court defined the term 'efficacy' as: "therapeutic effect in healing a disease or having a good effect on the body". However , the High Court refused to examine whether sec 3(d) was TRIPS compliant or not, leaving it to be contended at the WTO's dispute Settlement Body. The second appeal relating to rejection of the patent application for beta-crystalline salt

[38] Novartis AG v Union of India &others, Madras High Court, W.P.nos.24759 and 24760 of 2006: http://judis.nic.in/judis_chennai/qrydisp.aspx?filename =11121

was transferred to the IPAB after Govt. of India notified the IPAB to hear appeals relating to patents.

- There was a spate of litigations regarding competence of the Technical Member of the IPAB to hear the appeal, and alternate remedies and options, which were contested both in the High Court and the Supreme Court.
- IPAB, on 29 June 2009 reversed the order of the Controller in part and held that the beta0crystalline form of Imatinib Mesylate was novel and involved an inventive step, but held that Novartis's alleged invention did not satisfy the test of sec3 (d) since Novartis could not show any actual enhancement of known efficacy for its beta crystalline form of Imatinib Mesylate. The IPAB order observed that. "considering all the circumstance of the appeals before us , we observe that the Appellant's alleged invention won't be worthy of reward of any product patent on the basis of its impugned application for not only satisfying the requirement of sec 3(d) of the Act but also for its possible disastrous consequences on such grant as stated above , which also is being attracted by provisions of sec3(b)of the Act which prohibits grant of patent on inventions , exploitation of which would create public disorder among other things."
- Novartis filed a Special leave Petition before the Supreme Court challenging IPAB's interpretation and application of sec 3(d). Appeals were also filed by generic companies including Cipla and an NGO against the order of the IPAB which held that the Novartis's invention to be novel and inventive.

7.5 The Supreme Court finally decided the case on 1 April 2013 and held that:

"That the patent product beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clause (j) and (ja) of sec (2 (1) and sec 3(d) respectively , the appeals filed by Novartis AG fail and are dismissed with cost "

With regard to incremental innovation the order in para 191observed:

"we have held that the subject product, the beta crystalline form of Imatinib Mesylate does not qualify the test of sec 3(d) of the Act but that is not to say that sec 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be grave mistake to read this judgment to mean that sec 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of sec5 from the Patent Act. That is not said in this judgment"

7.6 On the trend of excessive patent litigation, that it should not be introduced in India, The Supreme Court, in para 156 of the order observed that:

"We would like to say that in this country the law of patent, after introduction of product patent for all kinds of substances in the patent regime is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent"

7.7 The Supreme Court observation in Para156 of its judgment is a very clear and a strong message that India should not be converted into a patent battlefield like the US and Europe with never ending quest to promote perennial patenting or what we understand as evergreening of patents The Court further strongly emphasized that holding sec3 (d) valid or rejecting patents for new form of known substance without enhanced efficacy did not imply that incremental innovations are not patentable. In fact an analysis of pharmaceutical patents granted in India post-2005 highlights that 90% of all pharma patents granted in India are for incremental innovations.

7.8 It is very important to note that sec 3(d) of the Patents Act, 1970 finds its origin in Article 10(2) (b) of European Drug regulatory Directive, 2004, which defines a generic medical product as:

"a medical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference to medicinal product has been demonstrated by appropriate bioavailability studies. <u>The different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ in properties with regard to safety and /or efficacy.</u> In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters, or derivatives of an authorized active substance must be supplied by the applicant"

The objective of sec 3(d) is to curb ever greening and not to restrict or reject patenting of incremental innovation

7.9 Novartis had also filed a divisional patent application for the alpha crystalline form of Imatinib which was rejected by the patent office through pre-grant oppositions which were neither appealed, nor challenged by Novartis.

The epic battle initiated by Novartis lasted over a decade of protracted legal gymnastics.

Chapter 8

The way out

Multi-pronged strategy

8.1 To ensure access to affordable medicines for all , it is imperative not only to address the factors that adversely impact on such access and affordability , but also to explore , including out of the box options , both at national , regional and global level to put in place a sustainable model. Some of the obvious issues are non-availability of disposable income and high costs involved in of drug discovery, development, and delivery. These constraints may be mitigated, and addressed to some extent, among others, through statutory drug price controls; parallel imports; enforcing stricter standards for grant of patents; grant of compulsory licenses to generic pharma companies as well as for govt. use; determined efforts to ensure that R&D for new drug discovery and developmentbe made more cost effective with improved productivity in pre-clinical and clinical evaluations; and faster drug approvals to bring down costs. Besides, India could take some measures as indicated below:

- India must safeguard its ability to ensure affordable access to essential medicine by firmly rejecting the US threat of placing India on the 'Priority Watch List' / label India as a 'Priority Foreign Country, under Section 301 of the US Trade Act of 1974, as a prelude to imposition of economic sanctions, to force India to change its IPR regime on pharmaceuticals.
- Modernization of Patent Office.
- Amendment of the Patents Act, 1970.
- Need for voluntary judicial rectitude in granting quia timet injunctions.
- Making efforts to seek liberalization of implementation mechanism of para6 of Doha Declaration.
- Curbing anti-competitive practices of market players
- Address the challenge of reducing the high costs of drug discovery and development through innovative mechanisms

8.2 India must safeguard its ability to ensure affordable access to essential medicine by firmly rejecting the US threat of placing India on the 'Priority Watch List' / label India as a 'Priority Foreign Country, under Section 301 of the US Trade Act of 1974, as a prelude to imposition of economic sanctions, to force India to change its IPR regime on pharmaceuticals.

As shown in the following paragraphs, the US threat is unfair, unethical, unfriendly, even immoral, and contrary to agreed obligations under the Dispute Settlement mechanism of the WTO and obligations under the TRIPS Agreement.It is incompatible with international law. It would also highlight that the Indian intellectual property regime is TRIPS compliant; that India is entitled to use the flexibilities legitimately available to it ; that India cannot be forced to accept TRIPS + obligations; that India cannot accept the unilateral application of the US trade law in place of the multilateral jurisdiction of the WTO in a bilateral trade dispute; and that India cannot barter away the rights of the poor , not only in India but in all the developing countries , to the legitimate human right to affordable access to essential medicines . According to a PWC report, from a global perspective, India is responsible for 20% of the global generic production, India produces 80% of drugs for HIV/AIDS as well as drugs for cancer and heart diseases. The study reveals that 70% of patients who received medicines from India belong to 87 developing countries. In Africa alone there are more than 2.5 million AIDS patients who rely on generic drug production in India for their treatment, Medicin Sans Frontier (MSF) relies overwhelmingly on affordable generic HIV/AIDS medicines produced in India to treat nearly 1, 80,000 patients in 20 countries as well as use medicines from India to treat other diseases such as tuberculosis and malaria[39]. MSF buys more than 80% of their HIV/AIDS drugs and 25% of the drugs for tuberculosis, malaria, and antibiotics from India. Approximately 50% of essential medicines that the UNICEF distributes in developing countries come from India, while 75-80% of medicines distributed by the International dispensary Association are made in India. Thus India which has been instrumental in supplying affordable generic drugs throughout the developing world and the Least Developed Countries, besides meeting the huge requirements of over 1.25 bn. people in India, can neither forsake, nor negotiate its TRIPS flexibilities, when the stakes are so high, even on humanitarian grounds.

[39] The Indian Pharmaceutical industry : Collaboration for growth , KPMG report 2006

On 14 October 2014, the US Trade Representative (USTR) began the out-of-cycle review (OCR) of India's intellectual property (IP) laws, the mandate which it gave itself in the 2014 Special 301 Report. Like several years in the past, the USTR once again included India in the Priority Watch List, but this time, India's IP laws are being subjected to the additional scrutiny through an OCR. It is to be seen whether the OCR sets the stage for naming India as a Priority Foreign Country (PFC). Although the USTR has listed several areas of its concerns in India's IP protection and enforcement regime, patents and regulatory data protection have been most extensively covered in the report. The issues listed here are the exclusions from patentability provided in Section 3(d) of the Patents Act, the use of compulsory licenses and India's refusal to introduce market exclusivity while protecting data on clinical trials before marketing approval is given to a pharmaceutical product, inadequacy of measures to prevent online piracy of films. The USTR raised serious concerns about the innovation climate in India, which, in its view, was hindering India's progress towards an innovation-focused economy.

8.21 USTR's inclusion of India for the OCR was a reflection of the influence that the domestic lobbies have on the country's engagement with its partner countries. The hawkish industry lobbies, especially the US Pharma Industry (Pharmaceutical Research and Manufacturers of America, PhRMA), whose support the USTR has often taken to push its global aspirations in IPRs, have been seeking the strongest possible action against India. In its 2014 Special 301 submission, the PhRMA had demanded that India should be included as a Priority Foreign Country (PFC) and has urged "USTR to take resolute action to remedy these violations, including the consideration of WTO dispute settlement, as necessary."

This threat of unilateral action against India using the provisions of Section 301 of its Trade Act brings out two bleak facets of US Trade Administration's conduct. In the first instance, the USTR has displayed the tendency to challenge the disciplines of the Multilateral Trading System and secondly, the Trade Administration has virtually downgraded the bilateral process of engagement with India, which it does through the Trade Policy Forum and which was recently revived after Indian Prime Minister Modi's visit to the US in Sept. 2014.

8.22 US challenge to India's TRIP compliant Patent Law

The TRIPS Agreement, which established global standards for IPRs, states in its objective that "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Further, the principles on which the Agreement has been founded emphasizes that while amending their laws, WTO members must "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development and that they need to adopt appropriate measures to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." In fact, the Special 301 Report itself talks about "market access barriers …that appear to impede access to health care" as a concern, (p.6) which seems to have been ignored when India's case was taken up. Each issue raised by the US Trade Representative in its Sec 301 Report is examined here one by one.

8.23 Validity of Sec 3(d) of the Indian Patent Act, 1970

India's Patent Act includes several provisions that do not allow the patent holders to exert excessive influence over the market for patented products, to the detriment of the interests of the public at large, by patenting frivolous inventions and seeking evergreening of pharmaceutical patents. Thus, Section 3(d) of the Patents Act does not allow grant of patents on "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."

This exclusion is aimed at ensuring that rights cannot be obtained if an inventor made only minor modifications to an existing product. After all, a 20-year patent term was agreed to only because the large pharmaceutical firms argued that they needed a longer period of patent monopoly torecoup their substantial research and development (R&D) costs for producing new molecules.

This logic, therefore, demands that entities making minor modifications of an existing product should not enjoy the rights as those making substantial investments in R&D.

Novartis AG, a pharmaceutical company based in Switzerland, filed a patent application in Chennai Patent Office on 17 July 1998, what has come to be known as the 'Gleevec case', and may be termed as' mother of all product patent litigations in India,Novartis had challenged validity of Sec 3(d) , on the grounds that the requirement of 'efficacy' was vague; that this requirement was violative of Article 14 of the Constitution of India ; and that the India's Patent Act,1970 was violative of India's obligations under the TRIPS Agreement. This epic battle which started in July 1998 culminated after a long journey through the Patent Office, IPAB, Madras High, and finally the Supreme Court, in April 2013 with a final Judgment of the Supreme Court of India, which has not been challenged. The Madras High Court upheld the Constitutional validity of Sec 3(d) of the Patent Act, 1970; defined the term "efficacy"; and directed that the compatibility of the Patents Act, 1970 be contested at the Disputes Settlement Body of the WTO. The High Court observed that:

"We state that in this case we have already found, analyzing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve, namely to prevent evergreening; to provide easy access to citizens of this country to lifesaving drugs and to discharge their constitutional obligations of providing good health care to its citizens"
The High Court defined the term 'efficacy' as: "therapeutic effect in healing a disease or having a good effect on the body".

The High Court refused to examine whether sec 3(d) was TRIPS compliant or not, leaving it to be contended at the WTO's dispute Settlement Body

The Supreme Court upheld the validity of Sec (3d), and rejected the Novartis patent application for Gleevec, as it failed the tests of patentability provided under clause(j) and (ja) of sec 2 (1) and Sec 3(d) of the Patents Act,1970. The Supreme Court commenting on the undesirable trend of excessive litigation also observed in para 156 of its Judgment that:

"We would like to say that in this country the law of patent, after introduction of product patent for all kinds of substances in the patent regime is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent"

Strongly dispelling the notion that Sec.3 (d) barred incremental innovation, the Supreme Court in para 191 of its Judgment, emphasized that:

"We have held that the subject product, the beta crystalline form of Imatinib Mesylate does not qualify the test of Sec 3(d) of the Act, but that is not to say that sec 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be grave mistake to read this judgment to mean that sec 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of Sec5 from the Patent Act. That is not said in this judgment"

The Supreme Court observation in Para156 of its judgment is a very clear and a strong message that India should not be converted into a patent battlefield like the US and Europe with never ending quest to promote perennial patenting or what we understand as evergreening of patents. The Court further strongly emphasized that holding Sec3 (d) valid or rejecting patents for new form of known substance without enhanced efficacy did not imply that incremental innovations are not patentable. In fact an analysis of pharmaceutical patents granted in India post-2005 highlights that 90% of all pharma patents granted in India are for incremental innovations.

It is also very important to note that sec 3(d) of the Patents Act, 1970 finds its origin in Article 10(2) (b) of European Drug regulatory Directive, 2004, which defines a generic medical product as:

"a medical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference to medicinal product has been demonstrated by appropriate

bioavailability studies. The different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ in properties with regard to safety and /or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters, or derivatives of an authorized active substance must be supplied by the applicant"
The objective of sec 3(d) is to curb evergreening and not to restrict or reject patenting of incremental innovation. Here is a list of some patents which have met the requirements /thresholds of incremental innovation prescribed in Sec 3(d).

An illustrative sample of some Patents which have met the threshold of incremental innovation prescribed in sec. 3(d) of the Patents Act, 1970		
Indian patent No.	Title of the invention	Patentee
223589	A crystalline polymorph of an Epothilone analog of Formula1	Bristol-Myers Squibb Co
223767	Indolylakylamine	Wyeth
223849	8-Azabicyclo[3.2.1.]Octane-3-Methanamine derivative compounds	Sanofi-Synthelabo
239408	Novel tyrosine derivatives	Orchid research laboratories Ltd
254576	Morpholine derivatives as Norepinephrine reuptake inhibitors	

Some frivolous Patents when challenged under Sec.3 (d) withdrew patent applications

In March 2006, the Indian Network for People living with HIV/AIDS, and the Manipur Network of Positive People filed an opposition against GlaxoSmithKline's (GSK)'s patent application for Combivir , an important fixed dose combination of two of the most widely used antiretroviral medicines in the developing world.. In fact the GSK sought a 20 year patent and

monopoly for combining two already known drugs-Lamivudine and Zidovudine neither of which are patentable in India. GSK, like Gleevec, had already obtained a patent for this in the US, the UK, and several other countries. In the face of strong opposition filed by activist groups, GSK withdrew the application at the pre-grant representation stage .later GSK also withdrew a patent application for a combination of asthma drug, presumably to avoid setting a negative precedent should the application be rejected on the basis of Sec.3(d).

In contrast to the GSK's strategy of withdrawing dubious patent applications. Another US based global pharma manufacturer Gilead Sciences has taken a different approach when HIV treatment activists and numerous Indian generic companies filed oppositions Gilead's application for an important AIDS drug Tenofovir in May 2006, Gilead responded by offering voluntary licenses to Indian generic manufacturers at favorable royalty rates, on an explicit condition of their withdrawing pending patent oppositions against Tenofovir. Thus, in a smart move, even before patentability of Tenofovir could be determined, Gilead had acted quickly to lock in the Indian generic manufacturers, and a steady stream of royalty from risk averse generic companies irrespective of whether or not the patent for Tenofovir was ultimately granted.

So the USTR's objection Sec. 3 (d) is not sustainable.

8.24 Compulsory License

Public interest considerations have resulted in the adoption of the system of compulsory licensing in India. These provisions can be invoked where the patent monopolies are in conflict with public interest. Such circumstances can arise when a patent holder charges exceptionally high prices for a patented medicine or does not make a medicine available when the country faces a public health crisis, namely, a national emergency or other circumstances of extreme urgency. Under these conditions, India's patent authorities can issue a license to anyone other than the patent holder who is willing to produce the patented product in the country, on payment of royalty to the patent holder, in accordance with provisions of Article 31, particularly Article 31 (b) of the TRIPS Agreement. This has been incorporated in Sec.84 of the Indian Patents Act, 1970. These provisions, in the Patents Act, 1970 are wholly consistent with the Doha Declaration on TRIPS Agreement and Public Health. In the Doha Declaration, adopted in 2001, Ministers of WTO Member states agreed that the "TRIPS Agreement does not and should not

prevent members from taking measures to protect public health." More importantly, they agreed that the "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." And last, but not the least, the Declaration affirmed that "[E]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

It should be noted that India has exercised a high degree of prudence in the use of compulsory licensing provisions. In the post-TRIPS regime, there has been a solitary instance of the use of these provisions. This was done when the German firm, Bayer, the patent holder of an anti-cancer drug (Nexavar), charged extra-ordinarily high prices for the product and also did not make the drug available in sufficient quantity even through import. The generic drug producer, Natco, was granted a compulsory license in Feb.2012 , to ensure that patients paid Rs. 8,800 (nearly $ 130) for a month's supply of Nexavar instead of Rs 280,000 ($ 4600) charged by Bayer. Natco is also to pay royalty of 7 % to Bayer (This was done after the generic manufacturer's request made in Dec.2010 and pursued for over an year, failed to evoke a favorable response). Incidentally, the Bayer has sued Natco, which obtained a legitimate license, in accordance with the due process of applicable Indian Law. Bayer has also filed infringement proceedings against other Indian companies too, and the matter is sub –judice in different High Courts. Nexavar case has been discussed in detail in this Paper at Para … above. It is very important to note that despite strong recommendation from the Ministry of Health, the government has not issued a Compulsory license for production of Bristol Myers Squibb's cancer drug Dasatinib, even for governmental use, which is permissible under the TRIPS flexibilities, so far. India has not issued any compulsory license for export to the least developed countries and developing countries with inadequate manufacturing capacity for essential drugs, permitted under para 6 arrangements of the Doha Declaration.

While the US has targeted the inclusion of compulsory licensing system in India's Patent Law, the US has issued more compulsory licenses than any other country in the world. Issuance of most of these licenses have been authorized by the Federal Trade Commission, which has often forced the patent-holders to license their patents on a royalty-free basis such as in the cases of

Bosch and Google, which were not even aimed at meeting the critical needs of the public, unlike in India's case.

There is, therefore, no case for criticism of India's exercise of legitimate TRIPS flexibilities.

8.25 Regulatory Patent Linkage

There is a continuous international pressure on developing countries to extend the scope of pharmaceutical patent protection beyond the TRIPS Agreement and patent regulatory linkage is one such area which developed countries, including the US are pursuing through bilateral or multilateral agreements. Patent linkage is one of the strategies to enhance patent monopoly. It involves linking generic drug marketing approval with the originator drug's patent and refusing marketing approval status until the relevant patent expires. Patent linkage systems in various jurisdictions vary to a large extent.In the US patent linkage applies only to an Abridged New Drug Application (ANDA). EU does not allow linking marketing authorization to the patent status of the originator reference product. Article 81 of regulation EC 726/2004 and Article 126 of Directive EC2001/83 provide that authorization to market a medicinal product shall not be refused, suspended, or revoked, except on grounds set out in the Regulation and the Directive. Since the status of a patent is not included in the grounds set out in the Regulation and the Directive, market approval is not linked to the patent status. However, EU incentivizes the originator's interest by providing long term data exclusivity, EU has the longest data exclusivity in the world for a new chemical entity which may extend to 11 years. There is a national procedure for drug approval in each member country and also the EC Directive. In contrast to the EU, the US model provides a shorter data exclusivity period with patent linkage. Interestingly, as a consequence some, European firms prefer US as their main place of operations. Nevertheless, some countries in the EU have been using patent linkage system. Multinational pharmaceutical companies, are trying to enforce patent linkage in many countries through litigation strategies. Bayer and Bristol Myers Squibb have been trying to enforce patent linkage in India, where it does not exist.

As observed in many studies patent linkage results in evergreening of patents, patent litigation, and reverse settlements. Presently there is noexpress provision on patent linkage in India. Bayer

Corporation and others v Union of India , (162, (2009) DLT 371) is the leading case onthis subject In this case the Delhi high Court discussed the experiences of various countries like the US, Canada, , the EU, with respect to patent linkage . It also discussed the incapability of the Drug Authority to judge the status of patent and TRIPS mandate on patent linkage. It concluded that there was no patent linkage in India.

The objectives of Drugs and Cosmetics Act, 1940 and the Patents Act, 1970 do not indicate any interface. The legislative intent behind the Drugs and Cosmetics Act is to examine the safety and security of drugs and good manufacturing practices which are to be applied by every importer or manufacturer of a drug. On the other hand the patents act creates a regime containing standards for conferring private rights to inventors. Controllers and Examiners at the Patent Office are experts in examining patentability in all areas of technology. However mere grant of a patent is not a conclusive proof of validity. Patents can be opposed at pre-grant ad well as post grant under Sec 25,or even revoked under sec 64, Section 13(4)provides that the examination under Sec. 12 is not the conclusive proof of validity of any patent. The govt. is in no way responsible for validity of a patent. The drug authorities as per the Drug and Cosmetics Act, 1940 have expertise in testing safety of the product and the therapeutic efficacy claimed. Nevertheless, the drug authorities have no legislative backing to examine the patent validity. Moreover, if an applicant fulfils all the essential conditions for grant of marketing approval under the Drug and Cosmetics Act, 1940, the Drug Controller of India (DCGI) is under a statutory duty to grant the manufacturing approval and marketing license. Allowing linking of patent status to drug regulatory approval will result in deciding of the patent validity question by the drug controller for which there is no legislative basis. The patent Act was amended in 2005 when several important amendments were introduced such as: Sec 2 (ta); Explanation to Sec 3 (d); Sec. 92 and 92 A; particularly pertaining to the pharmaceutical sector. Even so, there is no legislative intent to provide for patent linkage in India under the Patents Act, 1970 and theDrugs and Cosmetics Act, 1940.

In the absence of any obligation under the TRIPS on the Patent-Regulatory linkage, the absence of the Patent Linkage in India, cannot be held against India. India cannot be forced adopt or embrace any TRIPS + obligations.

8.26 Data Exclusivity

Data exclusivity adds an extra layer of protections for the drugs irrespective of the patent protection status, thus controlling access to medicine. Data exclusivity provides protection of clinical test data and results submitted to the regulatory authorities in order to confirm safety and efficacy of pharmaceutical products. Data exclusivity, in principle is applicable irrespective of the patent status of the drug, and hence will be applicable to unpatented medicines as well medicines whose patent terms have expired. So it essentially acts as an extra layer of protection for the originator. Pharmaceutical companies need protection for the data on safety and efficacy tests to prevent generic producer companies from using them for same compounds .generic companies need not only the test s data on bioequivalence and bioavailability, but also data on clinical trials. Data exclusivity (DE) provisions are different in different countries. .The US has NCE data exclusivity for 5 years; 3 year exclusivity for first generic entrant; 180 days exclusive marketing rights for first to launch an ANDA application who successfully challenges a patent; 7 year exclusivity for an orphan drug for rare conditions and diseases etc. The US has enforced data exclusivity provisions in bilateral agreements with many countries such as Jordan, Thailand, Malaysia, Vietnam, Singapore, Guatemala, and other countries. For instance Thailand had to enforce dataexclusivity for period of 5 years in the case of pharmaceutical products and ten years in case of agricultural chemical products from the date of initial regulatory approval of the original product. This has prevented the drug regulatory authority fromgranting market approval to generic drugs on the basis of bio-equivalence, or on the fact that original product has got marketing approval in a foreign country. The USTR proposed that Thailand includes a provision obligating the Thai drug regulatory authority to inform the patent holder as to any attempt to register a generic drug. The drug authority is also barred from approving registration for a generic medicine unless it is certain that the manufacturing, importing, and selling of the generic will not infringe the patent rights of other companies.

In the ongoing EU-India FTA negotiations EU has been insisting on inclusion of data protection. Dataexclusivity as demanded by the EU would require Indian generic manufacturers either to conduct their own clinical trials to get marketing approvalsor wait till the specified exclusivity period (6 to 11 years) before a generic product gets marketing approval. Immediate impact of the countries which have accepted on data exclusivity provisions in bilateral, or FTA agreements

with the US or the EU has been steep rise in prices of medicines. India's acceptance of the data exclusivity provisions would imply signing a death warrant for the generic pharma industry in India and a good bye to the dream of access to affordable medicines. It would mean that the generic versions are delayed for years as the generic companies would be required to conduct clinical trials for which neither they have the financial resources, nor the skills , and not the capacity to wait for years for completion of clinical trials. Only a handful of generic pharma companies in the developing world have such a capability to conduct and sustain clinical trials.

India has not adopted DE in the national legal provisions. TRIPS Agreement is the first international property agreement to include obligations for the protection of trade secrets, especially the proprietary submitted by innovators to the governments. Though provision for DE is not expressly mentioned in the TRIPS Agreement, the interpretation of Article 39 is done in favour of DE. Article 39 generally deals with protection of undisclosed data, which relates to trade secrets; Article 39.2 is a general clause to respect trade secrets, and is an obligation for all WTO members; while Article 39.3 constitutes obligations in the particular case where such trade secret data are submitted to govt. agencies as a qualification for seeking marketing approval. Duration of protection is not expressly mentioned in the text of Article 39.3. As the protection of the data is against the unfair commercial use, an unpatented medical product can get market exclusivity for a certain period of time, while in case of patented drugs the marketing of generic medicines will be prevented for the period of exclusivity. Further the protection of test data would be available only when it is submitted for marketing approval, and involved considerable effort in gathering it, is of undisclosed nature and relates to a new chemical entity. There is enough flexibility in the provisions of TRIPS for a member to determine appropriate means for protecting the test data. Para 4 of the Doha Declaration provides that the TRIPS provisions are to be interpreted and implemented in a manner supportive of the members right to protect public health and in particular to promote access to medicines for all .In India , obligation under Article 39 of the TRIPS is met by non-disclosure of data submitted for market approval to the regulatory authority , and further that the regulatory authority is not precluded from relying on such data for the same product by any subsequent applicant. Provisions of DE is not a mandate under the TRIPS but a conscious legislative policy or an assumed obligation under the FTA.

India's deliberate choice not to adopt DE it in its legislation is a conscious sovereign choice, while not accepting it in bilateral agreements or FTAs is a conscious choice not to assume any TRIPS+ obligations.

8.27 What seems to have troubled the US is that the grant of a compulsory license to Natco for Nexavar patented by Bayer and the adverse decision in the case of Gleevec, coupled with India's steadfast opposition to any TRIPS+ obligations on Data Exclusivity and Patent-Regulatory linkage might inspire other developing countries to follow suit. The US would think twice before taking the Gleevec case or the Sec 3 (d) incompatibility with the TRIPS to WTO for rekindling the 2001 scenario which led to Doha Declaration and changed the discourse fron trade aspects of essential drugs to a human right to accessible and affordable drugs. the issue to decides to the During her recent visit to London ,Nirmala Sitharaman, Minister of State for Commerce , when asked by the media on the US reviewing Indian IPR Laws , responded that it could at best be a 'pedagogic exercise' and added that India had robust laws to deal with such issues. "We stand our ground" she said[40]. This is reiteration of our position that our IPR regime is TRIP compliant and that the multilateral forum of the WTO is the appropriate platform for resolution of such bilateral disputes. India has been keen to promote innovation contrary to the view being propagated by the USTR that India's innovation climate remains grim because of its patent regime

In September 2014, the heads of Governments of India and US endorsed the first "Vision Statement for Strategic Partnership", which included a significant agreement on IP-related issues. The two governments "committed to establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and technical-level meetings as part of the Trade Policy Forum." India clearly faces the challenge to prevent the Working Group from being used by the US Trade Administration to establish a tacit link with the Section 301 process. While the US is keen to resolve contentious pharma IPR issues, India would have to propose that sub-groups on traditional knowledge, copyrights, music and online piracy, IT, and geographical indication be included and without disproportionate attention to the pharma sector, the IPR issues need to be discussed more holistically. The main issue is that given the US's scant regard both for the due processes mandated by the multilateral trade rules, and the solemn undertakings

[40] Hindustan Times 29 October 2014. Page 15.

accepted by the US Trade Administration, whether the bilateral process of engagement put in place during Prime Minister Modi's visit to the US in Sept. 2014 would become yet another platform for the US lobbies to seek changes in the Indian patent regime

8.3 Modernization of Patent Office

In October 2014 the Patent Office issued guidelines, fifth in the series of documents, for examinations of patent applications, in the field of pharmaceuticals, to supplement the ' Manuel of Patent Office Practice and Procedure' which provides guidance to the Examiners, as well as stake holders as to how the applications would be dealt with by the Patent Office. The new guidelines are a welcome steps in streamlining of various procedures for examination of patent applicationsand would bring more transparency, clarity, and consistency in the practice and procedure in handling of patent applications for pharmaceutical products. The Patent Office has been facing a lot of problems, includinghuge backlog of pending applications; backlogof both pre-grant opposition and post grant objections; shortage of human resources, poor morale, and high attrition rates; poorly examined patents It is obvious that when the patent filings are increasing at a predictable rate, it is essential to plan ahead for the requirement of the requisite professional staff which seems to have been lost sight of. As shown below, the patent office has been ill equipped to deal with the increase in number of applications from 10,592 in 2001-02 to 43,197 in 2012; large number of vacancies,disposal rates of 24.2% and 32.4% for pre-grant objections and post grant oppositions over the 8 year period from 2005-06 and 2011-12. From the data below the patent Office granted 11751 patents in 2007-08 and 10296 in 2008-09. Given the number of patent examiners on the rolls, it looks impossible, unless there was laxity in examinationstandards to clear the backlog in a rush. It is conjectured that the new Controller-General in 2009 ensured that strict standards were adopted in patent examinations and as a result the number of patents granted each year thereafter fell drastically as the Patent Office did not have the requisite manpower to deal with the increased filing of patent applications. Indian patent examiners have,perhaps, the world's highest workload- while a patent examiner at the European patent office handles less than 7 patents applications per month, and a US patent examiner would handle 8 applications per month, an Indian patent examiner is expected to handle at least 40 applications per month-15 new cases (FER) and 25 disposals (including further examination reports). Quantity expected impacts on quality of examination.

Table 8.2 Sanctioned strength of controllers and number of those in position*

Year	Sanctioned strength of Controllers of all ranks	Working Strength Of Controllers of all ranks	Vacancies	Number of patent applications filed
2001-02	33	31	2	10592
2002-03	34	30	3	11466
2003-04	41	35	6	12613
2004-05	45	39	6	17466
2005-06	43	39	4	24505
2006-07	42	38	4	28940
2007-08	43	37	6	35218
2008-09	94	83	11	36812
2009-10	94	80	14	34287
2010-11	93	75	18	39400
2011-12	94	74	20	43197

Table 8.3 Sanctioned strength of Examiners and number of those in position*

Year	Sanctioned Strength for the post of examiners	Working Strength for the post of Examiners	Vacancies	Number of Patent Applications Filed
2001-02	189	33	156	10592
2002-03	189	91	98	11466
2003-04	189	172	17	12613
2004-05	212	164	48	17466
2005-06	156	140	16	24505
2006-07	156	133	23	28940
2007-08	146	126	20	35218
2008-09	337	75	262	36812
2009-10	337	80	257	34287
2010-11	282	79	203	39400
2011-12	337	200	137	43197

*(Source: Annual Reports of Patent office and information from patent Office)

Table 8.4Number of pre-grant objections and post- grant oppositions filed and disposed of*

Year	Pre-Grant representation filed	Pre-Grant representation disposed (Including for previous years)	Post-Grant oppositions filed	Post-Grant oppositions disposed
2005-06	155	100	6	4
2006-07	44	19	27	4
2007-08	64	17	34	6
2008-09	153	39	71	7
2009-10	103	32	28	4
2010-11	294	19	29	30
2011-12	193	18	27	17
Total	1006	244	222	72

*(Source: Annual Reports of Patent office and information from patent Office)

8.31 Patent office need to allocate more resources to attend to pre-grant representations , post –grant representations and address the issue of pending backlog of patent applications.

Apart from increasing the sanctioned strength of the patent office and putting in place a system of timely recruitment and regular training of the staff, including institutional tie-ups with patent offices in the US, EU, South Korea, Japan, Brazil etc. to ensure that the staff has and retains cutting skills to examine patent applications in all the emerging technological areas, ample opportunities for career growth should also be provided to them. At present some 74 Assistant Controllers can look forward to only 10 positions distributed between three ranks of Deputy Controller, Joint Controller and Senior Controller, while 334 Examiners have only 74 positions of Assistant Comptrollers at the next level of promotion. There need to be better promotional avenues to motivate the staff. One way could be that the Examiners with 5 years' experience against the existing requirement of ten years, be made eligible to register themselves as Patent Agents.

According to the Patents Act, 1970, the examiner examines the application and submits his report to the Controller who has the authority to grant or refuse to grant the patent. As the Patent Office is often dealing with patent applications involving cutting edge inventions and emerging new technologies, it is quite possible that it may be beyond competence of a single Examiner or a single Controller assigned to the patent application, in which case it may be expedient to allow

the Patent Office some flexibility to assign the staff on each patent application according to the complexity of the invention being claimed. It may also be worthwhile to reconsider the recommendation made by Justice Ayyangar Committee in its Report in 1959, on the need for outside help, in the form of inputs from academia, in examination of complex issues involved in a patent application. It is reproduced below:

"380. A provision on the lines of Section 11 (2) of the U.K. Act, 1949 is useful and may be added. Section 44 of the Patents Law of 1957 of Czechoslovakia contains a provision for a Commission of Experts as the advisory organ of the President of the Patent Office, with assignments to be fixed by the latter. A similar provision for a panel of experts to advise the Controller, if he desires at any time to consult them on questions involving novelty or subject matter might be usefully adopted here. The references should be made confidentially and if the report of the expert is adverse to the applicant, the Controller might be directed not to act upon the report without making the report available for the applicant and giving him an opportunity to be heard"[41]

8.32 As per Sec.144 of the Act the report from the examiner to the Controller is supposed to be confidential. There have been demands from some groups to make the reports of the Examiners available to the general public. Most patent offices around the world allow for such examination reports to be made public. The parliamentary Standing Committee in its 88th. Report in 2009 recommended that sec.144 of the Act should be repealed and a transparent examination system should be made available for all to view.; and doing away with the confidentiality of Examination Reports, as provided in sec. 144 of the Patents Act 1970, to bring in transparency in functioning of the Patent office.

[41] P.133 of the Ayyangar Committee Report

8.4 Amendment of the Patents Act, 1970

The following amendments to the Patents Act, 1970 which might make it more effective, in the context of subject matter of this Paper, merit consideration:

8.41 Scope of patentability

i. A slight modification in the definition of the term 'invention' would clarify the scope of 'invention' more clearly and unambiguously.

Clause (j) of section 2 defines invention as "invention' means a new product or process involving an inventive step and capable of industrial application"

Changing definition of 'invention' to "invention' means a basic new product or process involving inventive step and capable of industrial application'' would limit the scope of the patentable subject.

(The 2005 Amendment of the Patent Act 1970, has introduced some irreconcilable contradiction by introducing the tern 'new invention', in sec 2(l) which allows prior use anywhere in the world to qualify as anticipation in India, while Chapter VI limits the geographical limitations to India. It needs to br resolved either through a legislative route or a judicial interpretation. This discussion, is however beyond the scope of this Paper)

ii. Modification of definition of pharmaceutical substance

Clause (ta) of sec 2 defines pharmaceutical substance as "pharmaceutical substance means any new entity involving one or more inventive steps."

This definition is quite broad and not specific and could be changed to "'pharmaceutical substance' includes new drug molecule involving one or more inventive steps". This definition is in line with the recommendation of the Mashelkar Committee on R&D for pharmaceuticals

8.42 Introduction of a new section 84A.in the Patents Act,1970

Article 31of the TRIPS Agreement deals with 'use of patents without authorization of the Rights Holder. Article 31(b) provides for conditions under which, a member country may issue, what may be described as grant of Compulsory License without authorization of the patent holder. Article 31(b) clearly stipulates that a member can allow the use of the subject matter of a patent provided that: (b) such use, may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. Based on this provision various countries have specified what they consider as the reasonable period. For instance Brazil has prescribed a period of 60 days and in the absence of a reply from the patent owner, the proposal shall be deemed accepted under the conditions offered.

Sec.84 of the Patents Act, 1970 which has incorporated provisions of Article 31 of the TRIPS Agreement has not prescribed any time limit within which the patent holder may respond to the request for grant of a voluntary license, which has been grossly abused by the major pharma patent holders. It is instructive to note that some of the international pharma patent holders have ingenious strategy of not rejecting voluntary license application but to continue correspondence with the applicant, without leading to any closure of the negotiations, and seeking out as much information as possible to be used in the infringement proceedings, which linger on over the years through multiple adjournments. In the light of the above, it is suggested to introduce a new Section 84 A, which would limit the time of response from the patent holder to a maximum of 100 days. Proposed text is as follows:

84 (1) 1. When the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a period not exceeding 100 days, the controller shall at any time after the date of grant of patent grant compulsory licence to the applicant on such terms and conditions as he may deem fit.

84(2) The commercial terms and conditions offered by the applicant shall be considered reasonable by the controller if royalty and other remuneration offered by him are within five per cent of the annual sale turnover at net ex-factory sale price (exclusive of excise duty and sales tax).

8.43 Deletion of clause (vi) of Sec. 90 (1)

Section 90, Sub-section 1 clause (vi) provides for a shorter term for the compulsory license. No one would be interested to take compulsory license for a shorter period and hence shorter term may be deleted.

8.44 Obligatory License for life saving drugs[42]

There may be a need to introduce a new clause under sec 92of the Patents Act, 1970 for grant of an obligatory license for life saving patented medicines as advocated by Dr. Yusuf Hamid of Cipla. This proposal seems to be a hybrid between Compulsory License and License of Right which was available in the Patents Act prior to the 2005 Amendment.

8.45 Price Control

TRIPS Agreement is silent about the price control of patented products. Essential lifesaving patented drugs are generally priced beyond affordability of ordinary people. The products protected under patents enjoy monopoly in the market place and would certainly command high prices. Since the TRIPS Agreement must be interpreted in harmony with the objective and purpose of the TRIPS Agreement to enable the member states to meet their obligations to provide access to affordable medicines, it may be necessary to regulate prices of such patented medicines, at least for an initial period of 5 years, by a transparent mechanism established by law.

8.46 Other suggested changes in the Patents Act, 1970

[42] http://www.thehindu.com/business/Industry/cipla-chief-calls-for obligatory-drug-licensing/article5029408.ece(14 October 2013)

8.461 Need for detailed rules and guidelines to handle pre-grant representation and post-grant opposition

As a result of the judgment in Network for People living with HIV/AIDS v Union of India of the Madras High Court in Dec.2008, the Indian Patent Office is now required to provide a hearing in all pre-grant representations under sec 25(1) of the Act.. In Europe a pre-grant representation is allowed where the Patent Office is of the opinion that that a hearing must be granted. In the US the recent patent law reforms through the 'America Invents Act' the US has brought in only post grant opposition and dispensed with the pre-grant opposition mechanism. Under the Patents Act, 1970, the pre-grant representation under sec 25(1) and post-grant opposition under sec 25(2) are open ended. A pre-grant representation can be filed any time between the filing of a request for examination and grant of a patent, and a post –grant opposition can be filed any time within a year of the grant of the parent. Filing of serial pre-grant representations and post-grant oppositions is an abuse of the stated objectives of the Patents Act and needs to be curbed. Besides, there is a need for detailed rules and guidelines to guide the Controllers to handle pre-grant and post –grant oppositions.

8.462 Certification of validity of a patent Sec.113

The Patents Act, 1970, unlike the US, does not provide for a presumption of validity of an issued patent. The only exception is contained in sec113 which allows the High Courts or the IPAB to issue a certificate of validity of a patent which has survived an attempt at revocation. This certificate of validity ensures that cost of any future proceedings regarding the same patent is borne by the person challenging the patent in case he fails to prove invalidity of the patent. Besides, a presumption of validity of a patent makes it easy to secure an interim injunction. There is, therefore, a need to consider application of sec 113 of the Act to all pre-grant and post-grant opposition proceedings

8.5 Need for voluntary judicial rectitude in granting quia timet injunctions. Protracted Indian Pharma Litigations and quia timet injunctions

8.51 Patent litigations in India exhibit both frivolous protracted, largely abusive of the process of law, and the application of quia timet injunctions, both of which largely operate to the disadvantage of the generic pharma manufacturers. While post-2005 there have been many patent infringement suits involving Indian pharmaceutical companies , the 'nib' patent wars have been in the limelight- Imatinib (Gleevec), Sorafenib ((Nexavar), Erlotinib and Dasatinib, are subject matters of ongoing litigation on both the infringement related injunctions and damages as well as patent regulatory linkages. While patent –regulatory linkage was contested by Indian pharmaceutical companies successfully, a few cases are still languishing for final orders in High Courts.

In the only CL legitimately granted by India, so far, the litigation has been going on for years to frustrate and tire out the Indian generic manufacture and drain them out financially through multiple adjournments, in multiple litigations. There are extensive and protracted litigations sub-judice in Indian courts, where the cause of action is either applying for a regulatory approval, or obtaining a product manufacturing license from the FDA or seeking a voluntary or compulsory license. It is instructive to note that some of the international pharma patent holders have ingenious strategy of not rejecting voluntary license application but to continue correspondence with the applicant, without leading to any closure of the negotiations, and seeking out as much information as possible to be used in the infringement proceedings. These infringement suits are filed in most cases purely based on application for regulatory approvals, Indian pharma companies, lacking financial strength and expensive legal back up , are unable to and drawn out litigations. Even if these costly litigations eventually vindicate their position, the generic companies get financially exhausted by the time the suit is decided, dismissed, withdrawn or settled. Notwithstanding the fact of sec 106 of the Patents Act of 1970 which relates to the groundless threats of infringement proceedings, sec 48 relating to right of patentees, sec 47 providing for general exemptions, sec107A, relating to certain acts which cannot be construed as infringements, lack of data protection and data exclusivity in in India, and lack of patent

regulatory linkage which was categorically ruled out by the Supreme Court in Roche v Cipla [43], there are extensive and protracted litigations in Indian Courts where the cause of action is merely related to applications for regulatory approval of a medicine, either to the DGCI at the Central Drugs Standard Control Organization or to the State Food and Drug Administration. In one case the cause of infringement suit was filing of a CL application. Listing of a patented drug on the website with disclaimers of not for sale has been considered as a cause of action. (It is relevant here that sec107A of the Patents Act ,1970 provides the exemptions available under the Hatch – Waxman Act in the USA and EU Directive no. 2004/27/EC and 2004/28/EC). The list of following ongoing cases would highlight tendency of the foreign major pharmaceutical patent holders to browbeat, harass, frustrate and tire out Indian generic producers from attempting to encroach their turf by abuse of the process of law through protracted and multiple litigations with no intentions to settle the issues litigations but to prolong the cases via repeated adjournments:

8.52 Sunitinib Case

It is typical case of protracted litigations. Sunitinib imported into India and marketed by Pfizer under the brand name Sutent had initially obtained a patent which was subsequently revoked on post grant opposition by Cipla. While protracted litigation has been going on, the Sugen/Pfizer has initiated infringement proceedings against other Indian generic companies. .

The Sunitinib patent no. IN 209251 granted on 5 October 2007 was subsequently revoked. This revocation was challenged initially in the High Court and later appealed in the Supreme Court. The Supreme Court sent it back to the Patent Office for re-hearing with a direction to provide a copy of the 'Recommendations of the Opposition Board' to the appellant, Pfizer in this case. The Controller again revoked the patent and thereafter Pfizer filed a writ petition in the High Court who directed them back to the IPAB. IPAB referred it back to the Patent Office and ordered a new Opposition Board to be constituted. , their recommendation made available, and the hearing to be conducted by another Controller. Consequently the new Opposition Board was constituted to hear the matter de novo. The decision is awaited. In the meantime Sugen has filed two writ petitions the first Writ[44] challenging the observations of the IPAB in Order No. 107 of 2013

[43] M/s BDR Pharmaceuticals Pvt Ltd v Bristol Myers Squibb, Controller of Patents, Designs, and Trademarks, C.L.A No.1/2013. Order fated 29 August 2013

[44] Sugen Inc. & Anr v Union of India & Anr , Delhi High Court , W.P.(C). 5353/2013

dated 17 may 2013 on sec 8 and second Writ[45] in relation to the recommendations of the Opposition Board dated 26 July 2013. Concurrently an infringement suit is pending against Cipla[46].This is typical case of persistent and protracted pursuit of legal fights to tire out the opponents and exhaust them financially.

Dasatinib case

Dasatinib litigation which commenced in 2008 is still continuing in various courts .Natco, Hetero and BDR have been sued by Bristol Myers Squibb Company from 2008 onwards. Fresh cases have been filed in 2013. However these cases have not yet reached substantive hearing. Initially the litigation started on the ground of patent regulatory linkage. Currently the proceedings are related to injunctions, potential infringements, and drug approvals.

Dasatinib 5

Bristol Myers Squibb Company & Anr v Dr. BPS Reddy & Ors CS (OS) No. 2680/2008

This case continues to be heard through adjournments and procedural issues. Bristol Myers Squibb Company appears to be impleading additional defendant for which the matter has been adjourned. The large number of adjournments on procedural issues extending over 4-5 years without any substantive hearings leads to the conclusion that these are protracted litigations to tire out the generic companies and to dissuade , and discourage them from applying for regulatory approvals under sec107A (a) during the validity of pharma patents.

Dasatinib 4

Bristol Myers Squibb Company & Anr v Mr. M Adinarayana and Anr CS (OS) No. 2279/2009

A similar suit no. CS 22779/2009 has been filed in 2009 against Natco, the hearings for which are also in progress. The issues are being consolidated and framed.

8.53 There have been a recent surge in patent cases relating to quia timet injunctions recent cases. In Bristol Myers Squibb Company V Bhutada, and Ors, the defendants requested the Court to dismiss the plaintiff's quia timet action. The Court, however did not dismiss the

[45] Sugen Inc. & Anr v Union of India & Anr , Delhi High Court , W.P.(C). 5358/2013 Court
[46] Sugen Inc. & Anr v Cipla Ltd, Delhi High Court, C S (OS).(C). 3429/2012 before

application, nor was the injunctive relief granted. In this case the plaintiff claimed that the defendant's action of obtaining a manufacturing license from the Drug Controller Licensing Authority, Karnataka for its patented drug Dasatinib and the listing on its website that Dasatinib was a product under development, all pointed to an imminent threat of infringement of a patent. The Court deferred the ascertainment of these claims to the stage of trial as they found that such a decision involved examination of facts and law which could not be adopted by examining merely the plaint. However, the plaint was admitted on the basis that apprehension was 'prima-facie'credible.

8.54 In a recent case of Bayer Corporation v Union of India and Ors[47], Natco raised the legal availability of the provisions of Section 107Aof the Patents Act, but the Court still granted an injunction order against Natco. The legal of export for regulatory approvals under Sec 107A will hopefully be resolved in this case. The international practice of filing infringement suits purely on regulatory initiatives is being extended to Indiaeven though India does not have any data/marketing exclusivity as in developed countries.One unique feature of patent litigation in India is protracted adjournments and procedural delays.

8.55 Novartis has been successful in obtaining interim quia timet injunctions. In April 2014, the Delhi High Court granted a host of interim quia timet injunctions to Novartis against several generic manufacturers such as Bajaj Healthcare, Alembic Pharmaceuticals, Glenmark Generics, and Cadila Healthcare, over its anti-diabetic drug Vildagliptin. Novartis' patent is valid till 2019. In the first two cases the court expressly ordered ex-parte interim injunctions against the generic manufacturers. In response to an RTI application, Novartis had learnt that both of these companies had obtained manufacturing licenses and marketing permissions to sell generic Vildagliptin from the Drug Controller in early 2014. Further neither of them had opposed or challenged Novartis patent. At the time of obtaining injunction, the generics had not yet been launched. Novartis contended that on the basis of the information, the two generic manufacturers were in the process of launching the drug and irreparable damage would arise if the injunctions were not issued. Merely on this basis, the Court restrained the defendants from manufacturing,

[47]Bayer Corporation v Union of India and Ors, High court of Delhi , W.P(C) 1971/2014, High Court Order dated 26 March, 2014.

importing, selling, offering for sale, exporting, and directly or indirectly dealing in Vildagliptin and its combinations except as provided under sec 107A of the Patent A, till the next hearing. The other two manufacturers gave voluntary undertakings, which were equivalent to injunctions.

8.56 Yet another set of quia timet injunctions were obtained by Novartis in March 2014against Biocon and Wockhardt. Wockhardt had initiated revocation proceedings before the IPAB, in an attempt to annul the patent over Vildagliptin. Upon which Novartis filed an RTI and obtained a list of manufacturers who had obtained regulatory approvals for Vildagliptin. Thereafter Novartis filed two infringement suits in Delhi high court against Biocon and Wockhardt. In both the cases injunctions were granted till the next hearing and the generics were prevented from manufacturing, selling, exporting etc. the impugned product.

8.57 The issue is a quia timet action is an action based on a possible future injury and therefore stems from a threat of infringement. As there are no standards for granting such injunctions, these become subjective and at times speculative. It appears that patent cases are not appropriate matters to grant and allow such quia timet actions particularly when there are complexities involved in assessing infringement in patent matters; availability of alternatives for monetizing losses that may be suffered by the patentee; public interest involved in speedy disposal of such cases; and all the more so, as there is a possibility of questionable quality of patents being issued by the overburdened Indian Patent office. Such quia timet actions may adversely impact on innovation and larger public interest in access to affordable medicines, without unnecessary delay.

8.58 There is no presumption of validity of a patent and the defendant can always challenge the validity of a patent. Given the state of affairs at the Patent office as explained above; and given the fact that patents that are litigated are the ones which society most value; and given the fact that even if the threat of infringement materializes, the injury caused to the patentee may not be irreparable or irreversible because he can be compensated; and also give the fact of subjectivity and speculation involved in the application of quia timet actions in patent cases in India, such quia timet injunctions may be contributing to the abuse of the process of law. The relief available in sections 105, and 106 against groundless threats of infringements by the patentees is not commensurate with the effect of ulterior purpose of resorting to quia timet actions which are merely speculative, and often designed to use injunctions as a weapon against

to curb otherwise legal activities and to assert dominance. It could also be strategically designed to cut off legal and successful businessof competitors or to deliver a chilling blow to the legitimate manufacturers. As the patent itself is a preventive legal tool, because it allows the patentee to initiate action on infringement, the scope of the patent law is curative and not preventive, thereby placing quia timet actions beyond the scope of relief contemplated by law. Voluntary judicial rectitude is perhaps the need to curb the unholy tendency of protracted prolongation of frivolous litigations which militate against the public interest and retard the delivery process of access to affordable medicines.

8.59 It was, perhaps, in this context that the Supreme Court was distressed to observe in para 156 of its Judgment in the 'Gleevec' case that:

"We would like to say that in this country the law of patent, after introduction of product patent for all kinds of substances in the patent regime is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent"

8.6 Making efforts toseek liberalization of implementation mechanism of para 6 of Doha Declaration

It is ironic that while the WTO launched the Trade Facilitation Agreement recentlywith such a fanfare that it would increase trade opportunities by lowering transaction costs through harmonization, mutual recognition, and easier access to information; reduce time to deliver products to markets and customers; enhance market access; add US $1 trillion to global GDP and also can generate 21 million jobs by slashing red tape and streamlining customs. It also reaffirmed members' commitment for duty free and quota free market access for LCDs. Yet the same WTO, perhaps by design, in 2003, devised an extremely complicated and unworkable mechanism for implementation of para 6 of Doha Declaration on the TRIPS and Public Health of 14 Nov. 2001. The decision on agreed legal changes, 'to make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines', announced on 30 August 2003, calling it 'a historic agreement for the WTO', made the procedure so complicated and has such a dismal legacy that only one license could be issued in over a decade!.

India should take the initiative at the WTO to get the procedure for user friendly to facilitate, rather than complicate for poorer countries to import cheaper generics made under compulsory licensing, from other developing countries. India has a vital stake in this for the twin reasons that the LDCs exemption from TRIPS obligations until 2021, provides a lucrative market for Indian pharma industry, and provides India an opportunity to generate a lot of goodwill. Indian assistance/grants in the form of essential medicines is a win –win situation both for the Indian foreign policy as well as for the Indian pharma industry. India should strive to build a coalition of like-minded countries like Brazil, South Africa to highlight this concern at the WTO and even at the Human Rights Committee of the United Nations, to set this process in motion.

8.7. Curbing anti-competitive practices of market players

While the patent owners enjoy monopoly over their rights as envisaged under sec 48 of the Patents Act, 1970, these rights are subject to other provisions of the Act, such as exemptions to right enshrined in various sections of the Act, provisions relating to compulsory licensing, and governmental use. It is also subject to other laws of the land. Besides, the trade involved in marketing of the pharmaceutical products is also subject to the provisions of the Competition Act, 2002 and other laws of the land. The Competition Commission intervened in a pharma related complaint and restrained anti-competitive pharma distribution practice indulged in by the All India Organization of Chemists and Druggists**,** which had effect of inflating price of pharma products for the end consumers.[48] The competition Commission has also intervened in other similar cases to stop anti-competitive practice of the trade. (Google case). Frivolous and imaginary , protracted litigation, largely abusive with ulterior objective to limit competition from generic Indian pharma companies , indulged in by major international pharma companies , which may amount to abuse of their dominant position, and perhaps unfair trade practice to restrain competition, could be challenged through the Competition commission of India. The collusive and unholy practice indulged in by some doctors and the diagnostic service providers, by which the doctors recommend unnecessary investigations and receive commissions from diagnostic service providers, also needs to be looked at from the angle of unethical and anti-consumer trade practices.

[48] M/s Santuka Associates n Alcod and Ors, Competition commission of India , (March 2014)

8.8 Challenge of reducing the high costs of drug discovery and development

It is a challenge to achieve a balance between the economic interests of the originator companies and the public interest to access to affordable medicines. The ground reality is that virtually all the all the modern lifesaving or life supporting biotechnology drugs essential for intractable chronic diseases, even when made available at the generic price level through compulsory licensing costs more than 6000-8000 Rupees per month, far beyond affordability of the poor not only in India but also in poor developing countries with a per capita income of less than US$ 2 per day. Drug discovery and development has been an expensive affair. Global R&D expenditure in the pharmaceutical sector has increased from US $ 35.3 bn.in 1996 to more than US$95 bn. in 2009.

According to a study [49] the average cost of developing an innovative new drug, called NME (New Molecular Entity) is more than $800million, including expenditures on failed projects and the value of forgone alternative investments.Actual expenditures make up only about a half of the total reported cost. The rest represents the financial cost of tying up investment capital in multiyear drugdevelopment projects, earning no return until and unless a project succeeds. On anaverage, developing an innovative new drug takes about 12 years. Research and development spending per NME has grown significantly in recent years, for various reasons:

- First, failure rates in clinical trials have increased

- Second, larger drug firms are said to have shifted the focus of their development efforts away from drugs for acute illnesses and toward drugs for chronic illnesses

- Third, greater technological complexity in drug development and greater specificity in disease targets to identify drugs with particular molecular characteristics rather than using trial-and-error methods to find compounds that work in some desired way.

[49]Joseph A. Di Masi, Ronald W. Hansen, and Henry G. Grabowski,"The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, vol. 22, no. 2 (March 2003), pp. 151-185.

Most new drug products, also called Incrementally Modified Drugs, have much lower R&D costs than NMEs because they are incremental improvements on existing drugs.. These account for only about one-third of the industry's R&D spending, and their average directcost may be only about one-fourth that of an NME. However, costs can still be considerable if the new product requires clinical trials.

8.81 NME approvals shot up for a fewyears in the mid-1990s and then fell again; on the whole,such approvals have consistently ranged between about20 and 30 per year. Global pharma R&D has not been able to produce a blockbuster for many years.Non-NMEs constitute about two-thirds of thedrugs approved by the US FDA. Measured by the number of drugsapproved per dollar of R&D, the innovative performanceof the Global drug industry appears to have declined.

8.82 Around 40% of the R&D expenditure going to pre-clinical functions and 30% towards completing the Phase I, II,and III clinical trials required by the FDA. 70% of all the R7D expenditure is targeted towards gaining regulatory approval. Only 3 out of ten drugs introduced in the United Statesfrom 1980-84 had returns higher than their average after tax R&D costs. Comprehensive drug testing in the clinical trial stage alone can cost US$150 mn. For a single medication. Average rate of drugs ever clearing the full set of pre-clinical and clinical trials ranges between 10-20%.Time spent on clinical trials eats into the patent monopoly of 20 years

Stages of drug development[50]			
Research Stage	Preclinical Stage	Clinical stage	Marketing stage
Basic research Prototype design Time: 2-3 Years	Initial synthesis Animal testing Time: 2-3 Years	Phase I-trial on number of healthy volunteers Phase II-Trial on 100-300 patients Phase III- Trial on 1000-3000patients Time : 5-7 years	Marketing approval by drug regulatory authority Phase IV- Trial for post – marketing studies Time : 1-2 years (marketing approval

8.83 In contrast to major Indian pharma companies have been making strides and increasing their footprints in the US, Europe and other developed countries and entrenching themselves with impressive list of products in the pipeline, increasing their R&D expenditure, and basically focusing on new generics, the Indian companies have not been able to produce an NME or any blockbuster in over a decade, but given their increasing level of R&D expenditure, creation of R&D infrastructure in India and abroad, tie-ups, acquisitions, and joint ventures with various international pharma companies to unleash and harness synergies, it is inspiring and reassuring that the Indian pharma companies would continue to meet the requirements generic medicines of off patent medicines, and given the requisite financial support , they may be able to discover, develop, and deliver medicines relevant to disease burden of India and the developing world .

- Indian companies received final approval for 154 ANDAs during the year 2013 from US FDA and 38 tentative ANDAs approval. The US FDA has approved a total 400 final ANDAs during the year 2013. With higher R&D investments, Indian companies secured 81 ANDA approvals

[50] Simon N.G Drug Discovery and Development, http://www.lehigh.edu/~inbios21/PDF/Fall2011/simon_09162011.pdf

from US FDA during the first eight months i.e. January-August 2014 which worked out to almost 31 per cent of total ANDA approved during this period

- The Research and Development (R&D) spending of 25 leading Indian pharmaceutical companies increased by 20.6 per cent to Rs. 6,103 crore during the year 2013-14 from Rs. 5,060 crore in the previous year. For the last three years the R&D investment as percentage of net sales of Pharmabiz sample of 25 pharmaceutical companies worked out to over 7 per cent despite higher growth in net sales. During last 10 years i.e. 2004-05 to 2013-14, the major 20 Indian pharmaceutical companies spent aggregate amount of Rs. 32,495 crore on R&D activities on standalone basis and these companies generated aggregate net sales of Rs. 4,24,220 crore However, these companies failed to produce any single blockbuster new drug during last ten years.
- Dr. Reddy's Laboratories incurred aggregate R&D expenditure of Rs. 5,070 crore during last 10 years and remained on top among the 20 companies, followed by Ranbaxy (Rs. 4,877 crore), Lupin (Rs. 4,589 crore) Cipla (Rs. 2,716 crore) and Cadila Healthcare (Rs. 2,608 crore).

- Investments in R&D offered higher approval from US FDA, EDQM, MHRA, TGA, ANVISA, WHO and other regulatory bodies. These companies developed strong product pipeline for future introduction.

- During the fiscal year ended March 2014, Dr. Reddy's Laboratories (DRL) remained as top R&D spender at Rs. 1,071 crore (standalone) .DRL has set up eight R&D, product and technology development centers across globe which empowered it to deliver solutions across therapeutic areas. It has filed 13 product in the USA and its cumulatively, 62 ANDAs are pending for approval from US FDA. Of these, 39 are Para IVs – out of which nearly nine have 'First to File' status. Its revenue in North America increased by 46 per cent to Rs. 5,530 crore during 2013-14. DRL entered into an alliance with Merck Serono, a division of Merck KGaA, Germany, in 2012 to co-develop a portfolio of bio similar compounds in oncology. The company is developing more than 15 proprietary products with lower risk. It acquired OctoPlus, a specialty research facility, in the Netherlands during 2013.

- Other Indian pharma companies such as Sun Pharma, Lupin, Biocon, Wockhardt, Aurobindo, have also enhanced their R&D expenditure and acquired valuable R&D assets , and approvals in the US and Europe and built up impressive growth strategy, for a long haul.

- The Indian companies' investment in R&D will play important role when the returns from R&D investments by international giants is diminishing. For several years major international players have not brought any block buster drug despite huge investment in R&D activities. Thus, on one hand, the outcome from investment in R&D is diminishing and on the other hand several new products are creating new competition for old products. The indigenous developed manufacturing process & technologies and availability of talent pool offered competitiveness to Indian players.

8,84 An integrated growth strategy of the Indian pharma sector on public-private model, through a Special Purpose Vehicle,(SPV), comprising major players from the Indian pharma industry, public research institutions like CSIR, and other related research institutions, mandated to produce new molecules, one or two new molecules for tropical diseases prevalent in India , in every two-three year cycle ,with a sustainable source of funding – which could be mobilized from a portion of the CSR pool, fortified with dedicated cess on a selected basket of goods and services, and donations from major Indian industry philanthropists such asN. R. Narayana Murthy of Infosys , Azim Premji of WIPRO, and public funding from the govt. budget, etc. – a beginning could be made for discovery and development of medicines relevant for Indian population. This SPV could explore all possibilities of Open Source Drug Discovery, as well as possibility of making use of Patent Pools. There could a large number of unexploited pharma patents as at the end of 2011-12, out of a total of 39,989 patents in force in India, only 7431 were being worked.

Chapter 9

Limitations of the research and future work

9.1 Limitations of the research

- The research did not examine the rationale for the government not making use of the full flexibilities available to it under the TRIPS including generous use of compulsory licenses and grant of licenses for government use to make available essential life savings drugs at affordable prices.

- The research also did not examine as to how the government intends to respond to persistent US threat of placing India on the 'Priority Watch List' / label India as a 'Priority Foreign Country, under Section 301 of the US Trade Act of 1974, as a prelude to imposition of economic sanctions, to force India to change its IPR regime on pharmaceuticals. This issue has political overtones and is linked with larger strategic issues and bilateral political, strategic, and economic relations with the US, and has to be addressed in that context. It, perhaps, cannot be addressed as a standalone bilateral commercial issue, like others, even though it has much wider ramifications.

- The research has also not ventured into relationship between the Convention on Bio-diversity and TRIPS, and the progress on ongoing efforts to protect misappropriation of genetic resources of the developing countries. While the Convention on Bio-diversity predates the TRIPS and mandates disclosure of origin of genetic resources in patents, largely in pharmaceutical products, and also requires prior informed consent and an agreement on benefit sharing with the communities which own such genetic resources. India has rich bio-diversity and has initiated efforts in the WTO to seek amendments of the TRIPS. It has implications for access to affordable medicines in the developing countries.

- Though the research has identified the gross abuse of the process of law and the need for a voluntary judicial restraint on granting Quia timet injunctions, the issue is far more serious and needs to be examined in depth for appropriate remedial steps, which might include legislative amendments of relevant substantive and procedural statutes.
- The research has noted and emphasized that India has no option but to develop indigenous capacity to discover, develop, and deliver medicines particularly for the its own disease load, as MNC pharma companies have little interest either in developing for such diseases and or even seeking patents for latest generation of medicines for cancer and other life threatening diseases for various reasons. It is therefore imperative that the pharmaceutical industry be developed in a 'Mission Mode' this needs to be studied in depth for appropriate policy recommendations and plans.
- It is only a matter of time that the evolving jurisprudence would bring access to affordable medicines as an enforceable right, from mere vague directive in Part IV of the Constitution. The issue of public health has also to be seen from a larger strategic perspective too. The strength of a nation depends on the health of its people.

- The research has also not delved into various modalities of insurance or other schemes that could be devised to mitigate and address this issue of ensuring access to affordable medicines.

Future Work

Future research is needed into how far the recommendations of the Consultative Expert Working Group (CEWG) established by the WHO, in pursuance of the 61st. World Health Assembly Resolution (WHA 61.21) has been implemented .The Resolution WHA61.21 required the WHO to establish a result oriented and time-limited expert working group under the auspices of WHO and link up with other relevant groups to examine the current financing and coordination of research and development , as well as proposals for new and innovative source of funding to stimulate R&D in Type II and Type III diseases ,and the specific R&D needs of developing countries in relation to Type I diseases .Two WHO expert working groups (Expert Working Group(EWG) and Consultative Expert Working Group (CEWG), examined the current state of financing as well as the new and innovative sources of financing to stimulate R7d directed at specific needs of developing countries. The CEWG recommended adoption of a binding agreement based on Article 19 of the Constitution of WHO for providing effective financing and coordination mechanism to promote R&D focused on health needs of developing countries. While the content of the proposed agreement was left to the member states, CEWG set out the principles and objectives to support the negotiation process. It suggested that the objectives of the proposed Convention could,inter-alia, include:

- Implementing states' obligations under international human rights instruments related to national health;
- Delinking R&D costs and prices of products;
- Enhancing innovative capacity in developing countries and transfer of technology to these countries;
- Securing sustainable funding for identified priorities in developing countries;
- Generating R&D outcomes as public goods freely available for further research and production;
- Core elements the proposed convention to focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries in relation to Type I diseases.

The CEWG[51] required all member countries to commit 0.01% their GDP on government funded R&D devoted to meet the health needs of developing countries. The CEWG suggested a Global Health R&D Observatory, with relevant advisory mechanisms, under the auspices of the WHO to monitor financial flows to R&D and to identify gaps to avoid unnecessary duplication.

It would be very helpful to research into the work of the CEWG, as it was a logical follow up on the recommendation contained in chapter 6 of the 'Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004'

[51] Research and development to Meet Health Needs in developing Countries: Strengthening Global Finance and Coordination, report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), world Health Organization, April 2012, p.15, 110-112, 123.

Chapter 10

Conclusion

10.1 To ensure access to affordable medicines for all , it is imperative not only to address the factors that adversely impact on such access , but also to explore , including out of the box options , both at national , regional and global level to put in place a sustainable model . Some of the obvious issues are non-availability of disposable income; high and unaffordable prices of drugs- which are inter-alia due to high cost of drug discovery and development, low productivity in research and development of newer molecules, long gestation periods, heavy investments in manufacturing facilities particularly in new technology areas, high rates of obsolescence of even established drugs due to adverse reactions, threats of liability suits, short shelf life of drugs due to emergence of better drugs, threat of cheaper generics ,and consequent dependence on a few blockbuster products to sustain the revenue stream-; non- availability of medicines ; reduced focus on development of newer medicines for the disease load of the poor countries because of their inability to afford them are some of the constraints . While these constraints may be mitigated and addressed to some extent , among others ,through statutory drug price controls; parallel imports; enforcing stricter standards for grant of patents; grant of compulsory licenses to generic pharma companies as well as for govt. use; determined efforts to ensure that R&D for new drug discovery and developmentbe made more cost effective with improved productivity in in pre-clinical and clinical evaluations; and faster drug approvals to bring down costs. India has been very conservative not to make use of compulsory licensing, even for govt. use for essential lifesaving drugs. A large part of the TRIPS flexibilities which could be used by local pharma companies has been denied to them by major international pharma companies by engaging them in protracted legal battles .Liberal judicial dispensation of generous adjournments, injunctions, particularly quia timet injunctions, more so, when there is no presumption of validity of patents in India, has the potential to effectively delay/deny entry of cheaper medicines, thereby adversely impacting on availability of affordable medicines. An acceptable and pragmatic mechanism needs to be evolved , perhaps, imperative to address the unholy practice of

protracted, frivolous, abusive ,and exorbitantly expensive, litigations indulged in by major international pharma companies to frustrate legitimate efforts of Indian pharma companies to launch cheaper generics. Large R&D based Indian pharma companies should be encouraged and supported to take initiatives in discovering and developing newer drugs for neglected diseases as major international pharma companies have little interest in such low yield products. Innovative means need to be explored to mobilize resources for development of new drugs, apart from their ongoing R&D to evolve and develop new formulations, new drug delivery mechanisms, single dose medicines , and other incremental innovations to extend their reach and footprints in the developed world. In fact the Indian pharma sector needs to be developed in a 'Mission Mode' because it has the potential to emerge as a sunshine industry for India like the IT sector in the years to come if it is nurtured and sustained with a vision and a long term perspective . While there is a lot of talent in the R&D and also a huge base at the grass root level for mass production of the R&D outcomes. Since research for newer molecule (NCEs) take a long time for discovery and development, and the clinical trials thereafter takes a long gestation period to establish safety, security and efficacy to secure for approvals for marketing, a long term vision and perspective is essential. In any case, it is also imperative for the simple reason that for a population of 1.25 bn, and still growing, India needs an indigenous industry to cater to the medicine needs for the tropical diseases of its population, keeping availability, accessibility, and affordability in mind. This is possible only if we develop indigenous competence and capacity. Innovative mechanisms need to be evolved to meet the huge financial resources for this Mission, on a sustainable basis. There is also a need for modernization of patent offices, increase number of patent examiners for pharmaceutical molecules, and training them for effective examination of patent applications, and strengthening of Intellectual Property Appellate Board and staffing it with Technical members of requisite expertiseand impeccable integrity. Some amendments to the Patents Act, 1970 would enhance its effectiveness in ensuring access to affordable medicines to the poor. Competition aspects of the pricing practice of major international pharma companies also need to be considered. Low cost health insurance coverage, provision of essential medicines for critical diseases, at subsidized rates to be made available through state agencies, and promotion of indigenous alternate systems of treatment , which are already being implemented may be further accelerated , and validated , to help access to affordable medicines. India also needs to be careful not to undertake any TRIPS+ obligations, on data exclusivity etc., under

international pressure, particularly the persistent US threat of section 301 sanctions, which might constrain development of Indian pharma sector and impact adversely on availability, accessibility, and affordability of essential medicines.

10.2 At the global level, the focus of the discourse has to shift from trade to human rights of poor to access affordable medicines in a sustainable manner. As the largest vibrant democracy India could and should play a lead role in the relevant fora. Multinational pharma companies were in the forefront and primary drivers behind the developed countries, to mainstream TRIPS, and make the WTO as the primary institution on trade in health related issues. After a heroic struggle the developing countries were able to secure some concessions enshrined in the so called Doha Declaration. In fact it only clarified the existing rights, reaffirmed centrality of TRIPS on intellectual property, and emphasized that the WTO members should interpret the TRIPS Agreement in the light of objectives and principles of the TRIPS and in a manner to harmonize the responsibility of member states to meet their public heath obligations and access to needed drugs. Whatever little benefit could accrue to the developing countries through these insignificant, so called concessions, have been systematically taken away by the developed countries by insisting rather coercing some developing countries to accept TRIPS+ obligations in bilateral/FTA agreements. The mechanism to implement para 6 of the Doha Declaration, as explained above, has been so complex and complicated that so far only one compulsory license could be granted/ obtained to provide HIV/AIDS drugs to a poor country Rwanda by Canada. Whatever little benefit could be extracted by the poor developing countries has been systematically scuttled by the vested pharma interests through their developed countries .There is, therefore a need for concerted action by developing countries to seek and secure more than cosmetic changes in the rules of the game. India could, perhaps, take the initiative.

10.3 Both the Commission on Intellectual Property Rights, Innovation and Public Health, and the Consultative Expert Working Group (CEWG[52]) , set up in pursuance of the Resolutions of the World Health Assembly, have recommended establishing a global R&D treaty to address the health needs of the developing countries. The CEWG had recommended adoption of a

[52] Research and development to Meet Health Needs in developing Countries: Strengthening Global Finance and Coordination, report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), world Health Organization, April 2012, p.15, 110-112, 123.

binding agreement based on Article 19 of the Constitution of the WHO for providing effective financing and coordination mechanism to promote R&D focused on health needs of developing countries, and had required all member countries to commit 0.01% their GDP on government funded R&D devoted to meet the health needs of developing countries., and delinking R&D costs and prices of products. The CEWG had also recommended that R&D outcomes be treated as public goods freely available for further research and production. But divergent views of the developed member states on sustainable funding, priority setting, and equitable distribution of R&D funds, priority setting, , ensuring accountability, transparency and affordability of R&D outputs, coordination and continuous monitoring, delinking cost of R&D from cost of products, R&D outcomes' relation with TRIPS, and their reluctance on contribution of a fixed percentage of GDP to fund the proposed global R&D treaty ,forced the WHO to postpone further deliberations on the proposed treaty till 2016. While the deliberations on the proposed global R&D treaty/agreement have bogged down, Prof Kevin Outtterson, of the West Virginia University, proposed a 'Patent Buy-Outs for Global disease Innovations for Low- and Middle - Income Countries' which addresses the challenge of providing access to patented medicines at marginal (generic) pricing, while ensuring innovation by reimbursing the innovator companies for all lost R&D cost recoveries. This needs to be explored, examined, and embellished further to resolve conflicting concerns and priorities, so that the dream of access to affordable medicines for all could be realized

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Annexure A1

DOHA WTO MINISTERIAL 2001: TRIPS

WT/MIN(01)/DEC/2
20 November 2001

Declaration on the TRIPS agreement and public health

Adopted on 14 November 2001

Past WTO Ministerials:
> Seattle, 1999
> Geneva, 1998
> Singapore, 1996

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.

In this connection, we reaffirm the right

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Doha Development Agenda

> The otherdeclarations and decisions

> Negotiations, implementation and development

> The Doha Declaration explained — TRIPS

> The Doha implementation decision explained — TRIPS

> How the negotiations are organized

> The Trade Negotiations Committee

of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing

under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annexure A2

TRIPS: TRIPS AND PUBLIC HEALTH
The separate Doha Declaration explained

WTO member governments adopted the Declaration on the TRIPS Agreement and Public Health by consensus at the WTO's Fourth Ministerial Conference in Doha, Qatar, on 14 November 2001.
Its purpose is to respond to the concerns that have been expressed that the TRIPS Agreement might make some drugs difficult to obtain for patients in poor countries.

See also:
> Text of Doha Declaration on TRIPS and Health
> Fact sheet on TRIPS and pharmaceutical patents
> Developments since Doha

The doubts back to top

Inventors are allowed patent rights in order to promote research and development. That includes the creation of new drugs. The TRIPS Agreement, which has been in force since 1995, also enshrines in public international law, governments' right to take various kinds of measures that qualify or limit intellectual property rights, including for public health purposes.

However, some members and public interest groups queried whether the flexibility written into the TRIPS Agreement was sufficient to ensure that it supports public health, especially in promoting affordable access to existing medicines while also promoting research and development into new ones.

Different views were expressed about the nature and scope of the flexibility in the TRIPS Agreement, for example about compulsory licensing or parallel imports (see explanation in fact sheet).

Questions were asked as to whether this flexibility would be interpreted by the WTO and its members in a broad, pro-public-health way.

There was concern about whether governments would feel free to use this flexibility to the full, without fearing pressure from

trading partners or industry.

The declaration's response back to top

The special declaration responds to these concerns in a number of ways.

First, it emphasizes that the TRIPS Agreement does not and should not prevent WTO members governments from taking measures to protect public health. It reaffirms the members' rights to use fully the provisions of the TRIPS Agreement, which provide flexibility for this purpose.

These important statements are a signal from all WTO members: they will not try to prevent each other from using these provisions.

Second, the declaration makes it clear that the TRIPS Agreement should be interpreted and implemented in a manner that supports WTO members' right to protect public health and, in particular, to promote access to medicines for all.

It also highlights the importance of the objectives and principles of the TRIPS Agreement for interpreting its provisions. Although the declaration does not refer specifically to Articles 7 ("Objectives") and 8 ("Principles") of the TRIPS Agreement, developing country members attach particular importance to these provisions.

These statements therefore provide important guidance both to individual members and — in the event of disputes — to WTO dispute settlement bodies.

Third, the declaration contains a number of important clarifications of some of the flexibilities contained in the TRIPS Agreement. It does this while maintaining members' commitments under the TRIPS Agreement.

On compulsory licensing, the declaration makes it clear that each member is free to determine the grounds upon which the licences are granted. This, for example, is a useful corrective to the view sometimes expressed that some form of emergency is a pre condition for compulsory licensing.

The TRIPS Agreement does refer to national emergencies or other

circumstances of extreme urgency in connection with compulsory licensing. But this is only to indicate that in these circumstances there is no need to try to obtain a voluntary licence before resorting to compulsory licensing.

The declaration makes it clear that each member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, and that public health crises can fit the bill, including HIV/AIDS, tuberculosis, malaria and other epidemics.

The declaration also refers to the "exhaustion" of intellectual property rights, and therefore a member's right to allow parallel imports (for an explanation see fact sheet.

The TRIPS Agreement says that a member government's practices in this area cannot be challenged under the WTO dispute settlement system.
The declaration makes it clear that the TRIPS Agreement's provisions on exhaustion in effect leave each member free to establish its own regime without challenge — subject to the general TRIPS provisions prohibiting discrimination on the basis of a person's nationality.

Countries' follow-up back to top

While WTO members have clarified the flexibility in the TRIPS Agreement and their right to use it to the full, the story does not end there. It is a country's domestic law that has direct legal force within that country. Therefore, the declaration does not remove the need for each country to take the necessary steps domestically to use this flexibility where necessary if it wants to ensure that medicines are available at affordable prices.

For least-developed country members of the WTO, the declaration says they do not have to protect patents and undisclosed information rights for pharmaceuticals until 2016. For these rights, the least-developed countries therefore have 10 years added to their transition period for applying the TRIPS provisions.

Doha assignment back to top

An issue which arose in the work on the declaration was the question of countries with limited manufacturing capacities and how they could make effective use of compulsory licensing.

It is not in dispute that members can issue compulsory licences to import as well as for domestic production. The concern that has been expressed is about whether supplies of generic medicines made in other countries will be available for importing, particularly in the light of the provision of Article 31(f) of the TRIPS Agreement.

This states that any compulsory licences granted to generic producers in those other countries shall be "predominantly for the supply of the domestic market of the Member" granting the compulsory licence.

This concern may become greater as countries with important generic industries, such as India, are obliged to provide patent protection for pharmaceutical products from 2005. In this regard, the declaration recognizes the problem and instructs the TRIPS Council to find an expeditious solution to it and to report on this before the end of 2002. (Members failed to reach consensus by that deadline. In the preparations for the Cancún Ministerial Conference, attempts are underway to try to break the deadlock.)

More on the Doha Development Agenda here; more on the TRIPS Council's work here.

Importance of intellectual property protection back to top

While emphasizing the scope that the TRIPS Agreement gives to governments to take measures to promote access to medicines, the declaration also recognizes the importance of intellectual property protection for developing new medicines. It also reaffirms WTO members' commitments under the TRIPS Agreement.

Annexure A3

WTO NEWS: 2003 PRESS RELEASES

Press/350/Rev.1
30 August 2003
INTELLECTUAL PROPERTY
Decision removes final patent obstacle to cheap drug imports

WTO member governments broke their deadlock over intellectual property protection and public health today (30 August 2003). They agreed on legal changes that will make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

OFFICIAL TEXTS:
> The decision
> The General Council Chairperson's statement

TRIPS and public health notifications
> Dedicated webpage on the decision of 30 August 2003, with details of notifications

SEE ALSO:
press releases
WTO news archives
Supachai Panitchpakdi's speeches

The decision settles the one remaining piece of unfinished business on intellectual property and health that was left over from the WTO Ministerial Conference in Doha in November 2001.

"This is a historic agreement for the WTO," said Director-General Supachai Panitchpakdi. "The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people.

"It proves once and for all that the organization can handle humanitarian as well as trade concerns," he went on. "This particular question has been specially difficult. The fact that WTO members have managed to find a compromise in such a complex issue bears testimony to their goodwill.

"It also gives WTO members a good momentum to take to the Ministerial Conference in Cancún. I sincerely hope ministers can work together to reach agreement on the other outstanding issues that they will deal with in Cancún," he said.

The decision waives countries' obligations under a provision of the WTO's intellectual property agreement. Article 31(f) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement says that production under compulsory licensing must be predominantly for the domestic market. This effectively limited the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.

In the decision, WTO member governments have agreed that the waiver will last until the article is amended.

Background back to top

Flexibilities such as "compulsory licensing" are written into the TRIPS Agreement — governments can issue compulsory licenses to allow other companies to make a patented product

or use a patented process under licence without the consent of the patent owner, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.

But some governments were unsure of how these flexibilities would be interpreted, and how far their right to use them would be respected. The African Group (all the African members of the WTO) were among the members pushing for clarification.

A large part of this was settled at the Doha Ministerial Conference in November 2001.

In the main Doha Ministerial Declaration of 14 November 2001, ministers stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing.

And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. (The TRIPS Council completed the legal drafting task on this in mid-2002, see press release 301.

On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and health.)

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies directly to countries that can manufacture drugs — it limits the amount they can export when the drug is made under compulsory

licence. And it has an indirect impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

Members were deadlocked over how to resolve this question, and the original deadline of 31 December 2002 was missed.

The decision back to top

This 30 August 2003 agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision (text below). All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.

A separate statement by General Council chairperson Carlos Pérez del Castillo, Uruguay's ambassador, is designed to provide comfort to those who feared that the decision might be abused and undermine patent protection. The statement (see below) describes members' "shared understanding" on how the decision is interpreted and implemented. It says the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives, and that issues such as preventing the medicines getting into the wrong hands are important.

A number of other countries announced separately that if they use the system it would only be for emergencies or extremely urgent situations. They are: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates

The decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits.

It is designed to address the public health problems recognized in Paragraph 1 of the Doha Declaration on TRIPS and Public Health, which says that WTO ministers "recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from

HIV/AIDS, tuberculosis, malaria and other epidemics."

The decision takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licences to export the products to eligible importing countries. The waiver would last until the WTO's intellectual property agreement is amended.

The negotiations on the decision were conducted by the chairpersons of the TRIPS Council: Ambassador Eduardo Pérez Motta of Mexico (2002) and Ambassador Vanu Gopala Menon of Singapore (2003).

The text of the decision and the General Council chairperson's statement follow.

Annexure 4

GENERAL COUNCIL

WT/L/540 and Corr.1
1 September 2003

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

Decision of the General Council of 30 August 2003 *

TRIPS and public health notifications
> Dedicated webpage on the decision of 30 August 2003, with details of notifications

** Secretariat note for information purposes only and without*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

prejudice to Members' legal rights and obligations: This Decision was adopted by the General Council in the light of astatement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

See also:
> Press release: Decision removes final patent obstacle to cheap drug imports

Decides as follows:

1. For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (**1**)

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification (**2**) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (**3**) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out

in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (**4**) has made a notification (**2**) to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed (**5**);
(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (**6**);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
(iii) before shipment begins, the licensee shall post on a website (**7**) the following information:
- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (**8**) the Council for TRIPS of the grant of the licence, including the conditions attached to it (**9**). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is

also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX back to top

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Annexure B

Terms of Reference and Recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004

Terms of Reference

• Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;
• Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;
• Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;
• Analyze proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them;
• Produce concrete proposals for action by national and international stakeholders.

Recommendations

Innovations and Discovery

2.1 Governments of developed countries should reflect adequately this objective in their research policies. In particular, they should seek to define explicit strategies for R&D and devote a growing proportion of their total health R&D funding to the health needs of developing countries, with an emphasis on upstream and translational research.

2.2 Developing countries should establish, implement or strengthen a national programme for health research including best practices for execution and management of research, with appropriate political support, and long-term funding.

2.3 Government and funder attention should be paid to upstream research that enables and supports the acquisition of new knowledge and technologies that will facilitate the development of new products, including drugs, vaccines and diagnostic tests to tackle the health problems of developing countries. Attention should also be paid to the current inadequacy of the research tools available in these fields of research. These include techniques to understand new pathways to discovery, better ways to use bioinformatics, more suitable animal models and other disease-specific technologies.

2.4 When addressing the health needs of people in developing countries, it is important to seek innovative ways of combating Type I diseases, as well as Type II and Type III diseases. Governments and funders need to assign higher priority to combating the rapidly growing impact of Type I diseases in developing countries, and, through innovation, to finding affordable and technologically appropriate means for their diagnosis, prevention and treatment.

2.5 Actions should be taken by WHO to find ways to make compound libraries more accessible to identify potential compounds to address diseases affecting developing countries.

2.6 WHO should bring together academics, small and large companies in pharmaceuticals and biotechnology, governments in the form of aid donors or medical research councils, foundations, public–private partnerships and patient and civil society groups for a standing forum to enable more organized sharing of information and greater coordination between the various players.

2.7 Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries. Public funding bodies should introduce policies for sensible patenting and licensing practices for technologies arising from their funding to promote downstream innovation in healthcare
products.

2.8 Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements, particularly to address diseases that disproportionately affect developing countries.

2.9 Developing countries need to consider in their own legislation what form of research exemption might be appropriate in their own circumstances to foster health-related research and innovation.

2.10 Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.

2.11 Developing countries should ensure that their universities and public research organizations maintain research priorities in line with their public health needs and public policy goals, in particular the need for innovative research of benefit to the health problems of their populations. This should not exclude support of health-related research which meets their industrial or export objectives and that could contribute to improved public health in other countries.

2.12 Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices.

Development

3.1 Governments and the appropriate national authorities and funders should assign a higher priority to research on the development of new animal models, biomarkers, surrogate end–points and new models for assessing safety and efficacy, which would increase the efficiency of product development. They should also work with their counterparts in developing countries to formulate a mechanism to help identify research priorities in this area for Type II and Type III diseases particularly relevant to developing countries, and provide funding for this R&D.

3.2 To enhance the sustainability of public–private partnerships:
• Current donors should sustain and increase their funding for R&D to tackle the health problems of developing countries.
• More donors, particularly governments, should contribute to increase funding and to help protect public–private partnerships and other R&D sponsors from changes in policy by any major donor.
• Funders should commit funds over longer timeframes.
• Public–private partnerships need to continue to demonstrate that they are using their money wisely, that they have transparent and efficient mechanisms for accountability, that they coordinate and collaborate, and that they continue regularly to monitor and evaluate their activities.
• The pharmaceutical industry should continue to cooperate with public–private partnerships and increase contributions to their activities.
• Research institutions in developing countries should be increasingly involved in executing research and trials.

3.3 WHO should initiate a process to devise mechanisms that ensure the sustainability and effectiveness of public–private partnerships by attracting new donors, both from governments and the private sector, and also to promote wider participation of research institutions from developing countries. However, governments cannot passively rely on what these partnerships could eventually deliver; there is a need for a stronger commitment on their part for an articulated
and sustainable effort to address the research gaps identified in this report.

3.4 Further efforts should be made to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards. WHO has a role to play, in collaboration with interested parties, in an exploration of new initiatives that might be undertaken to achieve this goal.

3.5 Governments should continue to develop forms of advance purchase schemes which may contribute to moving later stage vaccines, medicines and diagnostics as quickly as possible through development to delivery.

3.6 Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision.

3.7 Practical initiatives that would motivate more scientists to contribute to this field through "open source" methods should be supported.

Delivery

4.1 Governments need to invest appropriately in the health delivery infrastructure, and in financing the purchase of medicines and vaccines through insurance or other means, if existing and new products are to be made available to those in need of them. Political commitment is a prerequisite for bringing about a sustained improvement in the delivery infrastructure and health outcomes. Health systems research to inform policy-making and improve delivery is also important. The integration of traditional medicine networks with formal health services should be encouraged.

4.2 Developing countries should create incentives designed to train and retain health-care workers in employment.

4.3 Developed countries should support developing countries' efforts to improve health delivery systems, inter alia, by increasing the supply of their own trained health-care workers.

4.4 Governments have an important responsibility to put in place mechanisms to regulate the quality, safety and efficacy of medicines and other products. As a starting point, adherence to good manufacturing practices and effective supply chain management can ensure product quality and will also curb the circulation of counterfeit products.

4.5 Policies for biomedical innovation must take account of the fact that health systems in many developing countries remain resource-constrained. Policies must emphasize affordable innovations adapted to the realities of health-care delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and non-communicable diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved.

4.6 All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis for low and lower middle income developing countries. Products, whether originator's or generic, should be priced equitably, not just in sub-Saharan Africa and least developed countries, but also in low and lower middle income countries where there are a vast number of poor patients.

4.7 For non-communicable diseases, governments and companies should consider how treatments, which are widely available in developed countries, can be made more accessible for patients in developing countries.

4.8 Continuing consideration needs to be given to the prices of treatments for communicable diseases, particularly of second-line drugs for HIV/AIDS treatment.

4.9 Governments of low and middle income countries where there are both rich and poor patients should formulate their funding and price regulation with a view to providing access to poor people.

4.10 Governments need to prioritize health care in their national agendas and, given the leverage to determine prices that patents confer, should adopt measures to promote competition and ensure that pricing of medicines is consistent with their public health policies. Access to drugs cannot depend on the decisions of private companies but is also a government responsibility.

4.11 Corporate donation programmes can be of great value in a number of fields in collaboration with the actions of governments and nongovernmental organizations. However, addressing health needs in developing countries requires more structured and sustainable actions by governments and other parties that stimulate accessibility to products, while generating new treatments and products adapted to the needs of developing countries.

4.12 Governments should remove any tariffs and taxes on healthcare products, where appropriate, in the context of policies to enhance access to medicines. They should also monitor carefully the supply and distribution chain to minimize costs that could adversely influence the prices of medicines.

4.13 The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.

4.14 Developed countries, and other countries, with manufacturing and export capacity should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS agreement.

4.15 The WTO decision agreed on 30 August 2003, for countries with inadequate manufacturing capacity, has not yet been used by any importing country. Its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary.

4.16 Companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income developing countries, they should avoid filing patents, or enforcing them in ways that might inhibit access. Companies are also encouraged to grant voluntary licences in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities.

4.17 Developing country governments should make available full and reliable information on patents granted. WHO, in cooperation with WIPO and others, should continue to pursue the establishment of a database of information about patents, in order to remove potential barriers to availability and access resulting from uncertainty about the patent status in a country of a given product.

4.18 Developed countries and the WTO should take action to ensure compliance with the provisions of Article 66.2 of the TRIPS agreement, and to operationalize the transfer of technology for pharmaceutical production in accordance with paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

4.19 The restriction of parallel imports by developed countries is likely to be beneficial for affordability in developing countries. Developing countries should retain the possibilities to benefit from differential pricing, and the ability to seek and parallel import lower priced medicines.

4.20 Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

4.21 In bilateral trade negotiations, it is important that governments ensure that ministries of health be properly represented in the negotiation, and that the provisions in the texts respect the principles of the Doha Declaration. Partners should consider carefully any trade-offs they may make in negotiation.

4.22 Governments and concerned international organizations should promote new purchasing mechanisms to stimulate the supply of affordable new products and to enhance the number of suppliers in order to provide a more competitive environment.
4.23 Developing countries should adopt or effectively implement competition policies and apply the pro-competitive measures allowed under the TRIPS Agreement in order to prevent or remedy anti-competitive practices related to the use of medicinal patents.

4.24 Countries should provide in national legislation for measures to encourage generic entry on patent expiry, such as the “early working” exception, and more generally policies that support greater competition between generics, whether branded or not, as an effective way to enhance access by improving affordability. Restrictions should not be placed on the use of generic names.

4.25 Developing countries should adopt or effectively implement competition policies in order to prevent or remedy anti-competitive practices related to the use of medicinal patents, including the use of pro-competitive measures available under intellectual property law.

4.26 Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.

4.27 Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consid**er** changes to national patent legislation.

Fostering innovation in developing countries

5.1 A prerequisite for developing innovative capacity is investment in the human resources and the knowledge base, especially the development of tertiary education. Governments must make this investment, and donors should support them.

5.2 The formation of effective networks, nationally and internationally, between institutions in developing countries and developed countries, both formal and informal, is an important element in building innovative capacity. Developed and developing countries should seek to intensify collaborations which will help build capacity in developing countries.

5.3 WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public health policies.

5.4 Developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this makes economic sense and promotes the availability, accessibility, affordability and security of supply of needed products.

5.5 Developed countries should comply with their obligations under article 66.2 of the TRIPS Agreement and paragraph 7 of the Doha Declaration.

5.6 Developing countries need to assign a higher priority to improving the regulation of medical products. Developed countries, and their regulatory institutions, should provide greater financial and technical assistance to help attain the minimum set of regulatory standards needed to ensure that good quality products are available for use. This assistance should also support infrastructure developments within a country, to ensure that good manufacturing practice and supply chain management standards are implemented and sustained.

5.7 The process of the International Conference on Harmonization currently lacks immediate relevance to the needs of many developing countries, but those countries should maintain their participation in the process. In the meantime, developing country governments and regulatory institutions should give support to regional initiatives, tailored to the current capacities of their member countries, which offer more scope for lifting standards over time, exploiting comparative advantages, avoiding duplication, sharing information and facilities, and promoting appropriate standardization without erecting barriers to competition.

5.8 WHO has an important role to play, in collaboration with interested parties, in helping to strengthen the clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa, including the improvement of ethical review standards.

5.9 Apart from the European & Developing Countries Clinical Trial Partnership, donors together with medical research councils, foundations and nongovernmental organizations, need to offer more help to developing countries in strengthening clinical trials and regulatory infrastructure.

5.10 Digital libraries of traditional medical knowledge should be incorporated into the minimum search documentation lists of patent offices to ensure that the data contained within them will be considered during the processing of patent applications. Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.

5.11 All countries should consider how best to fulfil the objectives of the Convention on Biological Diversity. This could be, for instance, through the establishment of appropriate national regimes for prospecting for genetic resources and for their subsequent utilization and commercialization; contractual agreements; the disclosure of information in the patent application of the geographical source
of genetic resources from which the invention is derived and other means.

The way to support a sustainable global effort

6.1 WHO should develop a Global Plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.

6.2 WHO should continue to monitor, from a public health perspective, the impact of intellectual property rights, and other factors,

Annexure C1

Text of observation/comments by Professor Carlos Correa and Professor Pakdee Pothshsiri members of the Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004, on Report of the Commission

Carlos Correa and Pakdee Pothisiri

As the report recognizes, patents are irrelevant for the development of the products needed to address the diseases prevailing in developing countries. Pharmaceutical companies decisively shape the global R&D agenda in this field and invest only where profitable markets exist. The extension of pharmaceutical patent protection to developing countries, mandated by the TRIPS Agreement, can do very little to prompt the development of such products, while it generates costs in terms of reduced access to the outputs of innovation. Where patents exist and are enforceable, medicines can be unaffordable for governments and patients in developing countries. This is why it is crucial to promote generics competition, which is essential to drive prices down and improve access to medicines to all, and to ensure a pro-competitive implementation of the TRIPS Agreement through the utilization, *inter alia*, of compulsory licenses and government use provisions,
when needed. Further analysis is required on the negative implications for public health of TRIPS-plus provisions (such as data exclusivity) contained in free trade agreements. WHO should continue to assess these developments and alert developing countries on their possible impact on public health.

More analysis is also needed on the drastic decline in the capacity of the pharmaceutical industry to innovate, in spite of the availability of new powerful scientific and technological tools. Changes in the industry's structure, the focus on highly profitable products and a relaxation of the requirements of patentability, contribute to explain the industry's emphasis on the emulation or modification of existing products rather than on the development of genuinely new compounds. The report addresses but has not sufficiently elaborated on the profound distortions

currently observed in the functioning of the patent system, which allows the proliferation of pharmaceutical patents on trivial developments that are used to obstruct generics competition.

The coverage in the report of a broad set of issues ranging from discovery to delivery – which we personally did not favour – has led to the consideration of issues that are not central to the Commission's mandate and for which reliable evidence is limited. One case in point is companies' donation programmes. Data on quantities, duration and other conditions of supplies, and the implications for the sustainable access to medicines need to be better examined in the appropriate context.

Annexure C 2

Text of observation/comments by Professor Trevor Jones member of the Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004, on Report of the Commission

Trevor Jones

The report contains much thoughtful and useful material which I am sure will be influential in shaping future policy and helpful to a wide group of stakeholders.
While I support a large proportion of the report, it contains a number of proposals with which I do not agree for the reasons outlined below.

The report implies a direct link between patent ownership, product price and access in the developing world. Patents rarely confer a monopoly in a therapeutic field and are not the basis for price setting. Companies set prices largely on the ability/willingness to pay, also taking into account the country, the disease and regulation. They differentially price by country/market, offer volume-based (competition law compliant) discounts, tier prices between and within countries depending upon public or private market supply, have schemes for the medically indigent and operate company/consortium donation schemes.

Concerning access, patents are not the issue but the overwhelming poverty of individuals, absence of state health-care financing, lack of medical personnel, transport and distribution infrastructure plus supply chain charges which can make affordable originator or generic products unaffordable. In many countries, medicines are unaffordable from whatever source, price or patent status e.g. medicines in the WHO Essential Medicines List which are now virtually all out of patent, cheap, generic products are not available to the majority of the poor. The word "price" is used in the report without qualifying whether this is the originator or generic company list price, or price to the patient/purchaser including taxes, tariffs, supply chain mark-ups etc.

The report calls for further reform of the "patent system". There is a need to improve the competence of patent agencies and enforcement procedures in developing world countries but

the basis for granting a patent and the TRIPS agreement do not need reform, especially following the WTO General Council resolution of 6 December 2005.

The report calls for further action on the patenting of "upstream" technologies.
In reality this is not a problem; vide the recent NAS report on this issue.

The report confuses so-called "evergreening" with incremental innovation which is the lifeblood of medical progress and requires strong IPR to stimulate further innovation. The suggestion that public–private partnerships seek breakthrough products rather than incremental innovation as compared to the industry is simply wrong and fails to understand both the reality of their portfolios and the process of drug discovery and development.

The report proposes that companies should avoid filing or enforcing patents in developing countries. Companies do not patent in countries where there is an insufficient market and where enforcement is not possible. This does not mean that they will not then make those products available there at appropriate prices.

The report assumes that compulsory licensing will increase access. Companies can and do retain intellectual property rights while making alternative arrangements for access to their know-how/products. Countries should have the right to enact TRIPS-compliant compulsory licensing but should only use this when all other reasonable steps have been taken.

Trevor Jones

Annexure C 3

Text of observation/comments by Professor Fabio Pammolli, member of the Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004, on Report of the Commission

Fabio Pammolli

I. Developing countries and health policy: the need for a taxonomy

The term "developing countries" encompasses very different countries, which experience different levels of economic development and disease burdens. In order to design solutions that have relevance in different national and local settings, relevant macroeconomic and institutional features need to be taken into account.

The analytical work that should be performed to assess which policy is relevant to which type of developing country is not fully articulated in the report. There are attempts in the report to introduce such a taxonomy, but it is not adequately used as a basis for policy recommendation. As for intellectual property rights, an undifferentiated recommendation, as the one that the reader might infer from the report, that all developing countries should lower IP standards, is not supported by analysis.

II. On patents, access, and competition

As for the relation between patents and access, the following issues should have been articulated further:

(i) Patent protection per se does not create monopoly positions in the final market. The legal definition of a relevant market for competition purposes in pharmaceuticals is a difficult and case-specific analysis.

(ii) The patent status of pharmaceutical products does not prevent such products from being subject to either procurement schemes (formularies, tenders, buyer groups, etc.), or to direct price controls (administered prices, reference pricing schemes). Such prevalent policies in the vast majority of countries qualify the link between patent status and price levels.

(iii) Countries that do not protect pharmaceutical patents do not necessarily experience higher rates of access, even if generic products are manufactured locally.

In general, a more systematic reference to the nature and extent of coverage and procurement schemes in pharmaceuticals and health care would have better served policy making, with a higher emphasis on the responsibility of governments and international agencies in designing solutions that can promote access, delivery, and public health.

Fabio Pammolli

Annexure C 4

Text of observation/comments by Professor Hiroko Yamane, member of the Commission on Intellectual Property Rights, Innovation and Public Health, set up in pursuance of the Resolution of the World Health Assembly (WHA56.27) in February 2004, on Report of the Commission

Hiroko Yamane

The CIPIH contributed significantly to the international dialogue among hitherto scattered or divided groups, and created solidarity to find solutions for those who suffer from many diseases in developing countries. I share this solidarity which constitutes the basic consensus of the report.

A wealth of important information has been gathered by the CIPIH. To shed more light on current controversies on the role of patents in health policies, however, the report should have provided more evidence-based analyses of different patent policy options for developing countries, considering both their short and long-term consequences.

The report does not analyse the role of patents in different types of developing countries (levels of development, burden of diseases, research or manufacturing capabilities etc.) in the context of their markets and industrial policies.

The recommendations cover drug discovery, development and access for all Types I, II, and III, indiscriminately. Nowhere is there a clear picture of what types of medicines (old or novel) are actually needed, and which policy tools and incentives are specifically required. More attention should have been given to Type III (truly neglected) diseases which offer no commercial incentive.
The actual level of patenting, the scope of protection and the effects of such factors on price and competition were not adequately examined. Instead of collecting empirical data, the report relies on the untested assumption that relaxing rules on intellectual property rights will generally benefit developing countries. The assignment of intellectual property rights, however, may lead to more efficient use of resources (information etc.) and licensing can promote the transfer of technology into the local economy. Furthermore, small patents around basic technology can

work as a barrier against monopolization and help local businesses or applied research enter the market.

The report advocates “pro-competitive policy” at both ex-ante and ex-post patenting phases. However, it omits the important fact that ex-ante control is problematic, as linking correctly patentability (or patent scope) to competition in future technology or product markets is impossible. Patents do not necessarily confer significant market power in developed countries, and the price of a drug often depends on other factors (therapeutic substitutes or price regulation). In developing countries, the real issue may be the absence of reasonable substitutes due to other factors (small market, insufficient health cover, types of quality or price control, existence of patents in developed countries, etc.).

The report did not analyze the effects of patents on competition in any pharmaceutical markets in developing countries and left for future studies to explore. In the absence of an international definition of “anti-competitive behavior”, competition law can be applied in a non-transparent and arbitrary manner. The report should have indicated possible consequences of adopting recommended policy tools on the entry of drugs, investment and ultimately the access and innovation.

It is my hope that further analysis and study will be given to better understand these points.

Hiroko Yamane

Annexure D

The Patent Buy-Out Proposal

(Kevin Outtterson, Associate Professor of Law, West Virginia University
Kevin.Outterson@mail.wvu.edu)

This Article proposes marginal cost (generic) pricing of patented pharmaceuticals for low- and middle-income populations (more than 84% of the world's population). Innovation is assured by reimbursing the companies for all lost R&D cost recoveries in those markets. Risks are minimized because the present IP system is retained for more than 80% of the global patent-based cash flow of the pharmaceutical companies. The following steps are proposed:

1. The purchaser acquires the patent and exclusive marketing rights for a patented global medicine from the patent owner, limited to a particular geographic market. (Example: the Global Fund purchases from GSK the global non-OECD rights to
GSK.s new cervical cancer vaccines. GSK retains the rights to the vaccine in all OECD countries).

2. The purchaser offers an open, non-exclusive, no royalty license to any legitimate generic manufacturer, but only for sale in the target markets. (Normal patent-based pricing remains in all OECD countries; generic pricing through multiple manufacturers prevails in all non-OECD countries).

3. The patent owner is compensated under a buy-out formula which mimics the lost R&D cost recovery from the foregone sales. (Example: GSK is paid for the lost R&D cost recovery from cervical cancer vaccine sales in non-OECD countries).

A. The Purchaser

The purchaser could be a government (the US or the EU), intergovernmental organization (WHO, UN, WTO, or the Global Fund), or a foundation donor (Gates). Governments can exercise compulsory licensure powers within their territories, but this proposal cannot rely solely

on the current scope of compulsory licensure. The transaction costs and political opposition to negotiating compulsory licenses for each market country have proven to be almost insurmountable. In the years since the much-hyped 'Doha Solution' to compulsory licenses for export, not a single pill has been produced under that protocol.77 By offering compensation in exchange for the non-OECD license, it is hoped that pharmaceutical companies will embrace this proposal rather than force governments to pursue parallel compulsory licensure processes.

B. **The Target Market**

The simplest formulation would divide the world in two: the thirty relatively richer countries that are members of the OECD78, and all other countries. Simplicity means rough justice, but surely rough justice is better than no justice. Poverty does not strictly follow political boundaries. Some elites in poor countries will gain access to generic-priced medicines when they could have afforded full price.

Some poor people in OECD countries may not be able to afford their prescriptions, and could have benefited from generic pricing.79 Perhaps the latter group can be left to the care of their relatively affluent governments (although in the US, approximately 66 million people lacked prescription drug insurance in 2005 prior to the introduction of Medicare Part D). Over-inclusion of developing-country elites is more likely to attract controversy.

Over-inclusion results in lost patent rents, particularly in countries like China, India and Brazil with millions of upper-middle class consumers. If simplicity is desired, this over inclusion will simply be tolerated. It will increase the buy-out price, so the companies still receive their due rewards. If anything, the inequity is between the donor and the target country government. Perhaps China, Brazil or India (or similar countries) could compensate the donor for this inappropriate subsidy.

Alternatively, PhRMA companies have demonstrated remarkable skill in segmenting markets with tiered differential pricing within particular countries. The persistence of domestic differential pricing within the US, even in the face of extensive donor programs, is a testament to the effectiveness of market segmentation by PhRMA companies and the apparent weakness of actual pharmaceutical arbitrage pressure. Possible mechanisms are brand campaigns with trademarks, differential pricing by payor, and domestic legal restrictions on arbitrage.80

[DoC testimony] [Non-OECD members of EU? parallel trade restrictions within EU]

The Generic License

The purchaser will offer a non-exclusive, no-royalty license to all legitimate pharmaceutical manufacturers. Negotiations will not be required, and transaction costs will remain very minimal. In order to maximize the geographic reach of the generic licenses, and to ensure competition in each country, drugs licensed under this system which are pre-qualified by the WHO should be granted automatic marketing approval in all of the target countries, a form of reference approval in lieu of a country by country ANDA process.81

D. Setting the Buy-Out Price82

The buy-out price must be set high enough to optimize global pharmaceutical innovation and low enough to be affordable for all global diseases. Lanjouw and Jack effectively set the price at zero by requiring drug companies to choose between patents in rich countries or poor countries.83 If global pharmaceutical appropriation is already supra-optimal, then zero (or a negative value) is the correct price.84 Policymakers should have transparent access to reliable data on global
Pharmaceutical innovation in order to answer that question.

If the goal of the buy-out price is to mimic what would have happened under best-case competitive market conditions, then the price should be based on expected profits rather than sales or costs. Ganslandt, Maskus & Wong used cost data to calculate their buy-out price, which rewards effort rather than success.85 Gross sales are certainly an element of pharmaceutical appropriation, but the relevant market metrics are the net present value (NPV) of the cash flow or the NPV of
the profit stream. The purpose of the buy-out price should be to restore the expected profits, and more particularly, the lost R&D cost recovery.

Expected future profits will of course be difficult to estimate and subject to gaming. The following formula relies to the greatest extent possible on externally generated data, to avoid data manipulation and methodological squabbles, with retrospective experience adjustments:

BOP = NPVt (d) (U * M) p

BOP is the buy-out price;
NPV is the net present value over the patent period
t at discount rate d;
U is the number of generic units sold in the target markets by all sellers during t;
M is the marginal cost of production per unit, estimated as the lowest sustained actual price per unit during t;
p is a profit adjustor, reflecting the percentage of profits allocated to R&D cost recovery (17% in the simple models above).

Estimated payments could be made at buy-out, subject to periodic and retrospective adjustment as actual data developed on u and m, and perhaps for changes in d. The formula minimizes the need to know actual costs, profits, or average sales prices. The only data required are actual number of generic unit sales and the lowest sustained price by any generic seller in the target markets. Both are relatively easy to collect and difficult for the patent holder (or anyone else) to manipulate.

This formula aligns incentives against rent-seeking and allocative inefficiency in helpful ways. The license encourages any pharmaceutical company to manufacture and sell the drug generically in all target markets. Competition will drive the unit price down towards the actual marginal cost of production. In a competitive market with multiple entrants, no single company controls either ‘u ‘or ‘m’, but they each have strong market incentives to maximize u and to minimize m, which translates into the greatest access for a market determined low price.

CONCLUSION

For a remarkably modest price, the battles over TRIPS and essential medicines could be resolved. Pharmaceutical rent appropriation could be avoided in low- and middle-income countries, while fully protecting innovation incentives. As the chronic diseases of the rich and poor worlds converge, a noble opportunity arises for doing well while doing good.

77 The Fourth Ministerial Conference was held in 2001. As of December 1, 2005, no country had provided notice of intent to export under the Paragraph 6 statement.

78 Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States.

79 These issues of over-inclusion and under-inclusion are discussed at greater length in Outtterson, Pharmaceutical Arbitrage, at § I.D.4.iii.
80 Within the U.S. market, internal diversion is illegal in many cases. See Heather Won Tesoriero & Gary Fields, FBI, FDA Investigates Big Drug Wholesaler, WALL ST. J., Sept. 19, 2003, at B1 (reporting alleged diversion from discounted hospital markets to higher-priced secondary markets).

81 For an expanded discussion on this reference approval idea, see Outtterson, Pharmaceutical Arbitrage, at 236-38.
82 An expanded version of the buy-out price analysis, together with discussion of the literature and alternative models, may be found in Outtterson, Fair Followers, at § 5.3.
83 J.O. Lanjouw & W. Jack, Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation?, 4 CENTER FOR GLOBAL DEVELOPMENT BRIEF 1-8 (Nov. 2004) (available at http://www.cgdev.org/docs/CGDbrief%20pharmaceutical.pdf).
84 Outtterson, Pharmaceutical Arbitrage, at 220-22.
85 M. Ganslandt, K.E. Maskus, & E.V. Wong, Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal, 24 THE WORLD ECONOMY 779-795 (2001)